Witness Name: Dr Frank Jones
Statement No.: WITN5559001
Exhibits: WITN5559002
Dated: 22 September 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR FRANK JONES

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 12 March 2021

I, Dr Frank Jones, will say as follows: -

Section 1: Introduction

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

    1.1. My name is Dr Francis George Charles Jones (retired). My address is known to the Inquiry. I was born in 1948. My professional qualifications are as follows; MB, BCh, BAO, FRCP, FRCPath

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. My employment history is set out in my previously supplied curriculum vitae [WITN5559002]. I have summarized the relevant parts below.

2.2. From 1976 until 1981 I was a trainee in clinical and laboratory haematology at the Royal Victoria hospital. I was one of the junior doctors looking after patients with congenital bleeding disorders as well as patients with haematological malignancies.

2.3. From 1982 until 1991 I was a consultant haematologist based at the Ulster Hospital. My work was that of a general haematologist – there was no Haemophilia Centre at the Ulster Hospital either then or now.

2.4. From 1991 until 2001 I was a consultant haematologist based at the Royal Victoria Hospital. My main role concerned patients with haematological malignancy but also with patients undergoing bone marrow transplantation. Together with other colleagues I provided clinical cover for patients with haemophilia both on call and during our colleague Dr EE Mayne's leave.

2.5. In 2001 I transferred to the Belfast City hospital with the unit until my retirement in 2009.

2.6. Following the retirement of Dr EE Mayne (Haemophilia Centre director) in 1999, I continued to provide clinical cover for the Haemophilia Centre, whilst actively seeking a replacement consultant.

2.7. We were fortunate to have Dr Julia Anderson as a colleague for several years from 2000 to 2004 or thereabouts.

2.8. In 2006 we had another consultant appointed as Centre Director, Dr O'Keeffe who was with us for about 7 months before he left for personal reasons.

2.9. In 2008 Dr Gary Benson was appointed and remains in post to this day.

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. If applicable, please ensure your answer addresses your involvement with the UKHCDO.**

3.1. I was a member of the following relevant professional bodies:

3.1.1. British Society Haematology 1984: ordinary member

3.1.2. Royal College of Physicians 1976

3.1.3. Royal College of Pathologists 1981

3.1.4. Royal Victoria Hospital Transfusion Committee 1992-2009

3.1.5. Regional Transfusion Committee 2003-09

3.1.6. UKHCDO Advisory Committee: I was never a full member. I attended twice when providing cover for the Haemophilia Centre, firstly around 1999. My initial attendance was as much to make contacts with our colleagues in Scotland but also to seek advice in finding candidates for the post of haemophilia centre director in Belfast. On the second occasion around 2004 my attendance was largely driven by the need to understand and implement the agreed policy for variant CJD.

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 can confirm that I have not provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or

hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.

Section 2: Decisions and actions of the Haemophilia Centre at Ulster Hospital and the Royal Victoria Hospital

5. Insofar as relevant to the Terms of Reference, please:

a. describe the roles, functions and responsibilities of the Haemophilia Centre at i) the Royal Victoria Hospital ('the Royal Victoria') and ii) the Ulster Hospital ('Ulster') during the time that you worked there.

5.1. The Haemophilia Centre at the Royal Victoria Hospital provided diagnosis and treatment facilities for patients with both congenital and acquired bleeding disorders.

5.2. There was no Haemophilia Centre at the Ulster Hospital either then or now.

b. outline the facilities and staffing arrangements for the care of patients with bleeding disorders;

5.3. Royal Victoria - for inpatients, there was a Haematology Ward 22, which admitted patients with bleeding disorders as well as haematological malignancy.

5.4. For outpatients – there was a day clinic which ran from 8:30 a.m. to 5:30 pm Monday to Friday. There was a mixture of patients, some of whom were day attenders while others were attending individual clinics.

c. identify senior colleagues at i) the Royal Victoria and ii) Ulster 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.

5.5. Dr EE Mayne was the haemophilia centre director during both periods that I was employed at the Royal Victoria. She had responsibility for organizing the care for patients with bleeding disorders.

5.6. Prof JM Bridges-during the first period when I was a junior doctor Prof Bridges worked mainly in the children's hospital caring for children with haematological malignancy as well as bleeding disorders.

5.7. During the second period until his retirement in about 1995, Prof Bridges was working solely in the adult haematology Ward looking after patients with haematological malignancy. He would have provided clinical cover for Dr Mayne on call and when she was on leave, in the same way that I did.

6. Please describe:

a. your role and responsibilities at i) the Royal Victoria and ii) Ulster and how, if applicable, this changed over time;

6.1. Royal Victoria Hospital - the first period (1976 to 1981): I was working as a trainee, I was looking after the clinical care of the patients with haemophilia and was not involved in policy or the selection of products.

6.2. Ulster Hospital: from 1982 until 1991 I was a consultant haematologist based at the Ulster Hospital. My work was that of a general haematologist.

6.3. Royal Victoria Hospital - the second period (1992 to 2001): I was working as a consultant haematologist at the Royal Victoria Hospital from 1992, having been appointed to organise the Bone marrow transplant service and look after patients with haematological malignancy as my principal roles.

b. your work at i) the Royal Victoria and ii) Ulster 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.

6.4. Royal Victoria Hospital - the first period (1976 to 1981)

6.4.1. My role was to see and assess patients who were admitted as an emergency –usually with a joint bleed or electively – the latter often for dental extraction . I would also have seen and assessed patients with bleeding disorders who were attending the day clinic who may have had a bleeding episode.

6.4.2. The patients' chart contained a proforma at the beginning of the current chart detailing their diagnosis for example as Factor 8 deficiency together with the level and a treatment section detailing which product currently being used with target levels to be achieved in particular circumstances depending on major or minor procedures or joint bleeds.

6.4.3. The hospital Blood bank held a register of patients' current treatments, enabling them to crosscheck the product order and also for use in an emergency if the chart was unavailable.

6.4.4. This was very useful – on one occasion I was called urgently to Casualty to see a patient with a head injury who was unconscious and said by family to have haemophilia. The Blood Bank were able to confirm that the patient in fact had Christmas disease or Factor 9 deficiency.

6.4.5. The patient received prompt emergency replacement of the correct product. Naturally all unplanned patient visits were discussed with senior staff.

6.4.6. I was also working with patients who had haematological malignancies, who were having chemotherapy or being treated for serious neutropoenic infections.

6.5. Royal Victoria Hospital - the second period (1992 to 2001)

6.5.1. I was providing cover for patients with haemophilia out of hours and during colleague leave.

6.5.2. I acquired an additional role following the retirement of Dr E E Mayne in 1999. and our subsequent move to Belfast City Hospital in 2001.

6.5.3. I held a watching brief during periods when we had no dedicated consultant Haemophilia Centre director. This entailed, in addition to an already full time work plan, providing consultant input for outpatients at the haemophilia centre and seeing new and old patients who required admission. The day to day working of the Haemophilia Centre was largely carried out by Sister McAfee, Dr McNulty together with staff nurses and junior doctors. The centre had dedicated secretarial support.

6.5.4. My first involvement with product selection and purchase was during the national procurement in 2006/2007.

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

7.1. There were no patients with congenital bleeding disorders under the care of the Ulster Hospital as there was no haemophilia centre as previously stated.

8. **To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by i) the Royal Victoria and ii) Ulster, 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, and on what basis, and by whom were decisions made about the selection and purchase of blood products?**

8.1. I have no knowledge of how and on what basis decisions were made about the selection and purchase of blood products.

8.2. Doctor Mayne would have been involved in these decisions.

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?**

8.3. I had no involvement, but I would think that the Eastern Board for Health and Social Care and the Northern Ireland Blood Transfusion Service would have been involved.

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

8.4. I had no involvement. I suspect availability and continuity of product supply would have been important factors.

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

8.5. I had no involvement or relevant information

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

8.6. During in between periods post Dr Mayne's retirement I would have continued on with the previous year's order, which would have been organised by either Dr Anderson or Dr O'Keeffe.

8.7. My first direct involvement with product selection and purchase was during the national procurement in 2006/2007. These products were recombinant where available.

f. What products or treatments were generally used for treating:

8.8. In general terms each patient's notes had a proforma indicating their diagnosis, their factor level and which product they were currently receiving together with levels to be achieved for various clinical scenarios.

8.9. Sample times for factor levels were normally suggested.to confirm adequate levels.

8.10. Previous reactions and suggested pain relief regimes were also noted and a note of their blood group.

8.11. The proforma was filed at the start of the current chart and moved to a new chart as required. This provided continuity of product selection and approach and was produced by Dr Mayne and her secretary.

8.12. These proforma became laminated at some point.

i. patients with severe haemophilia A;

8.13. Factor concentrates were usually used.

ii. patients with moderate haemophilia A;

8.14. It would depend on the clinical indication and previous product use , either factor concentrates or cryoprecipitate.

iii. patients with mild haemophilia A;

8.15. It would depend on the clinical indication, either DDAVP if they had been shown to have a satisfactory response in the past or cryoprecipitate or factor concentrate in rare emergency circumstances e.g. head injury.

iv. patients with haemophilia B;

8.16. Most usually factor concentrates with a high level of factor 9, in as far as I remember.

v. patients with von Willebrand's disease?

8.17. This would depend on the type of von Willebrand disease and could be cryoprecipitate or factor concentrate with a high concentration of von Willebrand factor.

9. What was the relationship between i) the Royal Victoria and ii) Ulster and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on Ulster'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.

9.1. I have no knowledge of the relationship between the Royal Victoria and pharmaceutical companies manufacturing and supplying factor concentrates. For the Ulster Hospital this question does not apply. There was no Haemophilia Centre.

9.2. If the responsibility for the selection and purchase of blood products lay with an organisation other than i) the Royal Victoria and ii) Ulster, please specify which organization and provide as much information as you can about its decision-making.

10. If the responsibility for the selection and purchase of blood products lay with an organisation other i) the Royal Victoria and ii) Ulster, please specify which organisation and provide as much information as you can about its decision-making.

10.1. I had no involvement in the selection and purchase of blood products prior to national procurement in 2006/2007 and cannot assist on this aspect.

11. 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 Ulster 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?

11.1. Cryoprecipitate was used, particularly for less severely affected patients where it was practically possible to raise the therapeutic level of factor 8 to the required level.

11.2. There was no Haemophilia Centre at the Ulster Hospital.

12. What was i) the Royal Victoria and ii) Ulster's policy and approach as regards:

a. The use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and if so how?

12.1. I had no involvement in policy aspects.

12.2. Cryoprecipitate was used, particularly for less severely affected patients where it was practically possible to raise the therapeutic level of factor 8 to the required level.

b. home treatment? When was home treatment introduced?

12.3. I had no involvement in the Home Treatment programme. I think it was probably introduced during the 1980's.

12.4. It would have required the use of factor concentrates

c. prophylactic treatment? To what extent and when was treatment provided on a prophylactic basis?

12.5. I had no involvement in the provision of prophylactic treatment. I think its use started, probably quite some time after the introduction of home treatment.

12.6. There was no Haemophilia Centre at the Ulster Hospital.

13. What was i) the Royal Victoria and ii) Ulster'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?

13.1. I had no involvement in the treatment of children, but I believe that cryoprecipitate would have been used until the availability of recombinant product.

13.2. There was no haemophilia centre at the Ulster Hospital.

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

14.1. There was no Haemophilia Centre at the Ulster Hospital.

Section 3: Knowledge of, and response to, risk

General

15. When you began work as a consultant haematologist at i) the Royal Victoria and ii) Ulster, 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? How did your knowledge and understanding develop over time?

15.1. The Royal Victoria Hospital

15.1.1. In 1991 at the Royal Victoria, this included hepatitis B and bacterial infection together with HIV and in the transplant area CMV (cytomegalic virus) This latter was immune suppression related. Through the 90's I would have added hepatitis C to this list.

15.2. Ulster Hospital

15.2.1. In 1982 at the Ulster Hospital the risks of infection that I would have considered included hepatitis B and bacterial infection.

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

16.1. The Blood Transfusion Committee would have considered only looking at immediate or delayed complications of transfusion. This was not specifically infection related.

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

17.1. I had no specific knowledge of relative risk, but I would have assumed and hoped that there would be less risk from NHS factor concentrates prepared from plasma obtained from volunteer donors (NHS).

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

18.1. I would regularly have read Blood, Bone Marrow Transplantation and less often the Lancet and the New England Journal of Medicine, usually for a specific article of interest.

Hepatitis

19. When you began work as a consultant haematologist at i) the Royal Victoria and ii) Ulster, 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?

19.1. During the 80s, at the Ulster Hospital, I would have been most concerned with infection due to hepatitis B, though I was aware that all donations were

screened. During the 90s at the Royal Victoria especially following the available testing for hepatitis C it would have been added to my concerns.

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

19.2. Hepatitis B has always had the potential to be fatal. NANB hepatitis/hepatitis C potential severity only became clear to me through the 90s. I remember being shocked during the 90's by news of patients with bleeding disorders developing serious liver diseases.

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

20.1. Sources of knowledge would have ranged from conversations with colleagues together with journal articles and general news.

21. What, if any, actions did you and/or i) the Royal Victoria and ii) Ulster take to reduce the risk to patients of being infected with hepatitis (of any kind)?

21.1. Throughout my time in the 80s at the Ulster and in the 90s at the Royal Victoria a major concern was to reduce the risks of blood and blood products transfusion by educating the clinicians and asking them to reduce use as far as possible e.g. by developing maximum blood order schedules for specific cold surgical procedures. This task would have been overseen by the blood transfusion committee.

HIV and AIDS

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

22.1. During the 80s all transfusion centres began testing their donors and it would be around that time that I became aware there might be an association.

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

23.1. During the 80s all transfusion centres began testing their donors and it would be around that time that I became aware. My knowledge of HIV risks developed in relation to live donor bone marrow transplantation. All prospective bone marrow donors would have consented to have an HIV test, in addition to other tests.

24. What, if any, actions did you and/or i) the Royal Victoria and ii) Ulster take to reduce the risk to your patients of being infected with HIV?

24.1. For the general hospital population the major action would be to encourage appropriate and less use of blood and blood products.

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

25.1. This issue does not arise. There was no haemophilia centre at the Ulster Hospital.

Response to risk

26. Did you and/or your colleagues at i) the Royal Victoria and ii) Ulster take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps?

26.1. This was not an area of my responsibility regarding patients with bleeding disorders until the retirement of Dr Mayne in 1999.

27. Did you or your colleagues at i) the Royal Victoria and ii) Ulster revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, when and how was it determined which patients would be offered a return to cryoprecipitate?

27.1. At the Royal Victoria, I had no involvement at the material time - I have no information.

27.2. There was no haemophilia centre at the Ulster Hospital.

28. When did i) the Royal Victoria and ii) Ulster 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.

28.1. I am unable to assist with this aspect as I was not working in the Haemophilia Centre at the Royal Victoria at the relevant time.

28.2. There was no haemophilia centre at the Ulster Hospital.

29. Looking back now, what decisions or actions by you, i) the Royal Victoria and ii) Ulster or any other relevant organisations or individuals, could have avoided, or brought to an end earlier, the use of infected blood products?

29.1. I do not believe I have the requisite knowledge of decisions and actions taken at the Royal Victoria at the material time to comment in a meaningful way. As stated, there was no Haemophilia Centre in the Ulster Hospital.

30. 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?

30.1. I do not have the requisite knowledge of these matters to comment in a meaningful way.

Recombinant Factor VIII

31. Please provide (to the extent that you are able to from your own knowledge) a chronological account of the introduction of recombinant products in the UK.

31.1. I have no knowledge of the chronology relating to the introduction of recombinant products in the UK.

32. Please explain your involvement, and that of UKHCDO, with efforts to obtain recombinant blood products for patients with haemophilia. What difficulties were encountered and why? You may wish to consider the enclosed minutes of a meeting of the Haemophilia Directors for Scotland and Northern Ireland held on 5 October 1999, which discusses recombinant Factor VIII treatment policies and supply issues [GGCL0000122_003].

32.1. The meeting referred to made me aware that there were problems with supply of recombinant product. Beyond that, I have no specific knowledge of the issues mentioned.

33. In your view, should recombinant blood products have been made available to all haemophiliacs earlier than they were? If so, when?

33.1. As stated, I have no knowledge of the relevant timelines.

34. When were recombinant products available to patients (and which categories of patients) treated at the i) the Royal Victoria and ii) Belfast City Hospital?

34.1. See 34 above.

Section 4: Treatment of patients at the Haemophilia Centre at the Royal Victoria and Ulster

34.2. As stated, there was no haemophilia centre at the Ulster Hospital.

34.3. For the haemophilia centre at the Royal Victoria I had no patient responsibility in respect of any of the below issues. It is important to note that HIV status

was known to only to the patient and their consultant for a long time for patients with bleeding disorders.

HIV

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

35.1. I had no involvement in these aspects.

36. How many patients at i) the Royal Victoria and ii) Ulster 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?

36.1. I am unable to assist as I had no involvement.

37. How and when did you learn that patients under your care/the i) the Royal Victoria and ii) Ulster's care had been infected with HIV?

37.1. Does not arise. I had no involvement in these aspects.

38. How and when were patients told that they had been, or might have been, infected with HIV? What if any involvement did you have in this process?

38.1. Does not arise. I had no involvement in these aspects.

39. Please describe the i) the Royal Victoria and ii) Ulster's process for HIV testing, including pre-test and post-test counselling.

39.1. I had no involvement in these aspects.

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

40.1. I had no involvement in these aspects.

41. In the enclosed written statement, witness W2340 describes that they and other patients at the Royal Victoria Hospital were given the choice whether or not to be informed about a positive HIV result [WITN2340001]. Witness W2340 described this as a 'dangerous and unusual decision'. What were your views on whether patients with a positive HIV result should or should not have been informed? How, if at all, have your views changed over time?

41.1. I have no knowledge of this. HIV status was known to only to the patient and their consultant during this time period. Other medical and nursing staff did not know.

NANB Hepatitis/Hepatitis C

41.2. As already stated, there was no haemophilia centre at the Ulster Hospital.

41.3. For the haemophilia centre at the Royal Victoria I had no responsibility for the organisation of services for patients with bleeding disorders who had hepatitis C.

41.4. For items 42 to 50 excluding item 45, I have no knowledge.

42. How many patients at i) the Royal Victoria and ii) Ulster were infected with hepatitis C?

42.1. See above.

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

43.1. I have no knowledge of this. I had no involvement.

44. When did i) the Royal Victoria and ii) Ulster begin testing patients for hepatitis C? Please describe i) the Royal Victoria and ii) Ulster's process for HCV testing, including pre-test and post-test counselling. What involvement did you have in this process?

44.1. I have no knowledge of this. I had no involvement.

45. Please see the enclosed letters which reports that some patients in Northern Ireland were given inaccurate PCR test results for hepatitis C in 1999 [BHCT0000024, BHCT0000025 & BHCT0000026].

a. Karen Pappenheim, Chief Executive of the Haemophilia Society, stated that members of the Haemophilia Society 'were informed that their hepatitis status had been misreported during the past 12 months' [BHCT0000024]. To your knowledge, how and why did this occur?
b. How many patients were affected? What were the consequences, if any, for those patients?
c. Please explain the process for recalling, informing, retesting and counselling patients, ensuring that your answer addresses the extent of your involvement.

45.1. These were patients who were having treatment for Hepatitis C and were attending regularly for blood checks to ensure they could continue with their treatment and monitoring their response. At that time, samples for PCR Hepatitis C were sent to Edinburgh for testing and the staff of the Virology laboratory at the Royal Victoria Hospital were keen to get this testing started locally.

45.2. We began by sending samples to both Laboratories and found we were receiving results faster from our local laboratory. The patients were always keen to know their results, and a number were told that their tests showed a response from the local tests (had become negative) but no treatment changes were to be made until this was confirmed with the test result from Edinburgh. It quickly became apparent that there was a problem because the Edinburgh results did not confirm these local results (I was informed of this problem by Dr Coyle, our local virologist).

45.3. This was discussed with our medical director Dr Carson and we agreed that the patients concerned should be contacted for counselling and information. I wrote personally to each patient to ask them to come to outpatients to discuss their test and spoke to every patient. Where possible a member of the nursing staff or Dr McNulty would have been present at these discussions. (See also copies of letters from myself. Items 2 and 3 in the attached list) From memory I think there would have been perhaps 7 to 12 patients who were affected. As stated above, no treatment changes had been made and no patients suffered physically, though obviously it was a great disappointment to them.

Delay

46. Were the results of testing for HIV and hepatitis C notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

46.1. I was not involved with the counselling or discussion with patients of their diagnosis, treatments or test results until after the retirement of Dr E E Mayne in 1999.

Consent

46.2. As stated, there was no haemophilia centre at the Ulster.

47. How often were blood samples taken from patients attending i) the Royal Victoria and ii) Ulster 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?

47.1. I would have seen patients with a bleed while on call. Once a decision to give factor replacement had been made, the patient would have expected routine blood tests to be taken just before the factor replacement was given followed up by checks to see the required level was achieved. This was a routine most patients would be familiar with and consent was implied rather than recorded other than indirectly by a description of the episode and treatment plan.

48. Did i) the Royal Victoria and ii) Ulster have a bank of stored samples? If so, was that storage undertaken with patients' knowledge and consent?

48.1. There was no haemophilia centre at the Ulster Hospital.

48.2. My only knowledge of stored samples relates to studies relating to carrier status of relatives of patients. I believe that all would have consented to both the tests and storage, but I have no knowledge beyond that.

49. Were patients under your care/under ti) the Royal Victoria and ii) Ulster's care 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?

49.1. The Royal Victoria: the choice of factor concentrate or other blood product would be made based on the patient's proforma (in their chart) which would state which product was to be used (assuming that product was available). If not the choice would have involved discussion with Dr Mayne and the patient and a note made in the chart to that effect. The patient would have consented verbally and this would be shown in the note of the treatment plan (also see answer to Q 48).

49.2. Ulster: there was no haemophilia centre at the Ulster Hospital.

50. Were patients under your care 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?

50.1. There was no haemophilia centre at the Ulster Hospital.

50.2. I have no knowledge of the initial testing which would have occurred prior to Dr Mayne's retirement. For patients having follow-up while on treatment for Hepatitis C that would be covered by their initial consent for that treatment.

PUPs

51. Please detail all decisions and actions taken at i) the Royal Victoria and ii) Ulster by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS).

51.1. The Royal Victoria: I have no knowledge of this. I had no involvement.

51.2. Ulster: there was no haemophilia centre at the Ulster Hospital.

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

52. How was the care and treatment of patients with bleeding disorders and HIV/AIDS managed at i) the Royal Victoria and ii) Ulster? In particular:

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

52.1. The Royal Victoria: I have no knowledge of this. I had no involvement.

52.2. Ulster: there was no haemophilia centre at the Ulster Hospital.

b. What treatment options were offered over the years?

52.3. See (a) above

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

52.4. See (a) above

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

52.5. See (a) above

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

53.1. I have no knowledge of this. I had no involvement.

54. How was the care and treatment of patients with bleeding disorders and hepatitis C managed at i) the Royal Victoria and ii) Ulster? In particular:

54.1. There was no haemophilia centre at the Ulster Hospital.

54.2. I have no knowledge of this other than during periods when there was no haemophilia centre director after the retirement of Dr Mayne. If my other duties allowed, I would have been at a follow-up clinic for patients with Hepatitis C who were having ongoing treatment (see also answer to Q46)

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

54.3. Regular follow up and monitoring of patients was in place before the retirement of Dr Mayne in 1999

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

55.1. Ulster: There was no haemophilia centre at the Ulster Hospital.

55.2. The Royal Victoria: I have no knowledge of this. I had no involvement.

56. Did i) the Royal Victoria and ii) Ulster 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?

56.1. The Royal Victoria: I have no knowledge of this aspect.

56.2. Ulster: There was no haemophilia centre at the Ulster Hospital.

57. What, if any, difficulties did you/the Royal Victoria/Ulster encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or hepatitis C?

57.1. The Royal Victoria: I have no knowledge of this aspect. I had no involvement in setting up treatment programmes.

57.2. Ulster: There was no haemophilia centre at the Ulster Hospital.

58. Please consider the enclosed minutes of meetings of the Eastern Health and Social Services Board Pathology Sub-Committee [RHSC0000214 & RHSC0000220]. At the meeting held on 20 March 1985, it was noted that the DHSS was reluctant to provide funding for AIDS screening services. At a subsequent meeting held on 18 September 1985, Dr Darragh reported that the DHSS had agreed to provide the necessary funding, if only for a six month period.

a. For what purposes was the funding sought?

58.1. To provide an AIDS screening service for all patients who required it

b. At which hospital or haemophilia centre did you work at the time of this meeting? Was there sufficient funding to provide AIDS screening services? If not, what were the implications, if any, for patients under your care/the Centre's care?

58.2. I was a general haematologist at Ulster Hospital with no direct responsibilities for patients with congenital bleeding disorders.

c. Was the necessary funding eventually provided by the DHSS? How was it used, and what impact did it have?

58.3. I assume so - I have no knowledge.

59. 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.

59.1. None I far as I know - I had no involvement.

Records

60. What were i) the Royal Victoria and ii) Ulster's policies 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.

60.1. The Royal Victoria: I have no knowledge of this. I had no involvement.

60.2. Ulster: Issue did not arise. There was no haemophilia centre at the Ulster Hospital.

61. What were the retention policies of i) the Royal Victoria and ii) Ulster in regards to medical records during the time you were practicing there?

61.1. There was a standard 8 year default retention. Specific groups had permanent retention, which included patients with congenital bleeding disorders.

62. As far as you are able to recall, 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?

62.1. No

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 i) the Royal Victoria and ii) Ulster? If so, why, what information and where is that information held now?

62.2. No.

Research

63. Please list all research studies that you were involved with as a consultant haematologist at the i) the Royal Victoria and ii) Ulster (or any other relevant positions of employment) insofar as relevant to the Inquiry's Terms of Reference, and please:

a. Describe the purpose of the research.

63.1. Not applicable.

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

63.2. Not applicable.

c. Explain what your involvement was.

63.3. Not applicable.

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

63.4. Not applicable.

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

63.5. Not applicable.

f. State the number of patients involved.

63.6. Not applicable.

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

63.7. Not applicable

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

63.8. Not applicable

i. Please provide the same details in relation to any other studies in which you were involved or articles you have published relevant to the Inquiry's Terms of Reference.

63.9. None

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

64.1. Not applicable.

65. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or shared with third parties without their express consent? If so, please explain what data was used, and how/why it was shared.

65.1. The only data sharing I am aware of was anonymized data as part of annual returns to UKHCDO for the purposes of audit.

Section 5: Haemophilia care at Belfast City Hospital

66. Please describe:

a. how the provision of care and treatment for bleeding disorders was organised at the Haemophilia Centre at Belfast City Hospital ('Belfast');

66.1. Please see the report from a UKHCDO audit of the Northern Ireland Haemophilia Comprehensive Care Centre conducted in 2006, when I was the

acting Director of the haemophilia centre at Belfast City Hospital [WITN3082025]. E.g. "At Belfast City Hospital the centre is sited in a purpose-built area adjacent to the haematology oncology unit. It is bright, modern and well fitted with plenty of space and facilities for meetings, offices and consultation rooms with patients. Full facilities of a busy teaching hospital are available on site. The haematology laboratories and Blood Bank are only a short distance away on the same level."

b. your current roles and responsibilities at the Centre.

66.2. None – I retired in 2009.

67. Please outline the treatments provided to patients with bleeding disorders at Belfast.

67.1. Please see earlier sections.

68. Please describe how you typically obtained your patients' consent to treatment. In particular:

a. What information was provided to patients by you or others regarding the risks, benefits and potential side-effects of treatment options?

68.1. My standard practice for all patients was to supply a booklet (where available) describing the treatment proposed and outline the risks, benefits and potential side-effects. The patient was normally asked to attend with a member of family and encouraged to ask questions and take part in the discussion.

b. What information was provided to patients by you or others regarding the consequences of forgoing treatment?

68.2. As to the consequences of forgoing treatment, this naturally was part of the discussion about the proposed treatment. The patient was invited to consider the proposal and to return another date to give their decision.

c. How was patient consent typically recorded?

68.3. The patient decision was noted, together with the discussion in their chart. If they chose to go forward, they were asked to sign a consent form and offered a copy of the same form. That form would then form part of their patient record.

69. Did you routinely take blood samples from patients attending Belfast? If so, what information was provided to patients by you or others about the purposes for which the samples are being taken? Did you obtain patients' consent to the storage and use of the samples and if so, how?

69.1. Patients were informed of the tests to be carried out and normally asked for verbal consent. If storage in excess of the normal laboratory storage for quality control purposes was proposed this required separate written consent.

70. If applicable, how many patients at the Centre were infected with HIV, HCV, HBV through blood products or were co-infected with HIV and HCV through blood products?

70.1. I do not have this information.

71. What if any involvement did you have in the treatment of Belfast's patients for HIV and/or HCV and/or HBV? Are there multidisciplinary clinics (e.g. haematology and hepatology), and if not, would such arrangements be beneficial?

71.1. Where patients were receiving treatment for hepatitis C they attended for routine monitoring of that treatment with us and be seen also by hepatologists at the Royal Victoria Hospital.

72. What if any psychological services were available at Belfast to patients infected with HCV/HBV/HIV?

72.1. I do not have this information.

73. What has been the impact of the infection of patients with HIV and/or hepatitis through blood products:

a. upon patients at Belfast (without identifying any individual patient); and
b. how treatment was decided, arranged and provided at the Hospital?

73.1. I am unable to assist with these aspects.

74. Has the infection of patients with HIV and/or HBV and/or HCV through blood products changed or influenced your professional practice and approach, and/or that of your colleagues, and if so, how?

74.1. Working through various Blood Transfusion committees my colleagues and I have tried to reduce blood and blood product usage through education and establishment of maximum blood order schedules for specific cold surgical procedures.

75. The enclosed document is a report from a UKHCDO audit of the Northern Ireland Haemophilia Comprehensive Care Centre conducted in 2006, when you were the acting Director of the haemophilia centre at Belfast City Hospital [WITN3082025]. The report discusses a number of concerns, including low staff morale, nursing and administrative issues, diminished training, teaching, and research and development, and a lack of long term management plans (pages 24 - 29).

a. Please detail the issues raised in the report and how they developed.
b. What were the consequences, if any, for the treatment of patients with bleeding disorders?
c. What steps did you take/did the Centre take to correct these issues?

75.1. The major reason for the problems described was the absence of a long-term dedicated Haemophilia Centre Director and the steps we took were to continue to try to fill the vacant post.

75.2. This eventually succeeded in 2008 with the appointment of Dr Gary Benson.

75.3. Whilst I was nominally 'acting director', I already had a more than full time post being Stem Cell bank director, transplant director and Clinical lead etc.

75.4. I was 'acting director' in between times because there was no one else available with significant experience of working with this group of patients.

75.5. I relied heavily on the nursing staff and Dr McNulty to contact me when there were particular problems or issues.

75.6. My major concern was that the clinical service for our adult patients, both old and new was maintained to as high a standard as we could for both inpatients and outpatients.

75.7. It was fortunate that we had expert input from Dr Anderson and Dr O'Keeffe in between the periods where there was only the Centre staff and myself.

75.8. This reassured me that we were managing to provide a reasonable standard of clinical service for our patients, though clearly there was little possibility for staff or service development at a time when we were struggling to maintain as high a standard as was possible.

Section 6: Your role at NIBMT

76. Please outline the roles, functions and responsibilities you had at the NIBMT during your period as Director.

76.1. There would appear to be some confusion over this description for which I apologise.

76.2. The Northern Ireland bone marrow transplant service (NIBMT), which comprises both the clinical and laboratory elements is out with the remit of this inquiry.

76.3. The clinical and laboratory service aspire to the standards set out by the European blood and bone marrow transplant group viz. The Joint

Accreditation Committee ISCT (JACIE) and the stem cell bank elements are under the jurisdiction of the Human Tissue Authority.

76.4. Collection of either bone marrow or peripheral blood stem cells is undertaken for the sole purpose of transplantation. There is no element of blood donation per se. This service would be a user of the Northern Ireland blood transfusion service

77. Please describe the following in respect of the NIBMT during your period as Director:

a. its structure, staffing and hierarchy;
b. its remit;
c. its aims and objectives;
d. how it was funded;
e. how decisions were made;
f. and to whom the NIBMT was answerable.

77.1. See reply 76 above.

Sufficiency and safety of blood supply in Northern Ireland

78. Please explain how NIBMT's functions and practices contribute to maintaining the sufficiency of the blood supply in Northern Ireland. For example, you may wish to comment on the NIBMT's policies, guidance or practices that relate to:

a. public information campaigns to recruit donors;
b. maintaining adequate infrastructure;
c. maintaining adequate logistical arrangements to ensure the appropriate storage and distribution of blood and blood products;
d. methods to maximise the yield of blood products from donated blood; and
e. the setting and reviewing of targets for the amount of plasma required to be collected by the NIBMT.

78.1. Not relevant. See reply 76 above.

79. Please explain how NIBMT's functions and practices contributed to maintaining the safety of the blood supply in Northern Ireland. For example, you may wish to comment on the NIBMT's policies, guidance or practices that relate to:

a. collecting information about blood donors;
b. screening blood donors;
c. identifying risks of infection associated with the use of blood and/or blood products;
d. risk reduction measures, including but not limited to donor selection policies, the screening of blood donations for infections, the tracing of blood donations and other policy measures;
e. Sharing information with relevant stakeholders about infected donations;
f. sharing information to the public about infections that may affect the safety of the blood supply; and
g. achieving and maintaining self-sufficiency of the blood supply.

79.1. Not relevant. See reply 76 above.

Relationship between NIBMT and government

80. Please explain the relationship between the NIBMT and the Department of Health Northern Ireland (DHNI) during your time as Director. What authority and decision-making power, if any, did DHNI hold over the functions and responsibilities of NIBMT as an organisation?

80.1. Not relevant. See reply 76 above.

81. Was NIBMT required to report to or advise the DHNI in respect of its functions or responsibilities? If so, please provide details. Were such reports and/or advice provided on a regular basis, or were they provided on request? What form did these reports and/or advice take?

81.1. Not relevant. See reply 76 above.

82. Did you, or any of your staff, attend meetings with DHNI staff? If so, please provide details of the frequency and subject matter of such meetings, as far as you can recall.

82.1. Not relevant. See reply 76 above.

83. Did NIBMT share responsibility with DNHI to ensure a sufficient and safe supply of blood and blood products in Northern Ireland? If so, please provide details.

83.1. Not relevant. See reply 76 above.

84. Please describe NIBMT's relationship with any other relevant government departments.

84.1. Not relevant. See reply 77 above.

Relationship between NIBMT and other blood services

85. Please explain the relationship between NIBMT and the other UK blood services during your time as Director.

85.1. Not relevant. See reply 76 above.

86. Did you, or any of your staff, attend meetings with staff from other UK blood services? If so, please provide details of the frequency and subject matter of such meetings, as far as you can recall.

86.1. Not relevant. See reply 76 above.

86.2. The Northern Ireland bone marrow transplant service (NIBMT), which comprises both the clinical and laboratory elements is out with the remit of this enquiry Questions 76 to 86 are not applicable

Other issues

87. The enclosed note from a meeting of the Northern Ireland Regional Transfusion Committee held on 2 May 2003 records your involvement in the establishment of the Regional Haemovigilance Service in Northern Ireland [DHNI0000006_015]. Please explain:

a. the aims and purpose of the Regional Haemovigilance Service;

87.1. Our blood bank at the Royal group of hospitals had taken part in the reporting to the SHOT enquiry (serious hazards of transfusion) since its inception in 1996. It was clear that a more proactive local organisation was required, however funding would be difficult.

87.2. The background to the service was a need to comply with various European directives viz. the quality and safety standards for blood and its components as set out in Directive 2002/98/EC, also referred to as the European Blood Directive. It covers all steps in the transfusion process from donation, collection, testing, processing, and storage to distribution.

87.3. Commission Directive 2005/61/EC on the traceability requirements and notification responsibilities in case of serious adverse reactions and events.

87.4. Commission Directive 2005/62/EC that sets out Community standards and specifications relating to the quality system for a blood bank.

b. your role in its establishment;

87.5. I took the lead role in discussing this with the then chief medical officer for Northern Ireland. Clearly, funding was required and the business case had to be developed. The core aims were to make sure that donor blood was used safely and appropriately and that all staff connected with blood transfusion had training and competency checks to enable them to do this to a high standard. We were fortunate to be able to appoint Ms S Murray as a transfusion nurse specialist at the Royal group of hospitals. I worked closely with Ms S Murray, who did an enormous amount of work both for the business

case and job descriptions for the staff who would subsequently work with the Regional Haemovigilance Service.

c. any decisions, procedures or policies implemented by the service; and

87.6. Decisions, procedures and policies implemented by the Regional Haemovigilance Service were to achieve compliance with the relevant European directives as detailed above

d. how the service affected the treatment and care of patients with bleeding disorders.

87.7. If the patient with bleeding disorders required blood transfusion, this service applied to them just as any other patient.

Section 7: Pharmaceutical companies/medical research/clinical trials

88. Have you ever:

a. Provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products?
b. 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?
c. Sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?
d. Received any financial incentives from pharmaceutical companies to use certain blood products?
e. Received any 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?
g. Undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products?

h. **Provided a pharmaceutical company with results from medical research studies that you have undertaken? If so, please provide details.**

88.1. For all sections of this 88 (a to h), the answer is no.

89. **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?**

89.1. Not applicable.

90. **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?**

90.1. Not applicable.

Section 8: Interaction with the financial assistance trusts and schemes

91. **Please explain as fully as you can any involvement you have had in relation to any of the trusts or funds (the MacFarlane Trust, the Eileen Trust, the MacFarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund) which were set up to provide financial assistance to people who had been infected. Relevant involvement may include:**

a. **Occupying a formal position within any of the trusts or funds;**
b. **Providing any advice to any of the trusts or funds, including for the development of any eligibility criteria or policies;**
c. **Informing patients about or referring patients to the different trusts or funds;**
d. **Determining or completing any part of applications made by patients.**

91.1. My role in regard to these various trusts was limited to informing patients about their existence and helping patients to complete applications at their request. This would previously have been done by Dr EE Mayne.

Section 9: vCJD

92. 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?

92.1. I was certainly aware of the theoretical risk of transmission of the CJD by 2000 as I had received a letter from Mr Jenkins in 2000 and subsequently from Dr McClelland (NIBTS)

93. Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so, please answer the following questions:

a. What steps were taken/put in place at the NIBMT and at haemophilia centres at i) the Royal Victoria and ii) Belfast for informing patients about the risks of or possible exposure to vCJD?

93.1. I think that my involvement was limited to the 3rd notification re v CJD in 2004 Dr Julia Anderson would have been involved with the initial patient notifications.

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?

93.2. I had no involvement in decisions as to what information should be provided to patients about vCJD.

93.3. The steps and mode of informing patients about the risks of possible exposure to vCJD followed exactly the lines advised by UKHCDO and I assume the relevant advisory committee on dangerous pathogens which would be UK-based.

93.4. It was to find out what the proposals were that I attended a meeting of the Scotland and Northern Ireland haemophilia directors group in September 2004. Dr McNulty, myself and the nursing and secretarial staff at the Haemophilia Centre in the Belfast City hospital discussed and read over the documentation which we had been advised to send to patients.

93.5. This additional workload, which had to be coordinated with information being sent to patients throughout the UK was completed by the hard work and planning of our centre staff. It was vital that, subject to the exigencies of the Postal Service, that all patients were informed at the same time and were offered various ways of contacting us for further information or counselling.

94. What measures were put in place from a public health perspective at the haemophilia centres at i) the Royal Victoria and ii) Belfast in relation to the care and treatment of patients?

94.1. By 2004 there was only the Haemophilia Centre at the Belfast City hospital. Information given to patients included advice that they should inform health professionals and or ourselves before any planned procedures. This was in line with national advice.

Section 10: Look-back and tracing exercises

95. In as much detail as you are able to, please explain your knowledge and involvement in hepatitis (of any kind) look-back or tracing exercises at any of the institutions at which you have worked. In answering this question, you may wish to consider the enclosed documents referring to your involvement in HCV look-back exercises [NIBS0001311_002 & NIBS0001405].

95.1. In 1996, I received a letter from the Northern Ireland Blood Transfusion Service (NIBTS) regarding the HCV look back exercises. They had identified in their donor panel a number of donors who tested positive for HCV and required assistance from our blood bank in tracing the recipients of products such as fresh frozen plasma red blood cells or platelets from these donors. Our blood bank was able to trace all of these blood products to their recipients. I then requested the patient's charts from medical records and went through them to confirm that the patient had received the identified product. It was not uncommon to find that the patient was deceased, as someone who has sustained major trauma will inevitably have a considerable number of units of blood and blood products. Where the patient was alive, I had to identify the relevant clinician or GP and inform the NIBTS of these details. Further follow-up would have been arranged subsequently by the relevant clinician or GP.

96. In as much detail as you are able to, please explain your knowledge and involvement in HTLV-III/HIV look-back or tracing exercises at any of the institutions at which you have worked. In answering this question, you may wish to consider the enclosed letter dated 13 September 2002 in which Dr Morris informs you of an HIV look-back exercise [NIBS0001184].

96.1. The HIV look-back exercise followed the pattern described above for hepatitis C where the patient who had received the unit of blood or blood products was identified and their details communicated to the transfusion centre. (NIBTS).

97. In as much detail as you are able to, please explain your knowledge and involvement in vCJD tracing exercises at any of the institutions at which you have worked. You may wish to consider the enclosed letter from Dr Cuthbertson dated 7 September 2004 which discusses tracing recipients of potentially vCJD-implicated blood products [NIBS0000640_008].

97.1. As discussed below at section 99 , the major difficulty with tracing albumin from implicated batches was that there were no computerised systems to allow this to be done. Dr Cuthbertson specifically asks us to confirm that these batch numbers were received by the Royal Victoria.

98. The enclosed letter from Dr McClelland to you dated 12 January 2001 discusses a batch of albumin which was made from a plasma pool that included a donation from a patient diagnosed with vCJD [NIBS0000507_001]. What do you recall about the process for dealing with vCJD implicated batches of albumin, or any other blood products?

98.1. Information about the vCJD implicated blood products most often involved plasma pools, which had been used for the fractionation to produce albumin. At that time, albumin was commonly issued in bulk to units around hospital for example cardiac Theatre, which used albumin in quantity. There was no computerised method for tracing which patients had received which batch of albumin and the relevant information was not always filed in the patient's chart. Hence, I was not involved in any vCJD tracing exercise for this type of product, as it was not possible.

98.2. See section 98 answer above.

Section 11: Other Issues

99. 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.

99.1. As far as I am aware, the only complaint made about myself (insofar as relevant to the Inquiry's Terms of Reference) has been referred to earlier; the letter from Karen Pappenheim (BHCT0000024).

99.2. I note that she states "that this was unacceptable practice particularly since the consultant haematologist who broke the news has not been available to patients since". I have a clear memory of this, as it was my practice to tell patients that should then have any questions subsequent to our discussions that they should get in touch. Coming up to my annual holiday I had informed patients that I would not be available after a certain date. I believe this is what she refers to.

100. 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.

100.1. None.

Statement of Truth

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

Signed GRO-C

Dated 22nd September 2021.

Table of exhibits

Date	Notes/Description	Exhibit Number
1 February 2021	Curriculum Vitae of Dr Frank Jones	WITN5559002