Witness Name: John Anthony Francis Napier
Statement No.: WITN6915001
Exhibits: WITN6915002 – WITN6915006
Dated: 20th October 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR JOHN ANTHONY FRANCIS NAPIER

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 1 March 2021.

I Dr John Anthony Francis Napier, will say as follows:

Section 1: Introduction

1. Before addressing the specific questions, I would like to make some general introductory comments which set the context of my recollections and this evidence and the process which has been followed to gather information to enable me to respond.

2. I retired from my full-time position with the Welsh Blood Service (and its predecessors) in 1999 and the events about which the questions relate happened in the main many years before that. I have therefore attempted to answer the questions to the best of my recollections but some of the events over which questions have been asked I have been unable to recall or have limited recollection of.

3. I have been assisted in the preparation of this statement by Suzanne Jones of the Welsh Blood Service who has provided assistance with the provision of documents and in establishing dates or years when certain things happened. Where I have given dates in this statement they are often based upon information provided by Suzanne or taken from contemporaneous documents. However, I have been informed that the documents held by the Welsh Blood Service only date to the early 1990s and earlier documents are not available. I have therefore attempted to answer questions relating to these earlier periods to the best of my recollection but without any assistance from documents other than those to which I have been directed by the IBI team.

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

4. My name is Dr John Anthony Francis Napier.

5. My address is GRO-C

6. My date of birth is GRO-C 1939.

7. My Professional Qualifications are as follows: MB BS London, PhD Cambridge FRCPath.

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

8. 1964-65 House Officer posts in Medicine and Surgery Charing Cross Hospital London.
   1965-69 Junior Assistant Pathologist. Department of Pathology University of Cambridge.
   1969-72 Welcome Research Fellow: Research topic Purification and Assay of Erythropoietin.

1972-77 Lecturer in Haematology, University Hospital of Wales, Cardiff. Responsibilities included: Inpatient and outpatient care of haematology patients. Research and teaching in haematology and blood transfusion.

9. 1977-98 Appointed Medical Director Welsh Regional Blood Transfusion Service. Responsibilities: Care and selection of blood donors, preparation and testing of blood and components to ensure safety and efficacy, provision of plasma to the national fractionation centre, distribution of blood and components to hospitals, education, research and public communication regarding blood transfusion matters.

10. Following retirement, I held a part time position at WBS supervising research. From 1990 to 2001, I organised/participated in international assistance projects in Albania, the former Yugoslavia states, Belorussia and Jordan. These were funded variously by DIFID, WHO or the European Commission.

11. Between 1999 and 2002, I was invited to return to WBS as Medical Director on a part time basis pending recruitment of a new permanent appointment because the post had unexpectedly become vacant.

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.

12. I cannot put accurate dates on these activities:
    1970 – 2004 Member of British Society for Haematology.
    Secretary to British Society for Haematology committee for Standards in Blood Transfusion.
    Member of Serious Hazards in Transfusion (SHOT) Working Party.
    Member of British Blood Transfusion Society (Recipient of Oliver Memorial award for services to Blood Transfusion 2001).
    Member of Clinical Pathology Laboratory Accreditation inspection team.
    Royal College of Pathology Membership Examiner.

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

13. Regular reader and sometimes contributor to the British Medical Journal ("BMJ"). Lancet, British Journal of Haematology, British Blood Transfusion Society Journal and various other international publications.

14. Author of numerous papers in the field of Haematology and Blood Transfusion. Contributor to chapters in textbooks on Haematology and Blood Transfusion. Author of textbook "Handbook of Blood Transfusion Therapy."

5. Please confirm whether you have provided evidence or have been involved in any other inquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement

15. I have not been involved.

Section 2: Your role at the Welsh Blood Transfusion Service and the Welsh Regional Transfusion Centre

Welsh Regional Transfusion Centre

6. Please describe the organisation of the Welsh Regional Transfusion Centre ("WRTC") during the time you worked there, including:

a. its structure and staffing;

16. The Welsh Regional Blood Transfusion service was based at Rhydlafar on the outskirts of Cardiff. The Centre employed over the years 1970s to mid-1990s between 250-400 staff. These comprised a management team with administrative and clerical support, mobile Blood Collecting teams, Laboratory staff for testing and processing of blood and components, Research and development and a quality

management team. From the early 1980s, the working processes of the centre were computerised and managed by an in-house team.

17. In 1997, the whole operation was moved to a purpose-built new centre on a site at Talbot Green adjacent to the new Royal Glamorgan Hospital.

b. to whom you were accountable (you may find SCGV0000053_013 (at page 6, paragraph 1-2) of assistance);

18. Accountability was initially (and for the most relevant part of the time) to South Glamorgan Health Authority which managed the WRTC on behalf of the Welsh Office. I was medically and professionally responsible to the Chief Medical Officer. In 1991, Management of the service was transferred to the Welsh Health Common Services Agency (WHCSA) and later on in 1999 to Velindre NHS Trust.

c. its funding and whether this funding changed over time (you may find DHSC0000795, DHSC0000796 and NHBT0097018_003 of assistance);

19. The service was funded from South Glamorgan Health Authority. This was largely based on historical funding with inflation based uplifts (or reduction if the NHS was facing particular constraints). The funding was at times increased subject to successful bids for service enhancements, e.g. the need to further increase plasma procurement for fractionation.

20. Prior to 1990, the traditional arrangement for funding the "Regional Service" had been by "top slicing" from the overall Welsh health funding to reinforce the funding of South Glamorgan HA. This was then changed to a system based on recovery of costs from the supplied Trust/Regions of Wales based on patterns of blood and product usage.

d. its remit, including the geographical area it covered, the hospitals within its area, and any changes made to these arrangements;

21. The WRBTS supplied all hospitals in Dyfed, Powys, Gwent and South and West Glamorgan Hospitals. In North Wales, (Gwynedd and Clwyd) hospitals were supplied from the Mersey region. This arrangement was not changed during my tenure.

e. its place in the National Blood Transfusion Service ("NBTS") together with information as to whom the centre was answerable to at the NBTS, if anyone. When answering this question, please refer to paragraphs 4-16 of Dr Harold Gunson's statement in A and Others v National Blood Authority and another [2001] 3 All E.R. 289 ("A & Others") and explain whether you agree with what is said there (NHBT0000025_001; NHBT0000026_009);

22. The various changes in the organisation of transfusion services in England and Wales did introduce improved mechanisms for coordination and information collection and sharing but did not alter the fundamental problem that improvement and funding was entirely dependent on Regional Health Authorities or in the case of the WRBTS, South Glamorgan Health Authority.

23. Problems and issues arising within the UK blood services were channelled to the Department of Health through the consultant advisor on transfusion matters who at times chaired the Committee of Transfusion Centre directors.

f. whether the WRTC was associated or linked with other Regional Transfusion Centres ("RTCs") and, if so, how and for what purpose (you may find SCGV0000053_013 (at page 6, paragraph 6) and HSSG0010054_008 (page 2, paragraph 3) of assistance);

24. The WRTC had no managerial links to other Regional Transfusion centres. However, there was a high level of coordination between regions of the blood service

but variations were inevitable certainly partly as a consequence of funding differences.

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

25. The operations of WRBTS were subject to the requirements of the Medicines Act and subject to regular inspection by the Medicines Control Agency. There were during my appointment professionally agreed guidelines for donor selection and after 1989 a more formal set of guidelines covering all aspects of transfusion centre activities was published in 1990 ("The Red Book"). This served as a basis for audit of the centre's activities.

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

26. There was no formal contractual arrangement with the BPL. The WRBTS endeavoured to supply as much plasma as it could. I don't think plasma was ever supplied to any other fractionation agency (or third party involved in the production of blood products or processing of blood);

i. The WRTC's relationship with any pharmaceutical companies involved in the production of blood products; and

27. The WRTC had no relationship with any pharmaceutical companies.

j. **the approximate number of donations collected each year (you may find NHBT0003378 and NHBT0006284 of assistance).**
You may also find BMAL0000023 of assistance when answering these questions.

28. This Information has been provided by the WBS from its computerised records dating back to March 1984. These may differ from those recorded at

the time due to differences in recording definitions. These include donations commenced, and the computerised record system recording blood donations was introduced in 1984:

1984 Total	60703
1985 Total	79995
1986 Total	90664
1987 Total	90437
1988 Total	88782
1989 Total	98765
1990 Total	108734
1991 Total	116056
1992 Total	114209
1993 Total	113381
1994 Total	110372
1995 Total	110113
1996 Total	114607
1997 Total	120174
1998 Total	118870
1999 Total	121796
2000 Total	123949
2001 Total	123105
2002 Total	119851

7. Please describe the position of the WRTC with regard to the Welsh Blood Transfusion Service ("WBTS"), Welsh Office, the Welsh Health Commons Services Authority ("WHCSA"), the NBTS, and the Department of Health ("DoH") and how this changed over time.

29. The title of WRTC was replaced by that of WBTS and latterly changed to WBS (Welsh Blood Service). The Welsh Office held ultimate responsibility for the service but management of the WRBTS was delegated successively to the South Glamorgan Health Authority, the Welsh Health Common Services Agency from 1991 to 1999 and finally the Velindre Hospital Trust in 1999. Around 1990 a Joint Working Group comprising representative from WBTS and South Glamorgan Health Authority was in existence to consider issues faced by the service.

30. The relationship with NBTS and other Regional Centres was that of professional liaison without any formal management role. The formal relationship with the DoH was mediated through the Welsh Office.

8. Please describe the roles, functions and responsibilities you had at the WRTC during your period as:

a. Director; and

b. Consultant haematologist

and explain how these changed over time.

31. I was appointed with the title of Medical Director but this was in effect Director of the service with responsibility for every aspect of the blood transfusion services activities. With the increasing amount of non-medical management duties, I felt that the balance of my duties was moving in the wrong direction and therefore a separate Director role in the late 1990s was established with the Medical Director reporting on medical issues via the Director. The title of consultant haematologist was in effect a notional title reflecting that some of the responsibilities concerned direct medical care of donors or patients. This arrangement did not change over time.

Welsh Blood Transfusion Service

9. Please describe the roles, functions and responsibilities you had at the WBTS during your period as Medical Director and explain how this changed over time.

32. Please see answer to Q8

10. It appears from correspondence during your tenure at the Welsh blood services that you signed off interchangeably as Director of the WRTC and Medical Director of the WBTS. Please explain how the roles and responsibilities of Director of the WRTC and Medical Director of the WBTS overlapped.

33. The title changed with the change in title of the service (Q7 above). There was no change in role or responsibility

11. Please explain whether the WBTS' geographical remit covered the whole of Wales.

34. The WRBTS supplied all hospitals in Dyfed, Powys, Gwent and South and West Glamorgan Hospitals. In North Wales, (Gwynedd and Clwyd) hospitals were supplied from the Mersey region. This arrangement was not changed during my tenure.

12. Please describe the following in respect of the WBTS during your tenure:

a. its structure, staffing and hierarchy;

35. The service was headed by the Medical Director but during the late 1990s, by an Executive Director (see Q8/9 above).

36. The Medical Director headed a Senior Management team comprising heads of the major departments. I was assisted by a Deputy Medical Director (who took on professional medical oversight principally of donor services and plasmapheresis and research activities).

37. The departments of the service included Laboratory Services (responsible for blood testing, grouping and microbiology screening, component processing blood banking and issues to hospitals). Donor Services (organisation of the donor panel, of blood collection, collecting team staff, publicity and recruitment). Quality Control and latterly Quality Assurance (this department coordinated all documentation including all standard operating procedures and record keeping). Computer Services responsible for all aspects of process control and data handling and General Administrative functions, finance and personnel and transport.

38. Also, forming an integral part of the WRTCs activities was a Tissue Typing service providing a tissue matching service for the Cardiff Renal and Bone Marrow Transplant units and identifying donor matches for the Transplant units in the UK and abroad.

39. Staff of the service comprised medical laboratory scientific officers, research scientific officers, computer staff, and medical doctors (employed for blood collection duties although latterly largely replaced by nursing staff). Medical staff also operated together with nurses, the plasmapheresis clinics. Other staff included nursing and donor collection team staff, admin and clerical staff, drivers etc.

b. its remit;

40. The remit was to collect blood donations from general public volunteers and to supply blood products and components to hospitals throughout the region of supply whilst maintaining the highest standards of safety and efficacy. The remit also included a commitment to supply source plasma to the plasma fractionation laboratory to enable the manufacture of blood products. This would also include with all relevant supplemental activities such as research and education, communication with hospitals and clinical staff with regard to best practice in transfusion medicine. The remit also included maintaining appropriate working arrangements with other blood services in the UK to ensure commonality in practices and procedures.

c. its aims and objectives;

41. See above

d. how it was funded;

42. The service was funded by an annual negotiated allocation from South Glamorgan Health Authority. Please see 6 (c) above.

e. how decisions were made;

43. New developments such as initiation of a plasmapheresis facility or increases in the supply of plasma for fraction would be subject to a funding bid detailing the required resources for staff and equipment. This was an ongoing activity as the demand for blood and components was constantly increasing.

44. Decisions were made on the basis of trend analysis of demand and the best way of meeting demand. Decisions about changes in practice with regard to microbiological testing, donor recruitment etc would arise as a result of decisions agreed at meetings of Transfusion Service Directors. These would have been informed by discussion with expert advisory bodies (e.g. committee on microbiological safety of blood reporting to the DoH).

f. to whom the WBTS was answerable.

45. The WBTS was answerable to the managing health authority (See Q7) but ultimately the Welsh Office Chief Medical Officer.

13. Please describe the WBTS' position within the NBTS, whether it was autonomous with regards to decision making and/or to whom it was accountable.

46. There was no formal accountability to the NBTS although it was understood that decisions taken by the NBTS represented agreed best practice and should be adhered to as far as possible.

47. Licensing by the Medicines Control Agency (MCA) would be contingent on following agreed best practice. Latterly best practice in all areas of blood service operations was codified in a National produced set of guidelines. Reports from the MCA inspection would be submitted to the managing health authority, in this way any deviations from national guidelines would be brought

to their attention. Significant deviations form agreed practice would have led to failure on the part of the Medicines Control Agency to issue a licence.

14. What was the relationship between the WBTS, the Welsh Office, the WHCSA, and the DoH?

48. Please see Q7 above. The DoH had a working relationship with officials in the Welsh Office and would have shared policy and objectives, this arrangement would complement my own communications with Welsh Office officials. The managing health authorities would for the main part not be active participants in these deliberations.

15. Please explain the WBTS' relationship with BPL during your tenure, including in relation to the procurement of blood and blood products.

49. I don't recall that there was initially any formal contractual arrangement for plasma provision to BPL. Regional centres operated on the basis of sending as much source plasma to BPL as local circumstances permitted. However, BPL would have been aware from historical patterns of supply what the likely contributions would be.

50. Latterly I believed the WRTC shared with BPL the expected level of source plasma supply. Orders for products (albumin, immunoglobulins, clotting factors etc) would be placed with BPL and supplied subject to availability.

16. Did the WRTC have any involvement with the Protein Fractionation Centre ("PFC") during your tenure? If so, please give details.

51. No

Section 3: Blood collection at the WRTC

17. Please explain the system for blood collection at the WRTC during your employment there. Did this system change over time? If so, please

provide details. You may find NHBT0006284 (point 6) and CVHB0000002_056 of assistance.

52. The system of blood collection was essentially as described in NHBT0006284. The donor management department would plan a schedule of blood donor sessions in various public buildings, factories and offices. This department would maintain a panel of donors the records of which were computerised and held all information of concern. This department would also call up donors to their traditional donation session and arrange publicity to attract new donors. There may be information, if appropriate sent to donors at call up, or donors would be presented with information on attendance at the sessions providing guidance regarding fitness to donate. Prior to donation, there would be an interview to confirm understanding and compliance. The system did not greatly change over time apart from:

53. (a)The introduction of plasmapheresis to provide plasma as the amount that could be obtained from routine whole blood collection (where targets were largely set by the demand from medical and surgical needs for blood) would not be sufficient.

54. (b)The replacement of doctors managing the donation sessions and performing the actual blood collection venipuncture by trained non-medical staff. State Registered Nurses managed the donation session and medical staff were always available at the headquarters to deal with enquiries.

55. (c) Initially most donation sessions were held in fixed premises, factories, offices or public buildings. These sessions were later supplemented by mobile blood collection sessions taking place entirely within large purpose-built vehicles.

56. (d) A significant safety step was enabled in about 1990 when the system of plasma collection which required opening the blood pack to extract plasma was replaced by a “closed” process. This was enabled by the purchase of

blood collection packs which included integral connected satellite packs. After centrifugation of the whole blood donation layers above the red cells, platelets and plasma could be decanted aseptically into the satellite packs.

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

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

57. Traditionally a doctor would manage a team of about 8-10 trained blood collection assistants, one of whom would be a team leader. Donor acceptance would be on the basis of written guidance based on NBTS advice. Prospective donors would read guidance literature and answer questions to ascertain their understanding and compliance. Doctors would make decisions should suitability questions arise. Doctors would also perform the donation venipuncture and ensure donor health and wellbeing throughout.

b. Were the staff involved medically trained?

58. This system was replaced and state registered nurses took on the doctors' role, questions regarding suitability were referred by the headquarters medical staff. I am not sure of the exact date of this change.

c. Where did these sessions take place?

59. See Q17

d. How frequently could a person donate blood? You may find DHSC0002203_019 (point 1) and NHBT0000191_144 (point 7.6) of assistance.

60. Once every six months

e. How were blood donors recruited? (you may find SCGV0000053_013 (point 9.1) of assistance)

61. Recruitment was by all methods possible including: radio and TV appeals, press appeals, local publicity, volunteer recruitment workers and workplace recruitment

f. Did any of these matters alter during your tenure? If so, how? You may also find NHBT0002331_001 of assistance.

62. I believe that a purpose-built blood mobile collection unit was introduced in approximately 1984 and a Cardiff city centre donation suite and plasmapheresis unit was opened also in about 1984.

19. Did the WRTC have donation collection targets that it was required to meet during your tenure? If so, how were these set? Did the WRTC meet these donation targets? If not, why not? What were the consequences of not meeting the targets? You may find BPLL0000918 of assistance.

63. Overall Blood collection targets were set to meet anticipated demand from hospitals for red cell donations, platelets etc. For the most part these were amply met save for occasional temporary shortages. Where the demand for source plasma exceeded what could be recovered from conventional donations plasmapheresis targets were set. The Welsh service generally performed well in terms of interregional comparisons.

64. Once the principle of pro rata return of finished products was established there was an incentive for the WRTC to supply as much plasma as it could. However, as developments in haemophilia care advanced so did targets for fresh plasma collection. The consequences of a shortfall of source plasma supplied to BPL would be a corresponding shortfall in amount of Factor VIII received. Overall however I believe there was insufficient processing capacity

at BPL to enable national self-sufficiency and the deficit was made good through commercial purchases.

20. What measures, if any, were taken to improve blood collection at the WRTC during your tenure? Do you think these measures were sufficient in light of the donation targets? Please provide details, including information regarding barriers to improving blood collection (if applicable).

65. Donor recruitment and its attendant publicity was an ongoing activity (see 18/ e) the intensity of which was stepped up during shortages. Blood is a labile material with a relatively short shelf life and stocks held in transfusion centres and hospital blood banks are small in relation to demand and turnover. A close to "just in time" stocking system operated to minimise wastage. Under this arrangement, relatively small fluctuations in demand or collection success can quickly diminish stocks and create shortages. Even under these "shortages" the actual quantities supplied to hospital do not drop dramatically. However, under these circumstances a proportion of patient needs (usually elective surgery) cannot be met at the time required.

21. The Inquiry understands from the letter you wrote in September 1989 (NHBT0094250_004) that there was a shortage of blood in Cardiff. What were the reasons for this? How frequently did this occur during your tenure? What steps were taken to ameliorate this? How regularly did RTCs ask each other for assistance in fixing shortfalls?

66. At the time this letter was written, it was presumed the waiting list initiatives may have precipitated the blood supply shortage. For the most part the reasons were not readily apparent. However, from my explanation given above (Q20) it can be seen that there is a trade-off between over collection, overstocking and consequential blood wastage and the risk of blood shortages. Part of this debate also involves consideration of prudent e.g. non-wasteful clinical usage practices.

67. Severe shortages were not a usual phenomenon, I cannot recall details but I would say that only a few times each year at most would help be sought from other blood services.

22. What steps, if any, did the WRTC take to publicise itself to potential donor populations in order to increase donations? How successful were these steps? You may find DHSC0200019_002 (pages 2-3, paragraph b) of assistance.

68. The measures outlined in response 18/e were ramped up. Generally, the public were very responsive and collection levels increased.

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

a. When did this practice cease? You may find NHBT0113565 of assistance.

69. I believe the practice of collecting donations from prisoners ceased in Wales early in 1985 in line with policy throughout the NBTS. Prior to that, offering prisoners the chance to donate was seen as a social benefit in the rehabilitation of inmates. I do not have information about the number of prison sessions that were held although I believe they would be held at the same frequency as other public donations and that the proportion of prisoners who gave blood was consistent with that in the general population, i.e. slightly less than 1%.

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

70. My role in this activity was the same as for the donation process in general.

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

71. There would have been no cost difference between prison and routine donations.

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

72. There would have been no inducements to donate.

e. What information, if any, was presented to prison donors before they gave blood?

73. Prisoners were provided with the same pre-donation information as the general public.

f. Were hepatitis and HIV considered risks in this specific population? If so, how were these risks managed?

74. At the time prison donations were accepted it was believed that, properly screened, they presented no increased microbiological risk. When appreciation of this risk emerged the practice of prisoner donation ceased. Prison donations therefore ceased shortly after recognition of HIV in the UK when it became inadvisable to collect blood donations from prisoners.

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

Production of fresh frozen plasma

24. The Inquiry understands that the WRTC procured plasma from blood donor sessions to produce fresh frozen plasma ("FFP") for BPL (CBLA0012435). Please describe:

a. where the production of FFP took place;

75. FFP production took place in the laboratory of the WRBTS.

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

76. (See Q17/d). As part of the general evolution of clinical transfusion practice almost all donations were centrifuged to enable fresh plasma removal. This was enabled by the introduction of multipart plastic bag collection systems which enabled this to be done aseptically. Over the space of a few years red cell donations supplied to hospitals changed from unmodified whole blood to being mostly either red cell concentrates or red cell concentrates suspended in a special storage nutrient solution (optimal additive solution, OAS). The salvaged plasma provided the greater part of the supply to BPL.

77. Plasma collection was later enhanced by the establishment of plasmapheresis in dedicated clinics where the principal objective was fresh plasma collection.

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

78. The exact dates are uncertain but I believe this conversion to use of plasma depleted red cells took place around 1984.

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

79. Having converted to almost entirely red cell concentrate or OAS red cells provision to hospitals the supply of plasma from this source was largely dictated by clinical demands for red cells.

80. Flexibility to produce extra FFP was enabled via the plasmapheresis functions so that the total amount of FFP could be produced according to the processing capacity at the BPL. I think WRBTS largely met expected requirements from BPL. The rate of scaling up would be determined by what would be understood to be the agreed national targets for plasma collection which in turn would be decided by BPL capacity.

25. As far as you are aware, how was plasma procurement at the WRTC funded throughout the 1980s? You may find BPLL0000918 (page 2, paragraph 1) of assistance.

81. Resources for FFP to BPL - Plasma derived from whole blood collection was in essence a by-product of the overall blood collection process apart from the extra cost of utilising the expensive blood collection packs and laboratory processing staff and equipment.

82. This was built into the budget and increased as the resourcing for general blood collection was negotiated. Plasmapheresis would be a separate cost centre. Increase of all the resources associated with these activities would be obtained by bids submitted to the managing health authority who I believe in turn negotiated with the Welsh Office.

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

83. FFP was supplied to hospitals on demand, very little if any during my tenure was utilised for haemophilia care. FFP had largely been superseded by cryoprecipitate. Most FFP was destined for fractionation rather than clinical use. Whenever appropriate cryo supernatant plasma (a by-product of cryoprecipitate production) was offered to hospitals in place of FFP, since the clinical need would not be for FVIII replacement.

Plasma targets

27. Did the WRTC have targets for the amount of plasma that had to be collected by the centre? If so, who set these targets and what were they? If there were no targets, why was this? What was the purpose of the targets? You may find DHSC0000400 and NHBT0003378 of assistance.

84. Annual plasma collection targets were established based on the consideration of BPL requirements and WRTC capacity to produce plasma. My recollection is that the WRTC for the most part met agreed targets, in fact figures showed that on a population basis the Welsh service was consistently at the top end of the league table for regional centres plasma supply. However, the capacity to expand was limited to a very large extent by the fact that the WRTC was housed in an antiquated cramped building.

85. Relocation to a modern purpose-built facility had been highlighted as a pressing need for many years but despite energetic attempts to argue the case the blood service was only moved to new premises in 1997. This was approximately twenty years after the need had first been identified.

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

86. The need to meet plasma and blood collection targets was central to all decision making at WRTC. Bids for expansion of staff and equipment resources and the need for new premises were a constant theme.

29. Were there consequences for the WRTC if the targets were not met? If so, please provide details

87. The return of finished blood products (FVIII principally) was on a pro rata basis. The more plasma supplied, the more clotting factor was returned with a consequentially lesser need for imported products.

30. Were there any benefits to the WRTC if the targets were exceeded? If so, please provide details.

88. After 1990, cross charging was introduced and WRTC obtained income from plasma supplied to BPL and paid BPL for finished products returned.

31. What obstacles, if any, did the WRTC face in their ability to meet those targets? You may find BMAL0000023, DHSC0000798, and NHBT0003378 of assistance.

89. The WRTC had to press its case for resourcing the above mentioned activities to the managing Health Authority. These bids would be in competition with all other funding issues faced by the Health Authority. In my opinion, a more appropriate solution would be for the service to have been funded directly from central sources where the significance of the issues at stake might have been better appreciated.

32. During a meeting of the Western Division of NBTS Consultants in January 1984, item 7 noted that reduced Factor VIII production at BPL would result in regions receiving less Factor VIII for the plasma they supplied. It was further stated: "It was felt that a reduced return of Factor VIII during 1984/85 would not help RTDs with their negotiations with health authorities for more money to produce FFP during 1984/85" (NHBT0092854). Please explain:

a. Did reduced Factor VIII production at BPL affect the ability of the WRTC to obtain funding for plasma procurement?

90. Whilst the reduction of returned products (for understandable manufacturing reasons) was undesirable I don't think that it had any direct effect on South Glamorgan HA decisions about funding. If the reduction had been more significant there may well have been questions as to whether Health Authorities were getting value for money but I am not aware that this situation ever arose.

b. Was this an isolated incident or do you recall this occurring on other occasions? (See NHBT0113569 at item 7 for example). If yes, please provide further details

91. I think that the reduction in the proportion of finished product that could be returned probably reflected increasing manufacturing standards and safety precautions. In that sense, the reduction would not be a temporary phenomenon.

c. To what extent, if any, did the WRTC's perception of BPL's production capacity inform decisions about the quantity of plasma that would be supplied for fractionation?

92. The only insight into BPLs production capacity was gained through the dialogue during which BPL targets and the WRTC's capacity to respond was discussed. My perception was that whilst BPL was expanding its capacity to meet self-sufficiency, advances in haemophilia care were outstripping the plasma sourcing and processing. An additional problem would be that QC demands and the potency loss due to safety enhancement such as heat treatment reduced the amount of finished product yields.

33. In 1989, cross-charging was introduced in England and Wales to act as an incentive for RTCs to increase the amount of plasma being sent to BPL (see NHBT0057426_002). Please provide context or additional information regarding:

a. what the advantages and disadvantages of cross-charging were;

93. In theory cross charging should have provided an automatic mechanism whereby, provided that the end user had the capacity to pay, the finance and the mechanisms to deliver a service could be resourced according to need.

94. Since the costs of blood and blood products were to be met by users there would in theory be a powerful stimulus towards economy and reduced wastage. In practice the costing process, as practiced by different health organisations was often inconsistent, and led to considerable tensions during negotiations between providers and end users.

95. Purchasers would always be pressing providers to reduce costs to greater extents than could be achieved. Additionally, it was never possible for purchaser's users to limit themselves to their budgeted uptake of blood since urgent needs always had to be met.

96. The process for costing itself imposed a considerable cost burden on producers such that the prices of blood service significantly increased. I believe that the objectives of greater economy in blood usage were achieved to a much greater extent later as a result of professionally led good practice initiatives.

b. how cross-charging worked, including how prices for plasma and NHS blood products were determined;

97. Financial expertise was drafted into the service to help with costing. It was clear from the outset that costing and charging was to cover operating costs alone and no element of profit would be allowed. A major difficulty, and one which would have a significant effect on unit costs, was the decision about apportionment of overheads and whether any circumstances would justify charging on a marginal cost basis. Essentially product costs would have to take account of direct labour, materials, use of equipment and service overheads etc.

98. The WRBTS also provided specialist diagnostic services which are low volume high cost activities which also had to be resourced under the new arrangements. An unfortunate (although to some opinions a desirable)

consequence was that costing and charging brought a competitive element into what previously had been efficient harmonious cooperative arrangements between transfusion service providers and hospital users.

99. Another problem that required careful PR management was the need to reassure volunteer donors that their freely given donations were not being used in a seemingly profiteering system.

c. what impact cross-charging had on the WRTC increasing its plasma supply to BPL;

100. At the time cross-changing was introduced there would have been progressive increases in all volumes of activity and I am not able to say whether its introduction had a significant and beneficial effect.

d. what impact cross-charging had on the supply of NHS blood products to Wales by BPL; and

101. See (c) above.

e. what impact cross-charging had on the quantity of commercial blood products purchased in Wales.
You may find NHBT0091141_003, NHBT0091141_004, NHBT0091141_005 and NHBT0000189_066 of assistance.

102. Before cross charging was introduced by the WRTC, commercial blood products were purchased by hospitals direct from manufacturers. The change to supply from the WRTC would not have affected usage.

34. As far as you are aware, what effect (if any) did cross-charging have on the plasma supply in England and Wales?

103. I am not aware of a significant effect

35. As far as you are aware, what effect (if any) did cross-charging have on the production of plasma via plasmapheresis?

104. I do not recall that this altered the activity of plasmapheresis which was determined by the limited accommodation which could be made available.

Plasmapheresis

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

a. whether manual or machine plasmapheresis was preferred;

105. The WRTC did implement a programme of machine plasmapheresis. I do not recall whether any manual procedures were ever undertaken. From my recollection manual procedures are lengthy and cumbersome and most importantly require a whole blood donation to be taken and the red cell concentrate to be later returned to the donor after plasma removal in the laboratory. This is a major safety issue. I don't think manual procedures could have been a serious consideration for the volume of FFP required.

b. the relative cost differences between each method;

106. I can give no figures for this but they will have been well known at the time.

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

107. The WRTC did institute plasmapheresis collection. A dedicated team of medical staff and nurses was set up and automated machines purchased. The capacity limitation (see Q27) prevented expansion of the collection activity to anything like the figures proposed in CBLA0001287. This would have required a donor panel of 3000-5000.

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

108. Plasmapheresis undoubtedly increased plasma supply.

37. Please set out the extent of the plasmapheresis programme at the WRTC during your tenure. As far as you are aware, did this programme differ from other RTCs? If so, in what way and why?

109. I do not know what the situation was in other services although it is likely I had this information at the time.

38. In 1982, at a Western Division Consultants meeting, it was stated that plasma targets may not be met "as RHAs had no money available to expand plasmapheresis" (NHBT0105384). What was your experience with obtaining funding for plasmapheresis?

110. WRTC did obtain funds to establish plasmapheresis.

Use of plasma reduced blood and red cell concentrates

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

111. I was in regular contact with consultant haematologists and attended events at hospitals where this change in practice was explained. A considerable amount of education and persuasion was necessary. Although it was not uniformly welcomed, within a short space of time provision of RBC concentrates or red cells in optimal additive solution amounted to the vast majority of output. From the figures I have seen, it seems that over a five-year period (1979-1985) the proportion of red cell concentrates or red cells in optimal additive solution issued increased from about 25% to almost 90%.

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

40. Please describe the arrangements in place in Wales for the purchase and holding of, and the allocation to haemophilia centres within the region, of (a) NHS factor concentrates and/or other blood products ("NHS blood products") (b) imported factor concentrates and/or other blood products ("imported blood products"). In particular:

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

112. The WRTC performed a warehousing function for the supply of clotting factor concentrates within the region. Haemophilia centres were at Cardiff (the major centre) and Swansea but patients would receive treatment under the care of Haematologists throughout the region. All of these were in close liaison with Professor Bloom and either he or his team generally advised regarding choice of product [WITN6915002]. My recollection was that these products were ordered on the basis of need following figures supplied by Prof Bloom.

b. Please outline the respective responsibilities of the WRTC, BPL, the South Glamorgan Health Authority, and haemophilia centre directors, and how these responsibilities changed over time.
You may find NHBT0000189_066 (point 3) of assistance.

113. Since hospitals using products reimbursed the costs to WRTC the effect on the WRTC budget was neutral. After the inception of this system, at which time it was necessary for the Welsh Office to negotiate with BPL regarding transition costs, the scheme ran without need for much intervention from the WO or South Glamorgan Health Authority. It would have been up to hospitals to seek funds to provide local haemophilia care. I don't recall that these arrangements altered significantly over time. I am not now able to gives dates and quantities of supply.

114. It would be up to clinicians and the haemophilia centres to negotiate for funds (from health authorities) to purchase the products they required

41. Please explain whether any forums were established between the WRTC, BPL, the South Glamorgan Health Authority, and haemophilia centre directors to discuss and facilitate these arrangements. Were meetings held regularly? Were they minuted? If so, by whom? What was discussed at these meetings?

115. If there were any I don't recall that I was involved.

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

116. I never had any precise information as to how these arrangements operated in other regions.

43. Did you, or anyone else at the WRTC, contract directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of imported blood products? If so, please describe:

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

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

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

117. I do not think WRTC ever had any direct negotiation with commercial companies supplying clotting factors. The WRTC may have negotiated contracts for supplies of albumin, a plasma expander product but I don't have any recollection of these details.

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

118. The WRTC was never involved in these decisions.

45. If haemophilia centre directors were responsible for these decisions, did the WRTC have any influence over their product choices? You may find the correspondence in CBLA0000627 (page 2, paragraph 2) of assistance.

119. I don't recall that the WRTC had any influence on the prescription of clotting factor materials. This was not an area where WRTC medical staff had more expertise than the consultant haematologists and it was these who had responsibility for individual patient care.

120. There was a shared understanding of the role of cryoprecipitate and its unsuitability (until the [advent] of HIV) as the major component of haemophilia care. We did agree it would continue to have a role in certain categories of patients and efforts were made to minimise the inherent limitations of the product.

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

121. I have never doubted that the UK should be fully self-sufficient as far as blood products are concerned for the simple reason that voluntary UK donors carry a significantly lower risk of transmitting infection. I believe there were times that certain commercial FVIII products could be claimed to have superior clinical efficacy to their UK counterpart.

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

122. I can only surmise that for the most part clinical prescribing freedom would have favoured the UK NHS product. However, I don't have direct knowledge of this.

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

123. I think Professor Bloom was thoroughly conversant with the merits of all available FVIII products and I suspect that any commercial promotion would have had limited impact. Consultants in Wales would have discussed these

matters with him. Regarding advice on use of products, there may well be some aspects related to usage they (commercial companies) advised on but I was not involved.

Section 6: Production of cryoprecipitate at the WRTC

49. The Inquiry understands that the WRTC produced cryoprecipitate. Please describe:

a. where the production of cryoprecipitate took place;

124. Cryoprecipitate was produced from whole blood donations and the process took place in the Transfusion Centre blood component laboratories.

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

125. Blood was collected into plastic packs with two integral empty satellite pouches. This was centrifuged following which the supernatant plasma was decanted into one of the pouches. Both satellite packs were then detached from the residual red cell pack and frozen rapidly, after this step the plasma pack was allowed to slowly thaw. After some hours a still undissolved residue was present which was the FVIII rich cryoprecipitate.

126. After centrifugation the fully thawed protein of the pack was then decanted into the third satellite. The cryoprecipitate was then rapidly frozen and stored. The storage life was limited I believe to about six months. A single donation thus provided a red cell concentrate donation, a small volume (10-20ml) of cryoprecipitate and a pack of cryo supernatant plasma.

127. A proportion of cryoprecipitate packs were sacrificed to allow FVIII assay as part of routine quality control. Cryoprecipitate was produced to meet demand

although fluctuations in demand sometimes may have led to issue restrictions. The major limitation to production was that it was a very labour-intensive process. From time to time this was the subject of resource bids.

128. I cannot give precise figures for cryoprecipitate production but from the information I have been able to gather, cryoprecipitate appeared to be at a peak level (about 17000 units in 1980) but reducing (7400 in 1985) as Factor VIII concentrate became more readily available. By 1986 production had increased again to about 12600 units pa. [WITN6915003].

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

129. Cryoprecipitate product for more immediate local needs probably took some priority on a day to day basis but the bulk of plasma would have been destined for BPL. I do not recall any specific changes to this general practice over time nor how it fluctuated in practice. From what I recall we would use whatever was needed locally and the rest was sent to BPL.

d. how much funding was provided by the South Glamorgan Health Authority for the production of cryoprecipitate; and

130. I don't think funding was ring fenced for cryo precipitate alone. Resource bids would have been submitted to support general expansion of component laboratory staffing. These would principally include FFP for BPL, cryo precipitate and platelet concentrates manufacture.

e. how quickly the WRTC could have increased its manufacture of cryoprecipitate, had it wished to, during the early 1980s.
You may find NHBT0001573_007 of assistance.

131. I don't think this challenge was ever tested as it had been for some time assumed that FVIII concentrate would be the preferred product. The position changed in the early 1980s when the risks (HIV in particular) of imported FVIII were recognised and NHS FVIII was of restricted availability. My recollection is the WRTC was for the most part able to meet Cryoprecipitate demand.

50. At the Regional Transfusion Directors' meeting on 6 July 1977, Dr Jenkins requested: "a policy which distinguished between those patients who required freeze dried concentrate and those for whom cryoprecipitate was suitable" (DHSC0200019_002 at page 4).

a. To your knowledge, was such a policy ever implemented?

132. I cannot speak with authority on clinical usage of clotting factors since this was largely the preserve of haematologists with a special interest. In WRTC I believe we took our cue from the haemophilia centre pattern of usage. It was a shared understanding of the categories of patients who would most beneficially be treated with Cryoprecipitate.

133. I think there was a clinical treatment policy that WRTC accepted in principle and provided materials on demand. It was possible to base production planning on historical patterns of usage.

b. In your view, what factors were relevant in determining whether cryoprecipitate was suitable for some patients? For which patients was cryoprecipitate suitable?

134. Practice with regard to cryoprecipitate use changed over time. The earliest attempts to make good the deficit in patients FVIII and to arrest bleeding utilised large infusions of FFP. Although partially successful the volumes of plasma needed were more than could be tolerated. A great advance was the discovery of cryoprecipitate as a rich source of FVIII although the practicalities

of its administration, the frequencies of reactions and the difficulty of not losing FVIIII in the administration procedure were limited.

135. In the early years of haemophilia treatment cryoprecipitate was used for most haemophilia patients only being superseded when FVIII concentrate became available. FVIII for the first time offered the prospect of near normal lifestyles for patients with haemophilia and their effect was transformative. After that time cryoprecipitate was generally used for treatment of smaller bleeds in less severely affected patients. This policy had to be urgently reviewed when the scale of the problem of commercial FVIII contamination became apparent. Cryoprecipitate became a treatment option (together with NHS FVIII for those previously untreated (hence not already exposed to risky products).

136. A significant argument in favour of cryoprecipitate in this scenario was that the pool of donors contributing to each treatment episode was much smaller that it would be for any form of concentrate although for any given patient, the number of donor exposures even with UK donors meant that NANB infection would be likely. This would have a greater bearing on HIV transmission (which was exceptionally rare in the UK) than it would for HCV/NANB.

51. In a letter dated 14 July 1977 to Dr Maycock, you stated, in reference to cryoprecipitate, that you were surprised that "we are exercising our minds towards the improvement of a product which is destined for obsolescence" (CBLA0000627). Please explain your views. Did your opinion regarding cryoprecipitate change? If so, why? If not, why not?

137. My thoughts at the time could hardly have anticipated the appearance of HIV in the early 1980s. I understood that the advantages of concentrates, which were enormously welcomed by patients, would suggest that maximum efforts should be directed to diverting plasma for concentrate production.

138. The more cryoprecipitate used the less FFP would be available for BPL. The issues I raised in the letter referred to, illuminate the fact the cryoprecipitate had a number of very serious limitations. The product quality was variable and hard to standardise. Dosage was imprecise, adverse clinical reactions sometimes occurred, the amount of FVIII that could be administered was limited by the fluid volume that patients could accept. Both the laboratory preparation and bedside administration were cumbersome.

139. This latter point being particularly relevant where administering staff were not experienced. Furthermore, unless great care was taken significant amounts of the product could be wasted if packs were not rinsed out thoroughly. Despite these limitations cryoprecipitate did have a role in haemophilia care (see Q50/b above). Cryoprecipitate was usually stocked in District General Hospitals for other clinical purposes. If a haemophiliac patient was admitted with an emergency bleed cryoprecipitate might be the only product which was instantly available. In contrast concentrates were of a consistent standard, and had the advantages of enabling higher and more precise doses than could be obtained with cryo. The product was stable and could be stored more easily. Administration to patients was a simpler procedure.

140. Efforts were made to address the quality concerns associated with cryoprecipitate and in the early days of realising the HIV risk of commercial products the practice using cryo precipitate had to be re-energised. My views regarding the undesirability of cryoprecipitate did not change but had to be reconciled with the fact that, with the infected concentrate crisis, cryoprecipitate would be the better option. Once the risk of HIV became apparent, safety was the paramount concern and clinicians would have had to resort to therapeutically less advanced product.

52. Please explain what consideration the WRTC gave to increasing the production and use of cryoprecipitate in response to the growing

awareness of the risks associated with Factor VIII concentrate products in the 1980s.

141. I am sure WRTC did what was required but I don't have the figures. Please see response to Q 49(b)

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

142. The WRTC would have responded to meet demand from haemophilia clinicians. I don't recall discussions about projected needs as I suspect these might have been difficult to plan.

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

143. Products were supplied on demand subject to availability. I think failure to supply would be a rare occurrence if it ever happened. Supply requests would come at the instigation of medical staff trained in haemophilia care. Rarely cryoprecipitate was used for blood coagulation problems other that haemophilia.

Section 7: Self-sufficiency

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

144. I always believed, along with most, if not all, of my professional colleagues, that self-sufficiency should be an absolute priority. This belief was strongly reinforced as other infective risks (particularly HIV) from transfusion became

apparent. Most imported blood products were from the USA. It was understood that paid donors selected for the manufacture of FVIII concentrates in the USA could be from an inherently riskier section of the population.

56. In your experience at the WRTC, to what extent was 'self-sufficiency' a concept that informed the following:
You may find DHSC0000795 and BMAL0000023 of assistance.

a. plasma procurement;

145. Plasma procurement was entirely driven by the attempted need to meet national demands for blood products.

b. decisions with regard to cryoprecipitate production;

146. Local needs for cryoprecipitate always had to be met but it was recognised that this would unavoidably detract from plasma supply to BPL.

c. purchases of commercial blood products;

147. Purchases of commercial products were for the most part only necessary because of the shortfall in home produced blood products. I cannot say for certainty whether at any time imported products were believed by clinicians to have any therapeutic advantages.

d. the funding of the WRTC.

148. Funding was a constant issue at this time. There was always competition for funding within South Glamorgan Area Health Authority, who had all the other pressing immediate local issues to consider, and who would not instinctively prioritise what was in effect a national imperative. An additional major

constraint was the cramped and substandard accommodation of the WRTC for which capital investment in a new build was needed.

57. What was your view on the prospect of the UK achieving self-sufficiency? Did your view change at all during your tenure at the WRTC? If so, what factors or events affected this change in opinion? You may wish to refer to HSOC0004692.

149. Although self-sufficiency was an agreed ambition, I don't recall having a very clear idea of the "gap" that had to be surmounted and how close we might be to achieving this objective. This partly derived from the improvements in haemophilia care (prophylactic therapy, home care) and the problems of FVIII inhibitors over the years which meant that annual figures for national FVIII needs tended to increase. Also differences in manufacturing methodology could mean that FVIII production yield could change and hence influence the volume of source plasma required. One of the justifications for WRTC warehousing commercial products was to provide usage information and thus show whether progress was being made in the pursuit of self-sufficiency.

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

150. Yes, as far as I am aware.

59. It is understood by the Inquiry that in 1983, under your recommendation, a system was established whereby an RTC with excess red blood cells could supply them to other RTCs with deficient supplies of red blood cells. The central liaison for this system was to be the WRTC. Please explain:

Please see NHBT0092855_004 (at point 8) and CBLA0001742 (at point 8) for further context.

a. Whether RTCs were receptive to the new system and why or why not;

151. I think the system was generally welcomed.

b. Whether this system led to a decline in the use of whole blood;

152. The arrangement would not influence the use of whole blood which was a declining commodity.

c. How the excess red cells system contributed towards self-sufficiency.

153. This excess red cell sharing system had no bearing on self-sufficiency.

Section 8: Services for donors at the WRTC

60. How effective was the system described at page 2 of HSSG0010054_008 in identifying donors who may be infected with HIV, HBV and/or HCV? What more could or should have been done?

154. HSSG0010054 refers only to HIV. I cannot comment on how efficient this process was. It would be a great challenge to ensure that every medical practitioner would be aware and be able to act as required. It may have helped that at that time HIV infection was extremely rare and hence noteworthy.

155. The belt and braces system of medical staff notifying both CDSC and the WRTC and CDSC also notifying the WRTC was perhaps as robust as it could have been. It is unlikely that all medical staff attempting to report HIV/ Kaposi's cases would themselves have ready access to WRTC contact.

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

156. Information was provided to donors prior to donation that their blood would be tested for HIV and hepatitis. They would have already been informed through advice provided at call up or at sessions to forewarn them about aspects of their medical history or sexual activity which precluded donation. Because of this, donors were regarded as a low risk population with the expectation that HIV positivity would be a very rare occurrence, formal counselling as might otherwise take place prior to HIV testing was not appropriate.

62. What counselling and psychological services were available for donors who tested positive for hepatitis or HIV? Were such services delivered by the WRTC or were referrals to other agencies made? Please describe the process. You may find NHBT0009740_001 (at point 2.8), NHBT0000077_085 and NHBT0005392 of assistance in answering this question.

157. Personal counselling visits by a medical officer would be made to HBV infected donors and also to those (exceptionally rare) who were found to be HIV positive. HIV positive donors would be put in contact with a specialised referral consultant. A letter was also sent to donors and General Practitioners for HBV infections. I believe subsequent medical and psychosocial support would be organised by the General Practitioner.

63. What was the process (if any) for informing recipients of infected donations that they may be infected?

158. The practice of informing recipients evolved over time. Initially patients who were recognised as having received HBV infected donations would be contacted by the hospital in which they had received care and their General Practitioner notified. Later, a hepatitis lookback programme was instituted in which a specially appointed doctor was assigned to investigate hospital records and identify patients who had received blood from infectious donors.

These patients were then contacted counselled and tested for evidence of transmission.

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

159. See above.

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

160. Unfortunately, hospital records were sometimes missing or incomplete and some recipients could not be contacted because their own contact details had changed. In terms of the counselling it was carried out by trained people with whom we did not have close contact. I cannot therefore confirm whether or not it was sufficient. At least in terms of HIV infection it was something that was rarely, if ever, used because of the low rates of infected donations in Wales. I may be mistaken but my recollection is that there was never a case of HIV being transmitted by blood transfusion in Wales.

Section 9: Meetings of various committees

Meetings of Regional Transfusion Centre Directors

66. The Inquiry holds meeting minutes between the Directors of RTCs in the United Kingdom from approximately 1948 to 1989, some of which you attended in your capacity as Director of the WRTC. Who established these meetings? What do you consider to have been the purpose(s) of those meetings?

161. I do not know the history of the establishment of RTC directors meetings.

162. As far as I understood it the purpose of the meetings was to discuss and come to agreement about almost all the important aspects of RTC activity. A member of the Department of Health was usually present to enable two-way exchange of information, I believe the chairman sometimes acted an advisor on transfusion matters to the Chief Medical Officer.

163. Expert advisory groups such as that on microbiological safety of blood would, when necessary, attend. The directors of BPL and the `Blood Group reference laboratory' would also be members.

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

164. Although collective decisions were usually reached regarding the desirability of various courses of action there was no absolute imperative to carry out or implement decisions, this was not a management structure and there were no funds. Many decisions needed support from funding authorities. In such instances the RTCs collective decisions were the most authoritative arguments to be deployed in local negotiations with Health Authorities. In other instances, particularly with regard to medical practice, the collective decision of RTCs would be seen in a medico legal sense as best practice. Many decisions concerned working arrangements within regional centres which did not have significant resource implications. In the case of WRTC, these would be discussed within management team meetings and actioned if appropriate.

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

165. Whilst there were obvious shortcomings in the system as referred to above I believe the meetings provided an extremely important role in enabling coordination and development of the blood transfusion services throughout the UK.

69. The Inquiry understands that you attended the final meeting between the Directors of RTCs in January 1989 (NHBT0018188). What was your understanding of why the meetings were abolished?

166. I really cannot now recall this with any clarity. I personally had felt that this committee had the potential to be influential but the proposal to have regional divisional meetings (which involved all BTS consultants) and reporting to a National directorate may be more effective. The basic problem was that the RTD committee was only ever advisory. Health Authorities held the funds. There was no robust system of communication between the professional advisory system (RTD committee) and the funding bodies.

70. From your perspective, was there a reason why the advantages and disadvantages of dissolving the RTC meetings were not discussed, as indicated in a separate note of the final RTC meeting? (SBTS0000628_011).

167. See Q69 Above.

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

168. I think the divisional meetings might have replaced them but I cannot recall for certainty. I can't recall how this affected the operation of WRTC.

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

169. See Q71 above.

Western Division of NBTS Consultants

73. The Inquiry understands that you attended meetings of the Western Division of NBTS Consultants between 1982 and 1992. The minutes of the meetings you attended have been provided for your assistance. As you are able, please describe:

a. the remit and composition of this group;

170. All the medical consultants within the transfusion centre participated. I think the remit was to draw upon all the opinions and expertise of RTCs so as to better inform the deliberations of the RDTs committee. In turn the mechanisms of implementing RTD committee directions could be discussed.

b. the frequency of these meetings; and

171. Meetings were approximately quarterly.

c. the relationship between these meetings and those of the RTC Directors.

172. See (a) above.

Advisory Committee on the NBTS

74. The Inquiry understands you were a member of the Advisory Committee on the NBTS. Please explain the remit and composition of this group and outline its primary objectives.

You may find CBLA0002277, PRSE0000128, and BPLL0007202 of assistance.

173. The meeting comprised chairs of the various divisional transfusion committees and the SNBTS director, Representatives of RHA's & the Welsh office. Director of BPL, the consultant advisor to DoH, the CMO or representative and the DHSS secretariat. I think its principal remit was to address the major issues facing the collective transfusion services; these included blood safety, plasma self-sufficiency, professional and technical standards, improved financial and management arrangements Professional and technical staffing.

75. As far as you are able, please describe:

a. When did the meetings end?

b. Why were the meetings discontinued?

c. Were the meetings replaced with another forum?

174. I don't have recollection or information about this.

Red Book Executive Committee

76. The Inquiry understands you were a member of the Red Book Executive Committee. Please explain the remit and composition of this group and outline its primary objectives.

You may find JPAC0000154_280 and JPAC0000154_251 of assistance.

175. The Red Book set out the operational principle and standards governing all aspects of transfusion service activities. It served as a basis for the formulation of detailed Standard Operating Procedures within centres. As such it served as a reference point for Medicines Control Agency inspection of Transfusion Services. These Red Book guidelines took account of European Directives so as to ensure UK practice was not at variance.

176. The Red Book Executive Committee comprised medical consultants and senior scientific staff of the UK Transfusion Services who oversaw the work of subcommittees, drawn from various specialisations of the transfusion services, allotted to draft various sections of the Red Book. The final drafts were circulated within the Service for comments.

Section 10: Information handling by and information sharing between RTCs

77. Please describe the record keeping system in place for blood donations and blood donors during your tenure at the WRTC. In particular, please explain what records were kept, in what form, where and who had access to them.
You may find NHBT0002331_001 of assistance.

177. A computerised system of record keeping was established and the intention was for these records to be kept indefinitely, there would have been no need for destruction. Access would be to authorised staff only.

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

178. See Q77.

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

179. See Q77.

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

180. There would have been general similarities but I cannot comment further.

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

181. This aspect would have been the subject of external audit and was found to be secure.

82. 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: You may find NHBT0113565 of assistance.

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

182. I was aware of this database but cannot recall the dates.

b. Who proposed the creation of the database?

183. Not known.

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

184. I believe so.

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

185. I believe so. It would only be of value if all Regional Centres contributed.

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

186. The WRTC maintained records of HIV positive donors as part of the overall record keeping system.

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

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

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

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

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

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

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

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

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

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

187. The WRTC had a protocol for the management of donors involved in cases of post transfusion hepatitis (they were rejected from the donor panel) which

would be in line with UK practice. However, I have no recollection of the 'J' donor system and I cannot comment further.

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

188. I cannot now recall the arrangement with any certainty but I believe the UK NBTS had a central reporting system for such donors. I am however not sure about this.

85. In his statement in A and Others, Dr Gunson expressed the view that "there was no central organisation to ensure that...all RTCs operated in a uniform manner" (NHBT0000025_001; NHBT0000026_009). Do you agree? In your opinion, were the information sharing measures in place between RTCs adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations?

189. This statement was true although efforts were generally made to keep the RTCs in step despite, on occasion, widely differing views about the appropriate course of action.

190. From this distance in time and without access to all the contemporary documentation I cannot recall the practical details of information sharing in enough detail to comment with any certainty.

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

HIV/AIDS

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

191. I would have read and participated in discussions about the appearance of HIV/AIDS first as a disease of completely unknown cause, then as knowledge progressed, that it was a blood borne transmissible infection. At first most information we were getting was coming from America. Since this information was published in prominent medical journals, and would have discussed in professional meetings. I would have gained a growing awareness of the potential risks of blood and blood products as the evidence became conclusive.

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

192. See Q86.

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

193. Fortunately, the prevalence of HIV/AIDS in the donor population in Wales in this initial period was too low, in fact almost zero, to be able to draw any local conclusions.

Hepatitis

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

194. HBV had from the 1970s been a well understood cause of blood born hepatitis and procedures had been established for risky donor exclusion and progressively more sensitive blood screening tests followed the evolution of knowledge about what was initially known as non A non B hepatitis and then later identified as a viral transmissible illness to be known as HCV hepatitis. It was long recognised that other blood born viruses might transmit hepatitis.

195. Before reliable HCV assays were developed attempts to identify and exclude donors who might provide a risk proved exceptionally difficult and decisions applicable to donors in one part of the world could not be applied elsewhere. Knowledge about the NANB/HCV evolved over time but significantly increased when the morbidity following use of pooled donation blood products emerged.

196. Within the general transfused patient population, the very long incubation period and relatively low infection rate hampered recognition of the seriousness of post HCV transfusion hepatitis.

197. Perhaps not surprisingly the routine systems of notifying the WRTC of post transfusion hepatitis never disclosed NANB/HCV hepatitis since symptoms only appeared many years after the transfusion episode. Donor selection (the lifestyle exclusions, drug use etc) for HBV and syphilis screening were thought to be surrogate measures which would minimise HCV occurrence within the UK donor population.

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

198. See Q89.

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

199. The WRTC did not carry out specific research into post transfusion hepatitis but collaborated with any national investigations. The WRTC followed nationally agreed practices with regard to donor selection and post transfusion follow up.

200. Hospitals were requested to notify the service whenever a recipient patient showed evidence of post transfusion hepatitis and the service would seek confirmatory information. Procedures would then be put in place to re-examine the donor, identify all other recipients of blood from that donor, to recall for examination and destruction of any unused materials, notify BPL etc. It was generally possible to examine archive sample for evidence of infection.

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

201. I think I had a reasonable understanding of this and set out my knowledge in my own textbook of transfusion in which a chapter is devoted to transmissible infection (Handbook of Blood Transfusion Therapy Auth. JAF Napier).

202. I think that the extent of HCV infections in multi-transfused patients and the serious long term consequences was not something I had initially understood when NANB was a rather ill-defined concept.

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

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

203. I don't recall when I first became aware of this paper but I would have had some general understanding of figures of the incidence of NANB from other literature around the time.

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

204. I don't recall details but I believe my colleagues would have been broadly acquainted with some statistics of the risk of NANB hepatitis.

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

205. Other articles covering this NANB hepatitis would have been available in the scientific literature. It was thought that donor screening, surrogate testing and, by international comparison, the generally low prevalence in the UK population would mean that UK donors would have a low incidence.

General

95. How did your understanding of the seriousness of HCV and HIV/AIDS impact the donor selection policies and practices in place at the WRTC?

206. I would have been informed about this topic from publications in the medical literature, scientific meetings and regular meetings between professionals in the UK transfusion services referred to earlier (section 9 above). As knowledge advanced so did refinement of donor selection policies. These were constantly revised in the light of any new information regarding risky donor categories.

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

207. The WRTC implemented nationally agreed policies and procedures which were conveyed to the internal management team.

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

208. The WRTC issued annual reports summarising statistics for local transfusion transmitted infections. Medical staff from the service gave lectures at hospitals

concerning blood usage and attended meetings of hospital transfusion committees when these took place.

209. A booklet was issued from the service to all hospitals and blood users concerning all products available from the service. This contained advice for product use as well as a caution regarding risks of transfusion. A UK wide initiative to distribute a booklet "handbook of transfusion medicine" to all junior medical staff was also implemented [NHBT0099310_002]. This would have provided advice regarding transfusion risks.

210. Coupled with that was the initiative to formalise and improve patient consent for transfusion which would act as an opportunity to explain that the decision to transfuse was a balance of benefit and risk.

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

Donor selection

98. What donor screening processes were in place during your tenure at the WRTC, and how did these change following the emergence of:

a. HBV

b. AIDS/HIV

c. NANB/HIV

211. The WRTC followed agreed national policies regarding implementation of all these screening processes. There may have been minor differences in the exact dates of introduction of test procedures or variations thereof according to local circumstances but for the most part there was alignment. Pre-donation, donors were selected following national agreed criteria to exclude those with a medical history or lifestyle behaviours which were thought to put them at greater risk. Following donation all blood was screened according to

accepted techniques and standards. When new information came about procedures were adjusted accordingly.

212. All these potential infections would be screened for by Enzyme Linked Immunosorbent Assays - ELISA followed by reference centre confirmation.

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

213. Decisions followed a national (UK) consensus about donor selection and set out in national guidelines reproduced for WRTC as a local set of guidelines available to all medical stall and blood collecting teams. There would be every effort made to ensure conformity. I would have had the ultimate responsibility for the process. The process was always under review.

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

214. Implementation of donor selection is not always straightforward. Donors are asked about factors relevant to donation and their answers sometimes require professional assessment regarding their suitability to proceed to donate. For the most part decisions could be made following advice set out in the donor selection guidelines which were always available. Sometime reference had to be made to medical staff at the centre to determine suitability.

101. What information (either written or oral) was given to donors about the risk of them transmitting infections via their blood? When was such information provided?

215. Before donation donors were provided with written information designed to deter those who might be potentially risky and they were then questioned regarding their understanding of the contents.

102. In September 1983, a UK-wide leaflet on AIDS and blood donors (BPLL0007247, NHBT0020668) was distributed to RTCs. What, if any involvement, did you have with the production of this leaflet? If you were involved, please outline the extent of your involvement and input.

216. I would have been aware of the production of this leaflet and possibly contributed to discussions about the contents. I was not involved in deciding the final text.

103. In particular, did the WRTC use a nationally agreed leaflet prepared by the NBTS or did the WRTC produce its own leaflet? You may find NHBT0092855_002 (paragraph 4), NHBT0020668, NHBT0113565 (point 3) NHBT0018200 (paragraph 20), and NHBT0097016_008 of assistance.

217. I do not recall whether WRTC would have produced its own version but I think that it would have been unlikely.

104. How regularly were these leaflets updated, and how was their content decided? You may find BPLL0007202 (paragraphs 23 to 25), SCGV0000069_059 (page 1), NHBT0007533 and NHBT0034821 (paragraph 3.1) of assistance.

218. I believe these leaflets were updated whenever there was new information that necessitated it. I cannot recall how frequently this was. The content was changed according to advice from groups such as the Expert Advisory Group on Aids or the Advisory group on the microbiological safety of Blood. Recommendations would be considered within the advisory Committee of the NBTS or RTDS meetings with regard to implementation.

105. How effective, in your view, were leaflets and other communications at reducing the risk of donations from high-risk individuals? You may find DHSC0002237_014 of assistance.

219. Judging by the very small number of donations in Wales found positive for HIV or HBV and of reported post transfusion transmission I believe the arrangements to have been very effective.

106. Should other steps have been taken to reduce the risk of collecting donations from high-risk individuals? If so, what steps?

220. I am unable to suggest any other measures that could have been taken. I don't recall what messages about this would have been incorporated into media campaigns (radio or TV & press) for donor recruitment or whether this could have been counterproductive.

107. Please refer to PRSE0002062 (at items 4d and 7) and CBLA0001937. These documents relate to discussions surrounding donor leaflets and screening which you appear to have been party to. It is apparent from these documents that Regional Transfusion Directors ("RTDs") felt some frustration, "there being as yet no new leaflet, no finance, and no positive move towards full donor screening."

a. What were your thoughts on these issues, and why? Did you share the frustration of the other RTDs?

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

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

221. I do not now have a clear recall of these events. From the documents supplied it seems we (Regional Transfusion Service Directors) were frustrated at the inability to finalise the AIDS material at a time when it was felt the there was a pressing need to ensure the safety of the blood supply. I do not know

the reasons for this delay. Once leaflet content had been agreed, I think implementation within the service would have been prompt. I don't think there was a noticeable impact on blood collection.

Introduction of virally inactivated products

108. What role do you consider the WRTC had (or should have had) in pushing for factor concentrates to be virally inactivated in the late 1970s and early 1980s?

222. WRTC along with the other regional blood services were entirely dependent on fractionators to do their utmost to adopt viral activation. However this was entirely within their (fractionators) expertise to investigate and develop methods for doing this. To my knowledge there were no pre-existing technologies so the service was in no position to be other than be supportive of BPL efforts to develop a process.

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

223. The issue of "safe" products had been very much bound up with the imperative for UK self-sufficiency. This had been a matter of extensive debate with all parties involved. Once the universality of NANB and the HIV risk had become apparent the implementation of viral inactivation became a matter of great urgency.

224. The whole history of UK plasma procurement was concerned with everyday aspects of maximising safety. This would have been a constant dialogue concerning donation screening, recall of potentially risky donations, plasma handling procedures etc.

225. There would have been no such direct dialogue with commercial companies.

110. In 1984, the Western Division Consultants meeting suggested that they were concerned about the "lack of information from the DHSS, particularly in relation to heat treatment for Factor VIII" (NHBT0113565). Did you share this concern? If so, why?

226. I cannot recall my thoughts at the time but I imagine that once it had been intimated that heat treatment was capable of viral inactivation colleagues were impatient to see the process implemented. It was understood however that there could be complications arising from the heat treatment process that could take time to resolve.

111. In November 1984, the cost implications of the introduction of heat treatment were noted at a meeting called by the Chief Medical Officer of the Welsh Office. (see HSSG0010054_008 page 3).

a. When were the measures set out in the meeting introduced?

b. How did the costs of introducing the measures affect the WRTC?

227. I don't have information available to answer these questions. My recollection was that HIV antibody screening was universally introduced once criteria for accuracy, sensitivity and specificity were met.

Recall of non-heated products

112. The Inquiry believes that unheated Factor VIII products were never formally recalled in England, even once heated products (such as 8Y) became widely available. What was your view on the continuing usage of unheated Factor VIII products?

228. I was not involved in these decisions. It could have been argued that save for "never yet treated" patients (who should be priority for low risk products) most

haemophilia patients had already had a lifetime of treatment with untreated products and the options were to continue until 8Y was available or to provide a less satisfactory alternative (e.g. cryoprecipitate). The prospect of no longer having concentrate would have been alarming for patients used to the near normal lifestyle that FVIII concentrated enabled.

Provision of diagnostic screening kits

113. Please describe the arrangements in place at the WRTC with regards to the provision of diagnostic screening kits for donation screening ("screening kits"). You may find NHBT0002331_001 of assistance.

229. The arrangement for choosing diagnostic materials for blood screening evolved over time. The principle adopted was to use test systems approved by the Microbiology test kit evaluation group. This would additionally ensure that donations met BPL quality criteria.

114. Did you, or anyone else at the WRTC, contract directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of screening kits, or were contracts negotiated on a national basis?

230. I believe the WRTC negotiated directly with test kit manufacturers.

115. What were the key factors influencing choice of screening kit and/or pharmaceutical provider? You may find CBLA0013304 and NHBT0002031 of assistance.

231. See Q113 above.

232. Test kits would have to meet stringent QC criteria. They would have to show consistent sensitivity and reproducibility. For example minimum detection

levels for the target analysis would be set and monitoring would have to show that this was achieved within every batch of assays. False positive results should be kept to a minimum.

233. Cost would also be a consideration as well as the need for analytical equipment and staff training. The correspondence from BPL refers to the possible adoption of a radio isotopic assay for HBV. The WRTCs position was that it was already satisfactorily using an enzyme linked immunoassay which amply met all QC criteria. I believe the BPL was under a misunderstanding that the WRTC was using a much less sensitive version of an ELISA.

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

234. Manufacturers provided precise instructions for the technical use of their assay kits. Deviation from this would invalidate results and jeopardise WRTC licensing. Apart from the proviso that the kits were for blood screening alone manufacturers would not have any influence on use of screening kits.

Hepatitis B screening

117. In June 1980, you were present at a meeting of Regional Transfusion Directors, at which the Directors were informed that BPL's RIA test would be delayed due to Burroughs Wellcome developing their own RIA (SBTS0000290_004). Some RTDs wrote to their Regional Treasurers to protest this (CBLA0001261). Ultimately, BPL RIA was not rolled out to RTCs until March 1981.

a. What was your view on this delay at the time?

b. Did you contact your Regional Treasurer on this issue? Are you aware of anyone else doing so?

235. I do not think WRTC would have had concerns about this (see Q115).

118. A letter to you from Dr Snape (CBLA0013304) indicates that as of August 1984, WRTC were screening for HBsAg using ELISA rather than BPL RIA, on the grounds of cost.

a. Did WRTC begin using RIA after this date, as Dr Snape suggested? If not, why not?

236. Please see Q114 & 115 above.

b. What if any resources were offered to the RTC by NBTS, government, or other central bodies to assist in the introduction of new assays?

237. I don't now recall discussions about this but I believe WRTC was always resourced sufficiently to implement the required standard of blood screening.

119. In July 1993, you informed Dr Gunson that WRTC had been sending plasma to BPL that had not been assayed according to BPL's specification (NHBT0000938). WRTC was testing for anti-D, but not anti-HBc, anti-tetanus, and anti-HAV as required. In turn, you called for clearer guidance for RTCs on the specification they needed to follow:

a. As far as you can recall, for how long was Cardiff sending plasma tested only for anti-D to BPL before you informed Dr Gunson about the situation? Why did you decide to alert Dr Gunson to the issue when you did? When did WRTC become aware of the BPL Plasma Specification?

b. What can you recall about the circumstances that led to WRTC not testing their plasma for these other infections?

c. What can you recall about the outcome of this letter? Did it impact upon future plasma specifications? Was action taken at either BPL or WRTC in response?

238. This question, I believe, concerns plasma collection for the preparation of therapeutic immunoglobulin (not source plasma for FVIII). This is a material designed to provide broad spectrum passive immunity against a range of infections. That being the case the antibodies referred to (anti-HBc etc) are wanted constituents contributing to effectiveness of the final product. They are not markers of potentially dangerous infectivity.

239. BPL may have had a point of view that a natural population of donors would enable a sufficient range of protective antibodies to be present in the final product or they may have sought to include donations contributing known ingredients so as to better guarantee potency. The point of my letter was an attempt to clarify this.

240. Anti-D is mentioned because anti-D immunoglobulin is a specific material used in the management of rhesus haemolytic disease and the anti-D content of the source plasma is of paramount importance. I don't have any recollection of the outcome of this discussion but I don't think it is relevant to blood safety.

120. You were a member of SNBTS Medical and Scientific Committee in the early 2000s. The Committee discussed whether routine anti-HBc screening should be introduced as a risk reduction measure (PRSE0000874). Other committees such as SACTTI and MSBT also discussed this matter from the early 1990s into the early 2000s.

a. What do you recall about the arguments put forward, both in favour of and against the introduction of routine anti-HBc screening?

b. What was your personal view on this issue? Did this change over time? If so, how?

c. In your view, why was this issue revisited so often by the committees without a final decision? Do you feel that this continued reassessment was appropriate?

241. I was not in fact a member of this committee, it is a Scottish Medical and scientific committee.

242. The arguments for introducing anti-HBc have never been very clear cut. In the absence of a specific test for HBC this antibody which (confusingly is part of the immune response during HBV infection) has been proposed as a surrogate marker for HBC since it was claimed the two infections (HBV and HBC) sometimes coexist.

243. Purely considering HBV infection, the presence of anti-HBc sometimes is part of the recovery convalescent response but in chronic HBV infections it may indicate persistent infectivity. I was not aware that there was any international consensus on this. I regret that I do not have the knowledge to comment further. Any proposed new test such as this can only be introduced if the interpretation is clear cut. I think the fact that the topic was revisited reflected the difficulty of demonstrating that there could be significant benefit.

Introduction of HIV testing

121. HTLV-III antibody screening was rolled out in all RTCs on 14 October 1985 (CBLA0002277, page 2). How did WRTC ensure that they would be able to begin screening on this date?

244. I don't recall the local negotiations with the Welsh Office or Health Authority prior to implementation. The Health Authority would have been aware of the need for coordinated simultaneous implementation of testing. Prior to the agreed date equipment would have been commissioned and the testing process set up and need to be demonstrably capable of seeing donations to the requisite standard.

122. Please describe the implementation of HIV screening at the WRTC. In particular:

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

245. The test process would be similar throughout the UK services. The testing programme was launched following a national evaluation of available test kits and of reference laboratories to enable confirmatory testing. It was also considered essential for alternative testing facilities to be readily available to the general public to avoid the possibility that the worried "at risk" would seek to get tested via the Blood Transfusion Services. Before a test could be used and certainly before the launch of a screening programme it would be subject to an "in house" evaluation for sensitivity, specificity and reproducibility. The screening test used the Enzyme Linked Immunoassay (ELISA) to detect anti-HIV and positive results confirmed by Western Blot analysis at a reference laboratory.

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

246. I don't recall any significant impact on the operation of the blood service. Positive donations were exceptionally rare (about one per annum).

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

247. I don't have access to records of the time but I think there will have been screening of donations before the official implementation date so that at that time everything in stock would have been cleared. It would not have been possible to discard all the blood donations in the WRTC and hospital banks as this would have catastrophic consequences for clinical care.

d. What happened when a donation was found to be infected with HIV? Please set out the steps that had to be taken, both with respect to the donation, the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.

248. The donation would be immediately quarantined, the screening test repeated and also a screening sample taken for testing from the actual blood pack itself. Samples would be sent for confirmatory testing at a reference centre. When positivity was confirmed the counselling medical officer would meet the donor, collect further samples for testing and arrange for specialist clinical referral.

249. All previous donations, the samples from which would have been archived, would be retrieved for testing. Hospitals would have been notified to enable previous recipients to be traced, tested and counselled. Information regarding positive donors was reported to the NBTS National Directorate.

Surrogate testing for NANB

123. What was your opinion of surrogate testing as a potential method of donor screening, and how did this change over time? Please comment on each infection with reference to specific surrogate tests for:

a. HIV; and

b. NANB/HCV.

250. Screening for HBV viral markers to some extent had a surrogate effect. I do not recall that other surrogate testing for either HIV or NANB were regarded as effective or implemented in the UK. The value of surrogate testing varies

greatly internationally reflecting the very marked differences in prevalence of these infections.

124. You were present at the thirteenth meeting of the NBTS Advisory Committee, which took place on 17 June 1987 (BPLL0007202). At paragraph 32, the minutes state that "There was insufficient evidence of NANB after the HIV deferral of donors had been introduced." What do you understand to have been the meaning of this sentence? Please elaborate as much as possible.

251. I do not think I can provide any specific help with this. My understanding of the statement is that following HIV risk deferral of donors (which removed a further category of potentially risky donors) too few blood recipients showed surrogate marker changes.

125. A report prepared by Dr Gunson in August 1987 set out the conclusions of a Working Group established by the Council of Europe Committee of Experts on Blood Transfusion and Immunohaematology to consider the introduction of routine surrogate testing ("the Working Group report") (NHBT0008816_002). The Working Group concluded it could not provide a recommendation on the introduction of surrogate testing in light of the following considerations:

a. the use of surrogate tests to reduce the incidence of transfusion associated NANB and its possible value as a public health measure remained controversial;

b. there was no guarantee, in a given country, that there would be a significant reduction of NANB;

c. the introduction of surrogate testing in some countries could lead to a severe depletion of donors which could compromise the blood supply; and

d. if surrogate testing was introduced, provision would have to be made for interviewing, counselling, medical examination and treatment of anti-HBc positive donors and donors with raised ALT.

Please advise whether you were aware of the Working Group's report. If you were, did you agree with the conclusions reached by the Working Group? If n not, why not? You may find SCGV0000069_059 of assistance.

252. I would have been aware of the working group report. I was unsure that surrogate testing would be beneficial in the UK context. As far as I was aware post transfusion NANB hepatitis was never reported to the WRTC (HBV was).

253. Considering the life expectancy of many transfusion recipients (the elderly or those with malignant conditions) and the slow progression of NANB it seemed likely that not many clinically significant cases could be prevented. This benefit had to be balanced against recognised disadvantages to blood supplies that might follow introduction of surrogate testing.

254. I was not sure that surrogate testing with all its limitations would be able to reduce the risk of infection for recipients of multiple donations or pooled products. I cannot however speak with expertise on microbiological matters and would defer to expert opinion.

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

255. The measure of safety should include all consequences of the proposed test or procedure. If the effect is a benefit in one direction but offset by penalties in another direction, for example loss of donors and donations leading to blood shortages, the ultimate effect on blood safety may be counter to that intended.

127. In October 1989, Dr Gunson, the Chairman of the Advisory Committee on Transfusion Transmitted Diseases ("ACTTD") recommended: "The routine introduction of non-specific tests should be deferred, unless this is necessary for the acquisition of product licences in the UK for fractionated plasma products" (NHBT0000188_072, paragraph 7.5). Then, in November 1989, the ACVSB concluded that there was no case for using surrogate testing for non-A non-B Hepatitis (NHBT0005043). Please advise whether you were aware of the decisions made by ACTTD and ACVSB. If you were, did you agree with the decisions made by ACTTD and ACVSB? If not, what were your objections?

256. I think I would have been aware of the general conclusions and would have had no reason to disagree.

128. The Inquiry understands that ALT testing was introduced at the WRTC in 1990 but by October 1991 neither ALT nor anti-HBc testing was undertaken (NHBT0000077_085 and NHBT0000189_066 (page 6)). Please advise whether surrogate testing (namely ALT or anti-HBc testing) was introduced at any other time at the WRTC during your tenure.

257. I have no recollection of this.

129. Please explain what impact surrogate testing had on the WRTC. In particular:

a. How was the surrogate testing performed?

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

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

d. What happened when a donation tested positive? Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.

e. What were the circumstances in which the WRTC stopped surrogate testing?

258. Not Applicable.

Introduction of anti-HCV screening

130. When did the WRTC begin anti-HCV screening?

259. I don't have this information to hand but it is most likely the WRTC started at the same time as the rest of the UK. Having checked records I have been informed that this began on 1st September 1991.

131. Dr Gunson wrote a letter to all RTC directors suggesting a delay in commencing anti-HCV screening from July to September 1991 so that a "'second-round' comparative evaluation" of the screening kits could take place (NHBT0000073_065). Did you agree or disagree with Dr Gunson's suggestion to delay testing to undertake this comparative evaluation? Please explain the basis for your answer.

260. This was a matter for expert advisors to recommend the most secure approach and I would not have the knowledge to disagree. It was believed that the first generation test gave a high proportion of false positives which would create a problem of donor loss and the need for counselling.

261. This would be particularly difficult in the UK where the HCV prevalence rate was low. (It would mean that most "positive" screening results would in fact be false positives).

132. In response to Dr Gunson's letter, some RTC directors suggested a staggered start date for the implementation of testing (i.e. different start

dates for different RTCs) while others supported a uniform start date. Which view did you take? Why?

262. I do not recall. Instinctively I would have favoured simultaneous implementation but there may have been good reasons for doing otherwise.

133. Despite Dr Gunson's suggestion to delay the introduction of screening, the Northern RTC led by Dr Lloyd introduced routine testing in April 1991, becoming the first centre to do so. Dr Lloyd's view, in contrast to that of Dr Gunson's, was that, the "second Generation HCV tests were acceptable tests for donor screening" by June 1991 (NHBT0000076_009), and that deciding not to implement testing despite having the capability "would be indefensible under the current Product Liability Legislation" (NHBT0000074_014). As to this:

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

263. My interpretation of Dr Gunson's communication was that proof of second generation test would be expected by September. I don't now recall my thoughts at the time but anticipate that as there was an established expert advisory mechanism for handling these questions I would have felt their advice would be best taken.

264. It seems that Dr Lloyd's interpretation was not generally accepted. The argument based on practice in other countries may not be sound as HCV prevalence varies widely and the UK prevalence was I believe relatively low.

b. Have your views changed since then? If so, why?

265. With regard to whether this decision was correct, the points I make in Q126 are relevant.

134. What impact did HCV testing have on the WRTC? In particular:

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

266. I believe screening would have been done by ELISA with confirmatory tests assayed by immunoblotting at a reference laboratory. The process would be as described in Q122 (c).

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

267. I do not have certain recall for this but I believe consideration was given to advancing screening before the publicly announced date so that everything "in stock" would have already been screened.

268. As a matter of practicality it would have been necessary to commission new equipment and confirm satisfactory performance of test kits well before the official implementation of screening.

c. What happened when a donation tested positive? Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.

269. This would be the same process as described in Q122(d) and Q135

Autologous transfusion

135. In March 1990, during a WRTC working group meeting, it was noted that you were drafting a proposal to construct a facility for autologous transfusion.

This was being drafted for consideration by the South Glamorgan Health Authority before submission to the Welsh Office (NHBT0000189_066 (page 4)). Please explain:

a. **what the advantages of autologous transfusion were, including how effective you perceived the procedure to be as a method of reducing the risk of transfusion-transmitted infection;**
b. **what the disadvantages of autologous transfusion were;**
c. **how widespread the use of autologous transfusion was amongst hospital clinicians; and**
d. **how long the WRTC's autologous transfusion service ran for. You may also find NHBT0000188_054 of assistance.**

270. Autologous transfusion had become a matter of public debate fuelled by press articles extolling its supposed safety. In fact the known risks of homologous transfusion in the UK were exceptionally low and the risks of autologous transfusion performed in other than trained settings could be much greater (insecure donation identification, bacterial contamination, uncontrolled handling and storage procedures blood wastage). In recognition of public concern The WRTC initiated a small pre-deposit programme.

271. To avoid the aforementioned safety problems this was operated by trained WRTC staff although the take up was never very great.

272. The procedure is more expensive and imposes logistical constraints on prospective donors and clinicians. In many situations in which pre-deposit was used blood loss was too small to mandate blood replacement. For larger transfusion needs pre-deposit would have been insufficient.

273. I don't have any information about the duration of these facilities. Red cell salvage procedures for clinical situations in which extensive blood loss is expected to reduce the risk of transmitted infection and have other blood conservation advantages. These procedures were performed in hospitals.

Quality Control

136. Please outline the procedures in place at the WRTC to prevent infected donations from contaminating plasma pools at BPL. You may find BMAL0000023 (page 2) of assistance. In your opinion, how effective were these procedures?

274. All donations were logged into the computer system. The system was set up to ensure all donations were tested for microbiological safety. Only those donations passing microbiological screening were allowed to be issued and this included donations of plasma for BPL.

275. The system was set up to be as secure as possible and to my recollection this was the case. The physical systems for issue and dispatch of blood and components were subject to computer control. In addition the computerised process was set up to ensure that unsafe donations were consigned for destruction. Documentation showing donation numbers would have been sent to accompany plasma donations sent to BPL.

276. I do not now have information about these security arrangements proposed by BPL in 1991. The discovery of any erroneous dispatch of a plasma donation to BPL would have been regarded and investigated as a serious quality management issue.

137. Please outline the procedures in place at the WRTC and BPL (as far as you are able) to enable a contaminating donation to be traced. You may find NHBT0001549, BPLL0001756_006, HSSG0010054_008 and NHBT0003792 of assistance. In your opinion, how effective were these procedures?

277. (Further to Q136) Contaminating donations should never advance to the "eligibility for issue" status since this was contingent on negative screen test results. The computer system would in any case hold information about the status of all donations including the issue destination.

278. This information would allow retrieval of any donation that had not left the premises. If information subsequently came to light suggesting potential risk concerning donations that had been issued the recipient organisation would be informed.

279. The BPL would also have been notified had there been a need to recall any donation. The system was set up to be as secure as possible and to my recollection this was the case.

138. Please outline the procedures in place at the WRTC to enable the recall and quarantining of infected blood and blood products. You may find NHBT0009740_001 (at point 4.3) of assistance. In your opinion, how effective were these procedures?

280. Recall would be organised by the QA department in liaison with medical staff. If WRTC was notified of a clinical adverse reaction from a donation any other constituent parts of that donation would be recalled and investigated.

281. This arrangement depended on the systems available in hospitals for record keeping and recall but I believe it worked satisfactorily.

139. Please refer to BPLL0003074, a letter from yourself relating to the recall of several products in May 1990. In this letter you expressed dissatisfaction, calling the episode "a serious failure of communication." Please give as much detail as you are able to on this incident, referring particularly to your experience of the following:

a. the circumstances of the recall;

b. any instructions received from BPL about the recall and about press liaison; and

c. how things changed, if at all, following this incident. Were you satisfied by any changes made?

282. I do not remember this episode. This was a matter of handling public relations rather than process control or blood safety. I think my concern was that a BPL product recall incident was headlined in the press before we at Cardiff had any knowledge of the problem. I can't provide any more details. Normally if there had been concern about a batch of BPL products issued to Cardiff the centre would have been notified and the information passed on to recipient hospital/clinicians.

140. Please refer to CBLA0000010_208 and DHSC0001111, which relate to the recall of Factor VIII Batch HL3186. As you will note, a total of 338 out of 400 vials were successfully recalled from Cardiff.

a. What, if anything, can you recall about this incident?

b. What processes and procedures were followed at Cardiff when responding to this product recall?

c. Did you have any involvement with following up recipients of this batch, or was this largely left to Dr Craske? If you were involved, what was the extent of this involvement?

d. Did the incident prompt any changes, as far as you can remember, in terms of how BPL or WRTC dealt with similar incidents?

283. I have only the vaguest memory of this incident but there were systems in place for recall of issued products and the notification of hospitals/clinicians. In an incident such as this haemophilia haematologists would have been notified and would have had records of recipients. They would also have been involved with any follow up with Dr Craske.

284. The WRTC would not have been involved in this recipient follow up. Although I don't remember the details I presume the WRTC's arrangement for quarantine and recall proved satisfactory and did not require change.

General

141. Please describe all other steps or actions taken at the WRTC during the time you worked there to ensure blood safety and to reduce the risk to recipients of blood or blood products of being infected with a transfusion transmitted infection.

285. Blood safety has always been an overriding concern for Blood Services as evidenced by a wealth of publications in the scientific and medical literature. From the earliest years as soon as evidence accrued regarding transmissible infectivity attempts have been made to identify potentially risky donors and screen for the infective agent or to utilise surrogate markers.

286. The process of developing surrogate markers of test for infectivity is beset by the requirement that the test system should offer workable performance in terms of reproducibility, sensitivity and specificity, ie that it should reliably identify truly infectious donors and not produce unacceptable numbers of false positives.

287. False positives produce problems for donor management and counselling. These complex issues have been considered by various expert advisory bodies already referred to (eg advisory committee on microbiological safety of blood, UK advisory committee on transfusion transmitted diseases) and it was the advice that was influential with regard to the times of introduction of the measures referred to above.

288. This advice was communicated to Regional transfusion directors or later the Advisory committees of the NBTS who would oversee the implementation

process. A further dimension to blood safety was the systems set up through transfusion centres for the notification of post transfusion infections and their central reporting.

289. A special UK wide committee was also set up, the Serious Hazards of Transfusion, SHOT, comprising clinicians and blood service medical staff to address these various aspects of blood safety.

290. A further aspect of blood safety was that of education regarding the safe use of blood and products. This would be carried out by the educational activities of blood service medical staff working through hospital transfusion committees and clinical colleagues. Booklets on the same topic (Handbook of Transfusion Medicine) for junior medical staff were also widely distributed to all hospitals.

142. Was blood safety ever subject to cost, time, staffing or any other constraints? If you felt a particular course of action needed to be taken to ensure blood safety, were you free to take it? You may wish to refer to BMAL0000023.

291. I believe WRTC did implement agreed safety measures. Nevertheless the part the WRTC was able to contribute to the self-sufficiency objectives was constrained by the lack of provision of a new purpose built centre. For the time period concerned the WRTC was housed in very inadequate accommodation which made achieving all of these objectives more difficult.

143. How did the desire for consensus across RTCs in England and Wales impact efforts to achieve blood safety in Wales?

292. I believe the debates around achieving consensus were helpful in this regard. Consensus ensured that no regional centre had any occasion to be in ignorance of or lag in implementing necessary safety measures.

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

293. I think I have answered this already (Q141) Safe blood would be defined by the proof that it had been collected from selected screened donors and tested according to the standards of the time and stored and transported according to approved monitored conditions.

294. These specifications would have been set out in national guidelines for the operation of blood services and compliance would be audited by the Medicines Control Agency.

295. I don't think there was any occasion when I had any reason to disagree with this arrangement.

145. In January 1992, Dr Marcela Contreras wrote, ahead of an ACTTD meeting, that "the attitude towards transfusion safety has veered away from the concept of 'maximum benefit at minimal cost' towards the notion that if a procedure shown to prevent transfusion-transmitted infection and disease is available, it should be introduced" (NHBT0000044_095). Do you agree that a shift occurred? Did this shift impact the WRTC? Please explain the reasons for your answer, including any relevant references to discussions with colleagues and official policy within the NBTS.

296. I think a balanced approach lies between these two concepts. Any new interventions have be assessed in terms of risks and benefits (see Q126).

146. If you do consider a shift occurred:

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

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

c. What caused the change to occur?

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

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

297. I don't recall any explicit formal policy expressed in these terms or that a step change in policy took place. Policy evolved as knowledge expanded.

Section 13: Look back programmes at the WRTC

147. Were you involved in setting up any national or local look back programmes for HIV or HCV during your time at the WRTC? If so, please describe this process and your role in it and how it was funded.

298. I am not aware that any instance of HIV transmission occurred in recipients of blood or blood components in the Welsh region (during my time) although from this distance in time and without access to all the records I cannot be categorically certain. On that basis there would have been no requirement for any look back programme for HIV in Wales.

299. Recipients of contaminated coagulation factors would not have been investigated through the WRTC. An HCV look-back programme was instituted UK wide.

300. Funding was provided by the Welsh Office and a member of the medical staff was specifically tasked to take on the local look back programme and to liaise

with the National Directorate. I would have been instrumental in preparing the request for funds and for the overall implementation of the programme [WITN6915004] [WITN6915005].

148. Were you involved in implementing any look back programmes during your time at the WRTC? If so, please describe what this involved.

301. Please see Q 147 above. Recipients of any potentially infectious donations were sought out investigated and referred for specialist advice. This would be in collaboration with hospital staff or family doctors. WRTC would have information regarding the hospital destination of the implicated products and the hospital would have records of recipients [WITN6915006].

302. Attempts were then made to contact recipients and arrange, where possible, for counselling and HCV testing. WRTC was also notified of Welsh residents who had been transfused in other parts of the UK. Statistics were prepared to show:-

- The success rate of contacting recipients
- The portion of recipients found to be either HCV positive or negative
- The clinical outcome/ death rate post transfusion
- The numbers of HCV test positive survivors successfully counselled and tested
- Where death had occurred an attempt was made to ascertain whether hepatitis had been evident or had contributed to mortality

149. How was any additional work funded?

303. See Q 147 above [WITN6915005].

150. Please confirm whether you were involved in a look back process relating to any other infection during your time at the WRTC. If so, please provide an overview of the relevant programmes and detail your involvement.

304. See Q147/148. Before the advent of recognised HCV post transfusion infection, the numbers of recipients known to have received blood from donations suspected as being infectious was very small. Hospitals would have been notified and attempts would have been made to contact the recipients and their family doctors. This activity was accepted as a normal part of medical responsibilities.

151. Did you consider there was an ethical obligation to inform patients who may have received transfusions from infected donations? If not, why not?

305. Certainly, the more so if treatment and counselling are possible.

152. To what extent could an RTC implement its own local look back programme? Did the WRTC do this? If so please give details. If not, why not?

306. WRTC in common, I believe, with most RTCs would have regarded investigation for the recipients of infected donations as normal practice. As mentioned earlier, for blood and components, transmitted infections notified to RTCs were a rarity.

Section 14: Your relationship with commercial organisations

153. Have you ever:

a. provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products?

b. received any pecuniary gain in return for performing an advisory/ consultancy role for a pharmaceutical company involved in the manufacture, sale and/or importation of blood products?

c. sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture, importation or sale of blood products?

d. received any financial incentives from pharmaceutical companies to use certain blood products?

e. received any non-financial incentives from pharmaceutical companies to use certain blood products?

f. received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?

If so, please provide details.

307. (a-f) No.

154. What regulations or requirements or guidelines were in place (at any time relevant to your answers above) concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

308. Not Applicable.

155. Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture, importation or sale of blood products? If so, please provide details.

309. No.

156. Have you ever provided a pharmaceutical company with results from research studies that you have undertaken? If so, please provide details.

310. No.

157. 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? If not, why not?

311. Not Applicable.

Section 15: Reform of the BTS in the 1990s

National Directorate

158. In his witness statement for the A v Others litigation, Dr Gunson discussed the creation of the National Directorate to oversee the work of RTCs, although he noted that the Directorate "did not have executive authority and its successes came about by persuasion" (NHBT0000025_001; NHBT0000026_009). What are your views on the success or otherwise of the National Directorate?

312. I believe that the National Directorate enabled a more cohesive sense of policy but, because it lacked executive authority, its powers were limited. As long as every resource dependent initiative depended on support from Regional/Area health Authorities the capacity to act with the capacity and speed required would be limited. This has throughout been a significant constraint.

159. In the same statement, Dr Gunson commented that the work of the National Directorate became marginalised as a result of the devolution of health budgets to District level and eventually replaced by the creation of the National Blood Authority ("NBA"), which had responsibility for "both the central laboratories and the RTCs." What are your views on the need for centralised responsibility for RTCs?

313. In terms of overcoming the fragmented responsibility that previously existed this change was overdue. Wales remained outside the NBA but closely shadowed its operation and cooperated with it.

National Blood Authority

160. During a meeting of the Western Division Blood Transfusion Service in October 1991, Dr Entwistle reported on the reorganisation of the Blood Transfusion Service. This discussion concluded with Dr Ala expressing the view that the introduction of the NBA would diminish the role of RHAs and establish the NBA as the central contracting body of the Blood Transfusion Service, which "everyone agreed was the ultimate desired goal" (NHBT0009826, page 2-3). Did you consider this to be the ultimate goal? If so, please provide details. If not, why not?

314. I think taking over organisation of RTCs blood collection and component production activity was for the most part a rational objective. However the Welsh Office (Secretary of State for Wales) decision was that WRTC would not be absorbed into the new NBA.

315. There were advantages and disadvantages of the new arrangements. A concern could be that the very close professional working relationships developed locally, e.g. with hospitals being the RTCs customers, might be weakened. I am not aware of such fears ever being realised.

161. During the same meeting, Dr Entwistle summarised an ad hoc meeting of RTC Directors which had discussed the ideas of Mr David Hans who was tasked by the Welsh Office to look at the management arrangements for the WRTC (NHBT0009826 (page 3)). Were you present at this ad hoc meeting and/or aware of Mr Hans' review? If so, did you agree with the recommendations as set out at page 3 of NHBT0009826? Have your views changed over time?

316. I probably was at that meeting but I don't clearly recall it now. I was familiar with Mr David Hans recommendations which I thought would be a significant improvement on the status quo. I did have reservations about an over-centralised bureaucracy which might arise with a national authority. Since the WRTC was not absorbed into the NBA I cannot comment further.

162. A report for the future management arrangement for the NBTS in Wales was produced in October 1994 (SCGV0000053_013). With reference to the recommendation at point 16, did you agree that the best option was chosen for future management arrangements? If yes, why? If no, why not?

317. I did agree with the final recommendations of this report. Indeed I was a participant in the decision making process. Accordingly I agreed that the chosen option would best serve the people of Wales and make best use of the capital asset (principally the long awaited new transfusion centre), it could be most responsive to the needs of clinical users in Wales and would best retain accountability to the Secretary of State for Wales.

Section 16: Relationship between blood services
Relationship between the NBTS and the Welsh Office

163. Please outline and explain your understanding of the relationship between the Welsh Office and the NBTS during your tenure, including any forums or reporting lines established to aid any cooperation.

318. As Medical Director I had professional accountability to the Chief Medical Officer. The Welsh Office (WO) had ultimate responsibility for WRTC although operationally this was delegated to South Glamorgan Health Authority. A management group was established including representatives from the WO, South Glamorgan HA and WRTC to enable policy formation,

information sharing and discussion of resource requirements to meet the agreed objectives.

164. Please explain the NBTS and Welsh Office's approach to policy development and implementation. Was policy developed and implemented on a UK-wide basis unless otherwise agreed, or was the approach discussed on a case by case basis?

319. To a very large extent the WRTC adopted policies developed within the UK transfusion services (NBTS) and professional advisory groups most of which have been referred to earlier. Policies were developed as far as possible on a UK wide basis. The WO would be briefed on policy developments but the major impetus for change would be professionally led within the service and its advisory bodies. The latter would have been set up under the auspices of the DoH with the appropriate officials of the WO being involved.

165. Did the Welsh Office share information with the NBTS about excluded donors, donors that posed a risk to the safety of the blood supply, or infected blood donations? If yes, was this on a formal or informal basis? Please describe the mechanisms in place to share this information, if any.

320. I don't think the Welsh Office would have been involved in excluded donor notification. This information (for conditions such as HIV positivity) would have been reported centrally but I don't recall details.

Relationship between the Welsh, Scottish, and Northern Ireland Blood Transfusion Service

166. In your role as Medical Director of the WBTS, did you often engage with directors and/or other staff members of the Scottish National Blood

Transfusion Service ("SNBTS") and/or Northern Ireland Blood Transfusion Service ("NIBTS"). If so:

a. **Please explain the nature of the relationship between the WBTS and SNBTS and/or NIBTS.**

b. **Please outline the arrangements in place to enable cooperation between the WBTS and SNBTS and/or NIBTS during your tenure, including any forums or reporting lines established to aid any cooperation.**

321. The meetings of transfusion directors included those from Scotland and Northern Ireland. Apart from professional communication and cooperation there was no formal relationship.

322. Latterly after the establishment of the NBA a committee was set up involving medical directors of the services of England, Scotland, Wales and Northern Ireland to facilitate policy coordination and implementation.

167. Please outline any statistics or studies of which you are aware that demonstrate the difference in morbidities and fatalities between Scotland, Northern Ireland, and England/Wales.

323. This Information would have been shared amongst the various regional and national services. I think it will also have been made available to the Serious Hazards of Transfusion Working Party but I cannot now provide any details.

Section 17: Variant Creutzfeldt-Jakob disease (vCJD)

168. When and in what circumstances did you first become aware of the risks of transmission of vCJD associated with the use of blood and blood products? How did your knowledge develop over time? What if any involvement did you have in addressing or responding to these risks? You may find NIBS0000557 of assistance.

324. I was aware of the possibility of vCJD transmission via human growth hormone products but only later in the 1990s, and I can't recall dates was it was realised that blood transmission might be possible.

325. I don't recall the donor selection measures considered as a means of identifying risky donors or of minimising transfusion transmission When a risk of vCJD was appreciated a system was establish to share patient/donor data confidentially within blood services so as to enable donor exclusion, product recall and look-back. As "data custodian", I would have received such information. The WRTC would have undertaken look-back as necessary but I cannot recall details.

169. Was the WRTC involved in a lookback programme for vCJD? If so, please provide details. You may find NHBT0009032 and NHBT0009028 of assistance.

326. From scientific knowledge at the time it was agreed to remove white blood cells (a therapeutically unnecessary constituent) from transfused blood and because of the special UK risks of vCJD the practice of harvesting plasma for product manufacture would cease. Whilst I recall these changes I have no recollection of any specific look back programme for vCJD.

Section 18: Other matters

170. Please provide a list of any articles you have had published relevant to the terms of reference.

327. I regret that I don't now have a record of previous publications. It is nearly 20yrs since I retired. I did write a textbook "Handbook of Blood Transfusion Therapy" and one chapter is concerned with transmissible infections and that summarises my knowledge and views at the time (1987-1996).

171. 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.

328. None

172. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry. To assist, we have provided a list of issues (attached).

329. I cannot see any other topics from the list of issues that I can help with.

Section 18 (Other matters)

173. 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?

330. Yes this statement is true. The UK was self-sufficient and I don't know that there would have been any need for imported blood/components.

174. During your tenure at the Welsh Regional Transfusion Centre, 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?

331. No such transfusions of red cells from the USA were ever given.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 20/10/21

Table of exhibits:

Date	Notes/ Description	Exhibit number
30/01/1990	Letter from Prof. Bloom to Dr Napier	WITN6915002
1979	South Glamorgan Health Services Report 1979	WITN6915003
18/01/1995	Letter from Dr Robinson to Dr Napier	WITN6915004
22/06/1995	Letter from Miss Paterson to Dr Napier	WITN6915005
15/04/1996	Memorandum from Dr Hutton to Dr Williams	WITN6915006