Witness Name: Professor Jean-Pierre ALLAIN
Statement No.: WITN3599001
Exhibits: WITN3599002 - WITN3599023
Dated: 9 June 2022
Jean-Pierre Allain

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF JEAN-PIERRE ALLAIN

I, Professor Jean-Pierre ALLAIN, provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 7th October 2021.

I, Jean-Pierre Allain, will say as follows:

1. I have dedicated my professional life to medicine and saving lives. The last 40 years of my professional career were dedicated to improving blood safety by conducting research on blood borne viruses and on the means of detecting them in transfused blood products to prevent transfusion-related infections. As such I wish to acknowledge the considerable pain and suffering experienced by the individuals, and the families of the many people who were infected with HIV, hepatitis B and C through transfusion of blood and blood products during the time I was involved in medicine and patients' care.

Section 1: Introduction

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

2. My name is Professor Jean-Pierre ALLAIN. My details are as follows:

a) Address: My address is known to the Inquiry
b) Date of Birth: GRO-C 1942
c) Place of Birth: Chateauroux, Indre, France
d) Nationality: French

3. My education and employment history are outlined in my curriculum vitae, a copy of which is attached with this statement at (WITN3599002) and which I can summarise as follows:

Education

- 1967 University of Paris Medical School, MD Thesis Platelet Factor 3
- 1967 Diploma in Haematology, University of Paris
- 1967 Diploma in Medical Microbiology, University of Paris
- 1968 Diploma in Medical Biochemistry, University of Paris
- 1971 Master's Degree in Human Biology, University of Paris
- 1986 PhD in Biochemistry: Immunologic and biochemical characterisation of antibodies to Factor VIII:C in man
- MSc in Clinical Psychology

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

4. Posts Held

- 1965-1967 Assistant Professor of Haematology, Hôpital St Louis, Paris
- 1967-1971 Assistant Professor of Haematology, Hôpital Bicêtre, University of Paris South Medical School
- 1971-1977 Director, French Red Cross Haemophilia Centre, La Queue Les Yvelines, France
- 1977–1981 Senior Research Scientist (Haemostasis), National Blood Transfusion Centre, Paris
- 1981-1986 Head of Department of Research & Development for plasma derivatives, National Blood Transfusion Centre, Paris
- 1986-1989 Medical Research Laboratory Manager (Hepatitis & AIDS Diagnostics Products), Abbott Laboratories, N. Chicago, IL, USA
- 1989-1991 Medical Director, AIDS & Hepatitis Division, Abbott Laboratories, N Chicago IL, USA
- 1991-1992 Director East Anglia Blood Transfusion Centre, Cambridge, England
- 1991-Sep 2009 Professor of Transfusion Medicine, Department of Haematology, University of Cambridge, Cambridge, UK
- Oct 2009-present Part-time Emeritus Prof Transfusion Medicine, Dept

Haematology, University of Cambridge, Cambridge, UK

5. Fellowship

- 1973-74 Department of Pathology, University of North Carolina, Chapel Hill, NC, USA
- Royal College of Pathologists, 2 Carlton House Terrace, London SW1Y 5AF, England (FRCPath)
- 2000 Fellow Academy of Medical Sciences
- 1999-2000 Sabbatical leave, Dept of Medicine, Head of Blood Transfusion Centre, Komfo Anokye Teaching Hospital, Kumasi, Ghana

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.

6. Memberships

- International Society of Thrombosis and Hemostasis until 1986
- International Committee in Thrombosis and Hemostasis (Consultant) until 1986
- French Society of Haematology until 1986
- French Society of Blood Transfusion until 1986
- World Federation of Haemophilia (Medical secretary 1972-1986)
- International AIDS Society

- American Association of Blood Banks (AABB)
- British Blood Transfusion Society
- British Society for Haematology
- International Association of Biological Safety (chair Blood Committee)
- International Society of Blood Transfusion (ISBT) member until 2019
- ISBT council member 2010-2012

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

7. I kept abreast of medical and scientific developments through reading the literature and participating in national and international meetings and congresses.

8. EARTC had a library receiving the main journals in medicine, haematology and transfusion I regularly consulted.

9. For the past 30 years I have been a reviewer for approximately 100 articles per year from 48 international and national journals including The Lancet, New England Journal of Medicine, Nature, JAMA, BMJ.

10. I was the editor of the British Transfusion Medicine journal for 7 years.

11. I contributed to 86 reviews and book chapters.

5 The Inquiry is aware that:

a) you gave expert opinion to Lord Penrose. The Inquiry has PRSE0005140 and correspondence PRSE0005130 from Lord Penrose to you which you may find of assistance.

12. I was called to discuss with Lord Penrose and his legal team as a sounding board.

b) You gave an advice to the Procurator Fiscal in relation to the death of GRO-A

13. I have no recollection of the GRO-A case. The documents listed did not reveal the name of the patient who apparently died after receiving PPF (plasma protein fraction). At the time, this batch of PPF had been viral inactivated according to SOP known to inactivate the Hepatitis B virus. In 1983, HCV had not been discovered and the product safety towards this virus could not be determined. From a clinical point of view about which my expert opinion was not requested, it is relevant to note that the patient having had at least 2 liver transplantations was under immunosuppressive treatment increasing considerably his/her susceptibility to infections.

c) Please review these documents. Do they remain true and accurate as far as you are concerned? If there are matters contained in these statements that you do not consider to be true and accurate, please explain what they are.

14. As far as I can tell, the documents remain accurate.

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

15. No, I have not provided evidence or been involved in any other inquiries in the UK.

16. However, as the inquiry will know I was indicted in a civil case in France. The trials in France arose at a time of national outrage and media uproar, with charges being made against a range of expert advisors in public health and medical sciences as well as politicians in charge of public health including a prime minister.

17. The legal system in France is radically different from that in the UK in that cases are assigned to a particular section of the Code of Justice that determines what can and cannot be included in the procedures.

18. The first trial was set up on the basis of 'unsuitable distribution of goods' that could apply to any dietary product to avoid having depositions by experts (WITN3599003).

19. The initial and the appeal trials were both run on that narrow legal frame carrying a maximum of four years imprisonment. At the end of the first trial, I was convicted and given four years imprisonment, two years suspended, based on four infractions including having chaired a large collaborative study including 7 haemophilia centre directors and 22 leading virologist and immunologist experts revealing the potential infectivity of pooled donor blood products from France and abroad. It also included participating in blood product distribution and failing to adequately inform the French Haemophilia society. During the appeal trial, these three counts were dismissed as proven inaccurate but another set of four counts were retained leading to an identical sentence (WITN3599004).

20. The steps I took to promptly respond to and inform others of the implications of the findings are detailed in the appended report (WITN3599005).

21. In 1994, a set of criminal charges for poisoning was initiated. It included several producers and prescribers of plasma derivatives for haemophilia treatment, myself included (WITN3599006). This investigation by a 'juge d'instruction' was used to retain me in France between August 1995, when I was freed on parole (WITN3599006), and December 1995 but was ultimately declared inadmissible by the French supreme court (Cour de Cassation) and all charges were dropped on 6 June 1998.

22. My actions and ethics during the initial years of the AIDS epidemic have been clearly vindicated in two inquiries that were conducted independently in England by peers from the East Anglia Regional Health Authority (WITN3599007) and the Royal College of Pathologists (WITN3599005) which both concluded that my behaviour during the period 1983-1985 was beyond reproach. It is on that basis that the University of Cambridge as well as EARHA maintained my professor appointment, consultant status and salary following my stepping down from the directorship of the EARTC in November 1992 and my return to England in December 1995.

Section 2: Your roles prior to becoming Director of the East Anglian Regional Blood Transfusion Centre

7. The Inquiry understands that you spent several weeks in 1978 as a visitor to the Blood Products and Plasma Fractionation Laboratory, Oxford in the Control Laboratory (page 25 of CBLA0000840). Is this correct?

23. I was hired at the National Blood Transfusion Centre (CNTS) in Paris in September 1977. One of my responsibilities was to supervise the quantification of Factor VIII and Factor IX content in CNTS products. For training and information, I visited Dr E Bidwell at the Oxford Churchill hospital and BPL in Elstree in 1977 and 1978, respectively.

8. If so, what was your role there?

24. I enquired and learned about methods of Factor VIII quantification with the 2-stage assay.

9. The Inquiry understands that between 1986-1989 you were the Manager of Medical Research Hepatitis and AIDS Diagnostic Products at Abbott Laboratories in the USA and between 1989-1991 you were the Director of Medical Affairs, Abbott Laboratories. Is this correct?

25. Yes, the information during my tenure at Abbott laboratories is correct.

10. Please describe the roles, functions and responsibilities you had in these roles and how if at all, these changed over time.

26. Initially I was organising collaborative studies on HIV-1 and Hepatitis B with opinion leaders in the USA utilising Abbott's products in development or in the market. Subsequently I was supervising the confirmatory laboratory where customers were sending samples reactive with the Abbott HTLV-I/II screening assay for differential diagnosis between these 2 viruses. Ultimately, I was supervising the scientific affairs group preparing and submitting to regulatory authorities, files for new HIV and HCV products approval.

11. The Inquiry understands that at some point either before or during 1986 you carried out a study of Koate HT, to assess the transmissibility of HIV and NANB hepatitis in that product. Please provide details (and any supporting documentation you still hold) of that study, and in particular:

a. How you came to carry out the study and the financial arrangements for doing so between you and Bayer.

27. The study in question (Koate HT) was coordinated by myself but I did not participate in the clinical study per se since I did not have any paediatric patient under my care. However, it was my remit at CNTS to examine potentially imported FVIII concentrates and supervise distribution including in the context of a clinical trial. To my recollection, there was no other arrangement between the manufacturer and CNTS than receiving the Koate HT required by the clinicians free of charge.

b. How the study was carried out.

28. The 4 clinicians involved selected suitable patients and treated them exclusively with that product for the duration of the trial.

c. Whether the study was subject to any ethical assessment by an ethical committee or equivalent.

29. At the time of initiation of the study (March 1985) there was no ethical committee established in France. The French National Study Group including the 4 clinicians involved and 8 other members examined and approved the project.

d. The size of the study.

30. The initial protocol included 10 patients. Ultimately, 11 were assigned and per protocol data was collected in 8 patients.

e) Whether consent was obtained from participants in the study, and if so, details as to how that consent was obtained. If no consent was obtained, please explain why.

31. Parents of each selected patient were informed by the clinician in charge but formal ethical methodology being unavailable, no unified formal informed consent was offered to carers to sign.

f) The results of the study.

32. Although of small size, the study confirmed the absence of HIV-1 seroconversion (HTLV-III/LAV) but noted 2 of 8 patients having elevated ALT levels occurring at 3 and 4 months post-treatment, respectively that were compatible with what was, at the time, non-A, non-B infection transmission. This observation was taken on board by Bayer and presented in their product package insert. Similar studies examining other heat-treated FVIII concentrates at the time obtained similar results even before efficacy on HTLV-III was demonstrated.

12. The Inquiry has seen correspondence from Bayer, in which the results of the study are said to be that there is no risk of AIDS transmission and a low (40%) risk of transmission of NANB hepatitis from Koate HT [BAYP0000009_021]. Is this an accurate reflection of the results of your study:

a) If so, would you describe a 40% risk of transmission of NANB hepatitis as low? Why?

33. No, not exactly. To my recollection results of this study were not published other than presented in the form of an abstract at an international haemophilia conference before the study was completed. This explains the difference between the abstract indicating: 1/6 patients with elevated ALT level justifying the 'low risk of transmission of non-A, non-B hepatitis' and the 2/8 cases in the final report indicating: 'infectivity for non-A, non-B hepatitis is not completely eliminated but probably attenuated.' It is not surprising that a commercial company tended to present the most favourable interpretation of the data.

b) If not, were you aware that this was the way your study was being reported? If so, when did you become aware of this?

34. This was translated by the manufacturer as 40% transmission in the letter to Dr Barlow without my knowledge.

Section 3: Your role at the East Anglian Blood Services

13. Please describe the roles, functions and responsibilities you had at the East Anglian Regional Transfusion Centre ("EARTC") during your period as Director and explain how these changed over time.

35. My directorship at the East Anglia Regional Transfusion Centre spanned between April 1991 to the autumn of 1992 when I stepped down as director. My responsibility was supervising collection, preparation and distribution of blood components from volunteer non-renumerated donors. A small amount of apheresis was in place for plasma and platelet concentrate preparation.

14. Please describe the organisation of the EARTC during the time you worked there, including:

a. Its structure and staffing and in particular to whom you were accountable (you may be assisted by NHBT0045585);

36. As RHA employee, I was accountable to the RHA director Dr Michael O'Brien who recruited me. I was directly supported by two University lecturers/NHS consultants, Dr Lorna Williamson and Dr Willem Ouwehand. Probably in view of my situation as a foreigner unfamiliar with the RHA and UK ways of operating, the RHA appointed Dr McDougall as adviser. At the level below, there was an administrative director Mr Hawdon in charge of HR and finances. Dr Williamson supervised blood component production and Dr Ouwehand immunohaematology (red cells, platelets and antenatal screening). During my stay (end 1991/early 1992), Dr Caffrey was recruited as head of blood collection and donor care.

b. How the EARTC was funded and how this changed;

37. EARTC revenue came in majority from annual contracts with the region's hospitals who evaluated their need and were charged according to a national scale of product charges.

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

38. EARTC's remit was to provide blood products to East Anglia NHS trusts in Cambridgeshire, Norfolk and Suffolk, mainly Addenbrooke's in Cambridge, NHS trust in Peterborough, Queen Elizabeth hospital in Kings Lynn, Norwich NHS, Great Yarmouth, Bury St Edmonds and Ipswich.

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

39. EARTC was answerable to the Director of EA RHA. The RHA provided directives and yearly review focusing mainly on finances. Major changes in the EARTC such as the creation of a bone bank were discussed in advance with the RHA. When the National Blood Authority was created more coordination between BTCs took place, but autonomy remained at least until my departure.

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

40. There was no official link with other BTCs but geographically, EARTC was closer to Colindale BTC in London.

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

41. To my recollection the EARTC was not submitted to other regulations than emanating from EA RHA including technical and financial audits. With the NBA, medical audits such as those conducted by Dr Lee took place annually.

g. the EARTC's relationship with the Blood Products Laboratory ("BPL") and any other laboratory involved in the production of blood products or processing of blood; (You may find NHBT0001851 and NHBT0003253 of assistance in answering this question); and

42. EARTC had a contractual relationship with BPL regarding the delivery of fresh-frozen plasma for preparation of plasma derivatives. Plasma was prepared out of each whole blood unit collected and approximately 80% of this was sold to BPL at a nationally accepted price.

h. the approximate number of donations collected each year.

43. In 1991, the predicted number of blood units collected was 95,000. In 1992 it increased to pass 100,000.

15. Please describe the reorganisation of the EARTC in 1990.

44. In 1990, I was not in the UK and have no information on the 1990 re-organisation.

Section 4: *Blood collection at the EARTC*

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

45. The vast majority of EARTC blood collection was at mobile sessions organised in a variety of locations in cities, towns and villages of the region. During my tenure, a fixed collection site in addition to the site in Cambridge was set up at the Norwich NHS trust.

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

46. Plans were made to visit in general twice a year each collection site. Adverts for blood collection were put in place by local helpers by posters. Heads of blood collection were connecting with local helpers and providing basic background organisation in new sites. This organisation was highly successful and over a one-year period, blood collection increased significantly (to my recollection from approximately 90,000 per year to >100,000 donations per year)

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

a. When did this practice cease?

47. To my recollection there were no prisons visited for blood collection in the EA region.

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

48. See my response at question 18 (a) above.

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

49. See my response at question 18 (a) above.

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

50. See my response at question 18 (a) above.

e. Were hepatitis and HIV considered risks in these specific populations? If so, how were these risks managed?

51. See my response at question 18 (a) above.

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

a) What were the staffing arrangements during blood donation sessions? Were staff medically trained?

52. At EARTC, blood donation sessions were supervised by a medically qualified person supported by specialised nurses in the number required according to the expected number of donations at each site.

b) Where did these sessions take place?

53. Sessions took place in various locations, mostly town halls or schools.

c) How frequently could a person donate blood?

54. To my recollection, collection sites were visited twice a year and the interval between donations of whole blood was 4 months.

d) How were blood donors recruited?

55. Donors were locally recruited by volunteers organising locally for advertisement. The vast majority (80%?) were repeat donors, limiting efforts to recruit. At one point, EARTC had an excess of blood and considered donating surplus donations outside (NHBT0041282_003).

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

56. The system in place at my arrival was essentially kept; advertisements for local support and new sites were limited changes. However, discussions took place with Norwich Trust to set up a fixed blood collection site in the NHS premises. This plan was implemented in 1992.

20. Did the EARTC have donation collection targets that it was required to meet? If so, did the EARTC 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?

57. The collection target was internally determined. The overall objective was to provide volumes of products requested by client hospitals, each of them having yearly contracts with EARTC determining their expected needs. According to my recollection, there were no occasions in 1991-92 of shortage of blood components in our region.

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

Production of fresh frozen plasma

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

a) Where the production of FFP took place;

58. FFP at EARTC took place exclusively at the Cambridge blood centre under Dr Williamson's supervision.

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

59. Whole blood units were centrifuged and the plasma separated either after platelet preparation from PRP or without platelet extraction. The process was done during the period of time and at temperatures imposed by BPL. Other procedures were in compliance with standard Operating Procedures (SOPs) and recommendations in the Red Book.

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

60. The plan for FFP production was determined in advance and carefully monitored in regular meetings with collection and production heads. >90% of blood units collected were processed and FFP flash frozen in specifically designed freezers.

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

61. An increase in production was planned in advance and took approximately 2 months from decision to implementation

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

62. Supply of FFP for East Anglian hospitals was requested on an annual basis by each trust with a contract covering blood products supply.

Haemophilia treatment centres got the little FFP they needed through their respective hospitals.

Plasma targets

23. Did the EARTC 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?

63. The amount of FFP produced at EARTC was planned to meet its contractual obligations, first with the East Anglian hospitals and second BPL. The split between the two targets was approximately 20/80%. FFP for fractionation was contractual with BPL exclusively. The target was set more according to EARTC prediction of blood collection than dictated by BPL as indicated in NHBT0003342. The discussion as shown in documents NHBT0003242 and NHBT0003342 was more about cost and price.

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

64. The objective of the FFP production meetings was to meet our targets which on occasions put pressure on collection and production teams.

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

65. If targets were not met it meant less revenue for EARTC. In the period 1991-92 EARTC targets to BPL were met.

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

66. There was no benefit to the EARTC in exceeding targets except easing the overall budget predictions.

27. In 1989, cross-charging was introduced in England and Wales to act as an incentive for RTCs to increase the amount of plasma being sent to BPL (see NHBT0057426_002). As far as you are aware, what effect (if any) did cross- charging have on the plasma supply in England and Wales?

67. The effect of cross-charging was already in place when I came to EARTC.

Plasmapheresis

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

68. To my recollection, apheresis at EARTC was mostly intended for platelet concentrate production. However, in 1992/93 approximately 10% or less of our plasma output originated from apheresis (NHBT0003380 and NHBT0003342). This part of the overall operation of the EARTC was mostly deferred to Dr Williamson.

29. whether manual or machine plasmapheresis was preferred;

69. Machine plasmapheresis was in place and performance of apheresis equipment was scrutinised. See: Walton JD, Caffrey EA, Allain JP. A comparative study of plateletpheresis using Baxter autopheresis C and Haemonetics PCS plus. Transfusion Medicine 1994; 4: 57-61 (WITN3599008).

70. Manual plasmapheresis was not considered.

30. the relative cost differences between each method

71. In mid-1991, at my arrival, apheresis was already in place (see

NHBT0003342)

31. the infrastructure, expertise and capacity of EARTC to introduce plasmapheresis; and

72. The infrastructure was limited by space. Several staff members including donor doctors had been trained but capacity was limited.

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

73. Yes, it would. In 1992, Dr Williamson predicted apheresis might procure 10% of total EARTC FFP to BPL (NHBT0003380).

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

74. As mentioned above apheresis plasma was no more than 10% of total plasma delivered to BPL. I have no recollection of the situation of other RTC's in that regard and regret that I am not able to comment.

34. Were there problems with the price the BPL were prepared to pay for plasma which impacted on the collection of plasma by plasmapheresis? Please give details.

75. The RTCs including EARTC did not want to produce apheresis plasma below cost and discussions were ongoing with BPL to solve this issue.

35. Did BPL's decision not to produce Factor IX from plasma produced by apheresis impact on the use of plasmapheresis at EARTC? (NHBT0041277_002).

76. No, it had no impact.

Use of plasma reduced blood and red cell concentrates

36. What steps, if any, did EARTC 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?

77. To my recollection, whole blood was not a product available at EARTC, therefore only red cell concentrates were available. Clinical use of FFP was left to clinicians to decide without pressure from the EARTC.

Section 6: Arrangements for obtaining and allocating blood products at EARTC

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

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

78. To my recollection, only Addenbrooke's hospital was a designated haemophilia centre. Other hospitals in the region treated a small number of patients attached to their hospitals. They received products as requested. This system was in place before my arrival and after my departure.

b. Please outline the respective responsibilities of the EARTC], BPL/PFC, the relevant Regional Health Authority ("RHA"), and haemophilia centre directors, and how these responsibilities changed over time.

79. To my recollection, EARTC held a small stock of BPL products to be distributed to hospital treating haemophiliacs, essentially Addenbrooke's in Cambridge, Norwich and Ipswich.

38. Please explain whether any forums were established between the EARTC, BPL/PFC, the relevant Regional Health Authority, and haemophilia centre directors to discuss and facilitate these arrangements. Were meetings held regularly? Were they minuted? If so, by whom? What was discussed at these meetings?

80. I have no recollection of specific meetings with either BPL or directors of Haemophilia treatment centres to address BPL product distribution.

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

81. I do not know what other RTC arrangements with BPL were.

40. Did you, or anyone else at the EARTC, contract directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of imported blood products? The letter at NHBT0000482 suggests that the EARTC did. If so, please describe:

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

82. To my knowledge, no one at EARTC was connected with pharmaceutical companies for the manufacture or importation of any plasma derivatives.

83. Contact was made in 1992 with Octapharma in order to organise the clinical trial for the solvent-detergent-treated FFP called Octaplas. Results were published:

- Freeman JW, Williamson LM, Llewellyn C, Fisher N, Allain JP, Bellamy M, Baglin TP, Kline J, Ala FA, Smith N, Neuberger J, Wreghitt T. A randomised trial of solvent/detergent and standard fresh frozen plasma in the treatment of the coagulopathy seen during Orthotopic Liver Transplantation. Vox Sanguinis 1998; 74: 225-229 (WITN3599009).

b) The broad terms of the contractual agreements made; and

84. As indicated above, there was an agreement with Octapharma for the clinical trial of Octaplas. This was shortly before my stepping down from the RTD and Dr Williamson and Dr F Ala from Birmingham RTC took over the project.

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

85. At the time discussions with Octapharma took place, there was no other company manufacturing pathogen-reduced FFP. The RTC in Lille, France had developed a heat-treated FFP without producing supporting clinical data.

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

86. To my recollection no such shortfall occurred in 1991-92.

42. Was the EARTC 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?

87. There was no involvement of EARTC in the choice of products used to treat patients. We were simply the supplier for NHS products to those centres/hospitals who requested them.

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

88. EARTC was not involved in product choice by clinicians.

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

89. I have no knowledge or information allowing me to answer this question.

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

90. From a therapeutic point of view, it is always better to have a choice of products to adjust therapy to the therapeutic products available.

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

91. In 1991-92, EARTC had no contact with pharmaceutical companies regarding products for haemophiliacs.

Section 7: Production of cryoprecipitate at EARTC

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

92. To my recollection EARTC produced very little cryoprecipitate in 1991-92. Dr Williamson was in charge of components production as

indicated in NHBT0001565. This document was dated November 1992, after my stepping down from directorship of EARTC.

48. If EARTC did produce cryoprecipitate, please describe:

a) where the production of cryoprecipitate took place;

93. Production took place at EARTC

b) broadly, the process that was undertaken, the capacity of the EARTC to manufacture cryoprecipitate and whether this changed during your tenure and why (NHBT0001565);

94. FFP units were overnight brought from -40°C to 2°C. Thawed plasma was centrifuged and supernatant plasma was expressed making cryo-poor plasma. To my recollection the procedure did not change during my tenure.

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

95. A very small amount of cryoprecipitate (~1000/y) was produced according to the limited demand from clinicians.

d) how much funding was provided by the East Anglian Regional Health Authority for the production of cryoprecipitate; and

96. To my knowledge, cryoprecipitate production was included in the overall budget of the EARTC.

e) please describe the arrangements for supplying cryoprecipitate to hospitals and haemophilia centres within the region covered by the EARTC.

97. To my recollection, as for other blood products, predicted demand for cryoprecipitate was included into yearly contracts with NHS trusts in East Anglia.

Section 8: Self-sufficiency

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

98. Self-sufficiency at EARTC meant that blood and blood components requested by clinicians in East Anglia were collected and provided from the country's own voluntary donor population and the blood service's own production without additional products being procured from other sources. In general, national self-sufficiency is beneficial and was a major principle in the foundation of national blood services in Western Europe such as the UK and France. Unfortunately, changes in the therapeutic demands for haemophilia treatment made importation of commercial concentrates inevitable, particularly when product treatment to inactivate infectious agents became necessary and technically feasible and effective.

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

a. Plasma procurement;

b. Decisions with regard to cryoprecipitate production;

c. purchases of commercial blood products;

d. funding received from the East Anglian Regional Health Authority.

99. Self-sufficiency meant our ability to fulfil our contractual obligations with East Anglia users and BPL to meet the needs of the population for blood and blood products.

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

100. My view was that each regional blood centre was responsible for providing requested products in their regions. As to plasma derivatives it was the responsibility of both BPL and the DoH to decide on provision of adequate amounts of products to users.

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

101. I have no recollection of this issue having been discussed with other BTC directors.

Section 9: Services for donors at EARTC

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

102. Whether for HIV, HCV or HBV there was no prior to donation counselling but simply information that testing was taking place. To my recollection, specific information and consent for donors prior to blood donation was not in place in 1991-92. Specific questions were asked prior to donation for identification of HIV high risk donors regarding male homosexuality, IV drug use etc. To this set of questions, the option of indicating donated blood as unsuitable for transfusion was given. The increased knowledge on HCV and the implementation of anti-HCV screening led to additional information and restrictions with particular emphasis on IV drug use, piercing, tattoos and, later, transfusion.

103. Once considered suitable for donation, blood was collected and tested for HBsAg, anti-HIV-1/2 and anti-HCV. A reactive result led to discarding the donation. A reactive result was followed by confirmation either in house or externally. Any confirmed result was followed by recall of the donor for information and counselling as well as informing the GP in charge of the donor.

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

104. Regarding post-donation HIV-1 counselling, between 1985 and Feb 1992 (NHBT0003253) only one donor was confirmed positive and counselled.

105. As to HCV, provisions were made in May 1991 for funding requested to the RHA for anti-HCV testing and confirmation as well as a third consultant whose task would include HCV positive donor counselling. HCV counselling was provided by Dr Caffrey before and after her consultant appointment after in depth training by me.

106. In 1991-92, I have no recollection of enquiry following the identification of a single HIV infection prior to my arrival at EARTC. After implementation of anti-HCV screening, donor information and counselling were provided by Dr Caffrey. Confirmed cases were notified to GPs and referred to hepatologists for follow-up.

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

107. Soon after initiation of anti-HCV screening and confirmation including PCR, some East Anglian donors were found confirmed positive (approximately 1/week). I have no recollection of reports of

post-transfusion HCV infection during the period separating initiation of anti-HCV screening in August 1991 and my stepping down in October 1992. As detailed in NHBT0000073_071 HCV infection was rarely symptomatic and transfused patients were not systematically tested for ALT or anti-HCV. No systematic lookback procedure was in place in 1991-92.

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

108. While information and counselling were directly the EARTC responsibility, it was understood that potential patient care was provided by the hospitals with support from EARTC when required. Retrospectively, lookback was not straight away put in place. To my recollection, systematic collection of small volume of archive plasma samples was in place that would have made lookback technically possible. However, it was suggested as a collaborative study in June 1991 (NHBT0000050_016).

Section 10: Meetings of various committees

Meetings of RTC Directors England

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

109. I'm afraid I do not have enough recollection of these meetings and I attended only a small number of them. It is therefore difficult to precisely understand their purpose and evaluate their functioning.

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

110. As indicated above, not being present at the onset and participating in only a few meetings, I cannot really reply appropriately.

Meetings of NBS NAT Scientific Group

59. Please explain, as far as you are able, the purpose and decision-making remit of the group.

111. To my recollection, this group was established after my departure as EARTC director. However, I participated in this group after my return from France around 1996/97.

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

112. Discussing new approaches to blood safety was clearly useful. In that respect, efforts from my research group since 1999 focused on the development of methods to screen for HCV RNA and then to develop a NAT triplex HIV-1/HCV/HBV. The latter was offered to NBA but not implemented or evaluated.

Standing Advisory Committees on Blood Components and Transfusion Transmitted Infections

61. The Inquiry understands you joined this committee for its ninth meeting. Please explain, as far as you are able, the purpose and decision-making remit of the group.

113. This committee provided an opportunity to discuss issues with colleagues, to present data and to suggest and potentially organise

multicentre studies. It was also very useful to receive criticisms helping to improve projects.

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

114. I believe they were beneficial as a source of exchange of views on projects.

NBS UK Advisory Committee on Transfusion Transmitted Diseases

63. The Inquiry understands you joined this committee for its ninth meeting. Please explain, as far as you are able, the purpose and decision-making remit of the group.

115. My participation in this committee was brief and of very few meetings. Being new to the British transfusion environment I was not in a position to evaluate it.

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

116. I had too little exposure to answer this question helpfully.

NBS Research Review Committee

65. Please explain, as far as you are able, the purpose and decision-making remit of the group.

117. After my return from France, approximately in 1996, I was part of this committee whose purpose was the evaluation of research proposals submitted by NHSBT R&D PIs to determine whether or not they should be funded.

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

118. Yes, I believe these meetings were useful and fair as they were chaired and led by three foreign transfusion specialists who examined and ranked the proposals with comments from representatives of Bristol, Cambridge, and Oxford on projects external to their own R&D group.

Eastern Division of NBTS

67. Please explain, as far as you are able, the purpose and decision-making remit of the group.

119. I have no recollection of these meetings.

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

120. I cannot usefully reply to this question.

Section 11: Information handling by and information sharing between RTCs

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

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

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

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

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

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

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

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

b Who proposed the creation of the database?

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

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

e Did EARTC maintain a separate, or additional, database to track HIVpositive blood donors?

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

a The use of the word "re-introduce" implies that the J donor system had been operational at an earlier time. Is this your understanding?

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

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

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

e Was the J donor system widely used during your tenure? If no, why not? If yes, who was responsible for overseeing the system?

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

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

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

121. Questions 69-78. I have no recollection of record keeping for blood donor information. Details regarding these questions might be obtained from Dr Caffrey. I have no recollection of being made aware of CDSC tracking of post-transfusion infection cases since, to my recollection, a single such case occurred at EARTC in 1985-1991/92.

122. The database system mentioned was established in 1989, 2 years prior to my appointment at EARTC, explaining my lack of information.

Section 12: Knowledge of risk of infections while at EARTC

HIV/AIDS

79. During your time at EARTC, 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?

123. HIV-1/AIDS. At the time of my appointment at EARTC in 1991-92 the knowledge of HIV-1 (HTLV-III/LAV) was considerable and it was well known that nearly 100% of anti-HIV-1 confirmed positive contained infectious virus. My involvement with a series of studies conducted in France in 1983-85 in collaboration with a large group of virologists, immunologists and haematologists informed the group and the world through major publications. My knowledge of the issues was further increased during my 5 years as medical director of the HIV-AIDS and hepatitis business unit at Abbott laboratories. No further knowledge was acquired at EARTC where HIV-1 infection was exceptional (1 case in >0.5M donations).

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

124. My first suspicion of such transmission dated to 1983 and was supported by results of collaborative studies I participated in. Evidence of the transmissibility of HIV-1 by French plasma derivatives was obtained in December 1984 and of the potential efficacy of at least one heat-treated FVIII concentrate in February 1985.

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

125. Considering the vast amount of knowledge on the topic, no specific further studies were conducted at EARTC in 1991-92.

Hepatitis

82. 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 EARTC? How did your knowledge and understanding develop over time?

126. In 1991-92, the transmission of the agent of non-A, non-B hepatitis, by then identified as HCV, by transfusion was well known. The question at the time was whether or not the anti-HCV screening assays becoming available could effectively prevent such transmissions. While I was at Abbott, the virus was discovered and the first assays to detect the virus by genomic amplification and specific antibodies by enzyme immunoassays were actively developed by Abbott. As indicated in document NHBT0000073_071, EARTC was actively involved in furthering knowledge on HCV. On 15th April 1991, confirmation algorithms for anti-HCV and genomic detection by RT-PCR were in place suggesting that a vast majority of confirmed anti-HCV positive donors carried the virus and were assumed infectious, hence the efficacy of

screening. I personally participated in two studies including one on haemophiliacs published prior to my coming to EARTC.

127. Allain JP, Dailey SH, Laurian Y, Vallari DS, Rafowicz A, Desai SM, Devare SG. Evidence for persistent hepatitis C virus (HCV) infection in hemophiliacs. J Clin Invest 1991; 8: 1672-1679. (RLIT0000138

128. Allain JP, Coghlan PJ, Kenrick KG, Whitson K, Keller A, Cooper GJ, Vallari DS, Delaney SR, Kuhns MC. Prediction of hepatitis C virus infectivity in seropositive Australian blood donors by supplemental immunoassays and detection of viral RNA. Blood 1991; 78: 2462-2468. (WITN3599010)

129. Further studies were initiated at EARTC in collaboration with groups at Addenbrooke's hospital:

130. Goffin E, Oliveira DBG, Alexander GJM, Wreghitt T, Lockwood CM, Keogan M, Allain JP. Association of type III cryoglobulinaemia and hepatitis C virus-related cirrhosis. J Intern Med 1992; 232: 284-285.

131. Wreghitt TG, Gray JJ, Allain JP, Poulain J, Garson JA, Deville R, Maple C, Parameshwar J, Calne RY, Wallwork J and Alexander GJM. Transmission of hepatitis C virus by organ transplantation in the United Kingdom. J Hepatol 1994; 20: 768-772. (WITN3599012)

83. 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?

132. Transmission of non-A, non-B hepatitis by blood products was already suspected by experiments in chimpanzees in 1975 but in humans by HCV was demonstrated in 1989-90. As was the case for HIV-1, it was difficult to determine whether the presence of antibodies to HCV indicated the presence of circulating infectious viruses or were an

indication of contact and recovery from the infection. It turned out that for both viruses, contrary to what was observed with HBV, presence of antibodies indicated presence of virus in 100% for HIV-1 but only 60-80% for HCV.

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

133. In 1990-1991, initial testing with the first generation of anti-HCV screening assays in blood donors was initiated first at Abbott laboratories then at EARTC. Considering the relatively low specificity of these assays, the issue of confirmation was raised suggesting the need for confirmation prior to concluding that a seroreactive individual was truly HCV infected. This issue was published in two articles, one at Abbott, the other one at EARTC:

- Smith D, Delaney S, Allain JP, Vallari D, Lee H. A comparison of two supplemental procedures for confirmation of antibody to hepatitis C virus c100-3 antigen in Louisiana blood donors. Transfusion 1992; 32: 415-419. (WITN3599013)
- Allain JP, Rankin A, Kuhns MC, McNamara A. Clinical importance of HCV confirmatory testing in blood donors. Lancet 1992; 339: 1171 - 1172 (letter). (WITN3599014)

a) Did the study outlined in NHBT0000050_016 take place? If so, please give details. If not, why not?

134. To my recollection, this study did not receive sufficient support from the RTCs and was not conducted.

b) Were the ethical problems raised by Dr D Lee in NHBT0000192_102 and by Dr Harrison in NHBT0000075_003, resolved? If so, how?

135. Ultimately the study was not launched in part for concern about litigation from some of my colleagues.

c) Did the study on HCV infectivity by transfusion take place (SBTS0000021_088). If so, please give details. If not, why not?

136. No, the study did not take place.

85. 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? Did the study outlined in NHBT0000051_007 take place? If so, please give details. If not, why not.

137. In 1991-92, it was clear that despite systematic HBsAg testing, rare HBV transmissions by transfusion were occurring. However, it was also known that, except in young children and immunodeficient or immunosuppressed patients, spontaneous recovery was the rule. It was only in the late 1990's that genomic screening for HBV and anti-HBc screening were considered to decrease this residual risk.

138. As to HCV, the risk of transmission by transfusion was relatively high prior to implementation of mandatory anti-HCV screening. However, at that time, the pathogenicity of the agent of non-A, non-B hepatitis was considered mild since the only marker of liver disease available at the time was ALT level which was rarely elevated.

139. At that time, only examination of a liver biopsy would have evidenced ongoing liver fibrosis and inflammation. This procedure was not undertaken unless clinical evidence of liver disease such as elevated ALT was present. In addition, liver biopsy carried risks, particularly in individuals with coagulation deficiencies such as haemophiliacs which meant that they were rarely performed and only by highly specialised surgeons.

140. For HCV infected donors or infected recipients, the risk of chronic hepatitis was high (~80% in UK) as discovered when systematic follow-up was in place and additional means of liver disease evaluation were developed. The benefit of antibody screening was therefore considerable provided tests had high specificity and that confirmation was in place.

141. The document NHBT0000051_007 reviews the three main markers for diagnosis and follow-up of HCV infection: 1) presence of anti-HCV but need for efficient confirmation, in view of the relatively high frequency of false positive; 2) detection of viral genome in anti-HCV confirmed positive but, at the time (May 1991), the sensitivity of genomic detection was not high enough to be used as confirmation. However, a positive PCR result clearly indicated infectivity at least by transfusion; 3) Elevated ALT level was solid as a test but there was evidence that a large proportion of HCV infected individuals initially at infection or later at the chronic stage kept normal ALT level. The study outlined in the document was not completed but data collected at EARTC was published as indicated in (84).

86. repeat of 85.

142. Please see my response to Question 85.

87. What was your understanding of the prevalence of NANB post-transfusion hepatitis in the general population?

143. In 1991-92, the answer to this question was not known since large scale data collection could not be obtained in the first few months of donor screening and an absence of lookback studies. As indicated in document SBTS0000374_052, the prevalence of anti-HCV was approximately 0.5% in EARTC donors prior to confirmation. However, among seroreactive results, nearly half was false positive and blood donors are

not representative of the general population.

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

144. Further details were not available at the time.

General

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

145. In 1991-92, anti-HIV-1 donor screening was in place as well as confirmation of seroreactive samples. The preliminary data mentioned in document NHBT0000073_071 shows that the vast majority of confirmed anti-HCV positive were RT-PCR positive, therefore infectious. Understanding or suspecting the seriousness of HCV infection led EARTC to initiate anti-HCV screening during the summer 1991.

146. The seriousness of HIV-1 infection was very clear in 1991 and 1992 since the median period for the development of clinical AIDS was around 5-10 years and, at that time, no truly effective anti-viral treatment was available. It was therefore of utmost importance to prevent HIV transmission by transfusion by identifying infected donors.

147. As indicated above, the seriousness of HCV infection in terms of transmission by transfusion was identified by lookback studies. Realising the long-term clinical seriousness of HCV chronic infection took considerably longer time since it tended to be asymptomatic for decades before becoming clinically identifiable.

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

148. The decision to initiate anti-HCV screening at EARTC was taken after consultation with top staff and the head of the testing laboratory.

91. What if any role did EARTC 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.

149. I have no recollection of how anti-HCV screening was communicated to East Anglian hospitals. In 1991/92 hospital transfusion committees were established at least with Norwich and Ipswich trusts. This issue might have been raised during HTC meetings.

Section 13: Reduction of risk of infections while at EARTC

92.What donor selection policies and processes were in place during your tenure at EARTC, and how did these change?

150. My recollection is that by the time I started at EARTC, donor selection questionnaires had already been modified to limit HIV-1 infection and to some extent for HCV. For HIV-1, male homosexuals, IV drug users and sexually promiscuous individuals were excluded. For HCV, in addition to IV drug use, tattoos, scarifications and transfusions were added.

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

151. Donor selection followed recommendations and procedures in place at the beginning of 1991.

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

152. High risk donors were excluded according to the questionnaire. To my recollection it was not significantly modified during my tenure at EARTC.

95.Were there any difficulties in implementing the exclusion of high-risk donors at EARTC?

153. I was not made aware of any such difficulties.

96. What information (either written or oral) was given to donors about the risk of them transmitting infections via their blood? When was such information provided? In particular, was there a nationally agreed leaflet or did each RTC produce its own leaflet?

154. This information was given to donors by the donor physicians headed by Dr Walton initially, then by Dr Caffrey.

97. How often were these leaflets updated, and how was their content decided?

155. I have no recollection of this issue being raised during staff meetings nor of having been involved in discussions on this topic.

98. 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?

156. As previously indicated, this information was in place prior to my arrival and delivered by the donor doctors.

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

157. It was highly effective since only one HIV-1 infected donor was detected in 6 years, in part because East Anglia was an area of low prevalence.

100. NHBT0017532 relates to minutes of the Advisory Committee on Transfusion Transmitted Diseases, held on 7 May 1992, at which you were present. It was decided that the present policy of accepting sexual partners of HCV infected persons would be continued. Did you agree with this approach? How did your view develop over time? Please explain your answers.

158. At the time of this meeting, very little epidemiologic data was available to determine whether or not HCV was sexually transmissible. The little data published did not find such transmission and those there were might have been too few to be considered as evidence. Later on, it was confirmed that heterosexual transmission did not occur to a large extent because of the relatively low level of viral load in infected individuals. Sexual transmission was nevertheless demonstrated in homosexual males undertaking sexual practices during which issue of blood took place.

Treatment with cryoprecipitate

101. In September 2013, you wrote to Lord Penrose regarding treatment with cryoprecipitate as a strategy to reduce the risk of AIDS (PRSE0005140). As to this:

a. You stated that a cryoprecipitate strategy was "rejected in ...the UK by patients through their associations (and some clinicians)" (PRSE0005140,

page 1). To the best of your knowledge, which patient associations rejected the strategy and when did they do so? To what extent, if at all, did patient associations understand the risk of AIDS in cryoprecipitate as opposed to concentrates? Which clinicians rejected the strategy? What was your view of this strategy?

159. This statement essentially referred to the situation in France where at a meeting of the French Haemophilia Society (FHS) in summer 1983, Prof Soulier and myself presented the option of treatment of haemophilia A with frozen or freeze dried cryoprecipitate prepared from less than 10 donations instead of concentrates prepared from pools of several 1000 donations in order to limit the potential for transmission of the potential infectious agent associated with AIDS. Members of the FHS including haemophiliacs rejected this option as retrograde preferring to take the still uncertain risk rather than losing their recently acquired freedom provided by concentrates and home/self-treatment to live a normal life. Several physicians in the audience supported this position and put on the table suggestions of prophylactic treatment. My contacts with UK haemophilia treaters indicated a similar position with the UK Haemophilia Society.

160. Having in the past conducted treatment of young haemophilia A patients with fresh frozen and lyophilized cryoprecipitate including initiation and development of self-treatment with cryoprecipitate, I knew it was feasible even when therapy took up to one hour instead of 10-15 minutes with concentrates. Considering the risks associated with the still poorly understood AIDs agent, I was in favour of the return to cryo-only treatment policy.

b. You stated that patient information was emphasised in the late-1980s, prior to which "most patients trusted completely their physician" (PRSE0005140, page 2). Given this, was it appropriate that the decision in 1983-84 to reject treatment with cryoprecipitate was taken by patients, rather than by their clinicians? Please give reasons for your answer.

161. This was certainly true for patients whether in the UK or in France but different for leaders of both countries' haemophilia societies who represented the patient population and took decisions as a body superseding their physicians' advice or choosing their preferred policy when their advisers' opinions differed.

Viral inactivation

102. At a meeting of the Executive Committee held on 27 January 1992 you discussed providing virally inactivated FFP (see NHBT0035861 page 6).

162. In 1992, plasma derivatives for therapy of both haemophilia A and B were heat-treated or submitted to other means of viral inactivation such as solvent-detergent. There was then evidence that these measures eliminated HIV-1 transmission and were largely effective against HCV and HBV. At that time, HBV vaccination was recommended and largely in place. The protection of patients treated with FFP, often with several units, although at lower risk of HIV, HCV and HBV infection related to anti-HIV-1/2, anti-HCV and HBsAg, remained incomplete and needed to be improved.

a) What method was used to inactivate the FFP?

163. There were at the time two methods considered: one from the BTC in Lille France using, if I'm not mistaken, heat-treatment; the other developed by Octapharma with the solvent-detergent method developed by the New York blood centre was known to be highly effective against enveloped viruses including HIV, HCV and HBV.

b) Was this taken any further? If not, why not?

164. As indicated in document NHBT0017532, plans were made to explore the safety and efficacy of both products in both England and Scotland.

As far as EARTC was concerned, a protocol was designed to examine the Octaplas product in collaboration with the RTC in Birmingham. This project was initiated by myself and completed by Dr Williamson and Dr Ala after my departure from EARTC directorship. Data was published in 1998:

Freeman JW, Williamson LM, Llewellyn C, Fisher N, Allain JP, Bellamy M, Baglin TP, Kline J, Ala FA, Smith N, Neuberger J, Wreghitt T. A randomised trial of solvent/detergent and standard fresh frozen plasma in the treatment of the coagulopathy seen during Orthotopic Liver Transplantation. Vox Sanguinis 1998; 74: 225-229. (WITN3599009)

c) If so, was such a product supplied by EARTC? If so, to whom?

165. The Octaplas was imported by BPL and distributed by both EARTC and RTC Birmingham as requested by participating clinicians.

103. What steps did you and/or others at EARTC take during your tenure with respect to the viral inactivation of blood and blood products?

166. In 1991-92 the main measure intended to improve safety of blood components was the implementation of anti-HCV screening of blood donations. The only measure considered regarding the viral inactivation of blood components was the investigation of the solvent detergent method applied to FFP offered by Octapharma.

a) In particular, please explain your role in the progression or promotion of virally inactivated blood products during your tenure as Director of the East Anglian Blood Transfusion Service.

167. The method used was solvent-detergent (SD) developed initially by the New York Blood Centre as inactivating enveloped viruses including HIV, HCV and HBV in plasma pooled for preparation of plasma derivatives

(FVIII concentrates) as an alternative to heat-treatment. In our case, it was applied to FFP for patient treatment in order to improve product safety. However, it was known that non-enveloped viruses such as HAV and parvovirus B19 were not or were only poorly inactivated. In early 1992, I initiated exploration of the SD inactivation method developed by Octapharma applied to English plasma including from EARTC.

b) Did you carry out a trial for Octopharma? If so please give details. You may find NHBT0010346 and JPAC0000036_104 to be of assistance.

168. I did not carry out the Octaplas trial as it started after my departure. I was the initiator and involved in the design of the trial together with Dr Williamson at EARTC, Dr Baglin at Addenbrooke's hospital, Dr Ala at Birmingham RTC and the director of Newcastle RTC. Dr Lane was involved in arrangements for procurement of the SD-treated plasma provided to Octapharma for product preparation from EARTC, Birmingham and Newcastle RTCs.

c) Did you undertake clinical trials of solvent detergent treated plasma? If so please give details of that trial.

169. As indicated above, I initiated the trial and drafted the protocol (NHBT0003749) together with Dr Williamson and Dr Baglin. 300L of FFP was collected in equal volume between 3 RTCs, the plasma was shipped to Octapharma in Austria where the SD treatment was applied and treated FFP was returned for clinical use in frozen state. This product was intended for treatment of patients likely to receive several units that otherwise would make them at higher risk than a single unit. It was limited to Warfarin reversal, correction of coagulation deficit prior to liver biopsy and TTP.

104. Please refer to BAYP0004681_001, a Cutter Pharmaceutical memo dated 21 July 1983. The memo cites a conversation in which you stated your

belief that heat treatment was not the answer to virus inactivation in Factor VIII concentrates. Please can you explain:

a) The reasons for your scepticism at this time.

170. At the time (1983) heat-treatment of FVIII concentrate was at a preliminary stage and laboratory means to determine efficacy were not available. There were only very limited animal models such as chimpanzees to examine efficacy for the non-A, non-B agent limited to the indirect marker of ALT level. At CNTS, Prof Soulier had conducted experiments of heat-treatment on local products concluding at deterioration of lyophilized concentrates. Means for viral inactivation assessment were not available. At that stage, heat-treatment appeared as more of a potential method than a method with demonstrated efficacy.

b) To the best of your knowledge, whether Oxytannic acid was adopted beyond Immuno and Kabi as a method for viral inactivation of concentrates.

171. To my knowledge, although Immuno may have conducted experiments regarding Oxytannic acid, it was not what they ultimately used as viral inactivation treatment which was heat in the presence of high-pressure vapor. I have no information on what Kabi was doing at the time.

105. Please refer to CGRA0000505 which cites that the French Blood Transfusion Service, Behringwerke and Travenol were conducting their own Factor VIII heat treated studies under your direction. Please can you explain:

172. At the time of the report quoted (NHBT0096602_024), mid-February 1985, the first clinical study demonstrating the efficacy of heat-treatment developed by Travenol had been published in the Lancet by Mannucci, Gazengel, Montagnier and others. As indicated in the same document by

Prof Egli, heat-treatment has been shown to be inefficient against non-A, non-B agent in several studies in Germany, or in the UK (Kernoff).

a) The extent of your role in these studies.

173. My role at this time was to be part of a French haemophilia study group chaired by Prof MJ Larrieu and to be co-chair of the MIR group together with Prof JF Bach. The study apparently referred to in the document was a collaborative study of the FHSG that examined the immunological side effects of FVIII concentrates heat-treated and not heat-treated, with different levels of purity including Travenol, Bheringwerke, Armour and French products. The results of this study were published:

Allain JP, Frommel D, Bosser C, Gazengel C, Larrieu M J, Sultan Y. The role of HIV infectivity and composition of Factor VIII concentrates on the immunity of haemophiliacs positive for HIV antibodies. Vox Sang 1987; 53: 37-43 (WITN3599015).

b) any significant findings such as post-treatment transmission.

174. To my recollection, this study was not examining HIV-1 transmission but compared patients anti-HIV negative or positive.

c) Whether you assumed a similar capacity for the UK National Blood Transfusion Service.

175. At that time, CNTS was not considering utilizing its own heat-treatment but was in discussion with Immuno for a technology transfer of their method.

106. Please refer to NHBT0039191. What were the grounds for your plea to the French Blood Transfusion Service in urging them to acquire technology for heating factor VIII for the treatment of haemophilia? Furthermore, what was the response of the French Blood Transfusion Service to your request?

176. My plea to introduce heat-treatment for plasma derivatives utilized for haemophilia treatment started in the second quarter of 1984 when I suggested to Prof Soulier and to his successor to be, Dr Garretta, to enter in a discussion with Immuno in place of the failed negotiation with Travenol in order to negotiate the conditions of a heat-treatment technology transfer for Factor VIII and factor IX concentrates produced by CNTS. After preliminary contacts, CNTS tabled a technology exchange involving a unique product developed by CNTS and other potential arrangements. Prof Soulier delegated Dr Garretta to finalise these discussions in August 1984 in Vienna where a transfusion international conference was taking place. I accompanied Dr Garretta to this meeting with Dr Eibl CEO of Immuno and two of his co-workers. During the meeting, Dr Garretta and Dr Eibl vocally disagreed leading Dr Garretta to prematurely leave the meeting and break out of the negotiation.

177. It was only in January 1985, after the retirement of Prof Soulier and Dr Garretta's directorship that I attempted to renew the negotiation for a technology transfer with Immuno taking arguments from the information received in December 1984 and published in Feb 1985 that a heat-treated FVIII concentrate prevented seroconversion to anti-LAV. This argument was developed in strong and urgent words in the letter I sent as noted by Prof Lachmann's letter in document NHBT0039191. Negotiations resumed soon after and the first lots of heat-treated CNTS FVIII concentrates were produced in May 1985, initially by Immuno, then at CNTS.

178. The continuous disagreements between Dr Garretta and myself over these issues in the following months led to my dismissal GRO-D in early 1986 and my move to the USA.

Autologous transfusion

107. What steps did you and/or others at EARTC take during your tenure with respect to autologous transfusions?

179. In 1991, autologous blood transfusion programmes were put in place in Norwich and Ipswich Trusts as one of the potential means to reduce the side effects of allogeneic transfusion, immunological as well as microbiological. This programme was particularly active in Ipswich under Dr Dodd's leadership. The collaboration between hospitals and EARTC was in the provision of the materials and the testing of collected autologous blood for blood grouping as well as viral testing.

Provision of diagnostic screening kits

108. Please describe the arrangements in place at EARTC in regards to the provision of diagnostic testing kits for donation screening ("screening kits").

180. I have no recollection of the arrangements in place for procurement of screening kits. This was supervised by the finance officer Mr Hawdon. Prior to ordering kits, comparative studies were conducted to identify the test with highest performance.

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

181. I have no recollection of any specific contacts with potential test providers. My recollection is that until NBA was in place and operating, each RTC was free to order their own kits.

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

182. The policy in place at EARTC in 1991/92 was that the choice of assay for donation screening was strictly performance i.e. sensitivity and specificity. This was valid for both screening tests and confirmatory assays. The development of anti-HCV second generation assay, adding further viral antigens to increase sensitivity, and abandoning one antigen source of considerable false positivity rate, significantly improved the performance of tests from both Ortho and Abbott. The availability of a confirmatory assay to exclude false positive in order to appropriately inform deferred donors was critical (NHBT0000073_071). In that regards, EARTC not only examined RIBA from Ortho/Chiron and the Abbott MATRIX confirmatory assay (SBTS0000417_022) but also developed a RT-PCR assay enabling identification of the presence of virus in circulation and therefore infectivity (NHBT0015082_004).

111. 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?

183. In 1991, essentially two companies had put in the market screening assays for anti-HCV: Ortho first in 1989 followed by licensing of Abbott in 1990. These companies subsequently improved the first generation of tests that presented unsatisfactory sensitivity and specificity by better second-generation assays that were ultimately implemented together with the RIBA confirmatory assay. Having been staff of Abbott laboratory for five years prior to my appointment at EARTC and having been in the USA directly involved in the development of HCV assays, it was natural to continue collaborating with my former colleagues in a strictly research mode as shown in the publication: Allain JP, Rankin A, Kuhns MC, McNamara A. Clinical importance of HCV confirmatory testing in blood donors. Lancet 1992; 339: 1171 - 1172 (letter) (WITN3599014).

184. This in no way influenced practical matters in anti-HCV implementation.

112. In March 1995 you were involved in a study which found no evidence that anti-HBc screening would significantly reduce the evidence of post-transfusion Hepatitis B (NHBT0004108_045). This contrasted with views put forward by Liverpool following their own study in 1993 (NHBT0009842).

a. In your view, what accounts for the disparities in these views?

185. Screening for anti-HBc was a logical approach to improve HBV blood safety beyond HBsAg screening since it indicated prior contact with the virus known to be only immunologically contained by anti-HBs. Samples with low anti-HBs (<100IU/L or 0.1IU/ml) or negative anti-HBs were considered potentially infectious. The only assay enabling identification of infectious samples was genomic amplification (PCR). The disparity of conclusion between the study conducted in Liverpool RTC and EARTC was that the latter included detection of HBV DNA by PCR. This assay did not detect any suspect anti-HBc sample carrying detectable virus, therefore concluded non-infectivity while the Liverpool study limited to serological assays had no means of recognizing infectious samples and proposed to continue the screening until clinical data might help conclude. Another discrepancy between the two studies was the absence of a confirmatory procedure in Liverpool (NHBT0001954_001) and strict confirmation at EARTC by confirming Abbott Corzyme repeat reactive with the Ortho HBc ELISA decreasing by a factor of 2 the number of positive results.

b. As far as you remember, how was your study received by blood services at the time?

186. I have no recollection of comments made by other RTCs.

113. Routine anti-HBc screening was discussed at ACTTD throughout the 1990s) and at other committees, such as SACTTI, into the 2000s

a) What was your personal view on the subject and did it develop over time?

187. In the following years, anti-HBc screening was nationally considered and concluded that the cost of screening superseded the potential safety benefits. However, in 2004, my laboratory resurrected the issue and spent the next 10 years studying what was called 'occult HBV infection or OBI' with molecular assays of considerably higher sensitivity than what was used in 1993. It is highly likely that the negative results obtained in 1993 were caused by poor sensitivity of the PCR assay. As a result of the OBI issue, manufacturers of NAT screening systems (Roche and Novartis) included HBV DNA in triplex assays simultaneously screening for HIV-1, HCV and HBV genomes. Sensitivity of these initial assays for HBV DNA was revealed to be insufficient, leading both manufacturers to develop assays of higher sensitivity. Despite such increase in sensitivity, rare cases of HBV transmission by transfusion still occurred exemplifying the considerable difficulties in reaching full HBV safety.

b) What do you recall of the arguments for and against its introduction?

188. The main arguments raised against anti-HBc screening of blood donations were:

1) The specificity of the tests available was insufficient and there were no reliable confirmatory assays to identify false positives;

2) the relatively high prevalence of repeat reactive results (~0.5%) would deplete UK blood supply;

3) Clinical evidence of HBV transmission was very low, hence limited safety benefit;

4) the cost was considerable and the cost-efficiency unconvincing. I was not involved in any stage of these discussions held mostly in the SACTTI of which I was not a member.

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?

189. As indicated above, the availability of triplex NAT to a large extent superseded the utility of anti-HBc screening, although several countries with epidemiology similar to the UK such as Germany, France, Australia, USA and Canada implemented anti-HBc screening in parallel with NAT. Ultimately, it appears that the economic issue was in the forefront of decision-making.

Introduction of anti-HCV screening

114. When did EARTC begin anti-HCV screening? You may be assisted by NHBT0041282_003, NHBT0041280_003 and the minutes of the Executive at EARTC on 15 April 1991 which suggested that the EARTC would be able to carry out routine screening of HCV by July 1991.

190. My recollection is unclear on this point but the start of testing should have been 1st of August 1991. EARTC had all elements in place to start screening and initiation of screening was decided accordingly. This one-month advance from the national starting date of 1st September permitted that all labile blood products were already tested at the official starting date.

115. Dr Gunson wrote a letter to all RTC directors suggesting a delay in commencing anti-HCV screening from July to September 1991 so that "'second-round' comparative evaluation" of the testing kits could take place. Did you agree or disagree with Dr Gunson's suggestion to delay

testing to undertake this comparative evaluation? Please explain the basis for your answer.

191. On the 8th of April, the EARHA had agreed to fund anti-HCV screening of blood donation (NHBT0041282_003). Second generation anti-HCV assays with improved sensitivity and specificity were available and tools for confirmation (RIBA and RT-PCR) were in place at EARTC. In addition, Dr Caffrey was trained by myself as counsellor for donors identified as confirmed positive for HCV infection. The EARTC was therefore ready to start screening by 1st August 1991 (NHBT0041281_003; NHBT0045589) and it was to the clear advantage of blood safety to start screening as soon as technically feasible.

116. It appears that this suggestion was discussed at a meeting you attended on 8 April 1991 at which meeting you indicated that you would prefer to introduce routine HCV testing at an earlier date which would be dependent on the research Dr Caffrey was undertaking. What was this research and what relevance did it have to the start date for HCV testing?

192. I do not recollect the exact nature of Dr Caffrey's project but on 15th April, EARTC was ready to start screening on 1st July/August 1991 (NHBT0041281_003).

117. In response to Dr Gunson's letter, some RTC directors suggested a staggered start date for the implementation of testing (i.e. different start dates for different RTCs) while others supported a uniform start date. Which view did you take? Why?

193. My view was that anti-HCV screening implementation should be initiated as soon as the RTC was technically ready to do so, meaning, as indicated above that funding, screening assay procurement, confirmatory algorithm, laboratory arrangements, and counselling were in place. Being in favour of a staggered start, EARTC did so as soon as ready.

118. Despite Dr Gunson's suggestion to delay the introduction of screening, the Northern RTC led by Dr Lloyd introduced routine testing in April 1991, becoming the first centre to do so. Dr Lloyd's view, in contrast to that of Dr Gunson's, was that, the "Second Generation HCV tests were acceptable tests for donor screening" by June 1991 (NHBT0000076_009), and that deciding not to implement testing despite having the capability "would be indefensible under the current Product Liability Legislation" (NHBT0000074_014). As to this, did you agree or disagree with Dr Lloyd? Please explain the view you had at the time.

194. Discussion regarding the decision of Dr Lloyd to start screening in April 1991 preceded my arrival at EARTC. After reading the correspondence provided, my tendency would have been similar to Dr Lloyd's although he did not specify what he considered sufficient preparation to initiate screening. I have listed those factors above and as soon as EARTC met these criteria I and my staff decided to initiate testing.

119. What role (if any) you or others at the EARTC play in the trials of the HCV testing kits?

195. The team at EARTC did not participate in the large comparative studies of second-generation Ortho/Abbott screening assays that had started prior to my arrival at EARTC. We concentrated our effort into confirmation at three levels (NHBT0000051_007):

196. Exclusion of screening false positive by use of serologic confirmatory tests: essentially RIBA-2 distributed by Ortho/Chiron and MATRIX by Abbott that was not ultimately made commercially available.

197. We had been undertaking the development of a molecular test detecting viral RNA by RT-PCR using primers selected in the most conserved regions of the genome to avoid failures caused by mutations. However, as always in early stages of test development optimal sensitivity took

time to reach. However, the 80-90% sensitivity obtained was in line with later data showing clearly that approximately 20% of anti-HCV confirmed positive samples had spontaneously recovered from the infection and carried antibodies without circulating virus and were not infectious.

198. ALT testing was a useful approach in patients with clinical hepatitis and data rapidly accumulating in 1991/92 showed that most infected people remained asymptomatic, and a considerable proportion did not present elevated ALT, hence a limited value of this approach when a normal result was obtained but considerable value when found elevated.

120. What impact did HCV testing have on EARTC? In particular:

a) What was the process for screening donors and/or blood donations? Please explain the process that you used for repeat tests.

199. I do not precisely recollect the algorithm used when initiating anti-HCV screening. The primary screening assay was 2nd generation and repeat reactive donations were discarded. Samples were then submitted for confirmation, initially by Professor Tedder who had access to RIBA-2. Other approaches such as retesting with an alternative screening assay and performing RT-PCR was only on a research basis.

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

200. I do not recall whether or not at this point (August/September 1991) systematic aliquots of each donation were archived. To my knowledge, no lookback testing was undertaken.

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. You may find NHBT0045589 of assistance.

201. As indicated in NHBT0045589, repeat reactive donations were excluded from use. Reactive samples were submitted for confirmation and a confirmed result initiated recall of the donor, counselling (Dr Caffrey) and referral to the Addenbrooke's Hospital hepatologist Dr Alexander. Donors with indeterminate results were flagged (the donation destroyed), retested at subsequent donation and handled according to the recent result considered together with the initial one. Donors with an unconfirmed result (reactive screening test but negative confirmatory assay(s)) were allowed to donate, their plasma was suitable for fractionation and cellular components were destroyed.

d) Did you have a practice of allowing a donation to be used if it had tested positive where there was a test result from a different manufacturer that was negative? If so, why was this your practice? Did you continue with this practice throughout your tenure at EARTC?

202. No, we did not. However, a research project was developed according to which the result of repeat testing of an initially repeat reactive sample was evaluated as a potential alternative to RIBA-2. The performance of this assay was disputed to a large extent in view of the fact that the separated antigens used in RIBA were identical to those used for the screening test. An alternative screening assay using different antigens as recombinant protein or specific peptide appeared as a better potential option. Results of this approach were published as a collaboration with North London RTC:

Allain JP, Kitchen A, Aloysius S, Reeves I, Petrik J, Barbara JAJ, Williamson LM. Safety and efficacy of hepatitis C virus antibody screening of blood donors with two sequential screening assays. Transfusion 1996; 36: 401-405 (NHBT0000030_124).

e. What impact did the introduction of testing have on the risk of transmission of HCV through blood donations?

203. As far as EARTC was concerned, by the time of my departure, no clinical result estimation was possible over just a year of screening implementation.

121. What funding and operational support was EARTC provided with to aid in the implementation of testing? Did this have an effect on EARTC's ability or willingness to commence testing earlier?

204. At EARTC, a budget covering anti-HCV screening had been submitted to Dr O'Brien, director of the RHA and was accepted. The date of commencement was left at the discretion of EARTC as soon as the various steps required for implementation were fulfilled.

122. The Inquiry understands that you attended a meeting of the UK ACTTD on 13 August 1991 (NHBT0000062_096). In this meeting, your trial of HCV patients was discussed and results tabled. What reception did your results receive?

205. After 30 years, I have no recollection of what the study mentioned in document NHBT0000062_096 might be. The fact that 5 transfusion centres expressed interest in participating suggests that it was well received.

123. You carried out screening on 11 donations for the Oxford RTC in June 1992 (NHBT0046307). Please explain how this came about and what the tests were for.

206. In June 1991, the RTC in Oxford did not have access to confirmatory assays for reactive anti-HCV samples. 11 samples were shipped to EARTC because at that time we were comparing results between Ortho

RIBA-2 and Abbott MATRIX. As shown in the result table both assays provided concordant results; one confirmed, one indeterminate reactive only with C511 and 9 non-confirmed.

124. The Inquiry understands that you undertook a comparison study of Anti-HCV assays: Ortho, Abbott, UBI/Organon and Murex in September 1992 and noted that each of these assays should have "equivalent sensitivity" (NHBT0017530_003). How were your findings received by your colleagues at ACTTD?

207. This is not the case. The assumption indicated at the beginning of the proposal came from a variety of studies examining on its own or comparing two assays in various RTCs in the UK. None of these studies were conducted at the EARTC. Although antigens used for screening in the Abbott and Ortho assays were identical in 1991, some differences in the way they were used in each assay might have differed sufficiently to generate different false positives. Organon and Murex assays appeared to utilize their own antigens, including peptides, that made them highly suitable for a confirmatory role.

125. The Inquiry understands that in a 1998 Journal article you stated "very early on, it was recognized that antibody to HCV was more difficult to detect and its clinical significance more difficult to interpret than other viral markers such as antibodies to HIV." (NHBT0057720, page 1). Do you believe that these difficulties contributed to HCV being 'sidelined' in favour of a focus on HIV? Please explain your answer.

208. The statement quoted reflects the fact that antibodies to HCV take a longer time to become detectable than antibodies to HIV, the window period being on average 55 days (range 14-90 days) compared to the HIV-1 mean of 21 days. This suggests that the host immune system takes a longer time to recognize HCV antigens and mount a detectable immune response. This delay might also be connected to the viral load of

HCV typically 10E4 to 10E5 IU/ml while HIV-1 viral load typically reaches 10E6-10E7 IU/ml.

209. There is also evidence that in truly infected individuals, some antigens such as C22 or C33 trigger a more robust immune response than other antigens such as C100.

210. Finally, significantly different from HIV-1 or HBV titres of antibodies tend to be relatively low and as a result tend to become undetectable months or years after infection followed by spontaneous or therapy-induced recovery. This is due to a relatively low level antigenicity of HCV proteins eliciting antibody production. Since antibodies decrease level with a half-life of approximately 21 days, a low titre antibody remains detectable for only a few months. High titre antibodies such as elicited by HIV-1 proteins or by HBV core antigen remain detectable for years and tend to remain stimulated by low level replication of the virus. In the case of HCV, recovered individuals no longer harbour the virus, hence metabolic decline of antibodies takes place.

211. I do not believe this led to side-lining HCV but it explains the difficulties encountered to obtain high performance (sensitivity and specificity) screening assays and uncertainties regarding confirmation. Ultimately, genomic screening able to reach very high specificity and sensitivity turned out to be considerably more reliable than serologic assays.

126. The Inquiry understands that you co-authored a 1999 journal article, "HCV/HIV NAT in individual blood donations using the method developed by Gene Probe/Chiron: a comparison with minipool testing". You undertook a comparison study between two different HCV NAT testing assays. Please outline your findings. Was any further action taken as a result of this study?

212. In 2000/2001, the research laboratory of molecular virology I conducted entered into a collaboration with the American company Gen-Probe who

had developed a NAT duplex assay simultaneously able to detect HIV-1 and HCV genomes with high sensitivity and high throughput intended for blood donation screening. The laboratory was the first external evaluator of this novel technology. Results of these evaluations were published in two consecutive articles:

- Candotti D, Mundy C, Kadewele G, Nkhoma W, Bates I, Allain JP. Serologic and molecular screening for viruses in blood donors from Ntcheu, Malawi: high prevalence of HIV-1 subtype C and of markers of hepatitis B and C viruses. J Med Virol 2001; 65: 1-5. (WITN3599016)

- Candotti D, Richetin A, Cant B, Temple J, Sims C, Reeves I, Barbara JAJ, Allain JP. Evaluation of a transcription-mediated amplification-based HCV and HIV-1 RNA duplex assay for screening individual blood donations: a comparison with a minipool testing system. Transfusion 2003; 43: 215-25. (WITN3599017)

213. As shown by the authorship it was a collaboration between the Cambridge lab and blood centres at Colindale and Tooting.

214. This assay was subsequently modified to accommodate HBV molecular screening in a Triplex assay called Ultrio on the Tigris instrument that has been used extensively all over the world.

215. However, the high cost of this system made it unaffordable in developing countries, particularly sub-Saharan Africa where prevalence of HIV-1 and HBV are the highest in the world. We therefore developed our own triplex based on the Real-time PCR technology and made it available to developing countries at a cost approximately 4 times lower than Ultrio. Data were initially published in 2004:

Candotti D, Temple J, Owusu-Ofori S, Allain JP. Multiplex real-time quantitative RT-PCR assay for hepatitis B virus, hepatitis C virus and

human immunodeficiency virus type 1. J Virol Methods 2004; 118: 39-47. (WITN3599018)

127. The Inquiry is aware of an email chain dated 29 August 2003 - 3 September 2003 between Marcela Contreras, Elizabeth Love and Martin Gorham discussing your proposals for your own HCV, as well as HIV and HBV NAT testing kits developed by you. These proposals were rejected by Contreras as being impractical. Contreras went on to suggest that you should be considered as an "external expert". You may wish to refer to NHBT0063403.

216. My research interest in molecular diagnostics for viral infections in donor blood started in 1997-98 following assay developments for molecular confirmation of anti-HCV. In 1999, a large-scale screening of donor blood was published in collaboration with the North London RTC:

Petrik J, Hewitt P, Barbara J, Allain JP. Large-scale HCV RNA Screening in First-Time Blood Donors: The First Step Towards Genomic Screening of Blood Donations. Vox Sanguinis 1999; 76: 159-162 (WITN3599019).

It was followed by a Triplex development and our expertise was recognized by Gen Probe to evaluate their own Triplex assay.

a. From your perspective, did you believe that Contreras prioritised apparent practicality over any safety factors?

217. My impression was that Dr Contreras was reluctant to consider exploring new ways to improve blood safety unless there was a clear clinical need. Cost was also a concern of hers. At the time of the discussions referred to in the question, there was little interest by NHSBT in NAT triplex as a means to improve blood safety. The main issue was the cost of such testing. In view of this economic reluctance, I offered to consider the Real-time PCR Triplex developed in my laboratory which was suitable to massively reduce cost while keeping efficacy. In the following years, I

raised the issue of OBI as a risk for blood safety and this issue was considered not clinically relevant by NHSBT.

218. It took until the late 2000s to recognize the OBI issue in England although HBV DNA screening remained in pool. The first data and acknowledgement of the problem came out in 2021;

Harvala H, et al. Hepatitis B infections among blood donors in England between 2009 and 2018: Is an occult hepatitis B infection a risk for blood safety? Transfusion 2021. PMID: 34114670 (WITN3599020)

b. Did you believe that your views on HCV NAT testing were being sidelined or ignored within the NBS at the time?

219. My research group had developed an HCV NAT, robust assay but it was not considered by NBS suitable for donor screening since it was not submitted or approved by the regulatory authorities as commercial assays are required. This assay utility was therefore restricted to research projects. As a result, my research interest shifted towards sub-Saharan Africa where major HCV discoveries were made using this assay.

Recall practice and procedure at EARTC

128. Please give an overview of product recall practice at EARTC, and how this changed during your tenure.

220. I have no recollection of the procedure in place for recall of products.

129. What, if anything do you remember about any formal recall or notification procedures in place?

221. I do not remember any product recall in 1991-1992.

130. 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?

222. If and when product recall was necessary EARTC had established excellent relationships with clinicians in the region's hospitals and I have no doubt that they would have complied.

General

131. Please describe all other steps or actions taken at EARTC 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.

223. Ensuring safety of blood products for patients was a constant concern of the EARTC team. Blood safety was a major topic of the research I initiated such as: development of confirmatory assays for anti-HCV reactive samples, screening for anti-HBc, developing a RT-PCR assay for HCV genome, introducing virally inactivated FFP in 1991/1992, support of autologous transfusion.

224. After my return from France in 1995 I resumed research projects intended to further improve blood safety such as development of Triplex NAT, evaluation of Gen-Probe Ultrio, initiating discovery and analyses of OBI in donor blood, developing blood safety in sub-Saharan Africa during and after my sabbatical as head of the blood Centre at Komfo Anokye Teaching Hospital in Kumasi, Ghana in 1999/2000.

132. 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?

225. Research on blood safety was always supported by EARHA as well as NBA and subsequently NHSBT through fund allocation or grants that supported my research. The results and suggestions emerging from such research were presented to my colleagues and coordinating bodies but were not always followed up, often for economic reasons but also for clinical or scientific disagreements.

133. How did the desire for consensus across the RTCs impact efforts to achieve blood safety at a local level?

226. At EARTC, discussions regarding blood safety took place at each clinical and research weekly or biweekly meetings involving not only Dr Williamson, Dr Caffrey, Dr Rankin, Dr Walton but also people in the lab such as Mr D Wenham. We operated by consensus but, following my arrival, it took some time to turn the local culture into a more academic and research-oriented view of transfusion.

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

227. Rapidly after the creation of the division of Transfusion Medicine in the Dept of Haematology at the University of Cambridge within the EARTC, it became apparent that through the research conducted the organisation would shift position from follower to leader. We freely decided on the directions of our research and regularly presented the data generated to our colleagues for discussion and potential adoption. As expected, opinions differed among colleagues in the UK, some supporting, some contesting. As shown in the documents collected, there was free exchange of opinions, arguments and data leading to progress.

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

228. It appeared clearly in the transfusion organisation in developed countries after the shock generated by the HIV crisis that the policy of the precautionary principle superseded the 'maximum benefit at minimal cost' suggested by Dr Contreras. Large amounts of public money were spent for little if any benefit such as the introduction of blood filtration during the variant CJD crisis that was introduced on the basis of research data that ultimately turned out to be incorrect. The HIV crisis initiated a general movement from policies developed by experts and transmitted to health authorities for decision and implementation to political decisions made under the pressure of media leading the public into 'scandals' resolved for emotional and political motives rather than science and reason. This evolution was not yet perceptible in 1991-1992 so it was not specifically discussed with my colleagues at the time. It was much clearer in 1995 when I returned from France but at that time I was ostracised by NHSBT and had no contacts with former colleagues.

136. If you do agree:

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

229. Around 1995

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

230. My experience was that during and after the HIV crisis, the influence shifted from experts to media and public and elaboration of the precautionary principle with its utility, advantages and excesses.

c) What caused the change to occur?

231. To a large extent the society changed towards considering that the public knew the truth, not the specialists. However, the recent experience of the COVID-19 pandemic exemplified a return to government decision-making based on scientific advice.

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

232. Decision-making in terms of blood safety on the basis of cost-effectiveness has been applied in the UK for anti-HBc screening and, to a lesser extent, for introduction of Triplex NAT. For the latter, despite evidence of higher efficacy when applied to individual donation samples, a pooling policy was adopted for economic reasons. In my view, considering cost-effectiveness in terms of decision making for a measure affecting blood safety is inevitable but is only one element. Other elements such as severity of the targeted infection (very high for vCJD, low for HTLV-I/II), performance of the proposed measure, solidity of the evidence pro or con the measure need consideration. There is a fine tuning to find between evaluating what is the limit of an acceptable risk and what would be the societal cost of its elimination.

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

233. I do not believe that in 1991, cost-benefit was clearly identified as a determining factor. Delays in implementation of anti-HCV were more related to uncertainties about test performance, testing algorithms and preparedness of RTCs.

Section 14: Look back programmes at EARTC

HIV

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

234. No, I was not involved. I believe these decisions were made prior to my arrival at EARTC.

138. Were you involved in implementing any HIV look back programmes during your time at EARTC? Please give details.

235. Not to my knowledge since, between 1985 and 1991, only 1 HIV-1 positive donation was identified in East Anglia.

139. Were you involved in setting up any HCV look back programmes during your time at EARTC? If so, please describe this process and your role in it and how it was funded.

236. In 1991, the proposal I made was not the same as what is today understood as lookback studies. It was intended to determine the background anti-HCV seropositivity in recipients of transfusion and the prevalence of transfusion in patients prior to transfusion. Proper lookback studies were initially discussed in 1995 with Dr Hewitt and Dr Williamson and subsequently extended to hepatologists such as Dr Alexander in Cambridge, Dr Dusheiko at Kings College Hospital and Prof H Thomas at St Mary's. The process started with identification of a repeat donor seroconverting to anti-HCV confirmed positive. Then, recipients of transfusions from prior donations from such donors were identified and tested for markers of HCV should previous donations have been HCV infectious. In the meantime, archive samples from previous donations

were tested for markers of HCV, particularly by highly sensitive reverse transcribed (RT)-PCR and recipients of such donations were traced and tested when informed and consenting.

140. Were you involved in implementing any HCV look back programmes during your time at EARTC? If so, please describe what this involved.

237. No, I was not. As indicated in question 139, studies I proposed in 1991 were not what would now be considered proper lookback studies and ultimately, after my departure, were not completed and published. Proper lookback studies I participated in were in 1995 after I returned from France and was no longer in charge at EARTC. The 1995 collaborative study including North London RTC and major hepatologists lead to a major publication:

Allain JP, Dong Y, Vandamme AM, Moulton V, Salemi M. Evolutionary rate and genetic drift of hepatitis C virus are not correlated with the host immune response: studies of infected donor-recipient clusters. J Virol 2000; 74: 2541-9 (WITN3599021).

141. NHBT0022321_003 suggests that you were involved in a prevalence study of HCV in donors and the hospital population in East Anglia. Please set out how this study operated, and its results. Was consent obtained from all those who were entered onto the study? If so, how and at what stage?

238. As indicated above, this study was not completed and the partial data collected was not reported. Informed consent was part of the protocol and was offered to patients eligible prior to study entry.

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

239. The anti-HBc study was conducted in 1996, long after my departure from directorship of EARTC. The study included a part of lookback but ultimately, since no HBV DNA positive samples were identified, lookback became redundant.

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

240. In the 1995 HCV lookback study as well as the 1996 anti-HBc study, information for patients, informed consent and signatures of eligible patients to enter the studies were included in the protocols. It should be understood that an infected donation was defined as carrying a virus detectable by genomic amplification: PCR for HBV and RT-PCR for HCV. Donations serologically positive with confirmed anti-HCV or anti-HBc without anti-HBs were 'potentially' infectious.

241. My general view is that information given to patients should be as transparent as possible when a risk is identified. When it comes to a potential risk such as whether a patient was transfused or not, it can be very difficult since patients do not always know whether or not they have been transfused and hospital records are not always able to indicate which patient has received what product. It comes to a difficult probability assessment. In cases of high probability, patients should be informed. In the lookback studies I participated in, I was not involved in such assessment and that was made by others.

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

242. At the time of the lookback studies in 1995 and 1996 I was not in charge of EARTC and I am not aware of what the policy was at the time. My involvement in these studies was strictly on a research basis as a molecular virology laboratory.

Section 15: Your relationship with commercial organisations

145. 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?

243. The reply to this question is different between when I was in France or in the UK in a research-only position. During my 8 years at CNTS in France I was in charge of quality assurance of imported plasma derivatives for haemophilia treatment. In that position I was in contact with all manufacturers but did not provide advice or consultancy of any sort to any manufacturer. The results of my laboratory and clinical evaluations were provided to the head of CNTS for decision-making regarding importation. I was not providing pharmaceutical companies any advice or consultancy but provided each of them with the results obtained with their respective products.

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

244. In France I did not receive any pecuniary gain from plasma derivative manufacturers but was invited to participate in workshops and meetings organized by these companies. I was in the same position during my time as director of EARTC.

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?

245. I did not sit on any advisory panel, board or committee of plasma derivative manufacturers while in France. In the UK, I was in an advisory position for international or national transfusion organizations such as WHO, AABB and ISBT. While in the UK being in a strictly research position from 2000, at the time of development and implementation of multiplex NAT, I participated in the early 2000's in a small number of advisory meetings for Novartis and Roche and in the 2010's for Terumo on the pathogen reduction project for whole blood intended for developing countries.

d) Received any financial incentives from pharmaceutical companies to use certain blood products?

246. I was not in a position of therapeutic activity and had no influence on the use of plasma derivatives. I did not receive any such financial incentives.

d) Received any non-financial incentives from pharmaceutical companies to use certain blood products?

247. I did not receive any non-financial incentives from pharmaceutical companies to use their products.

f) Received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.

248. At EARTC, I was not positioned to prescribe, supply, administer, recommend, buy or sell blood products from any pharmaceutical company. EARTC was supplying clinicians with products they requested. When clinicians required advice on therapeutic issues, EARTC responded through its medical advisers essentially Drs Williamson, Ouwehand and Caffrey. I was not part of this clinical advisory group.

146. 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?

249. In 1991-1992, my involvement with diagnostics companies was essentially regarding research projects for which free of charge commercial or in-development products were provided. I have no recollection of specific guidelines in that regard being in place at the time other than guidance from the RHA.

147. 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.

250. As indicated above, research at EARTC in 1991-1992 was not initiated by pharmaceutical or diagnostic companies. Research was initiated internally, and companies were contacted for participation through provision of materials, not funds.

251. After my return from France, my research laboratory collaborated with Abbott to evaluate the PRISM instrument for blood screening without personal benefit.

252. In the early 2000s, my lab collaborated with Gene Probe to evaluate their duplex NAT screening system called TMA without other funding than goods and running costs.

253. In 2005-2012, Novartis provided my laboratory with a grant to study international samples found HBV DNA positive and HBsAg negative (OBI) with the Ultrio triplex NAT.

254. In 2014-2015, after my official retirement, I obtained a grant from Terumo to study the pathogen reduction system called Mirasol to inactivate

Plasmodium falciparum (the agent of malaria) in whole blood and to supervise a clinical trial of the efficacy of this system to limit transfusion-transmitted malaria in Ghana. The latter included a personal stipend.

255. None of these projects involved the manufacturing, importation, or sales of blood products.

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

256. As indicated above, it was current and legitimate practice that if a company was supplying tests free of charge for research, data collected with their product was shared with the provider. When such materials were used for comparative studies with a competitor, only data pertaining to the company was shared, data from another company was kept confidential until data was published and made public.

149. 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?

257. In 1991/1992, neither I personally nor EARTC received any commercial funding for research. In the 2000's the laboratory of molecular virology received funding for evaluation of Gen-Probe NAT, Cerus for developing a molecular evaluation system of pathogen reduction with Amotosalen and from Terumo for evaluation of whole blood pathogen reduction with Riboflavin and UV light as University of Cambridge projects that were declared internally within the Dept of Haematology. Results of these three collaborative projects were published in peer-reviewed journals soon after completion.

258. The research projects described above conducted after 1995 were declared to the Dept of Haematology as well as in the annual reports of research within the NBS.

Section 17: Complaints and allegations

150. Concerns were raised about financial irregularities at the EARTC during your tenure. An allegation is made in NHBT0094518, NHBT0094534 and NHBT0094503. What impact did these allegations have on the running of the EARTC?

259. At EARTC, finances were supervised by Mr D Hawdon. In 1991-1992, I was not aware of any financial issues raised by the supervising authority: the EARHA. I had full confidence in his dedication and integrity and was not aware of any irregularities. Of note, Mr Mann's letter encompasses 1992-1995 a period after my stepping down from EARTC directorship.

260. As to the complaint from Dr Voak, it should be understood that, at the time of the creation of EARTC as a division of University of Cambridge Dept of Haematology, a considerable culture change occurred from a routine provider of blood products to a leading academic unit dedicated to research and progress. This change of culture was understood and welcomed not only by academic lecturers' Dr Williamson and Dr Ouwehand but also by EARTC staff such as Dr Caffrey, Dr Rankin, Dr Walton, Mr Wenham and Mr Slopecki. Each of these individuals enthusiastically participated in research projects and co-authored reports published in peer-reviewed journals. A minority of staff was resistant to this culture change. This was particularly the case of Dr Voak who had in the past been somewhat productive in research on blood groups but who refused to involve himself in new projects in 1991-1992. On several occasions, I as well as my assistants had commented on this resistance and attempted to convince Dr Voak to participate. This situation is exemplified by the fact that during this period and the following years, no

research output came from Dr Voak who isolated himself and developed resentment to his self-inflicted isolation.

151. Please list all the complaints made against you insofar as relevant to the Inquiry's Terms of Reference.

261. Although I was aware of occasional discontent of some EARTC staff, no official complaint ever came to me from EARTC, NBA, NHSBT or University of Cambridge.

152. The inquiry understands that allegations of financial irregularity and bullying were made against you during your time at EARTC and at the Cambridge University. Can you please provide an outline of the allegations in so far as they are relevant to the Inquiry's Terms of Reference and the process that was undertaken to investigate them, and the outcome. Please provide any supporting documentation you retain in respect of these matters. In particular please consider the allegation made at NHBT0094518 that you contracted with a supplier who later donated money to your 'fund'.

a. Do you accept this allegation as being accurate? If not, what is your account?

262. The documents appear to refer to some administrative difficulties in separating finances pertaining to EARTC and University of Cambridge for research and R&D. Although I have no recollection of any inappropriate use of research funds it is possible that exchanges between the two systems may have occurred and were sorted out by Mr Hawdon. The EARHA included part of EARTC budget to R&D.

263. As to bullying, I assume that my insistence on Dr Voak to initiate research projects and be academically productive was considered by him as bullying.

b. What was the product being contracted for?

264. I have no recollection of what the 'product' indicated might have been.

c. What was your 'fund'? Please give details.

265. University of Cambridge academic staff members were encouraged and largely successful over time in raising research funding through grant submissions to various research funding bodies. The funds raised were administered separately from EARTC budget and finances.

Section 18: Variant Creutzfeldt-Jakob disease (vCJD)

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

266. Information regarding vCJD was received in 2000 and a risk of transfusion-transmission appeared at that time. I kept abreast of the developments through published reports. It was a deliberate decision on my part not to engage into any research on that topic and to remain concentrating in viral safety.

153. You attended a meeting of the Standing Advisory Committee on Blood Component and Transfusion Transmitted Infections on 22 November 2000 [NHBT0001972] at which there was a discussion as to where responsibility for blood safety lay, whether with the Department of Health or with blood services. What was your view on this issue? How was it resolved?

267. As always when a new blood safety issue arose, information was unclear and the understanding of risks and measures to limit these risks were incomplete, leading to assumptions and guess work against the

background of the precautionary principle. It is in that context that the decision of implementing universal leucodepletion was taken under the assumption that vCJD was largely transmitted by nucleated blood cells. This assumption, based on a very limited uncorroborated research, turned out to be incorrect and plasma was shown to be as, if not more, infectious. This information was generally accepted but the other benefits of blood filtration in terms of decrease of immunologic reactions due to HLA incompatibility and reduction of transmission of intra-cellular viruses such as cytomegalovirus or HTLV-I/II were considered sufficient to pursue this measure once implemented. This information also led to the ban of UK plasma for fractionation and importation of foreign plasma in replacement.

154. Also at that meeting there was a discussion about the information the NBTS should be giving to clinicians and the public about vCJD. What was your view on this issue? Did the messaging change after this meeting?

268. At the time the vCJD crisis occurred, transfusion services had the experience of both HIV-1 and HCV crises to guide the NHSBT position in terms of information. My view was that information should be as transparent as possible but guided by reliable scientific evidence. Information to the public should come from knowledgeable official bodies or government and not left to the media.

Section 19: Your role at the Cambridge University

156. The Inquiry understands that you took up your post of Professor of Transfusion Medicine at the University of Cambridge at the same time as you took up your role as Director of EARTC, and resumed this role on your return to the UK after serving your sentence of imprisonment in France. Please outline your roles and responsibilities in that post in so far as they are relevant to the Inquiries terms of reference.

269. The post I took on April 1st 1991 was a combination of Director of the EARTC under the supervision of EARHA and a professorship of transfusion medicine at the Department of Haematology, University of Cambridge. The former post was intended to re-organise a blood centre that had been left with minimum activity in the region and no visibility among RTCs in England and the UK. The latter post was intended to develop an academic unit focused on training, education and research. Ultimately both entities considerably benefited from close interaction.

157. Please outline the links that you had with the National Blood Authority during your tenure as Professor of Transfusion Medicine on your return from France, including the use you had of their facilities and the basis upon which this was afforded to you, and the roles you played in any committees, and centres.

270. During the 1992-1995 period, while I was dismissed from my RHA post, the University of Cambridge, on the basis of two separate inquiries which both concluded with my exoneration from any wrongdoing, continued my employment. As a result, upon my return to England I resumed my academic duties, but I was banned from my laboratory at the EARTC for approximately one year. At the end of 1996, I was permitted to return to my laboratory in a strictly academic position. It remained that way until early 2000s when, after negotiation with Mr M Gorham, CEO of NHSBT, I was reinstated as research director of the molecular virology laboratory based at EARTC within NHSBT. However, although my salary was strictly limited to its academic part and did not include any salary support from NHSBT, I was representing EARTC at the R&D committee and allowed to apply to NHSBT for grant funding for my research.

Section 20: Other matters

158. Please provide a list of any articles you have had published relevant to the Inquiry's Terms of Reference.

271. In the verbatim above, I have quoted a selection of the published articles relevant to specific questions. Below is the complete list of peer reviewed articles published by my laboratory between 1991 and 2016 relevant to Transfusion in the UK and in the world:

i. Allain JP, Rankin A, Kuhns MC, McNamara A. Clinical importance of HCV confirmatory testing in blood donors. Lancet 1992; 339: 1171 - 1172 (letter).

ii. Lelie PN, Cuypers TH, Reesink HW, van der Poel C, Winkel I, Bakker E, van Exel-Oehlers, Vallari D, Allain JP, Mimms L. Patterns of serological markers in transfusion-transmitted hepatitis C virus infection using second generation HCV assays. J Med Virol 1992; 37: 203-209.

iii. Laurian Y, Blanc A, Delaney SR, Allain JP. All exposed hemophiliacs have markers of HCV. Vox Sang 1992; 62: 55-56 (letter).

iv. Goffin E, Oliveira DBG, Alexander GJM, Wreghitt T, Lockwood CM, Keogan M, Allain JP. Association of type III cryoglobulinaemia and hepatitis C virus-related cirrhosis. J Intern Med 1992; 232: 284-285 (letter)

v. Allain JP. Early infection and serological markers associated with HIV infection. J Clin Apheresis 1993; 8:7-12.

vi. Quaranta JF, Delaney SR, Alleman S, Cassuto JP, Dellamonica P, Allain JP. Prevalence of antibody to hepatitis C virus (HCV) and HIV-1 infected patients (Nice Seroco Cohort). J Med Virol.1994; 42: 29-32.

vii. Walton JD, Caffrey EA, Allain JP. A comparative study of plateletpheresis using Baxter authopheresis C and Haemonetics PCS plus. Transfusion Medicine 1994; 4: 57-61.

viii. Wreghitt TG, Gray JJ, Allain JP, Poulain J, Garson JA, Deville R, Maple C, Parameshwar J, Calne RY, Wallwork J and Alexander GJM. Transmission of hepatitis C virus by organ transplantation in the United Kingdom. J Hepatol 1994; 20: 768-772.

ix. Allain JP. Molecular diagnostics for infectious diseases: new approaches and applications. Trends in Biotechnology 1995; 13: 143-145.

x. Williamson L M, Allain JP. Virally inactivated fresh frozen plasma. Vox Sang. 1995; 69: 159-165.

xi. Allain JP, Reeves I, Kitchen AD, Wenham D, Williamson LM. Feasibility and usefulness of an efficient anti-HBc screening programme in blood donors. Transfusion Medicine 1995; 5: 259-265.

xii. Allain JP. Can the recombinant immunoblot assay generate an erroneous diagnosis of hepatitis C virus infection? Transfusion 1996; 36: 476-477 (letter).

xiii. Allain JP. Future trends for provision of safer blood components/blood products. Transfusion Sci. 1996; 3: 335.

xiv. Chan SW, Bye JM, Jackson P, Allain JP. Human recombinant antibodies specific for hepatitis C virus core and envelope E2 peptides from an immune phage display library. J. Gen Virol 1996; 77: 2531-2539.

xv. Allain JP, Kitchen A, Aloysius S, Reeves I, Petrik J, Barbara JAJ, Williamson LM. Safety and efficacy of hepatitis C virus antibody screening of blood donors with two sequential screening assays. Transfusion 1996; 36: 401-405.

xvi. Lawal Z, Petrik J, Wong VS, Alexander GJM, Allain JP. Hepatitis C virus genome variability in untreated and immunosuppressed

patients. Virology 1997; 228: 107-111.

xvii. Petrik J, Pearson GJM, Allain JP. High throughput PCR detection of HCV based on semiautomated multi-sample RNA capture. J Virol Methods 1997; 64: 147-159.

xviii. Allain JP and Williamson LM. How can we best achieve optimal transfusion practice? Med. J. Australia 1997; 167: 462-463.

xix. Allain JP. Human plasma derivatives for developing countries. Transfusion Today 1997; 33: 10-11.

xx. Jackson P, Petrik J, Alexander GJM, Pearson G, Allain JP. Reactivity of synthetic peptides representing selected sections of hepatitis C virus core and envelope proteins with a panel of hepatitis C virus-seropositive human plasma. J Med Virol 1997; 51: 67-69.

xxi. Hewitt PE, Barbara JA, Soldan K, Allain JP, Dow BC. Unexplained hepatitis C virus antibody detection with various confirmatory assays. Transfusion 1997; 37: 987-988.

xxii. Keeling DM, Luddington R, Allain JP, Lawrie AS; Williamson LM. Cryoprecipitate prepared from plasma virally inactivated by the solvent detergent method. Br J Haematol. 1997; 96: 194-7.

xxiii. Allain JP, Hewitt PE, Barbara JAJ, Dow BC, Follett EAC, Davidson F. Reproducibility of hepatitis C virus antibody detection with various confirmatory assays. Transfusion 1997; 37: 969-990.

xxiv. Allain JP. Screening blood donors for markers of new viruses. Lancet 1997; 349: 584-585.

xxv. Allain JP. Emerging virus in blood transfusion. Vox Sang 1998; 74: 125-129 (State of the Art Paper).

xxvi. Allain JP, Palmer CR, Pearson G. Epidemiological study of latent

and recent infection by toxoplasma gondii in pregnant women from a regional population in the U.K. J Infection 1998; 36: 189-196.

xxvii. Petrik J, Guella L, Wight DGD, Pearson GM, Hinton J, Parker H, Allain JP, Alexander GJM. Hepatic histology in hepatitis C virus carriers coinfected with hepatitis G virus. GUT 1998; 42: 103-106.

xxviii. Allain JP. Screening blood for viral genomes: which way to go? Transfusion Medicine 1998; 8: 5-7 (editorial).

xxix. Allain JP. The status of hepatitis C virus screening. Transfusion Medicine Reviews 1998; 12: 46-55.

xxx. Prati D, Zanella A, Farma E, de Mattei C, Bosoni P, Zappa M, Picone A, Mozzi F, Rebulla P, Cappellini MD, Allain JP, Sirchia G. A multicenter prospective study on the risk of acquiring liver disease in anti-hepatitis C virus negative patients affected from homozygous ß-Thalassaemia. Blood 1998; 92: 3460-3464.

xxxi. Freeman JW, Williamson LM, Llewellyn C, Fisher N, Allain JP, Bellamy M, Baglin TP, Kline J, Ala FA, Smith N, Neuberger J, Wreghitt T. A randomized trial of solvent/detergent and standard fresh frozen plasma in the treatment of the coagulopathy seen during Orthotopic Liver Transplantation. Vox Sanguinis 1998; 74: 225-229.

xxxii. Lee HH, Allain JP. Genomic screening for blood-borne viruses in transfusion settings. Vox Sanguinis 1998; 74: 119-123.

xxxiii. Prati D, Lin YH, De Mattei C, Liu JK, Farma E, Ramaswamy L, Zanella A, Lee H, Rebulla P, Allain JP, Sirchia G, Chen B. A prospective study on TT virus infection in transfusion-dependent patients with beta-thalassemia. Blood 1999; 93: 1502-1505.

xxxiv. Zhai W, Davies J, Shang DZ, Chan SW, Allain JP. Human

recombinant single-chain antibody fragments, specific for the hypervariable region 1 of hepatitis C virus, from immune phage-display libraries. J Vir Hepatitis 1999; 6: 115-12.

xxxv. Petrik J, Hewitt P, Barbara J, Allain JP. Large-scale HCV RNA Screening in First-Time Blood Donors: The First Step Towards Genomic Screening of Blood Donations. Vox Sanguinis 1999; 76: 159-162.

xxxvi. Murthy KK, Henrard DR, Eichberg JW, Cobb KE, Busch MP, Allain JP, Alter HJ. Redefining the HIV-infectious window period in the chimpanzee model: evidence to suggest that viral nucleic acid testing can prevent blood-borne transmission. Transfusion 1999; 39: 688-693.

xxxvii. Majid A, Jackson P, Lawal Z, Pearson GM, Parker H, Alexander GJ, Allain JP, Petrik J . Ontogeny of hepatitis C virus (HCV) hypervariable region 1 (HVR1) heterogeneity and HVR1 antibody responses over a 3-year period in a patient infected with HCV type 2b. J Gen Virol 1999 ; 80: 317-25.

xxxviii. Shang D, Zhai W, Allain JP. Broadly cross-reactive, high-affinity antibody to hypervariable region 1 of the Hepatitis C virus in rabbits. Virology 1999; 258: 396-405.

xxxix. Allain JP, Zhai W, Shang D, Timmers E, Alexander GJ. Hypervariable region diversity of hepatitis C virus and humoral response: comparison between patients with or without cirrhosis. J Med Virol 1999; 59: 25-31.

xl. Williamson LM, Llewelyn CA, Fisher NC, Allain JP, Bellamy MC, Baglin TP, Freeman-J; Klinck JR, Ala FA, Smith N, Neuberger J, Wreghitt TG. A randomised trial of solvent/detergent-treated and standard fresh-frozen plasma in the coagulopathy of liver disease and liver transplantation. Transfusion 1999; 39: 1227-34 (WITN3599022)

xli. Allain JP, Hewitt PE, Tedder RS, Williamson LM. Evidence that anti-HBc but not HBV DNA testing may prevent some HBV transmission by transfusion. Br J Haematol 1999; 107:186-95

xlii. Hunter JM, Allain JP, Akehurst RL. Autologous transfusion – 3 years on: What is new? What has happened? (Consensus Statement). Transfusion Medicine 1999; 9: 285-286.

xliii. Shang D, Lin Y H, Rigopoulou I, Chen B, Alexander GJM, Allain JP. Detection of TT virus DNA in patients with liver disease and recipients of liver transplant. J Med Virol 2000; 61: 455-461.

xliv. Allain JP, Dong Y, Vandamme AM, Moulton V, Salemi M. Evolutionary rate and genetic drift of hepatitis C virus are not correlated with the host immune response: studies of infected donor-recipient clusters. J Virol 2000; 74: 2541-9.

xlv. Allain JP. Cost and Public Perception. Chapter in Advances in Transfusion Safety. Brown F, Vyas G (eds). Development in Biologicals 2000; 102.

xlvi. Allain JP. Will genome detection replace serology in blood screening for microbial agents? Baillieres Best Pract Res Clin Haematol 2000; 13:615-29.

xlvii. Allain JP. Emerging viral infections relevant to transfusion medicine. Blood Rev 2000; 14:173-181.

xlviii. Soldan K, Gay NJ, Allain JP, Llewelyn C, Jones C, Reeves I, Ramsay M: The prevalence of hepatitis B infection in adults with no recognised increased risk of infection. J Infect 2000; 41:198-9.

xlix. Allain JP. Emerging Viruses in blood transfusion. Vox Sanguinis State-of-the-Art Paper 2000; 78: 243-248.

l. Allain JP. Genomic screening for blood-borne viruses in

transfusion settings. Clin Lab Haematol. 2000; 22: 1-10.

li. Candotti D, Adu-Sarkodie Y, Davies F, Baldrich-Rubio E, Lee H, Allain JP. AIDS in an HIV antibody seronegative Ghanaian woman. J Med Virol 2000; 62: 1-8.

lii. Candotti D, Sarkodie F, Allain JP. Residual risk of HIV and HCV transmission by transfusion in Ghana. Brit J Haemat 2001; 113: 37-39.

liii. Candotti D, Mundy C, Kadewele G, Nkhoma W, Bates I, Allain JP. Serologic and molecular screening for viruses in blood donors from Ntcheu, Malawi: high prevalence of HIV-1 subtype C and of markers of hepatitis B and C viruses. J Med Virol 2001; 65: 1-5

liv. Sarkodie F, Adarkwa M, Adu-Sarkodie Y, Candotti D, Acheampong JW, Allain JP. Screening for viral markers in volunteer and replacement blood donors in West Africa. Vox Sanguinis 2001; 80: 142-147.

lv. Hamaia S, Li C, Allain JP. The dynamics of hepatitis C virus binding to platelets and 2 mononuclear cell lines. Binding of free Hepatitis C virus to CD81 expressing and nonexpressing human cell lines and platelets. Blood 2001, 98: 1-8.

lvi. Li C, Candotti D, Allain JP. Production and characterisation of monoclonal antibodies specific to a conserved epitope within hypervariable region 1 of hepatitis C virus. J Virol 2001; 75: 12412-20.

lvii. Allain JP, Seghatchian J. Current strategies on pathogen removal/inactivation: an overview. Transfus Apheresis Sci. 2001; 25: 195-7.

lviii. Seghatchian J, Allain JP. Current strategies for the provision of safer plasma and its derivatives: an update. Transfus Apheresis

Sci. 2001; 25: 185-7.

lix. Pennington J, Taylor GP, Sutherland J, Davis RE, Seghatchian J, Allain JP, Williamson LM. Persistence of HTLV-I in blood components after leucocyte depletion. Blood 2002; 100: 677-681.

lx. Lelie NP, van Drimmelen HAJ, Cuypers HTM, Best SJ, Stramer SL, Hyland C, Allain JP, Montcharmont P, Defer C, Nubling M, Glauser A, ds Silva Cardoso M, Viret JF, Lankinene MH, Grillner L, Wirthmuller U, Coste J, Shottstedt V, Masacar B, Dax EM. Sensitivity of HCV RNA and HIV RNA blood screening assays. Transfusion 2002; 42: 527-536.

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clxxxvii. Wang Z, Zeng JF, Li TT, Zheng X, Xu XX, Ye XL, Lu L, Zhu WG, Yang BC, Allain JP, Li CY. Prevalence of hepatitis B surface antigen (HBsAg) in a blood donor population born prior to and after implementation of universal vaccination in Shenzhen, China. BMC infectious Dis 2016; 16: 498-507

clxxxviii. Allain JP, Goodrich R. Pathogen reduction of whole blood: utility and feasibility. Transfus Med 2017;27 Suppl 5:320-326.

clxxxix. Allain JP, Sibinga CT. Family donors are critical and legitimate in developing countries. Asian J Transfus Sci 2016;10:5-11.

cxc. Allain JP, Opare-Sem O. Screening and diagnosis of HBV in low-income and middle-income countries. Nat Rev Gastroenterol Hepatol 2016;13:643-653.

cxci. Li TT, Fu YS, Allain JP, Li CY. Chronic and occult hepatitis B virus infections in the vaccinated Chinese population. Annals of Blood 2016; 2. 4-4.

cxcii. Allain JP. Screen-and-treat for chronic hepatitis B: an overdue issue for sub-Saharan Africa. Lancet Global Health 2016; 4: 507-8.

159. 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.

272. No other issues.

Statement of Truth

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

Signed GRO-C

Dated 9 June 2022

developing countries. Asian J Transfus Sci 2016;10:5-11.

cxc. Allain JP, Opare-Sem O. Screening and diagnosis of HBV in low-income and middle-income countries. Nat Rev Gastroenterol Hepatol 2016;13:643-653.

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Table of exhibits:

Date	Notes/ Description	Exhibit number
	Curriculum Vitae of Professor Jean-Pierre Allain	WITN3599002
20 August 1994	J-P Allain: last chapter, or merely latest? - Editorial in The Lancet	WITN3599003
24 July 1993	Trial and tribulations of Jean-Pierre Allain - The Lancet	WITN3599004
19 November 1992	Registrar's Report: Statement of the Royal College of Pathologists	WITN3599005
13 August 1994	L'affaire Allain - The Lancet	WITN3599006
26 April 1993	Report of the Independent Enquiry Concerning Professor Jean-Pierre Allain to the East Anglian Regional Health Authority	WITN3599007
1994	Walton JD, Caffrey EA, Allain JP. A comparative study of plateletpheresis using Baxter autopheresis C and Haemonetics PCS plus. Transfusion Medicine	WITN3599008
1998	Freeman JW, Williamson LM, Llewellyn C, Fisher N, Allain JP, Bellamy M, Baglin TP, Kline J, Ala FA, Smith N, Neuberger J, Wreghitt T. A randomised trial of	WITN3599009

	solvent/detergent and standard fresh frozen plasma in the treatment of the coagulopathy seen during Orthotopic Liver Transplantation. Vox Sanguinis	
1991	Allain JP, Coghlan PJ, Kenrick KG, Whitson K, Keller A, Cooper GJ, Vallari DS, Delaney SR, Kuhns MC. Prediction of hepatitis C virus infectivity in seropositive Australian blood donors by supplemental immunoassays and detection of viral RNA	WITN3599010
May 1994	Justice and the French Court (BBTS Newsletter No 32)	WITN3599011
1994	Wreghitt TG, Gray JJ, Allain JP, Poulain J, Garson JA, Deville R, Maple C, Parameshwar J, Calne RY, Wallwork J and Alexander GJM. Transmission of hepatitis C virus by organ transplantation in the United Kingdom.	WITN3599012
1992	Smith D, Delaney S, Allain JP, Vallari D, Lee H. A comparison of two supplemental procedures for confirmation of antibody to hepatitis C virus c100-3 antigen in Louisiana blood donors.	WITN3599013
1992	Allain JP, Rankin A, Kuhns MC, McNamara A. Clinical importance	WITN3599014

	of HCV confirmatory testing in blood donors. The Lancet	
1987	Allain JP, Frommel D, Bosser C, Gazengel C, Larrieu M J, Sultan Y. The role of HIV infectivity and composition of Factor VIII concentrates on the immunity of haemophiliacs positive for HIV antibodies. Vox Sang	WITN3599015
1996	Allain JP, Kitchen A, Aloysius S, Reeves I, Petrik J, Barbara JAJ, Williamson LM. Safety and efficacy of hepatitis C virus antibody screening of blood donors with two sequential screening assays.	NHBT0000030_124
2001	Candotti D, Mundy C, Kadewele G, Nkhoma W, Bates I, Allain JP. Serologic and molecular screening for viruses in blood donors from Ntcheu, Malawi: high prevalence of HIV-1 subtype C and of markers of hepatitis B and C viruses.	WITN3599016
2003	Candotti D, Richetin A, Cant B, Temple J, Sims C, Reeves I, Barbara JAJ, Allain JP. Evaluation of a transcription-mediated amplification-based HCV and HIV-1 RNA duplex assay for	WITN3599017

	screening individual blood donations: a comparison with a minipool testing system.	
2004	Candotti D, Temple J, Owusu-Ofori S, Allain JP. Multiplex real-time quantitative RT-PCR assay for hepatitis B virus, hepatitis C virus and human immunodeficiency virus type 1.	WITN3599018
1999	Petrik J, Hewitt P, Barbara J, Allain JP. Large-scale HCV RNA Screening in First-Time Blood Donors: The First Step Towards Genomic Screening of Blood Donations. Vox Sanguinis	WITN3599019
2021	Harvala H, et al. Hepatitis B infections among blood donors in England between 2009 and 2018: Is an occult hepatitis B infection a risk for blood safety?	WITN3599020
2000	Allain JP, Dong Y, Vandamme AM, Moulton V, Salemi M. Evolutionary rate and genetic drift of hepatitis C virus are not correlated with the host immune response: studies of infected donor-recipient clusters.	WITN3599021
1999	Williamson LM, Llewelyn CA, Fisher NC, Allain JP, Bellamy MC, Baglin TP, Freeman-J; Klinck JR, Ala FA, Smith N, Neuberger J,	WITN3599022

	Wreghitt TG. A randomised trial of solvent/detergent-treated and standard fresh-frozen plasma in the coagulopathy of liver disease and liver transplantation.	
27 January 1994	Appeal to Mitterrand in blood scandal (Nature)	WITN3599023