Witness Name: Dr David Brian Lorimer McClelland

Statement No.: WITN6666001

Exhibits: WITN6666002-WITN6666026

Dated: 22nd December 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR DAVID BRIAN LORIMER McCLELLAND

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 19 August 2021.

I, Dr David Brian Lorimer McClelland, will say as follows:

Preliminary comment

1. I resigned from my position as Director of SEBTS in 2002. My principal reason was that Senior Lecturer, Dr Marc Turner, was clearly ready to take on the job and was looking for posts elsewhere. I knew he could soon move on from SNBTS if we could not offer a new challenge, and for myself, there were new areas that I wanted to work on. A further factor was I had suffered for several years from painful osteoarthritis and needed to undergo surgery for bilateral total hip replacement: In retrospect, this may have affected my decision more than I realised at the time.

   After I ceased to be regional director, the General Manager asked me to take on the role of strategy director for the service, and I worked for two years consulting many colleagues and developing proposals for the service. From 2004 to 2008, I was Chair of the Joint Professional Advisory Committee for the UK transfusion

services [JPAC], and I became joint project leader for the EU Optimal Use of Blood Project. Over the period from 2002 to 2009, I worked with the SNBTS Better Blood Transfusion team on the development of the *Learnbloodtransfusion https://www.learnbloodtransfusion.org.uk/*

distance learning programme and on the development of a new system for tracing blood components to the individual recipient using new software to link to the various hospital blood bank computer systems. *[SNBTS Account For Blood https://www.nss.nhs.scot/blood-tissues-and-cells/snbts-transfusion-team/blood-transfusion-data-audit-and-quality-improvement/]*

2. I retired in April 2009 and from then to 2011 worked on personal witness statements and SNBTS documents for the Penrose Inquiry. Since completing my written and oral evidence to the Penrose Inquiry in November 2011, I have been fully retired and have had no involvement with blood transfusion until Summer 2021, when I responded to questions that the Inquiry had put to SNBTS.
3. I received this R9 letter on 20th August, with a deadline of 14 October, and I have done my best to comply. Inevitably this has limited the extent of my replies, so I have concentrated on areas where I had more personal involvement.

   I have depended largely on my memory of events up to 40 years ago and on my evidence to the Penrose Inquiry. Where I believe that my evidence to Lord Penrose provides the best answer to a question, I have referred to it.

Section 1: Introduction

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

4. David Brian Lorimer McClelland, My address is known to the Inquiry
   Date of birth GRO-C 1944
5. **Professional qualifications**

   BSc Honours Physiology (1st Class), University of Edinburgh, 1965

   MBChB University of Edinburgh, 1968

   MRCP (UK), 1971

   Doctoraat in de Geneeskunde (cumlaude), University of Leiden, 1977

   FRCP (Edinburgh), 1986

FRCPath, 1990

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

6. Employment History

- Chair JPAC, Co director EU Optimal Use of Blood Project 2005-2009
- Strategy Director, SNBTS 2002-2005
- Director: Edinburgh & South East Scotland Blood Transfusion Service [SEBTS]
- Senior Lecturer, Department of Medicine, University of Edinburgh Medical School 1979-2002
- Consultant: Edinburgh and South East Scotland Blood Transfusion Service

19771979

- Research Fellow Department of Internal Medicine University Hospital, Leiden

1973 -1974

- Registrar, Senior Registrar, and MRC Research Fellow
  Department of Therapeutics and Clinical Pharmacology University of Edinburgh

1969-1977

- House Surgeon to Professor Michael Woodruff, 1969-1970
- House physician to Professor RH Girdwood. 1970

My House Physician appointment was interrupted when I contracted severe hepatitis, spending 3 weeks in the Infectious Diseases Unit, City Hospital Edinburgh, followed by several months' convalescence.

Professional training and experience prior to appointment with SNBTS

7. After pre-registration posts in the professorial units of Surgery and Therapeutics and Clinical Pharmacology in the Royal Infirmary of Edinburgh, I embarked on training in gastroenterology, supervised by Dr NDC Finlayson and Dr DJC

Shearman. I obtained an MRC Clinical Fellowship and commenced a joint clinical training and research post.

8. My clinical training was in general medicine and gastrointestinal and liver disorders. My research focus was on the immunological factors that control normal and abnormal microbial populations in the gastrointestinal tract of adults and on the role of antibodies and other anti-microbial factors in breast milk in controlling intestinal microorganisms in the young infant. Within my clinical duties, I was responsible for managing patients with antibody deficiency syndromes and undertook research with these patients aimed at developing better treatment, leading eventually to the production of Intravenous Immunoglobulin by the PFC.
9. I spent one year in the Department of Infectious Diseases, University Hospital, Leiden, under Professor Ralph van Furth and in 1977, I defended my Dutch doctoral thesis and graduated cumlaude in 1977. I attach the title page of my PhD Thesis University of Leiden 1977 as an exhibit(WITN6666002). I was then appointed Senior registrar in Therapeutics and Clinical Pharmacology, Royal Infirmary of Edinburgh and completed my professional training before joining SNBTS in 1977.

Appointment to Blood Transfusion Service

10. My decision to join SNBTS related to my interest, arising from my research, into the therapeutic potential of antibody preparations derived from human plasma to improve treatment for patients suffering from antibody deficiency syndromes. At the time, the SNBTS was the only place where I could find the expertise to develop a novel plasma derivative, and I welcomed the opportunity to apply for a post there. Working with Dr Peng Lee Yap and the Protein Fractionation Centre, we developed the SNBTS intravenous immunoglobulin product and undertook all the clinical trials that led to the licensing of this product.

Regional Director, Edinburgh and South East Scotland Blood Transfusion Service [SEBTS]

11. It may be helpful to refer to the Job Description for the RTD and the attached schedule of information about the SEBTS

12. I was responsible for the medical direction and managerially accountable for the performance of a Regional Transfusion Service licensed by the Medicines Control Agency and accredited by Clinical Pathology Accreditation Ltd. The population of patients and donors served by SEBTS was 1.12 Million, and the revenue budget in 1977-8 was £1.254 Million. The Director's job involved day to day management of Medical, Nursing, Scientific, Technical and Support personnel. There was constant professional and managerial contact with NHS and private hospitals and individual clinicians, with the Protein Fractionation Centre and other elements of the Transfusion Services in the UK and internationally.

13. *Specific responsibilities included:* Budget holder and responsible to the General Manager and before his appointment, to the National Medical Director of the Scottish National Blood Transfusion Service (SNBTS) for all aspects of the performance of the Regional Transfusion Service. This applies from the time when the first GM was appointed. Before that, I reported to the National Medical Director of SNBTS. I was a member of the Board of SNBTS in the capacity of RTD.

Duties of the RTD position

14. Responsible for ensuring the availability of properly qualified, trained, and accredited staff to carry out the work of the Service.

15. Responsible for ensuring that the Service was licensed by the Medicines Control Agency and accredited by Clinical Pathology Accreditation Ltd. Also for ensuring that it complied with other relevant standards and regulations, both National and E.U. These included the Guidelines for the Transfusion Services in the United Kingdom and later, the Blood Safety and Quality Regulations.

16. Deputising for the National Medical and Scientific Director on operational, policy and public relations matters for the whole service.

17. For NHS Trusts in Lothian, Borders and Fife I was responsible for the provision of blood and blood products together with 24 hour medical and laboratory support to ensure provision of appropriate and compatible products, investigate immunological problems and assist with clinical management decisions.

18. I was also responsible for ensuring provision of the region's clinical immunology diagnostic laboratory service and histocompatibility service for organ and tissue transplantation, the regional service for collection of peripheral blood stem cells and for therapeutic plasma exchange, provision of tissue transplantation products, and developing this service to support orthopaedics and cardiac surgery in line with SHHD/SOHD policy and national and international guidelines and standards.

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.

19. National

- Secretary and Editor: CRAG Working Group on Optimal Use of Donor Blood (1994-1955).[Working Group on Blood Products]
- Chair: Scottish Committee on HIV and Drug Misuse (Reported 1986).
- Chair: Scottish Working Party on Prediction of HIV and AIDS (Reported 1990).
- Member of Departments of Health Expert Advisory Group on AIDS (till 1991).
- Member of SACTTI 1996 - 2009
- Member of the Expert Advisory Group on AIDS 1985 – 1988
- Member of the Departments of Health Advisory Committee on Microbiological - Safety of Blood and Tissues [MSBT] from its inception until its termination. In 2008

- Chair of Joint Professional Advisory Committee of the UK Transfusion Services responsible for the Guidelines for Transfusion Services in the UK 2004 -2008
- Steering Committee Member and Founding member of SHOT: [UK Serious Hazards of Transfusion reporting system]
- Council member. British Blood Transfusion Society (till 1994).

20. International

- UK Coordinator and Joint Project Coordinator for Sanguis - European Union multi-country study on use of transfusion for elective surgery in Europe (1990-94) (WITN6666003).
- Member of the Council of Europe Committee of Experts on Transfusion on Council of Europe Committee of Experts on blood transfusion. [Dates not available]
- Member: European Commission DGV Working Parties on blood donor safety and optimal use of blood 2003-4 This was during the early development of the EU Directive on Blood Safety [transposed in the UK, as the Blood Safety and Quality Regulations 2005].
- UK Project Leader: International study on perioperative transfusion (ISPOT). (Investigation of the factors governing dissemination of technologies to minimise the use of donor blood). This study resulted in many published papers: one example is cited (attached as exhibit WITN6666004): [Does acute normovolemic hemodilution reduce perioperative allogeneic transfusion? A meta-analysis. The International Study of Perioperative Transfusion G L Bryson 1 , A Laupacis, G A Wells Anesth Analg 1998 Jan;86(1):9-15. https://pubmed.ncbi.nlm.nih.gov/9428843/]
- Investigator and report author: EU multi country study European clinical quality management system for the therapeutic use of blood components [EU Optimal Blood Use Project [2006-2009]

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

21. I maintained a library of scientific papers on my areas of interest, assisted by a part time librarian /information scientist. From about 1980, this was maintained on a database designed by this person and the SEBTS IT professional. I read journals including: New England Journal of Medicine, Lancet, British Medical Journal, Transfusion, Vox Sanguinis, Transfusion Medicine, and the Morbidity and Mortality weekly reports from the CDC. In the pre internet era, I also looked at the contents of other potentially relevant journals in the weekly publication Current Contents

22. I edited several books, which required thorough study of the literature, and I took part in a number of multi-centre projects that involved contact with other professionals in the field. I also ran teaching and training courses for transfusion professionals that required me to keep up to date.

- I was the first editor of the UK Handbook *of Transfusion Medicine,* four editions [1989, 1996 2001, 2007] This guide to transfusion practice that is widely used by NHS staff, and has been used as a basis for other national handbooks.
- Co-editor: The Clinical Use of Blood Handbook WHO 2001
- Author: [on behalf of CRAG working group] Optimal use of donor Blood. The Scottish Office 1995
- Co Author: The Sanguis Study: European Commission. [study period 1990 to 1992] https://cordis.europa.eu/project/id/MR4*0237
- Co Author: WHO Handbook: The Clinical use of Blood 2001
- Co Author: WHO Distance Learning Manual The Clinical Use of Blood 2000 [No Copy available at time of writing]
- Co Author: Manual of Optimal Blood Use. Report of a multi country project funded by the European Commission 2006 -2009 http://www.optimalblooduse.eu/
- Director or Co-Director of specialist courses and conferences including: British Council Course in Transfusion Medicine: Director 1988, 1990 1994, 1997.

- International Course in Transfusion Medicine, Patras Greece Co Director 1994.
- International School of Haematology Course in Transfusion Medicine, Paris 1993.
- Organising Committee and Panel Member: Consensus Conference on Leucocyte
- Depleted Blood Products, Royal College of Physicians, Edinburgh 1993.
- Director: Consensus Conference on Red Cell Transfusion, Royal College of Physicians of Edinburgh 1994.

Publications

23. A list is provided as part of my CV - WITN6666023

Multi centre projects

24. My main professional goal in the later part of my career in SNBTS has been to improve the clinical aspects of blood transfusion practice, both prescribing and the supply process. I have worked to identify where improvements are needed, to communicate these to clinicians, patients and other stakeholders, and to motivate change.

25. *The Sanguis Study* on the use of transfusion in 43 European hospitals was coordinated by Professor G Sirchia, Dr A M Giovanetti and myself, and I was responsible for the UK element. This work has been widely communicated and continues to be influential in demonstrating the extreme variations that exist in transfusion practice and the need for improvement in the prescribing and use of blood.

26. *The CRAG Working Party on optimal use of donor blood.* I acted as secretary and prepared the Group's report. This has been widely read in Scotland, the rest of the UK and in Europe. It has been published in French translation. Its recommendations form the agenda for transfusion practice improvements in the National Health Service in Scotland.

27. *Studies to identify the incidence of serious transfusion errors* brought this topic to wide attention. This work was one of the influences leading to the foundation of the UK reporting system for Serious Hazards of Transfusion (SHOT).

28. *Measurement of clinical use of transfusion* I initiated a line of work that has produced the first large analysis of the demography of blood recipients and by linking the various blood bank IT systems to the SNBTS system allows each unit of blood component to be traced to its final fate. I pursued this between 1995 until my retirement in 2009 It can now be accessed on the internet under the title: NHS Account for blood https://www.nss.nhs.scot/blood-tissues-and-cells/snbts-transfusion-team/blood-transfusion-data-audit-and-quality-improvement/

29. *Tissue banking* with Dr S Lumley and Sister A Murphy, we established the regional bone bank [operated by SNBTS] in1989 to support orthopaedic surgery This is now a national service provided by all SNBTS Centres and has extended to provide other tissues.

Academic

30. I obtained the support to establish the first University Senior Lectureship in Transfusion Medicine in the UK and for a small Academic Unit to support the first appointee, Dr William Murphy.

5. In addition to the Penrose Inquiry, 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.

31. Hepatitis C Inquiry: Crown Office and Procurator Fiscal Service (WITN6666005)
I was responsible for drafting a report responding to the Deputy Crown Agent's letter of June 21, 2005 in which a number of specific questions were raised about Hepatitis C and blood transfusion.

Section 2: Previous statements and evidence

6. What materials were made available to you when you gave evidence to the Penrose Inquiry?

32. I had access to a large number of documents that were assembled by SNBTS in response to a request from the Penrose Inquiry for "All documents held by SNBTS"

7. Did anyone else assist you in preparing your evidence? If so, who, and what assistance did they provide?

33. I had assistance in obtaining documents from Ms Carol Bienek and the staff responsible for records at the PFC. My written evidence was prepared by myself and was reviewed with my solicitor before being submitted to the Inquiry. From time to time I checked matters of fact with colleagues in SNBTS, including Dr Foster, Dr Perry and Dr Gillon and possibly others.

8. The Inquiry understands that you were involved in preparing one or more SNBTS submissions for the Penrose Inquiry. Please list these documents and describe the background to your involvement in them. In particular, please explain who proposed and organised the papers, who assisted in their preparation, and who, if anyone, approved final versions. Please also confirm whether, in addition to the SNBTS, you were involved in any other collective or corporate submissions to the Penrose Inquiry.

34. My written submissions and transcripts of my oral evidence to Lord Penrose are listed below. I assisted in preparing one or more Key Topics papers that SNBTS submitted to Lord Penrose. I cannot remember details of my contribution.

35. I responded in June 2021 to a number of questions related to a document being prepared by Professor Marc Turner at the request of the Inquiry.

My written submissions were intended to address specific questions put to me by the Inquiry.

I was not involved in any submissions to the Penrose Inquiry other than those from SNBTS.

9. The Inquiry understands that you provided the following written statements and oral evidence to the Penrose Inquiry:

Topic C1: 28 January 2011 statement (PRSE0002653) and 22 March 2011 oral evidence (PRSE0006009 pages 1-147).

Topic B1: 28 January 2011 statement (PRSE0002627) and 25 March 2011 oral evidence (PRSE0006012).

Topic B2: 9 December 2010 draft statement (PRSE0003972), 6 May 2011 oral evidence (PRSE0006021 pages 81-174) and 15 June 2011 supplementary statement (PRSE0002760).

Topic B5: 27 April 2011 statement (PRSE0000444) and 30 June 2011 oral evidence (PRSE0006040 pages 81-116).

Topic B4: 14 September 2011 statement (PRSE0003157) and 29 September 2011 oral evidence (PRSE0006050).

Topic C2: 15 February 2011 statement (PRSE0003729), 8 November 2011 supplementary statement (PRSE0002536) and 15-16 November 2011 oral evidence (PRSE0006063 and PRSE0006064 pages 1-143).

Topic C4: 27 October 2011 statement (PRSE0004442) and 23-24 November 2011 oral evidence (PRSE0006068 pages 146-162 and PRSE0006069).

Please confirm whether these statements and the oral evidence you gave are, to the best of your knowledge and belief, true and accurate. If there are any matters within your evidence to the Penrose Inquiry that you do not consider to be true and accurate, please explain what they are and how the inaccuracy occurred. Please also identify any evidence you gave to the Penrose Inquiry which is not listed here.

36. I confirm that, to the best of my knowledge and belief, the written statements that I submitted to the Penrose Inquiry and the oral evidence that I gave before the Inquiry are true and accurate.

Section 3: Your role at the Edinburgh and South East Scotland Regional Blood Transfusion Service

10. Please describe the roles, functions and responsibilities you had at the Edinburgh and South East Scotland Regional Blood Transfusion Service ("the SEBTS") during your period as Director and explain how these changed over time.

37. I was responsible for the medical direction and managerially accountable for the performance of a Regional Transfusion Service licensed by the Medicines Control Agency and accredited by Clinical Pathology Accreditation Ltd. The population of patients and donors served is 1.12 Million. The revenue budget in 1977-8 was £1.254 million. The Director's job involved day to day management of Medical, Nursing, Scientific, Technical and Support personnel.

11. Please describe the organisation of the SEBTS during the time you worked there:

a. structure and staffing,
b. to whom you were accountable,
c. how it was funded
d. its remit, geographical area and hospitals covered,
e. to whom the centre was answerable,
f. was SEBTS associated or linked with other RTCs within SNBTS,
g. whether SEBTS was subject to any form of regulation and if so what,
h. SEBTS's relationship with the PFC,
i. the approximate number of donations collected each year.

38. **a**. A general outline of the functions, organisation and staffing of SEBTS in 1979 is given in the information accompanying the RTD Job Description (PRSE0000950).

39. In outline, the organisation of SEBTS was as follows:

- *Blood donor section: T*he motivation, retention, assessment, of donors and collection of blood from suitable donors: the care and counselling of donors found to have evidence of an infection transmissible by transfusion.
- *Microbiology/virology section:* Testing blood donations or transfusion transmissible infections
- *Blood components section*: processing into components and storage of blood components and the supply of plasma to the PFC
- *Blood bank section*: Receiving requests for blood for patients, blood type testing of patient samples, selecting compatible blood components and ensuring their timely supply to meet patients' needs.
- *Immunology section:* Tissue typing for organ transplantation, testing patient samples for signs of immune disorders.

40. There were approximately 200 staff. A medical consultant, supported by nursing and donor attendant staff was responsible for the care of donors. The Blood Bank, Microbiology and Immunology sections each had an assigned medical consultant. Laboratories were operated by technical (MLSO and Laboratory Assistant Staff. There were 2 or 3 Research Scientists, often supervising postgraduate students.

41. **b**. As Regional Director, I was budget holder and, from the time of the appointment of Mr David McIntosh, in 1990 as the first General Manager [GM] of SNBTS, I was responsible to him [and to his successors in the post of GM] for all aspects of the performance of the Regional Transfusion Service. Before the GM appointment, the RTDs' lines of responsibility were less clear, as outlined in my written statement to the Penrose Inquiry [PRSE0002653 14 October 2010]

42. **c**. SEBTS was funded by the Scottish Home and Health Department, later the Scottish Government Health Department, by an annual allocation for revenue and for capital items. This was preceded by the submission of estimates of financial requirements for future years from each centre.

43. **d**. I cannot recall that I ever received a remit for the SEBTS. My own 1979 job description as regional director of the SEBTS contains no specifics of the managerial or professional accountability of the regional director. I dealt with this at some length in my written evidence to Penrose [PRSE0002653 Statement 14 October 2010].

44. The SEBTS served Edinburgh and the South East of Scotland, i.e. the Lothians, the Borders and Southern Fife. There were many hospital closures during my service as Director and I do not recall the dates of these. At the time I retired in 2002, SEBTS served the Edinburgh Royal Infirmary, Royal Hospital for Sick Children, Western General Hospital, Victoria Kirkcaldy, Queen Margaret, Dunfermline, Borders General and the Spire Murrayfield private hospital in Edinburgh.

    Hospitals now closed that had been served by SEBTS include: The City Hospital, Bruntsfield, Eastern General, Elsie Inglis Maternity, Deaconess, and Northern General.

45. **e**. As Regional Director, I was budget holder and, from the appointment of Mr David McIntosh, in 2000 as General Manager [GM] of SNBTS, I was responsible to him [and to his successors] for all aspects of the performance of the Regional Transfusion Service.

46. Before the first GM appointment, the RTDs' lines of responsibility were less clear. The job description issued to me on my appointment as Regional Director illustrated this. The following is the extract that I included in my evidence to Penrose. I do not have access to the original document.

    "overall responsibility for ensuring that range of activities in the service is carried out efficiently".

    "In practice the responsibility for the administration of the budgets is delegated to the transfusion directors"

    With respect to the national management of the service the addendum to the job description states:

the director "*will be expected to share with the other transfusion directors the responsibilities involved in co-ordinating the national service as a whole*"
"the transfusion directors meet regularly to discuss matters of common interest, usually with the national medical director in the chair."

47. **f.** There were regular meetings of the Directors, but otherwise I do not recall that there were formal links with the other SNBTS Centres. There was cooperation at various staff levels, but I recall this as being essentially informal.

48. **g**. At the time of my appointment in 1979, my recollection is that the SEBTS was covered by Crown Immunity, and that it was the view of the SHHD at that time that SEBTS should not come under the remit of the Medicines Control Agency [as I recall it was then termed Medicines Division of DHSS]. By 1982 this situation had changed and SEBTS was inspected by the Medicines Inspector, Mr David Haythornthwaite. Thereafter, SEBTS was subject to the Requirements of the MCA. Clinical Pathology Accreditation and later subject to an EU Directive that was transposed as the UK Blood Safety and Quality Regulations. [2005]

49. **h**. My recollection is that the principal relationship related to the supply of plasma for fractionation, and that this had several aspects including quantity of plasma, quality in terms of factor VIII content, and virological safety. There were informal professional contacts, and communication among the PFC and RTC Directors at SNBTS meetings. I do not recall if there was any formal contractual relationship between SEBTS and the PFC.

50. **i.** 59,000 donations per annum in 1973-4, rising to 81,000 in 1984-5

YEAR	ATTENDANCES	DONATIONS	% DONATING
1973-74	67,891	59,326	87%
1974-75	71,548	62,239	87%
1975-76	78,234	69,878	89%
1976-77	83,636	75,302	90%
1977-78	86,050	77,318	90%
1978-79	84,842	75,639	89%
1979-80	83,407	74,537	89%
1980-81	83,976	73,985	88%
1981-82	83,261	74,034	89%
1982-83	81,927	72,977	89%
1983-84	84,767	79,466	94%
1984-85	87,227	81,389	93%

The above figures do not include plasmapheresis donations.

Table reproduced from SEBTA Annual Report 1984-5 (WITN6666025)

Section 4: Blood collection at the SEBTS

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

51. There were frequent changes in various aspects of the blood collection programme and system over the years of my employment at SEBTS aimed at improving donors' safety, reducing the risk of collecting a donation that was potentially infective or that could harm the recipient patient in some other way, improving the quality of the blood that was collected, and improving the integrity of the process from donor to patient by introducing machine readable labels and computerised tracking of each donation. One major change preceded my appointment by perhaps 3 years – I am uncertain of the precise date – and I should mention this because of its importance to later questions about plasma supply.

52. My predecessor as Director, the late Professor [then Dr] John Cash was acutely aware of the shortages of plasma for factor VIII production and took what was then quite a radical step by instructing that a proportion of donation packs of

blood should be converted to plasma and concentrated red cells, thus providing about 200 ml of plasma from each blood donation. This plasma was frozen and supplied to the PFC. There was however an important downside to this change. After removing the plasma, the remaining concentrated red cell suspension was very viscous and could not be infused quickly through standard blood administration sets. This was highly unwelcome to clinicians, especially obstetricians, surgeons and anaesthetists who often had to administer blood quickly to patients with major bleeding. I do not know if any patient was thought to have come to harm as a result of this change, but I know that it was a serious concern for some clinicians. By the time I was appointed it remained a major cause of concern and this continued until, some years later, a good answer was found. [This was Optimal Additive Solution. This was added to the blood pack to replace the plasma removed. It was a clear solution formulated to protect red cells during storage. It diluted the concentrated red cells [reduced the haematocrit] so that they flowed freely through the blood administration set.

13. What, if any, steps did the SEBTS take to publicise itself to potential donor populations in order to increase donations? How successful were these steps?

53. When I was appointed SEBTS had successfully relied for many years on a network of voluntary donor organisers who were based either in the community or in workplaces in the SE region. The publicity budget remained small, because excellent blood donor attendances were achieved essentially by voluntary donor organisers in the community who employed word of mouth supplemented with very simple paper publicity material. Shortly after I was appointed, the doctor who had been responsible for the donor programme retired. I appointed a new, young, and very capable manager to be donor organiser and we quickly concluded that major changes were needed, mainly because of concerns about the security of blood donors' data These changes will be described in answering later questions. Publicising the need for donations increasingly used radio, television and more recently social media. As the data on donor attendances and donations show, these efforts were effective.

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

a What were the staffing arrangements during blood donation sessions?

54. The sessions were staffed by a medical officer, usually an Associate Specialist, and a number of Blood Donor Attendants sufficient to ensure that each donor would be attended during and immediately after giving their blood donation. The blood samples for microbiological and blood group serological testing would be obtained from the donation line by the attendant at the completion of the donation. The medical officer was responsible for the decision on any medical questions about a donor's fitness to donate, and for the aftercare of any donor who had a reaction – usually a faint - after donating.

b Where did these sessions take place?

55. In a variety of venues such as village and church halls, school premises, workplace canteens and in the blood donor centre that was a part of the Transfusion Centre.

c How frequently could a person donate blood?

56. The general rule during my time was that a donation of 420ml [later increased to 450 ml], could be taken up to 3 times per year, provided the donor's haemoglobin test before donation was satisfactory. Male donors were more likely to be able to give more often than females, as the males typically had higher haemoglobin levels, More frequent donations might be taken, from donors who maintained normal levels of haemoglobin, when there were shortages of certain blood types, usually Group O Rhesus negative. The current Red Book guidelines state: "*An interval of 16 weeks between donations of whole blood is reasonable. The minimum interval is 12 weeks. Normally, no more than three donations should be collected from a female donor and four from a male donor during any 12-month period.*" www.transfusionguidelines.org

d How were blood donors recruited

57. Up to about 1980, recruitment was by volunteer organisers who often depended on their knowledge of the community and word of mouth communication. They also used posters and probably other printed materials supplied by SEBTS. More recently, radio, television and social media have been increasingly used.

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

58. The recruitment of blood donors changed very considerably. For example, the role of the voluntary organisers was phased out, donor records were computerised, radio, television, and social media were increasingly used and specialist agencies were brought in to advise on promoting donation. As mentioned in the answer to question 14 d above, the recommended frequency of donation changed. There were continuing changes in the rules and procedures for donor selection: these are referred to in the answers to later questions.

15. Did the SEBTS have donation collection targets that it was required to meet? If so, did the SEBTS meet its donation collection targets during your tenure? If not, why not? What was done to improve blood collection? What more could or should have been done? What were the barriers?

59. I do not recollect any detail of target levels of donation, other than that there were regular discussions at the Director's meetings, about the amounts of plasma expected from each RTC. My recollection is that SEBTS was able to collect sufficient donations to meet the expected supply of plasma to the PFC. Our efforts in SEBTS were, I think, directed more to maintaining the levels of collection than to increasing them.

60. Looking back, it may well have been possible for SEBTS to collect a larger number of whole blood donations, but this would have required additional funds

for staff and for blood collection packs. We would not have been permitted to increase expenditure on collection without approval for more funding.

16. You gave written and oral evidence to the Penrose Inquiry regarding the acceptance of blood from high- risk donors (PRSE0002653 and PRSE0006009 pages 1-148). Do you stand by that evidence? Is there anything you now wish to add to it?

61. I stand by that evidence, but I would like to comment on one phrase of my answer to a question from Counsel in which I said that "I wasn't worried about hepatitis among prison donors." This was a poor choice of words that does not reflect what I was attempting to explain. I will deal with this in my response to question 17.

17. Please consider the following questions relating to the collection of blood by the SEBTS from prisons, borstals, and other correctional institutions:

a. According to PRSE0002164 (page 8), a document submitted by the SNBTS to the Penrose Inquiry, the SEBTS ceased blood collection from prison donors in April 1980. In your statement, you recorded that the last SEBTS donor session in a penal institution took place in December 1981 (PRSE0002653 page 5). Are you able to reconcile those dates? If not, which of those dates do you believe to be correct? Please provide reasons and describe the source for the information you provided.

62. I do not at present have access to documents that would resolve this discrepancy, but I am reasonably certain that 18 December 1981 is the correct date. I say this because SEBTS had preserved the blood donor session cards indefinitely. As a result I was personally able to recover from the archive filing cabinets the blood donor cards for sessions held in prisons and to check the handwritten entries on the cards, which I believe showed the last prison session was held on 18th December 1981.

b. The minutes of the 29 March 1983 meeting of SNBTS directors, at which you were present, state that it "was reported by all Directors present that sessions were held in penal institutions in all regions..." (PRSE0000193 page 5). Do you believe that the minutes are incorrect, or that the SEBTS may in fact have continued to collect blood from penal institutions into 1983? If it is the latter, from which penal institution was blood collected by SEBTS in 1983?

63. To the best of my belief, the minute is incorrect for the reasons given in my answer to question **17 a** above.

c. According to NHBT0057149_087, the NBTS stopped prison collections in 1986. As far as you are aware, what led the SEBTS to stop collecting from prisons several years prior to the rest of the Scottish RTCs and the NBTS?

64. I cannot give a definite answer but I have explained the reasons for SEBTS ending the collection of blood in prisons. I am not in a position to comment on the decisions taken by other Regional Transfusion Directors. However I do remember that there had for some years been considerable debate about the merits of collecting blood from prisoners, with at least one senior public official. I believe it was the then Chief Medical Officer in DHSS, Dr Henry Yellowlees, explicitly supporting the practice. This debate may well have influenced the decisions of some RTDs I have seen the relevant letter from Dr Yellowlees, as it was available during the Penrose Inquiry

d. What were the relative costs of collecting blood from prisons, borstals and similar detention institutions as compared to collecting blood from RTCs?

65. I do not recall that I ever had this information

e. What involvement, if any, did you have with this practice?

66. I did not take part in any blood donation sessions in any penal institute

18. Please consider the reasons you gave for the SEBTS ending blood collection from prisons in your written statement to the Penrose Inquiry (PRSE0002653) and in oral evidence (PRSE0006009, in particular pages 30-37), and answer the following questions:

a **What did you mean when you described a concern that the prison was "*just an unsuitable environment in total*" and that you were worried about the "*totality of the environment*" (PRSE0006009 page 33)? If you were referring to concerns other than those related to the risk of transmitting infections, please explain what they were.**

67. I had recently appointed a very able young woman to the post of Blood Donor Organiser. She brought a fresh eye to the blood donation system including the sessions which were held in one prison, [and possibly one young offenders' institution]. She observed that in the accommodation where these sessions were held it was impossible for a donor to be questioned in a confidential environment, so individuals could be reluctant to divulge information about reasons why their donation should not be accepted.

68. She also pointed out that our donor attendants [all of whom were at that time female] were extremely uncomfortable in the presence of an all-male group of prisoners as well as the fact that the venue offered by the prison for the blood donation session was in other ways quite unsuitable for carrying out blood collection. As soon as I was alerted by my new colleague I instructed that all further SEBTS sessions in prisons be cancelled.

b **You told the Penrose Inquiry that "*it would not be correct for me to say that we were worried about hepatitis in the prisons. We were worried about the totality of the environment and I was certainly aware that infection with hepatitis and related viruses was a problem in prisons. I was certainly aware of that information in the United States*" (PRSE0006009 page 33). Please clarify and expand upon this statement.**

69. I cannot add any recollection beyond the evidence I gave to Lord Penrose. When I took up my consultant post at SEBTS in 1979, Dr Cash gave me a copy of a book by Dr John Wallace "Blood transfusion for clinicians," 1975, Churchill Livingstone I read this thoroughly. Dr Wallace describes studies done by the West of Scotland BTS in which it was shown that male prison donors had higher prevalence of HbsAg and of elevated liver enzyme [ALT] than other donors. I also remember being puzzled by the fact that later in the book, Dr Wallace goes on to discuss reasons for c*ontinuing to accept* prison donors.

I also remember that soon after taking up my post I looked at Dr J Garret Allan's book describing his extensive studies on hepatitis related to transfusion. I believe that he also presented data showing a high prevalence of hepatitis in prison donors.

Subsequently I have read a number of other early papers giving evidence of the higher rate of hepatitis among prisoners.

Were you referring to hepatitis B, non-A non-B ("NANB") hepatitis or both?

70. I was referring to infectious hepatitis, in general. I have no recollection that I intended to specify specific causes. Hepatitis C had not been identified or named at this time.

Why were you not worried *about hepatitis – whether hepatitis B or NANB – in prisons*

71. The wording in my oral evidence was intended to explain that our concerns were about the whole process of collecting blood in prisons. In my oral evidence I said that "*We were worried about the totality of the environment".*

72. I should have added – "and not only about hepatitis". My donor manager colleague was not a clinician and she had not included hepatitis in her list of concerns: She had given me more than sufficient reason to terminate these sessions and I did so forthwith.

c As far as you can recall, did you receive any recommendations or advice regarding the continued collection of blood from prisons from the time you

were appointed Regional Director of the SEBTS in 1979 to the point at which SEBTS stopped this practice? If so, please describe them as far as possible.

73. I have no recollection of ever receiving any advice or direction about blood collection in prisons.

74. As I have mentioned above, differing opinions about the merits and demerits of collecting blood in prisons were still being voiced at the time in question.

d You told the Penrose Inquiry that you thought that the SEBTS should have stopped the collection of blood from prisons sooner than it did (PRSE0006009 pages 76-79). Does that remain your view? Either way, please explain why.

75. I have not changed my view. Since the time of my decision to stop donor sessions in prisons more evidence has emerged of reasons why blood should not be collected there. [a] The problems of drug use in prisons has increased. [b] Injecting drug use and sexual abuse in prisons are causes of transmission of HIV and [c] It is now known that injecting drug use is the most important route of transmission of Hepatitis C

You may wish to consider the following documents in answering these questions: 1972 article by Wallace et al on the screening of blood donations for Australia antigen (PRSE0004840); a 1982 Medicine Inspectors' report on the SEBTS and the SEBTS response (SBTS0000407_007 and MACK0001898_001); minutes of the 13 September 1983 meeting of SNBTS directors (PRSE0002617).

76. I have not changed my view.

19. During a special meeting of the Co-ordinating Group on 2 October 1979 to discuss the Howie Report (SBTS0000226_049), you discussed categories for

biological material handled by RTCs, which had been employed by the SEBTS: Low-risk, intermediate-risk, and high-risk.

a. Please explain the purpose(s) of the Howie Report and what its recommendations were.

77. The Howie report and the Howie Code described a set of procedures designed to prevent infection in clinical laboratories. My understanding that both were produced following an incident in Birmingham in which smallpox virus escaped from a laboratory.

b. Please explain if the categories proposed by the SEBTS were adopted by the Health Boards and other Scottish transfusion centres. If not, why not?

78. I have no recollections about this. I have read SBTS0000226_049, and although the minute records that a proposal put forward by me was endorsed by the directors, I have no recollection of receiving the data referred to in the minute, and I suspect that the proposal was not implemented at that time. I do not recall seeing any relevant document during preparation for the Penrose Inquiry. The use of specific procedures for "High risk" clinical samples became established in SNBTS and generally in the NHS clinical following the emergence of HIV *[Howie JW, Collins CH. The Howie Code for preventing infection in clinical laboratories:comments on some general criticisms and specific complaints. Br Med J1980;280:1071.] (WITN6666006)*

c. Please outline the advantages of the category system proposed by the SEBTS.

79. I cannot answer this as I have no recollection that the system proposed in 1979 was implemented

Section 5: Plasma procurement and production of fresh frozen plasma at the SEBTS

80. **Initial comment:** As I have considered these questions, I have been reminded that by the time I became Director of SEBTS, the service was already highly focussed on the provision of plasma for fractionation, driven by the demand for factor VIII concentrate. This was part of the legacy of my predecessor Dr John Cash, who had recognised that demand for factor VIII was bound to increase with the emergence of new products for haemophilia treatment. It is a matter of fact that the operations of SEBTS and least one other Scottish RTC over a number of years gave so much emphasis to plasma collection from blood donations that it led to substantial surpluses of red cells, which often had to be discarded. It also led to the provision of a red cell product [concentrated red cells] that was difficult to transfuse quickly and so less than optimal for patients requiring urgent, rapid blood transfusion.

Production of fresh frozen plasma

20. The Inquiry understands that the SEBTS procured plasma from blood donor sessions to produce fresh frozen plasma ("FFP") to provide to the PFC. Please explain:

a where the production of FFP took place;

81. In 1979 when I became Director FFP was being prepared in a basement area in an elderly property in Lauriston Place Edinburgh. This facility was heavily criticised by the Medicines Inspector and is detailed in his report of that inspection: I accepted all his criticisms and we set out immediately to improve the situation. In 1983 the production of FFP was transferred to an improved, though still far from ideal environment in a refurbished and re-equipped space in Livingstone House, Cowgate, Edinburgh. Later, the blood components laboratory, where FFP was prepared, was transferred to modern premises in the Phase 1 New Royal Infirmary Building where a purpose - built laboratory had been constructed, of adequate size and well equipped. I have not yet been able to ascertain the date of this transfer.

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

82. The basis of the process of preparing FFP is to allow whole blood [which contains the anticoagulant/ nutrient solution that prevents the donor's blood from forming clots as it flows into the collection pack] to separate into layers containing the red blood cells, white blood cells and the plasma respectively. This will occur slowly under gravity but in practice is accelerated by the use of centrifuges that apply several times the force of gravity. There were many changes in these procedures during my tenure, resulting in a higher yield of plasma of better quality. Eventually, in 1998, due to concerns about the possibility that variant Creutzfeldt Jakob Disease [vCJD] could be transmitted by blood, a UK government level decision was taken that plasma from British donors could no longer be used in any form.

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

83. From about 1975, in SEBTS, an increasing proportion of whole blood donations were separated to prepare FFP - yielding about 200 ml per donation, - and concentrated red cells [CRC.]. The CRC was more viscous than whole blood and much slower to transfuse. This led to some clinicians experiencing difficulties in administering rapid transfusions of red cells to patients needing urgent blood replacement due, for example to bleeding in childbirth. I do not now have access to any documentation relating to this problem but I am clear in my recollection that I received many expressions of concern and complaints from clinicians about this.

84. An improved system was introduced [probably in the late 1980s] in which the removed plasma was replaced with a solution [Optimal Additive Solution, OAS] that avoided the viscosity and slow infusion problems and also allowed a greater volume of plasma to be extracted from each donation. This made it possible to recover FFP from the large majority of donations.

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

85. The use of OAS maximised the plasma that could be obtained from the existing number of whole blood donations. If more FFP was to be produced, one option was to increase whole blood collections. However, SEBTS already produced more red cells than required for patients in its regions and if, as was usually the case, we were unable to transfer them to regions experiencing shortages, there was a high level of wastage of donated red cells.

86. The alternative was to expand the use of plasmapheresis. Any increase in the very small number of manual plasmapheresis procedures was judged to be unacceptable from a safety viewpoint because of the intrinsic risks. [These risks arise because during the manual procedure, the pack containing the donor's blood must be disconnected from the donor and placed in a centrifuge to allow separation of the plasma from the red cells. If more than one donor is undergoing plasmapheresis, this creates the risk that an error can result in a donor receiving a retransfusion of the incorrect red cells]. Machine plasmapheresis removes this risk because the donor remains connected to the collection device during the whole procedure]

Given the necessary funding for the machines, accommodation, staff, and disposable plasma collection could have been expanded to substantially increase production of FFP.

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

87. I am uncertain of the details but I am sure that funding would have come from the Scottish Health Department following the approval of bids submitted from the RTC's. I have no recollection that there were other sources of funding for plasma collection.

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

88. The Edinburgh Royal Infirmary [RIE] was the largest user. Its demands were met from FFP that was held in the SEBTS blood bank, where it would be thawed and supplied in response to a clinical request accompanied by a request form. Hospitals with their own blood bank [Western General, Victoria Kircaldy and Borders General] would hold a stock of FFP from which clinical requests would be met. They would receive deliveries from SEBTS to replenish their stock. The haemophilia centre in the RIE would request FFP from the SEBTS blood bank as described above.

Plasma targets

23. Did the SEBTS have targets for the amount of plasma that had to be collected by the centre? If so, who set these targets and what were they? If not, why not? What was the purpose of the targets?

89. My recollection is that each Scottish RTC would, each year, following discussions at meetings of the Directors, be allocated a target quantity of FFP to meet the needs of the PFC as it aimed to meet the clinical demand for factor VIII. This would be in addition to the quantity used as FFP for patients in the region's hospitals.

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

90. My recollection is that SEBTS usually met the targets, and as explained in my responses above, the only realistic option to collect more plasma was to increase machine plasmapheresis collection. This was the subject of many discussions within the SNBTS. My recollection is that SEBTS made modest increase in plasmapheresis collections, but at the time of writing I do not have historical data on SEBTS plasma collections.

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

91. My recollection is that SEBTS usually met the targets, and as explained in my responses above, the only realistic option was to increase machine plasmapheresis. This was the subject of many discussions within the SNBTS.

26. Were there any benefits to the SEBTS if the targets were exceeded?

92. I have no recollection that SEBTS received or expected any benefits if plasma targets were exceeded.

Plasmapheresis

27. At a meeting of the Advisory Committee on the NBTS in February 1981, Dr Cash noted that the need for plasmapheresis in Scotland was being studied (CBLA0001287, paragraph 18). Please explain, as far as you are able, what consideration the SEBTS gave to implementing plasmapheresis, including:

a whether manual or machine plasmapheresis was preferred;

93. Machine apheresis was considered to be the only option, because of the safety issues with manual plasmapheresis, referred to in the answer to question 19 d

b the relative cost differences between each method;

94. I do not have any data on this question but my recollection is that that machine plasmapheresis was considerably more costly due to the greater complexity of the disposables required, and the capital or leasing costs of the machines.

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

95. SEBTS had staff with the necessary skills and experience. An in increase in funding would have been required for any large expansion of plasmapheresis, to meet additional costs of staff and equipment, and possibly also for additional accommodation.

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

96. Provided that sufficient doors could be recruited, an increase in plasmapheresis collections would have increased the availability of plasma

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

97. I have very little recollection of how plasmapheresis developed at SNBTS. There had been for many years a continuing program of plasmapheresis of donors who had high levels of antibodies suitable for preparation of hyperimmune globulins. I do not have data on the quantities of FFP collected by SEBTS using plasmapheresis.

98. At present, I only have the FFP data for all of SNBTS. [Table below.], plasmapheresis did not lead to an increase in FFP sent for fractionation.

SNBTS PRODUCTION OF FFP 1990/91 TO 1995/6

Year	Total FFP to PFC [kgs]	Apheresis (FD) plasma to PFC [kg]
1990/91	75,482	
1991/2	78,282	
1992/3	71,618	9,198
1993/4	75,753	10,502
1994/5	77,950	11,408

1995/6 77,122 10,262

29. At a meeting in September 1984, the SNBTS Ethics Committee discussed a proposed trial of a new plasmapheresis machine at the SEBTS (SBTS0000139_084, page 2):

a To what extent did this trial reduce the waste of surplus red cells?

b Did this trial result in more machines being purchased and used by the SNBTS? If so, how many machines in total? Were the machines purchased all manufactured by MSE Fisons?

You may also find SBTS0000294_079 useful in answering these questions.

99. After some aspects of the evaluation programme had been completed, the conclusion was reached that the machine was not adequately developed to be considered for use in the collection of plasma from donors. There were concerns that the manufacturer [MSE – Fisons] was not allocating sufficient resources to develop the machine to a clinical standard. This work was therefore discontinued. It had had no effect on blood and plasma collections

Use of plasma reduced blood and red cell concentrates

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

100. As mentioned above, some clinicians, especially those responsible for patients needing rapid transfusion, had concerns about using red cell concentrate. Dealing with this issue occupied a fair amount of my time during my early years in SNBTS. We encouraged clinicians to mitigate the problem by infusing saline solution with the concentrated red cells, which was effective but added to the manipulations and to the time required to set up a transfusion. However, we felt that there was also a "Hearts and minds" problem, perhaps understandably due to the rather sudden and substantial change in the characteristics of a very familiar and important product. With the help of the senior

anesthetist in RIE, we established a working party with members from the Regional Divisions of Surgery and Anaesthetics, the Surgical Audit Committee and SEBTS to engage clinicians in discussion about this and other aspects of their transfusion practice.

101. It was decided to undertake a survey of the opinions and practices of transfusion, in which all the surgeons and anaesthetists in the South-East Region would be personally interviewed, with use of a standard questionnaire. We appointed a very able trainee in anaesthetics to undertake these structured interviews covering details of their transfusion practice. Our reasoning was that this process would involve many of the more concerned clinicians in discussions with colleagues, some of whom we knew were relatively unconcerned about the change, and appeared to manage well with the red cell concentrate packs. The results of the completed survey were analysed and returned to all 99 interviewees many of whom shared them with colleagues or presented them at departmental meetings. *Routledge L A for the Blood Transfusion Advisory Group, Royal Infirmary, Edinburgh. A survey of anaesthetists' and surgeons' views on blood transfusion in the South -East Region of Scotland in1981 Unpublished. (WITN6666024)*

I have no objective data about the longer term outcomes of this exercise, but my recollection is that the complaints had largely subsided. This was well before we solved the problem definitively when we transferred production to the Optimal Additive packs mentioned above.

31. In a letter to Dr Cash dated 04 October 1984, regarding decanting of surplus red cell concentrates, you expressed concerns about the excess production of red cells in the South-East Region (SBTS0000616_120). You stated: "*My opinion is that it is desirable that we continue to supply red cells to Edgware, at least during the next year or so, during a period when we would expect to be slowly building up our capacity for plasmapheresis.*" Please explain what you meant by this statement.

102. In this letter I was simply making a recommendation to the National Medical Director that, since SEBTS had a surplus of CRC over regional requirements, we should continue to supply the Edgeware [North London} RTC which was experiencing shortages and that we should formalise this with the Common Services Agency so that it could if it so decided, make some charge. The letter refers to my expectation [or hope] at the time of writing, that we would be able to begin building a plasmapheresis program for FFP in the fairly near future.. As I have already stated, I am unable to recall further information about the scale of developments in plasmapheresis for FFP in SEBTS.

Section 6: Arrangements for obtaining and allocating blood products at the SEBTS

103. **The view from 40 years on:** Looking back from this distance, my scant recollections about the topic of this section are consistent with the dominating message in the documents supplied, that if patients' expectations and needs for treatment were to be met, this could only have been achieved by the ever - increasing purchase of commercial Factor VIII. Frequent exhortations to clinicians to moderate the use of PFC factor VIII [see for example PRSE0003593, PRSE0003044, PRSE0003294, PRSE0001840, PRSE0003653] were not noticeably effective. This at least in part reflects the fact that the haemophilia clinicians had a duty of care to provide the best treatment for their patient, although they were also under pressure to avoid increasing the costs to the NHS of commercial blood products. As the years passed, I think it became apparent that SNBTS did not have the capacity or the funding to keep pace with this increasing demand. I must add that my personal opinion was then, and remains, that there would have been both practical and ethical problems in obtaining the increasing quantities of plasma required from volunteer, non - remunerated donors whether by whole blood collection or by plasmapheresis

32. Please describe the arrangements in place in the Edinburgh and South East Scotland Region for the purchase and holding of, and the allocation to haemophilia centres within the region, of (a) PFC factor concentrates and/or other

blood products ("PFC blood products") and (b) imported factor concentrates and/or other blood products ("imported blood products"). In particular:

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

104. Haemophilia treatment in the area served by SEBTS was concentrated in the Royal Infirmary of Edinburgh, [RIE] so that, as I recall, the majority of blood products for patients with haemophilia supplied by SEBTS was to the RIE. It is probable that some patients with haemophilia were managed by haematologists in other hospitals, especially the more distant such as the Victoria Hospital in Kircaldy. In such a case, SEBTS may have issued blood products directly to the hospital concerned.

b. Please outline the respective responsibilities of the SEBTS, PFC, the Lothian Health Board, and haemophilia centre directors, and how these responsibilities changed over time.

As well as the documents referred to below, you may wish to consider the minutes of the 14 January 1981 meeting of the Lothian Health Board (PRSE0004847).

105. The SEBTS was responsible for providing blood components for patients in the South East region of Scotland.

The PFC was responsible for manufacturing fractionated plasma products for patients throughout Scotland.

The Lothian Health Board was responsible for providing health care to the population of the Lothians.

106. During the period before the provision of recombinant factor VIII, the demand for plasma derived factor VIII continued to increase inexorably. When I was first employed as a Consultant in SEBTS in 1977, I recall that the SNBTS blood bank held a small quantity of a commercial coagulation product [Factor VIII Bypassing

Activity, FEIBA] used in the treatment of patients with inhibitors [antibodies] to factor 8.

107. Referring now to PRSE0004847, the March 1981 meeting of Lothian Health Board officers, Haemophilia and SEBTS directors, (PRSE0004847) it was noted that blood products supplied by the PFC were funded by the Common Services Agency [CSA] and that this was an atypical arrangement since the norm was for Health Boards to carry the cost of purchasing Factor VIII and IX . It was minuted that in future any commercial blood products purchased for haemophilia care would continue to be ordered through SEBTS, but funded by the Lothian Health Board and supplied at the request of the responsible consultant. Later, Dr Ludlam became responsible for ordering commercial products for his patients through the hospital pharmacy. [This funding arrangement is described in the addendum to the 1979 Job Description for the RTD at SEBTS]

33. Please explain whether any forums were established between the SEBTS, PFC, the Lothian Health Board, and haemophilia centre directors to discuss and facilitate these arrangements. Were meetings held regularly? Were they minuted? If so, by whom? What was discussed at these meetings? You may find the documents at PRSE0000144, PRSE0001736 and PRSE0002106 useful.

108. There were regular meetings of haemophilia directors, SEBTS and representatives of SHHD. My recollection is that these were held about once per year. I do not remember if there were regular meetings with the Lothian Health Board. The annual meetings with the SHHD covered a wide range of topics related to haemophilia care. Referring to PRSE 1736, there was a meeting on 21 January 1983 at which the issues discussed included the adequacy or otherwise of supplies of factor VIII from the PFC, the need to supplement this with commercial products , and a timely alert from Dr Cash about the information emerging about acquired immune deficiency syndrome. There was also a factor VIII research group that was specifically concerned with the development of products.

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

109. I do not remember any details of the arrangements elsewhere. It is probable that in the Dundee, Aberdeen and Inverness RTCs, PFC factor VIII would have been held in the RTCs and issued at the request of a clinician caring for a patient. Commercial products would probably have been purchased through the hospital pharmacy. The arrangements in Glasgow and West of Scotland region may be different.

35. The minutes of the 30 January 1981 meeting of SNBTS and haemophilia directors suggest that PFC factor VIII was, at that time, distributed according to population rather than the amount of plasma sent by each region (PRSE0000144 page 3).

a **Is that correct? What was your view on the merits or otherwise of the system in place at the time of this meeting, as well as the apparent proposal to change it?**

110. I believe that was the case. I have no recollection of my opinion at the time. Looking back, and reviewing the correspondence that the Inquiry has provided, it seems clear that varying the mode of allocation would not have provided a solution to the fundamental problems of ever increasing use and a finite capacity of the PFC.

b **As far as you can, please clarify the meaning of the final sentence in paragraph 5 of the minutes: "*In general members agreed that Mr Watt should continue to maintain a reserved supply of factor VIII at the PFC and were of the view that while issues of VIII should be related to the amount of***

plasma submitted for processing it was for the transfusion of service to rationalise the collection of plasma appropriately."

111. This appears to reflect a desire among the directors [rather than an instruction] that the PFC should hold a reserve supply of Factor VIII. I really do not know what, if anything, is meant by the directors "rationalising" the collection of plasma.

36. When did the allocation of PFC concentrate change to a system based on the amount of plasma supplied by each region? What was your view of the merits or otherwise of the change? In answering this question, please address issues relating to the amount of concentrate used by the Edinburgh Royal Infirmary in the early 1980s. You may wish to consider the following documents: 7 February 1980 letter from Dr Cash to you (PRSE0003593); 10 May and August 1982 letters from Dr Boulton to Dr Ludlam (PRSE0003044 and PRSE0003294); Dr Boulton's notes of a 23 August (most likely 1982) meeting with Dr Ludlam (PRSE0001840); 28 October 1982 letter from Dr Cash to John Watt (PRSE0000028); 7 December 1982 letter from Dr Boulton to Mr Watt (PRSE0001487); 2 February 1983 letter [PRSE...4847]

112. I have no recollection of when these changes were made, and having reviewed the correspondence provided, I am no clearer. Dr Cash's letter [PRSE0004847] suggests that the pro rata issues may have been suspended before October 1982, but also suggests reinstating the system.

37. Did you, or anyone else at the SEBTS, contract directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of imported blood products? You may find PRSE0002222 of assistance. If so, please describe:

113. The letter PRSE0002222 records some technical information offered by a representative of the company Immuno. This was not my special area, so I passed it on to Dr Cash. I did not normally see representatives of companies

marketing plasma fractions in the UK: their targets were the haemophilia clinicians.

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

114. I did not at any time contract with any of these companies and I have no knowledge that any member of staff at the SEBTS did so.

b the broad terms of the contractual agreements made; and

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

115. Not applicable.

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

116. My recollection is that these decisions were entirely the responsibility of the Health Board haematologists responsible for the patients.

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

117. SEBTS did not have any influence on the choice of products: Dr Boulton certainly discussed the issues about cryoprecipitate and SNBTS factor VIII concentrate. I cannot say if commercial products figured in these discussions, but the decisions on choice of product would have rested with Dr Ludlam. Haemophilia care, at least in Edinburgh, was the preserve of the Haemophilia Treatment Centre. Dr Boulton, as can be seen in some of the correspondence provided, encouraged the use of cryoprecipitate. Dr Boulton had the appropriate

training and experience in haemophilia management at consultant level to advise on treatment. Dr Boulton may have offered advice on this matter to clinicians in other hospitals, but the choice of product would have been made by the clinician.

40. What, in your view, were the key factors influencing the choice between PFC blood products and imported blood products? Please comment on (i) what influenced your personal choice (if you were involved in such decisions), (ii) what, to the best of your knowledge, influenced the choices of others involved in such decisions.

118. I was not involved in these decisions. My understanding is that the factors influencing choice included [a] convenience in use. Commercial concentrates were easier to dissolve than the early PFC products and therefore more convenient for patients and staff. [b] Commercial products may have had a higher specific activity [factor VIII content per mg of protein] This would have been considered important in relation to the theory that the immune response could be impaired by infusion of foreign proteins. [c] Some commercial suppliers introduced procedures intended to inactivate the infectivity of HIV or Non A non B hepatitis at a time before the PFC could supply these products. [Some of these products were later found to be still capable of transmitting viral infection.] [d] A critical factor was availability. As many documents show, the PFC's output was frequently less than clinicians felt their patients needed. In contrast, cost, and infection risks were. the main concerns about the use of commercial products.

41. The Inquiry has heard evidence about the importance of the concept of clinical freedom, i.e. doctors being free to make decisions as to the best course or product to adopt in the treatment of their patients. Please explain, from your knowledge and experience, the impact of clinical freedom on the relative use of PFC blood products and imported blood products in the UK.

119. I have little doubt that the principle of clinical freedom was an important factor in the choices that clinicians made about the products they selected for their patients. It was, and remains my belief that those clinicians with whom I had

contact were motivated very strongly by their belief that it was their duty to provide the best treatment that they could. I am sure that clinicians felt they were responsible for choosing the most suitable product for their patients, but the choice of product could also be influenced by availability.

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

120. I cannot speak from personal experience of the marketing efforts of these companies because I was not a potential customer and they did not view me as one. I was aware that pharmaceutical companies provided information for both patients and clinicians that was often usefully informative, but that could also contain messages that were essentially promoting a company's product.

43. In a letter to Dr Ludlam dated 15 May 1984, you stated: "*it looks as though we are now entering a situation where factor VIII supplies should be stable and adequate. As a result we hope to be able to achieve a steady regular delivery arrangement with the PFC and to maintain our chosen minimum stock level*" (PRSE0000585). Please explain whether the SEBTS was able to ensure a stable supply of Factor VIII and maintain its minimum stock level. If not, why not? You may find PRSE0001122 useful.

121. I think this must have been written during a brief period of optimism. I think it would be fair to say that while there were periods when our stock remained adequate to meet the clinical demand, the overall situation was often precarious, and became ever more so as the demand for factor VIII continued to rise. PRSE0001122 gives the impression of this as does much of the correspondence among SEBTS, PFC and Dr Ludlam around this time.

44. In a letter from Dr Ludlam to you in November 1984, he stated that it was the fourth occasion that there was no factor IX available (SBTS0000687_217). What

was the impact on the SEBTS of shortfalls in blood products coming from PFC? Please explain

a How frequently did the SEBTS run out of factor VIII or factor IX supplies during your tenure?

122. I do not remember this particular incident. This may have been the result of a production problem at PFC, or possibly a communication problem leading to a failure to replenish supplies in SEBTS. I do not remember if there were other occasions when SBTS could not supply product requested by clinicians.

b What steps, if any, did the SEBTS take to address these issues? How effective were these steps? You may find PRSE0001736 (page 3) and PRSE0002081 of assistance.

123. I am assuming that this question relates mainly to factor VIII. The correspondence between SEBTS [Dr Boulton and myself], Dr Ludlam, and the PFC illustrates the reality that SEBTS, and hence the clinicians and patients we served, had effectively no control over supplies from PFC. In retrospect, I think the reality was that there were periods when supply was adequate, interrupted by periodic acute shortages. On some of these occasions, PFC product was obtained from other centres, but I think there must have been occasions when the clinicians would have had the choice between [a] requesting the hospital's pharmacy to purchase a commercial product or [b] being unable to provide what they believed at the time was the most effective treatment for the patient.

This extract from PRSE0001736 and the following paragraphs give a good impression of the type of discussion that made a good-looking minute but in reality failed to address the elephant in the room - the fact that there were finite limits on the amount of factor VIII that could be provided by non-remunerated donors, according to the standards that applied in the UK.

From PRSE0001736

(a) Trends in Supply and Demand for Factor VIII concentrates. Figures quoted for the 5 year period 1978 to 1982 showed that:

. *(i) there had been a sustained increase in the total amount of fresh plasma processed, although it was anticipated that the increases would probably now level out, unless there was significant further financial investment at the Regional Transfusion Centres.*
(ii) there had been a decrease in the amount of cryoprecipitate issued •from the RTCs; and
(iii) there had been a substantial increase in issues of the PFC intermediate factor VIII concentrate.

45. In a letter from Dr Peter Foster to you in August 1982, Dr Foster stated "*my initial reaction to the claim that PFC FVIII concentrate is of poorer quality than commercial "intermediate-purity products" is that this is probably a fair comment.*" Dr Foster also described an "*inverse relationship between yield and quality*" (PRSE0001361). Insofar as you are able to do so, please explain the context of this letter, and the reason why Dr Foster addressed this claim. As far as you can recall, did you agree with Dr Foster's comments in this letter at the time? Please explain your answer.

124. I do recall discussions about the quality of PFC factor VIII. I think that Dr Foster was probably pointing out the reality that with each manufacturing step that is added to improve the *purity* of the Factor VIII [ie to reduce the proportion of non factor VIII proteins in the product] the *yield* , the amount of factor VIII obtained from the starting FFP, is reduced.

125. A product that has a higher concentration of protein may be more difficult [slower] to dissolve before it is infused. This is time consuming and inconvenient for patients and for clinical staff. A quite different concern arose as AIDS emerged, that it was thought that the regular infusion of a product with a higher protein content might cause the immunological changes that are now known to be a result of infection with the HIV agent, although this was eventually shown not to be of great importance.

126. I do not know why Dr Foster addressed this claim.

46. At an SNBTS Directors meeting in January 1983, Dr Ludlam stated *"Edinburgh perhaps did not receive as much PFC Factor VIII concentrate as it should pro-rata"* (PRSE0001736). Did you agree with this assessment? If so, and as far as you can recall, why did the Edinburgh region not receive as much PFC Factor VIII as it should have? Were these issues resolved?

127. I do not have access to any data on this point. In any case, it is evident from many of the documents, that the allocation of Factor VIII was often debated. In part this was because a valid calculation of fair shares would always be difficult.

47. In May 1983, Dr Ludlam suggested "*to aim for a figure of 2.75 million units of factor VIII per million of the population*" and "*3 or 3.4 million units for S-E Scotland by 1985*" (PRSE0002081). Please explain, as far as you can recall:

a Whether you agreed or disagreed with this target and if so, why;

b Whether this target was ever proposed officially and if so, what the result was; and

c Whether the target was achieved by 1985.

128. I do not have this information and I am unable to remember my opinion at the time if this target was agreed upon or whether it was achieved.

48. In December 1983 you wrote a letter to Dr Ludlam regarding the receipt of "*substantial deliveries*" of PFC Factor VIII from Belfast. In this letter you stated you were aware of a prior exchange whereby Dr Ludlam provided commercial Factor VIII to Dr Mayne (Northern Ireland) in exchange for PFC Factor VIII, but you were not aware that these exchanges had continued. You stated: "*So far as I know our stock level is low, and indeed the total stock situation within the SNBTS is at present very healthy and I wonder if there is some specific reason why the exchanges with Belfast are still necessary and obviously I am concerned that there may be some difficulty in our local supply situation which I am not aware of*" (LOTH0000005_071). You may also wish to consider Dr Ludlam's 11 January 1984 response (LOTH0000005_085).

a Please explain, to the best of your knowledge, why Dr Ludlam supplied commercial Factor VIII to Northern Ireland in exchange for PFC Factor VIII.

129. There appears to be an error in the letter quoted: The reference to our stock level is low" is not consistent with the rest of the text. I think this exchange of products was probably because of Dr Ludlam's wish to treat as many as possible of his patients with PFC Factor VIII. It may have been that Dr Elizabeth Main was willing to use the commercial product. I never discussed this with her. I do not remember being aware of this exchange at or near the time it took place.

b **As you understand it, why did the SNBTS continue to receive deliveries of PFC Factor VIII from Belfast? Please give your view of this decision by the SNBTS**.

130. I imagine that the reason is that given in the answer to question **48 a** above.

c. Was there some difficulty in the SNBTS's local factor VIII supply situation that you were not aware of? If so, when did you become aware of it and what steps did you take to address the issue? How effective were these steps?

131. The intermittent problems with Factor VIII supply have been discussed in earlier answers. I cannot add to these comments.

d. Were there any procedures in place to monitor agreements of this type? If so, what were they?

132. I am not aware that at this time there were any arrangements to oversee the exchange of products between centres. This exchange was probably the result of an informal agreement between the two doctors. I am not aware that there was any prohibition on such arrangements at the time.

e. Were there arrangements to exchange blood products with other jurisdictions? If so, please provide details.

133. SEBTS from time to time supplied red cells surplus to local clinical needs to the North London and South London RTC's. These arrangements had the support of the National Medical Director. There was no reciprocal supply.

49. On 19 September 1988, you wrote a letter to Dr Cash regarding PFC and RTC plasma figures and discrepancies between them (SBTS0000627_027). In this letter you stated: "*Over the past 4 years the average difference between the PFC figures and the RTC figures show that the PFC records about 11.5% greater weight than the RTC's.*" Please explain what effect this discrepancy had on arrangements for the supply of PFC blood products to RTCs. As far as you are aware, did it result in RTCs receiving a greater quantity of blood products for the plasma supplied?

134. I cannot recall how this was resolved. Referring to SBTS0000627_027, the data collated by the person responsible for the components section of SEBTS appears to have indicated that this discrepancy was the result of the rounding up of the weights of plasma packs received in the PFC. I cannot see that this could have affected the total production of plasma products, although it could have had an effect on yield calculations.

50. In a letter dated 26 November 1984, you wrote to Dr Ludlam regarding the purchase of commercial Factor VIII (STHB0000104); Dr Ludlam responded on 30 November 1984 (LOTH0000005_063). In your view, did the purchase of commercial material from 1983 to 1984 reflect a failure on the part of the SEBTS to supply a sufficient quantity of Factor VIII? You may also find what is said at page 3 of PRSE0001736 useful in answering this question.

135. If "sufficient" is taken to mean the quantity of factor VIII that the clinicians felt was necessary, then I believe the evidence shows that the SEBTS did not supply a sufficiency, because of the ever - increasing demand for Factor VIII.

Section 7: Production of cryoprecipitate at the SEBTS

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

136. The SEBTS produced cryoprecipiate.

52. If the SEBTS did produce cryoprecipitate, please describe:

a where the production of cryoprecipitate took place;

137. Cryoprecipitate [cryo] was produced in the blood component section. As described above, the accommodation changed in 1983 from Archibald Place to Livingstone House, and later [I have not yet ascertained the date] to the new components laboratory in the New Royal Infirmary Phase 1 Building.

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

138. The process involves rapidly freezing the plasma, in a plastic blood pack, then allowing it to thaw under controlled conditions to a temperature of 4C. Under these conditions the larger molecular weight plasma proteins, including Factor VIII, Fibrinogen and von Willebrand factor form a precipitate. This is then concentrated by centrifugation, after this, the supernatant [called cryo-depleted plasma] is expressed, leaving the cryoprecipitate in the initial plastic pack. This is done using a device called a plasma expressor. The cryoprecipitate [cryo] is then stored at -40C and is thawed immediately before use. The capacity of SEBTS to produce cryo was at first limited by the inadequate accommodation of the components section. With improvements in the laboratory, including the use of mechanical blast freezers, more centrifuge capacity and space for more plasma expressors, the capacity increased.

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

139. These are the figures that I have been able to access from SNBTS Annual Reports for cryoprecipitate production at SEBTS.

YEAR	DONATIONS PROCESSED TO CRYOPRECIPITATE
1986 - 87	12728
1987 - 88	14375
1988 - 89	11600
1989 - 90	12399

d How much funding was provided by your region for the production of cryoprecipitate; and

140. As far as I can recall, we did not receive a separate allocation for production of cryo: I cannot now remember how the revenue allocation was sub-categorised.

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

141. I cannot give a quantitative answer. Expanding cryo production would have been dependent on receiving funding to obtain improved accommodation, additional equipment and additional staff. This did not happen until the function was moved to improved premises in the RIE Phase 1 Building. It had taken several years to achieve financial approval and complete the planning, construction, equipment and commissioning of this laboratory.

53. Please explain what consideration the SEBTS gave to increasing the production and use of cryoprecipitate in response to the growing awareness of the risks associated with Factor VIII concentrate products in the 1980s.

142. Cryo production was adjusted to meet the clinical demand: this was for both haemophilia care and for the management of patients with coagulation disorders.

I cannot say to what extent the clinicians' requests for cryo were influenced by awareness of risks associated with the use of factor VII concentrates, but I have no doubt that this would have been an important consideration.

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

143. I have responded to this in my answer to question **53**

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

144. I have described these arrangements in my response to **Question 32.**

56. In May 1983, Dr Ludlam wrote to you regarding intermediate purity factor VIII concentrate (PRSE0002081). In the first paragraph he stated that Edinburgh used 25% cryoprecipitate, as opposed to the UK average of 10%.

a To your knowledge, why did haemophilia clinicians in Edinburgh use more cryoprecipitate than the rest of the UK? Was there a concerted effort to use cryoprecipitate? If so, why?

145. I do not have access to data on the usage of cryo in Edinburgh and other haemophilia treatment centres, and I do not know the source of the figure referred to above. I know from discussion with other colleagues, including Professor Ian Franklin, speaking of his time as a consultant in Birmingham, that Factor VIII concentrate from BPL was always in short supply. This may well have encouraged the use of commercial concentrates.

b In your view, why did other regions not increase their use of cryoprecipitate?

146. I do not have this data for other regions. It may be important to consider the use of cryo for haemophilia treatment separately from the use of cryo for coagulation disturbances in which there are reduced levels of fibrinogen].

57. In your evidence to Lord Penrose, you explained that, had it been considered to be a clinical necessity, "*it would have been possible at any time to make a fairly modest investment into a bit of premises somewhere, equip it and make large quantities of cryoprecipitate*" (PRSE0006021 pages 157-159).

a During the first half of the 1980s, were you involved in any discussions within the SNBTS or with haemophilia clinicians about the practicalities and logistics of increasing cryoprecipitate production?

147. I do not recall such discussions but I am fairly certain that they would have taken place. Over this period, SEBTS scientists were exploring modifications to the cryo production method to improve the factor VIII yield. I cannot remember all the variations that were examined, but one of these was brought into the routine production process. This was the Thaw-Siphon method developed in Australia by Dr Ernest Mason. I do not have access to data but as I recall, this did provide a useful increase in yield. There were also improvements in the method of freezing plasma, namely the replacement of the alcohol /CO2 process with the use of mechanical blast freezers that froze plasma more rapidly, also increasing yield.

b Had the steps you referred to in your evidence to Lord Penrose been taken, do you think that it would have been possible to produce sufficient cryoprecipitate to provide a level of treatment for people with haemophilia that was broadly equivalent or similar to that which they received through the use of factor concentrates? Please explain your answer, including in respect of any differences that you think would have resulted. Please address this question, insofar as you are able to do so, in respect of (i) Edinburgh and South East Scotland, (ii) Scotland as a whole, and (iii) the UK as a whole.

148. Given the funding and access to suitable facilities SEBTS could have produced more cryoprecipitate from the existing level of blood collection. It is important to emphasise the rate of increase in the total units of factor VIII being prescribed over the period in question. I think it is probable that there would have been a period, when the *quantity* of Factor VIII considered necessary for haemophilia treatment might have been met through an increase in cryoprecipitate production. However, I cannot speculate as to whether the responsible clinicians would have been prepared to abandon the use of concentrates, even if the supply of cryo was unlimited. In later years, I do not believe that cryoprecipitate could have met the increasing demand for factor VIII treatment. Even if more cryo had been available, I believe treatment using only cryo would not have been accepted by patients or clinicians due to the incidence of reactions to cryo infusion and the inconvenience of administration.

149. I have no personal experience of the clinical care of patients with haemophilia, but I am certain that the experts who have already informed the Inquiry will have demonstrated that effective care for some patients could, in reality, only be delivered by using factor VIII concentrate.

150. I believe that these comments would have applied to patients with haemophilia and to their clinicians in any area of the UK.

58. **During the early 1980s, the possibility of producing freeze-dried cryoprecipitate in Scotland was explored. See, for example, the following documents:**

- **Letter from Professor Bloom to Dr Ludlam, 8 September 1980, concerning freeze-dried cryoprecipitate (LOTH0000012_132).**
- **Letter from Dr Ludlam to Dr Rizza, 16 September 1980, proposing a discussion of freeze-dried cryoprecipitate at the next meeting of the Regional Haemophilia Centre Directors meeting, which refers to consideration of this topic in Scotland, including at the PFC (LOTH0000012_131).**

- **Minutes of the Regional Haemophilia Centre Directors, 22 September 1980, at which the issue was discussed, and at which reference was made to work being undertaken on this matter in Scotland (HCDO0000406).**
- **Letter by G S Gabra, Robert Crawford and Ruthven Mitchell to the British Medical Journal, vol. 281, page 1006, 11 October 1980 (BPLL0002088).**
- **Note of a meeting of Haemophilia and Blood Transfusion Working Group, 4 March 1981 (PRSE0000181).**
- **Note of a meeting of Haemophilia and Blood Transfusion Working Group, 4 November 1981 (PRSE0004212).**
- **Letter from Dr Watt to Dr Cash, 2 December 1981 (SBTS0000269_013).**
- **"Liver disease complicating severe haemophilia in childhood", McGrath et al, Archives of Disease in Childhood, 1980, 55, 537-540 (as referred to in Dr Watt's letter of 2 December 1981) (OXUH0001751_003).**
- **Minutes of the meeting of the Directors of the SNBTS and Haemophilia Directors, 21 January 1983 (PRSE0001736).**

Freeze Dried Cryoprecipitate

151. I did not recall these discussions but I have reviewed the above references. Dr Bloom's short letter to Dr Ludlam [LOTH0000012_132] is moderately positive about the prospects of wider use of cryo, including for home therapy. His view was based, I believe, on information from the Netherlands and Belgium. The Haemophilia directors, at their meeting in September 1980 minuted that the use of Freeze Dried Cryo was a matter for individual clinicians:

152. The other documents provided relate to discussions within SNBTS. The long letter from Mr John Watt, PFC director, to Dr Cash [SBTS0000269_013] goes into the regulatory problems that would preclude the preparation of single donor FD cryo in the existing PFC building. It also reflects a view that efforts would be better directed to developing virus-safe factor VIII concentrate, and suggests that the freeze drying equipment at West of Scotland BTS could be upgraded. [See **58b**]

153. The minutes of the meeting of the Directors of the SNBTS and Haemophilia Directors, 21 January 1983 (PRSE0001736) record that:

Dr Cash expressed SNBTS thanks to those who undertook the successful clinical trial of this product [freeze dried cryoprecipitate] *in the west. Notwithstanding this work, it had been decided to abandon production of FDC meantime, having regard to the closure of the plasma freeze drying plant at Law and the cost of meeting the standards demanded by the Medicines Inspectorate. The prospective availability of a hepatitis risk reduced factor VIII concentrate also cast uncertainty over the future of FDC at the present time.*

Please explain your understanding of discussions over the production of freeze-dried cryoprecipitate in this period. In particular, please consider:

a Any contribution made by the SEBTS to the issue.

154. SEBTS did not contribute to production of freeze dried cryoprecipitate. It did not have the necessary equipment and could not have undertaken production of FD cryo.

b. The other organizations or individuals involved in exploring it.

155. The Glasgow and West of Scotland Centre at Law Hospital had, as far as I know, the only freeze drying plant with capacity to process cryo packs. [This was an old machine which, I believe, the Medicines Inspector had pronounced unsuitable for making clinical products.] I know that there were transfusion services in Europe that were working on FD cryo. One of these centres was in Groningen, Northern Netherlands. I also have a recollection that SNBTS did have contact with a doctor from Belgium who had built a substantial treatment program based on cryo .

156. I am unable to comment on the decision not to pursue the production of Freeze Dried Cryo in the light of the apparently encouraging results of the

Glasgow clinical study. [BPLL0002088)], but the letter to the British Medical Journal gives a hint of a possible explanation "The material has only so far been given to a small number of patients but it has been found to be efficacious and no side effects have been reported." I am not aware of a subsequent publication giving substantive data on efficacy and adverse reactions.

c. The perceived advantages and disadvantages of freeze-dried cryoprecipitate.

157. My response is based on what I have understood over the years from personnel with direct involvement in the preparation and clinical use of cryoprecipitate. I do not have personal experience of using this product in the clinical setting. I have no recollection of freeze dried cryo being supplied by SEBTS and no personal experience with it, so I can only offer comment on the non freeze dried product.

Advantages of cryoprecipitate [cryo]:

158. For a patient receiving a given dose of factor VIII, this may be provided by using a number of single donor packs of cryo. Typically, each pack would contain perhaps at least 70 i.u of factor VIII according to the current Red Book. However my understanding is that factor VIII is difficult to measure reliably in cryo, the content is variable and is usually only measured on a sample of packs. This makes accurate dosing difficult. The single donor packs would typically be combined into one pack containing 6 single donor units. For a patient who does not require a large dose or doses, their requirement could be provided as cryo and this would involve exposure to a smaller number of individual donations than the use of a factor concentrate prepared from a large plasma pool.

Disadvantages of cryoprecipitate:

159. Inconvenient to use

Frozen cryo: has to be stored at deep-freeze temperatures and then thawed at the correct temperature before use. A number of packs of the thawed material have then to be pooled together to provide the required dose.

Freeze dried cryo: could, I believe be stored at domestic refrigerator temperatures, but would have to be reconstituted with sterile water and mixed before infusion.

Preparing a dose of cryoprecipitate is a laborious process in the laboratory setting, and for home therapy must have proved very difficult for many patients to carry out correctly.

The following points would, I think, apply to either frozen or freeze dried cryo.

160. Factor VII content variable

The content of factor VIII is variable, making accurate prescribing impossible.

161. Incidence of adverse reactions

Although one small Scottish study of freeze dried cryo referred to in BPLL0002088 and PRSE0004212 did not report adverse reactions, my understanding is that clinicians generally report that reactions to cryo infusions are frequent and often severe. Although I do not know that this was also true of the freeze dried product, I think that it is probable that it would also have been a cause of acute reactions. All these factors would, for the patients, have made it a very unsatisfactory treatment when compared with a factor VIII concentrate.

162. Volume and protein load:

The volume of cryoprecipitate to be infused could be substantial, probably risking volume overload, especially in smaller patients.

It is my understanding that large doses, required for example to cover joint surgery to reverse damage due to rbleeding, can in practice only be provided by using a factor VIII concentrate

163. Hepatitis risk?

Scottish National Blood Transfusion Service Supporting paper: HCV & Cryo 27 September 2007 (exhibit WITN6666007) presents a calculation of the risk of a patient with haemophilia contracting Hepatitis C. The model assumes that the prevalence of hepatitis C in the population is 0.1% Assuming a patient received

600 single donor packs per year the risk of Hepatitis C was calculated to be 45% after one year. With higher doses, the risk would be proportionately greater.

d. The views, insofar as you are aware of them, of those within management positions within SNBTS and PFC on whether freeze-dried cryoprecipitate should be pursued further.

164. I have dealt with this as far as I am able in my answer to question **58** above.

e. The views, insofar as you were aware of them, of haemophilia clinicians in Scotland and Northern Ireland in this debate.

165. I know from LOTH0000012_131 that Dr Christopher Ludlam had offered to discuss this with the UK Haemophilia Directors. I have so far not seen other documents that could help with answering this question.

f. **The knowledge those involved in the debate had of freeze-dried cryoprecipitate programmes in Europe at that time.**

166. I cannot add to what I have stated in my answer to question **58b** above.

g. The reasons why, ultimately, freeze-dried cryoprecipitate was not explored further, and in particular the significance of the Medicines Inspectorate.

167. In the documents that I have so far reviewed, I cannot find a contemporary reference that would help to answer this. The PFC director was of the opinion that the Medicines Control Agency would not have permitted the PFC to produce single donor FD cryo in its existing facility. I believe that they had also pronounced that the only other freeze drying plant in SNBTS was not usable for preparing clinical products.

168. I have no knowledge of the consideration given to producing FD cryo by other transfusion services in the UK.

59. In an October 1983 letter, Dr Ludlam asked you about the possibility of freeze drying plasma (LOTH0000005_083). So far as you can recall, was this ever done, whether in response to this request or others? Please also briefly outline the purpose of freeze-dried plasma and the extent to which it was used in South East Scotland during your time as SEBTS director.

169. I am confident that following Dr Ludlam's request, SEBTS did not produce freeze dried plasma. SEBTS did not have the equipment required for this process,

Freeze dried plasma was not used during my tenure. In the 1960's, as a medical student, I was aware that it was still used occasionally in the management of major haemorrhage.

Section 8: Self-sufficiency

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

170. My understanding of self-sufficiency was that the SNBTS would collect sufficient blood donations, and from them prepare sufficient amounts of blood components and plasma derivatives to meet the needs of the population of Scotland. This remained my understanding of the term.

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

a plasma procurement:

171. Plasma procurement was certainly influenced by the desire to achieve self-sufficiency.

b decisions with regard to cryoprecipitate production;

172. I do not recall whether self-sufficiency influenced the level of cryo production.

c. purchases of commercial blood products;

173. I believe such purchases were driven by each clinician's assessment of the treatment needs [both quality and quantity] of each individual patient.

d. the funding of the SEBTS;

174. My recollection is that the annual bids for finance, certainly for quite a number of years, included funding for the blood collections and processing needed to pursue self-sufficiency.

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

175. I am not sure to what extent I reflected on this during the relevant years, but I certainly became aware as time went on, that the self-sufficiency in Factor VIII was probably not achievable in the face of the ever rising demand for factor VIII concentrate, unless a very large new plasma procurement programme could be maintained.

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

176. At least in the earlier years of the tenure, I believe that there was acceptance of the concept of self-sufficiency among my colleagues in SNBTS. I cannot comment on the views of the other UK services' personnel, but I suspect that as

time went on, some would have admitted to some doubts about the feasibility of achieving self-sufficiency.

Section 9: Services for donors at the SEBTS

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

177. **HBV testing:** When this was the only viral screening being performed, I do not remember what if any information was given to donors about the testing of their blood.

HIV Testing: In my written and oral evidence to the Penrose Inquiry I have given details of the work done in SEBTS from early 1983 onwards to develop donor information about the risks of HIV. The focus of this effort was to reduce as far as possible the risk that individuals in groups with a higher than average chance of carrying the AIDS virus would donate blood. The emphasis was on patient safety.

178. In later versions of donor information, there was text intended to inform the prospective donor that their blood would be tested for infectious disorders that could be transmitted by blood. Current donor information leaflets (WITN6666008) have this wording:

All donations are tested for Hepatitis B, C and E, HIV, and Syphilis. All donors will be tested at least once for HTLV (human T-cell lymphotropic virus)

https://www.scotblood.co.uk/media/2740/donor_information_leaflet_sept21-digital.pdf (WITN6666008)

179. A working party of the UK Regional Transfusion Directors was set up with a remit to develop procedures and protocols for screening of donors, confirmatory testing and communication with and further management of donors found to be positive. The report produced by the working party was accepted by the Regional Directors at their meeting on 11 July 1985. This included a statement that efforts should be made to trace recipients of donations found to be positive and to inform

the consultant in charge of the patient. [Report of the Working Party of the UK Regional Transfusion Directors Committee "Screening of blood donors for anti-HTLV III in Regional Transfusion Centres, 11 July 1985"] This report formed the basis of standardised procedures implemented after a training exercise for donor centre staff held at SNBTS Headquarters in the run-up to the implementation of routine screening Full testing commenced on October 15th, 1985, by which time the UK transfusion services had agreed to carry out lookback on the same basis as in the USA. Procedures were agreed and staff trained before testing commenced.

180. Although a consent process has always been in place for surgical and other invasive procedures, historically consent for treatments such as blood transfusion was not specifically required, unless included within the consent for a surgical procedure. In 2010 Scotland was represented on group convened by the Advisory Committee on the Safety of Blood, tissues and Organs (SaBTO) to make recommendations on consent for transfusion. Following extensive stakeholder consultation between March and May 2010 guidance was issued in 2011 and recently updated in 2020 (SaBTO consent December 2020 Guidelines from the expert advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) on patient consent for blood transfusion - GOV.UK (www.gov.uk). Since then LearnBloodTransfusion has developed an educational module on consent, patients have been offered patient information leaflets and the opportunity to discuss the risk and benefits of, and alternatives to, transfusion (WITN3530073 SNBTS Leaflet: Receiving a Blood Transfusion).

Hepatitis C testing

181 I had less personal involvement in the SEBTS response to hepatitis C and the Introduction of the HCV test. By this time, the donor consultant post was held by Dr John Gillon who was trained in GI and liver disease and whose responsibility was for the care and selection and counselling of donors., Dr Gillon, at the request of Dr Cash assembled and led a small group that developed detailed standard procedures for the

counselling of donors found to be hepatitis C. [PEN180112 p8 and onward provides detail] (WITN6666026)

"This is a letter of 21 June [from Dr Cash] *asking you,* [Dr Gillon] *because it is a high priority, to produce operational guidelines for BTS doctors in the context of counselling anti-HCV confirmed positive donors"*

This group's report also dealt with the look-back process. The report, including the proposals for lookback, was accepted by the Directors of the UK Transfusion Services. Under Dr Gillon's leadership, a visiting doctor [Dr Yasmin Ayob, who later became director of transfusion in Malaysia] initiated the first HCV look back, among donors and recipients of SEBTS.

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

181. My recollection is as follows. A donor with a confirmed positive HIV test would be contacted by the donor medical staff and asked to attend the Blood Donor Centre in Edinburgh for a confidential interview . My recollection is that Dr Gillon usually conducted these interviews. The donor would be informed of the test result. The donor would be asked if they would give their permission for their own GP to be informed. They would be offered counselling which I believe was given by Dr Gillon or Dr Davidson, both of whom had attended AIDS counselling courses at St Mary's Hospital in London. [I believe these courses had been organised by Dr Anthony Pinching.]. A senior SEBTS doctor, usually Dr Gillon, would review the records of any previous donations by the donor concerned and arrange for testing of stored archive serum samples for any evidence of HIV. If any further positive samples were found, every effort would be made to identify the recipient [s] of any blood components prepared from the relevant donation and to inform the doctor responsible for the transfusion of the further action needed. PFC would be informed if plasma had been sent for fractionation.

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

182. SNBTS is responsible for general communications with regard to blood donation but responsibility for general communications with regard to patient health lay with the Government, Health Boards and public health authorities.

183. The counselling and psychological support for recipients of infected donations was the responsibility of the clinician: it was the duty of SEBTS to inform the clinician that his or her patient had received a donation that could transmit infection.

184. In Edinburgh, Dr Ludlam's colleague Dr Geraldine Brown was given responsibility for counselling, and providing information and support to patients with haemophilia who had been infected. Her witness statement [Thursday 16th June 2011, PRSE0006034] describes her role and the support she received from Dr Ludlam. Dr Gordon Lowe has recently given evidence to the Inquiry about the support provided for patients in Glasgow.

185. Patient information explaining the risks and benefits of transfusion was recommended in the second edition of the Handbook of Transfusion Medicine (1996). It was around this time that UK Blood Services started to develop patient information leaflets. SNBTS now produces its own leaflet 'Receiving a Transfusion' (WITN3530073) the next version of which will be a UK-wide leaflet covering all blood components for transfusion to adults and children.

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

186. I believe that the counselling of donors by the SEBTS staff was performed well and conscientiously. I could not in all honesty express an opinion as to what would have been "sufficient", but I believe what was done was appropriate. The situation for patients was dependent on the actions of the clinicians. SEBTS had

no authority to monitor this. It is safe to assume, I believe, that there would have been variability in the adequacy of the process.

68. In a letter to Dr Cash dated 28 November 1984, you noted concerns regarding the impact of HIV donation screening on donors (SBTS0001287_001). You stated: "*Perhaps the most important message is to underline all the concerns which I have been expressing for more than a year now about the consequences for the donor if and when we introduce screening. It seems inevitable that there will be substantial difficulties in providing suitable counselling, clinical follow up, and laboratory facilities for antibody positive donors.*" Please provide further details in regards to the concerns you held and explain whether these concerns were resolved adequately prior to the introduction of screening.

187. The letter reflects my concerns at that time and the need to draw attention to what would be needed to provide proper care for donors. I believe that these concerns were well dealt with before the start of HIV screening, as summarized in my answer to question 64

<u>Section 10: Meetings of various committees</u>

Meetings of SNBTS Directors/SNBTS Medical and Scientific Committee.

Please see the attached schedule for copies of the minutes the Inquiry holds of the meetings of this group that you attended.

188. I have responded to questions 69 -74 from memory.

69. As far as you are aware, who established the regular meetings between regional directors of the SNBTS? What do you consider to have been the purpose(s) of those meetings?

189. I believe that these meetings were instituted by Dr John Cash when he was appointed as National Medical Director following the death of the previous

director, Major-General Hugh Jeffrey. The purpose – in general terms – was to ensure effective communication among the Directors and to agree matters of policy and in some cases, of practice.

70. Please explain the decision-making remit of the SNBTS directors' group. Did the directors meet in a decision-making capacity or otherwise? Were the directors empowered to make collective decisions that affected the policies and procedures of all RTCs?

190. I have tried to deal with this in my evidence to Penrose. The authority - or lack of it - of these meetings was never totally transparent. The history of the SNBTS was one of the independent evolution of each of its centres. By the time the Directors meetings started, each centre had a doctor in charge. If one refers to the Job descriptions of the Regional Directors and that of the National Medical Director, it is difficult to define clear lines of responsibility and accountability. It was never clear to me that the directors, as a group, had the authority "to make collective decisions that affected the policies and procedures of all RTCs"

71. The minutes of a meeting of SNBTS directors held on 23 June 1981 record that Dr Cash and Dr Mitchell had been invited to attend meetings of English and Welsh directors. In return, SNBTS directors agreed to invite Dr Wagstaff and Dr Tovey to the meetings of SNBTS directors as "*observers*" (PRSE0003924). Please explain the purpose(s) of attending meetings in an observational capacity and how this worked in practice. In your view, was this development successful in aiding cooperation between the NBTS and SNBTS?

191. I understood that was simply an effort to improve the communications among the Regional Transfusion Services in the UK. It did, I believe make some valuable contributions that helped the services to work together, but it must be said that since, as far as I know, the purpose of the arrangements was never clearly defined, it is difficult to evaluate its success

72. It appears that a representative of the Northern Ireland Blood Transfusion Service ("NIBTS") was also sometimes present at meetings of SNBTS directors (PRSE0002617). Was the NIBTS similarly represented in an observational capacity? Please explain the level of cooperation between SNBTS Directors and the NIBTS and whether this differed in any way to the SNBTS's cooperation with the NBTS.

192. As I recall NIBTS also attended as an observer. I am not aware that the level of co -operation with NIBTS was different from that with the other UK RTC's

73. The Inquiry understands that the final meeting of SNBTS Directors took place in June 1990. This forum was replaced with a Medical and Scientific Committee ("MSC") to "*consider medical and scientific matters presented by its proposed sub-groups and to reach decisions as to how to advise the Management Board*" (PRSE0002954). Please explain:

You may find PRSE0000171 of assistance in answering these questions.

a **Why the meetings of SNBTS Directors were replaced with meetings of the MSC**;

193. The intention as I understand it had been that the Medical and Scientific Committee [MSC] was intended to focus on more technical aspects of the work, and on the medical care of donors, the medical use of the products supplied by the service. Also to take account of relevant research findings. In practice, the membership of the MSC was very similar to that of the Directors Meetings, and it was not unusual for the discussions in the two groups to overlap.

b How the MSC meetings differed from the SNBTS Directors meetings in terms of remit, composition, and matters discussed;

194. I do not have a recollection that this was ever defined in any formal way.

c. **How responsibility for decision-making by the SNBTS was delegated between the MSC and SNBTS Board.**

195. In practice, despite the intentions of the General manager PRSE0000171 the participants in both meetings were largely the same, and my feeling was that the distinction between the business of the two groups became quite blurred.

74. At the final SNBTS Directors meeting, it was noted that Dr Lee would be invited to future meetings of the MSC to maintain the link with the Northern Division of the NBTS. Dr Maurice McClelland of the NIBTS was also invited to MSC meetings (PRSE0002954). In your view, was the same level of cooperation between the SNBTS, NBTS and NIBTS maintained following the conclusion of the SNBTS Directors' meetings?

196. So far as I can recall the cooperation between these Services was unchanged following the conclusion of the SNBTS Directors' meetings.

SNBTS and Haemophilia Centre Directors / Coagulation Factor Working Party

Please see the attached schedule for copies of the minutes of the meetings of these groups that you attended

75. The Inquiry holds minutes of meetings between regional directors of the SNBTS and directors of Scottish Haemophilia Centres ("haemophilia directors") which commenced in 1973. You attended these meetings as director of the SEBTS. As far as you are aware, who established these meetings? What do you consider to have been the purpose(s) of those meetings?

197. I do not know who initiated these meetings, I would guess that the decision was a result of discussions between Dr John Cash and officers of the Scottish Home and Health Department [SJHHD]. The main purpose of the meetings was, I believe, to maintain some measure of control over the use of Factor VIII and to alert the SHHD and the Common Service Agency to the financial implications.

76. The Inquiry also holds minutes of meetings of the Coagulation Factor Working Party, which was comprised of representatives from the SNBTS and haemophilia directors. As far as you are aware, who established these meetings? What do you consider to have been the purpose(s) of those meetings? How did the meetings of the Coagulation Factor Working Party differ from the meetings of SNBTS directors and haemophilia directors?

198. I believe these meetings were instituted by Dr John Cash with the purpose of ensuring good communication between clinicians using SNBTS products and the SNBTS

199. As the name implies, these meetings were very much focused on the supply, quality, future development and clinical acceptance of PFC products. I imagine that FFP and Cryoprecipitate would also have been considered. The participants included haemophilia clinicians, and some doctors and scientists from the PFC and the Regional Transfusion Centres.

77. Please explain, as far as you are able, the decision-making remits of the groups discussed in questions 64-65 above

200. I have no recall of this information.

78. As far as you can recall, were any other forums established to aid cooperation between the SNBTS and haemophilia directors?

201. I don't recall any other groups of this type within SNBTS, but there would have been communications in other gatherings, including meetings of the haemophilia directors, the professional associations [for example, the British Society of Haematology], British Society of Haemostasis and Thrombosis] and during the many medical/scientific meetings at which new clinical/scientific data on aspects of coagulation disorders and treatments would be presented and discussed.

Expert Advisory Group on AIDS

Please see the attached schedule for copies of the minutes of the meetings of these groups that you attended.

79. The Inquiry understands that you were a member of the Expert Advisory Group on AIDS ("EAGA"). What was your understanding of the function and remit of the EAGA? In particular:

a Who did EAGA report to, how frequently and by what means?

202. EAGA reported to the Chief Medical Officers of the UK administrationsIts remit , as recorded at https://www.gov.uk/government/groups/expert-advisory-group-on-aids was: *"The Expert Advisory Group on AIDS (EAGA) provides advice to the Chief Medical Officers of the health departments of the United Kingdom on matters relating to HIV."*

203. The minutes of each meeting would have been one route of communication. I do not know what, if any, other routes were used to inform the Chief Medical Officers of EAGA's deliberations.

b Did EAGA have any powers or was it purely advisory?

204. Its title indicates that the intention of the Chief Medical Officer was that it was to be advisory. However, my recollection is that I had the sense that its advice was taken seriously by officials in the Department of Health and ultimately by Ministers. Para 22 of PRSE0001239 [below] touches on this issue but does not answer the question. I am not certain that this question was ever answered explicitly.

"...some discussion of the extent to which the NBTS Directors would wish the EAGA to take decisions on the detailed procedures to be operated within the BTS. The Chairman explained that EAGA was supposed to give unequivocal advice to CMO on the principles involved".

c To the best of your knowledge, why were you appointed as a member of EAGA?

205. I think this was because, with my consultant colleague Dr Anne Smith [nee Dewar] and others in the SEBTS, I had since 1983 been actively addressing the AIDs issue as it related to transfusion. SEBTS was, I believe, the first UK RTC to produce, implement and rapidly evolve donor exclusion criteria and procedures to reduce as far as possible the risk of an infectious person giving blood, [in the absence of a specific test for the agent causing AIDS,] With colleagues I obtained funding to initiate a new confidential testing facility in the effort to avoid individuals attending to give blood for the primary purpose of having an AIDS test.

206. HTLV-III antibodies in an Edinburgh clinic. Lancet 1986 May 10;1(8489):1099. R P Brettle, J Davidson, S J Davidson, J M Gray, J M Inglis, J S Conn, G E Bath, J Gillon, D B McClelland PMID: **2871367** DOI: 10.1016/s0140-6736(86)91367-x
(WITN6666009)

207. We worked closely with the leaders of the local Homosexual Rights Group [later renamed the Scottish AIDS monitor.] I was, I believe, one of only two people from the UK Transfusion Services to attend the first World Health Organisation International Aids conference in Geneva.

80. As far as you are aware, did Health Ministers generally take the advice of the EAGA? Please set out any instances, relevant to the Inquiry's Terms of Reference, where the EAGA's advice was and was not accepted.

208. I believe that in general, ministers took EAGA's recommendations seriously. At this distance in time I am unable to remember specific instances. It is not easy to identify any such incidents from the minutes.

81. Please explain the relationship between the EAGA and the SNBTS, including but not limited to:

a whether the EAGA made decisions or provided advice that the SNBTS was either required or encouraged to implement;

209. To the best of my recollection, EAGA, directly or indirectly via the Departments of Health was the source of advice that the Blood Transfusion services were expected to follow in respect to microbiological safety issues.

b There is no question against this paragraph number

c. whether, and how frequently, you provided feedback to SNBTS on the recommendations made by the EAGA

210. As far as I recall I reported to the National Medical Director after meetings of EAGA. I think these reports were at times discussed at the MSC meetings.

82. On 14 June 1988, you wrote a letter to Dr Harris regarding selective HIV-2 screening of blood donors (NHBT0003674). You stated: "*I don't see my role on EAGA as a nationalistic one!*" Please explain this statement.

211. From (NHBT0003674) it would appear that the suggestions I was making in this letter were carefully considered and intended entirely constructively. This almost certainly was one of a number of occasions when the SNBTS had expressed some disagreement with proposals being brought to the EAGA. I think my phrase, possibly not well considered, was merely trying to make the point that "Those Scots" were not simply trying to be awkward.

Standing Advisory Committee on Transfusion Transmitted Infections

Please see the attached schedule for copies of the minutes of the meetings of this group that you attended.

83. 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 ACTTD was replaced with the Standing Advisory Committee on Transfusion Transmitted Infections ("SACTTI") following the creation of the NBA in 1993 (DHSC0006906_013). Please explain the extent of your involvement in these committees.

212. From the References provided I can see that I attended most SACTTI meetings between 1999 and 2004. I was not a member of either ACVSB or ACTD. My contributions to SACTTI are evidenced in the minutes of its meetings.

What was your understanding of the function and remit of SACTTI? In particular:

d. Who did SACTTI report to, how frequently and by what means?

e. Did SACTTI have any powers or was it purely advisory?

f. In a letter from Dr Robinson to Dr Jeremy Metters, Dr Robinson states that "*an attempt to formalise links*" between SACTTI and MSBT "*could potentially compromise their respective remits*" (DHSC0006906_013). As far as you can recall, did the Department of Health and/or Scottish Home and Health Department ("SHHD") ever take advice from SACTTI?

g. As far as you are aware, how did SACTTI's remit differ from its predecessor ACTTD?

d to g [There is no a, b or c]

213. These questions are well addressed in DHSC0006906_013

SACTTI: Remit

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

To commission, conduct and co-ordinate trials of new technology involved in the

screening of donors for infectious agents transmissible by transfusion, consistent with the work of the national research committees."

214. As I understand it, ACTTD was set up by the then National Director of NBTS, Dr Harold Gunson, to provide him with advice. I discussed the evolution of these groups in my evidence to Penrose.

Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation. **Please see the attached schedule for copies of the minutes of the meetings of this group that you attended.**

85. In 1993, the Department of Health Advisory Committee on the Virological Safety of Blood ("ACVSB") was replaced by the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation ("MSBT"). The Inquiry understands that you were a member of the MSBT. What was your understanding of the function and remit of this committee? In particular:

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

215. It reported to the Chief Medical Officer of DHSS [CMO]. He chaired many of the meetings. The CMO in turn reported to Ministers.

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

216. Its title [Advisory Committee on Microbial Safety of Blood and Tissues] suggests that the intention of the Chief Medical Officer [or of officials at Dept of Health] was that it was to be advisory. I suppose that this may have been a way of indicating that it did not have statutory powers. However, my recollection is that its advice was taken seriously by officials in the Department of Health and ultimately by Ministers.

c. As far as you are aware, did the Health Ministers generally take the advice of the MSBT? Please set out any instances, relevant to the Inquiry's Terms of References, where the MSBT's advice was not accepted.

217. I have no direct knowledge of this. I believe that Ministers would generally have accepted the recommendations of MSBT. I do not remember instances where MSBT advice was rejected by Ministers, but I probably would not have known unless the decision, and its origin, were communicated to MSBT members.

86. Please explain the relationship between the MSBT and the SNBTS, including but not limited to:

a whether the MSBT made decisions or provided advice that SNBTS was required or encouraged to implement;

218. My recollection is that the norm for SNBTS was to comply, as far as possible with advice from MSBT.

b whether, and how frequently, you provided feedback to SNBTS on the recommendations made by the MSBT.

219. I believe that I did report fully to SNBTS following meetings of MSBT.

Serious Hazards of Transfusion

87. The Inquiry understands that you were the SNBTS representative on the Steering Committee for the Serious Hazards of Transfusion ("SHOT") project. In a letter to Dr Robinson on 4 October 1996 you gave the SNBTS's formal support to the project (NHBT0007370).

a Please explain what steps the SNBTS took to support the SHOT project and implement the project across the SNBTS.

220. SNBTS fully embraced the SHOT project. It appointed specialist transfusion Nurses whose duties included identifying, reporting and investigating transfusion errors -with or without adverse effects on the patient. Guideline documents, training materials and handbooks for safe transfusion were developed and promulgated and a Distance Learning Programme was initiated which has developed into the UK on-line programme for teaching and certification in transfusion practice This can be seen in detail at *LearnBloodTransfusion* Programme https://www.learnbloodtransfusion.org.uk/

b What were the remit and functions of the SHOT scheme? (you may find of assistance)

221. SHOT Steering Group The Terms of Reference at the time that SHOT was founded 1996 [from NHBT0077594_005] provide a good overview of its remit and functions.

1. To be the strategic and policymaking body for the SHOT Scheme, and to ensure that ownership of SHOT, its activities and data remain confidential and firmly within the professional bodies to whom it belongs.

2. Its members bring to the Steering Group the views of the professional body which they represent, and in turn seek endorsement from their professional body for major changes to the Scheme.

3. Its members communicate to their professional body information about new SHOT initiatives, and promote SHOT activities through their professional network.

4. To review and oversee the activities of the Standing Working Group from whom regular reports will be provided.

5. To provide financial oversight of SHOT activities.

6. To produce periodic reports to an agreed format.

7. To ensure that recommendations resulting from these reports are disseminated via professional bodies in an open fashion whilst maintaining strict anonymity/confidentiality.

8. The Steering Group may convene one or more Working Parties for specific functions as required.

9. All reports, publications and written media communications must be approved by the Steering Group. In urgent situations the Chair and Secretary of the Steering Group may approve written media statements without reference to the whole group.

10. Any proposed changes to questionnaires must be submitted to the Steering Group for approval

c. Was the SHOT project a success? Please give reasons for your answer.

222. SHOT has been very widely adopted in the UK. It was one of the first schemes in the area of what is now called haemovigilance that has seen a major expansion in many countries. SHOT produces a comprehensive Annual Report which is widely studied, and a range of teaching and learning materials based on the findings of the programme. All past reports, teaching resources etc can be viewed at www.shot.org.uk. I do think the SHOT project was, and continues to be, a success.

88. You also attended meetings of the SHOT Working Group in 1995 (NHBT0019435_010; NHBT0007858_002). Please explain whether the Working Group differed from the Steering Committee, and if so, how it differed.

223. Broadly, as I recall, the steering group was responsible for policy, finance and for maintaining good relations with participating professional organisations. The working group was tasked with assembling and managing the data from the programme and assembling it for inclusion in each year's Report.

89. Please describe how SHOT operated. In particular:

a Who did SHOT report to, how frequently and by what means?

224. SHOT produced extensive annual reports which were freely available on the internet and communicated with hospital staff through local and national

meetings. Clinicians were encouraged to submit brief reports of any adverse incidents or "near miss" incidents during the provision of blood for a patient or of concerns over other aspects related to blood safety such as product quality, labelling or user information. These reports would then be followed up by a SHOT investigator to determine the cause or causes of the problem and advise preventative action, or on a need to review systems or training. An essential aim of Shot was to ensure that reports remained confidential to avoid the risk that reporting would be inhibited by fear of disciplinary action. The underlying philosophy is to encourage reporting as an essential part of learning and quality improvement. its findings and recommendations are disseminated as widely as possible to the people who actually do the work of providing blood transfusions for patients in the clinical setting.

b Did SHOT have any powers or was it purely advisory?

225. As I recall, SHOT has no formal powers. It is in the nature of the programme that it acts by influencing motivation to maintain the safest practices and supporting the "doers" with the knowledge and understanding required.

c How was SHOT funded? (NHBT0007373 may be useful in answering this question).

226. I cannot recall with clarity. Ref NHBT0007373 reflects only the start-up of the project rather than any longer term funding. My recollection is that when the UK Blood Transfusion Services Forum was established. SHOT made its funding application to this group which then allocated funds from the budget of each National Transfusion Service. I do not know if any funds were provided centrally by DHSS or SHHD.

Membership of other committees

90. The Inquiry understands that you attended the meetings of the following committees/groups. In each case please explain the primary objective(s) and remit of each committee/group. Please refer to the attached schedule of documents for a full list of the minutes of meetings you attended:

a Working Group on Blood Products;

227. Working Group on Blood Products;

This group was set up by the SHHD Clinical resources and Audit Group. It was charged with producing a guide for the safe and effective use of donated blood within the Scottish Heath Service. The chair was Professor Brian Jennet. He was an eminent neurosurgeon. He became president of the International Society for Technology Assessment and author of *High Technology Medicine: Benefits and Burdens, 1984.*

228. I acted as secretary and wrote the draft report submitted to the group and the final report which was published by the SHHD, entitled *Optimal Use of Donor Blood* (WITN6666010). This report established a wide agenda for work on practice improvement in the clinical aspects of transfusion.

b Medicines Inspectorate Ad Hoc Project Steering Group;

229. *The Medicines Inspectorate Ad Hoc Project Steering Group* was a short-term working group with members from SNBTS, SHHD and the Common Services agency to oversee the response of the SNBTS regional centres to the Reports of the Medicines Inspector. I participated to present the actions taken or planned by SEBTS.

c. Working Party on Transfusion Associated Hepatitis;

230. Working Party on Transfusion Associated Hepatitis;

The terms of reference, noted at its first meeting on September 27th 1982 were:

"To promote the investigations of the epidemiology of transfusion-associated hepatitis, to promote research into the methods of prevention, and to make

recommendations to the Directors of the U.S. Transfusion Service regarding procedures and screening tests necessary for its prevention."

231. At its second meeting on January 18th 1983, there was discussion of possible lines of investigation and a proposal was presented for a prospective study of NANBH, and the need to locate samples from an early MRC study. At his meeting Dr Craske informed the group of his plans to investigate AIDS transmission to haemophilia patients by factor concentrates from the USA. There were no further meetings till the group was reconvened November 24, 1986. I am not sure of the reason for this long break. It met once more in January 1987.

d. AIDS Working Group;

232. AIDS Working Group;

This group was set up after the CBLA had formed the Central Research Committee for Research and Development in Blood Transfusion. At its first meeting the members of that committee agreed that this ad-hoc Working Group should be set up to consider the problem of AIDS in relation to the transfusion of blood and blood products. As I recall it had few meetings and was soon superseded by EAGA.

e. CBLA Central Committee on Research and Development;

233. CBLA Central Committee on Research and Development;

CBLA formed the Central Research Committee for Research and Development in Blood Transfusion which, at its first meeting in June1983, had agreed that this ad-hoc Working Group should be set up to consider the problem of AIDS in relation to the transfusion of blood and blood products. It held meetings at least until its 7th in December 1985. I do have recollection of discussions about the possible development of genetically engineered coagulation factors in collaboration with UK scientists and my sense of a missed opportunity when this came to nothing. My recollection is that the work of this committee did not have a great deal of impact.

f. Red Book Standing Advisory Committee on Blood Components;

234. *Red Book Standing Advisory Committee on Blood Components;*
This was a subgroup of the JPAC which was tasked with maintaining the specifications for blood components that were published in the Red Book. I was chair of this group from December 1994. I do not have a record of the date of the last meeting that I chaired.

g. Blood Transfusion Sub-committee of the Standing Advisory Committee on Haematology;

235. *Blood Transfusion Sub-committee of the Standing Advisory Committee on Haematology*; This was a British Society of Haematology [BSH] meeting, attended by NBTS/SNBTS staff. It was a vehicle through which the BSH could be involved in the training standards for transfusion which was considered, at least by the BSH, to be a sub branch of haematology. I do not have any recollection of my contribution to this committee.

h. SNBTS Ethics Committee (Clinical Research Investigations).

236. *SNBTS Ethics Committee* (Clinical Research Investigations). The remit of this committee, which as I recall had two lay members, was to scrutinise proposals for research studies in which blood donors would be invited to participate. Some of these proposals were submitted by SEBTS. I attended the meetings where these proposals were discussed. I do not recall if I was an appointed member of this group.

91. The minutes of a meeting of the Standing Advisory Committee on the Care and Selection of Donors held in January 2005 state that you had formed a small Executive Committee responsible for "*managing the JPAC business*" and "*dealing with issues which need to be fast tracked*" (JPAC0000183_035). Please explain the

role of JPAC and elaborate on what your work on the JPAC Executive Committee entailed.

237. JPAC is the Joint Professional Advisory Committee of the UK Blood Transfusion Services. It is charged with maintaining the Guidelines for the Transfusion Service in the UK and regularly producing an updated new edition, published in book form and online. I served as Chair of the JPAC for the period 2004 to 2008.

General

92. You served on multiple committees relating to blood transfusion and the blood services. Please set out, in broad terms:

a the relationship between these committees and the SHHD; and

b the relationship between these committees and the SNBTS.

238. My answer reflects the fact that I have little detailed memory of which groups met when, for how long, and their relationship to SNBTS and SHHD. Many of these were, I believe, groups set up by the Transfusion Services, often but not always acting for the four UK territories. Some were relatively short-term groups to deal with a particular issue. Generally, any findings or recommendations from these groups would be made available to all the UK transfusion Services, including SNBTS, and might, depending on the issue, also to the SHHD.

93. Given your role as Director of the SEBTS whilst also chairing and serving on various committees, please describe:

a the relationship between these committees and individual RTCs;

b how committee recommendations would be communicated to RTCs;

c how committee recommendations were implemented at RTC level; and

d whether there were any common barriers to implementing committee recommendations. If yes, what were they?

239. I have difficulty in giving specific responses to these questions. The answers would, I think, have been quite different depending on the topic, the reason for the existence of the group and its origin. For example, there would have been groups working on specific aspects of plasma fractionation which may properly have had little need to communicate regularly with other parts of SNBTS, but may have had important interactions with counterparts in BPL.

94. More generally, please comment on how the work of the different organisations and individuals involved in providing NHS patients with blood and blood products was coordinated in Scotland, and how that differed (insofar as it is within your knowledge) from other parts of the United Kingdom. In particular, please consider the following matters:

a the degree to which the structures in Scotland allowed for, and/or hampered, the sharing of information and ideas among the different individuals and organisations involved.

240. I do not recall having any sense that in Scotland there were structures that stood in the way of communications among the RTC's. We had good links with the hospitals through the technical staff in the blood banks, the doctors responsible for the blood banks, usually haematologists, and with clinicians in those specialties that used blood or blood products. SEBTS housed and operated the blood bank for the Edinburgh Royal Infirmary and also provided other services to the hospital. SEBTS staff as a result had more contact with clinicians and patients in the RIE than in many other hospitals.

b the degree to which the structures allowed for, and/or hampered, the effective development of policies and practices in Scotland in the short, medium- and long-term;

241. I find it very difficult to answer this, as my experience was almost entirely of working within the structures in place during my tenure. I have given evidence to Penrose that bears on one aspect of this question as it applies to the regions of

SNBTS. In outline, there was, for much of my time in SNBTS, a strong sense of the autonomy of each Region and of each regional Director. Even when the National Medical Director [NMD] post was created, the extent of its authority was unclear from the Job Description and remained uncertain both to the Regional Directors and perhaps also to the NMD himself. This degree of assumed professional independence may not have hindered sharing of ideas, but I believe that it did hinder the adoption of common practices.

As outlined above, SEBTS had, I believe, quite good communication with the hospitals and also with the Health Boards and the Scottish Home and Health Department.

c. the degree to which the structures allowed for, and/or hampered, an effective knowledge of and response to the risk of infection through the use of blood products in Scotland;

242. I think there were some situations in which, the structures, and the way in which they affected decision making about funding, did to some degree affect the rate at which measures to reduce infection risks were introduced and became consistent across the regions of the UK including Scotland. Examples are the early responses to AIDS, the failure to properly evaluate surrogate donor testing for Non A Non B hepatitis and the delays in the introduction of Hepatitis C testing. However, I do not know how one might begin to estimate the degree to which the then existing structures contributed to these issues.

d. any tensions or difficulties that arose as a result of those structures, and - if there were any - the steps taken to resolve these problems

243. There were difficulties and disagreements from time to time, between the SNBTS and the Common Services Agency and the Scottish Home and Health Department. [And also between the SHHD and the DoH and on occasion, the NBTS] Many of these issues were essentially negotiated between the respective authorities and the National Medical Director, and have been detailed in

statements by the late Professor John Cash. Incidents that come to mind, about which I have some personal recollections, include:

244. Early in my career [1979 or 1980] a decision from SHHD ended a long standing arrangement for the payment of laboratory staff in SEBTS who provided a 24 hour blood bank service to the Royal Infirmary of Edinburgh. This led to withdrawal of labour by the laboratory staff and the need for an emergency service to be provided by the centre's doctors. Negotiations failed and eventually the SHHD withdrew its instruction. This event marred relationships within the SEBTS for some considerable time.

245. I believe that the delay in the implementation of hepatitis C antibody testing was also the result of a failure of the existing structures. While I believe the principal issue was the delay in decisions at a central level about funding the testing programme, there was also a lack of balance in some of the opinions expressed by experts. While there were undoubted problems with the specificity of the earliest tests, and uncertainty about the best confirmatory procedure, I feel that these concerns were never set sufficiently clearly against the numbers of potential infections that could be avoided, even with a less than perfect procedure.

246. A third example was the prolonged argument about lookback for hepatitis C in which arguments over cost, which involved NBTS, DoH and I imagine probably also SHHD delayed an action which I personally felt was an obligation on the Transfusion Services.

e. the extent to which the structures in place allowed for factors specific to Northern Ireland to be taken into account when making decisions about the operation of the PFC;

247. I cannot say that I am aware now of any particular arrangements of this type. I think that if there were problems, they would most likely have related to availability of fractionated products and have been dealt with by the PFC Director.

f. any shortcomings that, on reflection, you see in the structures that were in place;

248. I have provided some examples in my answer to the preceding question The structures we worked with [and in] had evolved, rather than being the result of a grand overarching design. There were of course shortcomings – in the location of facilities, the quality of facilities, funding and so on. I cannot imagine that other parts of the Health service did not have similar issues to overcome.

g. how, based on your knowledge and experience, the structures in Scotland compared to those in place in the rest of the United Kingdom in this period.

249. I am not competent to comment on differences in the structure of the Health Service in different parts of the UK in respect of the transfusion Services, all the UK Services had a similar history – with small beginnings often involving volunteers, followed by rapid expansion during World War 2, when major efforts were made to provide plasma in a form that could be dropped to troops on the ground. The processes of plasma fractionation were invented and developed by Zanvil Cohn and his team in the USA during and after World War 2, first to provide albumin for management of haemorrhage in war injuries. These techniques soon began to be explored and developed in some UK regional transfusion centres.

250. To my knowledge, the broad structure of the Regional Transfusion Services evolved to be quite similar in each part of UK, although there were important differences in the way funding was channeled: In England, by the time I started in SEBTS, this was through the Regional Health Authorities while in Scotland, funding came from the SHHD, and later was routed via the Common Services Agency for the Scottish Health Service [CSA], now NHS National Services Scotland.

251. SEBTS was unusual in that it provided hospital blood banking and other clinical services to the Edinburgh Royal Infirmary and most of the surrounding hospitals.

Section 11: Information handling by and information sharing between RTCs

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

252. This changed dramatically during my tenure as RTD. When I started, the records of each donor and each of their donations were maintained in a file card system. These cards were organised by donor session location. They were kept indefinitely. In 2010 when preparing my evidence for Penrose, I was able to examine the original donor cards for sessions in Saughton Prison for 1980, 1981 and subsequent years.

253. In or very close to 1980 I purchased two early Cromemco computers so we could begin converting our donor records into a more manageable form that provided greatly improved confidentiality of the donors' data. At around the same time, I was able to appoint an expert computer professional from Edinburgh University and we began the process of specifying and obtaining funding for a more comprehensive IT solution. Initially this was developed as separate components for each of: the blood grouping laboratory, the hospital blood bank and the donor management service. This eventually led to a comprehensive IT system, and this was later implemented for the Dundee, Inverness and Aberdeen RTC's, with data connections between these centres. The West of Scotland retained a system previously developed there.

254. I cannot remember details of the data fields in the first computerised donor record. Certainly they included all the donors' demographic data, the data on each donation, any relevant medical information, and any history of faints or other events during donation. The record also recorded information such as blood type,

the components into which each donation had been processed. Much later, with the current Computer system [eProgesa], information about the final "fate" of each component is available.

96. **Please set out how long these records were kept for**.

255. SEBTS donor record cards were, in my time kept indefinitely. I do not know the current policy for retention of data held in computer systems.

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

256. SEBTS donor record cards were not destroyed during my tenure. That was the policy then. I do not know what is the present policy and system for retaining donor information, since cards are no longer used.

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

257. I have assumed this question relates to the retention of records. I think that before computerization, it is likely that there would have been broad similarity in the way each centre handled donor record cards. Again, I do not know what policies are now in use for the retention of computerised records, but I would expect that with a national IT service, there would by now be standard record formats and a standard protocol for retention and destruction of records.

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

258. I believe this to be the case, because my recollection is that the standard procedures required that any donation from a donor suspected of carrying a blood borne infection must be destroyed, the donor removed from any further call up

and the donor record marked accordingly. The decision would take into account the results of confirmatory testing.

100. 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). Did the SEBTS contribute to the CDSC database? If not, did the SNBTS have a comparable scheme for data collection?

259. To the best of my recollection, SEBTS supplied data to the CDSC scheme.

101. A NBTS departmental memorandum dated 15 May 1989 notes that "*it has been decided to re-introduce the original 'J' donor system*" to identify donors involved in cases of post-transfusion hepatitis (NHBT0005388). Did the SEBTS also operate the J donor system? If not, was a comparable system in place in Scotland?

260. As I recall the "J" donor system was about trying to identify and exclude donors with a history of Jaundice. As far as I can remember, SEBTS did not ever use a procedure named thus. In reference PRSE0002653 [pages 15-17] , my written evidence was as follows:

[Quoted from PRSE0002653] "*During the first period [up to 1983] I believe that the measures taken by SNBTS were essentially those described in the National Blood Transfusion Service Memorandum on the selection, medical examination and care of blood donors (2) although to date I have not located donor selection guidance documents used by SNBTS earlier than 1982".*

"Individuals who give a history of jaundice or hepatitis or in whose blood anti HBsAg is present may be accepted as donors providing that they have not suffered from jaundice or hepatitis in the previous twelve months…"

261. My recollection is that some of the SNBTS services modified this policy, restricting acceptance to donors with a jaundice history under the age of 12 years, and that the rationale for this was that in that age group, where there was

any evidence of infection with a hepatitis virus it was almost always found to be antibody to hepatitis A virus. I have not found documentary evidence of this policy.

262. From 1983 onwards, donor selection measures aimed at reducing the risk of AIDS were introduced. In 1985 testing for HIV antibody was implemented. These measures would also be expected to reduce the risk of NANB PTH. This was later shown by the fact that the prevalence of HCV in Scottish donors when HCV testing was introduced was about 10 - fold less than in the general population.

History of jaundice as a donor screening test.

263. It can be difficult or impossible to learn from a brief blood donor assessment whether an individual has had jaundice or hepatitis in the past, especially in the case of individuals who have never received the results of a specific test for one of the hepatitis viruses. Not everyone understands the terms or has an accurate memory of what may have been a mild illness. Many individuals have a recollection of being told that they were jaundiced as a baby, and this may often be due to a cause other than infection with a hepatitis virus. Published data on the frequency of a history of jaundice among blood donors may be greatly influenced by the judgement of different donor selection staff and so may be of uncertain reliability.

102. In addition to the database(s) mentioned above, did the SEBTS 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 SEBTS used to share this information, if any

264. I do not remember what if any arrangements were in place to do this when the manual file cards were used for donor/donation records. It is my recollection that this requirement was addressed some considerable time ago within the computerised donor system with the introduction of a national [SNBTS] system for alerting each RTC of any donor who should be excluded on the grounds of

infection. I do not know what, if anything has been put in place to share this information across the UK RTC's

103. In January 1992, you wrote a letter to Dr Cash regarding a pilot project to carry out a quality assurance check on the available databases on HIV-positive individuals against the database of relevant blood donors to exclude the possibility that there could be known HIV positives existing on the blood donor panel for some reason unidentified by the BTS (SBTS0000661_162). In the same letter you stated: "*I appreciate that this exercise will cause some technical computing problems due to the fact that the clinical HIV database uses soundex identifiers.*"

88.a. Did the SNBTS use more than one form of database? If yes, did this affect how data was stored and accessed by different departments within the SNBTS?

Databases in SEBTS:

265. I have no expertise in this area but I have no doubt that during the progressive adoption of computerization over the years in SEBTS, as in many other organisations, a variety of microcomputer based systems were introduced in the laboratories, serving both research and routine service functions. These will have employed different operating systems and applications including a number of different data management tools. The first, and very
basic computerized donor management system was introduced at my request in 1979, and from then on we moved towards a more integrated system for the SEBTS, based on Data General Hardware and one of the then standard languages. As I understand it, today's IT support for all of SNBTS is based on a single system [e-Progesa], so I assume that there is now commonality in the major software elements used by the SNBTS.

266. The Edinburgh, Aberdeen Dundee and Inverness RTCs used variants of the same computer system and database. The West of Scotland used a system

developed there and I assume the database was different. The Soundex system referred to above was not used by SNBTS to my knowledge. This reference is, I believe, to a system used at the CDSC.

88.b. Please can you confirm if this pilot project was adopted by the SNBTS?

267. I cannot confirm that this project went ahead. I have examined SBTS0000661_162 and unfortunately this provides no clue. I think it is possible that a project along these lines was carried out by CDSC. Those directly responsible for the care of donors in SEBTS at this time may be able to shed light on this.

88.c. What was the outcome of the pilot project?

268. I do not know.

88.d. How did the SNBTS adapt their practices to accommodate the findings of this pilot project?

269. As stated in my answer to the Question above, I believe that the project did not go ahead as proposed.

104. In August 1981, you wrote a letter to Dr Lane regarding the reporting of Hepatitis transmission incidents in the SNBTS. In this letter you stated: *"I completely agree with you that there is a serious problem in the reporting of possible hepatitis transmission incidents, follow up and central documentation*" (CBLA0008819).

a **Please elaborate on what you meant by "*serious problems in the reporting of possible hepatitis transmission incidents.*"**

270. I was concerned, as were some of my colleagues, that the transfusion services may not be receiving reports from clinicians about patients who they believed had become jaundiced following a blood transfusion and that we had no idea of the likely scale of this non reporting.

b. For how long did you know that there were problems in the reporting of possible Hepatitis transmission incidents?

271. My letter to Richard Lane is dated 7 January 1992 but I have no recollection of when I began to be concerned about this issue. I was aware that there were intrinsic difficulties in achieving better reporting, one reason being that if patients developed jaundice or other evidence to suggest hepatitis, this would frequently occur only after the patient's discharge from hospital. Other aspects are mentioned in my answer to question **101.**

c. **Please detail the steps taken, if any, by yourself or the SNBTS to address the problems associated with reporting hepatitis transmission incidents**.

272. We could only have obtained useful data about the incidence of post transfusion jaundice by undertaking a large prospective study of recipients and their donors. I had proposed such a study, based on the American TTV study but this did not receive support or funding. I do not remember what other action we took about this. I think it would have been raised in information for clinicians and in discussion with individual clinicians, and probably also in lectures to doctors, medical students and nursing staff.

Section 12: Knowledge of risk of infections while at the SEBTS

HIV

105. You gave written and oral evidence to the Penrose Inquiry regarding HIV and AIDS (PRSE0003972 and PRSE0006021 pages 81-174). Do you stand by that evidence? Is there anything you now wish to add to it?

273. I stand by that evidence.

106. During your time at the SEBTS, 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? As well as the documents referred to below and in the next section, you may find PRSE0003481, PRSE0003709 and PRSE0001556 of assistance.

274. At this distance in time I cannot provide chapter and verse of a learning process that lasted over a number of years. I regularly received and read the Mortality and Morbidity Weekly Reports [MMWR] published by the US Centres for Disease Control [CDC] which was, in the early stages, a definitive source of information about the epidemic. Dr Bruce Evatt of CDC was central to the efforts to define the nature and scale of the problem for haemophilia patients receiving concentrates. I read relevant articles in mainstream journals including the New England Journal of Medicine [NEJM] and Lancet and also in the transfusion journals as they began to publish on AIDS.

I gained information from colleagues during my attendance at various committees or working parties in the UK. I attended the first international conference on AIDS held at the World Health Organisation, Geneva in 1983 and subsequent International Aids Conferences in Atlanta [1985] and Paris [1987]

My Report on the WHO International meeting on AIDS Geneva 1983 is attached as an exhibit (WITN6666011)

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

275. I cannot be certain of this. I may have heard from Dr Peter Foster about the report at the 1982 Budapest conference of ISBT [at some time after the conference] or from the CDC MMWR or when I attended a meeting of the RTD's Transfusion Associated Hepatitis Working party on January 18th 1983, at which Dr John Craske made reference to this as below:

Extract of minute: TAH WP Jan 18 1983 [NHBT0000023_002]

"AIDs (Acquired Immune Deficiency Syndrome)

Dr. Craske summarised the current situation and mentioned the involvement of homosexuals. (In the USA it is recommended that homosexuals with AIDs be deferred from donating blood organs). Dr. Craske will be studying the effects of American factor VIII in recipients and will be examining immunological markers"

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

276. In my answer to question **106** I have given an indication of how I [and my colleagues] endeavoured to keep up with developments in the early stages of investigations on AIDS.

277. I have no recollection that SEBTS undertook any investigations into transmission of AIDS apart from the "look back" carried out with recipients of the small number of blood donations that had tested HIV positive

109. In August 1982, you and Dr Foster attended the Budapest joint meeting of the ISBT and ISH (PRSE0003972 page 3 and PRSE0006021 pages 91-92). According to Dr Foster's report of the meeting, Dr Aledort described 3 deaths from pulmonary infection as the most recent problem in the treatment of haemophilia in the USA, and stated that this had "*been linked with the development of Acquired Immunodeficiency Syndrome*". So far as you can recall, did you discuss this development with other members of the SNBTS and/or with any haemophilia clinicians in the second half of 1982?

278. This was a large International conference with many parallel lecture sessions. I did not attend the same sessions as Dr Foster. I may have seen Dr Foster's report after the Budapest meeting or he may have told me about this new information.

110. When commenting on the minutes of the 21 January 1983 meeting of SNBTS and haemophilia directors during the Penrose Inquiry, you expressed surprise at the lack of a specific reference to the connection between AIDS and haemophilia treatment (PRSE0006021 pages 96-107, PRSE0001736 and PRSE0003235). In your view, why was the connection not discussed, or not discussed in more detail, at this meeting?

279. I can only offer conjecture about this. I believe that in early 1983, there was not much awareness of the potential gravity of this apparently new disease among most of the medical community other than a relatively small number of specialist virologists, virus researchers and a few clinicians. In early 1983, AIDS was already a substantial problem in parts of the USA, but only a very few clinicians had seen AIDS patients in the UK. I think that transfusion personnel were occupied with many other challenges and most took some time to realise the seriousness of this infection.

111. In February 1987, you wrote a letter to Dr Ludlam regarding irradiated platelets for HIV-positive patients (LOTH0000005_039), in which you stated: "*for obvious logistic and costs reasons, I would therefore be anxious that we do not establish the practice of issuing irradiated platelets for HIV-positive patients unless you [Dr Ludlam] are aware of some compelling reason for doing so.*"

a Has your view of irradiated platelet treatment for HIV remained the same since making this statement? If not, please explain how it has changed.

280. I have had no cause to remain up to date with the nuances of platelet therapy since I retired. I expect that guidelines for irradiated platelets have changed since then and certainly since 1983.

b In your view, would irradiated platelets have been a beneficial treatment for HIV? Please explain your view.

281. I have looked at several recent reviews of transfusion therapy in AIDS: They do not appear to advise the use of irradiated platelets in patients with HIV. One such paper is referenced below and exhibited as WITN6666012.
(A review of the use of blood and blood products in HIV-infected patients South Afr J HIV Med. 2012 Jun; 13(2): 87–104. NIHMSID: NIHMS819378 PMID: 28479876)

112. In March 1987, Dr Ludlam wrote to you regarding a patient he believed had been infected with HIV through cryoprecipitate (LOTH0000005_041). So far as you can recall, did this prove to be the case? Were you aware of other patients infected with HIV by cryoprecipitate?

282. I have no other documents relating to Dr Ludlam's letter to me. I am sure that this would have been fully investigated but I do not remember the conclusion reached. I do not remember other reports of patients suspected of being infected as a result of cryoprecipitate transfusion.

113. In September 1987, Professor Kendall wrote a letter to the heads of department at the SNBTS regarding AIDS research in Edinburgh (LOTH0000096_040). In this letter he stated that "*recent Edinburgh applications for research grants for AIDS Research had been handicapped by a lack of epidemiological as well as of clinical immunology expertise.*" Please detail your understanding of this comment, and state whether you agree with the matters raised.

283. Professor Kendall was the Dean of the Edinburgh University Faculty of Medicine. His letter was addressed to "all potentially interested heads of department" [in the Medical Faculty] rather than to heads of department at the SNBTS. The letter shows that I was sent a copy for information. The comment quoted was made by Dr Keith James, Reader in Immunology. It reflects the reality of the situation at that time. I agreed with the comment.

Hepatitis

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

284. I was well informed about hepatitis before I joined the SEBTS as I had spent time as a trainee in hepatology and gastroenterology, and also in Infectious Diseases. I was aware that there were patients who developed hepatitis after surgery with no evidence of infection with either type A or type B. I do not remember when I was first aware that transfusion was one of the possible causes. I have personal experience of NANBH as I was extremely ill with hepatitis during my pre-registration year and subsequently learned that this was probably due to Non A Non B infection. I became ill in April 1970, towards the end of the outbreak of hepatitis in Edinburgh described in Dialysis-associated hepatitis in Edinburgh; 1969-1978 B P Marmion, C J Burrell, R W Tonkin, J Dick-son, 1982. PMID: 6812192 DOI: 10.1093/clinids/4.3.619 – (WITN6666013)

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

285. I was aware of transfusion transmitted hepatitis due to hepatitis B before I joined SEBTS. As I have stated above, I was aware during my earlier training that hepatitis could follow transfusion in the absence of detectable laboratory evidence of hepatitis A or B but that other factors such as exposure to certain anaesthetic agents could cause evidence of liver disturbance such as a raised levels of alanine aminotransferase in the blood.

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

286. Around the time of my appointment in 1977, SEBTS had appointed a scientist [Dr Robert Hopkins] to study hepatitis. There was increasing awareness that the use of sensitive HbsAg tests had not eradicated post transfusion hepatitis [PTH]. A PhD student, supervised by Dr Hopkins was appointed specifically to attempt to identify a marker that could be used to detect the Non A Non B agent in the blood. She obtained her PhD degree for this work.

Field S. Investigation of a serological marker detected in blood from a donor twice implicated in the transmission of non-A, non-B viral hepatitis. PhD thesis University of Edinburgh 1984 [RLIT0000807]

287. Others, including Dr Brian Dow in the West of Scotland BTS were also attempting this. Ultimately, none of these research efforts succeeded and it was not until 1989 that the responsible virus, designated hepatitis C was identified using state ~~of~~ the art genetic techniques.

117. 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? Please address the following in your answer:

a Hepatitis B.

b NANB hepatitis/HCV.

c The sources for your knowledge. In particular, please explain which journals you read and what other sources you relied upon (including any committees and groups with which you were involved).

You may be assisted by considering the evidence you gave to the Penrose Inquiry on this issue (in particular, PRSE0003729).

288. **Hepatitis B:** I had personally been aware of the seriousness of Hepatitis B from 1968-9 when I was a pre registration House Officer, and had learned about it during my undergraduate training. There was a very serious outbreak of hepatitis affecting patients and staff in the Royal Infirmary and the Western General Hospital, Edinburgh that caused the death of patients, laboratory staff and clinicians. This outbreak was later described in a published paper. In 1982 The authors concluded that the outbreak was not due to hepatitis A or B. I do not

know if samples from the patients were retained, nor do I know if these were ever tested for hepatitis C

289. It was near the end of this outbreak that I also had very severe hepatitis. I had never received any blood component or blood product other than anti-tetanus immunoglobulin. At that time, I assumed that I had contracted hepatitis B, although I later learned that this was not so.

290. During my clinical training, I had read about its discovery, clinical consequences of infection and the nature of the virus, in medical journals and standard textbooks. When I joined SEBTS, I was made responsible for the lab that tested donations for hepatitis B and learned about the test for the virus, from work colleagues and reading transfusion and virology journals. I also gained information from attending various groups already listed that were specifically concerned with hepatitis and whose memberships included experts such as professor A Zuckerman and Dr J Craske who often shared new and unpublished information.

Non A non B hepatitis [NANBH]:

291. I was aware, from the time I joined SEBTS, that hepatitis was a frequent complication of transfusion in the United States. I was aware of the work of Professor J Garret Allan who had collected and published data about this over a number of years. All the American data that I was aware of emphasised that the blood provided by paid "donors" was much more likely to transmit hepatitis to recipients than that of voluntary non remunerated donors [VNRD]. Around 1980 I visited the New York Blood Bank [NYBB] and learned about the Transfusion Transmitted Virus Study (Aach et al 1978 (PRSE0002540, Aach et al 1981 PRSE0001650). I obtained from the NYBB Director, Dr Aaron Kellner the complete protocol for the TTV study and, based on this, I submitted an outline proposal for a prospective study of transfusion transmission of NANBH hepatitis and the impact of surrogate testing. The events around this are fully described in my Penrose evidence. [PRSE 6063 page 60 onwards] The study was not supported and never took place.

292. Viewed in retrospect, it seems difficult to understand why NANB post-transfusion hepatitis [PTH] was believed to be a relatively small problem in the UK. In part this was due to a widespread [and correct] belief that because blood was only collected from volunteer donors, it was intrinsically safer than blood provided in return for payment.

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

293. There were various attempts to determine the prevalence of NANBH in UK donors, based on what were called "Surrogate" tests – essentially blood tests that, when the result is above an arbitrary normal range, can suggest that there is something wrong with the liver cells, but not what is wrong. These tests are able to show evidence of acute, transient or chronic damage to cells of the liver associated with factors such as alcohol, many therapeutic drugs, a variety of infections and obesity. As a result, they cannot be relied on to give an estimate of the prevalence of a transmissible NANB agent such as Hepatitis C virus. This could only be done once there was a reliable, sensitive and specific test for Hepatitis C [Strictly, the first tests were for *antibody* to HCV] .

Prevalence of hepatitis C

294. During the first months of Hepatitis C testing, all donors attending SEBTS were tested for the first time. The prevalence of Hepatitis C was 0.088%.
(Crawford RJ, Gillon J, Yap PL et al. Prevalence and epidemiological characteristics of hepatitis C in Scottish blood donors. Transfusion Med 1994; 4 : 121-124 – exhibited as number WITN6666014*)*

295. A 2006 review assembles the data from a number of studies of HCV epidemiology in Scotland from the mid 1990's to 2005. **For blood donors, the prevalence fell from 0.088% to 0.008%.** In male surgical patients in Glasgow, the prevalence was 3.8% and among healthcare workers, 0.28%. Among

injecting drug misusers, who had undergone a voluntary confidential HIV test, the prevalence figures ranged from 62% to 87% (Hutchinson et al 2006. Hepatitis C infection in Scotland: Epidemiological Review and Public Health Challenges. Scottish Medical Journal 51, 2, 2006 – exhibited as number WITN6666015).

General

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

HIV.

296. I was aware from the earliest information that I received about AIDS that this was a serious problem and one that would be likely to have a profound effect on the Transfusion Services. I was closely involved with the development of BTS responses during the early years of AIDS. It often occupied much of my working time and that of my Consultant for donor care, Dr Anne Smith-Dewar.

297. I have included two extracts from my witness statement on AIDS and donor selection for the Penrose Inquiry, as that statement provides much more detail than I can now recall.

298. Extract from PRSE0002627

Since we did not know if or when there would be a reliable specific test, the challenge was to devise some form of screening procedure that might reasonably be expected to have some ability to detect individuals who might be materially more likely than the donor population as a whole to transmit AIDS to a transfusion recipient. The most obvious approach was to follow the principles of the US Public Health Services Interagency Guidelines which made use of epidemiological data to identify subgroups within the population that appeared to have an excess incidence of AIDS. We slightly adapted these recommendations for the first version of a donor selection policy for Edinburgh because in early 1983, almost all the epidemiological information that I was aware of had been obtained in the United States. We were aware from the start that the epidemiology of AIDS might prove to be different in the UK so that the donor

selection criteria might well prove to need alteration as we gained more data about the condition in the UK.

The measures were under constant review and changed frequently as new information became available.

299. We studied the successive recommendations from the CDC and the US Public Health Service concerning the developing knowledge of those who were at risk of AIDS and the developing recommendations defining those individuals who were thought to carry a high [or higher] risk of transmitting the agent by means of blood transfusion. Based on this information, we prepared, in May 1983, a first leaflet designed to inform donors about AIDS and about those who should not donate.

300. The wording of the leaflet underwent a series of changes as more information became available about the groups at risk, and as we undertook consultation with the Scottish Homosexual Rights Group who were at the time the main advocates for gay peoples' rights in Scotland.

301. Extract from PRSE0002627

"Distribution of the original SEBTS leaflet. My recollection is that this was intentionally shared with the SHRG, I recall that Dr Smith, together with one or two SHRG members, visited a number of gay clubs in Edinburgh over the summer of 1983 to distribute the leaflet and explain its rationale to individuals or small groups. I know that the various drafts were available to all the SNBTS directors. My recollection is that it was at this time still considered to be the responsibility of each director to decide on the information to be given to donors and the means by which it should be delivered"

302. At the end of 1983 a new leaflet was prepared for use in all the UK transfusion Services It was issued in 1984, but the centres adopted different approaches to making it available to donors. In November 1984 the SEBTS issued redesigned donor questionnaires which required the donor to sign a declaration that they did not belong to one of the high risk groups.

Hepatitis C

303. I have answered a very similar question above {Question No 64] This response contains similar information. I had less personal involvement in the SEBTS response to hepatitis C and the introduction of the HCV test. By this time, the donor consultant post was held by Dr John Gillon who was trained in GI and liver disease and whose responsibility was for the care and selection of donors. The care and counselling of donors found to be positive was undertaken by Dr Gillon, who, at the request of Dr Cash led a small group that developed standard procedures for the counselling of donors found to be hepatitis C. PEN180112 p8 and onward provides details:

"This is a letter of 21 June [from Dr Cash] *asking you,*[Dr Gillon] *because it is a high priority, to produce operational guidelines for 21 BTS doctors in the context of counselling anti-HCV 22 confirmed positive donor" (WITN6666026)*

The report also dealt with the look-back process. It was accepted by the Directors of the UK Transfusion Services. Dr Gillon and a visiting doctor - Dr Yasmin Ayob, who later became director of transfusion in Malaysia – initiated the first HCV look back, among donors and recipients of SEBTS.

120. What advisory and decision-making structures were in place, or were put in place at the SEBTS to consider and assess the risks of infection associated with the use of blood and/or blood products? How well did they operate?

304. I cannot say that we put in place any "structures" for assessing risk. Our consultant staff kept informed by reading the literature, attending meetings and by informal discussions with medical and scientist colleagues. Blood safety and our efforts to minimise risks to patients were a regular topic at our SEBTS staff meetings.

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

305. I do not remember the details of this. I know that SEBTS medical and technical staff were in regular contact with hospital personnel and would certainly have kept them up to date. Our medical staff were regularly consulted about transfusion of individual patients and this provided excellent opportunities for sharing information about the use of blood components and plasma fractions and the risks to be considered before prescribing them. The deputy director of SEBTS, Dr Frank Boulton was a consultant haematologist experienced in the management of patients with hemophilia, and was in regular communication with Dr Ludlam, and with other clinicians in relation to the care of patients with coagulation disorders. Factor concentrate labels carried warnings about infection risk. I was personally responsible for editing four editions of the Handbook of Transfusion Medicine which was distributed free of charge to all hospitals in the numbers they requested. Each edition contained updated information about transfusion related infections. From the second edition the handbook was published online: the current edition is at www.transfusionguidelines.org

122. In your written and oral evidence to the Penrose Inquiry (PRSE0003972 pages 1-2 and PRSE0006021 pages 84-86 and 153-158), you described having worked for Dr Howard Davies at the Edinburgh Royal Infirmary in 1969, and Dr Davies being a strong proponent for cryoprecipitate over concentrate in order to reduce infection risks. After Dr Ludlam became director and the amount of concentrate used at the Royal Infirmary grew, did you become concerned that there was a greater likelihood of infections being transmitted to patients? If so, did you ever discuss your concerns with Dr Ludlam or any other clinicians involved in the care of bleeding disorder patients?

306. This was a regular subject of conversation between Dr Boulton and Dr Ludlam and myself. Dr Ludlam had worked for some time with Dr Davies and I am sure was conversant with his views. I was aware that there was a risk of NANB hepatitis in patients treated with concentrates. Although I have no recollection, I am fairly certain that this would have been discussed frequently with Dr Ludlam, but ultimately neither Dr Boulton or I had consultant responsibility for the patients concerned.

123. During your Penrose evidence, you described a visit to Cutter in San Francisco in the late 1970s or early 1980s, including the company's Oakland plasma centre (PRSE0003972 pages 2-3 and PRSE0006021 pages 88-91). Did you ever discuss, with Dr Ludlam or any other haemophilia clinicians, your conclusion that plasma was being collected from individuals who might have an incentive to conceal their unsuitability as donors? Did you share your views with others concerned with policies affecting the use of blood products in Scotland or the rest of the UK? If so, please provide details.

307. I have a very clear recollection of the shock that I felt on visiting a commercial plasma centre. Its purpose was to collect plasma from paid providers who would undergo plasmapheresis at weekly intervals for the payment of, at that time, around 10 US dollars. The staff told me that the centre was empty on Thursdays, when social security checks were issued, leaving little doubt about the financial status of its clientele. I certainly emphasised this personal experience in discussions with colleagues, in my clinical teaching and lectures and at various meetings that I attended. It was already well known among haemophilia doctors as well as in the fractionation community that plasma was being obtained in the United States and elsewhere from underprivileged individuals who were already at risk of infections transmissible by blood.

Section 13: Reduction of risk of infection

Donor selection

124. What donor screening processes were in place during your tenure at the SEBTS, and how did these change over time?

308. When I was appointed Director of SEBTS, I inherited a system based on a 1977 memorandum issued by The "National Blood Transfusion Service on the selection, medical examination and care of blood donors" (WITN6666016). It quickly became clear that there was inconsistency in the decisions on donor acceptance or refusal being taken by our donor sessions staff. To begin to

address this problem, Dr Anne Smith Dewar, who I had recently appointed [as the first donor consultant in the UK,] prepared, during 1982, and in consultation with the donor staff a first detailed guide, arranged alphabetically and including locally used terms for conditions where these existed. It was called the ABC Guide and is referred to in the SEBTS response to the Medicines Inspector in 1983 (WITN6666017). This early document was the predecessor of the guide that is still a part of the Guidelines for the Transfusion Services in the UK. Soon after this first ABC Guide was released to SEBTS donor staff, we began a long series of modifications to the donor selection rules and procedures that are detailed in my Penrose evidence. [PRSE0006012] A continuous process of development of UK National Guidelines for donor selection began when the group that later became known as the Joint Professional Advisory Committee for the UK Transfusion Services was initiated by Drs W Wagstaff and JD Cash. The donor selection guidelines form a part of the Guidelines for Transfusion Services in the UK, often known as "The Red Book". They are updated regularly in the light of new evidence and changes in Government regulations. The Red Book can be found at transfusionguidelines.org

125. How were decisions made at the SEBTS as to which donors were high risk and should be excluded from donating? What was your role in this process?

309. In relation to the early period after the recognition of AIDS, in the SEBTS, decision were made by myself and Dr Anne Smith Dewar mainly on the basis of the guidance issued by the CDC and US Public Health Service and published regularly in the Morbidity and Mortality Weekly Report [MMWR] We also worked with representatives of the gay population, members of a group then known as the Scottish Homosexual Rights Group and with a Physician [Dr Alexander McMillan] who specialised in sexually transmitted infections among gay people. This collaboration is described in PRSE0006012..

310. I was a member of EAGA and later of MSBT and along with other SNBTS colleagues, I was an active member of the national guidelines group that became JPAC and in this I way learned from the discussions involving infectious diseases

experts among others and I was able to contribute to the later, developments in donor selection.

311. I led the work in SEBTS on donor selection to minimise risk of donations from higher risk donors over the first year or so, together with Dr Anne Smith Dewar, SEBTS consultant responsible for medical care of donors. After Dr Smith Dewar left to take up a new post in the United States, Dr Gillon who had been trained in hepatology and gastroentrerology was appointed and took on the Consultant responsibilities for donors.

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

312. The evolving information provided for donors is explained in some detail in my written and oral evidence to Penrose and is also described in my answer to question 64 above.

313. In 1983 and again in 1987, SNBTS commissioned research by Strathclyde University to discover more about public perceptions of blood donation. Information from this work was used to improve the donor information and consent process, notably by introducing personal interviews at each donor attendance.

314. As mentioned above, when SEBTS donors had their first test for HCV, the prevalence was found to be substantially lower than that in other populations tested, suggesting that the exclusion criteria previously introduced for HIV had had some effect in reducing attendance by individuals with hepatitis C.

127. In your written and oral evidence to the Penrose Inquiry, you described the introduction of donor selection measures – in particular through the use of leaflets – in response to the risk from AIDS (PRSE0002627 and PRSE0006012 from page 3). You also prepared a submission on behalf of the SNBTS on this and

related issues: "*Actions taken by SNBTS to protect patients from AIDS*" (PRSE0000502).

a. Do you stand by the evidence that you gave Lord Penrose on these issues? Is there anything that you now wish to add to that evidence?

315. I stand by the evidence that I gave to the Penrose Inquiry. [A small correction: the paper PRSE0000502 was prepared by a number of SNBTS personnel including myself as background information for the Penrose Inquiry] .My oral evidence on AIDS gives extensive detail of the issues referred to in question 127 a to l. [PRSE0006021]

b. Were leaflets nationally agreed by the SNBTS, or did each RTC produce their own? How often were these leaflets updated, and how was their content decided?

316. In my written statement to the Penrose Inquiry [PRSE0002627] I gave as much information as I could remember about the sequence of leaflets that were produced as new information became available. I cannot add to this now. During 1983 SNBTS centres had different information for donors. I do not remember the information provided by each SNBTS centre. The first leaflet was drafted in May 1983 by myself and Dr Smith-Dewar, and a copy dated June 1983 is at PRSE0004850. It was entitled "Aids, some background to the recent publicity". This is the first leaflet to be issued in SEBTS.

c. You referred in your evidence to having received a copy of the 4 March 1983 MMWR (PRSE0001115), and to SEBTS subsequently producing a first draft of a leaflet for donors in May 1983. Were you aware of earlier MMWRs in which AIDS had been mentioned (such as the 10 December 1982 report (PRSE0003276)? If so, did you consider taking any steps in response? Please explain your answer and provide further details of any steps that you did consider at that time.

317. I would not have seen this earlier edition of MMWR [PRSE0003276] at the time of its publication. In 1982 we did not have rapid internet access and we received MMWR by mail from the USA. Our librarian, Mrs June Macleod, circulated it to relevant staff. I tried to scan it regularly, but it could be a month after its publication before it was available to me. I cannot recall what action I took in relation to discouraging donors at increased risk of transmitting AIDS prior to May 1983.

318. As far as I know, the first SEBTS leaflet distributed in June 1983, was the first of its kind in the UK. At that time there was no official policy about providing prospective donors with information about AIDS. I informed our contact Medical Officer at SHHD [the late Dr AE Bell] of my intention to issue the leaflet to our donors, and sent a note to Dr Cash informing him of this conversation and my understanding that my course of action had been agreed by Dr Bell.

d. **Other than the 4 March 1983 MMWR, what were the sources of information you/SEBTS relied on when producing the May 1983 draft leaflet? In particular, what was the source for the answer given in the draft on whether AIDS could be transmitted by blood transfusion: "*It appears it can*"?**

319. I was by that time aware of reports indicating that patients with haemophilia had contracted AIDS. I would probably have been been informed by Dr Peter Foster of the report at the 1982 Conference in Budapest, which was, I believe the first evidence made public about transmission to patients with haemophilia. I was also aware, I believe, by early 1983, of a report in the Lancet USA of an infant in San Francisco contracting HIV from a transfusion of platelets. PRSE0000317 as we received the Lancet a day or two after its weekly publication date. Although there was a considerable controversy at the time about the possible causes of AIDS, with several non - infectious causes being proposed, I felt that the evidence available was strongly suggestive of an infective process in which blood could be the means of transmission.

88.e. In the June 1983 version of the leaflet, which was the first to be issued, the wording of the question and answer on whether AIDS could be transmitted by blood transfusion changed (PRSE0004850). Your evidence to Lord Penrose was that, by this time, you and Dr Anne Smith had "*little doubt that the evidence that had been assembled by the CDC had to be interpreted as showing that this was a blood transmissible disease. We think we really had no doubt about that*" (PRSE0006012 pages 28-29). So far as you can recall, what if any further evidence did you receive from the CDC or elsewhere between the drafting of the May and June 1983 versions of the leaflets?

320. I do not remember any details of this but it is very likely that I would have seen further copies of MMWR as it was published weekly.. This was becoming a hot topic so I may also have seen information in other journals or gained it from meetings I attended.

88.f. To the best of your knowledge, did any of your colleagues within SNBTS, or the clinicians with whom you worked, have doubts about AIDS being a blood transmissible disease? If so, what were those doubts, and why were you not persuaded by them?

321. Personally I had no doubt that the evidence for an infectious agent being the cause was strong. I believe my medical colleagues in SEBTS shared this view and I do not recall any discussions with them in which this interpretation was challenged. I do know that there was some reluctance in some quarters, including within the UK transfusion services to acknowledge the gravity of what was emerging and there was concern that any form of questioning of donors about their sexual habits, or even raising the issue in printed information issued to potential donors could discourage donors from attending, and lead to shortages of blood. I was not persuaded by these arguments that we should delay action, although I shared the concern that donors might be deterred from attending. Reluctance to accept and act on the emerging evidence was much more evident in the United States and is very well documented in several

excellent books including Douglas Starr: an epic story of Medicine and commerce [1998] HSOC0019915. Starr provides evidence that in the US potential loss of revenues was a concern for many commercial blood banks in the US. I have never been aware of any evidence that this was a factor in the UK.

322. Personally, I was aware that a fall in donor attendances was a risk. However, I had no doubt that our priority must be to do whatever we could to safeguard patients who needed transfusion, so I had no hesitation about taking whatever action we could that might reduce the risk that a transfusion could transmit AIDS.

88.g. Other than providing drafts of the early SNBTS leaflets to Dr Gunson (PRSE0002627 page 7), what if any involvement did you have in the NBTS's or Westminster Government's consideration of donor selection leaflets in May-September 1983?

323. I also discussed the leaflets and corresponded with Dr Bill Wagstaff of NBS Sheffield. I do not now remember having any other direct involvement but it is quite possible that I had discussions or correspondence about this with Dr Harold Gunson who had frequent contact with officials of the Department Of Health. The extract below provides some background.

Extract from PRSE0002627

My letter to Dr Cash dated December 23rd 1983 outlines suggested changes to the donor leaflet and refers to a new donor questionnaire…. I had acquired a great deal of new information during the WHO AIDS conference in November 1983, since this was the first time I had attended any international gathering of experts on AIDS, …it was the first large international AIDS conference to be held. This may well have been what led to the consideration of a new draft, As I had been careful to communicate with the NBS through Dr Gunson and there was a definite intention to use a common set of criteria, our intention may have been to use a new SNBTS draft to suggest changes in a UK leaflet. As mentioned above I was also in communication with Dr Wagstaff, Chairman of the NBTS Directors' group, about the new draft in early 1984. A letter dated January 10th 1984 gives a sense of the multiplicity of groups concerned with AIDS and blood safety at that

time. I explained that I was sending a reworded version of the AIDS leaflet, I stated that the changes were my personal suggestions and that they had yet to be discussed by the SNBTS regional directors, the AIDS working party of the Central Blood Laboratories Authorities subcommittee, the transfusion directors Hepatitis Working Party or any of the other numerous groups who were concerned with this problem.

88.h. On 1 September 1983, the SHHD announced the publication of a UK-wide leaflet on AIDS and blood donors PRSE0002778 and PRSE0004076) What, if any, involvement did you have in the production of this leaflet?

324. I have referred to the Penrose transcript PRSE0006012 in endeavouring to answer this question. It is evident from the transcript that I was uncertain at the time of my oral examination about the exact origins of this leaflet and I have not been able to clarify this since then. The transcript indicates that the confusion appears to originate in an early chronology of actions related to reducing AIDS risk that was prepared by my donor organizer in or around 1984 [document not available to me during preparation of this statement] which contained an erroneous date .This date was, years later, accepted by both myself and Dr Gillon in preparing statements. I am therefore unable to provide information about any contribution I may have made to this particular leaflet. I am however aware that the wording was criticized as being inappropriately reassuring and that this led to a further draft being prepared. My recollection is that I contributed to that later version.

88.i. The press release accompanying it recorded that the SHHD had emphasised that there was "*no conclusive proof*" that AIDS could be transmitted in blood or blood products. The leaflet answered the question of whether such transmission could take place with: "*Almost certainly yes...*". Were you aware of the use of the "*no conclusive proof*" expression around this time? Did you then, and do you now, consider that it was consistent with the contents of the leaflet? Was it, in your view then and now, a full

and accurate representation of the state of knowledge at that time? Did you raise any concerns about the use of the phrase at the time, whether within or outside the SNBTS?

325. I do not recall this press release or my reaction to it, if indeed I saw it at the time.

This wording was certainly quite inconsistent with my own view of the risk that blood transfusion had to be considered to carry a risk of transmitting AIDS. That has been my consistent view since my first learning about AIDS.

I do not know the origin of this wording.

I find it very difficult to believe that if I had been asked I would have agreed to the wording of this press release because all my other actions around this period suggest that I would have been confident that it was misleading and falsely reassuring.

128. At a 9 February 1984 NIBSC meeting, you presented data on the risk of transmitting NANB hepatitis, hepatitis B and AIDS by blood transfusion (PRSE0003071 pages 6-7). So far as you can recall, what was the source for this data?

326. I cannot now remember the source of the data that I presented. Almost certainly I drew on a variety of sources

129. You are also recorded as having outlined three main strategies in use in Scotland to minimise the risk of transmission of infection. Were you referring to the introduction of these strategies throughout Scotland, or only within the SEBTS?

327. The minute quotes me as referring to "Scotland". I think this correctly reflects what I would have said, as it is most unlikely that I would have made a statement about the actions of the NBTS.

130. In 1984, you were involved in the creation of a draft leaflet on AIDS designed to be sent to blood donors with routine call-up letters (PRSE0001302 and PRSE0006012 pages 59-62). The draft, which appears to be dated February 1984, answers the question of whether AIDS can be transmitted by blood or blood products with "*Probably it can*".

a. So far as you can recall, what was the reason for this change in wording compared to earlier leaflets (such as the June 1983 SEBTS document you prepared and the September 1983 UK-wide leaflet)?

328. I have looked carefully at PRSE0001302, and noted the handwritten "2/84" which seems to be the only indication of the possible date of the draft. On the print out from Egress, I cannot see evidence of the origin of this draft. My recollection is that there was some controversy within DoH with pressure from some to soften the wording from some quarters, and others who argued for a more evidence based message. I have a recollection that in the Penrose transcripts there is a reference to the effect that Dr Diana Walford was concerned that the text was inappropriately reassuring. I have no recollection of the preparation of this draft so I cannot confidently disclaim responsibility for this wording. As far as I can see, the transcript of my evidence to Penrose in pages 59 to 62 of PRSE0006012 does not clarify this point.

b. Why did the groups at risk of contracting AIDS not include people with bleeding disorders and their sexual partners? Please also answer this question in relation to PRSE0000286.

329. These patients were not mentioned in this early leaflet because they would not be expected to volunteer to donate blood and they would not have been accepted as donors if they had for any reason volunteered. In December 1984, I wrote to Dr Ludlam recording our agreement that partners of haemophilia patients should not donate as they could have an increased risk of infection (LOTH0000005_065).

131. In your evidence to Lord Penrose, you referred to the greater speed with which donor leaflets were prepared and updated in Scotland than in England and Wales (PRSE0006012 pages 64-66, with reference to the letter at NHBT0000190_063). Please provide any further detail that you are able to on this issue. In your view, did the approach taken in Scotland have an appreciable impact on the likelihood of HIV being transmitted in blood and blood products compared with England and Wales?

330. My recollection of many documents that I have had sight of in preparing this response and my evidence to Lord Penrose is that there was concern among political figures about the implications of Information distributed by the transfusion service that drew attention to homosexual behaviour and its associated risks. My impression – in hindsight - is that these pressures may have been greater in England, and that in Scotland, with rather less political involvement, it was possible to move rather more quickly.

331. I could not say if the exact timing of the availability of leaflets would have affected the likelihood of HIV being transmitted by transfusion, comparing England and Wales with Scotland. Because the prevalence of HIV among blood donors in all of the UK was low, I think it is rather unlikely that there would have been a difference in the risk per donation. I do not know if any evidence exists on the impact of these procedures on the incidence of transfusion transmitted AIDS

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

332. I do not recollect that donors were given information other than that contained in the leaflets. The leaflets stated that there was a risk that blood could transmit AIDS. The donor selection process evolved as more information became available. SEBTS was one of the first, or possibly the first RTC to require each donor to sign a declaration that they were not in a risk group. SEBTS was the first

UK service to introduce personal interviews for each donor at each attendance in which the issue of transmitting infection to donors was explicitly addressed.

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

333. This is difficult, or maybe impossible to answer in respect of HIV, as the prevalence in our donor population was low and any effect may not have been measurable. I am not aware of any studies that attempted to assess the impact of these selection procedures on the incidence of HIV in transfusion recipients.

However as mentioned above in my answer to question **56a,** the results of the first round of HCV testing of SEBTS donors [ie when each donor was HCV tested for the first time] showed that the prevalence of hepatitis C in our donors was lower than that in a large group of health care workers in Scotland. Later data supports this initial finding (A study of hepatitis C prevalence in healthcare workers in the West of Scotland. Thorburn D et al Gut 2001;48:116-120. https://gut.bmj.com/content/48/1/116.short - Exhibited as number WITN6666018)

334. In a related article, Professor Howard Thomas has pointed out the lack of good data about the prevalence of hepatitis C in the general population, but refers to data indicating a higher prevalence than found in blood donors (HCV in healthcare workers: a lightning strike: H C THOMAS Gut 2001; 48 8-9 Published Online 01 Jan 2001. doi: 10.1136/gut.48.1.8 – Exhibited as number WITN6666019)

These data can be taken to suggest that the selection procedures designed for AIDS risk had contributed to reducing the prevalence of HCV among blood donors, since the populations at risk of AIDS overlaps with those at risk for Hepatitis C.

134. In a letter dated 29 November 1984, you wrote to Dr Cash regarding the introduction of donor inquiry forms which asked the donor to sign a specific declaration that they had read the AIDS leaflet and were not in a risk group. You

stated: "*What we have introduced for the time being is a double checking procedure to make absolutely certain that no donor can reach the point of giving blood without two separate checks that the AIDS declaration has been signed*" (SBTS0000242_026).

a. In your view, how effective were donor declaration forms at preventing infected donors from donating blood?

335. Please see my answer to the question above. I do not know of any reliable data that could provide a confident answer to this question other than the evidence on hepatitis C prevalence that I mentioned. My answer to question number **133** is the best that I can offer in relation to the SEBTS donors.

b. What were the reasons for choosing this method of risk prevention?

336. The intention was that by asking for a signed declaration, donors would be motivated to give more careful consideration before they answered questions designed to allow exclusion of high risk donors.

337. As I recall, the intention of moving to a face to face personal interview was that it would allow the interviewer to be more confident that the donor had understood the questions and the importance of their replies

135. In your evidence to Lord Penrose, you stated that you were "*fairly sure*" that the introduction of the donor declaration was related to the identification of HTLV-III infection in a cohort of Edinburgh haemophiliacs (PRSE0006012 pages 70-72). Please explain why you reached this conclusion. In your view, should the declaration have been introduced sooner than it was?

338. I can be no more certain of this 10 years on than when I responded to Lord Penrose and I do not remember any specific details of why I thought the two events were related.

Viewed from 37 years later it is easy to say that perhaps we should have introduced the donor declaration earlier, but I do not know if it would have saved any patients from becoming infected and I am not sure that there was any way that this could have been determined.

136. In November 1985, you wrote a letter to Dr Scrimgeour regarding 'directed donations' (blood donations from relatives). You stated: "*We [the SNBTS] are strongly opposed to the introduction of any directed donations at present,*" and at point 4 of the document, you went on to state: "*There is no statistical basis for the implication that donors selected by relatives will be safer than most selected by the BTS. Since testing started on October 14 in Scotland approximately 20,000 donors have been tested and no individuals with HTLV-III antibody have been detected*" (NHBT0098037_010).

a. Please elaborate on the factors you discussed in this letter, and explain any other reasons why SNBTS were opposed to directed donations.

339. My letter to Dr John Scrimgeour explained my practice for the very occasional prospective patient who wanted to have a directed donation. These included a few very senior doctors. My practice was to arrange a meeting with the prospective patient, allowing plenty of time to express their concerns. and only I would then explain the rationale of our position. As I recall, all the individuals I met with in this way accepted that if transfusion was necessary, they would receive donor blood from the blood bank.

b. As far as you can recall, were directed donations used elsewhere in the SNBTS?

340. I have no recollection of this being done in any SNBTS centre but I would not necessarily have been informed if it had been done.

c. Please confirm if you still hold the view that this was the right approach to take.

341. My views have not changed. There are intrinsic problems with directed donation. including the following: The prospective patient may put the donor under some pressure to donate: this may put the donor in a difficult position if he or she has a history that should preclude donation. The donor may feel pressured to conceal this to avoid embarrassment. There can be pressure for the donated blood to be transfused, even if it is not clinically needed by the patient. There is an increased risk of immunological complications if the donor is a close relative of the recipient.

137. In December 1985, you and Dr Brettell wrote a preliminary report on a study into HTLV-III infection amongst individuals attending self-referral clinics in the Lothian area. One of the objectives of this study was "*to reduce the risk that the Blood Transfusion may be used as a diagnostic screening facility*" (NHBT0057006_001).

a. **Please explain the reasons for your concern about the risk about SNBTS being used as a "*diagnostic screening facility*".**

342. We were concerned to exclude or at least reduce the risk that a person who, for whatever reason wanted an AIDS test might be reluctant to attend the Sexually Transmitted Disease [STD] Clinic – the usual place for STD consultations but one that had connotations of "VD" that some individuals would prefer to avoid. Our concern was that once it became known that SEBTS was doing AIDS test on all its donors, individuals with behaviours that put them at higher risk of becoming infected might seek a confidential test by offering to donate blood, so avoiding the perceived stigma of attending the STD clinic. This could increase the risk of an infected donation being taken. [While we were confident that the laboratory tests would be effective, we could not exclude the risk that with early generations of test, there could remain the risk that a potentially infectious donation might be missed. The aim was to provide as many layers of safety precaution as possible.]

343. SEBTS recognised and acted on its responsibility to initiate a confidential AIDS testing service. We were instrumental in obtaining the funding for a "pilot" project that was soon allocated longer term funding by the SHHD. SEBTS did not "use" this facility. We did our best to make its existence and function known to professionals who dealt with high risk patients. I cannot now remember the details of how we shared information about the existence of the facility, but it quickly gained its own identity as the AIDS Unit in the City Hospital in Edinburgh, under the dedicated leadership of Dr Ray Brettle.

b. As a result of this study, what actions, if any, were taken by the SNBTS to utilise self-referral clinics as a means of deterring high risk individuals from donating blood

344. I do not recall what action was taken by the other SNBTS centres to provide a similar self-referral facility.

c. In your view, was the use of such clinics effective?

345. I believe that it would have been extremely difficult to design and implement a study to assess the effectiveness of the self-referral clinic in terms of reduction of risk of donated blood transmitting an infection to patients. Perhaps the best, although indirect, evidence comes from the low prevalence of Hepatitis C antibody that was found in blood donors once testing began. This is likely to be due, at least in part, to the measures taken to discourage donors at higher risk of AIDS, and the confidential testing facility was a part of these efforts.

138. In January 1992, you wrote a letter to Dr Cash regarding the age and sex stratification of the Southeast Scotland donor population. In this letter you proposed that the SNBTS should "*compare the age and sex-specific prevalence of HIV infection in the general population with that in the same age and sex bands of*

***the blood donor population*" to "*get a measure of the effectiveness of our present exclusion measures and to identify whether there is any suggestion at all that exclusion measures may be less effective in a particular set of the population*" (SBTS0000661_162).**

a. can you confirm if this pilot project was adopted by the SNBTS.

346. To the best of my recollection this study was not done. Although I do not remember why the proposal was not followed up, it was a study that would have been difficult and expensive to carry out. It is also possible that funding may have been an issue and there would also have been concerns about consent and information issues and the public reaction to HIV testing of a large sample of the general population.

b. If so, what was the outcome of the pilot project?

c. How did the SNBTS adapt their practices to accommodate the findings of this pilot project?

347. As far as I recall the study was not carried out, so there would have been no basis for altering practice.

d. Can you recall any other instances where the SNBTS undertook studies to determine the effectiveness of donor exclusion measures?

348. I do not remember any studies that were specifically intended to determine the effectiveness of donor exclusion. As I have said above, these would have been very difficult to design and implement.

139. In December 1984, you wrote a letter to Dr Ludlam regarding the policy on blood donation by partners of haemophiliacs (LOTH0000005_065). In this letter you stated: "*We are agreed that sexual partners of haemophiliacs must be considered a high-risk group and should not donate blood. We also agreed that*

the appropriate route of communication to this small group of individuals was through the haemophilia director." **This policy also appears to have applied to close family members of haemophiliacs (PRSE0001009).**

a. Please elaborate on why donor exclusion was delegated to haemophilia directors in these circumstances.

349. This refers to [I assume] a discussion with Dr Cash in which it was apparently agreed that the *haemophilia* directors should be asked to inform their sexual partners that they should not donate blood. This was a reasonable precautionary measure, but was not strictly "delegating donor exclusion" since the normal processes of donor selection should also have led to such an individual being excluded. I do know that in Edinburgh the patients with haemophilia, and their partners and close relatives generally maintained very close contacts with the Edinburgh Haemophilia Centre, and were considered very much to be Dr Ludlam's patients. It was probably felt that communication with them would be most effective. This point is emphasized in Dr Ludlam's letter to me [PRSE0001009]

Extract from PRSE0001009 Dr Ludlam to *Brian McClelland*

"As we agreed in our discussion it would be better to disseminate this information in the haemophiliac community by our existing lines of comrnunication, rather than add these potentially high risk donors to your "formal" list as published by the SNBTS, At the meeting of haemophiliacs on 19 December, at which you were present, this point was made clear…… we are arranging for a circular to be sent to every patient with moderate and severe haemophilia A and B."

b. As far as you can recall, was the circular referenced in PRSE0001009 effective in preventing any further donations from sexual partners and close family members of haemophiliacs in the Edinburgh and Glasgow regions?

350. I have no recollection that I was ever informed of a donation being taken from a sexual partner or a family member of a patient with haemophilia.

c. As far as you aware, was this practice adopted by other SNBTS RTCs?

351. I do not know if other SNBTS centres adopted the same practice:Dr Ludlam's letter [PRSE0001009] was apparently sent to all the patients with severe or moderate Factor VIII and Factor IX deficiency *and "We are planning to send the circular to the other three East Coast Haemophilia Centres asking them to distribute it amongst their patients.*

It is not clear from this letter that Dr Ludlam sent a similar message to the Transfusion Centres, but my recollection is that the donor selection guidelines continued to state that haemophilia patients, partners and relatives should not be accepted as donors

140. In a letter dated 15 November 1983, you wrote to Dr Cash [Actually Dr R Perry] regarding the labelling of plasma for Hblg production (SBTS0000104_076). Please explain whether the SNBTS followed the FDA recommendations with regard to labelling plasma for donors who may fall into the risk group for AIDS.

352. This letter refers to *"The FDA Recommendations with regard to labelling of plasma from donors who may fall into risk groups for AIDS..;.."*

I do not remember whether this FDA recommendation was adopted in SEBTS.

141. Please refer to an article published in The Scotsman, titled 'AIDS 'barrier' proves illusory,' dated December 1984 (HSOC0016029). Please consider the author's comments and state whether you agree or disagree with matters raised. In particular, please consider the following comment: "*Dr McClelland had liked to think that the infected blood had been given unwittingly . the system had no real protection against this or deliberate donation by a member of a high risk group.*"

353. The italicised passage above is not quite a verbatim quote from the article, as I think is implied. The words used in the article *were*

"Dr McClelland prefers to think that the contaminated blood had been donated unwittingly, but cannot rule out the possibility that the donor deliberately went ahead knowing himself[sic] to be a member of the at-risk groups The transfusion service has no protection against such an action because no practical means has yet been developed for testing individual donors to see if they are carrying the virus "

354. The quoted comments of Mr Derek Ogg reflect anger in the gay community at the continued efforts by the UKBTS to avoid donations from these individuals. This matter remained controversial for all of my career and was only finally decided by ASBTO within the past few years.

355. The statement that *"the transfusion service had no protection"* is, in my opinion, inaccurate and misleading, as we had continued to do our best to improve the deferral measures as new information became available.

356. The later evidence on hepatitis C prevalence provides indirect evidence, in that the measures previously introduced to reduce AIDS appear to have reduced the prevalence in the donor population of another virus transmitted by blood. It was an inescapable fact, however, that until we had a sensitive and specific test for the AIDS virus, we could, at best, reduce the risk of accepting a donor who could pass on infection.

142. In a letter dated 2 September 1986 (SBTS0000033_179), Miss Corrie mentioned that you had sent her explanatory instructions issued to donor staff in the Edinburgh Centre for the use of AIDS flash cards. Please explain what AIDS flash cards were, how they were used, and the advantages of using such cards.

357. As far as I can recall, these "Flash Cards" carried short, easily readable messages about the donor's health and behaviours that might debar a donor. This was one of many attempts to improve our communication with donors about who should not give blood. I cannot remember whether, or for how long, the use of these cards continued, or how effective they were felt to be or if any formal study of their effectiveness was attempted.

Provision of diagnostic screening kits

143. Did you, or anyone else at the SEBTS, contract directly with any pharmaceutical company involved in the manufacture and sale of diagnostic testing kits for donation screening ("screening kits"), or were contracts negotiated on a national basis?

358. I did not contract directly with any pharmaceutical company involved in the manufacture and sale of diagnostic testing kits and to the best of my knowledge, no one on the staff of SEBTS did so.

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

359. My understanding was, and remains, that the criteria for selecting a test kit were the performance of the test, i.e. its sensitivity and specificity during evaluation, the reliability of supply, and the actual performance and practicality in use in a laboratory that was testing hundreds of samples each day.

I did not have any involvement in the choice of pharmaceutical suppliers of plasma products

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

360. The test manufacturers had a duty to ensure that the laboratory staff were provided with all the information needed to perform the test. They also had a responsibility to assist, where requested, with resolving problems that arose in the course of routine use of their equipment and reagents. This could be described as " *provid*ing *advice on the implementation or use of the screening kits"* but I would consider this to be an essential part of their service to users, rather than "influencing" the users.

146. During your tenure, there were multiple commercially available testing methods for blood-borne infections.

a. How did you in your capacity as director of the SEBTS ensure that the tests being used to detect blood-borne infections were of appropriate sensitivity?

361. This was a complicated area and my recollections are at best of the general shape of the process. There was a hierarchy of evaluation steps. Initial evaluation would be by an expert reference lab, for example in the PHLS and NIBSC. If this proved satisfactory, SNBTS usually instructed a second assessment by the West of Scotland SNBTS centre which had particular expertise in tests for blood borne viruses in the context of transfusion. Thereafter, each regional centres' laboratory would carry out its own assessment. There were also nationally coordinated multi-centre evaluations. As Regional Director it was my responsibility to be guided by the recommendations resulting from these assessments.

b. **Please explain the extent to which cost considerations affected the SEBTS's decision to purchase different tests**.

362. To the best of my recollection, cost was not a factor in the choice of test systems although it may have been taken into account when the choice was made between two systems with comparable performance.

c. Please describe any occasions when a test of reduced sensitivity was chosen over a higher sensitivity test because it had a lower cost-price. Please explain your arguments for and against these decisions.

363. With the exception of HBsAg testing mentioned below, I cannot recall any instance during my tenure, where a selection of a test, whether or not with inferior performance, was made on the basis of lower cost. However, I was not directly involved in the procurement process, and I cannot state with certainty that this never happened. It is a fact that in the early days of RIA testing for HbsAg, both Edinburgh and West of Scotland Centres used modifications of the Abbot Laboratories Radioimmunoassay [RIA] that were specifically intended to reduce

the cost per test. This practice would not be permitted by regulators today as tests related to blood safety would be required to be performed strictly according to the manufacturer's instructions.

364. In contrast, in the 1970's, innovations and modifications such as this were considered quite reasonable so long as they were properly tested and shown to have acceptable performance. I have a distant recollection that when the Abbot test mentioned above first became available, the SHHD had refused to approve the additional costs over the current method.

365. A modified version of the Abbot RIA was used because it was much more sensitive than the older method then in use and the cost per test was much lower than the standard Abbot test. This modified method was used with the sole objective of improving the safety of blood for patients within the funds then available.

You may find NHBT0007975, CBLA0000974, PRSE0001999, PRSE0004725, NHBT0004290, SBTS0000352_076, SBTS0000177_035 and NHBT0004211 useful in answering these questions.

HBV testing

147. In 1979, you co-authored an article titled 'Possibilities for economies in testing donations for HBsAg.' The article stated that a modified, diluted version of Abbott's Austria II test had been "*in daily use*" at Edinburgh BTS since 1978, and that a different "*recycled*" version of the same test ("Law RIA") was used at Glasgow. The article recommended the establishment of a working group on quality assurance and test standards. It noted that British hepatitis tests, unlike those in the US, were not regulated (CBLA0001043).

a. Were Abbott made aware of these modifications to the Austria II test? If so, what was their response?

366. I am sure that Abbot was aware: I have no memory of whether we told them or if they found out by another route. I do not have any recollection of communications with Abbott Laboratories on this subject

b. Was this working group established? If so, when?

367. I do not remember. The references provided do not appear to shed light on this.

c. To your knowledge, were hepatitis tests ever regulated in the UK? If so, when did this begin?

368. I cannot remember what, if any regulation was in place in the early 1980's. My recollection is that these tests were not subject to a licensing regime similar to that for pharmaceuticals. Later, the tests were required to be CE marked, but I believe that this did not require evidence of their performance in a routine situation. However, I cannot imagine that the issue of test performance was not put under regulatory scrutiny once the Transfusion Services lost their Crown Immunity and became subject to Medicines Inspection. The current Red Book states "*All assays used must be CE marked and must have been assessed (in respect of sensitivity and specificity) and deemed suitable by the UK Blood Transfusion Services kit evaluation groups (NHSBT KEG or SNBTS/NIBTS MTEG) for the detection of the required markers in the donation types being screened.*"

148. In 1982, at a meeting of the Eastern Division of Consultants in the National Blood Transfusion Service, a proposal was discussed that BPL would hand over the manufacture of their RIA test, which was supplied to SNBTS, to Wellcome (NHBT0092845_026). However, lack of confidence in Wellcome was noted throughout.

1.a. Were you aware of this lack of confidence in Wellcome? If so, please explain the factors you believe led to it.

1.b. What was your view on handing over the manufacture of the RIA test to Wellcome? Did you have any concerns, and if so, did you raise these with anyone?

1.c. **Was the handover put into effect? If so, when**?

369. I do not remember anything about a handover to Wellcome, but by whatever means it was developed or acquired, Wellcome did market an HbsAg assay for some time. My recollection is that it was for a time used in SEBTS.

149. In 1986 you corresponded with Drs Mitchell and Cash about an evaluation scheme for an ELISA assay for HBsAg (PRSE0004725).

a. **Please explain what you were referring to when you wrote that "*there is a lot of pressure to implement this change as soon as possible*"?**

370. I do not remember what was behind this request, but I would assume that it reflected a desire to stop the use of radioactive materials [radioiodine [I^{125}] in the case of HbsAg assay] for health and safety reasons. Around this time, radioisotopes were used in many laboratory tests, but with the development of ELISAs [Enzyme Linked Immunosorbent Assays] it was now possible to substitute ELISA methods for the use of radioisotopes. This was increasingly viewed as a Health and Safety requirement

b. When did the evaluation take place and how long did it take? Which assay was recommended as a result?

371. I cannot recall any details of the evaluation. I can only state that my recollection is that the transition to ELISA was eventually made for all the routine viral screening tests on blood donations.

150. In March 1991, you wrote a letter to Dr Gillon which appears to relate to a case of post-transfusion Hepatitis B. You stated: "*Despite the good points put forward in your report, we will have to anticipate that the outcome of this case may lead to considerable pressure to move for the introduction of anti-core testing*" (SBTS0000377_062)

a. Please provide further details to explain why this case could have led to pressure to introduce anti-core testing.

372. I made this point because at that time there was a very active debate about the safety gains that could be made if anti Hepatitis B core antigen [AntiHBc] were to be added to routine testing of blood donations. The large US TTV study [Transfusion Transmitted Viruses] had produced evidence that this might be the case. My letter was expressing concern that by *not* using this additional test, the transfusion services could risk at best criticism and at worst legal action.

b. What were the benefits and drawbacks of anti-core testing?

373. The answer, as I understood the state of knowledge at the time of the Penrose Inquiry, is that routine testing for anti HBc offers no proven benefit in the detection of hepatitis C. However, this was a highly controversial issue on which may hundreds of pages have been written, and the discussion of it occupies many pages of the Penrose report. In the detection of hepatitis B, the current Red Book specifies certain instances which AntHBc should be tested in addition to the other routine tests.

"9.3.8: anti-HBc

The exclusion period for blood donors who have had body piercing, acupuncture etc. are given in the JPAC Donor Selection Guidelines. Certain of these categories may require donations to be tested for anti-HBc and negative results obtained prior to release of any blood component for clinical use. Tissue and stem cells donations have anti-HBc screening as a mandatory requirement."

374. Anti HB core testing can identify a few donors who can potentially transmit Hepatitis B despite being HBsAg negative.

375. The main drawback, if I remember correctly, is the fact that otherwise healthy individuals may have some level of AntiHbC so that the test could lead to the rejection of many healthy donors. The use of antiHBc testing in relation to Non A Non B hepatitis is a part of the issue of surrogate tests which is pursued in the answers to the following questions

c. Was anti-core testing introduced at the SEBTS?

376. Anti Hbc testing was not to my knowledge instituted at any time as a routine test on every donation. Current practice is I believe that described in the 8th edition [2013] of the UK "Red Book" Guidelines which require antiHBc testing in specific circumstances [Please refer to my answer to question **150b**]

151. When and for what reasons did SEBTS stop using BPL RIA to screen for HBV? What was your primary method for screening for HBsAg thereafter?

377. I have no recollection of the date or the reason for discontinuing use of the BPL test. I would assume that the change was due to problems with either the performance or the supply of the BPL test or the fact that it required the use of a radioisotope.

152. You attended meetings of SACTTI in the early 2000s which discussed whether routine anti-HBc screening should be introduced as a risk reduction measure (such as JPAC0000089_020). This issue was discussed at SACTTI and other committees such as MSBT from the early 1990s into the early 2000s.

a. What do you recall of the arguments for and against its introduction?

378. I have understood this question to be about routine anti HB core testing – ie testing of every donation - as a risk reduction measure for NANB hepatitis.

379. For clarity, I should say that testing for anti HBc has a role in detecting the occasional individual who has a negative test for HBsAg but whose blood may still transmit hepatitis B to a recipient. The SACTTI meeting minuted as JPAC0000089_020 refers to this application of anti HBc testing. The current recommended practice, as described in the current edition of the Red Book, is for very selective use of anti Hbc testing as described in my answer to question **150 b** above.

380. The second aspect of using HBc testing of blood donations relates to Non A Non B hepatitis and this use was extensively studied in the Transfusion Transmitted Virus Study, published first in 1978 [Aach et al 1978 PRSE0002540] and in 1981 [Aach et al 1981 PRSE0001650]. This study produced evidence that was interpreted to indicate that testing for anti HBc could identify some individuals capable of transmitting Non A Non B hepatitis.

This was a large observational study, as opposed to a randomized controlled study. Observational studies can demonstrate an association between, in this case, the presence of anti HBc antibody in the donors and an increased incidence of hepatitis in recipients. However, to prove that there is a causal relationship, a prospective study is required.

381. I know of only one prospective study that has tested this hypothesis. This is:

Blajchman, M., Bull, S. and Feinman, S and C.P.-T.H.P.S. Group (1995) Post-Transfusion Hepatitis: Impact of Non-A, Non-B Hepatitis Surrogate Tests. The Lancet, 345, 21-25. http://dx.doi.org/10.1016/S0140-6736(95)91153-7

This is also exhibited as number PRSE0004703.

382. The authors interpret the results of this study as follows. Before hepatitis C testing had commenced, the exclusion of blood units that tested positive for the surrogate markers [ALT and or anti HBc] was associated with a reduction of NonA NonB hepatitis in the recipients of tested blood.

Once hepatitis C testing had begun, the use of surrogate tests offered no additional reduction in Post transfusion hepatitis.

It was also shown that the majority of units that had tested positive with the surrogate tests were in fact Hepatitis C positive.

This is a complex study. I have found it difficult to interpret and it is possible that its results may have been interpreted differently by other scientists]

b. What was your personal view, and did this develop over time?

383. I have interpreted this question as referring to my view on the value of Anti HBc testing of donors for the prevention of Non A Non B hepatitis in blood recipients.This application is usually discussed together with the use of a test for raised levels of one of the enzymes produced by liver cells, typically ALT [alanine aminotransferase] . The ALT test is not specific for any virus: it merely indicates that there is, or may be some derangement of the liver's cells. It is not known, or at least not known to me, why the presence of anti HB core appears to bear some relationship to NonA NonB hepatitis.

384. My views on the possible usefulness of these tests did change as the science developed.

[a] At the start of the 1980's, I believed that there should be a prospective study to assess the value of "surrogate" tests [Anti HBc and elevated ALT] as a means of detecting donors who could transmit NANB hepatitis.

[b] Some years later, no study of this type had been done, and by then, I felt that it was probably too late to complete such a study before some form of more specific test became available. [c] Around the same time, I learned that Blood Services in the USA had, mandated by the FDA, started to use these tests in the routine testing of donors. I raised the concern that if the UKBTS did not implement these surrogate tests, the UK blood services could be at risk of future claims that a patient's NANB hepatitis could have been avoided by the use of surrogate tests.

c. For what reasons, in your view, did this issue keep returning to committees without a final decision? Do you feel that this continued reassessment was appropriate?

385. I think the principal reasons for the issue of surrogate testing [both anti Hbc and ALT] to reduce risks of NANB hepatitis in blood recipients returning to committee for further debate were:

[a] it was clearly important to reach a decision

[b] Although there was data from observational studies that suggested that surrogate tests could reduce the incidence of NANB hepatitis , its value had not been shown in a prospective study

[c] It was known that anti Hbc was detectable in some healthy people with no evidence of any liver disease, and that this would lead to more donations having to be discarded, and the donors barred from further donation.

[d] In the case of the use of measurements of ALT [or other liver enzymes] there were great difficulties in defining the level of enzyme measured in the blood that would be defined as a "positive" result, leading to the donor's exclusion.

[e] the use of either or both of these tests would lead to substantial increases in the donors rejected, the loss of their donations and difficult problems in providing the excluded donors with appropriate advice and counselling.

HTLV-III: testing and informing Edinburgh patients

153. On 29 November 1984 you attended a meeting of haemophilia directors and SNBTS representatives to discuss the finding of HTLV-III antibodies in Scottish haemophiliacs (PRSE0002066). The SHHD note of the meeting records that "*[v]iews were exchanged on the very difficult ethical problems which had arisen. These included whether patients and patient' relatives should be informed and perhaps subjected to needless worry...*". Why was it a very difficult ethical problem to decide whether to tell patients that they had antibodies to HTLV-III? What was your view, at the time, on whether patients should be told?

386. The words, "very difficult ethical problem" are not mine. I cannot claim that I recall the discussion at this meeting. It is probable that one of the issues debated was that of false positive or equivocal results and the reliability and availability of confirmatory tests. There was a legitimate concern about the problems of giving

patients such very serious information until there was confidence that the test results were definitive. I cannot reconstruct my own feelings at the time.

154. You gave written and oral evidence to the Penrose Inquiry on a meeting of haemophilia patients in Edinburgh on 19 December 1984 (PRSE0000444 and PRSE0006040 pages 81-110).

a. Do you stand by the evidence that you gave Lord Penrose on this issue? Is there anything that you now wish to add to that evidence? You may wish to consider the article in the Edinburgh Evening News you referred to during the course of your evidence (PRSE0004528).

387. I stand by my evidence to Lord Penrose. It will be clear from the transcripts that I remembered little detail about this meeting

b. **In describing your reaction to the news that patients who appeared to have only been treated with SNBTS factor VIII had HTLV-III antibodies, you stated: "*I cannot remember but I'm sure it would have been of surprise because we certainly did not really anticipate that this would happen so soon*" (PRSE0006040 page 82). Please provide further detail on what you meant by this. Why did you not anticipate this development as "*soon*" as late 1984? When did you expect it to take place?**

388. I did not and do not remember my reaction to this news and I made that clear in my evidence to Lord Penrose. I knew that there was a risk that a patient would become infected before we could deploy a specific test for the virus. I had, however anticipated that only a very small number of our donors would prove to have the AIDS virus, [as was shown by the results when testing began] so it was not unreasonable to expect, or perhaps hope, that transmission would not have occurred so soon.

c. In his evidence to this Inquiry, Professor Ludlam described the 19 December 1984 meeting as having been precipitated by a reporter intending

to publish a story on HTLV-III infection amongst Edinburgh haemophiliacs (3 December 2020 transcript pages 89-92). Were you aware of this sequence of events at the time? As far as you can recall, did you discuss them with Dr Ludlam?

389. Dr Ludlam did tell me that a reporter from an Aberdeen paper had the story, I cannot say if this was before or after the meeting in question. I have no recollection of discussing this with Dr Ludlam.

d. Patients and family members were invited to the 19 December meeting by a letter dated 12 December 1984 from Dr Ludlam, which mentioned Dr Forbes but not you (PRSE0003264). Did you see this letter at the time? As far as you can recall, when were you asked to attend the meeting (for example, was it before or after 12 December)?

390. I do not recall ever having seen this letter before the Penrose Inquiry. I was definitely asked to attend this meeting, but I do not remember the date or time of the invitation or whether it was verbal or written.

e. Did you have concerns about the length of time between the discovery that Edinburgh patients had tested positive in late October/beginning November and the announcement at the 19 December 1984 meeting? Please provide reasons either way and explain, as far as you can recall, whether you discussed any concerns with Dr Ludlam or anyone else. Looking back now, do you consider that the time it took for patients to be informed that some of them had been exposed to HTLV-III was appropriate?

391. I cannot say that I remember my feelings at the time. Today it would be considered very important to ensure transparency by informing patients about their own results with a minimum of delay, so, by today's standards, the patients should have been informed of the results of their tests as soon as possible.

f. Did you then, and do you now, consider that the way in which patients were informed of this development was appropriate?

392. I cannot say that I remember my feelings at the time although The meeting was held in the large Surgical lecture theatre of the Royal Infirmary, deigned to accommodate a whole year's class of medical students [perhaps 150 people] to receive traditional, didactic teaching. Those who spoke to the patients did so from behind the wide lecturer's desk on a raised platform. It was cold, on a dismal winter evening. I do remember feeling that this environment must be very daunting for the patients and relatives. I cannot in all honesty remember more about my feelings about nature and conduct of the meeting. The way to share information of such grave importance to the patients. Today, it would be expected that each patient should be given information about their results with a minimum of delay.

g. Did you have any involvement in or knowledge of the process, following the 19 December 1984 meeting, of informing individual patients who had tested positive for HTLV-III and inviting others to be tested?

393. I have no memory of having any involvement in this, and I would not have expected to be involved as these were all Dr Ludlam's patients and took very seriously his responsibility for all communications with his patients

Introduction of HTLV-III screening

155. You gave written and oral evidence to the Penrose Inquiry on the introduction of HTLV-III screening (PRSE0003157 and PRSE0006050). Do you stand by your evidence on this issue? Is there anything you now wish to add to it?

394. I stand by my evidence and have nothing that I wish to add.

156. Please describe your involvement in the development of a screening test UK-wide, across Scotland and within SEBTS in 1984. As well as your evidence to

Lord Penrose, you may wish to consider the following documents: 3 July 1984 letter from Dr Gunson to Dr Smithies (PRSE0003901); 7 August 1984 letter from you to Dr Cash (PRSE0002151); paper on the arrangements for the collection and testing of blood donations (CBLA0001934_003); your notes of a 27 November 1984 Advisory Group on AIDS meeting (PRSE0004191); minutes of an 11 December 1984 meeting of SNBTS directors (PRSE0001767).

395. For clarity I should say that I had no personal involvement in the development of any of the screening tests for HIV. I stand by my evidence to Lord Penrose. The best answer that I can offer to this question and to question 157 is to refer to my written and oral evidence to the Penrose Inquiry [Thursday September 29, 2011 PRSE0006050 and PRSE0003157].

157. Please answer the same question with respect to 1985, as well as address the questions below. You may be assisted by the following documents: 8 January 1985 letter from you to the Wellcome Foundation (PRSE0000750); minutes of the 29 January 1985 EAGA meeting (PRSE0002734); Dr Covell's note of the 29 January 1985 meeting (PRSE0003641); minutes of 15 February 1985 meeting of EAGA screening test sub-group (DHSC0000425); minutes of 1 March 1985 meeting of EAGA screening test sub-group (DHSC0000421); your 15 May 1985 paper on issues for RTDs to consider (PRSE0003014); 11 July 1985 report from the Regional Transfusion Directors' Committee working party (DHSC0000406); corrigendum to the working party report (PRSE0002402); 2 August 1985 letter from Dr Cash to RTDs (PRSE0000228); minutes of 19 August 1985 SEBTS meeting on preparation for the introduction of screening (PRSE0003243); 3 July 1985 letter from Dr Smithies to Dr Cash (PRSE0000310); July 1985 letter from Dr Cash to Dr McIntyre (PRSE0004362); 6 August 1985 letter from Dr Cash to Professors Timbury and Collee (PRSE0000916); minutes of 27 August 1985 reference laboratories meeting (PRSE0004844); September 1985 DHSS evaluation report (PRSE0004604).

a. **In your 8 January 1985 letter, you explained that the SEBTS would be "*very prepared to use, in the interim, some form of test procedure which might be***

***considered less than satisfactory for a large scale, long term screening programme*". Please explain the reasoning behind this position. Was such an approach ever discussed at SNBTS or UK levels? Did the SEBTS ever introduce any form of interim screening test? If not, why not?**

396. I think it is clear from this letter that I was looking for a solution that would allow us to begin to respond to what I believed was an urgent need, by using a procedure that would at least reduce the risk to patients until a definitive test could be obtained. The following is quoted from my January 1985 letter to the Wellcome Foundation:

"In the absence of Dr John Cash who is presently on sick leave, I am writing to you on behalf of the Regional Transfusion Directors in Scotland to ask if you are in a position to give any encouragement about the likely availability of some form of HIV antibody test in the near future. This has been a matter of great concern to us, as to all transfusion people, since the significance of positive antibody testing began to emerge almost a year ago. We were very encouraged by the news that a viral isolate and cell culture system suitable for the production of antigen for assay development had been produced in the UK. This led to optimism that some form of antibody screening test would be available in the fairly near future."

397. After I had been told that no test reagent material would be available from Professor Weiss's lab, I was pursuing Wellcome to see if there was any way that we could obtain the reagents to make the earliest possible start with testing our donors, or if need be a small subset, for anti HIV/LAV. A further extract from my letter follows:

"I would emphasise that in my own Centre at least, we would be very prepared to use, in the interim, some form of test procedure which might be considered less than satisfactory for a large scale, long term screening programme."

398. I believe the wording of my letter makes clear my opinion that we could, and should explore options that might offer any improvement in safety for at least

some patients [for example the very young or pregnant mothers]. I felt that this could well be achieved by using a test that had not yet been through the full process of development and evaluation leading up to routine large scale production, but that had been shown to be effective in detecting HIV antibody. Such a test could hopefully detect some potentially infectious donors, even if sensitivity was less than would be anticipated in a fully developed test procedure.

b. **The above letter also enquires about the likely availability of a test "*in the near future*" and refers to your concern about "*the apparent lack of progress*" being made. Was a letter received from Wellcome addressing this point and your concerns? Were any similar letters sent to other HTLV-III screening kit manufacturers? If not, why was the decision made to contact Wellcome over other screening kit manufacturers?**

399. I am sure that Wellcome would have replied but I don't now recall what, if anything was said. I have not seen any reply. The reason I would have approached Wellcome was because I knew that they had access to the essential virus material, and also that as a UK firm, they might be more responsive to needs in the UK. There was, as I recall, frequent SNBTS contact with the other potential suppliers. I cannot remember writing a similar letter to any other suppliers.

c. At the 29 January 1985 EAGA meeting, different views were expressed by Dr Gunson and Professor Zuckerman on the merits of radioimmunoassay and ELISA tests. So far as you can recall, what were your views on this issue at the time?

400. I had and have no claim to be an expert in the fine details of these two techniques, but I can say with confidence that I would have wished to minimise the use of radioisotopes in our laboratories for health and safety reasons so I would have favoured the non-radioactive ELISA methodology, provided it could be shown to have an equivalent performance to radioimmunoassay [RIA]

d. At the 1 March 1985 screening test sub-group meeting, it was decided that the field evaluation you and Dr Gunson had proposed would not require participants' consent because sera would not be identifiable with donors. Please explain further why this was approach taken. What was your position on the concerns relating to consent raised by Dr Pinching at the meeting?

401. I do not remember this particular discussion, but I have reviewed the minute [DHSC0000421] and noted Dr Pinching's comment. I do remember that there was a very active debate about the use of anonymised samples, informing patients or donors and obtaining their consent , I believe at both EAGA and MSBT.

402. I have not seen the proposal referred to in DHSC0000421 and I do not remember if it included the arguments in favour of using anonymised samples. This was a method that was used quite widely at the time in epidemiological studies and may still be used.

I remember that concerns were expressed about this on more than one occasion by Dr Pinching and other clinicians. In the study proposal prepared by Dr Gunson and myself this method was probably proposed because of concerns about alarming donors by providing information about AIDS at a time when there was little or no effective treatment available. There would also have been difficulties in securing confidentiality of the subject's data if each individual's sample had been identifiable, since the study required each sample to be tested in different sites.

403. I do not remember my views on this at the time. I am sure that I was sensitive to the need for patients to be informed about their treatment. However, I have a clear recollection of some very brisk discussions at EAGA and/or MSBT about the issue of informing patients about the intention to perform tests on their blood, including the use of blood samples that may have been stored some time ago after being taken for a different test. My recollection is that it was not unusual during the 70's and 80's and earlier for this to be done without consent. I think one could fairly go as far as to say that it was not considered in any way

exceptional for stored samples to be used in this way without consent. It seems evident from the study plan prepared by Dr Gunson and myself that I was prepared at that time to propose a plan that required anonymisation. I think it is probable that I felt at the time that the most urgent priority was to do whatever was necessary to expedite the start of AIDS testing of donors.

158. The Inquiry understands that HTLV-III screening was to commence on 14 October 1985. Your evidence to the Penrose Inquiry was that the SEBTS (as with the wider SNBTS) began testing before 14 October 1985, so that all blood in stock would be tested by then (PRSE0003157, pages 17-18, and PRSE0006050, pages 51-52).

a. Please explain the reasoning behind this approach. Was it discussed at a UK level?

404. We did this so that all patients needing a transfusion would start to receive AIDS-tested blood and components at the earliest possible date. By testing all the blood stocks, including those recalled from outside the RTC, we were able to ensure that all blood that was issued on or after October 14 1985 had been tested and shown not to contain evidence of HIV/LAV.

405. The following passage from Reference PRSE0004085 seems to confirm that this was policy across the UK:

406. "*I have a note on my desk with a message from you indicating that DHSS have now instructed RTCs to HTLV-III antibody test all existing stocks of products. The position in the SNBTS is as follows: (a) All stocks of products hold at RTCs were tested prior to 14th October 1985 deadline.*"

b. Please describe how the arrangements worked in practice. In particular, what did the SEBTS do with positive donations? Were donors whose blood had tested positive informed prior to 14 October 1985?

407. From the start of testing, all donations that tested positive on the initial screening test were discarded. I believe this was the practice in all RTCs in the UK. I do not remember what was done about informing donors who had an initial positive AIDS screening test result before October 14th 1985. Please refer to my answer to question **158,** where I have tried to explain the dilemma about information for donors with positive initial screening test results.

c. You informed the Penrose Inquiry of your belief that, as with Newcastle in England, a centre/centres in Scotland introduced screening ahead of others (PRSE0006050 page 55). As far as you are able to, please provide further details.

408. My recollection is that when Dr Lloyd announced the start of testing in Newcastle there was some embarrassment that the plan for a uniform implementation date had been breached. It was decided [I assume, by the NBS and SNBTS National Directors] that there should be further "National Evaluation" of the HIV test[s] and that one English centre [Newcastle] and one in Scotland should carry this out. Glasgow was selected as the Scottish evaluation centre because it had the most experience in evaluation of tests of this type. In effect, Glasgow commenced routine testing fairly soon after Newcastle, as the Evaluation involved the testing of all donor samples.

159. Please describe the practical implementation of HTLV-III screening at the SEBTS.

409. This is a very broad question. I cannot give a complete answer within the given time frame, but I have tried to provide concise responses to the sub questions.

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

410. Starting in June 1983, donors were given written information about AIDS to help those potentially at risk to identify themselves and avoid donation. This

written material was updated quite frequently in the light of new information. Later, new and more demanding questionnaires were introduced, signed statements were required at each donation and we commenced face to face interviews for every donor attending at which donors were asked direct questions about behaviours that could put them at risk of AIDS.

411. From October 1985 onwards, all donations were tested for the presence of HIV antibody.

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

412. The purpose of starting testing some weeks before the official start date was to ensure that all blood components in stock on or after the official start date all would have been tested.

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

413. As the following is taken from memory, I recognise that there may be documents that might require me to reconsider parts of this statement.
Before the start of testing I prepared a brief for the relevant staff in SEBTS [PRSE0003243] covering all aspects of the testing start-up including procedures for the handling of donations that gave a positive result on initial screening test. These procedures evolved with time, experience and with developments in the IT system that in particular assisted in maintaining confidentiality of the donation testing results.

414. Broadly, if the first test on a sample of a donation gave a result that was not unequivocally negative, the donation would be placed in the category "Initial Screen Positive" [ISP]. This would initiate further testing with one or more

additional methods until a decision could be reached as to whether the sample was definitely confirmed positive, or was false positive.

Regardless of this conclusion, it was the policy that further donations from these donors would not be transfused. If the result was definitely positive, the donor would be contacted as described below. If the result was false positive, the donor would not be informed. This meant that the donor would continue to donate but the donations would be discarded.

415. A donor with a confirmed positive HIV test would be contacted by the donor medical staff and asked to attend the Blood Donor Centre in Edinburgh for a confidential interview. Dr Gillon usually conducted these interviews. The donor would be informed of the test result. The donor would be asked if they would give their permission for their own GP to be informed. They would be offered counselling which I believe was normally given by Dr Gillon or Dr Davidson, both of whom had attended AIDS counselling courses at St Mary's Hospital in London. I believe these courses had been organised by Dr Anthony Pinching. A senior SEBTS doctor would review the records of any previous donations by the donor concerned and arrange for testing of stored archive serum samples for any evidence of HIV.

416. If one or more positive donations was found, the donor Consultant would then make every effort to trace the recipients of any components of each positive donation. He would make arrangements with the doctor responsible for the transfusion so that the patient would be informed that they had received a potentially infectious transfusion and invited to have a blood sample taken for testing. If there were several archive samples from the donor, they would all be tested to identify if there was a date before which the donor's samples tested negative for HIV antibody.

417. This lookback procedure was based on that used in the USA.

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

Financial impact:

418. My recollection is that the additional costs of HIV screening were met by an increase in recurrent funding from the Common Services Agency of the Scottish Health Service.

Impact on those working at SEBTS

419. Although I do not have any specific memory of this, I think it is probable that for some staff, concern about the risk of being infected with HIV infection would have been a cause of stress. Testing created a significant new workload, for the donor service, the virology laboratory, and the quality assurance and IT staff. There may have been requests for funding for additional staff.

Impact on the risk of HIV Transmission by donated blood.

420. Screening for HIV has been very effective. The following extracts from the UK handbook of transfusion medicine [5th edition 2013] gives a summary.

Table 5.3 **Estimated risk per million blood donations** of hepatitis B virus, hepatitis C virus and HIV entering the blood supply due to the window period of tests in use, UK **2010–2012** (data and information collected by the NHSBT/Public Health England Epidemiology Unit)

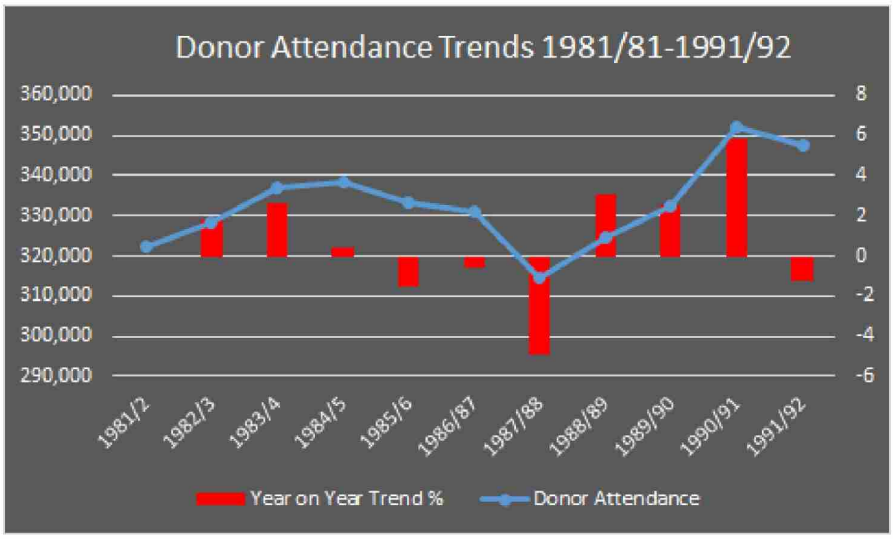
	Hepatitis B virus	Hepatitis C virus	**HIV**
All donations	0.79	0.035	**0.14**
Donation from repeat donors	0.65	0.025	**0.14**
Donations from new donors	2.23	0.133	**0.18**

Table 5.4 **Confirmed viral transfusion-transmitted infections**, number of infected recipients and outcomes reported to UK Blood Services **1996–2012** (extracted from SHOT Annual Report 2012)

Infection	No. of incidents	No. of infected recipients	Deaths related to infection	Major morbidity	Minor morbidity
Hepatitis A	3	3	0	2	1
Hepatitis B	11	13	0	13	0
Hepatitis C	2	2	0	2	0
Hepatitis E	2	3	0	1	2
HIV	**2**	**4**	**0**	**4**	**0**
HTLV	2	2	0	2	0
Parvovirus B19	1	1	0	1	0

Impact on Donor Attendance

421. The figure below illustrates the fall in SNBTS donor attendance as public awareness of AIDS increased. This was successfully reversed. This followed some time after the start of donor HIV testing and may well have been due in part to increasing public awareness of AIDS. SNBTS increased the scope [and costs] of its donor publicity, making more use of television, radio, and later the social media, and restored donor attendances to pre-AIDS levels by the early 1990's.



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5.3.1.5: Human immunodeficiency virus (HIV) 1 and 2

422. *"Transfusion transmission by both single-donor and pooled blood components was common early in the course of the 1980s epidemic of acquired immunodeficiency syndrome (AIDS). Modern donor selection and screening has made transmission a rare event in the UK. The two incidents identified since SHOT reporting began (1996 and 2003) were both* ***from HIV antibody negative window period donations*** *before the introduction of HIV RNA screening."*

160. Did you have any concerns, during 1984-1985, about the length of time it was taking to introduce HTLV-III screening of blood donations? Were you ever in favour of taking a different approach, whether at a UK, SNBTS or SEBTS level, to the one that was adopted? Please provide details if so. Looking back now, do you believe that there were any ways in which this issue should have been approached differently?

423. My letter to Wellcome on January 8th 1985 [PRSE0000750] indicates clearly that I was by then concerned by our inability to test donations, even to the extent of being prepared to use a less than ideal test. In the period before any HIV testing was possible, there had been a number of communications suggesting trial of other methods that might help detect the presymptomatic stage of AIDS. My Consultant Immunologist colleague, Dr Peng Lee Yap, had searched for any evidence that a non-specific or "surrogate" test could have any value and

concluded that there were no suitable candidate tests. A contemporary review cited below reached a similar conclusion.

"Surrogate tests for AIDS are nonspecific and unlikely to be helpful in screening blood donor units". A pilot study of surrogate tests to prevent transmission of acquired immune deficiency syndrome by transfusion T. L. Simon MD,A. D. Bankhurst,**https://doi.org/10.1046/j.1537-2995.1984.24585017822.x** (Exhibited as number PRSE0004694)

424. We concluded that it would not be useful to direct effort into evaluating these. Tests as the available evidence seemed to suggest that they were ineffective.

Were you ever in favour of taking a different approach, whether at a UK, SNBTS or SEBTS level, to the one that was adopted? Please provide details if so.

425. I am not certain what is meant by "a different approach". Assuming this relates to possible ways of reducing the risk of transfusion transmitted HIV to patient before a specific AIDS test was available, I felt it was correct to explore other options of testing, even if they could be less than ideal

My conclusion was that none of the so-called surrogate or non-specific tests for HIV were likely to offer any gain in the safety of blood.

Looking back now, do you believe that there were any ways in which this issue should have been approached differently?

426. Apart from starting testing earlier, I do not know how laboratory testing to reduce risks of AIDS being transmitted could have been approached in a different way that would have led to better outcomes.

161. In a letter dated 11 June 1990, Dr Boulton wrote to you expressing concerns regarding false positive HIV results and donor deferrals. In this letter he stated: "*The main issue is that of donors who have been found to be repeatedly equivocal on various confirmatory tests on the HIV system. There is absolutely no evidence that these people are at risk of contracting AIDS or passing HIV onto any recipients of their blood; and yet they are excluded from donating on the grounds*

***of what is almost certainly an artifactual technicality.*" In the same document, Dr Boulton went on to give an example of a man in his thirties who after receiving one false positive HIV test was prevented from giving blood. (SBTS0000632_170).**

a. As far as you can recall, what were your views on Dr Boulton's concerns at this time?

427. I do not remember my views on this particular letter but I was very well aware of the problem of donors being disqualified because of test results that were not unequivocally negative but were, in all probability, false positives. This is a problem that arises with all screening procedures and was certainly a problem with HIV antibody tests, although it diminished as the specificity of the tests improved over time.

Reading the letter now, it is evident that it contains assertions that are not correct: these are:

"There is absolutely no evidence that these people are at risk of contracting AIDS or passing HIV onto any recipients of their blood"

This is simply not proven and reminds one of the expression "the absence of evidence is not equivalent to evidence of absence"

"...what is almost certainly an artifactual technicality"

This could well have been true of some of the equivocal test results but it did not constitute a reason for ignoring the results.

b. How common were occurrences such as these? Did issues with false positive results affect the SNBTS's ability to meet donation targets and ensure sufficient supplies of blood and blood products?

428. I do not have access to data about the numbers of donors who were excluded because of equivocal results. The frequency of "false positive" donations that cause this problem was and still is governed by the specificity of the testing system. Although I do not have data on this, I know that both specificity and sensitivity of HIV tests have continued to improve.

I do not remember that false positive results caused problems with the SEBTS's ability to provide sufficient supplies of blood and blood components. I do not know if false positive results had an impact on the supply of plasma for the production of fractionated blood products.

c. Were changes in testing implemented to prevent the deferral of donors with false positive results?

429. There was a constant effort by the manufacturers to improve the specificity of the screening tests and the confirmatory procedures. Testing for HIV antibody would have been performed in SEBTS according to the procedures specified by the test manufacturers, so there would have been detailed changes from time to time in the prescribed laboratory procedures. There was frequent dialogue with the test manufacturers in which the need to minimise the number of false positives often figured, and there was progressive improvement in both the sensitivity and the specificity of the tests. These were the only ways in which the deferral of donors due to false positive results could be reduced.

162. On 12 August 1987, you wrote to Dr Cash regarding a letter you received from Dr Gunson about monitoring HIV-2 in blood donors (SBTS0000177_122). You stated: "*what was agreed was that 5 Centres (including Edinburgh) would for a pilot period send samples from these "African contact" donors to the PHLS as a simple form of HIV-2 surveillance.*"

a. **Please explain the background to this decision**.

430. The reason for the survey referred to was to determine the prevalence of HIV2 in UK donors who fell into the group that was designated "Africa contact". I cannot recall any further details of this. During my tenure, HIV 2 testing was not introduced, but for some years [I do not have the dates] the manufacturers have supplied tests that detect antibodies to both HIV1 and HIV 2.

431. Current UK standards require the use of a combined HIV 1 and HIV 2 test.

The background is summarised in this 1989 abstract [reference below]"HIV-2 is found in West Africa, Brazil and Europe. The total number of infected people known in Europe is 219. HIV-2 will spread further in Europe, but the rate of increase cannot be predicted. For the screening of blood donations assays detecting both HIV's (1 and 2) are soon available. With regards to the presence of retroviruses, blood donations in Central Europe have yielded a very high degree of safety. "

432. The significance of HTLV-1 and HIV-2 for transfusion medicine in Europe] L Gürtler et al PMID: **2481545]" (WITN6666020)**

b. **In your view, was this form of surveillance effective at reducing the risk of infected donors donating blood**?

433. I am not entirely clear what is meant by "this form of surveillance." In general terms, surveillance is one essential way of detecting the appearance of a previously unrecognised infection in a population, or of a change in the numbers of infected individuals. If the question refers to testing for HIV 2, It appears that there have been no transmission episodes recorded. I do not have data on the number of confirmed positive HIV2 tests.

c. Were similar forms of surveillance used for other transfusion-transmitted infections?

434. As other infectious agents have emerged as having potential importance for transfusion safety, a variety of measures would be taken to assess their potential impact on patient safety. It was the task of the Specialist Advisory Committee on Transfusion Transmissible Infections [SACTTI] to keep this area under review and recommend appropriate studies and, if necessary, changes in procedures. It appears that the Joint NHS Blood and Transplant (NHSBT) / Public Health England (PHE) Epidemiology Unit has taken over the functions of SACTTI. This unit is described thus:

Taken from the website listed below this paragraph

"It [the Joint Epidemiology Unit] comprises a small team of epidemiologists and public health specialists working with scientific and clinical colleagues across both NHSBT and PHE. The unit was established in 1995 to monitor infections in blood donors and transfusion recipients. Over time the role of the unit has expanded and it is now responsible for monitoring infections in blood, tissue and organ donors, and transfusion recipients. Data from the four UK blood services are collated and analysed by the unit to produce surveillance reports and inform/evaluate policy changes relating to infection risk.

435. Joint NHS Blood and Transplant (NHSBT) / Public Health England (PHE) Epidemiology Unit https://hospital.blood.co.uk/epidemiology-reports/

163. On 14 June 1988, you wrote a letter to Dr Harris regarding selective HIV-2 screening of blood donors (NHBT0003674). You stated: "*I can see a number of awkward problems developing rapidly if we persist with what appears to be mandatory testing.*" Please elaborate on your comments in this letter.

436. I was concerned that Dr Gunson had issued what appeared to be an instruction to start selective HIV2 testing. This could have led to an expansion of the problems associated with false positive results [see answer 161] and also the risk that plasma collected for fractionation might have to be destroyed unless individual donations could be identified and withdrawn, from donors found to be reactive in the HIV2 test.

My letter included the following passage:

"I can see a number of awkward problems developing rapidly we if persist with what appears to be mandatory HIV-2 testing. Not least of these is the possibility that one might be faced with decisions about a second stock-pile of plasma and product intermediates collected prior to the introduction of the new testing programme"[NHBT0003674]"

Surrogate testing

164. You gave written and oral evidence to the Penrose Inquiry on surrogate testing for NANB hepatitis (PRSE0003729, PRSE0002536, PRSE0006063 and PRSE0006064). Do you stand by the evidence you gave on this issue? Is there anything you now wish to add to it?

437. Generally, I stand by my evidence to Lord Penrose, but as mentioned in my answer to question **168**, some of the documents provided for this response have helped me to refresh my memory of the events around my proposals for a prospective study on transfusion associated NonA NonB hepatitis.

165. Whilst you were employed at the SEBTS, what was your opinion of surrogate testing as a potential method of donor screening, and how did this change over time? Please comment for each infection:

a. HIV; and,

b. NANB/HCV.

438. **HIV**: I concluded that surrogate testing for AIDS was unlikely to offer any safety benefit to patients and could cause the loss of many donations and expose them to the "False Positive" dilemma discussed in my answer to question 161.

439. **NANB /HCV hepatitis**: My position about surrogate testing was that it should be subject to a formal trial based on the methods and findings of the Transfusion Transmitted Virus Study in the United States. I pursued this line over a number of years, as described in my Penrose evidence. In PRSE0001444, which was written by me, I made a last attempt to argue for the introduction of surrogate testing. I stated that the time for a trial had passed. In view of the failure over several years to gain support for a trial designed to answer the important questions related to patient safety, I decided to try different lines of argument, based on medicolegal concerns, relative cost - effectiveness, and the fact that failure to test could influence clinicians to reject factor concentrates from the PFC and choose commercial concentrates that claimed greater safety in respect of virus transmission because of the use of surrogate testing.

166. The minutes of the 14 February 1980 meeting of the Working Party on Post-Transfusion Hepatitis record that "*work was proceeding at the South East Scotland BTC into the problem of non-A, non-B hepatitis associated with blood transfusion*" (MRCO0000029_003). As far as you can, please describe the nature of this work and its outcome.

440. As mentioned above in my answer to question **116,** Dr Robert Hopkins and his PhD student were attempting to identify a "marker" in blood that was strongly linked to Non A Non B hepatitis. Dr Hopkins also convened at least one international meeting to bring together information on NANBH and published the Proceedings in book form. He maintained contacts with other workers in the USA and elsewhere who were pursuing the same goal. None of the efforts to find specific markers for NANBH were successful. The ability to detect a new virus designated Hepatitis C Virus resulted from the work of Chu et al Kuo G, Choo QL, Alter HJ, Gitnick GL, Redeker AG, Purcell RH, et al. An assay for circulating antibodies to a major etiologic virus of human non-a, non-B hepatitis. Science. 1989;244:362–4 (WITN6666021)

167. On 25 June 1981, at the second meeting of the Working Party on Post-Transfusion Hepatitis, you tabled a protocol for a prospective study of blood transfusion associated hepatitis. Professor Zuckerman was opposed to this study as he believed it would be a repeat of the 1974 MRC study, Post-transfusion hepatitis in a London hospital (NHBT0000068_049). Yet in your evidence to the Penrose Inquiry, you stated that the 1974 MRC study "*didn't really tell us what we needed to know*" (PRSE0006063 page 71, lines 8-9).

a. What were your concerns about the 1974 MRC study?

441. I went into this at some length in my evidence to Lord Penrose. In PRSE0006063 Pages 2 -12 To avoid undue repetition I would ask that this be accepted as my response to this question.

b. Did you ever discuss these concerns with Professor Zuckerman or other members of the committee who were not in favour of your proposal?

c. If so, what were the results of these discussions?

442. I am fairly sure that I would have discussed it with members of that committee. I probably did not discuss it with Professor Zuckerman. I was very much junior to him, and evidently not a virologist. I imagine that I concluded that he was an unlikely source of support, since he had already dismissed the study I proposed as unnecessary.

443. My recollection of the flavour of the discussion is that there was concern that this would be a large and expensive study and that there was reluctance to make any decision about it in committee.

You may also wish to consider a 10 February 1981 letter from Dr Kellner of the New York Blood Center to you (PRSE0002555), as well as your proposal for the prospective study (PRSE0004584).

168. At the 27 September 1982 inaugural meeting of the UK Working Party on Transfusion Associated Hepatitis, you agreed to produce an outline protocol for one of two types of study into NANB hepatitis (CBLA0001625). At the second meeting, on 18 January 1983, you proposed a prospective study to investigate the possible value of one or more putative markers of NANB hepatitis for predicting transmission of the disease (NHBT0000023_002 and CBLA0001666). Your proposed study was discussed at the 20 April 1983 meeting (BPLL0009204_005) and was referred to in the agenda for the 27 September 1983 meeting (PRSE0003390), but does not appear in the minutes of that meeting (PRSE0001299). In your evidence to the Penrose Inquiry, you set out your understanding that the study did not in fact go ahead, and that this was (PRSE0006063 pages 81-93). Please expand upon why a focus on AIDS had this result. What, in your view, were its implications?

444. I think the extract from the transcript "*due to AIDS distracting the attention of the SNBTS and the blood service in England*" gives a fair impression of the

situation. By early 1983, it is entirely correct to say that I was becoming extremely occupied with developing the SEBTS response to the emerging information about AIDS. Despite several submissions to the hepatitis committee chaired by Dr Gunson, our proposal for a large study of NANB hepatitis had received no evidence of support from the MRC or the Departments of Health, and without that, it would not have been possible to undertake a study of the size required. I believe it was entirely correct to concentrate on AIDS at that time.

445. I am not clear what is being asked in the final sentence of Question 168. If it refers to the implications of having " a focus on AIDS " This was entirely true. We were concentrating on devising and implementing the best response that we could to reduce the risk of blood transfusions transmitting AIDS. I would say that this was entirely necessary, and the result was that in SEBTS we moved rapidly to take action to protect patients from risk.

169. **In a journal article from 1983, you recommended that there should be a thorough prospective study to determine the frequency with which post transfusion hepatitis occurred. You also commented that without undertaking such a study, the "*potential and actual scale of the 'benefit' side of the cost benefit calculation*" would be unknown and no decisions could be taken (PRSE0002815 page 10).**

a. Was this study different to that you proposed to the UK Working Party on Transfusion-Associated Hepatitis?

446. This suggested a study along the lines I had proposed before but with the addition of a health economic assessment

b. Was any such study conducted?

447. As far as I know, the closest approximation was the 1995 study of *[Blajchman, M., Bull, S. and Feinman, S., C.P.-T.H.P.S. (1995) Group*

Post-Transfusion Hepatitis: Impact of Non-a, Non-b Hepatitis Surrogate Tests. The Lancet, 345, 21-25.

http://dx.doi.org/10.1016/S0140-6736(95)91153-7

I have already discussed this study (PRSE0004703)

c. If so, what did it demonstrate, and what impact did it have on decisions around the potential introduction of surrogate testing?

448. The Blajchman et al study , in the authors' words, "... indicates that screening of blood donors with the NANB surrogate markers was of value in reducing HCV infection *before* HCV screening began, but subsequently the value of screening cannot be clearly established."

I think it is unlikely that the findings of this study would have provided any encouragement to commence testing donors with surrogate markers for NANB hepatitis, since by 1995 when it was published, specific testing for HCV was well established. As I understand it, this study concluded that surrogate tests may have offered some gain in safety. However, it is a complicated paper, and there may well be other interpretations of its findings that I am not aware of.

170. At the 20 April 1983 meeting of the UK Working Party on Transfusion-Associated Hepatitis, the "*problem of Edinburgh's likely low incidence of non A non B hepatitis numbers was raised*" (BPLL0009204_005). What were the reasons for and implications of Edinburgh's likely low incidence of NANB hepatitis? Why was it a problem?

449. The reason for the concern regarding the low incidence of NANB hepatitis in Edinburgh was that Edinburgh might have so few cases that it would take a long time to recruit a large number of subjects to collect information on a sufficient number of transmission events. For this reason, a second site at North London was proposed, where it was supposed that there would be more donors with NANB hepatitis. The short answer is that it was not a problem.

171. The minutes of the 25 March 1986 meeting of SNBTS directors record that "*certain clinicians and haematologists in this country had felt that the Transfusion Services had been slow to commence AIDS antibody testing and others had similar views in relation to non-A non-B hepatitis surrogate tests*" (ARCH0002254 page 8). What were your views on these issues at the time? As far as you can, please explain the references in the minutes to the provision of data on raised ALT levels and to an ethics committee proposal (and clarify whether the minutes in this passage refer to you or to Dr W M McClelland).

450. I have stated in responding to earlier questions that I was very exercised by the failure to obtain the evidence that would have established whether or not surrogate testing was likely to achieve a gain in patient safety and that I was also concerned about the slow introduction of HIV testing.

As far as you can, please explain the references in the minutes to the provision of data on raised ALT levels and to an ethics committee proposal

451. I believe that this refers to the study that is mentioned in my answer to question 172 relating to a 1986 ethics committee for a study later published by Drs Beckett and Gillon.

172. In 1986, you put forward a proposal with Dr Beckett and Dr Gilligan for a prospective study of blood donors with abnormal liver function tests possibly indicating carriage of NANB hepatitis (PRSE0001305). Please explain:

a. Whether this study went ahead.

b. If so, in what form and what were its findings?

c. Did any findings from the study impact your understanding and/or the SNBTS's understanding of NANB hepatitis?

452. I think one of the authors was Gillon, not Gilligan. My only recollection is that eventually I did not contribute to the work of the study and as a result asked for my name not to be included as an author. I think that the study did take place, I

would assume essentially as described in PRSE0001305. I have so far been unable to locate the publication and I do not remember what the study found.

173. In a letter from you to Dr Gillon dated 26 August 1986, you discussed developing a policy in relation to donor testing for non A non B hepatitis. You stated: "*We concluded that it would be very desirable to look very seriously at recipient follow-up studies, not least because all the American data is now quite old and precedes by a long time the introduction of HTLV-III testing*" (SBTS0000177_023). Please explain what you meant by this statement.

453. This correspondence reflects the uncertainty around this time within SNBTS about what, if anything we should do about surrogate testing. The "we" referred to above was, I think, intended to apply to those present at "last week's meeting" of the SNBTS Directors. I was uncertain myself about the correct course of action.. [see my answer to question **174]** I wrote this following the Director's meeting at which surrogate testing had been discussed. I agreed to discuss this again with Dr Gillon, and relayed the main message from the Directors to him in this letter. These are extracts from my memo to Dr Gillon, SBTS0000177_023.

" At last weeks meeting of the Directors, there was further discussion about how we develop a policy in relation to donor testing for Non A Non B Hepatitis (ALT, core)."

My handwritten note on the letter indicates that I felt that the moment for this study had passed.

The same letter stated that not long before this was written, Dr Gillon and I had decided that the time for this study had probably passed.

"Some months ago, we [JG and myself] *had concluded that although it might be desirable to do recipient follow up studies along the lines of the TTV study, we probably did not have the resources or energy for this and also that it was unlikely that we would get data which add very much to our present knowledge."* The handwritten note beside my signature reads *"personally I remain very doubtful about the value of a repeat TTV"*

174. In 1986, you wrote a letter to Dr Boulton and others at the SEBTS about the agreed points from the November meeting of the UK Directors Working Party, which discussed the possibility of introducing screening to reduce post-transfusion NANB (SBTS0000370_068).

454. Perhaps I have misunderstood the question, but I did not read this note to indicate that the discussion was about introducing screening to reduce post-transfusion NANB hepatitis. Point 1 of the note reads as follows.

"AGREED: *-i. Screening should not be introduced at present especially • in view of ARC postponement of core test start-up and reports of chaos in ALT screening programme."*

What was your view on the American Red Cross' introduction of surrogate testing at that time?

455. At this date, I believe the American Red Cross [ARC] had not fully implemented surrogate testing due to problems in the early use of the tests. My view, when surrogate testing was implemented, [and I think became an FDA requirement], was that this was not really based on the data from the TTV study, which although very important, had not provided proof of the likely effectiveness of the screening programme – proof that could only have been established by a prospective study. My feeling was that this was, to a large extent, motivated by concerns that there could in the future be claims that individuals had been harmed as a result of the absence of surrogate testing. This seemed to me to be an issue that SNBTS would need to consider.

I do not remember if I had an opinion about The ARC introduction of surrogate testing but I recall that I had read, or heard from colleagues, that there were quite serious teething problems. I think that among these were the need for decisions about future donations, and about information to be given to donors whose blood had been rejected on the basis of surrogate test results. The quotation above refers to the problems being experienced by the US transfusion services.

Do you recall your opinion on this decision to implement the limited study and its findings? You may also wish to consider your notes of the 24 November 1986 meeting (PRSE0001164), as well as Dr Forrester's (PRSE0003801).

456. I do not have a clear recollection and I regret that cannot extract any useful information from my notes [PRSE0003801] I had not read Dr Forrester's account of the 26th November 1986 meeting until I was preparing for the Penrose Inquiry I agree now with Dr Forrester's characterisation of the proposed study as "*research of no great significance or scientific interest*"

175. At an SNBTS Directors meeting on 3 March 1987, you were amongst the Directors that agreed to "*recommend to the SHHD that surrogate testing for NANB should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding. Each Director should let Dr Cash know what funds would be required in his/her region, assuming that both core testing and ALT would be undertaken in the Transfusion Centres*" (PRSE0004163).

Please expand on the following:

a. **Whether surrogate testing (namely ALT or anti-HBc testing) was introduced at the SEBTS during your tenure;**

457. Surrogate testing was not introduced during my tenure. I have therefore not offered any responses to the following questions b to f.

b. **If so, whether this had any impact on the SEBTS;**
c. **How the surrogate testing was performed;**
d. **What the process was for screening donors and/or blood donations;**
e. **What, if anything, happened to the unscreened blood that had been collected prior to surrogate testing being implemented; and**
f. **What happened when a donation tested positive. Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.**

You may also wish to consider correspondence between you and Dr Cash in March-April 1987 (PRSE0003742 and PRSE0000386), minutes of the 10 June 1987 SNBTS directors' meeting (PRSE0000633), minutes of the 16 June 1987 SNBTS Co-Ordinating Group (PRSE0001527) and the minutes of 5 May 1988 SNBTS and haemophilia directors' meeting (SBTS0000832).

176. In a letter to the editor of the Lancet dated 15 June 1987, you and others requested that NANB hepatitis screening commence in the UK despite the Lancet's opinion that a prospective study should be taken first. Together, you wrote: "*we do not wish to challenge this scientific conclusion. It is agreed that the size of the benefit that will be gained from surrogate testing cannot be accurately established without a prospective study. However we do argue that the time for this study has now passed. Starting now will give us an answer in 3 to 4 years and that is probably 3 to 4 years too late. The introduction of surrogate marker testing for non-A non-B is now virtually inescapable*" (SBTS0000177_106). The letter was subsequently published, with minor revisions, on 4 July 1987 (PRSE0001444). Please expand on the view expressed in the letter, including the reasons why a prospective study was not conducted timeously.

458. I had for some time been pressing for a prospective study to determine the extent of transfusion related NANB hepatitis in the UK, modelled on the TTV study in the USA. I had failed to get support for that. By mid-1987 I knew that the USA had introduced surrogate testing on the basis - whether valid or not - that it could reduce the risk of NANB hepatitis in transfused patients. I felt that the UK transfusion services should be considering the risk that they would become vulnerable to challenge based not least on the opinions expressed by Mr Justice Krever and his interpretation of the precautionary principle as applied to blood transfusion.

459. The prospective study referred to was not carried out, as far as I can surmise, because it did not receive support from the experts who were influential in the

virology field at the time and, if it was ever submitted to MRC or DoH for funding, it received no support at that level

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

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

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

460. Although I have no clear recollection of reading this report at the time it was produced, I would probably have been aware of it. Reading it now, I think its conclusions are entirely reasonable.

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

461. This question lies at the core of the issues referred to above in my answer to question 175. The Council of Europe report shows very well the variability in the evidence provided from different countries. None of the reports cited showed unequivocal evidence of improvement in patient safety. All the studies showed that there would be a material loss in blood donations: in some areas this in itself could result in increased risks for patients. The inevitable false positive results would also lead to donors requiring to be informed and counselled that they could no longer give blood because they had "something in their blood to do with hepatitis." [or however it was to be expressed]. This raises another risk of harm, as it is not hard to imagine that this news would be very disturbing for some individuals.

462. On the basis of these considerations, I think that the working group's conclusions comply with the principle of "First, do no harm". I could not give an opinion on whether they are compatible with "Maximum Safety" unless the term can be given a very clear definition. According to Lord Justice Krever, the conclusion that no recommendation could be given would not be in keeping with the "public heath ethos". I do not know how this would be defined.

Introduction of anti-HCV screening

179. You gave written and oral evidence to the Penrose Inquiry on the introduction of HCV screening (PRSE0004442, PRSE0006068[pp146 -163] and PRSE0006069).

a. Do you stand by that evidence?

463. Yes, I stand by this evidence

b. Is there anything you now wish to add to it?

464. I do not wish to add to it.

c. **In your written statement, you wrote that you agreed that there were "*failings in the process leading up to the introduction of HCV Screening*" (PRSE0004442). Please describe those failings and explain what you consider their implications to have been.**

465. I have not sought out documentary evidence of the points made in this reply, but I trust that the record of my oral evidence to Lord Penrose and my written statement give a sense of why I said this. I would refer also to the evidence given by Dr Robert Perry. There was, initially at least, some confusion about which committee [ACTTD, ACVSB] had a policy role as opposed to a more operational one, which reported to the Departments of Health and which to the Transfusion Service.

466. There were, I believe, several factors that contributed to the delay in starting testing. One issue was a lack of clarity about how, and how much evaluation was required of the first candidate tests [from Ortho and Chiron] and some confusion about the apparent need for Ortho to have FDA approval before it could supply kits to the UK.

Another factor that may have contributed to the delay was the protracted debate among Virology experts about how confirmatory testing should be done.

One other, and possibly critical element of delay seems to have been due to funding issues between the Department of Health and the Regional Health Authorities, who at that time, I understood, were the funders for the NBTS Centres. This apparently delayed the start of testing by NBTS centres.

467. The situation was complicated by what I understood at the time was a decision that all transfusion centres in the UK should start testing on the same date. I remain unclear by whom and at what level this decision was taken. I could at the time understand the reason for it, but as my own responsibility was for the safety of patients receiving blood from the SEBTS, I did make the case for SNBTS centres to start HCV testing as soon as possible. The strength of opinion against this was shown by the reactions to Dr Huw Lloyd's decision to start testing donors in Newcastle before the "official" date.

180. On 15 April 1987, you wrote a letter to Dr Cash regarding your views on the introduction of NANB donation screening (PRSE0000386), in which you stated: "*the obvious difficulty is that on commercial competitive grounds we need to introduce [NANB] screening, but on scientific and value-for-money for the Health Service grounds we should be opposing it.*"

a. What did you mean by this? Please describe how you view changed between writing this letter and writing your letter to the Lancet in June 1987? (see question 141(b) above).

468. I think the reference to question 141 [b] may be incorrect. The reference seems to refer to question **176.**

The reference to commercial and competitive grounds" was intended to draw attention to" the fact that commercial suppliers of coagulation factors were using the fact that they were now applying surrogate tests as a marketing point – intended to show that their products were safer than those produced by the UK Transfusion Services.

The reference to scientific grounds refers to the lack of scientifically rigorous data on the effectiveness of these tests. The reference to value for money raises the point that it may not be the best use of NHS funds to deploy tests that are not of proven effectiveness.

469. I cannot agree that my view had changed between writing these two texts.

The Lancet letter [PRSE0001444, SBTS0000177_106] makes essentially the same point as my letter to Dr Cash

b. As far as you are aware, was this view consistent with those of your colleagues?

470. I really do not know if my director colleagues held a consistent view at this time.

They were signatories to the letter PRSE0001444, but had not long before sent a letter, also to the Lancet expressing an opposite view. I do not know the IBI reference to this letter.

181. In August 1989, you and others wrote a letter to the Lancet regarding Anti-Hepatitis Blood Transfusion Services Confirmatory Tests, in which you stated: "*The apparent absence of a confirmatory test will cause serious problems in the context of blood services who are likely to bear the brunt of sensitive donor counselling. A repeatedly Elisa test is suggested but not definitive evidence for the presence of an antibody. Whilst we accept that the existing difficulty (the use of the same antigen) is scientifically less than satisfactory, we would suggest it is better than nothing and would strongly advise that pressure be brought upon Ortho Diagnostic Systems to make available, as a matter of urgency, appropriate reagents and/or tests...*"(NHBT0000188_022). Please elaborate on this statement. Were your concerns resolved adequately prior to the introduction of anti-HCV screening in 1991?

471. This letter is a plea for Ortho to expedite provision of reagents for a confirmatory test.

To give some background, there are three different types of test that can provide evidence of infection with a virus, each of which detects a different property of the virus or of the host's response to it. These are:

- polymerase chain reaction [PCR] tests for the *genetic material [RNA or DNA*] of a virus,
- tests for *antibody to* the virus and
- tests for an *antigen* produced by the virus.

472. At the time of writing the letter referred to, the only options available for a second test were based on the detection of antibody to the virus so there was a risk that there could still be a false positive result with a "confirmatory" test for

antibody. The PCR test not only detects a different property of the virus but is also much more sensitive. It is now used routinely as a confirmatory test by UK transfusion services.

473. PCR testing for hepatitis C was not generally available when transfusion services began HCV testing, but it was possible to gain more confidence in an initial test result by retesting using a different type of antibody test such as the Western Blot or a procedure called RIBA [recombinant immunoblot assay] This was the method chosen by Abbot labs to market as a confirmatory test. The above letter, as far as I recall, reflects the delays in this becoming available to the transfusion services.

182. In February 1990, you were copied into a letter from Dr Boulton to Professor Cash in which he stated that he had "*developed a very strong feeling that the screening of donors for HCV antibodies should be introduced at the earliest possible opportunity.*" Dr Boulton went on to state that his view was "*actually one based on the risk of future litigation*" (PRSE0001562).

a. Did you agree with this view at the time?

474. Yes, I shared his concern about this.

b. How did your view on this issue develop from 1990 to 1991? over that period

475. I remained concerned about this.

c. Was the risk of future litigation a driving consideration in the SNBTS' introduction of HCV screening?

476. I do not believe that risk of future litigation was a "driving" or even a major consideration. I am quite confident that the most important consideration for starting Hepatitis C screening was the desire to make blood safer for patients. We

were of course very concerned about delays in starting testing: it was our responsibility to ensure that blood for transfusion was safe. However, I also have little doubt that my colleagues were aware that litigation could result from avoidable delays in testing

183. On 2 May 1991, Dr Lloyd, director of the Newcastle RTC, wrote to all transfusion service directors to announce that Newcastle intended to begin HCV screening on 1 July 1991, the date previously set, rather than on a new provisional date of September 1991 (NHBT0000074_014).

What was your reaction to receiving this letter?
Did you discuss it with other members of the SNBTS?
Did you ever consider introducing testing earlier than the postponed start date?
You may also wish to consider letters from ProfessorCash to Dr Lloyd, referred to during your evidence to the Penrose Inquiry (NHBT0000074_019 and PRSE0002997).

477. I would probably have seen this letter at a meeting of SNBTS directors, or possibly I received a copy from Dr Cash. I do remember this correspondence. And I am sure that I would have discussed it with colleagues. I respected Dr Lloyd's decision. I was sure that it was motivated by a sense of his duty to improve the safety of the blood supply for which he held responsibility. I was dismayed by Dr Cash's letter to Dr Lloyd, I do not have a definite memory of discussing this letter with colleagues, but I think it is very likely that I did so.

Did you ever consider introducing testing earlier than the postponed start date?

478. Yes. I considered this and I am sure discussed it with Consultant colleagues in SEBTS. My decision not to proceed was largely because I did not have any funding approved for the purchase of HCV tests. Had I attempted to start testing before the agreed date without funding approval and against the declared policy of the National Director. NOT RELEVANT would, I believe, have been quickly forced to stop by lack of finance. NOT RELEVANT

NOT RELEVANT

NOT RELEVANT

184. In a letter to Dr Cash dated 11 June 1991 (PRSE0001759), you proposed that hepatitis C testing be discussed in a forthcoming Board Meeting. You stated: "*The recent newspaper and television attention has emphasised the importance of being able to make enhancive and positive statements about the completeness of the safety testing carried out on blood donations; the fact that some Centres are carrying out testing... leaves us in a very exposed position.*" Please explain what you meant by this statement.
As far as you know, did other consultants and directors within the SNBTS agree or disagree with your view at the time?

479. I must say first that the word "enhancive" must be an unnoticed typo. I don't remember what was intended.

480. I have only a vague recollection of the meeting at which this letter was discussed but I find it difficult to imagine that my Director colleagues would not have agreed with the point about the importance of SNBTS being in a position to make well founded statements about the measures taken to protect patients from transfusion related infection. I cannot say if they would have agreed with my comment about the apparent lack of Department of Health Policy.

185. In paragraph 2 of the same document, you stated how you wished to "*be reassured that we are taking the correct decision, both professionally and medical legally, to stay in line with the positions of the majority of English RHA's; I think this is in fact what we are now doing rather than abiding by a Department of Health policy because it seems to me that de facto, may no longer be a Department of Health policy in this area*" (PRSE0001759).

a. **Please explain what you meant by this. As far as you know, did other consultants and directors within the SNBTS agree or disagree with your view at the time? Please explain what you meant by this.**

481. I was questioning whether SNBTS was acting correctly to delay the start of HCV testing purely to remain in step with the rest of the UK. The reason for remaining "in step" was apparently that this was Department of Health policy, but I was questioning whether such a policy was still operative and whether it had been unequivocally communicated to all the transfusion services by the 4 UK health departments. [see PRSE0003619]

As far as you know, did other consultants and directors within the SNBTS agree or disagree with your view at the time?

482. I know that some were in agreement [eg Dr Boulton] I cannot remember if other consultants and directors expressed definite opinions about the correctness of this policy

b. As far as you can recall, was uniform action taken with the NBTS on this matter

483. My recollection is that the SNBTS West of Scotland centre started what amounted to routine HCV testing of donors not long after Newcastle had started. This was, I believe at the behest of Dr Harold Gunson and was described as a part of a national evaluation, [possibly to provide a post hoc explanation for the early start in Newcastle]. SEBTS and, as far as I know, the other SNBTS centres tested all donations taken after July 1995 as well as all blood components in stock in the RTC's and in the blood banks of the hospitals they supplied.

186. When did the SEBTS begin anti-HCV screening? As well as the documents referred to above, you may wish to consider the enclosed correspondence between SEBTS and Professor Cash (PRSE0003619 and PRSE0004708).

484. SEBTS started screening donations for hepatitis C antibody in July 1991. The reason for this date was that it allowed us time to ensure that by the approved

start date, all the blood held in the SEBTS blood bank as well as all that was held in the hospitals had been tested.

187. **What impact did anti-HCV screening have on the SEBTS? In particular:**

a. **What was the process for screening donors and/or blood donations?**
b. **What happened to all the unscreened blood that had been collected prior to the HCV testing being implemented?**
c. **What happened when a donation tested positive? Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.**

485. Other SEBTS witnesses will have more detailed knowledge of the introduction of HCV screening. My recollections are that we drew on the experience gained from the early period of HIV testing, and many of the procedures were similar. A working group led by Dr Gillon, at the request of Dr Cash, prepared a report detailing the procedures required for the HCV testing process, and as I recall, this was accepted for use in all the UKBTS centres. I have not had a recent sight of this report. IN outline, it would have covered the following aspects.

- Pretest information to donors
- Care of donors found positive
- Information to patients who received positive products. As described already, lookback involved identifying the patient and the responsible clinician, requesting the clinician to inform and advice the patient and refer for counselling
- Initial screen testing
- Confirmatory testing by RIBA and or PCR
- Donor reinstatement
- Lookback: previous donations tested and if any were hepatitis C positive, recipients would be followed up as above.

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Introduction of virally inactivated products

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

486. I have to make clear that I had no involvement in the work done by scientists at the PFC and the PFL at Oxford in the effort to develop virally inactivated factor concentrates, so I can only give very general replies. I know that this had been an important goal of the R and D team at PFC for a number of years before January 1985 when the first moderately heat treated [68C for 2hrs] factor VIII was released., but I cannot name the date when virus inactivation in factor concentrates became the subject of active research at PFC.

487. There was no call for me to raise the need for safe products with the PFC, as I knew they were actively pursuing this.

488. I do not recall engaging with commercial companies myself about this, but I know that haemophilia directors would have been in regular dialogue with the companies, and that they would have made it abundantly clear that virus-safe products were needed.

189. Please describe your role in the introduction of virally inactivated PFC concentrates in Scotland. In doing so, please address what was known, and when, about the effectiveness of PFC's inactivation methods against HTLV-III/HIV and NANB hepatitis. You may wish to consider the following documents: minutes of the 10 December 1985 meeting of SNBTS directors (PRSE0002258); a report for and the minutes of the 5 March 1986 meeting of SNBTS and haemophilia directors (PRSE0003457 and PRSE0001081); minutes of the 25 March 1986 meeting of SNBTS directors (a 27 June 1986 letter from Dr Boulton to Dr Perry (PRSE0003845).

489. I played little part in this. It was responsibility the responsibility of the relevant SEBTS staff to ensure full compliance with recalls of non-heat treated product and later, of the first and subsequent heat treated products as the PFC further

developed the technology: Dr Boulton who was himself a haemophilia specialist was the main channel of communication with the Haemophilia clinicians and the PFC

190. As far as you can, please describe what you knew, and when, about the development and effectiveness of virally inactivated concentrates in England and Wales (in particular, the BPL product 8Y). You may wish to consider the minutes of the 19 December 1985 meeting of the CBLA Central Committee for Research and Development in Blood Transfusion (CBLA0002287).

490. I was never involved in any way with the development of 8Y: It was the work of the team lead by Dr James Smith at the Protein Fractionation Laboratory [PFL] in Oxford. I was aware of the development through discussions with Dr Perry and Dr Boulton and Dr Ludlam.

191. Please explain what role, if any, you played in disseminating knowledge in Scotland about the effectiveness of 8Y in inactivating HTLV-III/HIV and NANB hepatitis.

491. I do not recall having an active part in this. I believe that the haemophilia doctors were well informed about 8Y. I doubt if there was any need for further dissemination of information about it. Supplies were very limited and there was difficulty in obtaining supplies.

192. In 1983, Dr Cash requested that Dr Ludlam conduct a trial of heat treated Factor VIII material NY 761 (MACK0001333). Were you aware of these trials? If so, please explain the following:

a. **What did coordinating the trial involve?**
b. **What comparisons were made between heat treated Factor VIII with cryoprecipitate and intermediate Factor VIII in terms of the quality of the products?**

c. **How was the efficacy of the product assessed? In particular, was the product's prevention of the transmission of infection part of this assessment?**
d. **How were patients selected to participate in the trial of a new heat treated product?**

492. I can offer no information about the trial referred to in MACK0001333. I do not know if it took place.

193. In November 1984, at the meeting of the CBLA Central Committee for R&D in Blood Transfusion, you explained that trials of SNBTS heat treated Factor VIII might have to be re-thought in view of the HIV virus (CBLA0001919, page 3). Please explain:

a. **The rationale for your statement;**
b. **The impact you believed HIV might have on the SNBTS trials.**

493. What I am quoted [CBLA0001919] as saying in minute 8.2, last paragraph is much less specific.

"Dr. McClelland referred to a batch of Factor VIII in Scotland, fractionated in November, 1983, which was discovered to contain anti-HTLV3 August, 1984. It was noted that a virus attack rate on this product could be as high as 80%. The remainder of the product had been withdrawn, but the incident served to highlight the difficulties which lay ahead in this context"

I did not refer to heat treatment. I was drawing the attention of the Committee to this finding that suggested that HIV could remain very infectious even when diluted in plasma pools.

194. In his evidence to the Penrose Inquiry, Professor Cash stated that there were no formal links between BPL and PFC, and that such links "*did not enjoy the support of Ministers*" (PRSE0000651, page 7). It was suggested that a formal relationship was "*in the public interest*" (page 7) and "*may have made a significant difference*" to research and development, particularly in respect of heat treated products (page 5).

a. **Do you agree with Dr. Cash's assessment that a formal relationship between BPL and PFC was desirable, but lacked support from ministers? Please explain your response.**
b. **If that is your view, why did ministers not support such a relationship?**
c. **In your view, did a lack of ministerial support have a material effect on the relationship between BPL and PFC? What was the impact on research and development, particularly in respect of heat treated products?**

494. I did agree that a good working relationship between the two manufacturing units was important. However, I am less sure that any "formal arrangement" would have got over the problems of the personalities at the head of each unit who from my limited viewpoint seemed often to be more focused on competition than on collaboration. I do not know how Dr Cash envisaged this "formal relationship". I have no knowledge about the supposed lack of ministerial support. I cannot express a view on the impact that a different view by Ministers might have had on development.

d. **Please provide any further comment that you consider to be relevant on the degree of co-operation between BPL and PFC (be it on a formal or informal basis) and how that affected research and development (i) in respect of heat treated products, and (ii) more generally.**

495. My impression from discussions in the past with senior scientists of PFC and the PFL in Oxford was that informal co-operation was good. I cannot comment further on relationships between PFC and BPL.

195. In March 1985, Dr Ludlam wrote to Dr Boulton regarding the issue of compensation for patients who had an adverse reaction to heat treated Factor VIII during clinical evaluation (PRSE0001819). What did you understand these adverse reactions to be, and what was your view on this issue? What effect, if any, did adverse reactions have on the speed with which the trial progressed?

496. I was aware that there had been difficulties in obtaining an arrangement that satisfied Dr Ludlam's concern. I can offer no further information.

196. Did you have any involvement in the continued trials of heat treated Factor VIII and IX during 1985 and 1986. You may find PRSE0003428 and PRSE0000732 useful.

497. I had no involvement in these trials, to the best of my recollection.

197. Please describe your/SEBTS's involvement in the trial of BPL's 8Y product in 'virgin haemophiliacs' in 1986. As far as you are able, please explain:

a. What constituted a 'virgin haemophiliac' for the purposes of the trial?

498. The term "virgin" haemophilia patients was used to denote patients who had not received any factor VIII treatment. I think this in effect meant no exposure to any blood product.

b. What was the benefit in carrying out a trial on these specific patients?

499. Should a recipient of the product under trial show evidence of hepatitis, this would not be confounded by evidence of a previous infection. These patients, having not received any blood product, would be expected not to have any pre-existing exposure to HIV or hepatitis viruses.

c. Why was the SEBTS trialling a product developed by BPL?

500. I do not remember the reason for this. The trial was the responsibility of Dr Ludlam. I do not know why it was considered necessary.

d. What was the outcome of the trial?

501. I do not remember. I do not know if the trial ever took place.

e. **Why was the PFC unable to produce a virucidal comparable product to 8Y until September 1986 (PRSE0003814)?**

You may find PRSE0002000, PRSE0003143, PRSE0004290, PRSE0001641; PRSE0002643 and PRSE0004097 of assistance.

502. This question can only be meaningfully answered by a scientist with detailed knowledge of the chemistry involved in the purification and stability of Factor VIII which is a very fragile, large molecule that exists in the blood in very small concentrations. I do not have the relevant knowledge. My very limited understanding is that there may have been a degree of serendipity in the discovery that allowed the PFL to make a factor VII preparation pure enough to remain stable during virucidal treatment.

198. **In October 1985, you wrote a letter to Dr Ludlam regarding the use of low purity Factor VIII concentrates in HTLV-III infected patients (LOTH0000005_059), where you stated: "*the use of low purity Factor VIII concentrates in HIV III infected patients could be the source of an immune illogical stimulus which could contribute to the activation of infection which could otherwise stay dormant. I have the sinking feeling that as well as being a brilliant marketing ploy for high purity products this could also be quite a sound hypothesis.*"**
Please elaborate on the matters discussed in this letter

503. I am not sure why I wrote this letter, because by that time, as I mention in this letter, Dr Ludlam was already engaged in researching this hypothesis. The answer may be in the final sentence which is drawing Dr Ludlam's attention to a powerful new piece of equipment that could assist in his studies. This was the new Fluorescence Activated Cell Sorter or FACS.

504. *"My purpose in writing to you just now is to say that if there are any ways in which you feel either us or the PFC should be working with you on this problem, we will obviously do everything we can to help. One possible source of practical*

assistance is that the new cell sorter is now operational in the Department of Surgery"

505. [The typed letter does use the word "Immunological" rather than the more colourful "Immune illogical" above.]

199. In his reply to the letter above, (LOTH0000005_058) Dr Ludlam expressed interest in your thesis that low purity products may modulate the immune system more than those of higher purity, and stated interest in setting up a small study using heat treated commercial product.

a. As far as you can recall, what were your views on this proposal?

b. Was a study undertaken? If so, what was the outcome?

506. I do not remember that a new study followed this suggestion. Dr Ludlam was already actively investigating this hypothesis.

200. Please refer to SBTS0000496_090, a letter from Dr O'Sullivan (Sandoz Pharmaceuticals) to you, discussing proposals for "*collaborative work on the inactivation of HTLV III in blood products and some associated clinical studies.*" Please discuss:

a What you recall about these proposals. What was proposed, and on what basis were Sandoz in particular approached?

b What was the SNBTS's response to the rejection by Sandoz?

c Dr O'Sullivan proposed two alternative areas of research, relating to i. the value of gamma radiation and ii. the yield and quality of end product. What degree of interest was there in these proposals? Did a collaborative relationship follow from the proposals? If so, what was the extent of this relationship?

507. I have no recollection of this correspondence or of preparing a project proposal on this subject.

201. In August 1990, you were copied into a letter from Dr Yap to Dr Cash regarding the SEBTS's purchase and use of a DNA/RNA extractor for HCV. In this

letter, Dr Yap discussed the testing of patients for HCV who had developed NANB following the use of BPL and PFC intravenous immunoglobulin ("IV IgG"). He stated: "*If we can definitively establish that HCV is the virus implicated in one or more of these four episodes, then I believe that PFC will have an important lead in deciding on the efficacy of virucidal steps involved in the production of IV IgG*" (SBTS0000651_118).

a. As far as you can recall, what eventuated from these testing studies? Was it confirmed that HCV was the virus implicated in the cases?

508. HCV was indeed confirmed to be responsible. There had been several incidents of patients developing Non A Non B hepatitis following the administration of intravenous immunoglobulin products from several different manufacturers including BPL. At the time Dr Yap wrote this letter it was not known if the responsible virus was hepatitis C, and he anticipated that by using PCR testing, the causative virus could be identified. He expressed the hope that if this work succeeded, the findings would assist PFC with the development of a virus inactivation process that would be effective against the Hepatitis C virus.

b. What action was taken by the SEBTS and/or the SNBTS with respect to the manufacture of IV IgG following the results of these studies?

509. The IvIG product that infected a group of Dr Webster's patients was made by a different method [chromatography] from that used by PFC [Cohn cold alcohol fractionation] There had been previous outbreaks of hepatitis C in Ireland that were attributed to Anti D immunoglobulin prepared by a chromatographic process,

Although the Cohn fractionation process was known to provide effective inactivation of many viruses, PFC also introduced an additional process [Ph4/pepsin treatment]

202. Please refer to HSOC0029319, in which you stated that SNBTS "*could not rule out the possibility that haemophiliacs had been infected with blood products*

imported by doctors since heat treatment to make the products safe had been used in Scotland."

a. Are you aware of any specific instances of HCV/HIV/HBV transmission in Scotland following the introduction of heat-treated material? If so, please give as much detail as possible.

510. My statement, as reported in The Glasgow Herald, referred to hepatitis C and imported factor VIII. It specifically refers to heat treatment, but other processes of viral inactivation were being used by different manufacturers. The question could be taken to imply that viral inactivated coagulation factor concentrates were introduced at one time for all patients: this was not the case.

511. There were reports of virus transmission by at least one supposedly viral inactivated commercial concentrate. I believe this was an Armour Pharmaceutical product but I do not have the details.

512. With respect to PFC Factor VIII products, I am not aware that there were any further instances of HIV transmission following the first PFC mild heat treatment process. Later products were further treated, successfully removing the risk of HCV transmission.

b. Were any such instances connected to heat-treated material, either imported or UK-made?

513. As above, I believe there were incidents of virus transmission involving imported products, one of which was produced by Armour, that had been claimed to be virus inactivated. It is my recollection that NOT RELEVANT these had been subjected to heat treatment. NOT RELEVANT

NOT RELEVANT

Recall of unheated product

203. PFC recalled all of its unheated Factor VIII product in January 1985 for heating (PRSE0001885). In a draft statement prepared in or around 1990, Dr Lane commented that BPL was unable to do the same owing partly to safety concerns:

"BPL could not take back, for reissue, unused unheated concentrate. The reason for this was quality control. We had no idea of the products which had been issued some time before and how they had been handled during transportation and storage. In these circumstances we would not be willing to heat treat products which had been out of our control for a period and then reissue them..." **(see CBLA0000005_002, page 136-137). Please answer the following questions as far as you are able.**

a. **Were you and others at the SNBTS concerned with these aspects of quality control?**

514. I think this would have been a concern for the PFC team, and the decision would have been based on their assessment of the risks versus benefits of the action taken. I was not involved in the quality assurance or regulatory aspects for a recall decision: This would have been the responsibility of the Responsible Person at PFC and the PFC Director.

b. **How, and by whom, was the decision made to effect the recall of unheated products?**

515. I would assume that this was a decision made by the Director and Responsible Person of PFC after extensive discussion with colleagues.

c. **To the best of your knowledge, why was PFC's approach different to that of BPL in this respect?**

516. This is speculation. I think it is likely that the PFC team made the judgement that recall and further processing would carry less risk for patients than the shortage of product that would have resulted from destroying the recalled product.

d. **Are you aware of any other entities (e.g. pharmaceutical companies) which recalled, heated, and reissued products in this way?**

517. I have no knowledge of this.

e. What was your opinion at the time on recalling unheated product?

518. I think I would have supported the decision.

204. In March 1986, you attended an SNBTS Directors meeting which discussed SOP product recall, in which you stated "*the requirement under the SOP to recall product which might subsequently be re-issued presented public relation problems*" and requested a "*standard approach*" be agreed upon (ARCH0002254, page 2). Please explain:

a. Did your colleagues agree with your view?

519. Unfortunately, the minute does not record any discussion of this and I do not remember the outcome.

b. **Was a standard approach decided on for recalling products that were**

520. I do not remember. The reference to an agreed Standard Operating Procedure agreed by the co-ordinating group suggests the intention to use a coordinated approach.

205. Please refer to HSOC0029319, which suggests that "*older stocks [of early heated products] were not recalled from hospital stores as the procedure was improved and higher temperatures used.*" You explained that "*what was intended was they would continue to use whatever stocks they had and just flow in the new material.*"

a. Why was this approach adopted?

521. I have no recollection of how this approach was arrived at, but it is very likely that there were two considerations: [a] stock of products was limited and would have been depleted by recall, as the recalled and already heat treated batches

could not have been subject to a further process [b] I am uncertain about sequence of events but it may be that evidence was already emerging that the since the use of very first heat treatment, no further evidence of HIV transmission had been detected.

b. What was your opinion on this approach? Did this change over time?

522. I do not remember my views at the time, I think this decision was probably made on the basis that destruction of the recalled, already heat treated material would have further diminished availability of product for patients. Gain, a decision on balance of risk vs benefit

c. Was it known that there could still be a risk with earlier heated products (for instance, Phase 1 heated products as opposed to Z8)? If so, why were such products not explicitly recalled once superior products became available?

523. My understanding is that the first SNBTS heated factor 8 proved not to transmit HIV. The initial heat treatment process did not inactivate HCV and this was not achieved until the BPL 8Y product was developed.

Recall practice and procedure at the SEBTS

206. Please give an overview of product recall practice at the SEBTS, and how this changed during your tenure.

207. What, if anything, do you remember about any formal recall or notification procedures in place?

208. In your opinion, were such practices and procedures effective? From your experience, did clinicians generally comply with recall requests and if not, do you recall why not?

524. 206, 207, 208 I do not remember any details of the evolution of recall procedures.

209. In November 1984, a decision was taken to recall a specific batch of Factor VIII (Batch 0231100090, which had been implicated in the infection of 16 Edinburgh patients) from Scotland and Northern Ireland. You addressed this recall in a 15 November 1984 letter (LOTH0000005_052) and a 20 November 1984 memo (SBTS0002206), which was responded to on 26 November 1984 (PRSE0001918). You may also wish to consider a 16 November 1984 letter from Dr Ludlam to you (LOTH0000005_069). You gave evidence on the recall to the Penrose Inquiry (PRSE0002760 and PRSE0006040 page 81-101). Please answer the following questions as far as you are able:

a. Do you stand by the evidence you gave to Lord Penrose on this issue? Is there anything that you now wish to add to that evidence?

525. I stand by my evidence to Lord Penrose.

b. Why was the decision not made to recall this batch prior to 3 November 1984?

526. The delay in making the decision to withdraw this batch of Factor VIII resulted from the fact that the information about the recipients and batches involved accumulated over several days. ON Friday evening, October 26th, Dr Ludlam reported to me that 3 patients who it was thought had only received PFC products, had positive HIV tests. [Dr Ludlam was clear that he wished to see confirmation of these results before taking further action] These patients had all received some of a single batch of factor VIII, but all had also received other batches. The relevant patient and product issue records were not unified or computerized at that time, so it took some time to make a complete list of the batches received by these three patients. I do not have a record of the day on which we obtained this information, but it may well have been towards the end of that week On Friday November 2nd [I think this is the correct date], Dr Ludlam received the test results from a further group of patients – about 16 in all – who

were also HIV positive, and who had received the same batch. I do not remember the exact time that he informed me of this but I immediately decided that the batch must be withdrawn. Dr Boulton and I telephoned all the RTC's in Scotland to withdraw any vials of this batch and return them to PFC.

Why was the batch not withdrawn until November 3rd?

527. My understanding [although I do not remember having any formal instruction or guidance on this point] was that a batch withdrawal decision was the responsibility of the PFC Director or his nominee, along with the National Director. I informed Dr Cash twice as the information became available and on both occasions, his decision was that we should not withdraw the batch or batches. I recorded at the time that I was in agreement with this, so I must share some responsibility. I did not at the time record my own reasons for delaying withdrawal of the batch. I can only assume that my concern was that, logically, we should withdraw all the product, or at least all the batches that had been received by the infected patients, from clinical use until the situation had been fully analysed. This would have left the Scottish patients with haemophilia with the choice of treatment cryoprecipitate or commercial factor VIII.

c. Why was it concluded on more than one occasion (27 October and 29/30 October 1984) that the information was insufficient to justify a recall?

528. This question is answered as fully as I can in the response immediately above.

d. Was the possibility of quarantining this batch raised? If not, why not?

529. Again, I cannot add to the account above.

e. In your view, how does this incident reflect upon the practice of recall more broadly? Were delays for 'confirmatory testing' typical?

530. I really cannot say if this incident was in any way typical of recall practices. I do not remember having any personal involvement in recall of plasma products as my recollection is that these events were generally handled by the PFC Quality Department or Director, in consultation with the National Medical Director. The testing in this incident was done using a very early HIV test that was still at the research laboratory stage. This may well have been a factor in Dr Ludlam's wish to await confirmation in this case.

f. Please summarise attempts made to trace the donors who contributed to this batch of concentrate. As well as your evidence to the Penrose Inquiry (PRSE0006040 pages 97-98), you may wish to consider your November-December 1984 correspondence with Drs Mortimer and Tedder (PRSE0003907, PRSE0000224 and PRSE0000933).

531. As I have explained above, this was done by Dr Ludlam and myself using information records from Haematology and SEBTS. We established that the batch contained about 4000 donors. All could be identified from the plasma pool records. SEBTS held retained samples from all the donors, but at this time we did not have any computerised retrieval system so that recovering all the samples was time consuming. We could immediately locate about 2000 of these samples and the remainder with a little delay. As we obviously wished to identify the source of the infection, I wrote to both Dr Philip Mortimer at the PHLS and to Dr Richard Tedder at the Middlesex hospital who at that time had the only two laboratories in the UK capable of doing these tests at that time. Both scientists declined to undertake to test such a large number of samples. As I recall, I also looked at the possibility of finding a lab in the USA to undertake the testing, but without success.

210. In December 1987, you wrote a letter to Dr Ludlam regarding PFC fractionation of HIV-positive donation incident 7. In this letter you stated: "*In light of this information and also of the sketchy information available from the West of Scotland you may wish to reassess the interpretation of the data related to your own patients*" (LOTH0000005_087).

a. Please explain what you meant by this statement.

532. I am not sure what "sketchy information" was intended to apply to. It may have been the records for donated blood units or the records of which patients had received this batch of factor VIII.

b. **Why was information available from the West of Scotland "*sketchy*"? Did this pose any difficulties in your ability to make appropriate risk assessments for the treatment provided to your patients?**

533. I have no recollection of this letter but I would assume from the context that I was referring to some doubt about the completeness of information about one or more donors who may have contributed to a suspect batch. It seems unlikely that this would have influenced our understanding of the source of infection in the implicated batch, since as I have said in my answer to question 209, we were unable to have all the contributing donations tested

c. As far as you can recall, were the products manufactured from this infected donation recalled?

534. Within the first few days after the initial 7 patients had been discovered to be HIV positive, it was shown three of them apparently had only received SNBTS factor VIII. One batch was common to all three patients. However, these 3 patients had, between them, received [I think] 9 other batches. This data is in a table appended to document SBTS0002206.

211. In January 1987, you wrote a letter to Dr Ludlam regarding a batch of IV immunoglobulin which was withdrawn when it was discovered that it contained a donation from a donor later found to be HIV antibody positive. In this letter you stated: "*In view of the relative shortage of IV IgG the decision was made some months ago that rather than destroying a large quantity of product it should be held and its used considered if there were patients who were HIV antibody*

***positive and he required high-dose IgG for management of thrombocytopenia*" (LOTH0000005_047).**

a. How frequently did the SNBTS retain infected products for these purposes?

535. I have no recollection, but I would speculate that this was an exceptional event. The product was to be reserved for a very particular use – in treating severely low platelet counts in patients who were suffering from HIV-AIDS

b. As far as you can recall, were there any incidents where infected products retained for these purposes were wrongly given to patients that were not antibody positive?

536. I have no knowledge of any such incident.

c. As far as you can recall, why did the SNBTS decide to take a conservative approach if there was such strong evidence that patients did not seroconvert to IgG?

537. I would imagine that this was a precautionary decision. Again it is a matter of balancing the potential risks against the hoped - for benefits.

Autologous Transfusion

Initial comments

538. Autologous Transfusion [AT] is a term that embraces several different methods.

These are:

- *Preoperative autologous blood donation [PAB]*: Blood is collected from the prospective patient using the normal blood collection methods. It is tested in the same way as a conventional donation and then must be labelled, entered into the IT system and stored in such a way that it can only be issued to the originating donor/patient.

- *Intra - operative blood salvage [IOBS]* :A surgical procedure, blood is collected from the surgical field using a machine that aspirates the blood, washes it to remove any contaminating materials, and holds it until the surgeon or anaesthetist decides to reinfuse it to the patient
- *Post-operative blood salvage*. Blood is collected from a tube draining the surgical site with the intention that it may be retransfused with or without further processing, depending on the equipment used.
- My answers to **214 a to c** apply to the first method [PABD]

212. Please refer to BART0000915_027, an article co-authored by you in 1987 with regard to autologous transfusion.

a. **You stated that a pilot programme was being developed by the SNBTS to assess the "*effectiveness, applicability, and cost*" of autologous transfusion and related procedures. To your knowledge, what was the outcome of this pilot scheme?**

b. **You stated that "*from practical experience... [autologous transfusion] is likely to be applicable only to a small proportion of patients*." Why did you come to this view? Was it borne out in Scotland and the rest of the UK? If so why, in your view, did autologous transfusion not have wider uptake in the UK?**

539. SEBTS ran a preoperative autologous donation transfusion [PABD] programme for several years under the leadership of Dr J Gillon. Patients were referred by a clinician, the patient having expressed interest in receiving their own blood, in connection with a planned surgical procedure. Prospective patient/ donors were invited to the main blood donor centre in Edinburgh which had a pleasant environment and all the facilities needed. The experience with this programme, as I understood from Dr Gillon, was that the number of referrals was always small. Most were from a small number of clinicians who had pressed for this service to be made available. Over time, the number of referrals fell, and the number of autologous donations obtained declined to a low level. My recollection is that the programme was eventually closed because of lack of demand. I am not sure if we ever attempted a formal assessment of cost and effectiveness. This

practical experience demonstrated that it was expensive in terms of the time of both BTS staff and the patient, and if the desired outcome was reduction of risk of HIV, Hepatitis B or hepatitis C it would have been impossible to demonstrate this with the small numbers enrolled. The impact on the need for donor blood would have been negligible.

540. There were other autologous donation programmes in the UK and I do not now remember if any had a greater and more sustained take-up then that in SEBTS.

213. In a 1998 report titled "Implications of vCJD", you stated that the "*SNBTS should give top priority to implementing its existing policy on autologous transfusion ...by implementing the proposal already submitted for a national predonation programme*" (NHBT0002369_006, page 7).

a. To your knowledge, was this proposal ever implemented? If so, when?

541. So far as I know it was not.

b. Following this report what developments, if any, occurred with regard to the implementation of autologous transfusion in Scotland?

542. I do not remember whether the SEBTS autologous predonation programme referred to in my answer to question **212** preceded or followed this paper, ie if it was an initial step towards following the action recommended in NHBT0002369_006. Otherwise, I have no recollection that the production of this paper had any effect on the use of autologous transfusion in Scotland.

214. In October 1997, at the meeting of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation, it was stated that "*autologous transfusion could be valuable if the arrangements were properly targeted and managed*" (SBTS0000522, page 10).

a. To your knowledge, what progress was made to arrange for autologous transfusion following this discussion?

543. I can remember no detail. Autologous transfusion in its various forms was certainly the subject of many presentations and publications and much discussion at meetings and conferences and there were groups in some parts of the UK who initiated local programmes. One could say that it was a fashionable topic for a number of years. I do not remember a UK-wide policy being promulgated by the Health Departments and I do not recall ever having seen any data about the scale of autologous collections across the UK. My impression, and certainly the experience in SEBTS, is that providing a service for autologous transfusion proved to be more difficult and less productive than had been hoped.

b. **In October 2001, at a subsequent meeting of the Advisory Committee, it was noted that "*there were active working parties on the Promotion of Autologous Blood Transfusion and Alternatives to Blood Transfusion.*" "*It was hoped that there would be a full cohesive strategy by 2002.*" In a discussion about "*reducing blood usage,*" one option was "*establishing widespread autologous transfusion facilities*" (NHBT0008588_002, page 6). To your knowledge, what was the outcome of these discussions? Did such discussions result in the increased adoption of autologous transfusion? If so, how? If not, why not?**

544. I do not have access to any data that would allow a properly informed reply to this question. My recollection is that there was no large scale increase in the use of predeposit autologous transfusion

In contrast, my impression is that perioperative red cell salvage using automated machines has been taken up quite widely.

c. **There is a four year gap between these two meetings. In your view, was there a delay in assessing the viability of autologous transfusion techniques? If so, why did it take place?**

545. I cannot comment on this. As I have said, predeposit autologous transfusion, in Dr Gillon's experience in Edinburgh, did not meet the expectations of the

enthusiastic promoters of the method. I do not have knowledge of the results of other assessments.

215. In May 1999, the Standing Advisory Committee on Transfusion Transmitted Infection (SACTII) recommended "*[maximising] the use of autologous transfusion*" to reduce the risk of transfusion transmitted infection (NHBT0017405_001, page 6). To your knowledge, what was the effect of this recommendation with regard to autologous transfusion and similar blood sparing techniques?

546. I am not sure that SACTTI were proposing anything more than the recommendation made in a report commissioned from Det Norske Veritas (20/99). SACTTI's rather guarded minute states *"....it was agreed that making appropriate use of autologous transfusion in clinical situations where it is likely to be of benefit, could well be included in point number 1."*

The DNV report had been commissioned to review the operations of the MSBT. Its proposals, I believe, led to the formation of a new advisory group – SaBTO (Safety of Blood, Tissues and Organs).

General

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

547. I have already responded to many questions about the work done to improve the safety of the *products*.

However, I would like to emphasise the point that the safety and effective care of *patients* also depends upon good practice in the prescribing, administration, storage and transport of blood. I have been asked no questions about this butt has been my own professional priority for much of my time in transfusion to promote the safe and effective use of donated blood,

[a] for the benefit of patients and

[b] to discharge the responsibility of the blood transfusion service to make good use of blood - the human tissue that is given voluntarily as an altruistic act.

548. Much of this effort has involved the development of teaching and training resources which I have listed in **section 1.** The report that I edited 1995, *"Optimal use of donor blood"* set the agenda for the next 10 years or so for work to improve the prescribing, administration, storage and transport of blood. The projects and publications that I have listed describe the range of activities that have been undertaken to identify problem areas and support staff in improving the clinical practice of transfusion.

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

549. The answer to the first question is that there were these constraints. SEBTS was a part of the Health Service in Scotland. Those with responsibility for allocating taxpayers' money would, I assume, have discharged their responsibility to make fair, balanced and equitable decisions about use of NHS resources. Inevitably, this would have meant there must have been difficult decisions about funding new, and often recurring, long term expenditures for both personnel and materiel. Examples would include tests for viral infections, or new blood packs or processing equipment that provided a better red cell product. There were occasions, notably the start of hepatitis C testing, when slow funding decisions did, in my opinion, delay the implementation of a change that would improve the safety of blood.

550. I was not always free to take a particular course of action which needed to be taken to ensure blood safety. As a regional centre director I did not have the authority to follow a course of action that had significant costs without obtaining approval, either from the National Director or General Manager [usually quite a quick decision] or by application to the Scottish Health Department via the Common Service Agency, usually a slower process.

It was part of the challenge of the Regional Director's job to find ways around these barriers, if necessary resorting occasionally to the principle of "Seek forgiveness, not permission."

218. How did the desire for consensus across the RTCs impact efforts to achieve blood safety at a local level?

551. I can only remember one specific example which was the implementation of hepatitis C testing, in which the aim to achieve a common start date delayed testing in most of the SNBTS centres.

Over the years that I was in post, there was ever more movement towards standardised procedures. Inevitably, this reduced the freedom of regional directors to make changes that had not been approved at a higher level. The timing of starting hepatitis C testing was one example.

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

552. Like the other RTD's, I endeavored to take note of the decisions of these various advisory bodies and to follow that guidance.

As I have said, as time went on, RTD's had less freedom. There were advantages and disadvantages to this. On important issues, the various advisory bodies often discussed extensively and sometimes over a long period before a clear recommendation emerged. There was in some cases a lack of clarity between "advisory" and decision making bodies. Where there were clearly promulgated policies or instructions, I certainly did my best to comply with them.

Who defines "safe blood"?

553. I am not aware that there is any widely accepted definition of "safe blood.". Nor can I say who or what was responsible for defining what it meant. As with many issues in healthcare, it depends on one's viewpoint.

554. For a prospective patient, safe blood is "a treatment that I can get when I need it and that will do me good and that I can be 100% confident that it will not do me any harm." [ie the risk to me is ZERO and there is an expectation that it will benefit me]

555. For an epidemiologist, if I may give a simplistic illustration, safe blood will be defined by a statistician's number such as a probability estimate of an individual risk or a composite of risks. It will not be zero but will be a very small number.

556. For a health economist. Safety which would be considered together with effectiveness] may be judged by the effect on life expectancy or quality of life, using a measure such as Quality Assured Life Years, [QUALYs], related to the cost of the treatment. NICE makes these calculations regularly in formulating its recommendations.

557. For a person responsible for providing blood for transfusion, safe blood is the safest product that we can provide, using the best techniques that are available to us. How the providers, or those representing patient interests should define "available" at a given point in time is a question that can be asked about many activities of the Health Services.

558. My own interpretation while I was an RTD was that there are three elements, safety of the product, availability and appropriate use. The safest possible blood can provide no benefit if a patient cannot get it when they need a transfusion. The job of SEBTS was to provide the safest blood that we could provide, when any patient in the hospitals we served needed a transfusion.
Our slogan was "Right blood, Right patient, Right time"

Section 14: Look back programmes at the SEBTS

HIV

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

221. Were you involved in implementing any HIV look back programme during your time at the SEBTS? Please give details.

559. 220 and 221 I was not personally involved. The look back programme for HIV was managed by Dr Gillon. A full description of the lookback, is provided in the document prepared for the Penrose Inquiry entitled Lookback: *Procedures to identify, trace and offer counselling and testing to patients who received blood components from donors subsequently found to be positive in tests for HIV and HCV* (PRSE0004042) I do not remember that any additional funding was requested or obtained: it was done within SEBTS' allocated funding.

HCV

222. Were you involved in setting up any HCV look back programmes during your time at the SEBTS? If so, please describe this process and your role in it and how it was funded.

560. I was not personally involved. SEBTS lookbacks were undertaken by Dr Gillon.

223. Were you involved in implementing any HCV look back programmes during your time at the SEBTS? If so:

a. **Please describe what this involved.**
b. **How was any additional work funded?**

561. I was not involved in HCV lookback. This task was the responsibility of our Donor Medical Consultant Dr Gillon. I am not aware that SEBTS received extra funding for lookback.

224. On 9 July 1990, Dr Cash wrote to you and others regarding look back programmes, in which he stated: "*it would not, after we start anti-HCV donation screening, be appropriate to introduce a systematic look back programme on previous recipients - as was done for HIV-1*" (PRSE0001133).

a. As far as you can recall, why did Dr Cash conclude that this would not be appropriate?

b. Did you agree with Dr Cash's conclusion?

c. **Is your view the same now as it was at the time Dr Cash made the statement?**

562. I do not know the reasons for his view.

I did not agree with his conclusion. I felt that it was a part of our responsibility - our duty of care, to undertake lookback. My view has not changed.

General

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

563. As far as I can recall, the only other programme of this type was set up to identify any evidence that variant CJD may have been transmitted by transfusion and identify possible source donors and affected patients. I may have taken part in some early discussions or meetings about this, but I was not involved in the main programme which was, as I recall, led by Dr Patricia Hewitt.

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

564. I did believe there was a requirement to inform patients who may have received transfusions from infected donations

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

565. I interpret this question as relating to variant CJD. My understanding was that this would have been impractical for an individual RTC to operate as it required the resources of the CJD surveillance Unit in Edinburgh to identify and investigate the very small number of cases.

Section 15: Relationship with commercial organisations

228. Have you ever:

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

566. I have never undertaken work of this type. I once took part in a group that was asked by Ortho to develop information about erythropoietin. I received my expenses but no fee or other remuneration

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

567. I have not received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture, sale and/or importation of blood products.

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

568. I have, as stated above, on a single occasion taken part in an advisory panel for the Ortho company in relation to indications for erythropietin therapy. My travel and accommodation was provided. I did not receive any remuneration.

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

569. I have not received financial incentives from pharmaceutical companies to use certain blood products.

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

570. I have not received any non-financial incentives from pharmaceutical companies to use certain blood products.

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

571. I have not received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company.

If so, please provide details.

229. 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?

572. I do not recall that I was aware of such regulations or guidelines relating to my employment by the Common Services Agency.

230. 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.

573. I was involved in a multi-centre clinical audit study, that received support from the manufacturers of Erythropoietin [Ortho Pharmaceuticals]. I had no part in handling funds for this study. I received no payment, monetary or otherwise.

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

574. I have no recollection that I have ever done this myself. Some results of the audit study mentioned above would probably have been communicated to the company by the Leader of the project.

232. 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?

575. I did not receive funding for research from any pharmaceutical company

Section 16: Relationship between the SNBTS and NBTS

Relationship between the SNBTS and NBTS

233. Please outline the arrangements in place to enable cooperation between the NBTS and SNBTS during your tenure at the SNBTS, including any forums or reporting lines established to aid this cooperation.

576. I do not recall that there were any established arrangements – such as regular scheduled meetings with an agreed agenda – to facilitate cooperation between NBTS and SNBTS until, around 2009, with the establishment of a regular meeting of a group known as the UK Transfusion Services Forum, attended by senior

officers of the four UK transfusion services. There were some short term arrangements, in which SNBTS participated such as the BTS/CBLA research committee.

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

577. I do not remember that during my time as RTD, there was any single identifiable mechanism for developing policy for SNBTS, or for joint policies involving SNBTS and NBTS. I cannot speak for NBTS. Policies emerged from the deliberations of a variety of meetings.

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

578. I do not remember if this was done.

Relationship between the Plasma Fractionation Centre and Bio Products Laboratory

236. Please explain your understanding of the relationship between PFC and BPL (NB: Reference to BPL also includes the associated Plasma Fractionation Laboratory in Oxford). In particular:

a. **What was the extent of collaboration and coordination between BPL and PFC? What impact did this have, if any, on the operation of RTCs in Scotland?**

579. I think there was good cooperation among the senior scientists at PFC and the Plasma Fractionation Laboratory in Oxford, which as I understand was the NBTS

locus of research and development on plasma coagulation factors including Factor VIII. There should be extensive information about these contacts in the evidence of Dr Peter Foster and Dr James Smith to Lord Penrose. It was my impression that relationships between the Directors of PFC and BPL were difficult. This may have influenced the cooperation with scientific staff at BPL

b. Do you consider there would have been merit in a joint UK approach to Factor VIII production and research, particularly given that PFC and BPL were both engaged in the development of similar severe heat treated products (8Y and Z8) in the 1980s?

580. I could not say whether a more formal co-operation would have led to better outcomes.

Relationship between SNBTS and NIBTS

237. Please explain the SNBTS's relationship with the NIBTS in relation to the supply of blood and blood products to Northern Ireland.

581. My recollection is that the relationship was informal: I cannot recall being aware of any formal arrangement for the supply of blood products to the NIBTS. It is quite likely that there would have been occasional transfers of red cell units to help with a severe shortage and any transfer from SEBTS would have needed my approval I do recall that on at least one occasion, there was an exchange of Factor VIII products between the haemophilia directors [Dr Main in Belfast and Dr Ludlam in Edinburgh]. I do not know any details of this.

238. Please outline the arrangements in place to enable cooperation between the NIBTS and SNBTS during your tenure at the SNBTS, including any forums or reporting lines established to aid this cooperation.

582. The relations between SEBTS and NIBTS were, as I recall, amicable. [Dr Morris McClelland is no relation to me] His successor, Dr Kieran Morris, worked for and received his training in transfusion medicine in the SEBTS. To my knowledge the first formal communication arrangement was the UK Transfusion Services Forum, referred to in **233.**

Outcomes in Scotland, Northern Ireland, England and Wales

239. Please outline any statistics or studies of which you are aware that demonstrate the difference in morbidities and fatalities associated with infections of NHS patients from the use of blood and blood products between Scotland, Northern Ireland, England and Wales. Please comment on the reasons for any differences between the four nations, and explain your reasons.

583. I am not aware of any data that provides this information.

Section 17: Variant Creutzfeldt-Jakob disease (vCJD)

Knowledge of risk

240. When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products? Please provide a chronological summary of the information held within your organisation of the key events relating to the emergence, discovery and scientific development over time of the risks of vCJD infection and the risk of secondary transmission via blood and blood products.

584. I probably became aware of vCJD in or around 1996, when Drs Will and Ironside published their report in the Lancet (1996 Apr PMID: 8598754**:** DOI: 10.1016/s0140-6736(96)91412-9 - Exhibited as number HSOC0010099).

585. I am not in a position to provide a chronological summary of the information held within SNBTS as I do not have access to relevant documents. Variant CJD was not my special field, as I had asked one of my consultants to take the lead on

vCJD. Some months after Dr [now Professor] Marc Turner was appointed to a consultant post in SEBTS, I asked him to refocus his activities on vCJD, as I realised this would develop into a large issue for the transfusion services. He became lead person on vCJD for the SNBTS and has been very much involved at a UK national level and recognised as an expert in vCJD.

586. I regularly attended SACTTI and MSBT. I think that any contributions that I made to the response to vCJD was mainly through my contributions to these groups. I have found some documents among the references provided that have reminded me of events that I did not at first recall.

587. I was part of an NBS/SNBTS group that in 1997 submitted a paper to MSBT *"TSE Transmission by blood: Approaches to reducing a theoretical risk"* This is partly reproduced in [NHBT0002408_001]. I was also reminded of preparing or contributing to a paper for MSBT dated 1998 which reviewed some of the issues that could arise if a practicable test for vCJD was to be found and deployed for blood screening. I was involved in preparing a paper for SNBTS on *"Actions to minimise the risk that vCJD could be transmitted by Transfusion"*. [NHBT0002408_001]. This was submitted to the MSBT meeting on 24 January 2001.

241. **What was your understanding of the relative risks of vCJD infection from the use of commercial or foreign produced blood and blood products as compared with the use of domestically produced blood and blood products?**

588. As far as I can recall, the main, or perhaps the only basis I had for forming a view on the relative risks of blood from the UK [as against blood from other countries] was the large scale of the BSE epidemic among British cattle and the fact that other countries were not declaring BSE on a similar scale. Assuming that the information from outside the UK was correct, it would follow that more individuals in the UK would have consumed contaminated meat products and been exposed to the agent or agents that cause the disease. On this basis, blood donors residing in the UK would be expected to have a greater probability of

being affected than individuals from other countries. Consequently, if the cause of vCJD were transmissible from human to human by transfer of blood, the risk would be expected to be greater in the UK.

242. Please provide an outline of any steps you are aware of which were taken to ensure that the UK Government, Blood Services, NHS bodies, medical profession and patients were informed and educated about the risks of vCJD transmission via blood and blood products. In doing so, please state your involvement, if any, in relation to those actions taken or in what capacity you came to know about these developments.

589. My recollection is that this was a very high profile issue that received considerable media attention. All those listed in Question 242 would have been exposed at some level to information about the horrors of the BSE epidemic and vCJD as it quickly became known as "Mad Cow Disease".

590. My feeling at the time was that the reaction of Government was coloured by the extensive criticism of Government response to the BSE epidemic [summarised in the article cited below and exhibited as number WITN6666022. The Phillips report on BSE and vCJD. The Lancet Volume 356, ISSUE 9241, P1535, November 04, 2000 DOI:https://doi.org/10.1016/S0140-6736(00)03116-0]

591. I do not remember what, if any, action I personally took to spread information about vCJD.

243. **The Inquiry is aware of a paper that you prepared on actions to minimise the risk that vCJD could be transmitted by transfusion and that you sought guidance from MSBT on the principles that should guide the selection of those measures (NHBT0002408_001). Please provide a brief summary of that paper and MSBT's response to the recommendations you made.**

592. The purpose of this paper was stated as :

" To seek guidance from MSBT on principles that should guide the selection of

measures intended to reduce possible risks of transmitting vCJD by transfusion of blood products. To invite MSBT to endorse proposals for further action."(NHBT0002408_001)

The paper was intended [i] to identify all the many directions that could be followed with the single intent of minimising the risk that transfusion of any type of blood product could expose a recipient to vCJD. It pointed out that most of these measures would also reduce the risk of transmission of other agents.

The paper in effect requested MSBT to develop a policy covering: how these measures should be evaluated, how any selected measures should be implemented and which authority should take responsibility,

MSBT Response

593. From Minute of January 22, 2001

"It was agreed that this issue would be brought back to MSBT in April_ MSBT should have EOR's risk assessment and a NBS implementation plan. MSBT would also need to address impact of this measure on reducing risk from recycling of viruses."

I do not remember that MSBT pursued the proposals in this paper.

244. **Where you have not already done so, please provide details of your involvement or knowledge of any discussions or proposals (irrespective of whether they materialised or not) that were made in an effort to protect the blood supply from the risk of vCJD, including but not limited to:**

a. **Development of screening or diagnostic tests;**
b. **Filtration policy;**
c. **Quarantine of batches;**
d. **Donor selection and exclusion policies;**
e. **Product recall;**
f. **Recombinant blood products;**
g. **Importation of product from the USA or elsewhere; and**
h. **Surveillance.**

In providing this outline, please state what proposals were made, by whom, whether they were accepted and what efforts were made to monitor their effectiveness. In particular, please reference actions or recommendations made by committees that you had direct knowledge of including (but not limited to) SACTTI and MSBT.

594. I can only respond to this in the most general way, as this question covers an enormous range of information. [a] and [b] relate to the extensive scientific investigations that were being done in all these areas. I did communicate frequently with the SNBTS scientists working on these issues and would have learned from my attendance at MSBT and SACTTI.

595. Questions [c],[d],[e]: as mentioned above I prepared a paper for MSBT, that went into some of the issues that would arise should some form of screening procedure be introduced.

245. Please provide your opinion as to whether the risk of secondary transmission via blood and blood products was adequately mitigated in the UK in line with what was known about the potential risks of vCJD at that time.

596. An immense amount of effort went into the attempt to achieve this. I believe that everything possible was done to mitigate a risk that has proved to be extremely small.

597. The situation is summarised in the Handbook of Transfusion Medicine 8th edn 2013

"By the end of 2012 there had been 174 cases in the UK, peaking in 2000. Four cases of transfusion-transmitted vCJD infection have been identified, from three apparently healthy donors who later developed vCJD. All occurred with non-leucodepleted red cells donated before 1999. Three of the four recipients died of vCJD a few years after the implicated transfusion. The fourth recipient died of unrelated causes but had abnormal prion protein in the spleen at post-mortem examination (significance uncertain). There are still many

uncertainties around the pathogenesis and epidemiology of vCJD and no practical screening test for blood donors has yet been developed. The vCJD risk-reduction measures introduced in the UK include (see also Chapter 3):

- *Importation of plasma for fractionated blood products (1998)*
- *Leucodepletion* of all blood components (1999)*
- *Importation (and viral inactivation) of fresh frozen plasma for all patients born on or after 1 January 1996 (when dietary transmission of vCJD is assumed to have ceased) (2002)*
- *Exclusion of blood donors who have received a blood transfusion in the UK since 1980 (2004)*
- *Importation of solvent detergent plasma for adult patients undergoing plasma exchange for thrombotic thrombocytopenic purpura (2006)[RLIT0000808].*

*Leucodepletion refers to the removal of white blood cells from a blood donation by a filtration process. The relevance to transmission of vCJD is that the responsible agent may be present in white blood cells.

246. Please provide your view as to whether any decisions or actions could and/or should have been made earlier and how this might have impacted the number of individuals considered to be at risk of developing vCJD.

598. This problem was the subject of the most intensive attention by researchers in epidemiology, statistics, virology and the science of transmissible spongiform encephalopathies. The vCJD Surveillance Unit in Edinburgh, with the UK Blood Transfusion Services has undertaken a thorough "look back/look forward" programme in the attempt to identify any further incidents that suggest transmission may have occurred. vCHD was taken extremely seriously by Government and by the Transfusion Services. I believe the response was timely and comprehensive. I don't believe more could have been done.

247. In respect of the response to the potential risks of vCJD, please comment on what lessons were learned and applied from the events that led to the infection of patients with HIV and HCV from the use of blood and blood products. Were there

further learning opportunities from those infections that you think were missed (and if so, why do you think they were missed)?

599. I do not think that learning opportunities were missed. The variant CJD problem was different from HIV and Hepatitis C in very many ways. For example:

- There has never been consensus about the causation of the disease:
- No agent has been shown to be the cause.
- No test has been found that reliably detects the condition in asymptomatic individuals.
- There is essentially no specific reassuring information that could be given to a patient who has received a transfusion from someone suspected of having vCJD. One must set against this the fact that, to my knowledge, since the introduction of leucodepletion in 1999, millions of units of blood component have been transfused with no evidence of further transfusion related cases.

Notification exercises

248. The Inquiry is aware of patient notification exercises between 2003 and 2009, in particular the large-scale notification exercises commencing 2004, notifying patients they were 'at risk' of vCJD. Please explain your involvement, if any, in those notification exercises between 2003 and 2009, giving as much detail as possible and focusing on:

a. **Details of the circumstances in which patients were notified of their 'at risk' status;**
b. **What guidance, toolkit or anything of that nature was given to clinicians in relation to notifying patients, if any;**
c. **What specific information was provided to at risk patients and/or partners/family members about vCJD, its significance, prognosis, treatment options and management;**
d. **What follow-up and/or ongoing monitoring and/or psychological counselling and/or financial support was arranged in respect of patients who were told they were at risk of vCJD.**

600. I had no involvement in the notification process, and I am unable to answer these questions.

Section 18: General/Other matters

Reflections on relevant events

249. Do you consider that the blood services in Scotland and the UK as a whole responded to the risks posed by infected blood and blood products in a timely manner? Please explain your answer.

601. I would say that given the knowledge available at the times that decisions had to be taken, I believe the UK Blood Services' responses were timely, with the possible exception of the commencement of hepatitis C testing, which I believe could have been started sooner.

250. Are there decisions that you, as SEBTS Regional Director and member of the committees and groups referred to above, could have taken that would have improved SEBTS's, Scotland's and the UK's response to, or preparedness for, the risks posed by infected blood and blood products? If so, are those decisions only apparent in retrospect, or did you have sufficient information at the time to have made them? If there are any such decisions, why didn't you make them at the time?

602. I believe that, given the limits to the authority that I had as a Regional Director, I took those decisions relevant to the infection risks of transfusion that I had the authority to take. In many other cases, I applied whatever pressure I could for action to be taken on issues that I believed were important for the safety of blood recipients, but were beyond my authority to undertake. In the case of blood donor sessions in the prison, I acted decisively as soon as the problems were brought to my attention. I have previously stated that, in retrospect, I feel that this action should have been taken earlier.

251. Reflecting more generally, and drawing on your wider professional experience, are there decisions that you think could and should have been made

by others that would have improved Scottish and UK blood services' response to, or preparedness for, the risks posed by infected blood and blood products?

603. I think that it may have been possible to start testing for hepatitis C at an earlier date if decisions to provide the recurrent funding required had been made earlier. If the proposals for a prospective donor recipient study of Non A Non B hepatitis had been funded when first mooted, reliable evidence about the usefulness of surrogate testing may have been available to aid decision making.

252. Were there any structural difficulties or failings within the way in which blood service policy in Scotland and the wider UK was administered that either increased the risk of infected blood and blood products being used in any part of the country, or prevented a more effective response to those risks?

604. I think that it may have been possible to rationalise the number of advisory bodies and groups rather sooner. The establishment of EAGA, the MSBT, and then ACSBTO have been moved towards a more coherent system. I cannot judge whether these bodies have resulted in better or quicker decision making.

253. Are there any lessons drawn from the events with which this Inquiry is concerned that you think are applicable today?

605. I think that one message that is extremely relevant to the provision of a national health service today is the extent to which financial priorities can conflict with the provision of the best available treatment and the need for an equitable provision of health care for the nation's population.

Other

254. 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?

606. To the best of my knowledge, during my time in the SEBTS, the UK was self-sufficient in the provision of whole blood and blood components. I do not know if this still applies.

255. During your tenure at SEBTS, 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?

607. I was not aware of this at any time during my tenure at SNBTS

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

608. This is provided as exhibit WITN6666023.

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

609. I do not have other issues that I wish to identify.

Statement of Truth

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

Signed: GRO-C

Dated: 22nd December 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
1977	Thesis – University of Leiden 1977 Titlesheet	WITN6666002
1994	Use of blood products for elective surgery	WITN6666003
	Does acute normovolemic hemodiltuion reduce perioperative allogenic transfusion	WITN6666004
September 2005	Hep C Inquiry – COPFS Report	WITN6666005
1985	SEBTA 1985 49th Annual Report	WITN6666025
1979	Director SE RTC 1979 Job Description	PRSE0000950
April 1980	The Howie Code for preventing infection in clinical laboratories	WITN6666006
	Routledge L A for the Blood Transfusion Advisory Group, Royal Infirmary, Edinburgh. A survey of anaesthetists' and surgeons' views on blood transfusion in the South -East Region of Scotland	WITN6666024
27 September 2007	SNBTS Cryoprecipitate and Hepatitis Supporting Paper	WITN6666007
October 2021	Current Donor Information Leaflet	WITN6666008
	SNBTS Leaflet – Receiving a Blood Transfusion	WITN3530073
1985	Report of the Working Party of the	WITN6666026

	Regional Transfusion Directors Committee	
16 June 2011	Transcript of oral evidence of Ms Geraldine Brown	PRSE0006034
May 1986	The Lancet - 'HTLV-III Antibodies in an Edinburgh Clinic '	WITN6666009
	Optimal Use of Donor Blood	WITN6666010
January 1984	WHO Aids Meeting – Report by Brian McClelland	WITN6666011
2012	A review of the use of blood and blood products in HIV infected patients	WITN6666012
May – June 1982	Dialysis associated Hepatitis In Edinburgh	WITN6666013
July 1984	Investigation of a Serological Marker Detected in a Blood from a Donor Twice implicated in the Transmission of Non-A, Non-B Viral Hepatitis by Sonya Field	RLIT0000807
1978	Aach et al 1978	PRSE0002540
1981	Aach et al 1981	PRSE0001650
June 1984	Prevalence and epidemiological characteristics of hepatitis C in Scottish blood donors (Abstract)	WITN6666014
June 2006	Hutcheson et al - Hepatitis C Infection in Scotland epidemiological review and PH Challenges	WITN6666015
1977	Memorandum Selection Medical Examination of Blood Donors	WITN6666016
1983	Response to Medicines inspector report SEBTS	WITN6666017

30 April 1983	Article in the Lancet, titled 'Acquired Immunodeficiency in an infant…'	PRSE0000317
1998	Blood - An epic history of Medicine and Commerce by Douglas Starr	HSOC0019915
2001	Thornburn et al – Hep C in Healthcare workers	WITN6666018
2001	Thomas et al – Hep C in healthcare workers	WITN6666019
January 1995	Blajchman et al – Post-Transfusion Hepatitis	PRSE0004703
1984	Simon et al – Pilot study of surrogate tests	PRSE0004694
	Abstract – Significance of HTLV-I and HIV-2 for transfusion medicine in Europe	WITN6666020
1989	Kuo et al – Assay for NANB Hepatitis	WITN6666021
	Report to the Penrose Inquiry, 'Procedures to identify, trace and offer counselling…'	PRSE0004042
April 1996	Lancet – A new variant of vCJD (Dr Will and Dr Ironside)	HSOC0010099
November 2004	Lancet – Phillips report on BSE and vCJD	WITN6666022
	Extract from the Transfusion Handbook (JPAC): 5.4 Variant Creutzfeldt-Jakob disease	RLIT0000808
	Brian McClelland CV	WITN6666023