Witness Name: Dr Jonathan Thornton Wilde
Statement No.: WITN3086011
Exhibits: WITN3086012- WITN3086014
Dated: 15 September 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DOCTOR JONATHAN THORNTON WILDE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 15 July 2020.

I, Dr Jonathan Thornton Wilde, will say as follows: -

Section 1: Introduction

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

   My name is Dr Jonathan Thornton Wilde of GRO-C GRO-C. I was born on GRO-C 1954. My qualifications are as follows: MB and BChir (CANTAB 1979), MA (CANTAB 1980), MRCP (1984), MD (CANTAB 1988), MRCPath (1991), FRCPath (1996). I retired from all clinical practice in August 2016.

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

   Previous positions.
   -Registrar in Haematology, Northern General Hospital, Sheffield November 1984 to October 1986.

-Lecturer in Haematology, Royal Hallamshire Hospital, Sheffield October 1986 to October1988.
-Senior Registrar in Haematology, Royal Liverpool Hospital, November1988 to November 1992.
-Consultant in Haematology with specialism in Haemostasis and Thrombosis and director of the Haemophilia Service, Queen Elizabeth Hospital Birmingham, November 1992 to August 2016.

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.*

I was a member of the UK Haemophilia Doctors Organisation from 1992 to 2016, a member and secretary of the UKHCDO transfusion transmitted infection working party throughout the life of this group from about 1996 to 2010. I was a member of the UK Haemophilia Alliance from its instigation in 2000 and subsequent co-chairman from around 2007 until the disbandment of this group around 2012.

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

I have not been involved in any other inquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or Creutzfeldt-Jakob disease ("CJD") in blood and/or blood products.

5. *The questions below focus, as appropriate, on your time as a consultant at, and director of, the haemophilia service in Birmingham. Some questions are also directed towards your earlier experiences as a registrar (and later lecturer) in haematology in Sheffield and as a senior registrar in Liverpool. If you have information concerning Sheffield and/or Liverpool which is not covered by those questions, but which is relevant to the questions posed in relation to Birmingham and/or to the broader issues being investigated by the Inquiry, please include that*

information in your response.

I think it is prudent to set out that I have not had access to any medical records answering these questions. I was sent a number of documents by the Infected Blood Inquiry, to assist with this Rule 9 General Request, however they are only helpful in respect of some questions relating to specific dates. I have done the very best I could to answer all questions posed, however due to the passage of time (some questions date back to a time almost 40 years ago) I have not been able to recall or recollect events, including some or all details requested. I should like to preserve my position in that regard, should further information become available at a later date.

Section 2: Employment in Sheffield and Liverpool

6. *In relation to your work in Sheffield as a registrar in haematology at Northern General Hospital between November 1984 and October 1986, please:*

   a. *describe your role and responsibilities and how they changed over time;*
   b. *describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products;*
   c. *identify senior colleagues involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products, and their roles and responsibilities during the time that you worked there.*

   a). As a registrar in haematology at the Northern General Hospital Sheffield, I had no involvement in patients with bleeding disorders as the hospital was not a designated centre for the care of this group of patients. I have therefore disregarded further questions relating to this post (questions 6 (b-c) inclusive)

7. *In relation to your work in Sheffield as a lecturer in haematology at Royal Hallamshire Hospital between October 1986 and October 1988, please:*

   a. *describe your role and responsibilities and how they changed over time;*
   b. *describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products;*

c. *identify senior colleagues involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products, and their roles and responsibilities during the time that you worked there.*

(Questions (a-c) inclusive). As lecturer in haematology at the Hallamshire Hospital Sheffield, I was given the responsibility of running the weekly Haemophilia Clinic with the haemophilia Sister. I would review patients with haemophilia on a regular basis assessing their bleeding pattern, their treatment regimens and their joint health. I would monitor patients with HIV infection and chronic viral hepatitis and manage any clinical problems as they arose. Although I had no direct responsibility for the day to day clinical care of bleeding disorder in-patients, I would be in primary charge of their care when I was on call.

My supervising consultants were Professor Eric Preston, director of the haemophilia centre and Dr Mike Greaves, consultant haematologist. I would consult with them with regard to management decisions concerning the bleeding disorder patient cohort. Hepatitis related issues were referred to Dr David Trigger, consultant hepatologist. I cannot recall the name of the consultants who advised on HIV related issues.

8. *In relation to your work in Liverpool as a senior registrar in haematology at Royal Liverpool Hospital between November 1988 and November 1992, please:*

   a. *describe your role and responsibilities and how they changed over time;*
   b. *describe your work insofar as it involved the care of patients with bleeding disorders and/or the patients infected with hepatitis and/or HIV in consequence of blood or blood products;*
   c. *identify senior colleagues involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products, and their roles and responsibilities during the time that you worked there.*

a). As rotating senior registrar in haematology at the Royal Liverpool Hospital, I attended the haemophilia clinic run by Dr Charles Hay, director of the centre as an observer for several months towards the end of my rotation after I passed my MRCPath exam and expressed an interest in specialising in the care of patients with bleeding disorders.

b). As this was a consultant led service, I recall having little input into direct clinical care decisions in patients with bleeding disorders apart from those who were inpatients when I was attending the ward during the rotation or when I was on call.
c). Apart from Dr Hay I cannot recall any other senior colleagues involved in haemophilia care, in particular those consulting on hepatitis and HIV related issues.

9. *To the best of your knowledge, what policies were formulated at (a) Northern General Hospital, (b) Royal Hallamshire Hospital and (c) Royal Liverpool Hospital regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked at each? What if any involvement did you have in the formulation and application of these policies?*

I have no recollection of the policies that were in place at the Royal Hallamshire and Royal Liverpool Hospitals for the selection and purchase of blood products. Presumably there were standard procedures in place for the appropriate use of factor concentrates for the treatment of bleeds in hospital and in the home setting, but I cannot recall these specifically. I would have had some involvement in the correct implementation of these policies at the Royal Hallamshire Hospital and to a lesser extent at the Royal Liverpool Hospital.

10. *Who had responsibility at (a) Northern General Hospital, (b) Royal Hallamshire Hospital and (c) Royal Liverpool Hospital for the selection and purchase of blood products and what decisions were taken at each as to which products to purchase and use? In addressing this issue please answer the following questions:*

    a. *How and on what basis were decisions made about the selection and purchase of blood products and how did those decisions change over time?*
    b. *What were the reasons or considerations that led to the choice of one product over another?*
    c. *Where were the products sourced and from whom were they purchased?*
    d. *What role did commercial and/or financial considerations play?*
    e. *What if any involvement did you have?*

My understanding was that Professor Preston and Dr Hay would have had responsibility for the selection and purchase of blood products at the Royal Hallamshire and Royal Liverpool Hospitals respectively. I had no involvement in this

process at either hospital and I am therefore unable to address the questions asked (a-e inclusive)

11. *What products were used for treating patients at (a) Northern General Hospital, (b) Royal Hallamshire Hospital and (c) Royal Liverpool Hospital, over what period of time and for which categories of patients? How were decisions taken at each hospital as to which products to use for individual patients? What involvement did you have in such decisions? What if any discussions took place with patients as to the choice of products?*

    I only have a vague recollection of the names of factor concentrates used around that time but cannot recollect which ones were used and/or in what proportions at either haemophilia centre. I would not have had direct involvement in the choice of product for individual patients nor in the discussions that took place with them with regard to this. The process would have been consultant led.

12. *What was the relationship between (a) Northern General Hospital, (b) Royal Hallamshire Hospital and (c) Royal Liverpool Hospital, and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions referred to above?*

    I am unable to comment on this as the relationships would have been at consultant level.

13. *What alternative treatments to factor concentrates were available for people with bleeding disorders? What were, in your view, the advantages and disadvantages of those alternative treatments? What use was made of them at the three hospitals referred to above?*

    As factor concentrate treatment was well established at the time, and I was involved in the care of haemophilia patients in Sheffield and Liverpool I cannot recall ever having the need to use cryoprecipitate for the treatment of haemophilia A or von Willebrand Disease. The only other alternative treatment I can think of is desmopressin in the treatment of bleeds in patients with mild Haemophilia A and type I von Willebrand Disease, to elevate von Willebrand factor and factor FVIII levels. On the whole, this was a very effective treatment in these patient groups and as far as I am aware it was used appropriately at both the Royal Hallamshire and Royal Liverpool

Hospitals. The main disadvantage was that the effect of the drug tended to wear off if several doses were required close together and it could potentially cause water retention. I cannot recall extensive use of tranexamic acid in either centre at that time.

14. *What was the policy and approach at (a) Northern General Hospital, (b) Royal Hallamshire Hospital and (c) Royal Liverpool Hospital in relation to:*

    a. *the use of cryoprecipitate for the treatment of patients with bleeding disorders;*
    b. *home treatment;*
    c. *prophylactic treatment;*
    d. *the use of factor concentrates for children?*

    Please set out whether and if so how the policy and approach in relation to each of the above changed over time.

    a). As mentioned above I cannot recall the use of cryoprecipitate at either centre.
    b). Patients who were able to self-infuse factor and use it appropriately were enrolled on home treatment programmes at both centres and although I cannot specifically recall the numbers on home treatment, they are likely to have increased with time.
    c). At the time I was at the Royal Hallamshire and Royal Liverpool Hospitals prophylactic treatment to prevent bleeds was yet to become an established treatment strategy and I cannot recollect any patients being treated in this way.
    d). I was not involved in the treatment of children as both centres cared for adults only.

15. *To what extent, and why, were people with mild or moderate bleeding disorders treated with factor concentrates at each of the three hospitals referred to above?*

    As patients with mild and moderate haemophilia have a far lower propensity to bleed compared to those with severe haemophilia they would tend to present infrequently for the treatment of bleeds. Those with mild haemophilia A under 70 years of age would be treated with desmopressin and those with moderate and mild haemophilia A and B and older mild A patients would be given appropriate factor concentrate.

Section 3: Decisions and actions of the Haemophilia Centre at Queen Elizabeth Hospital ("QEHHC") and my decisions and actions at the QEHHC

16. *Please describe the facilities, organisation, roles, functions and responsibilities of the QEH Haemophilia Centre ("QEHHC") from 1992 to 2016.*

When I took up post as director of the West Midlands Bleeding Disorder Service in November 1992, I was single handed with one clinical nurse specialist, two staff nurses (1.5 whole-time equivalents), one community sister, one social worker and the unit secretary. The centre was located in two rooms, one clinical room and one office on the third floor of the Queen Elizabeth Hospital, Birmingham. Outpatient clinics for bleeding disorder patients were held on a Thursday morning once weekly in the haematology outpatient clinic. Patients would be seen by myself and a rotating haematology registrar. Walk-in patients with acute bleeds or other issues were seen in the unit clinical room by either myself, the rotating haematology registrar or one of the unit nurses. In-patients were cared for on the haematology ward East 3A. In time an extra sister was appointed in 1995, a second haemostasis consultant in 2005 and a third consultant in 2015.

The unit moved to new premises in 2012 in the old QEH oncology chemotherapy suite and comprised two consulting rooms, a treatment room, a general office and a counselling room. Unit staff liaised closely with regard to patient management decisions. The focus of the working week was the Thursday lunchtime meeting at which all patient issues that had arisen the previous week were discussed and appropriate actions decided upon. Treatment protocols for patients with upcoming surgery and other interventional procedures were discussed and agreed by the team.

17. *Please describe your role and responsibilities as consultant haematologist and director at the QEHHC from 1992 to 2016.*

My main responsibilities during my time as centre director were the management of patients with bleeding disorders in the outpatient and inpatient settings, co-ordination of appropriate referrals to consultant colleagues when required, the writing and maintenance of unit protocols, management of the unit factor concentrate budget and making decisions with regard to choice and procurement of factor concentrates.

18. *Please identify your senior colleagues at the QEHHC and their roles and responsibilities from 1992 to 2016.*

My consultant colleagues were Dr Will Lester appointed in 2005 with responsibility for the thrombosis service and Dr Gill Lowe appointed in 2015 with responsibilities for both the bleeding disorder and thrombosis services.

19. *Approximately how many patients with bleeding disorders were under the care of the QEHHC when you became a consultant there in 1992 until your retirement in 2016? (If you are able to give exact rather than approximate figures, please do so).*

    Around 400 patients with bleeding disorders were registered on the UKHCDO database when I commenced post in 1992 rising to around 700 by 2016. The number of severe haemophilia patients ranged between around 80 to 120. This is to the best of my recollection and it is impossible to be more accurate without having access to the relevant database.

20. *When you took up your post at QEHHC what policies were in operation regarding the selection, purchase and use of blood products (in particular factor concentrates)? How did those change over time?*

    I am unable to recall exact details of this. The decisions with regard to clotting factor choice and procurement would have been made by Dr Ian Franklin and Dr Frank Hill, the consultants with responsibility for the service prior to my appointment. Once I was established in post, I would have taken over this responsibility but as it is nearly 30 years ago I cannot recall what factor concentrates were being used at that time or in what proportion.

21. *Who had responsibility at QEHCC for the selection and purchase of blood products and what decisions were taken as to which products to purchase and use? In addressing this issue please answer the following questions:*

    a. *How and on what basis were decisions made about the selection and purchase of blood products and how did those decisions change over time?*
    b. *What were the reasons or considerations that led to the choice of one product over another?*

    c. *Where were the products sourced and from whom were they purchased?*
    d. *What role did commercial and/or financial considerations play?*

e. *What if any involvement did you have?*

(a-e inclusive) I would have had sole responsibility for the choice of factor concentrate from the time I took up my post in November 1992. a). The main factors determining the choice of product would have been safety with regard to the risk of transmission of transfusion transmissible infection and a low risk of inhibitor development.

b). If products were thought to be similar with regard to these aspects, the cheaper ones would be chosen.

c). I have only a vague recollection of the actual products that were sourced or used, and I cannot be sure of the products used at any one time point as the products constantly changed over time. I recall that the BPL Factor FVIII and IX products were a consistent part of our factor formulary. I recollect having also used Armour and Alpha factors prior to the introduction of recombinant factor products. As far as I can remember the unit policy was to purchase at the very least two products so that if there was a manufacturing problem with one of them the other(s) could be substituted.

d) Once again, it is very difficult to provide a definitive answer to this, but I can say the cost of concentrates was determined by individual companies for each centre based on potential volume of usage and price varied significantly from product to product. Naturally the cost of the factor concentrate was an important consideration in the choice of product by individual units. As mentioned above at b) the cheaper product was often chosen.

e) As stated above, I would have had sole responsibility for the choice of factor concentrate. The choice of product would be discussed with patients individually, however. Occasionally patients had reactions to or efficacy issues with a product so were switched to an alternative.

22. *What was the relationship between QEHCC and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions referred to above?*

I maintained a professional relationship with all companies manufacturing factor concentrate but all decisions regarding choice of product were based on the above criteria and particular company / product favouritism was never an issue.

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

I can only recall the possible transmission of 'hepatitis G' in factor concentrate to some patients based on antibody testing, but as far as I can recall this turned out not to be a 'hepatitis' virus and had no associated pathogenicity so required no specific management action.

Section 4: Knowledge of, and response to, risk, testing; diagnosis; and treatment

Knowledge of Risk: General

24. *When you became a registrar in haematology at the Northern General Hospital in 1984, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge?*

I have no specific recollection of my knowledge but I would probably have been aware of the risk of transmission of hepatitis B, non A, non B hepatitis and HTLVIII having obtained this information from senior colleagues, junior doctor teaching received and reading medical journals.

25. *How did your knowledge and understanding of the risks of infection develop during the time you worked at the Royal Hallamshire Hospital, the Royal Liverpool Hospital and QEHCC?*

It is difficult to answer this question as these matters evolved over time. I became aware in the early 1980s that non A, non B hepatitis affected most haemophilia patients who had received non virally inactivated factor concentrate. I became aware that non A, non B hepatitis was caused by Hepatitis C when this virus was identified in the late 1980s. I became aware in approximately 1983/1984 that significant numbers of patients had acquired hepatitis B and HIV infection predominantly from non-virally inactivated products manufactured in the USA, with a smaller risk from concentrates manufactured from British sourced plasma.

26. *At each stage of your career, what discussions, if any, did you have with your colleagues about how and why patients had been infected by the use of blood and/or blood products?*

    I probably would have had such discussions on numerous occasions over the many years with regard to the causes of infection by the use of infected products, but I cannot recollect any specific details.

27. *At each stage of your career what was your understanding of the relative risks of infection from (i) the use of commercially supplied blood products and (ii) the use of NHS blood products?*

    In the early stages of my career I was very aware that commercially supplied products originating from the USA had a much higher risk of Hepatis B and HIV transmission compared to the UK NHS blood products, although the risk of non A, non B (Hep C) was similar with products from both countries. Following g the introduction of effective viral inactivation procedures, the risk of transmission of known viruses was removed.

Knowledge of Hepatitis

28. *When you became a registrar in 1984, what was your knowledge and understanding of the risks of the transmission of hepatitis, including hepatitis B and NANB hepatitis (hepatitis C), from blood and/or blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?*

    When I was a registrar in 1984, I was fully aware that blood / blood products could transmit hepatitis including hepatitis B and non A, non B hepatitis. I would have gained this knowledge from senior colleagues, junior doctor teaching and medical publications. I later became aware that non A, non B was caused by Hepatitis C when this was discovered in the late 1980s.

29. *What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?*

I was aware that hepatitis C could cause a transient hepatitis that then settled. It was initially thought that HCV persisted in the liver harmlessly but subsequently studies showed that although around 15% of patients eliminated the virus following infection a substantial proportion went on to develop progressive liver damage with the risk of liver failure and death. Hepatitis B caused an acute hepatitis, rarely fatal, that usually resolved with subsequent immune eradication. A proportion of patients however developed chronic infection with progressive liver damage leading to liver failure and death.

Knowledge of HIV and AIDS

30. *When you became a registrar in 1984 what was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular the risks of transmission from blood and blood products? How did your knowledge and understanding develop over time?*

    I have no specific recollection regarding the depth of my knowledge of HIV when I was a registrar in 1984 but I was aware that it was transmitted by blood transfusion and non-virally inactivated blood products. When I became a specialist in haemophilia care I rapidly accumulated more knowledge of HIV and AIDS.

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

    It is likely to be around 1984 from senior colleagues, junior doctor teaching, medical journals and mass media.

Response to risk of Hepatitis

32. *Did you or any of the hospitals you worked at from 1984 onwards take steps to ensure that patients/their parents were informed and educated about the risks of hepatitis? If so, what steps?*

    I cannot recollect when I became aware of specific counselling with regard to viral hepatitis risk. Counselling by senior colleagues however must have been part of the management of bleeding disorder patients at the Royal Hallamshire as a liver biopsy study was undertaken to determine the severity of hepatitis in patients with

non A, non B hepatitis. It is very likely that Dr Hay actively counselled patients about viral hepatitis at the Royal Liverpool Hospital when I was there. Counselling with regard to viral hepatitis was part of my routine clinic consultation when I became a consultant and patients were advised to avoid blood contact with relatives. When it was determined that HCV could be transmitted by sexual contact patients and partners were advised on safe sexual practice by both myself and the unit nursing staff. I cannot recall when exactly this was.

33. *What liver function tests and/or other forms of monitoring were undertaken at the centres at which you worked and how did that change over time? What was the purpose of such testing and monitoring?*

    Initially liver function was assessed by transaminases to determine if there was chronic hepatitis. Liver ultrasound was used to give an indication of chronic liver damage. Liver biopsy became part of my routine practice in the 1990s. Patients with significant liver damage on histology were offered interferon/ribavirin eradication therapy. Liver biopsy was replaced by fibroscan to assess the degree of liver fibrosis for prognosis and consideration of eradication therapy.

34. *What if any enquiries and/or investigations did you or the centres at which you worked carry out or cause to be carried out in respect of the risks of transmission of hepatitis? What information was obtained as a result?*

    I am unable to recollect what if any enquires were carried out at the centres at which I worked. I do know that the viral inactivation processes for the factor concentrates that we used were wholly effective as I cannot recollect any new case of viral transmission in my patient cohort.

35. *What if any actions were taken by you and/or at the centres at which you worked to reduce the risk to patients of being infected with hepatitis (of any kind)?*

    Use of virally inactivated concentrates and avoidance of cryoprecipitate which was not virally inactivated.

Response to risk of HIV and AIDS

36. *What, if any, enquiries and/or investigations did you or the hospitals you worked at 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?*

I am unable to recollect what enquires and/or investigations were carried out by me or the hospitals I worked at, if any. Therefore, I do not feel I am in a position to answer this question.

37. *What, if any, actions did you or the hospitals you worked at take to reduce the risk to your patients of being infected with HIV?*

Introduction of the use of virally inactivated concentrates that were considered to be safe with regard to transmission of HIV infection.

38. *Did you or any of the hospitals you worked at take steps to ensure that patients/their parents were informed and educated about the risks of HIV and AIDS? If so, what steps?*

In my practice, HIV infected patients were informed that they were at risk of transmitting the infection by blood and sexual contact. Patients were counselled to avoid blood contact and to adopt safe sexual practice. The patients that I worked with were adults and so the question with regard to parents of infected patients does not apply.

39. *Did you or any of the hospitals you worked at revert to treatment with cryoprecipitate for some or all of your patients? If so, how did you decide which patients would be offered a return to cryoprecipitate and which would not? If not, why not?*

I cannot recall reversion to cryoprecipitate treatment at either the Royal Hallamshire or Royal Liverpool Hospitals. I certainly did not revert to this treatment strategy in my consultant practice.

40. *How and when did you become aware of the recommendations made at the meeting of Haemophilia Reference Centre Directors on 10 December 1984 [PRSE0000890], including the recommendation to use heat-treated concentrates,*

and were those recommendations then implemented at the hospital at which you were then working?

I do not recall when I became aware of this directive but when I started caring for patients with haemophilia in 1986, they were already all being treated with virally inactivated products.

41. *Did you or the hospital at which you were then working continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why?*

No. See answer 40 above.

42. *Please see the enclosed correspondence between yourself and Dr B Spacey of the Wellcome Research Laboratories in February 1988, while you were at the Royal Hallamshire Hospital, regarding consent for a pilot study of Zidovudine in patients with AIDS and ARC [RHAL0000415]. Do you recall what your concern was about heat-treated samples? Please explain your recollection of this study.*

I have no recollection of this correspondence but I think my concern was about the impracticalities in our laboratory of heat treating patients' serum to ensure eradication of viruses to minimise risk to laboratory workers at the Royal Free Hospital as these individuals should have been employing safe laboratory practice on all samples regardless of source. I have no specific recall of the details of this study itself.

Response to Risk: Generally

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

I unable to express a view on this as I was not involved in haemophilia care prior to the widespread introduction of heat-treated products.

44. *Do you consider that your decisions and actions and those of the hospitals you worked at 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.

I have no reason to suspect that the actions with regard to the timely introduction of heat-treated products at the centres where I worked were out of line with national policy decisions. I do not consider that my decisions or actions in response to any known or suspected risk of infection were inadequate and inappropriate. I would like to make it clear that by 1986, the hospitals at which I was working were already using heat treated products. Hence, I have no reason to suspect that the actions with regard to the timely introduction of heat-treated products at the centres where I worked were out of line with national policy decisions.

45. *What decisions or actions by you and/or by the hospitals you worked at could and/or should have avoided, or brought to an end earlier, the use of infected blood products?*

Further to answer 44 above, I am unable to comment on this.

46. *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?*

I have a recollection that at centres using predominantly concentrates sourced from US plasma, there was a higher rate of HIV infection compared to centres predominantly using UK manufactured concentrates. From my vague recollection of discussions amongst UKHCDO colleagues, following introduction of viral inactivation procedures into factor concentrate manufacturing processes some centres continued using US sourced concentrates in preference to UK concentrates. Early heat treatment procedures in some of the US products were not fully effective resulting in transmission of HIV infection to some patients. It is easy in retrospect to comment that use of US manufactured concentrates should have been avoided due to the origin of their source plasma and patients switched to safe virally inactivated alternative products. I am unable to add any further detail.

47. *Do you consider that greater efforts 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?*

As I did not become involved with the care of haemophilia patients until 1986, I therefore have no particular opinion on this.

Consent

48. *In relation to your work at the Northern General Hospital:*

    a. *How often (typically) were blood samples taken from patients and for what purpose(s)? What information was given to patients about the purposes for which blood samples were being taken?*
    b. *Were samples stored for prolonged periods and if so, why? Did the Northern General Hospital obtain patients' informed consent for the storage and use of those samples? Was their consent recorded and if so how and where?*
    c. *Were patients under the care of the Northern General Hospital 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 the approach to obtaining consent for testing? Was their consent recorded and if so how and where?*

As stated previously, this question is not relevant as the Northern General Hospital was not a haemophilia centre.

Royal Hallamshire Hospital

49. *In relation to your work at the Royal Hallamshire Hospital:*

    a. *How often were blood samples taken from patients and for what purpose(s)? What information was given to patients about the purposes for which blood samples were being taken?*

b. *Were samples stored for prolonged periods and if so, why? Did the Royal Hallamshire Hospital obtain patients' informed consent for the storage and use of those samples? Was their consent recorded and if so how and where?*

c. *Were patients under the care of the Royal Hallamshire Hospital 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 the approach to obtaining consent for testing? Was their consent recorded and if so how and where?*

a.) Patients had blood taken at each visit to the outpatient clinic. I cannot recollect the whole list of blood tests requested but these would have included FBC (Full Blood Count), Chemistry including LFTs (liver function tests) and relevant viral serology. My usual practice was to inform all new patients of the nature of the blood tests being taken. Follow up patients were usually aware and familiar with the blood tests being done in clinic and therefore I did not inform them of the nature of them on every single occasion unless a new specific test was required.

b). I vaguely recollect that a serum sample was frozen and saved for any future retrospective testing that may be required. I cannot recollect if patients were asked to give informed consent for the storage of serum or for any future tests that were performed on these samples.

c). When I started working in the clinic at the Royal Hallamshire Hospital in 1986 the vast majority of patients had already been tested for HIV and HBV infection. I have no knowledge of how consent was obtained for these tests by my clinic predecessors and how this was recorded. As at that time HCV had not been characterised there was no serological test for this. I cannot recollect if I ever had to test any unscreened patient for HIV or hepatitis B but if I had I think it likely that I would have obtained oral consent and recorded this in the patient's medical record. Without access to the relevant medical records, it is not possible to say.

Royal Liverpool Hospital

50. *In relation to your work at the Royal Liverpool Hospital:*

a. *How often were blood samples taken from patients and for what purpose(s)? What information was given to patients about the purposes for which blood samples were being taken?*
b. *Were samples stored for prolonged periods and if so, why? Did the Royal Liverpool Hospital obtain patients' informed consent for the storage and use of those samples? Was their consent recorded and if so how and where?*
c. *Were patients under the care of the Royal Liverpool Hospital 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 the approach to obtaining consent for testing? Was their consent recorded and if so how and where?*

(a to c inclusive) As I had little direct contact with bleeding disorder patients at the Royal Liverpool Hospital. I cannot recall Dr Hay's practice so these questions are best addressed to him directly.

QEHHC

51. *During the time you worked at QEHHC:*

a. *How often were blood samples taken from patients and for what purpose(s)? What information was given to patients about the purposes for which blood samples were being taken?*
b. *Were samples stored for prolonged periods and if so, why? Did the QEHHC obtain patients' informed consent for the storage and use of those samples? Was their consent recorded and if so how and where?*
c. *Were patients under the care of the QEHHC 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 the approach to obtaining consent for testing? Was their consent recorded and if so how and where?*

a). Patients had blood taken at each visit to the outpatient clinic. These would have included a FBC, Chemistry including LFTs and relevant viral infection tests eg CD4 count and HIV load in HIV infected patients. It is unlikely that patients were specifically informed about the blood tests being performed every time they attended clinic but they would have been aware that they were having their FBC

and liver chemistry was being checked. HIV infected individuals would have certainly been aware that their CD4 count and HIV load were being checked.

b). I did not have a policy of storing serum samples prepared from blood taken at each clinic visit.

c). Patients who had not previously been screened for HIV or hepatitis B or C were fully counselled orally prior to testing and verbal informed consent was obtained. I cannot confirm that a written record of this consent was made.

PUPs

52. *Please detail all decisions and actions taken by you or with your involvement in regard to a category of people referred to as 'previously untreated patients' (PUPS)?*

As my practice was adult based it would have been a rare occurrence to have a previously untreated patient and I have no specific recollection of this situation. However, if I did have cause to treat a PUP I would have obtained the patient's informed consent to screen them for factor antibodies and HIV, HBV and HCV baseline serology. Following factor treatment, I would have subsequently performed the same tests to ensure that the factor concentrate administered had not induced inhibitor formation or transmitted a viral infection.

Testing and communication of diagnosis.

53. *During your career what involvement did you have in arranging for patients to be tested for (a) HIV and (b) HCV?*

On a number of occasions, I would have been directly involved in the testing of previously unscreened patients for HIV and HCV.

54. *If you were involved in arranging for patients to be tested for HIV, please address the following questions:*

    a. *What if any arrangements were made for pre-test counselling?*

b. *How, when and by whom were patients told that they had been, or might have been, infected with HIV? Were they told in person, by phone or in writing?*
c. *What information was provided to patients?*
d. *Was testing offered to the family members or partners of people known or suspected to be infected with HIV?*

(a, b, c inclusive) Patients would always have been invited to the haemophilia centre for pre-test counselling and been informed by either myself or my clinical nurse specialist in person of their possible risk. Verbal counselling would have been provided and patients encouraged to ask any questions they had prior to testing. Appropriate arrangements were made for individuals to attend the unit in person to be informed of their test result as soon as practically possible once the result was available.

d). The relatives of patients found to be HIV infected were subsequently managed in a similar way as described above.

55. *When did the QEHHC begin testing patients for HCV?*

I cannot be exact but presumably patients were tested by my predecessors around 1988 when the HCV antibody test became available.

56. *When patients transferred from Birmingham Children's Hospital to QEHHC, were they tested for (a) HIV and (b) HCV?*

Patients transferred to my unit at QEH from the children's hospital had already been tested for HIV and hepatitis C infection, so their status was known. I probably would have repeated these tests on one occasion at the time of their first clinic visit to confirm their status.

57. *How and when were patients told of their diagnosis of HCV? Was it your practice to inform patients in person, by phone or in writing?*

I would inform patients of their HCV status in person. I have no recollection of informing any patient by mail or by telephone.

58. *Were patients informed at routine or specifically arranged appointments?*

Patients would normally be informed at a specially arranged appointment rather than waiting until their next routine clinic visit.

59. *Do you consider that patients were promptly informed of their diagnoses or were there delays informing people of their infections?*

Previously untested patients on whom I had arranged testing would have been informed of their result as soon as it was available. The vast majority of regular patients had been tested for HCV prior to my appointment as consultant at QEH in 1992. I cannot recollect how I counselled the HCV positive patients in the early part of my consultancy. I may have assumed that they had all been informed of their status by my predecessors following testing and may not have placed much import on discussing their diagnosis at routine clinic visits as at that time as HCV was not considered to be a major infection in the majority of patients. Management of progressive HIV infection in this cohort was by far the most important clinical issue in this group and dominated my clinical practice. However I soon realised the importance of HCV infection in this cohort and in early 1994 established a joint clinic with hepatology to which we invited all patients who had previously been exposed to blood products to ensure that all were tested for HCV infection and formulate appropriate management for those with confirmed chronic liver disease.

60. *What information was provided to patients infected with HCV about the infection, its significance, prognosis, treatment options and management? What information was provided to patients about the risks of infecting others?*

In the joint hepatitis C clinic patients were fully counselled in person by myself and my hepatology colleague with regard to the natural history of HCV including the possibility of progressive liver damage through to liver failure. Investigations and possible management options were discussed in full. We decided that the only definitive way of assessing HCV progression at that time was to offer a liver biopsy to determine liver histology. Those patients with evidence of progressive liver inflammation and fibrosis were offered combination therapy with interferon and ribavirin, which had around a 30-40% permanent eradication success rate. A wait and see policy was adopted for patients with minimal liver damage. However, once more effective HCV treatment regimens were established these patients

were also offered eradication therapy rather than waiting to see if they went on to develop progressive liver disease. Patients were made aware that if they were to go on to develop end stage liver disease, they could be offered a liver transplant. The QEH was a major referral centre for liver transplantation in HCV infected bleeding disorder patients from other parts of the UK. Patients were made aware of the risk of transmission by blood/blood contact with others and when it was established that HCV could be transmitted through sexual contact patients were advised to adopt safe sexual practice. Once the joint haemophilia / hepatology clinic had served its purpose patients with persisting HCV infection continued to be monitored in the bleeding disorders clinic with six monthly checks on clinical condition, liver function and liver ultrasound surveillance to screen for the development of hepatoma. Patients with evidence of progressive HCV infection were referred to the hepatology clinic for further management.

61. *How many patients at the QEHHC were infected with HCV?*

I cannot recollect this figure exactly. I vaguely recall it was around 250 patients.

62. *Please detail your involvement, if any, in the "Look Back" exercise for diagnosing HCV. Please find enclosed examples of National HCV Look Back Programme Identification of Fate of Implicated Component Forms completed by you in November 1995 [NHBT0037878] and [NHBT0037879].*

I had no direct involvement with the administration of the HCV look back programme. At the request of the look back secretariat I simply submitted proformas relating to all patients I was informed of.

63. *Please find enclosed an email from Rowena Lecock to Charles Hay, dated 23 June 2010, about the HCV lookback [DHNI0000364], which refers to discussions (involving you) between the UK health departments and the Haemophilia Alliance. Please set out what you can recall about those discussions. Please explain your views about routine screening of patients' partners and children. Did such screening take place at the QEHHC? Why had such screening not taken place in the 1990s?*

I was not copied into this email, so I was unaware of it until I received this rule 9 request. I have no direct recollection of the exact discussion that took place but

because of the possibility of blood transmission of HCV to family members and sexual transmission to partners, it seemed a logical decision to advise testing of children and spouses. However, I am not aware that this ever became a formal recommendation by UKHCDO. At my centre we had been offering HCV testing to partners of infected patients from the time it was recognised that HCV could be transmitted sexually in the early 1990s. However, as the risk from direct blood spread within family groups appeared to be minimal, we did not recommend the routine testing of children. I am not aware of any other UK centres that were recommending the routine screening of the children of HCV infected parents.

HIV/AIDS treatment.

64. *How was the care and treatment of patients with HIV/AIDS managed at the QEHHC? In particular:*

    a. *What steps were taken to arrange for, or refer patients for, specialist care?*
    b. *What treatment options were offered 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?*

    If you were involved with the care and treatment of patients with HIV/AIDS prior to taking up your position at QEHHC, please also answer the above questions by reference to your pre-QEHHC experiences.

    (a, b, c, d inclusive) As HIV became established in bleeding disorder cohorts before other at-risk groups, haemophilia doctors were the first in the UK to develop skills in the management of HIV infection. In the early days of the disease they were often advising infectious disease and Genitourinary (GU) consultants when the infection started to manifest in other at-risk groups. During my time at the Royal Hallamshire Hospital, I would have been monitoring patients in the early stages of HIV infection prior to development of treatment but can only recall one patient progressing to AIDS. I recall we were able to obtain a supply of zidovudine pre licence to treat him.

Dr Hay managed his HIV infected patients directly. I had some involvement in the management of infected patients but cannot recall any specific details. When I became director of the QEH centre, the HIV patients were being managed directly by unit medical staff as at that time there was little expertise in other departments due to the low rates of infection in other patient groups in Birmingham. Due to my previous experience it was quite appropriate for me to continue their management directly. This was similar to management arrangements in many of the larger UK Haemophilia Centres. As HIV became more prevalent in other cohorts GU and infectious disease health care staff developed expertise in the management of HIV. Although a number of my patients elected to transfer their HIV care to these units the majority of patients decided to continue their care under me as they did not wish to mix with infected individuals in the other patient groups. I kept up to date with all developments in the management of HIV infection and its complications and developed a very close liaison with the GU and infectious disease consultants in Birmingham, attending and presenting at the monthly HIV 'Grand Round' on a regular basis. I would not hesitate to seek HIV management advice from colleagues, and they would often ask my advice on certain issues. I consider that I used HIV medications in a timely manner as they became available and would often discuss the optimal treatment combinations depending on HIV resistance testing results with my GU and virology consultant colleagues. Patients were fully counselled in person about all aspects of the drugs and drug combinations that I was prescribing. Medication counselling was also provided by unit nursing staff. HIV infected patients were seen almost exclusively by me in clinic initially every three months and latterly every four months once patients were stable on the highly active HIV medications.

65. *How was the care and treatment of patients with hepatitis B managed at the QEHHC? In particular:*

    a. *What steps were taken to arrange for, or refer patients for, specialist care?*
    b. *What treatment options were offered to those infected with hepatitis B?*
    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 on-going monitoring was arranged for patients who were infected with hepatitis B?*

If you were involved with the care and treatment of patients with hepatitis B prior to taking up your position at QEHHC, please also answer the above questions by reference to your pre-QEHHC experiences.

(a, b, c, d. inclusive) I cannot recall any details about the management of patients with HBV infection at the Royal Hallamshire or Royal Liverpool Hospitals. I can recall only four or five patients with chronic hepatitis B infection in the QEH cohort. These would all have been referred to my hepatology colleagues for investigation and management. I do not recall the management aspects of these patients.

HCV Treatment

66. *How was the care and treatment of hepatitis C managed at the QEHHC? In particular:*

    a. *What steps were taken to arrange for, or refer patients for, specialist care?*
    b. *What treatment options were offered to those infected with hepatitis C?*
    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 on-going monitoring was arranged for patients who were infected with hepatitis C?*

If you were involved with the care and treatment of patients with hepatitis C (or non-A non-B hepatitis) prior to taking up your position at QEHHC, please also answer the above questions by reference to your pre-QEHHC experiences.

(a, b, c, d inclusive) I cannot recall the specifics of the management of non A, non B infected patients at the Royal Hallamshire. I recall simply monitoring liver function tests at that time. The cause of the chronic hepatitis had not been established and there was no treatment. I vaguely recall patients with abnormal liver function tests undergoing liver biopsies under the guidance of Drs Preston and Hay, but I have no recollection of being directly involved in this. I cannot specifically recall Dr Hay's management arrangements for HCV infected individuals at the Royal Liverpool Hospital. With regard to my experience in the management of HCV infection at QEH please refer back to my answers at 59 and 60 above.

67. *Please describe the counselling and/or psychological support and/or social work available to patients at the QEHHC following diagnosis and/or treatment.*

Counselling and psychological support was provided by the unit health care staff with additional support from the haematology unit clinical psychologist when required. Social support was provided by very experienced social workers.

68. *Did the QEHHC have a dedicated counsellor or social worker to provide support? If so, how was this funded?*

There was no dedicated counsellor or social worker for the specific care of HIV and HCV infected individuals. The social worker attached to the haemophilia unit was responsible for all components of social care relating to bleeding disorder patients although aspects of HIV and hepatitis C was a major part of their work. The post was funded by Birmingham City Council.

69. *What, if any, difficulties did you and/or the QEHHC encounter in obtaining sufficient finding for the treatment of people who had been infected with HIV and/or hepatitis?*

I vaguely recall having some difficulty obtaining funding for the initially developed highly active antiretroviral medications within the Trust when these first became available, but the West Midlands specialist services team responsible for haemophilia and HIV care rapidly agreed to fund the medications and I do not consider there was any detrimental delay in starting these drugs.

70. *What, if any, involvement did you and/or colleagues at the QEHHC have with any clinical trials in relation to treatments for HIV and HCV? Please provide details.*

I cannot specifically recall any clinical trials in which I might have been involved in relation to HIV infection. I was involved in an in-house trial of PEG interferon / ribavirin combination therapy in the treatment of HCV infection in bleeding disorder patients. For details of this refer to attached documents 1, 2 and 3.

Research

71. *Please list all research studies that you were involved with during your career. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, 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 that 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 to inform patients of their involvement and to seek their informed consents.*
    h. *Provide details of any publications relating to the research.*

    Please find attached the list of research projects in which I was involved during my period of employment at the Queen Elizabeth Hospital Birmingham **(Attachment 1).** I have obtained this from the hospital Research and Development (R&D) database which dates from 1996. There is no record of studies in which I was involved prior to this. I have no record or recollection of studies in which I might have participated prior to 1996.

    More detailed information on the studies relevant to the Inquiry are shown in **Attachment 2.** All local and multicentre studies in which I was involved were presented to the hospital R and D department for appropriate LREC / MREC ethical approval. In all studies patients meeting the entry criteria were approached in person and given the study information sheet and encouraged to approach the trail investigators if they required clarification or further information. If a patient agreed to participate, written informed consent would be obtained on the approved trial consent form with copies given to the patient and filed in the trial documentation and the patient's notes.

    If further details of the listed trials are required may I suggest that the therapeutic companies are approached directly as they should have maintained all relevant trial information on file.

72. *What do you understand to be the ethical principles that should guide research? Did you apply those principles to the research studies referred to above and if so, how? If not, why?*

The basic principle is that any patient invited to participate in any form of clinic research should be fully counselled with regard to the aims of the research with outcome possibilities, all potential side effects of any medication. Fully informed written consent includes their right to withdraw from the research at any time, without any form of comeback on them, and their right to be fully informed of the outcome of the research. Participation should be anonymised. As far as I am aware, I fully complied with these standards at all times.

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

As far as I am aware no patient under my care was involved in a research project without their consent.

74. *Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose with patient consent? If so, what data was used and how and why did this occur?*

As far as I am aware, and can remember, all patient data was anonymised.

75. *Was patient data (anonymised, de-identified or otherwise) shared with third parties (e.g. UKHCDO or the Oxford Haemophilia Centre) without patients' express consent? If so, how, and why did this occur, and what information was provided to whom?*

Anonymised patient data with regard to factor usage and viral infection data is likely to have been submitted to UKHCDO without patients' expressed consent as obtaining consent for this use of anonymised data was not standard practise in the UK haemophilia centres.

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

Please see attached list of relevant publications **(Attachment 3).**

Records.

77. *What was the QEHHC's policy and practice for recording on death certificates when a patient had been infected with HIV and/or hepatitis?*

I have no specific recollection of my practice in this regard. I vaguely recall that in the early years of my appointment, due to the stigma of these viral infections to protect the dignity of the individual and the wishes of the family, I did not specifically mention HIV and HCV infections on death certificates. For HIV infection, I would probably have used the term 'retroviral disease'. In later years however I'm sure I would have named the specific viruses directly.

78. *What were the retention policies of the QEHHC in regards to medical records?*

In the earlier years of my directorship, the QEH unit policy was to retain all written medical records of patients infected with transfusion transmitted viruses indefinitely after death. All notes were kept on the haemophilia unit. When the Trust went to a paperless medical record it was agreed that all paper record files were to be retained in central records. It seems however that following death these written medical records have subsequently been destroyed.

79. *To the best of your recollection, did you maintain separate files for some or all patients? If so, why? Where were those files located and where are those files now?*

I was not in the habit of ever keeping separate patient medical records.

80. *Did you keep records or information (e.g. information being used for the purposes of research) about any of your patients at your home or anywhere other than the QEHHC? If so, why, what information and where is that information held now?*

I never kept any patient information anywhere outside of the QEH.

81. *Do you still hold records or information about any of your patients? If so, why and please identify the records or information you still hold.*

I hold no medical case records or patient information.

Section 5: vCJD

82. *For your answers to this section, you may wish to consider and/or refer to the following enclosed documents:*

- *Pro forma on vCJD from you, dated 29 January 2001 (WITN1387003).*
- *Minutes of the UKHCDO Transfusion Transmitted Infection Working Party Meeting, 5 March 2001 (HCDO0000592).*
- *Centre Doctors' Questionnaire from The Haemophilia Society on BPL products and vCJD: a look-back questionnaire to Haemophilia Centre Directors for vCJD, dated 17 December 2011 (HSOC0004241).*
- *Minutes from the Ninth Meeting of the UKHCDO Advisory Committee, dated 15 January 2003 (BART0000935).*
- *Minutes of the tenth meeting of the UK Haemophilia Centre Doctors' Organisation Advisory Committee, dated 19 May 2003 (HCDO0000254_104).*
- *Letter from you to Lynne Dewhurst at the UKHCDO enclosing the completed UKHCDO/DOH vCJD Surveillance - Appendix II Forms, dated 9 June 2003 (HCDO0000131_090).*
- *Comment on draft vCJD factsheet, 27 June 2004 (HSOC0012277, page 5).*
- *Minutes of the UKHCDO Transfusion Infection Working Party, 25 January 2008 (HCDO0000900_002).*
- *Minutes of the Haemophilia Alliance Meeting on 3 July 2009 (HSOC0028559).*
- *Letter from Andrew Thomas, Medical Director to Dr P Edwards, CJD Policy Team Unit about use of instruments, dated 2 May 2001 (DHSC0006838(1)).*
- *Letter from Dr Wilde to Dr Edwards, dated 11 March 2002 (DHSC0006838(2)).*

I note this list of relevant communications.

83. *When and in what circumstances did you first become aware of the risks of transmission of vCJD associated with the use of blood and blood products? How did your knowledge develop over time?*

I must have become aware of the hypothetical risk of transmission of vCJD in British blood products in 1997. I presume this was communicated through

UKHCDO. I recall attending a meeting of DOH officials, Haemophilia directors and BPL staff in 1997 which made the decision to cease the use of British sourced plasma for the manufacture of BPL factor concentrates. I was always sceptical that vCJD could be transmitted in blood products and as research progressed indicating there was no evidence of persistence of free prion protein in plasma, I became convinced that haemophilia patients were not at risk of developing vCJD from the blood products they were administered.

84. *How and by whom were decisions taken as to the information that should be provided to patients about vCJD and as to any steps that should be taken in relation to patients and their care and treatment?*

    These decisions were taken by UKHCDO in conjunction with the DOH and the Haemophilia Society.

85. *Do you consider that the vCJD surveillance study was completed successfully? Your attention is drawn to the enclosed documents: (i) your comments at the tenth meeting of the UKHCDO Advisory Committee on 19 May 2003 at 12(c) on page 6 [HCDO0000254_104]; and (ii) the minutes from the 2008 UKHCDO Transfusion Infection Working Party where it was stated: 'Concern was expressed that some Centres had failed to trace the fate of batches or which patients had received UK sourced plasma products. This would obviously result in a less than optimal adherence to the implementation of the vCJD risk reduction procedures' [HCDO0000900_002].*

    I think it unlikely that the vCJD look back exercise was fully completed as from my recollection some centres simply did not have the resources to undertake such an exercise comprehensively.

86. *Please describe the process at the QEHHC for informing patients about possible exposure to vCJD. In particular:*

    a. *How and when were patients told of possible exposure to vCJD?*
    b. *What information was provided to patients about the risk of vCJD?*
    c. *What counselling, support and/or advice was offered to patients who were being informed that they might have been exposed to vCJD?*

d. *What measures were put in place, from a public health perspective, in relation to the care and treatment of patients? Please find enclosed a letter from Andrew Thomas, Medical Director to Dr P Edwards, CJD Policy Team Unit, dated 2 May 2001, about use of instruments [DHSC0006838(1)]. Please find enclosed a letter from you to Dr Edwards on 11 March 2002 [DHSC0006838(2)].*

(a, b, c, d inclusive) As soon as we had the communication from UKHCDO requesting that we inform our patients of the risk of vCJD, I circulated the letter along with the Haemophilia Society information sheet (WITN1387003) to all patients in the at risk group. It was decided to inform all at risk patients immediately by post, so they all knew their status at once rather than waiting until their next clinic appointments to inform them in person. My letter invited patients to contact myself or any unit staff to discuss any concerns that they might have. The DOH instructed that special precautions should be taken in patients undergoing interventional procedures because of the hypothetical risk of adherence of the prion protein to surgical instruments that would be resistant to sterilisation techniques. Disposable instruments were to be used for dental procedures and instruments used in surgery were to be disposed of. Endoscopes were to be quarantined indefinitely.

87. *Was the possibility of transmission of vCJD via blood products communicated to (i) colleagues, and (ii) infected and affected individuals / their interest groups sufficiently promptly? If not, why not?*

I cannot recall whether or not I felt that the dissemination of information with regard to vCJD was communicated to colleagues and or infected/affected individuals occurred in a timely enough manner.

88. *Were estimations about the incidence of vCJD infection by blood and/or blood products accurate? If not, why not? Did this change over time?*

I have no recollection of ever being made aware of this data so I am unable to comment.

89. *Were 'look back' exercises designed to trace patients infected by implicated batches conducted competently and sufficiently promptly? If not, why not?*

Many centres completed the look back in a competent and prompt manner. Please refer to my answer at number 85 above.

90. *Please refer to the enclosed minutes of the Haemophilia Alliance Meeting on 3 July 2009 [HSOC0028559] and your comments concerning the 2009 vCJD communication that you had 'decided not to send the HPA letter out to patients as it was rather complex and could lead to confusion and unwarranted concerns'. Please explain the relevant background and why you reached this decision.*

I do not recollect the contents of the HPA letter, aside from a vague recollection of it being unnecessarily complex. I also do not recollect how many centres did not send it on to their at-risk patients. With regard to why I reached this decision; as the patients had already been informed of their possible risk of vCJD, by a letter from the haemophilia society and their own centres, for the reasons mentioned in the minutes of this meeting I decided not to send it to my patients.

Section 6: UKHCDO

91. *Please describe your involvement with UKHCDO (including any of its working parties, committees or groups). Please include reference to the UKHCDO Transfusion Transmitted Infection Working Party and your role of Secretary.*

I was a member of UKHCDO from 1992 until 2016. I attended the 4 to 6 monthly meetings and the AGM on a regular basis. I was a member and secretary of the transfusion transmitted infection working party, a member of the rare bleeding disorders working party and the orthopaedic working party.

92. *During the period that you were involved with UKHCDO, please outline:*

    a. *The purpose, functions and responsibilities of UKHCDO, as you understood them.*
    b. *The structure, composition and role of its various committees or working groups.*
    c. *The relationship between UKHCDO and pharmaceutical companies.*
    d. *How decisions were taken by UKHCDO.*

e. *How information or advice was disseminated by UKHCO and to whom.*

f. *Any policies, guidance, actions or decision of UKHCDO in which you were involved and which relate to:*

   i. *The risks of infection associated with the use of blood products.*

   ii. *Obtaining consent from patients for the testing and storage of their blood, for treatment or research.*

   iii. *vCJD exposure.*

   iv. *Treatment for HIV and hepatitis C.*

   v. *Any other matter relevant to the Inquiry's Terms of Reference.*

(a to f inclusive). The main functions of UKHCDO and its working parties were to disseminate information about bleeding disorder related issues, formulate clinical management policies, liaise with the DOH with regard to the health care of bleeding disorder patients and the procurement of blood products and direct research in bleeding disorder related issues. The executive committee comprising of the chairman, secretary and treasurer co-ordinated action decisions taken by the whole group following discussion of issues at the UKHCDO meetings. There was a close relationship between the UKHCDO executive and the pharmaceutical companies with regard to issues arising with individual blood products and over recent years the national tendering process for the purchase of blood products. Information was disseminated to smaller haemophilia centres via the UKHCDO secretariat in the form of the UKHCDO meeting minutes and other communications. As part of my remit on the transfusion transmitted infection working party, I was involved in the production of guidelines on the management of HCV infection.

Section 7: Pharmaceutical companies/medical research/clinical trials

93. *Please find enclosed an undated UKHCDO Reply Form from you declaring an interest in Bayer, Wyeth, Baxter and Aventis [HCDO0000110_150]. What was the nature of the interest? Have you ever provided advice or consultancy services to any pharmaceutical companies involved in the manufacture and/or sale of blood products? If so, please list the names of the companies and give details (including dates) of the advisory or consultancy services that you provided?*

My involvement with the listed companies would have been the provision of funding to attend international educational meetings and honoraria for presentations at educational meetings sponsored by them. I provided consultancy services at advisory boards for the following companies over the many years of my practice: Baxter, Bayer, BPL, CSL Behring (and their previous company names Armour, Cention, Aventis), Grifols, Novonordisk, Octapharma, Pfizer, Wyeth. I no longer have any record of the dates of these meetings which date from 1993 to 2016.

During the late 1990s / early 2000s I was also a member of the Scottish Blood Transfusion Service Pharmaceutical Committee which met twice a year at its headquarters in Edinburgh to discuss a range of topics related to the therapeutic products manufactured by SBTS. I cannot recall the exact dates I served on this committee.

94. *Have you ever received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.*

I received honoraria for attending the above advisory boards. I no longer have any record of the dates of these meetings or the details of the actual sums paid. For the purposes of my tax return I amalgamated all my private practice and other income including that earned for professional services. Since my retirement and subsequent relocation the records of individual items of income have been destroyed. From my vague recollection the total payments per annum for pharmaceutical company advisory boards would be around £2000 - £3000. The above-mentioned companies may still hold records of the exact dates of advisory board meetings and the payments made to individual board members.

I was paid an annual retainer by SBTS for my services, but I cannot recall the exact amount or the actual dates I served on this committee.

95. *Have you ever sat on any advisory panel, board, committee or similar body of any pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details of your involvement (including dates) and of any financial or other remuneration you received.*

See answer to 94.

96. *Have you ever received any financial or non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.*

I have never ever been offered financial / non-financial incentives by any pharmaceutical company to use certain blood products.

97. *Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood products from a pharmaceutical company? If so, please provide details.*

I have never received funding from any pharmaceutical company to prescribe, supply, administer, recommend, buy or sell any blood products.

98. *What regulations or requirements or guidelines were in place at the time you worked at QEHHC concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations or requirements or guidelines and what steps did you take to comply with them?*

I do not recall there being any requirements / guidelines in place when I worked at QEH to declare involvement with particular pharmaceutical companies. I always took annual leave days to attend advisory board meetings, so my professional services were provided in my own time. I always complied with the UKHCDO annual declaration of interests requests.

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

I cannot recall providing any pharmaceutical company with the results of any research that I had undertaken personally.

100. *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?*

I never received personal remuneration from pharmaceutical companies for any specific medical research project. Company remuneration for research studies would have been declared in the medical research ethics application and the monies would have been paid directly to the trust and following deduction of administrative fees the balance would be allocated to our unit research fund.

Section 8: The financial support schemes

101. *What if any involvement did you have with the different trusts and funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund) that were set up to provide financial support to people who had been infected? In particular, please describe:*

   a. *Any involvement you had in relation to the development of any criteria or policy relating to eligibility for financial assistance.*
   b. *Any involvement you had in providing advice to any of the trusts or funds.*

I had no involvement with any of these organisations.

102. *Did the QEHHC have policies or guidance in place for its staff to inform or refer patients to different trusts and/or funds for support and if so what were they?*

There were no formal guidelines for this. Seeking of monies from individual funds was led primarily by the unit social workers.

103. *What kind of information did the QEHHC (whether through you or otherwise) provide to the trusts and funds about or on behalf of patients who were seeking assistance?*

The information provided was that requested by the individual fund.

104. *What kind of support or assistance was provided by QEHHC (whether through you or otherwise) to patients making applications for financial assistance?*

Written supportive evidence was provided by members of the haemophilia team including myself.

105. *At the Nineteenth Meeting of the U.K. Haemophilia Centre Doctor's Organisation Advisory Committee, dated 19 September 2005 [HCDO0000244_040] at which you were noted as present, ex gratia payments for HCV were discussed. It was noted that some of your patients who had naturally cleared the virus had received payments and that you would write to the Skipton Fund for clarification as to whether patients who have naturally cleared the virus should receive payment or not. Please discuss any response you received, and provide a copy if you are able.*

I cannot recall receiving a reply to my request specifically and have no record of this.

106. *With reference to the letter of support you wrote to the Macfarlane Trust on behalf of an infected individual for a period of respite, dated 26 July 2005 [MACF0000101_091], and the response received from Martin Harvey, dated 11 August 2005 [MACF0000101_092], explaining that the Macfarlane Trust had declined your recommendation "because the (doctor's) recommendation was unspecific" and "the summer payment could be used for this (purpose)", please describe if any guidance was provided by the Trust on how recommendations should be provided by clinicians, and whether this was typical of your dealings with the Trust.*

There may have been guidance to doctors requesting MacFarlane Trust funding for their patients, but I cannot recall seeing this. I can recall that there were issues with release of funds at times.

107. *Based on your own dealings with 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?*

On the whole I cannot recollect that there were any major issues with how the funds operated.

108. *What, in your experience, has been the impact of the infection of patients with HIV and/or hepatitis through blood products:*

a. upon patients at QEHHC (without identifying any individual patient);
b. upon the ways in which decisions about treatment and care were taken, and treatment and care were provided, at QEHHC?

a). It goes without saying that the effect of transfusion transmitted infection had a devastating effect on the patients and families attending my centre.

b). I had an excellent team of fellow health care professionals throughout my consultant career and between us I consider that overall we provided an excellent quality of care to our patients.

109. *Did the infection of patients with HIV and/or hepatitis through blood products:*

a. change or influence your professional practice and approach and if so how?
b. change or influence the way in which haemophilia care at QEHHC was provided and if so how?

As I inherited a cohort of patients already infected with HIV and HCV, I do not have an opinion on this.

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

Throughout my clinical career I had no complaint made against me relevant to the Inquiry's terms of reference.

111. *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.*

I have nothing further to add.

Statement of Truth

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

GRO-C

Signed _____

Dated _____15/09/2020_____

Table of exhibits:

Date	Notes/ Description	Exhibit number