Witness Name: Professor Dame Carmen Marcela Contreras
Statement No.:WITN5711001
Exhibits:WITN5711002-006
Dated: 14 Oct 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR DAME CARMEN MARCELA CONTRERAS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 11 September 2020 and a supplementary request dated 29 March 2021.

I, Professor Dame Carmen Marcela Contreras, will say as follows:

Section 1: Introduction

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

1. Professor Dame Carmen Marcela Contreras
   Address: c/o NHS Blood and Transplant 500, North Bristol Park, Filton, Bristol, BS34 7QH

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

3. My qualifications are:
   - B.Sc. (Chile) 1963; L. Med. (Chile) 1967
   - Medico-Cirujano (Chile) 1968
   - E.C.F.M.G. (USA) 1968
   - M.D. (Chile) 1972

- Specialist in Haematology (Blood Transfusion) JCHMT of the Royal College of Physicians (1980)
- MRCPath, 1988,
- FRCP (Edin) 1992
- FRCPath 1997,
- FRCP (London) 1998
- Fellow Academy of Medical Sciences 2003

4. My GMC number is 2526320

5. I attach at exhibit ' **WITN5711002'** my curriculum vitae setting out full details of my qualifications, past appointments, work history, publications, memberships and honours.

6. A fuller list of my publications up to 2008 is included at exhibit ' **WITN5711003'**.

7. I believe it is right to open by saying that the entirely voluntary blood donation service largely depends on the altruism of British blood donors.

8. The National Blood Service, the NHS, dedicated staff and patients rely on that unique 5-6% of the population who voluntarily and altruistically come to give their blood for the benefit of others; 85% of UK donors are repeat or regular and only 15% are new donors.

9. Many repeat donors have given over 50 - 100 donations throughout their lifetime. Some donors become plasma and platelet donors by apheresis, attending clinics on a fortnightly basis in order to help many patients who are dependent on their donations, because of coagulation disorders, traumatic or surgical bleeding, bone marrow failure due to leukaemia or bone marrow transplantation and many other disorders.

10. Remarkably, many blood donors become bone marrow donors, risking their health for the benefit of others.

11. Many life-saving therapies would have been impossible without blood donors. To name but a few:-

    a) Bone marrow and stem cell transplantation requires numerous red cell and platelet donations. A large number of such patients become refractory to the transfusion of routine donor platelets and need to be given HLA - matched platelets. Hence, HLA - typed compatible donors feel a duty to come regularly to donate their platelets by apheresis.

    b) Liver, heart and heart-lung transplantation would have been impossible in the absence of blood components.

    c) Thalassaemic and sickle cell disease patients are dependent on especially typed red cell transfusions as life support.

    d) Haemolytic disease of the newborn due to RhD antibodies, or "Rhesus disease" has become a very rare disease due to its prophylaxis. RhD-negative donors with anti-D used to come regularly to our apheresis clinics to donate their plasma and used to be boosted often, in order to produce anti-D immunoglobulin for RhD negative pregnant women at risk of becoming immunized. Until the advent of vCJD, the UK was self-sufficient in anti-D immunoglobulin.

    e) Fetal and neonatal medicine have made great progress due to the provision of safe "baby blood".

12. These are but a few examples of why we are indebted to routine blood donors.

13. During my long career, I visited many countries in the western world and in the developing world. It is difficult to find a country with a national blood

service such as ours, with the reliability and safety of the blood supply and its national organization. In a number of countries, patients, including children, die or suffer permanent disabilities due to lack of blood or blood components; hospitals have to fend for themselves and patients' relatives are tasked with finding donors because of the absence of national blood stocks.

14. I have worked to encourage governments of countries in Africa, Asia and Latin America to emulate the basis of our service, which is dependent on the generosity of donors. They all come willingly to give their blood and time in order to help others.

15. I hope that their gift is not forgotten.

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

16. I was chairperson of Blood Transfusion International from 2008 until 2016 when it was dissolved.

17. I was Professor in Transfusion Medicine at the Royal Free and University College Hospitals Medical School, from April 1998 - 2008.

18. I was visiting Professor in the Faculty of Applied Sciences at the University of the West of England, Bristol, from June 2004 - 2007.

19. I was National Director of Diagnostics, Development and Research at NHS Blood and Transplant (NHSBT) from August 1999 to February 2007.

20. I was Executive Director of the London and South East Zone (Colindale, Cambridge, Brentwood and Tooting blood centres), National Blood Authority (NBA), Colindale Avenue, London, NW5 9BG from November 1995 to August 1999.

21. I was Chief Executive, Medical Director and Consultant in Blood Transfusion at the North London Blood Transfusion Centre from 1 February 1984 to November 1995.

22. Honorary Senior Lecturer in Haematology at the St Mary's Hospital Medical School, London from May 1990 to 1998.

23. Honorary Member, MRC Blood Group Unit from 15 January 1987 to 1995.

24. Deputy Director and Consultant in Blood Transfusion of the North London Blood Transfusion Centre, Edgware from March 1980 to February 1984.

25. Home Office appointed Tester for Paternity Testing from 1980 to 1989.

26. Senior Registrar in Haematology at St Mary's Hospital London and Northwick Park Hospital Middlesex from 20 July 1978 to 28 February 1980.

27. Medical assistant in Blood Transfusion at North London Blood Transfusion Centre, Edgware from 1 June 1976 to 19 July 1978.

28. Senior Scientific Officer at the North London Blood Transfusion Centre, Edgware, from October 1974 to May 1976.

29. British Council Scholar from 1972 to 1974 at the Royal Postgraduate Medical School and the MRC Blood Group Unit.

30. Lecturer in Immunology and Immunohaematology at the Blood Bank and Centre of Immunohaematology, University Hospital JJ Aguirre, Santiago, Chile 1971 – 1972 under Professor Pablo Rubinstein.

31. Training programme in internal medicine (equivalent to SHO) in Immunology and Immunohaematology at the University of Chile from 1968 to 1972.

32. Internship (general medicine) at the Hospital San Juan De Dios, Santiago, Chile, from March 1967 to March 1968.

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.*

33. My past and current memberships include:

- Founder member and current honorary member of the British Blood Transfusion Society, President 2001-2003
- Current honorary member of the International Society of Blood Transfusion (ISBT); member since 1975. Elected member of Council, 1992 – 2000 and President of ISBT 1996-1998. Chair of membership Committee of ISBT 1994 -96.
- Chairman of the Committee on Socio-economic aspects of Blood Transfusion of ISBT (2000 - 2008).
    - ISBT: Working Party on Nomenclature of Red Cell Antigens and Related Markers. Chairman of the group on High and Low Incidence Antigens until 1995.
    - Chair of the ISBT Congress 1988 Poster Committee.
    - Chair of the ISBT Congress 1988 Social Committee.
    - Executive Committee of the ISBT Congress 1988

- Board member of WIRHE, the Worldwide Initiative for the Eradication of Rh haemolytic disease of the fetus and newborn 2018 – now.
- Royal College of Pathologists (RCPath) Member of the Council of the Royal College of Pathologists, 1994 to 1995 and 1999 – 2002.
- Ex officio member of the Histocompatibility and Immunogenetics Sub-committee of the Royal College of Pathologists, 1994 to 1995.
- Member of the Standing Committee on Academic Activities of the Royal College of Pathologists, 1994 to 1995; 1999 to 2002.
- Member of the Standing Advisory Committee on Haematology of the Royal College of Pathologists, 1994 to 1995.

- Chairman of the sub-committee of Transfusion Medicine, RCPath 1999-2002.
- Member of the Intercollegiate Committee in Haematology, 1999-2002.
- Royal Society of Medicine (RSM), member since 1980. President of the Section of Pathology and member of Council of the RSM: 1992/93 and 1993/94; Vice- President of the Section 1994 to 1999. Honorary Secretary - Council of the Section of Pathology, 1989 to 1990.
- Founder member and member of Council of NATA, the international, multidisciplinary Network for the Advances in Transfusion Alternatives, now renamed Network for the Advancement in Patient Blood Management, Haemostasis and Thrombosis, from 1998 to 2010. Membership continues up to now.
- Member, British Society for Haematology until 2007.
- Current member, British Medical Association, No D155935E.
- American Association of Blood Banks, No. 06500262 CONC 1P1283, until 2007
- Member of the Board of Directors of NetCord (International Network for Cord Blood Banks), 1999 - 2008.
- Member of the Board of the European School of Transfusion Medicine, from 1993 - 2008.
- Member European Society for Blood and Marrow Transplantation (EBMT) until 2007.
- Member European Society for Haematology (ESH) until 2006.
- Faculty Member of the 'Autoimmunity and autoimmune/inflammatory diseases' section of Rheumatology and Clinical Immunology for the Faculty of 1000 Medicine.

34. Committees and Working Parties:
    - WHO Adviser on Blood Transfusion from 1988 -2010.
    - Adviser to the Panamerican Health Organization 2008-2011 and chairperson of the Committee to evaluate the Plan for the Blood Programme in Latin America and the Caribbean Region.

- Member of the CMO's National Blood Transfusion Committee since its creation until 2005
- MRC Stem Cell Liaison Committee, 2003 to 2007.
- Chair of Steering Committee of MRC/NBS Clinical Studies Unit, 2000 to 2007.
- Founder member of the Steering Group of SHOT (Serious Hazards of Transfusion), the UK Haemovigilance programme, 1999 to 2007.
- Department of Health Advisory Committee on Hepatitis, active member for more than 10 years.
- Member of the USA Pharmacopeia (USP) in Washington (invited as international expert), 1996 to 2002.
- UK invited scientific member on BEST (Blood Experts for Standardisation and Technology Advancement), from 1996 to2007.
- Elected member of Council of the British Association for Bone Marrow Transplantation, 1996 to 2002.
- Chairman, UK Association for Cord Blood Banking, 1995 to 2000.
- Chairman, organising committee for the Consensus Conference on Platelet Transfusion, Royal College of Physicians, Edinburgh, October 1997.
- Member, organising committee for the Consensus Conference on Anti-D Prophylaxis, Royal College of Physicians, Edinburgh, April 1997.
- UK BTS Working Party on Immunoglobulins, active member until 1998.
- UK-NBTS National Working Party on Autologous Transfusion, 1990 to 1999.
- National Blood Transfusion Service representative at the British Standards Institute from 1992 until 2007 (Technical Committee HCC/11).
- International Society of Blood Transfusion: Working Party on Platelet Serology, member until 1998.
- Hospital Transfusion Committee, Hammersmith Hospital, 1991 to 1999.

- Hospital Transfusion Committee, St. Mary's Hospital, London W.2, from 1991 to 2007.
- Hospital Transfusion Committee Royal Free Hospital, from 1999 to 2007.
- UK representative on the Scientific Committee of the European School of Transfusion Medicine, (May 1993- 2007).
- Chairman, Special Interest Group on Haemolytic Disease of the Newborn of the British Blood Transfusion Society, December 1993 to 2001
- Chairman of the Committee for the study and reorganization of the National Blood Service, with the collaboration of medical and scientific consultants, as well as managers, accountants and IT experts, assisted by the management consultants, Bain & Co (1993 – 1995). This committee showed gross inequalities amongst blood centres and led to the consolidation of the 15 regional blood centres into a National Blood Authority consisting of 3 administrative Zones: North, London and South East and South West in 1995.
- Associate Partner, European Cord Blood Banking Group, 1995 to 2007.
- Member, UK Cord Blood Banking Group, 1995 to 2000.
- Chairman NBA - London & SE Zonal Research & Development Committee, 1996 to 1999.
- Member of the Working Party on Audit in Transfusion Medicine of the Royal College of Physicians, London.
- Chairman of the Professional Advisory Group on Transfusion Medicine, North West Thames RHA, 1993 to 1995.
- UK NBTS/NIBSC Liaison Group, active member until 1994
- U.K. NBTS and NIBSC: Standing Committee on National Standardization of Blood Grouping Reagents, Chairman until 1995.
- Management Committee of the National Blood Transfusion Service, member from December 1988 until Dec. 1990.
- North West Thames Regional Health Authority Professional Advisory Group on AIDS, active member until 1990.

- National Blood Transfusion Service-Bone Marrow Volunteer Registry Executive Group, active member, until May 1989.
- NBTS - CBLA Liaison Committee, active member until 1990.
- U.K. Advisory Committee of the National Blood Transfusion Service on Transfusion Transmitted Diseases, active member until 1993 (delegated to Dr Barbara for many of the meetings).
- Department of Health Expert Advisory Group on AIDS (EAGA), from its creation in 1985 until 1987.
- Initiator and Chairman of zonal CME meetings for Consultants, 1995 to 2000.

4. *Please set out how you kept abreast of scientific developments and research in your field.*

35. I read and studied a great deal and I gave numerous lectures at home and abroad.

36. I performed, directed and published my own research and had regular meetings and discussions with internal and external experts, including microbiologists, epidemiologists, immunohaematologists, haematologists, surgeons, anaesthetists. I did a great deal of teaching to junior doctors, medical students, nurses, student nurses and MLSOs. I participated and attended national and international meetings and congresses. I had a well-stocked library with the main medical journals: BMJ, New England Journal, the Lancet, Vox Sanguinis, Transfusion, Transfusion Medicine and many books. I also made use of the libraries at PHLS and the Royal Free Hospital, where I attended staff rounds. I belonged to several academic and scientific committees, many of which I chaired (see above). I was a member of the Editorial Boards of several scientific journals, such as Vox Sanguinis, TATM, Transfusion Medicine Reviews, Transfusion Medicine, Revista Medica de Chile.

37. I was the Review Editor of the international transfusion medicine journal Vox Sanguinis from 1989 until 1996 and from 2003 until 2007.

38. I was the Editor in Chief of Vox Sanguinis from 1996 – 2003.

39. I kept abreast with CME and chaired the local CME meetings.

40. I also reviewed the MMWR (Morbidity and Mortality Weekly Reports) from the Centres of Disease Control (CDC) in the United States to which the North London Blood Transfusion Centre subscribed and which came straight to my office. After reading it, I forwarded it to Dr John Barbara and the medical consultants at the centre.

41. I refereed manuscripts for several medical/ scientific journals, such as Vox Sanguinis, Transfusion, Transfusion Medicine Reviews, The Lancet, BMJ, BJH.

42. Perhaps the most important piece of work in terms of learning and research was my collaboration with Professor PL Mollison, in writing the textbook *'Blood Transfusion in Clinical Medicine'* which was regarded internationally as the 'bible' of blood transfusion in those days and is still held in very high regard among the transfusion medicine world. I had to keep fully abreast of all developments in order to be one of the 3 co- authors of this textbook.

43. I first met Professor Mollison when I came to England, as a British Council scholar at the MRC Blood Group Unit. I then became a Senior Registrar at the department of haematology in St Mary's Hospital in London. I applied for this job on the back of a scientific discovery of a new Rh blood group I had made whilst involved in clinical and scientific research at NLBTC, Edgware. Professor Mollison was leading the department, doing research in immunohematology, clinical blood transfusion and in the investigation of haemolytic transfusion reactions and haemolytic disease of the fetus and newborn. Professor Mollison was writing the 6th edition of his well known, single-authored textbook "Blood Transfusion in Clinical Medicine" and invited me to help him with the proof-reading, which I did. He then invited Professor CP Engelfriet, from Amsterdam and myself to join him as co-

authors of the 7th edition of the book, published in 1983. We shared the first drafts of the chapters; I was in charge, amongst others, of the new chapter on Transfusion Transmitted Infections. I was a co-author of 4 editions. Professor Mollison was regarded as the world-wide authority in Transfusion Medicine, in fact, he was known as the father of Transfusion Medicine.

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.*

44. In the 1980s I was involved as a witness in criminal proceedings, whilst I was deputy director of the North London Blood Transfusion Centre (NLBTC), in Edgware. I witnessed our Chief Medical Laboratory Scientific Officer (MLSO), John Harris, leaving the centre at weekends and after hours with full and heavy black plastic bin bags. Around that time the plasma blood grouping reagents, which had been collected from donors and which were very valuable to the Centre, had started disappearing. This made me suspicious as I knew John Harris had access to the freezers where the reagents and clinical plasma were stored. Since I had a good relationship with the Regional Health Authority chairperson, Dame Betty Patterson, I told her, in confidence, that I had a suspicion that John Harris was stealing large quantities of plasma from the Centre. I was told that this would be investigated and not to do anything as it would be taken care of. Around six months later, in 1983, I was asked to go to Dame Betty's office at the RHA, where I met the head of the investigation at Scotland Yard and was shown a photograph of a young John Harris, as a prisoner, and was asked whether I recognised him. I was informed that he had a past criminal record and was under investigation for stealing plasma in association with Dr Mark Patterson the consultant haematologist at the National Heart Hospital and Mr Lesley Dobson, a technician. I understand that the suspects' houses were raided and plasma was found in their freezers. They were charged

with selling plasma from the NBTS and the Army to a Scandinavian company for profit and sentenced with imprisonment at Ford Open Prison.

45. I was required to give evidence under oath during this investigation and attended the Central Criminal Court of England and Wales (the Old Bailey) to give my oral testimony.

46. I have not been asked to give evidence or opinion in relation to any other inquiries, nor have I been involved in any other criminal, civil or coronial investigations.

47. I was not involved in any inquiries in relation to HIV, HBV, HCV or vCJD.

48. I should add that I was involved with the National Look Back exercise on transfusion transmitted infections, including HIV and hepatitis C and I have been involved in the investigation of cases of transfusion transmitted infections but not as part of any inquiry or criminal / civil litigation / investigation.

Section 2: Your role at the North London Blood Transfusion Centre

6. *Please describe the roles, functions and responsibilities you had at the North London Blood Transfusion Centre ("NLBTC") during your period as Director and how they changed over time.*

49. My various roles at the North London Blood Transfusion Centre were as follows:

    a. Senior Scientific Officer at the North London Blood Transfusion Centre, Edgware, from October 1974 to May 1976. My responsibilities were the running of a small laboratory, doing research and immunohaematology and some teaching.

    b. Medical assistant in Blood Transfusion at North London Blood Transfusion Centre, Edgware from 1 June 1976 to 19 July 1978. My

responsibilities were the same as above, but with greater involvement in the running of the routine donation typing laboratory and the hospital reference immunohaematology laboratory.

c. Deputy Director and Consultant in Blood Transfusion of the North London Blood Transfusion Centre (NLBTC), Edgware from March 1980 to February 1984.

d. Chief Executive, Medical Director and Consultant in Blood Transfusion at the North London Blood Transfusion Centre from 1 February 1984 to November 1995.

e. I was Executive Director of the London and SouthEast Zone, National Blood Authority (NBA), Colindale Avenue, London, NW5 9BG from November 1995 to August 1999.

50. In my role as Chief Executive and Medical Director of NLBTC, I had overall managerial, budgetary and medical responsibility for the running of the North London Blood Transfusion Centre and, after that, the London and South East Zone, comprising four regional centres: Colindale (North London), Brentwood (North East London) Tooting (South London) and Cambridge. Ultimate executive responsibility lay with the NW Thames RHA for the NLBTC and with the NBA for the zones.

51. For NLBTC, the Regional Treasurer provided a cash allocation administered by the Edgware Hospital District Treasurer. In addition, we had authorization to charge Special Health Authorities and private sector hospitals for blood components and services.

52. I was responsible for budget control, collection, processing, testing, storage and distribution of blood, plasma and blood components.

53. I was responsible for the provision of reference services in Transfusion Medicine and for the provision of advice and training in transfusion medicine.

54. I was also responsible for regulatory compliance and research and development into blood transfusion.

55. With my management team I was responsible for advising the Regional Treasurer and the architects on the design and technical requirements of the new blood centre in Colindale. Consequently, I was responsible for the move of NLBTC from Edgware to Colindale.

56. Whilst I had overall responsibility, I was a good delegater to the excellent team of consultants, scientists and managers. We evolved and developed together, as a cohesive team.

57. When I took over the directorship of the North London Blood Transfusion Centre, in February 1984, my team and I established firm relationships with the hospitals which the Centre served. We were quite advanced in that area, compared with other centres.

58. I encouraged training and research in transfusion medicine and transfusion transmitted infections; this was not being done in a significant way before I took over the directorship. In addition to research and publications by the heads of departments and their teams, I contributed to a great deal of research which was published in over 200 papers and many letters or abstracts, as shown in my list of publications. We did research in transfusion medicine and adverse effects of transfusion, transfusion microbiology, donor research, HLA and transplantation, immunohaematology and haemolytic disease of the newborn, cord blood banking, tissue banking, blood components development, quality.

59. We trained a large number of senior registrars from the teaching hospitals in London. They came to us for 6 months training. Many of them held prominent positions when they became consultants.

60. We were very well funded by the Regional Health Authority because the Centre showed results and achieved targets. I am aware that that was not the case in all of the regional transfusion centres. In fact, we had the highest plasma production output per million population in the country. We also published the highest number of scientific papers and gave the highest number of lectures compared with other RTCs; we also served the highest number of complex specialist hospitals.

61. The RHA had a special interest in us and funded us by responding to detailed business plans which were achieved successfully. I met monthly with my direct superior, the Regional Medical Officer and regularly with the Regional Treasurer, signs of a very close and effective working relationship.

62. With respect to the funding of the research element of my role, this came from the RHA as part of our budget. All regions had a fund to allow for research and training. We had to justify, in our business plans, the research that we were proposing.

63. To my knowledge, we did not have any commercially funded research, although we did have a close relationship with Wellcome and Professor Richard Tedder, with whom we worked in developing the HIV test. However, Wellcome did not provide any commercial funding for our research.

64. My responsibilities day to day included, but were not limited to, budgetary responsibilities, managerial responsibilities and the responsibility for providing sufficient, safe blood, blood components and transfusion medicine advisory, diagnostic and therapeutic services to hospitals in the Region. I was also responsible for meeting our regional plasma targets.

65. Realizing that the NBTS, with its expertise in the care and selection of donors, as well as Good Manufacturing and Good Laboratory Practice (GMP and GLP), and Transplantation Immunology, with the help of the RHA and our clinical and scientific staff, in addition to the interest of clinicians in London hospitals, we expanded our activities to found the first and only NHS CORD BLOOD BANK, followed by the LONDON TISSUE BANK. Both these initiatives served many patients, improving the quality of and saving many lives. At the Cord Blood Bank, our staff, with the help of obstetricians, midwives and management in NHS hospitals, counselled and consented antenatal patients to give blood samples for mandatory testing and donation of their placental blood, rich in stem cells. Cord blood was screened, HLA typed and stored in liquid nitrogen for future transplantation of matched patients, mostly leukaemic children. At the Tissue Bank, prior agreement with clinicians and hospital managers, our staff obtained informed consent from relatives in order to collect tissues, such as bones, skin and cartilages from cadaveric donors. These tissues would be quarantined and stored as appropriate, in order to help many patients, especially in orthopaedic and burns units.

66. I had to deal with any complaints from donors, the public, clinicians and hospital blood banks.

67. I had responsibility for training in transfusion medicine and for research and development related to transfusion medicine in the Region.

68. I also had responsibility for the donor panel.

69. The overall responsibility for running NLBTC fell to me, but I delegated the various components, mostly to consultants but also to a business manager who shared responsibility for the budget. My business manager was Patrick Sullivan and the consultants were Dr Patricia Hewitt, Dr Mahes De Silva, Dr Ruth Warwick and Dr Branko Brozovic. I delegated different areas of the service to each of these consultants; for example, production and quality was Dr Brozovic; Dr Hewitt was donor services to start with and then the

clinical aspects of transfusion-transmitted infections, including donors' follow-up and look-back.

7. *Please describe the organisation of the NLBTC during your period as Director, including:*

a) Its structure and staffing and in particular who you were accountable to;

70. Blood services are very staff demanding because a high volume of manpower is required in the mobile teams and static clinics to collect the blood and apheresis components.

71. The North London Blood Transfusion Centre had staffing of around 350 people by 1995; consisting of medical and scientific doctors, MLSOs, scientific officers, nurses, technicians, laboratory aides, admin and clerical staff, drivers, team leaders, donor attendants, cleaners and porters.

72. Staff numbers increased annually (I would estimate approximately 450 before we became zonal), as demands for blood, plasma, products and services grew (e.g. creation of Cord Blood Bank, Tissue Bank, Luton apheresis clinic, increase in HLA complexity and typing, compliance with GMP and accreditation, etc.).

73. Advances in medicine and surgery such as Bone Marrow Transplantation, Liver and Heart Transplantation, significantly increased demands for blood and platelets as well as for diagnostic services.

74. The structure comprised a Management Team formed by medical consultants in charge of the different departments (see below) and a business manager in charge of the finances, facilities, IT and personnel.

75. The structure comprised of departments, as follows:

a) Donor Services, with;

- Donor records
- Donor organization;
- Donor recruitment and publicity,
- Call-up and donor communications

b) Mobile teams: doctors, nurses, donor attendants and drivers. This section had the majority of staff members.

c) Static clinics for routine and apheresis donations: doctors, nurses, donor attendants and receptionists.

d) Components Laboratory or Processing of Blood. A laboratory with temperature control for the processing of whole blood into red cells, platelets, plasma and cryoprecipitate. Managed by scientific officers and staffed by laboratory aides.

e) Biochemistry Lab, staffed by scientific officers and lab aides, doing haemoglobin electrophoresis for blood from donors coming from areas with hemoglobinopathies. Biochemical profile (liver function tests and protein/ albumin, FBC) on all apheresis donations.

f) Microbiology Lab; headed by a Senior Scientific Officer and staffed by scientific officers, MLSOs and lab aides. In charge of screening for all the mandatory microbiological markers (at the beginning only HBV and syphilis and occasionally HAV; then from 1985, HIV, CMV, Chagas' disease and malaria on selected donors). Also dealt with the investigation of transfusion- transmitted viral and bacterial infections.

g) Blood Group Serology or Red Cell Immunohaematology, headed by a Chief MLSO and staffed by MLSOs and lab aides. Performed blood grouping and red cell antibody screening on all blood donations. Provision of especially typed donor panel for testing of patients immunized to red cell antigens, provision of typed blood for patients with Thalassaemia and sickle cell disease. Investigation of haemolytic

transfusion reactions referred from hospital blood banks. Follow -up of anti-RhD in antenatal patients. Quantitation of anti-RhD in plasma destined for the production of anti-D immunoglobulin by BPL. This laboratory also provided red cell panels to all hospital blood banks for pre-transfusion testing.

h) Histocompatibility and Immunogenetics laboratory headed by a Senior Scientific Officer and staffed by scientific officers and lab aides. Performed HLA typing for the British Bone Marrow Registry (BBMR), for transplant patients, for the provision of HLA-typed platelets for leukaemic and bone marrow transplant patients.

i) Administration, Human Resources and Finance.

j) Teaching and Training Department, planned training for all grades of staff at the Centre as well as for Senior Registrars, nurses and MLSOs on rotation. The training and teaching were performed by consultants, scientists, nurses and MLSOs.

k) Cord Blood Bank.

l) Tissue Bank.

m) Quality Department, in charge of Total Quality throughout the Centre as well as GMP and GLP compliance.

76. The medical consultants and the business manager were in charge of the different departments and formed the management team that met every Monday morning.

77. I was accountable to the Regional Health Authority through the Regional Medical Officer (Dr Frank Seymour and then Dr Sheila Adam) with whom I met on a monthly basis, submitting a written report of our progress to date.

b) How it was funded;

78. The funding was subject to a business plan which was comprehensively produced every year and which summarised achievements of the previous year. According to that, we were granted a cash allocation, administered by the Edgware Hospital District Treasurer. In addition, we were allowed to charge Special HAs and the private sector for blood components and services; this revenue was added to our annual allocation. The RHA received an allocation for plasma for fractionation, mostly in finished blood products (albumin, Factor VIII, Factor IX, intramuscular immunoglobulin, intravenous immunoglobulin and specific immunoglobulins) which was never enough to recover our costs. Hence RHAs had to subsidize plasma for BPL; the greater the plasma contribution, the greater the subsidy.

79. The money was administered by the District Treasurer, as delegated by Region so, at the end of the year, if there was any surplus of money, it went back to the RHA via the District Treasurer, who at the time was Mr Tom Binns.

80. There was a capital budget and a revenue budget; the capital budget was for equipment, buildings and vehicles and the revenue budget for staffing and disposables such as reagents/ consumables. With respect to how the budget was spent, the majority went to the collection of blood in terms of staffing the mobile teams, recruitment of donors and blood packs.

81. As soon as I was appointed Director of NLBTC, I asked for a new blood centre, as the quality of the centre in Edgware was not fit for purpose. The RHA granted the capital and a new centre was purpose built in the grounds of Colindale Hospital, adjacent to the PHLS. We moved to the new centre in 1989.

82. Another large item of expenditure is blood packs, for which we had to tender on an annual Regional basis. Equipment and reagents were also another item of high expenditure. Each regional transfusion centre had to tender for

the supply of equipment and blood packs, reagents and disposables until the creation of the NBA with the formation of zones.

83. As Regional Transfusion Centre Director I had autonomy, guided by the RHA, over how the budget was spent and on tendering for supplies until the service became zonal and zonal contracts were introduced. Before the creation of the NBA, there was no central purchasing and, to my knowledge, each centre operated in this way, with greater or lesser autonomy.

84. When the service became zonal, except for IT services and issues related to the logo and national publicity, we purchased and tendered as three separate zones until we became a unified national service, under the National Blood Authority, at which point the purchasing and tendering became national. This, in my opinion, was a major advantage of the reorganisation of the national service.

85. When the 3 zones were created and I became Chief Executive of the London and South-East Zone in 1995, we appointed Ian Gorrard, a zonal purchasing manager who tendered efficiently for all our needs.

86. We were the only zone that broke even; the other zones had big deficits. The reasons for our success were as follows:

    a) Pricing: since pricing was zonal, we were more aggressive justifying increases to cover legitimate costs.

    b) Efficiency: we were more efficient, as I demanded it from all heads of function.

    c) Control of headcount: although painful, we reconciled Finance and HR to give us a proper baseline. In fact, we implemented our share of the headcount reduction, mandated by the NBA.

d) Enterprising: for example, we charged rental for the space freed up at Cambridge as a result of transferring processing and testing to Brentwood.

e) Cost efficiency: we abolished the Centre management teams.

f) Self-sufficiency in red cells and platelets: we created 2 new mobile teams in Thetford and Ipswich, which enabled us to meet the rising demand, thus improving our financial equation, due to cross-charging.

g) Capital: we were good at spending our capital. Although this meant higher capital charges, the extra efficiencies of the new equipment meant greater revenue benefits.

h) Aggressiveness in closing inefficient or obsolete labs and departments, such as the HLA typing lab in Brentwood and the processing lab in Cambridge.

c) Its remit;

87. The remit of the North London Blood Transfusion Centre, was the provision of sufficient safe blood and blood components to all hospitals in the North West Thames Region (public, private and special health authorities) and of sufficient plasma to the BPL. The remit was also to provide diagnostic services and transfusion medicine services to all hospitals in the region and to keep abreast with advances in transfusion and transplantation medicine, to provide training to junior doctors, nurses, scientists and MLSOs, to liaise with hospitals and to comply with regulatory authorities. All this had to be provided within a budget and a quality framework. Eventually, we also provided peripheral blood stem cells, cord blood stem cells and tissues not only to our Region but also to other Regions.

d) Any targets for the amount of plasma collected by the centre and whether the meeting of these targets was linked to the funding of the NLBTC;

88. I cannot recall the exact plasma targets that were set before the financial year 1989/90 but I can recall surpassing them with recovered and apheresis plasma, as well as with specific plasmas (e.g. anti-D, anti-HBV, anti-rabies, anti-VZ, anti-tetanus). From the papers supplied to me by the IBI, the plasma targets for 89/90 were 8.82 tonnes of FFP per million population.

89. The targets and prices of recovered and apheresis plasma must have been set by the Department of Health in conjunction with BPL. Regional centres had no say in setting the plasma targets, nor in the pricing of the different types of plasma. Understandably, apheresis plasma achieved a higher price than recovered plasma and specific plasmas were priced even higher. RHAs were given the monies/ finished plasma products by the Department of Health or BPL according to production by the respective centres, but the price did not cover the costs, so good performers were penalized and RHAs had to cover the excess costs, thus subsidizing BPL. The payment by BPL was in finished product, such as Factor VIII, albumin, immunoglobulins.

90. We had three very successful and state of the art apheresis clinics for the collection of platelets and plasma, as well as specific plasma (anti-D, anti-HBV, anti-rabies, anti-tetanus and anti-VZ). In fact, NLBTC was a pioneer apheresis centre under Dr Tom Cleghorn, a past director in the 1960s and 1970s.

91. The meeting of these targets was linked, in part, to the funding of the North London Blood Transfusion Centre (see 78-82).

92. The Centre was particularly good at meeting targets because we had a very committed and dedicated team that was pulling in the same direction and took pride in the work that it was doing. Staff commitment was a product of good education and training, as well as good management.

93. I am not certain what information was used to set the targets year on year, but I assume that this was done based on population size for the particular regions and on past performance. The targets of plasma kilograms per million population were the same for every regional blood centre. I did not know how the targets were set and I did not ask this question. As the demand for plasma increased over time, the targets would also increase.

94. By meeting and exceeding targets, the North London Blood Transfusion Centre was able to achieve a consistently good level of funding for plasma for fractionation, from Region. However, NW Thames RHA was subsidizing the cost of plasma for fractionation. For example, for the financial year 1990/91, the price paid by BPL for recovered plasma was £35 per kg and for apheresis plasma £60 per kg. On the basis of a detailed costing exercise, following national guidelines, our costs were £54 and £89 respectively. Hence, NLBTC's estimated shortfall for that year was over £1 million, which had to be covered by Districts purchasing our blood components and services, with the advent of the internal market. Ironically, precisely because we were the most successful blood centre in plasma procurement, this shortfall was one of the highest in the country.

95. In 1990/91 NLBTC supplied BPL with 12.77 tonnes of plasma per million population compared with an England and Wales average of 9.28 tonnes. Because of the introduction of the NHS internal market, we had moved into a contractual position where the Centre was forced to recover all costs in contractual arrangements with purchasers. Hence, the above shortfall had to be met by individual contracts with purchasers of blood and blood components, mainly NHS hospitals. This had the effect of increasing our prices for blood and blood components by about 20%. As a result, hospitals were heavily subsidising the procurement of plasma for BPL. In the preceding years our BPL deficit had been funded by the NW Thames RHA.

96. I should make clear that the targets were not just centred around the collection of plasma for fractionation, but also the collection of other blood components such as red cells and platelets, which were also vitally

important and covered many more patients. We had to provide essential specialized blood components, such as HLA-matched platelets for bone marrow transplant patients, red cell antigen-compatible blood for patients with sickle cell disease and thalassaemia, especially typed blood for intrauterine transfusions and several other tailor – made blood components on a daily basis.

97. We were also assessed on the quality of service we provided to hospitals and the care given to donors. Having minimal or no complaints from the hospitals or donors would be another measure of performance against the centre.

98. So, whilst plasma collection was part of our target, there were other aspects such as the provision of labile blood components like red cells and platelets as well as stem cells, tissues, diagnostic and transfusion medicine advisory services which were also extremely important for patient care. All of these issues formed our targets.

e) How decisions were made, in particular how you incorporated the views of the scientists and other experts working at the NLBTC;

99. As I have stated, I did not make decisions on my own. I was surrounded by consultants and scientists in the Centre who developed and became international experts in their fields over time. I consulted with these experts, as well as with external experts, such as Dr David S Dane, Professor RS Tedder, Professor PL Mollison, as appropriate, before decisions were made.

100. For example, Dr M De Silva became an expert in red cell immunohematology and haemolytic disease of the newborn, Dr M Brennan in donor services, Drs P. Hewitt and Dr J. Barbara in transfusion transmitted infections, Dr C. Navarrete in HLA and transplantation immunology, Drs D Fehily and R Warwick in tissue and cord blood banking.

101. The Centre was also situated next to the PHLS and CDSC, so I was in close contact with Dr Phillip Mortimer, Dr John Parry and Janet Mortimer with whom I could consult before making decisions.

102. I was in contact with the other transfusion centres and we had the Regional Transfusion Directors (RTD) meetings where information, at a national level could be exchanged. We also had close links with the Scottish Blood Transfusion Service and with IBGRL (the International Blood Group Reference Lab).

103. The Regional Transfusion Directors meetings took place on a monthly basis. If I was unable to attend the meetings, I would ask a deputy such as Dr Patricia Hewitt to attend in my place. She would feed back to the Centre management team.

f) The impact on decision making of having targets for the collection of plasma;

104. In order to meet and surpass the targets, I asked the Regional Health Authority for funding, making the appropriate justifications in writing. This is how we were given funding for the creation of the apheresis clinic in Luton (in addition to the 2 existing apheresis clinics in Edgware and central London), for the blood-mobiles and for extra blood collection staffing, etc.

105. The collection of plasma and the drive for self-sufficiency was very important but not all consuming as there were other important aspects, as I have stated above (87) and for which we were appraised as a centre. For example, road traffic accidents, post-partum haemorrhage, heart-lung and liver transplants and leukaemia patients require urgent transfusion of red cells and platelets, as these patients could not survive without these blood components, for which there is no alternative. We also collected stem cells from peripheral blood and from cord blood (placenta) for adult and paediatric patients with conditions such as leukaemia, lymphomas, sickle-cell disease, etc. We collected bones, skin and other tissues for hip replacements, burns

patients and many others. Hence, the collection of plasma for fractionation was only part of the remit of the blood centre.

g) *Its place in the NBTS together with information as to whom the centre was answerable to, if anyone. When answering this question, please refer to paragraphs 1-17 of Dr Gunson's statement in A and Others v National Blood Authority and another [2001] 3 All E.r. 289 (A & Others) and say whether you agree with what is said there (NHBT0000026_009);*

106. I have read and agree with paragraphs 1 – 17 of Dr Harold Gunson's statement given in the case *A & Others – v – National Blood Authority and another* [2001] 3 All ER 289 (NHBT0000026_009).

107. Regional centres were answerable to the Regional Health Authorities and as expressed in Dr Gunson's statement, achievements under the National Directorate, such as (limited) inter-regional transfers of blood components, national standardisation, quality improvements, national criteria for donor selection and recruitment, national Management Information systems (MIS) were all agreed by the 15 RTC directors on a voluntary basis.

108. The Regional Transfusion Centres were answerable to their respective Regional Health Authorities.

h) *Whether NLBTC was associated or linked with other Regional Transfusion Centres, if so, how and for what purpose;*

109. With respect to the other RTCs and directors, the best way I can describe it is likened to a feudal system, where we had autonomy over our own regions.

110. The only link with other RTCs was through the meetings of Regional Transfusion Directors (RTD meetings). In 1978 the divisions were created and the North London Blood Transfusion Centre was tangentially linked with three other RTCs (Brentwood, Tooting and Cambridge).

111. Consultants and scientists at the Regional Transfusion Centres met at divisional meetings to collaborate, share information and inform decision-making.

112. Because, by physical proximity, BPL was close to the North London Blood Transfusion Centre, I would say that we had a relatively strong link and relationship with BPL. For the same reason of proximity, NIBSC and the PHLS would make special requests to the North London Blood Transfusion Centre, for example, for the supply of special plasma for testing and controls. We shared our libraries and scientific meetings with the PHLS, as we were located next to each other.

i) Whether the centre was subject to any form of regulation;

113. Yes, we were regularly inspected / regulated by:

- The Medicines Inspectorate for compliance with Good Manufacturing Practice (GMP) and Quality Standards. The Inspectorate had the power to close a Centre for non-compliance
- Financial control by the Regional Treasurer
- External audits, from other RTCs
- Internal audits
- RCPath accreditation of laboratories
- NIBSC controls for microbiological testing
- NEQAS for blood group serology
- PHLS microbiology panel was tested by us on a voluntary basis

114. Regulation of the blood services and BPL really started formally after the removal of Crown Immunity in April 1991 and the appointment of the MCA (Medicines Control Agency) under the Medicines Act (now MHRA) as the licensing authority, i.e. blood centres needed a licence from then on and inspections of Transfusion Centres were mandatory every 2 years for holding a manufacturer's license.

115. The MCA had the power to close a Blood Centre if critical deficiencies were found. Before then we had inspections by the Medicines Inspectorate (Mr Mike Cavanagh), with quality systems based on BS 5750 and accreditation by BSI in some centres, such as NLBTC. The inspections by the Medicines Inspector were "advisory, rather than enforceable". Inspectors used the Orange Guide, in force at the time, as the standard and also the Red Book guidelines (written by UKBTS and NIBSC staff; I was a member of the working party that drafted different editions) as an interpretation of requirements relating to blood services. The first edition of the Red Book was written in the 1980's; it was first published by HMSO in 1989, as "Guidelines for the Blood Transfusion Services in the United Kingdom 1989".

116. In 1984, the CBLA started to introduce some national standardisation in the various regional transfusion centres.

117. Also, during Dr Harold Gunson's time as National Director we had internal and external audits performed by the Quality Managers at each Regional Centre, based on TQM (Total Quality Management).

118. With the introduction of the European Directive for Blood and Blood Products, the MCA inspections were superseded by inspections against BSQR (Blood Safety and Quality Regulations 2005) and EU GMP.

119. There were elements of safety and control built into automated test systems and the basic IT systems that were eventually standardised into the nationally adopted "PULSE" IT system in 1991. PULSE was developed originally at NLBTC because of issues relating to the theft of plasma. PULSE became fully operational nationally in 1997, thus allowing every area of the country to have access to the whole national donor panel, to daily blood components stocks throughout the country and to all essential information of the NBA.

120. The record keeping of donors and donations was in the 101 cards for each donor, recording demographics, donation history and test results. Bleed sheets recorded each donor session, with the names of donors bled, partially bled and attended but not bled. Paper-based medical record files for apheresis donors were eventually replaced with computerised records.

121. We kept an archive of reference serum samples from all whole blood and apheresis donations. I do not know if and from when this was a practice for all RTCs but it certainly was at NLBTC. This started before my time, as advised by Dr D.S. Dane (Head of Microbiology at the Middlesex Hospital and Professor Richard Tedder's predecessor), storing serum samples from the glass pilot tubes used for microbiological screening of blood and apheresis donations. With the advent of microplates, the method of storage of reference samples was replaced by deep well microplate samples, which occupied less space and were more easily labelled and identifiable. Such microplates could be retained for longer; after the vCJD outbreak, they were retained indefinitely.

122. As blood donors gave their blood to be used for the benefit of others, there was implicit consent for testing and anything else necessary to ensure the safety of the blood donation to be given to patients. We took explicit consent when the NBS started screening for anti-HIV in 1985.

j) NLBTC's relationship with the Blood Products Laboratory (BPL) and any other laboratory.

123. The director and the Chief Executive of BPL normally attended the Regional Transfusion Directors Meetings, so I would say we had a good relationship with BPL through those meetings, but also given our Region's proximity to BPL, we had a closer relationship with BPL than perhaps other regions did. BPL would send their staff to us for training and learning regarding the production of plasma and the screening of blood donations.

124. My Centre would be given targets to meet which included plasma to be sent to BPL.

125. We had meetings between the NBTS and the CBLA, which were separate liaison meetings attended by representatives from BPL such as Dr Richard Lane, Director and Mr Bernard Crowley, Chief Executive.

126. I would say that the Centre had a healthy relationship with BPL, but BPL's main interest was in the collection of plasma, whereas the Centre had many other functions and purposes and other patient and hospital demands that we had to meet. So, whilst the focus of BPL was solely on the collection of plasma for fractionation, this was not the sole focus of the North London Blood Transfusion Centre or of any other Blood Centre.

127. With respect to other laboratories, we had relationships with, there was the NIBSC and the PHLS, but these were not plasma-producing laboratories. The NIBSC (National Institute for Biological Standards and Control) was located near to us and we were invited to join their meetings. The Public Health Laboratory was located in shared grounds with us, with just a fence separating us. As stated above, we had a close relationship with the Virology Department at the Middlesex Hospital and with the Haematology Departments at the Royal Free and St Mary's Hospitals. Our consultants had close relationships with several hospitals and their laboratories, as members of their hospital transfusion committees.

8. *On 19 July 1990 you wrote to Dr Gunson setting out your view on the proposal for a nationally managed blood transfusion service in England and Wales (NHBT0001875). Why were you against this proposal?*

128. The rationale behind my thinking at the time is clearly set out in my response of 19 July 1990 (NHBT0001875).

129. As I stated clearly in my letter (and as shown later with my work, that led to the reorganisation of the NBTS), I was not against a nationally managed

blood transfusion service in England and Wales, but rather against the specifics of the proposal that Dr Harold Gunson was making, set out in his draft proposal to the Department of Health for National Management of the Blood Transfusion Service in England and Wales of July 1990 (NHBT0001781) .

130. I did not agree with the proposal Dr Gunson was making. I was in support of a national blood service, as can be seen in my CV, but I felt that this specific proposal went against the ethos of the Department of Health at the time, with respect to the internal market and the devolution of services from Regional Health Authorities to Districts. The trend at the time was to dispense with large national organisations and move management accountability and responsibility, including budgetary control, as far down as possible. I felt that Dr Gunson's was a badly proposed initiative and my reasons for that are clearly set out in my letter, as referenced above.

131. I felt that there was a lot of inequality between the different blood centres at the time with respect to performance, how and to what extent they were funded and managed and their relationship with their hospitals and patients. The proposal lacked clarity in terms of how this inequality would be addressed and how we would level up this service rather than levelling down, since no additional funding was envisaged/proposed. No concrete evidence was given that national management would improve local management.

132. I felt the North London Blood Transfusion Centre was performing well by all indices and targets. We surpassed our plasma targets significantly, we had no shortages of blood, we were innovators in Transfusion Medicine and well respected by our peers in hospitals. We had the best track record in R&D; national management might have curtailed this, as no extra money was proposed for R&D. The issue of flexibility for local pay and conditions was not addressed. The costs of establishing National Management were not considered, despite the DoH having considered them too high in 1987. The provision of transfusion medicine services to hospitals was completely

ignored in the proposal. If there was a possibility of levelling up the service, then I would have been fully behind the proposal, but I did not feel that what was being suggested in Dr Gunson's proposal would improve the service.

133. The situation analysis and strategic plan we developed in 1994/95, with the collaboration of Bain and Co (funded by the Department of Health), concluded that we had too many centres nationally, and the only way to make the Service cost effective was to consolidate the number of centres. This study led to the creation of the 3 Zones by the National Blood Authority, (NBA) and eventually to a nationally managed service. Consolidation was not addressed in Dr Gunson's proposal, nor was the plasma collection programme or the relationship of the NBTS with BPL.

134. I had a lot of respect for Dr Gunson and tried to support him with the proposals and recommendations he would make, but I felt that this particular proposal was adding an extra layer of management, which was not in the best interests of the service, without achieving the desired aims or benefits. I recognised and sympathised with the issues that Dr Gunson had sought to address in his proposal, but my feeling on this occasion was that the solution being proposed was not a good one. The paper did not address the White Paper principles, i.e. the concepts of purchaser-provider and resource management initiative, nor the benefits for patient care that could be accrued by a nationally managed Service. I can see that Dr Gunson was aiming for national consistency, for which I was fully behind him but, for the reasons set out in my response, I did not feel that the solution proposed was a properly considered or funded one. The other consultants at North London agreed with me, except for Dr Branko Brozovic who agreed with Dr Gunson's proposal.

Section 3: Meetings of Regional Transfusion Centre Directors

9. *The Inquiry holds meeting minutes between the Directors of Regional Transfusion Centres ("RTCs") in the United Kingdom from approximately 1948 to 1989, some of which you attended in your capacity as Director of the NLBTC.*

Who established these meetings? What do you consider to have been the purpose(s) of those meetings?

135. The Regional Transfusion Directors Meetings were established by Dr William Maycock and the Ministry or the Department of Health long before I first took up the post of Director of NLBTC. My understanding of their purpose was for information exchange and for unifying criteria and standardisation as well as compilation of national guidelines and to achieve consistency and best practice between the Regional Transfusion Centres.

136. The meetings were useful, but in my opinion, the same could have been achieved with fewer meetings and more communication by other means, such as letters or circulars.

10. *Please explain, as far as you are able, the decision-making remit of the group. Did the RTC directors meet in a decision-making capacity or otherwise? As far as you are aware, 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.*

137. The remit of the meetings was more to do with the sharing of information, but there were some areas where we made decisions, for example, in relation to national guidelines and best practice, and the criteria for donor selection. So, in my opinion, there were some positive things that came out of these meetings, with respect to collective decisions that were made. We also agreed on principles of quality assurance and external Quality audits between RTCs and eventually on the movement of blood components from areas of surplus to areas of need.

138. We also achieved a national management information system (MIS), which came about from these meetings and was the precursor of the NBA national IT system.

139. With respect to the running of the centre, and meeting demands for products and services as well as for R&D, those decisions were made by me and my management team. So, at a local level, we made our own decisions with the Regional Health Authority as the overall body overseeing these. With respect to national standards, these were agreed by consensus at the Regional Transfusion Directors Meetings. Decisions on the national introduction of screening tests for blood donations were made by the DoH.

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

140. I had no involvement in the preparation of the terms of reference for these meetings as they were set up before I took up my director post.

141. I have stated above that my feeling is that the same outcome could have been achieved from these meetings with less frequency. We had limited to no executive power at the meetings to make decisions. Days were spent travelling to and from the meetings as these were held around the country. For RTCs, the executive power lay with the RHAs, delegated to a greater or smaller extent to RTDs, depending on each RHA. Decisions of a national nature, such as the introduction of a screening test on blood donations were taken by the Department of Health officials, following advice from the ACVSB (the Advisory Committee for the Virological Safety of Blood) at first and then from MSBT (committee for the Microbiological Safety of Blood and Tissues for Transplantation). Decisions on self-sufficiency for blood and plasma for fractionation were taken by the Department of Health. However, many decisions were regional, following advice from the RTC management team, such as regional targets for labile blood components, liaison with hospitals, innovations, such as creation of a cord blood bank and of a tissue bank

12. *The documents the Inquiry holds indicate that the last of these meetings took place on 18 January 1989. A copy of the minute from the last meeting is attached*

(NHBT0018188). According to the minute, you "proposed that the RTD meetings be abolished". Please explain the reasons for your proposal.

142. The minutes do not state that I proposed that RTD meetings be abolished. This was a proposal made by the chairman, Dr Wagstaff, and was unanimously approved as there was no point of holding such meetings any longer, further to the creation of the National Management Committee (NMC). As proposed by Dr Gunson, it was decided that Divisions would meet regularly to discuss papers coming from the NMC.

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

143. I cannot remember it specifically, but the minutes of the meeting seem to set out the reasoning behind the decision, which was that Dr Gunson reported that, since the last RTD meeting, the National Management Committee (NMC) of the NBTS had been established and had met on 2 December 1988. Thus RTD meetings had been superseded by the National Management Committee. Dr Gunson felt it important that the minutes of the NMC meetings should be discussed in the Divisions so that the views of all medical staff in the service could be provided to the NMC. He proposed that the Divisions should meet 3-4 weeks after the NMC meetings to discuss the minutes and provide any input for the next meeting. This would involve five meetings per annum and if this proposal was agreed then he asked us to consider the future of RTD meetings. He proposed one annual meeting a year of all consultants in the NBTS.

144. The business part of the annual meeting would be shorter, with the National Director summarising management activity and the remainder of the meeting would be devoted to scientific and technical aspects such as cross-accounting, research and quality control. The regular slot for BPL update would no longer be needed because of the creation of the CBLA/NBTS

liaison committee which would meet regularly, probably quarterly, and report to the NMC. It is noted that the meeting discussed Dr Gunson's proposals and the need for change and the national structure was welcomed. As the discussion of an annual medical/scientific consultants meeting developed, it became clear that any managerial role for the RTD meetings was superfluous. It was agreed that there was value in meeting once a year for a one-day scientific symposium, which would be separate from the BBTS meetings.

145. Dr Gunson confirmed that contact with SNBTS would be maintained by regular meetings between himself and Dr Cash (Director of the SNBTS). Dr Pickles confirmed that the Department of Health accepted the changes and Dr Gunson noted that three avenues of communication with the Department would be maintained: - direct contact between himself and Dr Pickles and between Dr Moore and Mr Canavan; via the NHS Management Board Coordinating committee and via the annual report submitted by the National Director on Management Objectives in the NBTS. Dr Rogers asked how the Department's performance would be evaluated and the Chairman indicated that Directors would be watching to see that Dr Gunson's views were conveyed by the Department to Regional Health Authorities.

146. Hence, since the creation of the NMC was a fait accompli, the RTD meetings were redundant and there was no point in discussing the advantages and disadvantages of such meetings.

147. The chairman, Dr Wagstaff summarised the position and asked if it was the wish of those present that RTD meetings should be discontinued and replaced by an Annual Meeting open to all NBTS Consultants with a scientific agenda; it is recorded that this was agreed unanimously.

14. *Please advise, as far as you are able, why these meetings ceased and whether they were replaced with another forum with which RTC Directors could communicate.*

148. As explained above, with the creation of the NMC, the RTD meetings became redundant. They were replaced by Divisional meetings to discuss the papers from the NMC, 5 times a year and by an annual one-day meeting of NBTS medical and scientific consultants which was mostly of a scientific and technical nature.

149. Whilst meetings themselves stopped, there were still lines of communication between the different centres, mostly in writing, if we needed to get in touch. As I said, we also had the Divisional meetings.

150. My recollection is that the divisional meetings continued until we became a National Blood Authority.

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

151. The RTD meetings were replaced, as stated above. The changes had no impact on the North London Blood Transfusion Centre.

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

152. I agree with Dr Gunson's statement with respect to the National Directorate.

153. Although the National Directorate had no executive or budgetary powers, the Regional Transfusion Directors agreed several national policies by persuasion and consensus. We had national criteria for donor selection, instituted an MIS, reported daily to the National Director on regional blood components stocks, agreed the transfer of blood components between RTCs, agreed on how and when to test for microbial agents, on quality standards, etc.

154. The RTD meetings and the National Directorate were non-executive coordinating bodies that advised the Department of Health on policy regarding plasma on one side and blood components and services on the other. RTDs were given targets of plasma for fractionation by the Department of Health

155. The first time that the English and North Wales blood services were ever under a single management organisation was with the formation of the National Blood Authority (NBA) in April 1993, responsible for the CBLA, the IBGRL and the National Directorate. In 1994, the NBA became responsible for the NBTS, with the attendant transfer of responsibility for the RTCs from the RHAs. Prior to that, anything that was "agreed" was through committees, working parties, etc. and executed through the RHAs, possibly under directives from the Department of Health.

156. It was the RHAs that were responsible for the RTCs until 1994.

157. It was the lack of executive authority which caused a significant problem for the success of the National Directorate but, nevertheless as mentioned above, we agreed several important national policies and implemented important initiatives, perhaps most significant of which was the creation of the national management information system. In 1990/91 a truly national IT system, was introduced; it was improved and developed and was used with great success for many years.

17. *In the same statement, Dr Gunson commented that the work of the 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?*

158. I became a firm believer in a truly national blood service. The multi-professional committee that I chaired and led to the situation analysis of the

NBTS, with the assistance of Bain & Co management consultants, showed that, in the 15 Centres, there was a great deal of inequality, inefficiency, duplication and wastage. There was a need for restructure of the service with consolidation, a national IT system and common standards.

At the time that Dr Gunson's proposal was made, it coincided with the introduction of the internal market and devolution of budgets to Districts; it was a very difficult and uncertain time for devolved services. To have a nationally managed blood service in the manner in which it was being proposed by Dr Gunson, without proper funding and plans for consolidation, made no sense to me. This was eventually achieved, but it meant drastic change, not proposed in Dr Gunson's document.

159. My view was that it would be too expensive and impractical to have the 15 independently operating RTCs under one centralised management, with no additional funding and no plans for efficiency savings. The Department of Health-funded situation analysis performed by Bain & Co consultants and the NBTS senior staff demonstrated this. There was a need for consolidation of services because the costs of the blood services were increasing in view of:

a) The measures seeking to attain "zero risk" of blood and blood products as demanded by the public and the media. (The public and the media will accept risks of anaesthesia, driving, smoking, attending football matches, etc. but will demand zero risk from the blood supply.) These measures, such as expensive screening tests and confirmatory assays, universal leucodepletion, CMV antibody testing, molecular HLA typing, etc. meant a considerable increase in the cost of processing and testing of blood.

b) Need for licensing, certification, accreditation and audit.

c) Need for novel therapies and novel products.

d) New and expensive technologies.

e) Need to improve the quality of the estate and equipment.

The benefits of a truly national blood service, under national management were numerous, to name but a few:

a) National inventory with proper monitoring and movable blood stocks

b) Standardization

c) Centralized deployment efficiency

d) Single national standards

e) Better use of resources and decrease of wastage

f) Single, centralized IT system

g) National donor panel and unified message to donors

h) Shared expertise: medical, scientific and technical

i) National Quality systems and national audits

j) National Quality Incident reporting: easier to learn from mistakes

k) Bulk processing and testing: no need for 15 RTCs

l) Easy access to specialist products nationally

m) National Research & Development

n) Improved quality of the estate, with consolidation into fewer, better sites.

Section 4: Information handling by and information sharing between RTCs

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

160. We had a Records Department established before the time of computerisation. Details of donors with his / her date of birth, address, preferred donor session and donor history were kept in 101 cards. These were cardboard cards that had different colours according to donor blood groups. The first time a donor gave blood, a 101 card was made for them by the Records Department. We had donor panels for different geographical areas; the 101 cards were taken to the appropriate donor sessions, according to the panels. The doctor or nurse responsible for that session signed the 101card following each donation.

161. The donor session details with donation details, donors accepted and rejected, location of sessions and incidents etc. were kept in *'bleed sheets'*. Whilst the 101 cards were specific to donors, the bleed sheets were specific to donor sessions and had the names of all the donors who attended to donate at that particular session. This was then cross referenced with the 101 cards by the Records Department. So, we had records for the donor session and individual records for each donor.

162. This method of record keeping was in place when I became director of the North London Blood Transfusion Centre, and I did not make any changes to the system until we became computerised, which coincided with the move from Edgware to the newly built Colindale Blood Centre in 1989.

163. We also had a *'read and sign form'* or NBTS 110, where the donor signed that he or she had read the donor exclusion criteria and agreed to give blood.

164. Letters to donors and medical professionals were kept in separate files in lockers in my office along with paper files for each of the hospitals in the NW Thames Region.

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

165. These records were never destroyed.

166. In 1990 the 101 cards were computerised, condensed and sent to Iron Mountain for storage. If we needed to access them for any reason, such as lookback studies, we could ask Iron Mountain and they would retrieve the information confidentially for us.

167. Other records were microfiched and stored. To my knowledge no donor records were destroyed.

168. Apheresis donors (plasma donors, platelet donors and donors of specific immune plasma) had a medical file each, where all their data was kept, including date and volume of donation, mandatory donor test results, FBC and biochemical profile (proteins, ALT and other liver enzymes) which were done every time they attended. These files were examined by a medical consultant before each attendance. Anomalous results were investigated and often donors were temporarily suspended until normalisation of results. These medical records were also microfiched and never destroyed.

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

169. As set out in my response to question 19, to my knowledge the records were never destroyed, so there was no policy or practice, so far as I am aware, in relation to the destruction of records.

170. Records were stored in Iron Mountain but not destroyed.

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

171. I do not know what the record keeping practices were at other RTCs, save that it is my understanding that other centres also used 101 cards because we could exchange and transfer these when donors moved, but beyond that I cannot comment further on the record keeping practices at other centres.

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

172. Yes, I consider that the measures in place at NLBTC, regarding record keeping were very adequate to prevent donors who were suspected of carrying blood- borne infections from continuing to give blood.

173. Donors who were suspected of carrying infections were personally approached and counselled by a doctor about why they could not donate and, because of the altruistic nature of blood donation, donors are very well – natured people who do not want to harm and, only, want to help people (see Titmuss, "The Gift Relationship" [1970]). So, in my experience, if we told a donor that he or she could not donate for any given reason, they would abide by the advice and not continue to donate. I believe that the measures we had in place were good at preventing donors who carried or were suspected of carrying blood-borne infections from continuing to donate.

174. The 101 cards were all marked in bold to the effect that a particular donor was removed permanently from the panel.

175. When it came to counselling donors and informing them that they were carriers of infections, we never delegated this to hospitals or GPs. Medical consultants or associate specialists at NLBTC would personally contact the donors and speak to them. Dr Patricia Hewitt and her team were in charge

of the medical aspects of transfusion-transmitted infections and donor counselling.

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

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

176. I became aware as soon as the database was created. The NLBTC was based next to the CDSC, so when testing for anti-HIV started in 1985 and positive results were found, Dr Barbara's team reported all donors found with positive Hepatitis and HIV markers weekly to the CDSC for the CDR reports.

b) Who proposed the creation of the database?

177. I do not know who proposed the creation of the database, but presume that it would be the Department of Health or the CDSC who asked that we report HIV positive donors along with HBV positive donors (and any other occasional communicable diseases, like HAV).

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

178. Yes, on a weekly basis.

179. My recollection is that there was a form to complete for any positive donors. This is a task I would most likely have delegated to Dr John Barbara

180. The reports would have been sent by fax or, if things had to go to PHLS or CDSC, then given the proximal distance to our centre, our porters would take the documents across.

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

181. I believe that all centres did contribute.

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

182. Yes, we had our own records and produced a file for every positive donor. Dr Patricia Hewitt managed those files and organised follow ups, post donation interviews (originally called *'counselling'*), interaction with the hospital consultants to whom donors were referred and regular meetings with Ms Riva Miller, an expert social worker and counsellor, at the Royal Free Hospital for updates and to refine our interview and follow-up procedures.

183. There was no local or separate database in the traditional sense consisting of a structured set of data held in a computer, for example.

24. In a memo dated January 1991 from you to Dr Barbara and Dr Brennan, you referred to a proposal for an "anti-HCV database" (NHBT0000052_016). Please answer the following questions regarding this database, as far as you are able:

a. Who proposed the creation of the database?

184. I think it must have been me, assisted by Dr Barbara and Dr Brennan.

185. This was an NLBTC database.

186. At the time, we knew very little about anti-HCV because it was new to us and so we wanted to understand everything we could, from the point of view of public health and preventative medicine; for example, understanding risk factors in donors.

187. At the time my deputy, Dr Patricia Hewitt, was on maternity leave and therefore Dr Mary Brennan, a young consultant in the management team, stepped in to assist with the creation of the database.

b. What was the intended scope of the database? Were all RTCs expected to contribute to it?

188. I have covered the scope of the database in my response to question 24a. It was to gather information on the magnitude of the problem in our catchment area (NW Thames), to analyse donations given in the past by anti-HCV positive donors and learn about the risk factors for infection in these donors, to help us to understand the epidemiology of the virus, transmissibility, etc.

189. This was not a database used by all RTCs but, when we became zonal, it was used by the four centres in my zone. I do not know whether nationally there was a database.

c. Was the proposal made to a committee or forum similar to the regional transfusion centre directors' meetings?

190. No, because the database was local rather than national.

d. What was your view of the proposed database? How was the proposal viewed by other RTC directors?

191. I must have thought it was a good idea as I proposed it.

192. I considered that Dr Barbara should be in charge of this as is stated in my memorandum.

193. Other Directors were not involved, as this was a Centre–based database.

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

194. The database had information on all confirmed anti-HCV positive donors found at NLBTC.

195. At the NLBTC we kept records, individual files and follow up data on all anti-HCV positive donors.

196. It was a learning database. The purpose of the database was to keep a record and follow up data on HCV positive donors. It also helped us learn how the tests were performing and helped us understand the risk factors and number of donations that the anti-HCV positive donors had given in the past.

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

197. Yes, as I have stated, the database was created.

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

198. Dr John Barbara and Dr Brennan were responsible for overseeing it and eventually Dr Patricia Hewitt replaced Dr Brennan when she returned from maternity leave. Aside from being part of the initial proposal with Dr Barbara and Dr Brennan, I did not have much involvement in the running of the database, but did have weekly 'catch up' meetings with my consultants and heads and this database would have been part of those discussions. So, I was kept informed of developments.

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

199. I do not know whether the database is still in existence, but my presumption is that it must be somewhere. My understanding is that, with the creation of the NBA, Dr Angela Robinson took over the database and made it national in or around 1995, but I had no involvement in this.

200. I retired over 13 years ago, so it is impossible for me to comment on what is and is not currently in existence.

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

a. The use of the word "re-introduce" implies that the J donor system had been operational at an earlier time. When was the J donor system first introduced, and why did it stop operating?
b. Who proposed the re-introduction of the J donor system?
c. What was the intended scope of the J donor system? Were all RTCs expected to contribute to it?
d. Was the proposal for the re-introduction made to a committee or forum similar to the regional transfusion centre directors' meetings?
e. What was your view of the proposal for the re-introduction of the system? How was the proposal received by other RTC directors?
f. What was the purpose of the system and what information being 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?

201. I have considered the memorandum dated 15 May 1989 (NHBT0005388). This was a local memorandum for the Manchester RTC written by Mr Peter Howell. As far as I can gather this was not a national decision / proposal.

202. At the NLBTC we were lucky to have Dr David S Dane, discoverer of the 'Dane Particles' of HBV, as an honorary consultant. Following the advice of Dr Dane at NLBTC, Dr Barbara's team always prepared *'JE'* (jaundice enquiry) files for any reports of post transfusion jaundice, or indeed of lab test positive results for viral hepatitis in patients following blood transfusion. Dr Dane's lab would have done the reference work on our implicated donors and quite often on samples from the patients, so that we could confirm that they were indeed recently infected, i.e. that there was a confirmed case of transfusion-transmitted hepatitis. Unfortunately, until a national IT system was set up, one centre would not know if a donor from another RTC was implicated in a jaundice enquiry, unless the relevant 101 donor card had been transferred to the other RTC.

203. Very occasionally, we found a *'test positive'* donor who, on follow up of the donor history records, was found to have been excluded by another RTC.

204. Data sharing between centres about *'positives'* would have been inadequate until a national IT system was in operation. This sharing would have had to come with maximum data protection procedures.

205. Dr Barbara prepared an annual post transfusion infection report for the NLBTC which was reviewed by Dr Dane; a copy would then be sent to Dr Sheila Polakoff at CDSC, until SHOT (Serious Hazards of Transfusion, our national haemovigilance system) was in place.

206. Because at the NLBTC we had had our own *'JE'* system I cannot comment further on this local memorandum from the Manchester RTC.

207. This is just one example of local variation of practice.

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

208. There was no mechanism for a centralised database shared with other RTCs about excluded donors. It was only when donors told us they had moved, but otherwise we did not really share information, until the national IT system was created in 1995/96. Every donor found by NLBTC to be positive for a blood-borne infectious agent (transfusion transmissible agent), was counselled by a doctor about the reason they could not donate blood again.

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

209. I agree with Dr Harold Gunson's statement that *'there was no central organisation to ensure that all RTCs operated in a uniform manner.'*

210. With respect as to whether I believe the measures in place between the RTCs were adequate in preventing donors who were suspected of carrying blood- borne infections from continuing to give blood, I have to say that I do not think the systems were adequate because we did not really have a system that would have prevented the risk of an infectious donor donating somewhere else. All we could do was to advise donors known or suspected

of carrying blood-borne infections that they should not continue donating, giving them the reasons for this advice.

211. The occurrence of blood donations by donors known to be carrying blood-borne infections would have taken place only where a donor was maliciously doing that which, in my opinion and experience was an extremely rare occurrence. In fact, I never encountered such an event. There is no reason for a voluntary, altruistic donor to wish to continue donating if he/ she has been asked to discontinue donating his / her blood.

Section 5: Your role as Medical Director of the NBTS

28. Please outline the period you were a medical director of NBTS.

212. I was never medical director of the NBTS (National Blood Transfusion Service).

29. Please outline the roles, functions and responsibilities you had at the NBTS during your period as Medical Director.

213. Please refer to my response to question 28. I was never medical director of the NBTS.

30. The Inquiry understands that you were appointed as Medical Director in 1987, one year after your appointment as Director of the NLBTC. Please describe the relationship between these two roles and whether performing them together ever gave rise to a conflict of interest. If so, please explain.

214. I was medical director of the North London Blood Transfusion Centre (NLBTC) and I have set out in detail my roles and responsibilities in relation to this in response to Section 2, questions 6, 7 and 8.

215. In 1984 I was appointed director of the North London Blood Transfusion Centre and this position embraced being chief executive and medical director of the regional centre (as per my CV exhibited to this statement). I held this position until November 1995, when I became chief executive and medical director of the London and South East Zone of the National Blood Authority or NBA.

218. As director of the NLBTC, I never felt that there was a conflict between my roles as chief executive and medical director. On the contrary, I found that the two roles complemented each other as I had medical and public health strategic vision which enabled me to draw the centre's business plans for the benefit of patients and donors.

219. Never in any of my roles did I have final say as 'medical director' or 'chief executive' regarding policy. Whilst I was influential, I never was the ultimate decision maker.

220. It was the Regional Health Authority, the Secretary of State and the Department of Health who had ultimate responsibility in those days

31. Please provide the following details about the NBTS during your period as Medical Director:

a. its structure and staffing;
b. how it was funded including its operational budget and whether its funding was linked in any way to its performance;
c. its remit;
d. the level of interaction with the various RTCs;
e. the level of interaction with Blood Products Laboratory (BPL), including if the role, if any, NBTS played in setting plasma targets;
f. how decisions and policies were made;
g. to whom the NBTS was answerable, if anyone;
h. whether the NBTS was subject to any system of regulation or oversight, and if so, by whom.

221. Please refer to my response to questions 28 and 30 for questions 31a – h) above.

32. *In his witness statement in A and Others, Dr Gunson commented that the lack of national standardisation between RTCs created major inconsistencies in "the way in which the different RTCs supplied plasma to the BPL" and "in introducing testing for the HIV virus" (NHBT0000026_009). Do you agree with this statement? Please explain your views.*

222. I agree with Dr Harold Gunson's statement that there was a lack of national standardisation between RTCs which created inconsistencies in the way in which different RTCs supplied plasma to BPL and in the introduction of testing for the HIV virus. My views are the same as those stated in Dr Gunson's statement.

223. We were all regional centres who supplied different volumes and quantities of plasma to BPL. We were very different centres with different standards and different approaches to quality; I believe that Dr Harold Gunson has explained this quite correctly in his statement.

224. As I have explained above, both the RTD meetings and the National Directorate were non-executive coordinating bodies that advised the Department of Health regarding policy on the one side and blood components and services on the other. RTDs were given annual targets regarding plasma for fractionation. The first time that blood components and services were only ever under a single organisation was with the formation of the NBA in April 1994 and the attendant transfer of responsibilities for the RTCs from the Regional Health Authorities. Prior to that, anything that was 'agreed' was through committees, working parties, etc. and was executed through the Regional Health Authorities, possibly under directives from the Department of Health. The Department of Health had ultimate responsibility for the blood services in those days.

33. *Do you agree with the way Dr Gunson describes the history of the NBTS in paragraphs 12 to 16 of the same statement?*

225. Yes, I agree.

34. *What in your view were the strengths and weaknesses of the NBTS?*

226. I consider the strengths of the NBTS to have been:

a) Since its creation, donors have been altruistic, voluntary and mostly repeat/ regular.
b) It is a truly public service.
c) In the eyes of the public the service was always national rather than regional, and therefore the creation of the NBTS brought the service in line with expectation.
d) I believe that staff had pride in working for a national service.
e) There was improved information exchange between the centres.
f) The 'Red Book' which was an initiative started by Drs John Cash director of SNBTS and Geoffrey Schild, director of NIBSC. The book set national standards for the UK Blood services. Doctors and scientists from the 4 UK National Blood Transfusion Services met to develop guidelines and standards for the blood services across the UK. The quality guidelines were split in different groups such as donor selection, transfusion microbiology, Immunohaematology, etc. The first edition of the Red Book was in 1989. It was called this because it had red covers. It was published by the HMSO. It covered guidelines and practice for blood transfusion medicine and included all the activities of the blood service. It is now under the Joint Professional Advisory Group of the UK Blood Services.
g) There were external quality audits between centres
h) There was increased exchange of information at the RTD meetings.
i) The creation of the management information system (MIS). This allowed improved information sharing between centres and, for us to all see what the blood stocks were country-wide; this information was particularly useful when a centre was short of a blood component or red cells of a

certain blood group, as we would be able to request an allocation from a centre that had plenty.

j) There was national publicity for donor recruitment from the Department of Health.

227. In relation to the weaknesses of the national blood transfusion service, I consider these to have been:

a) It was a non-executive body with no real powers other than the power of persuasion.
b) The regional transfusion centres had different levels of funding and involvement by their respective regional health authorities.
c) There were different IT systems in place, idiosyncratic to each centre despite the later creation of the national management information system (MIS).
d) The title of Dr Harold Gunson as national director was, in my opinion confusing and inappropriate since he had no executive power. He was only advising and persuading the different RTDs. The ones who had executive power over us were the Regional Health Authorities.
e) Some RTCs had severe structural deficits.
f) RTCs were very different administratively and managerially.
g) There was duplication of research and development and little collaboration between centres.
h) Productivity was different at different centres.
i) Innovation was different at different centres.
j) Efficiency was different at different centres. This was clear when comparing collections of blood and plasma per million population.
k) Liaison with hospitals was different at different centres, as consultants and scientists at some centres had little or no relationship with clinicians at the hospitals they served.

Section 6: Other Committees

35. *In addition to the meetings between RTC directors, you and a number of other RTC directors were involved in additional committees that considered the risks of blood borne diseases. Please answer the following questions regarding these committees. Advisory Committee on the Virological Safety of Blood*

218. I was never a member of the ACVSB, so am unable to answer these questions. Please refer to my response below.

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

219. I was never a member of the ACVSB, so am unable to answer this question.

220. To my knowledge, there was no RTD representative in the ACVSB; the NBTS representative was Dr Harold Gunson and the SNBTS representative was Dr Ruthven Mitchell. The virologists were Dr R S Tedder, Professor Arie Zuckerman and Dr Phillip Mortimer. Dr R Lane represented BPL and Dr R Perry the Scottish Plasma Fractionation Plant. Dr P Minor represented NIBSC. The meetings were chaired by the Deputy CMO, first Dr EL Harris and later Dr J Metters. Secretariat and observers were from the Department of Health.

37. *What was the function and remit of this committee? In particular:*

a. *Who did the ACVSB report to, how frequently and by what means?*
b. *Did the ACVSB have any powers or was it purely advisory?*
c. *Did the Health Ministers generally take the advice of the ACVSB? Please set out any instances, relevant to the Inquiry's Terms of References, where the ACVSB's advice was not accepted.*

221. I was never a member of the ACVSB, so am unable to answer these questions.

38. Please explain the relationship between the ACVSB and the NLBTC/NBTS, including but not limited to:

a. whether the ACVSB made decisions that NLBTC/NBTS was required to implement;
b. how frequently the ACVSB met;
c. whether, and how frequently, you provided feedback to NLBTC/NBTS on the recommendations made by the ACVSB.

222. There was no relationship between the NLBTC and the ACVSB. I was not the director of the NBTS, so cannot comment on this aspect of the question.

233. The minutes from the ACVSB did not come to the NLBTC or to the RTD meetings. I knew that the committee existed, but that was the extent of my knowledge of it.

234. With respect to decisions made by the ACVSB, my understanding is that the committee was advisory, so that any decisions requiring implementation would have had to come from the Department of Health.

235. I cannot comment further on this question.

39. Please explain, to the best of your knowledge, the relationship between the ACVSB and other RTCs in light of the questions at 38(a) to (c). UK Advisory Committee on Transfusion Transmitted Diseases

236. I did not know anything about the ACVSB aside from the fact that it existed, so I cannot comment on the relationship between the committee and other RTCs. What I can say is that I was at the forefront of many of the initiatives at the time and a member of various committees as set out in my CV and

therefore if I was not aware of the ACVSB decisions, I would be surprised if other RTCs had a greater knowledge.

237. From the final report of the Penrose Inquiry, I learned that the first chairman, Dr Harris, reminded members that their advice could be publicly sensitive and should not be discussed outside the Committee, unless specifically indicated.

40. Also in 1989, the UK Advisory Committee on Transfusion Transmitted Diseases ("ACTTD") was set up by Dr Harold Gunson to consider the implications of transfusion-transmitted infections on the transfusion services in the UK and provide advice to the Department of Health. The Inquiry understands that you were one of the founding members of the ACTTD. Please explain your involvement in ACTTD.

238. My involvement with the ACTTD was as a member and I brought the knowledge and experience of my team from the North London Blood Transfusion Centre into the committee. I contributed with my own and my colleagues' experience and expertise by providing professional, medical, scientific and technical advice. We had a good team at the NLBTC dealing with transfusion-transmitted infections and we met regularly to exchange information which I took to the ACTTD.

239. At the time I realised that the committee would be better served by the membership of an expert transfusion microbiologist, so I stepped down and asked Dr John Barbara to take my place; this was accepted by the committee.

240. The committee was superseded by SACTTI (the Standing Advisory Committee on Transfusion-Transmitted Infection), part of JPAC - the Joint Professional Advisory Committee (JPAC).

41. What was the function and remit of this committee? In particular:

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

241. I believe that the committee reported to the Department of Health through the ACVSB (the chair, Dr Gunson, was a member of the ACVSB). It could also have reported to the Department of Health directly.

242. My recollection is that the meetings were infrequent – around four to six times per year.

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

243. To my understanding, the committee was purely advisory and had no decision-making powers.

c. Did the Department of Health generally take the advice of the ACTTD? Please set out any instances, relevant to the Inquiry's Terms of References, where the ACTTD's advice was not accepted.

244. I believe the Department did generally take the advice, but there are instances where the Department would have asked for more information or refused/ delayed funding at that specific time; one example being the introduction of anti-Hepatitis C virus testing (covered in section 59 onwards, below).

d. How frequently did it meet?

245. I think the committee met irregularly, about 4 – 6 times per year (sometimes monthly and sometimes every six months) from 1989 until 1993, when it must have been replaced by JPAC with its Special Advisory Committee on Transfusion Transmitted Infections (SACTTI)

42. Please explain the relationship between the ACTTD and the NLBTC/NBTS, including but not limited to:

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

246. NLBTC refers to the North London Blood Transfusion Centre, for which I was responsible and NBTS refers to the National Blood Transfusion Service, with its 15 regional blood transfusion centres. The ACCTD was advisory. It sometimes made recommendations, for example, that the NLBTC should perform a trial of a test on donations such as for the prevalence of anti-HTLV -1 before wide scale implementation at a national level. I think the NLBTC was picked over other centres given its location in central London and the demographics of the donor population which meant that there was a mixed cohort of donors to participate in the study. We also had the benefit of a well-established Transfusion Microbiology Department, under Dr John Barbara.

b. *whether, and how frequently, you provided feedback on the recommendations made by the ACTTD.*

247. I provided feedback regularly after each meeting to our management team and to Dr John Barbara on the recommendations made by the ACTTD until I handed my membership over to Dr John Barbara, who would then report back to our management team on the outcome of the meetings and the recommendations made at those meetings.

43. *Please explain, to the best of your knowledge, the relationship between the ACTTD and other RTCs in light of the questions at 42(a) to (b).*

248. The link between the ACTTD and the RTCs was Dr Harold Gunson who, in my experience, was a good communicator and I assume would have provided feedback to the other RTCs.

Section 7: Seriousness of infections

Seriousness of HIV/AIDS

44. *During your time as a clinician in transfusion medicine and at the NLBTC, 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?*

249. I knew nothing about HIV and AIDS until gradually publications from CDC started to appear in the MMWR in 1981 about the apparent clustering, in homosexual men, of pneumocystis carinii pneumonia, Kaposi's sarcoma and opportunistic infections in the USA, mainly California and New York. Such diseases had been associated with host immunosuppression.

250. At first, I did not link this disease, which was reported to be confined to homosexual men, with blood transfusion.

251. I believe a pivotal moment in my view shifting was when I read a report by the CDC in the MMWR of the possible transmission of AIDS to a multi-transfused infant in San Francisco; the donor of the platelets transfused to the infant was a homosexual male subsequently found to have AIDS. I believe that this report was published at the end of 1982.

252. I also learned from the MMWR, which we received regularly at NLBTC, that a few haemophilia patients had manifestations of P carinii pneumonia and opportunistic infections.

253. Reports of lymphadenopathy, Kaposi's Sarcoma and non-Hodgkin's Lymphoma in homosexual men also started to appear in the literature.

254. The blood service moved quickly to do something about the new, apparently blood-borne disease. At NLTBC we started writing our own leaflets and, with Dr Tom Davies, then Director and Dr John Barbara, we designed and tried the first very simple national leaflet, addressing male homosexuality and intravenous drug "abuse". The leaflet "*A.I.D.S and how it concerns blood donors*" was published by the DHSS on 1 September 1983. In 1984 I

went to the New York Blood Centre with Dr John Barbara to learn about the approach that Centre was dealing with prospective donors in order to prevent the transmission of AIDS by the transfusion of blood components.

255. We learned that AIDS prevention required the blood services to address detailed matters of personal behaviour that had been taboo up to then. Following this visit, we decided to start a confidential donor exclusion questionnaire at the NLBTC, being the first centre in the country to do this.

256. We worked closely with the Terrence Higgins Trust (a British Charity that campaigns about and provides services relating to HIV and sexual health) to draft the donor exclusion questionnaire.

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

257. My understanding and appreciation that there was an association between AIDS and the use of blood and blood products was a gradual evolution beginning in the early 1980s after I had seen reports in the MMWR, first about AIDS in patients with haemophilia and second about the San Francisco multi-transfused baby who acquired AIDS through a platelet transfusion from a homosexual male in late 1982.

258. However, this one account would not have led to a full appreciation or understanding of the association and I think this must have gradually occurred between 1982-84 reading the CDC publications in MMWR and the New England Journal of Medicine when AIDS began to be firmly associated with transfusions.

259. I formed part of a team with an interest in transfusion-transmitted infections, with external advisors nationally and internationally. At the beginning there was confusion as to whether AIDS was a lifestyle anomaly or caused by an infectious agent. I do remember a paper by JW Curran and others titled '*Acquired Immunodeficiency Syndrome (AIDS) associated with*

transfusions' published in January 1984 *(N Engl J Med 1984; 310:69-75) (PRSE0001931)* which clearly incriminated transfusions of blood and blood products as a risk factor for the transmission of AIDS

260. Whilst at the time I knew about transfusion-transmitted infections such as Hepatitis A and B, I (and the wider transfusion community) did not know about retroviruses and this publication was, I believe, a moment of realisation that there was convincing evidence that AIDS was caused by an infectious agent transmissible by blood.

261. What I am certain of is that by June or July 1984, when I made a trip to the New York Blood Centre with Dr John Barbara, we were very concerned about AIDS and the transmission of this disease through blood and blood products. In the absence of a blood screening test, this trip was made to see what we could do and learn, from the donor approach in New York, in order to avoid the transmission of this disease through blood.

46. *In an article in Vox Sanguinis dated 1984, you wrote that one of the factors for consideration in the context of screening blood donations was "the consequences of transmitting the agent, with special emphasis on mortality and chronic long-term effects" (NHBT0000030_008). You also wrote that the risk of transmission of HIV/AIDS was unsubstantiated and could be nonetheless managed by temporarily excluding "'high-risk' prospective donors (promiscuous homosexuals, drug addicts, and Haitian immigrants)". Please explain these views in more detail, in particular focusing on your understanding of the seriousness of HIV/AIDS, the basis for that understanding, and whether and if so how, it changed during your time at the NLBTC and then as Medical Director of NBTS.*

262. Although this article in Vox Sanguinis was published in 1984, I believe that I must have written the article in 1983, since in those days it would take a year or more for an article to be published, as they were all paper publications; before they were approved by the editor, they had to be peer reviewed by two or three international experts, which was a rather slow process.

263. The question misconstrues what I am saying in my article. I did not state that: the *risk of transmission of HIV/AIDS was unsubstantiated and could be nonetheless managed by temporarily excluding "'high-risk' prospective donors (promiscuous homosexuals, drug addicts, and Haitian immigrants.* The word "Nonetheless" suggests that my idea of excluding high risk prospective donors is a panacea, but that is not what I have said. I did not state that the risk of transmission of HIV/AIDS was "unsubstantiated". In addition, I could not have mentioned HIV, because the agent (LAV or HTLV-III) had not been named at the time I wrote the paper. What I stated in my article was that the exclusion of certain "high risk' subjects from blood donation was a temporary option and was really the best we could do in the meantime since, at the time, there was no direct evidence for an infectious agent for AIDS, hence, no possibility of a screening test. The paragraph from my article reads as follows:-

"***Acquired Immune Deficiency Syndrome***

So far there is no direct evidence for an infectious agent for acquired immune deficiency syndrome, and blood bankers are left with the temporary option of excluding 'high-risk' prospective donors (promiscuous homosexuals, drug addicts and Haitian immigrants). Non-specific tests to identify donors in high-risk populations need further evaluation in the donor population before any of them is recommended in routine donor screening".

264. One of the factors I gave for consideration in the context of screening blood donations was 'the consequences of transmitting the agent, with special emphasis on mortality and chronic long -term effects', but this should not be read in isolation of the other factors which I listed as contributing to the current and possible future requirements for safety of screening of blood donations, which also included:

a) The prevalence and epidemiology of the agent in the country;
b) The incidence of carriers of the agent in the donor population;

c) The magnitude of the risk of transmitting the agent by blood transfusion, i.e., the incidence of morbidity in recipients;
d) The availability and characteristics of screening tests;
e) The cost effectiveness of testing donors for a particular agent;
f) The availability of funds (and consequently of trained staff and specialised equipment) and the priority given by a country to preventative medicine;
g) The health status of the host: immunosuppressed, undernourished and / or splenectomised recipients posed major problems;
h) The immune status of the host with regards that particular agent;
i) Survival of the agent in fresh versus stored blood, with increase in demands for fresh blood and components, the relative significance of the transmission of some agents may be increased; and
j) The distribution of the agent in the different components of blood and plasma fractions.

265. I genuinely thought at the time that if we excluded donors who had behavioural characteristics that would be likely to transmit the agent of AIDS, then the risk of transmission would be significantly reduced. At the time there was not a test that we could perform on blood donations to identify the agent and I, as well as many other experts, considered that we could help avoid/ diminish the risk by excluding high risk donors.

266. The categories I gave; promiscuous homosexuals, drug addicts and Haitian immigrants, were because these were widely reported, at the time, by the CDC and others, to be the most prevalent carriers of the AIDS agent in the USA. My article really should have specified intravenous drug users rather than just 'drug addicts' as it was the intravenous injection and the sharing of needles which posed the risk of transmission. We later changed our views on 'promiscuous' homosexuals to 'practising' homosexuals. We learned from following up our donors and discussions with the Terrence Higgins Trust that even if a specific donor was not 'promiscuous' there remained a greatly increased risk of transmission if their partner had been.

267. My knowledge and understanding of the HIV / AIDS virus changed and developed over time. As I said, despite the publications in Science, the agent/ virus responsible had not been identified/ discovered, so we did not have an available test when I wrote this article. Hence, the most effective way I considered that we could protect our recipients was to exclude high risk donors, through education of our donor panel. The case of possible blood transfusion to a baby in San Francisco was published by the CDC in the MMWR at the end of 1982. The paper I have referenced above by JW Curran about the association of AIDS with transfusions was only published in the NEJM in 1984. I genuinely believed, when I wrote the article in Vox Sanguinis, that the risk of transmission of a causative agent of AIDS could be ameliorated temporarily by excluding, from blood donation, subjects at risk of being infected with AIDS. Retrospectively, this proved to be the case (see Barbara et al 1988 XX Congress of ISBT) **(NHBT0057883)**

268. All of the hospitals (including private hospitals) in my region were assigned to the 5 consultants at the NLBTC, including me. We regularly taught medical students and registrars and educated them on the appropriate use of blood and components. I counselled my students to think before giving blood and only use it when strictly necessary. I remember that I used to write on the chalk board *'BLOOD CAN KILL'* and urged my students to have as much, if not more, respect for blood as for the drugs they use in medicine. The NLBTC would perform audits on the usage of blood and queried with hospitals where there were significant unjustified usages.

269. At the time when it became public knowledge that AIDS could be transmitted by transfusion, many blood donors worldwide misunderstood and thought that AIDS could be acquired by "giving" blood. Blood stocks became dangerously low throughout the UK blood services and I had the idea at the time of inviting a senior public figure to give blood to demonstrate that it was safe. After a series of communications with, and visits to, Buckingham Palace, I managed to convince Prince Charles' private secretary to show him a letter I had written inviting him to donate blood and he agreed to come to our Edgware donor clinic. He went through the routine screening and

self-exclusion procedures and gave one unit of blood. His picture, giving blood, was on the front page of numerous newspapers in the UK and abroad. Blood donors were reassured and blood donations went back to nearly normal levels.

270. As I have mentioned above, at the end of 1984 Dr Barbara and I got funding from Region to go to the New York Blood Centre, a not -for- profit organisation. I had learned of their self - exclusion procedures. Since we only had donor leaflets, I wanted to see how the exclusion process worked and see if this was something that we could implement at our centre. New York has a very similar demographic to London and I was able to see first-hand how the self-exclusion questionnaire was working. We communicated with the New York donors and learned that they were not offended by the questionnaire asking them private life-style questions. We could see that at least one donor per session excluded themselves. On the return flight from New York, Dr Barbara and I designed our own self exclusion questionnaire based on what we had learned from our trip and implemented this upon return to the NLBTC. The trip was funded by the Regional Health Authority.

271. After the discovery of the HIV retrovirus by Dr Barre Sinoussi and Dr Montagnier in France and by Dr Gallo in 1984 in the USA, it took some time for the development of an HIV antibody screening test for blood donations.

272. At the beginning, we did not know if it would be beneficial to introduce HIV antibody testing on blood donations as we did not know if the presence of antibodies meant protection, as is the case for anti-HBs in Hepatitis B. It was only in 1985 that it was shown that HIV seropositivity was synonymous with infection and infectivity. Although the HIV antibody test was available months earlier, the UK blood services started screening for anti-HIV in October 1985, once alternative testing sites for anti-HIV were established. People in high- risk groups, who wished to know their anti-HIV status could go to those sites rather than going to donate blood with the attendant danger of contaminating the blood supply.

273. The first available HIV antibody screening tests from Dr Gallo were grown in cell cultures and were contaminated with HLA antigens, leading to significant numbers of false positives, due to HLA antibodies in the donor population, especially in females. In the NBTS we introduced a more specific HIV antibody assay for donation screening in October 1985.

274. The seriousness of transfusion transmitted HIV was a concept I grasped gradually over time, first as deputy director, and then director of the NLBTC (see para 44 above).

275. As I have said previously, I was never director of the NBTS.

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

276. As I mentioned above, we devised our self-exclusion questionnaire at the NLBTC and once anti-HIV screening was in place, we carried out in-depth interviews with donors found to be seropositive, in order to learn about their lifestyle risks, the reasons for them coming to give blood (despite the leaflet information and self -exclusion questionnaire given to them prior to donation). We went through the donation history of HIV seropositive donors and investigated the archived stored sera and the outcome of blood components made from their previous donations. Donors were informed about this lookback exercise.

277. We had our own list of HIV positive donors and communicated with the CDSC to add information to the database that they kept.

278. NLBTC consultants and I were heavily involved with education and training of the hospitals in our region and taught doctors and nurses at all levels about the safety of blood and the need to avoid unnecessary transfusions.

279. We tested archive samples from previous donations in order to learn when donors had acquired the virus and to track the recipients of their blood. We learned a great deal from these investigations about the behaviour of people at risk of acquiring and transmitting HIV and adapted our practice and information to donors accordingly. One example of this, as mentioned above, was the change of 'promiscuous' to 'practising' homosexual men in relation to the exclusion criteria.

280. We worked closely with the Terrence Higgins Trust to help form our exclusion criteria and educated gay donors on the risks of transmission of HIV by transfusion of blood.

Seriousness of HCV

48. What was your knowledge and understanding of hepatitis (including hepatitis B and NANB hepatitis) and in particular of the risks of transmission from blood and blood products during your time at NLBTC and as medical director of the NBTS? How did your knowledge and understanding develop over time?

281. My knowledge regarding Hepatitis and the risks of transmission by blood and blood products developed over time. It was a gradual process of learning. I repeat that I was never the medical director of the NBTS.

Hepatitis A

282. This was isolated in 1973 from faeces. This is quite an unimportant virus in terms of transfusion-transmitted infections because it can only be transmitted by blood when a donor is in the acute phase which lasts a very short time (up to around 6 weeks). HAV does not have a chronic phase. When the subject is asymptomatic and well it is unlikely that he/she will transmit the virus. The virus is mainly associated with contaminated food / water and transmitted by the oro-fecal route, mostly in the developing world. I can recall only two occasions where Hepatitis A was transmitted via transfusion of blood collected by our centre.

Hepatitis B

283. HBV was isolated in 1965. I was aware of the seriousness of infection by this virus since the start of my career in Chile.

284. I was aware from early on that HBV was a significant virus, transmitted by blood and sexual contact, associated with mortality and morbidity, that could cause serious health conditions, such as chronic hepatitis, liver cirrhosis and hepato-cellular carcinoma.

285. I learned about the 'Australia Antigen' (later named HBsAg) of Hepatitis B and the possibility of its transmission by blood, blood components and blood products when I was a junior doctor in Chile where I set up the first screening test for blood donations at the University Hospital blood bank.

286. When I started working at the NLBTC I learned a great deal about Hepatitis B from Dr Cleghorn, the director and, especially from Dr David Dane who was the discoverer of the 'Dane Particles', later known as the HBV virion. Dane particles and spheres and tubules containing only HBsAg are found in the blood of infected patients. Dr Dane was a consultant virologist at the Middlesex Hospital and an honorary consultant at NLBTC.

287. My microbiologist colleague, Dr John Barbara, used to spend part of the working week at Dr Dane's laboratory. He became an honorary lecturer at the Middlesex Hospital Medical School. I learned a lot about Hepatitis B from Dr Barbara, Dr Dane and the associated medical teams and also by reading the relevant journals such as the Lancet, BMJ, Vox Sanguinis, NEJM and the MMWR and by attending national and international meetings and congresses.

288. I learnt from the outset that Hepatitis B can cause severe disease due to an intense immune response to the virus. I also learned that 5 – 10% of those infected could become carriers, most of them asymptomatic, but if e-antigen

positive, they could develop chronic liver disease and hepato-cellular carcinoma.

289. I also learnt about the double stranded DNA structure of Hepatitis B, its mode of transmission and the distribution of Hepatitis B carriers worldwide, the highest being Africa and Asia, but also high in the Mediterranean compared with Northern Europe.

290. When I started at the NLBTC, the centre was already screening for Hepatitis B and would follow up HBsAg positive donors for years, to learn what would happen to the carriers of the virus.

Non -A Non- B (NANB) Hepatitis (Hepatitis C)

291. Non- A non- B Hepatitis was named in 1974 when patients presented with signs of a parenterally transmitted Hepatitis that could not be attributed to the Hepatitis A or B viruses. At Chiron in the USA, by ingenuous molecular genetics, the genome of the causative virus was cloned and identified as the Hepatitis C virus (HCV) in 1989. A screening test was soon developed. Screening in the UK started in September 1991.

292. I learnt of this strand of Hepatitis from publications from the USA and from reports from hospitals about cases of hepatitis possibly transmitted by blood transfusion and which could not be explained by other known forms of Hepatitis. My knowledge and understanding of this grew over time.

293. Before the virus was cloned, I did not know what the causative agent/s was for this other form of parenterally transmitted hepatitis. Infrequently, hospitals would report cases of post-transfusion jaundice or altered liver enzymes. We investigated such cases to see if they were due to HBV; in the majority of cases this was not the case and we would label such incidents as non-A, non-B hepatitis. Archive samples from the donors involved would be tested for ALT and anti-HBc and if found abnormal, the relevant donors would be recalled, sampled and investigated for signs of

liver disease. If found to have persistent raised ALT or anti-HBc positivity, such donors would be asked to refrain from future donations

294. Donors who were asked to discontinue donating might have had the agent for non-A, non-B and would be referred to a liver specialist. Serum samples from donors implicated in cases of NANB hepatitis transmission were archived for future reference.

295. Our initial understanding was that the recipients of blood could acquire a different type of Hepatitis not due to any of the known viruses at the time and we termed it non- A non -B Hepatitis (NANBH). I genuinely believed, at the beginning, this disease to be milder than Hepatitis B in most cases. I vaguely remember reading papers which showed survival curves for NANB Hepatitis and showing that the disease did not have severe outcomes in terms of increased mortality.

296. I eventually learned from Professor Sheila Sherlock (possibly the most authoritative source of knowledge of Hepatitis in the UK at the time) at the Royal Free Hospital, that a minority of cases of NANB Hepatitis could develop into chronic liver disease and / or hepato-cellular carcinoma. It took some time for longer term studies to show that the long-term outcome of a significant number of patients with NANB Hepatitis could be very serious.

297. The 6th edition of Diseases of the Liver and Biliary System by Professor Sheila Sherlock was published in 1981. Professor Sherlock commented that: "*Non-A, non-B hepatitis often progresses to a mild chronic hepatitis. The prognosis of this is, at the moment, uncertain but probably benign*"– p259. (*WITN4032023)*

298. The 7th edition of Professor Sherlock's Diseases of the Liver and Biliary System was published in 1985. This publication painted a developing picture that a high proportion (68%) of patients with NANB Hepatitis developed chronic hepatitis with a smaller proportion (19%) going on to develop symptoms of cirrhosis. Fluctuating transaminases were said to be

typical of the chronic state. It was commented, significantly, that a relationship with hepato-cellular cancer had not been established (p272). It was noted that there was no test for NANB Hepatitis and that there had been limited progress both in diagnosis and in assessing treatment.

299. The stance changed again in the 8th edition (*BAYP0000012_011*) in 1989 when dealing with NANB Hepatitis. Whilst the virus is described as rarely severe, a figure of 68% was quoted in terms of chronic disease for infected individuals, with 20% going on to develop cirrhosis over 20 years. Hepato-cellular carcinoma is described as a 'rare' complication (page 327). I think this is really when I began to appreciate the true significance of NANB Hepatitis.

300. I am aware of publications which express contrary views, which I would have almost certainly read at the time, such as:

a) Purcell, Alter and Dienstag 'Non A Non B Hepatitis' Yale Journal of Biology and Medicine, 26 February 1976, 49, 243-250 (*PRSE0000381)*

b) Craske J et al 'An outbreak of hepatitis associated with intravenous injection of factor VIII concentrate' August 2 1975, The Lancet at 221 *(PRSE0001794)*

c) Preston et al 'Percutaneous liver biopsy and chronic liver disease in haemophiliacs', The Lancet, 16 September 1978 p 592 *(PRSE0003622)*

301. I have reflected back on these publications and my interpretation today has not changed much from the one I had when I first read these papers. They do not point to serious chronic effects of NANB hepatitis. The situation in the USA was different from the UK, as the incidence of transfusion transmitted infections has always been higher there. I interpreted Dr Eric Preston's biopsy findings, in the patients found negative for Hepatitis B markers, as something particular to patients with haemophilia, i.e.

something related to repetitive immunological assaults. The paper by John Craske also dealt with patients with haemophilia.

302. It is fair to say that my knowledge evolved over time with respect to the seriousness of this virus because it takes a very long time for it to show its severe chronic effects in a proportion of infected subjects. Hence, I could not see at the time an obvious health problem in the population, and did not do so until the effects of the virus began to manifest much later in time.

Hepatitis D

303. This virus needs the surface antigen of HBV in order to be able to enter human cells. So, it can only be transmitted together with HBV or after a subject has been infected with HBV. Its route of transmission is parenteral.

Hepatitis E

304. HEV has 4 major types that infect humans: 1 and 2 are similar to HAV in its mode of transmission, i.e. by the oro-faecal route due to water or food contaminated with faeces. These types are more common in Asia. Types 3 and 4 are widely distributed in pigs and can be transmitted to humans by undercooked meats. HEV3 is the main type found in industrialized countries. The hepatitis of HEV3 is generally mild except in pregnancy, or the immunosuppressed where it can cause chronic hepatitis. In patients with pre-existing liver disease, HEV can cause liver failure. HEV can be transmitted by blood transfusion and testing of all blood donations for HEV was introduced in the UK in 2016.

CMV hepatitis

305. This is a rare form of viral hepatitis, which can occur in CMV-negative immunosuppressed patients, fetuses and new-born infants. CMV is cell associated and can be transmitted by secretions or blood. It has a high seroprevalence in the UK donor population. Infection can be prevented in vulnerable patients by leucodepletion or the provision of CMV-seronegative blood components.

49. What, if any, further enquiries and/or investigations did you carry out or cause to be carried out in respect of the risks of the transmission of hepatitis? What information was obtained as a result?

306. Whenever a case of post transfusion Hepatitis was reported to our blood centre from hospitals in our region, we conducted full investigations with further testing of the patient samples and of the implicated donors to identify a possible source of infection.

307. At NLBTC we tested for markers of Hepatitis B, including anti-HBc and LFTs. If any donor was found to have anti-HBc or raised liver function tests, we would exclude that donor from the panel, ask him or her to come for follow up samples and refer him/ her to a hepatologist as necessary. Some of the archive samples that were anti-HBc positive with raised ALT levels were found later, when Hepatitis C was cloned, to be Hepatitis C virus positive.

308. With regards to donors found to be HBsAg positive, we included them in a panel of donors who were seen annually with full medical examinations and LFTs. If alterations were found, they were referred to a hepatologist at their local hospital. These investigations contributed a great deal to our understanding of Hepatitis B carriers and the long -term effects of the infection (See Transfusion Microbiology by John A. J. Barbara (Editor), Fiona A. M. Regan (Editor), Marcela Contreras (Editor) 2008).

309. We also collected, under strict isolation conditions, plasma from subjects with high levels of HBe antigen, in a collaborative effort with Professor Arie Zuckerman at the Royal Free Hospital, in a project to make an HBV vaccine.

310. In 1989 a breakthrough was announced by Chiron with the cloning of Hepatitis C. All subsequent lab work on the virus was based on this clone. The first-generation tests for anti-HCV were susceptible to a significant number of false positives (for every true positive found there were

approximately seven false positives). In addition, the test was very expensive and there was no confirmatory test.

311. Later on, further commercial Elisa anti-HCV tests appeared in the market, in addition to confirmatory assays, the first being RIBA.

50. 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?

312. I have largely covered this in my response to question 48. My understanding and knowledge of nature and severity of the different forms of Hepatitis evolved over time.

313. My appreciation of Hepatitis B from the start of my career was that it was a virus that can cause significant disease, which could lead to chronic Hepatitis and a fatal outcome, hence my respect for this virus was very high from the outset.

314. With respect to Hepatitis A, my view at the time and now is that this is a fairly unremarkable virus in respect to transfusion medicine since it is not a blood-borne virus, it is not sexually transmitted and it is mainly transmitted by the oro-faecal route through contaminated food and water, mainly in the developing world. The period of viraemia in the acute phase is very short, usually in the symptomatic phase, hence the possibility of transmission by blood transfusion is small.

315. With respect to non-A, non-B Hepatitis, my knowledge developed over time and in hindsight my appreciation of the seriousness was perhaps later than others in the medical community. I remember looking at survival curves which showed that people who were positive for Hepatitis C virus did not have a significantly reduced survival rate from those who were negative. I have exhibited a copy of one such graph at ' **WITN5711004**'. In addition, the incidence of NANB hepatitis in our patient population was significantly

lower than in the USA (Barbara et al BBTS 1987; Contreras et al, Lancet, 1991) ('PRSE0003767 ')

51. *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 UK are transfused to 750,000 recipients annually...then one would expect 22,500 icteric or anicteric cases of NANB hepatitis each year.'*

    a. *When and in what circumstances did you become aware of Dr Gunson's view?*

316. Firstly, this document, SBTS001120 , is not a scientific paper. It is a discussion document prepared by Dr Gunson, presumably for discussion with the Department of Health and / or for the ACVSB with the purpose of considering introduction of ALT and/or anti-HBc testing on blood donations.

317. This document was never shared with RTDs. I had never seen this document before the Inquiry provided it to me, although Dr Gunson does quote results from ALT and anti-HBc for blood donations from the North London Blood Transfusion Centre.

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

318. As I stated above, I was never shown this paper before now. I cannot ever remember discussing the figures in this document at any RTD meetings or with other transfusion centre directors. I do not agree with the figures and my nature would have been to query them. I am certain that I would have contested the figures at any meeting or in writing had I been aware of this document at the time.

c. What is your opinion regarding the accuracy of these figures?

319. I believe the quoted figures of 22,500 cases of post-transfusion non- A, non-B Hepatitis (NANBH) each year in the UK to be inaccurate and exaggerated and most likely extrapolated from US data which had a much higher prevalence of NANBH than the UK (7 – 17% compared with 1 – 2.4%) In addition, the introduction in 1983 of self-exclusion of donors at risk of transmitting HIV and anti- HIV screening of blood donations in 1985, decreased the incidence of 1 – 2.4% of NANBH reported prior to 1983, even further to 0.26%.

320. In the context of the UK studies at the time, the prevalence of NANBH was much lower. A study in the United Kingdom by my colleagues and myself at the NLBTC, before routine donation screening for anti - HCV started, showed that the incidence of post transfusion NANBH was 0.26% [*Contreras M, Barbara JAJ, Anderson CC, Ranasinghe E, Moore C, Brennan MT, et al. Low incidence of non-A, non-B post transfusion hepatitis in London confirmed by hepatitis C virus serology. Lancet 1991;30:753-7*]. This paper is exhibited at 'NHBT0000042_095 '. 0.26% is significantly lower than the 3% quoted by Dr Gunson.

52. In December 1987, in a letter to Dr Rotblat, you expressed the view that "we do not know if [NANB hepatitis] is a problem—and certainly not its extent..." (NHBT0000187_010). In April 1991, in a letter to Dr Gunson, you expressed a similar view in the context of the proposed introduction of screening for HCV antibodies (NHBT0006421_002). You described HCV as "a virus that has not been shown by anybody to cause immense health care problems in the U.K." as well as "an agent that seems to be less aggressive and dangerous than HBV and HIV". Please explain these statements and set out:

a. what considerations (including scientific, professional and/or observational) shaped your view;

321. I am concerned that the extract taken from my letter to Dr Rotblat dated 22 December 1987 has missed my preceding sentence. To fully understand the context, my letter reads as follows:

> *"Second, I did not say that NANB Hepatitis after transfusion is not a problem in this country; I did say that we do not know if it is a problem – and certainly not its extent if indeed it does prove to be so'.*

322. The important part of this paragraph, which has been omitted from the extract in question 52 of my Rule 9 request, is that *'I did not say that NANB Hepatitis after transfusion is not a problem in this country'*. And importantly, the words *'after transfusion'* are omitted from the question. "*After transfusion*" is important because I am not suggesting NANB Hepatitis not to be a problem in other circumstances, such as in the case of treatment with imported clotting factor concentrates. (PRSE0001931, WITN4032023, BAYP0000012_011)

323. With the above in mind and with respect to what considerations would have shaped my view, I have to say that at the time I did not know about the long -term effects of NANBH. I knew about Hepatitis A and B and about HIV. There was a lot of focus on Hepatitis B and HIV because we knew the long-term effects and consequences, but at the time, NANBH was still an evolving entity and the incidence of post-transfusion NANBH had been shown by my group to be significantly lower than in the USA (Contreras et al BBTS 1987; Contreras et al Lancet, 1991) (PRSE0003767).

324. I did not know at the time what the long -term effects of NANBH were and, whilst some of the haemophilia doctors may have been more aware, I can recall that there were a number of conflicting schools of thought about why patients with haemophilia might suffer a greater degree of susceptibility and morbidity from this agent. Factors such as repetitive infectious insults and autoimmunity were invoked as causatives of the liver damage.

325. My recollection is that there were many eminent specialists with different points of view about the virus and into the 1980s (See my references to Professor S Sherlock, above). So, it is in the context of the state of knowledge at the time that I wrote these letters.

326. It is therefore fair to say that in 1987 I would not have had the same level of understanding of NANBH (Hepatitis C) that I have now, because the chronic effects of the virus take a very long time to manifest themselves. Had I known its long-term effects, my response, in hindsight, might have been different.

b. the basis for your conclusion that NANB hepatitis was not known to be a problem and that HCV did not cause "immense health care problems"

327. Again, this question appears to be taken out of context. I stated clearly that NANBH did not appear to cause immense healthcare problems in the UK. I did appreciate that NANB Hepatitis was a problem in the USA and in patients with haemophilia in this country, following treatment with imported coagulation factors, albeit not to the extent that I now know it to be with the benefit of hindsight. At the time, specialists in the USA did not acknowledge severe long-term consequences of NANBH and certainly not as serious and severe as the long term consequences of HBV and HIV infections. Again, Prof. S Sherlock did not acknowledge serious healthcare problems caused by NANBH at the time. I am aware of publications at the time and before I wrote this letter, for example from doctors such as Dr Eric Preston [*Preston et al 'Percutaneous liver biopsy and chronic liver disease in haemophiliacs', The Lancet, 16 September 1978 page 592*] who had highlighted concerns about chronic liver disease in patients with haemophilia and altered liver function tests; he postulated that this might be due to Factor VIII concentrate replacement therapy, in addition to HBV infection. Although the liver damage found in the biopsies of those 8 patients could partly be due to NANBH, my recollection is that we thought it could have been due to other factors as there were many schools of thought at this time. As I mentioned above in response to question 52(a), there was a school of thought that

believed that patients with haemophilia were different because they had suffered such serious, repetitive immunological insults, due to numerous injections of cryoprecipitate and/or factor VIII, that their liver reacted differently from the general population. As I said, we were really in a state of developing knowledge at the time and I did not have the benefit of what I know now to inform my views. But even now, the morbidity and mortality caused by HCV infection in haemophilia patients seems to be different than that caused by HCV infection caused by transfusion of labile blood components. Seeff et al 1992, in the USA followed up, for 25 years, blood transfusion recipients with NANBH who had been identified in the early 1970's and compared their mortality with a control group of matched transfused patients; all case mortality was not significantly higher in test than control groups (*Seeff I.B., Buskell-Bales Z.,Wright E.C. et al (1992) Long-term mortality after transfusion - associated non-A, non-B hepatitis. The National Heart, Lung and Blood Study Group. N Eng J Med 327, 1906- 11* and *Seeff I.B., Blaine Hollinger F., Alter H.J., et al. (2001)Long-term mortality and morbidity of transfusion-associated non-A, non-B hepatitis: a National Heart, Lung and Blood Institute collaborative study. Hepatology, 33, 455-463*) *(PRSE0003622).*

328. The UK HCV National Register collects data from transfusion recipients traced during the HCV look-back exercise who tested positive for anti-HCV and from paired transfused controls, negative for anti-HCV. The analyses after 10 years show that mortality from all causes was not significantly different in the test and control groups (*Harris HE et al (2002) Clinical course of hepatitis C virus during the first decade of infection: cohort study. Br Med J 324, 450-53)* (DHSC0041457_044).

329. I have dedicated a great deal of my professional life to the care of voluntary blood donors and to the improvement of the safety of the blood supply in the UK. So, I would have had no reason to downplay any effects of transfusion transmitted infections. If I believed NANBH to be of greater significance at the time, I would have said so.

c. what you meant by "immense health care problems in the UK.";

330. By referring to *'immense health care problems'* what I meant was that there was no clear objective evidence that Hepatitis C or NANB post transfusion Hepatitis was causing significant morbidity and mortality in the UK at the time, to the best of my knowledge based on the evidence that I had.

331. I refer to the above at question 48 to a number of publications and studies that I would have read at the time. The one from the USA by Purcell et al, published in February 1976, has one line in the conclusion that type NANB Hepatitis can progress to a chronic state, demonstrating a problem with commercial blood donors. The paper does not point to any seriousness of the chronic state.

332. The paper by Dr John Craske in 1975, also referenced at question 48, is another example where the problem with NANB Hepatitis was attributed to commercial factor concentrates. The papers generally point to the chronic effects being in patients with haemophilia, which, as I have already confirmed, was thought to be due to their immunological compromise (PRSE0001794).

333. The study undertaken at NLBTC referred to in question 51, reviewed over 20,000 units of blood transfused. We found no signs of any transfusion-transmitted infections, including NANB Hepatitis, subsequently confirmed with anti-HCV testing.

334. The authoritative text-book by Professor Sheila Sherlock did not make the link to hepato-cellular carcinoma until the 8th edition in 1989:

"[The clinical picture] rather resembles hepatitis B infection. In 73% the patient is completely asymptomatic; in 25% the picture is that of any other acute virus hepatitis. There may be serum sickness like prodromata. Rarely the hepatitis is severe and even fulminant ....The

incubation period is about seven weeks. The acute attack is mild and in about one-quarter may be unrecognized. It can however be fulminant ….

…. In 68% the disease becomes chronic and in 20% cirrhosis develops [10%]. Hepato-cellular carcinoma, often of clear cell type, is a rare complication. Marrow aplasia may be fatal." [Page 327]

335. I knew Professor Sheila Sherlock very well. I had a chair in Transfusion Medicine at the Royal Free Hospital. My father had autoimmune Hepatitis and, when he came to the UK, Professor Sherlock examined him. I recall having a number of discussions with Professor Sherlock about NANB Hepatitis and the realisation dawning on us in the late 1980s that this was, in some cases, a chronic problem but with a long incubation period and we were only just seeing the effects materialise at that point. I think the realisation dawned on Professor Sherlock first, given the number of patients she was treating, and she really convinced me in the late 1980s / early 1990s that NANB Hepatitis could develop into a chronic problem in a proportion of patients, associated with significant mortality and morbidity. Our centre serviced Professor Sheila Sherlock's department.

d. whether others in the medical or scientific community shared your view at the time and if so who;

336. I am aware that in the NLBTC my consultant and scientific colleagues shared the same view as me.

337. I cannot speak for my other regional transfusion director colleagues, but I know that during our meetings of directors that if others had held the view that NANB Hepatitis was an immense healthcare problem in the UK, then they would have made this view known.

338. I knew Dr Eric Preston well, both on a professional and social level, and he never made it known to me that post-transfusion NANB Hepatitis was a chronic or immense problem. Dr Bill Wagstaff at the Sheffield RTC never

raised these concerns during any RTD meeting. I consider the reason for this is that, at the time, the evidence and general consensus in the UK was that NANB Hepatitis post transfusion of labile blood components was not an 'immense' healthcare problem.

e. whether your view changed over time;

339. My view did change over time. There was a gradual appreciation that NANB hepatitis (Hepatitis C) infection could, in fact, lead to chronic liver disease, with associated mortality and morbidity. I am not polarised in my views and am influenced by the evidence presented to me. Science and medicine are evolving subjects where we are learning all the time. When the evidence was available, my view did change, but this took some time

340. But I still maintain that the incidence and seriousness of disease caused by HCV infection is higher and greater in recipients of non-inactivated commercial clotting factor concentrates than in transfusion recipients of labile blood components, such as red cells, platelets and FFP. An example of the low incidence, as I have given above, was the study in the United Kingdom by me and colleagues at the NLBTC before the introduction of routine screening for HCV, showing that the incidence of post transfusion Hepatitis C was 0.26%.

341. As mentioned above, a pivotal turning point in my view changing was my discussions with Professor Sheila Sherlock in the late 1980s / early 1990s, where there was a realisation from her and her consultant colleagues at the Royal Free that Hepatitis C could lead to a chronic problem; her arguments were convincing.

342. By the time screening was introduced for anti-HCV in September 1991, I was convinced that the virus could lead to chronicity and severe liver disease.

f. if your view did change, at what point and why.

343. I have largely covered this in response to question 52e).

53. *Please provide us with the details of any studies that influenced your view of the seriousness and prevalence of HCV in the UK donor population.*

344. I have referenced a number of studies above, both external and internal to the NLBTC and my discussions with Professor Sheila Sherlock and the reading of various editions of her textbook over time, which would have influenced my view; coupled with reading of journals, attending meetings and from conversations with other medical colleagues at the Royal Free Hospital, such as Dr Geoff Dusheiko and Professor Arie Zuckerman.

54. *Did you share your view on the seriousness of HCV in meetings with RTC directors, NBTS staff members of government or others and if so when and with what aims?*

345. I always shared my views on transfusion-transmitted infections with my team, particularly with Dr John Barbara, Dr Patricia Hewitt, Dr Fiona Regan and Dr Mary Brennan, who were my consultant colleagues at the NLBTC.

346. I also shared my views with Professor Richard Tedder and with the other RTC directors at the divisional meetings.

55. *How did your views on the seriousness of HCV and HIV/AIDS impact the donor selection policies and practices in place at the NLBTC and the NBTS?*

347. My views and those of my team on the seriousness of HIV and AIDS had a profound impact on our donor selection strategy. From the start, there was ample evidence that HIV infection led to serious morbidity and mortality. As I have mentioned above, after my visit with Dr John Barbara to the New York Blood Centre, we were the first RTC in the UK to introduce a confidential donor exclusion questionnaire. Because of our geographical location, we had a high number of homosexual men and IV drug addicts amongst our

prospective donors; in those days we needed to give them an escape route if peer pressure forced them to give blood and the confidential questionnaire fitted this purpose. We also seem to have been the first centre to introduce a HIV look- back programme, based in our region. In order to safeguard the blood supply, we insisted to public health authorities on the urgent need for alternative testing sites for HIV.

348. With regards to Hepatitis C, policies were set nationally and implemented locally. The screening tests available commercially needed to be evaluated in trials together with appropriate confirmatory testing of screen-positive samples. As a Centre, we took part in those trials. After the trials, testing for anti-HCV started in September 1991 when a more specific second-generation test, with more antigens, other than C-100 was available and a confirmatory assay (RIBA) was in place.

349. The prevalence of anti- HCV was found to be one tenth of that found in the USA, i.e. one in one thousand donations, compared to the USA figure of one in one hundred donations.

350. The prevalence was found to be much higher in new donors than in established donors. The HCV lookback programme started in 1995, nationally.

351. My recollection is that we wanted to start the lookback earlier but that the Department of Health would not provide the funding for the programme at an earlier point in time. In a memo from me to Dr Thomson and Dr Brennan, North London Blood Transfusion Centre Colindale, dated 17 December 1990 (NHBT0000052_003), I said:

"I think that we should apply as soon as possible to the MRC and/or to the Wellcome Foundation for a grant to enable us to do "look-back" of those recipients of units of blood or blood components who are now confirmed positive for HCV antibodies. What I mean is that we should be able to go

back to recipients of previous donations given by donors who now test positive for anti-HCV."

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

352. At the NLBTC we had regular update meetings on the prevalence of infection markers in blood donations and possible transfusion-transmitted infections reported by hospitals and a follow up of donations, donors and recipients. Look backs were a topic for discussion. We also had annual meetings of consultants and Chief MLSOs of the hospitals we served where we informed them and updated them on the current risks of transfusion-transmitted infections. Our RHA was updated at our monthly meetings with the Regional Medical Officer. In addition, it was a requirement that cases of transfusion-transmitted infections were reported and discussed at Hospital Transfusion Committee meetings. All such cases were meticulously followed up; archive samples from the implicated donations were re-tested, patients' samples were investigated and pertinent donors were recalled and sampled.

353. We performed and published a number of studies of transfusion- transmitted infections and studied prevalence of infectious markers in new and repeat donors.(see *Barbara JAJ, Regan FAM and Contreras M. Transfusion Microbiology, 2008, Cambridge Univ Press*)

354. With respect to the NBTS and Department of Health, the following advisory committees were established to consider and assess the risk of infection associated with the use of blood components:
    a) ACTTD
    b) ACVSB (Dept of Health)
    c) SACTTI (successor of the ACTTD)
    d) MSBT (DoH) (successor of the ACVSB)
    e) EAGA (DoH)

f) SHOT: Serious Hazards of Transfusion, the UK Haemovigilance programme

Section 8: Reduction of risk of infections

57. What, if any, steps were taken during your time at NLBTS and NBTS to collect information about blood donors and screen blood donors so as to reduce the risk of the transmission of hepatitis and HIV/AIDS via blood and blood products?

355. This has largely been covered above. At NLBTC we introduced the confidential donor exclusion questionnaire before anti - HIV screening tests were available. We also introduced HIV look back at the centre. We followed up, in detail, all reports from hospitals of possible transfusion transmitted infections by testing the patients' blood samples and, if confirmed, by investigating the archive samples of the donations involved and, when appropriate, by contacting the relevant donors. If specific donors were found to transmit infections, then we counselled them and removed them from the donor panel; we studied the risk factors for their carrier status. If new risk factors were found, we modified our donor selection criteria accordingly.

356. I travelled to the New York Blood Centre with Dr John Barbara to collect information and study how that centre approached marginal donors who were at risk of transmitting infections such as HIV and we introduced the confidential donor exclusion questionnaire on the back of this. Next, we trained our blood collection staff on the risks of a transfusion-transmitted infection and adequate criteria for donor selection.

357. We worked closely with the Terrence Higgins Trust at the NLBTC, in order to better understand the behaviour of homosexual donors who were regarded as being at a higher risk of transmitting HIV.

358. We followed up and thoroughly investigated all cases of possible transfusion – transmitted viral infections reported by hospitals. A high proportion of such

cases were shown not to be due to infectious blood donations *(e.g. Hewitt, PE, Barbara JAJ, Contreras M Hepatitis C virus, BMJ, Nov 1991)* (NHBT0049737)

359. We thoroughly investigated risk factors in donors found positive for microbiological markers, especially after the introduction of new screening tests, such as anti-HCV (*see MacLennan S, et al , Lancet 1992; Barbara JAJ and Contreras M, Blood Rev 1991; Barbara JAJ and Contreras M, Vox Sang 1991)*)) (NHBT0052091 **).** We adapted our donor selection criteria, according to the findings of our investigations.

360. We joined multicentre studies for infectious and surrogate markers in blood donations (*eg Anderson et al , Transfusion Med 1992)* **(PRSE0001695)**

361. We tried to obtain research grants to enable NLBTC to do look-back studies of recipients of blood components given in the past by donors who then tested positive for anti-HCV. (*My memo to Drs Thomson and Brennan, Dec 1990* - NHBT0000052_003*)*

58. *What if any other steps were taken by NLBTS and NBTS to reduce the risk of blood borne infections being transmitted via blood and blood products during your time there?*

362. We had selective screening for other blood borne diseases like malaria and Chagas' disease for donors who were possibly at risk of carrying these infectious agents.

363. We had a panel of donors with high titres of microbial antibodies, such as anti-HBV, anti-Tetanus, anti-VZ, who we plasmapheresed regularly for the production of specific immunoglobulins by BPL.

364. Professor Richard Tedder in our team was the first to start prospective studies on Hepatitis E transmitted via transfusion.

365. Since Cytomegalovirus (CMV) infection can cause serious morbidity and mortality in bone marrow transplant patients and fetuses, we screened a proportion of our donors for CMV antibodies for the provision of CMV-negative cellular blood components for selected patients. This became less necessary with the introduction of universal leucodepletion of blood components.

366. We followed up and investigated all hospital reports of possible bacterial contamination of transfusion recipients. The vast majority of such reports were not due to contaminated blood components. We later introduced bacteriological testing of blood donations.

367. An important initiative that the consultants and I were very committed to was the liaison with the clinicians in the hospitals we served. We introduced the concept of Joint Transfusion Medicine consultant appointments and we educated clinicians in the *'appropriate use of blood"*, meaning that blood components should only be used when strictly necessary and in the absence of alternatives.

368. We started Hospital Transfusion Committees for education in transfusion medicine and to monitor blood component usage.

369. We performed audits of the usage of red cells, FFP and platelets and showed that there was a great deal of unnecessary transfusions.

370. We contributed to the preparation of national guidelines for the appropriate use of blood components, such as FFP (*See Contreras et al, Transfusion Medicine 1992*) (BSHA0000021_044)

371. We wrote a number of publications and gave numerous lectures regarding the risks of blood transfusion and measures to increase its safety *(eg Blood Transfusion in Clinical Medicine, Mollson, Engelfriet and Contreras 8th, 9th and 10th editions; Transfusion Microbiology, Barbara, Regan and Contreras*

2008; Contreras, Vox Sang 1984; Hewitt PE, Barbara JAJ, Contreras M, Vox Sang 1994; 67 (suppl 50 14 – 19, etc).

372. We organized meetings on transfusion-transmitted infections, to educate and update the medical community (e.*g. Meeting report on Viral Infections Transmitted by blood transfusion, J Royal Soc Med, 1990, Griffiths, PD and Contreras M)* **(NHBT0000030_037)**

373. In essence, we were the precursors of the 'Better Blood Transfusion Initiative' of the UK CMOs which eventually managed to significantly reduce the usage of red cells and FFP in the country. The less blood components are used unnecessarily, the less possibility of transfusion-transmitted infections.

374. As a result of this initiative, demand for red cells decreased dramatically and the need for blood collection in England and North Wales decreased from 2.4 million units of blood to under 2 million with no consequent shortages of blood components until the present time.

375. I think that it is important to raise that as a Centre we were not only dealing with Hepatitis and HIV, but a wide range of possible transfusion-transmitted infections and a wide range in demographic of patients and donors.

Introduction of anti-HCV screening

59. In your letter to Dr Gunson in April 1991 (NHBT0006421_002), you expressed the view that the proposed anti-HCV screening was "over the top". This is a view that you shared in a variety of forums, (see, for example, NHBT0000073_030). Why did you form this view? What factors did you take into account when coming to this view and how did you balance them? Specifically, please address:

a. what considerations (including scientific, professional and/or observational) shaped your view;

376. I would like to clarify my phrase 'over the top' and it is not a phrase that I shared in a variety of forums. It is fair to say that in 1991 I did not have the same level of appreciation in terms of the severity and chronicity of the Hepatitis C virus infection, as I did for Hepatitis B and HIV, but my use of the phrase 'over the top' was in relation to the proposal and method of the introduction of screening as suggested in Dr Harold Gunson's Minutes of the ACTTD and letter from Dr P Mortimer. I was definitely NOT opposed to the introduction of screening itself. My letter is very clear and detailed regarding my reasons for criticizing the unworkable confirmatory algorithm proposed by Dr Mortimer for donations found initially reactive for anti HCV.

377. I remember reading both documents and thinking that I had never dealt with routine virus screening of blood donations in such a cumbersome and expensive way. I felt that the proposal was quite unworkable and would have compromised/wasted many units of blood through the method of confirmatory testing proposed; this would have made things difficult, led to errors and confused our staff. It therefore was not the introduction of screening itself that I viewed as 'over the top' but rather the laborious methods and procedures for confirmation of anti-HCV screen positives and for counselling and referral of confirmed positive donors suggested by Drs Gunson and Mortimer. The proposal was impractical for centres dealing with over 500 donations per day.

378. The proposed introduction of anti-Hepatitis C screening of blood donations stated in Dr Gunson's letter was in my view 'over the top' and I gave the reasons for my views in my letter. To summarise:

    a) As set out in my letter (NHBT0006421_002) the proposal would be more cumbersome, laborious and expensive than any other screening test for blood donations in the UK – including anti-HIV and HBsAg.

b) The Department of Health had declined to fund the proposal, so user hospitals would need to find the monies to cover the excess cost of blood components.

c) The confirmatory testing proposed was very laborious and expensive, requiring extra laboratory and clerical staffing. The proposal would have led to mistakes and confusion of clerical and laboratory staff.

d) The counselling and referral of donors found to be anti-HCV positive was more complex than for all the other agents, considering that some centres did not do anything for Hepatitis B carriers.

e) The complexity of the procedures in the proposal was bound to lead to errors that might lead to the release of units of blood found positive for infectious agents other than the Hepatitis C virus.

f) The proposal for dealing with plasma for fractionation, suggesting that repeatedly reactive donations should undergo ALT testing, had no justification and was, in my opinion, unworkable.

g) Not enough attention was given to the monitoring and quality control of HBsAg screening of blood donations and pools of plasma were being discarded because of poor quality screening at some centres.

h) The proposal did not consider that RIBA could have been done at RTCs.

i) It seemed that the proposal was written by people who had little or no experience in dealing with testing 1000 donations a day in a busy blood centre, having to release lifesaving blood components, such as platelets, on many occasions as soon as they were tested. The delay entailed in Drs Gunson's and Mortimer's proposal for anti-HCV screening would have jeopardized the prompt release of platelets and blood for exchange transfusions and intrauterine transfusions.

379. My view expressed in my letter dated April 1991 was therefore in the context of the above points on the basis that the proposals made by Dr Gunson were, unrealistic and unworkable. Ultimately, screening was not introduced based on that proposal but in a much simpler manner, in accordance with procedures used for other screening tests.

b. whether others in the medical or scientific community shared your view at the time and if so who;

380. The screening test was not implemented in the manner set out in Dr Phillip Mortimer's and Dr Harold Gunson's proposal. I do not know if others shared my view.

c. whether your view changed over time;

381. My view that the proposal was 'over the top' did not change because that was my view based on the complexity and impracticality of the proposal being made.

382. When the proposed system changed to one that I considered was workable, then my view did change, and I have already explained how my views evolved over time.

d. If your view did change, at what point and why.

383. As I have said, my views regarding the necessity of screening evolved over time and was a gradual process based on my and the wider medical community's understanding of the severity and chronicity of some cases of HCV infection.

384. With regard to the method and introduction of screening, my view changed when the proposal was one which I regarded to be workable and practical in accordance with the practicality and resources available.

385. My appreciation at the time was that the magnitude of the problem of transfusion transmitted NANBH was not as great (i.e. considerably lower) than in the USA. Our blood donations showed a significantly lower percentage of high ALT levels and anti-HBc positives (surrogate markers for NANB Hepatitis) than the figures reported in the USA (5.7% - 17.1% in the USA compared with <3% in the UK).

386. At the time (1989 – 1991) there was no convincing evidence that Hepatitis C was causing significant healthcare problems or long-term morbidity in the UK and I have already explained that my first realisation was when I had discussions with Professor Sheila Sherlock in the late 1980s to early 1990s, which is when I began to understand the severity of the infection in some patients. The vast majority of Prof. Sherlock's ant-HCV positive patients had not been infected by labile blood components from UK donors.

387. Looking back at publications from before that time, it appears that there was a high prevalence of high ALT levels and anti-HBc positivity in donors who were from the USA and from commercial blood supplies and it was later shown that the prevalence of Hepatitis C in the USA was ten times higher than in the UK.

60. *On 3 April 1991, Dr Gunson wrote a letter to all RTC directors suggesting a delay in commencing anti-HCV screening from July to September 1991 so that "'second-round' comparative evaluation" of the testing kits could take place (NHBT0000073_065). Did you agree with Dr Gunson's suggestion to delay testing? If so, why? If not, did you make this known?*

388. Yes, I agreed with Dr Gunson's suggestion in his letter because we needed to complete the second-round comparative evaluation of test kits and gain more experience in confirmatory assays (RIBA and PCR) before reliable and more accurate and specific testing could begin.

389. It is unsafe to inform blood donors of a false positive test that would label them for a lifetime hence the need for confirmatory testing.

390. The National Reference Microbiology Centre as well as Blood Centres did not have experience of RIBA or PCR. These tests needed a new approach and specialised equipment that needed to be installed. In addition, staff needed training in these new techniques.

61. *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. What was your view and why?*

391. I supported a uniform start date because we were a national blood service with 15 different transfusion centres, all serving NHS patients who need the same standard of treatment.

392. We needed to act nationally in my view and to give the same level of screened blood to all of our patients so there was consistency with the service provided.

62. *Despite Dr Gunson's suggestion to delay, 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 Dr Gunson's opinion, 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). Did you agree with Dr Lloyd? If not, why not? Have your views changed since then? If yes, why?*

393. No, I disagreed with Dr Lloyd's view, principally because I always believed that all UK routine blood donations should be tested uniformly for the same mandatory agents and adhere to the same regulations.

394. The reasons for my disagreement are outlined in my letter to Dr Lloyd dated 3 May 1991 [NHBT0000192_009]; principally that the decision to commence

testing early would erode the concept of a National Blood Transfusion Service and potentially hinder any proposal to the DoH for central funding for testing.

395. I did not appreciate at the time that there would be harm caused in a delay in introduction of testing of three months. In medicine there is, inevitably, a *risk: benefit* analysis which is undertaken when a new treatment becomes available and we are a living example of this during the current Covid 19 pandemic (i.e. when to approve, purchase and administer an available assay or vaccine). It is not just a case of a treatment / test becoming available and being immediately introduced, there is a process that must be undertaken; otherwise it is feasible that early introduction could cause more harm than good.

396. I am aware that with the first generation of tests there were seven false positives for every one true positive and that would mean telling seven people that they may have the virus, requiring investigation for liver compromise, when in fact only one of those would truly have the virus.

397. My views have changed since then about the severity and chronicity of disease in some carriers of HCV, as more evidence has come to light. I have largely covered this above.

398. Even with the benefit of hindsight, I do not think I would have been agreeable to start testing early because the reality is that my and other centres were not ready and we had not tested the confirmatory assay. There was an issue over funding at the time and BPL would not pay for the testing of plasma. The test was expensive, the DoH would not fund it and, in the internal market climate, we needed to charge extra for our blood and blood components, so needed to convince the hospitals to pay for this screening test. The cost of the introduction of the test in our Region was of the order of £700,000 at the time.

399. I am sincerely sorry to anybody who might have been infected during the delay in introduction of the testing. Unfortunately, in medicine there is always a balance of risks, and the processes, equipment and IT tracking procedures were not in place to have introduced testing earlier. Introducing a screening test on all blood donations, is not a simple matter, as there is a knock - on effect on all the blood components that need to be issued, many of them urgently. As a Centre, we were relied upon heavily by many of the tertiary hospitals in the region who required the urgent issue of specialist blood components, such as HLA-matched platelets for bone marrow transplant recipients or phenotyped red cells for sickle cell anaemia in crisis or for intrauterine transfusions. All these blood components require attention and dedication by staff preparing and issuing them. If the correct processes were not in place, then introducing anti-HCV testing earlier, without the appropriate staff and procedures in place would have deviated the attention of senior staff, led to errors, with the consequent detrimental effect on the provision of these specialist blood components, itself also leading to some morbidity and even mortality.

63. *The Department of Health wrote to senior government medical officers on 9 May 1991 notifying them of the Northern RTC's decision and providing them with a "line to take" if there was press interest in the matter (NHBT0000062_060). The Department of Health recommended advising the press and other interested parties that "the risk of [HCV] being contracted through blood transfusion...is remote" and that anti-HCV screening should only be implemented once "the screening kits had been adequately assessed". The Department of Health also recommended advising that HCV "is normally a mild infection (not like AIDS)".*

a. *Did you agree with these statements? Please explain the views you held on these issues at the time. Have your views changed since then? If yes, why?*

400. The Department of Health memorandum describes Hepatitis C as *'"*a disease that] *may run a symptomless course, but in some cases, it can result in chronic liver damage, which may ultimately be fatal. There is also a rare but serious acute form of illness"*. I agreed with this statement and

my view has not changed. My appreciation of the seriousness of Hepatitis C evolved over time as set out in response to question 48.

401. I did, however, disagree with the Department of Health's view that the regional health authority should find the funding for anti-HCV screening from their allocations and that no new monies were offered to cover this expensive operation.

b. Did you receive any queries about implementation of HCV screening? If so, from who? Did you take the Department of Health's advice in responding to those queries?

402. I do not remember receiving any such queries.

64. In a letter to you in May 1991, Dr Gunson characterised the introduction of screening by Dr Lloyd as a "second trial" which gave the Blood Services the "opportunity, before testing is started routinely, to have further RIBA and PCR tests performed" (NHBT0000192_051). Dr Gunson refers to this as a "damage limitation exercise". What did you understand that expression to mean? Did you agree with Dr Gunson's statements?

403. My understanding of 'damage limitation' was that Dr Lloyd's decision to introduce testing early had 'damaged' the robustness and cohesiveness of the UK national blood service, hence considering the introduction of anti-HCV screening by the Newcastle Centre as a 'second trial' allowed the blood service the opportunity to get more acquainted with RIBA and PCR confirmatory assays and therefore, could be referred to as 'damage limitation'.

404. The second trial would have needed to be undertaken anyway, with a second -generation test which was more specific and added more antigens to the sole C100 antigen present in the initial assays.

405. I agreed with Dr Gunson's statement at that time.

65. *Dr Lloyd justified his decision not to inform other RTC directors of his earlier start date for testing by stating that he wished to avoid the risk of being forced to hold off testing until September 1991, which would have "resulted in the transmission of [HCV] to many patients in this Region, something that was avoidable" (NHBT0000076_009).*

a. *Could the other RTC directors have forced Dr Lloyd to hold off testing until September 1991 had they wanted to? If so, please explain how.*

406. Transfusion centres were answerable to their respective regional health authorities who held the executive power and budgets. Hence, it would have been impossible for regional transfusion directors to force Dr Lloyd to hold off testing until September 1991.

b. *Do you now agree that delaying the introduction of testing led to the avoidable transmission of HCV to individuals in the UK? Did you hold that view at the time?*

407. I should start by emphasising that I am sincerely sorry for any harm that has been caused by the delay in introducing the second -generation anti-HCV screening test for three months from July to September 1991, which would have led to the avoidable transmission of HCV to a number of transfusion recipients. The risk of post-transfusion NANBH at the time must have been less than 1 in 20,000 blood donations (Contreras et al, Lancet 1991) **(NHBT0000042_095)**.

408. As I have said above in this statement there were other factors to be considered aside from the human factor, and the processes and funding were simply not there when the testing was introduced by Dr Lloyd. The Centre in Newcastle was much smaller than the NLBTC, serving hospitals of lesser complexity and requiring considerably less specialist blood components. At the time I estimate that we were bleeding 1,000 donors per day, producing over 3,000 blood components/day and I truly believe that my

Centre would not have coped with the method and process of screening proposed; I expect that the same would apply to other RTCs who were much less well funded than the NLBTC.

66. *Dr Lloyd further stated that other countries had been using these tests for a year or longer, making the UK's delay "increasingly unrealistic and very hard to defend" (NHBT0000076_009). In a letter to Dr Cash, Dr Lloyd expressed concern that the UK was "dragging its feet" and described the NBTS as protectionist and displaying negativity (PRSE0001183). Did you agree with these views at the time? Has your view changed?*

409. It is true that other countries had introduced anti-HCV screening for a year or longer. However, I do not know how they handled so many false positive donors since the first-generation screening tests were associated with a significant number of false positive (for every true positive found there were approximately seven false positives). I do not know whether these countries informed the donors of the results or whether their blood was just discarded.

410. It was for the Department of Health to come up with a decision and the appropriate funding required to implement the testing. The introduction of a new screening test on blood donations requires significant funding, not only for the test kits but also for staffing in the laboratory, IT department, donor services, records and medical counselling and referral of donors found to be positive. As I have stated above, a number of RTCs were underfunded by their RHAs, at a time when the Department of Health was introducing cross-charging for blood components and services.

411. If there was no money to devolve to Districts with respect to anti-HCV screening, then other areas of blood services would suffer.

412. I do not believe that the National Blood Transfusion Service was *'being protectionist and displaying negativity'*, but rather being realistic with the resources, knowledge and funding it had at that time.

413. I have always considered that there are two sides to the blood services: patients and donors. We have a duty to donors who have given their blood altruistically and regularly, making significant sacrifices for those in need. To have had so many false positives in the first-generation tests was intolerable and I do believe that we had a duty to have followed these results up, by contacting the donors found to be positive. We could not have discarded their donations without giving the donors a reason and justification. I am not certain what the other countries were doing in this regard and if they were indeed following these results up.

414. In my view it would be immoral to discard a donor's blood and say nothing if a positive test had been returned, notwithstanding the high degree of false positivity in the screening.

415. As I have said above the false positive rate was seven to every one donor who actually had the virus; therefore we would have to be telling potentially seven people that they might be carrying a virus which they did not have and discarding their blood unnecessarily.

67. When was the earliest date that anti-HCV screening of blood donations could have commenced at the NLBTC? Please explain your view.

416. With adequate funding, staffing, etc., I believe that we could have introduced anti-HCV screening in July 1991 at the earliest.

417. In order to commence a new and additional test, extra staff, specialist equipment and funding are required. Staff need to be employed, trained and deployed at the screening and confirmatory laboratories, at the IT and records departments and at the various donation centres and this all needs to be in place and properly funded before testing can commence. It is not just as simple as starting a test, but all of the standard operating procedures and the logistics behind that, which need to be in place before testing can commence.

418. There was additional work on donor records and donor counselling and consent and we needed to amend the donor leaflets about the testing that would be undertaken.

419. My view, therefore, is that if we had started properly planning early in the new year in 1991, we might have been able to commence testing in July, but no earlier and, as it was, we commenced testing in September.

Section 9: Self-sufficiency and plasmapheresis

68. *In a letter to Dr Pickles dated 31 May 1990 (NHBT0000189_142), you wrote that "it is very sad that the Department of Health has decided not to support the principle of sufficiency in blood and blood products wholeheartedly". Please explain your understanding of the Department of Health's decisions, actions or inactions in relation to self-sufficiency at the time.*

420. With very few exceptions, the UK Blood services have always been self-sufficient in labile blood components, i.e. red cells, FFP, cryoprecipitate and platelets.

421. All I can say is that my perception was that the Department of Health decided not to appropriately fund and subsidise self-sufficiency in fractionated blood products.

422. I was on the board of the International Society for Blood Transfusion and was publishing papers with my Dutch colleagues, so had a good understanding of what they were doing in relation to pursuing self-sufficiency.

423. Finland especially is a relatively small country with a National Health Service, an efficient national blood service and good fractionation facilities. It has very low rates of blood borne infections.

424. It is well known that countries that are self-sufficient in blood products, derived from freely donated blood, such as the Netherlands, Finland, Australia and New Zealand, need to heavily subsidise their blood services and fractionation plants.

425. With the exception of when the Minister of Health was Dr David Owen, I do not believe that the Department of Health took a genuine interest in self-sufficiency in plasma derivatives from voluntary donors. The price they set for BPL to pay for recovered plasma and for the more expensive apheresis plasma, did not cover the production costs by the RTCs, so there was no incentive for RTCs to collect more plasma unless their RHAs were prepared to subsidise the plasma production costs.

426. As it happened, in my Region the subsidy for plasma to BPL was more than £1,000,000 a year in the 1980's.

427. In addition, in order to compete with the private sector, the Department of Health allowed BPL to deal directly with districts, undercutting the price of BPL products allocated to RTCs. If there had been a real interest by the Department of Health in self-sufficiency in blood products, blood centres would have been able to collect the required volume of plasma. The generosity and altruism of UK blood donors is well proven. However, as it was, BPL was never adequately funded to process the required volume of plasma with state - of – the - art technology. It was easier and cheaper for the Department of Health to buy fractionated plasma products from paid donors produced by USA commercial companies.

428. Until around the late 1980s, before the internal market was implemented, the NW Thames Regional Health Authority, had a strong interest in an efficient national blood service and self-sufficiency in blood components and blood products.

429. If NLBTC had a shortfall in its budget, I could go to the RHA and they would fund it; but when the internal market was introduced, we had to start properly

costing and charging hospitals for blood components and services. I had to employ a business manager and an accounting firm to cost blood components and services; this was essentially money going round in circles on a concept that cost equalled price which was fine for recovering money from hospitals, but not from BPL as they did not comply with the internal market and their prices were fixed by the Department of Health and the CBLA. Plasma for fractionation was under-priced, which meant that NLBTC and other blood centres had a considerable shortfall; the more plasma we produced, the larger the shortfall. For the labile blood components, the internal market did not really have a significant impact, but this was not the case for plasma for fractionation.

69. *What was your view on the prospect of the UK achieving self-sufficiency at the time? Has your view changed since then, and if so how?*

430. I am a firm believer in national blood and blood component self-sufficiency.

431. The UK has a tradition of committed voluntary donors since before the Second World War.

432. There were two issues with regard to achieving self-sufficiency in fractionated plasma products:
    a) The funding was not available;

    b) BPL did not have capacity or technology to produce everything that was needed to achieve national self-sufficiency.

433. If every centre had been funded like NLBTC we would have been flooded in plasma, with no problem in achieving self-sufficiency. The NLBTC provided BPL with 12.77 tonnes of plasma per million population, and the average of the centres was 9.28 tonnes of plasma per million population, a difference of more than 3 tonnes of plasma per million population.

434. My view of historical events has not changed and there is no way of the UK achieving self-sufficiency in plasma products now because we do not have a national facility for this anymore. In addition, fortunately, recombinant FVIII has taken over from plasma – derived FVIII in high-resource countries like the UK. A problem is that due to the precautionary principle, since it was realized that vCJD could be transmitted by blood components (it has never been shown to be transmitted in fractionated plasma products), tonnes of UK plasma which ought to be sent for fractionation have, until very recently, been discarded.

70. *In May 1991, you wrote that "the policy of self-sufficiency in plasma procurement is not being continued despite European policies which strongly favour self-sufficiency in blood and blood products" (NHBT0000191_131). Was the UK out of step with other European countries in relation to pursuing self-sufficiency?*

435. The European recommendation, in line with the WHO recommendation, was and is that countries should be self-sufficient in blood and blood products. My view is that the UK was out of step with some, but not all, European countries. The Netherlands, Finland as well as France and Spain to some extent, have achieved self-sufficiency in plasma products.

436. As I have stated, the UK has always been self-sufficient in blood components. In fact, we had to curtail the collection of blood by approximately 500,000 units/ year due the CMOs' recommendation (driven by NBTS consultants) for appropriate use of blood components in the Better Blood Transfusion initiative, now expanded and renamed Patient Blood Management programme.

71. *Broadly, what steps do you consider were required to achieve self-sufficiency in the UK at this time? Were any of these steps taken? What could and should have been done to achieve self-sufficiency?*

437. As I have stated, the possibility of collecting sufficient plasma from safe blood donors was always there, given the willing donor population in the UK,

but what was needed was the political will and funding from the government and the Department of Health to utilise the willing donor population to donate regularly by plasmapheresis. Even if we had collected all the required plasma for self-sufficiency in blood products, BPL did not have the capacity or state-of-the-art equipment to fractionate it all, nor the sophisticated equipment to produce the high purity products available in the commercial market.

438. We lacked resources and funding and, whilst I did my best to draw this to the attention of the relevant bodies, what was essentially needed was money for plasma donor recruitment, apheresis machines and apheresis clinics, with all the added expenditure that this entails, such as additional staffing, laboratory tests, etc.

72. *In a letter to Dr Gunson in April 1991, you wrote that "the principle of national self-sufficiency is praiseworthy. However, it is an expensive principle and if Ministers are to support it, considerable cash injection into NBTS or BPL will be needed" (NHBT0027439_004). Was the "cash injection" received by NBTS and/or BPL? If not, did this affect the UK's attaining self-sufficiency in your view? What if any representations were made by NBTS or BPL to government for a "cash injection"?*

439. As far as I am aware, the cash injection was never received by the NBTS nor by BPL, hence self-sufficiency in plasma products was never achieved. If all regional health authorities had funded their RTCs as North West Thames did, then there would have been enough plasma for self-sufficiency. However, I doubt whether BPL could have coped with that volume of plasma and whether it would have had the capital to invest in the required technology.

440. As I have said above, BPL needed the largest cash injection to have better facilities and therefore better yields of products that were of higher purity.

441. I made my views known to Dr Harold Gunson, to the RTCs, to my RHA and to the Department of Health via Dr H Pickles.

442. I was never director of the NBTS but believe that Dr Gunson made representations on behalf of the NBTS to the government, asking for money to fund plasma procurement.

73. In the same letter, you noted the costs of self-sufficiency for RTCs reliant on voluntary donations. These included that plasma obtained from paid donors is considerably cheaper than plasma obtained from voluntary donors, follow up of donors by RTCs, investigations and retesting of infected donations, and packaging limitations.

a) Please explain why plasma from paid donors was cheaper than from voluntary donors.

443. Plasma from voluntary donors is considerably more expensive than from paid donors. Voluntary donors require medical follow up. Their blood profile is checked and their health followed up in a much stricter way than with paid donors (see Contreras M, 1994, Blood Coagulation and Fibrinolysis) (NHBT0052106).

444. With voluntary donors you are at the mercy of their availability to come and donate, whereas with paid donors they come when they are told to, so clinics can plan their attendance with no 'dead time' or idle time for staff or apheresis machines. This means more efficiency of staff time.

445. Apheresis machines and disposables are expensive. With paid donors, machine occupancy is at its highest because bed occupancy is 100% all of the time.

446. Paid donors can donate more often and in greater volumes than voluntary donors. Paid donors can donate 50 to 60 litres of plasma/ year whereas voluntary donors can donate a maximum of 15 litres of plasma a year.

447. If a marker of a blood transmissible agent is found in a voluntary donor, extensive medical follow - up is needed, whilst this is not the case with paid donors, whose plasma is just discarded. In addition, if any abnormality is found in the haematological or biochemical profile of a voluntary plasma donor, donations are suspended until the parameters return to normal. This is not the case with paid donors who can give several times a week and are not followed up medically.

448. In the mid 1980's, I was able to attend a commercial centre in the USA which was part of Baxter Laboratories; I saw first-hand the difference in the treatment and approach to commercial and voluntary plasma donors. I remember thinking at the time that the type of donors was very different from our voluntary donors and so was the way they were treated. Donors came on a regular basis, for the money and the scene reminded me of a dairy farm.

b. To what extent did these financial challenges—not borne by commercial companies—affect the viability of self-sufficiency as a national strategy for the UK in your view?

449. I believe these financial challenges must have affected the viability of self-sufficiency in plasma products, as a national strategy for the UK. The NHS is, and always has been, short of money with many competing priorities in healthcare to deal with. This is a question best answered by the Department of Health.

450. What I meant by "packaging limitations", is that BPL demanded that the plasma for fractionation should be stored and frozen in especially designed rigid plastic packs, called the "international plasma packs". These packs were only used by BPL and were considerably more expensive than the plasma packs used by other countries and by the commercial plasma sector.

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

451. I believe that my views on self-sufficiency were in accordance with my professional peers. I never met an RTD without an interest in plasma self-sufficiency. As an example, the document that I have been provided with, entitled *'Mersey Regional Transfusion Service – Plasma Procurement 1989/90, 1990/91 – Two Year Scheme to Self Sufficiency'* (NHBT0019602_003) shows a genuine (albeit optimistic) interest in achieving the plasma target of 8.2 tonnes of raw plasma per million population, imposed by the Department of Health in order to attain self-sufficiency. As stated above, NLBTC had far surpassed this target.

75. *What role did you, as the Medical Director of the NBTS, have in the drive toward self-sufficiency in the UK?*

452. As already stated, I was never the Medical Director of the NBTS, I was the Medical Director of the North London Blood Transfusion Centre.

453. As recommended by WHO, the Council of Europe and ISBT, I believe in self-sufficiency in blood and blood products and did my best to achieve it by maximising my centre's production of plasma, exceeding targets and by communicating my views to the relevant bodies.

454. Self-sufficiency and safety were not competing alternatives, but distinct and compatible objectives. Self – sufficiency avoids the possibility of foreign infectious agents entering the national blood supply.

76. *In a letter to Dr Gunson in January 1991, you made reference to the "extra workload incurred as a result of the Gulf War" (NHBT0000073_030). Please explain the impact that the Gulf War had on your work, and, as far as you are able, on the blood service and blood supply more generally.*

455. We required large volumes of blood components to deal with possible large numbers of severe casualties. My centre was asked to supply fresh labile blood components such as red cells (mostly group O), platelets and FFP (not group O) on a daily basis.

456. Given the proximity of the NLBTC to Heathrow and to RAF Northwood, I believe there was an extra responsibility and pressure on my centre to meet the demands of the Gulf War. Since there was a call for donors to give blood for war casualties, we had to deal with a large number of extra donors who were eager to donate to help their fellow countrymen.

457. As a result of this there was additional work for our collection teams and processing and testing laboratories and I recall that everybody at the centre at this time had to work extra hours, which we did willingly and voluntarily when required.

77. *In a letter published by the BMJ in 1993, you wrote about self-sufficiency in response to the "German blood scandal" (NHBT0000030_097). You noted that where self-sufficiency has not been achieved, doctors should "[start] demanding to know the origin of the plasma used to manufacture the blood products they use rather than trying to make minimal cost savings, sometimes under the pretext of clinical freedom." Please answer the following questions in relation to this statement:*

a. *What information was provided and what information might have been available if doctors asked about the origin of plasma?*

458. My opinion is, and has always been, that the origin of plasma should have been available to the doctors who were prescribing it to patients and also to the patients receiving the product. The origin should have been stated on the label of the plasma product and if this was not clear, then doctors should have enquired with the hospital pharmacy and pharmaceutical companies about the provenance of the plasma. In this way, it should have been easy

for doctors to determine whether the plasma was from paid or voluntary donors and whether it was of foreign or national origin.

b. What cost savings could be achieved by not asking questions about it?

459. If no questions were asked, then whoever was in charge of purchasing medicines would presumably have bought the cheapest. Naturally, as long as the medicines were approved by the (then) MCA, then people in charge of purchasing medicines would have bought the cheapest available.

c. What role, if any, did you have to play in improving the system in your various medical capacities?

460. I played no role. All I could do was educate clinicians on the improved safety of plasma products originating from voluntary donors. I had no power over NHS purchasers of fractionated blood products.

d. What did you mean by "under the pretext of clinical freedom"?

461. By 'under the pretext of clinical freedom' I meant under the pretext of the accepted philosophy at the time, that the doctor was privileged to do what he or she believed was right and in the best interests of his / her patient. In other words, the doctor's freedom of choice and, in general his or her patient's acceptance of their doctor's recommendations without question or challenge.

462. The doctor was clinically free to use whatever product they wanted – so they could / should have demanded to know the source as part of making that decision.

78. Later in the same letter, you state with regard to the risk involved in transfusion of contaminated products, that "if patients receiving these products were adequately informed and knew of safer alternatives, would they not demand them?" Please answer the following questions in relation to this statement:

a. What would be being adequately informed have involved?

463. I have always pushed for adequate information for patients and, in relation to blood components and blood products, that they should be told the provenance of these.

464. Adequately informed would have meant informing patients of the need for therapy in the first instance and of the alternatives (for example saline instead of albumin). Patients should also have been informed of the provenance of the albumin and immunoglobulins, i.e. whether they were produced in the UK or abroad and whether they were produced from paid or voluntary donors.

b. What safer alternatives were available at that time?

465. The document referenced in this question is not in relation to factor VIII or other clotting products, but rather intramuscular immunoglobulin and albumin and my reference to safer alternatives is in relation to home produced, voluntary donor-derived albumin, and intramuscular immunoglobulin of which we had an abundance in the UK, rather than that purchased from commercial companies, originating from paid donors, which is known to be less safe.

c. What if any steps did you take to address this situation?

466. I was angry because we were self-sufficient in the UK in intramuscular immunoglobulin and albumin, with no need to import these products. I made this point clear by writing my letter to the editor of the BMJ in order to raise awareness. I also informed my regional health authority about the issue.

79. In January 1989, a meeting was held at BPL to discuss "plasmapheresis issues" and the "continued evaluation of Source Plasma (Human) collected by automated plasmapheresis systems" (CBLA0014265). Dr Lane wrote that the meeting

"hopefully will clarify some of the outstanding problems which may arise as the onus for new plasma collection falls increasingly on plasmapheresis systems". As far as the Inquiry is aware, you attended and presented at that meeting along with a number of clinicians. Later that year, a 1989 report titled 'Mersey Regional Transfusion Service—Plasma Procurement 1989/90, 1990/91—a twoyear scheme to self-sufficiency' discussed the crucial role that plasmapheresis was intended to play in increasing plasma supply for blood products and therefore achieve self-sufficiency (NHBT0019602_003). It concluded that "the expansion of plasmapheresis is recommended because of the better factor eight yield of plasma obtained in this way, which may receive credit with the proposed scheme of cross-charging in 1989". Please explain your views on the following as far as you are able:

a. *Did you agree that plasmapheresis was a crucial technique to increase plasma yields for blood products? Please explain the reasons for your view. Did your view change over time?*

467. It is scientifically proven that apheresis plasma provides larger volumes-better yields than recovered plasma.

468. Recovered plasma is where lots of units of whole blood are collected, transported by a driver to the local blood centre and then centrifuged to separate the components of the blood according to blood groups. Recovered plasma is less pure due to the operator – dependency and its possible contamination with red and white cells and the maximum yield for recovered plasma is approximately 300ml (average 150ml) per donor. The time for separation of the plasma from red cells is obviously longer than in apheresis where separation is immediate. The shorter the time for separation, the better the yield of Factor VIII and other clotting factors. Also, the temperature control between collection of whole blood and its separation in the laboratory is not ideal in the case of recovered plasma.

469. Apheresis plasma is plasma which is separated from the red cells, white cells and platelets during the process of collection by the apheresis

machine. The yield is much greater in apheresis plasma, maximum 700ml (average 550ml) per donor. You also achieve a purer product without contamination of red and white cells and the apheresis plasma can be sent straight to the laboratory for freezing.

470. The cost of apheresis plasma from voluntary donors is considerably more expensive than recovered plasma. The donation takes longer (30 minutes or more) and the donors require very good veins and a higher circulating blood volume; whereas with recovered plasma the donation process takes less than 10 minutes, smaller donors can donate and there is minimal equipment required, with donations taking place in, for example, churches and town halls. With apheresis plasma donations, the equipment is very expensive, specific dedicated premises and more specialized staff are required.

471. Additional expensive laboratory tests are required in apheresis in order to routinely monitor the donors' health.

472. I therefore agree that plasmapheresis is a crucial technique to increase plasma yields and reduce wastage of red cells and my view of this has not changed. Self-sufficiency in plasma products is not achievable on the basis of recovered plasma without a considerable wastage of red cells. Such wastage would be immoral and unacceptable.

b. Did others in the medical or scientific community share your view at the time?

473. Yes, I believe that my clinical and scientific colleagues shared this view.

c. Please expand on the "problems" referred to by Dr Lane in the context of the expansion of plasmapheresis.

474. I have not been able to locate document CBLA0014265, but have read the 1989 report entitled *'Mersey Regional Transfusion Service – Plasma Procurement 1989-90, 1990-91 – a Two Year Scheme to Self Sufficiency'*

(NHBT0019602_003) and I believe that the problems referred to by Dr Lane were mostly financial in that plasmapheresis was more expensive and required specialised equipment, and staffing in purpose-built premises. Our RHA subsidised plasma procurement to the tune of £1million/ year, as we had three apheresis clinics at the North London Blood Transfusion Centre. However, other centres did not have the necessary funding for the equipment and staffing required and therefore increasing plasma collections by apheresis meant a considerable cash injection for premises, medical, nursing, clerical and laboratory staff, as well as for machines, harnesses, donation beds, screening tests, freezers and transport. I think that the Mersey Regional Transfusion Service in their 1989 report perhaps naively underestimated the cost of apheresis plasma and thought that they would more than recover the costs when reimbursed by BPL by achieving a plasma target of 8.82 tonnes per million population. As I said earlier, NLBTC surpassed the plasma targets and BPL prices did not cover the costs of plasma collection, processing and testing.

d. To what extent was plasmapheresis adopted across RTCs? As far as the Inquiry is aware, some RTCs adopted the technique while others did not. Please explain why this was the case and how it was decided which RTCs would adopt plasmapheresis systems.

475. I was not the national director for the NBTS so can only answer for my regional centre (the NLBTC). I believe it was up to each RHA, informed by their respective RTD, to have a greater or lesser interest in plasmapheresis and self-sufficiency in plasma products.

476. I was fortunate that the North West Thames RHA supported my passion for self-sufficiency and funded the NLBTC adequately.

477. We were the major plasma producers per million population (producing more than 3 million tonnes per million population more than the other centres), and in fact my region was vastly subsiding plasma production as

the revenue we received from BPL for plasma procurement did not cover the production costs.

478. I was fortunate that we had three apheresis clinics two of which I inherited from my predecessor, Dr Cleghorn, who was an advocate for apheresis plasma from the 1970s. In fact, he started with manual plasmapheresis, before the time of automated machines.

e. *Was any, or adequate, central funding provided to each RTC to meet the additional costs of machinery and nursing staff required to increase plasmapheresis? If not, did the lack of funding affect the uptake of RTCs of plasmapheresis systems?*

479. I believe that no central funding was provided to RHAs to increase plasmapheresis. The absence of central funding must have affected the uptake of plasmapheresis by many RTCs.

f. *Please explain what cross charging entailed and whether it was implemented across RTCs.*

480. Cross charging in RTCs was part of the overall environment of the internal market introduced into the NHS. It was not discretionary. Regional allocations of funding disappeared and budgets were devolved to districts. The environment that we worked in was that cost should equal price, i. e. you could not make a profit. What this entailed was that we had to cost all of our products and services on a consistent basis. However, BPL did not abide by the internal market and did not give credit to the full cost of recovered or apheresis plasma which meant that my Centre, the NLBTC, was badly hit since we were by far the most efficient plasma provider in the UK at the time.

g. *Did plasmapheresis play the crucial role in increasing plasma supply that was suggested in this note? If not, why not?*

481. It did in part, but not as much as was required nationally for the financial reasons explained above.

h. To what extent did plasmapheresis bring the NBTS closer to achieving self-sufficiency of blood products?

482. Since I was never the director of the NBS, I am unable to answer this question, but my opinion is that plasmapheresis must have had a positive impact on achieving self-sufficiency for the reasons I have stated above.

Section 10: Sir Magdi Yacoub

80. In a letter to Dr David Beresford of the Medical Defence Union dated 19 May 1988, you refer to Sir Magdi Yacoub and his preference for using unscreened "fresh, warm blood" ("FWB") during complex or difficult cardiac surgeries at the Harefield Hospital in London (NHBT0093056). Please answer the following questions, as far as you are able, regarding this practice:

a. When did you first become aware of Sir Yacoub's use of FWB during surgery?

483. Sir Magdi Yacoub was an expert and unique cardiac surgeon at the Harefield and Brompton Hospitals in London and I came to know him well through my position as Director of the North London Blood Transfusion Centre, which served both the hospitals he operated from.

484. At the time I came to know Sir Magdi Yacoub, he was performing pioneering heart and heart - lung transplantation surgery as well as lifesaving cardiac surgery on very sick new-born infants. He was a hugely influential and respected figure in the medical world, particularly among his cardiothoracic colleagues, both nationally and internationally. He was highly respected and sought after by patients with heart conditions that required surgery.

485. I believe that Sir Magdi saved the lives of very many sick adults and children who would not otherwise have survived.

486. I first became aware of Sir Magdi Yacoub's use of fresh warm blood during cardiac surgery when the haematologist, Dr Sheila Amin, at the Harefield Hospital contacted me for help.

487. My recollection is that Sir Magdi was asking Dr Amin to perform retrospective testing on samples of the units collected by his staff and used as fresh warm blood during cardiac surgery procedures. She was uneasy about it, which is why she contacted me.

488. After several meetings with Sir Magdi, I concluded that it was better that my Centre provided him with same-day whole blood, generally tested, from known or repeat donors, rather than he obtain it from other sources, which would inevitably carry more risks. Altruistic voluntary known or repeat donors carry considerably less risk of transmitting infectious agents than first time donors who are under pressure to give blood. Sir Magdi was happy to accept my offer.

b. When did the NLBTC begin to provide FWB to Sir Yacoub and Harefield Hospital?

489. I am unable to remember the dates exactly, but I believe that this was around 1986.

490. The provision of blood for Sir Magdi was only one of many issues I had to deal with, as Director of the NLBTC, amongst requests from the numerous specialist hospitals we served in London, many with complex requirements, such as HLA-matched, CMV-negative irradiated apheresis platelets for bone marrow transplant recipients.

491. As far as I can recall, on very few occasions did we provide same-day unscreened blood because most of the time we could provide same-day whole blood screened for the mandatory infectious markers.

492. We could have never been able to provide 'warm' blood because when blood leaves the body it cools down to room temperature, but what we were able to provide was same-day whole blood from known donors and usually screened for the mandatory microbiological markers.

493. It was only on rare occasions, when it was impossible for us to provide same day screened blood, that we had to resort to providing unscreened same - day whole blood from regular voluntary donors, which had been screened in the past and would have been screened as soon as possible, so that in the rare eventuality that a unit of blood tested positive for a microbiological marker, we could recall that unit. Fortunately, we never had to recall a unit from Harefield Hospital as none of the donations we supplied as same-day blood ever tested positive for any mandatory microbiological marker.

494. We specifically selected units from donors who had given blood in the past (regular, established or known donors) because it is well established that they are significantly safer than first-time donors and it is very rare that they seroconvert, i.e. that they become positive for a microbiological marker on further donations (Transfusion Microbiology, by John A. J. Barbara (Editor), Fiona A. M. Regan (Editor), Marcela Contreras (Editor), 2008).

c. What prompted the NLBTC to become involved in the provision of FWB?

495. I take full responsibility for the decision to provide same-day blood for Sir Magdi Yacoub's patients.

496. Initially I was sceptical about Sir Magdi's arguments for using fresh warm blood, but over time, following lengthy discussions and after attending a number of his surgical procedures, I was persuaded that there was a clinical benefit because of the outcomes he was achieving; I could evidence that uncontrollable bleeding stopped in many cases. I understand that he gathered similar support within the cardiac and trauma surgery community.

497. There have since been studies to support its use; P Spinella, J Perkins, K Grathwol, A Beekley and John Holcomb: *Warm Fresh Blood is Independently Associated with Improved Survival for Patients with Combat-Related Traumatic Injuries. J Trauma, 2009 (April), 66(s69-s76)*- exhibit 'WITN5711005 ' and *P Kendingelen, Z Kamalack and MD Abat: Should warm fresh whole blood be the first choice in acute massive haemorrhage in emergency conditions? Ulus Travma Acil Cerrahi Derg, March 2016, vol.22 No* 2 – exhibit '**WITN5711006 '.**

498. There are more recent peer-reviewed publications in support of the use of fresh warm blood in exceptional circumstances, like in combat casualties in the USA army, but also applicable to massive haemorrhage in civilians, especially in paediatric cardiac surgery, such as:-

- *Spinella PC, Cap AC (2016) Whole blood: back to the future. Curr. Opin Hematol; 23 (6) 536-42.*

- *Cap, AP, Beckett A,Benov A et al (2018) Whole Blood Transfusion. Military Medicine, vol 183, issue suppl.2, 44-51*

- *Jones DR, Sesok-Pizzini D, Friedman D (2015) Reduced transfusion requirement with use of fresh whole blood in pediatric cardiac surgical procedures. Ann Thorac Surg 99 (5) 1706-11.*

499. NHBT0072688 is a letter by a cardio-thoracic surgeon in Newcastle to Dr Lloyd. It refers to a recent paper showing that one unit of fresh blood was equal if not superior to the haemostatic function of 10 units of stored platelets, which may explain why the bleeding stopped abruptly after 4 units of fresh blood (collected from volunteers after discussion with the family and administered within 30 mins with testing for Hepatitis B). This case report argues in favour of what I have stated, especially with reference to reducing multiple donor exposure which obviously decreases the risk of transfusion-transmitted infections. Fresh whole blood contains smaller volumes of anticoagulants (beneficial in a bleeding patient) and additive solutions

(decreases the possibility of volume overload and avoids foreign chemicals) than the equivalent amount of conventional blood components (red cells, platelets and fresh frozen plasma).

500. In addition, at ISBT and NHSBT, there is a renewed interest in the use of whole blood in trauma and massive haemorrhage, i.e. a move away from the use of separate blood components to whole blood as a more appropriate replacement therapy. St Bartholomew's Hospital and NHSBT are conducting trials on the use of leucodepleted whole blood in trauma patients who are bleeding pre-admission to hospital (in the air ambulance). The group is also assessing new leucodepletion filters that spare platelets, so that they can develop a "whole blood" component that will hopefully be used in clinical trials of major haemorrhage in the future.

501. What prompted me to become involved in the provision of same-day whole blood, were the complaints from the haematologist at Harefield Hospital, Dr Sheila Amin, as the pathology lab and blood bank could not deal with the number of urgent requests for testing (retrospectively) samples from units of blood which had been bled by Sir Magdi's team and transfused immediately into patients before they were screened.

502. As mentioned above, I visited Sir Magdi Yacoub and attended some of his unique procedures, particularly those involving very sick infants requiring complex and life-saving heart surgery, often with extracorporeal circulation. He was convinced that 'fresh warm whole blood' was essential to prime the pumps and for good haemostasis, hence good outcome. In a sense he convinced me that whole blood was better than component therapy for his very special cases because with the latter you had to reconstitute whole blood, exposing the patient to numerous more donors than when loading the extracorporeal machine with whole blood.

503. Whole blood contains considerably smaller quantities of anticoagulants and additive solutions than the equivalent amount of conventional blood components (red cells, FFP and platelets). Perhaps we have gone too far

with insisting on blood component therapy in cases of massive haemorrhage, bleeding trauma and cardiac surgery in infants. With regards to the freshness of blood, there is evidence that stored blood has red cells with a "storage lesion" that might be detrimental to the outcome of the critically injured. Many experts in the clinical world, especially in war situations, seem to be returning to the use of whole blood, as fresh as possible. So, the debate of fresh versus stored blood is still ongoing and so is the debate of whole blood versus component therapy for the treatment of massive haemorrhage.

504. In any event, since Sir Magdi would not accept component therapy for his difficult surgical procedures, I agreed, as an exception, to provide same-day whole blood from known donors, ideally screened wherever possible.

505. Although it was against the principles of good Transfusion Medicine, I took the decision because on the very rare occasion that we would have to issue unscreened blood, it was better to supply blood from established voluntary donors who would have donated in the past and who had answered the confidential donor exclusion questionnaire. This, in my opinion, was an option preferable to Sir Magdi's team bleeding staff, patients' relatives and people from the public in the surgical theatre area.

506. As stated above, the blood that I provided was almost always tested. On the rare occasions that the blood could not be tested prior to transfer, it was tested retrospectively as soon as possible, often whilst the packs were on the way to the hospital. We never had to recall a same – day whole unit of blood from Harefield Hospital.

507. I have noted in NHBT0004021 report, "*Coordinated research programme in blood transfusion (1988), plasma products and European self-sufficiency: collection preparation and use*", by Dr J Leikola et al, 1988. Prepared for the committee of experts on blood transfusion and immunohaematology, Council of Europe at page 48 refers to a situation which may arise where

emergency treatment of a patient requires transfusion of a fresh unit of blood that has not yet been tested for infectious diseases.

d. *For how long did the NLBTC provide FWB to Sir Yacoub and the Harefield Hospital?*

508. I do not remember exactly, but it must have been for a maximum of two years, ending in May 1988, according to the correspondence provided to me (NHBT0093056).

509. I was always uneasy about providing same-day whole blood to Harefield but made the exception for the reasons and pressures set out above. However, from recollection, it was the introduction of the Consumer Protection Act in 1987, which meant I had to declare and sign documents which would not necessarily accord with the arrangements in place at Harefield to deal with the provision of same-day whole blood, which led me to write to my medical defence organisation to seek guidance. This consultation ultimately led to the decision to stop providing this service to Harefield Hospital.

e. *How were the requests to the NLBTC to provide FWB received and by whom were they made? Did you understand the requests to be coming directly from Sir Yacoub or from the Harefield Hospital?*

510. The requests came from Dr Sheila Amin (Haematologist at Harefield Hospital) or her blood bank staff following Sir Magdi's urgent request. General discussions around the requirement and benefits of same-day whole blood were held directly with Sir Magdi, as mentioned above.

f. *What resources and costs were involved in the supply of FWB by the NLBTC?*

511. Not much was required in terms of resources because our duty was to supply blood and blood components to hospitals, so we would have had to provide the blood components anyway. Whole blood requires no processing, so, it is cheaper than component therapy.

512. The transportation of the blood was at Harefield Hospital's own expense in their own vehicles.

513. There was always a consultant (including me) at the NLBTC on 24-hour call who would receive urgent and exceptional requests, including those from Harefield for the provision of same - day whole blood. If the same-day whole blood had not been tested, then it could only be authorised and issued by the medical consultant on-call. I should add that this was always under my responsibility.

514. Except for Christmas day, the NLBTC collected blood every single day and in order to comply with Sir Magdi's request for same–day whole blood, this would be provided within 18 hours of collection. We had a system in place where we separated whole blood specifically for Harefield, in order to comply with their urgent requests. Hence, the on-call consultant would just have to authorise the centre staff to issue the blood. As I have said, this was all my responsibility and under my authority.

g. Was a clinical justification provided to you about the need for FWB in "difficult cardiac surgery operations"? If yes, by whom?

515. Yes, by Sir Magdi Yacoub as set out above. Through numerous discussions and after attending a number of his complex paediatric cardiac surgical cases and heart-lung transplantations, I was persuaded that there was benefit in providing same-day whole blood. Since he was a leading and world-renowned pioneering surgeon, who was saving lives in exceptional circumstances, I accepted his justification.

516. When asked to justify the use of "fresh warm blood" for his difficult cardiac surgery patients, I recall Sir Magdi saying that his experience showed that, when bleeding was uncontrollable in critical cases at the operating table, the use of fresh warm blood stopped the bleeding in the majority of cases. He said he had a choice, when confronted with uncontrollable bleeding, to give

fresh warm blood with a high possibility of patient survival and a remote possibility of transfusion-transmitted infection or not to give fresh warm blood and allow the patient to die, exsanguinated, on the operating table. He said he preferred the possibility of saving a life, with the remote possibility of transmitting infection.

517. With my own eyes I saw the transfusion of fresh warm blood stop bleeding, like magic, in heart surgery patients. So, it was difficult to challenge Sir Magdi's clinical expertise. The same would apply to same - day whole blood because this had been stored at room temperature rather than being cooled and the effect it had was really miraculous from what I witnessed, which led me to be convinced by Sir Yacoub's position.

h. Did the NLBTC provide FWB to any other surgeons or hospitals in London?

518. No, but I have been provided with a copy of a letter which I wrote to another cardiac surgeon (Mr Alun Rees) at the Harefield Hospital, dated 9 September 1988 [NHBT0088294] responding to his letter to me of 22 August 1986 (which I note should be 1988) in which I say, in response to a similar request from him, that although we had tried in the past to cooperate with requests for fresh (i.e. same-day) blood, tested or untested, in cases of dire emergency at Harefield, we had stopped this practice since it became clear that pre-agreed conditions were not being observed.

519. The letter to me dated 22 August 1988 states:

"*…whatever scientific evidence there is to the contrary, I know and so [do] all other cardiac surgeons I suspect, that fresh warm blood can be lifesaving under certain circumstances…*

I have, in fact, stopped using fresh warm blood, but I am not proud of that fact, but I realise that if I do so I stand completely alone, and if a patient dies on the table from bleeding, that hardly raises an eyebrow administratively. For the surgeons and the patient's family however, it is a catastrophe. If

however, a patient dies four years later because of HIV infection this is a big problem for everybody".

520. I do believe that cardiac surgeons held this view genuinely as to the benefits of fresh blood and I witnessed the effects of it for myself.

i. Are you aware of other RTCs in the UK providing FWB for similar purposes?

521. Not that I am aware of.

81. In NHBT0093056, you stated that the use of "unscreened blood is totally against the good practice of Blood Transfusion Medicine and against my own principles". Please expand on this view.

522. I have dealt with this to a large extent above. Best practice in blood transfusion medicine is to screen blood before it is used. These guiding principles are set out in a number of publications and adhered to by various organisations (the Red Book, Professor Mollison's Blood Transfusion in Clinical Medicine, WHO Guidelines, the Pan American Health Organization Guidelines). All these publications say that blood should be screened for blood groups and mandatory microbiological markers of infectious agents before it is used.

82. The NLBTC nonetheless "made exceptions on numerous occasions to give [Sir Yacoub] 'untested' blood from known donors", despite your belief there was "no scientific evidence in the world literature, nor from the world-renowned cardiac surgeons such as [Denton] Cooley and [Michael] de Bakey, showing that 'fresh warm blood' is ever needed in these times of component therapy" (NHBT0085681_039).

a. Who at the NLBTC was responsible for deciding to provide FWB to Sir Yacoub in exceptional cases?

523. I believe that there is a misconception here that the blood was never tested. That is not the case. The blood was always tested, but on the rare occasion that it could not be tested prior to issue and rarely prior to transfusion, it was tested retrospectively and as soon as possible. As I have said, not one single unit of same-day blood issued to Harefield Hospital was ever recalled due to a microbiological infectious agent being discovered retrospectively. The majority of the same – day whole blood issued was always tested before it was transferred to Harefield. In the two years that we were providing same-day whole blood to Sir Magdi, I believe that we provided less than 500 units in total, the majority of which (I would say 90% or more) was tested before issue.

524. I was responsible for the decision to provide Sir Magdi Yacoub with same - day whole blood (this was not fresh warm blood as it was impossible for us to provide fresh warm blood). Occasionally, the consultants on duty at NLBTC had to authorise the issue of same- day untested blood, but this was always under my responsibility.

b. On what basis were these decisions made? What factors were taken into account?

525. As I have stated above, the decision was made on the basis of lengthy discussions with Sir Magdi Yacoub and attendance at a number of his complicated surgical procedures, where I witnessed, with my own eyes, the miraculous effects of using fresh warm blood and same- day whole blood rather than blood component therapy. Also, on the basis of Sir Magdi Yacoub's conviction that he needed the blood, as a world- renowned pioneering surgeon.

526. I am a firm believer that in medicine you have to trust your clinical colleagues' judgement, particularly if they have vast experience and expertise, such as was the case with Sir Magdi Yacoub at the time. He was doing ground-breaking and pioneering surgery that very few others, if any, would have done worldwide. He was saving the lives of patients who had

no hope of surviving without cardiac surgery and I was persuaded by his argument for the provision of same-day whole blood.

c. *Please explain your basis for continuing to provide FWB to Sir Yacoub despite your view that FWB was unnecessary.*

527. I was not at liberty to question every request made by Sir Magdi Yacoub, nor did I have the necessary skills to challenge his rationale. I am not a cardiac surgeon and very few people in the world would have Sir Magdi's expertise. I have stated above that I had witnessed the miraculous effects of fresh whole blood and had to put trust in his judgement as a world - renowned cardiothoracic surgeon.

528. In addition, as a damage limitation exercise, I decided that if I did not provide the service he was requesting, then I am certain Sir Magdi, given his strong beliefs, would have continued as before. This would have presented more of a risk to the patients and donors; I therefore felt that supplying the blood from voluntary repeat donors was the preferable option.

529. We made great efforts to minimise the risks, some of which are recorded in a document which has been produced to me [NHBT0101365] which is a letter I wrote to the District General Manager of Hillingdon Health Authority following a meeting on this issue on Monday 17 October 1988. My letter responds to his notes of the meeting which include a decrease in the use of fresh warm blood in recognition of the risk of AIDS and that David Thomson was to work out with Tickles (the firm of solicitors who advised on these issues) an even clearer consent form for patients and for their relatives so that it was clear that, in extreme situations, fresh blood might be used and that there were risks associated with AIDS that could arise from this situation. (However, the consent form needed to also indicate that this step would only be taken should component therapy not have been successful and the person's condition be extremely critical.) Steps would also be taken to improve the testing of fresh blood.

d. *Do you believe that your actions to meet the requests of Sir Yacoub were justified?*

530. Yes, I believe so. To summarise what I have already said; Sir Magdi Yacoub thought it was necessary to use fresh warm blood as his patients would suffer harm without it. I believed that providing same-day whole blood, generally tested, from known or repeat donors would be safer than him obtaining it from other sources, which would inevitably carry more risks.

531. Ultimately, it got to a stage where I was conscious that I was not complying with European Legislation on Product liability, which is why I raised the issue with my medical defence organisation and the RHA. This led me to stop supplying Sir Magdi Yacoub with same-day whole blood.

83. *In a letter from you to Mr Alun Rees at the Harefield Hospital dated 9 September 1988, you stated that the "pre-agreed conditions were not being observed by the clinicians" at the Harefield Hospital in respect of the provision of fresh blood (whether tested or untested) (NHBT0088294). Please explain what these pre-agreed conditions were, and why you believed that the Harefield Hospital wasn't performing them.*

532. I believe that the clinicians at Harefield Hospital were abusing the service and over–requesting; they were asking for much more same-day whole blood than what we had agreed. The pre-agreed conditions were that same day blood would be requested in exceptional circumstances only.

84. *Please explain the steps you and the NLBTC took to provide treatments alternative to FWB to Sir Yacoub, including:*

a. *the provision of "screened and tested blood as fresh as possible for Mr Yacoub's difficult cases" (NHBT0093056);*

533. As I have already said above, we did not provide fresh warm blood, but rather same-day screened blood wherever possible and available, which was in the vast majority of cases. In the minority of cases, where same - day unscreened blood was provided, it was tested retrospectively and there was no instance of any units from NLBTC being found to be positive for an infectious agent on retrospective testing.

534. The alternative to this was the use of component therapy, but for the reasons I have set out above, Sir Magdi was convinced that the use of fresh warm blood or same day whole blood was what was required for his patients and I was not at liberty to challenge his expert opinion on this.

535. As stated in my memorandum to members of my zonal management team, in the 1990's, we continued trying to support Sir Magdi with leucodepleted whole blood, less than 5 days old, always screened for all mandatory microbiological markers. We also supplied him with leucodepleted platelet concentrates collected by apheresis. We explained that leucodepleted blood components are devoid of harmful cytokines released by white cells (leucocytes) in whole blood.

b. the proposed establishment of a panel of blood donors by the Blood Transfusion Service for use by Harefield Hospital (NHBT0101365);

536. This would be tantamount to Harefield's own blood centre but not subject to testing or to the national standards under which the National Blood Service operated, including well trained personnel and national criteria for donor selection. I therefore never agreed to this, so it was not considered. Blood in the UK should only be collected from truly altruistic voluntary donors, under no pressure, by the National Blood Service well trained staff, with the appropriate equipment and screening procedures, according to rigorous national standards.

c. any other measures.

537. With the help of the RHA, we appointed one of our well-motivated senior registrars, Dr Beverley Hunt (now Professor of Haematology at Guys' and St Thomas' Hospital) as a research fellow, to work in Sir Magdi Yacoub's department and investigate the derangements of coagulation and bleeding experienced in Sir Magdi's critical heart-lung transplant cases.

85. *In NHBT0093056, you stated that Sir Yacoub and his team were "bleeding large numbers of donors at Harefield Hospital" in contravention of the "routine pre-transfusion testing required by the National Blood Transfusion Service". Please describe what the routine pre-transfusion testing requirements were and how they were enforced by the NBTS. Please outline whether you had an obligation, in your capacity as Medical Director of the NBTS, to prevent contraventions of pre-transfusion testing requirements. If yes, how did you exercise this obligation in cases of contravention?*

538. The only times that I knew there was contravention was through my dealings with Dr Sheila Amin and with Sir Magdi Yacoub when he was bleeding his own donors and having them tested retrospectively at Harefield Hospital.

539. I had no power over Sir Magdi. I was never the Medical Director of the NBTS; I was the Director of NLBTC and I had no power over consultants outside my field. All I could do was try to educate cardiac surgeons, alert Harefield Hospital management and my regional medical officer, which I did.

540. At that time, in 1988, in addition to strict donor selection criteria, the mandatory routine pre-transfusion screening tests of blood donations were:
    a) Forward and reverse ABO typing;
    b) RhD typing;
    c) Red cell antibody screening;
    d) HBsAg;
    e) TPHA (syphilis); and
    f) Anti-HIV screening;

All tests were done within a framework of quality assurance. Donors' haemoglobin level was assessed pre-donation. All donors had to deal with the confidential donor exclusion questionnaire.

541. I repeat that I was only the regional director of the NLBTC, not the medical director of the NBTS and hence I had no obligation or power to prevent collection of blood outside the National Blood Service. All I could do was to educate and try to persuade clinicians to adhere to our terms of good "laboratory" practice (GLP) and good manufacturing practice (GMP).

86. *In a letter from Dr Beresford to you dated 2 June 1998, you were advised that blood and blood derivatives should be considered products under consumer protection legislation and that "the issue of unscreened blood to patients might well render the transfusion service liable in law, were damage to occur to a patient as a result of this" (NHBT0101369). Please explain what actions you took in relation to this advice, if any.*

542. It was I who pointed out to Dr Beresford at the MDU that the Consumer Protection Regulations on product liability were coming into effect that year. Consequently, blood and blood derivatives might be considered to fall within the remit of that legislation and I informed Dr Beresford that I had written to Sir Magdi informing him that I would stop issuing same-day untested blood for his cases.

543. We continued issuing same–day (or less than 5 day) tested whole blood wherever possible, and we stopped issuing unscreened, untested whole blood, as per my letter to Sir Magdi Yacoub dated 4 May 1988.

87. *Dr Beresford also advised you to "draw the attention of managers to [this] matter again and insist on adequate documentation of policies" if you felt you were "unable on clinical grounds" to provide FWB to Sir Yacoub (NHBT0101369). Please advise what actions you took in relation to this advice, if any.*

544. I had already informed Sir Magdi and my immediate superior at the RHA, Dr Frank Seymour.

545. I also informed Mr Mike Bellamy, District General Manager, at Hillingdon Hospital; Dr Sheila Amin, the Consultant Haematologist at Harefield Hospital; and Mr Alun Rees. I have referred above to the meeting which followed and the measures agreed.

88. *In NHBT0101365, you agreed to pass to Sir Yacoub "details of all known incidents where Harefield patients had become HIV positive or shown AIDS symptoms".*

a. Are you aware of the number of patients that became HIV or HCV positive as a result of the use of FWB supplied by the NLBTC to Harefield Hospital?

546. As stated above, the NLBTC never provided fresh warm blood to Harefield Hospital. We provided same day whole blood, a minority of which was untested prior to use. It was obtained from repeat and reliable donors who had undertaken the exclusion assessment and the blood was always screened retrospectively. No samples from donations of same-day blood issued to Harefield were ever found positive for any of the mandatory microbiological markers.

547. There were no cases of HIV transmission due to the supply of unscreened blood from the NLBTC to Harefield Hospital. HCV screening was not performed at that time. We stopped supplying unscreened blood to Harefield Hospital in May 1988 and anti-HCV screening started at the NBTS in September 1991.

b. Who was responsible for informing those patients?

548. There were no cases of an infectious agent being transmitted to a patient through the use of same-day whole blood from NLBTC and therefore no patients had to be informed.

89. *In an email from you to NBTS staff dated 18 March 1999, you stated that you had attended a meeting at Harefield Hospital with Sir Yacoub and other senior medics to once again discuss the use of FWB (NHBT0101360). Please answer the following questions, as far as you are able:*

a. *Was Sir Yacoub still using untested FWB at this time? If yes, what measures, if any, had been put in place to reduce the risks posed by the use of FWB since 1988?*

549. As stated in my memorandum, Sir Magdi was still using fresh warm blood (not supplied by the NLBTC) though less frequently, at Harefield Hospital but not at the Brompton Hospital where he also operated. I was not involved in the supply of this blood. I do not know what safety measures had been put in place.

b. *From where did Sir Yacoub source the FWB?*

550. I do not know from where Sir Magdi sourced blood at the time. I believe that donors were bled at the hospital, after approaching the local services such as the police force and perhaps the air force and the patients' relatives, and on occasion the Harefield Hospital staff, including himself.

c. *What was the result of your 6 month review of the situation?*

551. Sir Magdi was satisfied with the provision of screened leuco-depleted whole blood for his critical surgery and we were able to meet his needs.

Section 11: Blood supply to UK politicians, government officials and the royal family

90. *The Inquiry understands that the NLBTC provided blood for use by UK politicians, government officials and members of the royal family while undertaking overseas travel to countries that had an unacceptable risk of blood borne infections*

(specifically HIV and HBV) (See CABO0000117_055 and CABO0000117_005). Please answer, as far as you are able, the following questions regarding this practice:

a. Who decided which countries carried an unacceptable risk?

552. I believe it was the Foreign Office taking into account the World Health Organisation recommendations. The WHO provided a map with the relative risks of infectious blood-borne agents in the different countries worldwide.

b. What factors were taken into account when making this decision?

553. Neither myself nor the NLBTC made the decisions.

c. What steps did the NLBTC take to ensure the safety of this blood?

554. We took the same steps as we would take for the provision of any unit of safe blood, i.e. adequate selection of voluntary donors, ABO, RhD typing, red cell antibody screening and screening for mandatory microbiological markers, which at the time were syphilis, Hepatitis B (HBsAg) and anti-HIV.

d. How long did the NLBTC provide this service?

555. For royalty, we provided this service for a very long time. This started before my time as deputy director in 1980 and continued until the mid-1980s, when the Army took over, but I am not absolutely certain.

556. For ministers it was for a couple of years from 1987 to 1989 when the Army Blood Supply Depot took over this responsibility as they were already supplying the Royal family.

557. I cannot recall ever supplying blood for politicians.

e. *Was the NLBTC the only RTC involved in providing this service? If yes, why? If no, which other RTCs were involved?*

558. I do not know if any other RTCs were involved. I presumed our involvement was due to our proximity to Heathrow Airport, RAF Northolt and Luton Airport, among others.

f. *When and why did the NLBTC cease to provide this service?*

559. When the Army Blood Supply Depot, under Colonel Mike Thomas, first took over supply for royalty and then ministers.

91. *Are you aware of any instances of transmission of HIV, HBV or HCV to UK politicians, government officials or members of the Royal Family as a result of the use of this blood?*

560. No, I am not aware of any such transmissions. In fact, I am not aware that any of the blood provided for royalty or ministers was ever used. My understanding is that it was never used.

92. *Are you aware of whether a lookback exercise was undertaken to trace recipients of this blood?*

561. As I have said, I am not aware that the blood was ever used. This blood was sent as a precautionary measure to avoid a lack of blood supplies in an emergency and to decrease the transmission of infectious agents, should blood transfusion ever be needed. Many countries with limited resources do not have blood stocks readily available for emergencies; they rely on family donors and the blood is not as safe as it is in the UK. In some countries, patients die of acute haemorrhage due to the unavailability of stored blood and blood components.

Section 12: Pharmaceutical companies, medical research and clinical trials

93. *Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products? If so, please list the names of the companies and give details of the advisory or consultancy services that you provided.*

562. No, I have not.

563. I wish to mention however that I acted as an unpaid independent evaluator of the preliminary trials and assessments conducted in other countries by the Cerus company on the Intercept system (Cerus is an American multinational biotechnology company). This system, based on psoralens that target the nucleic acid of cells, acts through the photochemical microbial inactivation of labile blood components, particularly platelet concentrates.

564. Intercept is currently used in some countries, but not in the UK, as a means of increasing the safety of platelet concentrates.

565. I can't recall exactly when this took place, but I think it was in the late 1980's or early 1990's. My airfare and accommodation would have been paid for this two-day event which took place in the USA. I do not remember in which city the event was held.

94. *Have you ever 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? If so, please provide details.*

566. No, I have not.

95. *Have you ever sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture, importation or sale of blood products? If so, please provide details of your involvement and of any financial or other remuneration you received.*

567. No, I have not.

96. Have you ever received any financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

568. No, I have not. I did not and have not used blood products as part of my role at the NLBTC.

97. Have you ever received any non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

569. No, I have not.

98. Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.

570. No, I have not

99. 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?

571. I am not aware of any, as I have said above, I was not and have never been involved with a pharmaceutical company for pecuniary gain or otherwise.

100. 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.

572. No, I have not.

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

573. No, I have not.

102. 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?

574. No, I never received any funding from pharmaceutical companies for research so this is not applicable.

Section 13: Variant Creutzfeldt-Jakob disease (vCJD)

103. 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?

575. I first became aware of the risks of possible transmission of vCJD by cellular blood components when, at autopsy, it was shown that the abnormal prion was present in the lymph nodes and spleen of patients who had died of vCJD.

576. If the abnormal prion was present in lymphocytes, which are abundant cellular components of blood, then we assumed that it would be possible that the abnormal prion would be transmissible by the transfusion of blood and cellular blood components, such as red cells and platelets.

577. A study was set up by the UK blood services and the national CJD Research and Surveillance Unit to investigate whether there was an association between variant CJD and blood transfusion. Eventually, it was shown in December 2003 that an individual who had died of vCJD, had been a donor

in the past and had donated blood which was transfused to a patient who later developed vCJD.

578. The study later showed a further transmission of two cases of vCJD via blood transfusion.

579. A haemophilia patient who died of causes other than vCJD and who did not show signs or symptoms of vCJD was shown to have, at autopsy, abnormal prion in a section of his spleen. Hence, as far as I know there have only been three cases of vCJD transmitted by transfusion, all by cellular blood components and none by fractionated plasma products.

580. Due to the knowledge that it was the white cells or leucocytes in blood that carried the abnormal prion, it was decided to introduce universal leuco-depletion of all blood components in the UK. Since the introduction of universal leucodepletion of blood components, no cases of vCJD by transfusion have been reported in the UK. I would like to emphasise that no proven cases of vCJD transmission by fractionated blood products have ever been reported.

581. As a National Director of Diagnostics, Development and Research in NHSBT, I did not have any involvement in responding to these risks, apart from agreeing with the vCJD study and agreeing with the sensible introduction of universal leuco-depletion.

Section 14: Other issues

104. 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?

582. To my knowledge, the UK was self-sufficient in its need for whole blood and labile blood components for transfusions.

105. During your tenure, were you aware of patients being given blood transfusions with red blood cells imported from the USA? If so, was there any concern about its use at the time?

583. During my tenure I was not aware of patients, in the UK, being given blood transfusions with red blood cells imported from the USA.

106. 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.

584. I am sincerely saddened and sorry for the suffering of patients and their relatives, caused by the transmission of an infectious agent through the treatment with blood or blood products. I am sincerely sorry for any cases of infection with, or affected by, an illness caused by an agent contracted through the use of blood or blood components.

582. I have been (and remain) a major advocate of the appropriate use of blood and blood components and was a major promoter of the Better Blood Transfusion Initiatives of the CMO that contributed to a dramatic reduction in the use of blood components in the UK.

583. I was one of the initiators and founder members of SHOT, the UK "Serious Hazards of Transfusion" or national haemovigilance programme, which has shown what the real risks of blood transfusion are and their magnitude, and which has contributed greatly to make blood transfusion safer, through investigations, research, training and education.

584. I was also a pioneer in the establishment of Hospital Transfusion Committees.

585. If, on occasions, I failed to introduce measures or tests on blood donors or donations, this was due to my high respect for evidence-based medicine or to the lack of resources. As soon as I knew that a new measure or a new intervention/ test/assay would increase the safety of the blood supply, if resources were available, I would enthusiastically introduce it, for the benefit of patients.

586. Respectfully, I believe that not enough emphasis has been given publicly, in the evidence that has been given to the Inquiry, to the requirements of appropriate use of blood, or "Patient Blood Management" as it is called at present.

587. It was the National Blood Service and particularly NLBTC that started the Hospital Transfusion Committees and audits in the use of blood components in different clinical specialties. We showed that there was inappropriate use of FFP, platelets and red cells.in hospitals in our region. Audits then became national, showing that inappropriate use was a national problem. If transfusions are given unnecessarily or inappropriately, then patients are exposed to unnecessary risks. The initiatives of all four CMOs during my time as Director were facilitated by the appointment of Consultants in Transfusion Medicine in large hospitals and Specialists in Transfusion (generally nurses), mostly funded by the NBTS and later NHSBT. At NLBTC, we pioneered the concept of Consultants in Transfusion Medicine in hospitals.

588. Clinicians were made aware of the appropriate use of blood components, Pre-assessment clinics were introduced in hospitals, so that patients were treated for anaemia and other blood deficiencies weeks before their surgical procedures, thus avoiding the need for unnecessary blood transfusions. Blood usage decreased, hence the need to collect blood was drastically reduced. A National Blood Stocks Management Scheme was introduced, so that blood components were transported from areas of surplus to where there was a need, thus decreasing wastage.

589. The practice of Transfusion Medicine has changed dramatically in the last 30 years and this has been driven by the National Blood Services in the UK.

590. Another initiative originating in the blood services was the national haemovigilance scheme, SHOT (Serious Hazards of Transfusion) where hospitals are required, in a non-punitive way, to report all adverse effects of transfusion. SHOT has taught us that the majority of transfusion hazards are due to human error, that TRALI (transfusion- related lung injury) and TACO (transfusion-associated circulatory overload) accounted for a significant proportion of serious adverse events. After appropriate analysis and education, we have been able to act appropriately to reduce these risks.

591. Of the microbiological hazards, the most common was shown to be bacterial contamination, especially of platelet concentrates, hence we introduced bacteriological testing of blood components, in addition to leucodepletion.

592. I have dedicated a great deal of my professional life to the care of voluntary blood donors and to improving the sufficiency and safety of the blood supply in the UK and abroad. I am passionate about establishing national blood services and increasing the numbers of altruistic, voluntary blood donors in the developing world, where replacement and paid donors are still abundant and where patients are still dying due to the lack of blood.

593. I have been (and remain) passionate about increasing awareness of the risks of transfusion, not only infectious but others, such as errors of administration and immunological risks.

594. I have been actively involved in training and teaching in Transfusion Medicine to doctors, medical students, nurses, scientists, MLSOs nationally and internationally.

595. It is unfortunate that this Inquiry is taking place so late after the events, when many of the infected, as well as individuals who were working in the NHS and Department of Health at the relevant time, are no longer with us. Most

of those of us who are still here, are not in practice, unable to recall, with any degree of clarity, facts and events that took place 30 to 40 years ago.

596. I hope it will become clear, during the evidence given to the Inquiry, that the landscape has changed out of all recognition in the last 40 years, both in terms of clinical care and in the assessment and management of risk of the blood supply, in part shaped by learning from the past. Nothing stands still in medicine and I am sure that all those who work in enhancing and saving lives will be determined to do their best to learn and improve.

597. I feel proud to have worked in the UKBTS, one of the best blood services in the world, for so many years. We should not forget that voluntary and safe blood donors in this country have saved and improved the quality of life of countless numbers of patients. Many modern forms of therapy and advances in medicine would be impossible without the regular availability of blood components. It is unfortunate that, unintentionally and through no fault of their own, a very small number of donors transmitted infectious agents to recipients of their blood.

598. I am sorry and I apologize to any patients or persons who contracted and suffered infections and to the relatives of those infected due to failures or omissions on my part or the service I used to run.

Statement of Truth

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

Signed GRO-C

Dated 14 October 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
	CV	WITN5711002
	List of publications	WITN5711003
	Graph	WITN5711004
	P Spinella, J Perkins, K Grathwol, A Beekley and John Holcomb: Warm Fresh Blood is Independently Associated with Improved Survival for Patients with Combat-Related Traumatic Injuries. J Trauma, 2009 (April), 66(s69-s76)	WITN5711005
	P Kendingelen, Z Kamalack and MD Abat: Should warm fresh whole	WITN5711006

	blood be the first choice in acute massive haemorrhage in emergency conditions? Ulus Travma Acil Cerrahi Derg, March 2016, vol.22 No 2	