Witness Name: Dr Bernard McVerry
Statement No.: WITN3502007
Exhibits: N/A
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INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR BERNARD MCVERRY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 20 November 2020

I, Dr Bernard McVerry, will say as follows: -

I have made a previous general statement to this Inquiry under Rule 9. At that time, I was supplied with 8 documents. I have now been supplied with 57. My recollections of the matters which may or may not have occurred up to 45 years ago are now non-existent, poor or at best selective. I am sorry that in relation to a number of answers I cannot be more helpful. The additional documents and more detailed questions have enabled me to provide some further information to the Inquiry in this statement. It is against this background that I provide this statement.

Training and Experience

1. Please set out where and when you received your medical training, and in particular:

(a) What specialist haematology training you had?

(b) Whether you spent any time during your training or at all, in the blood services, and if so, how long, where, and what you did.

1.1 I qualified at University College Dublin in 1969. I then had a one year internship in Dublin. As far as I can recall I had no specialist haematology training in Dublin.

I then moved to the US for six years. I spent two years training/specialising in haematology in Boston. I undertook a research post in coagulation. I had no involvement in the area of Haemophilia either before or whilst in the US. I came to London in 1975 to undertake a temporary post at the Royal Free Hospital in Dr Dormandy's Haemophilia unit. This was largely an outpatient service providing patients with cryoprecipitate. I was there for two to three months. There was no Haematology training here.

1.2 I then undertook a position as a Senior Registrar at University College Hospital and was there for approximately five years. This post was in general haematology. I was not involved with haemophiliacs. As part of this position within the registrar training schedule I spent three months in the blood transfusion unit. I also now recollect that whilst at UCH I spent one year working in Professor Huehns laboratory (I think 1979-1980). This was undertaking full-time research regarding diabetes with no clinical involvement.

1.3 In 1980, a senior lectureship became available at the Royal Liverpool Hospital ("RLH"), which I accepted. I was acting head of department of hematology for the final six months of my term.

1.4 In 1985 I moved to St James's Hospital which is part the combined Leeds Teaching Hospitals ("Leeds") as Consultant Haematologist and worked until 68 years of age.

1.5 I retired almost ten years ago. The only experience I had of treating haemophiliacs prior to starting at the RLH was the few months that I spent at the Royal Free in Dr Dormandy's Haemophilia Unit in 1975.

2. Please provide a copy of the latest version of your CV.

2.1 Please see response to question 1, which I hope provides the detail required. As I am now 77 and have been retired for 10 years I do not have a CV.

3. In section 1 of your written statement dated 19 November 2020 you set out the history of your experience treating people with haemophilia. In that you state that

prior to 1980, your only experience of this was in the 2/3 months you spent at the Royal Free Hospital under Katherine Dormandy in 1975. Can you please explain how therefore you came to publish so widely on the treatment of patients with haemophilia prior to 1980? See for example:

(a) The paper published in The Journal of the American Society of Haematology (Blood, Vol. 50, Issue 1, pp. 1-9) in July 1977 (submitted on August 9th 1976) entitled 'Health of the Intensively Treated Haemophiliac with Special Reference to Abnormal Liver Chemistries and Splenomegaly', [RLIT0001221].

3.1 This paper was written whilst I was working in Boston

(b) 'Viral exposure and abnormal liver function in haemophilia' J Clin Pathol 32:3777-381, 1979 McVerry, Ross, Knowles, Voke [RLIT0000280].

3.2 I was not managing haemophilia patients at this time. I wanted to be in a teaching hospital and as I went through training, opportunities to be involved in research papers arose. However, being named on the paper does not mean that I was a treating member of the team.

(c) Levine PH, McVerry BA, Segelman AE, et al: Comprehensive health care clinic for hemophiliacs. Arch Intem Med 1976; 136:792-794 [RLIT0000283].

3.3 This paper was written whilst I was working in Boston.

(d) 'Incidence of allo-immunization and allergic reactions to cryoprecipitate in hemophilia.' McVerry BA and Machin SJ. Vox Sang. 36, 77-80 (1979) [RLIT0000285].

(e) McVerry, B.A, Voke, J., Mohammed, I., Dormandy, K.M and Holborow, E. J, 'Immune complexes and abnormal liver function in Haemophilia' J Clin Path 1977 30: 1142-1146 [RLIT0000281].

(f) The Lancet 23 April 1977 "Ultrasonography in the Management of Haemophilia" by Dr McVerry [RLIT0000284].

3.4 The papers that I published with colleagues, as a junior doctor, relate to an interest in this disease (haemophilia) but does not show any direct clinical

involvement. I was a junior doctor with no consultant or administrative responsibilities. I was not responsible for any treatment decisions before 1980. (Before 1980, the only experience I had of treating haemophiliacs prior to starting at the RLH was the few months that I spent at the Royal Free in Dr Dormandy's Haemophilia Unit 1975.) It is likely that the Factor usage data reflects visitors coming to London requiring temporary therapy. This would not be surprising as I do not think that home therapy was not fully established at that time.

4. Can you also explain:

(a) Why it was that you attended the second meeting of Directors of Haemophilia and Blood Transfusion Centres dated 23 September 1977. You will note from the minutes of that meeting that you requested more NHS factor 8 for your patients, due to having three more patients on home treatment [CBLA0000657].

4.1 Before 1980, the only experience I had of treating haemophiliacs prior to starting at the RLH was the few months that I spent at the Royal Free in Dr Dormandy's Haemophilia Unit 1975. I might have been asked to attend some meetings as I had an interest in the field of coagulations, but at each meeting senior UCH Haematology consultants would have been present.

(b) Why it was that you attended the UKHCDO annual meeting on 13 November 1978 [HSOC0010549] representing University College Hospital (UCH)?

4,2 Please see my answer to a) above I do not know, I was not involved with haemophilia patients at this time.

Time at UCLH between 1975 - 1980

5. Having had your attention drawn to the above documents, were you involved in the care and treatment of patients with haemophilia while a senior Registrar at UCH between 1975 and 1980?

5.1 No.

6. The Inquiry understands that the Haemophilia Centre Director during this period was Dr, then, Professor Prankard, Is that correct? Other than yourself, how many other staff were involved with the care and treatment of patients with haemophilia? It may assist you to know that the UKHCDO annual meeting minutes for 13 January 1977 [PRSE0002268] state that a Dr A Goldstone attended for UCH, and for 13 November 1978 record th at Dr J Richards attended along with you [HSOC0010549]. Does that accord with your recollection?

6.1 Dr/Professor Prankard was the head of department but as far as I can recall this was not a Haemophilia Centre it was more of a drop-in in the sense that patients came in if they needed treatment. I had no haemophilia patients at this time. I do not now recall why I would have attended the UKHCDO meeting referred to.

7. Please consider the Centre return from 1976 [HCDO0000048_002] and minute of the second meeting of Directors of Haemophilia and Blood Transfusion Centres dated 23 September 1977 [CBLA0000657].

(a) The 1976 returns show that 12 patients with Haemophilia A were treated. Was this number typical for the period you were at UCLH?

7.1 I have no recollection of haemophiliac patients being treated by me. It may be that these people were visitors to the city rather than regular/follow up patients.

(b) These documents suggest that there was a home treatment programme in place. Is that correct?

7.2 I do not think that this was the case.

(c) What products were given to patients on home treatment? Was it cryoprecipitate or factor concentrates, or a mixture of both?

7.3 I was not involved in home treatment before I went to Liverpool and so I cannot recall home treatment at this time.

(d) Why were commercial concentrates used during 1976? When were they first introduced?

7.4 I cannot recall now recall and the decision to use concentrates would not have been mine.

Time at the Royal Liverpool Hospital between 1980 – 1985

8. Who was the Centre Director when you arrived? Was it Professor Bellingham? If so, when did he retire (the last UKHCDO meeting he attended was October 1983 if that assists)?

8.1 When I arrived at Liverpool it would have been Professor Bellingham. I do not know when he retired. My recollection is that he left Liverpool shortly before I left, may be six months before I did, which would have been at the end on 1984/beginning of 1985. I was then the acting head of the department for about 6 months.

9. When did you become a Consultant Haematologist? The letter sent to Oxford dated 6 June 1984 [HCDO0000145_003] identifies you as the Centre Director. When were you appointed the Liverpool Centre Director?

9.1 I was appointed senior lecturer in Haematology with an honorary NHS appointment in 1980 (RLH) and this remained the case until I left in 1985. When I arrived I was appointed as centre director replacing Dr F E Bolton. I left the university (RLH) in 1985 to take up a full time NHS consultant post in Leeds.

10. What were the arrangements and what was the relationship, if any, between the Royal Liverpool Hospital, the Liverpool Royal Infirmary and Liverpool Alder Hey in terms of the care and treatment of people with haemophilia? The Inquiry understands that children were treated at Alder Hey, with the centre director there being Dr J Martin who was a Consultant Paediatrician, and adults at the Royal Infirmary.

10.1 I do not remember a Liverpool Royal Infirmary. I did not provide treatment or care for patients at Alder Hay only at RLH, and during my career I have never treated children.

(a) Is that correct, or did the haematologists at the Royal Liverpool such as yourself and Professor Bellingham have some input into the treatment decisions at Alder Hey?

10.2 I cannot speak for Professor Bellingham but I only treated patients at RLH as stated above.

(b) The Inquiry has also seen reference to there being a Haemophilia Centre at the Walton Hospital under the Directorship of Dr Stevenson [CBLA0001464]. How did this centre fit in?

10.3 I had no involvement with any centre at the Walton Hospital and am not aware that there was such a centre at Walton Hospital.

11. Were there any regional meetings between the Centre Directors/doctors and/or the Regional Blood Transfusion Centre Directors and/or representatives of the Regional Health Authority during your time in Liverpool? If so, how frequently did any such group meet, who attended the meetings, and what was discussed?

11.1 We were involved in training for the Regional Blood Transfusion Service and the Regional Health Authority, but I do not recall any meetings. I do not recall any formal collaboration between these organisations.

12. Please describe the treatment facilities available at the Liverpool Centre when you arrived, both in terms of physical space, staff (including nursing staff) and whether there were any joint clinics with other disciplines at the time (such as dentists/orthopaedics etc). It may assist your recollection to know that Professor Hay told the Inquiry in oral evidence on 4 November 2020 that when he arrived at the Liverpool Centre to take up his post as Director, he stated as follows:

(a) Patients were treated in a treatment room in the laboratory.

(b) There was at that time secretarial support and a junior member of staff to assist as part of the hospital rotation.

(c) However, there was no nurse in post, no counsellor, no physiotherapist and no joint clinics.

I have also provided you a copy of Dr Hay's article for the Bulletin on the Centre from 1990 as this may assist your recollection [HCDO0000276_001].

12.1 I think that this article more or less summarises the situation. I did not have a nurse or a dedicated junior member of staff. If a patient came in sick, they would be admitted to the general haematology ward. I could be called in on call if needed. If a patient had come in for Factor 8, a member of the haematology staff would give them Factor 8 which was kept in a fridge. These members of staff would be experienced technicians.

12.2 For a period of time Multi Disciplinary Clinics ("MDC"s) were held for example with the heamatologists, myself, an orthopaedic surgeon (as joint problems for these patients were quite prevalent). I think that the MDC was held once every couple of months. However, patients did not turn up for these clinics so they only ran for a limited time. During my stay I continued otherwise with the status quo (as per Doctor Bolton) offering an informal service directed from the Haematology Lab. The only staff I had was the on-call Haematology registrar who assisted when necessary. Patients would be reviewed by a registrar or myself. Factor 8 was available from the Haematology laboratory.

12.3 From the Article in the Bulletin in I vaguely recall someone called Dr Archer, but I cannot recall if he was from Liverpool or Leeds I also recall Alan Smith MLSO (technician).

13. Did the Liverpool Centre offer a 24-hour service to its patients, or were patients treated out of office hours at A&E? If the former, please give details of how such a service operated.

13.1 As these patients benefited from seeing practitioner who was experienced in dealing with the kind of care that they required we discouraged patients from attending at AE for a bleeding disorder. Instead we encouraged the patients to call us and we could then attend to the patient. However, if they did not or it was out of hours they would be seen in the general haematology department. If the patient had had a bleed they would be sent to the ward and be seen and treated by a doctor on the ward. I could also have been contacted by the hospital out of hours if needed.

14. The Inquiry understands that Professor Hay took over from you as Director of the Liverpool Centre in 1987. Was there a gap between you leaving and Professor Hay taking up his post? If so, how long was this? What arrangements were made for the care and treatment of patients at the Liverpool Centre in the intervening period?

14.1 I left in the middle of 1985 so there may have been a gap. Three to four years into my time at Liverpool Dr Mike Mackie was appointed as honorary consultant and so he would have taken over as Centre Director when I left, with Professor Hay arriving thereafter in 1987.

15. Why did you leave the Liverpool Centre to take up a co-directorship at the Leeds Centre?

15.1 I wanted a substantive NHS consultant post as there was more security in such a post and universities were having a hard time during this period. Most senior lecturers therefore move on to established NHS posts.

16. What was the system for recording the products received and batches used for individual patients while at the Liverpool Centre?

16.1 I would make a note of how much Factor was used.

(a) Where were the records kept?

16.2 These records would have been kept in my office. The data of how much factor was being used would have been sent to Rosemary Spooner in Oxford.

(b) Did they form part of the patient's medical records, or were they kept separately?

16.3 This data was kept separately in my room.

(c) Did for example the A&E or other hospital services have access to those records?

16.4 No but this information would have been available if required (how much factor 8 had been used by a particular patient).

(d) What was the expectation in terms of patients filling out and providing the Centre with home treatment records?

16.5 There was an expectation that patients would complete home treatment records but compliance was hit and miss. We would see these patients at regular clinics but I cannot now recall how the home treatment data was collected.

17. The 1983 returns suggest the Centre treated 48 patients with haemophilia A that year, and one with Von Willebrands Disease, 3 patients with haemophilia A and antibodies and 3 with haemophilia B [HCDO0000145_003]. Approximately how many patients were registered with the Centre at this time? If it assists, Professor Hay in his oral evidence to the Inquiry on 4 November 2020 said that by the time he arrived there were 162 patients registered with the Centre.

17.1 I cannot recall how many patients were registered in 1983, I would have to rely on the 1983 return. If Professor Hay arrived in 1987 this would have been 4 years after the 1983 figures and at least 18 months after I left Liverpool. I do not know how Professor Hay calculated his number of patients.

Treatment Policies at the Liverpool Centre

18. Did you have written treatment policies for patients with Haemophilia and Von Willebrands? If so, where were they kept? If not, why not?

18.1 There were written policies kept in my room and on the ward.

19. In your 17 October 2020 statement you refer to a conversation you had with Dr Peter Jones which influenced your treatment policy decisions. Please state when (roughly) this took place, and describe the content of that discussion in as much detail as you can.

19.1 We had occasional joint meetings. The problem was that there was not enough NHS Factor 8 available. In these circumstances he thought that commercial Factor 8 should be used. I think that this may have been 1982.

20. The Stock Record Cards (an example of which is at [LUHT0000011]) and the annual report of factor VIII used in 1980 [LUHT0000002] seems to suggest that during 1980 there were a number of patients on home treatment. The 1983 returns show an established home treatment programme:

(a) How were patients chosen for the home treatment programme?

20.1 I believe that home treatment may have started late 70s. As a category of patients severe or moderate severe haemophilia patients would be encouraged to do this. The severity is based on their base-line Factor 8 level or the number of bleeding episodes (even if their Factor 8 levels were quite good).

(b) How were patients trained up and by whom, to undertake home therapy?

20.2 The patients would come in for a training session with nurse over 3 day period.

(c) How was the decision made as to which product to put patients on for home therapy? There appears from [LUHT0000038] to have been a policy to only provide commercial products for home treatment. Was that a policy that continued during your time at the Liverpool Centre? If so please give the reasons for this.

20.3 Before my informal discussions with Peter Jones, I was issuing as much NHS Factor 8 as I had been supplied with and then I would have to use the commercial F8. Based on Dr Jones's experience I was encouraged to switch to commercial F8 for two reasons, the first related availability and reliability of supply, and second there was a mood at that time to continue using a particular product in an individual patient as this may reduce the prevalence of factor antibodies arising (although this later proved not to be the case). If it was a new patient diagnosis the patient would be a mild suffer and so would not need much Factor 8 and so DDAVP would be prescribed unless this proved unsuitable.

21. Was there a prophylaxis treatment programme during your time at the Liverpool Centre? If so, when did this start? Please give details.

21.1 One may have come in towards the end of my time at Liverpool, but I cannot recall nor when this would have started.

22. The 1980 monthly return for April [LUHT0000038] seems to suggest that in 1980 the policy was to provide the NHS factor product to the Alder Hey Hospital. Is this a policy that continued while you were at the Liverpool Centre? Please give details and explain the reason(s) for this policy and for its continuation.

22.1 I do not know anything about Alder Hey, I had nothing to do with Alder Hay, I think that this would have been John Martin's decision.

23. How were patients with mild haemophilia A, mild haemophilia B, Von Willebrands and inhibitors treated during your tenure at the Liverpool Centre?

23.1 The general approach for such patients would be that in the absence of acute severe bleeds DDVAP would be used. However, not all such patients responded adequately to this and tachyphylaxisis would occur with repeated doses so patients affected by this could not continue to take DDAVP and so would need a Factor 8 product, preferably NHS Factor 8. With inhibitors I would have tried using products such as Feiba or Autoplex.

24. The 1983 return shows the Liverpool Centre using cryoprecipitate as a treatment in hospital for patients with haemophilia A:

(a) Which cohort(s) of patients received cryoprecipitate at the Liverpool Centre during 1983 (and at any other time during your tenure there)?

24.1 I do not recall giving cryoprecipitate to a patient in Liverpool.

(b) Why were they treated with cryoprecipitate rather than with factor products?

24.2 Please see my answer to 24(a).

25. The 1983 returns show that the Centre was using NHS F8 and two commercial factor products. How did you choose which patient received which product?

25.1 My general recollection is that there was a move to keep patients on the same product that they had been using as there was a thought that a patient could develop inhibitors if the product was changed (which was later established to be ill founded).

25.2 A newly diagnosed adult patient would be a mild suffer and so would not need much treatment and so the general approach would be to try DDAVP. If the DDAVP was not appropriate then the patient would be started on Factor 8 and ideally NHS.

26. The 1983 returns do not show the Liverpool Centre using any DDAVP. Did you ever use DDAVP for patient with mild and/or moderate haemophilia while at Liverpool? If not, why not?

26.1 I have no patient specific recollection but would be surprised if DDAVP was not used in appropriate patients. As DDAVP was not a blood product this could explain why at this time the use of DDAVP was not included in the returns. However, Rosemary Spooner encouraged the reporting of the use of DDAVP and therefore at some point the use of DDAVP would have been entered on the returns.

Supply of FVIII while at the Liverpool Centre

27. Where did the Liverpool Centre get its cryoprecipitate from? Was it from the Mersey and South Wales Regional Transfusion Centre?

27.1 As I have said previously, I do not recall using cryoprecipitate in Liverpool so I do not know the source of Cryoprecipitate for Liverpool.

28. Were there any problems with the supply of cryoprecipitate? Was there always sufficient cryoprecipitate to meet the needs of your patients?

28.1 Please see my answer to question 27.

29. How did the NHS factor VIII and IX come to the Liverpool Centre? Was it directly from BPL or via the Regional Blood Transfusion Centre?

29.1 Although I cannot be certain I think that this would have come from BPL.

30. It appears from the letter written by Dr Martin to BPL dated 21 February 1985 [BPLL0010612] that the Children's Centre obtained their supply of BPL (and possibly also commercial factor concentrate) from the Royal Liverpool Hospital. Does that accord with your recollection? Can you recall the reasons for this?

30.1 Although I cannot recall now I think it highly unlikely that we would have supplied either cryoprecipitate or Factor 8 to Alder Hay, it would have had its own arrangements for supply.

31. Do you know how NHS Factor VIII and IX was allocated to the Liverpool Centre by BPL and/or the Regional Transfusion Centre? Were you involved in any meetings/forums in which this was discussed, for example with Dr F Roberts, the Director of the Regional Blood Transfusion Centre in Liverpool? Please give details?

31.1 I do not know how Factor 8 and 9 was allocated but suspect it was based on the previous year's return.

32. How did the Liverpool Centre determine how the NHS Factor VIII and IX should be divided between the Royal Liverpool Hospital, Alder Hay and any other hospital receiving its supply from the Liverpool Centre?

32.1 Please see my previous answers. I do not think that we received supplies for any other centre.

33. Were there any problems with the supply of NHS Factor and if so what were they? Did the Liverpool Centre have sufficient NHS Factor, or would more have been welcome? If so, why? What if any efforts were made to obtain more NHS Factor?

33.1 I do not have specific recollections now. However, in circumstances where there was an insufficient supply of NHS Factor, there would be a switch to

commercial Factor. I cannot recall what was done to try and secure further NHS Factor, but I anticipate that I would have telephoned the service.

34. Did the Liverpool Centre directly contract with pharmaceutical companies for the supply of factor VIII product? It may assist your recollection to consider the letter at [IPSN0000337_008]. It may also assist your recollection to know that Professor Hay in his oral evidence to the Inquiry on 4 November 2020 said that when he arrived at the Liverpool Centre he understood that during your tenure, you made the decisions as to which companies to contract with.

34.1 I personally did not contract for F8 supplies. It is likely that the companies would have supplied us for some time and had offered a good service and reliability of supply was important. If there had been any problems with supply I would have thought that this would have been dealt with the hospital purchasing manager. I did not deal directly with such matters.

35. If this is correct, what was the process by which contracts were made with pharmaceutical companies? It may assist your recollection to know that Professor Hay in his oral evidence to the Inquiry on 4 November 2020 said that the contracts had been made via the hospital purchasing manager.

35.1 Please see my response to question 34.

36. What criteria were applied by you for the selection of the product(s) to be used?

36.1 Generally, we sought to continue the patient's existing treatment for the reasons that I have previously referred to.

37. If you were not responsible for deciding which commercial products to buy for the hospital, what arrangements were in place?

37.1 I think that I would alert the purchasing manager what products the patients were on and say this this is what we needed for the following year. This was on the basis of continuity of care. When I needed Factor 8 it was supplied. I do not know who paid for it. I would not make contact with the supplier.

Knowledge of risk of NANB

38. What were you taught during your medical training about the risk of the transmission of viruses through blood and blood products?

38.1 NonA/NonB was a term attached to patients who had mild persistent abnormal LFT's. The cause was unknown. As part of my training rotation, I spent a short period at the Edgeware Blood Transfusion Centre. A non-reported study by us showed that 25% of blood donors have some abnormality of LFT. I knew of no association between abnormal LFT's and blood product infusions.

39. In the 1970s and the first half of the 1980s:

(a) What journals and periodicals did you read to keep yourself up to date?

39.1 British Journal of Haematology, Lancet, Blood (American Journal), New England Journal of Medicine.

(b) Did you receive the minutes of the UKHCDO reference centre meetings, or the reports and minutes various working parties that you did not attend?

39.2 I believe that I would have done.

(c) Were other centres or clinicians a source of knowledge? If so, please identify them.

39.3 Dr Jones from Newcastle was a source of information. There would have been the occasional haematology and haemophilia meetings where I might meet colleagues and have informal discussions.

(d) What other sources of information did you have in order to keep up to date?

39.4 Although I cannot recall the specifics now I went to national and some international meetings.

40. Did you read any of the following papers (or, if you cannot recall, do you think it likely that you read them) at the time they were published?

(a) Prince, A. M., et al., "Long-Incubation Post-Transfusion Hepatitis without Serological Evidence of Exposure to Hepatitis-B Virus", The Lancet, Vol. 304, Issue 7875, pp. 241-6. [PRSE0001431].

40.1 I do not recall reading this.

(b) Craske, J., et al., "*An outbreak of hepatitis associated with intravenous injection of Factor VIII concentrate*", *The Lancet,* Vol. 306, Issue 7927, pp. 221-2 [PRSE0001794].

40.2 Craske,J was very well known so I may have read this or scanned the summary.

(c) Purcell, R. H., Alter, H. J., and Dienstag, J. L., *"Non-A, non-B hepatitis"*, *The Yale Journal of Biology and Medicine*, Vol. 49, pp. 243-50 [PRSE0000381].

40.3 No.

(d) Alter H.J., et al., '*How Frequent is Posttransfusion Hepatitis after the Introduction of 3rd Generation Donor Screening for Hepatitis B? What is its Probable Nature?*', *Vox Sanguinis*, Vol. 32 pp. 346-63 [NHBT0000092_002]

40.4 No.

(e) Hoofnagle, J. H., et al.,*"Transmission of Non-A, Non-B Hepatitis", Ann Intern Med,* Vol. 87, Issue 2, pp. 14-20 [RLIT0000228]

40.5 No.

(f) Preston F. E., et al., '*Percutaneous liver biopsy and chronic liver disease in* haemophiliacs', *The Lancet,* Vol. 2, Issue 8090, pp. 592-4 [PRSE0003622].

40.6 Due to the author I think that I would have read this article.

41. Did you watch the World in Action documentary Blood Money (transcript enclosed) [PRSE0004591] when it was screened in December 1975? If not, have you watched it since? If so, when?

41.1 No.

42. The Inquiry notes that 17 of your patients were involved in the research study into liver disease published in 1983; Johnson. R.J., Zhu. X.P., Isherwood. I., Morris. A.I., McVerry. B.A., Triger. D.R., Preston, F.I., & Lucas. S.I. (1983) "Computed tomography: qualitative and quantitative recognition of liver disease in haemophilia.: Journal of computer assisted tomography, 7. 77- 82 [RLIT0000282]. When were the results of this study known to you?

42.1 I knew nothing about CT scans. This was a radiology based study where we supplied the patients with their consent. Although I do not recall the paper I would have seen this before it was published. It was not one of the journals that I would normally read and therefore I would only have seen this article if I had been sent a copy.

43. What was your knowledge of the risk of being infected with Non-A, Non- B Hepatitis ("NANBH") from treatment with blood and blood products at the end of the 70s/early 80s?

43.1 At this time I did not know what the cause was of NANBH and did not link this to viral transmission. This is why I wrote a paper on the possibility of immune complex precipitated by the transfusion of products but did not know the mechanism of how the NANBH was caused.

44. What was your knowledge of how serious Non-A, Non-B hepatitis was at the end of the 70s/early 80s? Did you understand it to be a serious disease with long-term consequences? If you thought of it as a mild and/or non-progressive disease, please explain why and on what basis.

44.1 We did not know what caused it or that it could be serious.

Information given to patients late 70s and early 80s while at the Liverpool Centre

45. How frequently (on average) were patients with a severe bleeding disorder seen at the Liverpool Centre?

45.1 I have difficulty in recalling now how frequently on average patients with a severe bleeding disorder were seen at the Liverpool Centre . I think that when we started off, we had a regular clinic and patients would come probably every six months but I cannot now recall the interval, However patients did not always come for these reviews and so regular clinics declined. The service therefore became more of a reactive service. I was always there for the patients if they needed me and they were aware of this.

46. What information did you provide to patients at the Liverpool Centre about the risks of treatment? In particular:

(a) Did tell your patients when you were at the Liverpool Centre, about the risk of being infected with NANBH from factor concentrates? If not, why not?

46.1 NANB was something that we did not understand and it was something where I did not think that here was a risk from factor concentrates in relation to NANBH.

(b) Did you record your discussions with patients about risks in their notes? If not, why not?

46.2 I cannot now recall what I would have recorded in the patient records, this is now between 35 and 40 years ago.

47. Did you arrange for your patients to have regular liver function tests (LFTs) while at the Liverpool Centre? Please set out which tests you carried out and the purpose of such tests.

47.1 LFTs would be performed, but I cannot say on how regular a basis these were done. If the patient came in for a review then an LFT would be done as this

was one of the blood tests that were done at the review.

48. Did your patients know their liver function was being tested regularly? If not, why not?

48.1 This was 35 to 40 years ago. I cannot now recall if specific patients knew their liver function was being checked, but the LFT was just one of the range of tests that were carried out at the patient review.

49. Were the results of the LFTs given to patients at routine appointments? If so, what were they told about the significance of this? If not, why not?

49.1 I cannot now recall what was said to patients about the result of their LFTs. As I have referred to above we were unsure what caused these abnormal results.

50. If you thought a patient had NANBH, did you tell the patient this? If not, why not? If you did, what was the patient told about NANBH and the significance of the diagnosis?

50.1 My general recollection is that at the time this was unknown entity and was thought to be of minor significance. Whilst I can no longer recall what was said it may have been that I would have avoided causing potential anxiety in a patient and so not informed them about a condition that I thought was benign.

51. What advice, if any, was given to patients with abnormal LFTs (including any advice about lifestyle and infecting others)? How was this advice delivered? In person, by leaflet? Please give details.

51.1 I cannot recall what advice, if any, was given about the fact of an abnormal LFT or if there was any written advice in the form of leaflets. As I have indicated earlier there could have been a number of causes of the abnormal liver function tests and I did not know about the possibility of patients infecting others at this stage.

Treatment of patients in the late 70s - 1982 while at the Liverpool Centre

52. What role in the late 70s and early 80s did your patients have in choosing their treatment? In particular, during this period, did you offer patients the choice between being treated with factor VIII products and being treated with other products such as cryoprecipitate or DDAVP?

52.1 I am being asked about matters from over 40 years ago and so I cannot recall specifics. However, in general if the patient had mild haemophilia the patient could be prescribed DDAVP or cryoprecipitate although due to the complications associated with the use of cryoprecipitate I would be surprised if I had used it. If the patient had severe haemophilia, then the patient would already have been on Factor 8. My first approach would have been to try a non-severe patient on DDAVP and if the patient responded well this would be used. In that sense the patient would not be given a choice. DDAVP was readily available and its use would be encouraged as this a synthetic product. Following treatment their Factor 8 levels would be assessed. If DDAVP did not work, I would consider trying Factor 8 or Cryoprecipitate (although again due to the complications associated with the use of cryoprecipitate I would be surprised if I had used it). I would advise the patient of these treatment options.

53. Did you consider treatment with cryoprecipitate during this time to avoid the risk of infection with NANBH? If not, why not?

53.1 As there was little information regarding the cause of NANBH in the early 80s it was difficult to know how to avoid it.

54. Did you take any steps to reduce the risk of transmission of NANBH to your patients during this time? If so, please give details.

54.1 We did not know the cause if NANBH and so it is difficult to say “what steps should be taken to reduce transmission”.

Knowledge of HIV

55. When and how did you first become aware of AIDS? The Inquiry notes that you were present at the UKHCDO annual meeting on 13 September 1982 [CBLA0001619] at which there was a discussion about AIDS. Were you already aware of AIDS before that meeting?

55.1 I had no awareness before this meeting. Professor Bloom said, even up to mid- 1984 that there was no proven association between HIV and the use of blood products. HIV was not seen as a complication associated with the treatment of Haemophilia.

56. Did you read any of the following publications when they were published (or, if you cannot recall, do you think it likely that you read them)?

(a) CDC *"Pneumocystis Carinii Pneumonia among Persons with Hemophilia A", MMWR*, Vol. 31, No. 27, pp. 365-7 [PRSE0000523].

56.1 No.

(b) Desforges, J. F., *"Aids and Preventive Treatment in Haemophilia"*, *New Engl J Med,* Vol. 308, No.2, pp. 94-5. [PRSE0002410].

56.2 Yes, I think I would have read this as I had worked with her in Boston .

(c) Editorial, '*Acquired Immunodeficiency Syndrome*', *The Lancet,* Vol. 321, Issue 8317, pp. 162-4 [SBTS0000315_021].

56.3 Unless directed to Haemophilia would not have seen this.

57. When was it reasonably clear to you that there was a real risk that AIDs was transmitted through blood and blood products?

57.1 The end of 1983 or beginning 1984 but it is difficult to say with any certainty. Please see my answer to question 55.

58. Please consider the attached letter dated 22nd March 1983 from Drs Craske, Rizza and Bloom [HCDO0000517_001, HCDO0000517_002 and HCDO0000273_078]. What if any steps did you take in response to this at the Liverpool Centre?

58.1 I cannot recall as at that time I do not recall any such patients, but would have reported that we had such patients if there had been any.

59. Please consider the attached letter dated 24 June 1983 from Prof Bloom and Dr Rizza [HCDO0000270_004]. What if any steps did you take in response to this at the Liverpool Centre?

59.1 We did not change the processes and broadly followed those set out in this statement.

Information given to patients about the risk of AIDS at the Liverpool Centre

60. Did tell your patients when you were at the Liverpool Centre, about this risk of being infected with AIDS from factor concentrates?

60.1 Please see my answer to questions 55 and 57. I am not sure what would have been said and when due to the uncertainties I have previously mentioned.

(a) If not, why not?

60.2 Please see my answers to questions 55, 57 and 60.

(b) If you did, what information did you provide to them and in what form?

60.3 See answer to 60 (a).

(c) What if any information was given about the risks of patients passing AIDS on to their partners/families, during this period?

60.4 I do not recall what specific information would have been given about the risks. I think that the risk of transmission through sexual intercourse would have been explained, but I cannot recall any conversations with specific patients.

(d) If none, please explain why.

60.5 Please see my answer to question 60 (c).

61. Did you monitor your patients for the sign of AIDS prior to 1985? If so, how? Did you inform patients of what you were doing?

61.1 I do not recall any monitoring being undertaken. All that I can recall is the testing that was undertaken through Dr Machin in late 1984 which is referred to in document RLIT0000127.

62. Did any of your patients show signs of AIDs before a test was available? If so, did you tell the patient this? If not, why not? You may find the article you wrote titled 'HTLV-III antibody and T cell subset ratios in haemophiliacs and their spouses' published in the British Journal of Haematology, 1986, 63, 347-352, helpful [RLIT0000127].

62.1 I cannot now recall. However, the article suggests that the Liverpool cohort was asymptomatic and had no evidence of AIDS or pre-AIDS type symptom complex. Earlier years testing would have been done retrospectively as I do not recall tests before the 1984 tests referred to in this article. As far as I can recall the test through Dr Machin was also not definitive. The article refers to spouses being tested and so there must have been some discussion with these patients and their spouses, but I cannot recall what this was.

Response to risk of viral transmission 1983 – 1985 while at the Liverpool Centre

63. Did you make any changes to your treatment policies in response to the threat from AIDS? In particular did you consider and/or offer treatment with cryoprecipitate during this time to reduce or avoid the risk of infection with AIDS? If not, why not?

63.1 I do not recall using cryoprecipitate in Liverpool as patients did not like this and there were practical concerns with its use. We changed to heat treated Factor 8 in 1985 when this became available. I may have increased the use of NHS factor 8 in 1983-85, but I cannot now recall.

64. When did you begin to treat patients in Liverpool with heat-treated Factor VIII products? Did you experience any difficulties in obtaining sufficient supplies of heat-treated products? What if any steps were taken to recall from patients any unheated products which they already had for home treatment? (You may find the letter sent to you with the initial rule 9 helpful on this point [CBLA0002051], as well as [BAYP0000024_149].)

64.1 This would have been from around early 1985. I do not recall any difficulty in obtaining heat treated supplies of Factor 8 then. We would have asked the patients to bring the unused (unheated) products back to the Centre.

65. When did you begin to treat patients at the Liverpool Centre with heat treated Factor IX products? Did you experience any difficulties in obtaining sufficient supplies? You may find the minutes of the North Western Supra Regional Haemophilia Meeting held on 7 May 1985 [NHBT0096599_043] in which it was recorded that the 'Liverpool centre is not anxious to use heat treated FIX'. Was that your view at this time? If so, why? Did you use heat treated FIX while at Liverpool?

65.1 We used very little Factor IX so I cannot say when heat treated Factor IX was first used but we would have wanted to move to it as soon as possible if Factor IX was required. What is referred to in the question [NHBT0096599_043] is

not a transcript it is a note that someone made of a meeting that took place over 35 years ago – these are not my notes. The interpretation that I would put upon "not anxious to use it" is that we had no anxiety or concern with its use, not that we were reluctant to use it.

Testing patients for HIV – Liverpool Centre

66. When did you start testing your patients at the Liverpool Centre to see whether they had contracted HIV? You may find the letter you co-wrote for the Lancet, published on 9 February 1985 of assistance on this issue [PRSE0001758].

66.1 Sera from previous years was tested, as referred to in RLIT0000127, but not as far as I can recall before 1984.

67. What were the arrangements for the testing of your patients to establish whether they had contracted HIV at the Liverpool Centre?

67.1 I do not recall the process now. I anticipate that when the patients came in the nurses would take a sample of blood and the test would come back in 4 to 5 days. I do not recall any testing in Liverpool outside the Machin study.

68. Did you tell your patients at the Liverpool Centre in advance they were being tested? If not, why not? If so, how did you go about this?

68.1 I cannot recall what discussion was had with the patients. However, as can be seen from RLIT0000127 spouses are referred to as being tested and so this would suggest that there were discussions with patients and spouses.

69. Did you test on stored samples at the Liverpool Centre? If so:

69.1 This must have been the case from RLIT 0000127.

(a) Where were those sera stored?

69.2 I assume that these were stored in the fridge in the haematology laboratory.

(b) When were the samples that were tested, taken?

69.3 I cannot say but please refer to document RLIT0000127.

(c) Did your patients know you were storing their samples and the purpose of their storage?

69.4 I cannot say.

(d) Did your patients consent to you testing their stored samples? If so, how? What information if any was provided to them about the storage of samples?

69.5 What is said in RLIT0000127 suggests discussion with patients but I cannot say what would have been discussed. We would have obtained verbal permission to obtain the original samples for tests performed at the time that test was taken.

70. What work did you undertake to investigate when your patients sero-converted? You may find the article you wrote titled 'HTLV-III antibody and T cell subset ratios in haemophiliacs and their spouses' published in the British Journal of Haematology, 1986, 63, 347-352, [RLIT0000127] of assistance on this issue.

70.1 I was part of the study in 1984/5 which is referred to in RLIT0000127.

71. In his oral evidence to the Inquiry on 4 November 2020, Professor Hay told the Inquiry that while he had understood that stored samples of some patients at the Liverpool Centre were tested to ascertain dates of sero-conversion, you did not leave any information about this for him, nor did you respond to his written letters to you asking about this. Please respond and provide an explanation for

this.

71.1 I do not recall receiving such letters and I do not believe that copies of these letters have been supplied to me by this Inquiry.

72. How did you inform patients of the results of their HIV tests? Were they informed in person, by letter, by phone? If in person, did you make a special appointment to tell them or did you do it at the next routine clinic appointment? It may assist your recollection to know that Professor Hay told the inquiry in his oral evidence on 4 November 2020 that when he arrived at the Liverpool Centre, his patients told him that they had been informed of their HIV diagnosis by letter delivered by post.

72.1 I cannot recall the actual arrangements. Usual practice would be for a patient to be contacted to make an appointment for a consultation at which it could be explained that their result was positive for HIV. If the result was negative the patient would have been informed at the next review. Results would not have been conveyed by telephone or letter.

73. What information did you give patients if they were infected with HIV? In particular did you advise them of the risk of sexual transmission?

73.1 I do not remember the specifics of what was discussed, but if I was having a consultation with the patient about HIV, it would have been discussed.

74. How many of your patients at the Liverpool Centre were infected with HIV? It may assist you to know that Professor Hay told the Inquiry in his oral evidence on 4 November 2020 that at the Liverpool Centre, he understood that 43 patients were infected of whom 4 were children.

74.1 I no longer recall please see RLIT0000127. I did not treat children.

75. Who did you share these tests results with, in particular did you inform their GPs, and/or UKHCDO and/or the blood services?

75.1 The results may have been shared with UKHCDO if UKHCDO had requested the information. The patients' consent would have been required. The patients' GP and dentists could be informed if the patient agreed. I do not think that this information would have passed on to blood services or public health agencies.

76. Did you offer testing to your patients' families and partners? If so, when? How many of them took this up? How many were infected? You may find the article you wrote titled 'HTLV-III antibody and T cell subset ratios in haemophiliacs and their spouses' published in the British Journal of Haematology, 1986, 63, 347-352, helpful. [RLIT0000127].

76.1 I do not recall, but this is referred to in RLIT0000127.

Treatment of those with HIV at the Liverpool Centre

77. What were the arrangements for the treatment of those infected with HIV at the Liverpool Centre? In particular:

77.1 As far as I can recall no treatment was available before AZT in 1987, I left Liverpool in the summer of 1985.

(a) Was their HIV care managed at the Liverpool Centre, or were they referred to other departments or clinicians? If so, at what point would they be referred and where?

77.2 Patient care for patients at the Liverpool Centre would have been at Liverpool but I cannot recall now if they would have been referred to other departments or clinicians.

(b) Were joint clinics with HIV physicians held for your patients? If not why not?

77.3 As far as I can recall there were no specialist HIV physicians in Liverpool.

78. Did you prescribe medication for those infected with HIV yourself e.g. AZT?

78.1 AZT did not come in until 1987 after I left Liverpool.

79. What kind of psychosocial care was available for patients infected with HIV?

79.1 I do not recall any psychosocial care being available at Liverpool.

80. Did you experience any issues with funding for care for HIV? If so, please provide details.

80.1 I do not recall funding issues.

Time at the Leeds Haemophilia Centre

81. The Inquiry understands that you became joint director of the Leeds Haemophilia Centre with Dr Swinburne in September/October 1985 [DHSC0103282_004]. Is that correct? If so, was that as soon as you arrived at the St James' Hospital or at some later date? If later, when?

81.1 I cannot now recall whether I became joint director upon my arrival at Leeds in September 1985. I think that this would have been a couple of months later, but I am not sure.

82. Why was the decision made to have co-directors of the Centre? How did you split the work between you? Were you responsible for adults and Dr Swinburne for children as suggested by Cutter in their internal memo of 14 November 1985 [BAYP0000007_149]?

82.1 My recollection was that it was Dr Swinburne's idea that we be joint directors of the Leeds Centre. She wished to look after the under 16 or 18s (I cannot now be certain of the demarcation age) and I would look after the rest. I think that she was interested in looking after the children. Initially I shared a clinic with her. We then moved to this split of age groups when we ran our own separate clinics.

83. When Dr Swinburne retired in 1992 were you sole Director of the Leeds Centre?

If not, who was your co-director?

83.1 Yes I was the sole director after this time

84. Were you the Director of the Leeds Centre until your retirement?

84.1 Yes.

85. When did you retire?

85.1 July 2011.

86. The Inquiry understands that there were regional meetings held between (amongst others) Dr Tovey, the Director of the Regional Blood Transfusion Centre, Leeds, and Centre Directors including Dr Swinburne, Dr Parapia, and Dr McEvoy (the Director of the Harrogate Centre). Do you recall attending such meetings? How regularly did they take place? What kind of issues were discussed?

86.1 I remember one meeting, but I do not remember there being regular meetings. I seem to recall that Dr Tovey retired soon after I arrived at Leeds. I cannot recall the contents of the meetings.

87. Please describe the treatment facilities available at the Centre when you arrived, both in terms of physical space, staff (including nursing staff) and whether there were any joint clinics with other disciplines at the time (such as dentists/orthopaedics etc). You may find the details in pages 13 and 14 of [HCDO0000279_011] of assistance in answering this question. The Inquiry also understands that from October 1988 there was a medical social worker Mrs Sheila O'Rourke attached to the Centre. Is that correct?

87.1 At the time I arrived there were no joint (multi-disciplinary) clinics. I think that Dr Swinburne ran weekly clinics. At the time of my arrival there was one haemophilia nurse and her role was to administer the Factor 8 (she left approximately six months after I arrived). There was no haemophilia doctor,

but we shared the haematology registrars. There was no counselling at the start and no technicians in my department. When the haemophilia nurse left we then had the use of a general services nurse and a secretary who maintained/kept the medication records.

87.2 We developed a Haematology out-patient department and the Haemophilia Centre. At the Leeds Centre there were 4 to 5 rooms outside the main buildings of the hospital (in Beckett Wing) where patients were seen and the blood products were stored. We then obtained some funding for a part-time physio from the Haemophilia Society.

87.3 In 1988 there was re-organisation to the central purchasing of blood factors which released funding to us which allowed us to recruit a senior Haemophilia nurse, 2 part-time physiotherapists, 1 and half time social workers and a data collection clerk which made a significant difference. Sheila O'Rourke was one of the social workers who arrived in 198 8. She was instrumental in setting up a number of patient support groups.

88. How did this change over the time you were there? For example, the document at [HSOC0019923_037] suggests that you obtained funding from the Haemophilia Society in 1991 for two years to fund a physiotherapist. Is that correct? The article at [HSOC0011607] suggests that a number of support groups were implemented in the late 1980s.

88.1 I do not have access to document HSOC0011607. Please refer to my answer to question 87.

89. Did the Leeds Centre offer a 24-hour service? How did patients access treatment outside office hours?

89.1 The Leeds Centre did effectively offer a 24-hour service. The Haemophilia Centre was physically manned for patients between 9am and 5pm. Outside of those hours, patients would be encouraged to attend the haematology ward

rather than A and E for treatment of bleeds. The patients would have all been advised where the haematology ward was located within the hospital and how to get there (originally it was above the Haemophilia Centre, it then moved into the main hospital and then the Bexley Wing which is the cancer wing). The registrars would evaluate the patient and then give Factor 8 or Factor 9. Should it be required I could be contacted and would be able to attend the hospital to consult with the patient.

90. What was the system for recording the products received and batches used while at the Leeds Centre? In particular:

(a) Where were records kept?

90.1 The main records for the haemophilia department were kept at the Haemophilia centre. The main hospital records would be kept in the main hospital pool. There would be abbreviated records held in AE and the haematology ward recording what the patient was receiving in the haemophilia centre in case they attended as an emergency. At the Haemophilia Centre where patients would collect their Factor 8, the nurse would record what was given out to the patient (the amount and the batch number) and this information would be sent through our secretary who would collate this information for the annual return . The patient would also record what they administered when they were at home in a log book. If the patient attended in the AE, the haematology ward or the orthopaedic department a record would be made of the name date of birth and treatment product that was given to the patient. Our data clerk would collect this information to add to our records.

(b) Did they form part of the patient's medical records, or were they kept separately? Did for example the A&E have access to those records?

90.2 These records were kept separately and would not be immediately accessible but A and E, for example, would be aware of which product the patient was using . A and E would always call a haematology registrar to come and assess a haemophiliac patient.

(c) What was the expectation in terms of patients filling out and providing the Leeds Centre with home treatment records?

90.3 The patients would have a log book and when this was completed they would hand this in and receive a replacement.

91. The 1986 returns [HCDO0000312_002] state that during the year the Leeds Centre treated 83 people with Haemophilia A, one carrier, 1 with antibodies, 9 patients with Von Willebrands and 6 with Haemophilia B. How many patients were registered with the Centre during this time?

91.1 I am sorry I cannot recall these statistics.

Treatment Policies at the Leeds Centre

92. Did you have written treatment policies for patients with Haemophilia and Von Willebrands? If so, where were they kept? If not, why not?

92.1 Yes we had policies. They were kept in the haemophilia unit and the haematology department.

93. Was there an established home treatment programme when you arrived? Did you have any involvement in arranging for patients to receive home treatment? How were patients chosen for the home treatment programme?

93.1 I think that there was. Selection criteria would generally be a patient suffering from severe haemophilia with very low levels of Factor 8 and having frequent bleeds.

94. Was there a prophylaxis treatment programme during your time at the Leeds Centre? If so, when did this start? Please give details.

94.1 Yes, this probably started in the early 1990s.

95. What was the treatment policy between your arrival and 1992 for those with:

(a) Severe haemophilia A and B

95.1 For severe haemophilia A, recombinant factor 8 product would be used and for haemophilia B I cannot now recall what products we used.

(b) Moderate haemophilia A and B

95.2 For moderate haemophilia we would use either DDAVP or recombinant Factor 8 and for moderate haemophilia B I cannot recall what products used

(c) Mild haemophilia A and B

95.3 For mild haemophilia we would use DDAVP and for mild haemophilia B I cannot recall what products used

(d) Von Willebrands

95.4 We would use DDAVP

96. What was the treatment policy for children at home and in hospital?

96.1 I did not treat children.

97. What was the treatment policy for patients with inhibitors A and B?

97.1 I do not remember what this is.

98. The 1986 return [HCDO0000312_002] shows the Leeds Centre using cryoprecipitate as a treatment in hospital for patients with haemophilia A.

(a) Which cohort of patients received cryoprecipitate in Leeds during 1986 (and at any other time during your tenure there)?

98.1 I think that this may have relate to Dr Swinburne as I do not recall using cryoprecipitate.

(b) Why were they treated with cryoprecipitate rather than with factor concentrates?

98.2 Please see answer in (a) above.

99. The 1986 return [HCDO0000312_002] shows that the Leeds Centre was using NHS factor VIII and three commercial factor products for patients with Haemophilia A and Von Willebrands. How did you choose which patient received which product?

99.1 There was a feeling at that time that we should keep patients on same brand of product as they were already using due to antibodies to F actor 8. The UKHCDO was keen not to use just one company/supplier as if it went out of business or there was a halt in supply we would have been in difficulty i n providing the products to the patients.

Supply of FVIII while at the Leeds Centre

100. Where did the Centre get its cryoprecipitate from?

100.1 I do not know, but I presume that it would have come from the Blood Transfusion Centre.

101. Was there any problem with the supply of cryoprecipitate? Was there always sufficient cryoprecipitate?

101.1 I cannot answer this Dr Swinburne may know.

102. How did the NHS factor come to the Leeds Centre – was it directly from BPL, or via the Regional Blood Transfusion Centre?

102.1 I think that this would have come from BPL.

103. How was NHS Factor allocated to the Leeds Centre?

103.1 I anticipate that this would have been based on the previous year's usage/return.

104. Did you have sufficient NHS Factor?

104.1 We were using heat treated or recombinant Factor and therefore I was not concerned about the supply of blood Factor but cannot specifically recall if there was sufficient NHS Factor.

105. The Inquiry understands that there was a regional contract in place for the provision of the commercial factor VIII used by the Leeds Centre. Is that correct? If so:

105.1 I had nothing to do with placing contracts.

(a) What was the process for concluding the regional contract and what if any role did you play?

105.2 I had no role beyond maintaining the patient on whatever product they were already on and trying to maintain a reliable supply of this product.

(b) What criteria were applied for the selection of the companies with which to contract?

105.3 We wished to maintain patients on their existing blood product and so if the service from the company supplying this product was good we would continue to use their products.

(c) How long did the regional contract last?

105.4 I do not know please see my answer to question 105.

Action taken at the Leeds Centre in response to risk

106. The Inquiry understands that you were informed by Bayer on 22 March 1988 that

a Koate HT batch of product was recalled because it had been reported that three patients had been infected with HBV as a result of using it [BAYP0000005_056 and BAYP0000005_057].

(a) What action did you take in response to this? You may find [BAYP0000011_058] of assistance.

106.1 Patients would have been informed to bring back any product they had, the products would have been taken off the shelf, and would have been returned to Bayer. I suspect that we tested the affected patients but I cannot recall the detail.

(b) In particular, what information did you share with the patients using this batch?

106.2 I cannot recall what we told the patients.

(c) Did you continue to use other batches of Koate HT? If so, why?

106.3 I cannot recall, it is likely that we would have switched product.

Testing patients for HIV – Leeds Centre

107. Were you involved in testing patients at the Leeds Centre to see whether they had contracted HIV? If so please provide details of your involvement. In any event the Inquiry assumes that as Centre co-Director you would be familiar with the arrangements that had been made for the testing of patients and requests your response to the following questions:

107.1 I was involved in testing for HIV. At my weekly clinic bloods would be taken and HIV status checked.

(a) What were the arrangements for the testing of the patients at the Leeds Centre to establish whether they had contracted HIV?

107.1 Patients came to general clinics and they were tested or if they came in for

some other reason but were not specifically called in for an HIV test.

(b) Were patients at the Leeds Centre told in advance they were being tested? If not, why not? If so, what information was provided to them?

107.2 Blood samples were taken for testing at every clinic. I cannot recall if patients were specifically advised that they were being tested for HIV. By the time I became involved at Leeds I think the patients knew their HIV status. If the patient had had an HIV test this would have been recorded in the records and the result. If it was negative there would be no need to undertake a further HIV test as the patients were receiving a recombinant product. An HIV test would only be required if there was no record of an HIV test or it was a new patient.

(c) Was testing undertaken on stored samples at the Leeds Centre? If so, where were those sera stored and when were the samples that were tested, taken? Did patients give consent to their stored samples being tested? If so, how was this raised with them?

107.3 I am not aware of any stored samples and therefore I am not aware of testing on stored samples.

(d) What work was undertaken to investigate when the patients sero-converted and what were the results? You may find [PRSE0001758] of assistance.

107.4 I am not aware that there were any stored samples so there would have been no investigations.

(e) How were patients informed of the results of the HIV test? In person, by letter, by phone? If in person, was a special appointment made to tell them or were they told at the next routine clinic appointment?

107.5 This would have been in person. This would have been in person and at the next regular clinic if the result was negative and if positive they would be called

in for the result.

(f) What information was given to patients if they were infected with HIV?

107.6 Most of these patients had been diagnosed by Dr Swinburne, and I do not know what she would have said to them. If it was a diagnosis by me I would have said that the patient was HIV positive, that their partner should be checked, that they should not have unprotected sexual intercourse and (post 1987) the patient could be prescribed AZT. I cannot now recall if they would have been advised to inform their GP or their dentist. Written information may have been provided. Patients would have been provided with information about the Macfarlane Trust. From her arrival in 1988, Shiela O'Rourke would also have provided support to the patients and their families.

108. How many patients at the Leeds Centre were infected with HIV?

108.1 I am sorry but I cannot recall.

109. Who did you share the test results with? You may find [PARA0000006] helpful when considering this answer with respect to the sharing of results with patients' GPs. When answering this question, you may also find the handwritten note on page 8 of [WITN1291007] which provides 'DO NOT TELL GP OF HIV STATUS' of assistance, if that is a note written by you.

109.1 My normal policy would be to seek permission to inform the GP, some patients did not want the GP to be told.

110. Did you share test results with the UKHCDO or the blood services or any public health agency?

110.1 The results may have been shared with UKHCDO if UKHCDO had requested the information. The patients' consent would have been required. The patients' GP and dentists could be informed if the patient agreed. I do not think that this information would have passed on to blood services or public health agencies.

If so, were patients aware of this? Did they consent to it?

110.2 Please see above.

111. Did the Leeds Centre offer testing to patients' families and partners? If so, when? How many of them took this up? How many were infected?

111.1 The Leeds Centre did offer testing to patients' families and partners and this would usually have been when the diagnos is was made. I cannot recall whether any family members or partners refused testing. As far as I can recall no family members or partners tested positive.

Testing for HCV – Leeds Centre

112. Was patient consent sought for HCV tests? If so, how? If not, why not?

112.1 Verbal consent was obtained.

113. How and when was testing for HCV undertaken? In particular:

(a) How did you determine which patients to test?

113.1 Any patient who had had Factor 8 or Factor 9 concentrate in the past.

(b) Were all patients tested?

113.2 Please see my response to 113 (a), but I cannot say if all patients were tested as I do not have this information.

(c) Were stored sera tested?

113.3 I am not aware that sera was stored.

(d) If so, where were those sera stored and when were the samples that were tested, taken? Did patients give consent to their stored samples being tested? If so, how was this raised with them?

113.4 Please see my answer to 113 (c) above.

(e) How did you inform patients of the results of the HCV tests? In person, by letter, by phone? If in person, did you make a special appointment to tell them or did you do it at the next routine clinic appointment?

113.5 This would have been in person and at the next regular clinic if the result was negative and if positive they would be called in for the result.

(f) What information did you give patients if they were infected with HCV and in what form?

113.6 Written information about the treatment and something about the condition itself would have been provided and patients would have been advised that the treatment for this condition is successful. Patients were also advised that they could be referred to the hepatologist, but most stayed with our department. Patients would also have been advised about the possibility of cirrhosis or even liver cancer and of the Skipton Fund.

114. How many of your patients at the Leeds Centre were infected with HCV?

114.1 I cannot recall but there were a number of such patients.

115. Who did you share the tests results with? Did you share test results with the UKHCDO or the blood services or any public health agency? If so, were patients aware of this? Did they consent to it?

115.1 The results may have been shared with UKHCDO if UKHCDO had requested the information. The patients' consent would have been required. The patients' GP and dentists could be informed if the patient agreed. I do not think that this

information would have passed on to blood services or public health agencies.

116. Did you offer testing to patients' families and partners? If so, when? How many of them took this up? How many were infected?

116.1 Yes when the diagnosis was made, but not that many took this up and I do not recall any partner that we tested developing HCV. If I was told that that a patient had a new partner the patient would have been advised that the patient should inform the partner that they should be tested. I cannot recall how many took up the offer to be tested. As far as I can recall none tested were positive for HCV.

Treatment of those with HIV – Leeds Centre

117. What were the arrangements for the treatment of those infected with HIV? In particular:

(a) Was their HIV care managed at the Leeds Centre, or were they referred to other departments? If so, at what point would they be referred and where?

117.1 The patients were managed at the Leeds Centre and were treated with AZT when this became available in 1987 with the involvement of the infectious disease consultant and a senior nurse to review results monthly and treatment adjusted if required.

(b) Were joint clinics with HIV physicians held for your patients? If not why not?

117.2 We did not have a joint clinic which included the patient's attendance, but we did have a monthly joint review of all the relevant results as described in answer to 117 (a) so there was multi-disciplinary input.

118. Did you prescribe medication for those infected with HIV yourself e.g. AZT?

118.1 Yes.

119. What kind of psychosocial care was available for patient infected with HIV?

119.1 Sheila O'Rourke provided this when she arrived I 1988 but prior to this there was no-one fulfilling this role.

120. Did you experience any issues with funding for care for HIV? If so please provide details.

120.1 I cannot recall any.

Treatment of those with HCV – Leeds Centre

121. What were the arrangements for the treatment of those infected with HCV? In particular:

(a) Was their HCV care managed at the Leeds Centre, or were they referred to other departments or clinicians? If so, at what point would they be referred and where?

121.1 Patients' care was managed at the Leeds Centre. We had a good relationship with the hepatologist and therefore we managed these patients at the centre with their input unless the patient wanted a referral to hepatology or they did not respond to the care agreed with the hepatologist.

(b) Were joint clinics with hepatologists held for your patients? If not why not?

121.2 There were joint clinics but please refer to my answer in 121 (a). I f there was a problem with the treatment under the agreed hepatology protocol this would have referred to the hepatologist.

122. Did you prescribe medication for those infected with HCV yourself e.g interferon?

122.1 Yes.

123. What kind of psychosocial care was available for patients infected with HCV?

123.1 Shiela O'Rourke would provide similar services for HCV as with HIV.

124. Did you experience any issues with funding for care for HCV? If so please provide details.

124.1 No.

Sharing of data

125. Did you share clinical data with PFL in exchange for 'minor products' being provided to you free of charge? You may find the memo on 19 April 1991 of assistance [PBLL0005964]. As to this:

125.1 No

(a) What is meant by 'minor products'

125.2 I do not know.

(b) Were patients aware that you were sharing clinical data with PFL? If so, did they consent to the same?

125.3 Data was not shared.

126. Were your patients aware that you were sharing their details with the UKHCDO, including their names and details of their treatment and reactions? Did you seek their consent to share this information? If so, how? If not, why not? You may find the correspondence at [HCDO0000119_160] and [HCDO0000123_048] helpful.

126.1 I refer to my answers to previous question relating to the "sharing" of data with the UKHCDO. The results may have been shared with UKHCDO if UKHCDO

had requested the information. The patients' consent would have been required.

Relationships with Pharmaceutical Companies

127. Please describe the relationship you had with Cutter. You may find the following documents of assistance:

(a) Their internal memos [BAYP0000007_045 and BAYP00000007_145].

(b) Some of their correspondence to you in 1986 can be found at BAYP0000008_078, BAYP0000008_116, BAYP0000008_324

127.1 A representative would invite us for something to eat or take us to national meetings and inform us about their products. I was not responsible for contracting with Cutter.

Statement of Truth

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

Signed GRO-C

Dated 8 March 2021