Witness Name: Dr Dennis Prangnell
Statement No.: WITN5591001
Exhibits: NIL
Dated: 18/8/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR DENNIS PRANGNELL

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 10 February 2021.

I, Dr Dennis Prangnell, will say as follows: -

Section 1: Introduction

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

1.1. Dennis Roy Prangnell

1.2. GRO-C

1.3. Dob GRO-C 1948

1.4. Qualifications: M.B.,Ch.B. Birmingham 1971; M.R.C.Path 1977

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. 1971

2.1.1. Medical House Officer Hallamshire Hospital West Bromwich (6 months).

2.1.1.1. Care of general medical patients from admission to discharge. First on call for inpatient emergencies

2.2. 1972

2.2.1. Surgical House Officer Selly Oak Hospital Birmingham (6 months).

2.2.1.1. Care of general surgical patients from admission to discharge. First on call for inpatient emergencies. Assistance in operating theatres and outpatient clinics. Some duties in the accident and emergency department.

2.2.2. Pathology Senior House Officer Birmingham Rotation.

2.2.3. Haematology Children's Hospital Birmingham (6 months)

2.2.3.1. Laboratory and clinical haematology including pathology on call (included children's bleeding disorders).

2.3. 1973

2.3.1. Microbiology Queen Elizabeth Hospital Birmingham.

2.3.1.1. Mainly laboratory work but included on call duties for haemophilia centre including emergency assessment of patients and the administration of therapy (6 months).

2.4. 1973-1978

2.4.1. Registrar in Haematology at the haematology department Selly Oak Hospital Birmingham (1year). This was mainly laboratory based.

2.4.2. Queen Elizabeth Hospital Birmingham. (1 year)

2.4.2.1. This was mainly laboratory based which included care of bleeding disorder patients including emergency assessment and the administration of therapy.)

2.4.3. Senior Registrar in Haematology West Midlands Rotation Children's Hospital Birmingham (1 year).

2.4.3.1. Assisted inpatient and outpatient care of all paediatric haematology (included children's bleeding disorders).

2.4.4. Blood transfusion Service Birmingham (6 months)

2.4.4.1. This was laboratory based with a rotation through all departments.

2.4.5. Staffordshire Royal Infirmary Stoke on Trent (1 year)

2.4.5.1. Laboratory and clinincal general haematology

2.4.6. Children's Hospital Birmingham (a few months)

2.4.7. General Hospital Birmingham (about 6 months)

2.5. 1978

2.5.1. Full time Consultant Haematologist Lincoln County Hospital and Grantham Hospital. Responsible for all laboratory and clinical haematology including inpatients in Lincoln There was

no haemophilia centre until 1981. A second consultant (Dr Adelman) was appointed in 1982

2.6. 2008

2.6.1. Retired. Re-employed part time for Outpatient sessions and Lead for Transfusion.

2.7. 2014

2.7.1. Fully retired

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

3.1. I have no current memberships of any committees.

3.2. Member of the Royal College of Pathologists 1971 – 2008

3.2.1. Attended educational meetings

3.3. Member British Society Haematology 1971 – 2014

3.3.1. Attended educational meetings including annual scientific meetings

3.4. In the 1980s I –

3.4.1. Attended regional meetings of haematologists

3.4.2. Attended meetings with the regional haemophilia reference centre approximately annually

3.4.3. Attended regional educational meetings

3.5. I cannot recall any other relevant meetings in the relevant time period.

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. There was an investigation into these matters and solicitors came to Lincoln and went through our files and removed all related documents. I cannot recall that we gave any statements. I cannot recall dates.

Section 2: Decisions and actions of the Lincoln Haemophilia Centre

5. **Please**:

a. **describe the roles, functions and responsibilities of the Lincoln Haemophilia Centre ("the Centre") during the time that you worked there;**

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

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

You may be assisted in answering these questions by considering an article that you co-authored with Dr Adelman for *The Bulletin*, published by the Haemophilia Society, edition 33, no. 2, p.9 [PRSE0000411].

5.1. As I have said the Lincoln Haemophilia Centre was established in 1981. From 1982 Dr Adelman and I were joint directors and shared responsibility for decisions about the organisation and treatment policy of the Centre. During working hours we saw general review patients and those requiring emergency treatment. We often made up the therapeutic material and gave the injections ourselves. The service provided a 365 day 24hour on call service.

5.2. Out of hours treatments were given by the on call SHO in general medicine and the on call SHO in paediatrics.

5.3. In 1982 a haemophilia sister was appointed to give treatment and provide support. A senior technician with special interest in coagulation was appointed.

5.4. An orthopaedic surgeon (Mr Ian Hyde) and a dental surgeon (several over the years – I cannot recall names) were identified as having a special interest in haemophilia and provided care.

5.5. We held outpatient clinics to see referrals, to provide annual review and deal with chronic problems.

5.6. We were initially responsible for managing patients with hepatitis and HIV. When treatment became available for hepatitis C our patients were managed by our local consultant gastroenterologist and hepatologist, Dr B.B. Scott. A new consultant was appointed to the genitourinary medicine department. He had experience of HIV management elsewhere and took over management of this aspect of care. (I cannot recall his name).

6. **Please describe:**

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

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

6.1. See answers to 5 above.

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

7.1. About 10 patients with severe bleeding disorders and about 30 with mild and moderate bleeding disorders. The number with less severe disease increased gradually over the years. I cannot now recall the specific numbers but these numbers should be available from the UK Haemophilia directors database. All patients were registered with them.

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

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

   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?**

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

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

e. **What involvement did you have? In answering this question, please consider the following documents: a letter sent to you from a Cutter sales representative dated 19 September 1986 [BAYP0000008_369]; an extract from an internal Cutter Laboratories document, believed to date from December 1984, recording a meeting between representatives of Cutter and you, Sister Brown and Dr Adelman [BAYP0000025_088]:**

i. **Insofar as you are now able to do so, please provide an account of what happened at these meetings, and what representations were made to you about Cutter products, including Koate HT and Gamimune IVIG.**

ii. **The internal Cutter document from December 1984 refers to a visit from a representative of a rival firm, Immuno (who manufactured Kryobulin, among other products). Insofar as you are now able to do so, please provide an account of what happened at any such visit, and what representations were made to you about Immuno products.**

iii. **Were you concerned about the approach adopted by the pharmaceutical companies, or those acting on behalf of the Centre, at these meetings (or any other similar meetings)?**

iv. **Did the Centre purchase (i) Koate HT, Gamimune IVIG or any other Cutter products, or (ii) any Immuno products, for use on NHS patients? If so, what factors influenced this decision?**

v. **Did the Centre change its choice of commercial concentrates at any time? If so, why?**

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

a.

8.1. From 1982 Dr Adelman and I jointly made these decisions on the basis of availability and national and regional opinion. It was our policy to keep

patients on the same treatment preparation whenever possible. When the Centre opened patients were continued on the same product that they had been receiving at their previous centre. Initially all concentrates where supplied from the Blood transfusion centre. As far as I can recall we used only untreated British concentrates until about 1985. We attempted to treat patients with the same batch number as far as possible.

b.

8.2. For a period there was a regional scheme for purchase of heat treated concentrate. These were expensive and it was presumably hoped that the price could be kept down by offering contracts for large volumes. I do not remember the details or dates when this was in operation.

c.

8.3. Availability, safety, price in that order

d.

8.4. Availability, safety, price in that order

e. i,ii,iii,iv and v.

8.5. I can only answer this in general terms as I have no recollection of the details of these meetings. There was strong competition between these companies and these meetings were essentially negotiations about price. Safety will have been discussed but we did not rely on the safety claims made by the companies (see answer to 18). There was no impropriety and no offer of incentives other than price. I do not recall which concentrates we chose but we would have been reluctant to change between companies because it was considered good practice to keep individual patients on the same preparation when possible.

f.

8.6. (i) NHS concentrate and heat treated when it became available. If there was insufficient NHS concentrate then commercial heat treated product. I do not recall which company's products were used. If a change was made the patient was continued on the new product limiting batch numbers where possible.

8.7. (ii) Varied – as above or cryoprecipitate.

8.8. (iii) Usually cryoprecipitate or DDAVP

8.9. (iv) II, IX and X concentrate. NHS until it was not available.

8.10. (v) Cryoprecipitate or DDAVP

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

9.1. I can add nothing to my answer to 8. I do not recall being pestered by sales representatives.

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 the decision-making.**

10.1. Please see my answer to 8 b. I cannot recall any other details.

11. **Please describe your relationship/the Centre's relationship with the local Regional Transfusion Centre. Please explain whether the Regional Transfusion Centre supplied the Centre with cryoprecipitate and with NHS factor concentrates and whether (and if so to what extent and with what frequency) there were shortages or other difficulties in obtaining sufficient supplies. Please confirm whether the Regional Transfusion Centre had any involvement in supplying commercial factor concentrates or whether those were obtained from the pharmaceutical companies directly.**

11.1. We had a very good relationship with the transfusion centre. We had no difficulty with supply of cryoprecipitate or British untreated concentrate in the early 1980s. I don't recall that we obtained commercial material from the transfusion centre but I am not certain of this.

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

12.1. Most of our patients were already on treatment when we took over their management and we continued on the same treatment. Patients who were starting home therapy were often transferred from cryoprecipitate to concentrate. Also some patients were offered or requested to change from cryoprecipitate to concentrate. When we had to transfer patients from NHS to commercial concentrate we did not offer them a choice of manufacturer.

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

13.1. For some procedures such as dental extraction it was often possible to reduce the quantity of factor given by adding Tranexamic acid.

13.2. Patients with milder disease often released their own factor VIII in response to Desmopressin. Not all patients responded so a trial had to be carried out making this treatment only suitable for elective use. The response was often short lived and sometimes blood products had to be given.

13.3. Patients with very mild disease could be managed expectantly. Keeping blood products in reserve for problems.

13.4. It was routine to use these alternatives whenever possible.

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

a. the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did the policy and approach change over time and if so, how?
b. Home treatment? When was home treatment introduced?
c. Prophylactic treatment? To what extent and when was treatment provided on a prophylactic basis? Did the policy and approach change over time and if so how?

a.

14.1. Cryoprecipitate was readily available in the early 1980s and was our treatment of choice for many patients. Some patients were already being treated with concentrate when we became a centre and we continued with this. There were practical disadvantages to cryoprecipitate. It had to be stored in a freezer. It was time consuming to thaw and draw up. It resulted in a relatively large volume (typically 50 – 150ml) to be given by intravenous injection. It was messy to draw from the bags often resulting in some spillage onto work surfaces. On call junior doctors required some training to use it.

14.2. Because of these problems it was difficult to use for home therapy (by the patient or carer) and difficult to use when intensive treatment was required over a number of days.

14.3. Nevertheless it was the preparation of choice for most patients with less severe disease and patients with Von Willebrand's disease.

b.

14.4. Home therapy was considered for patients who required frequent treatment and who had a relative/carer who was willing and able to learn how to give it. Distance to the hospital was also a consideration. Home

treatment provided the possibility of reducing delay between bleed and therapy as well as convenience. Home therapy was not new. I had experience of its use in the early 1970s.

c.

14.5. Many patients with severe disease developed chronic joint damage. Prophylactic therapy was given to such patients to minimise this problem. It was increasingly used as more patients became able to have home therapy.

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

15.1. I cannot recall that we had a separate policy for children. However, as far as I can recall they were on NHS concentrate

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

16.1. Patients with mild disease may still require intensive therapy for instance after trauma or major surgery. Treatment may have been more easily managed with concentrate.

17. 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?

17.1. I cannot recall identifying any cases of infection with other viruses.

Section 3 Knowledge and response to risk

General

17.2. This was a complex and evolving situation. I am not able to recall the detailed chronology nor the detail of the sources of my understanding of these problems, nor what I knew at any particular time.

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

18.1. My colleague Dr Adelman and I worked in partnership and any decisions were taken jointly. We had to rely on advice from other bodies and experts as we had no expertise or facilities to make these assessments ourselves.

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

19.1. NHS concentrates were made from voluntary donors who were under no pressure to conceal any risk factors. Commercial concentrates were mainly from paid donors who had an incentive to conceal risk factors.

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

20.1. See reply to question 3. Selected reading from – The British Journal of Haematology, British Medical Journal, Lancet, Blood, Seminars in Haematology, Blood reviews and others. The Hospital Library had a wide selection of journals

Hepatitis

21. When you began work at the Centre, what was your knowledge and understanding of:

a. **the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products?**
b. **the nature and severity of the different forms of blood borne viral hepatitis?**

21.1. I was aware that there was a risk of hepatitis transmission from blood. The risk was increased in people (such as patients with bleeding disorders) because of exposure to large numbers of donors. Factor concentrates, being made from donor pools had a further increase in risk. Hepatitis B was rare in the donor pool. Donors were screened but I cannot remember when this was introduced. Initially there were no tests for other forms of hepatitis. Many patients with bleeding disorders had persistently mildly elevated liver function tests assumed to be a form of hepatitis called non A non B at that time. The significance of this was not fully appreciated.

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

22.1. Please see my answer to question 20. Discussion with other haematologists. UK haemophilia directors association meetings. Over time it became clear that there were long term serious complications of hepatitis C

23. 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)?

23.1. The perceived priority at the time was to reduce the long term complications of severe bleeding disorders – particularly joint damage. To this end we were motivated to give early treatment at adequate dosage to this group of patients. We used the products that we considered had the lowest risk. We avoided the use of preparations from paid donors. In the early 1980s the complications and risks of hepatitis were poorly understood.

HIV and AIDS

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

24.1. Please see the introduction (*General*) to this section (para 17.2)

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

25.1. 1983 (see introduction to this section).

26. 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 Inquiry has obtained letters sent by Dr Adelman in March 1985 to the Blood Products Laboratory ("BPL") on behalf of the Centre: [CBLA0002102] (letter from Dr Adelman to Dr Snape, BPL dated 22 March 1985); [CBLA0001998] (letter from Dr Snape to all Haemophilia Centres, dated 24 January 1985 referred to in CBLA0002102) and [CBLA0002106] (letter from Dr Adelman to Dr Snape, dated 26 March 1985). It has also obtained an internal BPL memorandum from Dr Snape to Mr Pettet relating to the supply of blood products to the Centre, dated 2 May 1985 [CBLA0002153].

26.1. We followed the development of this problem in scientific journals and elsewhere.

26.2. CBLA0002102 is the letter From Dr Adelman of 22 March 1985 requesting factor concentrate which implies that he considered un-heat-

treated British product as likely to be safer than the heat-treated commercial product.

26.3. CBLA0001998 appears to indicate the timescale for supply of heat treated product and that there were limited supplies from February 1985.

26.4. A safer product (Hepatitis inactivated) was to be available from April 1985 but not in full production until June 1985. The new product "8Y" would be hepatitis inactivated whereas the then existing product was only HIV inactivated

26.5. CBLA0002101 I don't fully understand this document which is of a technical nature and contains abbreviations that I am not familiar with. It appears to raise concerns regarding the then available commercial products. It is not clear if it relates to factor concentrates and may be about immunoglobulin and plasma protein fraction.

26.6. CBLA0002106 is the letter to Dr Snape of 26 March 1985 which indicates that there were limited supplies of British heat treated concentrate available to us and so the therapy our patients were receiving (which was non-heat-treated BPL product) was not unreasonable in the circumstances

26.7. CBLA0002153 There appears to be implied criticism of "the provinces" by the Blood Products Laboratory. But they admit that they were not in full production of the safer product by this date.

27. Dr Adelman states in his letter of 22 March 1985 that, *"We are at present treating our patients with Cryoprecipitate and unheated BPL Factor VIII concentrate. We are not proposing to purchase heated commercial concentrate in anticipation of the availability of the BPL heated product."* What were the Centre's reasons for treating patients in this way? In particular:

a. Which categories of patients were treated with cryoprecipitate, and why;

27.1. Please see my answer to question 14

b. Why was unheated BPL product preferred to heat treated commercial concentrates?

27.2. Un-heated BPL concentrate was considered much safer than commercial unheated concentrate. The treated commercial concentrate was known to contain plasma from unpaid donors and from infected donors. There was anxiety that the treatment of these products did not render them safe.

c. In respect of the preference for unheated BPL product over commercial concentrates, please also consider and comment on a letter Dr Adelman wrote on behalf of the Centre concerning preferred treatment for one of your patients visiting London in April 1985 [ULHT0000006].

27.3. Please see my response to 27b.

28. Did the Centre maintain its position of not purchasing commercial concentrate? If not, why not?

28.1. We eventually had to buy commercial concentrate because of the limited supply of British concentrate. I cannot recall the details, but confidence in commercial concentrates improved as the manufacture of products improved.

29. In the internal BPL memorandum, dated 2 May 1985, Dr Snape records that the Centre was due to receive its first batch of heat treated BPL Factor VIII concentrate imminently. He stated that: *"I am a little surprised that Centres like the one at Lincoln are only now receiving their first consignment of heated F.VIII. Things must have moved pretty slowly in the provinces since the first batches of heated F.VIII left BPL."* Did you consider that there had

been any delay in providing heat treated Factor VIII concentrate from BPL to the Centre? If so, why do you think this delay occurred, what effect did it have, and what steps were taken to try to speed up the supply of the product?

29.1. Please see my answer to question 26. There was delay and the reasons were with the blood products laboratory and are admitted in CBLA0001998. I am not aware that it had any affect in terms of transmitting infection but clearly this was a risk. All our patients infected with HIV were infected before this time and probably also our patients with Hepatitis C.

Response to risk

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

30.1. All patients were invited for annual review and these issues would have been discussed according to the knowledge at the time. I am unable to give details or a time scale.

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

31.1. We maintained our preference for British products that were perceived to have lower risk.

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

32.1. Yes. We did not believe that there was a viable alternative. There was no choice other than to leave patients untreated. The UKHCDO view was not to revert to cryoprecipitate see page 10 of PRSE0004440.

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

33.1. All patients on unheated concentrate were transferred to heat treated concentrate. We were instructed to return all unheated concentrate for reprocessing. We did recall supplies from patients on home treatment.

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

34.1. Yes. Every effort should have been made to supply them earlier.

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

35.1. I can't recall for certain but I think not. I remember asking the Trent transfusion centre about supplies of cryoprecipitate at this time. I was told that supplies were limited because plasma was being sent for processing and so could not be used for increased cryoprecipitate preparation. See PRSE0004440 page 8

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.**

36.1. I think we were trying to do the best we could at the time with the materials that were available and the information that we had. I believed that our practice was in line with that in other centres.

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

37.1. It is difficult to see what we could have done locally. We were a new centre. We were not national experts in this field.

38. 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?

38.1. With the wisdom of hindsight it was the drive to produce a more effective and convenient therapy that resulted in the production of concentrate from pools of donors. However the use of concentrate was considered the way forward by haematology experts in this field and also I think the haemophiliacs themselves. The shortage of British factor concentrate was a contributory factor in some centres but we were fortunate that we did not have to buy unheated imported factor.

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

39.1. Probably, but this is outside my area of knowledge.

Section 4: Treatment of patients at the Centre

Provision of information to patients

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

40.1. I cannot recall specifically what information was given to patients at different times. Nearly all of our patients were already on therapy when the Centre opened. Fortunately we did not have to use unheated concentrate from America so we considered the risks of the treatment we were using to be small. The nature of Non A Non B hepatitis was not fully appreciated

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

41.1. As can be seen from my answers to questions 32-35 inclusive above it was thought that converting to the use cryoprecipitate was not a viable alternative. Patients were not offered the choice of discontinuing treatment with concentrate and transferring to cryoprecipitate.

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

42.1. We had an education programme which included: reconstitution of product; training in venepuncture and intravenous injection; the possible immediate complications; recognising early bleeding problems; dosage to be given, and; when to call for advice or assistance.

HIV

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

43.1. I cannot recall

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

44.1. Some of our patients had lymphadenopathy noted at annual review. This was reported to be a feature of HIV infection. We arranged for testing of these patients as soon as testing became available. I cannot recall the date of this

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

45.1. Most patients who had received blood products were tested at annual review. Pre-test counselling became standard practice but it may not have been for the first few patients tested.

46. How and when and by whom were patients told that they had been, or might have been, infected with HIV? Were they told in person, by letter or by phone? Were they seen individually or in groups? What if any involvement did you have in this process?

46.1. They were told individually by me or my colleague in person.

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

47.1. Patients were advised that the diagnosis was serious and had consequences for health and well-being (the risk of developing AIDS).

They were not told to keep the diagnosis secret but they were alerted to the possible stigma associated with it.

48. **What was the Centre /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?**

48.1. I cannot recall the Centre's policy. The Partners considering pregnancy would have been offered a test.

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

49.1. They would have been informed of the risk of infection from intimate contact with bodily fluids especially sexually, and the risk of blood borne infection.

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

50.1. All patients were seen for the results of the test by me or my colleague. They had rapid access to the clinic and continued to have an annual review. In practice most patients were seen regularly for management of their haemophilia. Concerns could be addressed on these occasions.

51. **How many patients at the Centre were infected with HIV in consequence of the treatment with blood products? Of those infected,**

a. **How many had severe haemophilia A?**
b. **How many had moderate haemophilia A?**
c. **How many had mild haemophilia A?**
d. **How many had haemophilia B?**
e. **How many had von Willebrand's disease?**
f. **How many were children?**

51.1. As far as I can recall there were 4 patients with severe haemophilia A. No others, No children.

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

52.1. I cannot recall details but my recollection is that our patients had become infected before we became a centre. I cannot recall the evidence that we had for this conclusion.

Hepatits B

53. **Were patients infected with hepatitis B in consequence of their treatment with blood products informed of their infection and if so, how? What information was provided to patients infected with hepatitis B about the infection, its significance, prognosis, treatment options and management? What if any involvement did you have in this process?**

53.1. I cannot recall a patient infected with Hepatitis B

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

54.1. I cannot recall a patient infected with Hepatitis B

NANB Hepatitis/Hepatitis C

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

55.1. This was a complex and evolving situation. I am not able to recall the detailed chronology nor the detail of the sources of my understanding of these problems, nor what I knew at any particular time. All patients were seen by me or my colleague, mainly at annual review. Initially patients had liver functions tests done at annual review. The significance of raised levels was not fully appreciated.

56. When did the Centre begin testing patients for hepatitis C and over what period of time were such tests first carried out? How, when and by whom were patients informed of their diagnosis of hepatitis C? Were they told in person, by letter or by phone? What if any involvement did you have in this process?

56.1. Patients were tested at annual review when tests became available. They were advised of the result by me or my colleague in person.

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

57.1. The results of tests were not withheld from patients. The information given to patients changed over time as understanding of this condition improved and management options became available. I cannot recall the timescale or what was said at different times. Further tests became available that offered some prognostic information regarding response to therapy.

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

58.1. We had complete records of all patients that we had treated with blood products. Every effort was made by mail and by phone to recall these patients and offer them a test.

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

59.1. I cannot recall the precise number of patients, but I would say bout 10.

Delay/public health/other information

60. **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.**

60.1. I cannot recall that there were delays

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

61.1. I assume that the question relates to the risks of our patients passing infection on to others. They were already aware that they should not donate blood. They were advised of the risk of transmission from blood from cuts and abrasions and how to deal with these safely. Also of the risks of sexual transmission and the use of condoms

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

62.1. Again no explanation of "other infections" is given. I cannot recall what specific discussions there would have been with patients regarding other infections but this may have occurred during our consultations. Patients who were significantly immune-suppressed would be advised of increased infection risk. They already had rapid access to the service

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

63.1. Patients would have been advised of the risk of infection from intimate contact with bodily fluids especially sexually and the risk of blood borne infection and the precautions needed to reduce this

Consent

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

64.1. Routine blood samples were taken at annual review as this was the only way to effectively review patients at the centre. Routine tests would include: factor levels; inhibitor screen; liver function; renal function, and; Hepatitis C and HIV when these tests became available. Blood samples would also be taken in order and to investigate specific problems encountered by patients. Blood samples would also be taken to manage specific treatment episodes. We explained what test we were going to do and why but we did not obtain written consent. We did not store samples except occasionally for a particular need such as for planned procedure and then only for a short period.

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

65.1. No

66. Were patients under your care or under the care of your colleagues at the Centre treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur?

What was your approach to obtaining consent to treatment? Was their consent recorded and if so how and where?

66.1. No patients were treated without consent. Most patients came for treatment and wanted to be treated. This was considered as consent. Most patients had multiple treatment over time and had already been informed about their condition and therapy. More time and detailed explanation would be required for some patients who were not on frequent therapy. Patients were not treated without their agreement unless they lacked capacity.

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

67.1. Patients were not tested without consent. Consent was not recorded.

PUPS

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

68.1. This was a relatively unusual event. If possible a treatment plan not involving the use of blood products was used. Sometimes advice was not to proceed with an elective surgical procedure. If blood products were required or might be required the patients were counselled according to the state of knowledge at the time. We did not participate in any studies.

Research

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

a. Describe the purpose of the research.

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

c. Explain what your involvement was.

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

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

f. State the number of patients involved.

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

h. Provide details of any publications relating to the research

69.1. We had no research projects originating in Lincoln.

69.2. One of our patients had a liver biopsy as part of Sheffield research in liver damage in Non A non B hepatitis. A consultant from Sheffield came to do the biopsy. We were not involved in the arrangements apart from supply of therapy. The study was published. I do not have the details.

69.3. We had one patient who took part in a study of safety of British heat-treated factor VIII organised by BPL. There was a very detailed protocol. Informed consent was obtained and recorded. There was ethical approval. We had to give the factor VIII and take follow up samples to send to BPL. I don't think it was ever published.

69.4. I cannot recall any epidemiological studies, but we supplied data to the UK Haemophilia directors association. We did not obtain consent for this.

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

70.1. No

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

71.1. No -as far as I can recall except see my answer to question 72 below.

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

72.1. No, as far as I can recall except that all patients were notified to the haemophilia centre directors organisation database as was the amount of blood product used for their treatment each year. The data was not anonymised.

72.2. I do not recall that we asked permission for this.

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

73.1. There are no such articles. None.

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

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

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

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

c. **What information was provided to patients about the risks and benefits of specific treatments and about side effects?**
d. **What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?**

74.1. All patients were referred to a local genitourinary medicine consultant who had experience of HIV elsewhere before coming to Lincoln. I cannot recollect any details of treatment. Information given to patients and follow up was not with us.

75. **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?**
d. **What information was provided to patients about the risks and benefits of specific treatments and about the side effects?**

75.1. I cannot recall that we had any such patients

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

76.1. I cannot recall that we had any such patients.

77. **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?**

77.1. a. These patients had mildly elevated liver function presumed by many to be caused by a viral infection. Patients were tested at annual review. They were not referred There was no need or benefit at that time

77.2. b. No treatment was offered or available until hepatitis C testing became possible. Most patients would test positive for hepatitis C and be managed as in 78 below.

77.3. c. There were no treatments for NANB.

78. 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?

78.1. All patients were referred to Dr Scott who was a gastroenterologist and hepatologist. He was recognised in the Trent Region as having expertise in this area.

b. What treatment options were offered over the years?

78.2. We assisted in treatment with interferon and with ribavirin

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

78.3. I do not recall these details.

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

79.1. Dr Scott was responsible for this. We continued to review the bleeding disorder.

80. 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?

80.1. We had no infected children.

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

81.1. This aspect of care was provided by ourselves, the haemophilia sister and a dedicated social worker. We had no access to clinical psychology.

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

82.1. I do not remember any funding for this.

83. 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?

83.1. I cannot recall any specific difficulty

84. 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.

84.1. None organised by us

Records

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

85.1. I do not recall whether the Centre had a policy for recording information on death certificates when a patient had been infected with HIV or hepatitis. I do not recall what I would have written on such a certificate or if I ever completed such a certificate. I was not involved in any inquests related to this question.

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

86.1. As far as I recall, records were kept for 6 years after the last visit to the hospital. Records could be marked for longer retention, I think such records were put on microfiche.

87. Did you:

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

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

87.1. Initially separate records were kept in the department for patients on blood products. These patients often attended for emergency treatment. There was no system in place for rapid access to general hospital records so without local records treatment could have been unacceptably delayed.

87.2. We were advised that having separate records was not good practice so we negotiated for a system of rapid access to hospital records. When this was achieved our separate departmental local records were amalgamated into the hospital records.

88. **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.**

88.1. No

Section 5: UKHCDO

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

89.1. I was a member only. Dr Adelman or I attended most annual general meetings

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

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

90.1. It advised and lobbied the Department of Health about arrangements for haemophilia care. It collected data about the numbers of patients and diagnosis. It collected data on blood product usage.

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

90.2. None

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

90.3. Information and advice was given at the annual general meeting. There was also an annual report, which was usually published in the British Journal of Haematology. Information was also generally disseminated through the professional network of doctors working in this field including reference centres.

Section 6: Pharmaceutical companies/medical research/clinical trials

91. 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 of 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?

91.1. No to all. It is possible that we received pens, note-paper etc.,with a company's logo/name on them but I cannot recall. I would not consider these any kind of incentive or inducement to use a particular product. If

BPL is considered to fall within question 91 please see my answer to question 69.

92. 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?

92.1. There were regulations. I cannot recall what they contained.

93. 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?

93.1. Not applicable, see my answer to question 91.

<u>Section 7: vCJD</u>

94. 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?

94.1. I cannot recall specifics in relation to vCJD but it was a prominent topic in the press and from searching the internet I can see that this was the case in 1996.

95. 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 to inform patients about possible exposure to vCJD and to provide information to them about vCJD?

95.1. We did not specifically inform patients.

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?

95.2. We did not specifically counsel patients unless they raised this at review. Dr Adelman or I would have discussed this with such patients personally. The risks were uncertain but considered likely to be very small which subsequently turned out to be the case.

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

96.1. I do not fully understand the question. The patients were not a risk to others. They were already excluded from blood donation.

Section 8: Financial Support Schemes

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

97.1. As far as I can recall several patients received support from the Macfarlane Trust. I have no knowledge of the other trusts.

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

98.1. I do not recall specifically but I think that they would mainly have been made aware through the Haemophilia Society.

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

99.1. Not that I can recall.

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

100.1. I cannot recall this.

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

101.1. I have no opinion.

Section 9: Other issues

102. 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.

102.1. None

103. 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.

103.1. I have nothing to add.

Statement of Truth

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

Signed GRO-C

Dated 18th Aug 2021