Witness Name: Dr Liakat Parapia
Statement No.: WITN0785003
Exhibits: WITN0785004 & WITN0785005
Dated: 2 September 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF
PROFESSOR LIAKAT ALI PARAPIA

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 13 February 2020

I, Professor Liakat Ali Parapia, will say as follows: -

Section 1: Introduction

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

   My name is Professor Liakat Ali Parapia. (My address is known to the Inquiry).

   I was born on GRO-C 1949.

   I hold the following qualifications MBBCh, FRCP, FRCPE, FRC Path.

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

   From 1982 to 2009 I held the following relevant posts:

   - Consultant Haematologist
   - Director, Bradford Haemophilia Centre
   - Visiting Professor, University of Bradford
   - I retired from the NHS in 2009

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*

   - Member of National Haemophilia Centre Directors Organisation
   - Member of The Regional Haemophilia Group, Yorkshire

- I was a member of a working party on Platelet disorders and rare coagulation disorders.

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, reports or documents that you provided. I note that in your statement dated 1 June 2019 made to the Inquiry, you state at paragraph 14 that you have already given information and documents to the 'commission'. By that I understand that you mean the Penrose Inquiry. Please provide a copy of the information and documents you provided to that inquiry.*

   I have not provided evidence to, or been involved in, any other inquiries (including the Penrose Inquiry), 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.

   To date I have responded to two previous inquiries from the Infected Blood Inquiry. This submission is my third response.

   In June 2019, I contacted the Haemophilia Society offering them my support in connection with the Infected Blood Inquiry. Subsequently, I was contacted by Malcolmson Law UK Ltd., who were at that time instructed by the Haemophilia Society. I met a Mr Raymond Bradley with his two assistants in Leeds in November 2018. They inspected and took from me a voluminous bundle of papers and articles which had been retained by me and which may be of interest to the Infected Blood Inquiry. I do not know how this material was used and whether it was copied. I do not know if any or all of this material was passed to the Infected Blood Inquiry by the Haemophilia Society. The material was subsequently returned to me with an accompanying letter. **See attached "WITN0785004".** I am happy to share this material with the Infected Blood Inquiry, but it is not in any order.

Section 2: Decisions and actions of the Haemophilia Centre, Bradford Royal Infirmary regarding the use of blood products

5. *Please describe the roles, functions and responsibilities of the Haemophilia Centre at the Bradford Royal Infirmary ("the Centre") during your period as director.*

   Bradford Haemophilia Centre is based in a district general hospital in Bradford and was one of the first haemophilia centres in Yorkshire. It's first director was Professor Robert Turner who retired in 1981 and my appointment as Director and Consultant Haematologist was confirmed in 1982. Since my appointment we have tried to offer a comprehensive care service which was generally better than the average district hospital. As we did not have enough treated severe haemophiliacs, we were not able to qualify as a Reference centre. The centre was a member of the UK Haemophilia Centre Director's Organisation but not a member of the Executive.

   The Centre's main function was to investigate, diagnose and treat bleeding disorders, mainly in the Bradford district. We also had a few patients from outside the district. We trained junior medical staff and promoted research. We collaborated with the University of Bradford. I was honoured with a Visiting Chair in Biomedical Sciences.

   The Centre was part of the Haematology Department which also treated other Haematological

disorders. We worked closely with Leeds Hospitals.

6. *Please describe your role and responsibilities as consultant haematologist and director of the Centre.*

   My role was as a Consultant Haematologist and I was responsible for treating Haematological disorders in general. Haemophilia and the care of other bleeding disorders was one of my roles. Since my appointment in 1982, Dr Adrian Minford, Consultant Paediatrician, took over the role of treating children. We carried out joint Clinics whenever possible

7. *What decisions and actions were taken, and what policies were formulated, by you and by the Centre, regarding the manufacture, importation and use of blood products (in particular factor concentrates) during the time that you were director?*

   I was responsible for the selection of blood products and followed guidelines given by the UKCDO and attended their meetings regularly. I had no influence regarding manufacture or importation of blood products.

8. *What responsibility did the Centre, and you as its director, have for the selection and purchase of blood products, and what decisions were taken by you or the Centre as to which products to 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?*

      The decision as to which products to use were made on clinical needs, availability of products and guidelines from the UKHCDO. I made the decisions on adult bleeding disorders and Dr Adrian Minford was in charge of the paediatric patients. I was the overall Director of the centre.

      The budget for blood products was not held by me but I advised on the products needed by our patients. The initial purchases were made through the pharmacy at the Bradford Royal Infirmary in 1984 and subsequently were bought on regional contracts.

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

      Generally, the BPL products were considered safer. Commercial products were purer and easier to prepare and therefore more suitable for home treatment.

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

      BPL products were generally cheaper. Products were mostly chosen based on clinical needs and safety. We were aware of the expensive nature of blood products. I never had to curtail my treatment due to financial constraints. The commercial products were easier to use and better presented for home packs.

9. *What was the relationship between the Centre/you and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Centre's and your decisions and actions? In addressing this question:*

   a. *I note in the previous statement that you made to the Inquiry on 1 June 2019 at paragraph 14 that you stated the pharmaceutical companies had 'considerable marketing influences' on the Haemophilia Centre Directors. Can you please explain what you mean by this and how this*

influenced you and/or (in so far as you are aware) any other Haemophilia Centre Directors?

The marketing budget of the Pharmaceutical companies was far greater than the BPL. They were primarily responsible for the education of the doctors and nurses as they sponsored local regional, national and International meetings. This is probably still the case but less so than before. They also funded travel and other expenses for Centre staff to attend the meetings. Extravagant hospitality was often available for Centres using large amounts of their products. I cannot recall if there was a requirement of the centres to declare the hospitality as is the case now. We were relatively a small centre.

The centres and their Directors using the most commercial products also received support in other ways. I do not know if financial incentives were given. Many Reference Centre Directors may have acted as paid Consultants and advisors to commercial companies.

My centre was given grants for staff travel to meetings nationally and Internationally. All grants were deposited in Haemostasis and Thrombosis Fund (Charitable Trust). As a medical doctor I had access to Hospital Postgraduate Funds. All applications were vetted and receipted and filed in the Hospital Finance Department. No financial gain was obtained by any individual member.

We were not influenced by the sponsorships to give preference to any one manufacturer's product.

b. *You refer at paragraph 15 of your statement of 1 June2019 to benefits and donations that were channelled into Bradford Hospital Charitable funds. Why were these benefits and donations paid? Who paid them, and what were the amounts and frequency at which these were paid?*

Donations were mostly from Pharmaceutical companies for purposes of Education and training for the staff. Very rarely, amount to less than £100 were from patients. These monies were deposited within the Hospital Charitable Funds and used according to Hospital Charity rules. No one was allowed to profit from them.

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

BPL Factor 8 was ordered via the Blood Transfusion Service. There were Regional contracts for commercial products delivered to the respective Centres.

11. *How were decisions taken as to which products to use for particular patients? What role did you have in such decisions?*

The products were chosen mostly by me in conjunction with other Centre Staff. We followed UKHCDO guidelines.

12. *What alternative treatments to factor concentrates were available for people with bleeding disorders?*

DDAVP was available for mild Haemophilics and patients with Von Willebrands disorder. Oral Tranexemic acid and topical agents were also used.

13. *What were, in your view, the advantages and disadvantages of those alternative treatments? What use did you 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?*

The alternative treatments were viral free but not always adequate for treatment of severe bleeds.

The alternative treatments were subcutaneous DDAVP, Oral Tranexemic Acid, and topical haemostatic agents. In general, these were used for Von Willebrand's disorder and mild Haemophiliacs. These were viral free but not always adequate for treatment of severe bleeds. These were used in preference to plasma products if the medical status allowed it.

For severe bleeds and for severe Haemophiliacs Factor concentrates were used. We were not aware which plasma products were infected.

However, there is no doubt with hindsight that there would have been less transmission of infections using cryoprecipitate and locally made NHS products. This had to be balanced against clinical efficacy and availability.

14. *What was the policy and approach at the Centre in relation to home treatment? Did that policy and approach change over time and if so how?*

Home treatment was a big bonus for severe Haemophiliacs as it reduced joint damage and could be given immediately. As the patients became more acquainted with home treatment more of it got used as replacement therapy.

15. *What was the policy and approach at the Centre in relation to prophylactic treatment? Did that policy and approach change over time and if so how?*

Prophylactic treatment was a major advancement and a great therapeutic benefit to the severe Haemophiliacs. We put this in place as soon as we could, and the practice continues to this day. I cannot remember the exact time prophylaxis was introduced.

16. *What was the policy and approach at the Centre as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and if so how?*

Cryoprecipitate was used at the time of my appointment in 1982. For Haemophiliacs this was gradually replaced by concentrates.

We continued using cryoprecipitate for many years for treatment of Von Willebrand and Factor XIII deficiency.

Now it would be very rarely, if ever used for Haemophilia bleeding as there are purer and safer products available.

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

Commercial products were avoided as much as possible. The safest blood products and alternatives were always considered first. With the introduction of recombinant products, the plasma derived products were replaced. Alternative treatments, in order to avoid plasma derived concentrates, were always given priority. The children were under the care of Dr Adrian Minford

(Consultant Paediatrician).

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

    Mild and moderate Haemophilics were treated with DDAVP but in rare instances this was not adequate and Factor 8 supplements were needed.

19. *Approximately how many patients with bleeding disorders were under the care of the Centre when you first started working there and over the years that followed? What proportion of those treated were children? (If you are able to give exact rather than approximate figures, please do so).*

    22 severe Haemophilics were treated in 1983.Total number of patients exceeded 100 of which 40 were Haemophilia patients. I am not sure of the exact figures.

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

    Only HIV and Hepatitis C viruses were transmitted as far as I know.

Section 3: Knowledge of, and response to, risk

General

21. *When you became a consultant haematologist and a director of the Centre in 1982, 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 that knowledge and understanding develop over time?*

    When I was appointed as a consultant and director of the haematology unit in 1982, I was aware of infections associated with blood donors and blood products. There was awareness of a higher number of abnormal liver function tests in patients treated with blood products and I think there was the same awareness for Hepatitis B at the time. It was part of our medical education to know about the possibility of transmission of bacterial, parasitic and viral infections in blood transfusions and therefore in blood products.

    HIV and Hepatitis C were not known then.

22. *What advisory and decision-making structures were in place, or were put in place at the Centre and and/or within the area covered by the Yorkshire Regional Haemophilia Service, to consider and assess the risks of infection associated with the use of blood and/or blood products?*

    The centre worked in close liaison with other centres particularly Leeds Hospitals and the Public Health Laboratories based in Leeds. There were regular regional and National meetings as well as communications from the National Haemophilia Centre Organisation and the Haemophilia Society

    The communication links were excellent.

23. *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?*

When I first used the commercial Factor 8 in 1984 the relative risks of infection from the use of fractionated blood products was not known to the same extent as we do now. One knew that BPL products were made from voluntary British donors and therefore were likely to be safer than imported Factor 8 from America.

24. *What decisions and actions were taken by the Centre and by you to minimise or reduce exposure to infection?*

    We were constantly monitoring our patients and severe haemophiliacs would be seen on at least every three months and their liver function tests and Inhibitor states monitored. They were all vaccinated in line with recommendations by the Haemophilia Centre Director's Organisation and the Public Health.

    We were informed almost immediately as soon as any blood products were suspected of viral transmission.

Hepatitis

25. *When you became director of the Centre in 1982, 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 blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?*

    All haematologists including myself were aware that blood products could transmit infections. We were aware of risks of Hepatitis A and B. Gradually we were made aware of risks with Hepatitis C. Hepatitis C was further categorised and all patients were monitored for the added knowledge. Our understanding about blood transmitted viruses has improved considerably over time.

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

    Patients were screened and counselled, and bloods tested on a three-monthly basis or when they attended clinics.

    All patients were screened clinically by relevant examination and blood tests.

    Patients were counselled and seen on at least a three-monthly basis. Abnormal liver functions were further investigated by specialist blood tests and appropriate advice given. Patients were referred to Hepatologists or Infectious Disease Specialists as and when indicated. Advice was offered to all patients regarding transmission, contacts, family life, schooling, hobbies, etc. Leaflets were given as appropriate.

    Our Nurse Specialist was also available for information, advice and support. We had a Counsellor/Social worker in the unit for a few years.

27. *What if any actions did you and/or the Centre take to reduce the risk to patients of being infected with hepatitis (of any kind)?*

    Where a product was known to be infected or had a significant risk of transmission of infection, it was not used.

28. *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?*

We were aware of viral infections and their dangers. It was a period of constant new knowledge and we acted accordingly. All haematologists including myself were aware that blood products could transmit infections. We were aware of risks of Hepatitis A and B. Gradually we were made aware of risks with Hepatitis C. Hepatitis C was further categorised and all patients were monitored for the added knowledge. This understanding about blood transmitted viruses has improved considerably over time

HIV and AIDS

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

As the first cases were noted of HTLV3, subsequently named HIV, we had a policy of stopping the use of these products immediately making sure the patients were tested, informed and counselled. Subsequently they were referred to the infectious disease consultant.

New information appeared every week from all over and we had to adjust our practice accordingly. Sometimes we were misinformed and sometimes the information given to us had to be modified. See attached letter from Haemophilia Society and the UKHCDO, attached as "PP3".

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

I cannot remember the exact date I was made aware of the association between AIDS and the use of blood products. That possibility obviously was always there in our minds. I think it may have been 1983 or 1984. Immediately we became aware, we made sure that our patients were not further exposed. They were given appropriate tests, counselling and information.

31. *What steps did you then take in light of that awareness? What steps were taken at the Centre?*

We discontinued using blood products that we felt had the possible risks of infections of HIV or Hepatitis C. NHS and commercial blood products were used on the basis of reassurances given by the suppliers. We followed the UKCDO guidelines. I cannot now recall the details of which blood products I/the Centre discontinued using. By "reassurances given by the suppliers", I am referring to the drug information which included statements on safety and as supplied by the pharmaceutical companies with the blood products. Information was also available in published literature and given by the pharmaceutical representatives. This information was in the public domain and not exclusive to us at the Centre.

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

The patients at highest risk were screened and counselled at three monthly intervals.

33. *What if any actions did you take to reduce the risk to your patients of being infected with HIV?*

We discontinued using blood products that we felt had the possible risks of infections of HIV or Hepatitis C. NHS and commercial blood products were used on the basis of reassurances given by the suppliers. We followed the UKCDO guidelines.

34. *Did you continue to use blood products to treat patients, after becoming aware of the possible risks of infection of HIV? Why?*

    We discontinued using blood products that we felt had the possible risks of infections of HIV or Hepatitis C. NHS and commercial blood products were used on the basis of reassurances given by the suppliers. We followed the UKCDO guidelines.

Response to risk

35. *Did you or the Centre take any steps to ensure that patients and/or the public were informed and educated about the risks of hepatitis and HIV? If so, what steps*

    Patients were well informed in our centre by our staff but also by communications from the Haemophilia Society. The media publicised infections very well and we had to then follow with the discussions with our patients.

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

    We acted promptly to any information regarding the risks of infection. We think they were adequate but obviously limited by the knowledge and information that was available to us at the time. It became generally known that British blood products from British donors were safer, but the commercial products were constantly being improved and were more convenient to use and usually more expensive. They were often promoted as being safer products based on scientific grounds.

37. *Or actions by you and/or by the Centre could and/or should have avoided, or brought to an end earlier, the use of infected blood products?*

    In retrospect we should have used more NHS BPL material, but it's use would have been resisted by the patients as the information they had received indicated that BPL material was inferior product. We never knowingly treated patients with infected material. As to the "information" received by patients that indicated that BPL product was inferior and from whom, my recollection is that the BPL products were often perceived by patients as not as up to date as the commercial material. The commercial material was often purer and more soluble. It was seen as being easier to prepare and came in handy home packs. Patients were well aware of the advantages of the commercial products. This "information" was probably received by patients from many sources available at the time including from other patients (by word and mouth), the press, other Centres, the Haemophilia Society,etc.

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

    We did not revert to treatment with cryoprecipitate but in retrospect maybe we should have used more of BPL material. There was also the general perception that there was a shortage of BPL

products although in practice we never found this so. We followed recommendations of the UKHCDO. We always used NHS material wherever we could.

Cryoprecipitate was inconvenient to prepare and administer. It also caused delays in administration.

As soon as we were informed that any product was infected, they were withdrawn immediately from the centre as well as from home treatment.

39. *What consideration did you give to the use of heat-treated products prior to the meeting of UKHCDO Reference Centre directors on 10 December 1984 (copy enclosed)? Did you (a) agree with and (b) follow the recommendations made at the meeting, including the recommendation to use heat-treated concentrates?*

We reverted to Heat treated products as soon as they were available to us.

The United Kingdom was very well organised in terms of disseminating information. There is no doubt that if more of the BPL material, heated or otherwise, had been available and used in the United Kingdom then there would have been less cases of Hepatitis C and HIV infection. I am not sure whether the UKHCDO could have promoted more the use of UK sourced concentrates. However, the centres that predominantly used BPL material had lower rates of infections with hepatitis and HIV whilst centres with larger use of commercially produced Factor 8 had a greater incidence of HIV.

40. *Do you consider that heat-treated products should have been made available earlier?*

Yes, that is the impression I have. Heat treated products were safer than untreated ones. There may have been a problem with availability of the BPL material. I do not remember all the dates.

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

We made correctional decisions as soon as we were made aware of any danger to the patients.

42. *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?*

The transmission of viruses was known before 1980 and therefore greater efforts should have been made to inactivate viruses in blood and blood products prior to that date. It was also known that British products based on voluntary single donations would be safer. I presume that the responsibility lies with the Blood Transfusion Service and Public Health Laboratories to have put more pressure on the relevant bodies. I suppose the UKHCDO should have given greater leadership in this respect

The Reference centres which made up the UKHCDO had themselves varying practices. Some centres used more NHS BPL Blood Transfusion Service products and there were some that were more likely to use commercial products

43. *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?

Greater efforts should have been made particularly by BPL and supported by the government and the Directors.

Section 4: Treatment of patients at the Centre

Provision of information to patients

44. *What information did you provide or cause to be provided and/or what information was (to your knowledge) provided by others at the Centre, to patients with a bleeding disorder (and to patients who did not have a bleeding disorder but were treated with blood products for other conditions) about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates), prior to such treatment commencing? Please detail whether and if so, how this changed over time.*

I was appointed in 1982 and the policy was always to keep the patients well informed. The information we gave was obviously limited to the knowledge that we had at the time. There is no doubt that as we and our patients became more aware that there was more dissemination of information via leaflets from the Haemophilia Society, the pharmaceutical companies and from members of our centre. I agree entirely that patients should have been kept well informed and they should have participated fully in their own treatment. We had a comprehensive care model that supported our belief that the best should be offered to the patients. We also formed a charity, Annette Fox Leukaemia Research Fund, which funded the day unit and an inpatient ward with all the facilities that patients with bleeding disorders with or without viral infection could be looked after on. The home treatment programme involved not only the doctors, but we were supported by one of the first Nurse Specialists, Sister Pauline Sharp, in Yorkshire. She carried out home visits and also trained the patients and their relatives.

All patients were seen and counselled individually by a Doctor often supported by the Nurse Specialist or a Counsellor. Written material was given out where available.

45. *Do you accept that patients should have been informed that it was well known that there were hepatitis viruses within blood?*

Yes

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

Alternatives to factor 8 were always considered. We followed the UKHCDO guidelines. The practice changed in line with National guidelines.

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

Certain criteria had to be met before the patients could be considered for Home treatment. We had to make sure it was safe for patients to enter the programme. This could only be done after detailed discussions and training.

HIV

48. *When did you first discuss AIDS or HIV (HTLV-III) with any of your patients at the Centre?*
I am unsure of the exact dates of when our first patient was diagnosed but we did discuss HIV with the patients as well as their relatives where relevant. They were never told by letter or by telephone. They had a personal private interview with me and usually in the presence of the Nurse Specialist. We also had our own counsellors in the 1980's.
In the mid-80's, there was debate as to if HTLV (HIV) reflected immunity or whether it was reflective of active viral infection. There is no doubt that it did show an exposure to the virus and accordingly this was discussed with the patient and appropriate advice given. In due course we learnt about the prognosis and treatment options and these were offered to the patients. I do not now recall whether we tried to establish the time period for the seroconversion. We had information of when the tests were done and could only guess when seroconversion could have occurred.

49. *Please describe how and when you learned that patients under the care of the Centre had been infected with HIV.*
The patients were informed of HTLV3 and HIV tests as soon as the results were obtained. Initially there was a debate on the implications of a positive test. I think we had our first HTLV3 antibody positive patients in 1984.The results came from Public Health Laboratories in Leeds. There was a debate about the interpretation of a positive HTLV3 result. **See attached "WITN0785005"** the information leaflet from the Haemophilia Society.

50. *How and when were patients told that they had been, or might have been, infected with HIV? Were they told in person, by letter or by telephone? Were patients seen individually or in groups?*
We had a separate clinic with our own counsellors and a Haemophilia Nurse Specialist. The information was given individually in privacy.

51. *What information was given to them about the significance of a positive diagnosis? Were patients told to keep their infection a secret? What information was provided about the infection, prognosis, treatment options and management?*
There was initial confusion about the HTLV3 antibody positive result. It soon became apparent that a positive result meant active infection rather than immunity. The prognosis improved over time and only the facts were given to patients as we received them.
We never destroyed their hopes for future improved treatment and survival.
Patients were never told to keep it a secret but advised to share where it was appropriate.

52. *What was the Centre's/your policy in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were the tests carried out?*The patients were counselled, and appropriate advice given as to the risk of transmission. A choice was given about the availability of the screening tests, particularly if they were unwell. Tests were not carried out routinely on the family members.

53. *What, if any, information or advice did the Centre provide to partners or family members of people that were at risk of infection with HIV or were infected with HIV?*

If partners were infected, they were counselled and referred to the Infectious disease consultant. If they were not infected, then appropriate advice was given on prevention and allaying any unnecessary fears.

54. *How many patients at the Centre were infected with HIV? Of those infected,*

- *How many had severe haemophilia A?*
- *How many had moderate haemophilia A?*
- *How many had mild haemophilia A?*
- *How many had haemophilia B or von Willebrand's disease?*
- *How many were children?*

As stated, we had less than 40 severe haemophiliac A patients, from memory I think probably between 20 to 30 patients were children. I do not have further details without looking at the records spanning from 1980 to 2000. The UKCDO collect this information and should be available to you.

Hepatitis B

55. *Were patients infected with hepatitis B informed of their infection and if so how?*

The number of patients infected with Hepatitis B was extremely low and these patients were referred to our infectious disease consultant and patients with abnormal live function tests were often referred to our liver specialist.

56. *What information was provided to patients infected with hepatitis B about the infection, its significance, prognosis, treatment options and management?*

Patients with Hepatitis B were referred to Consultant in Infectious Diseases.

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

None by Blood products as far as I can remember. Most patients were vaccinated.

NANB Hepatitis/Hepatitis C

58. *Were patients infected with NANB hepatitis informed of their infection and if so how?*

Patients with NANB Hepatitis and Hepatitis C were informed of their abnormal liver function tests and had information given about the interpretation of the Hepatitis C antibody test. Subsequently we also had information about viral loads and the differentiation between different Hepatitis C infections. These were in due course referred to our infectious disease consultant Dr Paul McWhinney or to our liver specialist consultant.

59. *What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management?*

As above.

60. *When a test for HCV became available, what if any steps were taken by the Centre and/or by you*

to ensure that all patients who had received blood products were traced and invited to be tested?

The blood products were withdrawn immediately. The Leeds Centre, Public Health and the manufacturers were all informed. A yellow notification card was also issued. Recipients were contacted, counselled and tested. If a batch of contaminated blood was discovered, the suspect batch was recalled and sent back to the manufacturers after notification. The 'yellow notification card' was to notify Public Health about infectious diseases. Only some diseases were notifiable. I think viral Hepatitis was one of them. Patients who were not in contact with blood products in question were not contacted. Only patients thought to be at risk were contacted for screening. All patients receiving blood products were screened regularly for HCV and HIV.

61. *When did the Centre begin testing patients for hepatitis C? How were patients informed of their diagnosis of hepatitis C? Were they told in person, by letter or by phone?*

The tests for Hepatitis C were carried out as soon as the tests were available by Public Health *Laboratories* in Leeds. The patients were never informed by letter or by phone and each result was discussed with the patient in private and usually in the presence of the Nurse Specialist. I do not have the details of how many patients were infected with Hepatitis C.

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

Patients with Hepatitis C were referred to the Consultant in Infectious Diseases. Some patients had stable *disease* not needing immediate treatment. A subgroup needed immediate investigations and treatment. Prognosis was variable. Many patients would have also been referred to the Liver specialist.

63. *How many patients at the Centre were infected with hepatitis C?*

I am not *sure*. Possibly about ten.

Delay/public health/other information

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

Results of HIV and Hepatitis tests were notified to patients promptly. They were seen individually and given the appropriate information and support. There were no delays that I know of.

All patients with bleeding disorders were reviewed in clinic depending on the severity they would be reviewed at *least* once per year, severe haemophiliacs were reviewed at least once every three months and there was no delay in informing the patients about their infection status and they were counselled accordingly.

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

We were aware of the implications to public health and appropriate advice was given. Where

necessary the Nurse Specialist visited schools etc and gave advice and support accordingly. Booklets and leaflets were given out where appropriate. We worked closely with the Public Health based in Leeds.

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

Patients were made aware of the relative risks of transmission of Hepatitis and HIV viruses to themselves and others. Written information was given where appropriate. They were also informed where more information could be available.

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

Counselling was available for all patients. This could only be done when all the relevant facts were available. Patients were made aware that not only could the viruses in question be transmitted by blood but they could also be transmitted by other body fluids and sexually. Leaflets were given where appropriate.

Consent

68. *How often were blood samples taken from patients attending the Centre? What information was given to patients about the purposes for which blood samples were taken? Did the Centre obtain patients' informed consent to the storage and use of those samples?*

Blood samples from the patients were taken at least once every three months besides tests for the viral status, a full blood count, liver function test and often tests for inhibitor. Patient consent was always obtained when samples were taken for HIV.

69. *Were patients under your 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? If it is your position that patients did give express and informed consent to treatment with factor concentrates, please explain the basis for that position.*

Patients were always treated with their informed consent. The normal practice at the time was verbal consent and entries were made in the notes. Facts were always explained by a doctor and/or the Nurse Specialist.

70. *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?*

No patients were tested or treated without their consent and only in relation to their medical condition

PUPS

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

New patients (PUPS) were rare as Haemophilia is uncommon. New patients gave an opportunity to use the safest new product and then monitor them for adverse events. Protocols approved by the ethical committees were adhered to. These were national trials approved by UKHCDO. We participated in PUP trials as part of National and International studies. It was not possible for any

single centre to accrue enough patients. The largest contributors were the Reference Centres who were part of UKHCDO. I cannot recall more details.

72. *Did you use the term PUP or PUPS when speaking about or referring to any of your patients? If so what did you mean by the use of the term?*

The term was not used. It was not necessary.

Research

73. *Please detail all research studies that you were involved with during your time as consultant or director of the Centre. 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;*

A list of my publications can be made available but may not be relevant to your Inquiry.

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

New studies were generated by outside agencies. They had protocols that were inspected and approved by our Hospital Ethics Committee. The studies had other collaborators and the studies would also have to have approval of their ethical committees.

c. *explain what your involvement was;*

I was the Director of the Haemophilia Centre and therefore my involvement was comprehensive. Any trial involving a child had to have Dr A Minford involved.

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

The factor 8 trials involved nationwide centres, all belonging to UKHCDO. Studies on Thrombotic disorders may have involved the University of Bradford.

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

Any cost pertaining to Factor 8 studies were remunerated by Factor8 companies. Other research was funded locally;

f. *state the number of patients involved;*

I can only remember two new Haemophiliacs. One was treated with Monoclate and the other with BPL material.

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

All patients in any form of intervention were counselled, informed of the study in detail and a written consent obtained. They had an option to withdraw any time. These studies were not published individually by me.

h. *provide details of any publications relating to the research.*

Please provide the same details in relation to any epidemiological or similar studies which you undertook (insofar as relevant to the Terms of Reference).

We tried to keep complete records of the patients for future studies. Our research in terms of Haemophilia was mainly to enter newly diagnosed patients in PUP studies in collaboration with other centres. As Bradford had a greater proportion of rare bleeding disorders, we tried to study the nature and treatments of these. Our interest also lay in Thrombotic Disorders.

Several studies were published and presented at international meetings. These patients did not receive factor 8 concentrates. They may have been treated with platelets or other concentrates particularly using Cryoprecipitate and factor 13.

74. *You entered two of your previously untreated patients into the UKHCDO trial of BPL's dry heat-treated factor VIII concentrate (8Y) in or around 1988. The report of the study published in the British Journal of Haematology in 1993 (84, 269 – 272, copy enclosed) by C Rizza, M Fletcher and P Kernoff called 'Confirmation of viral safety of dry heated factor VIII concentrate (8Y) prepared by Bio Products Laboratory (BPL): a report on behalf of U.K. Haemophilia Centre Directors' explains that factor VIII concentrate was used without selection from routine production lots and patients were followed up for 26 weeks after first exposure with blood samples being taken before exposure, then every two weeks for the first 16weeks, then every 4weeks up to week 26. Were your patients aware that they had been entered into this study? What information was provided to them and what steps were taken to obtain their consent? Were they aware that they were being reviewed for the purposes of the study on a regular basis?*

Any patients entered in any of our studies had a protocol which was adhered to in every detail. Informed consent was obtained, and the patients had been informed and consented. In relation to children, their parents would have been involved and they would have been aware that they were being reviewed for the purposes of the study. Children were under the care of Dr Adrian Minford although the Nurse Specialist would have also been involved.

75. *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?*

We followed the ethical principles of the Hospital and the trial protocols. The basic ethical principle is always not to do any harm to the patient. All our trial protocols were approved by the Ethical Committee and looked at by the Regional Committees. The national studies would have been approved by the UHKCDO.

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

The newly diagnosed patients were ideal to be entered into clinical studies using newer and safer factor 8 concentrates. Usually these were children and under the care of the consultant paediatrician Dr Adrian Minford. These patients were rare but very valuable for clinical studies. There was a full and complete protocol that was followed before entering any of these patients into clinical trials.

77. The patients were always entered into studies with their explicit informed consent.

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

The patient data was anonymised and 'Oxford Returns' done every year and would have mentioned the presence of a new haemophiliac and what products they had been treated with. Data given to pharmaceutical companies was always anonymised. Patient privacy was never compromised.

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

Other than treatment of new Haemophiliacs on rare occasions, we did not participate in studies that would be useful to the Enquiry. These new patients did not acquire HIV or Hepatitis viruses.

A list of my publications is available if required.

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

None that would be useful to the Enquiry, but I will provide on request.

Treatment of patients who had been infected with HIV or Hepatitis

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

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

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

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

All our patients with HIV or Hepatitis C were counselled and if positive referred to the consultant in infectious disease, Dr Paul McWhinney or the Liver Specialist Dr Morea.

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

Patients infected with HIV were followed up at least on a three-monthly basis at our centre. They would *have* also been seen by our Nurse Specialist/Consultant Paediatrician where appropriate, the dental surgeon and possibly the orthopaedic surgeon as well. We had our own counsellor in the centre. This was also true with Hepatitis C and Hepatitis B.

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

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

b. *What treatment options were offered over the years?*

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

Patients infected with HIV were followed up at least on a three-monthly basis at our centre. They would have also been seen by our Nurse Specialist/Consultant Paediatrician where appropriate,

the dental surgeon and possibly the orthopaedic surgeon as well. We had our own counsellor in the centre. This was also true with Hepatitis C and Hepatitis B.

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

    We carried out at least 3 monthly check-ups, but they were followed up by the Liver Specialist.

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

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

    b. *What treatment options were offered over the years?*

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

    All patients with known Hepatitis status were referred to a specialist clinic. We handed out treatment information where we could.

86. *How was the care and treatment of patients with hepatitis C managed at the Centre? In particular:*

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

    b. *What treatment options were offered over the years?*

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

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

    We followed them on at least 3 monthly basis and carried out monitoring blood tests.

88. *What involvement did you have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.*

    None actively.

89. *What arrangements were made for the care and treatment of children infected with HIV or hepatitis? How did those arrangements differ (if at all) from the arrangements made for adults?*

    They would have been managed by Paediatricians but more likely referred to Leeds Teaching Hospitals.

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

    All these supportive measures were available and offered to patients.

91. *Was the Centre allocated, whether by the Department of Health and Social Security or another source, any funding to help with counselling of patients infected with HIV?*

No

92. *What kind of counselling if any was made available to patients at the Centre?*

We had social worker/Counsellor for a while, Sister Pauline Sharp and I offered counselling. There were HIV counsellors available in the Hospital.

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

The Department of Health and Social Security had not given us extra funding to help with counselling the patients infected with HIV or Hepatitis C as we were not a reference centre, we would not have been given the same priority in terms of counsellors, physiological and social work support. Bradford Hospitals Management had to fund the care.

Records

94. *What was the Centre's policy as regards recording information on death certificates when a patient had been infected with HIV or hepatitis?*

Where possible HIV was not recorded on the death certificate but as far as I remember a note was made that added information was available. Usually patients dying of HIV or Hepatitis were under the care of the infectious disease consultant

95. *What were* the *retention policies of the Centre regarding medical records during the time you were director? Was there a policy of destroying records eight years after a patient's last visit?*

We followed the Hospital policies, although departmental records may have been kept longer.

96. *Did you maintain separate files for some or all patients? If so, why; where were those files located; and* where *are* those *files now?*

We had hospital case notes which were filed with all other case notes of the hospital, but we also had our own record of the treatments and the viral status. These were kept confidentially under lock and key in our department. I am not aware of where the records are kept now.

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

I have no information of patients at home.

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

No information kept on any individual patient at home.

Section 5: Self-sufficiency

99. *In December 1974 the Department of Health announced additional funding with the primary aim of making the NHS self-sufficient in Factor VIII blood products within two to three years. The Inquiry recognises that you did not become a director of the Centre until 1982. If you are able to*

respond, from your own knowledge, to the questions in this section please do so; if you are not, please say so.

a. *When did you become aware of this announcement?*

I was not aware of this announcement, but I was certainly aware that self-sufficiency was suggested due to the potential infections from imported blood products. Self-sufficiency was aimed at factor 8 blood products. I had great respect for the BPL and for British Donors of blood. If self-sufficiency had been achieved, then we would not have had such a large cohort of HIV and Hepatitis C infections. I always supported the BPL which sadly never had enough resources for research and development and for marketing their products.

b. *What did you understand the term "self-sufficiency" to mean? In particular, did you understand it to mean self-sufficiency in providing Factor VIII blood products prophylactically, or solely in response to bleeding incidents?*

Self-sufficiency was aimed at factor 8 blood products. Self-sufficiency as I understand it applied to both treatment and prophylaxis. I had great respect for the BPL and for the British donors of blood. If self-sufficiency had been achieved, then we would not have had such a large cohort of HIV and Hepatitis C infections. I always supported the BPL which sadly never had enough resources for research and development and for marketing their products.

c. *Did your understanding of what "self-sufficiency" meant change at any time? If so, when and why?*

No, I always thought the same.

d. *What was your understanding of how others defined "self-sufficiency"?*

I was not aware there was another definition.

e. *What if any role did you play, at any time, in any arrangements or initiatives designed to help achieve self-sufficiency?*

We all supported the concept of self-sufficiency. I did not have any means to influence decisions.

100. *How* were *estimates made of how much Factor VIII blood product would be required for use in England and Wales? In particular:*

a. *What was your role as director in making such estimates, and how did this change over time?*

Estimates for factor 8 blood products were always based on the amount of factor 8 used previously. We estimated the amount of factor 8 that we would need in the following 12 months and submitted this to our regional meeting or any other relevant bodies. The amount of BPL factor 8 used was less in proportion to the commercial products and I am not sure whether these figures were used to support or discourage BPL production of factor 8. The use of the commercial factor 8 usage increased each year to a level where BPL usage became a minor supplier. UKCDO collated these figures each year. I do not know whether these figures were used to support BPL production.

b. *What was the role of the UKHCDO and how did this change over time?*

I am not sure how the roles have changed. They are very influential as they have the Data, members and the finances. They were the main advisors to government and pharmaceutical bodies.

c. *What assumptions would underpin the estimates (including assumptions as to how the blood products would be used)?*

We estimated the amount of factor 8 that we would need based on previous year's usage and future developments. This was submitted to our regional committee and any other relevant bodies

d. *How would the estimate be made (e.g. by whom were they made, when and through what process)?*

We estimated the amount of factor 8 that we would need based on previous year's usage and future developments. This was submitted to the Regional Committee and to any purchasing body at the time by me.

e. *How were the estimates shared with other interested parties?*

We estimated the amount of factor 8 that we would need in the following 12 months and submitted this to our Regional committee or any other relevant bodies.

f. *How did any of these processes change over time?*

I do not think this process changed much over time.

101. *How were annual figures derived for how much Factor VIII blood product had been used over the course of a year?*

a. *What was your role as director in providing such figures, and how did this change over time?*

Records were kept of all the blood products which were then sent for "Oxford returns"

b. *What was the role of UKHCDO and how did this change over time?*

The UKHCDO collated this information and presented at their Annual meeting.

c. *How would the calculations be made (e.g. by whom were they made, when, through what process and using what data)?*

d. *How were those figures broken down geographically (e.g. by country, region or any other unit)?*

e. *How were the figures shared with other interested parties?*

The information was shared with other Directors.

f. *How did any of these processes change over time?*

I do not recall if the process changed over time.

102. *Were there significant differences between the estimates that were made and actual use? If so,*

why?

Actual use was always higher as more Factor 8 was used for Home treatment and prophylaxis.

103. *It may be suggested that England and Wales never achieved self-sufficiency of Factor VIII blood products, in the sense that clinicians were always reliant on commercially imported products to meet the actual demand of patients for such products.*

    a. *Is this correct, to the best of your knowledge?*

    b. *If so, why, in your opinion, was self-sufficiency never achieved?*

    c. *If, in your view, self-sufficiency was achieved, when was it achieved and why it was not achieved earlier?*

    We were never short BPL of products. I am not sure whether self-sufficiency was achieved. The commercial products were better presented and easier to use.

104. *It may be suggested that a significant contributory factor to England and Wales not achieving self-sufficiency (or not doing so earlier) was a failure by haemophilia clinicians to provide timely and accurate estimates of future demand for Factor VIII blood products. In particular, it may be suggested that haemophilia clinicians failed to identify the foreseeable increase in use of such products once they became available. How would you respond to these suggestions?*

    Not all Directors did a full "Oxford returns" but generally the information collected would have given a fair indication of the trends. Individual Directors had their preferences for what product they wanted to use. BPL material was not always the preferred concentrate. Haemophilia clinicians were able to predict for an overall total increase but not accurately for individual product.

    I was not privy to executive meetings of the UKHCDO where details of "self-sufficiency" would have been discussed and the Government bodies advised accordingly.

105. *If self-sufficiency had been achieved in Factor VIII products in England and Wales, what, in your view and in light of the experience in Scotland, would have been the effect on the numbers of patients infected with (i) HBV, (ii) HCV, and (iii) HIV? Please comment, if you are able to, on when self-sufficiency would have needed to be achieved (in your view) in order for any material difference to have been made in respect of each of these viruses.*

    There is no doubt that self-sufficiency would have meant less HIV and probably Hepatitis C cases. Self-sufficiency was predicted in 1984 but I do not know whether there was a real shortage of Factor 8 or it was perceived that there was a shortage.

106. *It may be suggested that England and Wales did achieve self-sufficiency in respect of Factor IX blood products. To the best of your knowledge, is this correct? Please explain your answer.*

    I think it is true.

107. *If self-sufficiency in respect of Factor IX blood products was achieved, did you nonetheless use commercially produced products in preference to domestically produced products? If so, why?*

We did not use commercial Factor 9 products.

Section 6: Blood services and BPL

108. *Please outline the interactions and dealings you had with the blood services, whether on a regional or national level, and/or with BPL in your capacity as director of the Centre.*

I was a member of the Regional Haemophilia Centre Directors and also a member of the UKCDO Directors. I did not have any direct interactions with BPL.

109. *Do you know what if any consideration was given to increasing production of cryoprecipitate, or producing a product with lower risk, in response to the risks associated with factor products, and what if any involvement did you have with any blood service (regionally or nationally) and/or BPL in relation to this?*

I cannot remember any consideration given to increasing production of Cryoprecipitate. I do remember discussions about producing Cryoprecipitate with lower risk, but I have no further information on this. I had no involvement in any decisions or actions taken by any blood service and/or BPL in responses to the risks.

110. *What if any discussions or meetings or interactions did you have with any blood service (regionally or nationally) and/or BPL in relation to:*

a. *the risk of infection with hepatitis from blood products;*

b. *the risk of infection with HIV/AIDS from blood products;*

c. *the steps to be taken to reduce the risk of infection?*

We worked in close liaison with Blood Transfusion and the Haemophilia Centre service in Leeds. We had a good communication system with them as well as with the Regional committee of the Directors and the Public Health. We saw the BPL representative on a regular basis.

111. *What if any involvement did you have with any decisions or actions taken by any blood service (regionally or nationally) and/or BPL in responses to the risks arising from blood and blood products?*

I had no involvement in decision making or any influence on actions taken nationally. I had input in so far as I gave information and opinion on a regional basis.

Section 7: UKHCDO

112. *Please describe your involvement with UKHCDO (including any of its working parties, committees or groups).*

Bradford as a haemophilia centre was part of the UKCDO. As director of the Bradford Haemophilia Centre I attended their meetings. I had no input in decisions about blood products. We did not qualify to be a Reference Centre and therefore were excluded from any decision-making bodies. I attended the annual general meetings and had a vote.

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

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

The UKHCDO's main responsibility was to collect data from around the country, arrange meetings, disseminate information and advise Government, etc.

The Directors of the reference centres were the core group in the UKHCDO that produced all the documents, guidelines etc. and carried out administrative work.

We (Bradford) were a member of the wider UKHCDO organisation and attended the annual meeting and gave our views. I attended as the Director.

b. *the structure, composition and role of its various committees or working groups;*

I have been on the working parties for rarer coagulation disorders because of the high incidence in Bradford but they did not discuss about factor 8 concentrates or therapies in general.

I have been on the working parties for rarer coagulation disorders which have a higher incidence in Bradford. I have not been on any subcommittees that discussed about factor 8 concentrates or therapies in general.

c. *the relationships between UKHCDO and pharmaceutical companies;*

There was no direct relationship between the UKHCDO and pharmaceutical companies however each reference centre and for that matter each haemophilia centre director had a varying amount of contact with pharmaceutical companies. The pharmaceutical companies supported many centres differently, I think this was largely based on the amount and type of product which was used. The support given by the pharmaceutical companies to each centre was not declared. I feel largely recommendations made by UKHCDO were impartial and open to inspection and comment.

d. *how decisions were taken by UKHCDO;*

By the executive largely.

e. *how information or advice was disseminated by UKHCDO and to whom;*

By post and at the UKHCDO meetings.

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

i. *the importation, purchase and selection of blood products;*

ii. *the manufacture of blood products;*

iii. *self-sufficiency;*

iv. *alternative treatments to factor products for patients with bleeding disorders;*

v. *the risks of infection associated with the use of blood products;*

vi. *the sharing of information about such risks with patients and/or their families;*

vii. *obtaining consent from patients for the testing and storage of their blood, for treatment and for research;*

viii. *heat treatment;*

ix. *other measures to reduce risk;*

x. *vCJD exposure; and xi.treatments for HIV and hepatitis C.*

I had no involvement relating to the importation of blood products depending on what our centre used I was involved in selection and purchase of blood products. I supported the concept of self-sufficiency and tried to support the BPL as far as I could.

We tried as much as possible to use alternative treatments for example DDAVP or tranexamic acid and we always did file our UK CDO returns in time and gave all the information that was required.

Section 8: Pharmaceutical companies/medical research/clinical trials

114. *Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products? If so, please list the names of the companies and give details of the advisory or consultancy services that you provided.*

I have never been employed in consultancy work to pharmaceutical companies. I have been involved in entering patients into clinical trials and have never given advice regarding manufacture or sale of blood products.

115. *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 have never 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.

116. *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 and of any financial or other remuneration you received*

I have not sat on any advisory panel, board or committee of any pharmaceutical company. I have not received any financial incentive from pharmaceutical companies to use certain blood products. However pharmaceutical companies have made grants for attending national and international conferences. The grants were payable into haemostasis and thrombosis fund which is part of charitable funds at the Bradford Royal Infirmary. I was entitled to claim expenses from Bradford Hospital NHS Trust for attending educational meetings quite separate to the grants given by pharmaceutical companies. The grants from the pharmaceutical companies were largely used for educational purposes of the non-medical staff in our hospital.

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

No

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

No. The support to the centre was not conditional.

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

No

120. *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 to comply with them?*

All donations were placed in the Hospital Trust Funds. These are Charitable Funds. We followed Hospital guidelines. Cannot remember any guidelines from UKHCDO to declare

121. *Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.*

No

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

I have given anonymised patient Data only on approved clinical trials (PUP studies).

123. *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?*

Any monies that were given by the pharmaceutical companies in any form were always deposited within NHS Bradford Hospitals and any expenditure from these funds were approved by the hospital management. I did not receive any direct remuneration to myself however our centre did benefit from the pharmaceutical companies.

Any monies that were given by the pharmaceutical companies in any form were always deposited within NHS Bradford Hospitals and any expenditure from these funds were approved by the hospital management. I did not receive any direct remuneration to myself.

Our centre was reimbursed by the pharmaceutical companies for the expenses incurred by the studies. There were also grants for attending International Educational Scientific meetings. These were allocated to the Centre staff via Hospital Charitable Trust Funds.

Section 9: vCJD

124. *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?*

We were made aware of the CJD infections though I cannot remember the year. We would have taken action accordingly and if there were patients to be informed, this would have been

done accordingly as per the instruction from Public Health Laboratories in Leeds. I do not think we had any patients that were exposed to CJD at the time.

125. *How and by whom were decisions taken (either nationally or locally or both) as to the information that should be provided to patients about vCJD and as to any steps which should be taken in relation to patients and their care and treatment?*

Any patients with vCJD would be referred to the Infectious Diseases Consultant and/or to the Neurologist. I cannot recall such a patient.

126. *What was the process at the Centre for informing patients about possible exposure to vCJD?*

Seen and counselled in privacy in our joint Haemophilia Clinic

127. *How and when were patients told of possible exposure to vCJD?*

I do not recall such a patient.

128. *What information was provided to patients about the risks of vCJD?*

Patients generally were aware of viral transmissions. I cannot recall details.

129. *What counselling, support and/or advice to be offered to patients who were informed that they might have been exposed to vCJD?*

Counselling was available. I do not recall any such patient.

130. *What measures were put in place, from a public health perspective, in relation to the care and treatment of patients?*

We had the option of referring to Specialists in that field.

Section 10: Involvement with the financial support schemes

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

I do not have any involvement with the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation and the Skipton Fund. Patients knew about this different trust and many are in receipt of monies from them. I personally did not have any direct discussions about these funds.

132. *To what extent did the Centre and its staff (including you) inform patients about the different trusts or funds?*

They were informed and literature made available. I think our Nursing Sister, Sister Pauline Sharp was very involved with the Haemophilia Society and may have had discussions about the funds with the patients. I am not sure of how much help the patients were given in relation to the eligibility criteria for the receipt of assistance

133. *Did the Centre have any policy or any guidance for staff members in relation to referring patients*

to the trusts and funds for support?

No

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

Applications in writing would be made to the Finance Department via me.

135. *Did the Centre, or any of its staff (including you), act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.*

There were no set criteria. Applications would have to approved by me and the Finance Department. Most case of needs went to the Haemophilia society.

136. *Was the Centre or any of its staff (including you) involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.*

Sister Sharp and Social workers would have been involved.

137. *It was agreed at the twenty-seventh meeting of the UK Haemophilia Centre Directors on 5 September 1988 [HCDO0000495] (copy enclosed) that individual Haemophilia Centre Directors might write to the Macfarlane Trust about IVF and AID if they wished to comment. Please explain whether you took the opportunity to write to the Macfarlane Trust about IVF and AID and if so please provide the Inquiry with any correspondence you hold regarding this matter.*

I cannot remember whether I wrote to the Macfarlane Trust about IVF and AID after the direction by UKCDO on 5th September 1988. I do not have any correspondence regarding this matter.

138. *Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of the Centre's 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?*

Bradford Hospitals had their own charitable funds. These were small and inadequate. Patient donations were rare as the money was usually donated to the Haemophilia Society. There was never enough money to carry out any major projects. Each year I do not think they were more than a thousand or two. I am not referring to the Macfarlane, Eileen, Caxton and Skipton funds and trusts.

Section 11: The Haemophilia Society

139. *Explain any involvement you have had in relation to the Haemophilia Society. In particular please address the following:*

a. *How you came to be involved in the Haemophilia Society, whether you held any formal position and if so for how long you held that position.*

b. *Did you provide any advice to the Haemophilia Society? If so, what?*

I used to be in communication with the Haemophilia Society and knew David Waters. I did meet David Waters at national and international meetings but I have never been part of the management of this society. I was a member, like all of the directors, never had any formal position with them. I have never been in an advisory capacity to the society

Section 12: Other issues

140. *Please describe how and when recombinant products became available to people treated at the Centre.*

I cannot remember the exact date recombinant products were made.

141. *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.*

I am not aware of any complaints about me to my employer, the GMC or the Health Service Ombudsman or any other body or organisation.

142. *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.*

There have been two complainants to the haemophilia enquiry which I considered unfair and opportunistic. These have been answered.

I have been retired 11 years, I have had a very successful career and I am very proud to have served the Haemophilia community well.

Statement of Truth

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

Signed GRO-C

Professor L Parapia

Dated 8/09/2020