Witness Name: Dr Vanessa Martlew
Statement No.: WITN4034001
Exhibits: [WITN4034002,
WITN4034003, WITN4034004,
WITN4034005]
Dated: 24 October 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR VANESSA MARTLEW

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 25 September 2020.

SECTION 1: INTRODUCTION

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

1. My name is Vanessa Joan Martlew.

2. My address is: c/o NHS Blood and Transplant, Head Office, 500500, North Bristol Park, Filton, Bristol BS34 7QH.

3. My date of birth is GRO-C 1952.

4. My professional qualifications are: M.A, MBChB, FRCP London, FRCPath, FRCPEdin.

2) **Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.**

5. Consultant Appointments

- Consultant Haematologist with special interests in haemostasis, thrombosis and transfusion medicine at the Royal Liverpool and Broadgreen University Hospitals (NHS) Trust (Appointed **1996 - 2020**)

- Co-Director Mersey and North Wales Comprehensive Care Centre for Haemophilia (Appointed **1996 - 2020**)

- Consultant Haematologist and Director of the Mersey & North Wales Regional Transfusion Service (**1988-1995**)

- Consultant Haematologist North West Regional Transfusion Service (**1984-1988**)

- Locum Consultant Haematologist to Christie Hospital **(June 1983 - August 1983**)

6. Training Posts

- Senior Registrar in Haematology, Manchester Rotation, (**January 1980-December 1983**)

- Registrar in Haematology, Wythenshawe Hospital, **January 1979 - December 1979**

- Medical Registrar, Liverpool Rotation Scheme, **October 1977 - December 1978**

- Senior House Physician, Aintree Hospitals Rotation Scheme **1976 - August 1977**

- Pre-Registration House Officer, Broadgreen Hospital, **September 1975 - August 1976.**

7. Honorary University Appointments
   - Senior Lecturer School of Medicine, University of Liverpool (**2004-2020**)
   - Director Graduate Entry (Four Year) MB.ChB Programme and Senior Tutor, Faculty of Medicine, University of Liverpool (**2002- 2013**)
   - Senior Tutor MBChB School of Medicine. University of Liverpool (**2006-2011**)

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 and the nature of your involvement.

8. Examiner in Haematology and Transfusion Medicine for the Royal College of Pathologists (**1985 - 2018**)

9. Member of Executive Committee of the British Voluntary Marrow and Platelet Donor Panel, (**1987-1989**)

10. Chairman of Taskforce on Implementation of Document Storage for the NBA (**September 1993**)

11. Chairman Mersey Advisory Group on Pathology (**1996-1998**)

12. Member of the UKBTS/NIBSC Standing Committee on Plasma for fractionation (**1995-1997**)

13. Chairman Working Group to draft NBA policy for disposal of waste/surplus material from blood donation (**1996**)

14. Member of Advisory Group of Clwyd and Oswestry Tissue Bank (**1996-1997**)

15. Secretary Mersey and Area Regional Transfusion Committee (**2001 -2006**)

16. Member North West Council of Royal College of Pathologists (**2001 - 2004**)

17. Associate Complaints Advisor to Healthcare Commission (**2006 -2008**)

18. External Advisor to General Medical Council on Fitness to Practise (**2008-2018**)

19. Appointed by Secretary of State as Medical Trustee to Macfarlane Trust (**2009 to 2018**)

4. **Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to 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 and copies of any statements or reports which you provided (other than those which are enclosed with this letter).**

HCV Lookback - 1995

20. I undertook the HCV Lookback exercise in 1995 in Liverpool according to Guidelines from the Department of Health. I had been involved in the ad hoc meeting of experts on 5 August 1994 which discussed the feasibility of initiating an HCV lookback policy to identify, test, counsel and, if necessary, refer surviving past recipients of blood components from donors later found to be anti-HCV positive after testing was introduced in September 1991. This was a Standing Advisory Committee on the Transfusion-Transmitted Infection (SACTTI) group. The ad hoc meeting concluded that there was a

serious case for considering a lookback policy for HCV (as had been done with HIV) but that the wider implications needed further consideration and this should be done as soon as possible (see documents [NHBT0009383] and [PRSE0001236]).

21. Document [NHBT0036440] - *Notes of the meeting of the Northern Zone Audit Group on 12 November 1996* - which has been provided to me by the Inquiry records that I presented a review of the HCV lookback in the Northern Zone. The slides I used for the projector are attached to this document. These discuss that the majority of the counselling had been undertaken by NBS staff which had been a major time commitment. During the exercise two doctors had suffered needle-stick injuries from infected donors. One doctor, who had undertaken the majority of home visits alone, had some concerns about her personal safety. It was evident that the Zonal SOP (Standard Operating Procedure) required review. It was not clear how many patients had been traced but not counselled either because they had declined (which I assume meant declined contact with the blood centre) or following advice from the GP. The reason for transfusion had not always been documented and the sensitivity of this omission was recognised. 17 litigation procedures had been commenced. Clinical feedback from hepatologists had been variable, but it was hoped this would increase. Action points arising were agreed.

22. The overheads for the presentation show that:
    - The total population served by the Northern Zone was 18.2million
    - A total of 2223 **LBF1** forms (relating to those who had received a unit from a HCV positive donor and so thought to be likely to transmit Hepatitis C) had been sent (0.012% of the population).
    - It is noted that most centres only had records from 1981.
    - The fate of donations based on hospital returns is summarised and shows that, by that time, of 2223 LBF1 forms sent out:
        - 1937 (87%) had been returned;
        - in 417 (18.7%) the records had been lost;
        - in 838 (37.6%) the patient had died;

- 503 (22.6%) patients were still alive and;
- 286 (13%) LBF1 forms were yet to be returned.

- Two of the patients who were still alive had been transfused twice.
- 513 **LBF2** forms (follow up in general practice) had been sent, of which
  - 499 (97.3%) had been returned and
  - 14 (2.7%) were outstanding.
- Several more patient deaths had been identified before the LBF2 was sent out.
- Of 427 patients who had been 'counselled'
  - 93 (22%) had been seen by their GP;
  - 67 (17%) by a non-blood service consultant and
  - 267 (61%) by an NBS doctor.
- 12 patients had not been counselled based on the advice of their attending physician.
- Of 390 recipients followed up,
  - 129 (33%) were antibody negative for hepatitis C;
  - 108 (27.5%) were antibody positive but PCR negative;
  - 149 (38%) were antibody and PCR positive and
  - 6 (1.5%) were antibody negative but PCR positive.
- 2 patients declined tests; in a number the PCR result was not known and there were a number who were HCV indeterminate.
- 270 had been clinically referred; 165 had been seen in outpatients; 52+ had abnormal LFTs; 36+ had evidence of changes consistent with chronic HCV on histology; 18 had received treatment with interferon; 2 patients had declined referral and a number of specialists had not yet provided feedback.

23. Dr Angela Robinson, the Medical Director, wrote to all consultants in the NBS with responsibility for the HCV lookback on 1 March 1996 [NHBT0036529], 11 months after commencement of the look back noting that the "instruction to identify all laboratory confirmed HCV positive donors has been subject to different interpretations such that some "indeterminates" had been included in the lookback. This letter records the fact that an analysis had been undertaken at each centre to see if there was a means of

defining as tightly as possible patterns of HCV serology that might be predictive of true HCV infection for the purposes of inclusion in the lookback programme. She attached a Standing Advisory Committee on Transfusion-Transmitted Infection (SACTTI) recommendation for the definition of selective HCV indeterminates to be included in the lookback, which had been endorsed by MSBT (the Department of Health's Advisory Committee on the Microbiological Safety of Blood and Tissues) with the recommendation that all UK transfusion centres extend the lookback to cover the cases identified, using the MSBT recommendations. She also enclosed the latest update on the status of the national lookback at that point.

24. It appears that (at that point) she had only received 400 **LBF3** forms and she expressed that there was concern about bottlenecks that were slowing down the process. Zonal Clinical Directors had been trying to establish what the problems were throughout the country to allow her to report back to the MSBT and advise whether any central assistance might help to expedite the process as the Minister involved was concerned that the programme was taking such a long time to complete.

25. At that time nationally, according to the update provided, 1,328 donors had been identified from whom 6,743 units had been produced; 4,280 recipients had been identified by hospitals; 922 sets of records could not be traced; 1128 recipients had been followed up; 313 were alive and untraced; 422 had been counselled; 223 had tested positive; 106 had tested negative; 11 were indeterminate; 19 results were awaited; 4 recipients had declined counselling; 7 were awaiting interview and 1863 had died.

26. It had also become apparent that procedures for counselling of donors with confirmed positive microbiological markers varied between centres. Information obtained from counselling donors was one way we could monitor the appropriateness and effectiveness of donor exclusions in relation to 'at risk' behaviour. An audit was to be undertaken to identify best practice in the interests of donor care. It was noted that national analysis of quality

information obtained from donor counselling would be of immense value in assessing our effectiveness in excluding volunteers with 'at risk' behaviour from blood donation. Questionnaires approved by SACTTI were to be circulated.

Transfusion Transmitted HIV – 1997

27. I investigated a case of transfusion-transmitted HIV in Liverpool in 1997. I also arranged the investigation of previous recipients of donors from the North West region found to be HIV positive after the introduction of universal UK donor screening in October 1985 (see documents [NHBT0081212_009], [NHBT0008797_004], [NHBT0008797_005]).

28. A chronology of the 1997 investigation and steps taken in investigating the window period donation which led to transmission of HIV is set out in document [NHBT0008797_002], a copy of which has been provided to me by the Inquiry. All of the implicated donor's 5 previous donations were negative by PCR as well as HIV antibody screening of the index donation, confirming that a technical problem was not responsible for the donation being released.

vCJD Lookback - 2004 and 2009

29. In 2004 and in 2009 whilst working in the Comprehensive Care Centre (CCC) for Haemophilia at the Royal Liverpool Hospital, I participated in the vCJD Lookback for patients registered with Inherited Bleeding Disorders as required by the Department of Health.

30. Over the last 30 years I have provided evidence to the Court in cases of alleged transfusion-transmitted infection occasionally.

Post Transfusion Hepatitis

31. From time to time over the years, I have investigated potential cases of post transfusion hepatitis reported to Blood Centres by hospital colleagues.

32. As referred to in paragraph 4.2, I note that the copy minutes provided to me by the Inquiry [NHBT0036440] refer to my presentation in November 1996 of a review of the experience to date with the HCV Lookback to the Northern Zone Audit Group

33. Over the years a number of standard operating procedures relating to transfusion transmitted infections were developed whilst I was at the MNWRTC including:

34. SOP MNW-96-CS05-00 - 'Investigation of Post Transfusion Infection with the Human Immunodeficiency Virus' dated 17 November 1993 [NHBT0087625]. This procedure described the action to be taken in the local follow up and central reporting to the NBA/CDSC of infected donors, to be done as soon as possible and documented. The Soundex code which was used to protect the donor's identity, but allow us to update reports, is described at page 7.

35. SOP MNW-96-CS05-00 - 'Infected Donor Surveillance and the Follow Up of Donors with Confirmed Positive Results of Microbiological Screening' dated 4 June 1996 [NHBT0087624]

36. SOP MNW- 93- CS01-01 - 'Investigation and Surveillance of Post Transfusion Infection' dated 13 September 1996 [NHBT0087626]. This includes the placing on unconditional hold of all products from the implicated donor in accordance with the recall procedure, permanent deferral of positive donors; liaison with consultants at other centres concerned, lookback, follow up and donor counselling. It also covers reports by donors of post-donation jaundice and the actions to be taken.

37. As far as I was aware, donors were not informed of specific lab results by post - they were advised that there was a laboratory result which needed

further discussion and invited to make an appointment with a consultant to discuss face to face.

38. For the calendar year of 1996 I was not working in Liverpool per se but was Donor Services Manager for the Northern Zone of the NBA. I was no longer the Medical Director of the Liverpool Centre.

SECTION 2: YOUR ROLE AT THE NORTH WEST REGIONAL TRANSFUSION CENTRE (MANCHESTER RTC)

5. **Please describe the roles, functions and responsibilities you had at Manchester RTC during your period as a Consultant Haematologist there. In particular, please describe the role you had in reporting incidents of infection. You might like to refer to a letter you wrote on 17 December 1986 to Mr Snape at BPL reporting an incident in which two boys developed Hepatitis B [BPLL0002444].**

39. This was my first substantive consultant appointment following a short locum consultancy at the Christie Hospital in the summer of 1983. After that, I had gone back to MRI to finish my 4-year Senior Registrar training post which ended in December 1983.

40. A large part of my activity at Manchester Blood Centre was directed at increasing plasma procurement towards national self-sufficiency.

41. Self-sufficiency was an overriding aspiration which I strongly supported. It was my belief that NHS blood and plasma products prepared from voluntary donors, who were screened and who did not receive payment for blood donation and, therefore, had nothing to gain from blood donation was far safer.

42. By contrast, in America in the late 1970s – donors could be paid for blood which meant that the blood could have been collected from individuals who

were very short of money including prostitutes, drug addicts and from those detained in prisons. Therefore, I felt privileged to be a part of this effort towards national self-sufficiency using voluntary donations in the UK.

43. The Blood Service was aware of the need for self-sufficiency and working towards it from the 1970s. By the time I was involved in the 1980's there was still much to be done as there was a significant deficit short of the national target.

44. The effort and ingenuity that went into national self-sufficiency were phenomenal – increasing the yield from every bag of blood, a new cohort of donors giving plasma twice a month in the middle of their working days, recruiting very large numbers of people as well as providing lots of other valuable services.

45. It is my belief that if the NBTS had been properly funded from the outset (from the late 1970's), without the delay, we might have achieved self-sufficiency nearer to the originally planned opening of BPL in the early 1980's. Unfortunately, we were so far behind that it was too late to achieve this by the time BPL opened in 1986 and by then the demand for plasma to provide factor VIII concentrate had already risen substantially for a number of reasons.

46. The only people who could conceivably have been caused harm by the move towards national plasma self-sufficiency were the donors as a result of our encouraging them to attend much more frequently. In essence the move towards national self-sufficiency was driven out of a want to provide safer blood products for patients.

47. One of my first tasks as a consultant was to set up a dedicated Apheresis Centre at Manchester Blood Centre in which donors could donate just plasma by a process known as plasmapheresis. The Apheresis Centre opened in 1985. This was a place where donors could attend more

frequently to make dedicated plasma donations and donations of platelet concentrate.

48. I was also asked to promote the use of SAG-M red cells which were introduced in the mid-1980's to increase the yield of plasma on each donation by 100ml with the addition of a fluid known as an optimal additive solution which would extend the storage period of red cells and enhance their rate of flow during transfusion when required.

49. Up until the early 1980's about 500ml of blood would be collected from the donor at the session and this was centrifuged to yield 250ml plasma. This process left plasma-reduced red cells which would flow well on transfusion at the bedside. If centrifugation were to be extended beyond that in an attempt to increase the volume of plasma obtained, the remaining red cells would become too viscous to transfuse easily, without some additional fluid being added to replace the plasma. The plasma yield was increased by the addition of an optimal additive solution such as SAG-M (Saline, Adenine, Glucose-Mannitol) to replace the extra plasma removed, thereby reducing the viscosity of the remaining plasma-reduced red cells in order that they would flow satisfactorily on transfusion at the bedside. The preparation of "SAG-M red cells" was one way of increasing the amount of plasma by an additional 100ml from each blood donation. After calculating how much more plasma could be obtained nationally using SAG-M donations this value still fell short of that required to achieve national self-sufficiency in order to provide all the plasma components required by British patients.

50. Dr Gunson quickly realised that we would need to use the new technology – apheresis – in order to collect dedicated plasma donations to make up the deficit between the desired annual regional contribution to national self-sufficiency and the actual annual plasma collected from blood donations. Plasma donors could attend much more frequently - once a fortnight – as they were unlikely to become iron deficient when not donating their red cells.

51. As noted above, one of my first tasks on appointment as a Consultant, was to set up a dedicated Apheresis Centre at which donors just donated plasma. This opened in Manchester in 1985.

52. In relation to general blood collection, the decision would be made before any session as to what was to be collected at any session. This would depend upon how far away the designated blood collection session was from the Blood Centre as well as current patient requirements (as advised to us by clinical colleagues in the region). Different sets of plastic collection bags were required for different component preparation, so we would send what was needed for the relevant collection, whichever it was – red cells, plasma for fractionation, fresh frozen plasma, platelets etc.

53. I also had some responsibility for the follow up of donors with clinical problems – either detected pre-donation during the course of their health screening or post-donation, and this would include follow up and referral of the small number of those with positive microbiological screening results as appropriate.

54. As already stated, I occasionally investigated cases of possible post-transfusion infection referred in by my colleagues in local hospitals.

55. When HIV antibody screening was introduced in October 1985, I conducted the lookback exercise concerning transfusion recipients of donors subsequently found to be HIV antibody positive.

56. I have been referred to a document [BPLL0002444] by the Inquiry. This is a letter I wrote to Mr Terry Snape, at BPL dated 17 December 1986, in which I note that earlier that month I had received a report of two boys with haemophilia on Factor VIII concentrate who had developed hepatitis B surface antigen positivity that year. I provided details of the treatment they had received within the relevant incubation period, back to their last negative test. I commented that they had received quite as much commercial material as the NHS (produced by BPL). Many of the NHS batches were common to

both boys. I had marked those which were given to only one or the other. I realised it would be very difficult for them (if not impossible) to determine the source of the infections, but I thought it was important to let them know because a large proportion of the NHS material was the new 8Y plasma-derived factor VIII concentrate. 8Y was prepared in the NHS from donations previously tested for hepatitis B surface antigen and found negative and the concentrate was subsequently heat treated to be virally inactivated. It was important therefore to do whatever was possible to determine whether these batches were implicated.

6. Please describe the organisation of Manchester RTC during your time there including:

a. Where it was physically located;

57. The Regional Blood Transfusion Centre was in Roby Street in Central Manchester when I started as a consultant in January 1984. It moved to Plymouth Grove at the end of August 1984 where the Manchester Blood Centre is still situated today.

b. Its structure and staffing and in particular who you were accountable to;

58. There were 2 full time consultants - myself and the late Dr Harold Gunson, who was the Director and to whom I was accountable. There were 2 part-time consultant haematologists - Dr Elizabeth Love and Dr Richard Wensley - and an Associate Specialist, the late Dr Alan Carter. A large staff of Donor Attendants was managed by Miss Margaret Walters, Senior Nurse and there was a large non-clinical workforce of clerical and transport staff managed initially by Mr William Mawson and latterly by Mr Peter Hynes.

59. The laboratory services included both donor screening and component preparation from collected donations with reference laboratories to investigate reported transfusion reactions, patients with red cell antibodies

and to provide a large antenatal screening service and all these were managed by Mr Peter Howell, the Laboratory Services Manager.

c. How it was funded

60. As the North West Regional Transfusion Service it was funded by the North West Regional Health Authority.

61. Additional funds were sometimes provided by the Department of Health for specific elements of new expenditure. The system of funding changed from 1990 (after I had moved to Liverpool) when financial cross-accounting was introduced as discussed below.

d. Its remit

63. Its remit was to provide blood and blood components for the patients in the North West Region, whilst ensuring donor wellbeing and to contribute to the national plasma pool pro rata.

7. Please describe Manchester RTC's place in the National Blood Transfusion service together with information as to whom the centre was answerable to if anyone. When answering this question please refer to paragraphs 1-16 of Dr Gunson's statement provided for the A v Others litigation [NHBT0000025_001] and say whether you agree with what is said there.

64. Dr Gunson has set out clearly the accountability of the Manchester Blood Centre over the years in his statement provided for the "A v NBA and Others" litigation [NHBT0000025_001]. I agree with what he says, subject only to what I add in the following two sub-paragraphs.

65. In paragraph 10 he has omitted to include the Mersey and North Wales Regional Transfusion Service (which is based in Liverpool) amongst the other members of the Northern Division of the Central Transfusion Committee for the period described.

66. The RTCs remained the primary responsibility of the RHAs [NHBT0000025_001] until the NBA took over.

8. Was Manchester RTC associated or linked with other Regional Transfusion Centres, if so, how and for what purpose?

67. Manchester Blood Centre was associated with a sub-centre in Lancaster, whose Director during the 1980's was the late Dr Douglas Lee.

68. The North West has a large population of variable density. Plasma components are best prepared as soon as possible after donation. As the journey from Barrow in Furness to Manchester could take up to 4 hours, the location of a Blood Centre in Lancaster enhanced the quality of the plasma components produced throughout the region.

69. The North West Regional Transfusion Service included both the Lancaster Centre and the Manchester Centre. Although the Centres ran similarly in clinical matters, Lancaster was responsible for its own donor recruitment and laboratory and contributed similarly to plasma procurement. It was also a significant contributor to the pool of specific plasma for the production of anti-D immunoglobulin.

9. Was Manchester RTC subject to any form of regulation? If so, please describe the system. Was this effective in your view?

70. Blood and blood components are licensed as Biologicals under the Medicines Act so the Blood Centres' production activities were inspected regularly by the Medicines Control Agency (now the MRHA) and, as they provided a storage and distribution service for products from BPL, required a Wholesaler Dealer's Licence as well.

71. The Reference Laboratory function was inspected by the Clinical Pathology Accreditation scheme. When the inspections were introduced during the 1980's this was recognised as an improvement in objective regulation.

10. **Were there any targets for the amount of blood or plasma collected by Manchester RTC? If so:**

a. What were these targets?

72. There were targets for plasma procurement which would have been agreed with Dr Gunson, and I would then have received a target for the contribution required from apheresis plasma - as well as contributing to the scaling up of plasma procurement by the promotion of the use of red cells suspended in SAG-M. See (b) below for more detail.

73. The red cell collection targets and local preparation of plasma components were related to the current needs of the local population.

b. How were these set and by whom? You may find it helpful to refer to the letter from Dr Gunson to you dated 19 December 1988 setting out targets for plasma supply [NHBT0071562_001]

74. By the time I was appointed Director of the Mersey and North Wales Regional Transfusion Service in November 1988, the plans for plasma procurement were made by the designated DHSS Medical Committee as indicated in the letter from Dr Gunson as National Director to me dated 19/12/88 [NHBT0071562_001], a copy of which has been provided to me by the Inquiry.

75. The letter discusses plasma targets. It encloses a report of the DHSS Medical Committee assessing plasma supply including the net stock at BPL and current yields. Dr Gunson advises that the National Committee (of the NBTS) had considered the report and recommended that Option 2 – which was BPL production to be set in accordance with attainable targets - should be followed. RTCs had anticipated a steady build-up of plasma supplies and were generally prepared to collect and return to BPL up to 400 tonnes in 89/90 reaching 450 in 1990/91. This build up needed to be

accelerated. Option 2 called for 420 tonnes of fresh plasma to be sent to BPL during 1989/90.

76. This meant that, in turn, each RTC should try to achieve as soon as possible within the financial year the target of 8.82 tonnes per million of the population. This was the same as the previous projection for 1989/90. It would however be necessary to increase the plasma supply in 1990 and consideration would be given as to how this could be achieved in the first months of 1989 and the proposals discussed with us as soon as possible. This could be further discussed at Divisional and RTD meetings. Letters were to be sent by the NHS Management Board to Regional General Managers. This would equate to 441 tonnes per annum. No regions were currently returning plasma at this level at that time although some were close. The range was 4.35 to 4.84 tonnes per million.

77. The report notes (following a survey) that the potential of the regions varied but that the most favoured means to increase the plasma supply was by additional plasmapheresis centres, although one centre planned to reduce the collection interval for whole blood from six to four months. Substantial additional capital expenditure and staff recruitment would be required for the new and enhanced apheresis services and considerable effort would be needed to build up donor recruitment and retention.

78. In relation to Option 1, it was noted that the last minute planning required to meet the new 1989/90 targets and the large leap required, made these targets unrealistic and unattainable.

79. By this time, I was the Director of the Mersey and North Wales Regional Transfusion Centre. As discussed in my response to question 5, almost the first thing I had to do on taking up this post was to explain how I would increase plasma production in order to meet the target.

80. I have been shown a document [NHBT0019602_003] – '*Mersey Regional Transfusion Service Plasma Procurement 1989/90, 1990/91 – A two-year scheme to self-sufficiency*' which I would have written. This notes that:

- The Mersey and North Wales Regional Transfusion Service was solely responsible for the supply of whole blood and certain blood derivatives to an area which differed substantially from that of the Mersey Regional Health Authority.
- BPL was now fully operational and allocations of plasma to be supplied were increasing monthly.
- Until recently, Mersey had met all its targets but when the completion of BPL had been held up it had been necessary to purchase imported blood derivatives such as albumin and factor VIII concentrate.
- There was therefore a pressing need for resources to be allocated to the Mersey Regional Transfusion Service to allow plasma procurement to reach its target level.
- The resource assumptions and planning guidelines in Health Circular 88/43 set the objective for authorities by 1990 to meet the Region's target based on 8.82 tonnes of fresh frozen plasma per million of population.
- The population served by the Mersey region was 2.82 million and the target set was 24.7 tonnes of plasma per annum by 1990.
- Since that target had been set, it had become apparent that the actual yield (130 u/litre of plasma) of factor VIIII concentrate fractionated by BPL was considerably less than originally estimated (165u/litre plasma) and a number of other factors including the need to heat treat to render the product free of transfusion-transmitted diseases such as hepatitis and HIV had contributed to the reduced yield. It was therefore necessary to increase plasma procurement so that the annual return proportionally from Mersey would go up to 31.35 tonnes.
- The current annual collection of plasma by Mersey RTS was barely 20 tonnes and the new target represented an increase of over 50%.
- This would be produced in two ways: by maximising plasma yield using additive solutions to give 21,600 litres and by collecting the remainder

by way of automated plasmapheresis, during which a single procedure would produce 500 to 600ml of plasma depending on the weight of the donor. As iron stores are preserved for the apheresis donor the process could be repeated more often (once a month or fortnight). To supply the remaining 10,000 litres would require about 20,000 procedures annually.

- It was proposed that cross-charging would be introduced between RTCs and BPL in April 1990, although the details of this were not yet available.
- There would be increased blood collection and to restore this to 125,000 donations per annum, there would be an energetic recruiting campaign and the possible need to increase weekend sessions.
- The cost of 10,000 packs of SAG-M additive solution, laboratory assistants, recruiting etc would be £63,797.
- There was also a need to replace some of the older less efficient plasmapheresis machines.
- A new consultant would need to be appointed as well as clerical staff, donor attendants and clinical assistants for the new expansion of the apheresis service.
- The full costings were set out in appendices which are not attached to the document provided to me.

c. Was funding linked to Manchester RTC meeting these targets?

81. I was not responsible for the budget in Manchester between 1984 and 1988. Dr Gunson's response to the HCV litigation in 2000 sets out the funding difficulties before the establishment of the National Blood Authority some years later.

d. How frequently were these targets missed? What was the reason for this?

82. Every effort was made to meet the annual plasma target but it took time to scale up plasma procurement both by the recruitment of an entirely new

cohort of plasmapheresis donors and increasing the plasma yield from red cell donors using SAG-M as an additive. I have described above my plan for this after I moved to MNWRTC in my response to question 5 and 10(b).

83. I am not able to say what the position was for the Manchester RTC or North West Region overall in terms of if and when plasma targets were reached. I did not have managerial responsibility for plasma procurement targets at Manchester.

e. What were the consequences for Manchester RTC of missing targets?

84. I was not aware of any direct local consequences in failing to meet these targets at that time. However, NHS coagulation factor concentrate was returned to us pro rata for the amount of plasma we sent to BPL for fractionation, so producing less plasma would result in less NHS factor concentrate being returned.

85. As far as I can remember at that time there was not enough NHS concentrate for all the adults and priority in Manchester was given to children. Before BPL was redeveloped at Elstree, the fractionation capacity at the smaller Lister Laboratories was limited.

f. How did Manchester RTC address any shortfalls in donations?

86. These are set out previously - in the establishment of a Plasmapheresis Centre in Manchester in 1985 and increasing the plasma yield from red cell donors using SAG-M as an additive. We also tried to maximise the number of donors.

11. What if any steps did Manchester RTC take to ensure a steady supply of blood donors? How effective were these steps? Could more have been done in your view?

87. There was a large separate donor recruitment department which ran advertising campaigns and rewarded regular donors at award ceremonies. There were also posters prepared nationally. I recall that those with babies seemed to be the most successful in terms of recruiting new donors.

88. Donors received postal call-ups from an established panel. Holidays and bank holidays would tend to be times of particular shortfall and we did what we could to maintain supply during these times by targeting special publicity in advance.

89. There were usually recruiting campaigns before Christmas and before summer holidays.

90. Weekend collections were routine and latterly centres moved over to targeted local collections using Bloodmobiles. I recall setting these up in Liverpool after 1988 but I am not sure about the timing of subsequent arrangements in Manchester after I left.

91. Great efforts were also made in order to try to achieve self-sufficiency in plasma but by the time it was achieved British plasma was no longer considered suitable for fractionation because of the potential risk of transmission of vCJD.

92. In particular, as described in a document provided to me [BART0002235] it was realised that vCJD occurs almost exclusively in the UK and it was likely that any risk of transmission would be reduced by using concentrates prepared from donor plasma collected in other countries e.g USA where there were no recorded cases of vCJD or BSE. The actions taken included not allowing people potentially at risk from vCJD to donate blood, tissue or organs (including eggs and sperm for fertility treatments); not accepting donations from people who have received a blood transfusion in the UK since 1980 and removing white blood cells, which may carry the greatest risk of transmitting CJD (leucodepletion), from all blood used for transfusions

93. This meant that there was not as much of a need/no need for British Plasma for fractionation after that time.

94. I am not sure what more we could reasonably and practically have done. If there was anything I think we would have tried it.

12. **What steps did Manchester RTC take if it was unable to collect sufficient blood to meet its patient population? In particular:**

a. Were blood and plasma on occasion sourced from SNBTS? If so, how often?

95. I was not aware of this if it happened. My role at Manchester RTC was not as a director but as a consultant. I would not have been responsible for this. I believe Scotland would have been too far away for this to have worked. Before there was a national service, we would try to obtain any additional blood that was needed from close by, wherever possible. I do know that Dr Gunson liaised closely with colleagues in Scotland, and particularly Professor John Cash, on a regular basis.

96. Until the new BPL factory opened in 1986, we did not have enough capacity for plasma fractionation in England and Wales. Although they did have the ability to do some fractionation at PFL in Edinburgh I doubt that this would have been enough to make up the shortfall.

97. I seem to remember that BPL had a batch failure of 9A (a plasma derived Factor IX concentrate) or stopped making it for a little time and a suitable equivalent from a voluntary British donor blood source was supplied from PFL in Edinburgh.

b. Were blood and plasma on occasion sourced from elsewhere? If so, where and how often?

98. In terms of the blood and plasma that we collected it was all from voluntary donors freely given in the UK.

99. At times, particularly later on, stocks could be transferred from other Centres when there was a particular shortfall in one locality. This was one of the benefits of the reorganisation to create the National Directorate in 1988, as they compiled a daily tally of national blood stocks to facilitate the process.

c. Was this blood/plasma paid for by anyone if so whom?

100. There has never been any payment for donated blood in this country

101. Plasma was not paid for in the UK. Any costs were to do with processing e.g. recruitment, collection, processing itself, testing, quality assurance and transport which are described as "handling charges".

13. Once Manchester RTC had collected a donation:

a. What happened to that donation? Who decided where it should go to be processed? How was that decision made?

102. In order to minimise the risk of transmitting bacterial infection the donation was made directly into a sterile closed system of bags with additional empty bags ready for processing in the same pack. The containers had different shapes and properties for preparation of platelets, red cells and plasma because each element requires storing in a different way to ensure optimum efficacy on transfusion to a patient or for fractionation.

103. Red cells and whole blood were best stored in a refrigerator at 4 degrees Celsius. Plasma-reduced blood in optimal additive solution had a shelf-life of about 35 days. Before 1978 the shelf life was 21 days.

104. Plasma for fractionation was stored in a "lollipop bag" which is cone shaped and made of relatively inflexible plastic. The plasma should have been separated by centrifugation and frozen to minus 30 degrees Celsius as soon as possible. Fresh frozen plasma for local transfusion is stored in a different plastic container and lasts 18 months to 2 years locally at minus 30 degrees Celsius if it is not sent for fractionation.

105. Using SAG-M as an additive increases the yield of plasma from the donation by 100ml. Saline/adenine/mannitol, glucose is added to help extend the shelf life of stored red blood cells in the refrigerator.

106. Platelets are stored in a large, flexible plastic bag with a porous back for gaseous exchange and have a shelf life of 5 days at room temperature in a state of agitation. Platelets have a very short shelf-life and must be kept at room temperature with gentle agitation to ensure maximal therapeutic effect on transfusion.

107. The sooner the different products are separated for storage, the better they will retain their beneficial therapeutic response on transfusion. The best output for plasma products will be achieved by separating it from the red cells as soon as possible after collection.

108. The decision as to how the donation would be used would be made before it was collected by issuing the appropriate packs for the collection session. This would be determined by the requirements for red cells and plasma components locally as well as the regional contribution to the current national target for plasma fractionation – the latter rising on a regular basis throughout the 1980's. Careful consideration would also be given to the transit time from the blood collection session to the Blood Centre and returns mid-session might be made if required for processing purposes.

109. The processing plans were tailored to clinical need, often depending on the amount of platelets needed in the area at any time. The clinical need would

be dependent on individual patient requirements and stocks. There would be an accepted minimum, but sometimes more would be needed.

110. Requests for routine blood components were received regularly from hospital transfusion laboratories but patients with individual requirements would be discussed between a hospital clinician and one of the clinicians at the Blood Centre who would then instigate their provision following liaison with the donor, laboratory – and sometimes apheresis – services.

b. What if any payment was received for each donation, and from whom?

111. No payment was received in the UK as per my response to 12(c).

c. Was it standard practice for donations to be tested further by the laboratory to which it was sent?

112. I would not send blood out to hospitals unless it had undergone standard tests pre-issue which included as a minimum ABO and Rh (D) type, screening for red cell antibodies and microbiological screening.

113. There are sausage sections in the tubes to the bags which allow sampling for the additional compatibility testing in hospital laboratories.

114. BPL would have carried out tests in accordance with its own system of regulation and good manufacturing practice.

14. **Please describe Manchester RTC's relationship with the Blood Products Laboratory (BPL). In particular:**

a. Was there a pro rata agreement with BPL to return an amount of blood product such as factor 8, proportionate to the quantity of plasma supplied to BPL? If not, what arrangement was in place for the supply of plasma and return of blood products?

115. Regional Transfusion Centres received the fractionated plasma products including coagulation factor concentrates back from BPL on a pro rata basis for the amount of plasma supplied.

b. Was there an agreement as to the amount of plasma Manchester RTC was to provide to BPL? If so, how was this set?

116. In 1984 we were doing everything we could to try to work towards self-sufficiency. I remember going in 1984 to a meeting at BPL where they set out what the national target was and what our target was in Manchester.

117. Manchester would have represented about 10% and Liverpool 5% of the total national requirement based on their relative populations. I seem to recall it may have been around 52 and 28 metric tonnes per annum respectively but it was a long time ago and I cannot be sure of the exact figures.

118. I have described above that in December 1988 regions were set the target of 8.82 tonnes/million by 1990 as a service objective. This would equate to 441 tonnes per annum [NHBT0071562_001].

119. In any population when the Blood Service is making plasma products, the amount of plasma needed to start with is determined by the component which is in the shortest supply. This was Factor VIII concentrate in the UK in the 1980's and 1990's. Plasma fractionation is more efficient on a larger scale so the calculations were made nationally and divided regionally to indicate the local contribution required from each Centre.

120. In order to set the plasma targets the questions would be: -

- How much Factor VIII concentrate is needed to treat haemophilia in the population served?
- How much raw material is needed as plasma for that amount of Factor VIII concentrate?
- How big is the total population?

- How large a population does your Blood Centre cover in terms of that population - what percentage of the whole?

c. What blood products did Manchester RTC receive from BPL?

121. I cannot recall exactly what blood products Manchester RTC would have received from BPL while I was working there. That was not within my role.

122. I think blood products were dealt with by Dr Richard Wensley who had a dual role at the RTC and as a haemophilia centre director at Manchester Royal Infirmary.

15. Did Manchester RTC have a relationship with any other laboratory fractionating or processing its donations? If so, please describe that relationship.

123. As this was not part of my role in Manchester, I am not sure.

124. I expect the only place it would have gone to if not to BPL would have been to PFL in Scotland.

125. I know from working with Dr Wensley in the early 1980s that the practice at that time was not to be reliant on one supplier for Factor VIII concentrate. This was based on the fact that batch failures occurred not infrequently at various fractionation centres and then nothing could be supplied by the manufacturer concerned for some weeks. It was considered better to have more than one supplier for this reason.

16. Did Manchester RTC enter into contracts for the purchase of blood or blood products with commercial organisations? If so:

a. What were the circumstances in which this would occur?

126. As I was only a senior registrar or junior consultant, principally involved in setting up and running the Apheresis Centre at the time, I would not have been responsible for contracting.

b. Which companies did Manchester RTC contract with and for what?

127. During my time at Manchester I did not have any responsibility for or involvement in contracting for the purchase of blood and blood components. However, there would have been a contract with BPL which was an NHS organisation.

c. How frequently did this occur?

128. I was not involved in contracting and am not able to comment.

17. Please describe the nature of Manchester RTC's relationship with the haemophilia centres that it supplied and with UKHCDO.

129. The Manchester Blood Centre was responsible for collecting local plasma for fractionation to provide the haemophilia centres with NHS Factor VIII concentrate from BPL. There was a Comprehensive Care Centre for Haemophilia at Manchester Royal Infirmary and two other Haemophilia Centres in the North West Region - one based in Lancaster and another at Blackburn Royal Infirmary. Apart from that, the regional haematologists were consultant colleagues. They would ask for advice if their patients had problems with blood transfusion. They were the clinical interface between the Blood Centre and individual patients.

130. In Manchester Richard Wensley was a consultant colleague who had a part time contract with the Blood Centre but also ran the Haemophilia Centre at Manchester Royal Infirmary. He took the lead on component preparation and he would have been involved with UKHCDO. I had no involvement with them during my time at Manchester where I was originally

a Senior Registrar and then the junior consultant who was given the job of setting up the Apheresis service.

18. Please explain whether Manchester RTC supplied particular products on a named patient basis and how this arrangement came about and the reasons for it.

131. Clinicians might request certain products on a named-patient basis on individual request. In my own experience, that would not have been for Factor VIII concentrate, but it might have been for the provision of selected red cells or platelets where there had previously been a transfusion reaction reported for the patient concerned. I cannot recall any specific requests for a Factor VIII concentrate and were it to have occurred it is likely to have been dealt with by Richard Wensley at that time.

132. I describe in document [DHSC0004351_045] – *'A Fully Functional and Comprehensive Blood Service, centred in Liverpool to Provide for Merseyside and North Wales'* (page 8) that machine apheresis platelet donations were regularly collected in Liverpool on a named-patient basis for the treatment of those with cancer and leukaemia who had developed antibodies to the standard product. Many of these patients had undergone bone marrow transplantation. Donors were called on their behalf who were specially matched to avoid this problem. These donations were microbiologically tested and fit for use within a few hours. A similar service had been available in Manchester while I was working there.

19. Please describe how individual hospitals physically obtained blood/blood products. Were they delivered by Manchester RTC or directly from BPL or another third party, or both?

133. The Manchester RTC stored the products made on site. From memory, the product was collected from the donor, processed and tested at the Manchester Blood Centre and was transported from there to the local hospitals on request from the hospital transfusion laboratories.

134. I am not entirely sure whether or not commercial product would have come to the Blood Centre first to then go to a hospital at Manchester Royal Infirmary which was just across the road. I was not involved in this in Manchester so am unable to comment.

135. In Liverpool from 1988 NHS products came to the Centre and then were taken to the hospitals alongside locally prepared blood components but I am not sure about the Manchester practice.

SECTION 3: YOUR ROLE AS DIRECTOR AND CONSULTANT HAEMATOLOGIST OF THE MERSEY & NORTH WALES REGIONAL TRANSFUSION CENTRE (MNWRTC)

20. Please describe the roles, functions and responsibilities you had at the Mersey & North Wales Regional Transfusion Service ('MNWRTC') during your period as Director.

136. As Director and Consultant Haematologist at the Mersey and North Wales Regional Transfusion Service from November 1988 until the end of 1995, I was responsible for the provision of blood and blood components to the local population (approximately 2.8 million at the time). This included donor recruitment, arrangements for blood collection, testing, processing and distribution including the regular delivery of frozen plasma to the Bio-products Laboratory at Elstree.

137. There was a multidisciplinary staff of approximately 250 people. I was a Regional Officer with Mersey Regional Health Authority, which was the direct source of funding initially in 1988. I was managerially accountable to the Regional Medical Director, who was Dr Peter Simpson originally and later Dr John Ashton.

138. I describe in document [DHSC0004351_045] the hospitals which were served by the Liverpool Centre in 1994 and the work that they did including:

- The Royal Liverpool University Teaching Hospital, then one of the biggest in Europe with 850 beds, with a large vascular surgery unit, the regional renal and bone marrow transplant units, and a busy accident and emergency department, soon to be the largest in the country with 150,000 episodes p a. We were making deliveries to them within 5 minutes.
- The Cardio-Thoracic Centre at Broadgreen Hospital which had increased its cardio-pulmonary by-pass procedures to 1,500 pa in addition to 840 thoracotomies; platelet concentrations were required urgently and could be delivered within 10 minutes;
- Alder Hey Children's Hospital with a supra-regional paediatric cardiac surgery unit serving the whole of the North West and an active haematology and oncology unit providing bone marrow and stem cells for transplantation for a variety of malignant conditions;
- The Aintree Trust in the north of the city had a very busy accident and emergency department (100,000 episodes pa), vascular and surgical specialties and neurosciences on the Walton site where neurosurgery was (is) performed. These services were associated with a high transfusion requirement.
- Wirral Hospitals, a large acute Trust had a busy obstetric department (5,000 deliveries p a) and Clatterbridge, the centre for radiology and oncology.
- Ysbyty Gwynedd a large busy hospital in Bangor with an active oncology and haematology unit where autologous bone marrow transplantation was undertaken.
- The Foetal centre at Liverpool Maternity Hospital provided a supra-regional service for unborn children with components for intra-uterine transfusion being provided on a named-patient basis.
- We also served as the regional therapeutic apheresis centre for treating, for example, acute myeloblastic leukaemia in children and provided therapeutic leucapheresis in the treatment of acute leukaemia.

- We also collected plasmas for the preparation of specific immunoglobulin – eg Anti-D, anti HBs etc.

139. Reference Laboratory Services were provided by MNWRTC to support hospital transfusion practice locally. These services had been awarded Unconditional Accreditation following a visit by Inspectors from the Clinical Pathology Accreditation scheme in 1993. There were three reference laboratories: - the Antenatal laboratory; the Hospital Reference laboratory; the Tissue-typing Laboratory.

140. We formed strong links with local haematologists through hospital liaison and RTC consultants sat on 7 of 11 Hospital Transfusion Committees. We had taken the lead in the audit of local transfusion practice. A clinical assistant was employed from the Blood Centre to collect data on a regional basis for comparison with agreed standards.

141. We had educational links with the University of Liverpool, John Moores University and the Liverpool School of Hygiene and Tropical Medicine, with involvement in undergraduate and postgraduate teaching. We ran BSc courses for Medical Laboratory Scientific Officers, with students regularly completing a sandwich year at the RTC. We were often approached to train doctors from overseas in transfusion medicine.

142. These are functions which are fundamental to the running of a clinical blood service to provide a timely and efficient supply of appropriate blood components for the practice of transfusion medicine.

143. When the managerial arrangements for the NHS had been separated in to Purchasers and Providers in 1990, Service Level Agreements had been contracted with colleagues in secondary care who were prescribers of blood components.

144. I was appointed Director in Liverpool in July 1988 three days after Dr Gunson, who had been Director in Manchester, was appointed National

Transfusion Director. The Liverpool Centre cooperated with the National Directorate, which was based in Manchester, and thereby participated in the development of national coordination. For example, we provided data on daily stock to ensure an adequate blood supply nationally with transfer of blood and blood products as required. This was an appropriate clinical development encouraged by the Department of Health, but did not provide direct managerial or fiscal accountability at the time.

145. In the early 1990's the National Directorate was disbanded in favour of a new Special Health Authority known as the National Blood Authority (NBA) which assumed full managerial responsibility for the centres previously affiliated to the "National Blood Transfusion Service" in England and Wales, including the funding. Hence my accountability – both professional and managerial - changed at that time. I became managerially accountable to the Chief Executive of the NBA and professionally accountable to the Medical Director of the NBA.

146. After a full review of the Service facilitated by the management consultancy firm, Bain, in 1994 a decision was made to completely change the managerial arrangements to a zonal level – there then being 3 zones - North, East and South. My post, which at that time was described as Chief Executive and Medical Director, therefore disappeared. I continued working full time with the NBA - the service component of which was then known as the National Blood Service (NBS) - as Director of Donor Services for the Northern Zone until early 1997 when I moved back into clinical haematology again in secondary care at the Royal Liverpool Hospital.

21. Please describe the organisation of the MNWRTC when you first arrived there including:

a. Where it was physically located;

147. The Mersey and North Wales Regional Transfusion Centre was based in West Derby Street, Liverpool, L7 8TW.

148. The Welsh teams had bases for staff employed in blood collection locally in Wrexham and Caernarfon and there was a donor centre in Lord Street Liverpool, collecting donations every day except Sunday.

149. The population served, geographical area, and the services provided by this centre are described in the document I wrote in 1994 setting out my objections to the proposed reorganisation of local services, largely relocating them to Manchester. This document is [DHSC0004351_045] – 'A Fully Functional and Comprehensive Blood Service, centred in Liverpool to Provide for Merseyside and North Wales'.

b. Its structure and staffing and, in particular, who you were accountable to;

150. I have described above at paragraph 20.2 my accountability in this role and how it changed over time.

c. How the service was funded and whether this changed over the years (you may find it helpful to refer to your letter dated 13 August 1991 to Warrington Community Health Council about this [NHBT0009832];

151. Mersey Regional Health Authority was the direct source of funding initially in 1988.

152. In the early 1990's the managerial arrangements for the NHS were separated into Purchasers and Providers and budgets devolved accordingly. Service Level Agreements were contracted with colleagues in secondary care who were prescribers of blood components.

153. The letter to Warrington Community Health Council in August 1991 [NHBT0009832] explains how the Regional budget had been devolved to District Health Authorities for subsequent distribution to hospitals to

reimburse the handling charges for blood and blood components issued to their local Transfusion Laboratory from the MNWRTC.

154. The National Directorate worked to establish national tariffs for handling charges for all locally prepared blood components and this practice was maintained by the NBS.

d. MNWRTC's place in the National Blood Transfusion Service;

155. From 1988 until the formation of the NBA the MNWRTC was one of a number of Regional Transfusion Centres in England and Wales, each managed by their Regional Health Authority but contributing professionally to the development of Transfusion Medicine throughout the country both clinically and professionally via the NBTS.

156. For example, we collaborated in the Handbook of Transfusion Medicine which was published in 1989 [PRSE0003047] which credits as contributors many of the Regional Transfusion Centre Directors, including me.

157. Where clinical improvements were agreed nationally, every effort was made to implement them locally with regional support in order to maintain best clinical practice.

e. To whom the centre was answerable to, if anyone, and in respect of which issues. In answering this question you may wish to refer to the letter from Dr Gunson to all RTC directors dated 7 October 1993 [DHSC0004709_153], the correspondence between you and Mr Mowat of Hill Dickinson Davis Campbell solicitors between 21 October 1993 and 5 November 1993 [NHBT0019425_002; NHBT0019425_001] and your subsequent letter to letter to Dr Gunson of the NBA dated 17 December 1993 [NHBT0019424]

158. By 1993, Dr Gunson was Medical Director of the NBA and John Adey was its Chief Executive. I was accountable to Dr Gunson professionally and to Mr Adey managerially.

159. I felt, therefore, obliged on their direct instruction to discontinue the pilot study of donor screening for core antibodies to hepatitis B (anti-HBc) which is acknowledged to detect a small number of chronic carriers of hepatitis B. This was despite my wish to carry on with the testing which I expressed to Dr Gunson verbally and in my letter to Dr Gunson dated 13 December 1993 [NHBT0019424].

160. My correspondence with Mr Mowat, a former colleague in the Mersey Regional Legal Department, reflects my clinical concern. In particular, I considered that it was beneficial to carry on with the additional hepatitis B core antibody testing in order to improve clinical care by preventing the transmission of hepatitis B from the small number of donor carriers each year whose infection went undetected otherwise by the standard HBsAg test. I felt that it was being stopped on the grounds that it cost too much.

161. I sought local legal advice as I perceived this might have a direct impact on patient care locally, notwithstanding the implications for plasma sent for fractionation to BPL. This letter confirmed my concerns about discontinuing the test and how this might later be judicially tested.

162. After this I wrote to Dr Gunson enclosing the advice from Mr Mowat in the hope that this approach might be reconsidered, as seen in document [NHBT0019424].

f. When answering this question please refer to paragraphs 1-16 of Dr Gunson's statement provided for the A v Others litigation [NHBT0000025_001] and say whether you agree with what is said there.

163. I concur with Dr Gunson's explanation of the changing managerial arrangements in the Blood Transfusion Service in the second half of the twentieth century.

164. At paragraph 19 of his statement for A v Others (NHBT0000025_001) Dr Gunson indicates that testing of blood donation for hepatitis B surface antigen (HBsAg) reduces the transmission of hepatitis B by 85% following blood transfusion; I believe that the addition of anti-HBc screening would have reduced further the risk particularly to those receiving locally prepared blood components including red cells, platelet concentrate and fresh frozen plasmas. Viral inactivation was by then well established for fractionated products.

22. Please describe the changes made to the Blood Service during your tenure as director of MNWRTC and set out in particular how these affected MNWRTC and your role there.

165. Within a year or two of my appointment as Director of MNWRTC, the managerial arrangements for the NHS were separated into Purchasers and Providers. The Regional budget was devolved to District Health Authorities and Service Level Agreements were contracted with colleagues in secondary care who were prescribers of blood components.

166. I refer to paragraphs 20.9 -20.11 above.

Please also describe:

a. The extent to which you and the MNWRTC were consulted about the need for reform, and the shape of that reform.

167. It was clear before 1988 that the term "National Blood Transfusion Service" was at best a euphemism and probably better described as a misnomer. In the absence of a national budget to support national clinical development, it was difficult to proceed at a pace. Once a clinical improvement was recommended by the NBTS clinicians, each Regional Transfusion Director

would have to secure funding from their Regional Health Authority in order to proceed.

168. The National Directorate was established in 1988. However, in the absence of a national budget they had to lead by persuasion. This led to the formation of a National Blood Authority as it was perceived that the clinical developments required eg. self-sufficiency in plasma, could not be achieved in a timely manner without full managerial control including the budget.

169. I do not recall any specific consultation about the need for reform although it was generally acknowledged by the RTD's to have been necessary for some time as far as I can recall.

170. I have seen a document NHBT0001833_002 which is a letter I wrote dated 28 October 1991 to Mr J Canavan at the Department of Health regarding a Consultation Document on the Proposal to Combine the Central Blood Laboratories and the National Blood Transfusion Directorate in a National Blood Authority. I refer to having "*received a copy of the discussion document at the end of September from Dr Walford [at the Department]*" and to her having asked me to respond to Mr Canavan as the author of the document, following consultation with colleagues locally and in North Wales. I go on to note that "*our staff here [at MNWRTC] had also contributed to the joint response prepared by Dr Wagstaff on behalf of the 14 Regional Transfusion Services in England and Wales*". I note that I thanked him first for "*producing such a concise report with scope for expansion to tailor the needs of the National Blood Transfusion Service*". I go on to make the following comments:

171. <u>The National Director</u>

Since the National Director had been appointed three years ago [1988], the Service had had the benefit of central coordination. Blood and blood products were now produced to an agreed standard, the quality of which was maintained by annual external audit. Coordination towards national

self-sufficiency in plasma procurement had been achieved and stocks of locally prepared products kept in equilibrium in England and Wales. Financial cross-accounting had been set up in advance of the NHS Act 1990 and a management information service had been established. All of this had been achieved in just three years reflecting the considerable hard work and enterprise of the National Director and his small staff.

172. The National Blood Authority

This must be seen to build upon the firm foundation of the National Directorate and enhance the rapid development of Blood Transfusion Centres onto a truly National Service, whilst maintaining their own individuality. The inclusion of the functions of the Bio-products Laboratory should complete the circle in the support of the transfusion needs of patients in this country. There was however some concern that BPL, as only one production site amongst 14 centres, had excessive representation on the NBA. We felt that a much greater contribution was required from the Blood Transfusion Services and recommended that individuals from the following disciplines be included in the non-executive appointments:

- 1 solicitor
- 1 accountant
- 1 consultant haematologist
- 1 consultant anaesthetist
- 1 Regional Transfusion Director (rotating)

173. We felt that, with appropriate constitution and membership, the NBA could prove beneficial in promoting a corporate image to support national donor recruitment campaigns and to better coordinate donor resources with patient needs on a larger scale. There should be economies of scale in central advertising, donor awards, uniform, livery etc. Once the NBA assumed responsibility for procuring blood as well as fractionating plasma the common aims of the service should prevail. The weighting of handling and plasma charges should therefore be agreed more easily. (I think this was around the time when BPL said they would drop their payment for

plasma supply to Centres who indicated that red cells etc would then need to be more expensive to balance the books, but I am not sure.)

174. However, we expressed considerable reservations about the contracting mechanism with users in the consultation document. We strongly recommended that contracts between Regional Transfusion Centres and the hospitals in their area of supply should be made locally in order to maintain the best standard of service. I continued that everyone must welcome the recognition of accepted minimum standards within the Service and audit to facilitate their maintenance and development. We felt that in the fullness of time this should be extended to the bedside where the effectiveness of transfusion could be assessed clinically and it would be most important to develop an agreed method of measuring effectiveness if it were to be compared with cost.

175. Funding

We recommended funding of the NBA and its daughter executive unit as a sort of Special Health Authority, top-sliced from Regions. This was, however , out of line with current accounting practice in the NHS. The alternative would be to add the cost on to the handling charges of blood and its components, taking the cost right down to the user. Since Regional reference and consultant services were to be maintained at local level, it seemed that the current financial arrangements for RTCs would continue in the Mersey Region, with total budget devolution to District Purchasing Consortia with money returned to RTCs for services provided. Central capital allocation could prove advantageous but the rules would need to be clearly defined.

176. RTC Arrangements

Both the NHS Act 1990 and the proposed NBA required a greater degree of self-containment within the RTC, whose contracting activities were rapidly becoming more complicated. The establishment of a board to the RTC would be advantageous although the issue of Trust status would

require careful thought in view of the voluntary nature of blood donation in the UK.

177. I went on to note that the association of RTCs with business objectives was unacceptable to many voluntary, unpaid donors and Trust hospitals were 'popularised' as 'opting out'. Such "opting out," if it occurred, would be disastrous for the Blood Transfusion Service, which might then be accused of selling blood or plasma. For this reason, I recommended that non-executive members of the board should include donors wherever possible so that 'our most valuable asset is well-represented'. Rather than a Trust, the organisation might then be seen as a 'Donor Co-operative Society' with non-executive donors from professions such as the law, accountancy, business and users – e.g. haematologists and anaesthetists etc.

178. Summary of comments from Haematologists

I note that opinion had varied throughout the region. One colleague was entirely opposed to a central authority which states business principles as its prime objective, fearing a loss of clinical representation; others would support the transfusion service's judgment on the benefits of national coordination but emphasised the importance of access to their RTC and the presence of a medically qualified Regional Transfusion Director. They could not see the necessity for a central contracting body of the sort proposed. The Haemophilia Director was noted to be dubious about the association of the National Blood Transfusion Service, which he considered to be an efficient local service, with the newly launched Bio-products Laboratory which was 'well known to have a singularly chequered history'.

179. In closing, I repeated my caution about the avoidance of marketing language in connection with blood donations, each of which is a priceless gift from one human being to another. I refer to this as having been carefully described in the transfer of handling charges both locally and nationally. If the NBA extended its role to provide an external fractionating role (not BPL) so that plasma was procured to donor capacity, it would be

difficult to construe this enterprise other than as a 'sale' to the private sector. No success could be achieved at the expense of donors, who I repeated were and remain our most valuable asset.

180. I hoped that our comments were helpful and felt that with the proper objectives and members, the NBA should be to the benefit of patients and donors alike.

b. Whether in your view reform was required, and if so, why. You may wish to refer to the letter sent by Aintree Hospitals to Mr Banks dated 17 October 1994 in which your views are set out [DHSC0004010_071] and the report you wrote called 'A fully functional and comprehensive blood service centred in Liverpool to provide for Mersey and North Wales' dated 21 September 1994 [DHSC0004351_045].

181. The need for the formation of a central fully funded National Blood Service is distinct from commenting on the outcome of the Bain review of the Service.

182. Prior to the development of a centrally funded National Blood Service, there were many local transfusion centres who all received different amounts of funding. I think that having a centrally funded service would have helped achieve national self-sufficiency in plasma sooner. Clearly this lack of dedicated financial support had previously led to difficulty in timely implementation of important clinical developments such as the synchronous introduction of hepatitis B surface antigen screening of blood donations in the early 1970's.

183. The Bain review initially suggested that the comprehensive functions of MNWRTC should effectively have been reduced to a small stock of blood and blood components prepared from local donors but processed and tested in Manchester and this was clinically unacceptable for a number of reasons as set out in Dr Stevenson's letter [DHSC0004010_071] .

184. I objected to the closure of the Mersey Regional Blood transfusion centre for many reasons as detailed at (i)-(vii) of [DHSC0004351_045] – *'A Fully Functional and Comprehensive Blood Service, centred in Liverpool to Provide for Merseyside and North Wales'*. I considered this would lead to a significant deterioration in the services provided from Mersey and North Wales blood service.

c. Whether in your view the reforms met the objectives

185. The reforms were intended to meet the financial targets at the time but eventually the MNWRTC was relocated to Speke as a new Centre with a Tissue Bank and Reference and Reagents Laboratories, as well as a Blood Bank, reflecting a redistribution of function but retaining the important specialist expertise locally.

186. I think views on this varied. Some RTDs welcomed it, but it was strongly opposed in MNWRTC because of the extremely detrimental effect it was considered to have locally. I noted in my report - document [DHSC0004351_045] – that the amalgamation/merger of 5 out of 15 transfusion centres which had been proposed to save £10million out of an annual revenue budget of £135million would seem to produce a small saving in relation to the total budget and the magnitude of change proposed.

187. I also noted that the consultation document showed that the greater part of the budget was spent on blood collection. Processing is labour intensive and removal of this service from Liverpool to Manchester merely created more jobs in Manchester at the expense of increasing unemployment in Liverpool. The major expense in testing is reagents and savings there could be made by bulk purchase of validated kits on a national basis. The report had also failed to consider transport costs and so was flawed.

d. What the impact was on the efficacy of the blood service of the closure of the Mersey Regional Blood Transfusion Centre.

188. MNWRTC did not close; it was ultimately relocated from central Liverpool to Speke as a purpose built new centre because the old site was considered unsafe because of the presence of asbestos. The new Centre had a Tissue Bank, took over the National Frozen Blood Bank and retained Reference and Reagents Laboratories, as well as a Blood Bank, reflecting a redistribution of function but retaining the important specialist expertise locally. The removal of processing and testing to Manchester Blood Centre in 1997 was occasionally associated with delay in the short term but after refinement of transport arrangements the service ran much more smoothly. Therefore, although a new centre was built elsewhere in the city with a number of specialist functions, laboratory processing and testing of blood donations were lost so overall the impact was both positive and negative from a local perspective.

23. **Was the MNWRTC subject to any form of regulation? If so, please describe the system. Was this effective in your view? Did the system of regulation change over time?**

189. Please see also my answer to question 9.

190. Blood and blood components are licensed as Biologicals under the Medicines Act so the Blood Centres' production activities were inspected regularly by the Medicines Control Agency and, as they provided a storage and distribution service for products from BPL required a Wholesaler Dealer's Licence as well.

191. The Reference Laboratory function was inspected by the Clinical Pathology Accreditation scheme. When the inspections were introduced during the 1980's this was recognised as an improvement in objective regulation.

192. I do not recall the system of regulation changing before I ceased to be Medical Director from 1995, although some consideration may later have been given to registration for the ISO9000 scheme in addition.

24. Was the MNWRTC associated or linked with other Regional Transfusion Centres, if so, how and for what purpose?

193. In Liverpool we had a Wholesaler Dealer's Licence to allow us to store and distribute British plasma products from BPL to hospitals in the region.

194. Liverpool won the transport contract and provided the haulage service to deliver frozen plasma from Blood Centres to BPL at Elstree on a weekly basis for the whole country. We put in a successful bid under a cost improvement scheme for national delivery. We were delivering every week to BPL and collected our own BPL products at the same time. It is likely we had contracts for this work with other Blood Centres and BPL. I cannot recall whether or not we returned BPL products to other Blood Centres or just collected their frozen plasma and delivered it to BPL for fractionation.

25. Were there any targets for the amount of blood or components of blood collected by the centre? If so:

a. What were these targets

195. There were annual targets for plasma procurement, red cell collection targets and local preparation of plasma components targets which were related to the current needs of the local population.

b. How were these set and by whom?

196. When I started in Liverpool in 1988 the targets were set each year according to local patient requirements for red cells and blood products as well as the local contribution to national self-sufficiency in plasma for fractionation - the latter being determined centrally.

197. By the time I was appointed Director of the Mersey and North Wales Regional Transfusion Service in November 1988 the plans for plasma

procurement were made by the designated DHSS Medical Committee. As the NBA took over managerial and fiscal responsibility the target setting was more centralised via the new zonal system of management.

c. Was the meeting of these targets linked to the funding of the MNWRTC?

198. No, the targets were not directly linked to funding but the region received NHS coagulation factor concentrate back from BPL pro rata for the plasma provided. It was the responsibility of the Director to anticipate any requirement for change in funding based on clinical developments in the interest of improved patient care - hence the need for a business case to support the expansion of the apheresis service.

d. How frequently were these targets missed? What was the reason for this?

199. Every effort was made to meet the targets but it took time to scale up plasma procurement both by the recruitment of an entirely new cohort of plasmapheresis donors and increasing the plasma yield from red cell donors using SAG-M as an additive.

e. What were the consequences for MNWRTC of missing those targets? How did the MNWRTC address any shortfalls in donations? Did they have to obtain plasma from other sources? If so, how was this achieved?

200. I was not aware of any direct local consequences in failing to meet these targets at that time. However, NHS coagulation factor concentrate was returned to us pro rata for the amount of plasma we sent to BPL for fractionation, so producing less plasma would result in less NHS coagulation factor concentrate being returned.

201. As far as I can remember there was not enough NHS concentrate for all the adults at the time and my colleague, the Director of the CCC for

haemophilia obtained the outstanding coagulation factor concentrate required from an alternative source.

26. **What if any steps did the MNWRTC take to ensure a steady supply of blood donors? How effective were these steps? Could more have been done in your view? If so, what and by whom?**

202. Please see my answer to question 11.

27. **What steps did MNWRTC take if it was unable to collect sufficient blood to meet its patient population? In particular:**

a. **Were blood and plasma on occasion sourced from SNBTS? If so, how often?**

203. Please see my answer to question 12(a).

204. I am not aware of this being the case. After 1988 one of the successes of the National Directorate following the appointment of Dr Gunson was the provision of data on daily stock to ensure an adequate blood supply nationally with transfer of blood and blood products between RTCs in England and Wales as required.

b. **Were blood and plasma on occasion sourced from elsewhere? If so, where and how often?**

205. Please see my answer to question 12(a).

c. **Was this blood/plasma paid for and if so, by whom?**

206. No. Please see my answer to question 12(c).

28. **Once the MNWRTC had collected a donation:**

a. What happened to that donation? Who decided where it should go to be processed? How was that decision made?

207. Please see my response to question 13(a).

b. What if any payment was received for each donation, and from whom? How did this change over time? In answering this question you may wish to consider the letter from the Department of Health dated 4 May 1990 to Special Health Authorities and the letter of explanation accompanying that from the National Blood Transfusion Service to you dated 4 May 1990 [NHBT0005620].

208. No payment was ever made for donations as I have set out above in response to 12(c) and 13(b). From May 1990 handling charges were applied following the changes in NHS funding following the introduction of the Purchaser/Provider split of activities within the NHS.

209. After the introduction of the internal market reforms, a system of cross-charging between NHS bodies was introduced. This system is evidenced in a document a copy of which has been provided to me by the Inquiry [NHBT0005620] which is a letter from J C Dobson in the Environmental Health and Food Division of the Department of Health to Regional General Managers and Managers of Special Health Authorities dated 4 May 1990, headed '*National Blood Transfusion Service: Cross-charging for plasma and blood products 1990/91'.* This letter is said to update the arrangements for cross-charging set out in EL (89) p/59 which was to operate in 1990/91. The letter notes that a price list for CBLA's therapeutic products is not included as the National Blood Transfusion Service Directorate was concluding negotiations with BPL over a national contract based on bulk purchase of therapeutic products by Regions.

210. Prices for plasma for 1990/1991 are given at Annex A. This included the price of recovered plasma at £35 per litre and plasma from plasmapheresis at £62.50 per litre (ALT tested)

211. Under a heading *Financial arrangements,* it is noted that BPL continued to have a plasma stockpile to which Regional Transfusion Centres had contributed before cross charging was introduced. Each month CBLA would credit RHAs at current values for 1/12 of their share of that year's estimated usage of the stockpile. In 1990/ 91 plasma valued at £3.3m was likely to be used. Annex B showed that the Mersey credit for stockpile in 1990/91 was £194,570

212. BPL would continue to issue monthly statements showing the value of plasma received and therapeutic blood products supplied and a summary would be sent to the Department of Health. On that basis the department would make quarterly adjustments to Region and SHA cash limits.

213. It is noted that in the previous year, Regions and SHAs received non-recurrent additions to their cash limits in respect of the distribution of top-sliced funds as a consequence of the move to cross-charging. In 1990/91, regions and SHAs were to receive recurrent additions to cash limits based on a total figure of £10,085,000 and after that these sums would be built into the main allocation. The distribution of these funds is shown at Annex C as being £534,000 for the Mersey region.

214. The arrangements for handling temporary shortages of blood remained unchanged. The value of the transfers of blood between the donor and receiving RTCs would be included in the cash limit adjustment arrangements.

215. I note that the letter concludes by saying that Ministers were firmly committed to self-sufficiency in blood products, echoing the World Health Organisation recommendation. BPL's output had now increased to a point where it was able to meet all home demand at competitive prices and purchasers should therefore be aware that there was no longer any need to resort to imported products to ensure supply.

c. Was it standard practice for donations to be tested further by the laboratory to which it was sent?

216. Please see my answer to question 13(c).

d. How regularly did MNWRTC receive notification that plasma pools to which it had contributed had tested positive for infections? (see for example document NHBT0001659).

217. Rarely BPL would notify RTCs that a plasma pool had tested positive. As all the plasma sent for fractionation was already screened to exclude those positive for HBsAg it was not a common event. The only available material was that which had originally been screened at the Blood Centre prior to despatch so the only explanations I can suggest are a laboratory error at either end or somehow the presence of undetectable trace HBsAg from a single donation might be magnified if the numbers were increased in the large pre-fractionation pool which might contain up to 10,000 donations.

218. This makes the assumption, however, that the BPL HBsAg screening was performed after thawing and pooling the larger volume prior to testing. I have no expertise in either microbiology or plasma fractionation so these comments are based largely on conjecture.

219. I cannot recall any specific examples of this or the frequency, beyond recalling that it occurred.

220. The Inquiry has provided to me a copy of document [NHBT0001659] which is a letter from BPL to all the Regional Transfusion Centre Directors (including me) dated 3 December 1990 and headed '*Plasma Incident PR90/26: HBsAg Reactive Plasma Pool.*' The letter notes that a plasma pool tested by BPL in November had had a reaction consistent with one of the donations containing a stated level of Hepatitis B surface antigen. It further states that each Blood Centre would receive details of its own

despatch notes indicating the donations contributing to this pool. Each Blood Centre was asked as a matter of urgency to confirm that:

i) The records for each donation have been reviewed and that the individual donations had been tested and found negative for HBsAg;
ii) The records for storage and despatch to BPL had been reviewed and at no point was an error of substitution made;
iii) That retained samples were available and would be subjected to repeat testing and the results provided to BPL as soon as possible.

221. In the meantime, no products from this pool would be made available for clinical use.

29. Please describe MNWRTC's relationship with the Blood Products Laboratory (BPL). In particular:

a. Was there a pro rata agreement with BPL to return an amount of blood product such as factor 8, proportionate to the quantity of plasma supplied to BPL? If not, what arrangement was in place for the supply of plasma and return of blood products?

222. Please see my answer to 14(a):

223. Regional Transfusion Centres received the fractionated concentrate back from BPL on a pro rata basis for the amount of plasma supplied.

b. Was there an agreement as to the amount of plasma MNWRTC was to provide to BPL? If so, how was this set?

224. There was a CBLA Liaison Committee, on which Dr Gunson was the RTC representative.

225. I have described the setting and operation of plasma targets above.

c. What blood products did MNWRTC receive from BPL?

226. On the advice of the Regional Transfusion Centre the Mersey Regional Pharmaceutical Committee set up a regional contract with BPL to supply available plasma components from BPL in order to command a discount for all the hospitals in the Mersey Region. As far as I can recall these included Human Albumin Solution, Anti D Immunoglobulin, Factor VIII concentrate, Factor IX concentrate and possibly some convalescent high titre immunoglobulins such as Varicella/Zoster.

227. We received fractionated products back from BPL for the region pro rata for the amount of plasma supplied for fractionation.

d. What was the impact on MNWRTC of cross-charging being introduced in or around 1989?

228. It was necessary to visit each hospital supplied to set up Service Level Agreements but did not really alter supply or demand.

229. There was no particular impact beyond a bureaucratic administrative system of accounting charges between NHS bodies relating to funds originally provided centrally, which was intended to encourage efficiency. These were established as Service Level Agreements with each organisation.

e. What was the impact on MNWRTC of BPL becoming part of the NBA in 1993?

230. I recall that it was beneficial in that it improved the coordination of plans for plasma procurement and fractionation. I found it helpful to understand other people's working difficulties. When it all came under one budgeting Health Authority the serious impact of dropping the costing of handling charges for procurement of plasma by BPL made immediately obvious the deficit in the budgets of the Blood Centres. This meant the NBA as a single

coordinating authority could then authorise alteration of handling charges for locally prepared blood products to overcome the shortfall in funding at the Blood Centres.

30. Please comment on the letter you wrote to BPL on 1 April 1993 [BPLL0005755] in which you state that 'every endeavour has been made in this region to make use of BPL products wherever possible'. Why was this?

231. The correspondence at [BPLL0005755] from March 1993 shows some frustrations with the supply from BPL. It consists of a letter from me to Ernie Gascoigne at BPL dated 24 March 1993, enclosing a letter from Dr Charles Hay, Consultant Haematologist at the Mersey Haemophilia Centre concerning the supply of Factor 8SM and asking if I have any idea why it had been turning up in 'dribs and drabs' over the last few months when BPL had denied that there was any problem with supply. By the 23rd of the month, Dr Hay had still only received 3/4 of the supply for the month. Fortunately, it was not causing a problem but if it had been a month of very heavy use it would be causing problems and it had resulted in their being late in sending their normal regular delivery of 8SM to North Wales, who were consequently running shorter of stock than they usually liked. He asked me to look into it. The letter was copied to David Watters at the Haemophilia Society.

232. On receipt of the letter, I wrote to Mr Gascoigne, enclosing a copy of Dr Hay's letter and commenting that, as he knew, I had made every effort to use BPL products wherever possible and it was most unfortunate that one of our best customers was experiencing difficulty in obtaining a supply from BPL. Our attempts at maintaining a stock locally had been difficult because of the intermittent nature of 8SM from BPL in the 500 iu size. I asked him to look into it and provide an explanation for the difficulties in supply over the previous six months. I added that he would be aware that the BPL contract was currently under consideration by the Drug Contracts Group

for the Mersey Regional Health Authority which was now being served by the North West Supplies Organisation.

233. There is also a letter from Dr Lorna Williamson, at the East Anglian BTC to Ernie Gascoigne dated 29 March 1993 noting that they seemed to be having difficulties with supplies of High Purity Factor VIII 500 iu vial which had resulted in receiving three different batches in the last four weeks. She refers to having discussed batch allocation at her last visit, but that they seemed to be moving in somewhat the opposite direction. She encloses a report setting out in detail the problems experienced.

234. The reason I recommended BPL coagulation factor concentrate was because I considered it was a better product . I preferred the NHS product because it was from a voluntary British donor source and it was virally inactivated – first by heat treatment and then by solvent detergent treatment. Voluntary donors were considered to be much safer from the point of view of the risk of transfusion transmitted infection compared to paid donors as they had no incentive to hide any medical issues. British blood donors are altruistic and considered far less likely to present a risk of passing on blood borne infections. Although the British plasma product was preferred by our local clinicians, unfortunately the frustration was that the supply was unpredictable from BPL month to month and that there was not enough because of a series of batch failures there.

31. Please refer to the letter cc'd to you, written by R Walker of BPL to Mr Canavan at the Department of Health dated 18 June 1992 [DHSC0004529_048]. BPL suggests that the requirements to test blood products had caused a problem because it identified infected product whilst almost every manufacturer was 'including donations which if re-tested would contain donations positive for HCV but their procedures do not include re-testing, retrospective advice etc.'

a. Did you consider BPL's response to this incident to be appropriate?

235. It is difficult to comment without seeing further documents and fully understanding what had happened as BPL insisted that there was no safety issue and by this time all products were virally inactivated.

236. When Hepatitis C antibody screening was introduced in 1991 the instruction from the Department of Health was that any blood product issued from a Blood Centre from 1 September 19991 must be screened for antibodies to HCV and found negative.

237. Therefore, everything issued from the Blood Centre was negative for antibodies to HCV from that date. This included platelets, which expire after 5 days, red cells, which expire after 35 days, and fresh frozen plasma which had a much longer shelf life (up to 18 months). We had to be sure that everything that was frozen and not expired had been tested and was negative before it could be issued from the Liverpool Blood Centre. This included testing in advance of issues all existing stock that had been collected before 1st September 1991. This took some time but we tested everything for HCV antibodies in advance of the relevant date and made sure that everything issued after that date was negative for Hepatitis C.

b. Did you agree with the views expressed about the amount of infected product on the market? If so, what steps, if any, did you take to address this?

238. The "problem" described in this letter [DHSC0004529_048], appears to refer to testing causing a supply shortage. It goes on to say that ... *In our opinion the question of issue of product in the current circumstances is not adequately covered by the current guidelines and this is an issue we have to resolve with the MCA and CSM. It should however be recognized that almost certainly every manufacturer is still including donations which if re-tested would contain donations positive for HCV but their procedures do not include re-testing, retrospective advice etc.*'

239. I suspect the last sentence refers to practice in commercial fractionation of plasma components in which I have no expertise.

240. For example, a regular plasma donor who had donated until 1989 and had moved away may find that when they returned to donate in 92/93 after a gap they had been found to be HCV antibody positive. If this happened, their donation would be discarded immediately and the donor invited to discuss screening results once these had been confirmed following further investigation at the Public Health Laboratory.

241. The donor would be informed after confirmatory testing, withdrawn permanently from further donation and referred to a hepatologist for expert advice. We would then check we had no stored plasma locally and inform BPL just in case they still had plasma awaiting fractionation.

242. It is difficult to remember individual donors as we did not do a routine comprehensive look back on HCV positive donors until 1995. We would not have issued product from an HCV antibody positive donor. We would know from all the samples when they first tested positive – ie between which donations they had sero-converted.

32. Did MNWRTC have a relationship with any other laboratory fractionating or processing its donations? If so, please describe that relationship.

243. Not that I was aware of. It would only have been BPL and possibly PFL in Scotland.

33. Did MNWRTC enter into contracts for the purchase of blood or blood products with commercial organisations? If so:

a. What were the circumstances in which this would occur?

244. I cannot remember requesting product from PFL but did not contract with commercial providers outside the NHS for coagulation factor concentrates

as I was working at the Blood Centre without responsibility for the direct patient care of those with haemophilia so this would have been done by the Haemophilia Centre Director at the Royal Liverpool Hospital at the time.

b. Which companies did Manchester RTC contract with and for what?

245. As per my response to question 32, only BPL and Scotland (PFL) that I was aware of.

c. How frequently did this occur?

246. As per my response to question 33(a), I did not contract with commercial providers outside the NHS for coagulation factor concentrates as this would have been done by the Haemophilia Centre Director in Liverpool at the time.

34. Please describe the nature of MNWRTC's relationship with the haemophilia centres that it supplied and with UKHCDO. The Inquiry has seen some minutes of the North West Supra Regional Haemophilia meeting which you attended [e.g NHBT0094580]. Please explain the purpose of these meetings. Did they occur annually? Were they useful?

247. The supra regional meetings were meetings between consultant colleagues at the Transfusion Centres and the Consultant Haematologists working in the Haemophilia Centres within the greater North West Region as I recall which would have included Manchester, Lancaster, Blackburn and Liverpool. In 1986 I was still working in Manchester. They were to discuss issues of importance for patients with bleeding disorders which were not addressed elsewhere eg at the twice yearly meetings of Consultant Haematologists in the North West Region (a larger less specialised group) and to provide appropriate liaison. The minutes in document [NHBT0094580] are from a meeting on 8 April 1986. I was a relatively junior consultant at the time and cannot now recall the frequency

of the meetings. The minutes themselves suggest that they would occur annually.

248. As the minutes' record, the discussion covered various issues including the Liverpool and Manchester experience of AIDS as well as supplies of NHS Factor VIII and Factor IX. It is recorded that Dr Wensley thought that the North West Region had been restricted. In Manchester the ordering of Factor VIII and IX was now done by the Regional Supplies Officer who was new in the role. The Liverpool Haemophilia Centre ordered their own commercial concentrate but this was reimbursed from the District budget according to the patient's address. Dr Evans (a Paediatric Haemophilia doctor from Manchester) thought that a non-medical person should not be ordering as they knew nothing of clinical indications for prescribing the products and Dr Delamore, from Manchester Royal Infirmary agreed to discuss the problem with Dr Gunson at the Manchester Blood Centre. It is noted that the NHS was dependent on plasma production and that the Manchester plasmapheresis centre was on target to meet Elstree requirements in 1986 but that Liverpool was not being allowed any extension next year and would have to purchase supplies.

249. These North West Supra Regional Haemophilia meetings were useful. During this time, it was becoming apparent that patients with haemophilia had been contracting HIV (from treatment received prior to viral-inactivation) and it was very important to increase plasma procurement to enhance the availability of British voluntary donor plasma for fractionation. The local meetings also had in addition an educational session on bleeding disorders.

250. All the above comments refer to my attendance at such meetings whilst working in Manchester before November 1988. Whilst I was working in Liverpool subsequently I do not recall attending such meetings. I would consult directly with Dr Charles Hay who was Director of the CCC for Haemophilia in Liverpool at the time about the care of patients with bleeding disorders. I also endeavoured to increase our plasma yield to

secure as much NHS procured Factor VIII concentrate as possible from BPL for his patients and those of Dr Tom Korn who ran the Haemophilia Centre in Bangor. I arranged for a regional contract to supply NHS plasma products from BPL to Mersey Regional Health Authority to this end.

35. Please explain whether MNWRTC supplied particular products on a named patient basis and how this arrangement came about and the reasons for it.

251. MNWRTC only issued locally made products or those from other centres (not BPL) on a named patient basis on specific request from a clinician at a hospital. This would only happen occasionally, often as the result of our investigation of a patient with red cell antibodies or antibodies to transfused platelets.

252. Any named patient would have been related to donations we were testing and processing at the Blood Centre –red cells etc but not BPL licensed products for patients with haemophilia. The only product we issued on a named-patient basis was in bags (which means it was not concentrate).

253. I have given examples of this above in discussing the hospital services we supplied.

36. Please describe how individual hospitals physically obtained blood/blood products. Were they delivered by MNWRTC or directly from BPL or another third party, or both?

254. The blood components were prepared at the Blood Centre from local donations; red cells, cryoprecipitate and plasma would have been delivered by our transport from the Centre to hospital transfusion laboratories. We also delivered Factor VIII concentrate and Factor IX concentrate from BPL to some - the Haemophilia Centres at the Royal Liverpool Hospital, Alder Hey Hospital and Ysbyty Gwynedd as well as Human Albumin Solution, Anti-D Immunoglobulin and Intravenous Immunoglobulin to the majority of other hospitals in our area of supply. I

do not know whether hospitals also received anything directly from BPL. I do not know the position with regard to deliveries from third parties or commercial sources.

37. In what circumstances did hospitals and other clinical settings enter into a direct contact for the supply of blood or blood products from a commercial organisation rather than obtaining it from the RTC?

255. At the time, I was not involved in this so I cannot say how hospitals and those in other clinical settings procured it.

256. As far as I am aware, MNWRTC did not purchase commercial blood product.

257. As I have already said, I do recall that some clinicians considered that they needed more than one supplier because of potential batch failure. This is because if they relied on just one supplier who had a batch failure, they were at risk of having no supply at all for their patients for an indefinite period. Batch failures of coagulation factor concentrates were not uncommon at that time.

258. Commercial products were subject to batch failure too so PFL might have been an alternative source. I seem to remember that BPL had a batch failure of 9A or stopped making it for a little time and a suitable equivalent prepared from voluntary donor plasma was supplied from PFL in Edinburgh.

SECTION 4: MEETINGS OF REGIONAL TRANSFUSION CENTRE DIRECTORS AND THE EXECUTIVE COMMITTEE OF THE NATIONAL BLOOD AUTHORITY AND OTHER GROUPS

38. The Inquiry holds meeting minutes between the Directors of Regional Transfusion Centres ("RTCs") in the United Kingdom from approximately

1948 to 1989, some of which you attended in your capacity as Director of the MNWRTC. Who established these meetings? What was the purpose(s) of those meetings?

259. These meetings were established in 1948 before I was born.

260. I have heard that the system stems from the Second World War when the Emergency Medical Service was established and blood transfusion had been included in the latter. It is my understanding that it was considered to be a good thing for this to carry on in a more coordinated manner and the Regional Transfusion Centres were established after the war.

261. The purpose of the NBTS was to improve clinical care of transfusion recipients and promote blood donor care, make sure there was enough blood to go around, keep up to date with clinical developments and make changes as the science advanced. Each centre was funded by its local Regional Health Authority (RHA) which decided its spending priorities locally. Self-sufficiency in plasma is quite an abstract concept which had been recommended nationally in the 1970's and these meetings helped persuade RHA's to make the necessary money available amongst other competing health needs, to allow advances in transfusion medicine.

262. I have been given sight of a document [BPLL0004826] which refers to the fact that from 1948 to 1978 the consultant advisor in blood transfusion was to chair ten meetings each year of the Directors of the regional transfusion centres. These were unofficial meetings but were attended by DHSS staff and were designed to formulate policy for implementation in the regional transfusion centres and to provide information for the consultant advisor. The blood product range was limited until the 1970s when it became apparent that a closer working relationship between regional transfusion centres and the central fractionating laboratories would be essential for continued development. The Regional Transfusion Directors' committee was reconstituted in 1980 and was chaired by an elected representative. One of the principal functions of the RTD committee had been to set up

working parties to examine the scope for new developments and any problems likely to be associated with them.

39. Please explain, as far as you are able:

a. Whether the RTC directors meet in a decision-making capacity or otherwise?

263. Yes, the RTC directors did agree things and made clinical decisions. However, they each received their funding from a different regional source.

b. Were the RTC directors empowered to make collective decisions that affected the policies and procedures of all RTCs? If yes, please describe the decision-making process.

264. The RTC Directors would attend the meetings and have a discussion and the Directors would decide what their position was. Sometimes there was agreement and sometimes there was not, but usually a clinical consensus was reached in the end. This advice would then be provided to the Department of Health ("DoH").

265. Sometimes the advice was accepted by DoH and then central money might be provided for it via the regional route but sometimes it was not accepted. There were some things that RTCs could do operationally, but a policy change or anything requiring major funding usually required DoH support. Before the National Directorate was set up, this funding was distributed to Blood Centres via their RHA.

266. If DoH did not commit centrally funded money, each local Transfusion Director had to go to their RHA to make the case for additional funding locally. The RHA's would give central money sometimes ring-fenced to transfusion centres to do something like HIV testing, but not always.

267. An example is the cost of introducing HCV testing. The need for this was accepted by the Department of Health and it became national policy, but it was not nationally funded. I have been given sight of document NHBT0000193_084 which is a letter from me dated 4 December 1991 to Dr Gunson responding to his enquiry about funding for screening for Anti HCV Testing. In this letter I advise that the Mersey region had funded this in full in 1991/92 and would fund 75% in 1992/93. The remainder of the cost would be obtained from products issued to Welsh hospitals.

268. This change was made in response to an agreement between Treasurers at the Department of Health and in the Welsh office that the funding for health care in Wales would be provided from within the Principality.

269. The RTD meetings did effect changes that affected the policies and procedures of all RTC's. For example, after the Gulf War the military hospitals were multi-national and it became apparent that different countries had differing choice of coloured labels for various blood groups which could have serious clinical consequences in a combined international field hospital. There was an international agreement to label them in the same way and this was agreed internally in the UK by the RTD mechanism. As this was not unduly expensive, the RTCs could do this without Department of Health approval and funding.

270. We also internally altered our Rhesus blood grouping nomenclature in the UK to describe any Rh(D) negative red cells as Rh negative rather than Rh CDE negative cells as they were known previously. This was a coordinated RTD UK agreed change designed to increase supplies of Rh (D) negative blood which was in particularly short supply in the South of England.

271. There were other professional organisations providing evidence to support the decision making process – the British Blood Transfusion Society (BBTS) which formed around 1982-84 – had an annual scientific meeting.

They also set up a journal "Transfusion Medicine". There was an International Society of Blood Transfusion (ISBT) and American Association of Blood Banks (AABB) and the American publication was "Vox Sanguinis" so there was a specialty growing and the journals would support and share developments at the time. Further specialist advice was also sought from experts in transfusion-transmitted infection including virologists, hepatologists and physicians treating infectious diseases as required.

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

272. I think they did the best they could have done within the constraints of the time. Uniform clinical decisions were made and steps taken to try to implement them, even though they were not always funded. This did help improve clinical care of transfusion recipients and promote donor care, and help make sure there was enough blood to go around. The meetings were also helpful in keeping up to date on clinical developments and making changes as the science advanced.

41. The documents the Inquiry holds indicate that the last of these meetings took place on 18 January 1989. A copy of the minute from the last meeting is attached [NHBT0018188]. According to the minutes, you asked what the legal position was of a donor found to be HIV positive:

a. Can you explain what you meant by that question?

273. According to the minutes in document [NHSBT0018188], Dr Gunson commented that SNBTS were looking at the possibility of recruiting donors from the age of 17 years (and technically still minors). I am noted to have: "referred to problems of confidentiality relating to sexually transmitted diseases if donors under the age of 18 are recruited. It was agreed that this matter might require further thought".

274. There was frequent discussion about collecting blood from the elderly or the young to boost donor numbers and blood supplies. There was longstanding legislation about the right to be treated confidentially for sexually transmitted diseases and that came to apply to HIV.

275. I believe that I would have been referring to the legislation around that and treating donors under the age of 18 as adults. In particular, I would have been thinking of donor selection and about the information before donating that we give about testing for HIV before obtaining their written consent pre-donation.

276. For example, when HIV screening was introduced, written consent was required and the form was amended accordingly to include being tested for HIV. Therefore, I believe I might have been querying whether children could validly sign this form at age 17.

b. The minutes do not record any discussion in response to that question, can you recall whether there was such a discussion and if so what was said?

277. I cannot recall any particular discussion around this but I note that I stated it required more thought so there may have been a discussion but no decision made.

42. The minutes also note that "there was no discussion of the advantages and disadvantages of dissolving the RTD meetings". As far as you are aware, was there a reason that this discussion did not take place? What were, in your view, the advantages and disadvantages of this decision?

278. There was a discussion regarding whether the RTD meetings should be discontinued which was summarized by Dr Wagstaff and this is recorded in section 4(a) of the notes of the meeting on 18 January 1989 [NHBT0018188].

279. In short, the reason why the meetings were dissolved was to do with a restructuring that occurred. In particular, the National Management Committee of the NBTS was established in 1988. This was embraced as it was funded directly. The National Management Committee met for the first time on 2 December 1988. The last RTD meeting was on 18 January 1989. As a result, neither the National Directorate Meetings nor regular RTD meetings in isolation were needed any more.

280. The minutes note that the meeting discussed Dr Gunson's proposals and the need for change. Even after the RTD meetings were dissolved, there were noted to be three other avenues to discuss with the Department of Health. In addition, there were:

- National management meetings.
- Liaison committee CBLA (Central Blood Laboratory Authority – the administrative body of BPL - and NBS.
- Consultants met in their three Divisions – as they had access to the notes of the National Management Meetings and they continued to hold these meetings and to make their contribution as before.

281. The three divisions would meet 3-4 weeks after the National Management Committee meeting to provide clinical input into the next meeting. Divisions would get minutes from the national meetings in advance.

282. There were three or four consultants in each centre and several centres in each of the three divisions. As the Northern Division included Liverpool, Manchester, Lancaster, Sheffield, Leeds and Newcastle, up to 20 consultants would be talking about this and giving their views just from the Northern Zone.

283. I think there was provision for more clinical views as a result of the restructuring.

284. If they were going to include more management items in the national management meeting – performance reviews and administration etc, then it was unnecessary for clinical colleagues to hear all the management details; they could look at the management report and add their clinical direction.

43. In his witness statement for the *A v Other* litigation, Dr Gunson discussed the creation of the National Directorate to oversee the work of RTCs, although, he noted that the Directorate "did not have executive authority and its successes came about by persuasion" [NHBT0000025_001]. What are your views on the success or otherwise of the National Directorate?

285. I agree with Dr Gunson's statement that the directorate did not have executive authority and its successes came about by persuasion as he sets out in document [NHBT0000025_001]. Their purpose was to retain management of RTCs by RHAs but with formal coordination of their work. The RTCs remained the primary responsibility of the RHAs. There were difficulties when proposals from the National Directorate requested a policy change requiring national resource and this had to be found from the budgets of the various RHAs. In the absence of additional funding from the RHA, the RTCs were restricted in following developments of the service recommended by the National Directorate. I agree with Dr Gunson that there were some successes including the inter-regional transfer of blood; establishment of a management information system; quality assurance at RTCs, together with audits and improved blood donor recruitment and retention.

44. Please explain, as far as you are able, why these meetings ceased and whether they were replaced with another forum with which RTC Directors could communicate. Was this the executive committee of the National Blood Authority?

286. On 1 April 1993 the DoH announced its intention to establish a single authority - The National Blood Authority (NBA) with responsibility for

both the Central Laboratories and the RTCs as Dr Gunson sets out in document [NHBT0000025_001].

287. The National Blood Authority superseded the National Directorate in 1993. The Executive Committee of the National Blood Authority was established to meet every month with John Adey as its Chief Executive and a headquarters in Watford.

288. After the Divisions were discontinued in 1993 by the NBA, we went back to meeting RTD colleagues monthly at NBA Executive Committees. We went to Watford for a meeting, dinner and stayed overnight for more meetings the next day. These were largely concerned with a review of the service steered by Bain and Co.

289. The majority of RTC Directors at that time were medically qualified but one or two were not.

290. After the review which was organised by Bain and Co and reported in the summer of 1994, the NBA was divided subsequently into three Zones each with an Executive Director, thereby simplifying the reporting mechanism to the Chief Executive. Each Zone also had a Medical Director who managed the consultants across the Zone and who subsequently met on a regular basis. As far as I can recall the new Northern Zone covered the geographical area of the former Northern Division.

45. What was the purpose of the meetings of the executive committee of the NBA? Were those meetings conducive to meeting that purpose in your view?

291. I have had sight of a document [BPLL0004826] which suggests that the central committee for the National Blood Transfusion Service was set up to consider whether any change should be made in the present organisation of the blood transfusion services in England and Wales and to make recommendations.

292. This accords with my recollection; these meetings were concerned with moves to streamline the service.

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

293. Please see my response to question 44.

47. The Inquiry holds minutes of the meeting of the Northern Division of BTS consultants, which you attended. What was the purpose of these meetings?

294. I attended these meetings regularly. Northern Divisional Consultants met at different Blood Centres before 1989. The management arrangements changed with the formation of the National Directorate in 1988 but the consultant meetings continued to advise the National Management Board.

295. After the reorganisation in 1995 the NBS was divided into 3 zones roughly equivalent to the previous geographical divisions. In the Northern Zone there was a Chief Executive, Medical Director and there was someone dealing with Finance. I was the Donor Services Manager for the first 12 months during 1996, but the consultants continued to meet in a zonal group to continue to provide clinical advice.

296. The purpose of these meetings was to centralise functions of Blood Centres in order to achieve a common high standard of practice and to gain economies of scale.

297. I have seen copies of minutes of the meeting of Northern Zone Board held at NBS Leeds on Wednesday 12 June 1996 [NHBT0036440] which include under the subject of 'Donor Services – Blood Stocks and Collection' that I gave a presentation on the blood collection plans for 1996/7 in the North of England.

298. Short term plans included increasing blood stocks by: - extending collection times; reducing the interval for donation to 17 weeks; sending reminders to lapsed donors as well as to those who had missed the last donation only; centralisation of blood stock control at Newcastle; setting up additional sessions; giving donors a choice of sessions.

299. Medium term plans included: - increasing flexibility between apheresis and blood donation; facilitating early return of donors after failed venepuncture; the assimilation of the extra statutory holidays.

300. Long term plans included: - producing an annual programme linked to the business plan but adjusted for seasonal trends; extending collection times when locality teams were introduced; raising the local media profile; lowering the minimum donor age (although this is annotated in hand-writing – 'how are we going to do this?') and implementing the NBA PR strategy.

48. The Inquiry holds minutes of the NBS Donor Service Functional Working Group which show that you attended some of those meetings. What was the purpose of these meetings? Were those meetings conducive to meeting that purpose in your view?

301. I was the Donor Services Manager for the north of England in 1996 and I was also responsible for response to donor complaints. I believe this was a national group which coordinated marketing campaigns for donor selection. Its purpose was to increase blood collection by recruiting and retaining donors and to ensure there was a national approach to it. I refer to my comments above on this point. It was then a truly national service with an appropriate budget making it possible to coordinate national campaigns to cover times of anticipated shortage such as Bank Holidays etc. The national budget would allow this where previously a number of smaller regional ones may not have done.

302. Another major clinical development around that time was to agree on a single national clinical handbook for donor selection.

SECTION 5: REGIONAL TRANSFUSION CENTRE'S KNOWLEDGE OF AND RESPONSE TO RISK

General

49. When you began work as a Haematologist at Manchester RTC, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge?

303. Throughout my career, I have always believed and taught that "blood is filthy stuff." We need to use it to save lives but it is not without risk and must be used appropriately.

304. From the moment I qualified I would use risk/benefit analysis when approaching my work. As I was in the transfusion service, I was acutely aware that blood transfusion is risky treatment so I always gave consideration to the risks involved in any particular action I took.

305. I began working as a senior registrar in Haematology in January 1980. I was aware of the risk of infection associated with blood and blood products.

306. At that time, I understood that Britain had healthy voluntary blood donors who were screened and who did not receive payment for blood and, therefore, had nothing to gain from blood donation. In contrast, in America in the late 1970s – donors could be paid for blood which meant that the blood could have been collected from individuals who were very short of money including prostitutes, drug addicts and from those detained in prisons who were in high risk groups.

307. Initially I was based at North Manchester General Hospital.

308. In 1981 I worked at Manchester Royal Infirmary (MRI) which was the first time I learned to care for patients with bleeding disorders as a trainee specialist at the Haemophilia Centre.

309. In 1982 I did a split job in Transfusion Medicine and Paediatrics. I was based at the North West Regional Transfusion Centre from January to April 1982, as a Senior Registrar and then from September to December 1982. I worked in Paediatrics with Dr David Evans at the Royal Manchester Children's Hospital from May to August 1982 where I learned a lot more about the care of haemophilia in children. I became increasingly aware of the risk of transfusion-transmitted infection associated with the use of commercial coagulation factor concentrates prepared from plasma collected from paid /or non-voluntary donors from overseas.

310. I then returned to working at MRI in 1983. I was doing standard training towards MRCPath sitting the written paper in October 1982 and passed the follow up practical examination in May 1983. During this time, I was doing a lot of reading in preparation for my forthcoming examinations. I was informed by my colleagues and as part of my academic training about the risks of infection associated with blood and blood products as more evidence became available and noted the good practice at the Children's Hospital of trying to avoid preparation from pooled plasma and to prescribe only British plasma products wherever possible in order to minimise the risk of infection.

311. Richard Wensley had already informed me in 1981 that the great majority of patients would contract Non-A, Non-B hepatitis on receiving their first dose of coagulation factor concentrate. This would be demonstrated by elevated serum transaminases and that only a small proportion of them would develop clinical jaundice. I understood from him that it was usually sub-clinical in the patients concerned after treatment.

312. I recall in 1982 that routine screening of donations included tests for syphilis and Hepatitis B. Hepatitis A was recognised to be transmitted via the faeco-oral route rather than in serum, although subsequently terminal filtration steps have been added by fractionation centres to reduce the potential risk of transmission of Hepatitis A which is not a lipid enveloped virus.

313. I also understood that both Non A Non B hepatitis and bacterial infections could be potentially transmitted in blood. I was aware that the risk of getting an infection with Non A Non B hepatitis increased with the number of donor exposures.

314. Whereas blood is given pint by pint, factor concentrate was prepared from a large donor pool of the order of 5,000 to 10,000 donations. I was aware that this, therefore, carried a much greater risk of viral transmission, mainly of Non A Non B hepatitis. I was not aware that it could transmit HTLVIII latterly known as HIV at that time.

a. The risk of contracting non-A non B hepatitis from some types of Factor VIII concentrate was considerable – probably in excess of 95% in the early 1980s. These facts must have been recognized by the early 1980s when plans were laid to develop the 8Y process to produce factor VIII concentrate from pools of plasma from voluntary UK donors in order to eliminate the risk of Non A non B hepatitis transmitted in blood products. Whatever the consequences of non A non B hepatitis, the transfusion service would always plan to eliminate any potential transfusion transmitted infection and a small number of factor VIII recipients did develop an acute hepatitis with jaundice following initial exposure as well as having elevated liver enzymes

315. I was relatively junior at this time, but in terms of the general state of knowledge within the blood service and specifically the position in relation to viral inactivation, I have recently seen a document [NHBT0017102] which is a report on a Council of Europe meeting in Lisbon held on 16-19

May 1983 prepared by Dr Gunson. This relates to a meeting of the Committee of Experts on Blood Transfusion and Immunohaematology and discusses the control of transfusion associated hepatitis. It discusses surrogate testing and also 'Safety of Products'. It notes that transmission of hepatitis has been the principal cause of concern following transfusion of fractionated blood products, particularly with coagulation factor concentrates including fibrinogen. Since there were several infective agents and definitive diagnostic tests were not available for each agent, efforts to eliminate, or at least reduce hepatitis had had, of necessity to encompass several approaches:

(i) Exclusion of the infectious agents from the source of plasma

Tests for the detection of HBsAg had been undertaken for about a decade with increasing sensitivity and with the third generation tests (ELISA, RIA) it was possible to exclude the great majority of plasma donations with potential Hepatitis B infectivity. Some donations within pools might still contain the virus with an antigen concentration below the level of detection. It continues that whilst the disease had not been completely eliminated in haemophiliacs' Factor VIII concentrates, the incidence of the disease was reduced.

No definitive test for NANB hepatitis had yet been found and non-specific screening tests did not seem to be the answer. Plasmapheresis could be used to prepare small pools of plasma, but I understood that this was impractical for large-scale fractionation processes at BPL. I had no personal expertise in fractionation on the industrial scale but understood there was better product yield starting from a larger volume of plasma.

It notes that the use of small pool or individual donations of cryoprecipitate should be borne in mind as a means of reducing transmission of hepatitis in patients who required infrequent treatment such as those with mild haemophilia.

(ii) Removal of Virus by Selective fractionation

Using HBsAg as the marker it had been possible to show that several fractionation procedures may reduce the concentration of the virus in the final product: polyethylene glycol in the preparation of Factor IX had been shown to reduce the concentration of HBsAg considerably but with concomitant loss of yield; the use of specific absorbents for the protein, also with concomitant loss of yield.

(iii) Neutralisation of the virus – by adding hepatitis B immunoglobulin – a potentially attractive method to increase the safety of products but it was questionable whether it would eliminate the transmission of NANB hepatitis; active immunisation with Hepatitis B vaccine was a possibility but would not prevent transmission of other forms of hepatitis.

(iv) Inactivation of the virus by physico-chemical means:

(a) – Use of pasteurisation. It had been recognised for many years that heating for 10 hours at 60 degrees would destroy the hepatitis virus and this method had been used successfully for human albumin solutions and other preparations. It had recently been claimed that Factor VIII preparations could be similarly pasteurised in the presence of protective agents such as sugars, although at considerable expense in terms of yield. There was also the possible use of heat to treat the dried product. Such methods still required evaluation, not only with respect to their non-infectivity but also with respect to the possible denaturation of proteins and practicality in terms of the yield of the final product.

(b) Chemical Treatment with virucidal agents had also been examined. The substance used however (B-propriolactone) was carcinogenic and may result in undesirable side-effects. Other virucidal agents and agents to disrupt viruses were being examined and could be potentially useful.

316. The paper concludes that there was considerable interest in both the USA and Europe in the preparation of safe products and that it was indicative

from the number of avenues being pursued that an ideal solution had not been found. The difficulties in conducting trials to establish safety are also mentioned – that there would not be enough chimpanzees, so direct clinical trials might be indicated, having first established the safety of the product.

50. How did your knowledge and understanding develop over time?

317. In 1981 I appreciated the risks of catching hepatitis for patients with haemophilia from factor concentrate. However, it was not at all clear that AIDS was caused by an infectious agent in 1981 although the clustering and spread of the first described cases did suggest that infection might be a likely pathogenic source.

318. I recall sometime in 1981/1982 I performed a bone marrow procedure on a young man with an enlarged lymph node in his neck at the request of a colleague who had read an article in the New England Journal about some young men in San Francisco with acquired immune deficiency syndrome (AIDS). I think the lymph node was reported as reactive but that would not have been diagnostic at that time some years before characterisation of the virus and its diagnostic tests.

319. Document [NHBT0018153], a copy of which has been provided to me by the Inquiry, dated November 1989, notes that consideration was given to use of heat treated Factor VIII and IX, certainly by 1982 and that at that time, heat treatment was planned to eradicate NANB hepatitis. The earliest work on heat treatment of Factor VIII concentrate was reported from Texas and presented at the combined meeting of the International Society of Blood Transfusion with the International Society of Haematology at their congress in 1982. The document, that is reasonably close to these events – at least in the same decade, also notes that the first report of multi-transfused patients acquiring immunodeficiency was reported in the Lancet in 1983; indicating that at that time the virus had not been identified and that it was possible that some suspicion had been roused in the United

States in 1982 but that we did not believe that this was prominent in the United Kingdom at that time. This document was the Mersey and North Wales RTC 'Response to Questionnaire Litigation Update', I think responding to the HIV litigation. It would have reflected the combined views of the Consultants at the Liverpool Blood Centre as I had only moved from Manchester to Liverpool in December 1988.

320. In 1982/83 I was going on courses and studying for MRCPath examinations. I was reading as much as possible. Once appointed in 1984 I was attending scientific meetings, reading the journals and I had the advantage of working with Dr Harold Gunson. He was always coming back from meetings - often international – and would discuss the dilemmas and the strategy and timing of introducing HIV donor screening. He told me that the Americans considered that we had the time and opportunity to get it right in the UK and avoid the mistakes which they considered that they had made with the introduction of screening of blood donors at an inappropriately early stage in the United States late in 1984.

321. I cannot recall exactly when the potential for transfusion transmission of AIDs was first discussed.

322. By 1983 most people thought AIDS was an infection but the virus was not identified until the summer of 1984 so we were focusing on high-risk behaviour as a means of trying to prevent those who might be present a risk of transmission from donating. It looked as if AIDS could be transmitted by blood so initially we asked individuals in high risk groups such as homosexuals to self-exclude and then later travellers to sub-Saharan Africa.

323. By the end of 1984, following the identification of the virus in August, HIV had taken priority in the planning for safety of blood and plasma. The other side of the coin was that the threat of HIV sped up the response to NANBH in the field of plasma fractionation as they are both lipid-enveloped viruses and were therefore susceptible to viral inactivation by

heat treatment and solvent detergent treatment. We had very few cases of post-transfusion NANB – we were investigating those, doing anti-core and asking them to stop donating. Virucidal processes had been looked at, but it was fortuitous that what worked for HIV covered NANB.

324. When it was discovered that HIV was lipid-enveloped it was realised that processes planned to eliminate Non A Non B hepatitis would effectively eliminate HIV by the same method. In August 1984, it was confirmed that there was an antibody test for HTLVIII (later HIV).

325. American specialists in transfusion medicine had advised us to "get it right before" we introduced routine HIV antibody screening of blood donors in the UK based on the problems they had experienced in the US. The advice from the virologists was that we should have 3 independent confirmatory tests before the donor was informed of a positive result.

326. The tests in the USA had been found to have a very high false positive rate. In principle, a donor could be told "you have tested positive on this, it is not a definite but for the moment we need you to take these precautions", but our American colleagues warned us that blood donors had committed suicide having been informed of false positive results in the absence of confirmatory testing.

327. It was really important to avoid false positive results because of the enormity of the implications for people's lives; not just in terms of the disease, but even where there was a positive screening result which was not confirmed by the PHLS and so turned out to be false, there were still insurance implications at the time. For instance, people with HIV could not get life insurance so they could not get a mortgage for a house.

328. Whilst the confirmatory testing was ongoing, no further donation would be used from that donor so the blood supply and recipients were protected.

329. Donor screening for HIV was introduced in the UK on 14th October 1985. We performed an HIV look back exercise for all positive donors from the outset after the introduction of routine HIV donor screening and then referred the donor and any previously infected recipients for specialist advice. All blood products in frozen storage were screened for HIV antibodies before 14th October 1985 to ensure all existing stock had been tested in advance. This meant that everything issued from 14 October 1985 was HIV antibody negative, even if collected before testing started.

330. We needed to have informed written consent to blood donation, confirming that the donors understood their blood would be tested for a number of organisms including for HIV and that they would be told if the result was positive. It was not an option not to be informed, so if they did not sign consent to this their donation was declined.

331. An example of such an agreement can be seen on page two of document [NHBT0004253] dated 5 August 1985 which has the subject 'Anti-HTLVIII testing of Plasma Donors. Dr Gunson had asked me to arrange testing of plasma donors to assist the evaluation of kits prepared for use with the Transfusion Service. This document is a memo to those who would be involved, including the other consultants. It notes that it would be necessary to advise donors that their blood was being tested in this way and I enclosed a copy of the new NBTS 110 which had been amended for this purpose, the use of which was to commence on 12 August. All apheresis donors should be asked to sign the form from that date and an extra 10ml of blood would be taken for that purpose. The attached form 'To Blood Donors' states: *'Please read the leaflet explaining about A.I.D.S. All Blood donations will be tested for the A.I.D.S. antibody and other infections. If your donation reveals a positive result, you will be asked to attend for further confirmatory tests. Please sign below to show that you have read this notice and that you agree your blood is tested. Signed….. Dated….'*

332. I set up the Apheresis Service and the new Regional Apheresis Centre was opened in Manchester in 1985 because of the recognition that British plasma was best to provide the raw material for fractionation at BPL. That was being done in other UK blood centres.

333. The DoH agreed to fund heat treated factor VIII concentrate from the mid 1980's at increased expense as the yield of Factor VIII goes down after viral inactivation, so treatment costs more. One of the most important messages identified at the HIV symposium in May 1983 that Dr Gunson reported back (see below) apart from donor selection was that you must only prescribe blood or blood products when there is no alternative. Colleagues were also spending a lot of time developing autologous transfusion by various methods in the 1980s because everyone was concerned to avoid transmitting HIV. Autologous transfusion was never practised on a large scale but the good practice of peri-operative cell salvage continues to the present day.

334. I have been shown a document [DHSC0001655] – which I would not have seen at the time - which is a 'Council of Europe Committee of Experts on Blood Transfusion and Immunohaematology Informal report' by Dr Gunson on the proceedings of the 6th meeting, held in Lisbon, 16th-19th May 1983. The issues addressed include AIDS, which is referred to as a newly-observed syndrome. The significance of AIDS to the Committee was noted to be in relation to its effects regarding blood and blood products, particularly with the coagulation factor concentrates given to patients suffering from haemophilia. It notes that absolute proof that AIDS was caused by an infectious, transmissible agent was not available, but the consensus in the Committee was that it should be regarded as such and that a recommendation should be made to the Council of Ministers at the meeting in June to take the necessary steps to minimise the transmission of AIDS by the transfusion of blood products. Since there was no specific test that could be used to detect potential carriers, the recommendations had to be general and were as follows:

(i) *'To avoid the use of coagulation factors prepared from large plasma pools except when such product is specifically indicated for medical reasons; this is especially important for those countries where self-sufficiency has not been achieved;*

(ii) *To inform physicians and selected recipients, such as haemophiliacs of the potential health hazards of haemotherapy and the possibility of minimising these risks;*

(iii) *To provide all donors with information on AIDS so that those in high-risk groups will refrain from donating (an example will be attached of the American Red Cross leaflet on this subject).*

(iv) *To pursue rapid and full implementation of the recommendations in R (80)5 and R (81) 14. These refer to the need to attain self-sufficiency in blood product production, national services from voluntary non-remunerated donors and the risks entailed from importation of foreign plasma products respectively.'*

335. The report notes that with respect to recommendation (iv), England and Wales were in the process of implementation with the rebuilding of the Blood Products Laboratory, but this would not be an effective production unit until 1986. To fully implement (i), small pools, would cause logistical and possibly also practical problems with respect to the capacity of BPL to produce such material. Freeze-dried cryoprecipitate was a standard product in many European countries but was prepared in centres which did not have regulatory authorities controlling good manufacturing processes to the same degree as in the UK. The claims for higher yields were not as impressive when there were quality control tests on each batch prepared from pools of 8-10 litres of plasma.

336. With respect to the importation of plasma products from the USA, Dr Gunson noted that he found it difficult to believe that these could be phased out in the near future, since the Haemophilia Directors had always maintained that they required up to 100% more Factor VIII for the treatment of haemophilia than could be produced by BPL. He added that no doubt views would be sought from CBLA on this.

337. Steps were in hand to attempt to reduce the risk of bleeding donors who may have AIDS by selective questioning before donation. Consideration had been given to a leaflet for this purpose and the consensus had been to put this on hold but it should perhaps now be revisited. This did happen and the leaflet was used from September 1983.

338. Dr Gunson concluded the report by saying that as would be evident from the above, the implications of AIDS in various aspects of blood transfusion practice kept appearing; it was undoubtedly an important disease with a high mortality rate that had attracted considerable publicity. Whilst it had not yet reached the proportions in Europe that it had in the USA, many members of the committee considered that we may be seeing the beginnings of a problem that might escalate 'if appropriate steps are not taken now'.

339. Blood use was also reduced by peri-operative cell salvage which came into theatre practice in the late 1980s although probably was not widely used until the 21st century. This procedure involves being connected to an apheresis machine which removes shed blood from the operative site, centrifuges it to remove tissue fragments and it is then transfused back intravenously after filtration in a closed circuit.

340. Pre-deposit autologous transfusion, which involves donating your own blood in advance of a procedure for subsequent transfusion back peri-operatively, was discredited when the SHOT Reports clearly demonstrated that most of the problems associated with transfusion were attributable to human error and this practice does not avoid that (as you could still be transfused with the wrong blood).

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

341. At Manchester RTC and MNWRTC we took expert advice from Consultant Virologists, many of whom were employed by the Public Health Laboratory Service and we followed the instructions given by the DoH. We attended many meetings as knowledge about transfusion-transmitted infections was advancing rapidly during the 1980's and 1990's. Harold Gunson was the specialist advisor on Transfusion Medicine to DoH for a long time. I understand that DoH also had health economists advising them, particularly when additional screening tests for markers of microbiological infections were being considered for blood donors.

342. From a local point of view, when new donor laboratory screening or selection criteria were recommended we then had to do what was required by DoH and had to make sure it happened at the right time. For instance, the donor selection criteria had to reflect the latest advice from the Department of Health, and they had other Expert Advisory Groups eg on AIDS – EAGA – which gave specialist advice.

343. The donor selection criteria used to change regularly – for instance malarial exclusion areas used to vary very frequently based on international information about local prevalence of the parasite.

344. When the Blood Centres had to implement new Departmental advice there would sometimes have been additional money allocated for this but the funds from the DoH would go first to the RHAs for distribution on to the RTCs. The distribution became a little more complicated after the Purchaser/Provider split introduced with the NHS Act in 1990.

345. The technical staff would have to go on training courses if new techniques were involved in the new screening tests. There was the British Blood Transfusion Society (BBTS) with an annual scientific meeting as well as the International Society of Blood Transfusion (ISBT) which provided continuing professional development for laboratory and medical staff.

346. Hospital colleagues were encouraged to report any untoward reactions to blood and blood components to the Blood Centre for further investigation and this would include suspected transfusion-transmitted infections.

347. On rare occasions when a product was issued which did not conform to the standard this would be discussed with the clinician who was going to prescribe it to make sure they understood what they were getting so they could take responsibility for unlicensed product. They would then advise the patient and should have made a note in the patient's records.

348. I have explained already my professional and managerial accountability.

349. We had discussions on important and emerging issues and reached consensus views in the RTD meetings, and later in zonal meetings of consultants when the structure and lines of accountability changed after the formation of the National Blood Authority.

Hepatitis

52. When you began work at Manchester RTC what was your knowledge and understanding of the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis) from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time? You may wish to refer to the document you wrote responding to questions arising in the HIV litigation in which you state that you appreciated the risk to haemophiliacs from blood product in 1981 (see page 9) [NHBT0018153].

350. Please see my answer to question 49 and 50.

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

351. My knowledge regarding Hepatitis developed over some years. It was a gradual process of learning

352. When I started my Senior Registrar training in 1980 I understood that hepatitis B could be transmitted by sexual intercourse and by blood transfusion, as I had learned as an undergraduate, but that screening had been introduced by the Blood Transfusion Service in the 1970's to exclude donors found positive for HBsAg. The majority of people with hepatitis B recover fully and many are asymptomatic at the time of their infection although a few become seriously ill and a small proportion remained long term carriers. Amongst the few who became seriously ill, it was possible for some to develop cirrhosis which placed them at increased risk of hepatocellular carcinoma, and that this caused more problems in populations where the prevalence was high – such as South East Asia.

353. It was recognised that there was also at least one other form of hepatitis which could be transmitted in blood known as Non A Non B hepatitis but at that time I knew nothing of its potential chronicity. Hepatitis A was known to be transmitted by contaminated food or water and is mainly transmitted faeco-orally, being common in childhood and it was not considered that its transmission was a potential risk of blood transfusion at that time.

354. In short, I understood that very occasionally Hepatitis A could make you very ill but the vast majority of infected people recovered and that Hepatitis B was often asymptomatic but could also prove unpleasant although the vast majority of patients with hepatitis B also recovered completely. A few people with hepatitis B would go on to get chronic hepatitis and hepatocellular cancer but for the majority in the UK who developed symptoms it was a nasty illness which you mostly got better from. Much hepatitis B was sub-clinical and it was not thought to go on to cause a lot of problems. In light of what I had been taught and knew regarding hepatitis A and B, one would not intuitively think that another

viral hepatitis – such as non A non B hepatitis – would be any more dangerous.

355. I remember being taught by Dr Wensley in 1981 about exposure to large pool plasma products causing a subclinical hepatitis referred to as non-A non B hepatitis with an elevated ALT although very few recipients developed clinical jaundice. I did not have any concept of the implications of chronic HCV infection then.

356. Dame Shelia Sherlock, was considered the expert in this area. In 1981 she was reporting Non A Non B hepatitis as mostly benign.

357. Knowledge of NANB emerged from expert studies during the 1980's and by the end of the decade a screening test for antibodies to hepatitis C became available from the Chiron Corporation. The full understanding of the potential severity of HCV followed a long path. From the late 1990's when we were able to treat people with haemophilia with HAART for HIV the true seriousness of HCV in patients with bleeding disorders was unmasked. A similar situation had occurred earlier with Crohn's Disease, the extent of which was not appreciated until TB was effectively dealt with by anti-microbial therapy as both conditions may cause inflammation of the alimentary tract.

358. Before this information became apparent, Hepatitis B was regarded as being the more serious transfusion-transmitted viral infection. In the early 1980s I had experience of a case of post-transfusion Hepatitis B which had occurred because the donor's chronic carrier state had not been detected by routine HBsAg testing and this is partly why I was keen to continue with testing for antibodies to Hepatitis B core, as discussed elsewhere.

359. In summary, I became increasingly aware during the 1980s that what became known as hepatitis C could cause chronic inflammation of the liver but it was some time before we understood fully what its long term consequences might be.

360. Once screening for antibodies to hepatitis C was introduced in 1991 it started to become even more apparent that only 20% clear the virus to be cured completely, the remaining 80% being at risk of developing cirrhosis and a smaller proportion of these may then present with hepatoma. Once this screening was available we were able to better understand hepatitis C but unfortunately clinical problems with HCV may often only become apparent 20 to 30 years after transfusion.

361. I have been given sight of document [GRAM0000028] which is a 1997 paper that suggests that over a 20 year period only 20% resolved and the other 80% developed chronic viraemia. Of those who developed chronic viraemia 80% went on to develop stable chronic liver disease and 20 % to develop progressive inflammatory, fibrotic liver disease and of those who developed cirrhosis, 75% resulted in a stable non-hepatitis death and 25% died as a result of the liver disease.

362. Therefore, it was not until the 1990s that I became fully aware of the very serious nature of chronic HCV and the fact that a lot of people died as a result of contracting it. This became increasingly apparent from the late 1990's when patients with haemophilia who were co-infected with HIV started on highly active anti-retroviral therapy (HAART) which restored their immunity and extended their life expectancy. Once the life-threatening diagnosis of HIV could be managed effectively, the severe clinical sequelae of chronic HCV as cirrhosis and hepatoma were evident amongst the community.

363. I recall Sheila Sherlock, saying that after the test for hepatitis C was found, she never really saw another case of "cryptogenic" cirrhosis thereafter.

364. It took a long time to develop any really effective anti-viral treatment for HCV and even when viral eradication is achieved, unfortunately pre-existing cirrhosis cannot be reversed so the risk of hepatocellular carcinoma remains.

365. There was a meeting in Scotland in August 1993 at which Geoffrey Dusheiko presented interferon as being a good treatment. However, a lot of people thought he was making unrealistic claims for it as it only worked for some people but it made many others feel awful. It was not licensed until late 1994, over a year after that meeting, and I believe the granting of its pharmaceutical licence for this indication prompted reconsideration of the HCV Lookback by the NBS.

366. Once there was some hope of treatment, in 1995 the DoH introduced the HCV Lookback in order to make it available to any previous recipients of blood products from donors found subsequently to be HCV antibody positive after 1st September 1995.

367. After really effective treatment for HIV came in 1997 and could suppress the virus and then very rapidly people with HIV got better, Hepatitis C took over as the main cause of death in co-infected patients with severe haemophilia.

368. The position in relation to Hepatitis C was not entirely clear until the end of the twentieth century. In 1996 – an article [by S Just, K Grau, J Georgsen, N Weis, S Cowan, K Groenback, H Krarup, P Christensen and the Danish HCV Lookback Group entitled Long-term follow-up among Danish transfusion recipients identified in the national hepatitis C lookback [PRSE0003043] concluded that that the natural history of hepatitis C infection was still debated and complications may develop decades after infection.

369. Now that there is effective treatment for many patients with haemophilia with transfusion transmitted HIV and no-one with haemophilia has so far been found to have vCJD, Hepatitis C is the biggest cause of continuing health concerns and cause of death for many and it is a tragedy that it was so poorly understood and that its serious effects were generally underestimated for so long. It was only fortuitous that because of AIDS far

greater efforts were made towards viral inactivation of fractionated plasma products and that the virucidal processes, including first heat treatment and subsequently solvent detergent treatment of plasma, ultimately proved to be effective against Hepatitis C, which like HIV has a lipid envelope. The subsequent introduction of recombinant coagulation factor concentrates eventually removed the risk of viral transmission from products derived from human plasma.

54. What, if any, enquiries and/or investigations were carried out at Manchester RTC and later at MNWRTC in respect of the risks of transmission of Hepatitis through blood donations? What was your involvement in these matters? What information was obtained as a result?

370. At Manchester RTC, I investigated cases of transfusion transmitted infections including Hepatitis B, HIV and non-A non-B hepatitis.

371. I performed the HIV Lookback in Manchester following the introduction of routine donor screening on October 14th 1985.

372. I also undertook the Hepatitis C look back in Liverpool in 1995. This followed on from the recommendations of the ad hoc group meeting in August 1994 and was formally launched by the CMO with the agreement of Ministers in the first half of 1995.

373. A relevant document the inquiry has is [HHFT0000002_002] which is a Letter dated 11/01/1995 from CMO's Office - Department of Health to All Directors of Public Health, Re: Hepatitis C and Blood Transfusion. Letter addressed as 'Dear Colleague' which discusses 3 attached documents: '1. A letter from Dr Metters about today's Government announcement of a 'look-back' study to identify recipients of blood transfusion who may have been infected with Hepatitis C, 2. Additional information for GPs, 3. Helpline Questions and Answers'.

374. When we did any lookback directed by DoH, they insisted that the prescribing clinician or the GP must be invited to approach the patient before a clinician from the Regional Blood Centre. Usually both treating hospital clinicians and GPs declined and the Transfusion Centre Consultants would see the recipients, arrange testing and onward referral. This meant that in practice the correspondence with those clinicians who had been directly involved with patients to assist in the process, usually merely delayed the process.

375. Occasionally a GP would say that the patient had died or was not in the right frame of mind to see us, because of age or terminal illness. In the majority of cases the recipients of infected blood donations were seen by NBS staff. We had gained experience of this in the HIV lookback exercise 10 years earlier.

376. From the introduction of HCV donor screening in September 1991, all products from a positive donor screen would be discarded and the donor sample would be sent to the virologist at the Public Health Laboratory for confirmatory testing before the donor was informed of the confirmed positive result. Following this the donor was permanently withdrawn from the panel and offered referral to see a specialist.

377. Educational sessions were arranged at hospitals, in undergraduate and postgraduate teaching and at regional specialty meetings. I would always advise colleagues that they must be able to justify their indication for prescribing transfusion as there was a small chance that the recipient could develop an infection from a blood transfusion, which might possibly only become apparent many years later. For instance, if someone had symptoms of jaundice or abnormal liver enzymes and they had had a blood transfusion, we would ask that they inform the Blood Centre. The cause of the jaundice on occasion might be multifactorial – for example after surgery on the biliary tract. This could be a complication of the surgery, but it could be from a transfusion and we needed to know so that

we could trace the donor and any other recipients after the date of seroconversion.

378. We encouraged clinicians who thought they had a patient who had an infection from blood transfusion to call us. We would impound any other blood components prepared from the donation they had received, test that blood and call the donor in for further blood test. I would have investigated all the cases referred in Manchester while I was there and some of those in Liverpool.

379. I would also have been asked by clinicians how to prescribe blood and to discuss the associated risks and I would provide them with advice in this respect.

HIV and AIDS

55. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and, in particular, the risks of transmission from blood and blood products during your time working at Manchester RTC.

380. Please see my response to question 49 and 50.

381. I was working at Manchester RTC for eight months as a trainee 1982 and from 1984 as a consultant.

382. It became increasingly apparent during 1983 that AIDS looked to have an infective cause. By 1984 it looked very like a virus but the HTLVIII antibody test was not published until August 1984 by Gallo.

56. How did your knowledge and understanding develop over the time you were working there?

383. Please see my response to question 50.

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

384. I believe I would have become aware that there might be an association between AIDs and the use of blood products at some point in 1983. This is qualified by the fact that once AIDS was realised to be connected to HIV, a newly identified retrovirus, it became clear that there was a risk of transmission.

385. I have been given sight of document [PRSE0001727] which is a letter dated 5 January 1984 from The Lord Glenarthur (Department of Health & Social Security) to Clive Jenkins, General Secretary, Association of Scientific Technical and Managerial Staffs which states:- " it remains the case that there is no conclusive evidence of the transmission of AIDS through blood products, although the circumstantial evidence is strong". This appears to suggest that this was the government position at the time although plans had been made to introduce donor information leaflets about activities considered to be associated with an increased risk of HIV at blood donor sessions late in 1983 to encourage implicated individuals to self-defer.

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

386. Please see my answer to question 54.

387. I did routine HIV look backs in Manchester from 1985.

Response to risk - screening and selection of donors

59. Did the individual RTCs have decision making powers as to the steps to be taken for the screening and selection of donors, or were they expected to take instruction or direction from the NBA or the Department of Health?

You may wish to refer to a letter from you to Dr Gunson dated 1 October 1991 where you set out the arrangements at your centre for the screening of donors and testing of donations [NHBT0000193_048].

388. The individual RTCS would receive direction from the NBA and DoH regarding donor screening and donor selection. Steps taken in the Mersey and North Wales Regional Transfusion Service were in line with national policy. The RTC's were given an opportunity to provide comments but the DoH had the final say.

389. The Transfusion Centre Directors collaborated for example in the Handbook already described [PRSE0003047] and in Guidelines for the Blood Transfusion Services in the United Kingdom, which ran to 200 pages and became the Red Book [NHBT0000013_001]. These were prepared jointly between the United Kingdom Blood Transfusion Services and the National Institute for Biological Standards and Control and consisted of three Volumes:

Volume 1 - Guidelines for blood components prepared at regional transfusion centres;
Volume 2 - Guidelines for the preparation of plasma fractions;
Volume 3 - Guidelines for reagents for blood group serology and HLA typing.

390. There were minimum requirements, but some RTCs did some things differently. For instance, the anti-HBc screening piloted in Liverpool for a time was not a requirement of DoH, but provided useful information about the detection of asymptomatic carriers of hepatitis B. This stopped following instruction from DoH to discontinue.

391. An example of the matters we would discuss is in NHBT0071759 minutes of a Meeting of the Northern Division of the National Blood Transfusion Service, dated 21 February 1991. Topics included: medical audit,

reorganisation of the NBTS, policy on donors between 65 and 70 years, AIDS leaflet, funding for Hepatitis C antibody screening.

392. The minutes note that this was the first time there was wide consultation within the BTS about the AIDS leaflet. Dr Wagstaff requested comments. These would be discussed by the blood components working group and proposals would be submitted to the EAGA. Following that they would be reworded in 'donor' language under the supervision of the National Directorate.

393. Donor selection criteria were agreed nationally by clinicians from Regional Transfusion Centres before any formal national organization in 1988, often taking advice from specialists in other fields where appropriate eg microbiologists, neurologists, hepatologists etc. The statement below set out by DHSS, places final responsibility for donor selection with the clinician at the collection session on the day, but it would be inadvisable for any practitioner to ignore the consensus view of colleagues:

394. [PRSE0003128] (undated)
Guidance compiled by the Department of Health and Social Security entitled Standards for the Collection and Processing of Blood and Blood Components and the Manufacture of Associated Sterile Fluids.

395. *Donors should be healthy persons of either sex and over 18 years of age and under 65. The removal of 420-440ml of blood from such healthy persons has in general no deleterious effect on health or resistance to disease and only temporary effect, rapidly recovered from on the circulation.*

396. *The decision whether a person is fit to give blood rests finally with the doctor who is ultimately responsible for the collection of blood.*

397. *Hazardous occupations – special note should be taken by the registered medical practitioner of the occupation and any hazardous hobbies the*

donor might engage in and arrangements made or advice offered as to the timing of donations to avoid increasing any hazard.

398. *The subject must, as far as can be ascertained after clinical and laboratory examination the study of his medical history be free from disease transmissible by blood transfusion and be in a state of health suitable for donation including: - anaemia, illicit drug taking, jaundice or hepatitis.*

399. The major laboratory screening initiatives - HIV antibody screening in October 1985 and HCV antibody screening in September 1991 were introduced on the basis of DoH approval, with additional funding and coordinated in England and Wales to start on the same day.

60. What decisions and actions were taken at Manchester RTC and MNWRTC and/or by you to select and/or screen the donor population so as to reduce the incidence of infections within donations? In particular:

a. What, if any, steps were taken to collect information about blood donors and screen blood donors so as to reduce the risk of the transmission of hepatitis and HIV/AIDS via blood and blood products? You may wish to refer to the document appended to the memo dated 5 August 1985, which provides a set of questions to donors presumably to assess the risk of HIV being present [NHBT0004253], and your memo dated 28 November 1986 to medical officers [NHBT0004481]. Could you also please explain the reasoning behind the approach set out in your memo dated 31 December 1984 [NHBT0092295]

400. I would follow current Department of Health instructions and guidance discussed in response to question 59 which would have been informed by advice from the blood services, through Dr Gunson and others including expert groups such as ACTTD/SACTTI, the ACVSB/MSBT and EAGA.

401. I have already described my memo relating to testing for HIV and the need to obtain written, informed consent to the test from donors before they

donated [NHBT0004253] and my memo of 31 December 1984 [NHBT0092295].

402. Document [NHBT0004481] dated 28 November 1986 provides a further example of a memo sent in line with the Department of Health guidance at the time. This follows the description of a second Acquired Immune Deficiency Syndrome virus known as LAV2 in Africa. I instructed the clerical staff to ensure that no donations were collected from individuals who had visited Sub Saharan Africa since 1978 and who had sexual relations with natives of either gender as clearly stated in the latest AIDS leaflet (NBTS 1181). The leaflet, which is attached, is titled: '**AIDS: what you must know before you give blood".** There is a list of people who must not give blood.

403. The clerical staff on blood collection sessions were instructed to ask every donor whether or not they had visited Africa since 1978 and to refer any such travellers for further advice before their offer of donation was accepted. I also requested that no blood was collected from any individual who was unable to confirm that they had had no sexual relations with men or women living in Sub-Saharan Africa during that period of time and if they had any doubt about their statement or any difficulty in finding a private place in which to discuss this matter, their donation should be politely declined and a note returned on the Director's report in order that they may be withdrawn permanently from our donor panel.

404. I considered this was imperative as there was a second strain called Lymphadenopathy Associated Virus Type 2 (LAV 2) and the screening test for antibodies to the Human Immune Deficiency Virus (LAV 1 or HIV) at the time lacked sensitivity to the second strain.

b. What, if any, steps did you take to ensure that donors were informed and educated about the risks of hepatitis and HIV?

405. Pre-donation information leaflets about HIV were provided for donors from September 1983 and updated regularly as additional risk factors associated with the transmission of HIV were recognized. In document [NHBT0004481] I enclose a leaflet that was provided to donors about AIDS. The risk factors for HIV and hepatitis were similar in terms of behaviour, apart from some of the specific geographical considerations.

406. Once laboratory screening for HIV antibodies was introduced in October 1985, donors were asked to provide their written consent to donation and its subsequent laboratory screening on the understanding that they would be informed of any positive results.

407. The internal memoranda to clinical colleagues were intended to keep them updated of these advances for sessional implementation.

408. [CBLA0001820] is a Leaflet from the Advisory Committee on the NBTS, regarding "the first six months' experience of AIDS" by region. In the first 6 months of the leaflets being available to distribute, Manchester RTC issued 139,000 with the call up cards and they were also available at industrial sessions.

409. At Liverpool 85,000 were issued with the call up cards and were available at sessions.

410. In addition, notices with similar information for donors would be placed up at sessions like the one in document [DHSC0002331_018] page 3.

c. Please describe how you came to the view that the steps you detailed in the letter dated 1 October 1991 were appropriate and effective [NHBT0000193_048].

411. I wrote to Dr Gunson on 1 October 1991 [NHBT0000193_048] setting out in response to his enquiry about our plans for the counselling of HCV sero-positive donors. At the time I understood it to be the correct thing to

do and I address my reasoning in this letter. In view of the geographical spread of our service, arrangements had been made for counselling and follow up of HCV antibody positive donors by Consultant Hepatologists with an interest in hepatic disorders locally. I enclosed our standard operating procedure together with standard correspondence for donors and doctors.

412. Before the arrangements were made, I had spoken to Dr Philip Mortimer about the place of PCR testing. He advised me that the results of PCR testing should be reserved for sorting out the RIBA 2 indeterminate donors who at that time were being reported as frequently by PHLS as true positives. The course agreed was that HCV antibody screening was performed on all donors. All those who showed a positive result in the first test (IR – initial reactive) had a repeat test in the next run. Those who returned a repeat positive result were designated repeat reactives (RR). Further tests were then carried out at PHLS. Those who were found to be RIBA 2 positive were marked HCV antibody positive donors and withdrawn from the panel, with the appropriate correspondence. Those who were RIBA 2 negative were flagged for repeat testing by PHLS following their next donation, irrespective of the initial screening result on that donation. Those with an indeterminate RIBA 2 result from PHLS were maintained on the panel pending PCR results but flagged. If any of those proved to be PCR positive, they would be handled in the same way as RIBA 2 positives.

413. Anti-HBc testing was performed in Liverpool at that time on donations of all blood and plasma by those who gave a history of jaundice outside of infancy. We had obtained more than 18 months experience of this locally and an extended pilot was due to start on 1 November 1991. If a donor was found to be hepatitis B core antibody positive in the absence of being surface antigen positive, the individual was withdrawn from our panel. Our experience over a number of years had revealed that a small number of these donors were capable of transmitting HBV which could not be detected in vitro by HBsAg screening alone.

414. ALT testing was also performed on plasma donors together with biochemical review, which was repeated every sixth visit (approximately every six months). If the ALT was raised, virological screening was arranged. If the ALT was reported in excess of 90 i.u,/L the donation would be discarded. The donor sample would also be sent for complete hepatitis screening and full biomedical profile. Provided that these were satisfactory they would continue to donate platelet poor plasma. If, however, the ALT was reported less than 90 i.u./L we would send it for fractionation under the appropriate code. If the ALT returned to normal, apheresis donors might be restored to the contribution of platelet rich plasma at the discretion of the consultant concerned. In short, we were collecting plasma donations and not platelets, unless their ALT was normal.

415. These decisions were made on the basis of expert advice. I understood that Dr Gunson obtained advice from a panel of specialist hepatologists and virologists at the time. I also wrote to Dr Gunson to confirm this procedure and he did not advise me to do anything differently.

d. describe whether these steps were changed and/or improved over your tenure. You may want to refer to the notes from 'The 7th Incident meeting' dated 17 April 1997 [NHBT0081212_009].

416. During my tenure at MNWRTC we carried out the pilot for anti-HBc testing. In 1993 we published this promising pilot study about anti-HBc screening but we were instructed to stop testing by DoH. The DoH did not take up my proposal to continue anti-HBc testing beyond the pilot study, as described above.

417. We carried on doing liver function tests and full blood counts intermittently on apheresis donors to monitor their own health.

418. We became aware of CMV in the 1990s. There are, occasionally, cases of post transfusion jaundice from CMV and it presents a real risk to transplant recipients. We developed a panel of CMV negative donors for both red cells and platelets to accommodate them.

419. Document [NHBT0081212_009] relates to HIV lookback.

420. From the 1970's it was recognised that there was also at least one other form of hepatitis apart from HBV which could be transmitted in blood known as Non A Non B hepatitis but initially its potential chronicity was not recognised. This became increasingly apparent during the 1980's as indicated by emerging evidence as described above. Hepatitis A was known to be transmitted by contaminated food or water and is mainly transmitted faeco-orally, and being common in childhood and it was not considered that its transmission was a potential risk of blood transfusion at that time.

421. Successive generations of new and more sensitive forms of testing donor blood for transfusion-transmitted infections have since been introduced which have shortened the window period, including nucleic acid testing (NAT) and I do not believe that there has been another case of HIV transmission. Nucleic acid tests look for HIV in a window period of around 10 to 33 days after infection rather than some weeks. They screen for the presence of HIV itself, rather than the presence of antibodies to it, and similar PCR techniques are now employed to exclude HCV.

422. There was concern about post-transfusion HIV through screened donations in 1997 because there was a transmission in autumn 1996 from a donation which had been screened for antibodies to HIV and found negative before issue. It was a transmission in the window period between viral transfer and the development of antibodies as part of the immune response. We looked at stored samples from all the previous donations to confirm when the most likely time of seroconversion was.

423. The HIV transmission reported in 1997 was most unfortunate. This was a donor who tested HIV antibody positive only some months after his last donation which, on PCR screening earlier would have been detected as positive. He had carried on donating although in a high risk category which should have led to self-deferral. We were not doing PCR at the time and in a tiny volume of blood HIV antibodies was not detected. The index case was a platelet recipient screened prior to stem cell transplant. The red cells went to a patient with myeloma and the fresh frozen plasma to an elderly lady during a surgical emergency. We visited the recipients and their families at their homes to tell them about their transfusion-transmitted infection and offer screening and specialist referral.

424. We also visited the previous recipients of prior donations to make sure they had not been infected and published the case to raise awareness.

61. In a meeting of the NBA Executive on 8 September 1994 [ARCH0002149_003], all RTC Directors were asked to comply with the A-Z guidelines in place from 1 April 1994:

a. Were these the first set of guidelines on donor selection? If not, what were the earlier iterations and who set them?

425. No, these were not the first set of guidelines on donor selection. There were several earlier sets of guidelines which would have been labelled "NBTS". I am unsure when they started and who set them, but there were certainly nationally agreed guidelines on donor selection before the NBA was established.

426. One example from the DHSS is [PRSE0003128] (undated) *Guidance compiled by the Department of Health and Social Security* entitled *Standards for the Collection and Processing of Blood and Blood Components and the Manufacture of Associated Sterile Fluids,* which I have described above.

427. The Handbook of Transfusion Medicine was published in 1989 [PRSE0003047] which credits as contributors many of the Regional Transfusion Centre Directors, including me, with clear recognition of the risks of transfusion- transmitted infection which guided donor selection criteria at the time.

b. Who set the A-Z guidelines?

428. The A – Z guidelines were circulated with the agreement of the clinicians from the transfusion centres. They were drafted under the guidance of Dr Virge James from Sheffield, circulated for comment and then they would be approved at the RTD meetings and later by clinicians within the NBA.

429. Document [ARCH0002149_003] refers to the fact that until such time as any amendments to the A-Z guidelines were issued, for consistency compliance with the current guidelines was requested. All suggestions for amendments should be directed to Dr Virge James, who was the Chairman of the Standing Advisory Committee on Donor selection.

c. The minutes of the meeting of 8 September 1994 state that there were some controversial areas that required amending. Do you recall what those areas were?

430. I cannot recall specifically. This may have referred to issues with vitiligo but I cannot be sure.

d. Did the MNWRTC comply with these guidelines? If not, why?

431. Yes, staff employed by MNWRTC followed the guidelines.

e. What were the consequences to the Centre of failing to comply with the guidelines?

432. Failure to comply with consensus guidelines in clinical practice would be detrimental to both donor and patient care and would therefore be outwith Good Medical Practice described as "The Duties of a Doctor" by the General Medical Council.

433. It is also likely that a healthcare professional would be open to litigation if they failed to follow nationally agreed guidelines.

f. How effective were these guidelines in your view? What more could have been done to screen the donor population?

434. The guidelines were effective and cautious with respect to both donor and recipient risk. They provided an effective way of stopping both patients and donors from coming to harm and the guidelines served as a useful reference for sessions.

435. The organisation of the NBA made it a lot easier to update the guidance. As per document [ARCH0002149_003] suggested amendments were directed to Dr Virge James, Chairman of the SAC on Donor selection. The guidelines became known as part of the Red Book (now in its 8th edition) which was taken over by JPAC – the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee and SaBTO – The Advisory Committee on the Safety of Blood, Tissues and Organs.

436. The JPAC web-site states: The 'Red Book' (as the printed version of these guidelines are known) aims 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. Every effort has been made to ensure that the guidelines reflect the legally binding requirements of the Blood Safety (and Quality) Regulations, UK Statutory Instrument 2005 No. 50.

437. SaBTO is the advisory committee on the Safety of Blood, Tissues and Organs. It advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion or transplantation. It also issues reports such as that in December 2020 on patient consent for blood transfusion written partly in response to audits showing variation in practice and the work of the Infected Blood Inquiry.

62. Do you consider that more could have been done to improve the selection and screening of donors by others? If so, what could and should have been done and by whom? In answering this question, you may find it helpful to refer to the letter copied to you written by Dr Mortimer and Dr Parry of the Public Health Laboratory Service to the Department of Health on 19 June 1997. In the relevant letter, frustration was voiced as to the Department of Health's delay in publishing your report which emphasised the importance of both donor self-exclusion and the continuing practice of donating blood in order to check HIV status [NHBT0008797_004 and NHBT0008797_005].

438. I consider the guidelines were cautious and effective but depended very much on the integrity of the donor in self-deferral for risk of any behaviour or previous illness likely to cause harm to the recipient of their donation after careful review of pre-donation information for donors.

439. I drafted the report of the HIV transmission in 1996 [NHBT0008797_005] with John Parry, Francisco J Belda and Tony Hart. In this report we noted that HIV transmission by blood transfusion in a UK blood donation is a rare event and that by 31 December 1996 only 0.001% of donations were confirmed as anti-HIV positive. However, almost half were from repeat donors and many subsequently admitted to HIV-risk behaviours. Within this report we discussed one such case, which was the second reported case of donor transmitted HIV. In this instance, the donor admitted that he should have excluded himself.

440. Donors were all given leaflets entitled "DO NOT GIVE BLOOD Without reading this leaflet" which impressed the importance of self-exclusion whenever they put themselves at risk of HIV infection.

441. We did consider in this report the possibility of introducing a third generation anti-HIV EIA which may reduce the window period by 6 days. However, we did not think this could be justified and in fact believed it possible that a more sensitive screening HIV test at blood centres actually might attract at-risk donors.

442. Despite strenuous efforts by the NBS to discourage it, donating blood to check HIV status continued. Unfortunately, as we concluded in our report, no single laboratory screening test for HIV infection can ever be regarded as infallible.

443. The DoH did have the ability to send a notice round to all doctors. For example, they did this when they found the third generation combined oral contraceptive pill was causing thrombosis. They did not, however, elect to do so after this transmission, despite our specific request.

444. Hospital Transfusion Committees were already established as a useful way of educating staff.

445. This case illustrates how dependent the safety of blood could be on the honesty of donors but in general donors are very well-intentioned, highly motivated and donating out of a desire to help save lives. I think there is support for the efficiency of the guidelines in the fact that after they were introduced for HIV there was a dramatic drop also in reports of potential transfusion-transmitted infection in patients so that we had successfully eliminated donors with risky behaviours. It also helped with HCV as IVDU (intravenous drug use) practice is associated with risk of either virus. It also helped to reduce both HBV and syphilis which may also be transmitted in blood.

446. When infection was detected, it was sometimes necessary to have more than one discussion with donors before identifying the likely source of their infection. It could transpire that the virus had been contracted by a single sharing of a needle for IV drug use many years before.

447. We were always very conscious of the gift relationship and the need to avoid unnecessarily upsetting or insulting donors who might be deterred from donating. Donors are essential to the functioning of NHSBT and the ability to provide British blood products to patients. Without them there would be no service and they donate out of their own good will freely on behalf of others.

448. We tried to foster links with and consult various interest groups in the framing of donor exclusion criteria including the Terence Higgins Trust when working on the AIDS leaflets. We were sometimes criticised in relation to geographical or ethnic exclusions and had to take account of many interests and sensitivities in preparing the information.

449. I do not recall any health care professional strongly criticising the clinical guidelines for donor selection in general during my years working in Blood Centres, although complaints were occasionally received from individuals excluded from donation on declaration of increased risk activity.

Response to risk - testing of donations

63. Did individual Transfusion Centres have decision making powers in relation to the testing the donations they collected or were they expected to take instructions from NBA or the department of health? You may wish to refer to the letter from you to Dr Gunson dated 1 October 1991 where you set out the arrangements at your centre for the screening of donors and testing of donations [NHBT0000193_048].

450. The transfusion centres would follow the guidelines set by the NBA or the DoH which were based on expert advice. These guidelines would be

drafted by the NBA or the DoH and circulated to the directors for implementation. Before the establishment of the National Directorate the directors would have approved the guidelines at RTD meetings in advance.

451. The mandatory standard tests were set out in the various guidelines and the Red Book. There was some variation particularly earlier on between transfusion centres as to whether they did additional tests such as for anti-HBc antibodies and ALT. I have described above the MNWRTC position on this as set out in document [NHBT0000193_048].

64. Was serum stored from each donation so as to allow them to be tested at a later date if necessary? If so:

452. Yes.

a. When did this practice start?

453. I am not sure exactly when the storage of serum started. I do not recall it being initiated while I was working in a Blood Centre so it must have started before 1982 and I expect well before.

454. As stated in the report [NHBT0008797_005] and in the SOPs for investigating cases of infection the practice of archiving an aliquot of each donation was crucial to investigating incidents and enabling us to test aliquots from previous donations for HIV, HCV or HBV.

455. These days, consent would be required for this but that was not the case in practice in the 1980s before the Human Tissue Act and the events which led to it. I am afraid it is about 25 years since I left the NBS so I am unfamiliar with current practice.

b. How long was the serum stored for?

456. As far as I am aware, the serum was kept for at least 12 months after donation.

c. Were the donors aware of this practice? Did they consent to it?

457. As far as I am aware, the donors were not told specifically that their serum would be stored nor did they formally consent to the storage between 1982 and 1995.

458. However, they did provide informed written consent for laboratory screening of their donation including HIV screening from 14 October 1985.

459. During the course of many investigations of hospital reported transfusion-transmitted infections, together with HIV and HCV lookback exercises I do not recall any donor commenting with concern on the storage of samples or their testing.

65. What decisions and actions, if any, were taken by you to test the donations collected during your time at Manchester RTC and MNWRTC for NANBH? In particular

a. Was surrogate testing for NANBH introduced during your time at either organisation? If not, why? When answering this question please refer to the letter you wrote to Dr Makar on 14 July 1987 when you were at Manchester RTC in which you request that Alt screening should be carried out on her donors [NHBT0054313_004].

460. When a case of post transfusion hepatitis was reported before specific screening for non A, non B hepatitis was available, ALT testing of the donors implicated was requested to see if they had any evidence of inflammation of the liver. It was used for donor investigation on an individual basis in this way, but there can be many other causes of a raised ALT such as increased BMI, consuming alcohol, medication eg statins.

461. Before ALT screening of dedicated plasma donations was required by BPL, ALT screening was carried out every 6 months on plasma donors together with a full blood count as part of their routine donor care.

462. The reason we did not continue ALT screening after the trial is that the instruction we received from the DoH was not do it. However, there are many other causes for elevated ALT other than hepatitis and we may have lost about 5-10% donations from healthy donors if this had been introduced at a time when we were trying to get to achieve national self-sufficiency in plasma.

463. In addition, because the donor consent forms state that donors will be told if the screening of their donation is abnormal we would, therefore, have been obliged to contact all those people with a high ALT. This would have caused unnecessary concern by sending them to a liver specialist when their raised ALT was a result of – for example - a high BMI, drugs, alcohol or another reason unconnected to hepatitis. As per my letter dated 14 July 1997 [NHBT0054313_004] we were conscious of not causing any unnecessary anxiety on the part of the donors. In this instance I had suggested retesting the donors when they came back in to give a donation. ALT screening is a very non-specific marker. For example, post Xmas and New Year there would be very large numbers with high ALT after parties. 30 years ago there was much less emphasis on health promotion in general and many people with HCV also have normal ALT.

464. Furthermore, there was very little correlation between those with a high ALT and those with chronic HCV and, when HCV antibody testing was eventually introduced there turned out to be little correlation between a high ALT and Hep C positivity. In fact, as per my letter dated 14 July 1987 [NHBT0054313_004] our investigations at Manchester had proved to be unrevealing.

b. Do you consider that surrogate testing should have been introduced during your time at either organisation? If not, why?

465. Please see my response to question 65b. Dr Gunson (who would have been far more involved in this than I would) discusses the position in relation to the studies in the UK on surrogate testing and their findings at paragraphs 60 to 69 of his statement in A v NBA [NHBT0000025_001]. He explains that policy on this was a matter for the ACVSB (paragraph 65) and how it was decided.

66. When was screening introduced for HIV at Manchester RTC? Could or should such screening have been introduced earlier in your view? If not, why?

466. Laboratory screening for antibodies to HIV was introduced on 14 October 1985. I believe this was put in place in as soon as possible in the best interests of both of donor and recipient. There had to be available quality assured tests for both screening and confirmatory testing of donors in advance of routine screening of all donations.

467. Testing had been introduced sooner in America, but before there was a reliable confirmatory test for donors, and the first generation of tests produced a lot of false negatives as well as some false positives. What would we be telling donors? We could cause them serious distress and harm their lives when they did not in fact have HIV if they had a false positive result. We had donor exclusions in place which were not a guarantee but were highly effective. There was relatively low prevalence in many regions the UK in the early 1980's and originally a shortage of the materials to develop testing. There was some discussion as to whether tests should be aimed at higher risk regions such as London initially – where the North London RTC had introduced enhanced questioning to donors because of the higher prevalence and worked closely with higher risk groups – or based on the vulnerability of recipients. Ultimately the

decision was made to introduce it uniformly throughout the country on 14 October 1985.

468. I believe that the thinking behind a nationally coordinated start date was to have a fair, standard and consistent service and avoid either a postcode lottery or attracting to particular areas those who were using blood donation as a means of being tested before HIV testing was generally available. If the tests had been introduced with the caveat that "they are not great and we will pursue confirmatory testing urgently", that might have had positive donors returning regularly e.g. plasma donors to have their donations discarded. This would expose staff to risk and collecting donations to discard was considered bad practice.

67. Once HIV testing was introduced at Manchester RTC, were all donations screened? If not, why?

469. Once HIV testing was introduced all donations were screened before issue. The only exception to this may have been in an emergency situation. For example, where a patient with thrombocytopenia had an intracranial bleed and the testing was not complete for that day and the patient needed platelet concentrate immediately in order to survive; but that would have only been authorised on clinical grounds after discussion between the requesting hospital consultant and a consultant at the Blood Centre.

470. However, even in an emergency, if unscreened blood or blood components were issued at the request of the treating clinician before microbiology testing had been completed, the testing would be completed and any necessary action taken on receipt of the results.

471. Although there were reasonable stocks which could be transferred between centres there were still occasions of shortage perhaps of certain blood groups particularly around holidays or bank holidays. I have described elsewhere what we did to try to avoid this by a flexible approach

to call-ups; collecting 7 days a week, after office hours, in mobile units, by visiting workplaces etc, but it was not always avoidable.

472. Whilst I was a Consultant Haematologist at the North West Regional Transfusion Service from 1984-1988 there was one patient who had specially selected red cells in 1981 who developed AIDS about 5 years later. She was very likely to have died in 1981 without the very urgent donation from a donor who had been called in specially to donate urgently because of the complex nature of her multiple red cell antibodies. However, at that time there was no HIV screening or donor information leaflet about risk activities associated with HIV. This donor had self-deferred on the basis of the donor information leaflet before routine HIV antibody screening of donations was introduced 4 years later.

68. Once Manchester RTC started testing donations for HIV, what happened to those donations obtained prior to testing? Were they put into circulation?

473. All blood products in frozen storage were screened for HIV antibodies before 14th October 1985 to ensure all existing stock had been tested in advance. This meant that everything issued from 14 October 1985 was HIV antibody negative, even if collected before testing started.

474. After microbiological screening was introduced, blood components were stored in a quarantine fridge until screening was complete and then they were moved to the issue fridge ready for distribution. They were only moved over for issue once they had been tested and found negative.

69. Was testing for HIV carried out on all donations released for use during your tenure at MNWRTC? When answering this question can you please comment on the letter from Dr Love to Dr Morgenstern which was copied to you, dated 25 November 1987 in which Dr Love states that from time to time the Manchester RTC issued platelets whose HIV status is unknown [NHBT0004924].

475. I was working as a consultant in Manchester from 1984 to November 1988 and thereafter as a consultant in Liverpool for MNWRTC. Occasionally when supplies of platelets were short and a patient had a life-threatening condition they were issued before microbiological screening was complete on a named-patient basis as an unlicensed product after careful discussion of the risks and benefits between the consultant at the Blood Centre and the requesting consultant, who should then discuss these matters with the patient and/or their relatives and make a record in the patient notes.

a. Did the MNWRTC make similar decisions during your tenure? If so, under what circumstances?

476. I did not make any decisions of this nature whilst working in Liverpool personally that I can recall but I did not work at MNWRTC until 1988. HIV antibody screening was carried out on all donations from 14 October 1985.

477. The letter refers to the fact that a disclaimer notice was always given and every step taken to try to minimise the frequency of platelet shortages at the Manchester Blood Centre. I think this would only happen where the alternative was that the patient would die. Dr Love refers to avoiding transfusion if they felt the patient could 'get away with it' – which I take to mean survive without it. They had been advised that wherever possible consent should be obtained and the risks were very small – quoted at lower in the region at that time than the national average of 1 in 59,000 for established donors or one in 25,000 for new donors compared with the risks of not transfusing.

478. I do recall actively encouraging hospital colleagues in Merseyside not to take autologous pre-deposit donations in the local hospitals because they were not licensed to quality assure the product without an MCA licence.

b. If untested blood products were released, was the recipient clinician/hospital informed of the risk at the time the product was supplied?

479. Before issuing an untested donation a consultant from the Blood Centre would speak to the responsible hospital consultant and explain that the results of microbiological screening were not all back and what the risks were. It would then be for the treating clinician to discuss with the patient, assess the risks and benefits of transfusion on an individual basis and make a note in the patient's records. As described above, Dr Love's letter refers to the disclaimer notice that would be provided. The only alternative that there would have been in an emergency situation like this would have been to refuse to provide any platelets.

70. As director of MNWRTC what role did you play in the decisions taken as to whether testing for HCV should be implemented across your centre and/or all centres?

480. We followed the direction of the DoH. Dr Gunson would communicate their decisions and those of the National Directorate to us and we would follow that advice. My role as Director was to ensure that everything was in place and everyone appropriately trained to implement HCV antibody screening on the appointed date. Prior to this there had been some consultation with the RTDs about when we considered it feasible to implement. In the Blood Centres we did what we were instructed to do, based on what was considered to be the best advice at the time.

481. On many occasions this would have been preceded by a feasibility discussion – particularly where new technology was involved - and some centres would participate in trials of laboratory kits, the results of which assisted decision-making about choice of screening tests and timing of their introduction to ensure a coordinated approach across the UK.

71. As director of MNWRTC what role did you play in the decisions taken as to when testing for HCV should be implemented across your centre and/or all centres? In particular:

g. You appear to have concluded in August 1989 that 'as there were no facilities for appropriate confirmatory testing available' it would not be appropriate to introduce HCV screening 'immediately' (see your letter to the Mersey Regional Health Authority of 24 August 1989 [NHBT0000188_027]). What did you mean by this? When did a confirmatory test became available to support the ELISA test? Did you use it once it became available?

482. In the document [NHBT0000188_027] I discuss the problems with introducing a new screening test of this sort, the planning of appropriate confirmatory testing and follow up of donors who must reasonably be withdrawn if they are considered to be carriers of this transfusion-transmitted disease. At that moment I did not believe there were facilities for appropriate confirmatory testing available at the Public Health Laboratory and it would not, therefore, have been appropriate to introduce routine donor screening for antibodies to HCV immediately.

483. This information was provided to the Regional Medical Officer at the Mersey RHA following publicity about proposed HCV antibody screening of blood donors. This was not long after the very first test was available and only preliminary review of potential screening tests had been possible. At the time I did not consider it appropriate to introduce HCV antibody screening of donors as no confirmatory tests were available from the Public Health Laboratory.

484. There were multiple reasons why HCV antibody screening of blood donors was introduced when it was and not earlier which I discuss below:-

(i) Confirmatory testing

485. I have been provided with a document [NHBT0000192_144] which is a memorandum from Professor Cash to SNBTS Board Members following an article in the Sunday Times, discussing the implementation of HCV testing, problems with first-generation test kits, statistics on false negatives

and false positives, advantages of delaying HCV screening for second generation kits and comparison of HCV antibody against HIV-1 antibody screening test kit evaluation.

486. Since early 1984, there had been growing concern throughout the UKBTS that microbiology donation screening kits should be appropriately evaluated before their large scale use was instituted. The primary concern in this context for the UK BTS was to ensure as much as is possible, that every effort has been made by kit manufacturers to maximise both sensitivity and specificity, that is to validate that the kit used will (a) not miss a donation which is infective (false negative) and (b) will not declare a donation positive when, in fact, it is negative (false positive).

(ii) Not FDA approved

487. As the new HCV antibody screening tests did not have FDA licences it was necessary for us to validate them ourselves. Kits also had to be tested for user-friendliness and reagent batch variation to reduce the risks of operator error. By reference to the well-validated tests for HBsAg and HIV, Dr Cash thought that this feature may now be the most important in avoiding adverse events. The FDA had not yet approved their use (given a product licence) nor was there any satisfactory data to confirm they were an improvement on the first generation tests.

488. By this time all plasma products, including coagulation factor concentrates, were virally inactivated by heat treatment, so the risks of transmission through those products had already been eliminated.

(iii) High false positive rate and false negative rate

489. When the first generation test was evaluated it was not very accurate as there were unacceptably high false positives and high false negatives. The outcome for patients with kits of significantly lower sensitivity is self-evident. Kits with high false positives ratings cause untold stress to blood

donors, escalate unit costs (confirmatory testing/medical) and produce expanding data handling problems.

490. Therefore, it was not appropriate to introduce these without confirmatory testing.

(iv) First generation kits withdrawn

491. In early 1991, just as the UK BTS validating team was in the process of advising ministers and RTCs that both these kits could be used and that UK BTS should commence full scale screening on 1st July 1991, the kit manufacturers announced their intention to withdraw their kits and replace them with second generation kits. These new kits were claimed by the manufacturers to be an improvement on those tested by the UK BTS validation team but no satisfactory data was yet available to confirm this and it was noted that the FDA had not yet approved their use (given a product licence). This meant that we could not roll out the first generation kits as planned as they were being withdrawn - and we would need to evaluate the second generation kits before their introduction for routine screening of all donations in the UK.

(v) Second generation need to be tested

492. When the second generation test was introduced this needed full evaluation before routine donor screening for antibodies to HCV could be introduced.

493. Some of this testing was carried out by way of a pilot study for the second generation test which was carried out at some centres. This meant that some centres were ready to roll out earlier than others.

494. It was concluded that an evaluation of these second generation kits should be undertaken as a matter of urgency at some Blood Centres and a start

time scheduled (for full RTC screening). The estimate for this was to be 1 September 1991 in the UK Transfusion Service.

(vi) Testing frozen product

495. In addition, we had to test all the frozen products already in storage to ensure they were HCV antibody negative before the start date of routine HCV antibody screening on 1 September 1991.

(vii) Changing to ELISA method

496. The inquiry has also provided me a document [NHBT0000073_034] which is a letter I wrote to Dr Gunson 24 January 1991 in which I say how pleased I am that the Department has finally agreed to routine testing of all the blood donations for antibodies to hepatitis C. I continue that as Dr Gunson was aware, BPL had decided to discontinue its supply of hepatitis B surface antigen testing by the RIA method with effect from the 31 March 1991. As a result of this Liverpool Blood Centre would be changing over to the ELISA method on 1 April for HBsAg screening. This was associated also with a change to ELISA technology which would be suitable for both anti-HCV and HBsAg screening. The change from RIA (radioimmunoassay) to ELISA screening involved a change in technique associated with the acquisition of new laboratory equipment to support the change in HBsAg screening as well as the introduction of HCV antibody screening. Staff training was also required to support the introduction of the new technology.

497. On a practical level, because of the safety implications, we were reluctant to introduce two new tests together. We had been advised by the representatives of Ortho that it would be difficult to deliver the second generation kits for HCV antibody screening before mid-summer so we changed the technology to ELISA for HBsAg screening in April 1991 followed by HCV antibody screening a couple of months later in the early summer.

498. As our current local budget would not support this since it would involve additional revenue outlay of £450,000 pa., I had to ask Dr Gunson to confirm that this money would be allocated by the Department of Health and that the new policy would not be associated with the need for surrogate testing by alanine transaminase (ALT) assay on all donors (which was also being considered as set out in Dr Gunson's statement discussed above). I added that we were eagerly looking forward to the protocol for testing with guidance on the follow up of donors found to be positive.

(viii) Gulf War

499. In January 1991 the Gulf War was very time consuming for the blood service as we were required to send blood supplies on wet ice to Aldershot for despatch to the Gulf. Such large quantities of ice were required that the help of Liverpool fishmongers was needed.

h. You attended a workshop arranged by Ortho in September 1989 in Birmingham in connection with the Ortho HCV Antibody Elisa Test. What was your view about the assay following this workshop?

500. I have been provided with document NHBT0000188_039 but I cannot recall attending this workshop.

501. My view at the time was, for the reasons given, that the test was too unreliable to introduce without an effective confirmatory test.

i. Please refer to the letter from Dr Contreras dated 20 April 1990 [NHBT0000189_101]. The letter from Dr Contreras is in response to earlier correspondence from you to Dr Contreras dated 10 April 1990 if you have it in your possession. You appear to have concluded from the results of the project on surrogate markers undertaken by the Department of Health, that HCV testing is to be recommended. Why did you not implement HCV testing at MNWRTC at that stage?

502. Unfortunately, I have been unable to locate the document referred to.

503. The letter of Dr Contreras is referring to surrogate tests (ALT) and their correlation (or lack of it) with HCV antibody positivity.

504. I discuss the reasons for the HCV testing being introduced in more detail in response to question 71(g).

505. In short, in light of the BPL changeover of the HBsAg test kit for screening donations for hepatitis B early in 1991, we had to implement two new tests together.

506. There was also a need to pre-test stocks of frozen products before implementing HCV antibody screening, which would have taken approximately 5 weeks. Therefore, we would not have been ready until approximately August 1991.

507. The studies were being organized by the DoH and at that stage we had a National Director and they recommended coordinated implementation of HCV antibody screening on the same date across the UK with the agreement of Scotland and Northern Ireland.

508. I have explained what happened subsequently. The letter from Dr Contreras also shows that there were different views and that these would be exchanged.

j. A decision appears to have been taken that all RT Centres should start testing for HCV at the same time. Who took this decision? Did you agree with it? In answering this you may wish to refer to your letter to Dr Lloyd expressing disappointment at his decision to introduce HCV testing early [NHBT0000074_031] and your description of his decision as a 'bombshell' [NHBT0071652_001; NHBT0000074_014]. In your view, was it important that all RTCs

should begin testing at the same time, even if this meant waiting and if so, why?

509. I think the decision would have been made by the Department with advice from the Directorate of the National Transfusion Service. We had to be sure the screening tests were effective and then get all the kit in place and staff trained for consistency. I did agree with the decision to all start together in the UK using fully validated test kits and considered this approach made sense. We did not want a situation to arise where your postcode could impact on whether you received blood screened for antibodies to HCV. This may have resulted in an episode where a patient in Newcastle (where routine donor screening was being done) who had a special requirement for a blood component not available locally might receive blood products from another Blood Centre which had not been HCV screened because it had not yet been funded. I thought every Blood Centre should start doing HCV antibody screening at the same time and this was standard practice and generally agreed to be important at the time throughout the UK.

510. I was not expressing disappointment that Dr Lloyd had introduced routine HCV antibody screening – merely at his timing. I was responding to a letter from him and considered it unfortunate that he had not followed the coordinated approach that had become accepted practice within the Service. His letter [NHBT0000074_014] suggested that he was primarily motivated by concern about being sued and if anything, his unilateral action probably impacted detrimentally on the rest of the Service in that respect. I note that he goes on to ask what the practice was at other centres in relation to anti-HBc and ALT testing, so he could still see the benefits of a consistent approach.

k. You appear to have informed Dr Gunson that you did not wish to commence testing for HCV until 1st August 1991 because you had recently changed over from the radio-immuno assay for HBsAg on 1st

April 1991 and were reluctant to introduce two new tests simultaneously (see page 37 of Dr Gunson's witness statement for the A v Others litigation and your letter to Dr Gunson dated 24 January 1991 [NHBT0000073_034]). Is this correct?

511. Yes, that was the position for the reasons explained in my responses to question 71g-j.

l. Please refer to your letter to Dr Gunson dated 13 May 1991 [NHBT0000015_066] in which you stated that you would be able to participate in a three centre trial for the second generation hepatitis C virus antibody kits by 17 June 1991 with a view to implementing the date for screening all donations by the time of the recommended start date of 1 September 1991. Was your view correct or could you in fact have been ready to implement the testing earlier?

512. This estimate was based on a number of things and I believed it was a realistic time frame. I explained our progress with preparations. Mr Rogan, who was in charge of the transfusion microbiology laboratory was in touch with Ortho to arrange delivery of equipment and Mr Lacey was sorting out the funding of capital outlay. It was not considered feasible to implement the testing by the end of the May. I hoped that we would be up and running in trial by 17 June 1991 to evaluate the second generation HCV kits and advised that every attempt would be made to start earlier if that proved possible. Once screening was established on blood donations, we would continue to test stored frozen product up to the time of the recommended starting date for screening of all donations of blood and plasma on 1 September 1991.

m. Could you MNWRTC have started testing earlier than 1 September 1991?

513. I do not believe it would have been feasible for the reasons outlined in response to 71L.

72. Was screening for HCV introduced timeously in your view, or should it have been introduced earlier than it was? If so, what were the barriers to the earlier introduction?

514. I believe that HCV antibody screening was introduced in the UK as soon as reasonably possible. I have explained above some of the reasons for delay and Dr Gunson also sets these out in detail in his statement for A v NBA and others at paragraphs 70 to 95 in far more detail than would have been known to me.

515. I would have been primarily concerned with local issues and what needed to – and could safely - be done at Liverpool Blood Centre. The first Ortho test was approved by the FDA in May 1990 and testing was to be introduced once the Ortho kit had been tested against the newly introduced Abbott. There were problems with both kits in practice according to paragraph 83 of Dr Gunson's statement. Once Dr Gunson was advised of Ministerial approval to the introduction of testing in January 1991, he wrote to all RTDs asking the earliest date on which testing could begin. My response for Liverpool is discussed above. Almost every RTC raised the need for confirmation of funding and/or major logistical issues such as the need to recruit staff, complete building work or upgrade computers and several, particularly Scotland mentioned the Gulf War and the potential need for supplies of blood on a large scale if there were significant casualties. There were also concerns that there might be failures in Good Manufacturing Practice if existing programmes were overstretched – which would have implications for the safety of supply.

516. Ideally we would have wished to introduce HCV antibody screening at the earliest opportunity.

517. We did not, however, want to introduce testing which was unreliable with unacceptably high numbers of false negative and false positive results

which might of themselves have caused undue harm to both patients and donors.

518. Progress during 1991 was further delayed by the need for evaluation of the second generation HCV antibody kits to ensure they were fit for purpose before their introduction into routine use as the first generation test kits were being summarily withdrawn by the manufacturer.

519. We may be regarded as having been cautious about HCV antibody screening of donors when other countries introduced it sooner, but we were determined to do it safely and properly for the reasons given.

73. Did MNWRTC test all donations for HCV after 1 September 1991? If not, why?

520. All donations issued at MNWRTC after 1 September 1991 had been tested for antibodies to HCV and found negative.

74. You were present at a meeting of the Northern Division of the Blood Transfusion Service on 26 March 1992 [NHBT0097468_024] at which it was stated that one centre was still sending remnants of HCV untested plasma (see page 9 of meeting minutes). Do you know which Centre that was? Are you able to provide any further information about this?

521. I cannot recall what centre this was or provide any other information about this. I note that it was some years after heat treatment for viral inactivation of plasma products had been introduced but I cannot understand why this would have been happening, or for what purpose, six months after routine HCV antibody testing had been introduced.

75. Once MNWRTC started testing donations for HCV, what happened to those donations obtained prior to testing that had not been tested? Were they put into circulation?

522. All donations obtained prior to 1 September 1991 would be tested and discarded if positive. No products positive for antibodies to HCV were issued after routine HCV screening of donations was introduced on 1st September 1991.

76. How soon after being collected was a donation tested?

523. From memory, the donation would usually be tested on the day it was collected or the next working day if it was returned late to the laboratories at the Blood Centre from a collection session.

524. Whereas component preparation proceeded as soon as possible after collection and often "out of hours" the Transfusion Microbiology Laboratory normally worked during the daytime with more regular hours supported by an on-call facility for use under exceptional circumstances.

a. Who made this decision and how?

525. The donations would be tested as soon as possible. When it would be tested would depend on what blood components it was destined for and when it arrived back at the Centre. We covered a wide geographical area.

526. The Transfusion Microbiology Laboratory was managed by a Chief Scientific Laboratory Officer and most donations would undergo routine microbiological screening within 24 hours of collection during the working day, but special on-call arrangements were available to support clinical needs.

527. Component preparation proceeded as soon as possible after collection and blood components were then quarantined pending satisfactory results of microbiological screening

528. Standard Operating Procedures prevented the issue of unscreened product in quarantine before satisfactory completion of microbiological screening

b. What allowance was made for the fact that an infection may be in the window period, when making the decision as to the timing of the testing?

529. I was aware that there would be an incubation period for transfusion-transmitted infection and that using serological screening methods to detect antibodies to viruses there would be a delay between a donor being infected and the detection of a serological response of up to 6 months for some infections. This period is referred to the "window period" before detection. Therefore, there would be a delay in detection of a positive result on serological screening (antibody tests) in light of the fact that it takes time to mount an immunological response to an infection.

530. During this time there would have been the possibility that a donation could transmit the infection to a recipient. I understand that in recent years this risk has been reduced by the introduction of direct screening for the presence of viruses using Nucleic Acid Testing (NAT) techniques to detect viral nucleic acid at an earlier stage.

531. Waiting to test a particular blood sample would not have had an impact on the result of that test. Technically certain blood components could be frozen and quarantined until the donor had returned some months later for repeat microbiological screening at the end of the anticipated window period. Once negative results were confirmed on second microbiological screening the products could then be released for issue.

532. Clearly this would not be possible for blood components with a shorter shelf life such as platelets and red cells because their shelf-lives are 5 and 35 days respectively – both being within the window period.

c. Did this practice change over time? If so, how and why?

533. I am not sure if this changed over time as I left in 1995.

534. The DoH accepted that there would be a very small risk.

535. It is my understanding that there are still window periods but these were reduced by successive tests which were more accurate including Nucleic Acid testing (NAT).

77. How was the additional cost associated with testing of HCV met by MNWRTC?

a. You are noted by Dr Gunson to have asked for additional financial allocations from the Department of Health so that the costs of screening could be met (see paragraph 37 of Dr Gunson's statement for A v Others [NHBT0000025_001]). Were additional funds provided or were you expected to charge more for your product (see paragraph 87 of Dr Gunson's statement for A v Others [NHBT0000025_001])? Do you agree with Dr Gunson that this was a successful way of funding the costs of testing?

536. We did receive some ring-fenced funding for new screening tests from DOH and this would have been distributed via RHA's at the time and recovered in handling charges. I have commented above on various different aspects of funding following the Purchaser-Provider split around 1990 and on how this affected the introduction of screening. Dr Gunson explains the position on this aspect of funding at paragraph 87 of his statement in A v NBA and others.

b. In a letter from Mr Snape of BPL to you dated 3 April 1991 [BPLL0008909], he states that BPL will pay a premium for ALT-screened plasma. Did that reflect the cost to the Service of the testing?

537. In this document [BPLL0008909] it states *BPL will receive from Liverpool RTC 6 tonnes of ALT -screened apheresis plasma. Bearing in mind the additional costs of ALT-screening, BPL will pay a premium of £2.50 per litre for plasma supplied against such a specification.*

538. The letter states expressly that the premium for ALT testing was supplementary to any premium agreed to cover the cost of HCV screening. I do not believe that BPL paid directly for HCV screening which was covered by central funding effectively. BPL's need for ALT screening was related to the fact that to sell any of their intermediate products in Europe they all had to be ALT tested as commercial products would be required to have had this test. Not all RTCs did this test which was not required in the UK and so BPL were prepared to pay a premium for it on apheresis plasma.

539. I do not believe that £2.50 per litre for plasma would have reflected the cost to the service of the testing but it depends. I understand from my colleagues in Chemical Pathology that ALT screening may be calibrated in different ways: and the cost would vary with technique.

540. Dr Gunson explains in his statement in A v NBA [NHBT0000025_001] at paragraph para 68 that BPL withdrew the request for ALT tested plasma in Feb 1991 except for a small quantity to supply the German market with anti-thrombin III.

78. Did you consider the decision by the NBA to stop routine screening for HBV in October 1993 to be appropriate? You may wish to refer to the letter from Dr Gunson to all RTC directors dated 7 October 1993 [DHSC0004709_153].

541. There was no decision to stop HBV screening in 1993. Hepatitis B surface antigen screening (HBsAg) continued on all donations as before but it was decided against introducing HBc antibody testing to identify the small number of additional chronic carriers of hepatitis B that were not detected

by the existing HBsAg tests. We were asked to stop by DoH via the National Directorate.

542. As discussed above, based on my own experience I was keen to continue HBc antibody testing in Liverpool before being advised of the decision that such testing could not be justified at the time in the letter from Dr Gunson to all RTC directors dated 7 October 1993 [DHSC0004709_153]. The rationale is set out in the letter which states that as all kits gave some false positive results and there were no agreed confirmatory tests it was difficult to estimate the number of transmissions that would be prevented. This was considered to be between 10 and 100 per year at a cost of £3million which would not be centrally funded so this would have to be added to the cost of blood products. Also anti-HBc testing was not widespread in Europe and there was concern about the effect in terms of withdrawal of plasma.

a. Was this decision contrary to the conclusion you had reached in the 'Chronological study of donor distribution (new versus established) during two years of Hepatitis B core antibody screening of blood donations' [NHBT0009842] which concluded that there was a need to continue to screen both new and established donors for anti-HBc beyond two years. This should be read alongside your note entitled: *'Do we need additional markers for Hepatitis B screening?',* date January 1993, [JPAC0000036_130] and the earlier study from 1991/1992 entitled 'Routine Hepatitis B Core Antibody Screening of Voluntary Donations – an extended pilot study in Merseyside and North Wales' [JPAC0000036_131]).

543. Document [JPAC0000036_130] was the report of a study we conducted at the MNWRTC over two and a half years to see if additional cases of hepatitis B would be picked up if we tested for hepatitis B core (HBc) antibodies in addition to the surface antigen (HBsAg) which had been the standard test since the early 1970s. We concluded that screening for HBsAg alone left a 1/4,000 chance of viral transmission by those with anti-HBc in the absence of a positive HBsAg result.

544. Document [JPAC0000036_131] is a report of the same study of the significance of a history of previous jaundice in donors. Over a period of 12 months (November 1991 to 92), all donors with a history of jaundice outside infancy were tested for HBc antibodies as well as HBsAg. It includes the annual cost of £20,000 but notes that false positive results led to the need for regular repeat tests, though this may be reduced with increased operator skill. If it became a mandatory test, it would be necessary to change to an ELISA test at a cost of £150,000 pa.

545. The conclusion I made in my formal report [NHBT0009842] was that there was a need to continue to screen both new and established donors for anti-HBc beyond two years.

546. Routine HBsAg testing continued in the same way, but HBV core antibody testing was not continued following the decision by the Department of Health in 1993. I was disappointed on the basis of my own experience of a case of Hepatitis B that had been missed by standard testing and I thought this was important. I do recognise that in almost all health interventions there is a balance between the cost and benefit and that not everything that is possible in healthcare can be afforded and that funds have to be targeted where they are considered to be most beneficially used. Views on what this is may differ and my opinion – as with anyone – was coloured by my own experience.

b. Did you implement the decision despite disagreeing with it? If so, why?

547. Document [DHSC0004709_153] lists the reasons i-vii why it was decided not to continue with screening for HBc antibodies in addition to the established test (HBsAg): - false positive results, inability to provide information to donors, provision of standards, not able to estimate instances of transmission of HBV, £3m a year added from RTCs as no central funding available, concern about withdrawing it for fractioned products where test is not mandatory, not wide-spread in Europe).

548. I have explained above that we were required to follow national policy when made and without acceptance of the policy to test for anti-HBc, there would have been no funding for it.

79. Once a donation tested positive for an infection, what happened? You may find it useful to consider the 'Chronology of HRL investigation of Liverpool post-transfusion HIV infection (March/April 1997) when answering this question [NHBT0008797_002] together with SOP MNW-96-CS05-00 [NHBT0087624], SOP MNW-96-CS05-00 [NHBT0087625]; SOP MNW- 93-CS01-01 [NHBT0087626].

549. I have discussed the investigation of post transfusion infections above.

550. If there was report of a possible transfusion-transmitted infection, we would follow the procedure as laid out in the current SOPs as detailed in [NHBT0087624] [NHBT0087625] [NHBT0087626]. These were reviewed and updated during my tenure.

551. The most recent SOP of those referred to was effective from 13 September 1996 and reviewed on 13 September 1997 [NHSBT0087626]. The procedure followed is detailed in paragraph 4.01-4.09. Some of the standard documents that would be sent are included.

552. In short, the donation samples would be screened and following confirmatory testing in the PHLS, the implicated donor would be invited in to meet a consultant at the Blood Centre. We would advise them of the result after confirmatory testing, the purpose of which would have been explained to them and refer them to a specialist. They would be permanently deferred from blood donation in the future.

553. We would retest all their stored sera from prior donations. Any blood products from implicated donors would be dealt with on the basis set out in paragraphs 8.1-8.6. They would be placed on unconditional hold and on

confirmation of positivity would be autoclaved and destroyed and the Quality Manager informed; all issued products would be traced; we would urgently advise BPL when implicated plasma had been supplied to them and this would be destroyed. We would notify any centres where implicated products had been transferred. NBA and CDSC would be notified in quarterly returns.

554. The document in [NHBT0008797_002] relates to a look back from an HIV infected recipient. In this instance we received a call about a patient with acute myeloid leukaemia whose previous specimens had conflicting serological findings and therefore a blood sample would be sent to us. We received it and tested it and referred it on to the Public Health Laboratory who confirmed that the transfusion recipient had been infected between July and November 1996.

555. A look back exercise was instigated at the Liverpool Blood Centre.

556. This included reviewing 72 donor specimens from those who had contributed previously to the recipient's transfusion support. It was found that one was weakly reactive on more sophisticated PCR screening at the Public Health Laboratory. She had received platelets from this individual about 8 months earlier and the virus identified in donor and recipient were phylogenetically identical. Results of the previous 5 donations from this donor were negative for HIV on PCR screening also. A report was then drafted and sent to me.

557. The patients co-infected from the other blood components of the donation identified were informed and referred for specialist advice and treatment.

80. What procedures did you have in place during your time at Manchester RTC and during your tenure at MNWRTC to counsel donors found to be carrying an infection and how did these change over time? In particular:

558. Donors were obviously crucially important to our service and we worked hard to look after them. At the same time, we had to ensure that any who might put the blood supply at risk were identified, excluded and permanently deferred and that appropriate specialist referral was arranged for their own wellbeing.

559. I should say at the outset that when we used the term 'counsel' we meant effectively *gently inform, advise and refer* rather than in the modern sense which would perhaps be attached to this of a longer term therapeutic relationship. We did not have the funds or structure for the latter and it would not have been appropriate for us to provide such a service as their ongoing care continued with the expert to whom they were offered referral.

560. Our main experience and learning on this came from the AIDS crisis, although the blood services had been following up cases of post transfusion hepatitis and syphilis for many years before that and advising donors accordingly.

561. I went on the first ever course on counselling for patients with HIV at St Mary's Paddington, which addressed how to break such terrible news. At the time my understanding of "counselling" in this context referred to the approach to providing information for and advice to donors who had the results of a positive screening test confirmed and prior to referral on to the appropriate specialist for further investigation and any appropriate treatment.

562. The SOPs were followed during my time at MNWRTC. As indicated above these would be updated periodically.

563. A donor confirmed to have a transfusion-transmissible disease would be invited in for a discussion with a consultant haematologist at the MNWRTC. Their invitation letter would be different depending on which infection they had. At a first interview we would explain why they had been

asked to see us and arrange for a further test. We would discuss with them their risk factors to identify the likely source and timing of their infection. Arrangements would then be made for referral to a specialist in genito-urinary medicine or another expert in the management of infectious diseases according to history and donor wishes. If the infection were hepatitis B or C we would recommend that they allow us to correspond with their family doctor and dentist in the interest of their own wellbeing. The donor was advised that the consultant and/or colleague would be available 24 hours on call through the blood centre to provide support and advice should there be a delay in specialist consultation. We also advised those with HIV to permit similar communication although in seeking medical attention for this condition the individual has the right to seek medical help on a confidential basis.

564. I have explained above that during the various lookback exercises, it often fell to blood service consultants to provide this service to transfusion recipients on the basis that treating clinicians and GPs more often than not declined. These were obviously people (unlike donors) with whom we had no prior direct therapeutic or other clinical relationship which meant that they were hearing this news from strangers rather than from clinicians they might have known for a long time, felt comfortable with and trusted.

565. If the donor was HIV positive, the donor was invited in to see us by a fairly bland letter and was then informed of their result face to face. When I saw them, I had already arranged an appointment for them to see a specialist consultant – whenever possible straight away that same day at the adjacent hospital. I would sometimes walk them over and introduce them to the specialist. Those found to have HIV were entitled to anonymous care in the Department of Genito-urinary Medicine.

566. We had a nominated consultant in GUM for referral at MRI for Manchester and at the Royal Liverpool University Hospital for Liverpool. There was a similar arrangement with the hepatologists for those with hepatitis

567. That was the end of our involvement and as they would have the right to be treated anonymously we would not usually see them again. The GUM clinic would also deal with their contacts and any tracing.

568. We were always very concerned to find out how and why they had given blood, to determine why their pre-donation screening had failed to achieve their self-exclusion. We always wanted to elicit what their risk factor(s) had been. It was important for us to know whether donors had donated when they knew they were at risk and how they had not been identified and excluded.

a. Was this information ever kept from donors? If so, in what circumstances was this considered to be appropriate?

569. I did not keep this information from the donors. We did not consider it appropriate to advise of the diagnosis of HIV by letter. We arranged the appointment as soon as possible to tell them face-to-face.

b. How were donors informed of their infective status?

570. The donor would initially be sent a letter as shown in pages 14-17 of document [NHBT0087626]. This letter would usually invite them in but in relatively vague terms. The one attached to this SOP (at Appendix 7 for HIV) says that examination of their blood had revealed certain abnormalities which may be of importance to their health and asked them to telephone as soon as possible to arrange a mutually convenient appointment to discuss this. If we did not receive a response, we would send a follow up letter before contacting their family doctor to confirm their address. They knew in advance what tests were to be performed on their donated blood and when HIV testing was introduced they had to give informed consent to their blood being tested for AIDS in the knowledge that they would be informed of a positive result or they were not allowed to donate, as described above.

571. Where we identified a case by tracing a donor from a case of post transfusion infection (for example a window period case or before HCV testing), the donor would be made aware of that in the letter. We were always extremely conscious of the delicacy and sensitivity of this communication because the vast majority of donors give their blood altruistically in the hope of saving lives and are devastated to learn that they might have unwittingly transmitted infection, in addition to obvious concern about their own health.

572. We would not advise them of their HIV diagnosis in this letter but face to face when they attended. When recipients were infected, we would often arrange to go to their homes.

573. When they came into the Blood Centre we would inform them face to face, refer them to a specialist then the specialist would retest them. Follow up support was provided via the clinics we referred the donors to. They could also be referred on for family services as appropriate. There was a full service support via the GUM service. The specialists relevant at the time of the SOP are set out in it.

c. What information was given to donors about the particular infection and their risk of passing it on to others?

574. When they were informed of the diagnosis they would be provided with information regarding the diagnosis. They would have an opportunity to ask questions and would be sent to a specialist the same day. Follow up support was provided via the clinics we referred the donors to.

575. When the HCV lookback was announced publicly, the CMO's letter included Annex B – *Transmission-Transmitted Hepatitis C; Guidelines for Counselling Patients*. This set out the advice to be given on transmission and protecting others and that a support network might be helpful with reference to the British Liver Trust as an appropriate source of help and support [NHBT0002796_002]. I believe that the counselling guidelines

in Annex B were based on British Liver Trust advice. We did always make clear that they could continue to contact us if they wanted to have any further discussion.

d. Was testing offered to their families and partners?

576. They could also be referred on for family services as appropriate. There was a full service support via the GUM service or Department of Infectious Diseases or the Liver Clinic.

577. This would be arranged by the specialists after referral.

e. Was follow up support such as psychological counselling available?

578. This was not something that the Regional Transfusion Centres were able to provide but we did ensure that referrals were made to consultants who would have access to appropriate support services and sought permission to advise the GP.

Response to risk – choice of product

81. What, if any, steps were taken to ensure that blood products known to be at lower risk of carrying infections (such as cryoprecipitate) were available in sufficient quantities once the risk arising from pooled products was known?

a. Did MNWRTC see a surge in the demand for cryoprecipitate at any stage? If so when?

579. I returned to Liverpool in December 1988 when patients with haemophilia were well established on virally inactivated plasma derived coagulation factor concentrates and I do not recall any surge for demand in cryoprecipitate at that time.

580. Administering cryoprecipitate was a very time consuming and difficult process. It would involve at least 20-30 bags of cryoprecipitate, each containing about 5ml fluid in a 500ml bag to provide a therapeutic dose to an adult of normal size. Saline was added to assist aspiration of the cryoprecipitate from each bag and the procedure would be repeated 12 hours later in order to provide sustained haemostatic support in severe bleeding episodes. The logistics of administration are very difficult and it was a tedious process which would have meant that going to work, or away on holiday would have been difficult or impossible for an individual previously on home treatment with the more convenient small bottles of coagulation factor concentrate.

581. It is my understanding that once factor VIII concentrate became available, this superseded cryoprecipitate and I do not recall a resurgence in demand or anyone requesting cryoprecipitate during my time at MNWRTC.

582. It is my understanding that cryoprecipitate was only administered as the principal treatment for haemophilia for about 10 years from the 1960's so it seems likely that improvements in life-expectancy in general followed the introduction of home treatment with coagulation factor concentrates from the 1970's.

b. Was there ever a shortage of cryoprecipitate? If so, when? You may find the letter you wrote on 13 October 1994 in connection with potential litigation helpful when answering this question [NHBT0083996_062].

583. I was not involved in the procurement of pooled plasma products for the treatment for haemophilia until after 1996 when I returned to work as a haematologist in secondary care and as a Haemophilia Centre Director.

584. I cannot recall any particular shortage of cryoprecipitate or surge in demand either while I was working in Manchester.

585. I have been provided with a copy of a letter which I wrote dated 13 October 1994 [NHBT0083996_062] to the Regional legal advisor at the time Mr Mowat (by then in private practice) in which I state that I believed that a deceased patient had been well-managed and that the only conundrum was in the belief of Whiston Hospital that cryoprecipitate was in short supply. I say that in fact our Laboratory Manager could not remember a time at which the centre had been short of cryoprecipitate since it is a product that can be made to order (which does assume that there was no overwhelming or sudden demand for it).

586. By this time fractionated products were virally inactivated and had been so for almost ten years. It had also been demonstrated that the viral inactivation processes used following fractionation of plasma were highly effective.

587. If there had been a surge in demand for cryoprecipitate then we would have had to reconfigure the laboratories and there would also have had to be a clear decision made to stop sending plasma for fractionation and Factor VIII production and to make cryoprecipitate instead. This would have been possible, though not immediately achievable, but it would have been a very significant policy decision. Such a change in practice would necessarily have reduced our return of frozen plasma to BPL without the enormous expansion of the donor panel which would have been required to fulfil both requirements.

82. Was the relative safety/infectivity of a particular brand of blood product a factor in Manchester RTC/MNWRTC's decision to purchase that brand?

588. I was not involved in deciding which commercial or NHS brand of blood product to purchase. I would not be purchasing commercial product as these would be for hospital prescription.

589. I did however set up a regional contract for the procurement of NHS plasma products from BPL via the Regional Pharmaceutical Committee because I believed that the source plasma from voluntary British donors made them the best available products.

590. While I was working in Manchester the overall responsibility for procuring adequate supplies of coagulation factor concentrates for his patients lay with Dr Wensley as Haemophilia Centre Director and in Liverpool with Dr Charles Hay as Director of the Comprehensive Care Centre for Haemophilia. Such procurement for paediatric patients was led in Manchester by Dr David Evans and in Liverpool by Dr Lynn Ball and Dr Paula Bolton-Maggs.

a. If so, how did the RTCs assess which were the safest products? In particular, did the RTCs carry out any testing of the safety of the products themselves? If not, why? If so, please give details.

591. It would not have been for the RTCs to assess what the safest product was. They would not have carried out any testing of products. We tested the source plasma that was submitted for fractionation until UK plasma was no longer used after 1997 because of the risk of possible transmission of vCJD.

592. Products had to be licensed in the same way as other medicines and these would be issues for the regulators (MCA and later MHRA). Choices between approved/licensed products, would be a matter for the treating clinicians who were treating the patients in the hospitals and not for the RTCs.

593. However, I did consider British plasma to be better and safer as it was from voluntary donors.

b. If not, why?

594. It would not have been for the RTCs to assess what the safest product was. This decision was made by regulators and prescribing clinicians involved directly with patient care.

83. What if any role did Manchester RTC have in securing heat treated blood products for patients? When did untreated blood products stop being supplied by Manchester RTC?

595. We prescribed the BPL plasma derived product from British donors as juniors at MRI in the early 1980's but were not involved in its procurement.

596. However, by the time I was a consultant working at Manchester Blood Centre in January 1984 heat treated coagulation factor concentrates were available and by January 1985 I understood that only virally inactivated coagulation factor concentrates were to be prescribed throughout the UK.

597. As the new BPL factory was not yet commissioned by this stage and the Lister Laboratories lacked capacity, hospital colleagues were obliged to supplement their supply from one or more commercial sources to meet the clinical needs of their patients with haemophilia but I understood that by this time they would have only prescribed virally inactivated products which were available commercially.

84. Were you ever involved in a product recall? If so, please give details and set out the steps that were taken in response.

598. It is difficult for me to recall specifics but it is likely I would have been involved in various product recalls.

599. The documents provided to me include:

600. A document [NHBT0000063_086] which is a blank BPL Complaints Procedures and Product Recall form which seems to be from a BPL Quality Control SOP dated May 1990 and sets out the process including

the need to notify all Regional Transfusion Directors and Haemophilia Centre Directors. The procedure is stated to be necessary to remove from the market an issued plasma product which is considered unfit for its purpose and should therefore be withdrawn from clinical use.

601. I am likely to have been involved on occasions both as a RTD and as a HCD.

602. A document [NHBT0000066_022] which is a fax from Dr Snape of BPL dated 18 June 1991. It advises product recall of a Factor VIII batch due to report of a serious event. No other adverse events related to this product were known. It refers to Dr Wensley, who was the Haemophilia Centre Director in Manchester, and the Haemophilia Centre Directors' Adverse Events Working Party. I was the RTD for MNWRTC in Liverpool at the time and as this is stated to have been a '*Notice to all Regional Transfusion Centres and all Haemophilia Centres in England and Wales'*. I assume we would have received it.

603. I have described above in response to question 28(d) how occasionally BPL would notify RTCs that a plasma pool had tested positive.

604. I do recall the vCJD lookback/recalls some years later in 2004 and 2009 which were tremendously difficult.

Response to risk – general

85. Do you consider that your decisions and actions, and the steps taken at Manchester RTC and during your tenure at MNWRTC, in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

605. I consider my response to risks of infection was appropriate and adequate.

606. I would, however, as I have said above, have preferred to carry on with the Hepatitis B core antibody testing at Liverpool in the long term after the pilot study but I assumed that decisions like this were properly made on the larger scale nationally by DoH based on the best evidence at the time.

86. Looking back now, what decisions or actions by you at Manchester RTC and/or during your tenure at MNWRTC, could and/or should have avoided, or brought to an end earlier, the use of infected blood and blood products?

607. On reflection, surrogate testing for Hepatitis C could have been brought in earlier but this would have carried with it considerable disadvantages with respect to the interpretation of results of investigations such as ALT screening and the subsequent implications for donor deferral and significant reduction in the register of available blood donors (and so supply) which was estimated to be of the order of 5% to 10% at the time.

608. Routine HIV antibody screening of donors could technically have been brought in earlier but this was not something that should have been done in a rush. The new laboratory screening methods had to be evaluated in the Transfusion Microbiology Laboratories at Blood Centres. It was important to ensure the tests were effective with appropriate sensitivity and specificity and good clinical correlation. Robust independent confirmatory testing had to be established by the Public Health Laboratory before donors could be approached for further investigation and specialist referral. It was essential that every blood centre started at the same time in order to avoid a post code lottery. In addition, we were dependent on getting funding for the big developments like introducing routine screening of all donations as these decisions were made centrally and it was unlikely any Blood Centre would have been funded for it or able to start without departmental approval.

609. I think we would have preferred to undertake a lookback for HCV when testing was introduced in September 1991, as had been done with HIV.

610. I understand, however, that this was not started in 1991 because there was no specific anti-viral therapy for HCV available at that time to offer infected recipients and HCV is not as readily transmissible as HIV and was not, therefore, considered to pose as serious a risk to the public health.

87. What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients? What, if anything, do you consider could or should have been done differently by these others?

611. Many actions and decisions of clinicians had an impact on the scale of the infection.

612. In general, the clinicians in both Manchester and Liverpool caring for patients with inherited bleeding disorders in the 1980's recognised the greater benefit of plasma derived from voluntary British donors in comparison with those from abroad as well as appreciating the risks associated with plasma products derived from large donor pools.

613. My experience was that every effort was made to avoid blood components where possible in those with mild bleeding disorders including von Willebrand's disease by using the synthetic hormone DDAVP. All the clinicians had a preference for NHS products issued first from Lister Laboratories and latterly but BPL, but until the new fractionation plant opened at Elstree the capacity of the older site was not sufficient to meet the needs of the patient group.

614. Furthermore, the drive to national self-sufficiency in plasma was well under way but the targets had not been reached by the Blood Centres before 1990.

615. Steps were taken by members of staff in attempt to limit multiple donor exposure. For instance, from the early 1980's at the Children's Hospital in

Manchester David Evans had the practice of limiting child exposure to pooled plasma products by using cryoprecipitate prepared locally from British voluntary blood donors. Latterly I looked after some men whom David Evans had cared for as children as he used to refer them to Charlie Hay, who was then in Liverpool, before moving to Manchester.

616. By contrast, when I came to Liverpool in 1988 some years later there was still no designated specialist paediatric haematologist at Alder Hey Hospital as the children with haemophilia were being cared for by a general paediatrician at Alder Hey whilst factor VIII concentrate was being supplied by a consultant haematologist treating adults with haemophilia at another hospital. Dr Lynn Ball was only appointed as the first dedicated haematologist for children with bleeding disorders at Alder Hey Hospital the following year in 1989. Before that there was a very experienced general paediatrician who took an interest in haematology, Dr John Martin. He received advice about coagulation factor concentrate from Dr Tony McVerry, who looked after the adult patients with haemophilia at the Royal Liverpool Hospital and sent factor for the children from there on request without necessarily aiming to maintain an individual within the same batch from the manufacturer (which was considered to be good practice). This practice some years later in Liverpool did not seem to reflect the attempts to limit donor exposure I had witnessed at Pendlebury in 1982.

Response to risk – provision of information

88. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to those hospitals to whom the Manchester RTC and MNWRTC supplied blood or blood products about the risks of infection in consequence of treatment with blood and/or blood products? Please detail whether, and if so, how this changed over time.

617. The NBTS tested all blood donations by a VDRL method for syphilis from the 1940's. Hepatitis B surface antigen (HBsAg) screening was introduced from early 1970's. HIV antibody screening commenced on 14th October

1985 at all UK Blood Centres followed by Hepatitis C antibody screening from 1st September 1991. The majority of the products which were made at the RTCs were not going to patients with haemophilia but were delivered to local hospitals as red cells, platelet concentrate and frozen plasmas. A larger volume of plasma was sent in quantity to BPL for fractionation to provide coagulation factor concentrates, human albumin solutions and various immunoglobulins. The NBTS was effectively a monopoly for blood and blood components processed by RTC's whereas there was a choice of Factor VIII concentrates available at the time between the BPL products and those made by various commercial companies

618. Prior to the introduction of viral inactivation processes by the fractionators it was generally accepted that products derived from voluntary British donors were safer from the point of view of viral transmission because of the inducements offered to donors by some commercial enterprises overseas and their use also of donors in prison. As microbiological screening of donors was gradually extended over the years in the UK as set out above and viral inactivation steps introduced this information was passed on to colleagues locally at educational sessions. In Liverpool we arranged a regional contract with BPL to optimise the use of NHS plasma products made from voluntary British plasma.

619. In view of the potential for transfusion-transmitted infection and the requirement of a large donor pool for fractionation self-sufficiency in British plasma was considered an important goal and this would have been communicated to the hospitals supplied by the Blood Centres in both Manchester and Liverpool. It was recognized that British product was better but I cannot recall how that was communicated at the time. Clinical decisions would have been made on comparative products. The NBTS were focused on trying to maximize the supply of plasma. The consensus both when I was at Liverpool and Manchester was that British product was less likely to transmit infection, but I was not having to make decisions about which of the commercial plasma products was superior as I was not

prescribing Factor VIII concentrate then for patients with bleeding disorders.

620. This was probably discussed at local and national meetings such as UKHCDO and some comparative studies would have been published.

621. I cannot be sure how this was communicated before I started working in the field of haemostasis and thrombosis in the late 1990's.

622. There were also local North West Haemophilia meetings and the Mersey Haematologists would meet twice a year. New products and clinical advances would be presented at these.

623. Dr Gunson also attended the meetings and BPL sometimes attended with HCDs/RCDs.

624. Hospital colleagues would have known when new screening tests were imminent as they usually followed the introduction of the diagnostic tests and the latter were widely published. Once a diagnostic test had been described, colleagues would then enquire frequently about the proposed date for its introduction in routine screening of blood donations.

625. In relation to the risks of infection through blood transfusion, I have described above that I always thought and taught that blood is filthy stuff and that screening makes it safer but not completely safe. I always talk about the 'Domestos' principle – kills 99% of all known germs – but there is no guarantee that it is free from infection because no test is 100% sensitive and new infections emerge, as was the case with NANB hepatitis, HIV and vCJD. Most unfortunately those which prove to be transmissible may be in the blood supply from asymptomatic donors before they have been identified.

626. The transfusion service was involved in the initiatives relating to Better Blood Transfusion to minimise transfusion in clinical practice, training for

haematologists through transfusion centres, attending hospital transfusion committees and audit of blood use and more recently in the establishment in the joint Blood Management scheme with participating hospital transfusion laboratories.

89. Was this information given in a form that could be provided to patients? If not, why?

627. Consent to blood transfusion was introduced, with leaflets for transfusion recipients which have been updated over the years.

628. It would be for the doctors prescribing the treatment to speak to the patient about risks and make a note in the same way they would before the prescription of any other medication listed in the British Pharmacopoeia. We provided a licensed product under the Medicines Act. The MCA – which preceded the MHRA - inspected the Blood Centre regularly to approve that it conformed to pharmaceutical standards.

629. If any blood products were issued on a named-patient basis before the test results were available, we would specifically discuss the risks with the treating clinicians and make sure the clinicians knew that it had been issued before our quality assurance procedures were complete. This should then have been discussed with the patient and/or their relatives before administration. In any event, the product would be quality assured in retrospect: as the screening tests would have already been in progress but the units had to be issued before the results were known. The letter of Dr Love refers to this being done with a disclaimer.

SECTION 6: INFORMATION HANDLING BY AND INFORMATION SHARING BETWEEN RTCS

90. Please describe the record keeping system in place for blood donations and blood donors at the time of your directorship of the MNWRTC. In

particular, please explain what records were kept, in what form, where they were kept and who had access to them. Please also set out how long these records were kept for.

630. When I started at Liverpool in 1988 all the records were on paper. The laboratory records were in many large ledgers. Donor records were kept separately elsewhere in filing cabinets. The register of units prepared from blood or plasma donations and available for issue was double-checked from these huge ledgers.

631. From memory the system in Liverpool was computerised in 1990. Funding was provided to go electronic from an HIV prevention initiative at the RHA. Donor records went over on to computer first. A few years after the NBS was established from 1 January 1997 all donor information was placed on the single national computer system - Pulse.

632. Access to records would be on a "need to know basis" so the donor and laboratory systems were entirely independent.

633. Access to the records was on a "need to know" basis, individual staff access would be dependent on what the record contained and who needed to use them. There would be staff inviting donors to come to a donor session and other staff making amendments to donor selection criteria – perhaps with temporary deferral such as pregnancy, travel to a malarial area, or people moving house, changing name etc.

634. There were panels for donors with special properties. There were also donors in geographical panels for routine call-up in the locality. For those with special properties, as these were usually detected in the laboratories, the donors would be listed by their unique donor number. The donor records staff might invite someone to come in on an individual basis if blood was needed from a special donor but the laboratory staff only knew the donor's number and their special property whereas the donor records staff had contact details but no knowledge of the special property.

635. There was a separate Medical File with details of certain donors with health issues. This was a system devised in Liverpool, as published in Transfusion Medicine: 1.The Medical File: A Systematic Approach to Donor Deferral: Shepherd, A.J.N., and Martlew, V.J. Transfusion Medicine Vol 1. Suppl 1. 45 (September 1990) [WITN4034003] and 2.The Medical File: Update on a further 12 Months Experience Shepherd, A.J.N., and Martlew, V.J. Transfusion Medicine Vol 1. Suppl 2. 77 (September 1991) [WITN4034004].

636. These papers describe how increasing standards for medical surveillance of blood donors and the importance of details of foreign travel in connection with microbiological screening, had created the need for a comprehensive system for reporting of clinical information about donors from mobile sessions to Consultant Medical staff at the Centre. There was also a need for consistency, regardless of whether the donors were in city centre venues or sessions in rural sessions in mid-Wales. We presented a novel method of data collection which superseded letters or memoranda and provided for donors to give us written consent to contact their doctor.

637. This was a development of the laboratory file, under medical supervision and designed to preserve confidentiality, incorporating an in-built system of letters to donors' GPs to deal with common reasons for deferral and reportage of blood counts in anaemic donors.

638. After 12 months' use, the system had facilitated rapid exclusion of unsafe donations from use, with associated withdrawal of donors and enabled swift retrieval of data on any donors who re-attended. Correspondence with donors' GPs was stream-lined, with a very favourable response from both parties. The Medical File was part of a comprehensive audit being introduced by MNWRTC.

639. The follow up report the next year notes that the full-time use of the Cardiff Consortium computer had only just commenced when we had previously

reported but we were confident that the computer programme and the Medical File would be rapidly adaptable to each other. The programme incorporated 11 categories for medical deferral (D0-D10) with intervals e.g. D1 medication (4-12 months), or D7 glandular fever (24 months maximum). Donors received standard letters giving reasons and time interval before the next invitation to donate. Withdrawn donors were archived to prevent further recall and also for identification and withdrawal of units, should they attend spontaneously.

640. There were 18 categories of medical withdrawal of donors, with abbreviations such as NG (malignant disease), or GIT – gastrointestinal disorders. We reported that the number of donors withdrawn varied considerably according to category, with fewer than 10 withdrawn for INF (infectious diseases) to more than 275 under CNS (neurological conditions and psychiatric disorders).

641. We noted that this observation suggested varying donor awareness of eligibility according to medical condition. I take that to mean that those with infectious diseases were far more aware of the need to self-exclude after perusal of the donor information leaflets. We were intending to present the study on the prevalence of hepatitis B in donors on another poster.

642. I do remember some of the rooms being locked. The lookback files were in filing cabinets in my room. We filed records in a cabinet before they were electronic. The majority were in the secretarial office next door to me.

643. The retention times varied from the 1980s, usually increasing. They were based on current professional recommendations. In the 1990s I believe we kept records for 15 years apart from the obstetric records which would be kept until the child was 18 years old. There was no case law at the time to support holding records electronically. Until the 1990's they had to be stored on microfiche.

644. I have been shown a document [PRSE0002954] Minutes of a Directors' Meeting on 12th June 1990 point 4.2 of which refers to 'Retention of records'. An ad hoc group had been established to consider the retention of records at Transfusion Centres within the general framework that records necessary to identify the donor to the donation should be retained for 15 years. This was a proposal only; the Committee was to make recommendations. [*Secretary's note: Despite the above, the newly published UK BTS/NIBSC Guidelines for the Blood Transfusion Services in the United Kingdom uses the following wording (para 2.6):- 2.6.1 Each RTC shall develop and maintain records that demonstrate that the quality has been achieved and that the quality system has operated effectively. 2.6.2 Specific requirement: product history file. The records of reference shall be maintained in a product history: file for at least fifteen years.*]'

91. The Inquiry understands that you chaired the MNWRTC records storage task force. What was the remit of this committee and what did it achieve?

645. I do not recall chairing such a committee locally but I did do some work on a divisional basis around that time. The remit in 1991 would have been to ensure we comply with the current recommendations of the National Management Committee of the National Directorate – between 1988 and 1993.

646. I have a vague memory of changes in recommendations for storage of documents in the NHS around that time and the NBTS had to be sure it was compliant with the changes.

647. The requirement for document storage eventually proved a challenge for space at the Blood Centre in Liverpool. I do recall finding a secure and reliable place off-site to store the paper records in St Helens. We would have microfiched them prior to storage. However, as it was the other side of St Helens it was not very convenient to retrieve them for review.

92. The Inquiry also understands that there was a working party of the Northern Division of the Blood Transfusion Service on the retention of records (see NHBT0097468_024 at paragraph 3.2) which made recommendations on the retention of records in 1992. What were those recommendations and did MNWRTC follow these?

648. I cannot recall exactly. I note that Dr Lloyd said (under a heading 'Working Party on Retention of Records') that the draft of his report had been circulated and that briefly, a retention policy must be simple and 3 classifications had been suggested – 2 years for transient documents, 10 years for intermediate data eg – 'personall' (sic), 30 years for documents relating to long-term protection against litigation. This included all QC/processing data relating to blood and blood components. Each Centre would have to consider the cost/benefit of such recommendations and a central storage facility may need to be considered [NHBT0097468_024].

649. I regret that I am not able to add anything from memory on this point after almost 30 years.

93. Please set out what policy or practice was adopted by the MNWRTC in relation to the destruction of records.

650. I do not recall any practice of record destruction, although it is possible that records of donor demographics from those lost to follow up were destroyed after a set period.

651. Any clinical records on donors would have been stored confidentially permanently.

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

652. I imagine that their practice was similar but I do not know the details of each of the others having only worked as a consultant in Blood Centres in the North West of England.

653. In Manchester I remember that the first thing I did on appointment in 1984 was get rid of records from people who were born in the 1880s and had been deferred over 30 years earlier when they tested positive for syphilis and by that time the majority would have been dead and certainly much too old to donate blood. When donors were deferred there in 1984, we had a paper card system in drawers. The active donors would be in one drawer and then be moved over when they were deferred.

654. PULSE came in as a truly national database from January 1997 just as I was moving back into clinical haematology.

95. Do you consider that the record keeping measures in place at the MNWRTC were adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations at that centre? The Inquiry understands that the organisation kept a panel of donors. How was this kept? Who had access to it?

655. Yes. I do consider that the record keeping measures in place at the MNWRTC were adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations at that centre, under most circumstances. I have described above the Medical File system.

656. All donations were cross-checked against donor records before authorization for issue.

657. Clinical notes about donors with positive microbiological screening results were kept on paper in filing cabinets as part of the Medical File. When donors were deferred, we had a paper card system in drawers. The active donors would be in one drawer and then be moved over when they were

deferred. When someone came in to donate, we would take their name and look them up.

658. These cards would be clearly labelled if the person had a blood-borne infection. For example, a card might say *"X positive"* or "*Syphilis positive"*. Donors with such properties were asked not to donate again and withdrawn from future call-up to collections sessions. They were thus permanently deferred from blood donation if they were found to have transfusion-transmissible infection.

659. Communications between blood centres would be on a consultant to consultant basis. This system would not allow us to prevent dishonest donors from giving blood. If a donor lied, providing a false name and stated that this was their first donation – when in fact they had been deferred – their donation history could not be looked up. However, donors are, in general, public-spirited, well-intentioned and altruistic and would understand the need to avoid giving further donations when it was explained to them why they had been deferred.

660. However, every time we took a donation, no matter what the donor said we would carry out comprehensive microbiological screening, so any current infection would be detected.

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

a. Were you aware of the database, if so, when did you become so aware? You may wish to refer to your letter to Dr Gunson dated 14 March 1990 in this regard [NHBT0027886_084].

661. I see from document [NHBT0027886_084] that I wrote to Dr Gunson :'*Thank you for your letter about the reporting of HIV antibody positive donors directly by consultants at the RTCs to the CDSC. I am sure this will improve the efficiency of the situation'.*

662. I have now been provided with the document [NHSBT0017601] by the inquiry which is the letter to which this was a response to. It was written over 30 years ago.

663. If a donor tested positive with a notifiable disease, PHLS did the confirmatory tests and hence made the diagnosis. The Public Health Laboratory Service (PHLS) would therefore make any required formal notifications. This appears to be an agreement that a notification should be made by the RTC Consultant. I have a vague recollection of there being an anonymous donor database about risk activity. I believe that the information about the risk factors i.e whether the donor was homosexual, prior IV drug-user or had visited sub-Saharan Africa for example, was required to monitor the position epidemiologically and to improve future practice in donor selection. It was also helpful to know why the donors had not self-excluded and gone on to donate and this information would guide subsequent updates of donor information including leaflets etc.

664. In short, it takes time to develop an antibody and so you need people to self-exclude. The idea was that nationally you would see who had given blood but shouldn't have and try to prevent that from happening again.

b. Who proposed the creation of the database?

665. I do not know.

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

666. As far as I remember, yes, although there were few HIV antibody donors detected.

d. Are you aware of whether or not other RTCs contributed data on HIV positive donors to the database?

667. I would have thought so, but I only have direct experience of clinical practice in the North West Blood Centres.

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

668. We did not hold any records for HIV positive blood donors electronically while I was in Liverpool.

669. When a donor tested positive and was referred they technically became a patient and a paper record was retained securely to reflect that. Their clinical care was transferred to a specialist in genito-urinary medicine or infectious diseases.

670. Their donor record would merely indicate "PERMANENTLY DEFERRED" and there were many reasons for that. We did not track HIV positive donors subsequently. We did not ask them to tell us if they moved house after they had been permanently deferred from donating. They understood the reason and importance of not donating.

671. By the time I was appointed to MNWRTC in 1988 most of the HIV positive donors will have been detected from the screening of established donors from October 1985. Most were picked up on the initial run when testing first came in and for the next 6-12 months. After that we would hope that there would only be an occasional donor who was HIV positive. At first donors were not surprised as they usually recognised that they had been at risk, but later on it came as a big shock when a donor was positive. Pre-donation information about risk factors for HIV had been provided in a leaflet since 1983.

97. Were you ever aware of a proposal for the creation of an HCV database? If so, please answer the following questions regarding this database as far as you are able:

672. Yes, I was aware of a proposal for the creation of a HCV database.

a. Who proposed the creation of the database?

673. I believe it would have been the NBS, although the correspondence below relates to a time before the NBA when the National Directorate was guiding UK practice. It was an initiative to provide a means of collating the information from the UK Blood Centres and maximizing its use to improve future practice.

674. I have been shown document [NHBT0000049_002] dated 27 November 1990 which is draft notes by Philip Mortimer (of the Public Health Laboratory Service) on the procedure for the introduction of an anti-HCV screening programme. The topics discussed included issues which must be resolved before universal anti-HCV screening is introduced to include a central anti-HCV database, a confirmatory algorithm, an epidemiological study, a scheme for management of HCV positive donors and funding requirements.

675. It is noted that a central database was needed first to collate the findings of the pilot study and then to collect the data (as was currently done for anti HIV screening) on the operation of anti HCV screening.

676. I do not recall that the database was introduced at the same time as screening as other documents (discussed below) suggest it was related to the lookback exercise which commenced some years later in 1995.

b. What was the intended scope of the database? Were all RTCs expected to contribute to it?

677. I believe the intended scope was to try to identify risk activity predisposing to infection, as well as studying the course of chronic HCV. As far as I can recall it was intended that all RTC's should participate.

678. I have been shown a copy of a document [NHBT0001619_001], which is an Editorial - A national register of HCV infections with a known date of acquisition, study of clinical course of HCV-related disease and register of patients, which sets set out the aims and intended use of the HCV Database. The intention was that the register would provide a national resource to assist in studies of, e.g.:

- Sexual, vertical and household transmission;
- Clinical trials of new antiviral drugs;
- Further evaluation of existing antivirals and of alternative treatment protocols;
- Determination of the relationship between viral load, genotype, treatment and disease progression;
- Studies of markers prognostic for progression to disease.

679. I have also been shown document [NHBT0004351] Minutes of the MSBT Advisory committee meeting on the 3 June 1999, which notes at page 6 that the Register did not contain patient names.

c. Was the proposal made to a committee or forum similar to the regional transfusion centre directors' meetings?

680. I expect so, but by that time I was moving back into hospital practice.

d. What was your view of the proposed database? How was the proposal viewed by other RTC directors?

681. I recall thinking it was a good idea but I was moving out of transfusion at the time. I cannot comment on the views of others. Looking at the objectives for data collection set out in 97 (b) I can see that some of the

information would have been useful later to my patients with transfusion-transmitted HCV. The later protocols for antiviral treatment combinations with Ribavirin and Interferon varied according to the subtype of HCV detected as by that time some phenotypes of the virus were considered to be easier to eradicate and therefore required shorter courses of therapy. As the anti-viral therapy had unpleasant side effects this was very beneficial to some patients.

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

682. I believe the purpose of the database was to try to identify risk activity predisposing to infection as well as studying the course of chronic HCV as described above.

f. Was the database ever created? If not, why not?

683. I thought so because of the data reported, but that was happening as I left the NBS. I have recently been shown the documents referred to above.

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

684. I believe Dr Angela Robinson as Medical Director of the NBA set up the database and oversaw it. From the documents provided Kate Soldan and others were involved.

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

685. I do not know.

98. The inquiry understands that viral hepatitis is a communicable disease and so notifiable. The inquiry further understands that a decision was taken by the NBA that a positive test result did not amount to a diagnosis and so the RTC should not notify the donor (see the letter from Dr Gunson dated 13

August 1991 NHBT0071686). On receipt of a positive test for HCV in a donation, other than notifying the donor of the likely diagnosis, what if any other steps did you take to ensure that a diagnosis was made and so notified?

686. A positive microbiological screening test result does not amount to a diagnosis for a donor. The donor should not be notified until they have received positive confirmatory testing from the PHLS who should have performed at least 2 other investigations. As the Public Health Laboratory made the diagnosis they made the notification of the communicable disease.

687. Whilst the confirmatory testing was ongoing any further donation from that donor would be discarded. After the confirmatory testing the donor would be permanently withdrawn from the donor panel.

688. The Blood Centre had to be sure that it was a positive result before causing possibly unnecessary worry for the donor and referral to a specialist. On receiving positive confirmation from the PHL, the donor would be invited into the Centre where they would be informed of the diagnosis and engaged in discussion about possible risk factors. They would then be referred for further advice to the consultant hepatologist at their local hospital. (Generally see above – the donation would be discarded.)

689. Document [NHBT0071686] which has been provided to me by the Inquiry, is a letter from Harold Gunson dated 13 August 1991, headed '*Reporting of Patients Suffering from Hepatitis C'.* It notes that we (I assume the Blood Service) have been asked to find out about notification of donors/patients suffering from Hepatitis C, that Hepatitis C is a notifiable disease and that Roger (presumably Roger Moore) had consulted with the DH and there was a general agreement that the test for anti-HCV (even accompanied by the confirmatory testing) did not constitute a proper diagnosis of Hepatitis C disease which can only be made after clinical

examination of the patient and other appropriate diagnostic tests. Since it was therefore unlikely that the clinical diagnosis would be made at the RTC, we should not send the notification. The onus for notification was on the person who defined that the donor (who by that time will be a patient) is suffering from hepatitis and this definition was made at the Public Health Laboratory.

690. Notifiable Diseases are to be notified by the diagnosing clinician – who, in this instance was based in the PHLS following confirmatory testing Therefore it was the diagnosing doctor who "notified" the infection. We would however speak to the donor and tell them they had tested positive and then refer them on to a hepatologist for diagnosis and treatment. Some of them are likely to have been HCV antibody positive but with no residual evidence of active infection on PCR testing.

99. 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:

691. I was aware of the existence of a system to identify donors involved in cases of post transfusion hepatitis when I worked in Manchester. This is a memorandum dated 15 May 1989 [NHBT0005388] relating to a time after I had moved to Liverpool.

692. I have been shown a document [NHBT0005387_002] dated 19 May 1986 'Report on 'J' System'. There is no author but there are some initials PH/JLC and a date of 19 May 1986, when I was still at Manchester. This lists steps for the J donor system in 1986 and I think this may be the Manchester system because of the references to Manchester Royal Infirmary and Dr Craske.

693. I have been shown a document from the time when I was working in Liverpool at MNWRTC dated 19 June 1990 [document NHBT0000060_019] responding to a query from Dr Gunson regarding our standard operating procedure. In this I stated that I had been operating off my old recollections of the famous " J " system but realised that there was no local modification of this in print; that it had given me a change (sic, I think I meant chance) to put thoughts down on paper and I had pleasure in sending him a copy of the result.

694. I have not so far seen a copy of the enclosure and do not now have any recollection of it.

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?

695. As far as I am aware the original" J "donor system dated back to the days of homologous serum jaundice following blood transfusion which was well recognised from the 1940's. In the past anyone who had a history of jaundice could not give blood. When HBsAg tests came in I believe that it stopped operating but I do not remember exactly when.

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

696. I cannot recall but the 1989 memorandum was circulated locally in Manchester some months after I had moved to Liverpool.

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

697. The "J donor system" was a title that we could use for identifying and deferring donors with jaundice. The initial system related to people with a history of jaundice but I suspect the later 1989 practice would have been for people who had been involved in an investigation of post transfusion

hepatitis B or C. I have deduced this rather than remembering the change in practice at the time.

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

698. I do not know.

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

699. I do not know as I had left at the time it was reintroduced.

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

700. I do not know as I had left at the time it was reintroduced.

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

701. I do not know as I had left at the time it was reintroduced.

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

702. I do not know as I had left at the time it was reintroduced.

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

703. I do not know as I had left at the time it was reintroduced.

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

704. Before the electronic system Pulse was introduced, medical staff would share information very occasionally on a confidential basis.

705. If a patient got vCjD and had been a blood donor, they (or their relatives) would tell us when they had given blood and where. I understand that the diagnosing neurologist would remind the patient and/or their relatives of the potential for transmission via blood, as this information would already have been provided to them prior to their previous blood donations. They would agree that this information concerning the affected donors could be shared by consultants between regions on a confidential basis.

706. Although I do not recall this happening, I suspect that if someone had been given results of positive confirmatory testing for hepatitis or HIV and had or was about to change their address outwith our catchment area, we would have spoken to a senior doctor at the Blood Centre which served their new residence.

101. In his statement to the court in *A and Others v National Blood Authority and another* [2001] 3 All E.R. 289 (A & Others), Dr Gunson expressed the view that "there was no central organisation to ensure that...all RTCs operated in a uniform manner" (page 3, para 9) [NHBT0000025_001]. 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?

707. I agree that there was "no central organisation to ensure that all RTCs operated in a uniform manner". I think the information sharing was as good as it could be prior to the National computer system Pulse in 1997. The laboratory in Liverpool was computerised in 1990. Different IT systems operated in different regions before 1997.

708. Providing the donors were donating in an altruistic manner and acting honestly then the system did work. However, if the donors used false names for instance then this would cause difficulty.

709. All donations, however, underwent microbiological screening, so all the blood products were quality assured prior to issue.

SECTION 7: SELF-SUFFICIENCY

102. What was your view on the prospect of the UK achieving self-sufficiency during your tenure as director of MNWRTC? Has your view changed since then, and if so how?

710. I was optimistic and considered that we would achieve self-sufficiency. The focus was on self-sufficiency because NHS coagulation factor concentrate from voluntary British donors was generally regarded as safer which I agreed with.

711. In 1984 I had already set up the Apheresis Centre in Manchester and apheresis was well established by the time I arrived in Liverpool in 1988. We worked very hard to scale up the plasma yield in Liverpool over the next few years.

712. Had the service been nationalised about 15 to 20 years earlier it would have been much easier to progress towards national self-sufficiency in plasma but this would have required quite a lot of foresight and additional funding sooner.

713. In particular, I think that if they had fully funded national self-sufficiency in the late 1970's or early 1980's we might have been able to keep up as demand for factor VIII concentrate increased. We were aware of the need

and Lord David Owen had expressed this as Secretary of State for Health in the 1970s.

714. The plasma demand was ever increasing for a number of reasons. The factor VIII yield achieved by fractionation was reduced by the viral inactivation processes necessary to eradicate HIV and HCV from the fractionated product. There were increasing opportunities for surgical procedures for men with haemophilia and their adoption of home therapy for haemostatic support and subsequently prophylaxis in paediatric practice which were also associated with increased usage.

715. The "goal posts" did, therefore, move during this time and this presented a challenge. I think we did as well as we could from 1988 to 1995. I have referred elsewhere (in response to question 28 b) to the stockpile that accumulated at BPL, to the difficulties we faced and the efforts made to increase donor numbers, maximise collection and yield of plasma and the other factors and obligations which we had to take into account and fulfil, as well as to the funding issues.

103. What steps do you consider were required to achieve self-sufficiency in the UK at this time? Were any of these steps taken? What could and should have been done to achieve self-sufficiency? Please explain the concerns you were expressing about the contractual arrangements put in place in February 1990 and the impact this would have on self-sufficiency in the letter to Dr Moore [NHBT0097035_080].

716. In order to achieve self-sufficiency, it was necessary to collect sufficient donor plasma to yield all the factor concentrate required by patients with bleeding disorders in the UK. This volume of plasma increased substantially during the 1980's and 1990's for the reasons set out in my response to 102.

717. I developed a strategy to increase plasma procurement steadily at Liverpool Blood Centre by the use of optimal additive solutions in processing (SAG-M) which increased the plasma yield by approximately 100ml from each 500ml donation and in addition significantly increased plasma procurement from dedicated apheresis donors who could attend as often as once a fortnight – donating 500ml of plasma at each visit. There was also a positive approach to increasing the donor panel and to making it easier for donors to attend sessions. We implemented mobile collections using coaches in the car parks of smaller firms after the large factories ceased to be a valuable resource in Liverpool during the 1980's. We attended at industrial estates in order to minimise the disruption to individuals and businesses in donating. We collected in the evenings, at weekends and during the holidays. We had staff and resources devoted to recruiting and retaining donors.

718. We also provided a delivery service transporting frozen plasma from other Blood Centres as well as our own to Elstree on a weekly basis and returning plasma products from BPL.

719. Although plasma procurement increased considerably across the 1980's and 1990's the UK was still not self-sufficient as a consequence of the increased demand for Factor VIII and of the reduction in yield as a consequence of the viral inactivation processes. If we had achieved self-sufficiency by the early 1980's we might well have been able to sustain this but only if BPL had been completed to time to facilitate the fractionation on the scale required.

720. At the time, funding was from DH to RHA. It was the RHA's who provided our funds and it really depended how enlightened they were about the need for certain things. This meant that there were budgetary constraints determining what we could do and their perception of the importance of funding their regional transfusion centre appeared to vary in different regions.

721. In my letter to Dr Moore dated 26 February 1990 [NHBT0097035_080] I expressed a reluctance to be tied into a restrictive contract with BPL for the year. This was because it was difficult to predict in advance the requirement for blood products by third parties around the region, although I do mention that this was becoming clearer. I had also worked hard to persuade colleagues locally to arrange purchase of BPL products on a regional basis through the Regional Pharmaceutical Committee and saw no need for the additional efforts of BPL sales representatives.

722. I was unsure as to the objectives of NBTS/CBLA and concerned that cross accounting made the goal of self-sufficiency less clear.

723. The detail of the fairly complex arrangements was not clear to me, but I had spoken to Dr Gunson about the proposals in order to better understand them and on that basis was reluctantly prepared to agree. I had not previously been aware of the implications of the forthcoming change in EEC Regulations scheduled for 1992 which would open up the European market to BPL.

724. The effort and ingenuity that went into national self-sufficiency were phenomenal – increasing the yield from every bag, donors giving plasma twice a month in the middle of their working days, recruiting very large numbers of people and many other valuable therapeutic services.

725. My closing comment – that I thought it was unfortunate that our colleagues in clinical medicine elsewhere did not share our commitment to the goal of self-sufficiency - was to note that some clinical colleagues were spending funds on commercial concentrates rather than NHS products and this appeared to undermine our efforts towards national self-sufficiency, although from time to time such practice had been inevitable at times of shortage of supply from BPL.

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

What did you mean when you stated in the letter to Dr Moore of 26 February 1990 that it was a shame that your colleagues in clinical medicine did not share your commitment to self-sufficiency? [NHBT0097035_080]

726. In the North West we were committed to self-sufficiency. I do not recall what the position was elsewhere. I have explained my comment about clinical colleagues above.

105. What role did you as the Director of MNWRTC have in the drive toward self-sufficiency in the UK?

727. I developed a strategy to increase plasma procurement steadily by use of optimal additive solutions in processing (SAG-M) and dedicated apheresis donations as well as endeavouring to increase the donor panel by providing mobile collection units, maximising donors' opportunities and convenience to donate etc as described above.

728. We also provided a delivery service transporting frozen plasma from other Blood Centres to Elstree on a weekly basis and returning plasma products from BPL.

106. How significant an issue was self-sufficiency for the RTC Directors and the Executive Committee of the NBA?

729. It was hugely important for me as a Director and it was one of the main focuses of our work nationally in the 1980's and 1990's. We worked very hard towards our regional contribution to it, used BPL products as far as they were available, facilitated transport of frozen plasma and BPL products around the country etc. The first thing I was asked when I got to Liverpool was how long it would take us to scale up our plasma contribution towards the national target and what steps we needed to put in place to achieve regional self-sufficiency in plasma. This included SAG-M, apheresis etc all the steps previously set out.

SECTION 8: LOOK- BACK EXERCISE

107. In or around August 1994 you were involved in the feasibility of initiating look-back exercise to identify those infected with HCV as part of an ad-hoc group of experts assembled by the Standing Advisory Committee of Transfusion-Transmitted Infection [NHSBT0009383]. Did the group recommend a look-back exercise? You may wish to refer the Recommendations made by that group [PRSE0001236].

730. I recall I was in an ad hoc group with the National Director Dr Angela Robinson from August 1994. The group was convened on behalf of the Standing Advisory Committee on Transfusion-Transmitted Infection (SACTTI) to discuss the desirability and feasibility of introducing a "look back" policy to identify, test and counsel if necessary surviving past recipients of blood components from donors later found to be anti-HCV seropositive after September 1991 when screening was introduced.

731. We had previously been advised against a lookback when routine screening of blood donations was introduced initially on the basis that the risks to public health were not the same as with transmission of HIV and there was no specific HCV anti-viral treatment for recipients available in 1991. I do not know the background to this, but my assumption would be that this was based on advice given to DoH by liver experts.

732. It was not until 1995 that Interferon became available to treat HCV and at that time lookback was more widely considered to be appropriate.

733. As the document to which I have been referred sets out [PRSE0001236] the ad hoc committee established to consider this felt that there was a serious case for considering a lookback policy for HCV by that time in August 1994 when antiviral treatment with Interferon had recently been introduced. To do otherwise when a lookback programme for HIV already existed would have suggested double standards. At the time that HCV

screening was introduced in 1991, it was known that Hepatitis C had the potential for long term and serious illness for some of those affected, but there was no way of knowing the extent of this, who would be affected or in what way, there was no treatment for it and it was not as readily transmissible as HIV.

734. The document sets out the respects in which this had changed by 1994, so that the consensus of the ad hoc group was that lookback should now be seriously considered and after some further consideration, this was accepted and national lookback instigated the following year in 1995.

108. The Inquiry understands that a look-back exercise was undertaken in 1995 by the NBA.

a. Can you describe what this involved and your views on the efficacy of it? You may wish to refer to the notes of the meeting of the Northern Zone Audit Group on 12 November 1996 [NHBT0036440] together with the report of the programme [NHBT0036735]. You may also wish to refer to the article entitled 'Transfusion transmission of HCV infection before anti-HCV testing of blood donation in England: results of the national HCV lookback program' [NHBT0097156_004], the article 'Probability of receiving testing in a national lookback program: the English HCV experience' [NHBT0097156_005] and the article 'The Contribution of transfusion to HCV infection in England' [PRSE0000620] when answering this question.

735. As described in document [PRSE0000620] the HCV lookback programme in England attempted to trace patients transfused prior to September 1991 with blood or blood components from donors who were subsequently found to be positive for antibodies to hepatitis C (anti-HCV) after routine screening of all donations for anti-HCV was introduced in September 1991. The aim of this lookback was to identify previous recipients of blood products with transfusion-transmitted HCV who might benefit from specialist care and new anti-viral treatment. For various reasons including

loss of records, movements of patients, best interests and wishes, not all recipients of blood from known anti-HCV-positive donors received further investigation. Also, as not all HCV-infected donors returned to donate blood after anti-HCV testing was introduced, some infected donors whose donations were collected between 1 January 1980 and September 1991 will not have been subsequently identified and will not have entered the lookback programme.

736. From a practical point of view, all the donors who had tested positive since 1991 had to be identified. The next step was to determine where their prior donations had been issued. We then had to write to the hospital to identify the recipients of the donations, each of which may have been made into a number of components. After this we would write to the recipient's specialist (for the majority had been transfused in hospital) and GP and ask them if they wished to see the recipient. If the specialist and GP indicated that they did not want to see the potentially infected recipient, we would write to them and invite them to make an appointment to come to see us at the Blood Centre.

737. It would be unlikely that the specialist or GP would wish to be involved. Assuming they did not want to be, then we would take it forward at the Blood Centre. This process did take some time, as there were a lot of steps that DH required and that we needed to work through, so it could take some months after the initial diagnosis before we would end up seeing recipients at the Blood Centre to advise them of the position, offer repeat testing and then arrange referral to specialists.

738. As described in document [PRSE0000620] data obtained from the lookback was used to estimate the total number of recipients infected by blood transfusion who were either dead or alive at the end of 1995. This paper (by Kate Soldan, Dr Angela Robinson and others) sets out that 13,500 recipients were likely to have been infected during the decade prior to the introduction of testing, over 60% of whom were expected to have died by the end of 1995. Transfusion had infected a large group, but this

was a small and declining proportion of those infected overall in the population. The infection rate of those who had received an implicated component was 55%, 10% of whom had been identified before the lookback began. A total of 25,864,035 donations were collected between 1980 and 1991 of which 17,086 were estimated to be anti-HCV positive. Overall, this paper concludes that the HCV lookback programme identified about 5% (677) of the total number of HCV infections transmitted by transfusion from 1 January 1980 to 1 September 1991, and over 13% of infected recipients who survived to 1995. Whilst we were not able to trace everyone, we were able to facilitate the diagnosis and referral for monitoring and for treatment as it became available, of a small but significant number of surviving recipients. I considered this to be very valuable.

739. The article '*Probability of receiving testing in a national lookback program: The English HCV experience'* [NHBT0097156_005] on which I have been asked to comment, notes that only approximately 20% of transfusable components entering the lookback resulted in a recipient being tested through the programme. 4,424 recipients of the 6,687 components issued were identified and recipients of 1,067 components were tested. The outcome in terms of identifying recipients who wished to be tested was low compared with the effort required and with other screening programmes, but within the range of published HCV lookbacks. Overall, for every 100 components which had been issued and entered the lookback (which is not the same as patients transfused as not all issued components are used at the hospital) 26 living recipients were identified and 8 HCV infections were found. The most common reason for identified recipients not being tested was death. 47% of the 873 recipients for whom the year of death was reported had died within less than a year of the transfusion and a further 23% after one year. Had lookback been restricted to PCR positive donors the reported data suggested that only 10% of the components identified would have entered the lookback.

740. I have described above in response to question 4, my presentation to the Northern Zone of our findings in that Zone by November 1996.

b. You wrote to Dr Flanagan on 18 July 1995 indicating that the look back exercise would not extend to any indeterminate reports unless there was a direct instruction to do so [NHBT0015670]. Was any such direct instruction given? You may wish to refer to the letter from Dr Robinson dated 1 March 1996 [NHBT0036529] and the letter you wrote on 5 August 1996 [NHBT0035104] when answering this question.

741. My comment in document [NHBT0015670] in relation to a direct instruction meant that there would have been no alternative but for us to extract the laboratory results of all indeterminate results reported since 1 September 1991 and to scrutinise them for appropriate detail which would take up a great deal of time with unknown benefit. I therefore advised Dr Flanagan that no action would be taken to extend the lookback to this group of donors unless there was a direct instruction with a clear definition of an indeterminate result.

742. Dr Robinson did give the instruction to extend the lookback to indeterminates by her letter of 1 March 1996 [NHBT0036529] on the basis that SACTTI had provided an agreed definition of selected HCV indeterminates in the lookback programme. This had been endorsed by MSBT with the recommendation that all UK transfusion centres should extend the lookback to indeterminates within the definition provided.

743. In my letter to Dr Robinson of 5 August 1996 [NHBT0035104] I responded that all the positives identified at MNWRTC were in fact positive and we were in the throes of investigating another six donors of indeterminate status. I am afraid I cannot comment further. I left the transfusion centre and moved back into secondary care when I was appointed Co-Director of Mersey and North Wales Comprehensive Care Centre for Haemophilia in October 1996

109. What other look-back exercises have you been involved in? How successful have they been? What could have been done to improve their efficacy? You may wish to consider the letter you co-signed to the NBA dated 4 April 1997 in which you raise concerns about the Transfusion Microbiology Laboratory in Liverpool and the fact that it seriously hampered your ability to undertake a look-back exercise [NHBT0007225].

744. I was involved in other lookbacks.

745. I did routine HIV look backs in Manchester from the introduction of HIV antibody screening of all donors from October 1985. By the time I was doing the last lookback which followed the investigation of a case of transfusion transmitted HIV in Liverpool in 1997 there was an effective treatment for treating HIV with highly active anti-retroviral therapy (HAART) and therefore the identification of these recipients was of direct benefit to their own health as well as being important from the public health point of view.

746. Our letter in April 1997 [NHBT0007225] was intended to raise concerns about the difficulty of performing such an investigation of reported post transfusion infection in the absence of a Transfusion Laboratory on site in view of the impending removal of this facility from Liverpool to Manchester in 1997 following the earlier Bain review of the NBS.

747. I was involved in the hepatitis C look back at Liverpool Blood Centre in 1995. An example of a letter I would have sent out can be seen in document [NHBT0099187_075].

748. I also participated in the two vCJD look backs in 2004 and in 2009 for patients registered with Inherited Bleeding Disorders at the Comprehensive Care Centre for Haemophilia in Liverpool, as required by the Department of Health according to their standard protocols.

SECTION 9: DECISIONS AND ACTIONS OF THE LIVERPOOL HAEMOPHILIA CENTRE AND YOUR DECISIONS AND ACTIONS

110. In relation to your work at the Liverpool Haemophilia Centre as a Consultant Haematologist please:

a. Describe your role and responsibilities and how they changed over time;

749. I was appointed Consultant Haematologist to the Royal Liverpool Hospital and Co-Director of Mersey and North Wales Comprehensive Care Centre (CCC) for Haemophilia at the end of 1996 and took up the post in February 1997. The CCC also provided these tertiary services to patients from the Isle of Man.

750. My Co-director was Dr Cheng Hock Toh (Professor Toh since 2005) who replaced Dr Charles Hay in 1995, when he moved to Manchester.

751. My role at the CCC involved the specialist care of those with inherited disorders of haemostasis with a small contribution to local research. This role developed as new treatments were discovered and evolved – both in the management of their blood disorders and their associated transfusion-transmitted infections.

752. In view of the aetiology of their transfusion-transmitted infections, our patients preferred to attend dedicated clinics within the CCC rather than to attend with others in different departments of the hospital and therefore joint clinics were established "in house" with colleagues from the appropriate specialties.

753. When I started at the CCC in February 1997 there was a Joint Liver Clinic held every 3 months with Professor Sir Ian Gilmore in attendance to advise on advances in anti-viral treatment, mainly for hepatitis C, some patients having already received a trial with Interferon as a single agent previously

for this infection. Anyone who was suitable for the original interferon treatment for hepatitis C and wanted it had received it, but it was not very successful in eradicating the infection. Professor Gilmore was later succeeded by Professor Martin Lombard.

754. Patients were subsequently offered dual therapy for HCV with Ribavirin and Interferon and then there was a little more success with a combination of pegylated Interferon and Ribavirin. The side effects of these regimes were unpleasant and a sustained antiviral response was not frequently achieved. In general, in treating HCV we started with mono-infected individuals and then offered the treatment to those co-infected with HIV once the latter were established with an undetectable viral load on anti-retroviral therapy.

755. Highly Active Anti-Retroviral Therapy (HAART) was introduced as effective triple therapy for HIV and some of our patients agreed to start this in 1997. This was delivered through a second Joint Clinic with a specialist in Infectious Diseases, initially Dr Peter Carey, followed by Professor Saye Khoo and latterly Dr Mas Chaponda. This was in light of the fact that Haemophilia patients who had acquired HIV or hepatitis, via their treatment often felt more comfortable having their treatment with the team they knew in the CCC rather than moving over to another.

756. The joint HIV clinics were held about once a month initially. The specific anti-viral regimes were recommended by the specialist and agreed with each individual during a joint consultation. The day to day laboratory monitoring and clinical care continued within the CCC with immediate access to the specialists in infectious diseases should the need arise. Regular specialist review continued and from time to time new treatments, usually with fewer side effects or a more simplified regime, were offered and taken up as time went by. When a new treatment became available all the patients on HAART were reviewed to see who might benefit from it. Some had a history of drug reactions and the demands of the therapies were sometimes quite high – whether they needed to eat first, how the

doses were carefully spaced- so careful consideration had to be given to any suggested change.

757. From the point of view of my involvement, we always had a specialist who would recommend which anti-viral treatment should be prescribed. We would not direct a change of anti-viral treatment ourselves without expert guidance. When we made a change in treatment for a patient who had HIV, we would have to assess and monitor how they dealt with it, but we would not be responsible for selecting the treatment de novo or their overall care which was provided by whoever were the relevant specialists at the time.

758. vCJD became an issue between 1997 and 1999 and it was decided that British plasma should no longer be used as a source for fractionation in the UK.

759. Following a change in Government in 1997 it was announced that recombinant products would be available for all patients with bleeding disorders who required factor concentrate. This was a gradual process that took place over 3 years; we were advised it would not be possible to move everyone onto recombinant therapy from day one as the increase in demand had not been anticipated in the UK and the manufacturers indicated that it would take some time to scale up production. Recombinant coagulation factor concentrate was introduced for the younger patients first, the change of brand requiring more careful monitoring in the short term in order to ensure that the new product produced the desired haemostatic effect and was associated with minimal side effects.

760. When the new and vastly superior anti-viral treatment for HCV was more recently introduced there was a dedicated service for its delivery between the Departments of Hepatology and Infectious Diseases. The patients from the CCC all knew the hepatologists by that time so they were happy to attend for its induction and monitoring.

761. Routine care of patients on haemostatic support includes regular full blood counts, routine biochemistry, liver function tests and a check for inhibitors of coagulation factors no less often than every 6 months.

762. Those with chronic liver disease also needed monitoring 6 monthly with fibroscan or ultrasound, depending on whether they were cirrhotic or not together with a check on alpha fetoprotein and prothrombin time.

763. There was a recommendation around the millennium that if patients had hepatitis C, it was very important that they did not contract another form of viral hepatitis, so we would check if they were immune to hepatitis A and B and if not would arrange for them to be immunised accordingly.

b. Describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products;

764. Please see my response to question 110a.

111. Approximately how many patients with bleeding disorders were under the care of the Liverpool Haemophilia Centre when you began your work there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so).

765. I cannot recall exactly but I anticipate it was in the region of 40-60 with patients with severe haemophilia and many more with mild bleeding disorders, von Willebrand's disease and platelet function defects.

766. UKHCDO should have a record of this as they did surveys of patients treated at haemophilia centres in their UK annual return as can be seen in document [CBLA0000295]. They also conducted surveys of HIV positive patients on behalf of the Communicable Disease Surveillance Centre (CDSC) during the 1980s and early 1990s.

Delay/public health/other information

112. Were the results of testing for HIV and hepatitis (of all kinds) notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

767. By the time I arrived at the CCC in Liverpool in 1997 the majority of patients had already undergone hepatitis and HIV screening and were aware of their diagnoses.

768. When someone came in to the haemophilia centre in Liverpool from a CCC of equivalent status we would accept their results but if they came from a local DGH saying they had a bleeding disorder such as von Willebrand's disease diagnosed 20 years ago in a peripheral laboratory, we would re-test to confirm the haematological diagnosis; in tertiary practice the results of investigations performed at another tertiary centre would be accepted but not necessarily those from a non-specialist centre. In 1997 we would only undertake microbiological screening for potentially transfusion-transmissible diseases with informed consent in those with a history of previous haemostatic support who had been referred from their GP or a DGH or if a former patient had returned to clinic after a long period of time. Under these circumstances we would screen them for Hepatitis B, C and HIV as well as checking their need for vaccination against HBV and HAV. They would be informed promptly of the results in clinic.

769. Where patients with possible post-transfusion infection were referred by hospital colleagues to consultants at the Blood Centre, we would trace the donors to see if there were any other implicated units and then advise the treating clinicians who would be involved with any other affected recipients in the hospital.

113. To what extent, if at all, did you/your colleagues take into account the public health implications of HIV, AIDS, HBV, and HCV, when taking decisions as to what information or advice to provide to patients or what treatment to offer?

770. We would always take into account the public health implications of HIV/ AIDS, HBV, and HCV, when taking decisions as to what information or advice to provide to patients or what treatment to offer.

771. For instance, there was an awareness about HIV and the public health implications because of the way it was transmitted. When providing advice, I would always offer to have a discussion with partners. When patients were told, they might say "what am I going to say to my partner". We would offer to find a reason to bring the partner in so we could tell them and explain it to them. Alternatively, they might come to see us with a new partner. We would also spend a long time discussing with girlfriends or fiancées about having children and the risk of passing it on.

772. The Sexually Transmitted Diseases legislation gave patients the right to be treated anonymously, in full confidence for HIV. However, we would strongly advise patients to allow us tell their GP and Dentist. One of the reasons for this was because it was important to ensure any changes in their condition were picked up quickly in the interest of their own wellbeing as well as for public health reasons.

773. I was never involved in selecting treatment or regimes for HIV patients as this was undertaken by an expert. I would, however, monitor patients on anti-viral therapy as they might suffer side-effects and would require regular monitoring with blood tests in the long term to ensure the continued efficacy of the therapeutic regime.

114. What information was provided to patients about the risks of other infections?

774. By the time I arrived in 1997 the majority of patients at the CCC who had received plasma derived haemostatic support had been screened and informed of their results.

775. I believe leaflets were provided to patients about the risks of other infections. An appointment would be made and they would come in. Leaflets would be provided after we had spoken to them about it. If there was written information, it would be given to take away after the discussion. That was really all before my time. Dr Charles Hay would have been there shortly after the material time in 1986 and his predecessor was Dr Tony McVerry. I believe they sadly had many deaths at that time.

776. Patients develop opportunistic infections with HIV which are atypical and like pregnant women, for example, they needed to avoid eating soft cheeses. They would be on prophylactic antibiotics until it was clear that the virus was suppressed and this could take months or years.

115. What information was provided to patients about the risks of infecting others?

777. Patients with HIV and Hep C were advised to practise "safe sex " and use barrier methods of contraception (condoms).

778. For many years the male patients were advised there would be a risk of passing it on to their partners and through them to their children. They would be advised to have sperm-washing when they wanted to start a family prior to IVF. Now it is recognised that provided the virus is suppressed on HAART and they keep taking the tablets, there is not a risk of transmission to either the mother or the child.

116. What actions or decisions were taken at any of the hospitals at which you worked to trace patients who may have been infected through the use of blood or blood products?

779. I carried out various national or individual lookback exercises as described in my response to question 109.

780. I participated in the national Hepatitis C look back exercise when I was at the MNWRTC.

781. When I was at the Royal Liverpool Hospital during my subsequent appointment, if there was any suggestion that there had been a post-transfusion hepatitis I would inform my colleagues at the transfusion centre. This would be likely to have been from a transfusion rather than from blood products. Once I left the RTC, I would just have reported it to a colleague at the transfusion centre who would then have implemented the lookback.

782. When the HIV transmission occurred in Liverpool in 1996 and was investigated in 1997 I had just started at the Royal Liverpool 4 weeks earlier but I did carry out that investigation, in spite of the fact I had moved on, because of its significance and my previous experience.

783. I also investigated transfusion-transmitted hepatitis infections when I was at the transfusion centre.

Consent

117. How often were blood samples taken from patients attending the Liverpool Haemophilia Centre, and for what purposes? What information was given to patients about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of the samples? Was their consent recorded? If so, how and where?

How often were blood samples taken from patients attending the Liverpool Haemophilia Centre, and for what purposes?

784. Routine blood monitoring was arranged for those on regular haemostatic support at least every 6 months.

785. If the patients were well, we would routinely check full blood count, renal and hepatic function and look for inhibitors to transfused factor VIII at a minimum of twice a year. If they were on some treatment for a virus, we had to monitor for efficacy and possible side effects according to the relevant treatment regimes, which varied.

786. The timing of the next clinic appointment would depend on the treatment regime and monitoring requirement.

787. We used to monitor HIV viral load on HAART with serial quantitative PCR. CD4 lymphocyte counts were also requested to assess the efficacy of HARRT.

788. We monitored for viral load similarly for patients with hepatitis C on specific anti-viral therapy.

789. For patients with HCV on antiviral therapy, this varied between every one and four weeks. For those with HIV on HAART it would depend on the stage of treatment which could be weekly to start with, then monthly or then quarterly with improvement and some are now only reviewed twice a year. If, however, there was evidence of viral recurrence the individual would be contacted as soon as the result was reviewed and invited in for repeat screening and further advice.

790. Those with chronic HCV also needed imaging of the liver every 6 months either by fibroscan to check for cirrhosis or ultrasound once cirrhosis was established to screen for hepatoma. Alpha fetoprotein assay provided an additional check for the latter.

791. If someone came in with a bleed or because they were ill we would check their Factor VIII level, give Factor VIII if necessary, check again to see if

the level was safe and also check they did not have antibodies to transfused factor VIII.

What information was given to patients about the purposes for which blood samples were taken?

792. The patients would know what the samples had been taken for and they would be told the results the next time they came to clinic.

793. Consent for the routine monitoring was verbal. They would go out of the clinic room with forms, do the blood tests and get results at the next visit.

794. Those with inherited bleeding disorders were invited to provide samples with informed written consent for genetic analysis to determine the specific bleeding disorder in their kindred. Such information could later be particularly useful to their female relatives in the management of pregnancy. Options for storage and further studies at a later date were included in the consent.

***Were patients asked to consent to the storage and use of the samples?* Was their consent recorded? If so, how and where?**

795. Any virology samples will have been stored routinely. The biochemistry and haematology samples were not.

796. I did not consent to them separately for sample storage as I did not request that the samples be stored in the laboratory.

797. We obtained written consent for screening patients for HIV.

798. Written consent was always obtained for genetic studies; all hereditary haemophilia patients had genetic studies done to identify the mutation in the coagulation factor gene in their kindred. Sheffield was our reference

laboratory for those. Consent was recorded in their notes and they were given an information leaflet.

118. Were patients under your care treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent to treatment? Was their consent recorded and if so how and where?

799. As soon as a haemophilia patient was admitted to hospital with an intracranial bleed they would come under the care of the CCC for advice about their haemostatic support. The only time we would treat with Factor VIII without consent would be if they were unconscious or if they had learning difficulties and were unable to consent. Under those circumstances we would speak to their relatives or guardians and that would be annotated.

800. Consent has changed over the years. We now have consent form for those who lack capacity. Consent forms are also now electronic but before that it would have been recorded on paper in the patient record with a copy for the patient.

801. In an emergency situation the relatives might be an hour or two behind the patient as the CCC served a large geographical area including the Isle of Man. In circumstances where survival or the avoidance of severe harm depended on immediate haemostatic support we might go ahead if the patient did not have capacity, with the consent of two doctors.

119. Were patients under your care tested for HIV or hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent for testing? Was their consent recorded and if so how and where?

802. I do not recall patients being tested for HIV without their express and informed consent. If we asked for HIV screening at the Royal Liverpool

using either the paper or electronic forms, we had to tick – "have they given informed consent?". We would usually also annotate this in the notes.

803. We obtained written consent for screening patients for HIV.

804. If we had previously treated patients who had come in for the first time in years we would test them for hepatitis A, B and C but we would speak to them before doing so. We would explain that we needed to know if they needed any extra vaccinations and see if there was any evidence of previous exposure to transfusion-transmitted infection. In the absence of previous haemostatic support we also did some tests (biochemistry and blood counts and check Hep A and B virology) and we would explain that someone with a bleeding disorder is more likely to need a blood product and we would like to protect them.

PUPS

120. Please detail all decisions and actions taken by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS).

805. It would have been very unusual for me to see any previously untreated patients as we did not treat children. Those who suffer from severe bleeding disorders are very unlikely to have come out of childhood undiagnosed without previous treatment.

806. I may have encountered an adult having an operation who had mentioned pre-operatively that they had problems with bleeding. Referral would be arranged to the CCC for investigation to see if they needed to be covered by haemostatic support for the surgery. Depending on the subsequent diagnosis every effort was made to avoid blood products but if these were necessary their plasma derivation would be explained to the patient with its inherent risk

807. If it was a first exposure to a coagulation factor concentrate even by 1997 we would have been likely to be using recombinant products. The patients with von Willebrand's disease who were unresponsive to DDAVP would still be having plasma-derived blood products because there was a delay of many years before recombinant was available for them but we would inform them what systems were available to them for haemostatic support with an assessment of their relative risks.

Treatment of patients who had been infected with HIV and/or Hepatitis

121. How was the care and treatment of patients with HIV/AIDS managed at the Liverpool Haemophilia Centre? In particular:

a. What steps were taken to arrange for, or refer patients to, specialist care?

808. Highly Active Anti-Retroviral Therapy (HAART) was introduced as effective triple therapy for HIV and some of our patients agreed to start this in 1997. This was delivered through a Joint Clinic with a specialist in Infectious Diseases-who was initially Dr Peter Carey, followed by Professor Saye Khoo and latterly Dr Mas Chaponda. This was in light of the fact that Haemophilia patients who had acquired HIV or hepatitis via their treatment often felt more comfortable having their treatment with the team they knew than moving over to another.

809. The joint HIV clinics were held about once a month initially. The specific anti-viral regimes were recommended by the specialist and agreed with each individual during a joint consultation. The day to day laboratory monitoring and clinical care continued within the CCC with immediate access to the specialists in infectious diseases should the need arise. Regular specialist review continued and from time to time new treatments usually with fewer side effects or a more simplified regimes were offered and taken up as time went by. When a new treatment became available all

the patients were reviewed to see who might benefit from it. Some had a history of drug reactions and the demands of the therapies were sometimes quite high – whether they needed to eat first, how the doses were carefully spaced.

810. From the point of view of my involvement, we always had a specialist who would recommend which treatment should be prescribed. We would not direct a change of anti-viral treatment ourselves without expert guidance. When we made a change in treatment for a patient who had HIV, we would have to assess and monitor how they dealt with the treatment within the CCC, but we would not be responsible for selecting the treatment or their overall care which was provided by whoever were the relevant specialists at the time.

811. Latterly we ran a specialist clinic once every other month on a Tuesday afternoon with Dr Chaponda for haemophilia patients rather than sending them over to GUM clinics. It was very important to our patients that the infectious diseases specialists attended them in the CCC rather than that they should have to go to their department so we arranged this for them.

b. What treatment options were offered over the years to those infected with HIV?

812. The specialists recommended various schedules of HAART for patients with HIV and advised on the risks and benefits when changes were to be made. Initially the treatment was focused on getting control of the infection and then how and when to take the medications. Over the years the treatments were modified and improved to simplify administration. Regular specialist review continued and from time to time new treatments, usually with fewer side effects, or less complicated regimes were offered and taken up.

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

813. The specific treatment regimes were introduced by the specialist in infectious diseases on an individual basis with full disclosure of benefits, administration schedule, risks, side effects and monitoring requirements.

d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?

814. The timing of the next clinic appointment would depend on the treatment regime and monitoring requirement.

815. For those with HIV on HAART it would depend on the stage of treatment – weekly to start with, then monthly or then quarterly with improvement and some patients are now only reviewed twice a year. If, however, there is evidence of viral recurrence the individual would be contacted as soon as the result was reviewed and invited in for repeat screening and further advice.

816. Once people were established on a treatment we might follow up once every 6 months but this would depend on the individual.

817. Please see my response to question 110 in relation to how the clinics worked above with care provided by a multi-disciplinary team in consultation with individual patients.

122. How was the care and treatment of patients with HBV managed? In particular:

a. What steps were taken to arrange for, or refer patients to, specialist care?

818. From memory I can recall only one individual with chronic HBV. As he was co-infected with HIV this was taken into consideration in recommendations made by his specialist in infectious diseases for his personalised HAART

regime to include Lamivudine which was also beneficial in treating his hepatitis B.

b. What treatment options were offered over the years?

819. Please see my response to question 122(a).

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

820. The specific treatment regimes were introduced on an individual basis to the patient in clinic by the specialist in infectious diseases with full disclosure of benefits, administration schedule, risks, side effects and monitoring requirements. On some occasions it would also be necessary to arrange special virological investigations to allow a specially tailored protocol to be established, taking into consideration response to previous therapy. The patient would then usually consider the information and then decide whether or not to start the new regime, with its attending initial monitoring recommendations.

d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HBV?

821. For a patient on specific anti-viral treatment for HBV the timing of the next clinic appointment would depend on the treatment regime and monitoring requirement.

822. By the time I was working as a Consultant in haemophilia care, the tests for Hepatitis B were sophisticated, a vaccine was available and treatment was mainly by recombinant products so this was not a particular issue. Where relevant we would check to see if it was appropriate to offer vaccination for HBV as well as HAV for protection in all patients registered with an inherited bleeding disorder.

123. How was the care and treatment of patients with HCV managed at the Liverpool Haemophilia Centre? In particular:

a. What steps were taken to arrange for, or refer patients to, specialist care?

823. When I started at the CCC in February 1997 there was a Joint Liver Clinic held every 3 months with Professor Sir Ian Gilmore in attendance to advise on advances in anti-viral treatment, mainly for hepatitis C, some patients having already received a trial with Interferon as a single agent previously for this infection. Anyone who was suitable for the original interferon treatment for hepatitis C, and wanted it, had received it but it was not very successful in eradicating the infection. Professor Gilmore was succeeded by Professor Martin Lombard.

b. What treatment options were offered over the years? When did you begin to treat patients with interferon?

824. I understood that a number of patients had received single agent Interferon for their HCV in the mid-1990's before my arrival in 1997.

825. They were subsequently offered dual therapy for HCV with Ribavirin and Interferon and then there was a little more success with a combination of pegylated interferon and Ribavirin. The side effects of these regimes were unpleasant and a sustained antiviral response was not frequently achieved.

826. In general, in treating HCV we started with mono-infected patients with bleeding disorders and then offered the treatment to those co-infected with HIV once the latter were established with an undetectable viral load on antiretroviral therapy.

827. The latest and far more effective anti-viral therapy for HCV eradication became available to our patients from 2016 and their response to this was excellent.

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

828. The specific treatment regimes were introduced on an individual basis by the specialist in infectious diseases with full disclosure of benefits, administration schedule, risks, side effects and monitoring requirements. Information leaflets were also provided.

d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HCV?

829. I have described above in my response to question 110, the operation of multi-disciplinary clinics and monitoring by alpha fetoprotein assay, prothrombin time and serial fibroscan or ultrasound at 6 monthly intervals as surveillance for hepatoma in those with cirrhosis.

830. A small proportion of patients were referred by our colleagues from the Liver Clinic to the supra-regional Liver Transplant Unit in Birmingham and some were selected for transplant. Others were treated locally for focal hepatoma in the Department of Interventional Radiology at the Royal Liverpool Hospital. Please see also answers to 110.

124. What arrangements were made for the care and treatment of children infected with HIV and/or hepatitis? How did those arrangements differ (if at all) from the arrangements made for adults?

831. We did not treat children under 16 years of age at the Royal Liverpool Hospital while I was working there as they were required to be managed by a paediatrician.

125. What if any involvement did you and/or colleagues at the Liverpool Haemophilia Centre have with any clinical trials in relation to treatments for HIV and HCV?

832. I do not recall carrying out any relevant trials concerned with anti-viral therapy.

126. What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?

833. I have been shown a document [HCDO0000276_001] which is the Haemophilia Society bulletin from 1990 – some years before I was working at the CCC.

834. This document notes that support was provided by the Liverpool Haemophilia Centre through the following positions:-

- Two senior Physiotherapists, Janet Lamb and Mike Callaghan appointed in 1987
- A haemophilia nurse/counsellor, Alison Jones appointed in 1988
- Social worker, Helen Rogers appointed in 1989 (previously the centre had a shared social worker).
- There was also a joint orthopaedic clinic set up to take place every three months with Professor Leslie Klenerman and John Walsh.

835. Long standing chronic problems were assessed in the follow-up clinic every Monday morning in G-clinic, or in the joint orthopaedic clinic with Professor Klenerman, and his senior lecturer, John Walsh.

836. Most severe cases of haemophilia were reviewed every three months. This clinic occupied five rooms offering both space and privacy. The haemophilia nurse, social worker and one of the physiotherapists all came to each clinic, permitting a comprehensive multidisciplinary review.

837. The same group of physiotherapists were responsible for both in-patient and out-patient physiotherapy and hydrotherapy. This ensured continuity of care and provided a valuable insight into the results of physiotherapy in our patients.

838. Blood was taken at each clinic visit to monitor HIV infection, liver disease, and inhibitors, as appropriate, and the results of previous tests often discussed.

839. Wives and girlfriends of HIV-seropositive haemophiliacs who wished to be, were also tested. The clinic also provided a valuable opportunity for me to bring the patient up-to-date and to discuss, in privacy any problems directly or indirectly related to haemophilia or HIV. They may also have wished to chat with Alison Jones or the social worker Helen Rogers.

840. As some wives were isolated and unable to attend meetings we also established a women's support group to try to help alleviate this situation. This was an informal meeting of wives, girlfriends and some mothers about once a month. Although Alison and Helen attended these meetings, the medical staff did not attend since this would tend to make them more formal. This bulletin provided a bleep number to contact Alison Jones in case they wanted further information.

841. During my time at the Liverpool Haemophilia Centre from 1997 to 2020 I worked with a clinical nurse specialist in haemophilia who had a Master's degree in Counselling and had been appointed in 1996 to the CCC in Liverpool.

842. There was, therefore, always a counselling service available when I was there. This service was extended to relatives and after bereavement.

127. Did any of the centres at which you worked receive funding from the Department of Health and Social Security or from any other source to help with the counselling of patients infected with HIV?

843. I do not know if we had DoH funding but I do not remember that we did while I was at the CCC from the late 1990's but I do know that funds were readily available in the late 1980's for the management of individuals with HIV.

128. What (if any) difficulties did you encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or hepatitis C?

844. As far as I can recall, we did not have difficulty in obtaining sufficient funding for specific and timely antiviral therapy or in the roll out of the conversion to recombinant factor concentrate.

129. What if any involvement did you or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

845. Any clinical trials in relation to treatment for HIV or hepatitis would have been dealt with by a specialist in infectious diseases.

Recombinant

130. Please explain your involvement with efforts to obtain recombinant blood products for patients with haemophilia. What difficulties were encountered and why?

846. When I started at Liverpool Haemophilia Centre in February 1997, one or two patients were already using Recombinant factor VIII. It was clearly the best treatment but initially there was not funding for everyone. There was a change of government in May 1997 following which it was brought in on a phased basis.

847. I was involved in rolling the recombinant blood product out in the priority order agreed nationally on clinical grounds (largely related to age) after we received funding. It was not possible to provide recombinant to everyone at the same time. This was due partly to funding by DoH but also to limited immediate manufacturing capacity. The manufacturers were not informed before the announcement that it was to be made available so at first even when there was funding, there was not enough recombinant immediately to go round.

848. In addition, trials had to be done by the manufacturers to work out the doses involved.

131. In your view, should recombinant blood products have been made available to all haemophiliacs earlier than they were? If so, when?

849. I cannot comment on practice before 1997 as I was working in the NBS until then. Had recombinant products been introduced sooner, however, a significant increase in production would have been required earlier by the manufacturers.

850. The production of recombinant factor VIII had to be scaled up rapidly by the manufacturers following the announcement by Mr Dobson as the total amount required to supply the UK market was not immediately available at that time. I seem to recall, however, that in fact all our patients were moved over on to it sooner than I had expected. I think it had originally been expected to be phased over about three years.

132. When were recombinant products available to patients (and which categories of patients) treated at the Liverpool Haemophilia Centre?

851. There were also one or two patients on recombinant Factor IX concentrate as Benefix quite early in Liverpool.

852. I cannot now specifically remember what happened after that, but I understand from the witness statement of Professor Hay [WITN3289039] that recombinant Factor VIII was available for children from 1998 and that the government eventually made a political decision to grant recombinant factor VIII to children (patients aged <18 years) in 1998 "to relieve the anxiety of their parents". Recombinant factor IX became available the same year and so it was possible to change children with both haemophilia A and B at the same time. When these children grew older, they remained on recombinant products and so by the time recombinant for all started to roll out, all the patients aged 23 and under were already using recombinant factor VIII or IX unless there was some specific reason to remain on plasma-derived products (patient choice or, in the case of factor IX, lack of efficacy in 5-10% of patients).

853. Certainly no children were converted back to plasma-derived from recombinant factor when they moved from paediatric to adult care in Liverpool.

854. Frank Dobson of the Department of Health made an announcement on 12 February 2003 that funding would be made available to extend the availability of recombinant factor products to all patients.

855. We then rolled it out to everyone in priority order on clinical grounds which appeared largely to be based on age with the youngest first.

856. There were some patients who did not feel it was as effective for them as plasma-derived but I cannot remember any patients in Liverpool who remained on plasma-derived factor concentrate after the recombinant rollout. I encountered a patient much more recently in North Wales after 2017 who was still using Optivate, but he told me that his treatment plan had been individualised by his previous physician to avoid an inhibitor problem.

Research

133. Please list all research studies that you were involved in during your career. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, please attach a list of publications and research.

Relevant work includes:

857. Hepatitis B Core Antibody Screening of Voluntary Blood Donors: An Extended Pilot Study.
Martlew, V.J., Rogan, P.D., Shepherd, A.J.N., Firth, S.
Transfusion Medicine (1993) Vol 3: No: 3 229-236.

858. A Case of Hepatitis B in a Haemodialysis Unit.
Parry C.A.I., Martlew V.J., Bell G.M., Ahmed R.,Muhoak S., Hart C.A.
Journal of Hospital Infection (1997) 37: 65-69

859. UK Multicentre Study on Blood Donors For Surrogate Markers of non-A non-B Hepatitis Part 1.
Alanine Transferase and anti-HBc testing Anderson, N.A., et al.
Transfusion Medicine (1992) 2: 4 301-310.

860. How Fit are Blood Donors?
Martlew, V.J., and Cockersole, Gillian M.
Plasma Therapy and Transfusion Technology (1988). Vol 9: No: 4 333-336.

861. Post-transfusion HIV Despite Donor Screening: a Report of Three Cases.
Martlew V.J, Carey P.B, Tong C.Y.W, Parry J.V, Belda F, Barlow K.L, Chu P and Syed Q.
J. Hosp.Infection (1999) 44: 2: 93-97

862. Identification of Risk Factors in Blood Donors Found to have HIV Infection
Bates C.M, Carey P.B, Martlew V.J and Shepherd A J.N.

Internat.J.of S.T.D and AIDS (2000) 11: 729-730

863. Emergency and out of hours care of patients with inherited bleeding disorders.
Fowler H, Lacey R, Keaney J, Kay-Jones C, Martlew V and Thachil J.
Haemophilia (2011) 1-6 DOI 10. 1111/j.1365-2516-2011.02721.x

864. Quality in Blood Collection:
Jenkins, J.A., and Martlew, V.J.
Transfusion Science (1994) Vol 15. No: 3 264-266.

865. The Hunt for Hepatitis B:
The Correlation Between Hepatitis B Core Antibody Screening and the Polymerase Chain Reaction for Hepatitis B Virus.
Martlew, V.J., Rogan, P.D., Shepherd, A.J.N., Yap, P.L., and McOmish, F.
Transfusion Medicine Vol 3. Suppl 1. 114 (September 1993).

866. The Medical File: A Systematic Approach to Donor Deferral:
Shepherd, A.J.N., and Martlew, V.J.
Transfusion Medicine Vol 1. Suppl 1. 45 (September 1990).

867. The Medical File: Update on a further 12 Months Experience
Shepherd, A.J.N., and Martlew, V.J.
Transfusion Medicine Vol 1. Suppl 2. 86 (September 1991).

868. Medical Audit and Quality:
Martlew, V.J., and Shepherd, A.J.N.
Transfusion Medicine Vol 1. Suppl 1. 42 (September 1990).

869. The Significance of Jaundice in Donors:
A Twelve Month Study in Merseyside and North Wales.
Martlew, V.J., Rogan, P.D., and Shepherd, A.J.N.
Transfusion Medicine Vol 1. Suppl 2. 86 (September 1991).

870. A Chronological Study of Donor Distribution (New Versus Established) During Two Years of Routine Hepatitis B Core Antibody (Anti-HBc) Screening of Blood Donations:
Martlew, Vanessa J., and Rogan, P.D.
Transfusion Medicine Vol 4. Suppl 1. 53 (September 1994).

871. I was also involved in the testing of the Ortho second generation HCV test kit trials as described above, the details of which are set out below.

a. Describe the purpose of the research.

(i) Ortho second generation HCV test kit

872. The purpose of this testing of second generation HCV test kits which took place in summer1991 was to look at the performance of these kits in Blood Centre laboratories as referred to in the minutes of a Meeting of the Northern Division of the National Blood Transfusion Service, dated 13 June 1991 in York [NHBT0071757].

873. I have also been shown a copy of a memo I sent to Mr Rogan, our laboratory manager on 15th September 1989 [NHBT0000188_052] which summarises the position in relation to the earlier testing of the first generation test kits, in which the Liverpool Centre had not been involved. I had received the results of the Pilot Study of previous Anti HCV testing of blood donors using the first generation test kits. This had been conducted in three other blood centres to reflect urban and rural populations. The sites chosen for the earlier study were Manchester, Bristol and Colindale (North London).

874. That study had been originally set up by the Department of Health to investigate the feasibility and value of testing of blood donors for two non-specific surrogate markers of Non A Non B Hepatitis in the form of Alanine Amino Transferase (ALT) enzyme assays and Hepatitis B core antibody

testing. While it was underway, the Chiron Corporation, who were marketed in the UK by Ortho diagnostics, released a specific test for one of the viruses thought to cause Non A Non B Hepatitis and subsequently identified as Hepatitis C. Residual material was available from the earlier study to determine the prevalence of anti-bodies to Hepatitis C in this selected pre-tested donor population.

875. This provided an opportunity to compare the specific anti HCV test with the results of surrogate testing already undertaken through correlation between anti HBc positivity and anti HCV positivity. In respect of elevated Alanine Amino Transferase, 3.28% of the London donors with an elevated result were found to be anti HCV positive whereas in the provinces the occurrence of associated anti HCV positivity was around 1%, in line with the prevalence of anti HCV in the community at large. I noted that this data was remarkably similar to that determined for the donor population in Germany. The purpose of the memo was to let Mr Rogan have early notification of this publication. I also wrote a letter on 24th August 1989 [MAIN 667/668/669] to Dr Peter Simpson, Regional Medical Officer, outlining these findings in advance of publication in the Lancet together with an estimate of the annual costs of routine screening of donors for antibodies to HCV at the Liverpool Blood Centre, in case it was discussed at the next meeting of the Regional Health Authority and to assist financial planning.

876. I have also been shown a memorandum from Professor Cash, to SNBTS Board Members, *re: the implementation of HCV testing, discussion of problems with first-generation test kits, statistics on false negatives and false positives, advantages of delaying HCV screening for second-general test kits, and comparison of HCV against HIV-1 test kit evaluation* [NHBT0000192_144].

877. This notes that since early 1984, there had been growing concern throughout the UKBTS that microbiology donation screening kits should be appropriately evaluated before their large scale use was instituted. The

primary concern, in this context, had been for the UK BTS to ensure, as much as was possible, that every effort had been made by kit manufacturers to maximise both sensitivity and specificity. In short, the task had been to validate that the kits used would (a) not miss a donation which was infective (false negative) and (b) would not declare a donation positive when, in fact, it was negative (false positive). The outcome for patients with donor screening kits of significantly lower sensitivity are self-evident as it meant that people who were infected had been told the opposite.

878. Kits with high false positive ratings, however, also caused untold stress to blood donors, escalated unit costs (confirmatory testing/medical care/counselling) and produced expanding data handling problems.

879. Just as the UK BTS validating team was in the process of advising Ministers and RTCs that both these kits could be used and that UK BTS should commence full scale screening on 1st July 1991, the kit manufacturers announced via Ortho their intention to withdraw their original kits and replace them with second generation kits to screen for antibodies to HCV. These new kits were claimed by the manufacturers to be an improved version of those tested previously by the UK BTS validation team, but no satisfactory data was available to confirm this and it was noted that the FDA had not yet approved their use and, therefore, they did not yet have a product licence. It was recommended that an evaluation of these second generation kits should be undertaken as a matter of urgency in the UK in advance of the introduction of routine donor screening throughout the UKBTS and the previously scheduled start time for this was then postponed to 1st September 1991.

880. I have also been shown a copy of a memo I wrote on 13th May 1991 to Members of the Unit Management Group in Liverpool [NHBT0000015_065] in which I note that it had now been recommended by the Department of Health that routine screening of all blood for antibodies to hepatitis C would be introduced with effect from 1 September 1991. This delayed

implementation date had been recommended by the Department since the second generation tests were relatively new and did not yet have an FDA licence (even in America where they had been devised). It was therefore necessary for them to undergo validation by the transfusion service in the UK.

881. MNWRTC had been asked to participate in a three centre trial for a minimum of 6 weeks to test the second generation Ortho kits on all blood donations collected during that period. Any donors found to have a positive result would have the antibody test repeated locally. Repeatable positives would then be referred as a serum sample to the Public Health Laboratory at Withington, Manchester for RIBA 2 testing and a plasma sample sent to the Public Health Laboratory at Colindale for PCR testing. The results of these confirmatory tests would be reported back independently to the Centre and funding would be provided directly to the Public Health Service Laboratory by the Department, as arranged by Dr Gunson. Any donations found locally to have a positive HCV antibody result would be discarded and a note made on the donor record for follow up.

882. I think these contemporaneous documents describe the purpose of this research and how I came to be involved in it.

(ii) Pilot anti-HTLVIII screening of plasmapheresis donors

883. Some years earlier I had also been involved in Anti-HTLV III testing of plasma donors in Manchester to assist the evaluation of kits prepared for the Blood Transfusion Service, as set out in a departmental memo which I sent on 5 August 1985 [NHBT0004253]. I stated that it would be necessary to advise donors that their blood was being tested in this way and attached a revised NBTS form 110 amended for this purpose (Appendix 2; NBTS 100, Rev 1967) to obtain their informed written consent.

b. Explain the steps that were taken to obtain approval for the research.

884. In relation to the testing of second generation HCV test kits, the initial tests had to be trialled to the standards set by the UK BTS to ensure sensitivity and specificity and avoid false negatives and false positives.

885. According to a memo, which I have been shown, from Dr Gunson as National Director, to me and Dr Angela Robinson who was then the Director at Leeds [NHBT0000192_037] dated 13 May 1991, he attached a draft protocol for the trial. I have not so far seen that document for the purposes of preparing this statement.

886. I have also been shown an earlier report of Dr Gunson dated 10 October 1989 [NHBT0000188_072] which explains what had happened leading up to this and includes conclusions and recommendations derived from presentations at the first International Meeting on the Hepatitis C virus in Rome. Tests had been conducted in various countries in Europe with varying findings, one of which was that the Scottish National Blood Transfusion Service had used the test on randomly selected donors and their study had estimated that the use of that generation of kits would have avoided only 21% of transfusion-transmitted NANBH.

887. The conclusions of this report in 1989 were that it seemed certain that the anti-HCV test detected a viral marker associated with NANBH. The evidence presented suggested that routine anti-HCV tests on blood donations would reduce the incidence of transfusion transmitted NANBH although this would depend on the incidence of transfusion-transmitted NANBH in a particular country. It was understood at that time that anti-HCV positivity in a blood donor might not necessarily mean that the seropositive donor transmitted NANBH and that an unknown proportion might be false positives. Although there was an association of seropositivity with abnormal non-specific tests (raised ALT and anti-HBc positives) in some individuals it was apparent that the majority of anti-HCV positive donors did not possess non-specific markers as elevated ALT and/or the presence of antibodies to HBV core. A confirmatory test was not

yet available and the Chiron Corporation was pursuing feasibility studies of a RIBA for HCV.

888. The recommendations were that the routine screening of blood donations for anti-HCV should be introduced when practical as the probability was that the incidence of transfusion transmitted NANBH would be reduced and that a confirmatory test for seropositive blood donors was urgently needed. The confirmatory test proposed by Chiron had limitations and every effort had to be made to ensure that a confirmatory test was available in the UK at the time when routine screening of all donations in the UK was introduced. It was noted that significant additional manpower and other resources would be required in reference laboratories. The Committee was asked to approve the routine testing of blood donations in principle and to request the National Directors of England and Scotland to arrange for the simultaneous introduction of the tests at an appropriate time when a policy for the counselling and management of seropositive donors had been defined. The Ortho/Chiron anti-HCV screening test was not yet licensed by the FDA and testing in the USA would not take place until authorisation had been given. Routine use of the test for blood donations in the UK should not commence before an FDA licensing procedure was complete. The studies to date had been conducted on frozen samples and pilot studies on the prospective routine use of the test in RTCs should be established as soon as possible. An application for a research grant of £25,000 had been made to DH to carry out such studies. The routine introduction of non-specific tests should be deferred unless these were required for the acquisition of product licences in the UK for fractionated plasma products. An estimate of the financial cost of testing was attached.

ALT testing

889. I had also participated in the planning for the original ALT study. I have been shown a copy of a memo [NHBT0009167] dated 5 May 1988 from Dr Gunson to me with letter (dated 28/04/1988) from Dr. M. E. Smith, Department of Health and Social Security, to Dr. H. H. Gunson, North

Western Regional Transfusion Service setting out: *Comments on the study on prevalence amongst blood donors for raised ALT and Hepatitis core antibody.* Dr Gunson asked me to arrange a meeting of the group, whose membership he set out and included Dr Contreras and Dr Barbara from Edgware, Dr Fraser from Bristol and Dr Shwe and myself in Manchester, to consider the attached comments by the Referees and procedures for commencement of this study. The letter attached from the Department of Health refers to Dr Gunson having already responded regarding problems over the research grant application to Dr Smithies at the Department and continues that his own response to external scientific comments would now be appreciated. The comments of three external referees on the design of the study, ethical considerations and what it was hoped to achieve are set out. As I moved from Manchester to Liverpool in November 1988 I did not have the opportunity to undertake this work "in the field" and I was replaced as Consultant Haematologist at the North West Regional Transfusion Centre by Dr Khin Shwe in 1989.

890. I think these are typical examples of how research in the development of the Transfusion Service developed nationally. Dr Gunson would submit a grant application to DH for approval and funding and the proposals would be reviewed, questioned and refined.

c. Explain what your involvement was.

891. Please see my response to 133(a-b).

d. Identify what other organisations or bodies were involved in the research.

892. Ortho would have been involved in the study of the HCV testing kits to the extent that they provided the kits we were trialling. Different centres were involved in different studies, I think partly arising from the different interests of the various Directors and their teams and dialogue that they had with Dr Gunson on different points, such as my interest in the value of Hepatitis B

core antibody testing. The Department of Health was involved in approving and funding the proposed studies.

893. I have no personal knowledge of, but have also been shown a document [NHBT0000015_117] dated 11 September 1989 which shows further involvement by the Department of Health. It is a letter from Dr. A. Rejman, Department of Health, to Dr. Gunson, regarding his report: *Hepatitis C Viraemia in United Kingdom Blood Donors: A Multicentre Study.* The letter makes suggestions for changes to the report in some detail and asks to see a copy of Dr Gunson's proposed letter to Dr Garson. I have also been shown Dr Gunson's response to Dr Rejman [NHBT0000015_119] dated 16 September 1991, in which he says that he has included most of the points suggested but did not think that we should attempt in a scientific article to justify any alleged delay in anti-HCV screening.

894. I have been shown a document which is a letter from Dr Gunson to Dr Smith (Senior Medical Officer, Department of Health) dated 6 January 1989 re: 'ALT and Anti-HBc screening of blood donations' [NHBT0000014_033] which explains that the start of the study in Bristol had been delayed due to difficulties in obtaining ethics permission but had by then commenced, three months later. There must therefore also have been involvement of at least one Ethics Committee or body providing that approval.

e. State how the research was funded and from whom the funds came.

895. From memory, I think it was predominantly the Department of Health.

896. I was not involved in obtaining funding for these studies as far as I can recall but I note from his statement in A v NBA and others, [NHBT0000025_001] that at paragraph 60, Dr Gunson refers to having made an application with Dr D B L McLelland to the Medical Research Council in 1981 for grant to set up a prospective study to investigate transfusion associated NANBH but the grant was refused and that

committee (The Blood Transfusion Research Committee, an MRC group) was disbanded in 1982.

897. I have also been shown a document [NHBT0000014_014] which is a letter from Dr Gunson to Mr G. Parker (Chief Accountant, North Western Regional Health Authority) dated 13 May 1988, regarding the *'Alanine amio-tranferase (ALT) and anti-hepatitis B core (anti-Hbc) screening of blood donations: a multi-centre study'.* Dr Gunson refers to an earlier letter from the DHSS in which approval was given to carry out this study and says that a non-recurring addition of £72,000 was made to the Authority's revenue cash limit for 1988/9. According to this, when the grant application had been made in 1987, it was agreed that if a grant was awarded by DoH it would be administered by the NWRHA. The letter goes on to discuss some detail of the logistics of recruitment and payment of staff, the cost of the tests and how the invoicing would work.

898. I have been shown a document [NHBT0000062_039] which is a letter from Alan Barton to Dr Metters *RE ACVSB decision to extend HCV screening evaluation* dated 8 March 1991, which states that the second round HCV test-kit trial/evaluation which ACVSB asked for will cost up to £117,000 from MDD's 1991/92 evaluation budget. [I am not able to say from my own knowledge or memory what MDD stands for]. Concern was expressed that the extra costs of the work at the second and third centres would be somewhere in the region of an extra £80,000. The MDD budget was likely to be stretched and the author wonders whether to seek an independent scientific view on whether the additional information which would be provided by expanding the evaluation would represent value for money. Concern is also expressed about whether there may be further demands for evaluation of HCV testing kits, to be paid for by MDD since this appeared to be an area in which technical advance was rapid and the author thought there was a lot to be said for NBTS itself being expected to evaluate kits it wanted to use and pay for that evaluation but he realised that the history of direct departmental involvement might make this difficult. At that time each Blood Centre was funded by its Regional Health Authority

so it is likely that had each Centre been required to obtain its own funding for the trial locally there would have been further delay in implementation.

899. I have been shown documents relating to funding of the anti-HCV study including [NHBT0000015_011] which is a letter from J Canavan at the Department of Health to Dr Harold Gunson confirming that the money for this study had been approved. He asked Dr Gunson to let Mark Fuller have the invoices for the test kits and the Medical Devices Directorate (which I assume is the MDD) would pay Ortho and Abbott. The money for the confirmatory testing and a small amount for the RTCs' costs would be channelled through the Directorate. Mark Fuller would also make the money available to the reference laboratories for the costs of the confirmatory testing. Other documents relevant to this are [NHBT0000189_212] and [NHBT0000061_180] .

900. Document [NHBT0000015_012] which has also been shown to me is a letter from Mr R Collins of the NHS Procurement Directorate to Dr H H Gunson re Comparative Evaluation of Hepatitis C Kits - Agreement NO 104/90 SEV/43/38/08. This states that in consideration of the work to be carried out, the approved limit of expenditure was £6,000 (£2,000 per RTC – Newcastle, North London and Glasgow). Other detailed contractual provisions are included.

f. State the number of patients involved.

901. The studies were performed on samples from donations made by blood donors and not patients.

902. I do not have personal knowledge or memory of this but the various studies and papers to which I have referred will set out the numbers, often in tables. There are different drafts and the studies evolved and developed as this was a fast moving field. I have been shown, for example:

903. Document [NHBT0000190_030] *Report from H H Gunson re Comparison of Anti-HCV tests using Abbott and Ortho test kits* dated 29 October 1990 which is a summary of the results of phase 1 of that trial (of the first generation kits) and refers to each of the three RTCs involved at that point (North London, Glasgow and Northern) each testing 3,500 donor samples (which would suggest a total in the region of 10,500). The Tables referred to with the actual numbers are not attached.

904. Document [NHBT0000015_145] - *Report: Trial of Anti-HCV test on blood donations in England and Wales September -October 1991 - Preliminary analysis of results.* This reviews three different tests and different combinations of tests, with no consistent results. The kits used were Ortho (8 RTCs), Abbott (5 RTCs) and UBI (3 RTCs). The tables referred to, which would include the numbers, are not attached to this version.

905. Another example shown to me is a letter from Dr Gunson to Dr Smith (Senior Medical Officer, Department of Health) dated 6 January 1989 re: *'ALT and ANTI-HBc screening of blood donations*' [NHBT0000014_033] which I have referred to above and discusses the significant development of Chiron cloning the material to make the first anti-HCV Elisa test and offering to test free of charge 1000 samples from our study for the antibody to the NANB viral protein. The original plan for the study had been to test 9,000 donors for ALT and 3,600 for anti-HBc, but with the availability of the Chiron test it was now important to also test all 9,000 for anti-HBc. In relation to funding, Dr Gunson set out the additional costs involved. He confirmed by letter to Dr Shwe and similarly to others involved by letters of 16 March 1989 [NHBT0000014_040] that this additional funding had been allocated by the Department.

g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent. You may wish to refer to the letter to you dated 3 April 1987 from the Central Manchester Health Authority Clinical Ethical Research Committee [NHBT0000014_003]. In the relevant letter, the question of consent is raised with respect to your

trial of Alanine Amino Transferase (ALT) and Anti-Hepatitis B Care Antibody (Anti HBc) Screening of Blood Donations. Did you design an appropriate form and ensure that all participants gave informed consent to being a part of the trial?

906. In document [NHBT0000014_003] Dr Taylor suggested that donors should sign a consent form confirming that they have read the data supplied to them and agreed to the tests being requested.

907. This work was undertaken on anonymous samples from voluntary blood donors who had given informed written consent to blood donation and its associated laboratory screening and not from patients.

908. A number of the early studies were conducted on samples and were anonymous. On a practical level, the HBc antibody screening study was a large trial because the occurrence of anti-HBc positive donors was one in 4,000 so we needed to test a lot of people.

909. [NHBT0000014_003] is a letter to me at Manchester from the Central Manchester Health Authority Clinical Ethical Research Committee dated 3 April 1987 which says that the protocol for the multi-centre trial of ALT and anti-HBc screening of Blood donation had been approved and I could proceed. The committee considered that donors should sign a proper consent form confirming that they had read the data supplied to them and agreed to the tests being requested and I was asked to provide an appropriate form.

910. In document [NHBT0000014_003] Dr Taylor suggested that donors should sign a consent form confirming that they have read the data supplied to them and agreed to the tests being requested. I am afraid that I cannot now recall if a consent form was created.

h. Provide details of any publications relating to the research.

Please see above.

1) ALT trials

a. Describe the purpose of the research.

911. These tests were a way of detecting a raised ALT which was considered to be associated with inflammation of the liver and was regarded as a surrogate marker of non A or non B hepatitis.

b. Explain the steps that were taken to obtain approval for the research.

912. I am not sure what steps were taken to obtain approval for this research.

c. Explain what your involvement was.

913. I was in Manchester then. Later I remember participating in ALT screening of plasma for fractionation whilst in Liverpool in the early 1990's.

d. Identify what other organisations or bodies were involved in the research.

914. ALT screening of donors at Liverpool Blood Centre would have been performed in the Chemical Pathology Laboratory at the Royal Liverpool University Hospital.

e. State how the research was funded and from whom the funds came.

915. I cannot recall how this research would have been funded.

f. State the number of patients involved.

916. This was a very large series involving apheresis donors.

g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent. You may wish to refer to the letter

to you dated 3 April 1987 from the Central Manchester Health Authority Clinical Ethical Research Committee [NHBT0000014_003]. In the relevant letter, the question of consent is raised with respect to your trial of Alanine Amino Transferase (ALT) and Anti-Hepatitis B Core Antibody (Anti HBc) Screening of Blood Donations. Did you design an appropriate form and ensure that all participants gave informed consent to being a part of the trial?

917. I am unsure now if there would have been donor consent for this, as it was anonymous and we were collecting in church halls etc. On a practical level it was a very large trial because the occurrence of anti—HBc positive donors was around one in 4,000 so a large number of people needed the additional test.

918. [NHBT0000014_003] is a letter to me at Manchester from the Central Manchester Health Authority Clinical Ethical Research Committee dated 3 April 1987 which says that the protocol for the multi-centre trial of ALT and anti-HBc screening of Blood donation had been approved and I could proceed. The committee considered that donors should sign a proper consent form confirming that they had read the data supplied to them and agreed to the tests being requested and I was asked to provide an appropriate form. I do not believe, therefore, that this work proceeded while I was in Manchester.

h. Provide details of any publications relating to the research.

919. To avoid duplication, I have set out above, below and in the attached list [**WITN4034002**], details of relevant publications.

134. Please provide the same details in relation to any epidemiological or similar studies in which you were involved, insofar as relevant to the Inquiry's Terms of Reference.

920. I have been involved several different studies throughout my career and I attach my most recent CV **[WITN4034005]**.

921. I understand that the Inquiry holds copies of the following publications which include my name as a contributor as a Co-Director of a CCC contributing to the UKHCDO database:-

922. *Report on 'HIV and Mortality in the UK Haemophilia Population: Demonstration of a Casual Relationship' by UK Haemophilia Doctors' Organisation* dated 31/07/2002 [HCDO0000572]. I am named in this document as part of the UK Haemophilia Centre Doctors' Organisation Members contributing data.

923. *Article on Immune Status in HIV-1 – infected men and boys with Haemophilia in the UK from Aids* magazine Volume No 12 Number 8 which includes a table of data on haemophiliac men infected with HIV surviving to 1 January 1994 [HCDO0000017_001]. I am named in this document as director of a participating UK Haemophilia centre.

924. *Mortality from liver cancer and liver disease in haemophilic men and boys in UK given blood products contaminated with hepatitis C* in the Lancet dated 15/11/97 [HCDO0000264_150]. I am named as a Director of a participating UK Haemophilia centre.

925. The publication below, which includes me as an author, reflects the findings of the HCV Lookback Study of the NBS:

926. *The Contribution of Transfusion to HCV Infection in England* dated 1/12/02 [PRSE0001715].

927. I also contributed to Soldan K, Ramsay M, Robinson A et al Epidemiology and Infection (2002) 129: (3):587-591.

928. The following set of publications reports the findings of a pilot study of additional anti- HBc screening conducted in Liverpool in the early 1990's to detect chronic carriers of HBV amongst blood donors screened negative for HBsAg:-

929. Hepatitis B Core Antibody Screening of Voluntary Blood Donors: An Extended Pilot Study.
Martlew, V.J., Rogan, P.D., Shepherd, A.J.N., Firth, S. Transfusion Medicine (1993) Vol 3 : No: 3 229-236.

930. The Hunt for Hepatitis B: The Correlation Between Hepatitis B Core Antibody Screening and the Polymerase Chain Reaction for Hepatitis B Virus.
Martlew, V.J., Rogan, P.D., Shepherd, A.J.N., Yap, P.L., and McOmish, F. Transfusion Medicine Vol 3. Suppl 1. 114 (September 1993).

931. A Chronological Study of Donor Distribution (New Versus Established) During Two Years of Routine Hepatitis B Core Antibody (Anti-HBc) Screening of Blood Donations:
Martlew, Vanessa J., and Rogan, P.D. Transfusion Medicine Vol 4. Suppl 1. 53 (September 1994).

135. Were patients involved in research studies without their express and informed consent? If so, how and why did this occur?

932. I cannot recall any details of the consent obtained at the time, including whether donors were consented if they were involved in research studies.

933. I cannot recall whether all the participants were consented if they were involved in research studies.

934. A number of these studies involved extended screening of voluntary blood donors and not patients in order to detect potentially transfusion-transmissible diseases. Blood donors are advised before donation that

their blood would be screened for various infections and since the introduction of HIV antibody screening in October 1985 have provided their informed written consent. I have described above how the forms were amended when AIDS screening was being trialled and, of course, when it was introduced into routine practice.

935. Some studies were performed on donor samples in the very early stages before we knew whether they would yield any useful information including as to how accurate they would be as a test for some infections and these were done on an anonymous basis on frozen stored samples. Where a result was positive, by a new test of unknown sensitivity with no confirmatory test, the donation would be discarded and the donor's file marked so that we could discuss what it might mean with the donor at the next attendance and what investigations, tests or referrals might be appropriate.

136. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose without their express and informed consent? If so, what data was used and how and why did this occur?

936. Whilst I was involved in the research into transfusion-transmitted infection in the Blood Service this work was performed on samples accompanying donations from blood donors who had given informed written consent to the laboratory screening of their donation and not from patients.

937. The majority of the papers were not designed by me apart from the extended HBV screening to detect core antibodies and this merely reflected an additional test for HBV which had already been screened out in blood donations using an HBsAg test for the previous 20 years.

938. With respect to the other studies I am therefore unaware if they had been used for another purpose. As far as I can recall, the donors were anonymised. I have explained this process and the thinking above.

137. Was patient data (anonymised, de-identified or otherwise) shared with third parties without their express and informed consent? If so how, and why did this occur, and what information was provided to whom?

939. I am not aware of any patient data I dealt with in the haemophilia centre being shared with third parties without individual consent.

940. In recent years, individuals have been required to give their written consent to data storage under the Data Protection Act and so this applied to all those registered with UKHCDO with a unique number.

941. I have commented above that the studies at the Transfusion Centre related to donors, not patients. I believe that donors were generally well-informed about the screening of their blood. They may possibly not have been aware that frozen samples would be retained and tested. I left the NBS in 1997 before the issues became apparent over retained human tissues in the late 1990s and before the Human Tissue Act. The approach to the use of blood samples and to consent in general at that time was far less well-developed.

Records

138. What was the policy at the Liverpool Haemophilia Centre in relation to recording information on death certificates when a patient had been infected with HIV or hepatitis?

942. It was our practice at Liverpool CCC that if a patient died of HIV we would record the cause of death on the death certificate. We would, however, endeavour not to mention HIV, although immunodeficiency might be mentioned if it were considered a contributory cause. This was partly out of confidentiality for the deceased but also for the benefit of the families as they would have to show the death certificate to many people. We were very conscious of the stigma and fear attached to a diagnosis of AIDS in

the community for some time and the problems it caused to families in many ways including relationships with neighbours, employers, schools etc.

943. UKHCDO were informed of the death of all patients registered with an inherited bleeding disorder and this included those with HIV. UKHCDO would have a record of this and their infection would have been notified at diagnosis through the PHLS some years earlier.

139. What were the retention policies of the Liverpool Haemophilia Centre in relation to medical records during the time you were practising there?

944. We aimed to retain the records in the long term as we knew of the importance of the blood product history when it came to investigation of transfusion-transmitted infection. This became important for providing evidence of infection to support enhanced Skipton Fund payments to bereaved relatives.

945. For example, we did recall paper records for a patient who died of HIV in 1985 in order to provide evidence to support a claim for a payment from the Skipton Fund to his widow quite recently.

140. Did you maintain separate files for some or all patients? If so, why, where were those files located, and where are those files now?

946. We did have books where we made notes of meetings held to discuss patients' progress on antiviral therapy. These were in separate books – one for HIV and one for HCV.

947. Patients were referred to by hospital number. These notes were in a room on a shelf in a department locked every night. I am unsure where they are now but I do not think they would have been thrown out intentionally. The meeting note for each individual was duplicated in each patient's case notes.

948. Separate files would be maintained on an anonymised basis for anyone who had been involved in a clinical trial - often with a new brand of factor concentrate as required by GCP and GMP. Informed written consent was always obtained from participants in advance of the trial. These separate folders were required to show that everything in the trial protocol had been complied with. These files would also be audited regularly by the trial coordinator and were subject to external audit by the MHRA. The maintenance of a separate document which were identified not by name but by their unique number as a trial participant also served to protect the anonymity of the trial participant.

141. Did you keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere other than the hospital where you worked? If so, why, what information and where is that information held now?

949. As far as I am aware, the information would not leave the hospital.

SECTION 10: PHARMACEUTICAL COMPANIES/MEDICAL RESEARCH/CLINICAL TRIALS

142. Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products? If so, please list the names of the companies and give details of the advisory or consultancy services that you provided.

950. I have occasionally provided advice but on anti-coagulants as part of an advisory service –the last being 5- 6 years ago as a paid consultant.

951. Although this large pharmaceutical company also happens to manufacture a recombinant factor VIII concentrate, I do not believe that this consultancy work falls within the Inquiry's Terms of Reference.

143. Have you ever provided a pharmaceutical company with results from research studies that you have undertaken? If so, please provide details.

952. As far as I can recall, I participated in a clinical trial of Eltrombopag for treatment of thrombocytopenia in 2006 which was funded by a pharmaceutical company and separate trial folders were maintained on an anonymised basis as required by GCP/GMP.

144. 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?

953. For many years the Royal Liverpool and Broadgreen University Hospitals (NHS) sent its employees a form every year in order to declare any funding we had received, which I would complete.

954. Ethical approval would be obtained before the start of research and after and the approval of the Research and Development Department was also required as the Trust would want to ensure that the NHS was properly funded for everything relating to the research.

SECTION 11: VCJD

145. 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?

955. My first recollection of this is that in October 1988 just after I had been appointed as Director of MNWRTC, I was at a meeting in Harrogate when Hilary Pickles said she had been asked to explore if there was a risk of transmission of vCJD associated with the use of blood and blood products, but I heard no more about it at that time

956. I think I became aware again about consideration of the risk of transmission of vCJD associated with the ingestion of processed meat sometime in 1990. BSE was in the press at the time when John Selwyn Gummer, who was the agriculture minister, was shown with his young daughter to eat a burger at an outdoor event to prove it was safe.

957. I have been provided with the document HCDO0000131_032 which is a revised draft of the UKHCDO/DoH Surveillance. In this I note it states that the Department of Health funded renewed CJD surveillance in 1990. The principal aim of this was to detect any change in the incidence or character of CJD in the wake of the BSE epidemic. In 1996 a new clinical pathological variant of CJD was described in a series of 10 patients (Will et al) as nvCJD – latterly vCJD. These patients were noted to have a significantly younger age of onset of symptoms and a more prolonged clinical course when compared with sporadic CJD.

958. I understand that nvCJD was first identified in 1996. As at 2002 there was no confirmed case of vCJD transmission by blood components, plasma products or peripheral tissues. However, as a precautionary measure UK blood services applied the agreed UK and European exclusion criteria in line with the WHO recommendations to exclude anyone in a risk category from donating blood. This was extended to include all previous transfusion recipients of blood and blood components.

959. I have been shown a document [CVHB0000011_015] concerning the v CJD Lookback which is a letter from Charles Hay and Frank Hill, United Kingdom Haemophilia Centre Doctors' Organisation, to Colleagues, 're: vCJD transmission in a UK patient treated with an implicated batch of factor VIII concentrate during the period 1980-2001'. Attachments to the letter include template letters to be sent to patients and haemophilia doctors, background information and actions for healthcare staff, and information for patients.

960. The information given to patients in 2004 was that all patients with bleeding disorders were to be told if they had received UK-sourced pooled factor concentrate or antithrombin between 1980 and 2001. Patients who had were to be:

961. a) informed that they had an additional risk of vCJD because they could have been treated with plasma made from donations from individuals who later developed vCJD.

962. b) given the opportunity to find out whether they had been treated with an implicated batch. They were told that if any more implicated batches were reported, then their exposure assessment might change.

963. c) informed that they were 'at risk of vCJD for public health purposes', and that their 'at risk' status would be recorded in their hospital medical records and primary care notes. Their exposure to implicated batches, and whether they had asked to know if they have received implicated batches, was recorded in their hospital medical records on a Patient vCJD Exposure Assessment Form. Patients who had not received UK-sourced pooled factor concentrate or antithrombin between 1980 and 2001 also had this fact clearly recorded on this form.

964. d) informed that special precautions needed to be taken to reduce the chance of any further spread of vCJD, and were given the following advice: • They should not donate blood, organs or tissues (many patients who have received plasma products may already be excluded from donation because of their underlying condition) • They should inform their doctors and other healthcare professionals of their 'at risk' status, so that special infection control precautions could be taken before surgery and other invasive procedures should they require future medical care. They were advised to inform their families, in case they needed emergency surgery in the future.

965. e) reassured that their clinical care should not be compromised in any way.

146. Please describe your involvement in decisions as to what information to provide to patients about vCJD,

966. This was decided centrally. The Department of Health made the decisions about what information to provide to patients about vCJD.

967. Initially we were required to get in touch with everyone who had received products made from pooled British plasma between 1980 and 2001. They were labelled "at risk" and had to be informed. We were asked to send them a standard letter drafted by DOH but under local signature for this purpose and I seem to remember that there was coordination of despatch. The letter contained quite a lot of information and the recipients were invited to come into the CCC to discuss this further. We set up additional clinics to support this work which took some months.

968. Latterly when sending such standard letters, I would write a covering letter saying that the DoH had instructed me to send them this letter, which I would enclose.

969. Once the patient was informed they could decide whether or not they wanted to know if they had received product from a pool containing a contribution from an "implicated donor". From recollection some would say they did want to know and others that they did not. Either way they had to be flagged as "at risk" in their clinical records and we were required to pass information on to their family doctor.

970. Their exposure to UK plasma derived plasma products between 1980 and 2001 and their wishes about whether they had asked to know if they had received implicated batches, was recorded in their hospital medical records on a Patient vCJD Exposure Assessment Form. Patients who had not

received UK-sourced pooled factor concentrate or antithrombin between 1980 and 2001 had this fact clearly recorded on this form.

971. When they were at risk we would have to inform all health care professionals who needed to know. We would also put a confidential stamp on their hospital file in order that if they were admitted out of hours and needed emergency treatment the staff should know. They were also advised to inform their doctors and other healthcare professionals of their 'at risk' status verbally, so that special infection control precautions could be taken before surgery and other invasive procedures should they require future medical care.

972. We had to advise them not to donate blood, organs or tissues and to inform their families, in case they needed emergency surgery in the future.

973. We would reassure the patient that their clinical care should not be compromised in any way.

974. There were also leaflets about nvCJD which we would provide to patients.

a. What procedures were put in place for informing patients about possible exposure to vCJD?

975. We followed the specific instructions from the Department of Health as discussed in my response above.

976. We also set up extra vCJD clinics as there was not enough time to discuss all the new information and arrangements about vCJD in the routine weekly clinics.

b. What steps were taken, and when, to tell patients of possible exposure to vCJD?

977. Practically, we followed the specific instructions from the Department of Health. We would invite them into a clinic and discuss the possible exposure. As above, additional clinics were set up to accommodate this discussion.

c. What information was provided, and when, to patients about vCJD?

978. As above, we followed the guidance set by the Department of Health.

979. Unfortunately, even if a potential transmission was suspected there was no treatment and no evidence to support prognosis. Therefore, the information provided in relation to treatment and prognosis was limited which caused distress to some individuals.

d. What counselling, support and/or advice was offered to patients who were being informed that they might have been exposed to vCJD?

980. The senior haemophilia sister was a counsellor so we in effect had a counsellor "in house" at the centre. We also made ourselves freely available to discuss any concerns.

e. What precautions were recommended, and why, in relation to patients notified to be at risk?

981. The special infection control precautions and other safety measures applied to patients who were considered at risk were set out by the Department of Health with guidance from specialist organisations such as the British Society of Gastroenterology etc.

982. When patients were considered at risk we would inform all health care professionals who needed to know. We would inform at risk patients that they must tell their doctor and their dentist about the risk. Unlike with HIV the Department of Health insisted that GPs were told, irrespective of the wishes of the patients. It would also be important to inform their healthcare

attendants if they were admitted to hospital in case they needed any procedures requiring special equipment. Procedures associated with neurological and lymphoid tissue were considered high risk and such procedures included endoscopy of the alimentary tract, eye surgery, back surgery and neurosurgery.

983. A confidential highlight of infective risk was placed on their hospital file in order that if they were admitted and needed emergency endoscopy out of hours the staff should know.

984. There was literature from the Department of Health about what procedures were considered a risk. From recollection it was anything involving neurological tissues such as spinal cord, brain, anything affecting lymph nodes, gut, tonsils and eye surgery. The appropriate specialists advised the Department of the precautions to be taken for procedures within their specialty.

147. Were you aware of and if so did you agree with the statement issued by the UKHCDO Executive Committee in November 1997 that non-UK plasma derived factors VIII and IX concentrates would be likely to reduce the risk of transmission of the infectious agents for vCJD? [BART0002235]

985. I was aware of this statement and I believe it would have agreed with it at the time and considered the suggestion reasonable.

986. In particular, I agree with the statement that *Patients for whom recombinant concentrates are not available will need treatment with plasma derived products…from our current understanding nvCJD occurs almost exclusively in the UK, it is likely that any risk of transmission would be reduced by using concentrates prepared from donor plasma collected in other countries e.g USA where there are no recorded cases of nvCJD or BSE* [BART0002235].

987. As a result of this everyone in haemophilia care has been keeping a lookout for vCJD in patients with inherited bleeding disorders ever since.

SECTION 12: THE HAEMOPHILIA SOCIETY

148. What if any involvement did you have with the Haemophilia Society?

988. I used to read their magazine. Over 10 years, when I was a MacFarlane Trustee I went to some special meetings with a small group of the members of the Haemophilia Society. I seem to recall that this was known as "The Partnership Group". I believe it was a subcommittee of the Society and I attended at their invitation.

989. Whilst I was a trustee at the MacFarlane Trust there were always two or three beneficiary trustees who had been appointed by the Haemophilia Society and they used to update the rest of us on Society matters.

149. What kind of support or assistance was provided by you to patients making applications for financial assistance from the Haemophilia Society. You may want to refer to the letter you wrote to the Tanner Fund dated 29 May 2013 in support of a patient receiving funding for a laptop [HSOC0012800].

990. I used to write letters of support for any patient who asked me, to organisations from whom they thought funds might be available. There were various different funds –Macfarlane (MFT), Caxton, the Eileen Trust, Skipton Fund. I would always write a letter or complete the appropriate form whenever they asked for it.

991. In the document [HSOC0012800] I supported this patient in his application for a new laptop which he required in order to assist him with online applications for employment. I recall this gentleman had a speech deficit and it was to help with communication. He had lots of neurological investigations but a cause was never identified. The Tanner fund awarded

up to £1,000 for people suffering from hardship as a result of their bleeding disorder.

992. I wrote letters to provide support and assistance for other items – eg. holidays with children/grandchildren, stair lifts, convalescence in Llandudno for someone recovering from orthopaedic surgery, money for a patient to buy new clothes after weight gain following successful treatment for HIV and money for specialised IVF in London for sperm-washing in an individual with transfusion-transmitted HIV.

993. Although beneficiaries with haemophilia were eligible for these funds because of their transfusion-transmitted infection, they were individuals with bleeding disorders in middle life so many of the problems they wanted help with were related to their arthropathy from haemophilia rather than the specific infection.

994. In the last years of the MacFarlane Trust, Reserve Funds were distributed in order to ensure beneficiaries were safe and dry. For instance, we would support funding for items such as wet rooms, new boilers, new windows, or repairing a roof.

995. Beneficiaries could also access specialist advice for benefit applications from Neil Bateman, a legally qualified Social Worker, via MFT. I strongly encouraged the Macfarlane Trust to continue the services of Neil Bateman to help with their applications following the change in benefits to PIP, EHA etc.

996. I would also assist patients with applications for benefits such as PIP and EHA at the CCC. This would involve asking the patient to come in so I could assess them to do the report. I considered this was necessary to ensure our report would be accurate and would correspond with the patient's own account.

SECTION 13: THE LIVERPOOL HAEMOPHILIA CENTRE INTERACTION WITH THE TRUSTS AND SCHEMES

150. To what extent did these centres and its staff inform patients about the different trusts and schemes available?

997. I understand that in the 1990's there was a social worker at the haemophilia centre in Liverpool whose role was to support the patients and advise them of the various funds available to them and also help them with benefits. Latterly the Social Worker was shared with the Haemato-Oncology Unit. I became more aware of all the different trusts and schemes when I became a Macfarlane Trustee and would advise patients of the trusts and schemes available where appropriate.

151. Did the centres have policy or guidance for staff members to refer patients to the trusts and/or schemes for support? If so, please provide details.

998. Any policy or guidance was set by the Department of Health. They would set the guidance and we would follow it.

999. We would always inform patients of any scheme for which they were eligible to apply, such as the more recent changes in the Skipton Fund allowances.

152. What information did the centres have to provide to the trusts and schemes on behalf of patients (i) for them to be accepted onto the trust and/or scheme, and (ii) in respect of applications for payments?

1000. The centres would usually provide a letter and often the patient would be examined and/or we would arrange the required investigations to support the application.

1001. From my recollection, the HCV Skipton Form required liver function tests, full blood count, ultrasound scan or fibroscan of liver and for those who did

not have a bleeding disorder liver biopsy was suggested. A statement that transfusion-transmission was the most likely source of HCV was also required.

1002. For HIV, proof of administration of potentially infected product was required plus a positive HIV test to register for Eileen or MacFarlane Fund.

153. What kind of support or assistance was provided by you and/or the Liverpool Haemophilia Centre to patients making applications for financial assistance?

1003. As per my response to question 149 I used to write letters to several different funds on behalf of patients.

154. Were the clinicians or other staff of these centres involved in the determination of whether a particular patient met the trusts and/or schemes eligibility criteria? If yes, please explain who set the criteria, what those criteria were and how they were applied.

1004. Other staff from the CCC might provide the information required and fill in the forms or write the required letter with accompanying results of laboratory tests and reports of imaging. We did not set any criteria or make any judgment locally, but complied with the regulations of the relevant scheme.

1005. When I was initially appointed a Macfarlane trustee there was a social worker in the office at Alliance House who could authorise requests up to a certain spending limit (around £250) according to "Office Guidelines" and anything over that had to go to a sub-committee of the Trust. The "Office Guidelines" were made known to the beneficiaries and provided a useful guide.

155. Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of your patients in relation to the

trusts or funds, do you consider that the trusts and funds were well run? Do you consider that they achieved their purposes? Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

1006. I felt that the trusts and funds were well-intentioned and reasonably well run.

1007. The issue was that when the MacFarlane Trust and Eileen Trust were first set up they provided a lump sum and as many of the recipients did not think they would live for very long, they understandably and very reasonably spent all the money.

1008. The amounts of regular payments available from the MacFarlane Trust were relatively small until the publication of the Archer Report. This did create an undignified situation where beneficiaries felt like they were asking for a "pound out of the poor box" until 2010 when more generous regular payments came in.

1009. My understanding of the purposes of the various schemes was that The Eileen Trust was set up for individuals with HIV from locally prepared blood products and was a large capital fund. Payments were based on the financial status and dependents of each beneficiary.

1010. The Skipton fund was set up for payments in relation to Hepatitis C. This was non-discretionary and on a scale dependent on the severity of disease. Extra funding was provided for cirrhosis and/or hepatoma (Part2).

1011. The Caxton fund was set up later to provide discretionary payments to those with HCV to provide parity with those who had HIV.

1012. There was also the Honeycombe legacy to help widows of those who died of HIV and was intended for educational purposes.

1013. The Macfarlane Trust was set up for discretionary payments only to administer small regular payments for HIV beneficiaries. A few years before its end the MacFarlane Trust decided to distribute the majority of its reserves and did also contact haemophilia centres to inform any relatives of deceased patients that we would be inviting applications for grants from surviving spouses and parents.

1014. All 5 schemes were later transferred to the NHS Shared Business Services which was administered by the BSA.

1015. I do not recall thinking that there was anything particularly wrong with the Macfarlane Trust apart from a period when there was a delay in the distribution of small payments by the office. A very experienced social worker, Neil Bateman, was available on a consultancy basis at MacFarlane and he was very good at helping with the benefits applications. We also provided counselling services and helped with payments for educational assistance.

1016. After the Archer Report in 2010 the DoH brought in regular larger non-discretionary payments for each infection (HIV and HCV). I was pleased when the non-discretionary payments came in and thought that this represented a real improvement for the beneficiaries and was much more dignified.

156. What if any dealings have you had with EIBSS? Have there been difficulties or shortcomings in the way in which it operates or takes decisions or in its dealings with applicants for assistance?

1017. I am not particularly familiar with EIBSS and am not able to comment.

SECTION 14: YOUR INTERACTION/INVOLVEMENT WITH THE TRUSTS AND SCHEMES

157. The 28 October 2008 minutes between the Department of Health and Macfarlane Trust acknowledge your appointment as a Medical Trustee of the MacFarlane Trust [MACF0000012_131]. Please provide a summary of your time as a Trustee of the Macfarlane Trust and in doing so, please respond to the following matters:

a. How you came to be appointed as trustee;

1018. From memory, I think an email was circulated from UKHCDO saying Dr Mark Winter was going to step down as medical trustee or it might have been mentioned in a meeting. I thought that it would be a good fit for my skills and interests so I expressed an interest and I applied. I was interviewed by the DoH and appointed.

1019. I attended my first board meeting on 27 April 2009. The minutes of this have been provided to me by the Inquiry [MACF0000012_044].

b. The functions that you carried out;

1020. As per document [HSOC0020874] which I have had sight of, the MacFarlane Trust was established to distribute monies provided by the DH on a discretionary basis to patients with bleeding disorders who had been infected with HIV as a result of transfusion of blood components.

1021. As trustee, I would meet with other trustees and discuss applications that had been made. A lot of them would have already been approved but it would be the more equivocal or very expensive ones that we might discuss at the Trust Board. As the Medical Trustee I was also there to advise on any clinical matters which arose in connection with these.

c. The responsibilities that you held in this capacity;

1022. I would discuss applications with other trustees and help make decisions about the award of funds. My unique contribution to the group was specialist haematological advice as a Co-Director of a Haemophilia CCC.

d. Whether your position and responsibilities as Trustee changed over time;

1023. I was appointed to chair one appointments committee whilst on the Trust Board and served as a member on a couple of others.

e. The duration of your role as a Trustee and the extent of your involvement with the Trust after expiry of your term as a Trustee;

1024. I was appointed a trustee in April 2009. My involvement ended when the Trust expired in November 2018. I was not involved with the Trust after the expiry of my term as a Trustee.

1025. Although I had only intended to be there originally for four years, there was a lot going on and it did not seem sensible to appoint new Trustees when we knew the services provided by the MFT would be reorganised substantially very soon.

f. What criteria were used for deciding applications for financial assistance and what input did you have as a medical Trustee in the development of the criteria.

1026. At the meetings there was an agenda with a pack of relevant documents for discussion enclosed. These would include a budget statement, minutes of the sub-committee dealing with grant applications and a presentation of a review of reserves annually. The majority of grant applications had a suggested decision for approval by the Trust Board but there was usually a small number for further consideration at the main meeting.

1027. Each application was considered individually. When considering applications, we would consider many different criteria including what was fair, how much the applicant had already been allocated, what it was they were requesting and what their income was.

1028. As the resource was for everyone it needed to be fairly shared between all beneficiaries, so we would be obliged to consider it in the context of other requests to some extent.

1029. As medical trustee, I would sometimes also be asked to consider whether the application was appropriately related to their health and if the medical condition they had would make them disabled in the way described. Such specific queries were few.

1030. There were also some instances where people were applying for funds for medical treatment which should have been provided to them on the NHS reflecting a degree of postcode lottery.

1031. When the practice changed to substantial non-discretionary payment all beneficiaries were given a reasonable regular payment. Small individual payments for capital sums went through office guidelines and the higher sums through the Grants Sub-committee. Anything declined went to the Trust Board.

1032. MacFarlane beneficiaries were individuals with inherited bleeding disorders or their intimates who had acquired HIV through transfused blood or plasma products and these properties made them eligible for payments from the Trust. When I started as a trustee in 2009 smaller payments could be issued from the office according to published office guidelines. These appear to have lapsed with a change of staff and were updated by the new Chief Executive in 2015 for circulation to the beneficiaries.

1033. Applications for larger amounts were reviewed by the Grants Sub-Committee for approval at the Trust Board when a very small number

might be considered by the larger group. As set out above, the trustees would consider unusual or higher value applications.

1034. Document [MACF0000171_042] shows grants guidelines which were agreed by all trustees and then published in May 2015. This document sets out the areas for which the Macfarlane Trust would consider making grant requests from 2014/15 onwards. These were approved by the Trust Board.

1035. It is my understanding that application guidelines and application forms would then be sent to beneficiaries applying for grants.

1036. Clear criteria were set out with the invitation to apply for the exceptional distribution of Reserve Funds.

158. In the UKHCDO Annual Report 2010 & Bleeding Disorder Statistics for the Financial Year 2009/2010 [HSOC0020874] it noted that payment of single grants to individual applicants who are principal beneficiaries was available on an "*exceptional basis*". It also noted that a *"needs based"* payment for non-infected beneficiaries, either on a single or non-recurring basis, was available. Please explain the MacFarlane Trust's criteria for assessing and determining the "exceptional basis" and "needs based" thresholds?

1037. "Needs basis" – would be small things like clothing and the trip to Llandudno to help aid recovery.

1038. "Exceptional basis" – would be bigger proposals – for instance someone who wanted to invest money in setting up a deodorant business before the Olympics. That request was for a lot more money - £60,000 in all I think and this was proposed on a staged basis.

159. In the Macfarlane Board of Trustee minutes held on Monday 26 October 2009 [MACF0000012_152] you expressed concern that the Trust will see an increase in requests for support in areas that should be covered by the

NHS. The Board suggested that in such cases, you could ask the PCT concerned why they were not paying for services routinely supplied by other PCTs. Which areas did you consider should be covered by the NHS? How did you manage cases in which support was requested from the trust but should have been covered by the NHS?

1039. I was concerned that we received requests for treatment that should have been readily available to patients on the NHS reflecting a postcode lottery. From memory, this may have been for plastics treatment for those suffering from facial lipodystrophy as a consequence of the side effects of some protease inhibitors (a class of drugs widely used in HAART to treat HIV) or specialist services like physiotherapy. I cannot recall if we wrote to the relevant PCT but I assume we did take that up with them.

1040. In document [MACF0000022_033] we discussed the funding for dentistry, but in relation to that, I gave my professional opinion about dental implants and how I would advise my patients not to use them because of the risk of bleeding and problems with infection on clinical grounds.

160. In the minutes of a meeting of the Macfarlane Trust held on 27 April 2009 [MACF0000012_044], the Chairman of the NSSC advised that the committee would formally recommend increasing the assistance to those receiving Incapacity Benefit but not on Income Support. You asked how quickly a beneficiary's regular pay would be increased if their financial circumstance were to change. The Chief Executive responded that this would be done the moment the Trust was informed. Were you aware of the Trust making untimely payments (including delayed pay increments)?

1041. I note from document [MACF0000012_044] which has been provided to me that I asked how quickly a beneficiary's regular payment would be increased if financial circumstances changed.

1042. As far as I can recall, I was not aware of any delays at the time and was just asking a question at my first board meeting. I think that as I had just started I was unsure how things worked.

161. The Minutes of The Macfarlane Board of Trustees Meeting held on 19 July 2010 [MACF0000015_002] discusses changes to the Macfarlane Trust Objects Clause. You questioned whether the Objects Clause should specify *inherited* bleeding disorder. The Board concluded it would be better to leave "inherited" out unless the DH picked up on it. Please explain your reasoning for suggesting the term 'inherited'?

1043. My reasoning for suggesting the term "inherited" was based on my medical viewpoint and a desire for accuracy. It was my understanding that funds had been intended for those with inherited bleeding disorders who had transfusion-transmitted infection whereas the Eileen Fund had been established for those with other diagnoses who had similarly been infected. As there are many other bleeding disorders, I considered that this would be an accurate way to describe which group of patients was intended to benefit from the MacFarlane Trust.

162. In the Minutes of The Macfarlane Board of Trustees Meeting held on 25 January 2010 [MACF0000015_067], the Chairman invited the Board to discuss the notion of utilising up to £4m to support the bereaved community. One Trustee suggested placing focus on current widows and dependants whose whereabouts were known. Conversely, you suggested that efforts to locate those unknown to the Trust may be achieved through the Haemophilia Centres with the help of UKHCDO. It was decided that the Chief Executive would draft a letter offering financial support to the bereaved which would be sent to the Haemophilia centres and the Haemophilia Society for their newsletter. Given that many Trustees, including yourself, were affiliated with Haemophilia centres, what enquiries did individual Trustees make to locate potential beneficiaries through their respective connections? Please comment on the outcome, generally, of efforts made to locate potential beneficiaries?

1044. At the time, I considered the UKHCDO network and Haemophilia Society to be good vehicles to assist in trying to locate widows and other female dependants with whom the Trust had lost contact.

1045. I advised MFT to write to all the haemophilia centres and the Society and was backed by the 3 beneficiary trustees.

1046. We tried hard to find as many relatives of deceased beneficiaries as possible and did the best we could. This was difficult in light of the fact that we were trying to find widows and mothers who had lost their sons in the 1980s and 1990s and therefore, at that point were likely to be at least in their 70s but certainly from our CCC we were successful in making some widows and mothers aware of the scheme. The family practice of clinical care for individuals with inherited bleeding disorders was helpful in this respect.

163. In the Minutes of The Macfarlane Board of Trustees Meeting held on 04 April 2011 [MACF0000023_021], the Chairman, Mr FitzGerald, shared his intention to resign in April 2012. You took the chair and several members raised concerns about the quality of Mr FitzGerald's chairmanship, in particular his relationship with the Trust Office. It was suggested that he should be allowed to go with dignity and remain in the chair until his resignation date. Please elaborate on these concerns voiced by the Trustees? What difficulties or shortcomings, if any, were encountered while Mr FitzGerald saw out his chairmanship?

1047. I recall that there was a disagreement of longstanding between one of the trustees and Mr Fitzgerald. I cannot recall the exact concerns, but I believe there was a personality clash between the two individuals.

1048. I recall that after he resigned some people wanted him to leave immediately but it was the consensus view that we would allow him to see out the rest of his chairmanship which was only a few months.

164. Minutes of a meeting with Messrs Evans, Patrick Spellman and the Macfarlane Trust Chief Executive on 5 October 2011 [MACF0000023_053] noted that you were part of a Shortlisting Panel. The Minutes of The Macfarlane Trust Board of Trustees Meeting, 24 October 2011 [MACF0000023_042], noted that you were a member of the interview panel for the Employment Affairs Committee. Please explain the nature and purpose of these internal panels? Please outline roles you undertook on any other internal committees and/or panels?

1049. These shortlisting internal panels were created to help appoint appropriate people. I was concerned at the proposed expenditure on a "head hunter" agency because I thought this was an unnecessary expense. After the October Appointments Committee was unsuccessful in making an appointment of a new chairman from applicants provided by the agency, I suggested an internal search from the existing trustees and Roger Evans was subsequently selected by a further Appointments Committee in January 2012.Therefore, as in document [MACF0000023_053] I suggested the composition of the interview panel.

1050. There was an Employment Affairs Committee which was a subcommittee of the Trust as set out in the minutes of 24 October 2011 [MACF0000023_042] but I only served to chair an appointments committee for it as set out above rather than attending regularly. I believe its main role was in the management and engagement of the office staff who were formally employed.

1051. I was subsequently invited by Mr Evans to serve on an Appointments Committee for a new Chief Executive when we appointed Ms Jan Barlow.

1052. I was also invited by Mr Evans to serve on an Appointments Committee for some new Trustees on one occasion.

1053. I was not a member of the National Support Services Committee or any liaison committee.

1054. In general, my role was more to do with the clinical side and the beneficiaries rather than administration.

165. In the Macfarlane Trust Board of Trustees Meeting, 30 April 2012 [MACF0000025_015], it was recorded that you voted *not* in favour of instructing solicitors to prepare the necessary loan contract and charge documents. Please explain why you voted against this proposal? What was the outcome of the vote?

1055. This application related to a request for a business loan of £55,000. From my recollection it was to enable the applicant to set up a business and sell some ecological toiletries for men in supermarkets before the London Olympics. There were some people on the Board who thought it was a good idea, but I did not. It was a large amount of money in comparison to many other beneficiaries' applications for a business proposal which I could not see would succeed, and these were the reasons why I did not support it.

166. The Minutes of Macfarlane Board of Trustees Meetings, 25 February 2015 [MACF0000022_039] and 9 April 2015 [MACF0000155_005] discuss a request received from Neil Bateman, Specialist Benefits Adviser, to work with additional medical experts on some of the tribunal cases, at a cost. The Committee was in favour provided that an additional medical opinion (preferably from you) was sought. Do you recall a conversation regarding this matter and if so, how was it managed?

1056. I cannot recall a particular case. I spoke with Neil Bateman myself over the years about various cases.

167. In the Minutes of the Board of Trustees of Macfarlane Trust held on Monday 30th January 2012 [MACF0000025_002], you reported that the Trustees

agreed that Mr Evans should be invited to become Chairman for a full term from 30 April 2012 on the condition that he divested himself completely of all his current responsibilities as a Trustee with the Caxton Foundation. Mr Evans said he would reflect on this condition and would advise of his decision. Please explain the conflicts that this condition aimed to avoid? What was Mr Evan's end decision?

1057. In the document [MACF0000025_002] provided to be by the Inquiry, at pg 8/ pg12 it states – *Dr Martlew reported that it had been agreed among the Trustees present that Mr Evans should be invited in to become chairman from 30 April 2012 on condition that he divested himself completely of all his current responsibilities as a trustee with the Caxton foundation. He said he would reflect on his condition and advise.*

1058. As far as I recall this related to Mr Evans' responsibilities as a trustee with the Caxton Foundation. I do not recall thinking that there was a conflict of interests as both trusts related to co-infected people and were moving forwards to one fund. However, I believe he was concerned that there was a conflict. There is reference in the minutes to an SLA and to legal papers having to be signed which may have been a factor. I believe he did leave the Caxton Trust but am not sure whether or not he remained on the Liaison Committee.

1059. Initially the MacFarlane Trust administered the office staff and controlled the budget. As far as I can recall, latterly the administration of the office staff passed to the Caxton Fund as it had a larger number of beneficiaries and then an SLA was set up for the office to continue to provide services to the MacFarlane Trust.

168. The Macfarlane Trust grants committee minutes of a meeting held 5 July 2017 [MACF0000170_018] refers to "Case 6" in which a grant of £2,400 towards a "respite break" for a primary beneficiary was declined. It noted that a break following negative side-effects from a clinical trial for

haemophilia treatment did not meet the criteria for a "respite break". The Committee requested that a copy of the case was sent to you to verify whether the side-effects were related to either HIV or hepatitis C. Can you please recall if you received a copy of this case and if so, what was your response and view on the matter?

1060. I am afraid that I do not recall this.

169. Please comment on any difficulties or shortcomings you encountered during your time with the MacFarlane Trust?

1061. There were some financial constraints imposed by the DoH on MFT. This limited the extent to which we could improve the quality of life for a number of our beneficiaries. Also, confirmation of the budgetary allowance for the forthcoming financial year was usually very late which made financial planning difficult.

1062. We always tried to be fair and sympathetic to the individual's needs. We did our best to provide meaningful support where there was hardship. A few years before the Trust was wound up we endeavoured to distribute a large portion of the reserves to our beneficiaries. When MFT was wound up we were able to transfer £1.16m of funds and assets to the Terrence Higgins Trust to enable continuing support to be provided to beneficiaries based on criteria similar to MFT.

SECTION 15: CURRENT HAEMOPHILIA CARE

170. Please describe:

a. How the provision of care and treatment for bleeding disorders is currently organised at the Liverpool Haemophilia Centre; and

1063. I retired in May 2020 although I stopped doing regular weekly haemophilia clinics in January 2014 so I may not be best placed to comment on current practice.

b. Your current roles and responsibilities at the Liverpool Haemophilia Centre.

1064. I retired in May 2020, so I do not have any current roles and responsibilities at the Liverpool Haemophilia centre.

171. Please outline the treatments currently provided to patients with bleeding disorders at the Liverpool Haemophilia Centre.

1065. Over time available treatment changed considerably for patients with severe haemophilia during the second half of the twentieth century.

1066. As far as I am aware the current treatments include but are not limited to;

- Recombinant coagulation factor concentrate
- Anti-retro viral therapy for HIV (HAART)
- Treatment for hepatitis C
- Emicizumab

1067. Factor VIII comes in a box with a bottle of water to make it up. Vial sizes are 500iu,1000iu, 2000iu and occasionally 3000iu. The standard dose would be 1,000-2000 units three times a week for prophylaxis in an adult or for a serious bleed 3000-4,000, all administered intravenously. Emicizumab is administered subcutaneously no more frequently than once a week so it is much more convenient and appeared to offer more sustained haemostatic cover. This has been a great advance in the care of people with haemophilia.

1068. When I left the centre a pharmacologist and physiotherapist had recently been appointed at the CCC.

1069. On an individual basis, factor usage is monitored regularly and this information sometimes gives advice about regimes for prophylaxis. Patients record what they use and consideration is given to whether they need to be on preventative treatment and whether it is effective. It is reported on the Haemotrak system via mobile phone. For the older patients, data collected on paper will be recorded on the system by a member of staff.

1070. The government required the use of Haemotrak as a condition before patients with haemophilia were transferred on to Emicizumab (Hemilibra).

1071. When Mas Chaponda took over as our Consultant in Infectious Diseases, more than five years ago, he decided to review all his HIV patients with haematological disorders together in a clinic every other month on a Tuesday afternoon but there has always been tailored specialist review covering haemophilia and infectious diseases in Liverpool in a joint clinic since effective anti-viral treatment has been available.

172. Please describe how you typically obtain your patients' consent to treatment. In particular:

a. What information do you give patients about the risks of the treatment?

1072. Typically, with any treatment, I would sit with the patient and discuss the pros and cons of their going on a certain treatment and provide them with written information to take away and consider before making a decision. I would not have wanted them to make a decision without having the opportunity to go away, read the information, think about it and ask any questions first.

b. What information do you give patients about the side-effects of the treatment?

1073. I would give them written information where appropriate as above.

c. What information do you give patients about the risks of not having the treatment?

1074. I would explain all the risks including any risk of not having treatment as it is the patients who have to live with the outcome.

1075. In my experience, people have different personal views about their own risks and options. For example, they may be more concerned either about risk of bleeding or of clotting, as a result of their own experience. Therefore, it was important that they take part in the decision-making process as it was their choice to make.

1076. For example, when Emicizumab became available the opportunity was first introduced verbally to suitable patients at clinic. They were then provided with written information about the benefits of the new treatment and its recognised side effects, with an indication of the increased frequency of attendance at the CCC required during the changeover period. At a follow up appointment they could then indicate their willingness to make the change or not.

1077. A similar approach was adopted for new antiviral therapies over the years.

d. What information do you give patients about the benefits of having the treatment?

1078. I would talk to the patient and discuss the reasons behind any recommendations before obtaining their consent.

1079. Whenever a new treatment came out, I would talk to them about it and give them a leaflet or information and then discuss their decision the next time I saw them. Wherever possible I would have given them a leaflet so they were ready. I would not want them to make any decision when it was first

mentioned without careful consideration and an opportunity to discuss it with their family or GP.

1080. We did this with the latest treatment too and It is surprising how many people accepted treatment with Emicizumab. I expected more patients to be dubious about it after everything they have experienced in the past but they all seemed remarkably keen from the outset.

1081. In some cases, we might have an MDT meeting – for example if an operation was likely to be particularly complicated. For instance, where the anaesthetic risk is considerable and we would be inclined to advise against it but the patient wants to go ahead. After the MDT meeting we would invite the patient to see all the relevant specialists. A specific plan would be written and agreed and given to the patient as well as the surgeons, anaesthetists and colleagues in the laboratory.

1082. As Liverpool Heart and Chest Hospital (LHCH) was the supra- regional centre for thoracic aortic root replacement, patients would be referred there from other parts of the country and so we had detailed discussions about what was involved in surgery then designed their haemostatic plans individually. When patients were referred in this way from other centres we invited them to come and meet us at the CCC to discuss any concerns prior to surgery so they would know what the plans were for their haemostatic support and could ask any questions in advance.

1083. Treatment plans have been prepared for the past 25 years or so. Once a treatment plan was agreed it used to be distributed on paper to all involved in the treatment but recently the planning process has become electronic which is more convenient and secure when the surgery takes place at another hospital.

173. Please describe how you typically record your patients' consent to treatment.

1084. For many years there would be a paper copy recording the patient's consent in the notes with a separate copy for the patient. I recall this changed to an electronic form on tablets some time in 2018. By the time I left the service there was also a Part 4 consent process for patients who lack capacity which needs to be signed by two doctors electronically.

174. Do you routinely take blood samples from patients attending the Liverpool Haemophilia Centre? If so, what information do you provide to patients about the purposes for which the samples are being taken? Do you obtain patients' consent to the storage and use of the samples and if so, how and is that recorded?

1085. I am now fully retired as described above.

1086. Blood samples would be taken routinely at least every 6 months in clinic from patients with severe bleeding disorders until 2014.

1087. Many patients on regular factor concentrate required routine monitoring. For instance, we would monitor blood count and liver function and inhibitors to factor VIII. When treating patients with HIV we would monitor the viral load and CD4 count also and for any specific side effects of drugs included in their HAART. It is also necessary to monitor alpha fetoprotein for those with chronic HCV as a marker of hepatoma and perform regular fibroscans to check for cirrhosis-followed by ultrasound monitoring of the liver if cirrhosis is established.

1088. The patients would be aware that they were having routine monitoring.

1089. HIV patients would be advised about this when they were placed on antimicrobial prophylaxis and monitored until their CD4s were satisfactory and they could stop taking them. In clinic, they would usually ask if their blood test results remained satisfactory.

1090. However, if a patient had an abnormal test unexpectedly we would advise them we were going to retest for this and would arrange this quite quickly before their next routine clinic visit.

175. Please describe how you typically (a) obtain and (b) record your patients' consent to testing (of any kind).

1091. Please see my responses to questions 172 and 173.

176. How many current patients at the Liverpool Haemophilia Centre (a) were infected with HIV through blood products; (b) were infected with HCV through blood products; (c) were infected with HBV through blood products; (d) were co-infected with HIV and HCV through blood products?

1092. I do not know as I left the service in May 2020.

177. What if any involvement do you have and/or does the Liverpool Haemophilia Centre have in the treatment of the Centre's patients for HIV and/or HCV and/or HBV? Are there multi-disciplinary clinics (e.g. haematology and hepatology)? If not, would such arrangements be feasible and beneficial?

1093. Please see my responses to questions 172 and 173 and more detailed questions on the viruses concerned.

1094. The Liverpool Haemophilia Centre is involved in the treatment of the Centre's patients for HIV and/or HCV and/or HBV and there are MDT meetings. Many of the treatments discussed in my response to question 173 have been in place for over 20 years

178. What if any psychological services are available at the Liverpool Haemophilia Centre? Do you have a psychologist as part of the staff team? Is there psychological support specifically for those infected with HIV and/or hepatitis in consequence of infected blood products?

1095. I understand that Alison Jones was the first haemophilia nurse/counsellor in Liverpool in 1988.

1096. Helen Rogers was appointed in 1989 in Liverpool to replace a shared social worker.

1097. Jayne Keaney, the haemophilia clinical nurse specialist who was a qualified counsellor, was appointed in 1996. A clinical psychologist was appointed in 2020 just before I left. We also had access to another counsellor who was part of the haematology department, if patients chose to see someone outside the centre. There is also a psychiatric service within the hospital.

179. What, if any, other support services are available at the Liverpool Haemophilia Centre?

1098. There was a physiotherapist also and a pharmacist was also appointed in 2020.

1099. There was a Haemophilia Focus Group for patients with bleeding disorders. This was not just for the infected group but all patients with bleeding disorders. It met intermittently.

1100. It was a meeting for the patients as a group at the hospital which was run by one or two of the haemophilia patients - almost like a patient forum. They met at the clinic usually out of hours, without any clinic staff - just patients.

1101. There was also the UKHCDO Triennial Audit which is now known as peer review which was done every three years. It included a satisfaction questionnaire sent at random to patients. The audits were organised by UKHCDO. Haemophilia was one of the first services to undertake such

peer review within the NHS. This provided valuable feedback to allow us to adapt services to patients' needs over the years.

1102. A doctor, nurse and patient would come to do the review with a pro forma to complete. They would speak to everyone in the clinical team, including the laboratories etc, review the questionnaire and meet clinicians from other specialties and other hospitals concerned with the evaluation of our tertiary service. The Triennial Audits have been helpful in getting developments in haemophilia care in the UK and making advances – for example recommending designated premises for the Comprehensive Care Centre which got us into the Roald Dahl Centre in Liverpool.

1103. It led to other specialities being engaged and promoted appropriate increases in staffing to the benefit of patients.

1104. As a national exercise it ensures standards remains consistently high throughout the UK for the care of patients with inherited bleeding disorders.

180. What has been the impact of the infection of patients with HIV and/or hepatitis through blood products on:

a. Patients at the Liverpool Haemophilia Centre (without identifying any individual patient);

1105. The impact of transfusion transmitted HIV and hepatitis has been catastrophic for all the patients and families concerned. From the 1980's there was a significant stigma associated with a diagnosis of HIV – however it had been acquired. In addition to grave concerns about their health, patients and their families suffered considerably socially, at work, at school, in obtaining insurance and even dental care most undeservedly, largely as a result of ignorance, prejudice and fear.

1106. In some kindreds several members of one family have been affected and they may have lost several close relatives. In one most unfortunate family

both young parents died tragically within a short time of each other leaving their family orphaned.

1107. Once effective antiretroviral treatment was available as HAART to treat HIV, the tragic impact of chronic hepatitis C with its attendant complications of cirrhosis and hepatoma became apparent with further devastating consequences for the families concerned.

1108. The stoicism and perseverance of these patients and their families cannot be overestimated and is much to be admired.

b) The ways in which decisions about treatment and care are taken, and treatment and care are provided, at the Liverpool Haemophilia Centre?

1109. As mentioned above I am now fully retired. Before I left the CCC in 2020 the standard practice in planning treatment and care for patients with bleeding disorders would include a clinical review within the multidisciplinary team, including representation from all groups of staff concerned. The recommended treatment would then be discussed with the patient, including risks and benefits, and the mutually agreed plan implemented on the basis described above.

181. Has the infection of patients with HIV and/or HBV and/or HCV through blood products:

a. Changed or influenced your professional practice and approach and if so how?

1110. I qualified in 1975 and started to specialise in haematology in 1979.

1111. At that time, I thought HBsAg screening had removed the risk of homologous serum jaundice or transfusion-transmitted hepatitis and HIV was unknown.

1112. Early in my training in 1981 I learned that the majority of people with haemophilia developed a subclinical hepatitis following first exposure to coagulation factor concentrate and this was designated non A-non B hepatitis.

1113. I started working as a Consultant in January 1984 in the Blood Transfusion Service when the impact of HIV on blood transfusion was becoming apparent and strenuous efforts were being made to exclude HIV from donor blood and to develop a viral inactivation process to exclude non A-non B hepatitis from fractionated plasma products. Within a few years I recognised also that HBsAg screening alone did not completely exclude HBV from the blood supply.

1114. Recognising the benefits of voluntary blood donation in the UK, I then worked very hard towards national self-sufficiency in plasma for many years.

1115. I have always worked on the principle that blood is filthy stuff and blood transfusion should not be prescribed unless there is no alternative. By this I mean that blood and blood products carry a risk of infection and that patients should not be exposed to this unless absolutely necessary. The risk of vCJD is a good example. If you decide to transfuse someone you need to be prepared to justify that the benefit outweighs the risk in case they develop an unanticipated complication much later - even in 40 years' time. I have endeavoured to teach these principles to undergraduate and postgraduate medical trainees and those engaged in professions allied to medicine for many years.

1116. If you decide to transfuse someone you need to annotate the reason and be prepared to explain it. I have always had a cautious approach to blood. I maintained this approach throughout my professional practice. The infection of patients with HIV and/or HBV and/or HCV through blood products strengthened my resolution in this position.

b. Changed or influenced the practice and approach of your colleagues and if so how?

1117. With enhanced education and mandatory training, the influence of hospital transfusion teams and committees, the appointment of specialist practitioners of transfusion (SPOT) together with the Serious Hazards of Transfusion (SHOT) haemovigilance scheme together with the NBS Blood Management Systems the majority of my colleagues have been influenced to be more cautious about using blood products and take steps to reduce use of blood and blood products to reduce risk.

c. Changed or influenced the way in which haemophilia care is now provided and if so how?

1118. As a result of the infection of patients with HIV and/or HBV and/or HCV through blood products changes were made to the care provided.

1119. Comprehensive care centres had a dedicated team of people who specialise in the care of those with bleeding disorders which has helped prevent a lot of complications and very much improved the support of those with transfusion- transmitted infections.

1120. The national registration system with UKHCDO allowed identification of patients with bleeding disorders and of good practice to enhance quality of care. Patients registered with UKHCDO had a green card so if they went on holiday they could show it to a local medical attendant indicating their diagnosis and recommended treatment.

1121. When an individual with a bleeding disorder is unwell, having a team of people helps enormously in the provision of prompt haemostatic support – if an individual with an inherited bleeding disorder does not have immediate access to the haemostatic treatment the attendant delay makes the whole thing worse.

1122. There have also been advances in haemostatic support – first with recombinant coagulation factor concentrates independent of human plasma and more recently with monoclonal therapy as Emicizumab.

1123. The use of complex drugs in the management of HIV with HAART and HCV eradication therapy have improved enormously in both efficacy and tolerability.

SECTION 16: OTHER ISSUES

182. Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

1124. Not that I recall.

183. Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.

1125. I would like to record my thanks and admiration to the very many volunteer blood donors without whom many life-saving or life-enhancing treatments would not be available and especially to those who were prepared to increase their attendance to fortnightly to support the drive towards national self-sufficiency in the 1980's and 1990's. We tried to ensure that they were valued and their gift was respected in a way they would wish. I am conscious that the small number found to carry transfusion-transmissible diseases were mostly devastated to learn that they were infected and might unknowingly have caused infection to others.

1126. I would like to put on record my respect and admiration for the haemophilia patients I have treated over many years and for the courage and good humour which they showed in spite of the repeated tragedies that had affected many of them and their families on top of the pain and suffering associated with their underlying conditions. I believe that in challenging – and at times quite overwhelming circumstances - the professionals involved in their care for the most part acted out of the best of intentions and in good faith. To the extent that we collectively and individually let our patients down I am deeply and truly sorry.

1127. I am aware that the work of the Inquiry is exceptionally sensitive and difficult but of the utmost importance. I wish it well in this important work.

Supplementary Rule 9 Request

184. 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?

1128. As far as I was aware the United Kingdom was self-sufficient in its need for whole blood for transfusion, although the majority was provided as plasma reduced red cells from voluntary British donors in December 1985.

1129. The one exception would be a patient whose acquired red cell antibodies were of such complexity that their transfusion needs could not be accommodated by either their local transfusion centre, or, indeed, the National Panel of Frozen Red Cells (which was stored in Birmingham at that time) necessitating a request to an international bank of frozen red cells abroad.

185. During your tenure, were you aware of patients being given blood transfusions with red blood cells imported from the USA? If so, was there any concern about its use at the time?

1130. I have a vague recollection of a colleague making such an enquiry for a patient with sickle cell disease some years ago when no compatible blood was available in the United Kingdom but cannot remember the outcome. There would always have been great concern about imported blood from the USA from the time I started working in the Manchester Blood Centre in January 1982. My recollection of it is very vague but I think that this special individual request was probably made when I was in Liverpool which would mean it was after 1988.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed ___ GRO-C _____

Dated ____October 24th 2021_____

Table of exhibits:

Date	Notes/ Description	Exhibit number
	List of relevant publications	WITN4034002
September 1990	The Medical File: A Systematic Approach to Donor Deferral: Shepherd, A.J.N., and Martlew, V.J. Transfusion Medicine Vol 1. Suppl 1. 45 (September 1990)	WITN4034003

September 1991	The Medical File: Update on a further 12 Months Experience Shepherd, A.J.N., and Martlew, V.J. Transfusion Medicine Vol 1. Suppl 2. 77 (September 1991)	WITN4034004
2021	Dr Vanessa Martlew CV	WITN4034005