Witness Name: Dr Stanley Dempsey
Statement No.: WITN5560001
Exhibits: n/a
Dated: 2nd Sep 2021

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF STANLEY IAN DEMPSEY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 from the Infected Blood Inquiry, dated 9 March 2021.

I, Stanley Ian Dempsey, will say as follows: -

Section 1: Introduction

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

1.1. Dr Stanley Ian Dempsey, GRO-C

1.2. DOB – GRO-C 1946

1.3. MB, BCH, BAO (Queen's University Belfast 1970)
FRCP
FRC PATH

2. Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as

the dates.

2.1. 1970 to 1971 Junior House Officer, Belfast City Hospital (BCH).

2.2. 1971 to 1973 Senior House Officer (General Medicine) (BCH).

2.3. 1973 to 1978 Senior House Officer, Registrar, Senior Registrar (Haematology) (BCH).

2.4. 1978 to 1979 Senior Registrar (Haematology) (Royal Victoria Hospital/Royal Belfast Hospital for Sick Children).

2.5. January to July 1980 Senior Registrar, Paediatric Oncology, (Royal Manchester Children's Hospital).

2.6. August 1980 to July 2008 Consultant Paediatric Haematologist, Royal Belfast Hospital for Sick Children.

3. Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

3.1. Member British Society for Haematology 1980 to 2008.

3.2. Member UK Haemophilia Centre, Directors Organisation 1980 to 2008.

4. Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to 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 and copies of any statements or reports which you provided.

4.1. I have not provided evidence to or been involved in any Inquiries, Investigations or Litigation in relation to viral or other infections in blood and/or blood products.

5. **The questions below focus on your time as consultant at the Royal Belfast hospital for Sick Children ("the Centre") but if you have information relevant to the decisions, policies or practices at any other institution or organisation where you previously/subsequently worked, please also set that out.**

5.1. I have no further information relevant to the decisions, policies or practices of any other institution other than the Royal Belfast Hospital for Sick Children.

Section 2: Decisions and actions of the Royal Belfast Hospital for Sick Children ("the Centre")

6. **Please:**

   a. **Describe the roles, functions and responsibilities of the Centre during the time that you worked there.**

   b. **Outline the facilities and staffing arrangements for the care of patients with bleed disorders;**

   c. **Identify senior colleagues (if any) at the Centre and their roles and responsibilities during the time that you worked there, insofar as they were involved with the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.**

6.1. The Children's Haematology Unit had responsibility to deliver a service to children with leukaemia and solid tumours presenting from across Northern Ireland as well as a responsibility to children with hereditary bleeding disorders in Northern Ireland. Children with hereditary bleeding disorders were usually referred for ongoing care to the Adult Haemophilia Centre in the Royal Victoria Hospital at age 14 years.

6.2. The Unit also provided a general haematology service for both inpatient/outpatient referrals within the Royal Belfast Hospital for Sick Children.

6.3. From 1980 to 1987 haemophilia patients were seen in/or admitted to the General Medical Wards in the Children's Hospital. An eight bedded specialist unit came on stream in 1987 and patients with bleeding disorders were seen there from then on and at a specific Outpatient Clinic when this became available about the same time.

6.4. Staffing of the Centre was with one Consultant Paediatric Haematologist, a part time Clinical Medical Officer initially appointed in 1987 and a full time Registrar in haematology training. A ward sister and a full complement of staff nurse were appointed when the new eight bedded unit opened in 1987.

6.5. The unit was managed by a single handed Consultant Paediatric Haematologist until a Consultant Paediatric Oncologist was appointed in 2000. The Paediatric Oncologist was not involved in the provision of haemophilia care.

7. Please describe:

a. Your role and responsibilities at the Centre and how, if applicable, this changed over time;

7.1. My role in the Children's Hospital ("the Centre") covered the care of children with malignant disorders and also children with hereditary bleeding disorders. Initially my time was spent primarily in managing the former group as there was only a small cohort of children with haemophilia and Von Willebrand's disease attending when I was appointed in 1980. All of the hereditary bleeding group were moderately/mildly affected and presented infrequently with bleeding episodes. This remained the case throughout the 1980s. Only from 1990 onwards did numbers presenting increase including a number of severely affected children, with a corresponding increase in workload.

7.2. In 2000 a Consultant Paediatric Oncologist was appointed to look after children with solid tumours. I remained responsible for the management of children with leukaemia and bleeding disorders.

b. Your work at the Centre insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products;

7.3. My role in relation to patients with bleeding disorders was to provide care, information and support. Regular six monthly reviews were organised with a view to monitoring joint function, dental supervision and blood testing for inhibitors together with viral screening when tests became available.

7.4. Specific follow up for patients with HCV infection was also provided.

7.5. Patients on home treatment/prophylaxis were also monitored for their history of joint bleeds and the effectiveness of treatment, when home treatment was introduced in 1990.

c. The relationship between the Royal Victoria Hospital and the Centre, and where decision-making lay between the two on policy matters concerning the Centre;

7.6. The Centre was and is based in the Royal Belfast Hospital for Sick Children

(RBHSC). The RBHSC is located beside the Royal Victoria Hospital (RVH) on the same site.

7.7. There was a unified management system in operation in 1980 and ultimately both Hospitals were organised into the same Hospital Trust.

7.8. I was solely responsible for clinical decisions relating to my patients. Decisions relating to product selection for management were my responsibility.

7.9. Dr Mayne was a valuable source of advice and support over the two decades of our association.

d. Your involvement (if any) with the Belfast Haemophilia Centre at the Royal Victoria Hospital;

7.10. I had no responsibility for patient management in the Belfast Haemophilia Centre at the Royal Victoria Hospital. Dr Mayne was responsible for management of the Coagulation Laboratory which was located in the Haematology Laboratory RVH.

7.11. Dr Mayne was also responsible for management of the blood bank in the Royal Victoria Hospital.

e. Your working relationship with Dr Elizabeth Mayne.

7.12. I was fortunate in having a good working relationship with Dr Mayne. We met for discussion about topics of mutual concern relating to haemophilia care. Dr Mayne played a prominent role in the UK Haemophilia Centre Directors Organisation. I was kept fully informed of its discussions both through her, my attendance at yearly meetings, and the minutes of those meetings. Dr Mayne liaised with the Scottish National Blood Transfusion Service (SNBTS) in relation to the supply of NHS Factor (VIII) Concentrate. Dr Mayne also supervised the purchase of commercial Factor VIII Concentrates.

7.13. She also liaised with the Eastern Health and Social Services Board to secure funding in relation to the eventual provision of recombinant products when these became available, in 1997. Prior to 1997 I had no knowledge of funding arrangements for the purchase of Factor VIII concentrates

8. Approximately how many patients with bleeding disorders were under the care of the Centre when you began your work there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so).

8.1. When I took up my post at the Centre in August 1980 there was a relatively small cohort of patients with hereditary bleeding disorders attending (I believe 12 in number).

8.2. They fell into the mild to moderately affected group. Attendances with bleeding episodes were relatively infrequent.

8.3. Numbers remained small throughout the 1980s but increased throughout the 1990s with a number of severely affected patients among them.

8.4. At the time of my retirement in 2008, 30 to 35 patients were attending the Centre.

9. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated concerning the Centre, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? In addressing this issue, please answer the following questions:

a. How, on what basis, and by whom, were decisions made about the selection and purchase of blood products?

9.1. I was responsible for the selection of blood products for use within the Centre. However, selection was from those available in the Blood Bank Royal Victoria Hospital. (Please see answer Question 11).

b. What (if any) other bodies or organisations or individuals (e.g. other centres in the same region, or the Regional Health Authority) were involved in the arrangements for the selection, purchase or use of blood products?

9.2. The Eastern Health and Social Services Board were involved regarding funding for the purchase of recombinant materials.

c. What were the reasons or considerations that led to the choice of one product over another?

9.3. Decisions regarding the choice of product were made on clinical grounds.

d. What role did commercial and/or financial considerations play?

9.4. Commercial and financial considerations played no part in my selection of product.

e. What if any involvement did you have?

9.5. Decisions around the selection of appropriate treatment products were mine.

f. What products or treatments were generally used for treating (i) patients with severe haemophilia A; (ii) patients with moderate haemophilia A; (iii) patients with mild haemophilia A; (iv) patients with haemophilia B; (v) patients with von Willebrand's disease?

9.6. Some commercial Factor VIII Concentrate (Armour and Hemophil) was

employed in the treatment of moderate Haemophilia patients between August 1980 and December 1982 as well as NHS Factor VIII and cryoprecipitate. My reservations about the use of cryoprecipitate are set out in my answer to question 15. In 1982 (and prior to 1982) no distinction between commercial and NHS Factor VIII could be made from the viewpoint of infective risk as set out in my answer to question 21.

9.7. Treatment products for patients post 1982.

9.7.1. **Severe haemophilia A Scottish National Blood Transfusion Service -** SNBTS Factor 8 Concentrate

9.7.2. **Moderate haemophilia** A - SNBTS Factor VIII Concentrate

9.7.3. **Mild haemophilia** A - D.D.A.V.P. (Desmopressin) Cryoprecipitate

9.7.4. **Haemophilia B -** SNBTS Factor IX Concentrate

9.7.5. **Von Willebrands Disease -** D.D.A.V.P. (Desmopressin) Cryoprecipitate

9.8. Factor VIII and Factor IX NHS concentrates were replaced by recombinant products when these became available.).

10. What was the relationship between the Centre and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Centre's decisions and actions? In answering this question, please describe the kinds of interactions and communications (such as visits from sales representatives) you had with pharmaceutical companies which supplied factor concentrates.

10.1. I had occasional visits from sales representatives of commercial companies, but these visits did not influence my decisions on which product to use.

11. If the responsibility for the selection and purchase of blood products lay with an organisation other than the Centre, please specify which organisation and provide as much information as you can about its decision-making.

11.1. Dr Mayne supervised the purchase and supply of blood products for delivery to the Blood Bank, Royal Victoria Hospital. As stated above, I selected from the products available in the Blood Bank, Royal Victoria Hospital.

12. Please describe your relationship/the Centre's relationship with (i) the Eastern Health and Social Services Board (EHSSB) and (ii) the Scottish National Blood Transfusion Service (SNBTS)/the Protein Fractionation Centre in Edinburgh (PFC) for the fractionation and supply of blood products.

12.1. It was Dr Mayne rather than myself who represented the interests of the Children's Centre and the Adult Centre in meetings with the Eastern Health and Social Services Board. She was primarily involved in obtaining funding for the purchase of recombinant products when these became available. In addition, Dr Mayne regularly attended meetings of the SNBTS/Protein Fractionation Centre in Edinburgh and represented both the adult and children's centres at those meetings. I attended occasionally and received minutes of those meetings.

13. Please explain how cryoprecipitate and NHS factor concentrates were supplied to the Centre, by whom and with what frequency. Were there shortages or other difficulties in obtaining sufficient supplies? Please confirm whether EHSSB and/or SNBTS/PFC had any involvement in supplying commercial factor concentrates or whether those were obtained from the pharmaceutical companies directly.

13.1. Both Cryoprecipitate and NHS Factor Concentrates were supplied to the Royal

Victoria Hospital Blood Bank from the Northern Ireland Blood Transfusion Service (NIBTS). From there a supply of Cryoprecipitate and NHS Factor Concentrate was delivered to a small haematology laboratory in the Children's Hospital for use with my patients. The latter was under my direction. Where Commercial Factor VIII was used prior to 1983 it was obtained from the Blood Blank at Royal Victoria Hospital which was under the direction of Dr Mayne.

13.2. Initially Factor Concentrate was dissolved ready for use and supplied from either the Children's Haematology Laboratory or directly from the Blood Bank RVH (at weekends or out of hours) to the relevant Children's Ward before administration. Later when ward facilities improved with the opening of a dedicated Paediatric Haematology Ward product was made up on the ward directly for use.

14. How were decisions taken as to which products to use for individual patients? What involvement did you have in such decisions? To what extent, if at all, were patients offered a choice as to which products to use?

12.1. Patients were treated dependant on diagnosis and severity as outlined above under 9 (f). I discussed treatment plans fully with the parents (and the patients where age appropriate). Parental opinion was taken fully into account, after discussion around perceived risks of viral infection. This perceived risk evolved over time.

15. What alternative treatments to factor concentrates were available in the 1970s and 1980s for people with bleeding disorders? What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the Centre make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

15.1. Desmopressin (D.D.A.V.P.) (for children over four years of age) and Cryoprecipitate were available as alternative treatments to Factor Concentrates for the management of haemophilia A and Von Willebrands disease during the 1970s and 80s.

15.2. D.D.A.V.P. is a synthetic pharmaceutical product capable of raising Factor VIII/Von Willebrand factor levels, in patients with Von Willebrand disease and mild haemophilia A. Its disadvantage lies in the fact that increased Factor VIII levels may not be sustained and response to continuing treatment with D.D.A.V.P. may tail off over several days.

15.3. Cryoprecipitate is a blood product. Each treatment with this product would expose the patient to a lower number of donations by comparison with factor concentrate made up of several thousand donations. In consequence the infective risk should be reduced.

15.4. In terms of disadvantage Cryoprecipitate is time consuming to make up and the large volumes of fluid associated with it make administration more difficult in children who tend to have small veins. The primary disadvantage however is related to the problem of dosing. The dose of Factor VIII in any given quantity of Cryoprecipitate can vary widely reflecting variations in Factor VIII levels in normal blood donors. The dose of Factor VIII administered with each treatment can vary as a result making Cryoprecipitate unreliable where dosing is critical as it is in many clinical situations including the management of joint bleeds and episodes of internal haemorrhage.

16. What was the Centre's policy and approach as regards:

a. The use of cryoprecipitate for the treatment of patients with bleeding disorders? The Inquiry understands from the evidence of Dr Mayne that a decision was made in the early 1970s that all children should remain on treatment with cryoprecipitate, a policy

you followed when you took over from your predecessor Professor Bridges. Is this consistent with your own recollection? What in your view were the benefits of treating children with cryoprecipitate? Did the policy on cryoprecipitate change of time? If so how?

16.1. When I commenced work as a Consultant in 1980 cryoprecipitate was employed in the Centre. I cannot recall if it was used exclusively. In my early years as a Consultant in the Centre I continued to use cryoprecipitate but some factor (viii) concentrate both NHS and commercial was also employed in patients with moderate haemophilia.

16.2. In 1983 I adopted the exclusive use of NHS factor (viii) concentrate (SNBTS) for children with moderate haemophilia A. I did this because of my reservations about cryoprecipitate as outlined in my answer to question 15. Increasing concerns about a possible link between imported commercial factor (viii) concentrate and AIDS saw the use of commercial factor VIII discontinued in the Centre.

b. Home treatment? When was home treatment introduced?

16.3. Home treatment at this Centre was introduced in 1990.

c. Prophylactic treatment? To what extent and when was treatment provided on a prophylactic basis? Did the policy and approach change over time and if so how?

16.4. Prophylactic treatment was introduced in 1990. It was introduced to cover severely affected patients. Moderately affected patients who showed a pattern of recurrent haemorrhage into a particular joint were also introduced to prophylactic treatment to break the cycle of repeat bleeding.

16.5. Home treatment had not been introduced prior to 1990 because the patient cohort up to that date had been mildly to moderately affected with a pattern of

infrequent haemorrhage and presentation for treatment. Around 1990 a number of more severely affected patients were diagnosed making the introduction of home treatment/prophylaxis essential for their effective care.

17. What was the Centre's policy and approach in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?

17.1. The Centre only treated children so all the previous answers apply solely to a paediatric population.

18. To what extent, and why, were people with mild or moderate bleeding disorders treated with factor concentrates?

18.1. Patients with mild haemophilia A and von Willebrands disease were treated with DDAVP wherever possible. Moderate haemophilia A patients were treated with factor concentrate (SNBTS) from 1983. My reservations regarding the use of cryoprecipitate are outlined in my answer to question 15. In situations where haemostatic control was essential cryoprecipitate could be an unreliable treatment.

19. What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at the Centre in consequence of the use of blood products?

19.1. No patients were recorded at this Centre as being infected by HIV or HBV.

19.2. Other than HCV no other infections were recorded at this Centre in consequence of the use of blood products.

Section 3: Knowledge of, and response to, risk

General

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

20.1. Risk assessment at the Centre relied on:

20.1.1. Relevant published material.

20.1.2. UKHCDO advice and comment.

20.1.3. Discussion with colleagues working in the Adult Centre.

21. What was your understanding of the relative risks of infection from commercially supplied factor concentrates and NHS factor concentrates?

21.1. Commercial factor concentrates had been associated with an outbreak of Hepatitis B in the early/mid 1970's. By 1980 Hepatitis B testing of donors and more careful donor selection had improved the safety profile of commercial concentrates. I was not aware of any difference between commercial concentrate and NHS concentrate with regard to any background concerns about the transmission of Non A Non B Hepatitis in the early 1980s. Concerns about a possible link between commercial Factor VIII Concentrate and aids were expressed in 1983 but not at that stage proven. Perceptions evolved as knowledge accrued however.

22. How did you keep up-to-date with relevant scientific and medical developments in knowledge? What journals did you regularly read?

22.1. Up to date information was obtained from:

22.1.1. Relevant literature

22.1.2. British Medical Journal

22.1.3. Journal of the British Society for Haematology

22.1.4. Haemophilia (Journal)

22.1.5. Blood (Journal)

22.1.6. Written advice and minutes of UKHCDO meetings.

22.1.7. Discussion with haematology colleagues working in the Adult Centre.

Hepatitis

23. When you began work as a Haematologist at the Centre, what was your knowledge and understanding of:

a. The risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products?

23.1. I appreciated that Hepatitis B could be transmitted from blood products. This had been especially notable with commercial concentrate in the early 1970s. Hepatitis B testing of donors had substantially reduced this risk.

23.2. In relation to Non A Non B Hepatitis I understood that occasional cases of jaundice had been noted in relation to the administration of factor concentrate.

23.3. A small number of cases of cirrhosis had been documented. Subtle variations in liver function tests were also noted in some patients. The problem was of concern and was actively monitored but not thought sufficiently serious to merit withdrawal of the only really effective treatment for severe/moderate haemophilia which carried a high risk of death and crippling from uncontrolled haemorrhage.

b. The nature and severity of the different forms of blood borne viral hepatitis?

23.4. I appreciated Hepatitis B carried a high risk of chronic liver disease. I understood Hepatitis A which had also been documented as transmissible from blood products was usually a self-limiting condition but could sometimes cause death in the acute phase from acute liver failure.

23.5. Non A Non B Hepatitis, I appreciated, could cause chronic liver disease and was transmissible by blood products but in most cases was a self-limiting condition without long term ill-effects.

24. What were the sources of your knowledge? How did that knowledge and understanding develop over time?

24.1. The sources of that understanding came from appropriate texts, editorials, papers and discussion at medical meetings.

24.2. Understanding improved in the mid-1980s. Liver biopsy studies showed the problem was more serious and wide spread than had been appreciated. Further understanding evolved over the following years especially with the development of testing for Hepatitis C in the early 1990's.

25. What, if any, actions did you and/or the Centre take to reduce the risk to

patients of being infected with hepatitis (of any kind)?

25.1. With hindsight, the only possible way to avoid or reduce the risk of Non A Non B Hepatitis was to maximise the use of D.D.A.V.P. and/or switch to the use of Cryoprecipitate. The latter course of action would have left patients open to increased risk of life threatening haemorrhage and crippling arthritis. (Cryoprecipitate also carried a risk of transmission of Non A Non B hepatitis although reduced by comparison with factor concentrate). The extent of the problem with Non A Non B Hepatitis was not fully understood in the early 1980s. Only with the development of new tests for its detection in the early 1990s did its extent become fully known. Heat treated Factor VIII was introduced when it became available.

HIV and AIDS

26. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular the risks of transmission from blood and blood products during your time working at the Centre? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

26.1. The possible relationship of AIDS to haemophilia was first noted in the USA in 1982 in literature reports. In 1983 AIDS was reported in the UK for the first time. A UK patient with haemophilia who developed AIDS was also reported in 1983 for the first time. Concerns were expressed then about a possible link between AIDS and transmission through blood products (UKHCDO). The evidence of linkage was not thought sufficient to warrant withdrawal of factor concentrates from use, at that time. (UKHCDO advice)

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

27.1. A possible link remained under review from 1983 into 1984. In October 1984 a cohort of patients with haemophilia in Edinburgh were identified as HTLV-III positive on testing. They had been treated solely with NHS factor concentrate (SNBTS). This information appeared to establish a firm link between NHS factor VIII Concentrate (SNBTS) and AIDS.

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

28.1. Further enquiry took the form of discussion with colleagues which kept me up to date with developing thought.

Response to risk

29. Did you or your colleagues at the Centre take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps? What information was provided to patients, and when, about such risks?

29.1. Initially advice about infective risk and blood products in the early 1980's centred around the possibility of jaundice which in most individuals was thought to be self-limiting although occasional patients were noted to have developed cirrhosis.

29.2. Initially concerns arose about a possible link between haemophilia and AIDS in the UK in 1983. These concerns focused around the use of commercial factor concentrate. A firm link however had not been established at that stage. As the Centre employed only NHS factor concentrate by that point, the perceived risk was probably underestimated in discussion with parents. As the perception of risk evolved in 1984 and 1985 around the transmission of both

hepatitis and HIV/Aids the discussion with parents took account of the new information and, in particular, developments in the production of heat treated concentrates to inactivate viruses.

30. What, if any, actions did you and/or the Centre take to reduce the risk to your patients of being infected with HIV? What changes (if any) did you make to the way in which patients were treated?

30.1. In the later part of 1983 and into 1984 the Centre was committed to the use of NHS factor concentrate as a measure to combat any possible risk between AIDS and the use of commercial concentrate.

31. Did the Centre continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why?

31.1. The possibility of switching patients to cryoprecipitate was considered in November 1984 but events in the form of the production of heat treated factor concentrate overtook the decision making process. Heat treated factor concentrate (SNBTS) was introduced in the Centre in early December 1984.

32. In a letter from Dr Perry to you dated 25 March 1988 which was included in Dr Ludlam's submission for a product licence variation for SNBTS Factor VIII Z8, the cause of a NANB hepatitis infection in one of your patients is attributed to an older generation of factor concentrate, NY, not Z8. Dr Perry writes that he presumes the old generation product has been consumed and future patients can be treated exclusively with the safer Z8 product [PRSE0000129, p 34]. Please explain:

a. When the Centre stopped using NY and the reason for doing so;

32.1. Z8 treatment commenced in this Centre in July 1987. This product appeared to have an improved safety profile and was substituted for NY. The Centre

stopped using NY after July 1987.

b. Whether surplus batches of NY continued to be used at the Centre after Z8 was available and if so why.

32.2. NY was withdrawn from use when Z8 was introduced in July 1987

c. Any further information as to why the patient received the old generation product, rather than Z8.

32.3. The patient referred to received old generation product after the introduction of Z8.

32.4. The two vials of NY Factor VIII concerned should have been returned from the Children's Haematology Laboratory to the Blood Bank (RVH) for disposal. They were mistakenly retained in stock and subsequently reconstituted for issue to the ward where they were administered by medical staff. This was an isolated error.

32.5. The patient concerned made a full recovery with return of liver function test to normal. Subsequent follow up showed no evidence of seroconversion to HCV when testing became available.

33. When did the Centre begin to use heat treated factor products and for which categories of patients? Please set out what steps were taken to obtain heat treated products. Please also set out whether steps were taken to recall any stores of unheated products which patients had.

33.1. Heat treated Factor VIII was introduced in this centre in December 1984 to cover all requirements for Factor VIII in patients with bleeding disorders. Heat treated Factor VIII was obtained from the SNBTS.

33.2. No patients were on home treatment at that time.

34. Do you consider that heat treated products should have been made available earlier? If not, why?

34.1. The HIV virus was initially identified in 1984 and a test for HIV was developed for the first time also in 1984. Against this rapidly evolving background, the SNBTS responded well in developing a heat treated product which was introduced for patient care in December 1984.

35. Did you or your colleagues at the Centre revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, how was it determined which patients would be offered a return to cryoprecipitate and which would not? If not, why not?

35.1. I considered reverting to cryoprecipitate in November 1984. A firm decision to do so was overtaken by the production of heat treated factor concentrate (SNBTS) in December 1984.

36. At the 20th meeting of the UK Haemophilia Centre Directors which was attended by you, Dr Kernoff reported that Reference Centre Directors felt that heat treated materials were safer than cryoprecipitate in terms of viral transmission [BART0002329, p3]. Did you agree with this view? Did use of cryoprecipitate and/or heat treated product change as a consequence of the discussion at this meeting?

36.1. I note the UK Haemophilia Centre Directors' recommendation in 1988 on the safety of heat treated products as opposed to Cryoprecipitate. I agreed with this recommendation based on the appreciation that heat treated products were safer. Cryoprecipitate was not in use at this Centre then and so no change in policy was necessary.

37. Do you consider that your decisions and actions, and those of the Centre in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

37.1. I believe the responses of this Centre to infection risk in blood products were adequate and appropriate. SNBTS heat treated products were introduced at the first opportunity, when they became available.

38. Looking back now, what decisions or actions by you and/or by the Centre could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

38.1. Before the advent of heat treated products the only alternative treatment policy would have been to substitute Cryoprecipitate for Factor VIII concentrate. I am not aware of any other interventions I could have undertaken. Only in October 1984 did I become aware that SNBTS FACTOR VIII might transmit HIV. A decision to revert to the use of Cryoprecipitate was overtaken by the advent of heat treated Factor VIII in December 1984

39. What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients with bleeding disorders? What, if anything, do you consider could or should have been done differently by these others?

39.1. I am not aware of any individual action clinicians known to me enacted which contributed to the scale of the infection in patients with bleeding disorders. With hindsight adherence to a policy of self-sufficiency on a nationwide basis might have reduced the scale of infection with HIV.

40. Do you consider that greater efforts could and/or should have been made to inactivate viruses in blood or blood products prior to 1980? If so, who should have made or coordinated those efforts and what steps should have been taken and when? If not, why?

40.1. With the benefit of hindsight, greater effort might have been made to investigate the possibility of viral inactivation in blood products prior to 1980. However, prior to 1980 the situation with regard to NonA NonB hepatitis was unclear and the widespread nature of the condition and its potential consequences were not appreciated.

High Purity clotting factor

41. Please explain your involvement (if any) in the debate around the use of high purity products for HIV positive patients, including any studies or investigations you took part in. You may be assisted by the following letters into which you were copied: Letter from Dr Ludlam to Professor Cash dated 9 October 1990 [PRSE0001539]; letters from Dr Ludlam to Mr McIntosh dated 19 November 1990 [SBTS0000706_223 and SBTS0000706_224] and 19 February 1991 [PRSE0003536];

41.1. I was not involved in the debate around the use of high purity products for HIV positive patients.

Recombinant

42. Please consider the enclosed guidelines from the Haemophilia Directors for Scotland and Northern Ireland on the use of Recombinant Factor VIII [PRSE0002401]. Please explain any involvement you had with efforts to obtain recombinant blood products for patients with haemophilia. What,

if any, difficulties were encountered and why?

42.1. Dr Mayne negotiated funding for recombinant material with the Eastern Health and Social Services Board.

43. In your view, should recombinants have been made available to all haemophiliacs earlier than they were? if so, when?

43.1. I feel the initial introduction date for recombinant products should have covered all patients with haemophilia.

44. In relation to the Children's Hospital, when were recombinant products made available to patients?

44.1. Recombinant products were introduced in the Children's Hospital (RBHSC) in 1997. All patients in the children's hospital had access to the new treatment.

Section 4: Treatment of patients

Provision of information to patients

45. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at the Centre with a bleeding disorder about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing? Please detail whether, and if so, how this changed over time.

45.1. Prior to treatment with blood products I discussed the benefits and risks with the patients and parents. With respect to HIV appreciation of risk was

evolving from 1983 onwards.

45.2. By mid-1983 some concern had been expressed by the UKHCDO about possible infective risk and imported commercial concentrate. No certain link however had been established at that time.

45.3. By mid 1983 the Centre employed only NHS SNBTS factor concentrate and locally produced cryoprecipitate. I saw possible risk of HIV infection as minimal at that time and parents were advised accordingly.

45.4. This situation remained the case until the late autumn October of 1984 when HIV infection was identified in a number of haemophilia patients in Edinburgh. At that stage there was no consensus about withdrawing NHS concentrate although that seemed the only possible approach to the developing situation.

45.5. That option was overtaken in early December 1984 when heat treated NHS Factor VIII (SNBTS) became available and this was immediately introduced into patient care at this Centre.

45.6. I explained the introduction of heat treated product to parents at that time. I explained that heat treatment was undertaken to inactivate any HIV virus in the concentrate.

45.7. With respect to Hepatitis in the early 1980s, I explained the situation in relation to Hepatitis B and Non A Non B Hepatitis. In the case of Hepatitis B infections had occurred in the 1970s but with the introduction of donor testing this had largely, but not entirely, been eliminated as a risk. In the case of Non A Non B Hepatitis in the early 1980s it was known that some patients had developed jaundice and Hepatitis in relation to blood products. Occasional patients had developed persistent Hepatitis and very occasional patients developed cirrhosis. By the mid-1980s the risk was known to be greater but still thought to occur in a minority of patients.

45.8. Mild disturbances of liver function were known to occur in some patients, the

full significance of which was not appreciated at that time. All of this information was explained by me, the emphasis changing as the perceived risk increased.

46. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients about alternatives to treatment with factor concentrates? Please detail whether, and if so, how this changed over time.

46.1. For patients with Von Willebrands disease and mild haemophilia A the possibility of treatment with D.D.A.V.P. existed. Cryoprecipitate too was an alternative treatment for these patients in certain circumstances. This was explained to the parents of these children.

46.2. Cryoprecipitate had been used in some children with moderate haemophilia up to 1983 in the Centre. This had been changed to SNBTS Factor 8 in that year for them. This was explained to the parents of these children by me. My reservation about the use of Cryoprecipitate in children with moderate haemophilia is described under question 15.

47. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients before they began home treatment/home therapy?

47.1. In the case of children starting home treatment the infective risks as under my answer to Question 45 were explained. Extensive education around the administration of Factor VIII was provided in oral and written form. Advice around which bleeds were suitable for home treatment, and which bleeds required hospital attendance, was given. Advice around hygiene and the importance of avoiding needle stick injury was emphasised to parents giving injections.

HIV

48. When did you first discuss AIDS or HIV (HTLV-III) with any of your patients?

48.1. AIDS concerns were first addressed in 1983. Concerns were discussed at routine review appointments and also when patients attended with intercurrent-bleeding problems.

49. Please describe how and when you learned that patients under your care/the care of the Centre had been infected.

49.1. No patient under the care of the Centre when testing was introduced in early 1985 was shown to be HTLV-III positive. I was aware that relatives of these patients attending the adult centre might prove to have positive test results although no details were known to me for reasons of strict confidentiality.

50. Please describe the arrangements that were made for the testing of the patients. Were they tested without their knowledge? What if any arrangements were made at the Centre for pre-test counselling?

50.1. Patients' parents were contacted by me by letter in early 1985 (March) when testing became available for HIV. An early appointment was provided. I saw the parents myself and arranged a blood test for the child concerned. Patients were not tested without the parents' knowledge and consent. Parents were advised about the need for testing by me. The implications of a positive test were explained. No separate psychology input was available.

51. How and when and by whom were patients told that they had been, or might have been, infected with HIV? Were they told in person, by letter

or by phone? Were they seen individually or in groups? What if any involvement did you have in this process?

51.1. Parents were advised by letter of the need for a child's test. The parents were seen by early appointment. I discussed the implications of a positive test with each. A blood sample was obtained. All of the tests proved HTLV-III negative. Parents were advised of the result by letter. If they wished to discuss the result in person I was happy to arrange a further appointment at that time.

52. What information was given to them about the significance of a positive diagnosis? Were patients told to keep their infection a secret?

52.1. This question relates to positive tests for HTLV-III. No positive tests for HTLV-III were recorded at this Centre.

53. What was the Centre's/your policy in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were the tests carried out?

53.1. Please see under question 52

54. What, if any, information or advice was provided by you or colleagues at the Centre to partners or family members of people who were at risk of infection with HIV or were infected with HIV?

54.1. Please see under question 52

55. What if any arrangements were made at the Centre for post-test counselling?

55.1. Please see under question 52.

56. How many patients (if any) at the Centre were infected with HIV in consequence of the treatment with blood products? Of those infected,

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

f. How many were children?

56.1. Please see under question 52

57. Was work undertaken at the Centre to establish the time period during which patients seroconverted? If so, please describe what work was done and what if any conclusions were reached.

57.1. Please see under question 52

Hepatitis B

58. Were patients infected with hepatitis B in consequence of their treatment with blood products informed of their infection and if so, how? What information was provided to patients infected with hepatitis B about the infection, its significance, prognosis, treatment options and

management? What if any involvement did you have in this process?

58.1. No paediatric patients were infected with Hepatitis B at the Centre.

59. How many patients at the Centre were infected with hepatitis B?

59.1. No paediatric patients were infected with Hepatitis B at the Centre.

NANB Hepatitis/Hepatitis C

60. Were patients infected with NANB hepatitis informed of their infection and if so, how and by whom? What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management? What if any involvement did you have in this process?

60.1. Non A Non B Hepatitis was diagnosed by the presence of a raised bilirubin level, jaundice and significantly raised liver enzyme levels.

60.2. If a child showed evidence of Non A Non B Hepatitis I saw the parents and explained the findings to them. In the early 1980s I would have been optimistic about complete recovery though emphasising that a small number of patients could have a continuing infection with long term liver damage. By the mid 1980s it was apparent that Non A Non B Hepatitis carried a more serious outlook and the possibility of progression over time was emphasised. No certain treatment to eradicate the viral infection was then available.

61. When did the Centre begin testing patients for hepatitis C and over what period of time were such tests first carried out? How, when and by whom were patients informed of their diagnosis of hepatitis C? Were

they told in person, by letter or by phone? What if any involvement did you have in this process?

61.1. Hepatitis C testing began at this Centre in 1992.

61.2. Parents were asked to attend with their child for testing by appointment. The reason for testing was explained in that letter and later fully explained by me in person.

61.3. Results of the tests were communicated by post. Those with a positive test result were given a prompt appointment at which time I explained the positive finding and its significance.

61.4. Those with a negative finding were notified by post and parents who wished to see me were invited to phone for an appointment. Testing and discussion continued over a period of about six weeks. All the parents given an appointment kept that appointment and all consented to have their child tested.

62. What information was provided to patients infected with hepatitis C about their infection, its significance, prognosis, treatment options and management?

62.1. When I saw the parents of children with a positive result I discussed the chronicity of the condition and the definite probability of progression over an extended period of time to permanent liver damage and cirrhosis which could ultimately be life threatening.

62.2. Interferon was under investigation in the early 1990's for treatment of Hepatitis C infection in patients with haemophilia. Treatment with Interferon had side effects and was not at that stage of proven efficacy. There was at that time no paediatric hepatologist in the Children's Hospital to allow the establishment of a joint clinic. I felt that it would not be appropriate to initiate

treatment at that point but to await therapeutic developments. This I explained to the parents.

62.3. See further under my answer to Question 90.

63. When the test for HCV became available, what if any steps were taken by the Centre and/or by you to ensure that all patients who had received blood products were traced and invited to be tested?

63.1. When Hepatitis C testing became available all patients attending the Children's Hospital with an inherited bleeding disorder were contacted through their parents by post. I personally oversaw that process and was satisfied that testing was complete for the patient cohort.

64. How many patients at the Centre were infected with hepatitis C in consequence of their treatment with blood products?

64.1. Testing for Hepatitis C revealed that 8 paediatric patients attending the Centre had been infected through exposure to blood products.

Delay/public health/other information

65. Were the results of testing for HIV and hepatitis (of all kinds) notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

65.1. The results of HIV and hepatitis C testing were notified promptly to the parents of children by post. Where a positive HCV result was identified the parents were given an early appointment to see me in person. No child was identified as HIV positive.

66. To what extent, if at all, did you/your colleagues take into account the public health implications of HIV, AIDS, hepatitis B, NANB hepatitis and hepatitis C, when taking decisions as to what information or advice to provide to patients or what treatment to offer patients?

66.1. The possibility of transmission of hepatitis C from contact with contaminated blood was discussed with the parents concerned. It was emphasised that reasonable hygiene precautions at all times should reduce that risk significantly.

66.2. Parents undertaking home treatment were reminded to avoid needle stick injury when injecting factor VIII. Parents were advised that dental care and surgery should be undertaken in the Children's Hospital. Staff in the Centre were reminded that Dentists and Surgeons should be informed prior to undertaking procedures on infected individuals.

66.3. No child was noted to be HIV positive.

67. What information was provided to patients about the risks of other infections?

67.1. The risk of infections other than hepatitis A, B and C and HIV/Aids was not discussed.

68. What information was provided to patients about the risks of infecting others?

68.1. The risk of transmission of infection to others was discussed in detail with the parents of infected children. Specific details are included in my answer to question 66.

Consent

69. Please consider item eight of the enclosed minutes of the 27th meeting of the UK Haemophilia Centre Directors which you attended; the Directors discussed the issue of informed consent and were unable to reach a consensus [HCDO0000495, p4]. What was your view in relation to patient consent and the need for informed consent?

69.1. My view at the UKHCDO Meeting in September 1995 was that signed informed consent should be obtained for all blood products given to patients with hereditary bleeding disorders prior to administration.

70. How often were blood samples taken from patients attending the Centre and for what purposes? What information was given to patients about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of the samples? Was their consent recorded and if so how and where?

70.1. Blood samples were taken from patients attending for review at 6 monthly intervals. Tests were taken for full blood picture creatinine and electrolytes along with liver function tests. Blood was also taken for viral antibody screening to include Hepatitis C, HIV and HBsAg. A sample was also taken for anti-HBS post Hepatitis B vaccination. A sample was routinely taken to screen for the possible presence of an inhibitor to Factor VIII.

70.2. Parents were informed of the need for all tests and their nature prior to sampling. Consent was not recorded. Samples were not taken for storage.

71. Did the Centre have a bank of stored samples? If so, was that storage undertaken with patients' knowledge and consent?

71.1. The Centre did not have a bank of stored samples.

72. Were patients under your care or under the care of your colleagues at the Centre treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent to treatment? Was their consent recorded and if so how and where?

72.1. Children were never given factor concentrate or any other blood product without parental consent. I personally took consent after detailed discussion around possible risk factors. This was recorded in the patient's notes.

72.2. After 1995, and as I recall for 2 to 3 years before, parents were asked to sign a specific internal consent form prior to the use of blood products.

73. Were patients under your care ever tested for HIV or hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent for testing? Was their consent recorded and if so how and where?

73.1. No patient was ever tested for HIV or HCV without consent. Consent was obtained verbally after discussion. The parents' consent was recorded in the patient's notes.

73.2. Parents were always made aware that routine monitoring at 6 monthly follow up reviews for Haemophilia included viral screening for HIV and HCV.

PUPS

74. Please detail all decisions and actions taken at the Centre by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS).

74.1. With relation to Previously Untreated Persons (PUPS) those with mild haemophilia A or Von Willebrands disease were treated with DDAVP or cryoprecipitate where appropriate. Moderately or severely affected patients received factor concentrate as necessary. To limit donor exposure we would aim to set aside one batch of factor for their regular use. Later Z8 Factor VIII was employed when it became available.

75. The minutes of the 29 September 1988 UKHCDO meeting [BART0002329] record that directors were encouraged to enter PUPS into a study of 8Y/9A, and that Dr Hill thought that parents should be encouraged to enter their children. Were any of your patients involved in this study, either before or after the meeting? If so, were any of them PUPS?

75.1. No patients of mine were entered into the study of 8Y/9A mentioned in the minutes of the 29th September 1988 UKHCDO Meeting.

Look back

76. The enclosed documents concern an investigation conducted by you into the possible infection of a patient with HCV as part of the national HCV look back programme [NIBS0001218[1]]. Please explain your involvement generally in this investigation.

76.1. I was contacted in July 1996 by Dr C Bharucha of the Northern Ireland Blood Transfusion Service. In her subsequent letter she advised me of a patient who received a platelet transfusion from a donor who subsequently proved positive for HCV. I was asked to see the parents of the child for counselling and arrange to take a blood sample from the child for testing.

76.2. I wrote to the parents. In my letter I outlined the need to see them and the

patient and the reason for making an appointment. On the 10th of July 1996 I saw the patient and the parents. I counselled the parents about the risk of the patient having contracted Hepatitis C. I described the condition and the potential for long term complications. With their permission a blood sample was taken and referred for Hepatitis C testing. This proved negative. I wrote to the parents with the result. They were invited to return if they had any further questions. I advised Dr Bharucha of the result.

77. Did you counsel all of your patients who had been infected, yourself? If so, please provide details.

77.1. I was not advised of any other patient involved in look back exercises.

78. Please describe, as far as you are able, any other look back exercises you were involved in to trace recipients of blood products from donors that were later known to be infected with HIV, HBV, HCV or any other blood borne infection.

78.1. I was involved in no other look back exercises involving recipients of blood products from donors later noted to be infected with HIV, HBV or HCV. For vCJD infection please see answer to Question 108.

Research

79. The enclosed April 1991 memorandum from JK Smith [BPLL0005964] refers to a practice whereby the Protein Fractionation Laboratory provided certain products, mostly free of charge to a number of clinicians, on the understanding that clinical data would be provided in return. Please also consider the report on antithrombin III Clinical Efficacy [BPLL0016048_002]. You were included on the list of product users and clinicians providing data. Please explain in detail the nature of the arrangement described by JK Smith and your involvement in the

practices.

79.1. I note that my name was included as a clinician providing data on the clinical safety and efficacy of Antithrombin III to BPL. In fact I did not have occasion to employ Antithrombin III in my practice and provided no data relating to it. I employed no product on the understanding that clinical data would be provided in return.

80. Please list all research studies that you were involved with during your time as a consultant at the Centre insofar as relevant to the Inquiry's Terms of Reference, and please:

a. Describe the purpose of the research;

b. Explain the steps that were taken to obtain approval for the research;

c. Explain what your involvement was;

d. Identify what other organisations or bodies were involved in the research;

e. State how the research was funded and from whom the funds came;

f. State the number of patients involved;

g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent;

h. Provide details of any publications relating to the research.

80.1. I was involved in no research studies relevant to the Inquiry during my time as a consultant.

81. Please provide the same details in relation to any epidemiological or similar studies in which you were involved, insofar as relevant to the Inquiry's Terms of Reference.

81.1. I was involved in no epidemiological studies relevant to the inquiry during my time as a consultant.

82. Were patients involved in research studies without their express consent? If so, how and why did this occur?

82.1. No, I was not involved in research studies.

83. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose without their express consent? If so, what data was used and how and why did this occur?

83.1. No patient data was used for research.

84. Was patient data (anonymised, de-identified or otherwise) shared with third parties without their express consent? If so how, and why did this occur, and what information was provided to whom?

84.1. Patients with hereditary bleeding disorders were routinely registered with the UK Haemophilia Centre Directors Organisation. The patient's name, investigations and diagnosis of the bleeding disorder would be provided. Subsequently the amounts of blood product usage would be provided to the UK Centre in Oxford for each patient.

84.2. In the 1980s I recall this data would be sent without requesting the patients' consent as was the practice at that time. Later the UKHCDO stipulated that

patient consent should be obtained before such data was forwarded. I adhered to that stipulation. I cannot remember when that requirement was introduced.

85. Please provide details of any articles or studies that you have published insofar as relevant to the Inquiry's Terms of Reference.

85.1. I authored no articles or studies relevant to the Inquires Terms of Reference.

Treatment of patients who had been infected with HIV and/or Hepatitis

86. How was the care and treatment of patients with HIV/AIDS managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?

b. What treatment options were offered over the years to those infected with HIV?

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?

86.1. No patients with HIV/Aids were diagnosed at this Centre.

87. How was the care and treatment of patients with hepatitis B managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?

b. What treatment options were offered over the years?

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

87.1. No patients with Hepatitis B were diagnosed at this Centre.

88. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis B?

88.1. No patients with Hepatitis B were diagnosed at this Centre.

89. How was the care and treatment of patients with NANB hepatitis managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?

b. What treatment options were offered over the years?

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

89.1. Only one patient was diagnosed at the Centre with an episode of overt non-A non-B hepatitis. The patient recovered fully with return of liver function tests to normal. Subsequent HCV testing proved negative. No specialist consultation was arranged as there was no paediatric hepatologist in post in the Children's Hospital at that time. The parents had been advised that the initial episode might give rise to ongoing liver problems. A policy of follow up was advised. No specific treatment was suggested as none existed.

90. How was the care and treatment of patients with hepatitis C managed

at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?

b. What treatment options were offered over the years?

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

90.1. There was no post of paediatric hepatologist in the Children's Hospital in the 1990s to allow local referral.

90.2. Early treatment for HCV was with Interferon alone. This was initially licensed in November 1994. It was associated with side effects and proved relatively ineffective at clearing the virus on a permanent basis.

90.3. Later in mid-decade (1996) the combination of Interferon/Ribavirin was introduced. This again was associated with significant side effects though with somewhat better results for permanent clearance of virus.

90.4. Side effects of the Interferon/Ribavirin combination included nausea, flu like symptoms, depression and visual problems.

90.5. By 1996 half of the Centre's cohort of HCV infected patients had been referred to the Adult Centre. The remaining patients were due for referral in the following 18 months at age 14 years. I was unhappy to introduce a treatment regime which had significant side effects in a paediatric group of patients without specialist hepatology input. On balance I preferred to recommend postponing treatment until after referral to the Adult Centre where increasing experience with combination treatment had been acquired.

90.6. This approach was explained to the parents of affected children.

90.7. None of those children who were HCV positive were clinically unwell or showed more than minimal derangement of liver function.

90.8. All children who were HCV positive had been referred to the Adult Centre by 1998.

91. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis C?

91.1. Children infected with Hepatitis C were followed every 4 months at the Haemophilia follow up clinic. They were monitored clinically and liver function tests performed at each review. No imaging studies were performed.

91.2. These children were referred to the adult unit at age 14. All had been referred to the adult unit by 1998.

92. Did arrangements for the care and treatment of children infected with HIV or hepatitis differ (if at all) from the arrangements made for adults? If so how?

92.1. Children only were seen at the Centre in the Royal Belfast Hospital for Sick Children.

93. What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?

93.1. Children infected with HCV and parents were seen at the children's

haemophilia follow up clinic every 4 months. Time was available to discuss any questions the parents may have had about hepatitis C with myself. No access to a specialist psychology service was available. Social Work support was available from the Unit's Social Worker who divided her working time across the totality of the Unit's clinical workload.

94. Did the Centre receive funding from the Department of Health and Social Security or from any other source to help with the counselling of patients infected with HIV?

95.1. The Centre did not receive specific funding from any source for help with counselling parents of patients with Hepatitis C. No children with HIV were diagnosed in the Centre.

95. What (if any) difficulties did you/the Centre encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or hepatitis C?

95.1. No application was made for funding of treatment for patients with HIV or Hepatitis C.

96. What if any involvement did you or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

96.1. No patients from the Centre were entered into clinical trials of treatment of HIV or Hepatitis C.

Records

97. What was the Centre's policy with regards to recording information on death certificates when a patient had been infected with HIV or hepatitis? Were you involved with any inquests in relation to patients who had been infected with HIV or hepatitis in consequence of their treatment? If so, please provide details.

97.1. No deaths of children infected with Hepatitis C occurred at the Centre. No children infected with HIV were diagnosed at the Centre.

98. What were the retention policies of the Centre in regards to medical records during the time you were practising there?

98.1. Medical records were retained within the Centre whilst the child attended. After the child had been referred to the adult unit the medical record would be returned to medical records within the Children's Hospital. Older records would usually be sent for storage in larger premises located offsite.

99. Did you:

a. Maintain separate files for some or all patients? If so, why; where were those files located; and where are those files now?

b. Keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere other than the Centre? If so, why, what information and where is that information held now?

99.1. No separate files were maintained.

99.2. No records relating to patients were kept at my home.

100. Do you still hold records or information about any of your patients? If so, explain why and identify the records or information that you still hold.

100.1. I hold no records on any of my previous patients.

Section 5: UKHCDO

101. Please describe your involvement with UKHCDO (including any of its working parties, committees or groups). Did you usually attend the annual general meetings?

101.1. I was a member of the UKHCDO. I recall I attended many of the annual meetings. I was not a member of any of the working groups or committees.

102. During the period that you belonged to UKHCDO, please outline:

a. **The purpose, functions and responsibilities of UKHCDO, as you understood them.**

b. **Any involvement which you had in the development of policies or advice by UKHCDO which are relevant to the Inquiry's Terms of Reference.**

c. **How information or advice was disseminated by UKHCDO and to whom.**

102.1. The purpose of the UKHCDO was to bring together consultants responsible for the care of patients with inherited bleeding disorders. Their aim was to further understanding of the diagnosis and management of these conditions and to establish a consensus as to best practice in the field. The UKHCDO maintained a patient register which allowed for the accurate collection of information relating to the numbers of affected individuals in the UK. Collection of data relating to the use of blood products allowed for the recognition of increased usage and planning for likely future needs.

102.2. Some investigational work was also undertaken but I was not involved in this.

102.3. I was not involved in the formulation of policy.

102.4. Information was disseminated to members in the annual minutes and where necessary by the provision of interim advice in written form. Nursing, Social Work and Psychology Groups were later established in relation to the UKHCDO and reported at each AGM.

Section 6: Pharmaceutical companies/medical research/clinical trials

103. Have you ever:

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

103.1. I have never provided advice or consultancy services to any pharmaceutical company.

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

103.2. I have never received any pecuniary gain for such work.

c. Sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?

103.3. I have not sat on any advisory panel, board, committee or similar body of any pharmaceutical company.

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

103.4. I have never received financial incentives from pharmaceutical companies to use certain blood products.

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

103.5. I have never received non-financial incentives from pharmaceutical companies to use certain blood products.

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

103.6. I have never received funding to prescribe supply recommend, buy or sell any blood product.

g. Undertaken medical research for or on behalf of a

pharmaceutical company involved in the manufacture or sale of blood products?

103.7. I have never undertaken research on behalf of any pharmaceutical company.

h. Provided a pharmaceutical company with results from medical research studies that you have undertaken?

103.8. I have never provided a pharmaceutical company with results from medical research.

104. What regulations or requirements or guidelines were in place at the time 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?

104.1. The UKHCDO at some point did introduce a requirement for members to declare any outside interest including shareholdings in pharmaceutical companies. I fully complied with the request for declaration.

104.2. At a local level any involvement with pharmaceutical companies would have required disclosure to hospital management. I had no occasion to make any declaration to local hospital management.

105. If you did receive funding from pharmaceutical companies for medical research, did you declare the fact that you were receiving funding and the source of the funding to your employing organisation?

105.1. I received no funding for medical research from pharmaceutical companies.

Section 7: vCJD

106. Please consider the enclosed letter from Dr Frank Hill addressed to UKHCDO Directors regarding vCJD notification [BART0000916]. Please confirm whether you received this letter? When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products?

106.1. I note the letter from Dr Hill UKHCDO Chairman dated the 19th January 2001. I can confirm that I received this letter.

106.2. From memory I believe I became aware of the possible risks of transmission of VCJD associated with the use of blood products in 1997.

107. On 14 February 2001 a letter from Drs Anderson, Jones and McMullin addressed to all consultant haematologists and the Northern Ireland Haematology Audit Group announced an urgent review of antithrombin III (ATIII) use due to the cost and the risks of transfusion-transmitted infections, highlighting the recent notification that plasma from a donor infected with vCJD was fractionated into a batch of ATIII and other products which was used in a number of Northern Ireland patients [BHCT0002591]. Did you receive this letter? If so what actions did you/the Centre take in response?

107.1. I note the letter of 14th February 2001 from Dr Anderson et al regarding the use of Antithrombin III.

107.2. I did not employ Antithrombin III in my paediatric practice. I did not know of any instances where it had been used in the Children's Hospital.

108. Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so please answer the following questions (you may be assisted by the enclosed letter from Dr Anderson to Dr Carson which was copied to you, where Dr Anderson explains the approach you jointly decided to take regarding notification of patients exposed to vCJD [DHNI0000049_036], and the questionnaire completed by you regarding possible vCJD infection [HSOC0004250]):

a. What steps were taken to inform patients about possible exposure to vCJD and to provide information to them about vCJD?

b. What steps were taken to arrange for counselling, support and/or advice to be offered to patients who were being informed that they might have been exposed to vCJD?

108.1. I note Dr Anderson's letter dated 22nd January 2001. In relation to this notification in 2001, Dr Anderson and I took the decision to notify those who had received possibly infected blood products of the fact. In the case of paediatric patients this meant informing the parents. I wrote to the parents concerned explaining the situation and enclosing information about vCJD. An appointment was made for each to be seen in the next 1 to 2 weeks by myself.

108.2. Each parent concerned was seen by me. Information and advice was provided at that appointment. I undertook to see the parents concerned again at the next Haemophilia review clinic or earlier if they expressed a wish to talk about the issues raised after they had thought through the implications. I was supported by the units Social Worker in this respect. Specialist psychology support was available if I or the parents concerned requested it.

108.3. In relation to a further vCJD notification in 2004 parents were given a choice about knowing if their child had been exposed to an implicated batch. Most asked to be informed. The counselling process followed that outlined above for the earlier notification.

109. What measures were put in place at the Centre from a public health perspective, in relation to the care and treatment of patients? If patients at the Centre were identified as at risk for public health purposes, did that impact detrimentally upon them in terms of their ability to access treatment and care (whether at the Centre or elsewhere?).

109.1. It was decided advice around public health measures would apply to all patients attending the Centre who had been exposed to treatment with blood products.

109.2. The dental department was informed and a list of patients provided; the list to remain confidential. The dentists concerned had been provided with information around precautionary measures to be taken.

109.3. Liaison was established with the surgery department in the Children's Hospital. They had been advised of appropriate measures to be taken around level of risk with various operative procedures. Protocols for the care of operative instrumentation had been received.

109.4. Arrangements for children requiring surgery were in place for the parents to liaise with the Centre prior to surgery and for surgery to be carried out exclusively in the Children's Hospital. Permanent medical staff covering the Centre were aware of the list of patients previously treated with blood products and patients on this list presenting for surgery and coagulation factor cover would be notified to the surgeon concerned.

109.5. All parents with children who had been treated with blood products were informed of these precautions regardless of whether they had received implicated batches. This was because further notifications were anticipated in the future. The patients' GPs were informed of these arrangements by letter.

109.6. None of these arrangements impacted adversely on the patients concerned accessing appropriate care.

Section 8: The financial support schemes

110. What if any involvement did you have with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund, EIBSS) which were set up to provide financial support to people who had been infected?

110.1. No patient tested in the Centre was diagnosed as HIV positive.

110.2. All patients with Hepatitis C had been referred to the Adult Centre by the time the Caxton and Skipton Funds became operative.

111. To what extent, during your time at the Centre, did staff (including you) inform patients about the different trusts or funds?

111.1. Please see under 110.

112. At the 29 September 1988 UKHCDO meeting [BART0002329, p2], Directors were asked to encourage registration with the Macfarlane

Trust. What if any steps did you/the Centre take in response?

112.1. Please see under 110.

113. Did the Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

113.1. Please see under 110.

114. What kind of information did the Centre provide to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?

114.1. Please see under 110.

115. Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of your patients in relation to the trusts or funds, do you consider that the trusts and funds were well run? Do you consider that they achieved their purposes? Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

115.1. Please see under 110.

Section 9: Other Issues

116. Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

116.1. No complaints have been made about me as far as I am aware to my employer, the GMC or any other body (in so far as is relevant to the Inquiries Terms of Reference).

117. Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.

117.1. I know of no further matters that I believe are relevant to the Infected Blood Inquiry.

Statement of Truth

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

Signed GRO-C

Dated 2nd Sept 2021.