Witness Name: Dr Peter Jones
Statement No.: WITN0841038
Dated: 06/01/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR PETER JONES

I, Dr Peter Mercer Jones, provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 22 October 2020 and will say as follows: -

Section 1: Introduction

1. **In response to question 3 of your statement, you stated that you had given evidence to: The General Medical Council; Canada (RCMP); and The Australia Supreme Court. Please provide copies of the statements, reports and or transcripts of this evidence.**

   I have some further documents which can be made available for collection.

2. **Please provide details of your training in haematology.**

   I trained as a paediatrician not as a haematologist. Having gained the Diploma in Child Health in Glasgow I went on to gain Membership of the Royal College of Physicians (London) in adult medicine. Before taking up my appointment as consultant paediatrician in Newcastle I spent a year practising haematology in Edinburgh. My doctorate (MD) explored fetomaternal bleeding in relation to haemolytic disease of the newborn.

3. **What medical journals or periodicals did you generally read during the 1970s and 1980s? What other sources of information, knowledge or advice did you have regarding (a) treatment for bleeding disorders; (b)**

risks of transmission of blood borne viruses; (c) hepatitis viruses, their nature and severity; and (d) AIDS/HTLV-III/HIV?

British Medical Journal, Lancet, Archives of Disease in Childhood, British Journal of Haematology, Hospital Medicine. After AIDS, Centers for Disease Control Morbidity and Mortality Weekly Report (MMWR).

a. Treatment of bleeding disorders: UK experts in the field especially Rosemary Biggs and Charles Rizza in Oxford and in the USA Donna Boone, Shelby Dietrich and Carol Casper in Los Angeles.

b. Haemophilia Centre Directors Organisation, Department of Health and Social Security.

c. Haemophilia Centre Directors Organisation, Department of Health and Social Security.

d. I attended the first AIDS conference in Atlanta in 1985 and visited AIDS centers in New York and San Francisco in order to gain experience in the recognition and treatment of HIV infection. My main contact over the years via the World Federation of Hemophilia was Dr Bruce Evatt of the Centers for Disease Control.

Section 2: Decisions and actions of the Newcastle Haemophilia Centre at the Royal Victoria Infirmary

4. Please set out the following information:

a. Precisely what your role as Consultant Paediatrician at the Newcastle Haemophilia Centre involved;

Caring for Children.

b. **What changed in relation to your role and/or responsibilities when you became Director of the Centre?**

I became progressively more involved with both children and adults with haemophilia and related disorders, eventually leaving general paediatric practice.

c. **What additional roles and/or responsibilities did you hold when the Northern Regional Haemophilia Service was established?**

With the retirement of Dr Boon I became Director of the Newcastle Haemophilia Centre with responsibilities for the outpatient and inpatient care of haemophilic patients of all ages.

5. **In response to question 3, please explain why you considered that there was a "compelling need" for adequate treatment as and when factor concentrates became available. What do you mean by "adequate treatment"?**

When I started in haemophilia practice there was virtually no treatment. Patients lived in constant pain with an outlook of crippling arthritis and severely shortened longevity. Adequate treatment at its most fundamental meant controlling bleeding episodes which occurred, on average, 35 times a year.

6. **In response to question 7, you state that it is not possible for you to give accurate figures on the number of patients with bleeding disorders who were under the care of Newcastle Haemophilia Centre ("the Centre") when you became director and in the years thereafter. Please give approximate figures to the best of your knowledge, if you cannot provide exact figures**

In 1973, 180 patients with haemophilia had been identified. Of these, 91 were severely affected. 21 patients had haemophilia B and 52 von Willebrands disease. Taking into account mildly affected patients, those with clotting disorders and carriers (known and putative) the total number of patients known to the Centre was 624.

Section 3: Selection of products to be used at the Newcastle Haemophilia Centre

7. **In response to question 8, you state that all products used by the Centre had to be licensed within the UK. In your response to question 9a, you state that there were annual meetings to discuss the selection and purchase of blood products.**

   a. **Were the meetings minuted?**

      No.

   b. **Was there ever a written policy setting out the process by which the Centre decided which products it would use and/or the criteria it would apply in making those decisions? If so, please provide a copy or set out what it contained.**

      No.

   c. **Who presented the information to the annual meetings to discuss selection and purchase of blood products? Specifically, who provided the information about the a) safety, b) efficacy, c) availability and d) price of the products under discussion?**

      I was lead presenter and I provided information on safety, efficacy, availability and price. Those present added to this knowledge.

   d. **What was the role of the patient representative at the meeting? Why were they included in the meeting?**

      The patient representative was there to give first- hand feedback on the choice and use of products used for home therapy. He or she also fed back any comments on inpatient treatment. The representative was an integral member of our team.

   e. **Who was the patient representative?**

      The patient representative was a member of the Northern Branch of the Haemophilia Society, usually the Chair.

f. Did the patient representative ever raise concerns about the safety of factor concentrates? If so, who was that, in broad terms what did they say and when did they raise the concern?

Yes, concerns were raised by the patient representative especially with regard to AIDS. We tried to ensure that everyone involved (staff and patients and their families) had up-to-date information on HIV infection and details on available products and their safety were always part of the discussion.

g. Did the patient representative ever indicate a preference for either imported factor concentrates or NHS factor concentrates? If so, who was that, when did they indicate a preference and why?

Yes. Again, that was always part of the discussion. There were usually 2 main items, scarcity of the NHS concentrate and presentation of the NHS concentrate. The latter occurred because in the early days the NHS concentrate was more bulky and harder to prepare than the commercial products.

h. What was the role of the member of Pharmacy who attended the meeting? How senior were they relative to your status as Haemophilia Centre Director?

The Infirmary Pharmacy team were usually represented by the head of pharmacy. All products were purchased by the pharmacy and decanted as needed to refrigerated storage in the Haemophilia Centre. The question of seniority never arose.

i. Who had the greatest influence on the decisions?

Given the paucity of products I cannot remember any major disagreements or need for a deciding vote.

j. **Were there disagreements within the meetings about the products to be used? If so, please set out what those disagreements were and who they were between.**

There were discussions about the products but rarely if ever disagreement.

k. **If there was a disagreement over which products should be used, who had the deciding vote?**

I have no memory of this ever happening; there was always a consensus.

l. **Did anyone in the meeting have the power to veto the decision made by the rest of the group? If so, who had a veto and was that veto ever exercised?**

No; never needed.

m. **What discussions took place about whether imported factor concentrates should be used? Please set out when those discussions took place and what the content of them were.**

There were discussions at every meeting. They always included knowledge of safety, efficacy, availability and cost.

n. **What decisions were made as to whether imported factor concentrates should be used? Please set out precisely who made the decisions and when.**

Consensus decisions as already stated. Given the shortfall in supply of NHS concentrate, the question of which imported concentrate always arose. Members of the Group made the decisions at the meetings.

o. **What decisions were made as to whether NHS concentrates should be preferred or not over imported factor concentrates? Please set out precisely who made the decisions and when.**

As above.

p. **Were any discussions or decisions made about reducing the amount of factor concentrates being prescribed? If so, please set out when these occurred and the content of the discussions and/or decisions.**

Yes. During the early years of the epidemic events moved fast and the supply of available therapeutic products varied between meetings. Part of the equation on choice was whether and when to curtail treatment to limit putative exposure to HIV. For instance, there was an occasion when planned surgery had to be delayed. The other part of the equation was use for prophylaxis.

q. **Were any discussions or decisions made about increasing the amount of factor concentrates being prescribed? If so, please set out when these occurred and the content of the discussions and/or decisions.**

Not to my knowledge.

8. **In question 9b you set out four criteria that you say was the basis for the choice of one product over another. Please describe your evaluation, during the 1970s and the first half of the 1980s, of the relative safety of (i) imported factor concentrates; (ii) BPL/Elstree factor concentrates; (iii) any other domestically produced factor concentrates; and (iv) cryoprecipitate. Please also answer the following questions:**

During the 1970s and the first half of the 1980s knowledge affecting choice of product and experience gained in the use of product evolved. This progress is set out in editions of Living with haemophilia published in this period and has been covered by other witnesses to the Inquiry. in brief, we started with fresh

frozen plasma (FFP) and moved to cryoprecipitate as soon as it became available. Then to concentrates because of the small volumes of known potency making intravenous therapy readily available both in the hospital and at home or work.

As to safety:

a. What factors were relevant to the safety of a product?

Sterility and asepsis during preparation and intravenous injection of product, source of product, licensing of product, experience in house and from other practitioners.

b. Where did you obtain your information as to the safety of a product?

Experience of other practitioners, product leaflets, published work,

c. When assessing the safety of a product, how important was the risk of a blood borne virus? Please set out precisely what you considered to be relevant to your decision making.

Always important, both to staff and patients.

As to efficacy:

d. What factors were relevant to the efficacy of a product?

Whether it worked or not, ease of preparation and delivery, cessation of bleeding, no short term side effects

e. Where did you obtain your information as to the efficacy of a product?

From experience and experience of others, published work, measurement of clotting in our laboratory

As to availability:

f. What factors were relevant to the availability of a product?

Supply and price. For instance, if NHS concentrates were unavailable choice was reduced to imported material for the majority of patients.

g. Where did you obtain your information as to the availability of a product?

Directly from the companies involved, including BPL.

h. What if any issues or difficulties did you experience in relation to availability of products?

As already stated, there was continuing shortfall in NHS material

As to price:

i. When assessing whether to use one product over another, how important was the cost of it?

Given safety, efficacy and availability being equal, cost became an important factor in making a decision

j. Was there ever a discussion that a more expensive product should be used because it was safer? If so, please set out when this occurred and in relation to which products.

Yes. When this occurred was the mid-1980s. This was regarding the prescription of heat-treated concentrates.

k. Was a decision ever made that a safer product could not be used because it was too expensive? If so, please set out when this occurred and in relation to which products.

No.

l. **In the Autumn 1976 Newsletter from the Haemophilia Society Northumbrian Branch (HSOC0021640) you wrote that due to economic constraints "some of you may find that you are asked to change your type of concentrate, the waiting list for home therapy may take longer to clear, and non-urgent surgery may be put back". Were changes to therapy made? What were the economic constraints that necessitated those changes? What role did your understanding of risk of infection play in informing such changes?**

Yes, the changes made were as stated. The constraints were a result of a general order to save 2.5% of the annual budget of the health authority. No changes which could have compromised safety were made.

m. **In your Personal Record (WITN0841007) you refer to a report you wrote in 1979 in which you stated "we have deliberately revised our policy of recommending that Region only buy the most refined (high purity) products, and we now bargain for the lowest price, for any product approved by the DHSS from any manufacturer" (p.13). When was the policy revised? Why was it revised? Were patients informed of the change to policy? Were patients informed that the concentrates that they were receiving were no longer "the most refined (high purity) products"?**

Prior to 1979; I cannot recall the exact date. Patients were always kept informed of changes in policy which, in this case, had been made because there was no benefit in continuing to pay more for highly purified products.

n. **In a letter you wrote on 18 March 1985 (TYWE0000014) you considered that "pricing alone would appear to give Travenol a substantial advantage" but noted that "the results of the recent trial of heat treated Hemofil [from Travenol] in Europe showed an 80% hepatitis non A non B attack rate" and that the "material we**

receive from Travenol will almost certainly be unscreened for HLTV-III antibody in individual donations". You considered that Profilate by Alpha was the safest product in the market, with clinical trial results indicative that "it is free of non A non B hepatitis, as well as AIDS". You advised that "the best option is to go for a proportion of the Travenol material but only for use in patients who have already had massive exposure to non A non B hepatitis, i.e. the older patients, and that we should use Alpha Profilate for patients without such exposure". Did this product choice represent a compromise on the safety of older patients due to financial constraints? Was your choice of products implemented?

No, if it had any change would not have been made. From memory, the changes were made. Please note, this letter underlines the open nature of all negotiations concerning blood products used in the Centre; as well as being copied to those directly involved in patient care it was sent to the Infirmary chief executive, and the Chair of the medicines board.

o. **In the same letter of 18 March 1985 (TYWE0000014) you wrote that "in the case of the Armour product, Factorate, there has been a recent outbreak of hepatitis B in Birmingham and two cases of hepatitis C have been confirmed at St. Thomas. It is probable that their non heat-treated product is being recycled through Germany to avoid FDA regulations and that the heat treated material still contains hepatitis B". In or around July 1985, the Centre returned 29 of 150 vials of Factorate to Armour Pharmaceuticals after two heat-treated batches were withdrawn due to HTLV-III contamination (ARMO0000417). Given the concerns you had expressed in March, how did the Centre come to treat patients with these batches of Factorate?**

I cannot now recall. I can only assume that the vials concerned had been released by home therapy.

p. **In 1986, a Cutter situation report records that a meeting was held with you and that "A lower price for Koate HT would not be an incentive for him to change at the moment" (BAYP0000008_189). Please explain what you were told at that meeting and what your concerns were.**

I have no memory of this meeting. Any concerns probably related to the previous report under o.

q. **In the Minutes of the UKHCDO meeting on 21 September 1990 (BART0002382) you are recorded as saying "The Northern Region was opting for commercial concentrates due to their lower price and they were fully licensed; he thought this was something BPL needed to consider". By 1990 therefore was price the key consideration when deciding which product to use?**

No. As already outlined, price was only one factor in the prescription of blood products and was never the key consideration.

r. **On 4 February 1991 at the Fourth Meeting of the UK Regional Haemophilia Centre Directors Committee it is noted that you "said that he required to be convinced about using a high purity product and he himself would probably continue to use an 8Y type of product ... [and] commented about the difficulty in convincing purchasers to buy high priced high purity products" (HCDO0000440). Why did you "require to be convinced"? What relevance did the price of the products have to your considerations?**

Because at the time there was no convincing evidence that high purity products were preferable to lower purity products in terms of efficacy and safety.

9. **In light of your answers above, please now provide full and specific information about the products used for each blood disorder, in a**

chronological account, in the 1970s and 1980s (up to and including 1988). In relation to severe haemophilia A:

a. **Precisely which products from which pharmaceutical companies were used in relation to those with severe haemophilia A? (OXUH0000757 may assist you in relation to the position in 1974).**

I have reviewed the reference document OXUH0000757 and this lists all products used in the Centre throughout the period.

b. **Why were those products chosen? Please explain why they were preferred over others.**

Products were chosen in the knowledge that there continued to be a shortfall in the supply of NHS concentrate.

c. **Your Personal Record notes that in 1977 you chose not to change patients from Hemofil to Koate because you were "reluctant to expose patients to another plasma pool from a different population of paid donors". Please explain what your rationale for this was.**

I was aware that the larger the donor pool the greater the likelihood of possible exposure to a pathogen, it seemed sensible at the time to try to limit this exposure.

d. **Why were commercial concentrates used in preference to NHS concentrates? Specifically, if you were sufficiently concerned about exposing patients to another plasma pool that you did not change to Koate, what impact did that concern have on your use of commercial rather than NHS concentrates?**

Because of shortfall in NHS supply choice continued to be limited.

e. **Your personal record notes that in 1979 you chaired a symposium on hepatitis. In your overview of it, you stated that "these dangers [of hepatitis] are compounded by the use of large**

plasma pools from commercial sources". Why then did you continue to use substantial quantities of commercial concentrates?

As above. This refers to a symposium on hepatitis I chaired in Israel. The only documents I have relating to the symposium were forwarded to IBI in the courier collection before Christmas. This symposium provides an excellent overview, by acknowledged experts, of the state of knowledge of hepatitis at the time.

f. **On 23 February 1988, you wrote to Dr Liam Donaldson setting out the products you were using for different patient groups (BPLL0002848_001). Please explain why you chose to use each of those products for those different groups and ensure that this is included in your account.**

This letter gives a detailed account of the use of therapeutic products by the Centre, together with the reasons choices were made. It is difficult to know what else IBI wants here, other than the copying of the letter contents into this reply.

g. **Precisely what safety and risk analysis was carried out whether formally or informally, orally or in writing when deciding which products to use?**

Safety and risk were dynamic at this time and were consistently dependent on shared information with colleagues in HCDOUK and CDC in the USA, together with peer reviewed papers in the scientific press.

10. **In relation to mild haemophilia A:**

a. **Precisely which products from which pharmaceutical companies were used in relation to those with mild haemophilia A?**

The decision on which product to use depended on the underlying factor level and the condition requiring treatment. Rarely, if ever (I

cannot recall details) a concentrate was prescribed, and this would have been NHS concentrate. When it became available DDAVP could be useful.

b. Why were those products chosen? Please explain why they were preferred over others.

Less likely to have side effects.

c. Why were commercial concentrates used in preference to NHS concentrates?

From memory, they weren't.

d. Precisely what safety and risk analysis was carried out whether formally or informally, orally or in writing when deciding which products to use?

As set out above.

e. What consideration was given to, and what use was made of, cryoprecipitate?

Cryoprecipitate was used.

f. What if any advice was given to those with mild haemophilia A about the possibility of avoiding the need for treatment through lifestyle management? Did that advice change over time and if so how? Was such advice given to patients with severe and/or moderate haemophilia and if so please provide details?

Lifestyle management was a feature of routine follow up and is detailed in Living with haemophilia and in a booklet on sports produced for the World Federation of Hemophilia (REF A). The advice changed over time. These references detail good practice for e.g. keeping fit, maintenance of good musculature, avoiding alcohol.

11. In relation to haemophilia B:

a. Precisely which products from which pharmaceutical companies were used in relation to those with haemophilia B?

None. There was sufficient factor IX concentrate fractionated by the NHS.

b. Why were those products chosen? Please explain why they were preferred over others.

Because of safety, efficacy and cost.

c. Precisely what safety and risk analysis was carried out whether formally or informally, orally or in writing when deciding which products to use?

As set out above.

d. What if any advice was given about the possibility of avoiding the need for treatment through lifestyle management? Did that advice change over time and if so how?

As set out above.

12. In relation to von Willebrand disease:

a. Precisely which products from which pharmaceutical companies were used in relation to those with von Willebrand disease?

None. Cryoprecipitate was usually the product of choice after consideration of DDAVP.

b. Why were those products chosen? Please explain why they were preferred over others.

As set out above.

c. **Precisely what safety and risk analysis was carried out whether formally or informally, orally or in writing when deciding which products to use?**

As set out above.

d. **What consideration was given to, and what use was made of, cryoprecipitate?**

As set out above.

e. **What if any advice was given about the possibility of avoiding the need for treatment through lifestyle management? Did that advice change over time and if so how?**

As set out above.

Section 4: Alternative treatments

13. **In question 13 of your statement you state that alternative treatments to factor concentrates were available. In question 14 you set out the advantages of factor concentrates but have not responded about their disadvantages. Nor have you set out the advantages of the alternative treatments. Please answer the following:**

a. **What were the disadvantages of factor concentrates?**

Disadvantages of factor concentrates were either short or long term. Short term side effects included allergic reactions and, especially with factor IX concentrates, thrombosis. Long term disadvantages included transmission of pathogens including hepatitis and HIV. A detailed appraisal of the risks of both short and long term side effects was published in the 5th edition of *Living with haemophilia* (Chapter 11).

b. **What were the advantages of the alternative treatments?**

Most alternative treatments avoided the risk of transmission of pathogens.

14. In your response to question 13, you do not refer to DDAVP. Please explain why not.

I cannot recall why I did not mention DDAVP here.

15. In relation to DDAVP:

a. What were the advantages of DDAVP?

Advantages were the obvious one of avoiding pathogen transmission and the reliance on a human resource.

b. What were the disadvantages of DDAVP?

DDAVP could cause water retention and I recall one episode of DDAVP induced coma due to this. When it was first introduced into practice there was concern that it could only be used once and should therefore be reserved for the treatment of the most severe bleeding.

c. What were patients told about DDAVP?

Our patients had as much information about DDAVP as we did and this changed as more knowledge became available.

d. How many patients were offered DDAVP instead of factor concentrates?

Patients with mild to moderate factor VIII deficiency and those with von Willebrands disease. I cannot remember exact numbers.

e. To what extent did you use DDAVP, over what period(s) and for which categories of patients?

As explained above, DDAVP became the treatment of choice for susceptible patients.

16. In the document "HIV Infection and Haemophilia" dated 16 July 1990, you state that "Mildly affected Haemophilia A patients should, when possible, be treated with desmopressin (DDAVP) rather than blood

products as should carriers, and people with type I von Willebrand's disease" (WITN0841022). Were such patients given DDAVP in Newcastle? If so, from what date? If not, why not?

Yes. After over 40 years I cannot recall the details.

17. **As to alternative treatments:**

a. **Were these alternative treatments offered to patients? If so, please set out the circumstances in which these alternative treatments would be offered.**

Yes, all forms of treatment were openly explained and discussed with patients and their families. On the whole, their knowledge was the same as ours, although a very small number of them decided not to avail themselves of the meetings and discussions freely available; we attempted to counsel these patients individually when they attended for follow-up.

b. **What were patients told about the alternative treatments?**

Yes, all forms of treatment were openly explained and discussed with patients and their families. On the whole their knowledge was the same as ours, although a very small number of them decided not to avail themselves of the meetings and discussions freely available; we attempted to counsel these patients individually when they attended for follow-up.

c. **Were patients told about any disadvantages to factor concentrates?**

Yes, all forms of treatment were openly explained and discussed with patients and their families. On the whole, their knowledge was the same as ours, although a very small number of them decided not to avail themselves of the meetings and discussions freely available; we attempted to counsel these patients individually when they attended for follow-up.

d. Were patients told about any advantages to the alternative treatments?

Yes, all forms of treatment were openly explained and discussed with patients and their families. On the whole, their knowledge was the same as ours, although a very small number of them decided not to avail themselves of the meetings and discussions freely available; we attempted to counsel these patients individually when they attended for follow-up.

e. How many patients opted for the alternative treatments rather than factor concentrates?

I cannot remember.

18. **On page 42 of "Aids and the Blood", published in February 1985, some information is given about alternative methods of treatment (RLIT0000046). When was this information first given to patients? Was it provided to patients in writing prior to the publication of Aids and the Blood? Was it provided to patients orally prior to this publication? If not, why not.**

As it became available. Not as far as I recall in writing, although it is difficult to remember when pieces of information were published in, for instance, the Haemophilia Society newsletters.

19. **At question 15, you state that cryoprecipitate was the "treatment of choice in factor VIII deficient patients until 1973, when sufficient factor VIII concentrate became available." Please explain what use was made of cryoprecipitate after 1973 in adult patients treated at the Centre. Were all adults and children under the age of 6 given factor concentrates from 1973 onwards?**

Cryoprecipitate for both adults and children continued to be used within the hospital as concentrates were introduced especially for home therapy. No, concentrates were not used for children from 1973 onwards.

20. In response to question 18 you state that it was "best practice" for a number of years before 1985, to treat children under 6 with cryoprecipitate. Please answer the following questions:

a. On page 43 of "Aids and the Blood" it is stated that the recommendation was for cryoprecipitate to be given to children under 4. Please explain the disparity of ages.

I cannot explain the discrepancy except to say that I was trying to cover the "youngest" children.

b. Why was it best practice?

Because it was best practice. Locally sourced cryoprecipitate was considered safer than concentrates at the time.

c. Given that both factor concentrates and cryoprecipitate required venous access, what was your understanding of the disadvantages of using factor concentrates on children?

Possibly more chance of pathogen transfer.

d. Were the risks of blood borne infections one of the reasons for this "best practice"? If so:

Yes, as above.

e. Which infections were of particular concern and why?

Hepatitis, although we later knew that the incidence was approximately the same in multi-transfused patients treated with either cryoprecipitate or concentrate. HIV had appeared at this time.

f. Why were they not a concern after a child was aged 6?

Of course they were always a concern, but at that time, a minor one especially in the context of the management of bleeds.

g. **What was the risk/benefit analysis that you undertook in relation to children over 6 years old?**

A mix of considerations including severity of the haemophilia, and ability of the family to manage home therapy.

h. **If blood borne infections remained a concern, what advice was given to parents about the issue? Were they given the choice of remaining on cryoprecipitate? How was that choice explained to them?**

Discussion of risk/side effects formed part of the formal training in home therapy given to all parents and guardians. This included choice of blood products including cryoprecipitate. From memory, no-one opted to stay on cryoprecipitate for home therapy.

i. **In your answer you appear to emphasise that the cryoprecipitate that was used up to the age of 6 was "locally produced". Were children over 6 only given "locally produced" NHS concentrate? If not, why not?**

Yes. All cryoprecipitate used in the Centre was locally produced.

j. **From which regional transfusion centre did you obtain supplies of cryoprecipitate? Did you have any difficulties obtaining cryoprecipitate in sufficient quantities? If so what steps did you take to ensure such difficulties were addressed?**

The DHSS Northern Blood Transfusion Service (BTS), sited in Newcastle and directed by Dr Shiela Murray. As cryoprecipitate was the source material for concentrates there was an inevitable shortfall over time. Despite this the BTS served our patients well and there was free and open discussion between the BTS and the Centre.

21. **In response to question 19, you state that concentrates were used for haemophilia A patients, prior to the introduction of DDAVP. Why was cryoprecipitate not used for patients with mild or moderate bleeding**

disorders, prior to the introduction of DDAVP? Once DDAVP became available, did you continue to use concentrates to treat patients with mild or moderate haemophilia?

In general concentrates were used as cryoprecipitate was phased out. Depending on the circumstances (the severity of bleeding/ the clinical need of a particular patient) all options were open, including the use of cryoprecipitate. DDAVP was used instead of blood products when indicated.

Section 5: Other infections

22. **In your response to question 20 of your statement you state that no viruses other than HIV, HCV and HBV were transmitted to patients at the Centre as a consequence of the use of blood products. Were patients at the Centre found to be infected by the following viruses:**

    a. **Parvovirus B19;**

    We did not routinely test patients (or staff) for evidence of infection with any of the pathogens listed. Parvovirus infection is covered in the fifth edition of Living with haemophilia (page 186). Hepatitis D (formerly I think referred to as delta) is dependent for its activity on the hepatic B virus, and vaccination for this was offered to everyone concerned when it became available. I cannot remember seeing cytomegalovirus, hepatitis G or Epstein-Barr virus as a result of transfusion.

    b. **Cytomegalovirus;**

    As above.

    c. **Hepatitis D;**

    As above.

    d. **Hepatitis G;**

    As above.

e. **Epstein-Barr virus?**

As above.

23. **If so, please set out in relation to each virus separately, whether you consider that they were transmitted in consequence of the use of blood products. If you consider that they were not transmitted in this way, please set out why not.**

They could have been transmitted without our knowledge. I cannot remember seeing any evidence that they were, or that there were any harmful consequences.

Section 6: Knowledge of, and response to risk

General

24. **In answering the questions below you may wish to consider the list of HIV/HCV General Documents and the Knowledge of Risk General Folder.**

I confirm I have considered these documents.

25. **In response to question 21 of your statement, you state that "general knowledge in 1970/71 concerned serum hepatitis". Please answer the following:**

a. **What did you understand about the seriousness of serum hepatitis in the short term (i.e. acute hepatitis)?**

My understanding at that time was that acute hepatitis could result in a short term episode of ill health characterised by jaundice, usually without long term sequelae.

b. **What did you understand about the seriousness of serum hepatitis in the long term (i.e. chronic hepatitis)?**

It was thought that serious long term effects of serum hepatitis were relatively rare.

c. **Did you understand that there might be other, as yet unidentified viruses that could be transmitted through blood? What did you consider the nature and seriousness of any such risk to be?**

Suspicions that there were viruses other than hepatitis A and B grew over time as patients with a history of neither infection displayed persistent abnormalities in liver function. It was generally accepted that serious clinical disease appeared to be uncommon in these patients.

26. **In your book 'Living with Haemophilia' published in 1974, you wrote at page 78, "Haemophiliacs seem to have a high resistance probably developed as a result of repeated blood transfusions. Although many have the antibody, few have had severe jaundice due to serum hepatitis." (HSOC0019621) What was the basis for your understanding that haemophiliacs had a high resistance to serum hepatitis? Was this reflected in information you provided to patients?**

It was a generally accepted opinion based on clinical observation of many patients over time. This opinion was reflected in the information provided to patients.

Commercial concentrates

27. **In your response to question 24, you state that commercial concentrates "were only used because of the continued shortage of NHS blood products". In your "Personal Record" document you similarly stated "There was no possibility of running the home therapy programme on NHS concentrate and I continued to advise the relevant authorities of the effects of the continuing shortfall.... There was a comment in this report that I was knowledgeable about potentially harmful side effects of the use of large amounts of factor VIII concentrate". However, there are a number of documents which suggest you considered commercial concentrates were preferable for home therapy: in 1974 you stated in a letter Dr Sackwood that Kyrobulin and Hemofil were "ideal for home therapy" (TYWE0000029); in 1976 you stated that the "size of bottle,**

volume of fluid required for reconstitution, time of reconstitution, viscosity ...rule out .. using the present British product in our home therapy programme" (CBLA0008631); see also (CBLA0000798), (NTHT0000042) and in 1985 (HSOC0002441). Please explain when and why you came to the conclusion that you have stated in your first statement and your Personal Record. Please also identify the "relevant authorities" whom you notified of the effects of the continuing shortfall, explaining who you discussed this ongoing problem with, when and what you advised them. What if any steps were taken by the relevant authorities to address your concerns?

I had, and still have, no doubt that if the NHS concentrates had been manufactured to the same general standards of the commercial concentrates, they would have been used exclusively for home therapy in the UK. As stated, in addition to the continued shortfall in supply, the commercial concentrates were characterised by low volume, ease of preparation and ease of administration. The relevant authorities included my local hospital and regional health authorities, colleagues in the UKHCDO and views expressed in the medical literature of the time. No significant steps were taken by the relevant authorities to address my concerns.

28. **A report which you co-wrote with Sister Maureen Fearns dated September 1974 "Optimum use of Factor VIII Preparations at Present Available in the United Kingdom" (OXUH0000757) states that at the Newcastle Centre at that time: cryoprecipitate was used for outpatients and inpatients attending with bleeds or undergoing surgery; FFP for adults with mild to moderate bleeds if insufficient cryoprecipitate was available; and Hemofil (produced by Travenol Laboratories) for home therapy, patients with factor VIII antibodies and other adverse reactions, and for severe bleeds when there was insufficient cryoprecipitate. How did perception of risk of infection inform these choices?**

Perception of risk was omnipresent in all prescription of therapeutic products. At the time, the major risk was considered to be serum hepatitis and, given

the need in severely affected patients for multiple doses over time, that risk was known to be the same following cryoprecipitate or concentrate use.

29. **By reference to the letter dated 30 September 1975 from Dr Sheila L Waiter, DHSS, to Dr Modle, regarding the use of commercially produced concentrate in preference to cryoprecipitate (DHSC0100006_071), and considering the World In Action programmes (MDIA0000113) in December 1975, please explain your position as at the end of 1975 concerning whether commercial concentrates or cryoprecipitate should be preferred in light of the relative risk of infection as you understood it.**

My position as I remember it depended entirely on the clinical need at the time. As already explained, home therapy required concentrates rather than cryoprecipitate.

30. **In the Minutes of the UKHCDO meeting of 13 November 1978, you are recorded as saying that "the Directors should set a new target for factor VIII production for the Department of Health ... In view of the high cost of commercial material he felt sure that it was better to spend the money on the British Fractionation plants rather than to continue to spend large sums of money in purchasing the foreign made commercial concentrates. ... Dr Jones and Professor Stewart both said that treatment could not stop while funds and plasma were being diverted" (HSOC0010549). You seconded a motion that the Department of Health should make every effort to reach the target figure for the factor VIII required. Dr O'Brien then commented that "the emphasis from Directors was always towards giving lots of treatment and no credit was given to those Directors who were economic in the use of the concentrates". What was your view at that time of the risks of infection from commercial and NHS concentrates? Did you consider Dr O'Brien's opinion to be accurate? Did you consider that you needed to change your practice to**

be more economic in the use of concentrates? Did you make any changes to your practice at this time and if so what?

At the time I recall that the risk of infection was higher in commercial concentrates than in NHS concentrates. I did not consider Dr O'Brien's opinion on emphasis always being given to high usage patients to be accurate. Each patient I followed was treated according to clinical need determined by, among other considerations, their blood product usage. I encouraged patients to use that dose of product that controlled bleeding, neither more nor less. It was imperative to follow the clinical pattern of bleeding and its control in each patient; clinical severity is not invariably in accord with underlying factor level

I do not recall making any changes in my practice at this time.

Hepatitis

31. **In your response to question 27b regarding your contribution to the "Wellcome Witnesses to Twentieth Century Medicine" seminar of 10 February 1998, you state that "Patients were given all available information available to us at the time". Please answer the following questions:**

    a. **When did you become aware that concentrates being used in the UK would not have passed FDA regulations in the USA?**

       I cannot remember.

    b. **When did you become aware that this was the cause of the first outbreaks of hepatitis B in the haemophilia population in the UK?**

       I cannot remember.

    c. **Prior to the outbreaks of hepatitis B, did you ever inform patients that they were receiving concentrates that would not have passed FDA regulations in the USA? If so, please set out**

precisely what information was conveyed to them and when. If not, why did you not?

I cannot recall, but patients were told everything we knew at the time of their follow-up.

d. **After the outbreaks of hepatitis B, did you ever inform patients that they were receiving concentrates that would not have passed FDA regulations in the USA? If so, please set out precisely what information was conveyed to them and when. If not, why did you not?**

If I had known that at the time I would have altered their therapy and, in any case, would have told patients why.

e. **After the outbreaks of hepatitis B, did you ever inform patients that you understood the cause of them to be the "dumping" of concentrates that would not have passed FDA regulations? If so, please set out precisely what information was conveyed to them and when. If not, why did you not?**

As above. I cannot remember what information was available 40 years ago.

f. **Please describe the "available information" to which you were referring in your answer.**

As above. I cannot remember what information was available 40 years ago.

32. **After hepatitis A and B were identified, what was your understanding of the seriousness of non-A non-B hepatitis in the short term (i.e. in the acute phase)? What was the basis for that understanding? What information did you provide to patients?**

The information I provided to patients was well documented (please see the first edition of Living with haemophilia, pages 78/79).

33. **After hepatitis A and B were identified, what was your understanding of the seriousness of non-A non-B hepatitis in the long term (i.e. in the chronic state)? What was the basis for that understanding? What information did you provide to patients?**

Again, well documented. All patients were given up-to-date information at their follow-up.

34. **At what point in time did you come to understand that non-A non-B hepatitis (Hepatitis C) had serious long-term consequences for some patients? What made you come to that realisation?**

There was never "a point"; knowledge grew over time and, in my case, was imparted mainly by colleagues in the UKHCDO, especially the liver disease working party led by Prof Eric Preston.

35. **Did you read and consider (or otherwise become aware of), at the time, the report by Prince and others in the Lancet in August 1974 entitled "Long-Incubation Post-Transfusion Hepatitis without Serological Evidence of Exposure to Hepatitis-B Virus" (PRSE0001431)? If so, what was your response? What if any steps did you take in light of the report?**

From memory, not immediately. There were no steps to be taken on the assumption of a nonA nonB virus.

36. **Did you read and consider (or otherwise become aware of), at the time, reports such as those by Purcell, Alter and Hoofnagle regarding non-A, non-B hepatitis and its potential severity (respectively: "Non-A, Non-B Hepatitis" published in the Yale Journal of Medicine in 1976 (PRSE0000381); "How Frequent is Posttransfusion Hepatitis after the Introduction of 3rd Generation Donor Screening for Hepatitis B? What is its Probable Nature?", published in Vox. Sang. in 1977 (NHBT0000092_002); and "Transmission of Non-A, Non-B Hepatitis", published in Annals of Internal Medicine in 1977(RLIT0000228))? If so,**

what was your response? What if any steps did you take in light of these reports?

No. Not in the literature immediately available to me.

37. **Did you read and consider (or otherwise become aware of) the report by Professor Preston and others in the Lancet in 1978 entitled "Percutaneous Liver Biopsy and Chronic Liver Disease in Haemophiliacs" (PRSE0003622)? If so, what was your response? What if any steps did you take in light of the report?**

Yes, and i agreed that the only course of action at the time was continued surveillance.

38. **What if any information did you provide to patients, and when, about the potential serious consequences of non-A, non-B hepatitis?**

As it became available.

39. **What if any steps did you take during (a) the 1970s and (b) the 1980s to seek the advice, input or assistance of any hepatology specialists, so as to inform your understanding of the nature and seriousness of non-A non-B hepatitis?**

As already explained, the Centre team had an excellent working relationship with local colleagues in gastrointestinal medicine and liver disease, with Prof Eric Preston's team in Sheffield and with other international experts through the World Federation of Hemophilia.

40. **In your Personal Record you stated at page 4 "In the mid to late 1970s it was thought that the long-term sequelae of infection with hepatitis were probably not going to be severe in the majority of patients..." In the "Wellcome Witnesses to Twentieth Century Medicine" transcript of 10 February 1998, you stated at page 64 that you had known "there was another virus in the concentrates which we then called non-A and non-B hepatitis and we now know as hepatitis C, but all the evidence then from around the world then was that this too produced a chronic**

disorder which might result in ill-health in a few people. It was not thought to result in a devastating disease of the liver which would kill more than a few people" (RLIT0000228). Yet in a report in 1977, referred to in your Personal Record at page 16, you referred to "unidentified hepatitis viruses" and stated "Whether or not repeated exposure to these or other agents will result in a rising incidence of chronic liver disease remains to be seen but the hemophilic population at risk should be regularly screened for evidence of sub-clinical abnormality". Your Personal Record goes on to record at page 23 your anonymous Lancet editorial in 1979 in which you stated "A substantial improvement in the quality of life… may be bought at the expense of shorter survival". Given your understanding of chronic liver disease, both in terms of its impact on morbidity and mortality, why did you consider that non-A and non-B hepatitis was not a "devastating disease"? What were your patients told about the likelihood of shorter survival?

Over time and with advances in the detection and management of hepatitis, especially with the discovery of the hepatitis C virus, the long term sequelae of infection became clearer. Until it did, the emphasis of treatment remained on the successful management of haemophilic bleeding. As to the last question, people with haemophilia were inevitably aware of shorter survival usually from their condition.

41. **In your Personal Record, you stated at page 4 that "Despite this apparently relaxed attitude the Directors did follow up reports of morbidity in patients and continued to express their disquiet at the importation of factor VIII which had been made from the plasma of paid donors". Please set out:**

    a. **what the Directors found when they followed up the reports of morbidity;**

    These questions have already been answered. Those looking after haemophilic patients maintained careful, long term follow-up and analysis of results through the Oxford Returns system. Everyone,

including the patients and the Haemophilia Society, knew of the continued effort to access NHS concentrates and of the need to bring pressure to bear on government decisions regarding blood products.

b. **what changes you made to your personal clinical practice in light of this knowledge;**

These questions have already been answered. Those looking after haemophilic patients maintained careful, long term follow-up and analysis of results through the Oxford Returns system. Everyone, including the patients and the Haemophilia Society, knew of the continued effort to access NHS concentrates and of the need to bring pressure to bear on government decisions regarding blood products.

c. **how, and to whom, you "continued to express …disquiet at the importation of factor VIII";**

These questions have already been answered. Those looking after haemophilic patients maintained careful, long term follow-up and analysis of results through the Oxford Returns system. Everyone, including the patients and the Haemophilia Society, knew of the continued effort to access NHS concentrates and of the need to bring pressure to bear on government decisions regarding blood products.

d. **what response, if any, you received following such expressions of disquiet.**

These questions have already been answered. Those looking after haemophilic patients maintained careful, long term follow-up and analysis of results through the Oxford Returns system. Everyone, including the patients and the Haemophilia Society, knew of the continued effort to access NHS concentrates and of the need to bring pressure to bear on government decisions regarding blood products.

42. **In your response to question 30, you stated that "When it became available all patients testing negative for hepatitis B were offered**

vaccination." In a letter you wrote to Dr Maycock dated 1 June 1977 (HCDO0000255_003), you noted a four year old patient had recently tested positive for Hepatitis Associated Antigen "this positivity probably being associated with commercial AHG concentrate". Was a vaccination programme in place by that time?

I cannot remember specific dates but do know that vaccination was offered as soon as practicable once the vaccine became available.

43. **In the same document, you recounted problems with "shortages of hyperimmune B globulin" meaning that family members of patients who had been infected with HBV could not be vaccinated. Was this issue resolved, and if so how and when?**

Again, I cannot remember specifics after 40 years.

HIV and AIDS

44. **In your response to question 32 you refer to the timeline at WITN0841014. That does not answer the question which was posed. Please answer the following questions:**

a. **When did you first become aware that there might be an association between AIDS and the use of blood products? Was it at the meeting of Reference Centre Directors on 6 September 1982? (HCDO0000410).**

After 40 years it is difficult to remember, but it would either have been via colleagues in UKHCDO or the World Federation of Hemophilia.

b. **Did you take any action (whether by way of undertaking or initiating further inquiries of your own, or providing information to patients, or otherwise) at that point in time? If so, please provide full details.**

I stepped up surveillance and initiated testing as it became available. Patients were kept fully informed at the time.

c. **Did you read (at the time of its publication in January 1983) the article in the New England Journal of Medicine by Jane Desforges (PRSE0002410)? If so, what was your response? Did you take any action as a result? If so, please provide full details.**

Desforges article was read and discussed most carefully when it was published in 1983, especially with regard to the suggestion that all patients should be switched to cryoprecipitate therapy. That her suggestion was not implemented was due to a number of factors. Firstly, the logistics involved in retraining patients and their relatives in home therapy with cryoprecipitate. Secondly, concern with possible secondary infection and allergic reactions. Thirdly, the removal of the source material for the manufacture of concentrates. Fourth, the difficulty in treating without knowing the dose (i.e. the amount of factor in each pack) and, finally, the knowledge that the author did not treat patients with haemophilia and therefore was not in a position to appreciate the consequences of suboptimal therapy. In retrospect, we now know that the patients had already been infected before the article was published.

d. **When and how did you first become aware of the San Francisco baby case? (See the report on 10 December 1982 in MMWR – PRSE0003276). Did you take any action as a result? If so, please provide full details.**

From MMWR. We continued surveillance.

e. **Your colleague Dr Hamilton attended a meeting at a London airport hotel on 24 January 1983 at which AIDS was discussed (see PRSE0002647). Did he report back to you what was said at that meeting? If so, please provide details. Please provide full details of any action which you took in response.**

I cannot recall discussing Peter Hamilton's London meeting.

f. In relation to the period up to 13 May 1983 (when a special meeting of Reference Centre Directors took place, HCDO0000003_008), please:

I was not at that meeting. Dr Hamilton reported back.

(i) provide a full description of all steps which you took in response to the risk of AIDS being transmitted to patients treated with blood products;

Continued surveillance. Treatment of children with cryoprecipitate.

(ii) state whether you told your patients about this risk and if so which patients? (not by individual name, but did you tell all patients, or only some? And if the latter, how did you determine which patients to tell?);

We did as they came for follow-up, and via members of the Haemophilia Society.

(iii) provide full details of the information given to patients during this period concerning this risk;

The information given to patients varied with time and was eventually published in AIDS and the blood.

g. On 13 May 1983 a special meeting of Reference Centre Directors took place, attended by your colleague Dr Hamilton (HCDO0000003_008). Did he report back to you what was said at that meeting? If so, please provide details. Did you agree with what was decided at that meeting? In particular:

As documented above.

(i) Did you agree with the statement, recorded in the minutes, that "there was insufficient information available from the US experience to warrant changing the

type of concentrate used in any particular patient"? Please explain the reasons for your agreement or for any disagreement.

Yes as there was insufficient information.

(ii) **Did you agree with the statement, recorded in the minutes, that "there would seem to be no clinical benefit to be gained by changing to another type of factor VIII"? Please explain the reasons for your agreement or for any disagreement.**

Yes because at the time there seemed to be no clinical benefit.

(iii) **Did you agree with the statement, recorded in the minutes, that there was "as yet, insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy"? Please explain the reasons for your agreement or for any disagreement.**

At the time: Yes. If there was a problem it was probable that patients had already been exposed. And change to what product? In retrospect we know patients had already been infected.

(iv) **The minutes state that it would be "circumspect" for directors to continue with a policy of reserving NHS concentrates for children and mildly affected haemophiliacs. Was that the policy in operation at the Newcastle Centre at the time? What if any steps did you and Dr Hamilton take immediately after the meeting of 13**

May 1983? What if any changes were considered and/or made to the Centre's treatment policies?

Yes. We also treated children with cryoprecipitate.

(v) **What if any information did you provide to patients following the meeting of 13 May 1983? Please provide full details.**

As already stated patients were kept fully informed of developments.

h. **On 24 June 1983 Professor Bloom and Dr Rizza wrote to all centre directors (HCDO0000270_004) setting out two "general recommendations". Did you immediately implement those recommendations at the Newcastle Centre? Please provide full details of the steps you took on receipt of the letter of 24 June. Please also describe the information you provided to patients following the receipt of that letter.**

Yes. The recommendations were already in practice. Patients were kept informed.

i. **Did you, at any time after the meeting of 13 May and/or the letter of 24 June and up until the period when you switched to heat treated products:**

(i) **treat any mildly affected patients with haemophilia A with factor concentrates? If so, please explain why and detail the information which you provided to any such patients about the risks of their treatment.**

As already stated we continued to use cryoprecipitate in children.

(ii) **treat any patients with von Willebrand's disease with factor concentrates? If so, please explain why and detail**

the information which you provided to any such patients about the risks of their treatment.

Probably not; we would have used DDAVP or cryoprecipitate.

(iii) **treat any patients with minor lesions with factor concentrates? If so, please explain why and detail the information you provided to any such patients about the risks of their treatment.**

As for ii.

(iv) **treat any children with factor concentrates? If so, please explain why and detail the information you provided to any such patients about the risks of their treatment.**

No.

(v) **treat any patients previously unexposed to imported concentrates with factor concentrates? If so, please explain why and detail the information you provided to any such patients about the risks of their treatment.**

No.

j. **When and how did you become aware of the recommendations of the FDA in the USA in March 1983? Did you explain to your patients the position taken at that time by the FDA? If not, why not?**

I cannot recall. As already stated, patients were kept informed of all developments.

k. **How and when did you first become aware of the Cardiff case (the patient under Professor Bloom's care who was believed to have AIDS – referred to obliquely in the letter of 24 June 1983)? What if any information did you provide to your patients about that case? Did you tell them that a patient with haemophilia in the**

UK was suspected to have developed AIDS as a result of blood product treatment? If not, why not?

Our patients (and us) already knew what was happening thanks to media interest. We kept them informed of the facts.

l. **When and how did you become aware of the letter written by Dr Galbraith on 9 May 1983 (CBLA0000043_040)? Please consider paragraphs numbered 1 to 6 in the document "Action on AIDS" prepared by Dr Galbraith contained in CBLA0000043_040. Do you agree that each of the points set out in those paragraphs was, on the basis of the information available in May 1983, was valid? If not, please explain any respects in which you would disagree with Dr Galbraith's reasons.**

In general, yes.

45. **What if any steps did you take, other than any you have set out above, in response to the risk of AIDS, in the period up to December 1984? Please include in your answer:**

a. **a full description of any changes you made to the Centre's treatment policies;**

As already stated we reserved cryoprecipitate for children and mildly affected patients when not using DDAVP. We continued to use concentrates including imported concentrates to treat bleeds. We put off non urgent surgery.

b. **a full description of the information which you say was provided by you to patients.**

As above, patients were kept fully informed.

46. **In your Lancet editorial in 1983 you rejected the argument that there should be a change in treatment policy, partly because the emergence of HIV/AIDS "in a few haemophiliacs does not necessarily reflect the tip**

of an iceberg" (PRSE0002723). You relied on the limited numbers of cases found in Germany and the USA. Please explain the basis of this decision. Why, if the disease was known to have a lengthy incubation period and was known to be fatal, did you not consider that treatment policy should be changed? Did you consider suggesting a change in treatment policy for children and those with a mild disorder? If not, why not?

I cannot recall writing this anonymous editorial. However, in the dynamic and rapidly changing circumstances the Lancet leader could only reflect on the state of knowledge at the time. This was that a minority of patients would go on to develop AIDS. As the leader suggests there was insufficienticient evilence to change practice at the time.

47. **In your response to question 36a you refer to "Initial findings in the United States" as the basis for your, and other UKHCDO directors, belief in 1981 that 1 in 1000 people transfused with contaminated product would go on to develop Aids. Further, in a newspaper article dated 9 December 1983 (PRSE0004601) you were quoted as saying the risk of haemophiliacs contracting AIDS was "about 0.8 per thousands". Please set out precisely which scientific papers and/or conference proceedings this was based on.**

The medical literature including MMWR from Centers for Disease Control and other reporting of results available at the time.

48. **In addition, were there personal conversations with doctors and scientists in the USA that informed your view? If so, please set out who those conversations were with, when they took place, and what the content of them was.**

Yes. I was in contact with colleagues in the USA, especially doctors treating haemophilia and at the Centers for Disease Control. After 40 years I cannot provide details of dates; contents were the dangers from blood products.

49. When your patients were informed of the one in a thousand risk, precisely what did you tell them? What information did you give them about the scientific basis for that belief and the confidence that you had in it? Did you make them aware of any dissenting opinions in relation to that risk? If so, what did you say? If not, why not? After providing information about the risk, were your patients informed of alternative treatments? How many of your patients decided not to use factor concentrates thereafter?

Yes to all. Patients were always told exactly what the state of knowledge was at the time of consultation. The information and the background to that information was reiterated in meetings thereafter. Patients were always informed of alternative treatments if they were available. I incorporated what was known at the time in "AIDS and the blood".

50. A memorandum from Dr Boulton to Dr McClelland dated 30 May 1983 (PRSE0003709) describes your attitude towards the risk of AIDS at that time as "somewhat less than cautious". Do you accept this as a fair description, and if not why not? What is your recollection of the conversation to which Dr Boulton refers?

I have no recollection of this. The letter does not make it clear whether the author is referring to Arthur Bloom or me; I have no idea what the "interests" referred to might be.

51. On page 15 of "Aids and the Blood" it is stated that "The virus or viruses that are thought to cause AIDS are not very infectious...Present evidence is that only a minority of people who are challenged by the AIDS virus(es) go on to develop the disease". You note on page 10 that the average incubation period was 28 months and ranged from 6 months to 6 years. Given the lengthy incubation period, please explain why you believed that the virus was not very infectious. What was the basis for your belief?

The question confuses infection and contagion. Although infectious AIDS is not spread like Covid, ie it is not contagious.

52. **On page 20 of "Aids and the Blood" (RLIT0000046) information is provided about how to prevent cross infection including having one's own eating and toilet utensils. Please explain why you considered it necessary to include this information if your view was that the virus was "not very infectious".**

Because I was reflecting the state of knowledge at the time.

53. **In "This Week, Next week" aired on 22 September 1985 you criticised the Government for failing, at that time, to test blood for HTLV-III. You stated that this "was a wrong decision taken here and it is putting people at an unnecessary risk" (DHSC0000490). This appears to contradict your statement in "Aids and the Blood" that only a minority of people challenged by the AIDS virus(es) would go on to develop the disease. Did your views change between February and September 1985? Please explain the apparent contradiction.**

As the Covid pandemic continues to demonstrate, the single most basic requirement for effective control is to test as many of those involved as possible. That is exactly what we did with HIV infection. At the time *AIDS and the blood* was published the number of infected people going on to develop overt disease was small. There is no contradiction.

54. **In your response to question 65, you state that in 1986 you thought that Newcastle Haemophilia Centre was particularly "vulnerable" to AIDS because "of the incidence of lymphoma". On page 12 of "Aids and the Blood", written in 1985, you stated that "People with haemophilia have without exception been in categories 1 [infections] or 3 [other immune disorders]. Only one cancer has been recorded in transfusion associated AIDS". Please explain the disparity and specifically what the incidence of lymphoma was between 1985 and 1986**.

This was difficult: I went through a period of worrying that my patients were more susceptible to lymphoma than was expected and worked with Dr McEvoy to determine if this was true. Thankfully this worry was not borne out

in results from other centres. At this stage I cannot remember the incidence quoted.

55. **Please provide a full account of the investigations that were undertaken in 1986 to consider why Newcastle Haemophilia Centre was "so vulnerable" compared to other regions of the UK. A high incidence of HIV is also recorded in DHSC0001381. Please include answers to the following:**

a. **What were the results of those investigations?**

As above, I worked with Dr McEvoy to determine the position and I shared all our results with her. That was why the details did not go directly to Dr Craske.

b. **In what ways were your impressions of increased vulnerability shown to be wrong?**

As a above.

c. **In what ways were your impressions as to vulnerability shown to be correct?**

As a above.

d. **In the minutes of the Haemophilia Reference Centre Directors on 14 April 1986, you declined to send your samples to Dr Craske and said you would send them directly to Colindale (HCDO0000420). Why was this? What was your response to Dr Craske's concerns that significant data would be lost?**

As a above.

56. It appears from your response to question 24, that you understood NHS blood products to be safer than commercial concentrates. If so:

a. What processes and procedures were in place to prioritise the use of NHS blood products?

There was insufficient NHS concentrate to prescribe in preference to licensed imported concentrates. In any case, there was no point in prescribing NHS product for patients already HIV positive.

b. Were specific patients or groups of patients given priority access to NHS blood products? If so, which groups of patients?

HIV negative patients.

c. What actions, if any, did you take to encourage and or seek to persuade the suppliers to increase the supply of NHS blood products?

Continued lobbying over many years.

d. Your Personal Record notes at page 12 that in 1979 prophylaxis was "having an effect on the average number of factor VIII units per patient per year". It is understood that the usage was increasing considerably. What actions, if any, did you take to encourage and/or support a reduced demand for all blood products?

Prophylaxis was usually assumed to result in an increased use of factor concentrate over time. However, this was not always the case and when the long-term sequelae of joint bleeding, and the need for surgical cover was taken into account, overall life-time prophylactic use was sometimes less than that used on demand. All patients/parents were counselled individually on factor usage at follow-up.

e. **In retrospect, do you consider that you could have taken any steps to reduce the demand on blood products such that more patients could have received NHS blood products rather than commercial concentrates?**

No.

57. **In your book 'Haemophilia Home Therapy' published in 1980 (RLIT0001201) you wrote at page 119: "In the present state of our knowledge there is no way to remove this threat [of hepatitis infection], apart from rigorous testing for hepatitis B, because it is probable that changes in liver function and architecture reflect challenge by more than one 'non A, non B' viral agent. It has been suggested that large pool factor VIII concentrates should not be prescribed for children, who should receive only cryoprecipitate (McGrath and colleagues 1980), but such an approach is impractical if severely affected children are to benefit from the early cessation of haemorrhage which home therapy affords, and it begs the question of exactly when to introduce concentrates. There is evidence that no long term difference accrues anyway..." Further, at page 120 you wrote that all patients on home therapy from the Newcastle Centre were receiving commercially prepared factor VIII concentrates. You noted that "Certainly we see changes in liver function tests" but no patient had the clinical stigmata of chronic disease and in the absence of biopsies the incidence of hepatic disease was unknown. Was it your view in 1980 that there was no long-term difference in risk for children between cryoprecipitate and large pool factor VIII concentrates? If so, what was your basis for holding this view? Did it change over time and if so why? What role did the "impracticality" of cryoprecipitate therapy play in your decision-making on how to address this risk? What experience did you actually have of using cryoprecipitate for home treatment?**

Yes; it was my view that children exposed to multiple donations (whether by use of cryoprecipitate or concentrate) were equally at risk of hepatitis

I considered it impracticable to try to use cryoprecipitate for home therapy, not least because of the increased risk of infection in family members especially in the person giving the cryoprecipitate

Because of this I never prescribed cryoprecipitate for home treatment

58. **Prior to the introduction of heat treatment, did you take any steps to reduce the risk to your patients of being infected with HIV? Specifically did you take any steps to:**

    a. **Advise or encourage patients to reduce their use of factor concentrates?**

       Only if they were seen to be using excessive amounts of concentrate at follow-up.

    b. **Increase usage of NHS products rather than imported concentrates?**

       Not possible.

    c. **Advise or encourage patients to use alternative treatments such as cryoprecipitate?**

       No, for reasons already stated.

    Please provide a full and detailed account of all such steps taken.

59. **In an article published in the BMJ on 10 December 1983 (HSOC0001285) you stated that "When AIDS was first linked with haemophilia, and the extent of the problem in the United States was unknown, some centres curtailed planned surgery and home treatment. Nevertheless, most have now reverted to their routine programmes, and throughout the world the opinion of the majority is that the risk of haemorrhage and its complications far outweighs the risk of developing AIDS or chronic liver disease." However, you suggested it would be sensible to treat very**

young, severely affected children with cryoprecipitate, DDAVP or danazol. Further, mildly affected haemophiliacs, those with Von Willebrand's disease and carriers should perhaps use "the new porcine material". Did you make changes to the treatment prescribed to these patient groups at or before this time? What were those changes? Who was "the majority" to whom you were referring? Did they include patients?

Yes, we curtailed cold surgery for a time and kept children on cryoprecipitate. The "majority" referred to the majority of centres and their staff.

60. **In the minutes of the HCDO meeting of 10 December 1984, you stated that "All concentrate [used in Newcastle] is now heat-treated commercial" (BPLL0001351_028). In your response to question 40 you simply state that "Recommendations for heat treatment were immediately enforced at the Centre".**

    a. **When was heat treatment "enforced" at the Newcastle Centre? What decision was taken, by whom, when and why? You may wish to refer to the 'Report of an Ad-hoc Group to Consider the Use of Heat-Treated Factor VIII Concentrate' which followed a meeting on 4 December 1984 (TYWE0000048).**

       Heat treatment in Newcastle was started immediately the recommendation was made on 4 December 1984; that morning I met with Prof Rawlings (later head of NICE) and finance was immediately made available by the authority for purchase of heat treated concentrates.

    b. **In a letter from Dr Smithies to Dr Abrams regarding the 10 December 1984 meeting, he stated that "Most agreed that untreated BPL Factor VIII could continue to be used until heat treated Factor VIII was available from Elstree. There will be some Directors who are not willing to do this, notably Dr P Jones of Newcastle who has declared that all patients will have 'safe' heat treated Factor VIII and has already had sanctioned by his District**

the extra money required to buy the heat treated product." (DHSC0001117). Is that an accurate representation of what you said? Is it an accurate representation of the views of other Centre Directors? Why did you take this view?

Yes. It took some time for the NHS product to be heated satisfactorily.

c. **On 14 January 1985 you wrote in a letter to Dr Lane that you had "no option but to change" from using non-heat treated NHS factor products to using heat-treated commercial products (BPLL0005849). What caused you to reach this conclusion?**

As b.

61. **The 14 January 1985 letter further states "we intend to use up present stocks of the NHS material" before changing to the heat-treated material. However, in 1988 you wrote to Dr Liam Donaldson and enclosed a "historical record" of the factor VIII preparations used in the Northern Region and stated that "Non-heat treated concentrates were rapidly phased out as people brought back their home therapy supplies" (BPLL0002848_001). The 'Report of an Ad-hoc Group to Consider the Use of Heat-Treated Factor VIII Concentrate' says at page 4 "Manufacturers have... indicated that they will accept this material for credit, or for heat treatment". In your evidence to the Lindsay Tribunal you stated that "there was no delay" and that you "immediately instituted heat-treated products in Newcastle..." (LIND0000312). You do not mention that you decided not to recall the non-heat-treated product. In your Personal Record you state that you "did not think that the**

available evidence warranted the fear that such a quick recall would invoke".

a. **Once it was agreed that the Newcastle patients would be prescribed heat-treated products, were non-heat treated products recalled? If not, why not?**

Yes, but patients were given the option to exchange to heat treated material as they came to the Centre for follow-up or fresh supplies.

b. **Please explain your thinking, particularly in light of a) the significant mortality implications of HIV/AIDS and b) the fact that heat treated product had been recommended as a result. If it was not recalled, was the fundamental reason for not recalling the non-heat treated material a concern about cost?**

No, there was no concern about cost; the authority immediately approved the prescription of heat-treated material.

c. **What if any information did you give to patients about the recall or the risks of using non-heat treated product?**

All patients were told about the recall and about how to switch to heat treated concentrate.

62. **Please set out the criteria on which you based your clinical decision whether to offer a return to cryoprecipitate. To what extent were patients given the choice to return? How was that choice presented to them? Did any of your patients ask to go back to cryoprecipitate because of the risks? If so, what did you say to them? If a patient had requested a reversion to cryoprecipitate, how would you have responded?**

The discovery of cryoprecipitate revolutionised the treatment of people with haemophilia A. But it was difficult to prepare to provide an effective dose, and that dose in terms of factor units was unknown. It had to be stored frozen and, in those days, not everyone had access to a deep freeze. However, if anyone

had asked to return from concentrate use to cryoprecipitate I would have prescribed it; no-one asked for this change to be made.

63. **In your answer to question 49 you refer to concerns you raised at the AIDS conference in Newcastle in February 1986 regarding the efficacy of commercial heat-treatment in preventing HIV transmission. You say this led to the withdrawal of one implicated product. What steps did you take in the Newcastle centre in response to these concerns? Do you consider that the product ought to have been recalled earlier? You may wish to refer to your letter of 27 February 1986 to Dr Harris (ARMO0000489), a memorandum of 14 March 1986 describing a conversation between you and Dr Harris (ARMO0000514), your letter of 20 March 1986 to Dr Evans (HCDO0000271_075), a Guardian article in which you are quoted (PRSE0003068) and a briefing paper (DHSC0001381).**

The product concerned was made by Armour. We did not prescribe it in the Newcastle Centre. Yes, I did think it should be withdrawn immediately concern that the heat treatment was inadequate was made.

Provision of information to patients

64. **In your response to question 39, you provided documents at exhibits WITN0841015, WITN0841016 and WITN0841017. Please set out precisely what information you provided to patients in relation to these issues. Please include what and how patients were told about:**

    a. **The short-term risks of serum hepatitis;**

    I have already covered these questions several times in my answers and in my publications. We ran a Centre with an "open door" policy; anyone could come and seek help including the answers to questions at any time. In addition, I wrote extensively for the Haemophilia Society (both nationally and locally) and published 5 editions of *Living with haemophilia* containing detailed information.

b. The long-term risks of serum hepatitis;

I have already covered these questions several times in my answers and in my publications. We ran a Centre with an "open door" policy; anyone could come and seek help including the answers to questions at any time. In addition, I wrote extensively for the Haemophilia Society (both nationally and locally) and published 5 editions of *Living with haemophilia* containing detailed information.

c. The risks of HIV in each of the following years – 1982, 1983, 1984 and 1985;

I have already covered these questions several times in my answers and in my publications. We ran a Centre with an "open door" policy; anyone could come and seek help including the answers to questions at any time. In addition, I wrote extensively for the Haemophilia Society (both nationally and locally) and published 5 editions of *Living with haemophilia* containing detailed information.

d. The short-term risks of non-A non-B hepatitis;

I have already covered these questions several times in my answers and in my publications. We ran a Centre with an "open door" policy; anyone could come and seek help including the answers to questions at any time. In addition, I wrote extensively for the Haemophilia Society (both nationally and locally) and published 5 editions of *Living with haemophilia* containing detailed information.

e. The long-term risks of non-A non-B hepatitis;

I have already covered these questions several times in my answers and in my publications. We ran a Centre with an "open door" policy; anyone could come and seek help including the answers to questions at any time. In addition, I wrote extensively for the Haemophilia Society (both nationally and locally) and published 5 editions of *Living with haemophilia* containing detailed information.

f. The short-term risks of hepatitis C;

I have already covered these questions several times in my answers and in my publications. We ran a Centre with an "open door" policy; anyone could come and seek help including the answers to questions at any time. In addition, I wrote extensively for the Haemophilia Society (both nationally and locally) and published 5 editions of *Living with haemophilia* containing detailed information.

g. The long-term risks of hepatitis C, including the relevance of liver function tests being (i) normal or (ii) abnormal.

I have already covered these questions several times in my answers and in my publications. We ran a Centre with an "open door" policy; anyone could come and seek help including the answers to questions at any time. In addition, I wrote extensively for the Haemophilia Society (both nationally and locally) and published 5 editions of *Living with haemophilia* containing detailed information.

65. Did you record the information which you provided to patients about the matters set out in the above question in patients' medical records?

No

66. In response to question 57, you state that "all patients or parents or families were informed about HIV/AIDS at the first opportunity". Please clarify what you mean by "the first opportunity".

At their follow-up appointment and/or at meetings held with the Haemophilia Society.

67. In your response to question 63 you state that "All partners/family members were given full information in accordance with knowledge at the time". What was that knowledge? What was the "full information"? Please provide a chronological account of precisely what partners / family members were told. Please include what you told partners/family members about the risks of transmission via sexual activity, day to day

contact such as sharing toothbrushes and razors, and using the same cutlery and crockery and from a person's tears.

I set out in detail all the information listed here in "AIDS and the blood".

Partners/family members in accordance with their age were told precisely what we knew at the time about HIV (then HTLV3) transmission.

a. **In the Spring 1976 Newsletter from the Haemophilia Society Northumbrian Branch (HSOC0021641) you wrote at page 4 that "plasma from paid sources in America is now said to be almost as 'safe' as that from voluntary sources". Did this reflect the information you provided to your patients at the time? What was your basis for the reassurance that commercial plasma was almost as safe as plasma from voluntary sources?**

   Yes. At the time the incidence of non A non B hepatitis in multitransfused patients was thought to be the same. (HIV infection was unknown in 1976).

b. **In your book 'A Handbook for Home Therapy' published in 1978 (NTHT0000056) you wrote at page 16 "There is always a risk of hepatitis virus being present in blood products and any of the materials you use could be contaminated." Did this reflect the information you provided to your patients at the time?**

   Yes

c. **In your book 'Haemophilia Home Therapy' published in 1980 (RLIT0001201) you wrote at page 74 "Every family knows that the use of human blood products carries the risk of hepatitis. They are aware that this risk has been linked particularly to commercial concentrates prepared from the blood of paid donors, and they know that these risks still exist despite the increased sensitivity of donor tests for hepatitis B." What was the basis for your understanding that every family was aware of**

these risks? What steps did you take at the Newcastle Centre to make patients and their families aware of these risks?

Because we told them and they could read about the risk in patient leaflets enclosed with the concentrates and in literature from the Haemophilia Society. In addition we held regular meetings for patients and staff.

d. **In the Autumn 1980 Newsletter from the Haemophilia Society Northern Branch (HSOC0021600) you wrote that "in view of the concern expressed by some families" you thought readers would be reassured to see that in your view that "although risks [of hepatitis infection] remain they are probably of less consequence than might be suggested by the literature, and are certainly outweighed by the need to treat haemophilic bleeding in the only way we know." What was your basis for considering that the consequences of hepatitis infection were less serious than might be suggested by the literature? Did this reflect the information which you provided to your patients at the time?**

Because follow-up and history of multiple patients at the time did not demonstrate increasing problems associated with chronic disease. Our patients knew what we knew at the time.

68. **In your evidence to the Lindsay Tribunal you were asked a number of questions about seroconversions following the use of heat treated Armour products.**

68.1 **Do your answers constitute an accurate representation of your position? Do you wish to change any of the answers that you gave to that Tribunal in relation to that issue? If so, please set out what you would wish to say.**

My answers do constitute an accurate representation of my position at the time.

68.2 **In your evidence to the Lindsay Tribunal you stated that "the state of knowledge at that time, which was not in the public arena, was there were question marks being raised about the safety of the heating process;..." Did you inform your patients about these "question marks"? If not, why not.**

As our patients were no longer on the particular product I suspected was inadequately heated I did not specifically inform them.

68.3 **In ARMO0000514 you refer to your wrists being "slapped" for making public statements. Who slapped your wrists? What did they say or do? Which public statements was this in relation to?**

The Chief Medical Officer for England, Dr Acheson in relation to what I had said at the AIDS conference in Newcastle in 1986. He alleged that the information was not yet in the public domain and that I had highlighted it prematurely. No action was taken.

Response to risk by other clinicians or organisations

69. In your response to question 46, you state that earlier heat treatment "might also have increased the risk of side effects from the need of measures to counter the loss of yield". Please set out:

a. What measures would have been required to counter the loss of yield;

Choosing only donors with higher than average factor levels, speeding up the manufacturing process, especially reducing the time between donation and separation and laying down of source plasma, adding chemicals designed to stabilise the factors.

b. The side effects that you believed might arise from such measures;

Anything added could result in allergic reactions and/or haemolysis.

c. The basis for your belief in the risk of side effects.

70. **Your response to question 45 does not answer the question. Please set out what actions or decisions or policies of other clinicians or other organisations played a part in or contributed to the scale of infection in patients with bleeding disorders.**

The failure of government to fully implement the development of the UK fractionating plants in Elstree and Edinburgh before the AIDS epidemic resulted in the shortfall in NHS concentrates. Although the decision in 1973 to import concentrates was welcome because it allowed us to treat our patients adequately, it did result in a higher incidence of infection in the patient cohort.

71. **Should those clinicians or other organisations, in your view, have done anything differently?**

Yes; fully funded the NHS fractionation plants.

72. **In the "Wellcome Witnesses to Twentieth Century Medicine" transcript of 10 February 1998 you stated that "At the beginning of the HIV epidemic … I felt very much like the brigadier in Dr Who because I felt that I had to be pragmatic and act, but there was nobody to turn to; there was no leadership whatsoever from central Government or the Department of Health. In fact, if anything, in the initial years there was antagonism. There was an enormous amount of money spent fannying around…" (HSOC0008596_012). Please explain what you meant by this. Please set out what you consider the Government generally and the Department of Health specifically failed to do at the relevant time.**

There was virtually no communication between those in the front line (ie the treaters) and the DHSS initially. What communication there was tended to be between members of staff at the DHSS and their superiors without reference to us. Decisions were very "London centric". No-one followed the simplest of measures (ie picking up the phone) to communicate. No encouragement was forthcoming but any criticism was swift.

73. In your response to question 49, you refer to a document titled 'Action Items from Armour 1985'. Please provide a copy of this document.

Appended.

Section 7: Treatment of patients at the Centre

Provision of test results to patients

74. In response to question 59 you clarify that "retrospective testing... principally at the Royal Free Hospital, showed that seroconversion occurred earlier, around 1978/79". Please explain:

a. Was the retrospective testing in relation to patients at the Newcastle Haemophilia Centre or patients at the Royal Free Hospital?

At the Royal Free Hospital (as outlined in oral evidence by Prof Lee to the IBI earlier).

b. If it was in relation to Newcastle patients, why did the Royal Free test retrospective samples?

The Royal Free tested their own samples not those from Newcastle patients.

c. If it was not in relation to Newcastle patients, please explain why in your letter of 23 February 1988 you expressly refer to "our patients". What information did you have about Newcastle patients to enable you to assess the likely date of seroconversion?

I have been unable to access a copy of this letter. However, I believe I would have been referring to our patients as a cohort within UK haemophilic patients in general. They would have seroconverted in the same time period as those attending the Royal Free

75. In your evidence to the Lindsay Tribunal you stated that "the maximum time between taking blood [for an HTLV3 test] and getting the result, if they just went for follow up, was three months". You were asked what happened if someone did not attend the three month follow up and stated "Yeah but that was pretty rare at that time". Do you recall any patients being given the result of the HTLV3 test more than 3 months after the blood was taken? If so, why.

No

76. Please set out precisely what patients were told about the significance of a diagnosis of HIV.

It depended on the timing. For instance, at the start of the epidemic patients were told that the likelihood of developing overt disease was low (ie 1:1000). The questions and answers given were set out in detail in *AIDS and the blood*

77. Please set out precisely what patients were told about the prognosis in light of a diagnosis of HIV.

As 76

78. Please set out precisely what patients were told about the significance of a diagnosis of hepatitis B.

Again, it depended on timing. Initially, the significance was underestimated, but this information was refined as knowledge of chronic disease developed

79. Please set out precisely what patients were told about the prognosis in light of a diagnosis of hepatitis B.

As 78; relevant patients knew the same as the staff treating them.

80. Please set out precisely what patients were told about the treatment options following a diagnosis of hepatitis B.

The treatment required depended entirely on the progression (if any) of liver disease.

81. Please set out precisely what patients were told about the management of a diagnosis of hepatitis B.

As recorded in *Living with haemophilia* patients were told precisely what was known about hepatitis B at the time.

82. In your evidence to the Lindsay Tribunal you stated that with regards informing people about a positive hepatitis C result, "there was a difference in terms of urgency of telling the result… With Hepatitis C, we already knew we were dealing with a long, drawn-out disorder; at the time thought to be perhaps 40 or 50 years before there was any overt sign of disease. So there was not the urgency of divulging the result to people". You acknowledged that meant that if someone did not attend their next routine appointment, there was a delay in telling them of the diagnosis. Is this an accurate representation of the position? Do you wish to change any of the answers that you gave to that Tribunal in relation to this issue? If so, please set out what you would wish to say.

Yes, that is an accurate representation; all patients were eventually told their diagnosis at the next follow-up they attended.

83. Please set out precisely what patients were told about the significance of a diagnosis of (i) non-A non-B hepatitis, and (ii) subsequently hepatitis C.

As already stated; at the time the prognosis was of a chronic, long drawn out condition.

84. Please set out precisely what patients were told about the prognosis in light of a diagnosis of (i) non-A non-B hepatitis, and (ii) subsequently hepatitis C.

As 83.

85. **Please set out precisely what patients were told about the treatment options following a diagnosis of (i) non-A non-B hepatitis, and (ii) subsequently hepatitis C.**

This changed over time as newer treatments became available. The options were discussed openly with all patients, both individually and in meetings.

86. **Please set out precisely what patients were told about the management of a diagnosis of (i) non-A non-B hepatitis, and (ii) subsequently hepatitis C.**

As above under 85.

87. **Please set out precisely what patients were told about the risks of the following infections as a consequence of the use of blood products:**

a. **Parvovirus B19;**

Already covered in 22 above.

b. **Cytomegalovirus;**

Already covered in 22 above

c. **Hepatitis D;**

Already covered in 22 above.

d. **Hepatitis E;**

Already covered in 22 above.

e. **Hepatitis G;**

Already covered in 22 above.

f. **Epstein-Barr virus.**

Already covered in 22 above.

Consent

88. In your response to question 75 you state that blood samples were taken at three monthly intervals from patients with severe haemophilia. Were any of these samples stored? If so:

a. Why were they stored?

No samples were stored.

b. How long were they stored for?

N/A.

c. Were patients told that samples would be stored? If so, what were they told about why they were being stored? Were patients able to refuse for samples to be stored?

N/A.

d. If they were not told, why were they not told?

N/A.

89. In your Personal Record you stated at page 48 that in relation to the first testing for HIV undertaken "formal consent was not a feature of the initial run of testing. In part this was because I had no idea what we were going to find and did not want to alarm patients (or staff) prematurely, and in part because we needed to make sure that as far as possible that the tests were accurate". Is this an accurate representation of the position? Do you wish to change this section of your Personal Record? If so, please set out what you would wish to say.

Yes; that was an accurate representation.

90. Subsequent to the first testing for HIV, when consent was sought to test a patient for HIV or for hepatitis, what were they told they were being

tested for? Were they told in terms that the test was for HIV? Were they told in terms that the test was for hepatitis? If not, why not.

Yes. After that first run, the results of which were subsequently published, consent was always obtained from individual patients before any test for HIV or hepatitis. The nursing team, who took the specimens, followed a rule that blood was not to be taken without that consent

91. **What steps if any were taken to gain consent for sharing information relating to your patients? It is noted that a briefing paper dated 6 December 1987 (DHSC0001381) recorded "Dr Jones does not return his results on his patients with HIV infection to Oxford". Was this due to confidentiality concerns? If so, please explain the nature of your concerns and any steps you took to address them. If not, please explain what your reasons were.**

All my patients knew that anonymised data, including data about them, was shared, principally in relation to the Oxford returns. The briefing paper cited (DHSC0001381) contains inaccurate information and is biased in terms of both numbers quoted and inferences on infection rates. I did return all information requested to my colleagues in Oxford apart from, at the time, information on sexual partners

PUPS

92. **What were PUPS told about the risks of receiving factor concentrates for the first time?**

From memory, the majority of PUPS were children in which case the parents were briefed on all available up-to-date information. This included the need to check on the safety of any product being used, including heat treated concentrate. Everyone, including PUPS or their parents, was aware that anonymous reporting of results occurred and no one ever to my knowledge raised any problem with that at any time. Of course, patients or their parents could decline any testing if they wished.

93. What were PUPS told about why they were undergoing testing before and after receiving factor concentrates? Were they told that it was to "see whether heat treatment was effective or not in removing the threat from hepatitis/HIV" (according to your answer to question 78)? If not, why not. If so, was it made clear to them that they were being used in medical research? Were they informed about how that data would be used? Were they given the opportunity to decline to undergo the testing?

As 92.

Research

94. Did you inform patients that their data would be included in the Oxford returns? If so, precisely what did you tell them about how their data would be used? If you did not, why not.

Yes. Information from the Oxford returns was routinely used in the regular counseling of patients and in talks and residential weekends for them and their families. So everyone knew that anonymized data from the Centre was used in publications.

95. Were patients asked to give their consent to their data being included in the Oxford returns? If not, why not.

At that time, it was not thought that specific consent was necessary because the data was anonymized.

96. If patients did not consent to their data being included, and you were aware that the data was used "within articles in the medical literature" (in your response to question 83), how does this correlate with your answer to question 81 in which you state that no patients were involved in research studies without their express consent?

My attitude to consent and patient knowledge was recorded in the minutes of 1986 (HCDO0000271-066). I cannot remember a single patient not consenting to anonymised data being used in "research".

97. In response to question 79, which asks you to detail all research studies you were involved with during your time as a consultant at, or director of, the Centre, you have merely answered that "all research at the Centre was carried out with reference to the hospital Ethics Committee. All research was either with the Haemophilia Centre Directors Organisation or the Medical Research Council." However, you list several studies as references used in your personal record (WITN0841007 at pp. 89-98).

a. Please advise whether you wish the Inquiry to consider the studies attributed to you in WITN0841007 as part of your response to question 79; and

I am unsure which studies IBI refer to here. Most of my publications referenced concerned general articles, although there were a small number of in-house investigations which could be listed under "research"; none used data which could have identified a patient.

b. Are there any other studies you wish the Inquiry to consider in addition to this list?

Without seeing the specific "list" mentioned I cannot answer this question.

98. In relation to the heat-treated Koate trial commenced in or around 1984 (BAYP0000003_247, BAYP0000025_003), were patients who would otherwise have been treated with DDAVP prescribed Koate commercial factor products? What explanation if any was given to patients regarding the relative risks of these treatment options? Was consent sought from participants and recorded?

Any patient eligible for treatment with DDAVP was treated with DDAVP. There was no point in changing DDAVP responsive patients to a blood product

99. In relation to the trials of heat-treated products by Cutter and Alpha commenced in or around 1985 (BAYP0000025_008), what information

was provided to patients regarding the potential risks of these treatments? Was consent sought from participants and recorded?

Any patient changed to a new product (for instance, heat treated concentrate) was fully informed of the reasons why the change was being advised. Consent was always obtained but not recorded.

100. **When the transition to the National Database was discussed, you are recorded as raising concerns about patient information and consent (Tenth meeting of the AIDS Group of Haemophilia Centre Directors on 2 July 1986 (HCDO0000271_066)). Please explain what your concerns were and whether you consider they were resolved satisfactorily or not.**

My concerns were as set out in the document. As far as I recall these concerns were addressed.

Treatment of patients who were infected with HIV and/or hepatitis

101. **In "The Counselling of HIV Antibody Positive Haemophiliacs" you advocated that the care and treatment of AIDS/HIV should be within the multidisciplinary team in the Haemophilia Centres (p.113) (WITN0841021). In your evidence to the Lindsay Tribunal you noted, in the context of neurosurgery, the importance of patients being cared for by "people who were skilled in the other disciplines" in association with the haemophilia centre (p.9 LIND0000312).**

a. **Were all patients at the Newcastle Haemophilia Centre with HIV/AIDS treated within the Haemophilia Centre?**

No. All patients with HIV/AIDS were followed up for their haemophilia within the Centre, but some individuals requested HIV/AIDS follow-up with Dr Snow who was a consultant in infectious disease at Newcastle General Hospital. Referral to Dr Snow was free and easy and we worked together with him to provide the best possible care for our patients. With time it became apparent that many of the diseases encountered with AIDS were already being managed in haematology

patients with compromised immunity on our ward in the RVI. As a result we were able to care for our own patients who needed admission. We continued to meet with Dr Snow and others with an interest in AIDS regularly so patient care was never compromised by lack of up to date knowledge.

b. **Did you refer any patients who were HIV positive for specialist care outside of the Centre in relation to their HIV/Aids?**

As in 101 a above.

c. **If so, in what circumstances and from what date were they referred?**

As in 101 a above.

d. **If you did not refer any patients, what steps did you take to ensure that specialist care was provided to those patients? For example, did you invite a specialist to join the multidisciplinary team at the Centre?**

As in 101 a above.

e. **If you provided all the care personally, without input from a specialist outside of the Centre, how did you ensure that patients were given the most up to date information and treatment options?**

As in 101 a above.

f. **Please provide a chronological account of the information that you provided about treatment options and potential side effects.**

As in 101 a above.

g. **How frequently were patients followed up and or monitored in relation to HIV?**

All patients were followed up regularly, usually at 3 monthly intervals but more often when required.

h. **What arrangements did you put in place for inpatient care when required?**

As in 101 a above.

i. **How were children infected with HIV treated? Was there any difference in approach and/or monitoring and/or inpatient care for children?**

By agreement with colleagues all children who needed admission were nursed in Ward 25 of Newcastle General Hospital where, until his untimely death, Dr Graham Watson provided paediatric and infectious disease cover.

102. **In your response to question 93, you refer to provision of social work support. In your response to question 94, you state that if DHSS funding was allocated for counselling of patients infected with HIV it would have been used by the Social Work Department. Was any psychological support available to patients at the Centre? If so, how was this arranged? If not, did you consider that specialist psychological support was needed? In retrospect, do you consider that specialist psychological support would have been more appropriate?**

Yes, specialist psychological support was available at the Centre. A clinical psychologist, Dr Peter Britten, was a member of the team.

Records

103. **In your response to question 95, you have addressed the situation of HIV/AIDS in the death certificate and stated that every death was referred to the Coroner. At the UKHCDO meeting on 1 October 1993 you stated**

that you did not put AIDS etc on the death certificate (HCDO0000493). Please explain why you did not.

I did not put AIDS on the death certificate because at the time it is presented to the Registrar it becomes a public document and is therefore available to the press. At the time there was a considerable risk of media attention to the relatives of the deceased and of ill-informed and hurtful comment. This decision was discussed and agreed with the Coroner's Officer and thereafter followed with the proviso that he be informed of each case as it occurred.

104. **Please explain the position with regard to hepatitis and death certificates.**

From memory, hepatitis was not excluded from death certificates, although I cannot recall specific cases. It was not excluded because hepatitis did not carry the same stigma as AIDS in the public mind.

Section 8: Work with Treloar's and Oxford Haemophilia Centre

105. **In question 102 you were asked to describe any research and/or trials and/or experimental treatment that you are aware of involving pupils at Treloar's. In your response you stated: "Only in as much as sharing of information". In the minutes of the Haemophilia Centre Directors on 18 September 1975, a study of hepatitis in haemophilic patients by Dr Kirk, Lord Mayor Treloar College is described in which 40 Newcastle patients were involved (OXUH0003735). This included the collection of samples for virology testing. Please give full details of the study, how it was carried out, which patients were involved and whether they consented to being part of the study.**

After over 40 years I have no recollection of any trials concerning Treloar's. We had a few patients referred to Treloar's with the full agreement of their parents and their local authority. Any treatments given were a matter for the doctors concerned at Treloar's (including Dr Kirk and Dr Aronstam) with whom we had excellent relationships. Any studies would have had full consent.

106. Is this the same study as that referred to in CBLA0000375? If it is not, please give full details of the study referred to within these documents, how it was carried out, which patients were involved and whether they consented to being part of the study.

Given the passage of time, I cannot now recall.

107. In the minutes of the UKHCDO on 30 September 1980, you stated that the Home Treatment Working Party "was planning to carry out a trial of prophylactic therapy at Alton and at Newcastle" (PRSE0003946). Please give full details of the study, how it was carried out, which patients were involved and whether they consented to being part of the study.

Again, given the passage of time, I cannot now recall.

108. Further, in the minutes of the Thirteenth Meeting of the UKHCDO held on 14 September 1982, you reported on a "recent collaborative study with the Treloar Haemophilia Centre" in relation to high potency factor VIII (LOTH0000012_122). Please give full details of the study, how it was carried out, which patients were involved and whether they consented to being part of the study.

Again, given the passage of time, I cannot now recall.

109. In the minutes of the Twelfth meeting of the UKHCDO on 9 October 1981, you addressed two studies "in collaboration with the Treloar Haemophilia Centre at Alton" (CBLA0001464). If these are different to those addressed in the above questions, please set out details of them

Again, given the passage of time, I cannot now recall.

110. Please explain why you did not mention these studies when answering the Rule 9 request.

Because I did not (and do not) remember them.

111. In your response to question 102 you refer to the sharing of information with Treloar's. Was any information shared about:

a. A patient being involved in research?

As stated above we shared information with Treloar's but I cannot remember details and have no record to rely on.

b. A patient being involved in trial treatment?

As a above.

c. A patient being involved in experimental treatment?

As a above.

d. If so, please set out:

(i) The research/trial/experimental treatment that was being undertaken.

As a above.

(ii) Whether you were asked to do anything in relation to your treatment of the patient to support that research/trial/experimental treatment. If so, please set out what you were asked to do and what you did.

As a above.

(iii) Whether you were required to provide any information about the patient for the purposes of the research/trial/experimental treatment. If so, please set out what information you provided.

As a above.

112. In relation to your involvement with Oxford Haemophilia Centre and research or studies undertaken by Dr Rizza, save for completing the Oxford Returns:

a. Did you undertake any research with Dr Rizza?

I cannot recall any specific research project shared with Dr Rizza other than projects detailed in the minutes of the Haemophilia Centre Directors Organisation, and published by them.

b. If so:

(i) When did you undertake the research?

As above.

(ii) What was the nature of the research?

As above.

(iii) Was the research published?

As above.

Section 9: Self-sufficiency

113. In addition to completing the Oxford Returns, what did you personally do to assist in producing the estimates of how much Factor VIII blood product would be required?

Reported our consumption to Oxford and our local authority.

114. You are quoted as suggesting a particular figure for the estimate of Factor VIII required in the minutes of the Haemophilia Reference Centre Directors meeting on 22 October 1976 (CBLA0000473). Why did you come to this figure?

I cannot recall.

115. Who within the UKHCDO worked to produce the estimates?

Oxford colleagues.

116. What process was used within the UKHCDO to produce the estimates? If the processes changed over time, please produce a chronological account of the processes.

I cannot now recall after such a long time.

117. What were the assumptions that were used to produce the estimates?

As above.

Section 10: Pharmaceutical companies / medical research / clinical trials

118. In relation to question 10 you state that there was "no formal relationship, no influence allowed" by pharmaceutical companies. Please set out:

a. Did representatives of pharmaceutical companies visit you and/or the Haemophilia Centre?

Yes

b. If so, please set out:

(i) Which pharmaceutical companies sent representatives;

each of the companies licensed to sell blood products. Also, in relation to my work in paediatrics, a representative from a company manufacturing medicines for the treatment of asthma

(ii) The frequency of such visits;

Several times a year.

(iii) **The purpose of such visits;**

To "touch base" and impart up-to-date information

(iv) **What took place on such visits;**

Discussions.

(v) **Whether the safety of blood products was discussed on such visits and if so whether this was your source of information that was relayed to the meetings addressed in question 9a of your statement;**

Yes.

(vi) **Whether the representatives negotiated with you and/or a member of the Pharmacy in relation to the price of products;**

No. Negotiations did not take place at these sessions

(vii) **What efforts and means the representatives used to try to encourage you to use their products.**

Of course the representatives encouraged the use of their products. That was understood by everyone involved

119. **In the minutes of the Third Meeting of the UK Regional Haemophilia Centre Directors Committee on 3 September 1990, you are recorded as stating that "there was currently very active marketing of French products…" (HCDO0000438). What form did that "active marketing" take? Were you persuaded to use French products thereafter?**

I cannot now recall who BioTransfusion were, or what products they were trying to market.

120. **In your response to question 125 you stated that you provided advice or consultancy services to pharmaceutical companies involved in the manufacture and/or sale of blood products on two occasions; (1) as**

Medical Director of Baxter Travenol in Belgium for a number of months; and (2) inspecting Revlon Armour facilities in the United States. Please answer the following:

a. **At the Haemophilia Centre Directors meeting on 13 January 1977 you stated that you had an interest in an agenda item (DHSS plans to expand provision of concentrate) because you were "a paid Consultant to Hyland Laboratories until the end of February" (PRSE0002268). Was this a separate position from the two described above? Please give details of the advisory or consultancy services you provided in this position.**

No. I was offered the job of International Medical Advisor to Travenol. As a result my wife and I considered a move to the USA but rejected this in favour of continuing to work within the NHS. I was then offered the job of European Medical Adviser and considered this over the period of time mentioned in the minutes. During this attachment, with full hospital authority approval, I produced the first textbook of haemophilia care which was translated into Japanese.

b. **On 7 March 1979 you received a donation of £500 each from Cutter Laboratories and Speywood Laboratories (IPSN0000339_018 and see also letter dated 2 March 1979 at IPSN0000564). What prompted these donations? Had you provided help or advice to these companies, and/or did they anticipate your help or advice in the future? Please provide details.**

I have no recollection or record of these donations.

c. **A Newsletter from Plasma Perspectives published by the Plasma Division of Armour Pharmaceutical Company in July 1981 (ARMO0000229) refers to the inspection visit you have referred to. It states that, "To allay the emotive and unsubstantiated allegations which have been made in connection with the supply of blood derivatives from commercial sources, Armour opened**

its doors to Dr. Peter Jones" and quotes you as saying that you found "a first class organisation with a sound commitment to quality control". Were you aware that your report would be used in Armour's promotional material to suggest that allegations of safety risks were unfounded? Did you agree with this approach?

No. I did provide a confidential report on the visit made to their facilities in the US. I was not aware this would be used in any promotional material. Had I been aware of this at the time I would not have agreed to this use of my report.

d. **In a letter dated 29 July 1987 (CGRA0000607) Jack Wood of Cutter noted that: (1) you had prepared a product profile for the new firm Octa-Pharma for a fixed fee; and (2) Cutter had agreed to provide you with funding of £4,000 to write a "Whole Earth Hemophilia Handbook". In relation to each, please give details of the work undertaken and the payment received.**

Again, no recall I am afraid. The whole earth book never materialized. No payment was received.

e. **In a letter dated 21 April 1988, J K Smith wrote to Dr Robinson regarding errors in a protocol you had designed for Octapharma (BPLL0003280). Is this consultancy in addition to that referred to at d above? If so, please give details of the work undertaken and the payment received. Please set out whether you accept the criticisms in the letter and if not, why they are incorrect.**

I do not have a copy of the protocol referred to and this is the first criticism I have seen of it, so I cannot comment. I do not remember receiving any payment.

121. Please confirm whether the confidential report referred to in your response to question 125 is the same as that referred to in your Personal Record at page 28. Please confirm that you still do not have a copy of it.

If this is the Revlon report it is the same. It was a confidential report and I do not have a copy.

122. In exhibit WITN0841028 reference is made to possible future collaborations. Were any of the following achieved:

a. Your participation in a study of the new Factor VIII from Armour in conjunction with Bonn?

Not to my knowledge.

b. Access to the Bonn data in relation to home therapy and/or antibodies?

Not to my knowledge.

c. Ongoing dialogue with Revlon Health Care in any manner beyond the visit which is referred to above?

Not to my knowledge.

d. A visit to their facilities in the US?

Yes. This was the visit already referred to.

123. If so, please set out full details of what took place, with whom and when.

N/A.

Section 11: vCJD

124. On 10 October 1997 you attended a meeting with the French Health Minister regarding the emerging threat of vCJD and drafted the enclosed memorandum (DHSC0041442_105). Please set out the details of your involvement. Please explain the reasons for your advice only to reveal if

pressed that the French authorities had decided to ban British blood products as an "ultra-precautionary approach".

This does not relate to me but to another person with the surname Jones.

Section 12: Your involvement with the financial support schemes

125. When you were appointed by the DHSS to be a trustee of the MacFarlane Trust, other than attending meetings, what did you do on behalf of the MacFarlane Trust? What other roles and responsibilities did you have?

I have no record of Macfarlane Trust meetings other than that provided by the IBI. I have not seen a copy of the report or its resume mentioned under minute 88.43 (0000017_006).

My answers therefore depend solely on my very vague memory of events over 30 years ago.

In general, I recall the underlying aim of the Trustees was to help as many people as possible given the scarce recourses available (roughly £10m for around 1200 people and their family members). I also remember being of the opinion at the time that the available money should be divided up and distributed immediately to those affected. My fellow Trustees disagreed with that view, arguing that payments should depend on demonstrable individual needs and that is the principle on which the Trust worked.

As to the specific question 125, other than acting as one of the team managing the Trust, my role was to provide medical input to inform decisions made by my fellow Trustees.

126. During an MFT board meeting on 20 July 1988 [MACF0000002_006] the Board recommended unanimously that no payment should be made by MFT in respect of artificial insemination by the donor where the

haemophiliac partner was HIV antibody positive. Why did the MFT board come to this view?

As I was not present at this meeting (see Apologies for absence) I cannot say how the Board came to the view they did.

127. **Please consider the minute of the MFT meeting dated 22 August 1998 (MACF0000017_006) which records under the heading 'A.I.D' that there was no clear consensus on the matter of principle and you offered to investigate specific cases brought to your notice and make recommendations after identifying what other sources of help are available. Please answer the following questions:**

a. **Did the MFT Board therefore alter the decision recorded in the minute of the meeting on 20 July 1988 not to provide payment for artificial insemination to any registrant with HIV? If this is not the way to read these two decisions, please explain how they relate to each other.**

I do not understand the question. The Board would have come to its decision in the light of further information which I assume I and others provided in the month between the meetings. Note that the dates specified by IBI appear incorrect; both meetings took place in 1988.

b. **Were applications for monies to pay for artificial insemination received by MFT and considered by you? If so, how many?**

I have no recollection.

c. **What criteria did you apply when determining these applications? Were these criteria written down and available for registrants?**

I have no recollection.

d. **Did you recommend making payments in respect of any of these applications? If so, please describe the kinds of applications you**

would recommend for payment and those you would recommend should not succeed.

I am sure I would have supported individuals depending on need, but I cannot remember any specific cases.

128. **At an MFT meeting on 22 June 1989 (MACF0000002_016) the minutes record:**

a. **a discussion about the means of effecting a 'disposable income' of not below £70 a week. Was this what the MFT was trying to achieve for each of its registrants?**

See answer to c below

b. **The Trustees were advised that expenditure was rising above the level the MFT could afford (MACF0000002_016). Was the MFT expected to fund all its charitable giving via the income it received from its capital?**

See answer to c below.

c. **How long were the MFT budgeting for their funds to last?**

As I recall, the Trust was acting within a framework of trying to answer the needs of people affected and their families equitably, given the finite resource of £10m provided by the government. No time period had been specified although, as minuted, there was a hope that more money would become available at some future date. So, the answer to b. above is "yes"; the Trust had no remit to receive other monies and therefore relied on its capital.

129. **The formation of a Consultative Panel, to consult with registrants about MFT policy, became MFT policy at a board meeting on 19 July 1990 (MACF0000002_024). The details of the panel appear at page 11 of that document. Was any consultation in fact undertaken with the panel during your tenure? (Note the minutes of the EGM on 7 March 1991**

convened to discuss the MFT future policy where it was decided not to consult with the panel (MACF0000017_028)). If there was consultation, what on, and how if at all, did the responses inform MFT policy?

I remember that I was wholly in favour of inviting affected people to give their opinions on the Trust i.e. to lobby Trustees on individual decisions. That is why I proposed the formation of the General Consultative Panel in July 1990. I have no recollection nor any record of what happened thereafter.

Section 13: Haemophilia Society

130. **The book published as the proceedings from the AIDS conference in Newcastle in 1986 records the attendance at the "trade exhibit" of a number of pharmaceutical companies, including Alpha Therapeutic, Armour Pharmaceutical Co. Ltd and Miles Laboratories (Cutter Division) (WITN0841029). What was the purpose of their attendance? What did you understand to be the advantage to them of attending?**

A trade exhibition was organised as part of the AIDS Conference. Such an exhibition was a normal part of any conference, giving participants access to information and the opinions of others. The companies mentioned would have attended in order to learn up-to-date information on AIDS and to share their experiences with others. There was nothing sinister in this; it was a part of the usual sharing of information at such venues.

Section 14: Other issues

131. **Please provide the Inquiry with copies of the two files you refer to in response to question 161.**

Available for collection.

132. With reference to question 164, please identify the evidence that was given to Archer, that you claim to be untrue. What statements were made to the Archer Inquiry, and by whom, that you believe to be false?

I am unable to provide further information as this is comprised in confidential clinical records.

Statement of Truth

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

Signed GRO-C

Dated: 06/01/21