Witness Name: Dr Patricia Hewitt
Statement No.: WITN3101009
Exhibits: WITN3101010-18
Dated: 24 November 2021

INFECTED BLOOD INQUIRY

THIRD WRITTEN STATEMENT OF DR PATRICIA HEWITT

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 23 August 2021.

I, Dr Patricia Hewitt, will say as follows:

Section 1: Introduction

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

1. My name is Dr Patricia Elizabeth Hewitt.

2. My date of birth is GRO-C 1951.

3. My address is known to the Inquiry.

4. My professional qualifications are MB ChB (Leeds), FRCP, FRCPath. I trained in medicine at Leeds University. I qualified in 1975.

5. The Inquiry has my statement dated 14 March 2021 in which I set out my employment history and membership of committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference.

6. I make this statement in addition to previous statements to the Inquiry, including my response on behalf of NHSBT to the Rule 9 request dated 14 August 2020 – the 'lookback' request. That statement exhibited my curriculum vitae and List of Publications and my membership of past or present Committees/groups relevant to the Inquiry's Terms of Reference. It also explained that I am now retained by NHSBT to provide occasional assistance and advice as and when required.

7. I would like to reiterate here the sentiments in my earlier statement (referred to in the Inquiry's wording at 2 immediately above), by way both of sympathy, and of apology, to those who have suffered harm through infected blood or components, and to those otherwise affected. I have devoted my working life to the safety of blood transfusion. It is a tragedy that treatments given so many years ago, intended to save and improve lives, had the opposite effect in so many cases, and that improvements in therapies, both for haemophilia and for HIV and HCV infections, have come too late for so many. I really am very sorry for any part I have played in this.

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

8. As covered later in this statement, from the early 1990s onwards I began to specialise in transfusion-transmitted infections. This required me to attain a working knowledge of virology as it related to blood-borne viruses, and I benefited from working closely with the NLBTC Consultant Microbiologist, Dr John Barbara. NLBTC also had close links with the Department of Virology at the Middlesex Hospital Medical School (see

paragraphs 117- 120) and we benefited from frequent meetings with senior members of the Department where my knowledge in respect of scientific and medical developments in the field increased. I attended relevant external meetings, both locally in London, elsewhere in the UK, and overseas. Dr Contreras always encouraged such activity, as long as it was directly relevant to our work at NLBTC. Over the years, we developed joint meetings between members of staff in the field of microbiology services at NLBTC (both clinical and scientific staff) with scientific and clinical staff at the Middlesex Hospital Medical School. I also initiated joint meetings with HIV specialists at the Royal Free Hospital.

9. As a member of SACTTI, which met 4 times per year, I benefited from gaining information and knowledge from a variety of virologists working within academic departments, in Public Health England (PHE), and in other blood services. With the appearance of vCJD I became involved in the CJD Incidents Panel (CJDIP) (and its predecessor), which exposed me to a whole new area of specialism in the field of prion diseases. I then became a member of the Advisory Committee for Dangerous Pathogens (ACDP) CJD Risk Management Working Group, again working alongside experts in a number of different fields. My work on the Transfusion Medicine Epidemiology Review (TMER) study involved me in frequent meetings with Professor Will and colleagues at the National CJD Research and Surveillance Unit (NJCDRSU) in Edinburgh.

10. In later years, when Dr (by now Professor) Tedder moved to a post within PHE at Colindale, next door to the blood centre, I worked even more closely with him and his laboratory at PHE. We had weekly meetings to discuss microbiology issues. We carried out joint studies, such as the hepatitis E study which was a first in the world.

11. Throughout my career, I read extensively. The major journals of relevance were "Vox Sanguinis", "Transfusion", " The New England Journal of Medicine", "Transfusion Medicine", and to a lesser extent, "The Lancet" and "The British Medical Journal".

12. I also published extensively during my career. It is impossible to publish in respectable scientific or medical journals without having read extensively around the subject in question and making sure one is up to date with relevant publications.

13. All doctors are required to complete an annual return to the relevant Royal College, in my case The Royal College of Pathologists, documenting all their activities in CPD (Continuing Professional Development) and achieve a minimum number of credits over a rolling 5 year period. I easily surpassed this minimum number throughout my career.

4. 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.

14. I have not provided evidence in any other inquiries in relation to the listed matters, nor in any other investigations or criminal proceedings. When the Hepatitis C Litigation was announced I was nominated by the NBA Medical Director, Dr Angela Robinson, to act as the liaison between the NBA and the legal team acting for the NBA. In that role I attended meetings and case conferences with the legal team and with potential witnesses, and attended much of the court proceedings. I have attended, to the best of my memory, three inquests held into the deaths of

individuals where a transfusion-transmitted infection had been raised as a possible contributor to the death. One case was a proven case of transfusion-transmitted HCV, and one was a proven case of bacterial contamination of a blood component. The third case involved a possible transfusion-transmitted HBV infection, but it was demonstrated that the individual had been suffering from chronic HBV infection which had been present before a transfusion had been given. I have also communicated with Coroners, either directly or through Coroners' Officers, in response to questions raised during investigations in a number of deaths. I am afraid that I do not have a record of the number of such cases.

Section 2: My role at North London Blood Transfusion Centre

5. Please describe the roles, functions, and responsibilities you had at the North London Blood Transfusion Centre ("NLBTC") during your period as:

a. Consultant haematologist;

b. Deputy Director

and explain how these changed over time.

15. I took up my position as Consultant Haematologist and Deputy Director at North London Blood Transfusion Centre (NLBTC) in June 1984. My main role was with the mobile blood collection teams. I had overall responsibility for the mobile blood collection teams, and managed the medical staff employed to work with the teams. I was responsible for the appointment, training, and oversight of the mobile team medical staff. Other mobile team staff, who were employed as Donor Attendants and drivers, were managed by others and were not directly accountable to me.

16. As part of the medical oversight, I had responsibility for ensuring that donor selection guidelines were followed, and for initiating any changes in donor selection when these were required.

17. As Deputy Director at NLBTC, I deputised for the Director as and when necessary, for example at local and national meetings. This function ceased when the zonal organisation of the blood service was introduced in 1995.

18. I relinquished my responsibility for the mobile blood collection teams in 1991, to concentrate on the area which became known as Transfusion Microbiology.

19. In October 1985, when HIV screening of blood donations was introduced, I became responsible for the management of donors with confirmed positive HIV test results. I and one other member of the medical staff, who worked at the static blood donor clinic at Edgware, received "counselling" training (one session) from the specialist HIV unit at St Mary's Hospital, London W2, and thereafter we managed the notification of HIV positive test results to donors, and then onward referral of the individual for specialist care.

20. As I have explained in my statement in response to the Rule 9 request dated 14 August 2020, I did not consider that the term "counselling" was appropriate for the activity which we carried out, and I have never considered myself a counsellor, but I became expert at the management of donors with positive HIV test results, partly because the numbers at NLBTC were greater than in other blood centres, and partly through joint working with a specialist Counsellor from the Haemophilia Unit at the Royal Free Hospital.

21. Over the years, as I assumed responsibility for the management of all donors with confirmed positive test results for all blood-borne infections, I built up a small team of medical and nursing staff to work in this area, and was responsible for their training, debriefing, and development. At some point after 1985, although I cannot remember the date, I assumed responsibility for donors with confirmed positive HBV test results, and later still for those with evidence of infection with syphilis. HCV was added to the list when routine screening of blood donations was introduced in 1991, followed by HTLV in 2002, and HEV from 2012 onwards.

22. As a consequence of the introduction of HIV screening of blood donations in 1985, and my involvement with the management of positive test results on donors, I took responsibility for the HIV lookback at NLBTC, discussed in detail in the questions relating to lookback (the request dated 14 August 2020, and Section 13 of the current request). I took responsibility for the HCV lookback at NLBTC, and I also managed the HCV lookback at South Thames RTC and helped to initiate a Zonal lookback database for the HCV lookback. I had responsibility for, and managed, the national HTLV lookback in 2002.

23. I was Lead Consultant for Transfusion Microbiology for the London and South East Zone of the National Blood Service from 1995 to 2000. I was then National Lead Consultant for Transfusion Microbiology from 2000 to 2005. In both these roles, I had overall responsibility, accountable to the Zonal or National Medical Director, for the management of donors with positive donation screening results and for the investigation of reports of cases of possible transfusion-transmitted infection. I was also responsible for representation of the transfusion microbiology clinical section in new initiatives elsewhere within NHSBT.

6. Please describe the organisation of the NLBTC during the time you worked there, including:

a. its structure and staffing and in particular to whom you were accountable;
b. how the NLBTC was funded and how this changed;
c. its remit, including the geographical area it covered and the hospitals within its area;
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);
e. whether the NLBTC was associated or linked with other Regional Transfusion Centres ("RTCs") and, if so, how and for what purpose;
f. whether the NLBTC was subject to any form of regulation and if so, what;
g. The NLBTC's relationship with the Blood Products Laboratory ("BPL") and any other laboratory involved in the production of blood products or processing of blood; and
h. the approximate number of donations collected each year.

24. a. Within NLBTC I was accountable to the Regional Transfusion Director, Dr (later Professor) Marcela Contreras.

25. b-h. I believe the remainder of this section is better addressed by the Regional Transfusion Director.

Section 3: Blood collection at NLBTC

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

26. Blood collection at NLBTC was based on mobile blood collection teams, who visited different locations throughout the area, and on static blood donor clinics. When I commenced employment at NLBTC there were two static clinics, one on the site of the RTC at Edgware, and one in the West End of London, namely the West End Donor Clinic (WEDC). A third static clinic was subsequently opened, in Luton.

27. The static blood donor clinics collected whole blood donations and also collected plasma donations by plasmapheresis. The clinic at Edgware also collected platelet donations by plateletpheresis. The mobile collection teams collected whole blood only. The mobile blood collection teams, for which I had responsibility during my early years at NLBTC, were based at Edgware and travelled each day to their booked venue. Approximately half the venues operated as public sessions, held in venues such as town halls, community centres, church halls, and school premises. Some venues, in smaller towns, might be visited only every 6 months, whereas other venues in areas of larger populations could be visited as often as every 4 weeks.

28. Each venue served a particular "panel" of donors. A panel consisted of donors who donated at a particular venue. Invitations to donate, with details of the session date and times, were sent out in advance to those on the panel who were eligible to donate. It was also possible for "walk-ins" not registered on that panel to attend, so both first time donors, not previously registered as donors, and existing donors who belonged to a different panel, could attend. The remaining half of mobile blood collections sessions were held for employees of companies. Very large employers could host a mobile blood collection team for as many as 5 consecutive days and would provide the premises for the session. Other

employers might be visited for one or two days. Smaller employers, for example offices with fewer employees, would be grouped together into a panel, which might be held in a work-place, or in a public venue, but would be restricted to the employees and not be open to the public.

29. At the time I was involved, public mobile sessions operated as open-access without any appointment system. Work-place sessions were by appointment, so that time away from work was minimised. A local organiser within the company/ies was responsible for organising the appointments, and for publicising the session within the workplace(s).

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

30. Much of the publicity for mobile blood collection sessions was through local publicity, such as banners, flyers, and pieces in local newspapers. Occasionally, in times of severe shortages, appeals would be made over local radio. Use of celebrities to publicise the need for donations was also employed. For work-place sessions, publicity material was provided to the local organiser for use within the company or companies, and there would be targets set for the number of donors expected to attend each day. These efforts were reasonably successful, but there was a constant need for a high profile to maintain donor numbers.

9. The Inquiry understands that the NLBTC discontinued the collection of blood from prisons in June 1972 (NHBT0016123, page 9). As to this:

a. Do you know whether this understanding is correct?

31. I commenced my employment with NLBTC in 1984. I understood that no blood had been collected from prison inmates for many years, but I cannot confirm the year from my personal knowledge. According to NHBT0016123, page 9, it had ceased **before** June 1972: this document is the minutes of a meeting in June 1972, where it is recorded that collection 'had' ceased. As Dr Cleghorn, who was at that time the Director of NLBTC, is listed as present at the meeting, there is no reason to doubt the accuracy of the minute.

b. To what extent did the NLBTC collect blood from prisons throughout your tenure?

32. NLBTC ran mobile blood collection sessions at a very small number of prisons during the time I was employed there. These sessions were held for prison staff only.

c. If the NLBTC did collect blood from prisons, were prisoners provided with any form of incentive to donate blood? If so, what?

33. As NLBTC did not collect blood from prisoners during my employment, the question of incentives does not arise.

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

34. I believe that it was the risk of hepatitis among prisoners that led to the then Director, Dr Tom Cleghorn, discontinuing blood collection from prisoners in the 1970s.

10. To what extent did the NLBTC collect blood from 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. What were the staffing arrangements during blood donation sessions? Were the staff medically trained?
b. When did this practice cease?
c. What role, if any, did you have in this practice?
d. What were the relative costs of collecting blood from such institutions as compared to collecting blood at the NLBTC?

35. I am not aware that NLBTC ever collected blood from borstals and similar institutions.

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

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

36. Mobile blood collection sessions were staffed by a team of Donor Attendants, usually 8-9 staff, with a Team Leader and a Deputy Team Leader. These staff were responsible for the care of donors before, during, and after the blood donation. There were two drivers. As well as driving the vehicles, one of the drivers acted as the Receptionist for the session, recording the details of individuals who came to register to donate, and issuing the labels which were used to identify the donation and associated samples and paperwork. The other driver performed the reconciliation of the blood collection packs, sample tubes, and associated paperwork, ensuring that they were in numerical order, that there were no missing packs/ tubes/ paperwork and packing the items ready for return to the blood centre.

37. A Medical Officer was assigned to each session. The Medical Officer checked that the donor was eligible to donate blood, performed the venepuncture, and was available to manage any untoward incidents or adverse effects of blood donation.

b. Where did these sessions take place?

38. I have described in response to Question 7 the location of mobile blood collection sessions.

c. How frequently could a person donate blood?

39. Most donors donated blood at 6 monthly intervals. The minimum period between donations was set. I believe it was 12 weeks for men and 16 weeks for women.

d. How were blood donors recruited?

40. I have described blood donor recruitment above in answer to questions 7 and 8.

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

41. I do not recall any of these matters changing during the time that I had responsibility for the mobile blood collection teams.

12. The Inquiry understands that the NLBTC had plasma collection targets it was required to meet (please see NHBT0019621 at pages 10 and 11). Did the NLBTC 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?

42. Plasma collection targets were not part of my remit.

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

43. This was not part of my remit, and therefore I cannot sensibly respond to Questions 13 to 23; I do respond to question 24, given that it refers specifically to me, in the circumstances described in my answer Otherwise there is nothing I can sensibly say.

Production of fresh frozen plasma

14. The Inquiry understands that the NLBTC procured plasma from blood donor sessions to produce fresh frozen plasma ("FFP") to provide to the Blood Products Laboratory ("BPL") (NHBT0000191_131). Please explain:

a. where the production of FFP took place;
b. broadly, the process that was undertaken, the capacity of the NLBTC to manufacture FFP and whether this changed during your tenure and why;
c. what proportion of blood collections were allocated to this process and how this decision was made, and whether this changed over time; and
d. how quickly the NLBTC could have increased its manufacture of FFP, had it wished to.

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

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

Plasma targets

16. Did the NLBTC 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?

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

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

19. Were there any benefits to the NLBTC if the targets were exceeded?

20. In 1981, the pro-rata system was introduced in England and Wales to act as an incentive for RTCs to increase the amount of plasma being sent to BPL (see CBLA0001337). As far as you are aware, what effect (if any) did the pro-rata system have on the plasma supply at the NLBTC and across England and Wales more broadly?

21. 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 at the NLBTC and across England and Wales more broadly?

Plasmapheresis

22. 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 the NLBTC gave to implementing plasmapheresis, including:

a. whether manual or machine plasmapheresis was preferred;

b. the relative cost differences between each method;

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

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

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

24. Please refer to NHBT0077390, a pamphlet published by Armour Pharmaceuticals in 1991. As to this:

A handwritten annotation (p. 1) states "cc Dr Hewitt." Do you recall seeing this document before and, if so, in what circumstances?

44. I do not recall having seen this document before, but this was 31 years ago and I do not expect that I would remember every document that I have seen in the last 31 years. I can see from her handwritten note that Dr Contreras was concerned about some of the claims made in the document and wished to share it with senior colleagues at NLBTC for information. As plasma fractionation was not in my remit it is possible that I did not give the document priority for my attention. Furthermore, at that time I had very recently returned to work after a period of maternity leave, and there would have been a large backlog of items requiring my attention, which is a further reason why I may well not have read the contents. I do not therefore feel able to comment any further.

b. At paragraph 15 (p. 11) the pamphlet states: "in the UK, whereas [sic] over 2,000,000 blood donations are collected annually, the number of donors is approximately 1,000,000, or around 50% of the donations." In your view, is this an accurate representation of the numbers of UK blood donors and UK blood donations in 1990-1991? If not, why not?

c. In the same paragraph, the pamphlet states: "where plasma is exclusively collected by plasmapheresis ...the donor pool required is significantly lower." Do you agree with this statement? If not, why not?

d. At paragraph 20 (pp. 17-18) the pamphlet states: "a production batch of plasma at Armour contains donations from (on average) approximately 1,100 donors… A production batch of plasma from UK NBTS donors could contain donations from as many as 10,000 donors." In your view, are these statements accurate? If not, why not? To your knowledge, how many donors, on average, contributed to batches of factor concentrate produced in the UK at this time?

e. To your knowledge, did the NBTS at any time consider a nationwide programme to increase the use of plasmapheresis for the express purpose of reducing the number of donors contributing to domestic concentrates? If not, why, in your view, was such a measure not considered? If so, when was such a measure considered and what was the outcome?

Use of plasma reduced blood and red cell concentrates

25. What steps, if any, did the NLBTC 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?

45. This was not part of my remit, although I am aware that it was an area where there was a great deal of activity throughout my time working for the Blood Service.

Section 5: Arrangements for obtaining and allocating blood products at NLBTC

46. This was not part of my remit, and I am unable to provide any information which might assist the Inquiry.

26. Please describe the arrangements in place in the North London 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 NLBTC and over what period of time.
b. Please outline the respective responsibilities of the NLBTC, BPL, the relevant Regional Health Authority ("RHA"), and haemophilia centre directors, and how these responsibilities changed over time.

You may be assisted by NHBT0017193, particularly what is said at point 5.

27. Please explain whether any forums were established between the NLBTC, BPL, the relevant RHA, 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?

28. 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)?

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

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

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

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

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

31. Was the NLBTC 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?

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

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

34. 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.

35. As far as you are aware, what influence did pharmaceutical companies have in the way that the imported blood products they supplied to the North London region were used? For example, can you recall

whether pharmaceutical companies provided advice on the use of the products?

Section 6: Production of cryoprecipitate at NLBTC

47. This was not part of my remit, and I am not able to provide any informed comment which might assist the Inquiry.

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

37. If the NLBTC did produce cryoprecipitate, please describe:

a. where the production of cryoprecipitate took place;

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

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

d. how much funding was provided by the North West Thames RHA for the production of cryoprecipitate; and

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

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

39. You have stated that the production of cryoprecipitate was "demand led" and that "if clinicians had been asking us to produce more cryoprecipitate than we did produce then we would have produced more" (NHBT0019621 at page 12).

a. How often, if at all, did you or others at the NLBTC instigate a discussion with clinicians about the production of cryoprecipitate?

b. To the best of your knowledge, what would lead to clinicians asking for an increase in production of cryoprecipitate?

c. How quickly could the production of cryoprecipitate be scaled up?

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

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

<u>Section 7: Self-sufficiency</u>

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

48. I understood the term "self-sufficiency" to indicate that the English BTS should provide the blood and plasma products required by the population.

43. In your experience at the NLBTC, 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 North West Thames RHA.

49. As plasma procurement and cryoprecipitate production were not part of my remit, I cannot answer this question.

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

50. I believed that self-sufficiency was a desirable goal, but that it required appropriate and adequate resources and funding. While the UK was self-sufficient in the supply of blood and blood components, the increase in production of fractionated plasma products to meet the requirements of all UK patients required further investment, not only at the level of RTCs, but also at BPL, and it was this which appeared to be the limiting factor.

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

51. At the time, I was not sufficiently aware of the views of my peers to be able to answer this question.

Section 8: Services for donors at NLBTC

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

process.

52. At the time of the introduction of HIV screening of blood donations in October 1985, all donors were informed, through a message on the "read and sign" sheet completed at the reception/ registration desk, that their donation would be tested for HIV and other infections, and that they would be informed of a positive result and given appropriate advice.

53. All donors were provided before donation with the "AIDS leaflet" published by the Department of Health. This leaflet gave information about AIDS and HIV infection, highlighted the recognised risks for HIV infection, and encouraged those who recognised themselves to be at risk of infection to self-exclude from blood donation.

54. In addition, all donors at NLBTC were provided, after registration but before donation, with the Confidential Unit Exclusion (CUE) questionnaire, which was first introduced at the WEDC in July 1984 and was then extended to all static and mobile clinics. This questionnaire was given to donors in private and reinforced the message about HIV infection and self-exclusion for those at risk of infection. It also stressed that those who felt that they could not leave the session without donating, which was a recognised problem for those who attended with work colleagues or family members, should indicate on the questionnaire that their donation should not be used for patients.

55. All donors were informed that they could speak, in confidence, to the Medical Officer if they had any questions or concerns. In this situation Medical Officers would send a confidential note back to the NLBTC medical team, who would follow up any issues with the individual concerned and offer appropriate advice. All potential donors who used the CUE to indicate that they could be at risk of HIV infection, and any who were the subject of a confidential message from the session Medical

Officer, were sent a follow-up letter inviting them to telephone to discuss their response and to receive appropriate advice.

47. What counselling and psychological services were available for donors who tested positive for hepatitis or HIV? Were such services delivered by NLBTC or were referrals to other agencies made? You may find NHBT0002874_009 of assistance in relation to HCV, but please elaborate on the process described.

56. All donors whose blood sample was confirmed positive for evidence of blood-borne infection were informed of the test result and offered further information and advice. Although this process was known as "donor counselling" I believed that the term "counselling" was inappropriate for the activity which was carried out, and later changed the name of the process to "post-test discussion", which more accurately described the activity.

57. When I took up my position at NLBTC in 1984, there were already procedures in place to manage confirmed positive test results for hepatitis B and evidence of syphilis. For a variety of reasons, these procedures were different for the two agents. For hepatitis B, the donor received a letter notifying the test result, and was offered the opportunity of a face-to-face meeting to discuss the test results. Most donors took up the offer of a meeting. Here they were seen either by the Consultant Microbiologist or a senior member of the medical staff, and received information about HBV, the meaning of a positive test result, and advice about the implications of the result. A repeat blood test was taken to act as confirmation of the original result. In the early years, donors were offered annual blood tests to monitor their HBV infection, and many took up this offer. At that time, I was not involved in this process. When I took over management of donors with HBV infection, I discontinued the annual follow-up, and ensured that all donors were referred to their GP

for further follow-up.

58. When HIV screening of blood donations commenced, each RTC had nominated two members of staff to receive HIV "counselling" training at St Mary's Hospital. I and one other member of my staff attended this training session. All donors whose blood was confirmed positive for HIV infection were sent a letter inviting them to attend an appointment to discuss test results. There was no mention of HIV in the letter, as we were very aware that letters could be opened by other people, for instance family members.

59. In the early days, most donors attended the appointment without question. A minimum of one hour was set aside for the meeting, which was held in private in a suitable office. The donor was informed of the test result, offered further information about the implications of the result, and given the opportunity to discuss a number of issues such as implications for family members, sexual partners, and occupation. We also discussed who to tell, or not tell, who could offer support, and the responsibility to inform the GP, dentist or other medical providers. There was then discussion of a plan for further management.

60. All donors were offered referral to a local specialist service. In the early days, we had forged close links with three specialist units: St Mary's Hospital and the Middlesex Hospital in central London tended to see large numbers of men who had sex with men and were usually appropriate for the majority of our donors with HIV infection, but the Royal Free Hospital had a specialist clinic for women with HIV, and we were more comfortable referring our female donors there. All donors were encouraged to attend the specialist service, and in all my time carrying out this work I only had one donor who failed to take up the strong advice we gave to attend the specialist centre.

61. We made referrals by telephone directly to a Health Adviser or clinician at the specialist centre, and made the appointment for the donor, so that they left our premises with a clear plan and an appointment, generally within the next few days. Before the donor left, we took a second blood sample, while emphasising that the result had already been confirmed and would not change, but to give the donor the reassurance that the result belonged to them. We tested this sample on a rapid test and provided the result within 24 hours. Finally, we made sure that the donor had a clear plan of where they could receive support in the period before attending the specialist centre, and assured ourselves, as far as we could, that the donor was safe to leave our premises.

62. We sent a written letter of referral to the specialist centre, giving as much information as possible about the donor and about particular issues which had arisen during our meeting, to ensure that the specialist centre had good background information for the appointment. We routinely contacted the specialist centre to ensure the donor had attended, and to receive any feedback on issues which we might need to address. We only considered that our responsibility towards the donor ended when we had confirmation that the donor had attended the specialist clinic.

63. We held regular monthly meetings with an AIDS Counsellor from the Royal Free Hospital, where we discussed all cases, highlighting particular issues and difficulties, with the aim of improving our service and practice.

64. When HCV screening commenced in 1991, we adopted a similar approach to that for HIV, with the difference that the donor was informed in the initial letter that the HCV test had been confirmed positive and offered an appointment for an interview. By this time, as HIV infection had moved out geographically from central London, and I had taken over management of positive HBV test results, which were much more spread across the geographical area covered by NLBTC, I had a team of clinical

staff who were involved in the post-test discussion work for HBV, based at Edgware/Colindale, WEDC, the Luton Donor Clinic, and the South Thames RTC at Tooting, which by then also fell under my remit.

65. Notification of HIV positive test results at that time remained with me and my one colleague, based at Edgware/Colindale, as the numbers were small and it was not ideal to have staff deal with only occasional cases, but we travelled to see donors in other centres, if this was more convenient for the donor.

66. Post-test notification for HCV was managed in much the same way as HBV. In the initial letter, the donor was invited to make an appointment for a face-to face interview at one of the centres. The appointment was for one hour, and the donor received information about the test results and the meaning of the results, which was not always clear in the early days of HCV screening, when HCV test "confirmation" depended on detection of the same HCV antibodies as used in the screening test.

67. We were fortunate in our close association with the Department of Virology at the Middlesex Hospital Medical School, where our HBV and HIV confirmatory testing was carried out, and we referred our HCV positive samples there so that an HCV PCR test could be performed. It was a huge advantage to have an HCV PCR test result so that we could be clear in explaining the test results.

68. All donors, whose results were confirmed positive, were advised they should be seen at a specialist centre to have further investigation of their liver, and an outline of the process was provided. In advance of HCV screening of blood donations, I had made contact with all the hepatology and gastroenterology units in the areas served by NLBTC and South Thames RTC, to ensure that they were prepared to see referrals. We then took consent from the donor to inform the GP and wrote to the GP to

strongly recommend referral.

69. We carried out an audit to determine the outcome (NHBT0002874_009), and subsequently strengthened our message to the GP, and to the donor, about the importance of referral, even though there was no licensed therapy for HCV in 1991. Of course, when licensed therapy became available, we included this information in our discussion with the donor. We devised a series of information leaflets for donors with confirmed positive test results. For HIV the leaflet was provided to the donor to take away and read after our meeting. For HBV and HCV the leaflet was sent with the notification letter. We also encouraged donors to contact us if they had any queries or burning issues before attending the specialist centre, whether for HIV, HBV, or HCV.

48. In October 1995 you wrote to Dr S Knowles on the subject of HCV Lookback (NHBT0096432_002). You stated that you were experiencing "problems accommodating the numbers of recipients who require counselling through the HCV lookback exercise" and that "the vast majority of general practitioners who have been contacted have indicated that they do not feel equipped for the task…"

70. My letter to Dr S Knowles in October 1995 (NHBT0096432_002) was in relation to the pressures of dealing with notification of unexpected numbers of **recipients** of blood transfusion, not blood donors. This had arisen during, and as a result of, the HCV lookback. This question is therefore not relevant to the services provided to **donors** at NLBTC (the heading of Section 8). I will answer the question in relation to **recipients** of blood transfusion, which was the subject of my letter.

a. Did the NLBTC recruit additional staff to accommodate these donors?

71. NLBTC did not recruit any additional staff to accommodate these blood **recipients**. No additional resources were provided for HCV lookback, and we had to accommodate the whole process, including dealing directly with the unexpected numbers of recipients of blood transfusion, within our existing resources at the blood centres.

72. We provided the same standard of care as we gave to blood donors, allowing time for a face-to-face interview, at which we explained the reason for contacting the person, gave a full explanation about HCV, and outlined the likely further management if the recipient was shown to be HCV positive on testing. We took a blood sample, agreed how the result would be communicated, and then communicated with both the blood recipient and the GP, making recommendation for a referral to a specialist unit for those who were HCV positive. We also explained that the assumption was that those who were contacted through the HCV lookback programme were likely to be infected with HCV, but this was not inevitable, and we explained the implications if the test result was negative.

b. Why, in your view, did general practitioners not feel "equipped" to carry out counselling?

73. In my view, many GPs did not feel that they had sufficient knowledge about HCV to confidently deal with individuals who were likely to test HCV positive. (see the letter written by Dr Barbara and I to Dr Angela Robinson in January 1995: NHBT0002755). It is also possible that they did not feel confident in discussing the circumstances in which the blood transfusion had been given and had insufficient knowledge of the transfusion process itself to discuss how individuals had been identified and contacted through the lookback. Many of the individuals (recipients) I saw in the HCV lookback had precisely these types of questions, and myself and my team were generally in a better position to be able to

discuss the detail that many recipients requested.

c. What impact, if any, did this have on the counselling of infected donors? If general practitioners did not carry out counselling, then who did?

74. See above, if this question is intended to refer to **recipients.**

d. What impact, if any, did this resourcing issue have on the HCV lookback programme?

75. We did not allow the resourcing issue to interfere with the standard of care that we believed was owed to the blood **recipients** identified in the HCV lookback programme. We gave the same high standard of care as we gave to infected blood donors. The impact was on what other work we could initiate and continue within the clinical team. Private study, reading of scientific journals, and preparation of manuscripts for publication, all of which are vital for keeping up to date with developments, and for (compulsory) Continuing Professional Development (CPD), were the types of activities which were put on hold by the clinical team during the period of most intense activity in the HCV lookback programme.

49. In June 1996 you wrote to Dr Peter Flanagan on the subject of a legal duty of care to donors (NHBT0009730). You relayed the advice that there was an arguable basis for the existence of a duty of care, which would "require the Blood Service to contact them, establish whether they are HCV-infected and offer counselling and treatment..."

a. What approach did the NLBTC take to the issue of a legal duty of care prior to receiving this legal advice in 1996?

b. Was prior legal advice sought?

c. What was your view at the time on the duty of care the NLBTC owed to blood donors?

76. I have dealt with the issue of duty of care at some length in my earlier statement in response to the Rule 9 request dated 14 August 2020.

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

77. Recipients of infected donations were not generally the responsibility of NLBTC. They were generally managed by their treating clinician. The exceptions were those recipients who were identified through the HCV and the HTLV lookback programmes. They were managed as outlined above.

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

78. I believe that the arrangements that were put in place were sufficient for many of the lookback recipients, but some would have benefited from different arrangements. I do not know the outcome for those recipients who were managed by GPs. I feel that some people would always prefer to be notified of unwelcome news by someone who knows them and their medical history, i.e their GP, but the disadvantage of the GP not being an expert in HCV or in the transfusion process may have counteracted this benefit.

79. I have not seen any studies which have described whether the arrangements were sufficient. My team has published results of a satisfaction study carried out on infected blood donors WITN3101010 but I am unaware of anything similar for look-back recipients.

Section 9: Meetings of various committees

Meetings of NBA Executive Committee

52. The Inquiry understands that you attended the meetings of the National Blood Authority ("NBA") Executive. The minutes of the meetings you attended are set out in the below schedule.

a. What do you consider to have been the purpose(s) of those meetings?

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

80. I was not a member of the NBA Executive Committee. I attended one meeting, in December 1993, representing Dr Contreras, Director of NLBTC, who was unable to attend (NHBT 0016378_002). I made one contribution to the meeting, during the agenda item to consider the revision of the "AIDS leaflet". I made a comment about a recent meeting I had had with the Commission for Racial Equality.

Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT)

53. In April 1989, the Department of Health Advisory Committee on the Virological Safety of Blood ("ACVSB") was set up for the purposes of giving advice to the UK Health Ministers on major policy issues (see NHBT0000041_003). Please explain your involvement in the ACVSB, if any.

81. I had no involvement in ACVSB.

54. The ACVSB was replaced by the Advisory Committee on the Microbiological Safety of Blood and Tissue ("MSBT") in 1993. What was the function and remit of this committee? In particular:

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

The Inquiry has provided minutes of the meetings of this group that you attended in the below schedule for your assistance.

82. I was not a member of MSBT. I attended an Extraordinary Meeting of MSBT, held on 29 June 2004, (DHSC0038559_048) as an observer. This meeting was called so that MSBT could consider the implications of a second case of possible transmission of vCJD by blood transfusion. I attended to represent the TMER study, through which this case was detected.

83. I also attended a meeting of MSBT on 20 January 2005 (SBTS0000530), again as an observer, in order to represent the views of Professor Will and the UK Blood Services in relation to notification of cases of vCJD by NCJDRSU to the UKBS (agenda item 5). We wished to seek support for our view that all cases of vCJD should be reported to all four UK blood services (see Section 15, paragraph 152 and 158). MSBT supported our proposal and appropriate action was taken.

55. Please explain the relationship between the MSBT and the NBTS, including but not limited to:

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

b. how frequently the MSBT met;

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

84. As I was not a member of MSBT, others will be better placed to answer these questions.

Meetings of UK National Advisory Committee on the Care and Selection of Blood Donors ("SACCSD")

56. The Inquiry understands that you participated in this advisory committee and has listed the minutes of meetings you attended in the Schedule below for your reference.

85. Please see the correct title of the Committee: Standing Advisory Committee on Care and Selection of Donors (SAC CSD).

a. What do you consider to have been the purpose(s) of those meetings?

86. SAC CSD existed primarily to set national minimum standards for the UK Blood Services with respect to the selection of, and care of, individuals who presented as blood donors. The meetings held by SACCSD provided a forum for national (UK-wide) discussions of current issues with regard to care and selection of blood donors, to consider new issues which had arisen, for example by a question being raised by one of the UKBSs or by new guidelines produced outside the UK (e.g. by the Council of Europe, the American Association of Blood Banks, and others). The SACCSD members were, in general, staff from within the UKBSs with a special interest in, and working within, Services to Donors,

but there was also representation from other relevant bodies.

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

87. SACCSD did not have the power to make decisions for the UKBSs. As with all SACs, it made recommendations to the Joint Professional Advisory Committee of the UKBS and NIBSC (JPAC). Members of JPAC considered recommendations. JPAC was the decision-making body.

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

88. I consider that in general meetings of SACCSD fulfilled the purpose for which they were established.

d. How influential was the committee in setting national policy on donor selection?

89. SACCSD made recommendations for national policy on donor selection and was the main body which made such recommendations. Other national bodies, such as MSBT or CJDIP, could also make decisions which directly impinged on UK donor selection policies.

e. Did any conflicts of interest exist between the aims of the committee and those of the organisations it was answerable to? If yes, what effect, if any, did these have on the development of policy?

90. SACCSD was answerable to JPAC, and I am unaware of any conflict of interests between SACCSD and JPAC.

f. What other organisations, if any, had influence on the committee's advice?

91. See my response under d.

g. How were the committee's decisions communicated to the NBTS?

92. SACCSD made recommendations to JPAC. Decisions made by JPAC were communicated through usual JPAC channels.

57. It appears the committee developed recommendations on the deferral periods of donors in particular categories, in particular, for donors who may pose a risk of HIV or hepatitis transmission.

a. How frequently were the deferral periods for donors reviewed?

93. There was no set frequency for the review of deferral periods for blood donors.

b. Please describe the process of reviewing whether a deferral period was appropriate, including the types and sources of evidence which were taken into account.

94. Deferral periods were set taking into account a number of factors, including, but not restricted to, scientific knowledge of the incubation period of the infection in question, knowledge of the epidemiology of the infection, availability or otherwise of donation screening tests for the infection and knowledge of the test characteristics, and expert advice from specialists, among others.

c. How were decisions ultimately taken on whether to revise an established deferral period?

95. Recommendations made by SACCSD took into account the factors noted in paragraph b. (above), but usually also incorporated a cautious element.

d. How frequently, if at all, were international approaches to donor selection and donor questionnaires analysed? Who instigated this research?

96. International approaches were constantly monitored. This was not research, but incorporated both use of international communication systems and an element of horizon scanning.

e. What impact, if any, did the practices in other countries have on the development of donor selection policies?

97. Practices in other countries were considered, but were not always relevant to the UK situation. For example, UK donor selection guidelines with respect to risk of malaria transmission took into account not only the documented episodes of malaria transmission due to blood transfusion in the UK in the previous 20 years, and detailed analysis of the features of these transmissions, but also the characteristics of the UK population and traditional routes of immigration, and a UK evaluation of the use of malaria antibody screening of blood donations.

98. The UK donor selection guidelines with respect to malaria could then be refined, to minimise both the risk of transmission and the unnecessary waste of valuable blood donations by utilising screening tests on certain "at risk" blood donations. When a further case of transmission was detected, the donor selection guidelines were further reviewed and refined. Differences in populations, assessment of malaria risk, and in the

approach to use of donor exclusion versus donation screening meant that no other blood service was capable of producing similar guidelines for their populations. It is an important underpinning of donor selection that decisions must be based on knowledge of local epidemiology, and what is relevant to one donor population may not be important to another. The UK has one of the best monitoring systems for epidemiology of infections, both in the general public (through Public Health England) and in blood donors and blood donations (NHSBT/PHE Epidemiology Section).

58. Please consider the Committee's role in respect of donor leaflets and blood safety leaflets aimed at excluding high-risk groups. In particular:

a. What role, if any, did the Committee play in determining the content of such leaflets?

99. The first editions of the "AIDS leaflet" were developed by DH and SACCSD played no part in their production. It was only in 1995 that SACCSD took ownership, through the production of the Blood Safety Leaflet, as comprehensively set out in Dr Peter Flanagan's briefing paper (JPAC0000001_014).

b. How often did the Committee consider the effectiveness of such leaflets? How often were they updated, and what did the review process entail?

100. The effectiveness of leaflets was monitored primarily through review of the annual reports from the NHSBT/PHE Epidemiology Section, from which it was possible to review details of risk for infection elicited during the post-test discussion with infected donors. Review of the annual reports was an integral part of SACCSD business, and a representative of the Epidemiology Section was a member of SACCSD.

c. In your view as a committee member, what role did donor leaflets and blood safety leaflets play when mandatory exclusion and selection criteria existed? How did both strategies work together to reduce the risk of infection?

101. I believe that the "AIDS leaflets", first introduced in September 1983 and updated over the years until 1995, played a major part in reducing the risk of HIV transmission through blood transfusion. Part of the reason for this statement is that, once HIV screening of blood donations was introduced in October 1985, low numbers of HIV-infected donors were detected, and the rate of HIV positivity in blood donations remained at a consistently low level over the following years, despite the increase in cases of HIV infection in the general population. It follows that donor education and donor selection was being generally very successful in deterring those individuals at risk of HIV infection from donating blood.

102. Furthermore, my detailed knowledge of the risk for HIV infection in those who were found to be HIV positive on donation screening points to these individuals not generally exhibiting easily recognised risk behaviour. We generally came across very few individuals who recognised themselves to be at risk (as set out in the AIDS leaflet), but nevertheless attended to donate blood. Donor education, through the use of leaflets, thus reduced the risk of HIV infected blood being collected.

103. The use of donation screening tests for HIV infection added a second layer of security, but as no screening test can be 100% sensitive, donor selection and donation screening are complementary, and not alternatives.

d. In 1995, the scope of the Blood Safety Leaflet was expanded to cover HBV and HCV. Why were these viruses not included earlier? In your view, what impact did their addition to the Leaflet have? You may wish to refer to

JPAC0000001_014.

104. See above. The "AIDS leaflet" was published by DH in response to the specific issue of a new infection, not previously encountered in the UK population. Over the following years SACCSD became convinced of the need to provide to donors a leaflet which was more all-embracing, and focusing less on one specific infection, when there was evidence to suggest that donors would benefit from more information on other infections, such as HCV.

Standing Advisory Committee on Transfusion Transmitted Infections

59. In 1989, the UK Advisory Committee on Transfusion Transmitted Diseases ("ACTTD") was set up by Dr Harold Gunson to consider the implications of transfusion-transmitted infections on the transfusion services in the UK and provide advice to the Department of Health. The Inquiry understands that ACTTD was replaced with the Standing Advisory Committee on Transfusion Transmitted Infections ("SACTTI") following the creation of the NBA in 1993 (DHSC0006906_013). Please explain the extent of your involvement in these committees.

The Inquiry has provided minutes of the meetings of this group which you attended for your assistance.

a. How frequently did SACTTI meet?

105. SACTTI usually met four times per year, at roughly 3 monthly intervals.

b. What was the function and remit of SACTTI?

106. The function and remit of SACTTI can be found in JPAC documents.

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

107. SACTTI reported to JPAC. A report followed each SACTTI meeting. Generally, there would be a verbal report by the Chair of SACTTI of any important issues at the next JPAC meeting (SACTTI meetings were generally scheduled 2-3 weeks before a scheduled JPAC meeting to allow SACTTI to report back to JPAC). After each SACTTI meeting, draft minutes were produced and circulated to members for comment. The minutes would be ratified at the next SACTTI meeting and then forwarded to the Chair of JPAC to be tabled and discussed, if necessary, at the following JPAC meeting.

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

108. As confirmed by the title, SACTTI was an advisory group, in common with all the SACs which reported to JPAC.

e. How did SACTTI's remit differ from its predecessor ACTTD?

109. I have never seen the remit of ACTTD so am not in a position to answer this question.

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

110. There was no direct relationship between SACTTI and any UK blood service or blood centre.

a. whether SACTTI made decisions that the NLBTC/NBTS was required to implement; and

111. Not applicable. SACTTI did not make decisions. JPAC was the decision-making body.

b. whether, and how frequently, you provided feedback on the recommendations made by the SACTTI. Please explain, to the best of your knowledge, the relationship between the SACTTI and other RTCs.

112. There was no direct relationship between SACTTI and UKBSs or UK blood centres.

c. What was the impact of there being so many committees in place at around the same time? Was there overlap between them? If so, how did this impact their effectiveness?

113. There was some overlap in the number of Committees in existence with a remit covering blood safety. This could create difficulties. For instance, there was no direct relationship between MSBT and SACTTI. The Chair of SACTTI therefore had no direct knowledge of issues being addressed by MSBT or decisions being made. I believe that the minutes of MSBT meetings were confidential, and I never saw them, so issues / decisions would only become known by informal communications or word of mouth.

114. During my time as Chair of SACTTI, we were fortunate in having one or more members who were also members of MSBT, and so had direct information through this dual representation, but this was fortunate circumstance rather than design, and if that member(s) was not able to attend a scheduled SACTTI meeting, we could be at a disadvantage.

Eastern Division of NBTS Consultants

61. The Inquiry understands that you attended meetings of the Eastern Division of NBTS Consultants between 1984 and 1992. The minutes of the

meetings you attended have been provided in the below schedule for your assistance. As far as you are able, please describe:

a. The remit and composition of this group;

115. I never saw a written remit of this group. As far as I know, it consisted of all the Consultant Medical staff at the four blood centres in south east England (North London, North East Thames, South Thames [and its Lewisham sub-centre] and Cambridge, and of the Army Blood Supply Depot (Aldershot).

b. The frequency of these meetings; and

116. I do not know how often it met, but probably 3 or 4 times per year.

c. The relationship between these meetings and the Regional Transfusion Centre Directors meetings.

117. As far as I know, the Divisional Meetings were an opportunity for all Consultant staff to be made aware of discussions and decisions made at Regional Transfusion Centre Director meetings.

National Directorate of NBTS

62. In his witness statement for the *A v Others* litigation, Dr Gunson outlined the creation of the National Directorate to oversee the work of RTCs, although he noted that the Directorate "did not have executive authority and its successes came about by persuasion" (NHBT0000026_009). As to this:

The Inquiry has provided minutes of the meetings of this group which you attended in the below schedule for your assistance.

a. Did you have a role on this committee? If so, what was it?

118. I had no role in the National Directorate of the NBTS. I attended one meeting (29th August 1989: NHBT0000188_033) deputising for Dr M Contreras, who was unable to attend.

b. How effective in your view was the National Directorate in overseeing the work of the RTCs?

119. I am unable to comment.

Section 10: Information handling by and information sharing between RTCs

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

120. At the time of my Deputy Directorship of NLBTC, records relating to donors were held as paper records in the Donor Records Department, accessible by staff of that office. Each donor had a permanent record card, the NBTS 101 card. The 101 cards were colour-coded, according to the donor's blood group. The 101 cards were filed according to the panel which the donor attended. The 101 card contained on the front an area for the donor's personal details (name, date of birth and address were the primary records kept). For donors who donated at work-place sessions, the name of the firm or employer would also usually be held.

121. On the reverse of the 101 card was a series of lines and columns on which to record the details of the attendances at blood donor sessions. Each line represented one attendance. The series of columns contained

details such as the date, a space for placing the unique donation number assigned to the donor for that attendance, a column for recording the result of the Hb (haemoglobin) screening test, a column to record the volume of blood obtained, a column for the Medical Officer's initials, and a column for any comments. There may have been other columns, but these are all I remember.

122. When a blood donation session was held, the 101 cards for that panel were sent out on the day of the session. If a donor attended and there was no 101 card available, either because this was a first time donor, or the donor normally attended a different panel, then a temporary card, known as the "buff card" (from its colour) was made out with the donor's details, and used to record the donation in the same way as for the permanent 101 cards. If it was a first-time donor, then a permanent record card would be produced in the Donor Records Office once the results of the blood screening tests were known and a colour-coded card could be assigned. In the case of a known donor attending and being given a temporary buff card, the Donor Records staff would transfer the details for the donation to the donor's permanent 101 card. The buff cards for all first-time donors were filed alphabetically as a master file, so each donor had a record on a buff card in the alphabetical index, and a permanent 101 card filed under the appropriate panel.

123. All donor record cards for donors who had attended a session were returned to the RTC with the blood donations and associated blood samples, and were handled by the Donor Records staff. At the blood donor session, there was a master sheet known as the "Session Sheet", which recorded all donors who attended and registered. The sheet was completed at the registration desk by the member of staff in charge of registration. The staff member would record the donor name, then would affix one pre-printed donation number from a sheet of identical numbers. Each donor was assigned a sheet of numbers, from one of two rolls of

numbers. Known donors, whose 101 card (and therefore blood group), was available at the session were assigned numbers from the "known donor" roll. Because the blood group was known, and the donor was previously tested, the donation could be utilised for component production, and the donation could be taken into a double or triple pack. Donors who were being bled on a buff card, and whose blood group was not available to the session staff, were bled on a "new donor" number and into a single pack, so only whole blood could be obtained. For both known donors and new donors, the rolls contained sequential numbers, and the new donor numbers were distinct from the known donor numbers.

124. The session sheet contained a number of other columns which were left blank but utilised in the processing laboratory at the RTC. The session sheet was returned to the RTC with the donations and associated blood samples, and subsequently used in the processing laboratory but I do not know the details.

125. The sheet of the unique donation number allocated to the blood donor contained a number of labels. The first was affixed to the session sheet. The second was affixed to the 101 or buff card. The remainder of the sheet remained with the donor record card until the donor reached the bleed bed, where a further label was removed and affixed to then blood bag selected for the donor, and two more were detached and affixed to the sample tubes used to collect the blood samples which were required for blood grouping and microbiology testing. Thus, the donor record card, the session sheet, the blood donation, and the associated blood samples were all identified by an identical pre-printed label giving the unique number assigned to that donation. This meant that the blood sample results could be married up with the blood donation and back to the originating blood donor.

126. At the time that I started work at NLBTC, the records for blood donations had been computerised. This meant that once the processing laboratory had entered details of the components produced from each blood donation, the components could be traced through computer records. Each blood component which was issued through the Issue Office would be wanded (such as at a supermarket checkout.; a wand is a handheld electronic device passed over a barcode to read the encoded data) through the computer, and its final destination recorded; usually this would be a hospital blood transfusion laboratory, but other destinations, such as issued internally for use in an NLBTC laboratory, or issued for non-clinical use such as in National External Quality Schemes (NEQAS), would also be recorded.

127. By entering into the computer, the donation number which had been allocated to the original blood donation, it was possible to ascertain what blood components had been produced from the donation, and to trace the blood components produced from that donation through to their final destinations. All issues from NLBTC were accompanied by a delivery note, which was generated by the computer, detailing the blood components included in the delivery. The receiving laboratory would use this delivery note to check the delivery. Copies of all delivery notes were retained in the records. If for any reason a blood component was returned to NLBTC, and this was a rarity, that would also be recorded.

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

128. I was not aware of any set retention period for either donor records or donation records. I can confirm, however, that when we started the HCV lookback in early 1995, NLBTC routinely searched for previous records of donors who had been found to be infected with HCV, and it was possible to trace paper donor records back to the late 1970s. It was then possible to identify, from the information held on the donor records, the donation

numbers which required tracing.

129. Although the records relating to blood donations had been computerised, it was possible for NLBTC to trace the fate of the donations which had been identified as needing inclusion in the look-back as far back as the late 1970s, and this included information which was held on paper donation records prior to computerisation.

130. At a later date, Dr Angela Robinson, Medical Director of the NBA, laid down a policy that all records relating to the audit trail from donor to recipient and vice versa (i.e donor and donation records) should be retained from 1980 onwards. This policy was set in order to ensure that NLBTC would have records available in case of late development of vCJD in a blood donor or a blood recipient, bearing in mind the possible long incubation period of vCJD and the importance of being able to complete the audit trail so that the fate of blood donations from a donor who later developed vCJD could be ascertained, and the origin of blood transfused to a recipient who later developed vCJD could be established. Further details are given in the CJD section (Section 15).

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

131. I was not aware of any policy or practice at NLBTC in relation to destruction of donor or donation records. As far as I am aware, no such destruction took place.

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

132. I am not aware of the detail of record keeping practices at other RTCs. I know that the donor record card (the 101 card) was used nationally. I also

am aware that most other RTCs, when they started computerising records, commenced with donor records, in contrast to NLBTC which concentrated first on donation records.

133. Each RTC developed its own computerisation. NLBTC appointed an in-house IT expert who started the work, and who then led an in-house team. A few RTCs had a common system, but I do not know more detail. Eventually, a national IT system, named Pulse, was adopted.

67. What were the record keeping arrangements the NLBTC had with the hospital blood banks to whom the NLBTC provided blood and blood products? What information were the blood blanks expected to feedback to the NLBTC 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?

134. Hospital blood transfusion laboratories had their own record keeping arrangements, and NLBTC played no part, and had no influence, on these systems. I cannot recall what information hospital laboratories were required to provide to NLBTC.

68. In a report authored by you, 'Investigation of Possible Transmission of HIV by Blood Transfusion" (DHSC0006351_032, page 3), you stated that "laboratory record keeping was generally deficient prior to 1985…"

a. What, in your opinion, were the reasons for the deficiencies?

135. My comment about laboratory record keeping was made in relation to hospital blood transfusion laboratories.

136. As pointed out in my report, in the early 1980s hospital blood transfusion laboratory records were held on paper, and it was clearly difficult for staff some years later to identify records from that time period. I do not know the particular reasons for this difficulty, and they may have varied between different laboratories. It is fair to say that some laboratory record-keeping was impeccable, but this was not universal.

137. There were huge improvements after the issue (in 1984) of HC 84(7) relating to Record Keeping and Stock Control.

b. Who had the ultimate responsibility for correcting this?

138. The responsibility for hospital blood transfusion laboratory records rested usually with the Consultant Hamatologist in charge of the Blood Transfusion Laboratory.

c. What steps, if any, were taken to address the standard of record keeping at the NLBTC?

139. My comments did not relate to record keeping at NLBTC. As can be seen from the detail in DHSC0006351_032, NLBTC did not have deficiencies demonstrated during the lookback described.

d. Did you consider it particularly important to keep accurate records of donations at the time? If yes, why? If not, why not?

140. It has always been vital to keep accurate records of donations. There must be a complete audit trail from which a donation can be traced back to the originating donor, and forward to the issue of the donation (or components produced from the donation) to a recipient laboratory.

69. 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 and, if so, when did you become so aware?

141. I cannot remember whether I was aware of the CDSC database of HIV positive donors. I do not recall reporting HIV positive donors directly to CDSC.

b. Who proposed the creation of the database?

142. I do not know who proposed the creation of the database.

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

143. I do not recall whether NLBTC contributed data on HIV positive donors directly to the database.

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

144. I do not know whether other RTCs contributed data.

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

145. NLBTC had its own records of HIV positive donors. It was not a database.

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

a. The use of the word "re-introduce" implies that the J donor system had been operational at an earlier time. When was the J donor system first introduced, and why did it stop operating?
b. Who proposed the re-introduction of the J donor system?
c. What was the intended scope of the J donor system? Were all RTCs expected to contribute to it?
d. Was the proposal for the re-introduction made to a committee or forum similar to the regional transfusion centre directors' meetings?
e. What was your view of the proposal for the re-introduction of the system? How was the proposal received by other RTC directors?
f. What was the purpose of the system and what information was it intended to collect?
g. Did the NLBTC provide data to the J donor system? If so, what data?
h. Was the J donor system re-introduced? If so, when and how did it work?
i. Was the J donor system widely used after the "re-introduction"? If no, why not? If yes, who was responsible for overseeing the system?
j. As far as you are aware, does the system still exist?

146. The NBTS Departmental Memorandum (NHBT0005388) was issued by Dr Howell and bears the initials "PH". It also makes reference to M.R.I. (Manchester Royal Infirmary). There is also a memorandum from Dr

Love, who was one of the Consultants at Manchester RTC. I therefore deduce that the memorandum was issued by Dr Peter Howell, who was a senior scientist at the Manchester RTC. I have no knowledge of the J donor system, which was clearly a local Manchester initiative.

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

147. Prior to computerisation of donor records, NLBTC did not share information with other RTCs about excluded donors.

72. 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?

148. I agree with Dr Gunson's statement that "there was no central organisation to ensure that …. all RTCs operated in a uniform manner", because there was no central organisation of the National Blood Transfusion Service. There were no formal information-sharing measures to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations, but in the presence of manual maintenance of records, it is difficult to envisage how such a measure could have been devised.

149. There was no effective measure which could prevent a donor who had been identified as carrying a blood-borne infection from donating again in

another venue, whether within the same RTC area or another area. But if a donor had been identified as carrying a blood-borne infection, he or she would have been notified and given appropriate advice. If for any reason that donor gave a further donation, it would be detected through testing and the donor would be re-contacted.

150. The vast majority of blood donors were, and are, highly responsible and conscientious members of society who would not knowingly put other people at risk. The majority of those who are told that they have evidence of a blood-borne infection are exceedingly concerned to not cause harm to others. Those who are identified as infected through investigation of reports of possible transfusion-transmitted infection are generally mortified that they have been the source of infection - and feel guilt that they have been the source of another person's infection.

151. In all my 34 years working in the blood service, I have only come across one blood donor who appeared to be malicious and repeatedly ignored advice to stop blood donation.

Section 11: Knowledge of risk of infections while at NLBTC

HIV/AIDS

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

152. I was aware of the association of AIDS with the use of fractionated plasma products before I commenced my appointment at NLBTC. During my Haematology training as a Lecturer in Haematology at the Middlesex Hospital Medical School, I was involved in the management of a small number of people with haemophilia. The first cases of AIDS in people

with haemophilia had been described.

153. During my training we were taught that it was good practice to always obtain a blood sample from a patient who would be receiving heavy or repeated transfusion support, and to store a frozen serum sample long term, in case it was required for investigation in the event of the patient testing positive for an infection. In that situation, it could be valuable to be able to refer to the sample obtained before any blood components or plasma products had been transfused.

154. We were also taught about minimising batch exposure for haemophiliac patients, and ensuring as far as possible that a patient was treated with the same batch until that batch ran out.

155. The report of the first case of AIDS in a recipient of a blood component was also reported during that time, and the association with a donor who had a recognised risk for AIDS was the start of blood services beginning to define which people should not be accepted as blood donors, because of the risk of AIDS.

74. 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?

156. See above.

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

157. From July 1984 onwards, when I was asked to implement the Confidential Unit Questionnaire (CUE) at NLBTC blood donor clinics, I carried out a careful follow-up of donors who used the CUE to indicate

that their donations should not be used. Each donor was contacted and was interviewed over the telephone to determine why they had used the CUE to exclude their blood donation from use.

158. When donors confirmed that they had a recognised risk for HIV, their blood sample was tested for additional markers of infection (a second marker for HBV infection, and a test for HTLV-III antibodies) not in use for routine blood donation screening at the time, as set out in NHBT0000030_002.

159. Our investigations showed that these individuals had a higher incidence of markers for sexually transmitted infections than men who did not categorise themselves as at risk, but much lower than that found in men attending sexual health clinics. These results suggested to us that some men who should have been excluding themselves from donation would have continued to donate without the use of the CUE, and that they did present a risk of infection, although none tested positive for HTLV-III, and they appeared to be a lower risk than men who attended sexual health clinics.

160. In the late 1990s I supervised the team conducting a prospective study involving the follow-up of 20,000 recipients of blood transfusion, who were tested at intervals after the transfusion for evidence of transfusion-transmitted infection. The study was initiated by Dr Contreras, and a Research Fellow and Research Nurses were appointed to carry out the work, but I was responsible for day-to-day management of the team. This was the largest prospective follow-up study of blood transfusion recipients carried out in the UK.

161. The study confirmed the very low risk of transfusion-transmitted infection in England, although given the estimated risk of transmission of HIV, HCV and HBV though UK blood transfusion, it is not surprising that a

study of 20,000 recipients revealed no transmissions. Nevertheless, at the time this study was ground-breaking, and one of the few pieces of scientific evidence to back up the estimated risk. The study was written up and published in 1999 (WITN3101011).

Hepatitis

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

77. 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?

162. As with my comments relating to HIV (see above), I knew during my Haematology training that there was a risk of transmission of HBV and non-A, non-B hepatitis (NANB) through the transfusion of blood components and fractionated plasma products. I was well aware of the serious outbreaks of HBV which had occurred in renal dialysis units in the 1960s, leading to deaths in patients and staff, and I was also aware that the risk of HBV transmission through blood transfusion had been drastically reduced through the introduction of HBV screening of blood donations many years before I started my Haematology training.

163. Because I trained at the Middlesex Hospital Medical School, which had a prestigious Virology Department with a special interest in blood-borne viruses through Dr David Dane, and his successor Dr (later Professor) Richard Tedder, we trainees had direct exposure to experts in blood-borne infections. Dr Dane had carried out seminal work on the hepatitis B virus, and Dr Tedder went on to work extensively on

retroviruses. I do not recall NANB, during the time of my training, receiving as much prominence.

164. When I commenced work at NLBTC there was already in post a Consultant Microbiologist. This was an unusual post in RTCs, but a previous Director, Dr Tom Cleghorn, had great foresight, and understood the importance of transfusion-transmitted infection, and the need to have a specialist microbiologist on the staff.

165. Dr Dane (until his retirement) and then Dr Tedder had an Honorary Consultant appointment at NLBTC, and both gave freely of their time and advice. There were also close links with the Virology Laboratory at the Middlesex Hospital Medical School, and with the other senior staff there, Dr Sam Cameron and Moya Briggs. I recall that Dr Contreras would invite Dr Dane to visit NLBTC 2 or 3 times per year, and we would discuss current issues and avail ourselves of the opportunity to ask advice.

166. Because of the close links with the Middlesex Hospital Medical School, NLBTC developed a special interest in, and expertise in, transfusion-transmitted infections. I began to work closely with the NLBTC Microbiologist, Dr Barbara, in late 1985 when I became responsible for the clinical aspects of HIV screening. I also took over responsibility for the investigation of reports of cases of possible transfusion-transmitted infection, most of which involved cases of hepatitis. Through my associations with Dr Barbara, Dr Dane and Dr Tedder my knowledge of HBV and NANB grew.

167. I also read extensively, chiefly reports in the scientific journals: the principal sources of relevant articles were “New England Journal of Medicine”, “The Lancet”, “Transfusion”, and “Vox Sanguinis”.

168. I also attended relevant meetings, such as the AABB (American Association of Blood Banks) annual meeting, and read reports published after such meetings. During the 1980s there was evidence emerging from the United States that NANB was not as benign a disorder as had previously been thought, but I recall that there was little evidence, at that time, that it was a major health problem in the UK.

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

169. See above (paragraphs 159 and 160 for a description of the prospective study into transfusion-transmitted infection carried out by NLBTC.

79. 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?

170. It was my understanding that HBV was an uncommon transfusion-transmitted infection in the UK, since effective donation screening had been in place for many years. It was also clear that the vast majority of individuals who became infected with HBV would recover and develop immunity.

171. There was a concern, however, for immunosuppressed individuals, who generally do not develop an immune response and are at risk of complications of chronic HBV infection. As a large number of transfusion recipients were/ are immunosuppressed, even with a very low risk of transmission, HBV transmission, rare as it was, was still a matter of concern.

172. The situation with NANB remained unclear for some time in the 1980s. Over the following years, evidence began to appear that NANB was not a mostly benign entity, and that although most individuals who had developed acute (icteric) NANB after transfusion had recovered and cleared the infection, they represented a minority of those who became infected, and it was the subclinical (anicteric) cases who were much more likely to progress to chronic infection and liver damage.

173. Of course, it was the clinical (icteric) cases which came to our attention through reports of possible transfusion-transmitted infection, so we were seeing a skewed population.

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

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

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

174. I was not aware of the paper produced by Dr Gunson in October 1986 (SBTS0001120). I do not think that I have seen it before now.

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

175. My knowledge of the prevalence of HCV in the UK donor population all dates from the introduction of HCV screening of blood donations in September 1991, when data began to be available.

General

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

176. With only a few exceptions, NLBTC followed national guidelines for donor selection. As noted elsewhere, NLBTC did make a minor amendment to the "AIDS leaflet" when we had evidence that the message needed to be strengthened to encourage self-exclusion of those at risk of HIV infection. In addition, we strengthened the self-exclusion message by applying the CUE questionnaire for all donors, before and after the introduction of HIV screening of blood donations.

177. In addition, in 1984 we produced a new leaflet for potential blood donors, to be read before registration to give blood. This leaflet was called "Some reasons why you should not give blood" (see PRSE0003435). We had found that potential donors were reluctant to be seen picking up and reading the "AIDS leaflet", which featured the acronym "AIDS" in a prominent position on the cover. This could be particularly the case at work-based sessions, and at those taking place in small towns, where many donors knew each other. We felt that a more general leaflet, which included some of the more common reasons why people should not give blood, would be more acceptable to donors. This was borne out, as

demonstrated in my letter to Dr McClelland. At a later date we no longer depended on donors picking up a leaflet, and we required that each donor read the AIDS leaflet, but this was not the case in the early days.

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

178. I am not aware that NLBTC had any local decision-making structures in place to consider and assess the risks of infection, since such decision-making structures were at a national level. We used local experts for advice (see paragraphs 162-165).

84. What, if any, role did the NLBTC 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.

179. I do not recall that there was any explicit role for NLBTC in advising hospitals and haemophilia centres about the risks associated with blood components and plasma products.

180. I do not recall when the initiative was taken to produce information leaflets for potential blood component recipients, but I believe that this was a national initiative, not local to NLBTC. All fractionated plasma products, as licensed medicinal products, were supplied with full information inserts produced by the manufacturer, which included data about risks. It would not be expected that NLBTC would have any additional role under these circumstances.

Section 12: Reduction of risk of infections while at NLBTC

Donor selection

85. What donor selection policies and processes were in place during your tenure at the NLBTC, and how did these change following the emergence of:

a. AIDS/HIV;

b. NANB/HCV; and

c. HBV?

181. NLBTC followed national donor selection guidelines.

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

182. There were national guidelines in place during all my time at NLBTC. The only occasion that I can recall when NLBTC departed from these guidelines was in 1984, when the "AIDS leaflet" advised that promiscuous homosexual men should be excluded from blood donation, but at NLBTC we changed the wording to include "practising homosexual", as we believed that there could be many at risk of HIV who would not consider themselves promiscuous. NLBTC also deviated from national practices by using the CUE as an additional donor selection procedure.

87. In an article co-authored by you in October 1987 titled 'Screening for AIDS: Transfusion Aspects' (NHBT0052307), you stated that "donor education and promotion of self-exclusion by those at risk of contracting AIDS should be continued vigorously..."

a. How were decisions made as to which donors were high risk and should be excluded from donating at the NLBTC? What was your role

in this process at the NLBTC? Were these decisions reviewed and, if so, how often?

183. The decisions about which donors were high risk (for infection with HIV) were made by those responsible for the content of the "AIDS leaflet". We adhered to the guidance as written in the leaflet, apart from the exception noted above.

b. What did you mean by "donor education"? Please give some practical examples of what this entailed.

184. We used the term "donor education" to cover the provision of written material to donors, chiefly through the use of the leaflet.

c. What impact, if any, did the introduction of screening for HIV have on the focus on donor "self-exclusion"?

185. We continued to focus heavily on donor self-exclusion after the introduction of HIV screening of blood donations. It is well known that no screening test is 100% sensitive, and the HIV screening test was no exception. Although the screening test will detect the vast majority of HIV infections, there will be a tiny number which will not be detected. The screening test was an antibody detection test, and absent or very low levels of antibody in the very early stages of infection will give a negative screening test result.

186. Therefore, donor self-exclusion was always emphasised as the first line of defence, with donation screening adding a second layer. An illustration of the importance that we placed on self-exclusion is the fact that we continued at NLBTC in the use of the CUE (Confidential Unit Exclusion) questionnaire for all donors and re-wrote the information on the questionnaire to emphasise that the introduction of the HIV screening

test did not mean that all donations were now "safe"; self-exclusion remained important.

88. Were there any difficulties in implementing the exclusion of high-risk donors at the NLBTC? You may find NHBT0000030_013 of assistance, where it is stated that "despite the [AIDS] leaflet, some male homosexuals still gave blood."

187. As discussed in NHBT0000030_013, a group of male donors who had donated blood in the second half of 1984, and who had designated their blood for "research purposes" on the CUE, were interviewed in private after their blood donation. Although they had revealed on the CUE that their blood should not be used for patients, they had attended to donate blood because they believed that only "promiscuous" men were required to exclude themselves, and many (as alluded to in the article) were in stable partnerships. When they read the information on the CUE, however, they declared that their blood should not be used.

188. The information that we obtained from the use of the CUE at the WEDC encouraged us to roll out the CUE to the other static blood donor clinics and to all mobile blood collection sessions, despite the very real logistic problems of introducing this initiative into the blood donation process.

89. In a memo written by you on 29 September 1989, you discuss the issue of "Blood Donors and HIV risk" and specifically how two cases had arisen as "written guidance on the selection of donors was not applied" (NHBT0047637).

a. How frequently were anti-HIV results due to the failure of medical staff to follow procedures?

189. It was exceedingly rare for positive HIV test results to be obtained on donors due to failure of the medical (and nursing) staff to follow procedures and exclude donors with recognised risk for HIV infection. The first incident outlined in my memo of 29 September 1989 involved a medical officer, but the second incident, as is made clear in my memo, involved nursing staff. As far as I can recall, these were the only two incidents which came to light. My memo was written almost 4 years after the introduction of HIV screening of blood donations, which illustrates how rarely such incidents arose.

b. What, if any, action was taken by you to rectify these errors?

190. I do not remember these incidents, but my memo states that the staff involved in the two incidents had been spoken to, which implies that they had received advice about where they had failed to apply donor selection guidelines and reminded about the need to follow guidelines. This would be my normal practice.

191. I followed up with the memo (NHBT0047637) to all medical officers and to those responsible for the static clinic nursing staff, to inform them about the incidents and to remind them all about the importance of always following guidelines.

90. 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? How often were these leaflets updated, and how was their content decided? You may find NHBT0020668, paragraph 3.1 of NHBT0097469_014, and paragraph 4.4 of NHBT0046958_002 of assistance.

192. NLBTC complied with the national policy of providing the "AIDS leaflet" to all potential donors before they registered for blood donation. These

leaflets were produced in the early years by the Department of Health, and updated leaflets were provided at periodic intervals. I do not know who was in the group deciding on the content of the leaflets, or who made decisions about updating the leaflets.

91. In a memo from you dated 14 February 1985, you stated that it had been "decided that 'each donor should be asked individually whether he/she has read the AIDS leaflet…' (NHBT0019439). What was the practice up until this date?

193. Up to the point when I issued my memo (NHBT0019439) there had been no check whether the donor had read the "AIDS leaflet".

92. 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?

194. As outlined elsewhere, donors at NLBTC were given further information about the risk of transmitting infection via their blood in the content of the CUE questionnaire.

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

195. We assessed that information provided in leaflets and other communications ("donor education") was highly effective at reducing the risk of donations from individuals at risk of HIV infection. As alluded to elsewhere, it later became apparent that there was less success in respect of HCV infection.

Introduction of virally inactivated products

94. What role did you consider the NLBTC had (or should have had) in pushing for factor concentrates to be virally inactivated during your tenure? In particular, was the need for safe products raised by you or anyone else at the NLBTC with BPL and/or pharmaceutical companies (or anyone else) during this period? If so, please give details. If not, why not?

196. I did not consider that NLBTC had a role in influencing developments in manufacture of fractionated plasma products. In my view, such conversations should have occurred between the manufacturer, the regulator, the Department of Health, and the treating clinicians.

Provision of diagnostic screening kits

197. Please note that, in my view, the use of "diagnostic" is inappropriate in relation to screening kits. Screening tests are just that and are not diagnostic tests.

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

96. Did you, or anyone else at the NLBTC, contract directly with any pharmaceutical company involved in the manufacture and/or sale of screening kits, or were contracts negotiated on a national basis? You may find NHBT0000188_039 of assistance.

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

98. 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?

198. I played no part in the assessment or selection of screening test kits for NLBTC.

Introduction of HIV testing

99. The inquiry understands that the second stage of the evaluation of HTLV-III screening tests took place at the NLBTC between August and October 1985 (PRSE0003165, pg.7). Please explain:

a. What made the NLBTC particularly suitable to undertake the second stage of the evaluation programme?
b. How the field evaluations were run at the NLBTC, including whether all donations were tested, the types of test kits used and whether any confirmatory testing procedures were applied. How were the decisions made as to how the field evaluation was run?
c. What were the results or conclusions drawn by the NLBTC and were these submitted to either PHLS, the DHSS or another relevant body?
d. Was an official report ever published and circulated detailing the conclusions of the second stage of the evaluation? If not, why not?

199. I played no part in the 1985 evaluation of HTLV-III screening tests.

100. The Inquiry understands that HIV testing was to commence on 14 October 1985. You have stated that the NLBTC started testing on 23 September 1985 (NHBT0019621, p. 18).

a. Please can you confirm that this was the date that testing commenced at the NLBTC.

200. I cannot confirm that NLBTC commenced HIV screening of blood donations on 23 September 1985 as I have no documents available to me which give the starting date, other than NHBT0019621, which has been provided. I do not recognise this document and am unable to say whether I have ever seen it in the past. It does not bear any date or any provenance but appears to have probably been produced in 1989. I have no reason to doubt the information given in that document.

b. Please explain how the NLBTC were able to commence testing of all donations on this date and why the NLBTC chose to commence testing early rather than wait for the date of national roll-out.

201. Plans had been made to start HIV screening of blood donation in mid-October 1985. NLBTC had obtained test kits and had trained laboratory staff to carry out the testing. Under these circumstances, it was possible to start screening in advance of the 14 October date. It is stated in NHBT0019621 that Dr Contreras preferred to be in a position of having only screened donations in stock ready for issue to hospitals on the agreed start date, rather than starting the screening on 14 October, and then issuing a mix of screened and unscreened donations until all the unscreened donations had worked their way through the system.

202. It is a fact that if a start date for the introduction of a new screening test is announced, this can be misinterpreted as meaning that all blood **issued** after that date will have been screened. I recall that in the case of HCV, it was made quite clear that the announced start date for screening indicated that all blood **collected** on or after that date would be screened, but for a very short period some blood issued after that date would have been collected before the start of screening, and would still be unscreened. I feel that hospital laboratories were perhaps uncomfortable with this dual supply situation.

101. Please describe the implementation of HIV testing at the NLBTC. In particular:

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

203. Blood samples relating to all blood donations were screened using the anti-HIV screening test. All samples which were non-reactive on the screening test were considered negative, and the corresponding donation was suitable for issue. Samples which were reactive on the initial screening test were known as IR (Initial Reactive). These samples were tested again, on the same screening assay, in duplicate. If both duplicate tests were non-reactive, the donation was considered negative and suitable for issue. If one or both of the duplicate repeat screening tests was reactive, the sample was RR (Repeatedly Reactive). The blood sample was then referred to the Reference Laboratory for further testing and the associated donation was discarded. The confirmatory tests conducted in the Reference Laboratory were decided upon by that laboratory, which would issue a written report on completion of testing.

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

204. In general, blood components prepared from donations collected before the implementation of testing were used in the usual way. Because NLBTC implemented screening well in advance of 14 October 1985, and platelets had a shelf life of 5 days, all platelets in stock on 14 October, in both NLBTC and hospital laboratories, had been screened. In addition, NLBTC encouraged hospital laboratories to run down their stocks of frozen products (FFP and cryoprecipitate) which have a long shelf-life, so that they had minimal stocks of unscreened frozen components by October 1985 which could be replenished with screened components.

There would have been some red cells in stock in hospitals which had not been screened, but the expectation was that existing stocks would be utilised.

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

205. See above for action with respect to any donation which was found to be HIV RR. The process for managing donors whose blood was confirmed positive for HIV infection has been described in response to Question 47 (Section 8). Recipients of previous donations were identified through HIV lookback, which is covered in Section 13 and in my earlier statement.

d. What impact did the introduction of HIV screening have on the NLBTC, including but not limited to the financial impact of screening, the impact on those working at NLBTC, and the impact on the risk of transmission of HIV through blood donations?

206. The introduction of HIV screening of blood donations further reduced the risk of HIV transmission through blood transfusion, which was already at a low level through the use of donor education and encouragement of self-exclusion. Transmission of HIV through screened donations has occurred extremely rarely in the UK.

207. I have no information about the financial aspects of HIV screening. While the introduction of a new screening test is always a major initiative in testing laboratories, the laboratory staff are adaptable and used to changes taking place in their established practices.

208. The introduction of HIV screening led to two of the senior medical staff being trained in "counselling" and some new procedures were required to manage the communication with infected blood donors, facilitate the arrangement of appointments, and manage the follow-up after the appointment.

102. In December 1985 you co-authored an article in the BMJ on AIDS antibody testing and counselling (NHBT0057362), in which you addressed the issue of false-positive test results.

a. What impact, if any, did the issue of false positive test results have on the implementation of HIV screening?

209. All screening tests have a "false positive" rate. The introduction of any new screening test into the blood service includes a detailed assessment of the sensitivity and specificity of the proposed test(s). Only those tests which meet the stringent requirements in terms of specificity and sensitivity will be considered as suitable for use. A test which produces an unacceptably high level of false positive test results will not be used.

b. What considerations went into deciding on an acceptable level of false positive test results? Who made these recommendations? Did you agree with these recommendations?

210. I do not know the detail of who set the levels for test specificity and sensitivity in 1985. At a later date, there was a group of scientists and experts who formed the Kit Evaluation Group, which had the responsibility of setting the criteria and requirements to be met by screening assays.

c. What impact did the issue of false positives have on recording those individuals who were ultimately found to be anti-HTLV-III positive? You may find

NHBT0053236 at paragraph 1 of assistance. Please expand on your concerns raised in paragraph 9 of NHBT0089119_029.

211. The two documents NHBT0053236 and NHBT0089119_029 were early (July 1985) iterations of proposals for handling initially reactive screening test results. They were not primarily concerned with the issue of false positive test results. We at NLBTC felt that the proposed handling of samples, packs and donor record cards relating to IR screening test results were unwieldy, unnecessarily complicated, and likely to lead to mistakes, delays, and errors. As is intimated in the documents, we later produced a much less complex, but more secure, process.

d. What impact did false positives have on the blood supply?

212. "False positive" test results (which I prefer to call "non-specific reactive" results) had very little impact on the blood supply as they occurred in manageable numbers in relation to the HIV screening test. They were much more of an issue when HCV screening tests were introduced.

Surrogate testing

103. Whilst you were employed at the NLBTC, what was your opinion of surrogate testing as a potential method of donor screening, and how did this change over time? Please comment on each infection with reference to specific surrogate tests:

a. HIV; and

213. After I commenced my employment at NLBTC, I became aware that certain blood centres in the United States, chiefly those in areas of high prevalence for AIDS, were introducing a surrogate test (anti-HBc: antibody to the hepatitis B core protein) for HIV infection. The reasoning

was that those at risk for AIDS were also at risk of other sexually transmitted infections, including HBV. I do not recall whether any scientific studies were carried out to support the hypothesis, or whether any calculations were made of the likely impact of the intervention. At that time, the AIDS "epidemic" in the US, and especially in San Francisco and New York, was much further advanced than in the UK.

214. At NLBTC we introduced the CUE questionnaire in July 1984 at the WEDC, the static donor clinic which we recognised to be situated in the highest risk area for AIDS, and we had evidence that the facility to designate a donation as "not for use" was utilised. We therefore extended the use of the CUE to the other static donor clinics, and then the mobile blood collection sites. Very soon we were planning for the implementation of HIV screening of all blood donations.

215. I think that I considered that our enhanced donor selection process was very effective, and that attempts to implement surrogate testing would be a distraction from the preparatory work needed to introduce specific HIV screening of donations.

b. NANB/HCV.

216. The situation with respect to NANB hepatitis/ HCV was different. There was accumulating evidence, from the US and from Europe, that screening for both anti-HBc and for ALT levels would identify some individuals at higher risk of NANB/HCV, and that excluding those individuals from acting as blood donors would reduce the risk of HCV transmission. I fully understood the need to carry out studies in the UK, to examine the likely impact of such interventions on UK donors and on the sufficiency of the blood supply.

217. It was clear from small studies, including one from NLBTC, that a large number of elevated ALT levels were associated with alcohol intake and with excess body weight, and I shared concerns that using ALT as a surrogate marker would exclude many donors who did not present a risk of transmitting infection. In my opinion there was a need for larger, well controlled studies, but these did not take place, probably because there was no national funding for such studies, and any studies were carried out by individual centres.

218. With respect to anti-HBc screening, I recall concerns that the tests were not as specific as many of the tests we were used to using, and there was again the concern that there would be a loss of significant numbers of donors, many of whom did not present a risk. Although it does not sound like a large proportion, the loss of 0.8% of donors would have been a huge concern. I well recall numerous occasions at NLBTC when we had blood shortages and needed to turn to other centres to help us maintain supplies to hospitals. These shortages would have been exacerbated by a loss of almost 1% of blood donors.

219. As time went on, and HCV screening tests were developed, I believed that the efforts should be directed on the introduction of screening tests, and that further work on surrogate testing would be a distraction.

104. The Inquiry understands that in 1985-1986 the NLBTC conducted a study that involved ALT and anti-HBc testing of a number of donors (PRSE0002161, p15-16).

a. Why was this study undertaken?

b. Why were recipients of donations not followed up as part of this study?

c. What reception did the results of this study receive upon publication?

d. As far as you know, did this study have any bearing on the decision to carry out the 1988 multi-centre study (PRSE0002161), or the aims and method of said

study?

220. I was not involved in the 1985-1986 study.

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

a. the use of surrogate tests to reduce the incidence of transfusion associated non-A non-B Hepatitis (NANB) and its possible value as a public health measure remained controversial;
b. there was no guarantee, in a given country, that there would be a significant reduction of NANB;
c. the introduction of surrogate testing in some countries could lead to a severe depletion of donors which could compromise the blood supply; and
d. if surrogate testing was introduced, provision would have to be made for interviewing, counselling, medical examination and treatment of anti-HBc positive donors and donors with raised ALT.

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

221. I was not aware of the Working Group's report.

106. The Working Group's report from 1987 commented: "If a stance is taken that blood should have maximum safety then the tests would be introduced"

(NHBT0008816_002). Please explain your views on this statement. In your view, did the decision not to introduce routine surrogate testing indicate a decision not to provide "maximum safety"?

222. Please see my response in para 103 b.

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

223. I do not remember whether I was aware of the reports in October and November 1989, and the decisions made.

108. Please advise on whether surrogate testing (namely ALT or anti-HBc testing) was introduced at the NLBTC during your tenure.

224. NLBTC had a long-established practice of carrying out ALT and anti-HBc testing on plasmapheresis donors. This was already in place when I started my employment. As this only concerned donors at static donor clinics, I was not involved in managing the results.

109. If surrogate testing was introduced at the NLBTC, please explain what impact this had on the NLBTC. In particular:

a. How was the surrogate testing performed?
b. What was the process for screening donors and/or blood donations?

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

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

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

225. N/A.

Introduction of anti-HCV screening

110. When did the NLBTC begin testing donations for anti-HCV, and which ELISA test kits were used?

226. NLBTC commenced screening donations for anti-HCV in September 1991, but I do not recall the exact date. I believe that the nationally agreed start date fell on a Monday, and it was announced that all donations collected on and after that day would be screened, but NLBTC also collected blood on Saturdays and Sundays, and the donations collected on those two days would have been screened on that Monday, although collected before the official start date.

227. I do not recall which ELISA test kits were used.

111. In a letter to Dr Gunson dated 22 April 1991, Dr Contreras stated that having "consulted with Pat Hewitt...the three of us are of the opinion that we are going 'over the top' with the proposed screening for anti-HCV" (NHBT0006421_002).

a. Did this statement accurately reflect your view on the proposals for anti-HCV screening at the time? If yes, why did you consider these to be 'over the top'? Did you agree with all of the concerns raised in Dr Contreras' letter?

228. Dr Contreras' letter of 22 April 1991 and her comment about the proposed screening for anti-HCV being "over the top" related to the proposals which had been made in relation to further testing of initial reactive and repeat reactive samples and arrangements for the transfer of samples to reference laboratories for further testing. It was not intended to suggest that the introduction of HCV screening itself was "over the top", and if the letter is read carefully, it can be seen that the comments related to the proposals and the additional costs that would result.

229. I agreed with Dr Contreras' concerns. The proposals for the further handling of initial and repeat reactive samples were, in our view, unnecessarily complex, were not in keeping with our way of working, and were impractical and expensive. They were also completely different from what was already being done for HBV and HIV screening. As a counsel of perfection, it was proposed that samples which were confirmed HCV positive by RIBA testing would also be screened for anti-HBc and have an ALT test performed.

230. As pointed out in Dr Contreras' letter, the implication was that all RTCs would need ALT screening on-site, which was not the norm. These additional tests would need funding, and the costs of HCV screening were being borne by the purchasers (i.e. hospitals) and we strongly objected to adding more costs to the cost of blood. We argued that if donors were confirmed HCV positive, the necessary additional tests would be carried out as part of a clinical assessment carried out on the donor by the GP or specialist clinic and was not a role that the blood

service should be undertaking.

231. There was clearly a desire on Dr Mortimer's part to garner as much knowledge as possible about individuals with positive HCV test results, but we did not believe that it was appropriate to add this cost to the cost of blood. Furthermore, the proposed arrangements for supplementary tests (RIBA) and then confirmatory tests (PCR) involved different samples being sent at different times, possibly to different laboratories, and we could see that this was unnecessarily complex and would lead to confusion.

b. If not, what were your views at the time? Have your views changed since then? If so, why?

232. N/A.

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

233. I was not an RTC Director, and therefore not in receipt of Dr Gunson's letter. I do not believe that I saw the letter.

113. 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?

234. See above.

114. What funding and operational support was the NLBTC provided with to aid in the implementation of testing? Did this have an effect on the NLBTC's ability or willingness to commence testing earlier? Were you aware of other RTC's being in the same position? You may be assisted by NHBT0000193_081 and NHBT0000026_009 (pp. 36-39).

235. I assume that this question will have been addressed by the Director of NLBTC.

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

a. Did you agree or disagree with Dr Lloyd? Please explain the view you had at the time.
b. Have your views changed since then? If so, why?

You may be assisted by (NHBT0000076_009) and (PRSE0001183).

236. I did not see the correspondence between Dr Lloyd and others in 1991.

116. What impact did HCV testing have on the NLBTC? In particular:

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

237. Blood samples relating to all blood donations were screened using the anti-HCV screening test. All samples which were non-reactive on the screening test were considered negative, and the corresponding donation was suitable for issue.

238. Samples which were reactive on the initial screening test were known as IR (Initial Reactive). These samples were tested again, on the same screening assay, in duplicate. If both duplicate tests were non-reactive, the donation was considered negative and suitable for issue.

239. If one or both of the duplicate repeat screening tests was reactive, the sample was RR (Repeatedly Reactive). The blood sample was then referred to the Reference Laboratory for further testing and the associated donation was discarded. The confirmatory tests conducted in the Reference Laboratory were decided upon by that laboratory, which would issue a written report on completion of testing.

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

240. In general, blood components prepared from donations collected before the implementation of screening were used in the usual way. Hospital laboratories had been informed that all donations collected on or after the agreed starting date would be HCV screened.

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.

241. The procedure for donors whose donations were confirmed HCV positive has been described above in answer to Question 47. Because the

Department of Health had not agreed to an HCV lookback, no recipients of previous donations were identified at this stage. That process was carried out when the Department of Health finally gave instructions for the HCV lookback to commence in January 1995.

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

242. The introduction of anti-HCV screening of blood donations had a very significant effect on the risk of transmission of HCV through blood transfusion. There remained a very small residual risk due to the possibility of a window period donation, where in the very early stage of infection the individual is seronegative (antibody-negative) but infected. Careful surveillance has revealed that HCV transmission due to window period donations is vanishingly small in the UK. The last documented transmission of HCV due to blood transfusion in the UK was in 1996, and the estimated risk is 1 in several million.

Recall practice and procedure at the NLBTC

117. Please give an overview of product recall practice at the NLBTC, and how this changed during your tenure.

243. As far as I can recall, there were set procedures for product recall, which were operated through the Quality Department.

118. What, if anything, do you remember about any formal recall or notification procedures in place? You may find NHBT0005376_002 of assistance in relation to the procedure in place at the NLBTC for the running of a "jaundice enquiry" for cases of post-transfusion hepatitis.

244. By reference to NHBT0005376_002, I can see that my memory is correct, and there were recall procedures in place, operated by the Quality Department. I believe that there was also a formal document from BPL, specifying the situations where BPL should be informed of donations which had been forwarded for fractionation but were now believed to be unsuitable.

119. How was information regarding possible cases of post-transfusion infection communicated to BPL?

245. BPL was notified of donations which had been forwarded for fractionation which originated from donors now under investigation in cases of possible transfusion-transmitted infection. As is clear from NHBT00005376_002, the involved donations were notified to Dr Brozovic, the Consultant with responsibility for the Quality Department, and he would ensure that the correct procedure for notification of BPL took place.

120. In a letter from you to Dr R J Moore concerning the reporting of hepatitis B cases to BPL, you stated that "we only report cases to BPL when we have assured ourselves that a report from a hospital concerning hepatitis in a transfusion incident is likely to be associated with the transfusion" (NHBT0003772).

a. What criteria were applied in deciding whether a case of hepatitis was associated with a transfusion?

246. As is made clear in my letter of 6 June 1990 to Dr R J Moore, each report of a possible case of hepatitis B associated with blood transfusion received a full assessment by myself and Dr Barbara, the Microbiologist, before a decision was taken whether it was a case which required

investigation.

247. It was very common to receive a telephone call from a hospital laboratory to report a possible case when the necessary information to assess the case was not yet available. It was necessary to know the date of the transfusion(s), the date that HBV had been diagnosed, to see the full HBV serology report on the patient, to understand what other interventions may have taken place, and to see the results of any pre-transfusion testing.

248. Many reports were received without a discussion having taken place with the local (hospital or PHLS) virologist. It was not uncommon to receive reports relating to patients who in fact had chronic HBV, and must have been infected before the transfusion, or relating to patients who had acute HBV diagnosed when the transfusion took place well outside the incubation period of HBV.

b. How did the time elapsed between a transfusion and the development of hepatitis B impact on your decision as to whether the case of hepatitis was related to a transfusion?

249. The incubation period of HBV is known and is between 6 weeks and 6 months. Any case reported to NLBTC which fell well outside those limits would merit further investigation at the hospital to determine what other risk for HBV might exist.

c. You went on to state that the process of "establishing the full background" to a case "may, of course, lead to delays..." How long would these delays typically be? What merit, if any, did you see at the time in notifying BPL more quickly of any possible case of transfusion associated hepatitis?

250. There was no typical delay. Frustratingly, it appeared to be very easy for someone to pick up a telephone to report a possible case, but it could take weeks for the necessary information to be provided in writing. As my letter of 6 June 1990 made clear, if we notified BPL at the time we received every first notification, usually a telephone call without supporting information, we would have been burdening them with many unnecessary notifications.

251. Given the length of time that elapsed between plasma being collected from a donation at NLBTC and being included in a product which was passed as fit for issue from BPL, the time taken to establish the facts of the case and determine whether it required investigation and notification to BPL would not lead to any product being released from BPL which would then require recall.

121. 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?

252. Recall procedures were effective. Hospital transfusion laboratories took recalls very seriously and always acted upon them without delay.

Autologous transfusion

122. In a meeting of the Anglo-French Round Table on Transfusion Related Viral Infections in May 1987 (NHBT0088727), which you appear to have attended, autologous transfusion was discussed. The report states "advantages and disadvantages with regard to compatibility and infection" were considered. Dr Haribi discussed "the lack of co-operation from patients and their medical teams when autologous transfusion systems had been attempted eight years prior."

a. What, if anything, can you recall about the reasons given for this lack of cooperation?

253. I do not recall any discussions during this meeting, which took place 34 years ago.

b. Considering the advantages and disadvantages discussed, why do you think autologous transfusion was not considered a viable way of reducing viral transmission?

254. As I do not recall any of the advantages or disadvantages discussed, I am unable to answer this question. I mention below, in answer to Question 123, some relevant factors of which I am aware.

c. In 1983, the US Public Health Service encouraged the use of autologous transfusions due to the risk from AIDS (PRSE0007003, paragraph 8.21). In your opinion, why was the approach to autologous transmission so different in the US compared to the UK (both generally and as evidenced by the Round Table Meeting)?

255. I am unable to locate the document PRSE0007003.

123. An article from February 1987 in 'Pulse' (SHTM0000659) discussed autologous transfusion and featured the contrasting opinions of yourself and Dr Lesley Kay. Dr Kay implied that autologous transfusion could be widely used to treat a large range of patients, something which you disagreed with.

a. Why do you think there was such a contrast in the positions you and Dr. Kay took regarding autologous transfusion?

256. Dr Kay was an enthusiast for autologous transfusion and set up a successful autologous transfusion programme in Sunderland, but she herself acknowledged that only possibly 25% of elective surgery could be managed with autologous transfusion. Even then, it depended on having a patient who was fit enough to donate blood, and to attend the hospital at weekly intervals. It also required that the date of surgery would not be altered or postponed.

257. In addition, the hospital blood transfusion laboratory would need to have two separate systems for storing blood: one for autologous blood and one for allogeneic blood, as the autologous units needed to be stored completely separately. Hospital staff would require additional training, both in the laboratory and on the wards and in operating theatres. Autologous transfusion was therefore resource heavy.

258. With an enthusiast in charge, it was possible to introduce such a system, but it applied to a minority of patients who required transfusion, as most transfusions are given not in the elective surgical setting, but in emergency situations such as trauma, and in medical procedures, especially in the supportive care of patients having treatment for cancer.

b. You implied in the article that cost was a limiting factor to the widespread use of autologous transfusion. However, at the April 1987 meeting of the Eastern Division of Consultants in Blood Transfusion (NHBT0072049_007, p.3), "it was estimated that the cost of units of blood for autologous and conventional would be about the same."

i. In your opinion, was autologous transfusion more expensive than conventional transfusion? Please give reasons for your answer.

259. The cost of an autologous transfusion programme is not limited to the cost of the blood. For the reasons outlined above, provision of

autologous blood would always be more expensive than allogeneic blood: collection costs were greater, and the additional costs of staff training and of the laboratory logistics added to the cost.

ii. If there were cost differences, were these significant enough for autologous transfusion not to be used as a nationwide risk reduction method in the UK? Please give reasons for your answer.

260. I believe that cost was one of the factors which prevented more widespread use of autologous transfusion in the UK. I also believe that the additional workload put extra strain on already stretched resources within haematology departments and blood transfusion laboratories.

124. In May 1999, the Standing Advisory Committee on Transfusion Transmitted Infections (SACTII) recommended "[maximising] the use of autologous transfusion" to reduce the risk of transfusion transmitted infection (NHBT0017405_001, p. 6). To your knowledge, what was the impact of this recommendation with regard to autologous transfusion and similar blood sparing techniques?

261. SACTTI did not recommend "[maximising] the use of autologous transfusion" (NHBT0017405_001) in May 1999. At that meeting, SACTTI was considering a report which had been produced by Det Norske Veritas (DNV), commissioned by SEAC (The Spongiform Encephalopathy Advisory Committee). The report included a discussion on the benefits and disbenefits of a range of measures suggested to reduce the risk of vCJD transmission through blood transfusion. One of the measures discussed in the report was autologous transfusion, and it was DNV who suggested maximising the use of autologous transfusion. SACTTI suggested qualifying the point: to make appropriate use of autologous transfusion in clinical situations where it was likely to be of

benefit.

General

125. Please describe all other steps or actions taken at the NLBTC 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.

262. It is not possible for me to describe all other steps or actions taken at NLBTC during the 34 years that I worked there to ensure blood safety and to reduce the risk to recipients of blood or blood products of being infected by transfusion-transmitted infection. There were any number of initiatives in areas other than those in which I had direct involvement, for example in the Quality Department and in the Microbiology Laboratory. A further example was in the Patient Services section, which worked with hospital transfusion teams to educate staff and to improve practice, some of which initiatives had an effect on patient safety, but I was not directly involved.

263. As my speciality was in transfusion-transmitted infections, I was directly involved in many blood safety initiatives and it may be helpful to the Inquiry if I summarise some of these actions under a number of headings.

264. **HIV:** I have already described the initiatives we took in advance of the introduction of HIV screening, to enhance the donor selection process and encourage self-exclusion of at-risk donors through refinement of the blood safety leaflet and the use of the CUE questionnaire.

265. After the introduction of HIV screening, we used careful and thorough interviews with infected donors to further define the risk for HIV infection

and to understand how at-risk donors had not excluded themselves from blood donation. The risk information which we elicited was fed back to the SAC CSD, to be taken into account in further refinements of the donor selection process.

266. **HTLV-1**: in the 1990s NLBTC carried out a pilot study of HTLV-1 screening of unselected blood donations. I believe this study involved 20,000 donations. The donors of positive HTLV-1 donations were interviewed, to try and elicit their risk for infection. At that time, it was known that HTLV-1 was particularly associated with certain geographical areas, and in particular Japan and the Caribbean. It had been suggested that screening of donations could be introduced based on whether a donor originated from these areas.

267. We were able to show that none of the 6 HTLV-1 positive donations which we detected originated from donors with a direct connection to those areas. We could, however, identify an indirect connection, often through a previous sexual partner. It was clear from this pilot study that selective screening of blood donors based on their country of origin would not be effective in reducing the risk of HTLV-1 infection as much as had been predicted, and that HTLV risk was more widespread in the UK population than previously imagined.

268. When the UK BSs were asked to develop proposals for cost-effective screening of blood donations for HTLV-1, the results of the NLBTC pilot study were crucial. After introduction of HTLV-1 screening of blood donations in 2002, we were able to demonstrate through the HTLV lookback that leucodepletion was effective in reducing the risk of HTLV transmission (WITN3101012). The results of this work have been used by many other blood services throughout the world to aid decision-making in terms of blood safety.

269. **Malaria:** NLBTC played a major part in developments which led to improved blood safety with respect to transmission of malaria. In 1997 we published a paper (Ref 81) WITN3101013 summarising collaborative work with two experts in malaria: Professor Peter Chiodini (Hospital for Tropical Diseases and Malaria Reference Laboratory) and Dr Alister Voller (Institute of Zoology). We evaluated an ELISA malaria antibody assay originally developed by Dr Voller, and showed that it could be used to reduce blood wastage if it was used to screen donations from individuals who would otherwise have been excluded from donation due to possible malaria transmission risk.

270. This initiative did not directly increase blood safety, but we also carried out in 2005 a very careful analysis of the documented cases of malaria transmission through blood transfusion which had occurred in the previous 25 years (Ref 123 and 124) WITN3101014. We were able to show that 4 of the 5 cases could have been prevented by enhanced donor selection, and by using the malaria ELISA assay to screen blood donations from all donors who were born in, or lived in, malaria endemic areas. Thereafter, the malaria antibody assay was used to screen all such donors on a single occasion, and this initiative reduced the already very small risk of malaria transmission through blood transfusion in the UK.

271. **Hepatitis E virus (HEV):** in 2012 a team from Colindale Blood Centre worked with Professor Richard Tedder and his team in the Blood-Borne Virus Division at PHE Colindale to determine the incidence of HEV viraemia in blood donors in south-east England, by carrying out retrospective HEV RNA screening of blood donations. The study was extended to examine the outcome of transfusion of HEV RNA positive blood components, and the results showed that 42% of recipients became infected, with particularly poor outcomes in immunosuppressed patients (Ref 168) WITN3101015. The results of this study were used by

SABTO in the decision-making in relation to HEV screening of blood donations in the UK. The results were also used by many other blood services world-wide.

272. **Trypanosomiasis Cruzi (T.cruzi)**: T. cruzi is a parasitic disease which occurs in South America, and is transfusion-transmissible. Until 2012, the only method of reducing the risk of T.cruzi transmission through blood transfusion was to exclude as donors all individuals who had been born in, or transfused in, certain areas of South America. We carried out an evaluation of a T. cruzi antibody screening assay; the first blood service to do this (Ref 156) WITN3101016 . We showed that the assay could be used to screen donations from those who would otherwise be excluded from blood donation, and this assay was introduced by NHSBT.

273. **Bacterial transmission:** NLBTC has a specialist Bacteriology laboratory as part of the Microbiology Department, and this laboratory has been involved in several initiatives which have made a significant difference to the rate of adverse reactions and deaths due to bacterial contamination of blood components. The laboratory has been involved over the years in the validation of the swabs used for cleansing of the donor arm prior to venepuncture, in setting up a programme of audit for the performance of arm cleansing by venepuncturists by monitoring pre-cleansing and post-cleansing bacterial swabs, and in validating the diversion of the first 20 ml of collected blood away from the main blood collection pack to reduce the risk of bacteria entering the collection pack. All these initiatives were adopted as standard practice with measurable results in blood safety.

274. **Epidemiology**: throughout my career I had always recognised the importance of collecting and analysing information obtained from donors and studying donor epidemiology in detail. Dr Angela Robinson had created an Epidemiology post for a Senior Scientist, who worked with,

and reported to, both Dr Robinson and Dr Mary Ramsay at PHE. When the post-holder left,and recognising that I had insufficient time to give this subject the attention it deserved, I proposed the creation of a new Consultant Epidemiology post, jointly between NHSBT and PHE. This proposal was accepted, and an appointment was made. The post-holder was able to develop a team of scientists working within the Epdemiology team which has become critical to estimating and assessing risk through UK blood transfusions, feeding into SHOT, SACTTI, SAC CSD etc.

126. 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?

275. Blood safety has always been given priority in NHSBT, but all blood safety initiatives make demands on cost, time and staff. These must be balanced against other demands being made at the same time. I do not recall any time when I considered that a blood safety initiative was needed but this was not supported by my superiors.

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

276. I do not feel qualified to answer this question.

128. To what extent were you and other RTDs reliant on the decisions of other bodies (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?

277. I was not an RTD, so cannot answer this question.

129. 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.

278. The question refers me to a letter from Dr Contreras (NHBT0000044_095) in 1992 and asks me to consider whether the BTS made a shift from the 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". I am not convinced that Dr Contreras in her letter was suggesting that the BTS had made this shift. I believe that it is much more probable that she was referring to the public attitude towards blood safety.

130. If you do agree:

a. When, in your view, was this shift made?
b. Who was responsible for the original policy and who for the change in policy?
c. What caused the change to occur?
d. What is your opinion of the merits of a cost-benefit approach to blood safety as against the latter approach?
e. Was the introduction of anti-HCV testing affected by this prior approach? What about other transfusion transmitted infections?

279. This question refers to the "attitude towards transfusion safety" referred to in Dr Contreras's letter and then proceeds to assume that this was a

policy. I do not believe there was ever such a policy operated by the Blood Service. But all areas of the NHS operate on a cost-benefit basis. There are many initiatives, such as expensive new drugs, which are assessed on a cost-benefit basis. It is difficult to think of any area in the NHS where there is sufficient funding and resources to introduce a new initiative without a cost-benefit analysis.

Section 13: Look back programmes at NLBTC.

HIV

131. It appears to the Inquiry that you were involved in the setting up and reporting on an HIV look-back exercise run from the NLBTC (DHSC0006351_032).

a. Please describe the details of your involvement.

280. As has been stated, I was responsible for the HIV lookback programme at NLBTC. This commenced with the introduction of HIV screening of blood donations in October 1985. It appeared to me and my colleagues that it was a necessary action to trace previous (untested) donations from donors who were newly confirmed HIV positive. This was therefore a natural outcome of the screening of blood donations.

281. When a donor was identified, my staff would trace the previous donations from records, and provide a list of the blood components produced from those donations. They would then trace the fate of the blood components through issue records. Starting with the most recent donation, I would write to the Consultant in charge of the receiving hospital blood transfusion laboratory, inform them of the situation, and advise that the fate of the blood component should be traced. I advised that any identified living recipient should be notified of the situation and offered an

HIV test. I also advised that in the case of deceased recipients, a check should be made to ensure that the deceased had not been an organ donor. I asked to be informed of the outcome of the enquiry and kept records of all the enquiries.

b. Please set out how this look-back exercise was funded.

282. I do not know the detail of how the HIV lookback exercise was funded, but I believe that the RHA allocated to NLBTC some "AIDS funding" and I expect that this budget covered the HIV lookback.

132. On 25 August 1992 you wrote to Dr Rejman (Senior Medical Officer at the DoH) regarding the 'HIV and blood transfusion/tissue transfer payment scheme'. You stated that in relation to recipients not yet identified as having been infected, unless RTCs received information about ex donors who were known to be infected, there would continue to be recipients who were not identified (NHBT0015096_002).

a. Do you consider that the issue of identifying recipients of infected blood from non-returning donors was adequately addressed during HIV look back? If no, what could have been done differently?

283. There was always a concern about the reluctance of Sexual Health clinics in particular to ask patients presenting with HIV infection whether they had been blood donors in the past. Furthermore, there was great reluctance to pass on the personal details of such individuals, who had been assured confidentiality by the clinic. Although some clinicians were sympathetic, it was not possible to persuade the clinics to routinely question new patients about previous blood donation. In my view, if this had been a routine question, more donations would have been identified as needing inclusion in the HIV lookback, and a small number of

additional infected recipients would have been identified.

133. In May 1992, you wrote to Dr Gunson to highlight your concern that merely sending details of donation numbers that were implicated in cases of possible transfusion-transmitted HIV infection to Consultant Haematologists at hospitals was not sufficient (NHBT0015105). You stated that, having carried out an investigation and identified the recipient, a "positive action" should be taken to notify them.

a. Please could you elaborate further on the concerns expressed in your letter, and outline what steps you considered were necessary to notify recipients.

284. My letter of 13 May 1992 to Dr Harold Gunson, was sent in response to a letter from him dated 11 May 1992. Dr Gunson's letter has not been provided, and it is difficult for me to remember the detail contained therein. I know that Dr Gunson wrote his letter after the announcement of the Blood Transfusion/ Tissue Transfer Payment Scheme, and I believe it concerned notification of potential cases. It is also clear from my letter that The Chief Medical Officer had also issued a letter about the scheme, which is also not provided. I raised several concerns in my letter, which clearly concerned the instructions we were being given to ensure that cases were notified to the Payment Scheme.

285. My first concern was that we (RTCs) were being asked to notify Consultant Haematologists of the donation numbers of donations which were believed to have transmitted HIV infection, or believed to be a risk for HIV infection. My point was that we had already carried out HIV lookback on those donations and that we, at least at NLBTC, had the details of the recipients who had been identified as infected with HIV. Therefore, we should be taking positive action to ensure that the identified recipients, for whom we had names, should be informed of the

existence of the scheme. It seemed to me that we were not utilising the information we already had, and that made no sense.

286. Secondly, it appears from my letter that we were being asked to repeat work we had already done, where we had carried out a lookback and established that the recipient was deceased, or that the recipient had tested HIV negative, or could not be traced, by notifying the donations again. I also pointed out that in addition to the lookback there were cases of possible transfusion-transmitted HIV infection which had been reported to us, and which had been investigated, where the transfusion had been excluded as the source of infection. I felt that it was vital that the loop was closed, and that the information we held was fed back to the Payment Scheme.

b. Were any changes made in response to your letter?

287. I do not know if any changes were made in response to my letter. Having voiced my concern, I proceeded to contact all the clinicians who had responsibility for recipients who had been identified as infected through the HIV lookback, rather than notify the donation numbers (again) to the Haematologist and advised that the patient was eligible for the Payment Scheme.

288. I know that in the following years I was contacted from time to time by the Department of Health about individuals who had made a claim under the HIV Payment Scheme, where the Department asked me to confirm whether this was a case which had been reported to us for investigation, and whether it had been demonstrated to be a transfusion-transmitted case. Most of these enquiries related to cases which had not been notified for investigation previously, and we would then initiate an investigation and report back to the Department of Health. I do not know

whether this process was a result of the concerns I had expressed.

134. In December 1994 and previously, you raised concerns about the Department of Health's policy to not provide RTCs "with information that could facilitate the tracing and testing of other recipients who may have been at risk of infection", once it was identified that a recipient had tested positive for HIV as a result of blood donated from the same donor. (NHBT0010151_001).

a. Please could you elaborate on the concerns expressed in your letter.

289. My letter of 12 December 1994 was written to Dr Rejman in respect of a case of possible transfusion-transmitted infection, where the recipient had made a claim under the HIV Payment Scheme. I believe this must have been a case which pre-dated the introduction of HIV screening of blood donations and had previously been reported to us as a possible case of transfusion-transmitted infection. We had been unable to complete the investigation because the HIV status of one or more of the donors had not been established, as they had not returned to donate since the introduction of screening.

290. Dr Rejman requested that I supply to Dr Noone at CDSC (where the database for reported HIV infections was held) the Soundex codes of the donors whose HIV status was not known to us. (The Soundex code is a method of anonymising the name of an individual, produced from the letters of the name).

291. The intention was that these Soundex codes would be checked against the CDSC HIV database to establish whether any of the donors (identified by the Soundex code) had been reported as HIV positive.

292. My concern was that if Dr Noone found a match between a donor's Soundex code and the HIV database and informed the Department of Health that a donor in the case had been reported HIV positive, there also needed to be a feedback step to ensure that the RTC was informed of the HIV positive donor, so that it could then carry out an HIV lookback on other blood components from that donor. Dr Rejman's original proposal did not contain this additional step. It is clear from my letter that I had expressed my concern on this matter on previous occasions.

b. As far as you can recall, what response did you receive from the Department of Health?

293. I do not recall whether I received a response from the Department of Health. It appears I had previously expressed my concern, and I surmise that I had not received a satisfactory response.

HCV

135. On 5 August 1994 you attended a SACTTI 'ad-hoc assembly of experts' to 'Consider the Merits of an HCV Look-Back Policy' (NHBT0009383). The meeting decided to 'refer the topic to the MSBT with a recommendation that such a policy is implemented'. At point 5, the meeting also conducted a brief review of other countries' HCV Look Back policies. In France, for example, the BTS decided to 'screen all blood recipients for viral markers, six months after transfusion, because their record-keeping [was] either unreliable or inconsistent.'

Was there any consideration of the UK BTS adopting such an approach to look back, namely inviting recipients of transfusion or components prior to the introduction of routine anti-HCV testing (September 1991 in the UK) to be tested for viral markers including anti-HCV? If yes, please provide details. If no,

please explain why such an approach was not considered or discussed.

294. Any policy to invite recipients of blood transfusion prior to the introduction of anti-HCV screening to be tested for viral markers including HCV would be completely outside the remit of the UK BTS and would have required a Department of Health/ Public Health approach. It was not therefore an approach that the UK BTS considered. It was considered that targeted lookback, using the starting point of known HCV infected donors, would be the most effective approach from the BTS point of view.

295. Non-targeted lookback depends firstly on individuals knowing that they have been transfused. Many people who received transfusion during surgery or when unconscious would not necessarily have that knowledge. We had evidence of this lack of knowledge when we carried out our prospective study of transfusion-transmitted infection, described in paragraphs 159 and 160. The research nurses would identify potential recruits for the study by obtaining from the hospital blood transfusion laboratory a list of patients who had been transfused in the previous 48 hours. These were generally patients who had undergone surgery. These patients were then approached, on the basis that they were known to have received a blood transfusion, but that information was often a complete surprise to the patient. So much so that we changed our approach to such patients and began our conversation with them by introducing our interest because "you may, or may not, be aware that you received a blood transfusion during your surgery…." We published a short report of this observation in the journal "Vox Sanguinis" in 1999 (Ref 99) WITN3101017.

296. In contrast, many people believe they must have received a blood transfusion during surgery, when they did not. It was certainly not commonplace in the 1980s for individuals to be informed that they had received a blood transfusion, and information about transfusion was not

routinely included in hospital discharge letters, so GPs would not hold that information.

297. Thus, inviting all those who had received a transfusion in previous years to be tested would have resulted in testing many people who had not been transfused, and not testing people who had received a transfusion but were unaware of that.

136. On 28 March 1995 you wrote to Dr Angela Robinson, NBA Medical Director, on the subject of HCV look-back (NHBT0097146_007). You referred to the testing of archive donations given at the NLBTC between January 1989 and the end of August 1991. You stated that the locating and testing of these samples "is not feasible, practical, or a sensible use of time and resources."

a. You further stated that "we estimate testing cost alone to be approximately £60,000." How great a factor was cost in your decision that the testing of archive samples was "not feasible"?

298. I do not believe that the cost of testing was a significant factor in relation to the testing of archive samples. Dr Barbara and I had summarised the issues arising from this suggestion in an earlier letter in January 1995 (NHBT0002755). One of the issues we raised was that stored samples were generally of very small volume, and even if sufficient for a retrospective initial HCV antibody screening test, there would likely be an insufficient sample to perform any confirmation of an initial reactive result.

b. Did you consider, if feasible, the testing of archive samples to be desirable? If not, why not?

299. I admit that I am puzzled by my letter of 28 March 1995 to Dr Angela Robinson. In my letter I have described in detail the logistics of

responding to a suggestion that we locate donation samples from the dates January 1989 to August 1991 (i.e. pre the introduction of HCV screening) and identify the samples relating to donors who had **not** reattended after the introduction of HCV screening, i.e. those donors whose HCV status was unknown. Those samples would then be manually retrieved and tested, to identify any which might be HCV positive. I have pointed out the resources which would be required for such an exercise.

300. My problem is that I do not now think that those samples would have still been in storage in January 1995. I thought that NLBTC did not have the capacity to retain so many samples, but my letter suggests that we did. It may be that my memory is incorrect.

c. You suggested that "it might be a more sensible use of resources to destroy all archive samples now so the issue of retrieving and testing samples does not arise!" Why did you make this suggestion? Were these samples ultimately destroyed?

301. My suggestion to destroy all archive samples was flippant, and an expression of my frustration at suggestions such as this one, which were often made by those who had no knowledge of processes and practices and did not appreciate the sheer magnitude or impracticality of their proposals. The recommended storage time for archive samples from blood donations for the UK BS was subsequently set at a minimum of 3 years. It was practice for NHSBT to discard samples after that time.

137. On 29 March 1995 you wrote again to Dr Robinson to pass on 'two major concerns' arising out of the requirement for HCV Look Back: the difficulty of tracing donations throughout the period where blood transfusion laboratory records were held manually; and, the significant

difficulty that Haematologists could see with obtaining patient case notes from Medical Records Departments (NHBT0096456).

a. Do you consider that the above 'major concerns' were adequately addressed in the implementation of the HCV Look Back? If not, what more should have been done?

302. The concerns which I raised in my letter of 29 March 1995 to Dr Robinson (NHBT0096456) had been raised with me by Consultant Haematologists in charge of the two largest hospital blood transfusion laboratories supplied by NLBTC. I was passing on their concerns, as they felt that the two issues raised would seriously impact upon their departments and their ability to comply with the proposed lookback procedure.

303. I do not know whether their concerns were addressed. I do not believe that my suggestion of a letter from DH to Chief Executives was taken up. I am aware that some individual Consultant Haematologists took up the issues with their Chief Executives and requested additional resources.

b. Do you consider that the BTS fulfilled their duty of care with respect to patients who received infected components from donors unable to be identified in the HCV Look Back process?

304. It was always accepted that the HCV lookback which was implemented in 1995 would not identify all individuals who had been infected with HCV through blood transfusion prior to September 1991. The UK BS did not have the means or resources to go further.

138. On 13 June 2000, in a letter to Davies Arnold Cooper Solicitors, you suggested that a record had been missed in the HCV lookback exercise due to a "change in the computer system at that time" (NHBT0011004_010).

a. How frequently were the computer systems changed? What systems existed to restore/back-up data when system changes occurred?

305. Computer systems within NHSBT were changed very infrequently. To my knowledge, NLBTC started to implement its own in-house computer system in the early 1980s, as referred to in Section 10. This was replaced by a national system, known as "Pulse", which was implemented on a Zonal basis in the late 1990s, and on a national basis a few years later. This system remained in place, with continuous enhancements, for at least 20 years.

b. In your view, what impact did the changing of computer systems have on the success of the HCV lookback programme?

306. In my view, the change of computer systems had minimal impact in the success of the HCV lookback programme. Issues such as the one I described in my letter of 13 June 2000 were exceedingly rare, and it was highly unusual to fail to access data during the lookback and in other routine work which required access to archived data.

General

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

307. NHSBT commenced screening of blood donations for anti-HTLV 1 over the summer of 2002. Lookback was included as an integral part of the introduction of donation screening. I was responsible for the HTLV lookback on a national basis for England. All the work was centralised in the Transfusion Microbiology department at Colindale Blood Centre, and

a small team of staff within that department managed the process. Because HTLV infection was uncommon, and because the lookback began as soon as screening commenced and cases were actioned as soon as the donor had been identified as infected, the impact on hospital blood transfusion laboratories was accordingly much smaller; they were notified of small numbers of cases over a period of time, rather than the "big bang" which occurred with HCV.

308. As HTLV 1 was at that time a rare infection and there was little knowledge of it outside a few areas of medicine, we did not ask GPs or hospital clinicians to undertake notification of their patients, and we offered to carry out the notification ourselves.

309. Disappointingly, although we started the lookback in 2002, and restricted our efforts to those donations accessible on our national Pulse database, which meant only the previous 4-5 years, it was still a huge effort for hospital blood transfusion laboratories to access the necessary records to identify the fate of blood components and verify the details of recipients who would require notification. Those difficulties are described in the publication which we produced describing the outcome of the HTLV lookback (Ref 162) WITN3101012.

310. In 2012, I was involved in a joint study carried out between NHSBT and the Blood-Borne Virus Division at Public Health England, examining the incidence of hepatitis E virus (HEV) in a cohort of blood donors in England. We extended the study to document the outcome of transfusion of blood components retrospectively shown to be HEV positive and carried out a lookback for those HEV positive blood components. I led the clinical team responsible for the HEV lookback and was part of the study project team. That work was written up and published (Ref 168) WITN3101015 and the results were used both in the UK and in other

blood services to make decisions about HEV screening of blood donations, which was subsequently introduced in the UK.

140. Minutes of the above SACTTI 'ad-hoc assembly of experts' (NHBT0009383) record general acknowledgement (in the context of HCV Look Back) that the BTS had 'an ethical responsibility and "duty of care" towards such recipients of potentially infectious blood components such that they deserve to be identified, counselled, tested and offered treatment where that is appropriate.'

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

311. I agreed that the blood service owed an ethical responsibility and duty of care towards recipients of potentially infectious blood components. I believe that my practice over my whole career amply demonstrates my commitment in that respect.

b. Further, do you consider that such an ethical obligation existed separately to any consideration of potentially available treatment? If not, why not?

312. I strongly believed that the obligation towards recipients existed separately to any consideration of potentially available treatment. HIV lookback in 1985 took place under exactly that situation, as there were no effective treatments for HIV at that time, and I never understood why the lack of available treatment for HCV could be used as an argument for not carrying out lookback, when a precedent already existed. Similarly, vCJD notification of those at risk has taken place, with my support, in the absence of any screening test to determine whether a recipient has been infected, let alone treatment, effective or not, being available.

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

313. From what I have outlined above, it should be clear that no RTC could implement its own local lookback programme. The resources required at hospital level were such that it would be highly improbable that hospitals would have cooperated without central direction from the Department of Health. When we carried out the HEV lookback in 2012, as part of a research study with ethical approval, we experienced opposition from some clinicians to the work we were carrying out. It was not generally the case that there were difficulties with blood transfusion laboratories, as the numbers for each laboratory were in single figures, and they were all recently transfused blood components, so the data was easy to retrieve in the laboratory, but some clinicians objected to our requests to carry out tests on their patients.

142. In November 1992, you stated that the National Blood Transfusion Service ("NBTS") was struggling to trace seropositive donors. You suggested that health advisers were reluctant to ask seropositive patients about prior blood donation.

a. In your opinion, how widespread was this issue?

b. What impact, if any, do you consider the reluctance of health advisors to ask patients about blood donation had on the success of lookback programmes?

You may find NHBT0004773 of assistance.

314. I believe that I have already dealt with this question.

<u>Section 14: Your relationship with commercial organisations</u>

143. Have you ever: (If so, please provide details.)

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

315. After my retirement from employment with NHSBT (June 2018), I accepted an invitation from the commercial company Grifols to sit on a Nucleic Acid Testing Expert Panel with three colleagues (from Poland, Italy and Spain). The Panel was asked in particular to define current and future perspectives on blood donor screening in order to encourage the improvement of existing pathogen screening tools and blood transfusion safety for patients. The Panel members provided an update on the current situation in Europe, the Middle East and Africa regarding emergent or potential emergent pathogens as well as advice on suitable blood donor screening assays. A whole variety of pathogens were included in the discussions, and the Panel members were able to highlight areas where development of new assays, or refinement of current assays, might contribute to increasing blood safety.

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?

316. In respect of the Expert Panel described in (a), my travel and hotel accommodation (one night) were arranged by Grifols. They also paid me an honorarium to cover two days' work. In November 2018, I accepted an invitation to give a lecture on a training course for the Polish Society of Haematology, funded by Roche Diagnostics. Roche arranged and paid for my travel and hotel accommodation (one night) and paid an honorarium for my time.

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?

317. I have not sat on an advisory panel, board, committee or similar body of any pharmaceutical company, other than the occasion outlined in para (a).

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

318. My position within NHSBT did not involve me in the use of blood or plasma products, nor did I ever advise clinical colleagues in the use of such products, and I therefore have never received any financial or non-financial incentive to use certain products.

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

319. See above.

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

320. See above.

144. 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?

321. There was a procedure in place at NLBTC for an annual declaration of interests. I always complied with the annual declaration.

145. 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.

322. I have not undertaken medical research for, or on behalf of, a pharmaceutical company.

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

323. I have not provided any pharmaceutical company with results from research studies that I have undertaken.

147. 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?

324. N/A

Section 15: Variant Creutzfeldt-Jakob disease (vCJD)

148. As regards to the questions outlined in this particular section, the Inquiry is interested in gaining an understanding of your knowledge of risk and your involvement in the discussions and actions taken with regard to vCJD, since 1985. We are particularly interested in your responses in respect of the introduction of a UK look back study for individuals who may have been infected with vCJD as a result of blood transfusions in 1997, and developments thereafter.

325. The disease which became known as variant CJD (vCJD) was recognised in 1995 by workers at the National CJD Surveillance Unit (NCJDSU). The Unit was later re-titled the National CJD Research and Surveillance Unit (NCJDRSU) and I will use this abbreviation throughout. A description of the first 12 cases of vCJD was written up and published in "The Lancet" in the summer of 1996. My knowledge of risk, and involvement in discussions and actions taken with regard to vCJD, therefore dates from 1996. The date of 1985 is irrelevant in terms of vCJD.

149. Please answer the following questions as far as you are able, drawing upon your roles in employment and membership of the committees and groups set out but not limited to those listed by you at Paragraph 8 of your Written Statement [WITN3101004] dated 14 March 2021.

150. To assist you in this process we draw your attention to specific documents which highlight your presence at particular meetings or involvement or awareness in the correspondence or information being shared or discussed.

Knowledge of risk of vCJD transmission via blood transfusions and blood products

151. Following the BSE outbreak in 1985 and the first human death from vCJD in 1995, the risk of vCJD transmission by blood was confirmed in 2003. The Inquiry is interested in your knowledge of risk, your involvement in discussions within the blood services, and any actions taken with regard to vCJD since 1985.

You may find NHBT0001722 and NHBT0000721 of assistance.

When and in what circumstances did you first become aware of the risks of transmission of vCJD through blood and blood products?

326. I first became aware of concerns about the risk of transmission of vCJD through blood transfusion in early 1996. I understand that, following the recognition of this "new" variant of CJD by NCJDRSU, contact was made by NCJDRSU with the UK Blood Services (UKBS). I do not know who made the contact, or when it was made. I am aware that a meeting took place in April 1996 in Edinburgh, involving representatives of the English and Scottish Blood Services, the plasma fractionators (BPL and PFC) and Dr James Ironside of the NCJDRSU. I did not attend the meeting as I was on annual leave. Following the meeting, I was asked by Dr Angela Robinson, Medical Director of the NBA, to work with my opposite number in the Scottish National Blood Transfusion Service (SNBTS), Dr Jack Gillon, and the NCJDRSU, to devise a study to investigate whether there was any link between vCJD and blood transfusion (NHBT0008485).

b. Please provide a summary of any discussions you are aware of relating to the development of scientific understanding of the risks of both vCJD infection and of secondary transmission via blood and blood products.

327. The development of scientific understanding of the risks of vCJD infection occurred over a number of years, from 1995 onwards, chiefly driven by discussions at SEAC (Spongiform Encephalopathy Advisory Committee), of which I was not a member. There were also discussions at the CJD Incident Panel (CJDIP) meetings, of which I was a member. As far as I am aware, the risk of secondary transmission via blood and blood products was first raised by NCJDRSU (see above) with other experts working in Prion disorders, both in the UK and elsewhere, contributing to the debate. There were extensive scientific publications over the years, which were subject to discussions in both SEAC and CJDIP.

c. What was your understanding of the relative risks of vCJD infection from the use of commercial or imported blood and blood products, as compared with the use of domestically produced blood and blood products?

328. As vCJD was early on recognised to be the likely human consequence of the BSE epidemic in cattle, which had occurred mainly in the 1980s, and was chiefly, but not totally, limited to the UK, or to cattle originating in the UK, it was considered that vCJD was also likely to be an issue predominantly affecting the population of the UK, or those who had lived in the UK during the relevant time period. It was therefore likely that the risk of vCJD infection was predominantly limited to those who may have been exposed through diet (consumption of BSE-infected beef) and this risk mainly affected the UK.

329. Similarly, the risk of secondary infection through transfusion of blood and blood products was likely to be predominantly a risk related to UK-derived blood and products, or to donations from donors who had eaten UK-derived beef in the 1980s. It was likely that commercial plasma products produced from non-UK plasma would present a significantly lower risk than domestic plasma. As blood components were not imported into the UK, the question of commercial or imported blood (as opposed to plasma) does not arise.

d. Please provide an outline of any steps you are aware of which were taken to ensure that the UK Government, blood services, NHS bodies, medical profession and patients were informed and educated about the risks of vCJD transmission via blood and blood products.

330. The possibility of vCJD transmission through blood and blood products was first raised, to my knowledge, by the NCJDRSU (see above). The Department of Health had set up the Spongiform Encephalopathy

Advisory Committee (SEAC), and subsequently the CJD Incidents Panel (CJDIP), which were responsible for assessing risk and advising on risk management and management of individual cases. The CJDIP issued a Consultation Exercise in 2001, which included the issue of transmission by blood and plasma products. A wide variety of bodies was contacted in respect of the Consultation.

331. NHSBT has for many years provided an information leaflet for patients who may require a blood transfusion. As well as outlining what a blood transfusion involves, and how it is administered, the leaflet summarises the main adverse events of blood transfusion, including the (low) risk of transfusion-transmitted infection. When the first case of transfusion-transmission of vCJD was recognised in December 2003, NHSBT took steps to include a short statement about vCJD in the leaflet. NHSBT also provided information for potential blood donors if there were any issues relating to vCJD. Later, when it was decided to exclude as blood donors all individuals who had received a blood transfusion, NHSBT prepared information which was provided to those affected, to explain the precautionary nature of the exclusion.

vCJD Lookback and Surveillance studies

152. The Inquiry seeks to understand what look back exercises and/or surveillance studies were considered and/or undertaken in order to gain epidemiological knowledge in relation to the potential risk of vCJD transmission through blood and blood products. This includes details in relation to the number of people who may have been potentially exposed to or infected with vCJD via blood and the ethical advice provided to any clinicians in charge of their care, in terms of notifying them of their at-risk status.

Transfusion Medicine and Epidemiology Review ("TMER") – The look back study

332. Please note the correct title of this piece of work : The Transfusion Medicine Epidemiology Review.

153. We understand you were involved in the drafting of the proposal for the Transfusion Medicine and Epidemiology Review ("TMER"), a look back study relating to vCJD where you held the role of Principal Investigator.

a. Please provide the following information, as far as you are able:

i. A chronological outline of the discussions leading to the proposal for a look back study, namely TMER;

333. As I understand it, the main outcome of the meeting held in Edinburgh in April 1996 (see above) was agreement that a piece of work was needed to try to establish whether there was any link between vCJD and blood transfusion. I was asked to participate, on behalf of the NBA, in drawing up a proposal to address this question (see above). My colleagues and I started discussions immediately after the request was received.

ii. A list of the names of the individuals and organisations who were consulted in relation to the merits of undertaking a look back study and what their views were in terms of what the study should aim to achieve;

334. I do not have any information on whom might have been consulted in relation to the merits of undertaking a lookback study. It appears that the Department of Health, through Dr Jeremy Metters, Deputy CMO, were involved in the proposal but I know no further details. I was involved from

the point where agreement had been reached that such a study was required.

iii. The aims and objectives of TMER;

335. The main aim of the TMER was to try to establish whether there was any link between vCJD and blood transfusion. The TMER was not designed to investigate fractionated plasma products.

iv. An account of how the scope of the look back was defined in the TMER study;

336. The scope of the TMER was to ensure as far as possible that any link between vCJD and blood transfusion would be detected. At the same time, it was agreed that the TMER would also investigate whether there was any possible link between sporadic CJD (sCJD, otherwise known as "classical" CJD) and blood transfusion. Although no such link had been demonstrated in both case-controlled studies and lookback exercises, in either the UK or world-wide, it was agreed that the TMER study would be an ideal opportunity to obtain further information which would add to the scientific knowledge with respect to sCJD.

337. The TMER study was therefore designed to include both vCJD and sCJD, and also to involve two separate "arms". The first, and most direct arm, is to establish whether individuals who have been diagnosed with CJD (sCJD or vCJD) have acted as blood donors. If so, the blood service would trace the blood donations through blood centre records, identify relevant blood donations, establish what blood components had been prepared from these donations and identify the fate of these blood components through to their final destination.

338. If the final destination was recorded as issued to a hospital blood transfusion laboratory for clinical use, the laboratory in question would be asked to trace, through laboratory records, the fate of the blood component. If it was recorded as transfused to an individual recipient, the details of the recipient would be notified to the blood centre. This part of the study is the lookback arm. Once the identity of the recipient is received, it is forwarded to NCJDRSU for passive surveillance purposes. That is, NCJDRSU will check the details against the database of individuals who have been diagnosed with CJD and will perform further checks at intervals over time in order to detect cases which might develop at a later date.

339. NCJDRSU also applies to the Office of National Statistics (ONS) (and its successor) for a copy of the death certificate when the individual dies, in order to check whether there was any evidence of CJD, or other recorded neurological disorder, recorded on the death certificate.

340. As far as the TMER is concerned, only cases of sCJD who were known (by their relatives/ next of kin) to be blood donors are notified to the UKBS for checking. In contrast, all cases of vCJD, whether or not known to be blood donors, are notified by NCJDRSU for checking as it is vitally important to ensure that no case is missed. This decision has been vindicated by the fact that donor records have been traced for a small number of individuals diagnosed with vCJD, whose relatives had not reported a knowledge of blood donation.

341. At the start of the study, the Department of Health (Dr Jeremy Metters, Deputy Chief Medical Officer) would only allow notification of cases of vCJD to the Blood Service (BS) covering the country of residence of the case of vCJD. All the UK Blood Service Medical Directors, myself, and Professor Will, felt this restriction might result in cases being missed and lobbied for wider dissemination of names to all four UKBSs, and this was

eventually agreed and implemented.

342. The second part of the TMER study is the reverse process, which we referred to as the Reverse TMER (R-TMER). It was devised as a way of double-checking that no possible case of CJD linked to blood transfusion would be missed. The R-TMER takes as the starting point a patient who has developed CJD and who has a history of blood transfusion at some point before the diagnosis of CJD. This is analogous to the process carried out by the BSs when a case of possible transfusion-transmitted infection is referred for investigation. The process is also known as "traceback". The traceback also involves both vCJD and sCJD.

343. The main difference between the TMER lookback arm and the R-TMER traceback arm is that in the latter, cases can only be investigated if the hospital of transfusion is known. This is because there is no national database of blood recipients, and enquiries can only be made to the identified hospital. The R-TMER acts as a double check, to ensure as far as possible that the TMER checks are complete, and that no case has been missed. The results of the TMER confirm this to be the case. No case of CJD diagnosed in a recipient of a blood transfusion and linked (through the R-TMER traceback arm) to a donor who had also developed CJD has not already been identified in the forward (lookback) arm. This evidence has given confidence that the process which was devised is operating as intended.

v. A detailed description of your role and responsibilities as Principal Investigator for England and Wales with respect to this study;

344. Professor Robert Will and myself were the joint Principal Investigators in the TMER, myself representing the UKBSs and Professor Will

representing NCJDRSU. My role and responsibilities were mainly as follows:

- To take responsibility with Professor Will for the conduct of the study;
- To act as the representative of the four UKBSs in the TMER;
- To liaise with all four UKBSs, and report to the Medical Directors through the UK Forum;
- To ensure that actions required by UKBSs (through their blood centres) were conducted according to the study protocol;
- To regularly review, with Professor Will and our respective Study Managers, the accumulating results of the TMER and to ensure that these results were reported to the relevant bodies;
- To prepare annual reports required by DH, chiefly relating to the costs of the study, and to prepare forecasts for expected expenditure in future years, with bids for continued funding of the TMER;
- To prepare, with my co-workers, scientific papers for publication arising out of the study, and to contribute to reports requested by others.

vi. A detailed description of the role and responsibilities of the co-authors of the TMER Study, namely Jack Gillon and Robert Will, and any other person who was involved in its creation;

345. Once the TMER study protocol was agreed, I had very little further contact with Dr Jack Gillon. I believe that he may have retired from SNBTS around this time, but this could be confirmed by SNBTS. Professor Will will be able to provide details of his role and responsibilities.

vii. Your understanding as to how the TMER study would work in practice;

346. The TMER was designed as far as possible to replicate processes already in place within blood centres, namely lookback (tracing of

previous donations from a blood donor whose donations were now known or suspected to present a possible risk of infection to recipients of those blood donations) and traceback, or investigation of the donors whose blood had been transfused to a recipient now reported to have a possible transfusion-transmitted infection. These processes were already embedded in routine practice.

347. The main difference for CJD was that there was no blood test that could be offered to determine whether an identified recipient (in lookback) or donor (in traceback) was infected with CJD.

348. In order to carry out lookback and traceback, the UKBSs were dependent on NCJDRSU passing on the personal details of those who had been diagnosed with CJD so that appropriate checks could be carried out at blood centres. The notification of personal details across two separate organisations was recognised to present a concern in terms of lack of consent for such sharing. Consent from cases of CJD was not possible, as capacity to give consent is lacking at the stage when a diagnosis of probable or confirmed CJD has been made. Such issues were addressed in the application for ethical approval for the study.

viii. An outline of the role of the Lothian Ethics Research Committee (LREC) in the approval of TMER and any points raised by them upon review of the TMER proposal;

349. Because the TMER was designed to provide new knowledge in a situation where there was no scientific evidence of a risk of infection through blood transfusion, it qualified as a research study. As such, it required ethical approval. It is also clear from the documents that I have seen that Dr Jeremy Metters (Deputy CMO) insisted on this step. At the time the protocol was drawn up, NHS organisations were required to apply to their local ethical research committee (LERC) for ethical

approval for a proposed study. The Lothian LERC was the committee local to NCJDRSU and had been involved in many previous research studies carried out by NCJDRSU, and it was agreed that it would be appropriate to also approach the Lothian LERC in respect of the proposed TMER study. Communication with the Lothian LERC was carried out by Professor Will, and all related documentation was held at NCJDRSU.

ix. An outline of the role of BPLL, NBA (and its successor organisations) the National CJD Surveillance Unit, Department of Health, and the UK Blood Transfusion Services with respect to this study;

350. The role of NCJDRSU and the UKBSs has been explained (see above). BPL had no role in the TMER. DH gave agreement to the study and eventually provided funding for the study, at first by specific funding from research funds, and later by transferring the required funding to the NCJDRSU core budget. I recall that Dr Metters (Deputy CMO, DH) wished to avoid the title incorporating the abbreviation "vCJD" with the word "transfusion" in the title of the study, so that the proposed title was altered slightly to accommodate this request.

351. DH also required advance sight of any intended publication relating to the study and was sent copies of manuscripts which had been accepted for publication.

x. Details of any practical or statistical concerns or considerations with the operation of the study and how these were addressed;

352. Practical concerns relating to the TMER mainly revolved around consent issues (see above) and confidentiality. In order to address the latter, it

was agreed that the TMER would include both cases and controls. The control patients were selected at NCJDRSU and their details were reported in the same way as the CJD cases, so that the identity of the cases was "blinded' to the UKBSs. This meant that staff working in blood centres and communicating with Consultant Haematologists in charge of hospital blood transfusion laboratories did not have the information to know which were cases and which were controls, and Consultant Haematologists could be warned not to take any action with respect to identified recipients, other than to trace their details, as some would have received blood donated by control donors.

353. Other practical concerns revolved around the ability of UKBSs and hospital laboratories to trace relevant records dating back over many years. Early on, the NBA took the decision to retain all records relating to the audit trail from donor to patient and vice versa from the year 1980 onwards, so that relevant records would not be destroyed. Hospital laboratory records were not generally retained for longer than approximately 12 years (with some variation) and NBA had no control or influence over this issue.

354. I do not recall any discussions about statistical concerns during the early years of the TMER. The study was designed to detect, as far as possible, a rare event, and as such statistical concerns were not an issue. When statistical input was required, statisticians working with NCJDRSU were consulted and provided the appropriate analyses.

xi. The source of funding for the study and what level of control, if any, the funding body exercised over the running of the study;

355. Initially, the TMER was funded by the NBA. It then became a formal project under the NBA Research and Development programme. When that funding ceased, the TMER was funded by DH from research funding.

DH Research exercised no control over the running of the study. Early on, Dr Metters, Deputy CMO, instructed that personal details of cases could only be shared in the country of residence (see above). After representations (see above) it was agreed that details would be shared across all four UKBSs so that all blood centres could carry out checks to establish whether a case had acted as a blood donor outside their country of residence. In the case of recipients who had developed CJD there was no such concern, since their details could only be passed on to the hospital(s) where transfusion was reported to have taken place, and therefore personal details were only passed to the relevant BS providing the blood supply to that hospital.

xii. Copies of all draft proposals, the final proposal and any applications for renewal of the study, whether rejected or accepted.

356. The TMER proposal submitted to the Lothian LERC is already available to the Inquiry (NHBT0008903). This was the final proposal. A (partial) draft copy is also available at NHBT0007193_001. Applications for renewal of the study were handled by Professor Will and I do not have copies of the correspondence, but the Inquiry has available a January 2000 letter from the Chair of the Lothian LERC withdrawing approval for the study (**NHBT0004364_004**) and Professor Will's subsequent letter to Dr Ailsa Wight at the Department of Health (**NHBT0004364_003**) explaining the background to the refusal, which followed the decision by MSBT that the identified recipients of blood components from donors who later developed vCJD should be notified, which was contrary to the earlier decision of the Lothian LERC.

You may find NHBT0008903, NHBT0016056_001, NHBT0008725_003, NHBT0008896, NHBT0008485, NHBT0009078_002, NHBT0008901, NHBT0011360, NHBT0009021, NHBT0008720_002, NHBT0008727, NHBT0008999_002, NHBT0009009_002, NHBT0011364, NHBT0017407,

NHBT0012019_001, NHBT0016056_002, NHBT0004117, NHBT0004345_003, NHBT0004047_002, and NHBT0007193_001 of assistance.

Transfusion Medicine and Epidemiology Review ("TMER") - Ethical issues

154. The Inquiry seeks to gain an understanding of the discussions which led to the ethical decision not to inform individuals of the use of their medical data in the look back exercise, in addition to the decision not to inform individuals of their at-risk status as a recipient of vCJD implicated blood. Please provide the following information, as far as you are able:

a. The names of the individuals and/or organisations who were approached to provide advice on the ethical basis for the TMER study;
b. Details of any person or organisation who were instructed to provide an opinion on the ethical position to be adopted for the TMER study;
c. A summary of the ethical and legal advice received from any individuals or organisations instructed to provide the same;
d. An outline of the concerns raised by any person or organisation consulted in deciding not to inform donors and/or recipients of their at risk status.

357. I know that I and colleagues from NCJDRSU approached both Professor Ian Kennedy (in 1996) and Professor Len Doyal (in 1999) for advice on the ethical issues raised in respect of the TMER study. The Lothian LERC was also involved, as it was approached for ethical approval of the finalised study protocol. Professor Doyal's views were summarised in a letter from him (NHBT0004392_002). I have been unable to locate a written reply from Professor Ian Kennedy in 1996 or 1999, but I am continuing to search my archived files in the hope that a letter might be located, in which case I will provide it to the Inquiry.

358. The advice given by Professor Kennedy in 1996 was summarised by me in my further letter to him in April 1999 (NHBT0017407). Professor Kennedy had considered, in the situation where there was no scientific evidence of transmission of vCJD through blood transfusion, no screening or diagnostic test available, and the lack of any effective intervention which could be offered to those infected, that the balance lay in not notifying those recipients who had received blood components from donors who later developed vCJD. He raised two caveats: should the capacity to diagnose infection change, or an effective intervention appear, then the situation should be revisited.

359. Professor Kennedy's advice was incorporated in the study proposal for the TMER, which was submitted to the Lothian LERC, which came to the same conclusion.

360. I approached Prof Kennedy again in April 1999 because of two new developments. The first was the potential availability of a diagnostic test for vCJD in the form of a tonsillar biopsy, which was being developed at the National Prion Clinic. The second was the UK BSs proposal to protect the blood supply by devising a means to exclude donations from individuals who had been identified as recipients of blood components originating from donors who had later developed vCJD. These issues are summarised in NHBT0017407. Later, Professor Doyal was approached.

361. Professor Doyal's advice in 1999 relied much more strongly on the individual's right to know information relating to them. He considered that there were possible tests available to detect vCJD infection, although it can be seen from Dr Knight's letter to me (NHBT0004320) that Dr Knight felt that Professor Doyal had been over-optimistic about the possible utility of such tests. Professor Doyal considered that individuals should be notified. It is clear from Dr Starkey's letter to Professor Will (NHBT0004364_004) that the Lothian LERC strongly disagreed with

Professor Doyal's opinion.

362. I later heard from Professor Will that a lookback study involving CJD had commenced in the United States of America. This study related to cases of sCJD, as vCJD has occurred only very rarely in the USA. The ethical committee which considered the study in the USA also came to the conclusion that identified recipients of blood components originating from donors who had later developed CJD should not be notified/ informed.

363. I do not recall that any legal advice was sought in respect of the setting up of the TMER in 1996. Legal advice was sought in 1999 (NHBT0004389) when the Blood Services proposed the "flagging" of records relating to Identified recipients.

155. In a letter to Professor Ian Kennedy dated 15 April 1999 (NHBT0017407) and Dr Angela Robinson (NHBT0001259) you refer to advice sought from him in 1996 as to the merits of informing recipients of a blood transfusion when it became known that they had received blood from a donor who later went on to develop vCJD. With respect to the above letter please provide the following information as far as you are able:

a. The dates and circumstances surrounding your approach to Professor Ian Kennedy for advice on the ethical issue of notification under TMER;
b. In what capacity this request was made, formally or otherwise;
c. Details of the advice provided to you by Professor Ian Kennedy;
d. Copies of any correspondence between Professor Ian Kennedy and yourself detailing any advice which was provided, where available;
e. Any reports you prepared for any organisation based upon the above advice and to whom those reports were submitted;

f. Details of any communications and/or a copy of any response you received from Professor Ian Kennedy following your request for updated advice on the 15th April 1999;

g. Details of any subsequent correspondence or conversations which have taken place since 15th April 1999.

You may find NHBT0009899_001, NHBT0008485, NHBT0004389, NHBT0004382_001, NHBT0015322, NHBT0015384, NHBT0004320, NHBT0009027, NHBT0004392_002, NHBT0008893, and NHBT0029719, of assistance.

364. I have been unable, to date, to locate any files which would provide further detail about the approach to Prof Kennedy in May 1996. I know that the approach was specifically in respect of the setting up of the TMER study, which was initiated after the meeting held in Edinburgh in April 1996. I believe that I agreed, in discussion with Professor Will and Dr Gillon, to seek ethical advice in relation to the proposed study, and I accordingly consulted Professor Kennedy. I have summarised the advice given by Professor Kennedy in 1996 in the answer above.

365. I do not have any further correspondence with Professor Kennedy after my letter to him in April 1999. I believe that it is possible that Professor Kennedy felt unable to assist again in 1999. This might be the reason that Dr Knight and I had a meeting later that year with Professor Len Doyal (see NHBT0004392_002 and NHBT0004320). I cannot otherwise see any reason why we would have consulted a different ethical expert.

366. Although I have not been able to identify any helpful documents in respect of Professor Kennedy's advice in 1996 and the further approach in 1999, I have very recently gained access to some old, archived files which may contain helpful information, and I undertake to provide any

update to the Inquiry as soon as possible.

Transfusion Medicine and Epidemiology Review ("TMER") - Ethical Approval

156. The Inquiry seeks to understand the process for obtaining ethical approval of the TMER study and how this developed or changed over time. Please provide the following information as far as you are able:

a. The role and remit of the Lothian Research Ethics Committee (LREC);
b. The circumstances in which the LREC would need to be approached;
c. An outline of the process for obtaining ethical approval of any study;
d. The role of the LREC in relation to the TMER study;
e. A chronological summary of the occasions in which the LREC were approached for ethical approval in relation to TMER and their response on each occasion. Please detail the circumstances when ethical approval was granted and when it was refused or withdrawn, with the reasons behind those decisions.

367. The role and remit of the Lothian LERC has been covered above, as have the circumstances in which the LERC would need to be approached, and the role of the LERC in respect of the study. All communications with the LERC was by Professor Will, and all associated documents were kept at NJCDRSU. See above.

You may find NHBT0004364_004, NHBT0011360, NHBT0004364_003, and NHBT0003492_001 of assistance.

Transfusion Medicine and Epidemiology Review ("TMER") – Product recalls

157. The Inquiry is aware of a series of product recalls between 1997-2000 following the decision of the Committee for Proprietary Medicinal Products

(CPMP) to recall batches where a blood donation to a plasma pool was subsequently found to have been received from a person who developed vCJD. Please provide the following information as far as possible:

a. An outline of the protocol followed by the NCJDRSU, NBA and BPL when they became aware that an individual who had developed vCJD had been a blood donor. What ethical issues did this raise?

368. Product recalls were a completely separate issue from the TMER. Product recalls of fractionated plasma products were required following the CPMP decision to require recall of batches of product where a blood donor whose plasma had been incorporated in a plasma pool for fractionation had subsequently developed vCJD. This requirement was outside the TMER.

369. Product recalls under CPMP related to licensed medicinal products, and not to blood components. In order to comply with the CPMP decision, the UKBSs needed to know the identity of individuals who had been diagnosed with confirmed or probable vCJD. They did not already have this information because the names included in the TMER were both cases and controls blinded to the BSs. Therefore, separately from the TMER study, NCJDRSU was required to pass on names of those with confirmed/ probable vCJD, so that BSs could establish whether plasma from any of those individuals had been forwarded to the fractionator(s) (BPL and PFC) for production of fractionated plasma products.

370. Once that information was known, BSs would notify the fractionator through already established recall procedures, as described in paragraphs 242 and 243. In addition to the established procedure, notification was also made to DoH so that they received an early indication of a potential vCJD recall of fractionated plasma products. The CPMP ruling therefore required that NCJDRSU "unblinded" the names of

cases of vCJD notified to the UKBSs. This unblinding produced no new ethical issues as far as the TMER was concerned, as the TMER was a completely separate process, and the existing ethical advice was followed.

371. Dr Terry Snape had requested that the NBA gave an early warning to BPL when a new case of vCJD was notified from NCJDRSU to the NBA. This was so that BPL was not caught unawares when it was notified of plasma donations which would require a product recall. We devised a procedure where Dr Snape was included as a recipient of the covering letter which was sent to all English blood centres when the details of a new case were circulated after receipt from NCJDRSU, as illustrated by BPLL0016089_005. Dr Snape did not receive the form which was sent out with the letter to all blood centres and contained the personal details of the new case. I added a handwritten note to the letter which I sent to Dr Snape with the words "not known to be a donor" or "reported to be a donor". If the case had been reported to be a donor, this would be followed by official notification of plasma donations which had been forwarded to BPL for fractionation, or by a follow-up note that no plasma had been forwarded for fractionation, so that the circle was closed and BPL was able to close the case, as requested by Dr Snape in NHBT0008722.

b. Whether the CPMP ruling and involvement of the NCJDRSU, NBA and BPL affected the ethical decision under TMER not to share the identity of recipients exposed to vCJD implicated blood with any organisations involved and if so how;

372. See (a.) above

c. Whether the CPMP ruling and involvement of the NCJDRSU, NBA and BPL affected the ethical decision under TMER not to notify those individuals that

they had received vCJD implicated blood or blood products and if so how;

373. See (a.) above

d. Following the CPMP decision, please outline how hospitals, plasma fractionators and other relevant organisations were notified when implicated products required recall.

374. Products requiring recall under the CPMP decision relating to fractionated plasma products were subject to BPL recall procedures. Once UKBSs had notified BPL of plasma donations which fell under the CPMP decision, they had no further part in the recall process.

e. Please comment upon how the confidentiality of patients was maintained during those product recalls.

375. The TMER was completely separate from product recalls. Decisions about identification and/or notification of individuals following recall of fractionated plasma products did not involve the UKBSs.

f. Please provide your opinion as to whether the ethical position set out under TMER was intended to be used as a basis for non-notification to individuals who were identified and/or contacted as a result of the product recalls. If not, why not? Were the relevant organisations alerted to this fact?

376. The ethical position set out in the TMER was restricted to the study. This ethical position may have been considered in part of the decision-making in relation to fractionated plasma products, but this was not an intended consequence when the TMER study was planned and implemented. I recall that at some point I was informed in a letter from Dr Jeremy Metters that the Department of Health had "separately" obtained ethical

advice, but I was never able to establish any details about when or from whom this advice had been sought, and in what circumstances.

You may find NHBT0001722, BPLL0016089_005, NHBT0005405_001, NHBT0011476_004, BPLL0016009_034, NHBT0009047, NHBT0008722, NHBT0002484, NHBT0009028, NHBT0009019, NHBT0001271, NHBT0009000, NHBT0029719, and NHBT0008875 of assistance.

Transfusion Medicine and Epidemiology Review ("TMER") – Efficacy

158. The Inquiry is keen to gain an understanding as to whether TMER achieved its desired objective as an epidemiological study and whether it has been effective in identifying donors and recipients of vCJD implicated blood and blood products as a risk reduction measure in the UK. Please provide a response to the following:

a. In your view, has TMER been successful in achieving the objectives it set out to undertake? Please provide your reasons.

377. The TMER was designed to determine whether there was any link between CJD and blood transfusion. The first possible link was detected in December 2003, when an individual died with a neurological disorder which had not been positively diagnosed before death, but which was confirmed at post-mortem to be vCJD. This individual had received a blood transfusion some years earlier which included a blood component originating from a donor who later developed vCJD. The recognition of this case appeared to demonstrate a link between blood transfusion and vCJD, and this case was reported as such.

378. The report of the case was published in "The Lancet" (Ref 120) WITN3101018 with the title including the word "possible" as it was felt that one case was not absolute proof of causality, although statistically it

was likely that there was a link. I recall that it was DH who strongly lobbied for the inclusion of the word "possible" in this context. Subsequently, two further cases of vCJD were confirmed in recipients who had both received blood components some years earlier from a common donor who had subsequently been diagnosed with confirmed vCJD. The occurrence of two cases linked to a common donor, all of whom developed vCJD, confirmed the link between vCJD and blood transfusion.

379. Sadly, the TMER had therefore achieved one of its objectives, by demonstrating a link between vCJD and blood transfusion. It remains the case that no such link has been established for sCJD. Once the link between vCJD and blood transfusion had been identified, and notification of affected individuals was put in place, the vCJD section of the TMER ceased being a research study and became incorporated into routine surveillance carried out by NCJDRSU. The TMER still continues for sCJD.

b. In a letter to Dr Cath Chapman dated 27th January 1998 (NHBT0012029) you indicate that the names of donors suspected of having vCJD were only given to the centres in the individual's home region. Please outline why this information was not shared with the wider regions.

380. At the start of the study, the names of donors who were diagnosed with confirmed or probable vCJD were only notified by NCJDRSU to the BS (not blood centre) which covered the individual's home address, which was a requirement laid down by DH (see paragraph 234), I believe on grounds of confidentiality and limiting the sharing of information on a "need to know" basis. Professor Will and I argued that it was possible that an individual could act as a blood donor elsewhere, when on holiday, for example, and lobbied for wider sharing to all four UKBSs for each case.

This argument was eventually accepted and implemented.

c. The total number of people who have been identified as being at risk of vCJD through blood transfusions as a result of the TMER study;

381. The total number of people identified through the TMER as being at risk of vCJD because they had received a blood component originating from a donor who later developed vCJD is available on the NCJDRSU website (RLIT0000777). The total number of such blood components traced to identified recipients is 67. This number has not changed for many years.

d. The total number of people notified of the risk of vCJD infection through blood transfusion;

382. Of the total number of people identified by the TMER as at risk of vCJD through blood transfusion, 53 are listed as deceased. I believe that no further action was taken with respect to individuals who died before the diagnosis of vCJD was made in the donor, but I stress that decisions about notification were not the responsibility of myself or Professor Will.

383. I am aware that one individual who was alive at the time of the notification procedure in late 2003 was not informed of the risk of vCJD. Further information should be sought from those who were responsible for the notification procedure.

e. The number of people who failed to respond to a notification that they were at risk of vCJD;

384. This question should be addressed to those responsible for the notification procedure.

f. An account of attempts made to establish contact with people who did not respond to notifications;

385. This question should be addressed to those responsible for the notification procedure.

g. How many people in total have been counselled as part of the TMER and what provision has been made available for support and counselling?

386. Notification, "counselling" and further management of individuals identified through the TMER as being at risk of vCJD through transfusion of blood components was managed outside the TMER and I had no part in this procedure, other than to ensure that details of the identified individuals were passed on to the team who were managing the notification.

387. Separately, in 2005 a notification procedure was implemented for blood donors who had been identified as at risk of transmitting vCJD because they had been linked through the R-TMER with a recipient who had developed vCJD following receipt of a blood transfusion. I managed the 2005 donor notification process.

h. How has the data obtained from TMER been used to facilitate risk reduction measures for vCJD in the UK?

388. Data obtained from the TMER has been made available publicly through the TMER section of the NCJDRSU website and through publications in scientific journals. It has also been provided to the CJDIP and has been used in modelling for various risk assessments commissioned by DH and CJDIP.

i. Please provide copies of any interim and final reports for TMER.

389. Reports of the TMER are available on the TMER section of the NCJDRSU website, which is updated at least annually. There is no final report, as the epidemiological study continues.

j. Please provide details of any other relevant look back or surveillance studies related to vCJD that you were directly involved in or had knowledge of.

390. I am not aware of any other lookback or surveillance studies relating to vCJD. Other studies on sCJD exist from outside the UK.

CJD Incident Panel Consultation

159. The Inquiry is aware of the CJDIP consultation (BART0002012 and NHBT0096710_001), of which you were a member, set up to develop a framework to manage exposure to vCJD and review the position on notification to recipients of blood and blood products. As to this:

a. **Please provide a summary of your views and contribution to the CJDIP consultation in 2000.**

b. How and why did the position on notification change?

391. I was a member of the CJDIP when the consultation exercise was carried out in December 2001. The consultation document was a distillation of the consensus views of the CJDIP. I strongly supported the proposal to carry out notification of recipients of blood components originating from donors who had later developed vCJD.

392. The position on notification changed between1999 and 2001. Part of this change was the result of risk modelling, which resulted in blood components being judged to be a high risk for transmitting vCJD from an infected donor. As can be seen from a number of documents such as NHBT0015384 and NHBT0004382_001, the UK blood services had been pressing for notification in order to protect the blood supply. In the absence of notification, they had decided to take interim action of "flagging" such individuals so that their donations could be recognised and not used in the unlikely situation that one of these individuals presented as a blood donor. The Blood Services had proposed this action in order to protect the blood supply, but continued to press for these individuals to be notified of their risk, despite the very real concerns about the enormity of that information and the possible effect on the individual.

393. The flagging alternative was less than ideal for a number of reasons, and the concerns of the UKBSs were transmitted to the CJDIP with some force. Over time, and with the availability of risk assessments, members of the CJDIP changed their majority view from non-notification to notification, as reflected in the December 2001 Consultation Document. I understand that notification was advised by the CJDIP to DH but action was not taken until December 2003, when the recognition of the first possible link occurred (see above). DH then instructed that notification should take place.

c. What was the outcome/what recommendations were made in relation to the patient's right to know information relating to their medical data and history?

394. See above. The main concern of the Blood Services was to protect the blood supply.

You may find NHBT0004311, NHBT0002488, NHBT0096710_001, and DHSC0004123_029 of assistance.

Notification exercises

160. The Inquiry has heard evidence of the experiences of a number of infected and affected individuals who were notified of their 'at risk' status of vCJD from 1997 onwards. The Inquiry seeks to gain an understanding of the rationale behind policy decisions made in relation to notifying at risk individuals and how this changed over time. The Inquiry is aware of further patient notification exercises between 2003 and 2009, in particular the large-scale notification exercises commencing from 2004, notifying patients they were 'at risk' of vCJD. Considering these issues:

a. **Please provide your opinion as to whether the initial ethical position underpinning the TMER Study not to notify recipients of vCJD implicated blood donations influenced the Department of Health, Blood Services, BPL and other relevant organisations not to notify individuals deemed to be at risk of vCJD.**

395. See above.

b. Please provide a summary of any ethical and/or legal advice that was sought by your organisation/s in relation to notification of individuals deemed to be at risk of vCJD. You may find NHBT0004320 of assistance.

396. I believe that I have already addressed this question in earlier answers.

c. In your view, at what stage should patients have been informed of their at risk status?

397. In my view, notification should have taken place before December 2003. I understood that there were concerns about the mechanism of notification and the provision/ availability of support for the affected individuals, but the result of the delay was that a notification procedure had to be initiated within a very short time frame, once the first case of transmission was recognised in early December 2003. Notification then took place over the Christmas period, when arguably there was less prospect of support being forthcoming.

161. Please provide an outline of any policies and practices which were implemented across the U.K. in relation to patient notification and de-notification. Please also provide:

An account of your organisation's involvement, if any, in those notification exercises between 2003 and 2009;

398. The UKBSs were not directly involved in the notification and de-notification exercises between 2003 and 2009 relating to recipients of blood components and fractionated plasma products.

b. An account of your organisation's involvement, if any, in any de-notification exercises post 2013 or earlier;

399. The UKBSs were not involved in any de-notification exercises post 2013 or earlier.

c. Details as to whether your organisation was aware of any circumstances where individuals were not informed of their risk status or at a later date and, if so, why;

400. See above.

An account of what, how, when and where patients were told that they might have been exposed to a greater risk of vCJD;

401. This question has been addressed elsewhere.

e. A summary of information or advice given to partners or family members of patients who were at risk of infection with vCJD.

402. The information or advice given to partners or family members was not part of my remit or that of the UKBSs.

Risk Reduction Measures

162. The Inquiry seeks to understand what actions the Government, Department of Health, NBA and other organisations took in response to the risk of vCJD transmission via blood and blood products. Please could you outline any proposals, whether accepted or not, that you were aware of that were made in an effort to protect the blood supply from the risk of vCJD, including but not limited to:

a. Development of screening or diagnostic tests (DHSC0014902);
b. Leucodepletion (NHBT0000721);
c. Filtration policy:
d. Quarantine of batches;
e. Donor selection and exclusion policies (NHBT0007193_001, NHBT0004640_001, NHBT0004598_002,NHBT0004389, SBTS0000293_007, and NHBT0011364);
f. Product recall (NHBT0004598_002);
g. Recombinant blood products; and
h. Importation of products from the USA or elsewhere (NHBT0000721).

403. These were not part of my remit, except for donor selection and exclusion policies. The section on donor selection and exclusion policies has been addressed in respect of the individuals who were deemed to be at risk through receipt of a blood component originating from a donor who later developed vCJD in response to earlier questions.

163. In providing this outline, please state:

a. When and by whom any proposals were made;
b. The factors considered when deciding whether to implement these proposals;
c. Decisions made on such proposals, including the date on which they were made or rejected; and
d. How any such measures were implemented in practice, including efforts made to monitor their effectiveness.

404. N/A

164. In addition to the above, please provide the following information:

a. Your opinion as to whether the risk of secondary transmission via blood and blood products was adequately mitigated in the UK in line with what was known about the potential risks of vCJD at that time.

405. In my view, the risk of secondary transmission of vCJD via blood transfusion was addressed in a very timely manner by the UKBSs and the NCJDRSU. NCJDRSU rapidly communicated the concerns about the newly recognised disease which became known as vCJD to the UKBSs. Despite the lack of any precedent, since sCJD had not been demonstrated to have any relationship to blood transfusion in studies carried out in the UK and elsewhere, and vCJD was a newly recognised disease, a joint meeting was rapidly organised in April 1996. The protocol

for the TMER study, the need for which was decided at the April 1996 meeting, was devised in a short time following that meeting, and was then subject to the necessary permissions, funding, and ethical approval.

406. The study commenced once all approvals had been received, without any delay. The study Principal Investigators and Research Managers from NCJDRSU and the UKBSs met regularly to review the accumulating results of the study, and once a possible link had been detected in December 2003, the appropriate bodies were alerted immediately, and further actions took place.

407. Until that link had been demonstrated, it was a matter of considering how to mitigate a potential risk, balanced against the possible disadvantages of mitigation. In parallel with commencing the TMER study, the UKBSs undertook within a very short time period, the planning necessary to introduce a major change in blood processing: the implementation of leucofiltration of blood components. Leucofiltration had not been demonstrated in practice or through appropriate trials to be effective in reducing the risk of vCJD transmission, but there was some suggestive scientific basis for it as a risk reduction measure.

408. The UKBSs also investigated a number of other risk reduction measures such as prion filters, collaboration with manufactures interested in developing blood screening tests for vCJD, and donor selection policies.

b. Your view as to whether any decisions or actions could and/or should have been made earlier and how this might have impacted the number of individuals considered to be at risk of developing vCJD.

409. In my view, the measures which are outlined in paragraph 164a, were taken in a timely manner and could not have been implemented earlier. The speed with which the introduction of leucofiltration was implemented,

together with the preceding planning required for such a major logistical change in blood centre practice, was in my view unprecedented. The UKBSs were very aware of the importance of the rapid introduction of the change, while not jeopardising the safety and security of the blood supply.

Impact

165. The Inquiry seeks to gain an understanding as to what impact a diagnosis of, or classification of, being at risk of developing vCJD has had on individuals and families. Please provide details of your knowledge relating to the impact of the various policies of notification since 1995, the information conveyed, the adequacy of such information, follow up or lack of. You may find JPAC0000029_108 of assistance.

410. The question directs me to JPAC0000029_108 but I do not find that this document is relevant to policies of notification.

411. As I was not involved in any of the patient notification (and de-notification) exercises from 2003 onwards, I do not have any detailed knowledge of the notification policies used, or of their impact. My only knowledge relates to the donor notification exercise which the Blood Services carried out in relation to a cohort of donors in 2005. This notification differed from the patient notification exercises carried out in respect of recipients who had received blood components and fractionated plasma products from donors who later developed vCJD. Firstly, it was carried out by the Blood Services who communicated directly with the blood donors, after a prior approach to the GP to ensure that contact was appropriate. Although the GP and the local Consultant in Communicable Disease Control were both informed in advance of the contact with the donor, they were not involved in the notification procedure. We sent them the extensive information which had been

prepared for the donors and provided there was no contra-indication we then wrote directly to the donor. We provided the important information in the letter to the donor, backed up with an extensive amount of written information prepared by the Public Health authorities, but targeted at donors. We invited the donor to telephone for a discussion, and many took up the opportunity. We provided a 24-hour help line, which was never used. Some donors were anxious, or upset, but for many the overwhelming emotion expressed was regret that they could no longer continue as blood donors. The one donor who I can remember as being seriously upset by the notification was an individual whose GP ignored our procedure and proceeded to contact his patient in advance of our communication being sent to the donor. Another was seriously distressed by the information, as predicted by her GP in a telephone call to us before the notification was sent, but who had a long and detailed discussion with a member of the Blood Service medical staff which went some way to addressing her concerns. The GP reported satisfaction with the action which had been taken.

412. The donor notification exercise was accompanied by a Press Release from the Department of Health, and arrangements were made for NHS Direct to be prepared to take calls from members of the public. This was little used, but the announcement produced a flurry of calls to the Blood Service from worried donors (who were not affected).

413. We asked all GPs to provide follow-up information after the notification, and compliance with our request was excellent. The majority of GPs had seen their patient since the notification and reported no serious adverse reactions.

414. I later received funding to carry out a donor satisfaction study, specifically examining the effect of notification of donors who had been confirmed positive for markers of blood-borne infection, and for the cohort of donors

notified of vCJD risk in 2005. I consulted an expert in behavioural psychology, with particular expertise in risk perception and communication, in setting up this study, which commenced in 2009. One of the issues of which we were very aware was the possibility of "re-traumatisation"; that is the reminder of painful events in the past serving to cause a recurrence of psychological harm. I recruited a Research Assistant to carry out the work and the section relating to donors with markers of blood-borne infection was completed and published (Ref 170) WITN3101010. The section relating to donors notified of vCJD risk was carried out, but the Research Assistant had to leave the study for personal reasons and the results were not analysed or published. Last year that work was resuscitated and a paper is being prepared for publication.

Counselling and Support

166. The Inquiry has heard evidence given by witnesses to the Inquiry of the psychological impact upon people who were treated with infected blood and blood products and subsequently informed of their 'at-risk' status to vCJD. A report written by the psychosocial expert group appointed by Sir Brian Langstaff in 2019 on behalf of the Infected Blood Inquiry noted that those individuals who acquired HIV and/or Hepatitis C through infected blood or blood products were further psychologically affected by the later knowledge that they might also have contracted vCJD. The Inquiry seeks to gain an understanding of what practical and emotional support was made available to those individuals who were later informed of the possibility of developing vCJD. Please provide the following information:

a. Any discussions, reports or recommendations you were aware of or participated in which discussed what support, counselling and after care was to be made available for those individuals who were notified

of their at risk status of developing vCJD. You may find NHBT0004374_002 assistance;

b. A summary of the steps taken by your organisation to offer psychological support or counselling programmes.

415. Although the UK BSs had begun to make plans for the notification process and the production of documents, guidelines etc (see NHBT0004374_002, for example), a decision was made that the process of notification of individuals who were considered to be at risk of vCJD through the receipt of blood components originating from blood donors who later developed vCJD would be managed outside the UKBSs by GPs and Public Health teams, and NHSBT was not involved in notification, or in subsequent support of these individuals. The notification (and de-notification) of individuals considered to be at risk of vCJD through receipt of fractionated plasma products was totally outside the UKBS remit. I understand that this was primarily managed through Haemophilia Centres.

Section 16: Your role as Lead Consultant in Transfusion Microbiology

167. Please describe the roles and responsibilities you had at the National Blood Authority ("NBA") during your period as Lead Consultant in Transfusion Microbiology.

416. In addition to my local roles and responsibilities at NLBTC (which by then was known as Colindale Blood Centre), my national role required me to have overall responsibility for clinical transfusion microbiology issues in all blood centres. The two main areas of responsibility were in the management of donors with confirmed positive test results for transfusion-transmissible infections, and in the investigation of reports of possible transfusion-transmitted infection. The clinical staff working in these areas were accountable to me for this work, and I ensured that all

clinical staff were working to national procedures.

417. I introduced national review meetings, to ensure that cases were discussed, so that all staff could learn from the experience of others. I had an overview and final sign-off of all investigations into possible transfusion-transmitted infection. In time, as colleagues retired, more of the work became concentrated within the clinical team based at Colindale. A third major strand of my national role was to ensure that the clinical Transfusion Microbiology team was represented in all relevant projects and new initiatives: some of these I undertook myself, and others I delegated to members of the team.

168. In March 2002 you wrote a policy document titled 'Investigation of Suspected Transfusion-Transmitted Infection' which set out how suspected cases of transfusion-transmitted infection should be investigated by blood centres.

a. Did this policy represent a significant change to prior investigation processes?

418. As is indicated in NHBT0062424, in September 1997 there was a review into the "Investigation of Suspected (non-bacterial) Transfusion Transmitted Infection" for the National Clinical Directors Group carried out by my colleagues in the London and South East Zone of the NBA. I believe that I initiated the review, involving my colleagues within the Zone who carried out this work. There were representatives from Brentwood and East Anglia Blood Centres, as well as from NLBTC (clinical and laboratory areas).

419. I believe that after the 1997 review we had agreed a Zonal procedure for such investigations and had operated that procedure for all cases following that date. When the Zonal structure was disbanded, there was a

need to agree, and then adopt, a national procedure. Given geographical jealousies, I was reluctant to impose a procedure originating in London and the South East, and asked colleagues from other centres to assist in the 2001 review, in the hope that we would agree a best practice document.

420. The colleagues who took part in the 2001 review included two Consultant Virologists from the Public Health Laboratory Service, who had been advising on, or managing, investigations in Oxford and Birmingham, and NHSBT colleagues from Leeds and Newcastle Blood Centres. The final document, as published in 2002, was a consensus, but basically represented the procedure which had been operating in London and South East Zone up to then. An important part of the agreed procedure was that I, as Lead Consultant, had overall responsibility for all investigations, and that all cases were logged on a national database held at Colindale, so that there was a true national overview of all cases.

b. Do you remember these investigations yielding any meaningful results and, if so, what were they? You may find NHBT0062424 of assistance.

421. The results of the investigations into reports of possible transfusion-transmitted infections were (and are) published in the annual SHOT reports. The investigations generally yielded meaningful results. The SHOT reports categorise the results of the investigation into 4 categories. In most cases it was possible to conclude that the infection had definitely not been transmitted by transfusion, and in a few cases there was confirmation that the infection was definitely transmitted by transfusion. In a few cases, transfusion-transmission was deemed possible, but not proven, or probable, but not proven. Over the years, the number of cases falling into the "possible" has reduced, as the quality of investigation and laboratory techniques available have improved. A summary of these investigations can be viewed in the latest SHOT

report:
https://www.shotuk.org/shot-reports/report-summary-and-supplement-2020/2020-annual-shot-report-individual-chapters/

169. In December 2002, you raised concerns about pre-donation screening. You stated that HIV donation testing was detecting more positive donations after changes had been made to the donor selection procedures, in particular that the lifestyle questions were no longer read out to the donor.

a. As far as you can recall, why was the decision made to stop reading out questions to donors about their lifestyles?

422. I do not recall why the lifestyle questions were no longer read out to donors.

b. What do you remember about your concerns and do you feel they were effectively addressed? You may find NHBT0011328_017 of assistance.

423. In the exchange of correspondence illustrated by NHBT0011328_017, I was concerned to learn further details of the donors who had been confirmed HIV positive at the Sheffield Blood Centre, as it appeared that we had seen an increase in the admittedly small number of positive donors usually seen. Part of our practice was to review in detail the risk behaviour which was identified in the post-test discussion interview, and this was normally done at our regular national review meetings, but in this case, I was anxious to learn of the details in advance of the next meeting. As pointed out in the first e-mail, it was perfectly possible that the small increase was a coincidence, and not related to the change in procedure with respect to reading out the lifestyle questions. Indeed, the response I received from Dr Hewson confirmed this, and illustrated the problems in firstly encouraging those who were at risk to recognise their risk, and exclude themselves from donation, and secondly in the difficulty for staff

trying to carry out individual assessments of HIV risk when details of a potential donor were discussed with them.

424. I do not believe there was subsequently any convincing evidence that the change in procedure had led to an increase in the number of HIV positive individuals donating blood.

170. You provided an expert report in September 2005, in which you stated 'even with the introduction of screening for detection of HCV antibodies, there would be a small risk of hepatitis C transmission by blood transfusion.'

a. Do you think anything further could have been done to reduce the risk?

You may find NHBT0030497_012 of assistance.

425. As is made clear in the document NHBT0030497_012, despite the introduction of screening for detection of HCV antibodies, there remained a risk of HCV transmission by blood transfusion through "window period" cases, since HCV antibody will not be detected in the very early stage of infection. The window period can be reduced by the use of NAT screening. As is stated in the document, such testing was introduced first by European plasma fractionaters, and then "by 2003 .... had been implemented in the majority of first world countries, and such testing is mandatory in those countries".

Section 17: Other matters

171. During Parliamentary questions on 10th December 1985, Mr Hayhoe stated that 'supplies of whole blood are not imported since the United Kingdom is self-sufficient in its needs for blood for

transfusions; it is only certain blood products which are imported' (HSOC0018830). To your knowledge, was the UK self-sufficient in its need for whole blood for transfusions?

426. To my knowledge, the UK was self-sufficient in its need for whole blood for transfusions, and in all blood components. It was not self-sufficient in fractionated plasma products.

172. During your tenure at NLBTC, were you aware of patients being given blood transfusions with red blood cells imported from the USA? If so, was there any concern about its use at the time?

427. I can categorically state that there was no facility for red blood cells to be imported from the USA for use on patients in the UK, other than in the very rare situation of a patient who had such an unusual blood group or combination of red cell antibodies that compatible blood could only be provided from the International Frozen Blood Bank, which might have involved red blood cells from the USA. I am not personally aware of any such case.

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

428. My publication list is attached WITN3101020.

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

429. I have tried in this statement to give as much assistance as possible to the Inquiry, and like many of my former colleagues I regret the fact that the Inquiry's task has been made much more difficult by the long

passage of time since many of the events it is examining. I have already expressed my sorrow that so many have been infected, and affected, by treatment that was given many years ago in the belief that this would help save and improve lives. I am happy to give any further assistance the Inquiry might require.

Statement of Truth

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

Signed _____

Dated _____

Table of exhibits:

Date	Notes/ Description	Exhibit number
07/06/1972	Minute of Regional Transfusion Director's meeting, 142nd meeting, 7 June 1972 at Department of Health and Social Security	NHBT0016123
12/03/1994	The British Medical Journal Article, 12th March 1994 Follow up of blood donors positive for antibodies to Hepatitis C virus by Kate E Ryan, Sheila MacLennan, J A Barbara, Patricia E Hewitt.	NHBT0002874_009
04/10/1995	Memo from Dr. P. Hewitt, National Blood Service, to Dr. S. Knowles	NHBT0096432_002

1999	99. Regan F., Hewitt P.E. Vincent B., Nolan A. (1999) Do patients know they have been transfused? (Letter) Vox Sanguinis 76: 248-249.	WITN3101017
13/01/1995	Letter from Dr. P E Hewitt to Dr. Angela Robinson re HCV Look Back - Draft 13/01/1995	NHBT0002755
15/09/2015	Reynolds CA., Brailsford SR., Hewitt PE. (2015) Notifying blood donors of infection: results of a donor satisfaction survey. Transfus Med. Dec 28. doi: 10.1111/tme.12268. [Epub ahead of print]	WITN3101010
10/12/1993	Minutes of NBA Executive, 3rd meeting, 10/12/1993 at unknown location, re: contracts for the purchase of blood packs and potentially contaminated plasma pools.	NHBT 0016378_002
29/06/2004	Minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation 33rd meeting, 29 June 2004	DHSC0038559_048
20/01/2005	Meeting of the MSBT Minutes	SBTS0000530
01/01/1991	Leaflet on Blood Safety, Background information for transfusion service staff, by Dr. Peter Flanagan, November 1995	JPAC0000001_014
29/08/1989	Minutes of National Directorate of the NBTS National Management Committee meeting, 29 August 1989	NHBT0000188_033
13/05/1993	Paper titled " Investigation of Possible Transmission of HIV by Blood Transfusion" by Dr Patricia Hewitt	DHSC0006351_032
15/05/1989	Internal Departmental Memorandum of the National Blood Transfusion Service (NBTS) from Mr Howell to Mrs Poole et al. regarding Re-introduction of the 'J' donor system	NHBT0005388
01/01/1977	Vox Sanguinis, “A Comparison of Different Methods of Screening Blood Donations for HBsAg”, by J. A. J. Barbara	NHBT0000030_002

01/10/1986	"Alanine amino-transferase (ALT) and hepatitis B-core (Anti-HBc) screening of blood donations" by H. H. Gunson	SBTS0001120
16/01/1985	Letter to Dr McClelland from Dr Hewitt re: AIDs questionnaire	PRSE0003435
09/03/1985	Journal from Marcela Contreras, Patricia Hewitt, John Barbara, and Peter Mochnaty, 'Blood donors at high risk of transmitting the acquired immune deficiency syndrome' (1985)	NHBT0000030_013
29/09/1989	Memo from Dr. Hewitt to all MOs Consultants for action at Static Clinics, re: Blood Donors and HIV Risk	NHBT0047637
14/02/1985	Letter from Dr. P. Hewitt to all M.O.S., re: aids leaflets	NHBT0019439
Unknown	Note of meeting with Dr Patricia Hewitt of North London Blood Transfusion Centre	NHBT0019621
03/07/1985	Comments on the draft flow-chart for the handling of anti-HTLV-111 positive results	NHBT0053236
04/07/1985	Minutes of the Eastern Division Consultants in the Blood Transfusion Service Meeting held on 4 July 1985 at Tooting Centre	NHBT0089119_029
08/06/1990	Report, "Initiation and Working of a Report of Hepatitis/Jaundice After Transfusion", North London Blood Transfusion Centre Standard Procedures	NHBT0005376_002
01/09/2010	Penrose Preliminary Report	PRSE0007003
05/05/1999	UKBTS/NIBSC Standing Advisory Committee on SACTTI meeting minutes held on 5 May 1999	NHBT0017405_001
2013	162. Hewitt Patricia E., Davison Katy, Howell David R., and Taylor Graham P. (2013) Human T-lymphotropic virus lookback in NHS Blood and Transplant (England) reveals the efficacy of leukoreduction. Transfusion 53: 2168 – 2175	WITN3101012

1997	81. Chiodini P.L., Hartley S., Hewitt P.E., Barbara J.A.J., Lalloo K., Bligh J., Voller A. (1997) Evaluation of a malarial antibody ELISA and its value in reducing potential wastage of red cell transfusions from blood donors exposed to malaria, with a note on a case of transfusion-transmitted malaria. Vox Sanguinis, 73, 143-148.	WITN3101013
2005	123. Kitchen A., Mijovic A., Hewitt P. (2005) Transfusion-transmitted malaria: current donor selection guidelines are not sufficient. Vox Sang 88, 200-201. 124. Kitchen AD., Barbara JAJ., Hewitt PE. (2005) Documented cases of post-transfusion malaria occurring in England: a review in relation to current and proposed donor-selection guidelines. Vox Sang 89, 77-80.	WITN3101014
2014	168. Hewitt PE., Ijaz S., Brailsford SR., Brett R., Dicks S., Haywood B., Kennedy ITR., Kitchen A., Patel P., Poh J., Russell K., Tettmar KI., Tossell J. Ushiro-Lumb I., and Tedder RS (2014) Hepatitis E virus in blood components: a prevalence and transmission study in southeast England. Lancet 384;(9956), 1766–1773	WITN3101015
2012	156. Kitchen A.D., Hewitt P.E. and Chiodini E.L.(2012) The early implementation of Trypanosoma cruzi antibody screening of donors and donations within England: preempting a problem. Transfusion. 52(9):1931-1939, September 2012.	WITN3101016
23/01/1992	Preliminary Discussion Paper for ACTTD: Two topics related to transfusion safety by Dr Marcela Contreras and Dr John Barbara	NHBT0000044_095
13/01/1995	Letter from Dr. P E Hewitt to Dr. Angela Robinson re HCV Look Back	NHBT0002755

29/03/1995	Letter from Patricia Hewitt to Dr Angela Robinson, re: HCV Look-back	NHBT0096456
1999	Regan FAM, Hewitt PE, Barbara JAJ and Contreras M (1999) Prospective investigation of transfusion transmitted infection in the recipients of over 20,000 units of blood. British Medical Journal 320: 403-406.	WITN3101011
22/04/1996	Letter from Dr. E. Angela E. Robinson, National Blood Authority (NBA) to Dr. P. Hewitt, National Blood Service (NBS)	NHBT0008485
Unknown	Detailed Report on "A retrospective study to examine a possible link between Creutzfeldt Jakob Disease and Blood Transfusion" by R. G. Will; J. Gillon	DHSC0042301_153
01/06/1996	Creutzfeldt Jakob Disease and Blood Transfusion: proposal for extension of the limited look-back study (Transfusion Medicine Epidemiology Review), original proposal by Jack Gillon, Patricia Hewitt, and Bob Will	NHBT0016056_002
January 2000	Letter from the Chair of the Lothian LERC withdrawing approval for the study	NHBT0004634_004
January 2000	Professor Will's letter to Dr Ailsa Wight at the Department of Health	NHBT0004634_003
20/12/1999	Letter from Len Doyal, Professor of Medical Ethics, Queen Mary and Westfield College University of London, to Dr P E Hewitt, National Blood Service, re: 'the debate about notifying both recipients of the blood of nvCJD patients.'	NHBT0004392_002

15/04/1999	Letter from Dr. Patricia E. Hewitt, National Blood Service, to Prof. Ian Kennedy, University College London	NHBT0017407
25/01/2000	Letter from Richard Knight, Consultant Neurologist of the National Creutzfeldt-Jakob disease Surveillance Unit, to Patricia E Hewit	NHBT0004320
30/01/2000	Letter from Dr Ian Starkey to Bob regarding the Lookback study in Creutzfeldt-Jakob disease	NHBT0004364_004
25/02/1999	Letter from Stephen Janisch, Le Brasseur J Tickle Solicitors and Privy Council Agents	NHBT0004389
20/12/1999	Letter from Len Doyal, Professor of Medical Ethics, Queen Mary and Westfield College University of London	NHBT0004392_002
03/11/2000	Email from Clive Dash, LBJT to Erine Gascoigne, Abigail Boxshall, Stephen Jenkings and David Wesley, BPL, re: PEH/S	BPLL0016089_005
05/02/1999	Email from Dr Snape to P. Hewitt requesting that BPL be provided the history of donations when a donor is diagnosed as a vCJD patient	NHBT0008722
2004	120. Llewelyn CA, Hewitt PE, Knight RSE, Amar K, Cousins S, Mackenzie J, Will RG (2004) Possible transmission of variant Creutzfeld-Jakob disease by blood transfusion. Lancet 363, 417 421.	WITN3101018
N/A	The National CJD Research & Surveillance Unit (NCJDRSU) University of Edinburgh, webpage	RLIT0000777
12/01/2000	Letter from Dr Mike McGovern to Dr E Robinson regarding the management of potential donors known to have received blood from people who have subsequently developed CJD	NHBT0015384
	Meeting Note from Meeting at Department of Health on 6 October 1999	NHBT0004382_001

	Letter from Patricia E Hewitt, National Blood Service, to Dr Gail Williams	NHBT0004374_002
	Report entitled "The investigation of suspected (non-bacterial) transfusion transmitted infection"	NHBT0062424
	Chain of emails between Patricia Hewitt, Nicola Hewson and Christine Moore	NHBT0011328_017
	CV	WITN3101007
	Updated publication list for this statement	WITN3101007

such case.

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

428.My publication list is attached WITN3101020.

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

429. I have tried in this statement to give as much assistance as possible to the Inquiry, and like many of my former colleagues I regret the fact that the Inquiry's task has been made much more difficult by the long passage of time since many of the events it is examining. I have already expressed my sorrow that so many have been infected, and affected, by treatment that was given many years ago in the belief that this would help save and improve lives. I am happy to give any further assistance the Inquiry might require.

Statement of Truth

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

Signed GRO-C

Dated 24th November 2021

Table of exhibits: