Witness Name: William Wagstaff
Statement No.: WITN6988001
Exhibits: Nil
Dated: 11 January 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR WILLIAM WAGSTAFF

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 24 September 2021.

I, Dr William Wagstaff, will say as follows:

Opening remarks

1. I began my career in Haematology when fresh frozen plasma was the only treatment for haemophilia. I saw lives improved with the advent of cryoprecipitate, and indeed administered the first dose given to a patient in my local Haemophilia Centre. Then I saw the introduction of effective Factor VIII concentrate and witnessed the dramatic changes it offered to patients and their families.

2. It came as a complete shock and horror when those of us involved in any way in this treatment, became aware that the dream was turning into a nightmare, for all concerned, and that patients were being made gravely, even fatally ill by the therapy we had provided.

3. Even after efforts to exclude risky blood donations, and after the introduction of HIV screening of donors, the nightmare continued for

patients with the realisation that there still existed the potential transmission to them of what came to be called the Hepatitis C Virus. This was eventually countered by the implementation of HCV tests, but many patients had already been left with a permanent illness, sometimes progressing fatally.

4. I hope that my statement is a fair representation of the activities of the blood services at that time, and of my involvement in them. Unfortunately, memories tend to fade and the events of 30-40 years ago are not necessarily recalled with clarity. I am grateful for the documents provided to me by the Inquiry team, which have been of great help in formulating my answers.

5. I wish to take this opportunity to express my sorrow for all the pain and suffering caused by these tragic events. Those of us who worked to keep the nation's supply of blood as safe as possible are especially sorry that the improvements in safety did not come sooner.

6. May I also express my admiration for the way in which affected patients and families have given their evidence to the Inquiry. It cannot have been easy to live through those terrible experiences again, but they have done so with great dignity. My apologies go especially to them.

Section 1: Introduction

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

7. My name is Dr William Wagstaff c/o NHS Blood and Transplant, Head Office, 500 North Bristol Park, Northway, Filton, Bristol BS34 7QH and my date of birth is GRO-C 1933. My professional qualifications are:

- MB, ChB – Manchester 1957

- DTM&H – London 1960
- MRCPath - 1968
- FRCPath - 1980
- FRCP(Ed.) - 1987
- FRCP - 1990

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

8. I set out below my employment history including my various roles and responsibilities:

Role	**Dates**
House Surgeon – Bury General Hospital	July 1957- Jan 1958
House Physician – Bury General Hospital	Jan1958 – July 1958
Senior House Officer (Pathology) – Bury General Hospital	July 1958 – Aug 1959
HM Armed Forces – Junior Specialist in Pathology	Aug 1959 – Aug 1963
Registrar (Clinical Pathology) Manchester Royal Infirmary	Sept 1963 – July 1965
Registrar (Blood Transfusion) Manchester Transfusion Centre	July 1965 – Sept 1966
Senior Registrar (Blood Transfusion) Sheffield Transfusion Centre and Honorary Clinical Tutor (Haematology), University of Sheffield	Sept 1966 – Oct 1968

Consultant Deputy Director, Sheffield Transfusion Centre (with one session per week with the Department of Haematology), University of Sheffield	Oct 1968 – July 1974
Honorary Clinical Lecturer, Department of Haematology, University of Sheffield	Oct 1968 – 1994
Director of the Regional Blood Transfusion Service, Sheffield	July 1974 – 1994
Executive Director of the Northern Zone NBA	1994-1998

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.

9. My memberships past and present are as follows:

Memberships	**Dates**
International	
Member and task force chairman, International Society of Blood Transfusion Working Party on Automation	1979-1987
Member and task force chairman, International Society of Blood Transfusion Working Party on Socio-Economic Aspects of Blood Transfusion	1982-1983
Treasurer and member, Executive Committee of International Society of Blood Transfusion	1984 – 1992

Member, Council of Europe select committee of Experts on Automation and Quality Control in Blood Transfusion Services	1974-1998
Co-ordinator, British Council Exchange programme, Sheffield/ North East Brazil	Dates unknown
National	
Member, Specialist Sub-committee in Blood Transfusion, Institute of Medical Laboratory Sciences	1976 -1980
Chairman, National Meeting of Regional Transfusion Centre Directors	1981-1984 1988-1990
Member, Sub-Committee on Blood and Blood Products Equipment, reporting to RTD's meeting	1974 - 1978
Member, Working Party on Proficiency Testing in Blood Transfusion, reporting to RTD's meeting	1974-1979
Member, Working Party on Control and Certification of Blood Grouping Reagents	1974 – 1979
Member, British Committee on Standardisation in Haematology (representing Association of Clinical Pathology) and member of	1976 - 1987

Blood Group and Transfusion Task Force	
Member, Blood Transfusion Task Force of British Committee of Standardisation in Haematology	1987 – 1992
Member, Specialist Sub-committee on Haematology, Association of Clinical Pathologists	1977 - 1980
Member, Working Party on Code of practice for the Use of Cell Separators (DHSS)	1976 - 1978
Member, Joint Sub-committee on prevention of Haemolytic Disease of the Newborn	1976 – 1982
Member, RTDs Working Party on the Use of Machine-readable Labels (Chairman 1983 – 1986)	1978 – 1986
Member, NBTS User Group in Automation	1981 – 1986
Member, Steering Committee for National External Quality Assessment Scheme in Blood Group Serology	1979 – 1991
Member, Advisory Committee for the NBTS	1982-1984 1988- 1989
Member, Council of Royal College of Pathologists	1987- 1990
Member, Management Committee of the NBTS	1988 -1993

Member, (Vice Chairman), UK NBTS Advisory Committee on Transfusion Transmitted Disease	1989 – 1993
Examiner in Haematology, Royal College of Pathologists	1974 -1992
President, British Blood Transfusion Society	1993 -1995
Honorary Consultant in Blood Transfusion to the Army	Dates unknown
Member, Training Committee of Royal College of Pathologists	Dates unknown
Chairman, UK NBTS/NIBSC Liaison Group and Executive Committee	1987-1988
Chairman, Panel of Examiners in Transfusion Medicine, Royal college of Pathologists	Dates unknown
Chairman, Sub-committee on Transfusion Medicine, Royal College of Pathologists	Dates unknown
Member, Specialist Advisory Committee in Haematology, Royal College of Pathologists	Dates unknown
Member, Specialist Advisory Committee in Haematology, Joint Committee on Higher Medical Training	Dates unknown
Member, The Standing Committee on the Care and Selection of Donors	Dates unknown

Member, The National Directorate of the NBTS – Management Committee	1988 onwards
Member, The National Blood Authority Executive	Dates unknown
Member, The National Blood Authority Technical Working Group	Dates unknown
Chairman, The UK BTS/NIBSC Working Group on Blood Components	Dates unknown
Chairman, the Standing Advisory Committee on Blood and Blood Components	Dates unknown
Member, The Blood Transfusion Sub-Committee of the Standing Advisory Committee on Haematology	Dates unknown
Member, The Advisory Committee on the Virological Safety of Blood	Dates unknown
Member (of the medical sub-committee of), The DHSS Plasma Supply and Blood Product Working Group	Dates unknown
Member, the Medical Staff Committee	Dates unknown
Chairman The UKBTS/NIBSC Standing Advisory Committee on Donor Selection	Dates unknown
Member, The Blood Transfusion Society	I am still a member of the British Blood Transfusion Society and served as President in 1993

Regional	
Member, Board of Faculty of Medicine, University of Sheffield	1976-1979
Chairman, Regional Scientific Committee	1981 – 1983
Member, Advisory Committee on Medical Laboratory Subjects, Sheffield Polytechnic	1974 -1988
Ex-officio member, Regional Advisory Sub-committee in Pathology (Chairman 1981-1986)	1974-1994
Member, The Northern Division of the National Blood Transfusion Service	Dates unknown
Member, The Northern Blood Transfusion Director's Meeting	Dates unknown
Executive Director and Chairman, The NBS Northern Zone Board	Dates unknown
Member, The Northern Division of BTS Consultants	Dates unknown
Member, The Trent Regional Health Authority Sub-Committee	Dates unknown
Member, The Regional Director's Working Party on Transfusion Associated Hepatitis	1982 onwards

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

10. I kept abreast of medical and scientific developments mainly by reading the appropriate journals, attending scientific conferences and having discussions with colleagues in their various specialist areas. I also undertook training and teaching at colleges and universities. I would teach and train junior medical students from undergraduates and graduates right up to their examinations at the Royal College of Pathologists. I would also train the technical staff at the Transfusion Centres and the blood banks at hospitals.

11. I read and subscribed to the following journals:
    - Transfusion medicine
    - Transfusion
    - Vox Sanguinis
    - The Lancet
    - BMJ

12. I also attended a number of conferences, including the International Society of Blood Transfusion (ISBT) – this was every 3-4 years, and I normally went to the European conferences in-between. The ISBT conferences were organised by committees of ISBT Members based in the countries in which Congresses (conferences) were being held - except in the case of the USA, when an AABB conference might act as host to ISBT Committee and Members.

13. I also attended American Association of Blood Banks (AABB) conferences – AABB meetings are held in a variety of cities in the USA.

14. IBST had a meeting in London in 1988 and Luc Montagnier, co-discoverer of the HTLV-III virus, was the speaker. I attended this conference, but I can't remember the exact date. As with all ISBT

Congresses the programme was designed to address a variety of current and developing matters of interest in all branches of transfusion.

15. We also had internal meetings with colleagues and the medical staff in the centre. Each consultant would have their own responsibilities, so it was important to get together to know what was going on. My role was like an overall practice manager, as I was running the centre.

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.***

16. I haven't been involved in any proceedings in the UK, but I attended a trial in Australia which was a case brought against the Australian Red Cross in 1990. (Australian Red Cross ATS – at the suit of PQ). I cannot recall whether this was a civil or criminal case. I was not required to prepare a witness statement in advance but during the hearing I was asked to give evidence about the measures taken at Trent RTC with regard to donor selection and screening etc, to be considered in court in comparison with similar measures taken by the Australian Red Cross. Such evidence was taken from medical representatives of other national transfusion services - I personally know of The Netherlands and Finland being similarly involved.

17. The outcome was that the Australian Red Cross was not liable/guilty.

18. I have never been involved in any other inquiries, investigations, inquests, criminal or civil litigation, relating 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.

6. ***The Inquiry has reviewed documents in which the terms Trent RTC and Sheffield RTC are used interchangeably. Please clarify which is the correct name. For ease of drafting, the Inquiry has referred to the RTC as Trent RTC throughout this Rule 9 Request. If this is incorrect, the Inquiry would be grateful if you could use the correct name throughout your response***

19. It is correct that Trent RTC and Sheffield RTC are sometimes used interchangeably. However, 'Trent' is the name I would normally use. I will therefore use the name Trent RTC ("TRTC") throughout this statement. TRTC extended over parts of South Yorkshire, Leicestershire, Derbyshire, Nottinghamshire and Lincolnshire.

Section 2: Your role at the Trent RTC

7. ***Please describe the roles, functions and responsibilities you had at the Trent Regional Transfusion Centre ("TRTC") during your period as the Regional Transfusion Director and explain how these changed over time.***

20. I became a Director of the Regional Blood Transfusion Service in July 1974. I was responsible to the Regional Health Authority in Trent for all of the organisation involved in the production and supply to regional hospitals and BPL of appropriate blood components and products. We also acted as a reference laboratory for hospital blood banks in Trent and provided a regional service for antenatal blood group serology and for histocompatibility.

8. ***Please describe the organisation of the TRTC during the time you worked there, including:***
   a. ***Its structure and staffing and in particular to whom you were accountable;***

21. The various departments of Trent RTC comprised Laboratories, Donor Panel and Organisation, Nursing/Donor Attendants, Administration/Finance, and Transport. Each of these had its own Departmental Head. The Chief Admin Officer and Transport Officer were directly responsible to me, as were the Head Nurse and Regional Donor Organiser. The various laboratory divisions worked through designated senior medical staff before ultimately becoming my responsibility.

22. The medical staffing during my tenure comprised: full time - a Consultant Director, a Consultant Deputy Director, two Consultant Haematologists, one Senior Registrar and one SHMO/Registrar; part time - two medical assistants (apheresis) and part-time medical staff for donor sessions.

23. I was directly accountable to the Chief Executive at Trent RHA, with medical/scientific oversight by the Regional Medical Officer.

b. How the TRTC was funded and how this changed (NHBT0027504).

24. I have had sight of a letter dated 12 July 1990, where it was confirmed that changes were to be made to the way that Blood Transfusion Centres were to be funded. Prior to this date, each Blood Transfusion Centre was given a lump sum by its Regional Health Authority to cover its running costs. The money was spent on everything from the salaries of the staff to sterile packs, storage and distribution of blood products.

25. From 1990 however, hospitals were given this money and they used it to pay the costs of the Transfusion Centre for the services they received. This included Trent RTC.

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

26. The Trent served 14 hospitals in the following locations:

- 3 in Sheffield
- 2 in Derby
- 2 in Nottingham
- 2 in Leicester
- 1 in Boston
- 1 in Lincoln
- 1 in Mansfield
- 1 in Chesterfield

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 [2000] 3 All E.R. 289 (A & Others) and explain whether you agree with what is said there (NHBT0000026_009)

27. TRTC formed one part of a loose federation of RTCs not answerable to anyone outside their own RHAs.

28. The structure of the organisation changed in 1984. Angela Robinson became the National Director in 1994 at the same time as the 'zones' were introduced. Zones were first proposed in 1993 in the run up to the change, but they didn't become operative until 1994.

29. My role and title at that time changed to Executive Director of the Northern Zone. Managerially, I reported to John Adey who was the Chief Executive. Dr Angela Robinson was the Medical Director. She had direct oversight of Dr Peter Flanagan who was the Clinical Director for the Northern Zone, but his actual accountability was to me as Executive Director.

30. I have read the witness statement of Harold Gunson and I agree with what he said about how the organisation of the Transfusion services in England and Wales developed.

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

31. The TRTC was linked and associated with other RTCs but only really by attendance at the RTC meetings. After the formation of the National Directorate in 1988, the centres were organised into 'zones' so Dr Gunson would meet with the Directors of the Northern zone centres all at once. The two other zones were South-West and London, and they would have their own centres within them. The liaison between centres was good but this was normally only done at Directorial level. It was always cordial and straightforward. Even though we may sometimes differ in our approaches, this would be discussed at the meetings, and we would try to reach a consensus.

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

32. We were regularly inspected by the Medicines Inspectorate – the MCA – which was the predecessor of the Medicines and Healthcare products Regulatory Agency (MHRA) Inspectorate. They had a statutory right to order us to cease operating so we always ensured everything was done as it should be.

33. Dr Gunson introduced RTC audits where we each went to other centres. I am sure I was involved in this, but I cannot remember anything specific. I think the idea behind it was to try to improve standards but from what I recall, there was already a good deal of uniform practice in place anyway and as set out above, the MCA Inspectorate had the power to close us down, so we were already maintaining high standards.

34. I was also involved in inspections of hospital laboratory systems. Those of us in the transfusion service who were involved were included in

multidisciplinary teams and we would inspect our areas of speciality so I would go in and inspect hospital blood banks.

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

35. We would send plasma to BPL and receive back the appropriate products and then distribute them to the hospitals. Originally, no money used to change hands but when cross-charging was introduced, that changed.

36. In my opinion, cross-charging didn't act as an inducement, it was another bureaucratic step which added nothing to the efficiency of what we were doing. I do not believe that it helped with the responsible use of blood in hospitals. We continued to supply them with what they wanted and then they went through the process of paying. It did not add to the efficiency of use. They continued to judge the need for blood and components on clinical grounds rather than cost.

37. Each of our hospitals was visited twice a week for distribution. The haemophilia centres in Trent preferred to deal directly with the private companies. We were not involved in the purchase or distribution of commercial concentrates only NHS/BPL for the distribution of BPL products.

h. The approximate number of donations collected each year (NHBT0006235)

38. The approximate number of donations at this time would have been between 170,000 - 175,000 each year. By 1994 it was probably verging on around 200,000. I think it would have maintained at that level up until my retirement in 1998.

9. What steps did you take to ensure that quality assurance was maintained at the TRTC? (NHBT0006235)

39. We set up a Quality Assurance department with an appointed quality control officer. This department was maintained on a regular and controlled basis. The quality control officer was accountable directly to me as the RTD. The officer at that time in our centre was Jill Magee.

40. The work being done by the Quality Assurance department included the checking of balances used at donor sessions (checked at 6 monthly intervals using standard weights) and the testing of copper sulphate solutions used at sessions for haemoglobin estimations. The solutions, bought from British Drug Houses (BDH), were tested for specific gravity and the results were recorded.

41. The Quality Assurance department was also involved in the production of Standard Operating Procedures (SOPs). Having studied the SOPs in use in Glasgow and West Midlands RTCs, a Sheffield format was devised, and the existing SOPs were updated to this format. They also carried out testing and reviews of the QC data of reagents produced in-house and signed them off for use.

Section 3: Blood collection at the TRTC

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

42. The Headquarters of donor organisation was at the RTC, and all policy decisions on the organisation and implementation of the bleeding programme would be made there. However, the day-to-day running of the panel of donors for South Yorkshire and North Lincolnshire was carried out in the office at the RTC. Donor panels and the organisation of their associated bleeding programmes were also maintained on a

"county" basis through four more county offices in Leicester, Nottingham, Bakewell (for Derbyshire) and Lincoln (for Central and South Lincolnshire). This arrangement had the obvious advantage of giving the donors in the periphery of the Region a greater feeling of personal contact with the Service and facilitated local publicity and donor recruitment. The county offices could, of course, call on the services of the "specialist" publicity and recruitment staff at the RTC, as and when necessary.

43. We didn't routinely run donor sessions at the RTC, but permanently equipped donor centres were set up in the centre of Sheffield, and in association with the donor panel offices in Leicester and Nottingham.

44. Plasmapheresis was developed using plasma for fractionation. We started off using manual techniques then used machines later on. Dr Angela Robinson set it up originally in our neighbouring RTC which was Yorkshire, based in Leeds, but I am not sure if we were influenced by that. I was quite easy about automated techniques, as the automation of blood grouping was one of my interests in general. I wasn't reluctant to take on the idea of machines.

45. Blood collection changed over time for a number of reasons. The first reason was simply geography. We were a spread-out region so initially we would go overnight in teams and do two consecutive days of collection. The team would stay in nearby hotels, so they didn't have to travel there and back two days in a row. However, when the costings were looked at, it was cheaper to travel there and back rather than stay in a hotel, so this was changed.

46. Secondly, prior to the 1970s, we had bleeding sessions in prisons. However, we were receiving reports about the increasing use of drugs in prisons, mainly in America but because of the perceived risks, we decided to stop it in Trent in the early 1970s. We didn't believe UK prisons had the same drug problems as in America, but we knew it was

on the increase, so we made the decision to stop. I understand the timing of this varied from RTC to RTC.

47. The other big change in the early 70s was that we went from using bottles to bags. This was a big change because as well as being more convenient, plastic bags changed the way in which blood products could be separated and used to treat a wide range of haematological conditions. Using bags made blood transfusions safer than before. With the glass bottles, separation into plasma and cryoprecipitate was complex and prone to bacterial contamination and lack of consistency. Plastic bags made separation of blood much easier, allowing targeted management of conditions such as anaemia and bleeding disorders. Before plastic blood bags were developed, it was not possible to separate platelets from whole blood.

48. During my tenure the donor panel also changed from being a paper-based exercise to being computerised. If memory serves, it must have been roundabout this point that we were able to close the small county office in Bakewell and run Derbyshire donors from the central office at the RTC.

11. What if any steps did the TRTC take to publicise itself to potential donor populations in order to increase donations? How successful were these steps? (NHBT0000077_103 and NHBT0118872_004)

49. We had a separate section in our donor panel department regarding publicity. We used to set up recruitment booths in market squares etc. We didn't advertise on the TV, but we did try to recruit donors using radio appeals.

50. We had problems with collection from some ethnic groups and even sought the assistance from the local MP in Leicester. It didn't really make much difference and it was a problem then and still is now.

51. We did use blood mobiles and blood buses, but these were only really used to transport us to the village hall or wherever we were going. We would set up the bleed beds upon arrival. I believe that the 'bleed on board' buses were more popular in London.

52. We didn't really have any problems in getting donors and we were quite successful in maintaining our donor panel. We normally had the bleed sessions twice a year, but we could increase this to every four months if we needed to.

12. To what extent did the TRTC collect blood from prisons, borstals and similar institutions? 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?

53. Trent RTC did collect blood from *prisons* prior to the 1970s but I cannot recall from how many. There would have been no more than two collections per year from each prison. The practice ceased at Trent RTC in the early 1970s. We did not collect from borstals or similar institutions.

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

54. My role was very limited. It was an already diminishing practice which I inherited in 1974. I was responsible for its cessation shortly thereafter.

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

55. The cost would have been the same as we would still have to have the team going in to collect the blood etc. It would therefore be the same cost if they were going into a village hall as it would if they were going into a prison.

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

56. There were no incentives given to prisoners.

13. ***The Inquiry understands that you were present at a Regional Transfusion Directors' ("RTD") meeting on 6 October 1971 at which it was stated that from 1 July 1971 the "American Red Cross had stopped collecting blood from donors in 'correctional institutions' because it was generally accepted that [...] the incidence of AU-positive individuals among prisoners is 10 times greater than among voluntary unpaid donors". Notwithstanding this admission, it was noted that "All RTCs collected blood from prison, borstals or other similar institutions. Several RTDs did not consider that the association of donations from such sources with cases of hepatitis was any greater than that of donations from other donors". Could you please explain why you think there was such a stark contrast in approach between the USA and the UK with regards to the risk of collecting infected blood from prisons? (NHBT0015758_001)***

57. It is correct that I was present at the meeting on 06 October 1971 however I didn't become a Director until 1974.

58. Drugs were far more prevalent in the USA and the prisoners were paid so they had an incentive. It was always our understanding that the risks were higher in the USA than in the UK. Trent stopped collecting from prisoners in the early 1970s because of this perceived risk but I understand that other RTCs in the UK stopped at different times.

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

a. What were the staffing arrangements during blood donation sessions? Were staff medically qualified to collect blood donations/undertake blood transfusions?

59. The staffing of a standard blood donor session would comprise: one driver for the multipurpose vehicle, one medically qualified doctor to perform the venepunctures and deal with any medical queries or donor reactions, two donor panel clerks with the donor records appropriate to that session, and a team of donor attendants including a senior, experienced team leader. For a larger donor session, staffing might be increased by the addition of a second doctor, a larger team of donor attendants, and a second driver if blood was to be returned to the TRC before the scheduled end of the session.

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

60. The sessions took place anywhere that was suitable and available, normally village halls.

c. ***How frequently could a person donate blood? (NHBT0003804 and NHBT0000191_144)***

61. These sessions normally took place every six months, but this interval could be reduced to four months if there was particular a need.

The document at section 7.6 suggests that you were responsible for a Standing Committee whose task was to appraise the frequency of donations. Please explain which committee this was and what input you had with regards to this topic.

62. I was chairman of the Standing Advisory Committee on Donor Selection, forming part of the Red Book organisation.

d. How were blood donors recruited?

63. Please see paragraph 11 above which sets out how we recruited blood donors

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

64. In 1994, the National Blood Authority (NBA) based in Watford, started a national campaign, though this was not implemented until after my tenure as Director at Trent RTC ended in 1994.

15. Did the TRTC have donation collection targets that it was required to meet? If so, did the TRTC 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? (JPAC0000186_001)

65. An annual donation target could be set on the basis of the previous year's consumption, taking into account any planned increase in activity communicated to us by the hospitals concerned. Based on these figures, a routine allocation was made to each hospital blood bank, delivered on a twice-weekly visit. If a hospital anticipated the need for extra supplies at its next delivery, this was communicated to the RTC despatch department.

66. The haematologist could telephone us a couple of days in advance if he could foresee that extra blood would be required, this would normally be for something like open heart surgery for example. This worked reasonably well.

67. We did occasionally have emergencies for example, the Kegworth air disaster in 1989 where we needed to get blood to Leicester Royal Infirmary as soon as possible.

68. I am not sure that any more could have been done during my time to collect more donations. We coped very well, we had an active donor panel department which had proper planning, and this was effective. If there was a need then we would normally be able to fill it. If it was

necessary, we may bleed the donors in the centre - for example if we urgently required a specific blood type then we would ring the relevant donors and ask them to come into the centre as soon as they could.

Section 4: Plasma procurement and production of fresh frozen plasma at the TRTC

Production of fresh frozen plasma

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

a. Where the production of FFP took place;

69. The production took place at the TRTC's laboratory.

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

70. Fresh Frozen Plasma (FFP) destined for fractionation came from two different sources. The first was plasma derived from whole blood donations and the second plasma collected by apheresis. The approach to production of FFP was determined by its source i.e. whole blood or apheresis plasma. The specification for both types of FFP in place in the early 1990s is contained in Volume 2 of the 1st edition of the Red Book.

71. Once the whole blood donations were returned from donor sessions, they were taken back to the TRTC laboratory. The laboratory was equipped with 10 Damon IEC DPR-6000 centrifuges and 3 Beckman 6-6B machines.

72. Essentially plasma should be frozen to a solid state as soon as possible. The rate of cooling must be as rapid as possible and ideally should bring the core temperature of the plasma down to -40 °C or below within 60 minutes. If this is not possible, the minimum acceptable rate of freezing must bring the core temperature down to -30°C within 4 hours, as demonstrated by regular performance tests.

73. There were two categories of recovered plasma. The first involved plasma where the period from collection to freezing is less than 8 hours and the second where the time is less than 18 hours.

74. The requirements for production of recovered plasma will also have been influenced by other factors, most importantly if the whole blood donation was to be used for production of platelet components. These donations will have been required to be processed within 6 hours of collection.

75. Once the plasma was separated from the whole blood (achieved by centrifugation) it will have been frozen using specific 'blast freezers' which will have ensured that the rapid freezing required by the Red Book specification was achieved. The 8-hour plasma will always have been the preferred option, but this might not have been achievable for some whole blood units collected in the evening at distant mobile collection venues.

76. Apheresis plasma did not require processing prior to freezing. The aim was to freeze this plasma as soon as possible following collection in order to maximise Factor VIII levels.

77. Once this was done it was then either sent down to BPL or used as clinical FFP.

78. TRTC always had the sufficient capacity to manufacture FFP. This did increase and change during my tenure because of the increase in demand. We had a new plasma processing / blood processing department built into the centre in the late 1980s to make a completely new department to keep up with the demand.

79. The build was funded by the RHA. At the time I was a Director, I had a very good relationship with the RHA, and any reasonable requests were almost always funded.

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

80. I believe that we would separate at least 50% of our donations to produce FFP and the majority of this would go to BPL.

81. The FFP which was not sent to BPL was used either as single dose FFP clinically in the local hospitals or to produce cryoprecipitate.

82. There was a pretty minor demand for local use compared with the amount of plasma that was going to BPL for fractionation. Initially, in the early 70s, it was quite high because there was widespread use of cryoprecipitate before they began to get Factor VIII concentrate but then in the late 70s this changed.

d. How quickly the TRTC could have increased its manufacturing of FFP, had it wished to;

83. As set out at point b above, TRTC did wish to increase its manufacturing and we built a new laboratory in the late 1980s. When the new transfusion centre opened in 1972, I believe we were running at about 120,000 donations. It then steadily increased to about 150,000 in 1974 (approximately) and then as set out above, the approximate number of

donations then further increased and would have been between 170,000-175,000 each year and we had to expand to keep up with the demand. By 1994 it was probably verging on around 200,000 each year.

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

84. It was funded by the RHA during the 1980s, but we were given funds by BPL when cross-charging came in for the amount of plasma we sent to them. I believe that was roughly 1989.

85. When cross-charging was introduced, the dealings in the Trent region with BPL for Factor VIII were handled by BPL themselves and the Haemophilia Centre Directors. Effectively, the Haemophilia Centre Directors put in their orders directly to BPL.

86. The only thing that we had to do with it was provide transport.

87. Plasma used for clinical FFP and Cryo was charged to hospitals through the cross-charging arrangement instituted in 1989.

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

88. The amount of Factor VIII coming back to the Trent region from BPL would be sent via our routine transport between the Transfusion Centre and BPL and then we would distribute it to the hospitals concerned.

89. Our refrigerated vans would take the plasma down to BPL and bring the product back and then we would distribute it to the hospitals. We went to each hospital twice a week anyway, so we just included this in our routine deliveries, which would include clinical FFP and cryoprecipitate.

Plasma Targets

19. Did the TRTC 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? (JPAC0000187_005)

90. I have read the letter dated 21 February 1991 from Dr Moore which refers to the national plasma targets being 385 tonnes of recovered plasma, 100 tonnes of apheresed and 12 tonnes of specifics (giving an overall target of 497 tonnes).

91. We generally worked out our own targets, as they were on a regional basis for the production of cellular components, by interaction with the hospitals themselves and the amount that we sent to BPL. So far as I can remember, we always met the amount that was asked of us by BPL. We reacted in accordance with local needs and that produced sufficient plasma for the BPL targets.

92. Certainly, during the time in question, donation targets were very much cellular driven, and the amount of plasma being sent to BPL, although it wasn't secondary, was certainly the result of the increase in the demand for cellular products

93. The letter asks for help to establish targets and quotas and encloses a form for the receiver to complete but I cannot recall ever completing this form, though I do recall mention by Dr Moore of a figure of 49 tonnes from TRTC.

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

94. This was really just the question of whether it could be achieved by recovered plasma without the need to go to apheresis. Generally, we were able to meet, as far as I can remember, what was required of us by recovered plasma.

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

95. I cannot recall any consequences if targets were not met.

96. We were not in a position to negotiate the numbers between BPL and the Haemophilia Directors because they did it themselves. One consequence, presumably, was that if the Haemophilia Centres received a lower proportion of BPL Factor VIII than they would have wished, then they had to buy more Commercial Factor VIII. However, I don't think that this would have been an issue because, as far as I know, the Haemophilia Centre Directors were quite happy with a mixture of BPL and commercial, they did not want to particularly increase allocation from BPL at the expense of commercial.

97. There was complete clinical freedom to decide what they wanted to use, plus there was a feeling at that time that, in some respects, and from some sources, commercial suppliers charged less to Haemophilia Centre Directors than BPL, for the supply of Factor VIII. I think commercial Factor VIII was probably cheaper than BPL Factor VIII.

98. I think at that time when HCDs were beginning to use both products (BPL and commercial) no alarm was being raised about safety. That rapidly came, but, initially, not quite so much, so it was entirely dependent on the clinical freedom for them to decide which they thought was their desired product to treat their patients. In relation to the basis on which they did that, we were never quite sure whether they thought that the BPL product was of, shall we say, a lower purity than commercial. You can suspect it was part of the argument, because certainly when BPL started to go into the business of heat treatment, I think it was then realised that their starting product was of a lower purity or concentration, than was really required to go through the heating process.

22. Were there any benefits to the TRTC if the targets were exceeded?

99. I do not believe that the TRTC received any benefits if the targets were exceeded.

100. However, it is important to bear in mind that there was a *national* target. One centre might under-collect whereas another might over-collect resulting in the overall national target being met so in my opinion, this was never an issue for the RTCs.

23. 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?

101. In my opinion, cross-charging had little, if any, effect on the plasma supply. It certainly didn't act as a particular incentive to produce more or impact on 'responsible use'. It continued to be dictated by clinical need.

102. The difficulty with cross-charging was that the amount paid for plasmapheresis plasma was way below the actual cost of producing it, so the more you produced and the more you provided, the more out of pocket you were. Pheresis plasma under our system, was much more expensive or potentially more expensive than recovered plasma from donations.

103. Due the fact that the price that we received for plasma was below what it cost us, it had a depressing effect on any urgent need for pheresis.

24. *Please describe any arrangements the TRTC had with regards to supplying the private sector, in particular whether any charges were associated with this supply. (NHBT0106207_001)*

104. I have recently had sight of the letter I wrote dated 03 January 1984 regarding the proposed service charges to the private sector. However, the *TRTC* did not directly supply the private sector and therefore there were no direct charges.

105. The letter sets out 7 points which were put before the Central Advisory Committee and passed on through the Committee to the Minister as being views expressed by RTDs. This gives a picture of the background, and to an extent rounded it off by introduction of cross-charging in 1989.

106. I am assuming that this question (24) is referring to the routine use of cellular products and as far as we were concerned, any use of blood for private patients was channelled through the hospital haematologists in charge of the hospital blood bank which, in turn, supplied blood to the private patients. Usually this would be private patients in NHS hospitals as they would generally have a private wing in the hospital.

Plasmapheresis

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

a. Whether manual or machine plasmapheresis was preferred;

107. At this time, we were using pheresis *only* for immune plasma harvesting. It was a mixture of manual and then machine pheresis. I think there is no doubt that it is more expensive to buy and use machines than to use straight forward manual plasmapheresis. We considered implementing plasmapheresis for plasma, but I think as I have already said, the capital outlay and maintenance were such that it seemed a very expensive way of producing normal plasma and our preferred route at that time was to carry on recovering plasma from routine donations. We did look at the

possibility of routine apheresis; we were considering setting up separate donor panels for the techniques using regular routine donors.

108. From the experience we had, we were not concerned about any ill-effects on the donor, and it did seem that donors were not averse to coming more often than they would do to give a routine pint of blood.

109. We didn't really have any difficulty in recruiting donors for machines because we recruited donors for apheresis just as we did from our panel of routine regular donors. They were already incentivised to come regularly.

110. This move towards machines was largely a consequence of early work performed by Angela Robinson. In 1983 she published the results of a pilot study for large scale plasma procurement using automated plasmapheresis – [DHSC0002263_064]. *The abstract of the paper concludes 'The results show that large-scale automated plasmapheresis could safely and economically produce high quality source plasma necessary for national self-sufficiency'.*

b. The relative cost differences between each method;

111. It goes without saying that it was more expensive to buy and use machines than to do manual plasmapheresis, though the pilot study mentioned above demonstrates the financial advantage of a large-scale operation as against one for one comparison with manual apheresis.

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

112. The capacity was certainly a factor in as much as the majority of our donations were in village halls etc., and we could only contemplate doing apheresis either by specially built mobile units, which were few and far

between in terms of electricity supplies or by taking on more permanent venues in the various towns and cities.

113. The main reason that we decided not to go for large scale apheresis was one of the costs involved (the infrastructure) and also the acquisition of the machines of course.

114. Since at that time we were meeting our plasma targets via the recovered route, we didn't believe there was a problem which needed fixing.

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

115. Potentially yes of course, plasmapheresis would increase the amount of available plasma, but we were able to produce all the plasma that we were required to do by straight forward single donations, so we just felt that there wasn't the need. However, if you had to go down the plasmapheresis route then it would increase the amount of plasma.

116. This was because plasmapheresis allowed the donor to donate more frequently and for more plasma to be collected on each occasion. It provided a realistic mechanism to increase plasma collection. One potential barrier was the cost of producing the plasma. All of the costs involved in the collection, processing and testing of the plasma will be reflected in the unit cost, whereas in the context of whole blood, the costs were often disproportionately allocated to the red cell component making the plasma appear less costly. In the end the ability to increase plasma collection by apheresis will, at least in part, have been limited by the willingness of authorities to fund it.

26. Please set out the extent of the plasmapheresis programme at the TRTC during your tenure. As far as you are aware, did this programme differ from other RTCs? If so, why?

117. Please see the answer to question 25 above with regards to the extent of the plasmapheresis programme at the TRTC.

118. The main difference with other RTCs would be the particular interest of the medical staff concerned.

119. No information on the level of plasmapheresis being performed at other RTCs was included in the documents provided to me for review.

120. However, from memory, there was a difference in programmes across RTCs as its implying here, and we belonged to the 'recovered' party rather than the 'pheresis' party. The other RTCs in the same camp as us from memory, were Newcastle and East Anglia, who were also in favour of recovered plasma. I am fairly sure, however this is all very much from memory.

121. We felt that we could reach what was demanded from us by BPL using our current techniques so there was no great urgency to go onto a more expensive method of plasma production. We were never pressured by BPL to produce more plasma; we were always able to satisfy their demand.

122. However, towards the end of my tenure at TRTC, the need for plasma was such that apheresis units were set up in Sheffield and Leicester.

27. The Inquiry understands that you wrote a letter to Mr J Adey of the National Blood Authority ("NBA") on 7 December 1993 in which you stated that "a combination of BPL requirements and the fixing of a unified price for plasma, irrespective of its method of procurement" would lead to a reduction in "plasmapheresis activity to as near zero level as possible". Could you please explain whether this occurred, your views on this situation and what impact, if any, this had on attaining national self-sufficiency. (NHBT0017589)

123. I have had sight of the letter dated 07 December 1993 to Mr Adey. I have recently read this letter whilst I was preparing this statement. The purpose of this letter was to set out my opinions on several matters prior to the forthcoming executive meeting.

124. The letter goes through the Bain proposals and I have gone through each of the topics that Bain was looking at so the first one was plasmapheresis, then platelets, bag cost reduction, ALT testing, diagnostics, marketing plan and the research plan.

125. I think, probably the point about plasmapheresis was that the policy for the next three years was virtually fixed by a combination of BPL requirements and the fixing of a unified price of plasma, irrespective of its methods of procurement. RTCs were underpaid if they had machines.

126. I state that "*all centres will now inevitably reduce their ordinary plasmapheresis activity to as near zero level as possible*". This was down to two factors, the stockpiles and the price. There is no doubt that the question of the differential cost of producing plasma would be a disincentive, in the context of a unified price being paid. However, what I think I meant, as far as I can remember was that this was just another way of saying that, from the point of view of producing plasma on a cross-charging basis, it would be better to get as much recovered plasma as possible and reduce plasmapheresis activity for BPL plasma.

127. I say that plasmapheresis will probably still be used for the harvesting of immune plasma, and then there's a body of feeling within the four major pheresis centres that the majority of this supply should come from those four centres. In addition, and after discussion with our regional clinicians, we intended to switch the provision of clinical FFP to apheresis, thereby releasing more recovered plasma for fractionation at BPL. This has the added advantage of being a preferred clinical product in that it reduces donor exposure as far as patients are concerned. By a combination of these two continuing plasmapheresis activities and the probable need to

harvest platelets by apheresis, I believed that we could and should maintain our expertise in the field against the time when circumstances changed and increased demands for plasma were made on us.

128. So, again, I am probably referring to the lull in demand and there is no doubt that directing apheresis plasma to local clinical use meant that the recipients were, potentially, exposed to fewer donors than having to have three or four or more units of recovered plasma, whereas the three or four or more units of recovered plasma would be subjected to viral reduction methods at BPL removing that particular danger.

129. This worked out quite well and takes account as well of the reducing demand for local clinical FFP due to the production of the coagulation factors of BPL and available commercial material. Once those things were up and running then the major users (of native FFP and cryoprecipitate) reduced, so as far as we were concerned, going this way meant that there wouldn't be an explosive need for apheresis because the demand for clinical plasma, either as full plasma or as cryoprecipitate, was diminished because of the production of Factor VIII.

28. In the same letter you wrote that "[...] we intend to switch the provision of clinical fresh frozen plasma to apheresis, thereby releasing more recovered plasma for fractionation at BPL. This has the added advantage of being a preferred clinical product in that it reduces donor exposure so far as patients are concerned". Could you please explain what this meant especially with regards to patient concerns.

130. These were *our* concerns about the number of donors the patients were exposed to, not concerns voiced by the patients.

Apheresis

29. The Inquiry understands that you attended a meeting of the National Directorate of the NBTS National Management Committee at which it was

intimated that HBsAG donors could be readmitted to the apheresis donor panel as per UK TTD Committee minutes of 6 December 1991 and that HIV donors could be "admitted according to the current programme agreed by EAGA. All ELISA positive donations should be discarded" (NHBT0097469_014). Could you please clarify what you think was meant by these two statements? Was this approach ever implemented at your RTC?

131. I believe that the EAGA imagined situations whereby there would be a combination of tests which would indicate that the donor wasn't, in fact, infective with HIV.

132. Under most circumstances, the donor could be readmitted to the apheresis programme, though all ELISA-positive donations should be discarded.

133. With Hepatitis-B, that again, was a combination of the testing criteria. Hepatitis-B was unlike HIV in that the donor could be regarded as being virus free completely when the testing criteria had been met. This probably involved Hepatitis-B core testing as a final arbiter of the absence of a viral load.

134. I do not believe that this approach was ever implemented at the TRTC.

Use of plasma reduced blood and red cell concentrates

30. What steps, if any, did the TRTC 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?

135. There were meetings, not on a terribly regular basis, but routine meetings between the consultant staff at the Transfusion Centre and the hospital haematologists, who would be in charge of their blood banks and blood usage in the hospitals, and the gospels were spread there.

Occasionally we would find that there would be a particular clinician or group of clinicians who were resistant to the use of more sophisticated cellular products and we would meet with them on an individual basis, particularly the cardiac surgeons.

136. The cardiac surgeons, initially anyway, were very keen on the idea that their patients were losing whole blood, so that had to be replaced by whole blood.

137. We would resort to individual persuasion where necessary. The cardiac surgeons did eventually come round (some of them reluctantly) to the fact that they didn't need to use whole blood.

138. Following on very closely after this concept of producing concentrate to harvest the plasma, the cardiac surgeons again in particular got into the realm of blood saving and blood recovery during operation which they took to enthusiastically. So, they were reducing their requirements on us anyway. In addition, the concept of using crystalloids and / or colloids instead of plasma products for volume replacement in acute blood loss situations, began to be more accepted in many surgical and A&E situations.

Section 5: Arrangements for obtaining and allocating blood products at the TRTC

31. Please describe the arrangements in place in the Trent 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:

139. I believe that I have already discussed this point above.

a. Please identify which haemophilia centres were supplied with such

products by the TRTC and over what period of time.

140. To confirm, BPL *produced* the products and the TRTC simply acted as a distributor.

b. Please outline the respective responsibilities of the TRTC, BPL, the relevant Regional Health Authority ("RHA"), and haemophilia centre directors, and how these responsibilities changed over time (NHBT0076990_060 and NHBT0017193)

141. TRTC was responsible for the distribution of BPL material and that function was funded by the RHA as part and parcel of our routine deliveries to the hospitals and to and from BPL. Haemophilia Centre Directors in Trent took responsibility for direct negotiations with BPL and with such companies as they used for their imported factor concentrates, based on clinical choice or clinical need.

142. Those responsibilities to the best of my knowledge didn't change over the period we are talking about. They started like that and it stayed like that. The product changed but not the arrangements.

143. I have reviewed the documents referred to being the standard Service Agreement / Contract to Supply for the provision of blood and its components to hospitals within the Trent region. The hospital named was not a Haemophilia Centre, but paragraph 2.3 confirms that the supply of fractionated products will be the subject of an individual agreement between the provider units (i.e. hospitals or haemophilia centres) and the supplier (i.e., BPL or commercial) direct.

144. The other document referred to, being NHBT0017193, notes that Dr Gunson was asked to contact "certain RTCs" – those not performing to their own targets for supply of plasma to BPL – and ask them to increase their plasma supply. The TRTC was not one of those centres.

32. On 27 September 1977 you wrote to Dr Maycock explaining that "In common with most regions, a fair amount of money is still spent in Trent on commercial Factor VII" (CBLA0000660). In contrast you wrote a letter on 14 July 1981 stating that "In the case of Trent, we act as a central distributor only for Factor VIII produced at BPL. An offer was made some years ago to coordinate regional ordering and distribution of commercial material but this was rejected at that time by the Haemophilia Centre Directors in this region. In view of the changes likely to come about in the next few years, I am going through the process again and any change in policy will be notified to the Advisory Committee as and when it comes about" (DHSC0002209_041). Could you please explain when and why the decision was made at the TRTC to stop obtaining commercial sources of Factor VIII? Was this decision later reconsidered?

145. I have had sight of the letter that I wrote to Dr Maycock dated 27 September 1977 stating that a fair amount of money was still spent in Trent on commercial Factor VIII. I note that some four years later I wrote a letter on 14 July 1981 stating that in the case of Trent, we acted as a central distributor only for Factor VIII produced at BPL.

146. We didn't stop obtaining commercial sources of Factor VIII at TRTC because we never started. I think I wrote the letter because at the time some of the RTDs said we needed to know what the overall view was. So, everything should come via us and then we would know what the sum total of Factor VIII was. Some regions managed to get their Haemophilia Centre Directors to agree to that and said that it worked very well but quite a lot of HCDs were resistant. Those in the Trent region didn't want anything to do with it. We did try twice to get them on board, but they still refused.

147. With regards to the letter dated 27 September 1977 where I state – "*In common with most regions, a fair amount of money is still spent in Trent on commercial Factor VIII*", I am referring to the ***haemophilia centres*** in Trent and not the TRTC.

33. The Inquiry understands that you were present at an RTD meeting on 17 March 1981 at which the purchase and distribution of commercial factor VIII was discussed. In particular, it was noted that this should be undertaken by RTDs and that costs "should not be borne by the BTS budget". However, it was recorded that you and Dr W Jenkins had "experienced opposition from Haemophilia Directors" in your region (NHBT0018341). Did you understand the reason/s why there was opposition from Haemophilia Directors in your region to RTDs purchasing and distributing commercial Factor VIII?

148. I was the chairman of the meeting on 17 March 1981 at which the purchase and distribution of commercial factor VIII was discussed. It was noted at the time that this should be undertaken by RTDs and that costs should not be borne by the BTS budget. However, Dr W Jenkins and I had experienced opposition from Haemophilia Directors in our region.

149. Dr Jenkins was the RTD of N.E. Thames RTC at Brentwood.

150. I believe that the opposition was because they wanted clinical freedom. There had been a clinical freedom to select treatments including their origin and I think this had been built into the ethos of the Department of Health since at least 1976 so it wasn't something new.

34. In 1988 the Chief Deputy Medical Officer, E L Harris wrote a letter to you in which he noted that "The present method of pro-rata distribution of blood products does not seem appropriate to ensure that the greatly increased amounts of Factor VIII reach the Centres where it is required. Plasma rich Regions are not necessarily those needing most Factor VIII" (DHSC0002404_122). To what extent do you agree with this statement? Was your RTC ever in a position where it supplied more plasma for Factor VIII production than it received? If so, were commercial alternatives procured to make up the shortfall?

151. I have recently had sight of the letter referred to above dated 14 April 1988 from the Chief Deputy Medical Officer, E L Harris to myself.

152. I think Factor VIII needs would inevitably be greatest in the largest regions, which will have had a higher proportion of haemophiliac patients but also a larger number of donors on which to draw for their plasma needs. In addition, an exceptional concentration of patients, such as was the case at the Treloar school, was catered for by an exceptional distribution of Factor VIII, designed to avoid any imbalance in supply/demand at the RTC concerned.

153. The TRTC was always able to provide the amount of plasma required by BPL to fulfil their contractual requirements with the haemophilia centres in Trent, bearing in mind that it wasn't 100% treatment with BPL material. The TRTC was not involved in the procurement of commercial Factor VIII used in Trent Region.

35. You were present at the meeting of the NBA Technical Working Group on 3 April 1992 at which it was noted that the price of BPL NHS plasma "was higher than that paid by its commercial rivals for plasma from paid donors abroad." To what extent do you think this had an impact on RTCs' abilities to purchase safe blood products? (NHBT0000488_012).

154. I confirm that I was present at the meeting of the NBA Technical Working Group on 3 April 1992 at which it was noted that the price of BPL NHS plasma was higher than that paid by its commercial rivals for plasma from paid donors abroad.

155. This does imply that commercial Factor VIII was cheaper to the user than BPL Factor VIII. Quite a few of the people producing Factor VIII also had their own donation systems and would run their own plasma harvesting, presumably with the benefit of scale. This would make the plasma cheaper than could be achieved by individual RTCs.

36. 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?

156. I think there was a degree of regional differentiation. Some regions (RTCs) had the situation of being the orderers, purchasers and handlers of imported blood products, so that it was centralised at Regional level but never, as far as I knew, did they have the choice of product, they just ordered what their Haemophilia Centre Directors wanted.

157. It rather looks as though the majority were involved in the handling of commercial material. I think there was only myself and John Jenkins who experienced the opposition from haemophilia directors.

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

158. Neither I nor anyone else at the TRTC contracted directly with any pharmaceutical company as referred to above.

If so, please describe:
a. how and by whom the decision was made to contract with the particular pharmaceutical company; Not applicable
b. the broad terms of the contractual agreements made; Not applicable ***and***
c. the factors taken into account when determining whether to contract with one pharmaceutical company over another Not applicable

159. Not applicable

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

160. The shortfalls in Trent didn't really happen, we were normally able to get the products that were required.

161. The haemophilia directors were able to get from BPL all of the BPL products that they contracted for. I was never aware that the Haemophilia Directors in Trent were ever told that they couldn't have as much of the BPL material as they'd ordered.

162. They decided amongst themselves on an individual basis what proportion of BPL and imported material they were going to have and as far as I'm aware, the amount of BPL material which they decided they would have, was generally fulfilled.

39. Was the TRTC 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?

163. No.

40. If haemophilia centre directors were responsible for these decisions, did the TRTC have any influence over their product choices? (BPLL0005770)

164. The consultants at the transfusion centre met with the Haemophilia Centre Directors to discuss the preferences of the directors. It all went back to the question of whether they wanted us to make more cryoprecipitate. We didn't have any influence on their choice as I have already said, of home grown as against importing Factor VIII.

165. There was also an ongoing debate about concentrate versus cryoprecipitate. People understood the risk of AIDS at those meetings, with the Haemophilia Centre Directors saying they were possibly going to need more cryoprecipitate, and this was for babies, minimally treated or previously untreated patients, on the basis that treatment with

cryoprecipitate would expose them to fewer donors than the use of concentrate, thus reducing the risk until heat-treated Factor VIII became universally available. This gave them a better chance of never having been exposed to infected donation.

166. That was one of the reasons for this sort of meeting, to discuss whether they wanted to change back to cryoprecipitate away from concentrate until the question of infectivity was sorted out, in view of the position of viral testing at that time, which was well known. At the beginning it was unknown as to whether these tests were trustworthy or not. In Trent, I think in common with the rest of the country, the treatment with concentrate was still regarded as the first line of attack and I don't think many people if any turned back to the increased production of cryoprecipitate.

167. It did cause me some discomfort because I think we would have preferred to use more cryoprecipitate, but it was felt by haemophilia centre directors that the benefits of concentrate outweighed the risk.

168. We did use our best endeavours to try and persuade them that we would have been more comfortable with a greater use of cryoprecipitate or certainly a way of finding less use of American imports, but they just wanted to carry on pretty much as they were, especially as the American import was fully licensed for use by the FDA and in the UK.

169. I have been made aware that Professor Bloom wrote a letter to haemophilia centre directors, following a meeting in May 1983, saying that cryoprecipitate should once more be considered as a treatment of choice for neonates and minimally treated boys. I understand that this letter has been provided to the Inquiry, however I did not see a copy of it at the time, I was just aware of its existence. Whilst we didn't receive direct communication on this, we were aware that physicians were looking at the concept of adjusting the type of treatment to the status of the patient. For example, if I remember correctly, when the genetically

engineered material came in, it was said that haemophiliacs under the age of 16 should preferably be treated solely with that. They were trying to protect those who hadn't already been exposed or had the least exposure.

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

170. I think that one of the points that did come up was the availability of heat-treated Factor VIII. BPL didn't exactly lag behind, but their product became available after the commercial product, so there was no impetus there to change immediately between imported and BPL material.

171. In addition, users were aware of initial production difficulties associated with the commissioning of plant at the new BPL, which had a transient effect on the purity and yield of the product, though safety was unaffected.

42. 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.

172. As I have explained above, the Haemophilia Centre Directors enjoyed clinical freedom to choose either NHS blood products and/or imported blood products in the UK.

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

173. The TRTC didn't have any contact with the pharmaceutical companies and in terms of the advice that was given by the pharmaceutical companies other than their generic product inserts I really don't know.

They may have had people going around on an education basis to speak to haemophilia directors.

174. I would have expected that the reps were available and would be up to date giving the advice that they could give on the use of their products and any changing advice due to changes in the production.

44. The Inquiry understands that you were present at a meeting of the National Directorate of the NBTS National Management Committee on 16 April 1991 at which it was noted that budget devolution had led to a "lack of uniformity and consistency in the approach by RHAs [...] Consequently the variation in the value attached to products is considerable". Therefore, a suggestion was made that the Directorate establish a uniform price for products. Was this achieved and what impact, if any, did budget devolution have on the ability of the TRTC to obtain blood products? (NHBT0000191_144)

175. I confirm that I attended the meeting of the National Directorate of the NBTS National Management Committee on 16 April 1991.

176. The minutes refer to the fact that the members reported that the chief difficulty in budget devolution so far encountered was the lack of uniformity and consistency in the approach by RHAs, since Treasurers had developed their own policies. Some RTCs had received development funds for anti-HCV testing, others had not. Some RTCs had also included a service element in the cost of their products and others had not. Consequently, the variation in the value attached to the products was considerable.

177. I note that Dr Harrison asked whether the Directorate would determine a single price for products to facilitate inter-regional ad-hoc stock transfers. Such a scheme would have needed the agreement of all RTDs if it was to work and at the time, members were uncertain whether this would be forthcoming. I note that six months after requesting regions' costings,

only five RTCs had responded. The Directorate did not therefore have the information to set a single price even if it were to be agreed.

178. I do not believe that the Directorate ever managed to establish a uniform price for products.

Product liability and Crown Privilege

45. The Inquiry understands that you attended an RTD meeting on 27 June 1979 at which it was noted that "Directors were worried that they, as producers of blood products at the RTCs, could be held personally responsible if the product was eventually found to be defective". It was further discussed that "Dr Cash thought that it was difficult to discuss product liability until the Department decided whether the NBTS should be covered by Crown privilege, and if there was to be no Crown privilege then the Government would have to provide financial support in the event of a mishap leading to liability" (DHSC0002367_003). Please answer the following questions:

a. Was a determination made by the Department of Health and Social Security with regards to whether Directors were to be held personally responsible for defective blood products?

179. As far as I know, no determination was ever made by the Department of Health and Social Security with regard to whether Directors were to be held personally responsible for defective blood products.

b. Do you know whether infected blood products fell within the scope of product liability at the time?

180. I don't believe that they did. This only became a legal requirement in March 1988. It was one of the Directives from the EU that fractionated products would be classified as 'drugs and medicine' and so they fell under product liability.

c. ***If so, were you or the TRTC ever found liable for producing or issuing infected blood which amounted to a defective product?***

181. No.

46. The Inquiry understands that you were present at a meeting of the Northern Division of the NBTS on 15 February 1990 at which there was a discussion about the unsatisfactory way in which BPL had communicated a reaction to a batch of albumin to different centres. Grave concern was raised "about the quality assurance of BPL products". Furthermore, it was stated that "There is no commitment to buy NHS Factor 8. NHS Factor 9 is regarded as an outdated non-pure product. Dr Lee reported that only 70% of BPL products appear to be taken up. A possible agreement that the RTCs have a commitment to take a certain amount of BPL product was not welcome. Concern was expressed for the future of BPL" (NHBT0070258). Could you please explain whether:

a. You agree with these statements;

182. It appears that I was present at the meeting on 15 February 1990. I do not recall the incident regarding albumin but from reading the minutes I can see that with regard to the Manchester RTC, a fax was received by a Medical Laboratory Scientific Officer but for Trent the information was imparted casually to Dr Forman following a phone call on a different topic. This would certainly have raised concerns regarding communication from BPL on quality assurance matters.

b. Whether BPL was producing products using outdated techniques;

183. The answer to this would lie in the transition from the old to new BPL. In the old BPL yes, they were using outdated techniques because they weren't equipped to undertake the modern techniques, but the new BPL certainly was. By 1990, the date of the next meeting, the new BPL had

been open for a few years and they were issuing 8Y which was an 'up to date' product.

c. Whether 30% of BPL products went regularly unused;

184. I do not believe that this would have been a 'regular' thing and I cannot imagine this applying to Factor VIII. There may have been instances where albumin was bought from a commercial source by a hospital, leaving albumin at BPL on the shelves, but as a general statement, I don't think this applies across the board. Not as much effort had been made into the production of Factor 9 in the new plant so there may have been old stock that was unused because the focus was very much on Factor VIII.

d. Why you think RTCs were reluctant to use BPL products; and

185. I do not believe that the RTCs were reluctant to use BPL products. They were keen to maximise the availability of BPL products. They were working towards self-sufficiency because they wanted everyone to have British products as far as possible.

e. Why the Division thought that BPL's future remained uncertain?

186. At that time, around 1990, we were still very much in the realms of clinical freedom of prescribing and a move towards technology which I don't think BPL had the time to embrace, during the transition from old to new laboratories. Old products were side-lined by new products which were rather less dependent on human plasma as a source. BPL were a *blood products* laboratory and focused on that rather than anything else.

187. When BPL moved into their new premises and started producing up to date products, I was quite happy with that. I think that one thing they had to put right which was missing at the beginning was the shop-floor interface with users. They didn't have a system where they would go

round routinely and talk to consumers until long after the commercial enterprises were doing it.

Section 6: Production of cryoprecipitate at the TRTC

47. Did the TRTC produce cryoprecipitate? If not, where was this produced for the TRTC region and what were the arrangements in place?

188. Yes, the TRTC produced cryoprecipitate.

48. If the TRTC did produce cryoprecipitate, please describe:

a. Where the production of cryoprecipitate took place;

189. The production took place at the transfusion centre.

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

190. Broadly, the plasma was rapidly frozen and left overnight at 4 degrees centigrade which resulted in a precipitate staying behind which was rich in Factor VIII. This would then be separated off in the closed bag systems to be used as a direct dose of Factor VIII for haemophilia patients. We were able to produce cryoprecipitate for quite a significant % of the whole blood donations. These couldn't *all* have been transferred to cryoprecipitate as we still had the demand from clinicians for whole blood. If this demand hadn't been there, technically, we could have transferred 100% of the donations to cryoprecipitate.

191. The capacity to do so changed during my time there because we built a separate plasma processing department in the late 80s. This substantially increased our ability to manufacture cryoprecipitate.

192. I am aware that it is being suggested that when it was understood in the early 80s that HIV could be transmitted by blood and blood products, all haemophilia patients should have been immediately treated by cryoprecipitate going forward. If this had been asked of us, then I do believe that we would have been able to provide enough cryoprecipitate to meet demands. We would have done this by taking on extra staff and it would have included changes, for example shift work.

193. As set out above, in the late 80s we built a new department to increase the floor space and the equipment for the separation of the plasma was fairly straightforward so we could have managed.

194. In 1983-1984 which is the relevant time referred to here, physical space would have been a problem, but we could have run shifts, so it *could* have been done, *if* we had been asked.

195. I do recall conversations nationally amongst HCDs and locally between consultants at TRTC and HCDs in Trent, taking place about whether we should be switching to cryoprecipitate. For example, I think it was Professor Bloom who said that haemophilia patients under the age of 16 should have been treated exclusively with cryoprecipitate but this only increased production marginally.

196. To switch over completely and treat all adult haemophilia patients as well would have taken much more persuasion of the patients. I think they would have been reluctant to switch because they were very much in the thought process of risk v. benefits. It was thought that the biggest risk was the risk of bleeding and the best way to deal with that was to treat with Factor concentrate.

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

197. We didn't send cryoprecipitate at all to the BPL. We produced it for local use.

d. How much funding was provided by the Trent RHA for the production of cryoprecipitate; and

198. It would not have been directly funded by Trent RHA, but it would be contained in our overall annual budget. This would have been up to 1989 roughly for the RTCs when cross-charging came in.

199. To confirm, the TRTC was never provided with *any* funding which was specifically for cryoprecipitate.

e. How quickly the TRTC could have increased its manufacturing of cryoprecipitate, had it wished to, during the early 1980s.

200. Please see my answer to 48(b) above.

49. Please explain what consideration the TRTC 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.

201. Please see my answer to 48(b) above.

202. We talked this over with the Haemophiliac Centre Directors in Trent about whether they wanted to switch back to cryoprecipitate, but this was never confirmed to us.

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

203. The TRTC didn't undertake any steps to increase the production of cryoprecipitate, we only produced what we were asked to produce by HCDs in Trent. In relation to increased numbers, please see my response above.

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

204. Our routine was to go twice a week to each hospital to deliver blood and blood products and this would be on the basis of a regular allocation together with a direct request for an increase if there was a particular need by the people at the receiving end. There would be feedback from the Haemophilia Centre Directors to the blood banks for cryoprecipitate allocation to be included in the regular orders.

Section 7: Self-sufficiency

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

205. It all depends on what we mean by self-sufficiency. To me, it meant the production of blood and blood products sufficient to meet the demands put on us by the clinical users. The Department of Health asserted that there should always be clinical freedom to prescribe products preferred by the medical staff concerned. This meant that there was, in practice, a proportion of Factor VIII which was supplied from outside the NHS. In those circumstances, self-sufficiency to me meant the provision of everything else, excluding the Factor VIII purchased from commercial sources.

206. The main driver for self-sufficiency was being able to produce Factor VIII. In relation to the other blood and blood products, it was achievable, and I think most people would say it was achieved.

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

a. Plasma procurement; yes, self-sufficiency was really the driving force behind plasma procurement.

b. Decisions with regard to cryoprecipitate production; yes, self-sufficiency was relevant to cryoprecipitate production in so far as we produced the level of cryoprecipitate requested by clinicians and so were self-sufficient in meeting the demand for that particular product.

c. Purchases of commercial blood products;

207. This is a two-way answer because self-sufficiency might direct the need to purchase commercial blood products but the desire to purchase it also influenced the definition of self-sufficiency. Some HCDs appeared to have a preference for commercial products but then on the other hand, some hospitals, such as Sheffield Children's hospital – never used any commercial to my knowledge, this was clinical freedom.

208. The Department of Health has always endorsed the principle of clinical freedom to prescribe properly licenced therapeutics, including in this case, Factor VIII. This means that the definition of self-sufficiency in the supply of blood products within NBTS ensures that the demands can be met.

c. Funding received from the Trent RHA.

209. I don't think this was ever increased purely because of a need to achieve self-sufficiency.

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

210. Again, this depends on the definition of self-sufficiency, if you exclude the purchase of commercial material at the clinical wishes of the users there was a good chance of achieving self-sufficiency in the rest.

211. The requests for some fractionated products decreased following an increased knowledge about the risks. People began to realise you didn't need to use some products in every instance; there was ongoing learning and education of the profession.

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

212. I think we all thought much the same.

56. The Inquiry understands that you were a member of The Technical Working Group on Operational Aspects of The National Blood Authority whose objectives, among others, was to ensure that the "policy in relation to self-sufficiency" was to be taken into account when framing its recommendations. Please explain whether the Working Group achieved this objective. (SBTS0000466_008)

213. I was a member of the Technical Working Group on Operational Aspects of The National Blood Authority. The Group was established to consider and report to Ministers on operational matters and in particular, the role of the NBA as the central contractor for blood supplies, its role in allocating capital to the Regional Transfusion Centres and the composition of the NBA.

214. I have had sight of the Report of the Technical Working Group dated July 1992.

215. I believe that The Working Group achieved its objectives as set out within its terms of reference in annex A of the Report. Of particular interest, the role of clinical freedom of Consultants was to be taken into account when considering the achievement of National self-sufficiency (paragraph 1.7 of the Report).

57. The Inquiry understands that you were present at a meeting of the Advisory Committee on the NBTS on 10 April 1984 at which it was noted that for some regions it may be "more economical to purchase commercially produced Factor VIII than to invest heavily in plasma procurement". Did the freedom of each region to choose where to procure their blood products stifle the UK's ability to achieve self-sufficiency? (CBLA0001835)

216. I confirm that I attended the meeting of the Advisory Committee on the NBTS on 10 April 1984. I have read the minutes from this meeting and note that it is recorded that for some regions it may be more economical to purchase commercially produced Factor VIII than to invest heavily in plasma procurement.

217. Again, this goes back to the definition of self-sufficiency, if we are looking at the production and supply of *everything*, then yes, it stifled it. However, if you accept the definition which takes into account clinical freedom to purchase commercial products, then I believe it didn't.

58. The inquiry understands that you chaired a meeting of the 209th Regional Directors Meeting held on 4 October 1988 at which it was noted that "Responding to the chairman, Dr Lane indicated that the attainment of self-sufficiency in Factor VIII remained problematic and was made more difficult by the independent line taken by Haemophilia Directors. He was concerned that guidelines prepared as recently as 6 months ago nominating 8Y as the product of choice were to be revised to include at least 2 other products as having equal merit". The minutes suggest that you summarised the point by stating that the current amount of fractionated plasma "would not achieve self-sufficiency for Factor VIII unless treatment policy was reviewed by the Haemophilia Directorate". What steps, if any, were taken by the Regional Directors to communicate this to the Haemophilia Centre Directors? What was their response? Did they review treatment policies? If so, what impact, if any, did this have on the ability of the UK to achieve self-sufficiency? (NHBT0018189)

218. I chaired the meeting of the 209th Regional Directors Meeting held on 4 October 1988. I have read the minutes from this meeting and note what was recorded.

219. This was one of the points that would be discussed by the HCDs, Richard Lane and Harold Gunson, not the RTDs.

220. I believe that I have already answered above regarding self-sufficiency.

59. At the same meeting "Dr Fraser expressed serious concern that any of those present could really achieve the increase in plasma supply which was being discussed because of problems not only with funding, and with staff but also falling donor panels". To what extent did these three factors have an impact on the ability of the UK to achieve self-sufficiency? Also, what do you think Dr Fraser meant when he mentioned falling donor panels?

221. Funding would have been required if you were going to increase plasma supply on a capital *and* revenue basis. Staff would need to be increased and working practices changed to include shift work.

222. Falling donor panels have always been a problem in as much as very often regular donors tend to be more middle aged and elderly people and they fall off the edge of the age spectrum and replacing them becomes more and more difficult. In addition, many people apparently believed that you could catch HIV by *giving* blood, this was putting potential donors off. We had to make it explicit in one of our subsequent leaflets that this was not the case and we tried to reassure potential donors that they could not catch AIDS by donating blood.

60. You chaired the 210th RTD Meeting on 18 January 1989 at which a Mr Crowley noted his "reservations about the concept of self-sufficiency since he was sure that Haemophilia Directors would always want a

product other than that available from BPL". Do you agree with this statement? Did Haemophilia Directors have the clinical freedom to purchase non-UK derived blood products and if so, do you think this had a direct impact on the impetus for the UK to become self-sufficient in blood products? (NHBT0018188)

223. I chaired the 210th RTD Meeting on 18 January 1989. I have read the minutes of the meeting and note that Mr B. Crowley voiced his reservations about the concept of self-sufficiency since he was sure that Haemophilia Directors would always want a product other than that available from BPL. I agree with Mr Crowley's reservations, with the proviso that, in my opinion, HCDs in general favoured the availability of both BPL and commercial Factor VIII, with the clinical freedom to choose either or both.

224. At this meeting, I welcomed the increase in F8 yields which prompted Mr Crowley to reflect on the diversity of assay results for F8 at PFL, BPL, NIBSC etc. He was taking a personal interest in resolving these discrepancies.

225. I believe that I have already answered above regarding self-sufficiency and how this was impacted.

61. You wrote a letter on 2 March 1990 to Dr R J Moore, Deputy National Director of the National Directorate of the NBTS, noting that "we are just about at this self-sufficiency rate for plasma now ". Could you explain when, if at all, the Trent region became fully self-sufficient and if so, what this meant? (NHBT0097035_070)

226. I have recently had sight of the letter I wrote to Dr R J Moore, Deputy National Director of the National Directorate of the NBTS dated 2 March 1990. I wrote that "*we are just about at this self-sufficiency rate for plasma now* ".

227. I believe that I was referring to the amount of plasma which would need to be sent to BPL for the manufacture of sufficient products for Trent to become fully self-sufficient without recourse to the purchase of commercial products.

62. On 16 July 1991 you were sent a letter by Dr R J Moore in which it was stated that "NBTS was able to supply more plasma than BPL would take". In light of this comment, do you think BPL's operational capacity limited the UK's ability to become fully self-sufficient? (NHBT0001090)

228. I have been provided with a copy of the letter dated 16 July 1991 sent by Dr R J Moore to myself.

229. I think that at this time BPL would only take sufficient plasma to match demands and that doesn't necessarily mean that their operational capacity was limited, it was demand driven.

63. In the same letter two definitions of self-sufficiency were mooted:
a. "Meeting the need for NBTS plasma products as expressed by user clinicians"; and
b. "An embargo on the use of any non-UK derived plasma"

Which definition did you think was the most appropriate?

230. I believe that the first definition was the most appropriate.

In that same letter Dr Moore stated that the Department of Health was not in favour of the latter definition. Why did you understand this was the case?

231. The question of an embargo would be in direct contravention of the DHSS policy on clinical freedom to prescribe any licensed pharmaceutical.

64. The Inquiry understands that you were present at the second meeting of The Technical Working Group of the National Blood Authority on 28 April 1992 at which it was stated that "BPL paid a higher price for unpaid UK donor plasma than its rivals did for paid plasma from abroad [...] In the long term it could be difficult to sustain the UK's position of fractionating its plasma within the health service and there would be pressure overtly to subsidise it or to make the system commercial". As far as you are aware, why did BPL pay a higher price for unpaid plasma donations? The statement also seems to suggest that the UK might not have had the financial resources to continue to fractionate NHS derived plasma. Do you agree and did this have an impact on the UK's ability to become self-sufficient? (NHBT0000488_003)

232. I was present at the meeting on 28 April 1992, and I have read the minutes.

233. BPL paid a higher price for unpaid plasma donations because this included the cost for producing the plasma at RTCs and included an element of payment for the organisation of donors and their handling and recruitment. In general, commercial Factor VIII producers had organisations whereby they could harvest their own plasma without going through an intermediary like a transfusion service.

234. If donors were paid it provided a tighter hold as to how the donors could be 'organised' to meet the requirements or the need of the producers.

235. In addition, it is possible that commercial producers were able to spread their costs over a wider range of pharmaceutical products.

236. To me, the quoted statement does not imply that the viability of fractionation at BPL, as a purely NHS activity, was threatened only by lack of financial resources. However, the suggestion that diversification of BPL activities might be an option was well made.

Section 8: Services for donors at the TRTC

65. Please describe the donation process at the TRTC and the services which the TRTC provided donors.

237. With regard to the procurement of recovered plasma, once the donor had completed the medical checklist and consent forms, a set of eight barcode labels was issued. One was stuck onto the donor's record card and one on the Blood Drawing Record Sheet (BDR), to which was also added the donor's name and a bar coded group label based on the donor's previous history. The remaining six barcode labels were given to the donor who then proceeded to the haemoglobin-testing table.

238. New donors (and walk-in known donors) were issued with pink edged barcode numbers and their details were entered onto a green BDR, blue being the colour for known donors. The card records system was also colour-coded according to blood group, new donors being issued with a temporary buff-coloured card. It had been the practice in the past to transfer new donor's records to a colour coded card once they had been grouped but because of the planned computerisation of records this was no longer done.

239. The haemoglobin limits of acceptance were 125g/litre for females and 135 g/litre for males. The copper sulphate solutions were used 25 times and then changed for fresh ones. If a donor failed the test, it was repeated. If this was also below the required level, the donor was not bled but a venous sample was taken and sent to the Haematology department of the Northern General Hospital for a full assay.

240. Accepted donors were then taken to a bleed bed by a Donor Attendant (DA) who prepared the donor's arm and collected the appropriate blood pack. Lignocaine (local anaesthetic) was not routinely used but was

offered to donors and was dispensed into disposable syringes from multi-dose vials.

241. Venepunctures were performed by the MO and, once the bleed had started, the DA applied the remaining barcode labels, one to each sample tube and one to each pack. Excess labels were put (undamaged) into a "burn bin". If a sample tube was ever dropped and broken, the practice was to obtain a fresh tube and label it with the barcode label removed from the broken one.

242. At the completion of the donation, a DA clamped off and cut the bleed tube and took the samples. The packs were taken to the processing table where they were stripped and sealed (two segments), put into polythene bags and crated. The samples were then racked. When the crates were full the driver would collect them (unless the donations were to be used for platelet preparation) and then they were loaded into a refrigerated vehicle. Temperature gauge readings were logged by the driver at regular intervals.

243. Blood from the sessions was then removed from the transport and put into overnight fridges on trolleys, together with the samples. Blood Products staff collected the donations each morning, they counted the packs and entered the details onto a daily record book which was used to calculate the number and type of product label required and reconciled the labels used.

244. These were then taken back to the TRTC's laboratory.

245. The services to donors included the opportunity for basic health screen, opportunity for interview with on the spot medical/ nursing staff, the availability for counselling and referral system for anything serious and the provision of transport for donors requested to attend for urgent/specific donation.

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

246. The process at the TRTC for calling up regular donors was always postal. The donors were sent a date for the session being held and we always included the AIDs leaflet so they would have read it before they came into the centre. We handed out the leaflets to the walk-ins and they were asked to read it and sign to say they understood it.

247. Form 110a was subsequently changed to specifically state that they would be tested for HIV and they had to sign to agree to that. We did this as part of the registration process.

248. Prior to testing for HBV and HCV, donor questioning included reference to significant previous medical history, including jaundice, as outlined in the Red Book Guidelines. This was included in a donor leaflet, along with other conditions which would lead to deferral of donation, again as defined in the Guidelines. If any of the routine questioning pointed towards deferral, the donor was offered the chance to speak with the medical officer or senior nurse conducting the session, who would advise regarding interpretation of the donor's answers to the questions and the need for any laboratory and/or medical follow-up.

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

249. The donor concerned would be counselled by a senior member of the medical staff of the transfusion centre. I think the one for Trent would have been Dr Virgie James, as she was the consultant in charge of the screening laboratory and had significant input with regard to donor selection etc.

250. The counselling at the RTC would have been at the level of explaining what the results were, what they meant and arranging for repeat testing to be done. Further follow-up would be done by referral to the donor's General Practitioner, and we would suggest a referral to an interested physician, usually a liver physician for those with hepatitis and a sexually- transmitted disease clinician for those with HIV.

251. Once they are referred clinically, it would then be up to their treating clinicians to refer on as appropriate in the circumstances and sometimes this would include psychological treatment.

68. On 9 November 1989 you wrote a letter to Dr H H Gunson in relation to a pilot study for Anti-HCV in which you stated that, "As you suggest, some of the financial aspects can only be roughly estimated at this stage, particularly so far as counselling is concerned, but we shall do our best to paint as black a picture as possible" (NHBT0000188_107). Could you please explain what you think you meant by this? Did this approach of painting "as black a picture as possible" figure in to your estimations when you advised Dr Alderslade on 29 November 1989 that the "horrendous arrangements which may have to be made with regard to counselling of those donors found to be positive cannot at this stage be estimated"? (JPAC0000042_042)

252. I have had sight of the letter I wrote to Harold Gunson dated 09 November 1989. I state that the crunch will come when it comes down to the enforced delay in the issue of components until the results of all tests are ready, but this is what this particular pilot study is about. I say that some of the financial aspects can only be roughly estimated at this stage, particularly so far as counselling is concerned, but we shall do our best to paint as black a picture as possible.

253. I think what I meant by 'as black a picture as possible' was in relation to the financial aspects, and that I would not, in my request for further

funding, be overly optimistic, as this would have risked an underfunding situation.

254. At that time, it would have been impossible for us to put a cost on the counselling and the reliance was on the counselling being carried out by the referred clinician. In 1989 it was very difficult with the early HCV testing to obtain a reliable result and potentially there were quite significant numbers of false positives, who would still have to be referred.

255. There was an arrangement for each transfusion centre to nominate a HIV counsellor who would go to an instructional meeting at one of the London hospitals. Virgie James was our nominated consultant.

256. In the second letter dated 29th November 1989, I also state that regions may well be hearing about the need for such counselling measures from the Department of Health, since the UK Advisory Committee on Transfusion Transmitted Diseases, working under the auspices of the National Directorate of the NBTS, was preparing a brief for presentation to Mr Graham Hart. We were hoping that funding for the inevitable testing of donors would include an element for follow up. It suggests that those who have so far helped might be completely overwhelmed so it may be that hepatologists would carry the burden at district level.

69. On 1 February 1990 you wrote a letter to Dr D Triger at the University of Sheffield in relation to the Anti-HCV testing of donors. Commenting on the situation of positive donors and their follow up you stated that, "As with HBsAg and HIV, there is little that a transfusion centre can do beyond initial contact with a donor found to be reactive [...]" (NHBT0000189_040). Could you please explain what you meant by this?

257. I have had sight of the letter dated 1 February 1990. I also recommend a referral system to be developed along the lines of that employed for donors found to be positive for HBsAg.

258. This was because there was a need for full medical follow up of these donors, repeat testing, clinical support and full counselling and the most appropriate person to deal with this would be the clinician to whom the patient would be eventually referred via their GP, not the transfusion centre. We all believed it to be proper policy to refer to the donor's GP in advance of a direct referral to consultant.

259. The possible financial consequences of such a system were the subject of my letter to Dr Alderslade, mentioned above.

70. The Inquiry understands that you were present at a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases on 8 January 1991 where it was noted that donors who tested positive by both RIBA and PCR may be counselled at the RTC or by hospital staff. Who was responsible for making the decision of where a donor would be counselled? Did the counselling services at the TRTC and local hospitals differ? If so, how? (section 4.5 of NHBT0000073_028)

260. I was present at the meeting on 08 January 1991. When a donation was reported positive, arrangements should be made for that donor to receive counselling and as set out above, this could be by trained medical or nursing staff either at the RTC or hospital.

261. Our designated counsellor was Dr Virgie James, and she was responsible for making the decision as to where a donor would be counselled.

262. The counselling services at the TRTC and the hospital differed in that the initial counselling at the RTC would be explaining the tests and what they meant and obtaining permission to go to their GP to obtain the referral to a specialist unit / consultant.

263. Any positive donors who were counselled at the RTCs were referred for specialist advice.

71. You were present at another meeting of the same group on 10 June 1991 at which it was stated that "finance would not be available at some RTCs to carry out the counselling of the donors by RTC staff". Please explain who funded donor counselling at the TRTC and whether finance was made available to the TRTC to carry out this service. If not, why not? Please see section 4.2.2 (ii) of NHBT0000044_003 for more detail.

264. I was present at the meeting on 10 June 1991. I can see that at section 4.2 that there was some concern that because of financial constraints, the ideal policies may not be feasible as finance would not be available at some RTCs to carry out the counselling of the donors by RTC staff.

265. The TRTC received funding from the RHA and the limited amount of counselling that we undertook was contained within the routine budget and existing staffing levels.

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

266. Please see my responses to questions 69 and 70 above. The counselling and psychological services available for recipients of infected donations was the same as it was for donors. The recipients of infected blood or blood products would already be under the care of a specialist clinician so it would be most appropriate for them to deal with any counselling or psychological support that a patient may need.

267. The RTC would be contacted by the treating clinician as part of the look-back routine.

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

268. Yes, I believe that they were sufficient. It was appropriate because the NHS had and still has services purely for patients with hepatitis and HIV and it needs to be holistic and take on that treatment. This would not be for RTCs to involve themselves in.

Section 9: Meetings of various committees

Meetings of Regional Transfusion Directors [England and Wales]

74. The Inquiry understands that you were the Chairman of these meetings for a time. Please outline this time period and describe what role this entailed.

269. There are two periods in which I chaired these meetings. The first was from 1981 to 1984 and the second was 1988 to1989.

270. My role was really one of monitoring the discussions going on round the table; there was very little that was needed to be done in terms of negotiating a consensus, if there were such a thing then that would have fallen to the chairman. Occasionally a point would be raised that required communication with an outside body and it would be the chairman's job to carry out that communication and provide feedback to the RTDs. It was a non-executive chairmanship because the RTD meetings had no remit to make decisions which were effective on other centres or the transfusion service.

271. The meetings would be minuted and circulated and it would be up to the individual RTCs to implement the decisions made at the meeting, but there was no compulsion to do so and there were no sanctions if they didn't.

272. It was up to each individual RTD to communicate to RTC staff any relevant matters discussed or decided at RTD meetings.

75. The Inquiry understands that you attended the final meeting between the Directors of Regional Transfusion Centres ("RTCs") in January 1989 (NHBT0018188). What do you consider to have been the purpose(s) of those meetings?

273. Yes, I did attend the final meeting. The purpose of these meetings was to inform and discuss all matters involved in the activities of the RTCs. These would be very wide-ranging and include every activity you could think of, including interactions with their own hospitals. Any consensus reached was not enforceable, but it was a very good outlet for people to bring forward developments or issues at their own centres. It was a very nice open forum and people were able to raise any concerns that they had. This was a beneficial aspect to it being informal, there was freedom to raise concerns about absolutely anything.

76. 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 so, please describe the decision-making process and how decisions were disseminated.

274. This was on the basis of round the table discussions leading if possible, to a consensus.

275. Those decisions when made were taken away by the RTDs and they were left to implement them into their own transfusion centres. They were not empowered to make collective decisions that would affect other RTCs.

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

276. Quite definitely yes, I believe that they were conducive to fulfilling the purposes for which they were established. They provided an excellent forum.

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

277. I chaired the final meeting on 18 January 1989. From reading the minutes it appears that there were a number of different matters that required discussion including Bone Marrow Panel, Associate Specialists, Clinical Grading and the National Director's Report. During the discussion about the latter, Dr Gunson reported that since the last RTD meeting, the National Management Committee of the NBTS had been established and had met on 2nd December 1988. He felt that it was important that the minutes of this and future meetings were discussed at Divisions to allow the National Directorate to have the opportunity to get the views from all medical staff in the service.

278. He therefore proposed that the Divisions should meet three to four weeks after the NMC meetings to discuss the minutes and to make an input to the next meeting. This would involve five meetings per annum. If this role for the National Management Committee and the Divisions was agreed he asked Directors to consider the future of the RTD Meeting and suggested that the business part of the meeting should be shorter with the National Director summarising management activity and the remainder of the meeting being devoted to medical and scientific aspects of the problems. Dr Gunson pointed out that the regular slot on the Agenda for BPL update would no longer be necessary because of the creation of a CBLA / NBTS liaison which would meet regularly, probably quarterly and report to the National Management Committee. This liaison group would meet twice before the 1st April to consider problems associated with initiating cross-accounting on 1st April.

279. The meeting discussed Dr Gunson's proposals and the need for change. The Committee Structure associated with the National Directorate was welcomed and as the discussion of a medical/scientific RTD meeting developed it became clear that any managerial role for the RTD meeting was regarded as superfluous.

280. It was agreed that there was value in meeting once a year for a one-day scientific symposium and it was agreed that this should be quite separate from the BBTS Meetings and should take place in the spring.

281. Dr Gunson confirmed that contact with the SNBTS would be maintained by regular meetings between himself and Professor Cash. Dr Pickles confirmed that the DOH accepted the changes and Dr Gunson confirmed three avenues of communication with the Department which would be maintained.

282. I therefore asked those present if they wished for the RTD meetings to be discontinued and be replaced by an Annual Meeting open to all NBTS Consultants with a Scientific Agenda and this was agreed unanimously.

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

283. Yes, they did because Harold Gunson in setting up the National Directorate decided that he would continue to form a forum with the RTDs but divided them into three geographical groups. I think they met about five times a year. Harold organised and chaired the meetings and was responsible for the agendas, whereas before in the 'old' RTD meetings he was simply a participant around the table. The National Director drew up salient points at each meeting and circulated them. These would be brought up at the Regional Meetings and this seemed to work very well. In addition to that it was decided that the new format, under the National Directorate, would concentrate on determining overall policies and priorities with discussion of any medical and scientific

matters which were of National importance and needed some sort of consensus type discussion. It was confirmed that on an annual basis the medical and scientific staff of all the RTCs would meet to have a medical / scientific meeting without any particular emphasis on regional variations.

284. Many of the meetings referred to in these questions took place in York and the majority of the time these York meetings were the medical / scientific meetings. York proved to be a very popular choice as a venue for the medical/scientific meetings. Our Scottish colleagues including John Cash would also come down for these meetings. The choice of York came through the TRTC; as I chaired the last RTD meeting, I arranged the first medical/scientific meeting. No previous meetings of RTDs included a social gathering so the York meeting was like an 'away day' and it gave us a chance to socialise with our colleagues from all over the country and share information, which was very useful.

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

285. N/A – Please see my response to question 79.

Meetings of SNBTS Directors / SNBTS Medical and Scientific Committee [Scotland]

81. The minutes of a meeting of SNBTS directors held on 23 June 1981 record that Dr Cash and Dr Mitchell had been invited to attend English RTD meetings, and that you should be invited to SNBTS Director meetings as an observer (PRSE0003924). Please explain the purpose(s) of attending meetings in an observational capacity and how this worked in practice. In your view, was this development successful in aiding cooperation between the NBTS and the SNBTS?

286. There was the need for mutual awareness of policies, difficulties and developments going on each side of the border. There was already of course cross information at National Director level. John Cash spent quite a lot of time at the English meetings and Harold (Gunson) would attend the Scottish meetings, but this was formalised by the decision that the chair of the RTD meetings south of the border would be invited as an 'observer' to the SNBTS Directors meetings and that came about in June 1981 which coincided with the beginning of my first short period as chairman of RTDs.

287. I attended the meeting in December 1981 as an 'observer' and it was very much in an observational capacity to find out what was happening in the other half of the UK. I think it was successful in aiding co-operation between the two transfusion services. It certainly lightened the atmosphere so any degree of suspicion that there might have been about developments being implemented at different times or things being done differently would be dispelled and so the collaboration was definitely constructive. Even though my role was observational, it would have been quite all right for me to chip in. It was a good system for sharing information.

82. Please confirm whether the SNBTS Directors' meeting you attended on 8 December 1981 was the first you attended (PRSE0003364).

288. I am fairly sure that was my first meeting as an ex-officio member as this coincides with my first stint as Chairman of RTDs. This would seem to be confirmed in the minutes of the meeting.

The UKBTS-NIBSC Liaison Group/The UKBTS-NIBSC Red Book Executive Committee:

83. Could you describe the main differences between the UKBTS/NIBSC Liaison Committee and its successor, The UKBTS/NIBSC Red Book Executive Committee (The "Red Book Committee")? (NHBT0000127_002);

(NHBT0002679), (NHBT0000126_001), (JPAC0000003_026), (NHBT0000125_001).

289. UKBTS/NIBSC Liaison Committee was set up in 1987 to identify and define guidelines for all components and other materials produced by UKBTS for therapeutics and diagnostics within RTCs.
4 working groups were formed, to consider:
- labile blood components
- Plasma for fractionation into stable products
- reagents for blood group serology and HLA typing
- microbiological aspects, providing advice to the other groups

290. Following publication of the 1st edition of the Guidelines in 1989, and taking advice from users into account, the groups were reorganised into 7 Standing Advisory Committees:
- on donor selection, with working parties on donor sessions and apheresis sessions
- on components
- on reagents, with a working party on histocompatibility testing
- on plasma for fractionation
- on transfusion transmitted infection, with a sub-committee on laboratory aspects of microbiological screening
- on information technology, with working parties on labels and on barcoding
- on tissue banking

291. In 1992 it was proposed that the overall Red Book system be regarded as having 3 levels of organisation:
- a Liaison Group, dealing with external policies and priorities which would impact on the Red Book
- an Executive Committee dealing with operational matters and revisions
- the Standing Committees, reporting to the Executive Committee

292. In practice, memberships of the Liaison Group and the Executive Committee were virtually identical, so separate meetings were unnecessary.

293. Although the UKBTS/NIBSC guidelines were well accepted in the UK, they had no formal legal status because the committee was an ad hoc organisation which was formed originally at the request of the Regional Transfusion Directors which was also a body without official status. The guidelines were originally introduced in anticipation of Product Liability Laws.

294. The Medicines Control Agency drew upon the Red Book for its standards but also paid attention to Council of Europe Guidelines.

295. The UKBTS/NIBSC was a complex Committee representing England, Wales, Northern Ireland, Scotland and NIBSC and there was no single authority.

296. In 1993, The Red Book Executive Committee was formed and following a request from Dr Angela Robinson, Chief Medical Officer of the NBA, the NBA became in 1997 the single sponsoring responsible authority on behalf of all the other authorities.

84. The Inquiry understands that you were the Chairman of both these committees. Please outline the responsibilities of your Chairmanship during your tenure.

297. My position as chairman of these committees could best be described as being organisational rather than executive. It was my responsibility to ensure that representation on the Liaison and Executive Committees would cover all foreseeable aspects on which the Guidelines might have an impact. Thus, there was representation from UKBTS (including English and Scottish National Directors), NIBSC, BPL, PFC Edinburgh,

Medicines Control Agency, NHS Procurement Directorate, and Department of Health.

298. In addition, chairmen of the Standing Advisory Committees attended meetings of the Executive Committee to present their deliberations and recommendations. My task would be to monitor discussions, identify a consensus where this was necessary, and ensure that any proposed additions or changes to the Guidelines were communicated to any other organisation which may be affected, and to users of the Guidelines, before incorporation into an amendment or the next edition of the Guidelines. Editorial appraisal of a new edition also fell to the chairman.

85. Is it right to say that various Standing Advisory committees reported to the Red Executive Book Committee? Was the Executive Committee responsible for all of these standing committees? Please describe the decision-making process between the Executive and the Standing Advisory Committees.

299. I believe that I have covered this in my response to question 84 above.

86. Dr Cash, Dr Schild and yourself were credited with the concept of national guidelines for the BTS (The Red Book Guidelines) in the UK which were started in 1987. What do you think led to these guidelines? (PRSE0004628)

300. Good practice is essential to patient care. Good practice commonly applied is also very important, in particular because all Transfusion Centres sent plasma to the Bio Products Laboratory and because blood products (e.g., red cells) may be transferred between Transfusion Centres in times of need and this is part of the concept of the Guidelines mentioned above.

301. I think some of the most important points were brought to our attention by Dr Schild. As Director of NIBSC he was extremely aware of what was going on in the European background and was reinforcing the fact that there was increasing interest on the part of the EC which led to the classification of human blood and substances prepared from it being classified as 'products' under the terms of the Consumer Protection Act, leading to product liability in March 1988.

302. With this on the horizon and the fact that there was an obvious increase in complexity in the preparation and use of blood components and products, there was a need to get some sort of uniform application of the methods and standards being used to put these components and products into use. This had already been pre-empted on the part of the Council of Europe who set up a select committee to produce a guide on the preparation and use of blood components. That didn't have the 'rule of law' because that isn't what the Council did, but it became inevitable that it would certainly be taken into account by the EC in the drafting of their Directives on this subject. It seemed sensible for a committee to be set up in the UK to produce guidelines for the UK BTS on this subject and this would be in collaboration with NIBSC because they held National and International standards of reagents and biological products which could be used as benchmarks within the type of guidelines we are talking about.

303. The setting up of the Red Book Committee was therefore essential. In the initial meetings, the approach taken by the Council of Europe subcommittee acted as a template upon which our own organisation would be drafted.

304. It was important that we were able to define guidelines for all materials produced by the United Kingdom Blood Transfusion Services for both therapeutic and diagnostic use. The Guidelines reflect an expert view of current best practice, provide specifications of products and describe

technical details of processes. This was to ensure consistency across the board.

87. The Inquiry understands that these guidelines were not legally binding. Could you please explain your view on this? What degree of influence did these guidelines have on the practice of blood transfusion medicine and what happened in cases of non-compliance? You may find JPAC0000168_194 of assistance.

305. I note the letter dated 3rd February 1992 from Dr Condie to myself highlights some concern from Dr Condie that the guidelines may not be commonly applied because some RTC Directors believed that the reasons for some donor exclusions were unproven or inappropriate. An example given is that his Regional Blood Transfusion Director / General Manager (Newcastle upon Tyne) saw no reason for excluding donors purely on the basis that they have an autoimmune disorder. This was in direct contradiction to section 5.4 of the guidelines which says this should be a reason for permanent exclusion (paragraph 3 of the document referred to above [JPAC0000168].

306. Since the guidelines weren't legally binding, the question of non-compliance would have been a difficult one to answer except that the organisation included at least one member of the Medicines Inspectorate who carried out routine audits and inspections of transfusion centres and they took on board the deliberations of the Red Book Guidelines. It wasn't legally binding on them to do so, but they certainly did take them on board when carrying out their routine audits and inspections of the centres. So, there was an opportunity for exposing and highlighting non-compliance and as I have mentioned above, the Medicines Inspectorate had the statutory power to close a transfusion centre. So, if the Medicines Inspectorate wanted you to follow it, you followed it. Any proposed variation which seemed to contradict the core guidance given in the Red Book was to be discussed by the appropriate Red Book Standing Committee.

307. When looking at what degree of influence these guidelines had on the practice of blood transfusion medicine, they would be used as the basis for the production of standard operating procedures (SOPs) within the transfusion centres.

308. One advantage of the guidelines not being legally binding was that there was easier feasibility for revision / amendment of the guidelines. Another advantage was that there was more possibility of feedback from users to be considered for possible amendments to the guidelines themselves. They were flexible in production and publication which meant changes in circumstances could easily be reflected, for example if a desirable development occurred, it was quicker and easier to get them amended and out to users than having to go through various levels of committee.

88. On 22 July 1993 you wrote a letter to all RTDs et al which seemed to imply that the Red Book Guidelines could be enforced. Could you please explain this position? (NHBT0116388_031)

309. I have had sight of the letter dated 22 July 1993. I note that I make reference to the fact that the Red Book had been published and it was decided that we were to have an 8 week "lead in" period before enforcement of the Guidelines would begin.

310. This letter was very 'tongue in cheek', this was exemplified as it was followed by an exclamation mark. It was certainly not meant to imply that enforcement of the Guidelines was planned from 8 weeks onward. The suggestion of an 8-week period was to allow RTCs time to make any appropriate alterations to SOPs.

89. In a draft letter from David McIntosh to you on 1 September 1994 he stated that one of the reasons that the Department of Health and the Scottish Office Home and Health Department may not have wanted to adopt the Red Book Guidelines was because the Red Book Executive Committee

was "in a sense largely self-appointed" which didn't accept responsibility for damage caused from the application of the guidelines. Conversely, the Departments of State had a responsibility "for service, delivery, safety and quality and also for full financial accountability [...]". David McIntosh also pointed to both a lack of formal mechanisms within the Red Book Executive Committee and that "none of the people involved officially represent their employing authorities". Lastly, he suggested that Ministers wanted to be reassured that "nothing appears in the Red Book [...] that could cause embarrassment or political difficulty". As far as you are aware, were you ever sent this letter? If so, what were your views on the points raised? (JPAC0000155_247)

311. I have no recollection of ever seeing this draft letter referred to, so I do not know what views I had on it at the time.

312. I have now read the letter whilst preparing this statement and reading it now, I accept the fact that from the point of view of legality and accountability especially, it is a grey area. There could be an argument made for these to be accepted on a legal level, but I think, at my time there anyway, the advantages of having it as a non-official document outweighed the disadvantages.

90. What steps were taken for the four nations to be represented on The Red Book Executive Committee? You may find JPAC0000154_297 helpful.

313. Scotland and England were already represented at this time. I note from the letter that it was 'highly likely' that we were to be joined by representatives from Wales and Northern Ireland.

314. In terms of medical and scientific persons, they were already represented. They had the two nominated National Directors, Professor Ian Franklin and Dr JAF Napier (senior RTD from Wales), and Dr Maurice McLelland from Ireland.

Meeting minutes of the DHSS Plasma Supply and Blood Product Working Group Medical Sub-Committee

91. The Inquiry understands that you attended the first meeting of this group on 28 April 1988 at which it was stated that the group's Terms of Reference were "to consider the problem of yields and how much plasma would be required for the fractionation of F8 and F9". To what extent did this group achieve this aim and was the group's remit UK wide? If not, why not? (DHSC0002017); (DHSC0002404_122).

315. I have read the minutes of the meeting from 28 April 1988. The minutes clearly highlight that there was an urgent problem regarding plasma supply, and this is what had initiated the meeting.

316. I have had sight of the letter referred to dated 14 April 1988. The letter confirms that the new Blood Products Laboratory in Elstree was nearing completion and we were expecting a greatly increased output of blood products within the next few months. The letter confirms that the plasma supply was 'buffered' by the stockpile at present. It must be able to keep pace with production. It states that the present method of pro-rata distribution does not seem appropriate to ensure that the greatly increased amounts of Factor VIII reach the centres where it is required. These issues needed to be addressed.

317. The letter then goes on to say that an ad hoc Departmental Committee to be known as the 'Plasma Supply and Blood Working Group' was to be set up under Dr Harris' chairmanship. He also nominated a medical sub-committee under the chairmanship of Dr Gunson.

318. The financial and distribution issues would then be examined by a Distribution Sub-Committee chaired by Malcolm Harris, and it was expected that he would give consideration to an internal market as one way of resolving plasma collection and distribution problems.

319. In February 1991, BPL set targets for 1991/92 at 385 tonnes recovered plasma and 100 tonnes of apheresed plasma for Factor VIII production, together with 12 tonnes of specific plasma (e.g. for therapeutic antibody production). In April 1992, NBTS performance was described as "record breaking", 504 tonnes having been supplied to BPL. Documents JPAC0000187_005 and JPAC0000186_001 refer.

320. I think generally speaking, the targets were met. The introduction of SAGM enabled at least an extra 30-40ml to be taken from each donation. In 1989, nationally, 73% of plasma sent to BPL came from SAG-M donations which is quite considerable. SAG-M really reduced the need for wholesale apheresis for plasma for BPL.

321. I don't think the group's remit was UK-wide because SNBTS had its own fractionation plant with different protocols for plasma fractionation which would have a bearing on the amount of Factor VIII being used.

Other groups and committees:

92. Please describe the remit, objectives, responsibilities and your professional position within the following groups, including matters you consider to be relevant to the Inquiry's ToR:
a. The Advisory Committee on the National Blood Transfusion Service (CBLA0001659); (DHSC0002217_016);

322. I was a member of the Advisory Committee on the National Blood Transfusion Service from 1982 – 1984 and then from 1988 until 1989.

323. The Advisory Committee was set up in 1980 to advise the Department of Health and Social Security and the Welsh Office on the coordination of the development and work of Regional Transfusion Centres and the Central Blood Laboratories in England and Wales, and the English and Welsh Blood Transfusion Service with those of Scotland and Northern Ireland.

324. Subsequently, once the Central Blood Laboratories Authority was set up, their role was slightly updated to advise the Department of Health and Social Security and the Welsh Office and, both, when asked to do so and when the Committee saw a need to do so, the Central Blood Laboratories and the coordination of the laboratories work with that of Regional Transfusion Centres and to advise the Department of Health and Social Security and the Welsh Office on the coordination of the development of the English and Welsh Transfusion Services with those of Scotland and Northern Ireland.

b. The Northern Division of the National Blood Transfusion Service (NHBT0071757); (NHBT0118148)

325. I have read the minutes referred to in this question, these being the minutes of a meeting held on 12 April 1990 and 13 June 1991 and I note that I was present at both these meetings.

326. I confirm that I was a member of the Northern Division of the National Blood Transfusion Service but unfortunately, I cannot recall the exact dates of my membership as this was over 30 years ago.

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

328. We discussed medical policy but also items such as budget devolution and how the regions would deal with it.

c. The Northern Blood Transfusion Directors' Meeting (DHSC0105495_044); (NHBT0108169)

329. I have read the minutes referred to in this question, these being the minutes of a meeting held on 07 March 1980 and on 11 January 1982 and I note that I was present at both these meetings and in fact chaired the meeting in January 1982.

330. As this was 40 years ago, I cannot recall the exact dates of my membership however I can confirm that the Northern Blood Transfusion Directors' Meeting was set up as a sub-committee of all the RTDs.

d. The NBS Northern Zone Board (NHBT0005713);

331. I have read the minutes referred to which are from a meeting held on 12 June 1996 and note that at this time I was the Executive Director of the Northern Zone and Chairman.

332. From memory I believe that the Board discussed items such as zonal training and development strategy together with zonal targets and finance.

e. The Northern Division of BTS Consultants (NHBT0015638);

333. I have read the minutes referred to and note that these are the minutes from a meeting held on 11 February 1993 and I was present. Unfortunately, I cannot recall the exact dates of my membership.

334. I note that in these minutes the future of divisional meetings was discussed, and it was accepted that they should continue in order to facilitate medical audits and so that there would be a greater, not lesser, coordination between centres. The minutes confirm that they also form the basis of medical advisory machinery which may be valuable for the new NBA and a means to disseminate information from the NBA. Other divisions were to be encouraged to meet and discuss proposals for the future of Division meetings.

f. The Standing Committee on the Care and Selection of Donors (PRSE0004625);

335. I was a member of The Standing Committee on the Care and Selection of Donors but unfortunately, I cannot recall the exact dates of my membership.

336. I have reviewed the document referred to in the question which is a letter dated 14 December 1990 from Dr Cash to myself regarding the care and selection of donors. Dr Cash states in the letter that the responsibility of the AIDS leaflet should rest firmly with this committee and he makes a suggestion to consolidate the position of this Standing Committee as the single UK BTS body responsible for all professional matters relating to the care and selection of donors.

337. The Standing Committee on the Care and Selection of Donors was created to set, and update as required, guidelines for:

- Care, pre and post donation, of people who offer to donate blood and components
- Donor selection to identify and exclude those for whom the act of donation could be unsafe
- Donor selection to identify and exclude those whose donation could be unsafe, of inadequate quality, or contrary to relevant legislation
- Staffing, environment, equipment and procedures for blood donation sessions
- Coordinate with the Standing Advisory Committee on Transfusion Transmitted Diseases to ensure integrated advice on all aspects of microbiological safety of donors and donations.

338. The Standing Committee reported to the UKBTS/NIBSC Liaison Committee.

339. During my tenure, responsibility for the AIDS leaflet remained with EAGA at the Department of Health.

g. The UK Advisory Committee on Transfusion Transmitted Diseases (NHBT0000043_039); (NHBT0000088_001); (NHBT0000043_047); (NHBT0000044_057); (NHBT0017534); (NHBT0017532); (NHBT0000073_063); (NHBT0000044_003)

340. The UK Advisory Committee on Transfusion Transmitted Diseases was set up in 1989 by Dr Gunson to consider the implications of transfusion transmitted infections on the transfusion services in the UK and provide advice to the Department of Health. I was a member and the Vice Chairman from 1989 to 1993.

h. The National Directorate of the NBTS - Management Committee (NHBT0118864_012); (NHBT0000188_033); (NHBT0071804); (NHBT0071715); (SBTS0000376_024); (NHBT0071601_001); (NHBT0071860_002)

341. I was a member of the National Directorate of the NBTS - Management Committee from 1988 onwards and have read the documents referred to.

342. Unfortunately, none of these documents provide me with any detailed information about the Committee's remit, objectives and responsibilities.

343. I note from document NHBT0118864_012 that these are the minutes of the *first* meeting on 1st December 1988. I note that the terms of reference were agreed but they are not actually included within these minutes.

344. I note from the other minutes referred to in this question that the Committee spent time discussing medical audits.

i. The National Blood Authority Executive (ARCH0002040_002); (NHBT0016378_002); (NHBT0074032_001); (PMOS0000058); (ARCH0002135); (ARCH0002149_003)

345. I was a member of The National Blood Authority Executive.

346. I have read the minutes referred to in the question and note that at the meetings we discussed matters such as the contracts for the purchase of blood packs, contaminated plasma pools, Haemonetics contracts, progress reports, the change over from Regional Health Authority to NBA, PR, donor services strategy, the Chief Executives report and ALT testing.

347. Document ARCH0002149_003 states that a matter for discussion in that particular meeting was the importance of maintaining an adequate supply of blood stocks and for these to be easily transferred. A request was made for all RTCs to abide by and comply with the A-Z guidelines which should be in place for 1st April 1994.

348. Unfortunately, these archived documents (ARCH0002040_002, ARCH0002135 and ARCH0002149_003) have some pages missing. I understand that the Inquiry have confirmed that these are the only copies they have.

j. The National Blood Authority Technical Working Group (NHBT0000488_012); (NHBT0000488_001); (NHBT0000488_002); (NHBT0000488_003); (NHBT0111411_001); (NHBT0111411_002); (NHBT0000494)

349. I note from document NHBT0000488_012 that the meeting held on 3rd April 1992 was the first meeting of this Technical Working Group and I was a member of the same.

350. Document NHBT0111411_001 confirms that the group was made up of a Chairman, five executive non-members, a Chief executive, 3 Directors and the BPL Chief Executive.

351. The NBA TWG were to consider and report upon the operational aspects of the NBA, in particular contracting, capital allocation and composition of the new authority. It was not for TWG to settle the detailed day to day workings of the NBA but to provide the framework on which the authority itself could take this forward.

352. Document NHBT0111411_002 is the minutes from a meeting held on 26 May 1992. These minutes state that TWG recommendations must be consistent with the work of the Department of Health's Working Group looking at capital allocation arrangements. There are a number of matters listed which are *not* considered to be in TWG's remit (paragraph 2) including essential duties of the NBA, such as its medical advisory, research and development, focal point business and national publicity functions but not a list of what *was* in their remit and unfortunately, I have no further recollection of the same.

k. The UK BTS/NIBSC Working Group on Blood Components (NHBT0007597)

353. I have reviewed the minutes referred to in the questions which are from a meeting held on 19 June 1987.

354. I was the chairman of the UK BTS/NIBSC Working Group on Blood Components but cannot recall the exact dates as this was over 30 years ago.

355. The aim of the BTS/NIBSC Liaison Group was to formulate guidelines for BTS activities, which could be accepted by the DHSS Licensing Authority as national guidelines when Crown immunity was withdrawn from the Transfusion Service.

356. It was agreed to call this working group TWG on blood components and that it should deal with blood donors, blood collection and single or pooled blood components prepared for clinical use. The guidelines for the Liaison Group were modelled on the Council of Europe Guide to the preparation, use and quality assurance of blood components and on the WHO requirement (which were to be updated). It would then be possible to build upon the updated international requirements.

357. The following were considered to fall in the remit of the Working Group:
    a. Whole blood and its components –
    - Red cell preparations (plasma-reduced, concentrated, frozen, filter-washed, lencocyte reduced and resuspended red cells
    - Platelet preparations (single, pooled, irradiated)
    - Non-cellular components, frozen fresh plasma, cryoprecipitate, cryoprecipitate supernatant plasma

    b. Donor selection and sessional procedures
    c. Storage transport, laboratory testing and documentation

358. This Working Group had the following priorities:
    a. Selection of donors
    b. Session procedures
    c. Laboratory testing
    d. Documentation
    e. Products, as listed
    f. Storage and transport

359. It was recognised that the work will overlap with that of TWG on Diagnostic Reagents (in blood grouping) and with that of TWG on plasma fractions on donor selections and procedures, documentation and handling of plasma donations. It would also overlap with work of TWG on microbiological testing if one was ever set up.

I. The Standing Advisory Committee on Blood and Blood Components

(NHBT0007514)

360. I was the Chairman of the Standing Advisory Committee on Blood and Blood Components.

361. This Committee was set up in roughly 1990/1991 and created to:
- Set specifications for blood components
- Develop and review validation of novel blood components
- Assess acceptability for use of novel blood components
- Assess and set requirements for storage and transport systems for blood components
- Develop generic protocols for evaluating methods for the collection and processing of blood and blood components
- Co-ordinate with other SACs and, other relevant UK Working Groups, as appropriate

362. At the time in question the SAC also assisted with a regularly updated leaflet specifying high risk donors. The leaflet was prepared at RTC level, but the SAC assisted with the updating information to be included.

m. The Trent Regional Health Authority Sub-Committee (DHSC0032165_115); (DHSC0032167_016); (DHSC0032167_042)

363. I confirm that I was a member of The Trent Regional Health Authority Sub-Committee.

364. This Sub-Committee was created to inform the RHA of activities and developments at the TRTC, especially those having a National or financial aspect.

365. I have not been provided with the Terms of Reference for this Sub-Committee however I have read document DHSC0032165_115 which is the minutes from a meeting held on 26 September 1986. We discussed 'personalising' the service regarding the donor newspaper – Bloodlink. It

is also noted that progress was being made in creating the second plasmapheresis team at Vaughan Way in Leicester and recruitment was good.

366. I also note from these minutes that I reported an issue of concern regarding AIDS. There had been a paper presented in America saying any blood for use by haemophiliacs should be ALT tested. I note the cost of this would be approximately £250k per annum and at the time I believed this to be 'unnecessary' in a UK setting. Dr Sewell fully supported my view. However, we both agreed to draw this to the attention of the Regional MO who would raise it nationally with the CMO.

367. Other matters that were discussed in this Sub-Committee included the national management arrangements, grading of donor attendance, the computer update, National recharging system and the short-term programme for 1989/1990.

n. The Blood Transfusion Society (NHBT0070660); and

368. The British Blood Transfusion Society was and is a professional and scientific society that promotes knowledge and advanced understanding of all aspects of transfusion medicine.

369. I am still a member of the British Blood Transfusion Society and served as President in 1993.

o. The Blood Transfusion Sub-Committee of the Standing Advisory Committee on Haematology (RCPA0000037_003); (RCPA0000037_004); (RCPA0000037_011); (RCPA0000037_014); (RCPA0000037_018); (RCPA0000037_020)

370. I was a member of The Blood Transfusion Sub-Committee of the Standing Advisory Committee on Haematology and also sat as chairman, unfortunately I cannot recall the exact dates.

371. The Sub-Committee was created to advise the Council of the Royal College of Pathologists, through SAC on Haematology, on all matters concerning recruitment, training, examinations and developments in blood transfusion in the UK.

372. We would discuss and review matters such as medical and scientific staffing of NHS pathology departments including training. We would provide advice to the SAC relating to capital and manpower required for various services etc.

93. Please confirm whether you were a member of the following groups and if so outline their remit, objectives and responsibilities, including matters you consider relevant to the Inquiry's ToR:

a. The Regional Directors' working party on transfusion associated hepatitis (PRSE0003729);

373. The MRC working party on post-transfusion hepatitis was disbanded in 1982. However, due to post-transfusion hepatitis being such an important issue at the time, Dr Gunson set up the Regional Directors' working party on transfusion associated hepatitis. Our first meeting took place in September 1982 and Dr Gunson was the chairman.

374. The aim of the working party was to promote the investigations of the epidemiology of transfusion-associated hepatitis, to promote research into the methods of prevention and to make recommendations to the directors of the UK transfusion services regarding procedures and screening tests necessary for its prevention.

b. The Advisory Committee on the Virological Safety of Blood (PRSE0003956);

375. I confirm that I was a member of The Advisory Committee on the Virological Safety of Blood.

376. This Advisory Committee was created to advise the Health Departments of the UK on measures to ensure the virological safety of blood, whilst maintaining adequate supplies of appropriate quality for both immediate use and for plasma processing.

377. The Committee was set up to embrace both clinical and scientific expertise of all interested groups. Its remit was to advise on measures to minimise virological contamination whilst maintaining adequate supplies. It was to embrace the cost / benefit concept without being ruled by it.

378. I note from the documents provided that one of our earliest tasks was to advise on current practice and policies for screening for infections.

c. The Standing Advisory Committee on Transfusion Transmitted Infection (NHBT0007465); (JPAC0000036_104)

379. I was present only at the inaugural meeting of this SAC, which superseded the SAC in transfusion transmitted diseases of which I had been a member. To confirm, I was not a member of The Standing Advisory Committee on Transfusion Transmitted Infection.

380. This SAC was created to advise the UKBTS/NIBSC Liaison organisation, the NBA and SNBTS on all matters concerned with the possible transmission of infection by the transfusion of blood, its components and, via donor plasma, fractionated plasma products. This advice was to also cover the possible transmission of infection by other banked tissues processed by and held at Transfusion Centres.

381. The SAC's role was also to commission, conduct and co-ordinate trials of new technology involved in the screening of donors for infectious agents

transmissible by transfusion, consistent with the work of the national research committees.

d. The DHSS Plasma Supply and Blood Product Working Group (DHSC0002404_122);

382. I have read document DHSC0002404_122 which is a letter dated 14 April 1988, from Mr EL Harris from the DHSS to myself. He confirms that the commissioning of the new Blood Products Laboratory at Elstree was nearing completion and was expecting a greatly increased output of blood products within the next few weeks. He advised that we needed to consider the volume of plasma supply which although it was buffered by the stockpile, must be able to keep pace with production. He also stated that the problems of Factor VIII yield and the necessary target production levels for Factor VIII might need to be re-assessed and the present method of pro-rata distribution of blood products did not seem appropriate to ensure that the greatly increased amounts of Factor VIII reached the centres where it was required.

383. A departmental committee (as above) was therefore set up under EL Harris' chairmanship and he proposed a medical sub-committee to be chaired by Dr Gunson and a distribution sub-committee to be chaired by Mr Malcolm Harris.

384. I was invited to serve on the Working Group and as a member of the medical sub-committee.

e. The Medical Staff Committee (NHBT0099134_003); and

385. I have had sight of the letter I wrote to Dr Love dated 20 December 1994 (Director of Manchester RTC) (NHBT0099134_003). I state that one of the statutory requirements of any Health Authority is the formation of a Medical Staff Committee, I therefore suggest that the consultants within each zone appoint their own Chairman and these would form the basis of

the Medical Staff Committee. I subsequently became a member of this committee.

386. Unfortunately, I have not been provided with any other documents which identify the remit, objectives and responsibilities of this particular committee.

f. The UKBTS/NIBSC Standing Advisory Committee on Donor Selection (NHBT0006960)

387. I was the chairman of the UKBTS/NIBSC Standing Advisory Committee on Donor Selection.

388. The original working group of the UKBTS/NIBSC Liaison Group formed in 1987 was re-organised in 1989 into four Standing Committees, the SAC on donor selection being one of them and having two working parties reporting to it on donor sessions and on apheresis sessions. The SAC reported to the Liaison Group.

389. The remit of the SAC and its working parties is to establish and monitor criteria for the selection of donors who can give blood or plasma with safety to themselves and to potential recipients as the prime objective.

Section 10: Information handling by and information sharing between RTCs

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

390. The card system for donors initially was a physical card system which was kept in the donor panel department for access by all the departments. It was then of course computerised. I cannot remember

what date it was computerised, but we had our own system which we then had to transfer to the national computer system, Pulse.

391. With regard to blood donations, please see my response to question 65 above.

392. With regard to donors who were suspected of having been involved in the transmission of some sort of virus, the blood donation documentation starts by the production of what is known as a blood donor record at the blood donor session at which a paper record was kept initially for all donors who were successful in giving blood. This was then linked with the numbers and the number of the donation itself was transferred by use of a bar-coded label which was part of a set, as described at question 65 above.

393. Access to the blood donation recordings (the BDR) was then transferred to the blood donor laboratory who were then responsible for recording the results of grouping on the donations and similarly the Microbiology Laboratory transferred the results of their tests on the blood samples.

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

394. The requirement for record keeping was a little bit in the air except that there was defined in the Red Book Guidelines a requirement for donor records of plasma sent to BPL for fractionation, to be kept for a minimum of 15 years. Our records of donations being linked to donors would be kept for that minimum time but possibly much longer and certainly at the time of computerisation, there was a suggestion, which I am not sure was ever implemented, that they *could* be kept up to 30 years before disposal.

395. In the 1980s there was still a system of kept records of donations that had been sent to BPL for fractionation and we would already have pre-empted that the records needed to be kept for 15 years. On this point,

the BPL were insistent that a sample of the donations which had been sent down for fractionation should be kept frozen at the RTC concerned for a minimum of one year. While this doesn't specifically qualify as a 'record', it did allow for immediate tracing.

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

396. When we had reached the allotted time for keeping of the records, which was probably in the region of 30 years, they would then be shredded, and the shredded paper was taken down to the neighbouring Northern General Hospital with whom we had an arrangement to use their incinerators.

397. In terms of the samples themselves, from recollection I think they were stored in tubes but later using multi-well plastic plates and again these were sterilised before throwing away. We had a specific department within the RTC which had very efficient and very up to date autoclaves, so we used these for the sterilisation of samples before disposal.

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

398. I think each centre had its own individual system, but they were near enough identical to be able to convert to a uniform system when centralisation came about with regard to the production and acceptance of the Red Book Guidelines.

399. There were variations on a theme, but the core activities in the record keeping practices were the same. They were all based on a system of safe donation, safe onward travel of the product and an ability to be able to trace a donation in either direction should the need arise.

400. BPL also issued their own specification for plasma storage, but this was not incorporated into the Red Book. The Red Book was designed mainly for activities at the RTCs and covered BPL only as far as the handling of the plasma donations and record keeping was concerned.

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

401. I would say so, yes. The trace back system of notification to the RTC of an index case of presumed transfusion-transmitted infection from the hospital to us was quite capable of tracing the donors concerned and the action taken on those donors in terms of either proving their negative status, when we became able, to or deleting them from the donor panel was quite well covered, so I was happy with that.

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

402. The blood and blood products originally were recorded on a paper-based system and were sent out after having had the donation numbers, marked appropriately on a register and kept in the dispatch department at the RTC. from this we were able to trace any donation if required to do so by notification of a possible case of transfusion transmitted infection by the hospital.

403. After computerisation, the recording of donor numbers was done by the reading of bar-codes at the time of dispatch and kept as a straightforward computerised record for the appropriate length of time.

404. Hospitals fed back to us details of any adverse or suspected adverse reactions to transfusions, especially any suspicion of involvement of viral transmission. Usually, this feedback would be via letter to the RTD at that time. I cannot recall any problems at all with compliance with this arrangement. We had a good relationship with the hospital blood banks concerned and they were very good at providing us with information.

405. In terms of blood stock management, when we were distributing blood and blood products to the hospitals this was done partly on a historic basis, looking at what the hospital had had in the previous year and allocating this across deliveries on the basis of going to each hospital twice a week. If any hospital needed more than their routine allocation, then they would communicate this to our dispatch department in advance of the next delivery and the routine delivery would be adjusted accordingly. So, we had, in effect, a reasonably good record of what each hospital had received from us, supplemented of course by returns of unused blood and blood components which was a routine event. The hospitals were normally fairly good at requesting just what they needed so the returns were fairly low. Our dispatches and returns department would deal with all aspects of dispatching and returns of blood and blood products.

406. From my recollection, there were never any problems with regards to the hospitals' compliance.

100. What information did the TRTC provide to the NBTS and at what frequency?

407. I am unsure what information this question is referring to.

408. If one RTC had an oversupply/undersupply, then they could move products around the country. Before that, there was an informal, but very efficient, system of communication between RTDs using the telephone. If

there was a requirement in one region for urgent replenishment of either general stocks or a particular group then a telephone call would be made for immediate help. Generally speaking, we would telephone another RTD directly. When the National Directorate was formed, I think there was a gradual move towards centralisation of this sort of activity, but it was quite obvious that the system of direct communication worked fairly well. In times when there were major disasters, for example when the Pan Am plane came down on Lockerbie, numerous RTCs including myself telephoned Dr Mitchell to ask him if he needed anything. We had similar calls with the Kegworth air disaster; we had enough stock, so we didn't need to accept the offers of help, but they were there.

409. We were always able to call in help from neighbouring RTCs.

410. In terms of frequency, it is hard to say, most of the time this would be ad hoc where Dr Gunson, in his role as Consultant Advisor to the CMO would be collecting information on certain things rather than regular routine requests. There were very few routine requests made before the National Directorate was formed. The RTDs knew that they could all contact each other if they needed anything, and we all communicated really well.

101. 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 aware?
b. Who proposed the creation of the database?
c. Did the TRTC contribute data on HIV positive donors to the database? If not, why not?
d. Are you aware of whether other RTCs contributed data on HIV positive

donors to the database?

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

411. My response below covers questions a-e.

412. I was aware from its inception that HIV positive data was contributed to by the TRTC and the other RTCs to Vi Rawlinson at Manchester RTC for collation and I believe that the results of Vi Rawlinson's efforts were centrally communicated by Harold Gunson. To the best of my knowledge, at that time the results were anonymised. I think reports were circulated monthly and/or quarterly to the best of my recollection.

413. With regards to a more centralised database, I believe that the TRTC did contribute data to CDSC, but I don't know whether this was the case for all RTCs.

414. The TRTC maintained a separate database to track HIV positive blood donors. This was a permanent record with their name on and they would be permanently deferred from donating. I think that a record of HIV Positive donors was kept by the Consultant in charge of the microbiology department. This was Dr Virgie James.

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

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

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

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

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

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

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

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

h. Was the J donor system widely used after the "re-introduction"? If not, why not? If so, who was responsible for overseeing the system?

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

415. This document describes action taken by Manchester RTC with regard to the follow up of donors who may be implicated in cases of post-transfusion Hepatitis. My response below covers questions a-i in so far as I am able to respond.

416. I am unaware that there had been a National system called the 'J donor system' which had been at some time discontinued. So far as I know, the proposed outline was not disseminated to other RTCs for the introduction or re-introduction of a standard system. Nevertheless, all RTCs including Trent had a system of receiving reports of cases of post transfusion Hepatitis and this would result in them immediately tracing and testing the donors who may have been implicated and marking their records appropriately. Those found to have positive markers, though negative at the time of the index donation, would be resigned as donors with immediate effect and entered into the current counselling and referral system.

417. Any donations given in the year prior to the index donation or given subsequent to it, would be traced from their donor records and the recipient hospital blood banks notified for identification of recipients of those donations. Donors of blood or blood products transfused to the index case who were negative on the viral marker test would have their donor records marked appropriately but were allowed to donate again.

Any donor with any more than one such marker would be withdrawn from the panel of donors and counselled accordingly. So far as I am aware, this system still exists at the TRTC, as it will in all other blood centres.

103. Was viral hepatitis, NANB hepatitis or hepatitis C a notifiable disease during your tenure? If so, what obligations did this place on the TRTC? Did the TRTC comply with these obligations? If not, why not?

418. Viral hepatitis of any kind was a notifiable disease during my tenure as RTD. The obligation to notify fell to the treating physician. If the disease was thought to be post-transfusional, the RTC concerned would be under an obligation to trace and investigate the donors possibly implicated as described above. However, the actual obligation to notify was not with us, it was with the treating physician. The RTC just undertook the screening, not the diagnosis. We would never see someone who had viral hepatitis of a type that would be clinically recognised, so we would never be in a position to notify them.

104. Did the requirement to notify change during your tenure? If so, how and when?

419. No, it didn't. The requirement of the physician to notify a case didn't change; it still exists now, and it is still notifiable.

105. In addition to the database mentioned above, did the TRTC 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 so, was this on a formal or informal basis? Please describe the mechanisms the TRTC used to share this information, if any.

420. In the absence of a centralised system, information was shared between RTCs usually on an informal basis between RTDs. If you became aware that an excluded donor had moved to another area for example, you would contact the local RTC and inform them, but this was only if we

became aware. However, I don't remember Trent ever having to contact another local RTC regarding this, or any other local RTC ever having to contact Trent.

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

421. Yes, I do agree with that. In my opinion, information sharing measures at the time were adequate but would have been improved if they had been carried out in a coordinated centralised manner.

Section 11: Knowledge of risk of infections while at the TRTC

HIV / Aids

107. During your time at the TRTC, 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?

422. The AIDS syndrome was first associated with homosexual men with multiple partners in Haiti and then in San Francisco. A positive association was then suspected as being involved with people injecting drugs through needle sharing and it became evident that it could be sexually transmitted. These three categories were included in the first AIDS leaflet in September 1983.

423. So far as the risk of transfusion-transmission of AIDS is concerned, the first issue I was aware of was an account of AIDS in three haemophilic men in the United States (reported by CDSC in 1982).

424. In 1983 there was a report by Amman of AIDS in an infant after several infusions and one of the donors subsequently developed AIDS himself. I became aware of this by word of mouth, and I am pretty sure I also read about it in the usual medical literature referred to above at question 4.

425. In May 1983, there were simultaneous papers published by Dr Robert Gallo in America and Luc Montagnier in France on the isolation of the virus possibly associated with AIDS. This causative link was confirmed when testing regimes became available.

426. With regards to the transfusion services, improved HIV tests began to be used in RTCs in the UK from 14th October 1985.

427. These are major landmarks that I remember from the relevant times. My knowledge and experience grew and increased over time, as did everyone else's.

108. 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?

428. Please see my answer to question 107 above.

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

429. None really, as we were not equipped to carry out investigations, since we had no virological expertise within our staff at the TRTC. I think Colindale with John Barbara was the only RTC who had their own consultant microbiologist, so they took the lead on this kind of research.

In this sort of situation, in the absence of an experienced virologist, the introduction of anything that might at all be regarded as already infective into the transfusion service, would be looked on rather askance so we would not wish to carry out investigations on known infected samples.

110. On 6 July 1983 you wrote a letter to your colleagues in the NBTS with an attached final copy of an AIDS awareness leaflet intended to be made available to donors at donor sessions in which it was stated that, "The majority of RTDs still feel strongly that approach to donors should be at the lowest key possible and were correspondingly reluctant to either hand the leaflet to every donor at a session or to send it out as part of the call-up material". Why did you understand RTDs to be reluctant to hand the leaflet to every donor, or provide it as part of the call-up material? What impact do you consider this reluctance had on blood safety? (NHBT0020668)

430. At that time, there was a great deal of publicity about AIDS in the National press, and on television. Transfusion transmission of AIDS was not really being regarded as a major cause. I think some of the reluctant RTDs were afraid that the type of information being put out in what they deemed to be an 'aggressive' approach would lead to the impression that transfusion transmission was a major cause of AIDs and this would put off many donors from coming to give blood at all. I do remember some donors becoming very offended by the questions being asked at donor sessions and there was a genuine fear that people would be put off from donating and this would have had an adverse effect on the blood supply.

431. There was also the fear amongst some RTDs that this sort of approach might lead to an uncontrollable number of people demanding more information and counselling at donor sessions themselves which would very much interfere with the smooth running of the sessions and this would have a knock-on effect on the total blood supply. As it turned out, there was no significant effect on blood safety and experience showed

that in fact again, infectivity rates in UK blood donors appeared to be low, especially when compared to America, which was the only other yardstick we had at that time.

432. I believe that some RTDs had a reluctance to hand the leaflet to every donor because they didn't want undue stress at donor sessions on the vague symptoms associated with AIDS.

433. There was the real fear of a disruptive effect on donor sessions and because of the concept of the two-way relationship which had been formed in some people's minds between AIDS and blood donation this led some people to believe they could catch AIDS by giving blood. A link had been established in the minds of a lot of people and some RTDs were concerned that pushing the leaflet too hard would reinforce this belief and deter donors from donating.

434. In terms of the impact this reluctance had on blood safety, it was really quite minimal because it wasn't really giving an inducement for people who were designated as 'risk' individuals to enrol as blood donors. This might have been something that occurred after it was known that a test for HIV was available and was carried out at sessions, so risk individuals would come specifically to get themselves tested. However, during the introduction of AIDS leaflets this didn't arise.

111. The Inquiry understands that you were present at an RTD meeting on 11 July 1984 at which the topic of AIDS was discussed. It was noted that "Dr Gunson had approached the Medical Defence Union. Their reply was that an adequate precaution if a patient has been given "at risk" blood was that the General Practitioner should be informed in confidence" (BPLL0007665_004).

Could you explain:

a. What you think this statement meant;

b. Whether recipients of "at risk" blood were notified about what they had been administered;

c. Whether recipients gave their express consent for their information to be shared with their GP; and

d. How the legal principle of consent was approached within this and similar information-sharing contexts?

435. It appears that I was present at the RTD meeting on 11 July 1984. My response below covers questions a-d in so far as I can remember.

436. In general, recipients (patients) would be notified by the treating physician who themselves should obtain consent for the GP to be informed because we are talking about the *recipients* at risk here.

437. It is completely normal for physicians to share information with GPs. With regard to any sensitive information about a *donor* rather than a *recipient,* then the TRTC and other RTCs always obtained the donor's consent for information sharing. This would normally be for their GP as the GP would always be the first line of contact. We might also at the same time ask whether the donor in need of counselling and further testing, would wish to be referred to a specialist physician, such as a Hepatologist or a Gastroenterologist, but that would be done through the GP acting as a link from us to the physician. This is a normal NHS referral process - from GP to consultant. In cases such as this, I believe that a GP would be more than happy for the RTC concerned to liaise directly with the nominated physician, but it would be absolutely essential that the GP was the first port of call.

438. On the advice of the MDU, if a patient had been given "at risk" blood then their GP should be informed in confidence.

439. As explained above, we obtained express consent for information sharing.

112. On 27 February 1991 Dr E Angela Robinson wrote a letter to you in which she described the current British Blood Supply as having a "proven safety record". To what extent do you agree with this statement? (JPAC0000044_135)

440. This was written in February 1991 so before the introduction of an accepted HCV test; by safety records being based on available technology yes, I agree with what Dr Robinson has written.

Hepatitis

113. 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 the TRTC? How did your knowledge and understanding develop over time?

441. Transfusion transmitted Hepatitis has been recognised since the 1940s, especially when large pools of plasma were used for the production of dried plasma; because of this the pools were reduced to 10 donations rather than 100.

442. What was termed syringe jaundice was also recognised. That would have been transmitted by needle sharing.

443. With Hepatitis B, the so-called Australian antigen was first found in 1968 and it was named Hepatitis B surface antigen at a later date when it was found that it was not something confined to the native Australian race. A search for suitable methods and antisera led to routine testing by all RTCs in 1972.

444. By 1980, NIBSC had developed a British standard for the virus antigen which was then adopted as the WHO standard and in 1993 a working standard was made available from the NIBSC for use in routine testing.

After HBsAg screening was introduced for Hepatitis B, transfusion transmitted Hepatitis still occurred. Hence its name, then, as NANB.

445. In 1989, a virus was identified from a chimpanzee which had been infected with a NANB virus and the first reagent for testing for this virus was produced in 1989. First and second-generation tests were developed by more than one manufacturer. The first-generation test was not universally thought to be a suitable test for blood donations in view of its rather erratic specificity and sensitivity. The second-generation test was an improvement on this and was introduced into all RTCs on 1st September 1991.

446. Confirmatory testing originally was carried out by radioimmunoassay, but our RIA systems were not particularly suitable for routine mass use in a transfusion centre setting as RIA was not amenable to automation which was why the development of the RIBA test as an approved confirmatory test at RTC level was welcomed by almost everyone. This could be automated, and results were obtained speedily enough to allow rapid throughput at RTC level.

447. Regarding the impact of NANB, we were aware that Dr Preston and Dr Trigger were undertaking biopsies on their haemophiliac patients in Sheffield in the late 1970s. This was a piece of essential research which showed just how severe the disease NANB could be. I think it helped in the appreciation of the possible clinical outcomes of NANB. The concept was that people were more likely to recover completely from a Hepatitis B infection, in general; I think Hepatitis C clinically appeared to be rather less severe but had potentially much more severe sequelae. The question of chronic disease leading to cirrhosis and possibly hepatic carcinoma was really only found with Hepatitis C, not with Hepatitis B.

448. These types of conditions can sometimes take years to manifest. During the end of my time as RTD, I think we were just then beginning to see a few cases coming through but since the development time of hepatic

carcinoma was potentially so long, the majority would have probably occurred after I retired. By this time of course, more advanced treatment had started so there was some initial success in treating Hepatitis C sequelae, but this was ongoing rather than completely routine.

114. 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?

449. I was always aware of the association between hepatitis (including hepatitis B and NANB/hepatitis C) and the use of blood and blood products.

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

450. Please see my answer to question 109 above.

116. 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?

451. Again, please see my answer to question 113 above.

452. Before Hepatitis B and HCV were recognised there was a broad spectrum of clinical jaundice and sequelae in terms of duration, severity and symptoms. Hepatitis B resulted in generally mild to moderate jaundice, normally with complete recovery. HCV was generally mild and could be asymptomatic but had a tendency to lead to chronic liver disease from mild chronic Hepatitis to cirrhosis to occasional carcinoma.

453. The major milestone for me was the realisation that we were still getting post transfusion Hepatitis even after screening for Hepatitis B. The screening hadn't seemed to have solved the problem at all.

117. 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 so, when and in what circumstances did you become aware of the findings of this paper? If not, when did you become aware of it and/or the conclusions set out within it?

454. I was not aware of this paper until receipt of the Inquiry documents, and I cannot remember any formal discussion about it at the RTD meetings.

455. However, I believe that the general opinion was one of some doubt about any NANB diagnosis being based purely on ALT and anti-HBc levels.

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

456. I don't remember any formal discussion of these figures at RTD meetings.

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

457. Before anti-HCV testing in 1991 the incidence of any NANB viruses in the donor population was based on feedback from cases of post-transfusion hepatitis and the action taken as set out in the answer to question 103 above.

458. With regards to severity, presumably, donors were asymptomatic at the time of donation, otherwise they wouldn't have been giving blood. Any subsequent symptoms revealed would either be as part of a feedback system from an infected recipient or by direct reporting by a donor that he/she had developed jaundice subsequently to the donation because all donors are asked to report any significant post donation illnesses including jaundice.

459. Initial estimates of the prevalence of NANB/HCV in the UK donor population were at a level of 3% but this was shown to be higher than actually found when testing was available. When testing was introduced, I believe it would have been less than that, probably a maximum of 1%.

119. The Inquiry understands that you were present at a meeting of the National Management Committee of the National Directorate of the NBTS on 7 September 1992 at which the "Use of plasma from anti-HCV reactive donors" was discussed. It was noted that "In Scotland, PFL wish to use plasma from HCV positive, RIBA negative donors for fractionation. However, BPL's policy is to use only plasma from which BTS is willing to use the red cells. The matter has been referred to the MCA as the Licensing Authority for a view". (NHBT0071601_001). Could you clarify what you think was meant by this statement? You may also find section 4.1 of NHBT0071593_001 helpful.

460. These minutes state that there was a continuing difference of opinion between Scottish and BPL views. Dr Brookes points out that Scotland was not at present fractionating HCV reactive plasma.

461. In 1992, the NBTS policy was to discard donations which were anti-HCV positive but RIBA negative. BPL extended this policy to include plasma fractionation on the grounds of maximum security. The SNBTS were willing to use the plasma in view of viral inactivation now available.

462. I am unaware of the MCA response to BPL's belt and braces approach, but I don't believe that BPL's policy was changed. I have no knowledge at all of the MCA's response to the SNBTS proposals.

120. At an SNBTS meeting on 16 March 1982 it was noted that a proposal had been made "to the NBTS Directors that a UK working party should be established on the subject of microbial contamination of blood products". However it is alleged that on 25 February you wrote "to all Directors asking for their views on a proposal to study post-transfusion hepatitis". Dr Cash resolved to inform you that the SNBTS' proposal was not limited to hepatitis and that the MRC's Blood Transfusion Research Committee had been wound up because there were already other hepatitis groups in the UK studying the condition (MDUN0000004_024). As far as you recall, what reasons led you to suggest limiting the scope of the SNBTS' proposal and was a hepatitis working group subsequently set up? Do you agree with Dr Cash's assertion that there were other groups looking at the same condition? If so, please give details.

463. There was a misunderstanding regarding the remit of the working party proposed by SNBTS. The RTDs' working party was on transfusion-associated Hepatitis alone and the same for the UK advisory committee on transfusion-transmitted disease which was subsequently set up. I believe that this committee had its remit extended beyond Hepatitis to cover other transmitted diseases as well.

464. The reference to microbial contamination was because very rarely, unusual bacterial contamination of the skin at the site of needle penetration during donation might fail to be removed by correctly applied

cleansing techniques, resulting in bacterial contamination of the donation.

121. Do you agree that there were multiple working parties with similar Terms of Reference within the UK? If so, did this stifle the ability for the NBTS to make national pronouncements on topics such as risk reduction policies? You may find section 4d of CBLA0001995 helpful and NHBT0007480.

465. I agree that multiple working parties existed, but the terms of reference were not usually overlapping: for instance – of the two AIDS working parties named in the presented documents: one was on virological and screening aspects, the other one, set up by DHSS, was to deal with public health aspects. So, I do not agree that it would have stifled the ability of the NBTS to make national pronouncements on topics such as risk reduction policies. Necessary consultation with EAGA and ACVSB may have been felt at times to delay some National pronouncements, such as the AIDS leaflet, but I do not think that such a delay amounted to "stifling".

General

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

466. The standard procedure for donor sessions as set out in the Red Book was designed to protect the health and safety of donors and recipients. Initial deferring of donors reporting previous jaundice was based on time since recovery, which would usually be 12 months. With reports indicating a link between AIDS and transfusions, specific acceptance criteria were defined based on the information that was available. The first leaflet was made available in 1983. This facilitated self-exclusion of donors. AIDS leaflets in the TRTC were sent out with invitations to donate and made available at all sessions. Donors were asked to sign to say that they had read and understood the leaflet and were encouraged

to seek advice if they were unsure about any points. After anti-HBsAg screening was introduced at RTCs in 1972, the seriousness of post-transfusion NANB was recognised. It was only possible to carry out established selection policies regarding previous donor jaundice episodes after identification of HCV virus in 1989 and deployment of acceptable tests in 1991.

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

467. Feedback from users was considered obligatory regarding adverse reactions to transfusions, with follow up and lookback on possible implications in transfusion transmitted disease as described in question 102 above.

124. What role, if any, did the TRTC 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.

468. Specifically, we had meetings with the HCDs in Trent to discuss the choice of treatment of their patients, this was updated by personal communication. The TRTC consultants attended regular meetings with consultant haematologists in Trent. Training was mandated by the Royal College of Pathologists to include a period at their local RTC, this included in Trent a 6-month attachment and included *all* aspects of transfusion being covered such as transfusion risks. Trent RTC also organised a course of one month for haematology registrars in Trent, including a lecture on the hazards of transfusions and a demonstration of microbiological screening. Basic and advanced courses were also organised in TRTC for scientists in Trent and hospital blood banks.

469. I think that a vital part of the education of HCDs was their own meetings of which we knew very little. I would have expected them to be aware of the risks and share these within their own community. In Trent, there would have been very little treatment of haemophilia other than by the nominated centre Directors. In addition, HCDs would be given updates on products since Dr Richard Lane, Director of BPL was a member of their regular HCD meetings. They were just as aware as we were about the dangers of transfusions but more advanced in their knowledge of the sequelae.

Section 12: Reduction of risk of infections while at the TRTC

Donor selection

125. What donor selection policies and processes were in place during your tenure at the TRTC, and how did this change following the emergence of:

a. AIDS/HIV;

b. NANB/HCV; and

c. HBV?

470. The selection policies are based on the avoidance of harm to both donors and recipients based really on answers to simple questions at the donor sessions desk regarding current and significant previous health. On arrival at the venue, the donor is given the leaflets containing reasons for exclusion including a statement that this is to protect the recipient as well as the donor. Samples of such leaflets are shown in an ISBT pamphlet on criteria for selection published in 1976 and in the ABC of transfusion 2nd and 3rd editions published in 1992 and 1998. The content of the leaflet / questionnaires given to donors in RTCs within the NBTS including the TRTC was based on the criteria for selection of donors laid down in the Red Book Guidelines. Any suggestion of changes to these criteria would be referred to the Red Book Standing Advisory Committee (SAC) on donor selection. If the suggested change was approved by the

SAC it would be incorporated by circulation of an addendum and then into the donor questionnaire.

471. A more significant change came with the emergence of AIDS and a specific AIDS leaflet for donors was produced in 1983 by EAGA and revised in 1985 and issued to every donor before giving blood. The method of distribution was varied at first, but DHSS issued an instruction that the leaflet should be included in repeat donors' postal call ups and handed to the new donors and the walk-in donors at the sessions, prior to donation.

472. In all cases, donors were required to sign a consent to donation which included an affirmation that they had read and understood all donor leaflets including and in particular the AIDS leaflet and in due course included consent to having the donation tested for HIV. The 2nd and 3rd editions of the ABC of Transfusion show these changes. In all cases, donors were given the opportunity to opt out as discreetly as possible if they felt that they could not meet the criteria and were given the opportunity to discuss it with the sessional MO or nurse if they should wish.

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

473. Decisions based entirely on the national approach are outlined in question 125. My own role was to ensure that the National Guidelines were followed. Regular meetings of heads of departments within the TRTC were held, including a senior MO with oversight of the sessions and the regional donor organiser. These regular meetings were monthly in origin. Donor selection was reviewed as necessary during the meetings.

127. What national guidelines, if any, informed the donor selection policies and processes at the TRTC? In the event that the TRTC processes departed from any such guidelines, please explain how and why.

474. I believe that I have covered this in my response to question 125 and 126 above.

128. How were decisions made at the TRTC as to which donors were high risk and should be excluded from donating? What was your role in this process? (JPAC0000044_229)

475. Decisions on exclusion of high-risk donors were based entirely on the national position, as explained above. In my role as Trent RTD, I was responsible for bringing forward to appropriate bodies within the NBTS, any doubts, queries and suggestions which had been brought up at local level.

129. Were there any difficulties in implementing the exclusion of high-risk donors at the TRTC? You may find NHBT0039762_049 and NHBT0096480_013 of assistance.

476. In practice we found little difficulty in implementing the exclusion of high-risk donors at the TRTC. Beyond occasional delays at sessions when a donor wished to consult with the MO, the leaflets provided were generally well accepted.

130. What information (either written or oral) was given to donors about the risk of them transmitting infections via their blood? When was such information provided? In particular, was there a nationally agreed leaflet or did each RTC produce its own leaflet? You may find NHBT0020668, paragraph 20 of NHBT0018200, NHBT0016142, NHBT0052209_262, paragraph 3.5 of NHBT0070258, paragraph 3.1 of NHBT0097469_014, NHBT0071771, NHBT0096473_014, NHBT0116798, paragraph 4.4 of

NHBT0046958_002, NHBT0101333_008 and NHBT0007485_001 of assistance.

477. There was a nationally agreed leaflet concerning AIDS which included a warning of possible HIV transmission by blood and its products. There was also a nationally agreed format for the form to be signed by the donor consenting to the donation and for it to be tested for HIV. The form also repeated the fact that the infections mentioned in the additional health leaflets given to the donors, particularly Hepatitis, could be transferred by blood.

478. These additional health leaflets were produced by RTCs, the questions contained in them being in agreement with the principles of donor selection set out in the Red Book Guidelines. In addition, EEC Directive 89/381/EEC includes the direction "*the criteria of the Council of Europe and of WHO shall apply to the selection of donors and blood donations*". The NBTS Red Book Organisation was founded on the principles set out by a Select Committee of the Council of Europe, the NBTS Guidelines developing in harmony with those of the Council by nature of UK representation on the select committee.

131. How often were these leaflets updated, and how was their content decided? You may find JPAC0000041_048 and JPAC0000041_049 of assistance.

479. Each leaflet was produced and updated by EAGA at approximately 2-year intervals with input from the Advisory Committee on the Virological Safety of Blood and NBTS National Directorate. Regional health leaflets were updated by RTCs, normally after any changes to the guidelines in the Red Book, these were in the form of a new edition or circulation of an agreed addendum.

132. 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?

480. It was common practice for information posters to be displayed at the entrance to donor session venues, emphasising the risks of transfusion transmitted infection.

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

481. I believe that self-referral systems worked well in the UK mainly because donors were voluntary, unpaid, altruistic and motivated to produce safe therapy.

134. Please consider NHBT0108651_003. To what extent did the Howie Report impact the TRTC's approach to blood collection, particularly in regard to risk reduction?

482. With regard to the impact of the Howie Report on the TRTC's approach to blood collection, points 1 and 4 of this witness statement are relevant.

483. Point 1 was obviously accepted since it was impossible for sessions to be held only in purpose-built accommodation and by definition only normal and non-pathological samples would be taken.

484. With regards to point 4, further consideration of sessions in HM prisons was indeed given and those remaining RTCs which had not already stopped did so.

135. On 22 November 1991 Dr G Galea wrote to you noting the difference in donor exclusion policies between some Transfusion Centres and home nations (NHBT0007516). Could you explain whether this was a frequent occurrence and to what extent did the UKBTS/NIBSC Standing Advisory

Committee push for UK blanket policies? Were these successful? If not, why not?

485. I don't believe this to be a frequent occurrence; generally, the system of reaching consensus on exclusion policies by referral to the Red Book SAC worked well, with home nations and the NBTS RTCs accepting the core policies laid down in the Red Book and its eventual subsidiary publication on medical assessment of donors.

136. In March 1993 you advised Dr F H Williams (Consultant in Transfusion Medicine, Welsh Regional Transfusion Centre) that "immunoglobulin, prepared for intramuscular use by Cohn Fractionation, has been discussed many times and has never been doubted" (NHBT0006970_001). Do you still agree with this statement? If your opinion has changed over time, please provide details

486. I still agree with this statement.

137. Please consider NHBT0053651_003. To what extent did North London Blood Transfusion Centre's processes differ from the TRTC's? Which centre did you consider to have better processes at the time? Has your opinion changed over time? Were there any extra steps which either centre could have incorporated to reduce the size of the risk of the "irreducible minimum"?

487. I have read document NHBT0053651_003, being a report into an incident of bacterial contamination of a unit of platelets prepared at the North London Blood Transfusion Centre. The processes at the TRTC at that time were essentially the same as those outlined for the North London Centre and in my opinion were equally as secure. I am afraid I can remember nothing of this now but have no reason to doubt what I wrote at the time.

488. My opinion as to the exemplary procedures being carried out has not changed. I can think of no extra steps that could have been taken.

138. CBLA0001707 refers to minutes of the 188th Meeting of Regional Transfusion Directors held 18 May 1983, where you referred to a letter from Dr. Gunson giving four self-exclusion options that RTDs could accept: 1. Questioning of donors at sessions 2. Sessions to be discontinued in areas of high risk donors 3. Pamphlets explaining AIDS to donors 4. Publications in newspapers. RTDs discussed the options presented above and rejected options 1 and 2. It was agreed that Dr Davies would contact the medical branch of the Gay Society stating that until more is known about the disease practising homosexuals should be asked not to donate blood.

a. Did you agree with the rejection of these proposals? Please provide reasons.

b. Subsequently, the 1983 AIDS leaflet excluded homosexual men from donating blood who had "many different partners" (BPLL0007247, page 2). What did you understand was meant by "many different partners"? Do you think this was clear to the reader?

c. What involvement, if any, did you have in the production of this leaflet?

d. The 1985 AIDS leaflet (NHBT0096480_022) excluded all homosexuals from donating blood. Do you consider that the explicit exclusion of homosexual men from donating blood in 1985 was an acknowledgment that the 1983 leaflet was unclear?

489. My response below covers questions a-d so far as I am able to remember. Rejection of the proposals at 1& 2 was, I believe, a consensus decision which all RTDs accepted after discussion. Questioning at sessions had always been a rather contentious idea and the majority of RTDs believed that in depth questioning with consequent referral to the sessional MO would be both off-putting to donors and disrupting at sessions, the latter possibly leading to mistakes being made. Discontinuation of sessions in high-risk areas was opposed, mainly through lack of definition of the term, in fact as described

elsewhere, a decision was made to discontinue sessions at HM prisons which were now accepted universally as 'high risk' areas.

490. At that time, and after consideration of the situation in San Francisco particularly, "many different partners" meant more than one. I think this was clear enough to the reader.

491. The AIDS leaflets were prepared by EAGA who were free to accept or reject proposals on their content made by RTDs and relayed to EAGA by the consultant advisor to blood transfusion to the CMO at DHSS, then at that time, Dr Gunson.

492. By 1985, it had become clear that a monogamous homosexual relationship was not protective so far as AIDS transmission was concerned. There would be instances of donors often not being aware of other activities in which their partner was involved. I do not consider that the change from the 1983 AIDS leaflet was an acknowledgement that this meaning was unclear, simply that there was a better appreciation of the situation after two more years' experience of AIDS, which was a new and unknown disease.

139. NHBT0020746 is a letter dated 14 June 1983 from Dr Entwistle to you which demonstrates a reluctance to press donors on self-exclusion in respect of AIDS. Please comment as to the following:

a. What did you consider the "aggressive approach" to be? Did you support this approach?

b. How did your views on donor exclusion issues change over time?

c. It was stated that asking donors questions about AIDS would lead to the truth being "positively concealed". Do you know how this opinion was formed? Did you agree with this?

d. It was stated that, as a consequence of questioning donors about AIDS, "the resulting loss of donors as well as the aggro [sic] could be awful." Did you share this view? Did this mean to you that blood supply should be prioritised over safety? What was your response?

e. Further, it was stated that "if an inordinate fuss were made about AIDS...important other donor information may be at risk of being overlooked..." As to this: Did you consider an "inordinate fuss" was being made about AIDS at the time? If so, what did you consider a proportional response to have been?

f. Dr Entwistle stated that the 1983 AIDS donor leaflet should not be handed to each donor at every session. This view was also supported by Dr Fraser (NHBT0039762_049). He stated that "we would not support the idea of handing out the AIDS pamphlet to all donors, this would slow down the session". It was later decided that the 1985 AIDS donor leaflet must be handed to every donor before donating blood (DHSC0002159). Was this an acknowledgment that not handing donor leaflets to each donor in every session before 1985 was an error in judgement? In hindsight, should AIDS leaflets have been handed to donors at every session from 1983?

493. My response below covers questions a-f so far as I am able to respond. An aggressive approach was mainly concerned in the minds of the RTDs with open questioning at a clerking desk regarding sexual orientation, risk behaviour, possible exposure to AIDS and the presence of non-specific symptoms associated with AIDS. I share the opinion, to some extent, since some degree of sensitivity was required, especially in an open forum such as mobile sessions where it is very likely that regular donors from a relatively circumscribed community know one another.

494. This view on circumspection did not change appreciably. Over time and with attention to the availability of updated leaflets etc., potential disruption of sessions by referring donors to the MO seemed to be minimised.

495. The situation was causing some anxiety since it wasn't impossible that some individuals, knowing themselves to be included in a risk group, would conceal the fact in view of the comparative openness of the venue and later as a means of securing a test for HIV. I accept that this was a

possibility but minimised by the character of the average national altruistic donor who would be adequately informed regarding the need for the safety of blood and its components.

496. The possible consequences of there being too much of an open forum on donor questioning has already been covered as has my own position on the subject. I most certainly did not consider that safety should not be prioritised but RTDs who raised their concerns also had a duty to protect the blood supply to the NHS as much as possible in the circumstances.

497. I believe the question of an "inordinate fuss" as against a proportionate response has been covered in the responses above.

498. I believe the departmental circular of January 1985 makes it quite clear that the new AIDS leaflet has been significantly updated as compared with the 1st edition in 1983 and in light of increasing knowledge and awareness, the problem must be brought to the attention of the donor before or at the time of each donation rather than simply making it available. In light of the developments which took place between 1983 and 1985 in terms of knowledge and experience, I do not consider that the change in methods of distribution of the leaflet represented an error of judgement in 1983.

140. Please consider the letter you received from Dr Fraser dated 15 June 1983 (NHBT0039762_049). In that letter, Dr Fraser noted that his RTC did not support the idea of asking donors, on questionnaires, if they had night sweats, weight loss or lymph gland enlargement. He also noted that his RTC would not support the idea of handing out the AIDS pamphlet to all donors as this would slow down the session. Did you share the views of Dr Fraser's RTC on this matter? Are you able to express what the rationale may have been for such an approach?

499. I shared Dr Fraser's views regarding the inclusion in health questionnaires of non-specific symptoms sometimes displayed by some

patients with AIDS as this was felt to be potentially confusing to donors and added nothing to the questions regarding general health and the need to seek medical advice etc.

500. I understand the view that handing out AIDS leaflets to all at donor sessions and requesting them to affirm that they had read it would have potentially slowed down the session not least by confused donors wishing to speak to the sessional MO. There was additionally the theoretical possibility that continued disruption of a session might lead to mistakes being made.

141. Please consider the letter you wrote to your colleagues dated 6 July 1983 (NHBT0020668). In that letter, it was noted that "The majority of RTDs still feel strongly that approach to donors should be at the lowest key possible and were correspondingly reluctant to either hand the leaflet to every donor at a session or to send it out as part of the call-up material. However, one or two regions felt that there might be some benefit in the slightly more aggressive approach and these RTDs may be asked to run a kind of trial in their regions, by either posting or handing out the leaflets."

a. Why were RTDs reluctant to hand donor leaflets to every donor at a session or send it to the donor as part of call-up material? Please provide details.

b. In what way were RTDs reluctant to distribute donor leaflets at sessions or send it out as part of call-up material? Please provide details.

c. Your letter noted that one or two RTDs felt that there might be some benefit in a more "aggressive" approach to distributing donor leaflets and that those RTDs may be asked to run a trial in their regions. Were those RTDs asked to run the trials? If so, what did those trials reveal?

If not, why not? Please provide details.

d. What are the strengths and disadvantages of adopting a more "aggressive" approach to distributing donor leaflets? In your view, which approach should have been adopted?

501. I will answer questions a and b together. At the time of introduction of the AIDS leaflet, AIDS was regarded as a modern 'plague' and a dreadful,

inevitably fatal disease. The finding that it could apparently be spread by transfusion of blood and blood products prompted the introduction of the leaflet, but this raised in the minds of some RTDs the fear that the emphasis on this possible linkage would raise concern amongst donors themselves regarding their safety in continuing to donate by emphasising yet again the link between AIDS and blood.

502. c. I do not recall there being a formalised trial of leaflet distribution methods, the emphasis remaining on ensuring that donors had access to the leaflets before every donation and the signing of the attendance form which contained the affirmation that they had read the leaflet and understood it. In the event, DHSS instruction followed publication of the 1985 leaflet to the effect that it should be included in the postal call-up of donors and handed to every new donor or walk in attending a session.

503. d. The disadvantages of adopting what had been termed this "aggressive approach" is discussed above. The advantage was that there was certainty that each individual donor received up to date information at every donation.

142. Please consider the SNBTS Directors minutes for the meeting held on 8 December 1983, at which you were present (PRSE0002899). At page 2, it was noted that "The leaflets had been available for some time at donor sessions and it was agreed that a more active approach would be acceptable now. It was felt that each blood donor should receive a copy and that the health questionnaire to donors should include the question, "Have you read and understand the leaflet on AIDS?"..."

a. What prompted the decision to adopt a "more active approach" to the distribution of donor leaflets? What did that approach entail? Please provide details.

b. Prior to the decision to adopt a "more active approach", was this approach ever deemed unacceptable? If so, why?

504. I have reviewed document MACK0001529 which is the minutes of the meeting held on 08 December 1983.

505. At the time of this meeting the 1983 AIDS leaflet had as noted, been available at donor sessions for sufficient time for its impact to be assessed. In view of its evident acceptability to the donors, the decision was made to adopt the more active approach ensuring that each donor received a copy prior to each donation, either by inclusion in postal call up or handed to the donor at attendance at a session. Prior to this decision, there was some concern regarding the distribution of the leaflet as detailed above.

506. This is of course the situation which applied in NBTS. The document deals specifically with the SNBTS approach, but I have no reason to believe that their leaflet distribution differed markedly from ours.

143. Please consider the 203rd Regional Transfusion Directors minutes for the meeting held on 15 April 1987, at which you were present (CBLA0002372). At page 3, it was noted that the opportunity for donors to 'opt out' during the donation procedure was considered "difficult, complicated and probably unworkable."

a. Please explain the 'opt out' procedure.

b. Why was the 'opt out' procedure considered unworkable? Please provide details.

c. Page 5 provides details of advice provided to the Committee, which recommended that if a donor had given blood in another region presented at a session, that "his/her blood should not be used until the donor's records have been checked". Do you recall whether this advice was considered or acted upon by the Committee? What was the outcome of this advice? Please explain your answer.

d. Should there have been a system in place for RTCs to alert each other to HIV positive donors earlier? Please explain your answer.

507. For an 'opt-out' procedure to work, the donor must have the opportunity at any stage before insertion of the needle to withdraw from the proceedings. This could be for instance through a decision to self-exclude after reading the available leaflets on health requirements and particularly upon reading the AIDS leaflet. It was considered difficult and probably unworkable through the necessity to provide a suitable private area at a donor session for the inevitable discussion between the donor and a competent member of NBTS staff, usually the sessional MO or nurse in charge. Not only would this potentially lengthy process be difficult to arrange without causing more embarrassment for the donor, it was also potentially disruptive to the running of the session by having the MO out of action.

508. I do not recall the question of a donor giving blood in more than one region being recorded in a uniform, formalised fashion. Certainly, a donor presenting themselves for the first time in a region would be asked if they had ever given blood before and if so, where and when. A check could then be made with the other region concerned. I cannot recall this being routinely held back from the RTC testing routine, since the exchange of information between the two RTCs involved would take place soon enough after donation for any necessary action to be taken.

509. For such a system to be fully operable, all mobile teams would have to carry a list of all people notified to their RTC as having been found to be HIV positive at another centre. The name of every donor presenting at their session would have to be checked against this list. This would have been impossible before all clerical duties at all mobile sessions were computerised. In addition, all RTCs began HIV screening at the same time and so a donor who was found positive in one region, would have undoubtedly produced anomalous results in a second region.

144. On 22 November 1991 Dr G Galea wrote to you noting the difference in donor exclusion policies between Transfusion centres and indeed home nations (NHBT0007516). Could you explain whether this was a frequent

occurrence and to what extent did the UKBTS/NIBSC Standing Advisory Committee push for UK blanket policies? Were these successful? If not, why?

510. Differences in donor exclusion policies between RTCs were not, to my knowledge, a frequent occurrence. In my experience, those policies laid down by the Red Book SAC were adopted by all RTCs as being comprehensive requirements for safety. Any significant suggestion for departure from or in addition to the guidelines would be referred to the SAC for consideration.

145. JPAC0000168_150 is a letter from Dr Moore dated 13 July 1992 to you, where it was noted that "One RTC has just stopped the practice they have followed since 1984 of not taking donations from people known to be ex-prisoners." Dr Moore also noted that "I would hope that we can be confident that present questioning covers health risks to which the donor may have been exposed whether in or out of jail."

a. Are you aware which RTCs had ceased their practice of not taking donations from ex-prisoners?

b. Do you recall the rationale for this decision?

c. Did you consider this to be safe? And if not, did you convey this to the RTC?

d. Did other RTCs follow suit and start collecting blood from ex-prison donors?

e. What impact, if any, did the practice of accepting blood donations from ex-prisoners have on the safety of blood/blood products? Please explain your answer.

511. My response below addresses questions a-e in so far as I am able to respond.

512. a. I am not aware of which RTC resumed the practice of taking blood from ex-prisoners.

513. b. I think the rationale behind this decision is well expressed by Dr Moore in his letter. By 1992, testing for significant viral markers had been added to comprehensive questioning regarding health risks.

514. c. I consider that this was a safe decision based on the answer in b above.

515. d. As far as I can recall, no RTCs published notification of their intention to resume the practice, if indeed they had ever stopped.

516. e. Please see my answer to c above.

146. Please consider the letter you received from Dr Angela Gorman dated 11 August 1993 (NHBT0007482). In that letter, Dr Gorman recommended that people who had had sex with a drug user, haemophiliac or homosexual man in the past should not be accepted as donors ("the past" was not defined by a date or length of time).

a. Did you agree with Dr Gorman's recommendations? Please explain your answer.

b. In that letter, Dr Gorman requested that you pass her recommendations on to the appropriate committee. What committee was she referring to? Did you pass Dr Gorman's request on to that committee? What, if any, was the committee's response to Dr Gorman's recommendations? Please provide details.

517. I have reviewed the letter referred to above [document NHBT0007482] however this is dated 11 *August* 1993, not November as suggested in the question.

518. When Dr Gorman wrote this letter in 1993, it was already acknowledged that sexual contacts of people in risk groups should also be excluded as blood donors as shown in the AIDS leaflet of 1985. However, her point about the time/length of the deferral of such contacts was relevant and

was referred to the Red Book SAC on care and selection of donors. In a subsequent publication of the guidelines on medical assessment of donors under the auspices of the SAC, this point was specifically covered and a deferral time of 1 year is stipulated.

Introduction of virally inactivated products

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

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

b. Please consider the minutes of the meeting on 18 December 1981 at paragraph 3.2 (CBLA0001565x). Why was the need to produce hepatitis free product considered to be an aim for the future, not for the present given what was known about hepatitis in 1981?

519. The need for safe products has been self-evident since the 1940s when the link between transfusion and some forms of hepatitis was acknowledged. In the ensuing years, I am certain that RTDs, including a representative from Trent would stress this need with the Director of BPL, individually and at regular RTD meetings. For my own part, I did not make representations to pharmaceutical companies who assumed contacts with Regional Haemophilia Centre Directors rather than with the TRTC.

520. I have considered the minutes of the meeting of the Working Party to advise on plasma supplies, particularly paragraph 3.2. It could well be that the reference to the future is directed towards an adverse effect on Factor VIII yields, not on the need to produce Hepatitis free products. The need for such products was well established at the time of this meeting in December 1981 but there are obvious constraints in that the

transition from the old to new Blood Products Laboratory was still in its early stages of development.

148. The Inquiry understands that you were present at an RTD meeting on 4 October 1988 at which it was reported that a patient had seroconverted to HIV positive after receiving "15 bottles from 3 batches of untreated Armour product prepared from untested plasma" (NHBT0018189). Could you please explain why untreated commercial products manufactured from untested plasma were being used in 1988 and whether you were aware of other similar cases like this?

521. I have no idea why untreated products manufactured from untested plasma were still being used in the UK in 1988, unless the commercial companies concerned were using up old stock of untested plasma. I am unaware of any other similar case.

149. The Inquiry understands that you were present at an RTD meeting on 15 April 1987 at which a discussion took place in relation to albumin supplies. It was stated that "Dr Contreras pressed for a reversal of the decision that no untested plasma could be fractionated since it was widely recognised that all albumin preparations were safe. Dr Smithies felt that this would be very difficult since the advice from the Committee on Safety of Medicines to commercial manufacturers was that no product could be imported after the end of 1986 which had been prepared from untested plasma; it was difficult to apply a different standard to B.P.L. [...] Dr Smithies confirmed that untested material could be used for commissioning of new plant. Dr Whitrow reported that the SNBTS Directors, faced with the same problem, had made a strong recommendation to SHHD that albumin could safely be made from untested plasma" (CBLA0002372). To what extent do you agree with Dr Contreras' position? To the best of your knowledge was a decision taken to use untested albumin in the production of blood products? If so, were there any cases of blood borne infections occurring after administration of blood products derived from untested albumin?

522. Dr Contreras' position was quite logical, but I must agree with the advice given by Dr Smithies. Any advice given to commercial manufacturers by the Committee on Safety of Medicines must also be seen to apply to BPL. Otherwise, there would almost certainly be an accusation of double standards. To the best of my knowledge, the decision was not reversed.

Provision of diagnostic screening kits

150. Please describe the arrangements in place at the TRTC in regards to the provision of diagnostic testing kits for donation screening ("screening kits"). You may find JPAC0000199_060 of assistance.

523. I find this question difficult to answer since I do not remember whether we had a central or direct contracting arrangement for the supply of these kits. From the wording of the letter from BPL, it sounds as though this was a direct contract to purchase their tests. Certainly, they would procure it long before any attempt at centralisation within NBTS, i.e., the National Directorate in 1988. However, mention is made in NHBT0000026_009 of the Procurement Directorate being involved in the decision for commencement of HCV testing (paragraph 93 of the document refers).

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

524. My answer to this question is very similar to 151 above, apart from there being a demonstration of methodology and equipment for HCV screening being organised on a National basis by the National Directorate of NBTS. I remember the demonstration, but I don't recall it leading onto National contracting.

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

525. The key factors involved in influencing the choice of screening kit were these:

- Ease of use, preferably automated
- Satisfactory sensitivity and specificity
- Consistency and reproducibility of results
- Reliability of supply of test kits
- Reliability of the machinery involved with ability of backup in case of breakdowns

153. 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?

526. All companies providing tests kits included detailed instructions for their use with each batch, together with expected results on testing included standard material. Failure to conform with the manufacturers recommended techniques was held by them as a reason to absolve themselves from any responsibility.

Introduction of HIV testing

154. The Inquiry understands that you were present at an RTD meeting on 23 January 1985 at which it was noted, in relation to AIDS, that "Most companies are approaching RTDs (these are Elisa tests). The preference within the NBTS is for an RIA technique" (PRSE0002062). Could you please explain the difference between ELISA and RIA tests and why a preference was made for the latter to be used by the NBTS?

527. Elisa and RIA tests are essentially similar in that each involves searching for a possible anti-body by allowing a serum sample from a donor to

react with a sample of the corresponding known antigen. Any reaction which has taken place, in other words, a positive reaction, can be determined by the detection of an indicator which has been initially applied to the known antigen, an enzyme linked dye in the case of Elisa and a radioactive label in the case of an RIA test.

528. The initial preference within the NBTS for the RIA test was based on its superior sensitivity over the first Elisa tests. Later generation Elisa tests proved to be at least as reliable as RIA tests with the added advantages that they did not involve the use of any radioactive material and could be automated. There was consequently a shift towards their use for HIV screening of donors.

155. On 2 March 1985 you and your peers from the NBTS wrote an article that was published in the Lancet expressing concern over the potentially high incidence of HTLV-III false positives using current commercial tests (PRSE0004824). You stated that careful consideration should be taken before rolling out these tests as it could have had a negative impact on donor wellbeing which in turn could lead to a "sizeable drop in the supply of blood and blood products". In addition you warned that the tests should first be implemented within the community otherwise "many high risk people, from a blood transfusion point of view, may present themselves at blood-donation sessions simply to find out their HTLV-III antibody status". You and your peers endorsed the need to test blood donations for HTLV-III but suggested that this be done after "test systems have been appropriately evaluated and efforts have been made to give all members of the public access to HTLV-III antibody testing". Please answer the following questions:

a. As far as you recall, how was this letter received?

b. Did it have the desired effect of taking a cautious approach to the introduction of HTLV-III donor testing?

c. If so, do you agree that first generation tests will inevitably have teething problems such as the ability to render accurate results and therefore with

hindsight and on balance do you think the tests ought not to have been delayed?

d. Did your fear that individuals would use RTCs as a way of finding out their HTLV-III antibody status materialise?

e. If so, what was done to deter this from happening? You may also find DHSC0002365_002 and NHBT0015638 useful for reference.

529. a. As far as I recall, the letter was well received.

530. b. Consideration of a cautious approach to the introduction of HTLV-III donor testing was certainly given, resulting in further evaluation taking place before introduction in October 1985. Beyond this time, some 8 months after the letter to the Lancet, it was not felt that introduction could be further delayed. The recommendation in the letter that arrangements should be made for testing of the general public before full screening of donors was not realised to any extent.

531. c. I think this is covered in my response to b above.

532. d. The fear still existed that risk groups would use or continue to use RTCs as a means of being tested for anti-HTLV-III. It is noted in document DHSC0002365_002 that some high-risk groups actually declined to attend STD clinics or GPs as a means of getting tested.

533. This same document also records that the Chief Medical Officer at DHSS, has sent a letter on the subject to all District Medical Officers. Document NHBT0015638 records the sending by RTCs of an appropriate letter together with the AIDS leaflet to Consultants and GPs in their regions. This same document also details the forthcoming meeting to be held at DHSS to discuss the setting up of alternative testing sites.

156. The Inquiry understands that the TRTC began testing all donations for anti-HTLV III on 11 October 1985 (BPLL0010765). How was this decision

made and did other RTCs start testing at the same time? You may also find DHSC0032165_156 useful.

534. The decision of a starting date was made after discussion of the possible difficulties with the actual test had been thoroughly discussed as instanced in the letter to the Lancet quoted above.

535. The discussion held at Trent RHA [document DHSC0032165_156 refers] was mirrored at other Regional levels in an attempt to pre-empt difficulties in counselling. There was agreement across all RTCs of a common National starting date for testing for anti-HTLV-I/II.

157. The Inquiry understands that HIV screening was to commence on 14 October 1985 (DHSC0002365_002). Did the TRTC commence screening on this date? What steps were taken to ensure that the TRTC could begin screening on this date?

536. In common with all RTCs, it was necessary to ensure supply and installation of all necessary hardware in advance of commencement with security of supply of reagents. Staff training was also finalised, both in the laboratories and any clerical and ancillary departments involved. Fortunately, training in non-laboratory departments was facilitated by having experience of similar procedures when screening for HBV.

537. In addition, a video was produced for the benefit of donor attendants as mentioned in document DHSC0002365_002 together with a document on counselling.

158. In the same document it was stated that some RTCs "felt they would not support discarding untested donations". As far as you are aware, were untested donations issued from the TRTC for the production of blood products after 14 October 1985?

538. As far as I am aware, no untested donations were issued from the TRTC after 14 October 1985, whether cellular components, locally prepared FFP, cryoprecipitate or plasma to BPL for fractionation.

159. On 30 October 1985 you dictated a letter to Dr A Smithies in which you said: "I have now put in hand measures to have returned to us any stock of untested (for anti-HTLV III) Cryo and FFP held in the regional hospitals. I am afraid that it may well prove impossible to test and re-issue these without severe prejudice to their therapeutic value. They will therefore have to be written off. Personally, I think it is a rather unnecessary step, but I can quite understand the position" (DHSC0002349_005). Could you please explain what you think you meant by this statement? What was your preferred alternative?

539. I believe I was referring to the fact that the writing off of returned, untested cryoprecipitate and FFP from hospitals, is made necessary only if back testing at the RTC was impossible. I believe that it would be impossible that the required conditions of storage during the whole procedure could be met, particularly if a sample for back testing had to be taken from the unit itself. The therapeutic value of these units would certainly be prejudiced.

540. Given the relatively small numbers involved, recall and disposal was my preferred option.

160. Please describe the implementation of HIV screening at the TRTC. In particular:

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

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

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.

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

541. My response covers questions a-d in so far as I am able to do so. In response to question a, preliminary screening of donors, through the use of health leaflets, the AIDS leaflets, questionnaires and questioning by the sessional clerking desk as described above, continued after the introduction of laboratory testing for anti-HIV. A blood sample taken at the time of donation and labelled with the unique donation number was returned to the RTC and its separated serum subjected to testing in the microbiologist laboratory by an approved method for the detection of anti-HIV. Confirmatory testing was carried out on all samples found to be positive or indeterminate by PHLS Colindale (Dr P Mortimer).

542. b. I do not recall any decision made for NBTS centres to have unscreened cellular products returned from hospitals for disposals at RTCs, as was done for frozen products as covered in my response above to question 159.

543. c. When a donation was confirmed as being infected with HIV, it was subjected to sterile disposal. A properly labelled sample of serum or plasma is retained in a frozen state for future reference. The donor would be informed of the result and its significance discussed with the RTC Medical Officer designated as the first line counsellor for this purpose. With the donor's permission, the General Practitioner would be informed for onward consultation with an appropriate specialist for example, at a sexually transmitted disease clinic. In the case of a confirmed antibody screening, the donor would be resigned from the donor panel, the results would be collated with those from other RTCs by Miss Rawlinson at the Manchester RTC and would also be sent to CDSC. The donor's records would be examined, previous donations identified, and recipient blood banks informed, together with BPL if plasma had been sent for

fractionation. Every effort would be made to contact identified recipients for counselling and testing.

544. Thanks to previous experience with screening for HBV, HIV screening could be introduced smoothly into the laboratory routine. Initially more questions were being asked by donors at donor sessions, but all donor staff received specific training to enable them to deal with the situation. The risk of transmission of HIV through blood donation had already been reduced by the measures taken to persuade and allow high risk donors to self-exclude. I believe that the risk was further reduced by the introduction of HIV screening, leaving only the risk of transmission during the so called 'window period'. The financial burden of screening was initially dispensed through Trent RHA but was included in the costing of components and products when cross-charging came into force in 1991.

161. The Inquiry understands that a memorandum was written on your behalf to Dr V James on 21 March 1990 stating that, "A national decision has been made to recommend the commencement of combined HIV 1 + 2 testing on 1 June 1990" (JPAC0000201_009). Please confirm whether this decision was implemented. If not, why not?

545. To the best of my knowledge, the National decision to begin combined HIV 1+2 testing on 01 June 1990 was implemented.

Surrogate testing

162. Whilst you were employed at the TRTC, what was your opinion on 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

b. NANB/HCV.

You may find PRSE0001411 and NHBT0009874 useful and page 5 of DHSC0032165_115 particularly useful in relation to AIDS.

546. Before the introduction of HIV testing, syphilis testing and HBsAg testing were regarded as surrogate testing for life-style risk in donors. Routine ALT testing was not generally supported as a life-style indicator, especially in the UK where the majority of results above the normal range were due to low-level alcohol consumption just before donation, or to the presence of obesity in an otherwise healthy individual. There was also relatively poor correlation between results found in different laboratories. The question of surrogate testing for HIV was rendered irrelevant by the introduction of specific anti-HIV testing in 1985.

547. The occurrence of post-transfusion hepatitis after the introduction of HBsAg screening led to much national and international discussion on the possibility of surrogate testing for NANB virus or viruses, centred mainly around ALT and anti HBc tests. The discussions lasted literally for years, especially regarding the deficiencies of routine, mass ALT testing mentioned in (a) above, but with additional consideration being given to the need for follow-up, further testing and counselling of donors. In the UK, and in many other countries, no recommendation for the introduction of these surrogate tests was felt, by the competent authorities, to be possible. The USA was an exception, understandable in view of a higher level of potential high-risk donors in the population, particularly intravenous drug abusers.

548. My own view was that surrogate testing for potential viral transmission was not suitable for NBTS implementation. This view did not change over time, and was reinforced by the deliberations of the Council of Europe Working Group, and of UKACVSB (documents NHBT0008816_002 and ARCH0002040_002). As detailed elsewhere in my statement, neither of these bodies felt able to recommend the introduction of ALT and anti-HBc testing as surrogates for NANB infection.

549. The use of an anti-HBc test at the TRTC, as mentioned in document NHBT0009874, refers to its specific use in the investigation of donors presenting with a history of jaundice. It was not being used as a surrogate test, but as part of the determination of HBV status.

163. The Inquiry understands that you were present at an RTD meeting on 22 September 1983 at which it was stated that "No tests for AIDS were available but early information suggested that the most risky populations, namely promiscuous homosexuals, may be distinguished by possession of positive results for hepatitis B core antibody (possible the most valuable marker) hepatitis B surface antigen and antibody and TPHA syphilis tests" (CBLA0001742). Could you please explain whether any of these tests were used as a surrogate testing method for an AIDS diagnosis at the TRTC, in particular whether Hepatitis B core antibody testing was used. If they were not used, why not?

550. In 1983, tests for Hepatitis B surface antigen and for syphilis with TPA tests were routinely carried out to exclude donors with these specific disease markers. Naturally, there was the added potential of detecting those people in the riskiest populations. The TRTC did have experience in testing for anti-HBc as can be seen in a letter to Dr Gunson as seen in document NHBT0009874, but I believe this was as an adjunct to routine screening for Hepatitis B surface antigen. I do not recall the question of anti-HBc testing being used on all donations being seriously considered at that time.

164. In a letter dated 14 October 1987 to Professor S Seidl, you stated that "we may have to speed up our [ALT and anti-HBc testing] deliberations when European law comes into effect next year, and the UK Transfusion Service becomes subject to product liability." (NHBT0000187_005). Please explain:

a. If and how this legal change sped up deliberations?

b. Whether deliberations proceeded slower than they should have up until this point?

c. Why deliberations had not already been expedited on the basis of human safety?

d. How this legal change affected the implementation of ALT and anti-HBc testing?

551. My letter to Professor Seidl was dated 14 October 1987. Prior to this there was worldwide interest in the viability of ALT and anti-HBc testing as surrogates for the detection of the NANB virus in donors with widespread conclusions as to their effectiveness. It was decided that a prospective study was necessary in the UK to determine the incidence of positive results for these markers, together with interviews with positive donors to exclude non-viral clinical explanation(s)?. An application to the DHSS for a grant for such a multi-centre study was submitted in April 1987, it was approved in April 1988 and the study began in 3 RTCs.

552. a. The comment regarding legal change was based on the knowledge that the forthcoming EU Directive would impose product liability on the UK Transfusion Services. This came into effect in March 1988 but in fact involved no requirements to routinely test donors for ALT and anti-HBc.

553. b. The results obtained in various trials in Europe and the USA were in many cases divergent so I do not believe that deliberations could have been expedited. The three-centre study referred to above was clearly necessary to properly assess the situation in the donor and prospective donor population covered by NBTS. No clear and universal opinion existed that the adoption of routine testing for ALT and anti-HBc was necessary.

554. c. At that time, we didn't believe it would influence safety at all, if we had to introduce it, it would have been because of its inclusion as a requirement by an EC Directive. However, we were quite sure that it did

require a prospective study in this country of our donor population to finally shut the door on it.

165. 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?

555. I was aware of the conclusions reached by the Working Group through personal communications. I had not seen the published report until I was provided with document NHBT0008816_002. I agree with the conclusions reached.

166. 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"?

556. I do not understand the intended meaning of this sentence in the Working Group's report which mentions maximum safety. From personal experience, I knew five of the members of the Working Group (Professor Dr Hogman (Sweden), Dr Habibi (ISBT) and Professor Van Aken (Netherlands), Dr Leikola (Finland) and Dr Gunson) and I am sure that their decision not to recommend the introduction of routine surrogate testing did not indicate a decision not to provide "maximum safety". All 5 of these members are from different countries and so were not all native English speakers. Maybe this choice of wording was a linguistic compromise.

167. The Inquiry understands that you were present at a meeting of the National Directorate of the NBTS at which it was recorded that "the only practical way in which BPL could produce i.v. Ig (Intravenous immunoglobulin) in a reasonable time period was to use a procedure licenced from a commercial manufacturer. All such manufacturers were restricted to the use of plasma which had been ALT tested. After careful consideration it was agreed that it would be feasible to test apheresed plasma for ALT [...]" (NHBT0000188_033). Could you please explain why it was more efficient to produce ALT tested plasma?

557. At the time of the named meeting of the National Directorate of the NBTS in August 1989, commercial manufacturers would be governed by the current rule in the USA that all plasma should be ALT tested before fractionation. This condition undoubtedly appeared as part of their licensing procedure with which BPL would need to comply if commercial processes were to be adopted. Volume for volume, fewer donors would need to be ALT tested by NBTS if apheresed plasma were to be collected rather than recovered plasma. The decision was made to follow the apheresis route for the production of intravenous immunoglobulin by BPL.

558. This untested plasma was *only* for fractionation and heat-treatment so whether or not it was ALT tested was immaterial, it was simply part of a licensing procedure in other countries, not the UK.

168. Please consider the SNBTS Directors' Meeting minutes for a meeting held on 13 December 1988 (PRSE0001626). At 3(e), under the heading "Donation testing for NANB", it was noted that "The Microbiological Validation Group had not done any significant work since the last meeting as the Anti-HBC project had a low priority". The document also states that "The Directors agreed that the Microbiological Validation Group had more important matters to fulfil."

Please explain:

a. What was the function of the The Microbiological Validation Group in relation to donation testing for NANB?

b. What was the "Anti-HBC project?"

c. What were the "more important matters" which prevented significant work from being carried out on the "Anti-HBC project"?

559. I am afraid I know no more of the SNBTS Microbiological Validation Group than the information mentioned in the above document [PRSE0001626]. Equally, the nature of the anti-HBc project with which this group was apparently concerned is unknown to me.

169. 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?

560. The decision made by ACTTD regarding the acquisition of product licences is covered in my response to question 167 above. I agree with the decision. The conclusion arrived at by the ACVSB in November 1989 referred to the routine surrogate testing of all donations and I agreed with this decision also.

170. The inquiry understands that you were present at a meeting of the Northern Division of the NBTS on 15 February 1990 at which ALT testing was discussed. In particular, it was noted that "After much heated discussion it was decided that until there is a uniform decision by the National Directorate to have a category of non-ALT tested plasma, different RTCs will follow different policies" (NHBT0070258). Please could you explain whether there were two types of plasma being produced at this time, namely: ALT tested and non-ALT tested plasma? Why do you think there was such a significant difference in opinion with regards to the option of producing non-ALT tested plasma?

561. The minutes of the Northern Division of NBTS held in February 1990 record my presence but I cannot remember much "heated discussion" over the question of ALT testing on apheresis donors. I can only conjecture that this was in some way linked to the decision made in August 1989 regarding the ALT testing of apheresis plasma for the production of intravenous immunoglobulin by BPL (my response to question 167 refers).

562. Dr Robinson plainly wished for platelet-rich plasma harvested by apheresis to be exempted from this exercise. It would obviously not have been suitable for BPL's purpose in any case. The request from BPL for ALT tested apheresis plasma for intravenous immunoglobulin production was not withdrawn until February 1991. The delay perhaps led to some confusion at RTC level as to whether they should continue to test

apheresis plasma for ALT levels in the intervening period. Dr Robinson was talking about *platelet-rich plasma,* so they were two different products.

171. The Inquiry understands that you were present at a meeting of the Northern Division of the NBTS on 21 February 1991 at which it was noted that "Dr Robinson was asked to write to BPL on behalf of the Division to express concern over the short notice given about this decision to cease ALT testing" (NHBT0071759). As far as you are aware when was ALT testing introduced and why do you think it was stopped at such "short notice"?

563. This question again refers to the intention of BPL to apply to a commercial fractionator for a licence to use their procedure, as covered in responses to questions 167 and 170. In August 1989, arrangements began for RTCs to produce ALT-tested apheresis plasma for this purpose. The failure of BPL to secure such a licence led to a cancellation by BPL of their need for this plasma, leading in turn to the concern felt by the Northern Division of the NBTS regarding the short notice given by BPL of cessation of ALT-testing of apheresis plasma.

172. The Inquiry understands that you were present at a meeting of the NBA Executive on 20 October 1993 at which it was noted that "Dr Contreras argued against the introduction of routine ALT tests on clinical grounds and Dr Gunson reminded the Committee that ACVSB had considered the test was not justified on this basis" (ARCH0002040_002). As far as you recall, did you agree with this position? If not, why not?

564. As far as I can recall, I agreed with Dr Contreras' position and with the decision made by ACVSB on routine ALT testing.

173. The Inquiry understands that you co-authored reports for the NBA in March and September 1994 with regards to ALT testing of plasma. The reports noted that several European countries required plasma to be

tested for ALT but that it was not required within the UK. In fact, on 21 February 1992, The Advisory Committee for the Virological Safety of Blood held that "there was insufficient reason to justify a recommendation to Ministers that ALT screening of donated blood should be introduced in this country" (NHBT0016380, NHBT0003628). What did you understand to be the reasons for the difference between the European and British positions?

565. These 1994 documents make clear that ALT-testing of plasma for fractionation was not an EEC requirement. They also make clear that several EC countries had not achieved self-sufficiency in fractionated products and therefore relied on supplementation by imported products. Some of these imports would have undoubtedly been from commercial producers in the USA, whose licence to fractionate included the requirement that plasma used should be ALT-tested.

566. Without knowing the precise background, I would have thought that the export of BPL products to affected countries would be subject to the same stipulation regarding ALT-testing to ensure a level playing field.

567. The British position remained the same in that ALT-testing was not required for *any* donation.

174. Please advise when ALT testing was introduced at the TRTC during your tenure. You may find BPLL0008955 of assistance.

568. ALT testing was introduced at the TRTC in 1991 restricted to the testing of plasma donations to be sent to BPL for production of intravenous immunoglobulin as detailed above. It was not universally applied to all donations as a form of surrogate testing.

175. Please advise whether any other forms of surrogate testing (e.g anti-HBc testing) were introduced at the TRTC during your tenure.

569. No forms of surrogate testing were introduced at the TRTC during my tenure as RTD.

176. If surrogate testing was introduced at the TRTC, please explain what impact this had on the TRTC. 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 the TRTC stopped surrogate testing?

570. Not applicable – please see my response to question 175 above.

177. At an SNBTS Directors meeting on 3 March 1987, the Directors agreed to "recommend to the SHHD that surrogate testing for NANB should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding. Each Director should let Dr Cash know what funds would be required in his/her region, assuming that both core testing and ALT would be undertaken in the Transfusion Centres" (PRSE0004163). Please expand on the following:

a. Whether surrogate testing (namely ALT or anti-HBc testing) was introduced at the TRTC during your tenure;

b. If so, whether this had any impact on the TRTC;

c. How the surrogate testing was performed;

d. What the process was for screening donors and/or blood donations;

e. What, if anything, happened to the unscreened blood that had been collected prior to surrogate testing being implemented; and f. 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.

571. Again, not applicable in view of no surrogate testing taking place.

178. In July 1987, many SNBTS Directors wrote to the Lancet to state that surrogate testing was "inescapable." They stated that "no large study to answer this critical question has yet been presented, and we agree that the size of the benefit to be gained from surrogate testing cannot be accurately established without such a study. However, the time for this study has already passed" (PRSE0001444). Did you agree with the reasoning provided in this article?

572. My response to the SNBTS Director's letter to the Lancet regarding the possible introduction of surrogate testing for NANB must be linked to the response to the following question regarding the report of the Working Group of the Council of Europe Committee of Experts on Blood Transfusion and Immunohematology. I was aware of the Working Group's report and agree with their conclusions as did ACVSB who also authorised the setting up of a study as mentioned in the SNBTS Directors' letter. I also agree with the setting up of this study involving three NBTS RTCs. I did not agree that the time for it had passed.

179. A report prepared by Dr Gunson in August 1987 set out the conclusions of a Working Group established by the Council of Europe Committee of Experts on Blood Transfusion and Immunohematology to consider the introduction of routine surrogate testing ('the Working Group report') (NHBT0008816_002). The Working Group concluded it could not provide a recommendation on the introduction of surrogate testing in light of the following considerations:

a. the use of surrogate tests to reduce the incidence of transfusion associated non-A non-B Hepatitis (NANBH) 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 NANBH;

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?

573. Please see my response to answer to question 178 above which deals with all of these questions.

180. 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.

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

574. a. I have to say that I disagree with the decision taken by Dr Lloyd to begin testing for anti-HCV in advance of the September 1991 date agreed by UK BTS Directors and by ACVSB. Although his letter to Dr Gunson states that the second-generation HCV tests were acceptable tests for donor screening, he goes on to acknowledge that their

evaluation tests had not been completed. The need to complete the evaluation of a test which was apparently superior to its first-generation predecessor was the sole reason for the delay in routine screening until September 1991. Had the second-generation tests also showed deficiency in specificity, this premature roll out would not have been in the best interests of patients.

575. b. My views on the decision made at the time have not changed. As it turned out, the second-generation test proved to be satisfactory for screening, but that could not have been known for certain, in the first half of 1991.

HBc testing

181. The Inquiry understands that you were present at a meeting of the same group on 7 May 1992 at which it was stated that "The potential morbidity resulting from transfusion associated with Hepatitis B, which still occurred, exceeded that from Hepatitis C before the introduction of donor screening. The meeting agreed that the introduction of anti-HBc donor screening therefore had a high priority" (NHBT0017532). Could you please explain this statement and why you think the position had apparently changed from three years prior?

576. This document dated May 1992 reports the situation whereby transfusion associated Hepatitis B was still occurring even though Hepatitis B surface antigen testing produced negative results. It was considered that these cases represented donors in whom HBsAg levels had diminished to an undetectable level but still represented possible viral transmission. It was agreed that a high proportion of such cases would be detectable by the presence of a high titre anti-HBc. This situation was really only identified after the elimination of NANB viral transmission by anti-HCV testing commenced in 1991.

182. The Inquiry understands that you were present at a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases on 12 January 1993 at which Anti-HBc screening was discussed. It was decided that "routine screening of blood donations should commence [...]" because trials had shown "that potentially infectious donations for hepatitis B were being transfused" and "that patients who had suffered from transfusion associated hepatitis B (when the blood was HBsAg negative) were being reported" (DHSC0006982_049). As far as you recall, was Anti-HBc screening soon introduced after this meeting? If not, why not? You may also find JPAC0000035_282 useful.

577. Document DHSC0006982_049 is the minutes of a meeting of the UK ACTTD held on 12 January 1993 which confirm that a recommendation should be made to ACVSB that routine screening of all donations for anti-HBc should be introduced. I confirm this in my letter to Collette Rivet of the Canadian Blood Agency dated 25 May 1993, document JPAC0000035_282. I also summarise for her the situation whereby we would accept donations for all uses if an anti-HBc positive result was accompanied by a level of anti-HBs of more than 100iu/ml. This level of anti-HBs is selected as being protective against any residual viral activity, referred to by Dr Barbara as "tail-end carriage".

578. The introduction of testing did not take place since MSBT, the Department of Health Advisory Committee decided against making it mandatory. I am not sure of the rationale behind this decision.

183. The Inquiry understands that you were present at a meeting of the UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections on 11 October 1993 during which it was discussed that the MSBT Department of Health Advisory Committee had decided that anti-HBc testing was not obligatory for routine blood donor testing. Dr Barbara stated his disappointment, noting 6 reasons in favour of adopting anti-HBc testing including the fact that it was cheaper than anti-HCV testing. Importantly, "Dr Barbara reiterated that the key role of anti-HBc screening

was to identify donors at the 'tail-end' of carriage, with subliminal levels of HBsAg" (NHBT0007465). Please could you explain whether you agreed with the MSBT decision to not make anti-HBc testing mandatory. If not, did you agree with any of the 6 points that Dr Barbara made at the meeting? (please see section 10 page 4 of the document). Could you explain what you think Dr Barbara meant by "tail-end of carriage"?

579. I was surprised that the MSBT DOH Advisory Committee had decided in October 1993 that anti-HBc need not be mandated as a routine test for blood donors given that the meeting of the UK AC on Transfusion Transmitted Diseases had argued that its introduction had a high priority at its meeting on Thursday 7th May 1992. The response to question 181 refers to that.

580. I had accepted the reasons put forward in favour of introduction and therefore shared Dr Barbara's surprise and understood his disappointment. He was incidentally quite right in that a go-no-go standard' for anti-HBs would not be a major problem.

581. Also, although central UK collation of NBTS matters had improved since the establishment of the National Directorate, it could be and was improved by the establishment of a centralised authority for blood transfusion, the NBA.

582. Dr Barbara's reference to "tail-end of carriage" refers I believe to the situation I have outlined in my response to question 181 above, i.e. donors in whom HBsAg levels had diminished to an undetectable level but still represented possible viral transmission.

184. You attended meetings of UKACTTD in the early 2000s which discussed whether routine anti-HBc screening should be introduced as a risk reduction measure (such as DHSC0006982_049, JPAC0000036_104). This issue was discussed at SACTTI and other committees such as MSBT from the early 1990s into the early 2000s.

583. I retired in 1998 and therefore did not attend the meetings of the UKACTTD in the early 2000s. I was a member of the UK Advisory Committee on Transfusion Transmitted Diseases until its reconstitution as the UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections in October 1993.

185. What do you recall of the arguments for and against its introduction?

584. It must be remembered that routine screening for anti-HBc was first discussed as a so-called surrogate test in conjunction with ALT testing primarily for indirect evidence of any NANB infectivity. Such a regime was adopted in some countries, particularly the USA and any other country which had significant contact with the USA, for instance, as consumers of products manufactured there from plasma they supplied to the manufacturers or as suppliers of red cells, such as the supply sent from Bern to the New York blood bank.

585. However, the position in the majority of European countries, including the UK, was summarised in a report from the Working Party of the Council of Europe Committee of Experts in Blood Transfusion and Immunohematology, please see document NHBT0008816_002.

586. This Committee felt unable to recommend the routine introduction of non-specific tests for evidence of any NANB infectivity, a decision echoed by the UKACTTD and by the DOH ACVSB. However, after the introduction of routine screening for HCV in 1991, it was confirmed that there was residual transmission of Hepatitis due to HBV. The question of employing anti-HBc as a routine test to pick up these donations was further investigated and the evidence in favour of its adoption was accepted by the UKACTTD but rejected by the MSBT DOH Advisory Committee, as detailed in my response to question 183 above.

186. What was your personal view, and did this develop over time?

587. My personal view of possible surrogate testing by employing ALT and anti-HBc tests was entirely in agreement with those of the Council of Europe Group, UKACTTD and the ACVSB - that it should not be recommended. This view developed with increasing awareness and knowledge of the persistence of post-transfusion hepatitis after the introduction of anti-HCV screening probably due to subliminal levels of HBsAg in some donors. I accepted the arguments put forward that such cases could be detected by the deployment of anti-HBc testing being used in this situation as a specific test for HBV carriage not in a non-specific surrogate manner.

187. For what reasons, in your view, did this issue keep returning to committees without a final decision? Do you feel that this continued reassessment was appropriate?

588. I believe that the recurrent examination of this issue was due in part if not wholly to the change in emphasis on the reason behind the possible use of the anti-HBc test as outlined above. From this point of view, the continued re-assessment of the use of anti-HBc screening was probably inevitable.

Introduction of anti-HCV screening

188. When did the TRTC begin anti-HCV screening?

589. The TRTC commenced routine anti-HCV screening on the nationally agreed date of 1st September 1991. Prior to that, the RTC was involved in a trial of UBI tests in the final stages of kit assessment.

189. The Inquiry understands that you wrote guidelines for the Blood Transfusion Services in the UK in 1989 which referred to routine screening for HCV as "undergoing evaluation" (NHBT0000027_030, pp.1.114, page 2). Please explain:

a. Which HCV Evaluation programme were you referring to?

b. How this evaluation was run including which screening kits were being evaluated and who was running the evaluation.

c. To the best of your knowledge, what similar evaluations were taking place in other countries?

d. Were any other evaluations of HCV screening taking place around this period? If so, please provide details, including which organisation was responsible for these.

590. a. In 1989 when the Guidelines for the Blood Transfusion Services in the UK were published, an evaluation of first-generation anti-HCV screening tests was set up by Dr Gunson, the National Director of NBTS, involving three RTCs.

591. b. Abbott and Ortho kits were included in the routine microbiological screening employed by RTCs in Bristol, the North West region and North West Thames region. Results were reported to Dr Gunson to form the basis of a decision on a starting date for the introduction of routine screening by NBTS to be confirmed by ACVSB. In 1991, Abbott and Ortho introduced their second-generation tests, solving difficulties and discrepancies experienced with their first-generation tests. It was thought essential to evaluate these improved tests before the introduction of routine screening and in addition, UBI had produced a test which also needed evaluation at RTC level. An extension of the original study was then therefore set up, dividing these three kits amongst six RTCs, as noted in the report of Northern Division of NBTS meeting on 13th June 1991 (document NHBT0071757).

592. c. I am not aware of similar evaluations taking place round this period though undoubtedly this would be happening.

593. d. Please see my answer to c above.

190. The inquiry understands that you were present at a meeting of the Northern Division of the NBTS on 13 June 1991 at which concern was raised at the fact that "...the Northern RTC had already started screening against agreed national policy..." (NHBT0071757). As far as you recall, why did this happen and was it usual for RTCs to set their own start dates for new testing regimes?

594. In his letter to Dr Gunson dated 24 June 1991 [document NHBT0000076_009], Dr Lloyd, RTD of the Northern RTC, makes it clear that in his opinion, the second-generation tests for anti-HCV could and should be put into use immediately. This was in spite of the fact that the evaluation programme of the kits had not been completed. Dr Gunson and all other RTDs disagreed with this opinion and accepted that some further delay in implementing nationwide screening was necessary to allow further test kit evaluation. This was in view of the fact that the first-generation kits had shown deficiency in specificity and that Abbott and Ortho had now produced kits which comprised a wider spread of virus derived antigen against which a donor sample could be tested.

595. Dr Lloyd however continued with the screening programme for Northern RTC. At this time, Dr Gunson stated elsewhere that Dr Lloyd was within his right to do so since the National Directorate had no executive authority over RTCs, the management of which at that time still remained with Regional Health Authorities. However, in matters such as this, RTDs had come to accept a decision on a unified starting date for any new testing regime as determined by the National Directorate in consultation with appropriate specialist committees.

191. 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.

596. I believe that my agreement with Dr Gunson's suggestion for a delay for implementing anti-HCV screening and the reason behind this agreement are set out in my response to questions 189 and190 above.

192. 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?

597. My view was that a uniform starting date was preferable given previous experience. When HBsAg screening was introduced, implementation took place in a staggered fashion across RTCs, resulting in a situation whereby a mixture of tested and untested donations was being issued across NBTS as a whole. With this in mind, anti-HIV and anti-HCV screening were implemented on a uniform start date with more manageable results.

193. The Inquiry understands that a letter was authored on your behalf to Dr H Gunson on 5 February 1991. It stated that, after accumulating enough data on the relationship between RIBA and PCR testing during the first few months of the HCV testing roll out, the latter could be dropped "as a confirmatory test in the presence of an undoubted positive RIBA". This seems to contradict somewhat with the following statement which was made one paragraph earlier in the letter: "[...] the RIBA test is currently only regarded by the manufacturer themselves as being a supplementary rather than a confirmatory test" (NHBT0008087). Could you please explain these two positions? Was the PCR test dropped as a confirmatory test when HCV testing began in September 1991? Were donations ever subject to only one assay such as RIBA? If so, why was it felt that confirmatory testing was not required?

598. The screening test for anti-HCV as implemented nationally on 1st September 1991 is an ELISA test which detects antibodies in a donor sample to two recombinant antigens derived from the Hepatitis C virus. The original recombinant immunoassay, RIBA-1, was a test that involved a search for antibodies against the same two recombinant antigens used in the initial ELISA screen. Thus, it can only be described as supplementary rather than confirmatory.

599. RIBA-1 was supplanted by RIBA-2 which contained a further two recombinant antigens, i.e., a total of four. Strictly speaking this was still a supplementary test rather than confirmatory but proved to be much more reliable than RIBA-1 and was accepted for regular use in the UK in April 1991.

600. The PCR test is a true confirmatory test in that it is designed to detect HCV *antigen* not HCV *antibody* and so differs from the screening ELISA test. However, it is a technically complex test and both false positives and false negatives results can occur. In view of this and the improved performance of RIBA-2, it was decided that RIBA-2 would be employed as the first test carried out as a confirmatory test by the designated reference laboratory to which ELISA positive donor materials had been referred.

601. The employment of a PCR test was to be decided by the reference laboratory depending on the result of the RIBA-2 test, as set out in the report from the UK ACTTD dated 10th May 1991 [document NHBT0071681]. It can be seen that donations found to be positive in the initial ELISA screen were always subject to confirmatory testing.

194. The Inquiry understands that you were present at a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases on 25 March 1991 at which the "Return of repeatably unconfirmed anti-HCV donors to active donor panels" was discussed. It was noted that "Certain donors may be retained on active panels for the purpose of donating plasma for

fractionation" (NHBT0000073_063). Could you please explain the definition of a repeatably unconfirmed anti-HCV donor and whether this category of donor was ever returned to the active donor panel? If so, why?

602. My understanding of a repeatably unconfirmed anti-HCV donor is an individual who on more than one occasion was found to be positive by the screening ELISA test but negative by the confirmatory test carried out by a reference laboratory.

603. I cannot remember such a donor ever being returned to the active donor panel.

604. The Medical Assessment of Donors Guidelines published under the UKBTS/NIBSC Liaison Committee (the Red Book organisation) states clearly in its July 1999 edition that in the case of Hepatitis C, seropositive individuals should be permanently excluded, even if this was unconfirmed.

195. At a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases it was noted that:

a. RIBA - 2 negative donations could be used but only "for plasma for fractionation" (see section 5.3 NHBT0071681); and

b. "RIBA - 2 reactive (or indeterminate) PCR negative would be reported as anti-HCV confirmed (or anti-HCV not confirmed), HCV RNA not detected [...] The index donation would be used for plasma for fractionation...but used only for plasma for fractionation" (see section 5.4). Please could you explain whether either of these protocols increased the risk of Hepatitis C being transmitted through plasma and why it seems that it was suitable to use these donations for plasma fractionation but not e.g. whole blood etc?

605. The two named protocols outlined in the document prepared for the UK ACTTD on 10th May 1991 by Dr Gunson refer specifically to plasma for

fractionation. The processes used at BPL in the preparation of therapeutic products included heat treatment - the manufacture of Factor 8Y for example – to ensure that the products were virus free so that the risk of Hepatitis C transmission would not be increased.

606. Components which would be prepared at RTCs, cellular components for example, could not be so treated making these protocols unsuitable for application to whole blood donations.

196. At the same meeting it was stated that anti-HCV PCR testing remained "controversial". Could you please explain why you think this was the case and whether you agreed?

607. As outlined in my response to question 193, the PCR test is technically difficult to perform and when applied to HCV testing proved to be unreliable with regard to specificity, producing both false positives and false negatives. I agreed that it should not have been regarded as a first line confirmatory test but reserved for the identification of HCV antigen when the combined results of ELISA and RIBA II testing required further interpretation.

197. What impact did HCV testing have on the TRTC? In particular:

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

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

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.

d. What impact did the introduction of testing have on the risk of transmission of HCV through blood donations?

608. My response below covers questions a-d as far I am able to recall. The introduction of HCV testing at the TRTC followed virtually the same steps

for the introduction of HIV screening described in my response to question 160 above. The exceptions were:

1. Onward consultation, counselling and treatment would involve an appropriate specialist such as a Hepatologist or a Gastroenterologist, not an STD specialist.
2. As described above, confirmation of positivity for HCV was rather more complex than that required for HIV so designated laboratories were selected for this task.
3. On a more official basis, results would be reported to and collated by The National Directorate.

609. In relation to question d specifically, please see my response to question 160 as to the impact the introduction of testing had on the risk of transmission of HCV through blood donations.

198. What funding and operational support was the TRTC provided with to aid in the implementation of testing? Did this have an effect on TRTC's ability or willingness to commence testing earlier? You may be assisted by (NHBT0000193_081, NHBT0000026_009 (p36-39), and NHBT0034936).

610. On 10 April 1990, I met with Dr Alderslade, Trent Regional Medical Officer and Mr Grute, Deputy Trent Regional Treasurer to discuss funding for the forthcoming implementation of the anti-HCV screening. As I remember, it was decided that Trent RHA would fund the provision of testing kits initially, but this should be included in cross-charging finances after the initial period of implementation. Any necessary hardware purchased would be covered by a small-scale capital product allocation. Further operational support was provided by the RMO liaising with the District Medical Officers (DMOs) with regard to identification of consultants who would be involved in the counselling of donors found positive. I found Trent RHA to be fully supportive of the need for anti-HCV screening at the TRTC and that it did not attempt to influence the date of commencement.

199. The Inquiry understands that you were present at a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases on 8 January 1991 at which it was stated, in relation to anti-HCV testing of blood donations, that "the definition of a positive result was crucial and that differentiation between reactive results which differed from the manufacturer's criteria for positive results should be made" (PRSE0003048). Please explain:

a. The difference between a reactive and positive result;

b. Who set the cut off values for either result; and

c. Whether these differed among RTCs.

611. The end point of a standard ELISA test, such as that used in anti-HCV screening, is the development or absence of a colour, the intensity of which is measured automatically. In the calibration of a test, the intensity of the colour developed using known negative and positive donor or patient samples, is used to set the cut-off point at which the result is accepted as being positive. Some colour development may occur which does not reach the stated end point for that kit, the sample then being reactive rather than being classified as positive.

612. Cut-off values are normally set by the manufacturer of the test kit and specified for each batch.

613. RTCs would not set their own cut-off values. Departure from the manufacturer's methods or parameters would call into question the validity of the test.

200. The Inquiry understands that you were present at the National Management Committee on 7 September 1992 during which it was stated that "All remaining non-HCV tested plasma will have been used and issued before 31st December 1992" (SBTS0000376_024). Could you please explain why non-HCV plasma was apparently being used after the introduction of Hepatitis C testing in September 1991?

614. As mentioned in my reply to question 195 above, the processes used at BPL in the preparation of therapeutic products ensured that they were virus free so the use by BPL of residual plasma which had not been tested for anti-HCV did not compromise the safety of the products.

201. On 18 August 1994 you were sent a letter from Dr Mahes de Silva regarding the "possible transmission of HCV via IV anti-D Ig supplied by the Blood Transfusion Board, Ireland". It was noted that your RTC had received supplies of this material (NHBT0100865_032). Could you please explain whether you took any measures, as the Director of the TRTC, to ensure that recipients of these products were traced and tested? If so, was there any definitive evidence linking these supplies with confirmed HCV positive cases?

615. Intravenous anti-D Ig as against intramuscular was not a product widely used and would normally be issued on a named patient basis and certainly on the basis of a named hospital blood bank or clinical consultant. The tracing and testing of the recipients of this batch was therefore comparatively simple.

616. To the best of my knowledge, no recipient was found to be positive for anti-HCV. The tracing and testing of the donors whose plasma was used in the production of this batch of haemoglobin was of course the responsibility of The Blood Transfusion Board, Ireland. I do not believe that we received notification of any results.

Hepatitis B

202. The Inquiry understands that you were present at an RTD meeting on 6 October 1976 at which it was noted that, "The Chairman reported that the Advisory Group had agreed that the proposed requirement that persons who had suffered from hepatitis should no longer be excluded from donor panels would now be permissive rather than mandatory" (NHBT0016475). Could you please explain what you think was meant by this?

617. The RTD meeting in question met on 6th October 1976 and I am afraid I have no recollection as to the identity of the Advisory Group mentioned. I can only suggest that at that time, awareness of post transfusion jaundice resulting from transfusion of HBsAg negative donations was accumulating so that RTCs were being given room to use their own judgment regarding the exclusion of donors who had apparently recovered from hepatitis rather than making this mandatory.

Recall practice and procedure at TRTC

203. Please give an overview of product recall practice at the TRTC, and how this changed during your tenure.

618. Recall of products or components manufactured at the TRTC would happen when either:
    1. Components from a donation had resulted in an immediate or delayed reaction in a recipient, or;
    2. A donor had either reported an illness in the post donation period or was found to have a positive screening test at the next donation.

619. In the great majority of cases, this would involve the recall of issued products with a long shelf life, cryoprecipitate for example. Identification of any components prepared from the index donation and their issued destination was obtained from appropriate RTC records.

620. The consultant in charge of the receiving hospital blood bank would be notified by telephone and in writing and a request made for the return to the RTC of any unused units concerned.

621. In the case of the recall of products issued by BPL, the RTC would receive details of the product concerned and the details of any onward issue obtained from RTC dispatch records. Again, a request would be

made of the receiving blood bank consultant for the return of any unused stock.

622. The major change in recall practice at the TRTC during my tenure as RTD came about with computerisation of the records, making the process simpler and quicker.

204. What do you remember about any formal recall or notification procedures in place?

623. Recall and notification procedures were carried out in accordance with written standard operating procedures (SOPs) which in common with all SOPs were subject to review.

205. 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?

624. In my opinion, the established practices and procedures were effective in dealing with product recall. As always, good communication between the parties involved was essential.

625. In my experience, clinicians in the Trent region generally complied willingly with recall requests, which were in any case, few.

206. The Inquiry understands that you were present at a meeting of the NBA Executive on 20 October 1993 at which a Hepatitis B incident was discussed. It was stated that a donor at the Sheffield RTC had developed Hepatitis B 8 weeks after donating and that it was demonstrated that "the red cells had transmitted HBV infection" (ARCH0002040_002). Could you explain how you think this happened? Were the tests used for detecting Hepatitis B not specific enough?

626. The asymptomatic carriage of the virus between the individual being infected and the development in his serum of a positive test for the virus (the so called "window period") is well documented.

627. Transfusion transmission of the virus by donation taken during the window period has always been acknowledged.

628. In the case quoted here, the donor developed jaundice over 8 weeks after donation so it is quite possible that he may have developed a positive HBsAg screening test before this time, effectively shortening the window period. Even so, a window period of the full 8 weeks is held to be unusual but not rare.

629. I do not believe that the test used for detecting HBsAg was in any way deficient.

General

207. Please describe all other steps or actions taken at the TRTC 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.

630. I believe that the major steps taken at the TRTC during my tenure as RTD to ensure blood safety and to reduce the risk of transfusion transmitted infection have been described throughout my statement.

a. Constant revision of pre-donation screening by means of leaflets and questionnaires as an aid to self-exclusion by high-risk donors and potential donors.
b. The introduction of specific screening for viral markers – HBV, HIV and HCV. Bearing in mind that transfusion transmitted infection may have a non-viral origin, particular attention was also paid to:

- exclusion of bacterial contamination by routine and regular checking of cleansing the skin at the donation site

- the choice, use and monitoring of equipment used in a potentially open process
- attention to and recording of the cold chain which must be involved in the storage and transport of most blood components and of plasma for BPL
- by regularly checking by culture of random units of platelet concentrates stored at a higher temperature and;
- by similar checking by cultures of units stored at sub-zero temperatures, e.g., cryoprecipitate and FFP.

631. Naturally these non-viral processes were checked by the Medicines Inspectorate on their regular routine inspections.

208. 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?

632. During my time at the TRTC, when all responsibility was directed to Trent Regional Health Authority, they understood the need for blood safety and co-operated with us to the fullest extent. I was never conscious of any imposed restraints in this respect.

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

633. The desire for consensus across RTCs was based on the accepted need for uniform and contemporaneous action to be taken by NBTS as a whole, especially so far as blood safety was concerned.

634. Since no one wished to see an apparent difference in application across regions, uniformity across RTCs was as a rule accepted with little or no impact on an effort to achieve blood safety at a local level.

210. 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?

635. RTDs took advice on blood safety from appropriate Advisory Committees, usually UKACTTD and from the National Directorate after its formation. They had an input to both of these bodies but as stated elsewhere were reliant on their parent RHAs for agreement on policies and priorities. RHAs in turn would normally seek agreement on action from the Department of Health.

636. From the late 1970s onwards, the Department of Health set up two committees, firstly EAGA, followed later by ACVSB (which became MSBT and later the Advisory Committee on the Safety of Blood, Tissues and Organs SaBTO), the latter becoming the final arbiter so far as policies and priorities on viral safety of blood was concerned, responsible only to Ministers. They would of course receive advice from the National Directorate and from NBTS level bodies such as UK ACTTD and also be informed by appropriate EEC Directives in their ultimate decision as to what constituted safe blood. Any disagreement with the decision made by ACVSB could only be sent back through the referral structure accompanied by the reason for the disagreement and a request for a review of the decision.

637. My understanding is that no action could be taken without explicit agreement of ACVSB.

211. 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.

638. I have read the discussion paper on routine anti-HBc screening of blood donations prepared by Dr Contreras in January 1992 [document NHBT0000044_095]. Whilst I agree that there had been a shift in emphasis away from cost-benefit considerations towards acceptance and introduction of procedures shown to prevent transfusion transmitted infection, I do not agree that this shift lay at the door of the BTS or that this was implied in the paper.

639. I remain convinced that the role of BTS was one of determining the relevance, suitability, performance and acceptability of such procedures for introduction into routine practice. The findings and recommendations would be submitted to the bodies responsible for the implementation of polices and priorities within the field of transfusion and it is at this level that any cost-benefit considerations were discussed.

640. It is my belief that it was at this level that the shift in attitude occurred, gradually perhaps but certainly influenced by the successful introduction of anti-viral screening programmes. The introduction of anti-HCV screening together with that of screening for other transfusion transmitted infections was not in my experience inhibited or delayed by financial considerations.

641. It is my opinion that the cost-benefit approach to blood safety should not be the starting point for any consideration of a procedure designed to improve blood safety, an opinion I believe which was shared by my peers.

212. If you do agree:

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

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

c. What caused the change to occur?

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

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

642. Please see my response to question 211 which also covers question 212 (a-e).

Autologous transfusion

213. The Inquiry understands that you were present at a meeting of the Northern Consultants on 19 January 1987 at which it was stated that "all members were very concerned at the pressure on Transfusion Centres by doctors, patients and donors to provide facilities for auto-transfusion, particular following the editorial in the B.M.J. 17 January 1987". The article suggests that concerns with regards to HIV and NANB being transmitted through blood products had given rise to an increased awareness of autologous transfusion. Please describe whether the TRTC provided an autologous transfusion service at the time and the nature of this activity. If not, why not and was it ever implemented? (NHBT0072052).

643. The TRTC did not provide an autologous transfusion service at the time of the Northern RTC Consultants meeting in January 1987. There were three main avenues which could be followed if such a service were to be offered to carefully selected patients:

1. Pre-deposit programmes – where a patient's blood could be taken in the period before operation and stored at 4 degrees centigrade until required.
2. Pre-operative donation – where blood is taken immediately before operation and replaced by an equal volume of a volume expander,

the withdrawn blood being used during or after operation as necessary.

3. Blood salvage – where the blood shed during operation is returned to the patient.

644. I was sure that the first of these would be better carried out at a hospital rather than BTS supervision. It was not implemented at the TRTC.

645. Guidelines for the procedures were produced by the Blood Transfusion Task Force of the British Society for Haematology recommending that Consultant Haematologists in charge of hospital blood banks should act as coordinators.

214. On 15 April 1997 you attended a meeting of the Regional Transfusion Directors at which it was agreed that "all directed donation, including that from mother to child, should be discouraged" and that "it was unlikely that central funding would be available either for pilot scheme or for support of autologous transfusion in the longer term". Could you please explain why you think this decision was taken and whether it was later reconsidered? (CBLA0002372).

646. If any RTC were to be involved in directed donations, it would mean having little or no choice or influence over the selection of the donor.

647. Family or friends approached by the patient or family would inevitably feel a degree of obligation and coercion and would be more likely to conceal reasons why they would not be accepted as a normal volunteer donor, potentially compromising the safety of the transfusion.

648. I believe the decision of the RTDs was *not* later reconsidered.

Quality assurance programmes

215. On 8 September 1982 John Cash of the SNBTS informed you that an inspection of all the RTCs had provided criticism of the "relative paucity and inconsistency of our quality assurance programmes, particularly in the area of blood component production at the RTCs" (NHBT0006083). Dr Cash expressed his concerns regarding "what tests are required (at RTC) on the products produced, how they might be performed, how frequently [...]" and proposed the creation of a UK wide working Party to deal with this matter. To the best of your knowledge did a lack of UK wide uniformity of quality assurance programmes undermine the safety of the blood supply chain in particular with regards to the testing of blood products within RTCs? Please also explain whether a professional body was established to oversee the implementation of national standards and whether it had advisory or executive authority.

649. To the best of my knowledge, the lack of UK-wide uniformity of quality assurance programmes raised by Dr Cash did not undermine the safety of the blood supply chain. Had it done so, I believe that the Medicines Inspectorate would have raised this as a matter of grave concern which would have led to their imposition of sanctions on any RTCs concerned.

650. However, Dr Cash was correct in my view in highlighting the need for uniformity of quality assurance programmes in UK BTS. A professional body was indeed established to produce guidance for this purpose, the UKBTS/NIBSC Liaison Group described elsewhere in my statement.

651. As stated, this organisation had an advisory rather than an executive authority. Implementation of its drawn-up standards was through consent of its users. This consent was universally observed throughout UK BTS.

Auto-immune donations

216. On 22 December 1992 you wrote a letter of response to Dr H L Lloyd in relation to the Red Book Guidelines', "exclusion of donors known to suffer from disorders known or suspected to be auto-immune in origin".

In your letter you accepted that "we will undoubtedly be bleeding people who have had auto-antibodies and are totally unaware of this" (JPAC0000002_121). Could you please explain:

a. What safety risk, if any, administering blood products with auto-immune antibodies has on a recipient?; and

b. If this does pose a safety risk, were any measures introduced to reduce this risk?

652. It was considered that a recipient could have an adverse reaction if transfused with blood or components which had a high-titre antibody directed against a specific organ. The risk, if it existed, would be minimised by the dilution of the antibody in the recipient's blood volume.

653. Steps were taken to further reduce this risk (probably to zero), by excluding those potential donors most likely to have a high-titre auto-antibody. To remove any ambiguity on this point, in the Red Book Guidelines the wording on this particular point was changed to *"individuals with active or multi-system disease of auto-immune origin should be excluded from donation".*

Section 13: Look back programmes at the TRTC

HIV

217. Were you involved in setting up any national or local HIV look back programmes during your time at the TRTC? If so, please describe this process and your role in it and how it was funded.

654. I was not involved in setting up national or local HIV look back programmes during my time at the TRTC.

218. Were you involved in implementing any HIV look back programmes during your time at the TRTC? Please give details.

655. I was not involved in the implementation of any HIV look back programmes during my time at the TRTC.

HCV

219. Were you involved in setting up any HCV look back programmes during your time at the TRTC? If so, please describe this process and your role in it and how it was funded. You may find NHBT0002895_002, NHBT0074969_007 and NHBT0036527 of assistance.

656. I was not involved in the setting up of any HCV look back programmes during my time at the TRTC. As can be seen from the documents cited, the National HCV look back programme was announced in 1995 at which time I had left the TRTC and the programme was organised by NBA headquarters staff, mainly Dr Robinson, the National Medical Director.

657. My only function was to act as a link between her and any RTC in the Northern Zone which had a query on the funding provided for the programme by the Department of Health.

220. Were you involved in implementing any HCV look back programmes during your time at the TRTC? If so, please describe what this involved and who the key people were in the process. You may find NHBT0093593 of assistance.

658. Although the case mentioned in document NHBT0093593 resulted in investigative action being taken, it cannot realistically be classified as a programme, rather as the following of a protocol.

659. On notification of a case or a suspected case of post transfusion hepatitis, the following steps were taken in the period before HCV testing:

1. The donation numbers of blood or its components transfused to the patient(s) are relayed to the RTC.
2. Dispatch records and the appropriate blood drawing record are consulted to confirm the donor's identity and to withdraw from potential issue any remaining components of the donation still held at the RTC.
3. Any such unissued components together with samples from the original donation still held at the RTC are subjected to repeat serum testing (after the introduction of HCV testing).
4. The donor or donors concerned are contacted, informed of their possible involvement in the development in a patient of the reaction to transfusion.
5. The donor is asked to come to the RTCs where another sample would be taken for repeat testing, including the performance of supplementary tests. At the time of this incident (1998) ALT and anti-HBc were available in house or by arrangement with specialist laboratories.
6. The results of these tests are entered into the donor's records and counselling given as appropriate. In the case of a high ALT result for example, it might be explained that the liver function tests were outside normal limits and the donor asked to come for a repeat test after one month.
7. Donors who were found to be negative for available markers would have their records marked, for example with a "J", as detailed in my response to question 102 and allowed to donate again. Any donor having more than one marker on record would be withdrawn from the donor panel and counselled accordingly.
8. Where the plasma from any of the donations concerned had been sent to BPL for fractionation, BPL would be informed.
9. Where the donor involved had donated previously, in the last 12 months, the donation numbers together with dates and destination of issue are obtained from RTC records. This information is relayed to the receiving hospital blood bank consultant with a request that where

possible, recipients should be traced, and samples taken for appropriate laboratory tests.

660. It will be appreciated that this process could be made more definitive after the introduction of anti-HCV screening.

661. The key people in the process were the clinician in charge of the patient, the consultant in charge of the hospital blood bank, RTC staff in charge of dispatch records and donor records, the RTC consultant in charge of the microbiology laboratory and the RTC Medical Officer with responsibility for donor counselling.

221. The Inquiry understands that you were present at a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases on 25 March 1991 at which the commencement of anti-HCV testing within both the NBTS and SNBTS was discussed. In particular, it was agreed that "There would be no retrospective tests carried on donations collected prior to that date (starting date for the commencement of tests)" (NHBT0000073_063). Please could you explain why you think this decision not to test previous blood donations for the presence of Hepatitis C was taken?

662. I note from item 4.14 of the minutes of the meeting of the UK Advisory Committee on Transfusion Transmitted Diseases held on 25 March 1991 [document NHBT0000073_063] that there was agreement that there should be no retrospective testing carried out on donations collected prior to the starting date fixed for anti-HCV testing nationally. The minutes make no mention of discussion leading to this agreement however I feel that it must have centred around the difficulties inherent in having a fractured de facto starting date as encountered in the introduction of HBsAg testing. A "clean starting date" was infinitely desirable.

222. The Inquiry understands that you were present at a meeting of the NBA Executive on 8 September 1994 at which it was noted that the Standing Advisory Committee on Transfusion Transmitted Infections had proposed that an HCV look back exercise be adopted within the UK "in the near future. This is to enable the NBS to extend its duty of care to the recipient as well as the donor" (ARCH0002149_003). To your knowledge:

a. Was this the first time that the concept of a duty of care had been considered in relation to donation recipients;

b. Was this duty of care implemented;

c. If so was it a legal duty of care;

d. Was there any opposition to its introduction?

663. I have reviewed document ARCH0002149_003 which are the minutes of a meeting held on 08 September 1994. However, I note that the contents of the minutes are accurately reflected in this question.

664. a. I would suggest that the concept of a duty of care with relation to donation recipients has always been there as evidenced by the constant striving to make transfusion as safe as current knowledge and technology allowed. In all discussions on potential changes to processes, policies and priorities, the final arbiter was always the logical and achievable degree of safety and efficacy.

665. b. The "extended duty of care" referred to by SACTTI in July 1994, i.e., the implementation of an extensive HCV look back exercise, was implemented by the NBA in 1995.

666. c. I am unsure as to whether the announcement of this look back in Parliament on 11 January 1995 makes it legally binding. However, the requirement to produce safe products was obviously reinforced by the application of the rules on Product Liability from March 1988 after materials prepared from blood and intended for human therapeutic use were understood to be classified as products within the terms of the Consumer Protection Act 1987.

667. d. To the best of my knowledge, this look back was introduced without opposition.

223. The Inquiry understands that you were present at meetings of the Advisory Committee of the MSBT, including a meeting which took place on 4 June 1998 (DHSC0004026_033). A study of Hepatitis C look back exercises was discussed at this meeting. To what extent were you aware of these exercises taking place at a national level?

668. I was never a member of the MSBT Advisory Committee, nor did I attend any of their meetings. My name appears in the minutes of the meeting held on the 4th June 1998 simply as a passing reference to my association with the Council of Europe Select Committee.

669. I was of course aware of the HCV look back exercise at National level referred to in response to question 222 above.

General

224. Please confirm whether you were involved in a look back process relating to any other infection during your time at the TRTC. If so, please provide an overview of the relevant programmes and detail your involvement.

670. So far as I can recall, I was not involved in the lookback process relating to any other infection during my time at the TRTC.

225. Did you consider there was an ethical obligation to inform patients who may have received transfusions from infected donations? If not, why not?

671. Yes, I consider that there was an ethical obligation to inform patients who may have received transfusions from infected donations. In fact, follow up of such patients formed part of a look back protocol. Unfortunately, I cannot recall the time periods relating to this.

226. To what extent could an RTC implement its own local look back programme? Did the TRTC do this? If so please give details. If not, why not? You may find NHBT0006939_001 of assistance

672. Prior to the formation of the NBA, the responsibility for the implementation of any look back process lay with the RTCs with possible guidance coming from the Medicines Inspectorate and from the National Directorate, after its formation.

673. RTCs would draw up their own protocols which were naturally similar across regions. The processes followed in the TRTC are, I believe, summarised in my response to question 220 above.

674. After the publication in 1990 of the Red Book Guidelines, there was additional guidance given to RTCs in the drawing up of protocols such as these as evidenced in document NHBT0006939_001.

Section 14: Your relationship with commercial organisations

227. 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.

675. a. No

676. b. No

677. c. No

678. d. No

679. e. No

680. f. No

228. 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?

681. As detailed elsewhere in my statement, the TRTC took **no** part in the purchase and/or distribution of blood products manufactured by pharmaceutical companies.

229. 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.

682. I have never undertaken medical research for or on behalf of a pharmaceutical company so involved.

230. Have you ever provided a pharmaceutical company with results from research studies that you have undertaken? If so, please provide details.

683. No, I haven't.

231. 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?

684. I have never received funding for research from a pharmaceutical company.

Section 15: Relationship between NHSBT/NIBTS/SNBTS/WBS and NHSBT/NIBTS/SNBTS/WBS

Relationship between the NBTS and SNBTS

232. Please outline the arrangements in place to enable cooperation between the NBTS and SNBTS, including any forums or reporting lines established to aid this cooperation.

685. Within both NBTS and SNBTS, regular meetings were held on behalf of the Directors of RTCs to discuss all matters pertaining to the supply of blood and its products. Each organisation was represented on the RTD meetings of the other by its National Director together with one other RTD. Through this link, mutual exchange of minutes of the meetings could take place for the benefit of all RTDs.

686. In addition, cooperation was enabled at a more specific level by the representation of NBTS and SNBTS on bodies such as UKBTS/NIBSC Liaison Group and its Standing Advisory Committees and specialist groups such as UKACTTD.

687. From 1989, an annual scientific meeting of the combined transfusion services was held, following cessation of the NBTS RTD's meeting.

233. Please explain the NBTS and SNBTS' approach to policy development and implementation. Was policy developed and implemented on a UK-wide basis unless otherwise agreed, or was the approach discussed on a case by case basis?

688. Of the two alternatives presented in the question, the second is perhaps more likely to reflect what actually happened in practice. Taking as an example, the introduction of screening for viral infections capable of transfusion transmission, the two National services came together in the form of UKACTTD to determine screening strategy and policy. Similarly, the need for a unified approach for the production of guidelines for the preparation of blood and its components for therapeutic use led to the formation of the UKBTS/NIBSC Liaison Group.

689. The implementation however of strategies and suggested policies which had been agreed at professional level more often lay in the hands of those bodies with managerial responsibility for the transfusion services, as previously discussed in the case of NBTS. This meant that the implementation at RTC level was subject to RHA agreement, at least until the formation of the NBA.

234. Did the SNBTS share information with the NBTS about excluded donors, donors that posed a risk to the safety of the blood supply, or infected blood donations? If so, was this on a formal or informal basis? Please describe the mechanisms in place to share this information, if any.

690. I do not recall any formal structure for the exchange of information on individual donors between NBTS and SNBTS.

691. As with NBTS RTCs, any donor presenting with a risky history and proving to have a positive screening tests and who gave a history of previous donations at another RTC would immediately be checked by records being requested from the previous RTC.

692. The case of an infected donation is different in that the tracing of a recipient or of recipients of previous donations from the same donor may well involve the other National Service as part of a formal trace and look back exercise.

235. In his witness statement for the A v Others litigation, Dr Gunson discussed the creation of the National Directorate to oversee the work of RTCs, although he noted that the Directorate "did not have executive authority and its successes came about by persuasion" (NHBT0000026_009). What are your views on the success or otherwise of the National Directorate?

693. The creation of the National Directorate was in my view a very good first attempt at coordination of the activities of RTCs. Organised multi-centre evaluation of materials and methods were put on a firm footing for the first time as was setting and monitoring of targets for the supply of plasma to BPL.

694. Much of the success achieved was due to the fact that Dr Gunson enjoyed the respect and trust of RTDs. The only drawback (a major one) was that the Directorate did not have executive authority; as Dr Gunson himself said, that lay with RHAs.

236. 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? You may find NHBT0001829 of assistance.

695. The NBTS historically was very much a loose federation of active centres, each located in one of the Regional Health Authorities

established by the Department of Health and each responsible to and effectively managed by their own RHA.

696. Certainly, from the 1980s onwards, there was an emerging need for national coordination of newer activities being undertaken by RTCs so that at times the managerial relationship between RTCs and RHAs came under pressure, if not actually strained. I believe that RHAs themselves were potentially constrained by the need to seek Departmental approval for implementation of processes and policies which had been formulated at regional level.

697. The establishment of centralised responsibility for RTCs immediately smoothed out some of these difficulties and enabled a truly national approach to the development and implementation of processes and policies, leaving only the question of priorities to be determined at departmental level.

698. Some centralisations also facilitated the monitoring of RTC's activities, especially where blood safety and the possibility of a look back are concerned.

699. The gathering of statistical evidence where indicated was also greatly facilitated. In addition, centralisation of the interaction between RTCs and an increasingly important BPL became a virtual necessity.

237. What in your view were the strengths and weaknesses of the NBA?

700. The taking of responsibility for RTC activities as outlined above, is an obvious strength of the NBA. Stock control of blood and its components can now be carried out on a formal, national basis. Transfer of the central laboratories to NBA control enabled, in particular, formalisation of the interaction between RTCs and BPL.

701. In addition, centralisation of what might be termed more "managerial functions" was an improvement, such as finance, human resources, IT, public relations, purchasing and stock control.

702. In my view, the weakness of the NBA lay primarily in its speed of introduction. Many changes were set in motion which may have since been proved to be logical and inevitable but were perceived by many staff at the time to be "too much, too quickly".

Relationship between the Plasma Fractionation Centre and Bio Products Laboratory

238. Please explain your understanding of the relationship between PFC and BPL (NB: Reference to BPL also includes the associated Plasma Fractionation Laboratory in Oxford). In particular:

a. What was the extent of collaboration and coordination between BPL and PFC? What impact did this have, if any, on the operation of RTCs in England?

b. Do you consider there would have been merit in a joint UK approach to Factor VIII production and research, in view of the fact that PFC and BPL were both engaged in the development of similar severe heat-treated products (8Y and Z8) in the 1980s?

703. a. To the best of my knowledge, there was no formal collaboration and coordination between BPL and PFC, other than through representation of each of them on appropriate committee structures. They did not regard themselves as being 'rivals' and informal interchange would be the norm. I do not believe that their relationship had any impact on the operation of English RTCs.

704. b. Although BPL and PFC were both engaged in research into a method of producing safe heat-treated Factor VIII, it is my understanding that there were differences in methodology, though each produced a valuable, safe product. In my opinion, such a difference in approach to

any problem can add to the knowledge required for its solution and I do not consider there would have been any merit or benefit in this case in having a more formalised joint UK approach.

Outcomes in Scotland and England/Wales

239. Please outline any statistics or studies of which you are aware that demonstrate the difference in morbidities and fatalities between Scotland and England/Wales.

705. I am not aware of any statistics or studies which demonstrate the difference in morbidity and fatality between Scotland and England/Wales.

Section 16: Variant Creutzfeldt-Jakob disease (vCJD)

240. 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? You may find JPAC0000166_131 of assistance.

706. Variant Creutzfeldt-Jakob disease (vCJD) was first identified in 1996 by the CJD surveillance unit in Edinburgh. It differed from classical CJD in that the abnormal prion was found in tonsillar tissue and so posed a theoretical risk of transfusion transmission through transfer of lymphocytes from blood donor to recipient. The first case of transfusion transmission was reported in 2004 by the Edinburgh CJD unit.

707. A transfusion recipient died of a non-neurological disease five years after transfusion. Abnormal proteins typical of vCJD were found in the spleen but not the brain. Tracing of the blood donor revealed that he had died of vCJD. After the discovery of vCJD in 1996, although there was still no apparent link with transfusion, an attempt was made to reduce any risk

by excluding certain categories of donors, specifically those who had received growth hormone derived from human pituitary glands or who had received transplants of cornea or dura mater or had a family history of CJD.

708. This latter exclusion was controversial since the family history would be of classical CJD which was not considered to be a specific risk factor. The inclusion of these donor exclusion measures in the Red Book Guidelines was the limit of my own involvement, coming as it did just before my retirement from NBTS. Measures such as leucodepletion and the use of non-UK plasma for fractionation were being explored but were not implemented until after I had left.

241. On 12 April 1996 Dr V James wrote a letter to you stating that "We have all now moved to the view that although direct questioning of donors about a Family History of CJD may not yield meaningful results we need to comply with European guidelines" (JPAC0000038_020). Similarly, on 13 July 1995 a letter was written on your behalf to Professor J D Cash stating that "The specific point on family history of CJD was introduced at a very late stage in the lead up to the latest edition of the European document, and was only admitted into the document with the greatest reluctance [...] If the application of this particular contentious item within the Council of Europe guidelines proves to be problematic, I for one would have no hesitation in going back to the Council and arguing for its removal at the next time of asking" (NHBT0002699_001). Why did you consider it unnecessary to question donors about a family history of CJD?

709. As mentioned in my reply above to question 240, to ask a donor about a possible family history of CJD was considered contentious in view of the scientific evidence that the abnormal prion of classical familial CJD was not found in material outside the brain, unlike that of vCJD. I believe that the majority of scientific opinion considered such questioning to be unnecessary and probably alarmist, but UK guidelines were obliged to comply with European guidelines as Dr James said in her letter.

242. Was leucodepletion used as a method to reduce the risk of vCJD infection in blood donations in the UK? If so, please explain how this worked. You may find paragraph 6.6 of NHBT0007396_001 helpful.

710. Leucodepletion of donations in the UK was introduced as a measure to reduce the risk of possible vCJD transmission. Differential centrifugation of a donation allowed for the removal of the layer of leucocytes which contained amongst other cells, the B-lymphocytes. These are the cells which had been identified as possible carriers of the vCJD prion. Although it is probably impossible to completely remove the lymphocytes, it has the benefit of considerable reduction in the number of any affected cells.

711. In the Red Book Guidelines, it states that from November 1999 all allogeneic blood components produced in the UK have been subjected to a leucocyte depletion process. (section 7.1 2015).

Section 17: Other matters

243. Please provide a list of any articles you have had published relevant to the terms of reference.

712. Since my major interests during my tenure as RTD at the TRTC lay in other fields, the number of articles published in my name on the subject here in question tends to be rather small:

- Quality Assurance of Transfusion Centre Derived Blood Products – Progress in Transfusion Medicine – Pages 1-20 (1987)
- Quality Assurance Monitoring of Blood Components in the Proceedings of the 5th Annual Scientific Meeting of the British Blood Transfusion Society (1987)
- Hewitt and Wagstaff – The Blood Donor and Tests on Donor Blood in ABC of Transfusion Medicine 2nd Edition 1992 and 3rd Edition 1998

- Contributions to the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components 1992 (and then annually from 1994 until 1999)
- Contributions to the guidelines for the Blood Transfusion Services in the United Kingdom (the Red Book) 1990-1996

244. Please describe the extent of your involvement in any cases overseas concerning infected blood.

713. In October 1990, I was one of several non-Australian transfusion medicine practitioners invited to give evidence in Court in Melbourne in the case of *PQ (a haemophiliac) v. The Australian Red Cross Society*. PQ had been infected by HIV due to his treatment. I was not required to provide a written statement, merely to give evidence regarding the measures taken in the UK Transfusion Services to minimise the risk of HIV transmission before the implementation of anti-HIV screening. I believe my name as a suitable representative for the UK BTS was provided to The Australian Red Cross Society by Dr Gunson, National Director of NBTS at that time in view of my involvement with the UK guidelines.

245. Please explain, in as much detail as you are able to, any other issue that you believe may be of relevance to the Infected Blood Inquiry. To assist, we have provided a list of issues (attached).

714. I believe that the issues covered in the sections above and individual questions forming the basis of this written statement are admirably complete and I can think of no other issues relevant to the Infected Blood Inquiry.

246. During Parliamentary questions on 10th December 1985, Mr Hayhoe stated that 'supplies of whole blood are not imported since the United Kingdom is self-sufficient in its needs for blood for transfusions; it is only certain blood products which are imported' (HSOC0018830). To your

knowledge, was the UK self-sufficient in its need for whole blood for transfusions?

715. To my knowledge the UK was self-sufficient in its need for whole blood for transfusions.

247. During your tenure at the TRTC, 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?

716. During my tenure at the TRTC, I was not aware of any patient being transfused with red cells imported from the USA.

Previous "Jaundice" Inquiry

248. On 29 May 1990 Dr Marcela Contreras wrote a letter to you in which she stated that she had been busy "answering questions and making reports for Harold, the Department of Health and my RHA regarding the jaundice enquiry which led to the recall of BPL products" (JPAC0000041_308). What did you understand her to be referring to? Was this a national or local Inquiry and were you aware of other UK Inquiries into the use of contaminated blood or blood products?

717. From the wording of Dr Contreras' letter, I think that she is referring to a local Inquiry into a case of transfusion associated jaundice. I cannot recall any such National Inquiry.

1990s HIV infection

249. The inquiry understands that you were present at the 5th incident meeting held on 14 April 1997 at which it was reported that a person who was confirmed as HIV positive had likely contracted the infection after receiving a blood donation in August 1996. It was stated that the recipient had received 111 donations, one of which was found to be HIV positive

and that "this could not have been picked-up by screening services [...] It was thought that the donor may have contracted the infection sometime after April, maybe whilst on holiday, and had given blood during 'the window period'". Furthermore, it was noted that the single donation "had been split 3 ways" and therefore 2 other recipients had received the same batch. The same donor had also made another donation in April 1996 which "had been split into 2 parts, one of which was sent to Wales and the other pooled for the purpose of producing fractionated blood products". Meeting members acknowledged that "there has only been 2 recorded cases of HIV transmission through blood products since testing commenced and this is a good record for the NBA". With reference to document NHBT0081212_013, please answer the following questions:

a. To the best of your knowledge were other recipients infected by blood donations from this donor?

b. Why do you think it was stated that screening services couldn't have picked up the infection?

c. To what extent do current tests detect HIV infection during the window period?

d. Did these incidents occur frequently?

e. What was your role within these meetings?

f. Do you know whether similar incidents have occurred since August 1996 and today?

718. a. The information I have is that the patient transfused as part of a surgical procedure referred to in the document as 'case B', was confirmed as having contracted HIV as a result of a transfusion. I have no other knowledge regarding the recipients of blood donations from the donor concerned.

719. b. Screening donations for HIV is based on detection of the antibodies of the virus. Since the development of an antibody is not immediate after the exposure, it is possible for there to be a short interval during which the virus is present in the blood but a test for the antibody to be negative, the so called 'window period'. If a blood donation is taken during this

window period, as seems very likely in this case, it may well be infected even though the screening test was negative.

720. c. By definition, the current screening tests for HIV are *negative* during the window period.

721. d. These incidents do not occur frequently, thanks to the combination of exclusion of high-risk donors and fine tuning of screening.

722. e. At the time of this incident meeting in April 1997, I had left the TRTC and occupied the role of Director at the Northern Zone of NBA. My role was one of support for the local RTDs involved in this case and providing a link as required between the local incident team and the NBA.

723. f. I know of no similar incidents since August 1996, though my knowledge is limited by my retirement from the service in April 1998.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 11 January 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
01/01/1983	Vox Sang, journal article by Angela Robinson et al	DHSC0002263_064