Witness Name: Dr Anna Pettigrew

Statement No.: WITN3527002

Exhibits: WITN3527003 Dated: 30 August 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ANNA PETTIGREW

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 14 April 2020

I, Dr Anna Pettigrew, will say as follows: -

Section 1: Introduction

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

Dr Anna Frances Pettigrew (Retired)
DOB[GRO-C] 949
Qualifications MBChB (Glasgow 1975) BscHons Biochemistry (Glasgow 1971)

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

I have never held the position of Consultant in Haematology nor in any other speciality. After completing my Pre Registration House Officer Posts in Medicine and Surgery, I took an additional Pre Registration House Officer Post in Medical Paediatrics at the Royal Hospital for Sick Children in Glasgow (RHSC) until February 1977. Thereafter, I was appointed to the post of Haemophilia Senior House Officer in the Professorial Department of Medicine at the Royal Infirmary, Glasgow. I was an SHO in Medicine, but also had duties in the Haemophilia Unit under the then Director Dr Colin Prentice and subsequently Professor Charles Forbes.

My recollection of treating adults with Haemophilia is of many who had debilitating joint disease and lives very much restricted by their Haemophilia, requiring frequent hospital admissions. Some of these patients had nephews whom I later treated in the RHSC.

I took Maternity Leave in February 1979, but was unable to return to my post as Haemophilia SHO as the then Professor of Medicine did not accept women returning from Maternity Leave in his department.

In May 1980, I was appointed by Dr Michael Willoughby, Consultant Haematologist, to the post of part time (6 sessions) Clinical Assistant in the Haematology/Oncology Department of the RHSC.I was based mainly in the Day Unit (which served all departments in the hospital) where

haematology and oncology patients attended for procedures such as chemotherapy, venipuncture, blood transfusion and clinical assessment. Children with bleeding disorders such as Haemophilia A, Factor IX deficiency and VonWilliebrands disease also attended there during office hours for treatment of bleeding episodes or for review.

I worked closely initially with the Haemophilia staff nurse and then with Sister Murphy when she was appointed as Haemophilia Nurse Specialist. We were both involved in the training of parents for home therapy; supporting families of newly diagnosed children and also carried out both home and school visits.

In latter years these children attended ward 7A. I also assisted in the weekly Leukaemia outpatient clinic and in the Haemophilia clinic. I held this post until January 1989 when I commenced training for General Practice and became a Principal (and later Senior Partner) in Springburn Health Centre, Glasgow in February 1991.

I refer to my CV as presented in my Written Statement to the Penrose Inquiry [PRSE0002690].

I retired from General Practice in November 2013 and from my post as VS tutor in the School of Medicine at the University of Glasgow in June 2015.

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

I have provided both written and oral statements to the Penrose Inquiry and these documents are available to, and have been cited by, this Inquiry.

In this written statement under Rule 9 of the Inquiry Rules, a number of my responses make reference to the above written and oral statements. The Penrose Inquiry took place 9 years ago when my memory of events referred to, though incomplete even then, was more accurate than is my current memory for events which took place between what is now 43 and 31 years ago.

4. Please consider the evidence that you gave to the Penrose Inquiry which is attached to this letter. Please confirm whether the contents of the statements are oral evidence are true and accurate. If there are any matters contained within the above statements or in the oral evidence you provided that you do not consider to be true and accurate, please explain what they are.

My oral and written evidence given to the Penrose Inquiry was given in good faith based on my recollection of events at the time of the Inquiry. However, with reference to my supplementary written response to topic B5 Q1 and 2 [PRSE0001126] and my oral evidence [PRSE0006020 p62 line 21-25 p63 and p64 line 1-7] I had stated that I had no recollection of informing a parent of the result of her son's test for HTLV3 in a corridor.

Some time after the completion of the Penrose Inquiry, Sister Murphy, former Haemophilia Nurse

Specialist at the RHSC, recalled such an incident as we were discussing our experience of the Penrose Inquiry. She reminded me that during a Haemophilia clinic I had left the consulting room (possibly to answer my bleep) where Dr Hann was continuing a consultation with a family. The parent in question stopped me and demanded to know there and then if her son had been found to be positive for the AIDS virus. Sister Murphy reminded me that I had tried to persuade her to wait until the family with Dr Hann had left the consulting room so that we could discuss this with Dr Hann in the consulting room. She refused and continued to insist that I tell her immediately of her son's results. Further attempts at persuading her to wait and come into the consulting room were to no avail and she gave me no option other than to give her the result. I continued to try to persuade her to come into the consulting room to discuss this with Dr Hann but she left abruptly and attempts to contact her by phone or letter were unsuccessful.

The corridor in question was fortunately out of site and earshot of the waiting room. There were no other consulting rooms available for our use in that area.

I do now recall this incident, after my memory for it was prompted by discussion with Sister Murphy, and I consider that Sister Murphy's recollection of events was correct.

At the time of the Penrose Inquiry I genuinely had no recollection of this incident. The questioning relating to informing a parent of results in a corridor brought to mind only those situations where I recalled giving the results of HTLV3 testing myself without Dr Hann being present and those discussions had taken place in the empty waiting room of the Day Bed Area.

Section 2: Decisions and actions of those treating patients with bleeding disorders at RHSC and the Glasgow Royal Infirmary

5. Please describe the facilities, organisation, roles, functions and responsibilities of the Haemophilia Centre at the Glasgow Royal Infirmary ("the Adult Haemophilia Centre") during the time that you worked there, and how they changed over time. The Inquiry understands that you worked at the Glasgow Royal Infirmary from approximately 1977 to 1979 and would be grateful if you could provide an account of the Adult Haemophilia Centre's history, its establishment and its activities during this time.

When I began working as the Haemophilia SHO in February 1977, the Haemophilia Centre was a small room on the corridor leading to the male ward 3 of the Department of Medicine Unit. The codirectors at that time were Dr Colin Prentice (Consultant in the Department of Medicine) and Dr George MacDonald (Consultant in and Head of the Haematology Department). Professor G D Lowe was a Registrar in the Department of Medicine with an interest in Haemostasis and Thrombosis. There was a Haemophilia staff nurse (whose name I cannot recall) and subsequently a Haemophilia Sister, Sister Agnes Ward. Patients would contact the staff nurse/Sister Ward by telephone usually round about 9 am if they required treatment for a bleeding episode. The staff nurse/sister would contact the hospital Blood Bank and order the treatment required. This would be mainly cryoprecipitate or SNBTS Factor VIII concentrate. The cryoprecipitate would be thawed and pooled in the Blood Bank and thus ready to infuse and the Factor concentrate sometimes reconstituted there or in the Haemophilia room after the patient had arrived.

I usually went to the Unit after the Medical Ward Round to administer the treatment and if patients had problems for which further advice was required, I would contact Dr Prentice, Dr Lowe or Dr Charles Forbes (though not at that time a Director was also involved in the Unit).

Patients also attended the Unit for Investigation of possible Bleeding Disorders. If it was deemed necessary to admit a patient this would be discussed with a senior colleague and arrangements made for admission to ward 3. The treatment given was recorded in a Treatment Book and a record also kept in Blood Bank. Patients could also sometimes come without prearrangement during the day for treatment of Bleeding Episodes.

6. Please do the same in respect of the treatment of children with bleeding disorders at the RHSC. The Inquiry understands that you worked at the RHSC from 1976 to 1977 and then from 1980 to 1989.

During my time as Post Registration Medical House Officer in the RHSC from August 1976 to February 1977, I was not involved in the Haematology Department other than administrating IV antibiotics to Haematology in patients when "on call" for Medicine and on rare occasions treating Haemophiliac patients in A&E after consulting with the Haematologist on call.

Dr Willoughby was the only consultant in Haematology and he also not only treated children with Haematological disorders and Malignancy, but also children with non Haematological cancers. He was also head of the Haematology laboratory service which I think he established himself on taking up his post as the first consultant in Haematology many years before I joined his staff as a part time Clinical Assistant GP sessions in May 1980. At that time there was no dedicated Haemophilia Unit. The patients attended A & E and were seen by a Haematology SHO, Registrar or Dr Willoughby. When I took up my post there was a Haemophilia staff nurse who was based in the Day Bed Area (this facility was used by the all specialities in the hospital) where parents requiring supplies for Home Therapy, or children requiring treatment for bleeding episodes, would attend though many still used A and E as first port of call for the latter-particularly those infrequent attenders.

After Dr Hann replaced Dr Willoughby, Ward 7A of the hospital became a dedicated Haematology Unit for inpatients and outpatients and the former small laboratory at the entrance to the ward became the Haemophilia Unit. By this time Sister Murphy was in post.

I refer to my oral evidence to the Penrose Inquiry [PRSE0006020]

page 3 line 24-25 page 5 line 1-4 page 6 line 11-25 page 7 and Page 8 page 41 line 11-20.

7. Please identify senior colleagues (a) at the Adult Haemophilia Centre and (b) at the RHSC, and their roles and responsibilities during the time that you worked at each.

In 1977-79 in the Adult Centre, as stated in Q5, the co directors were Dr C Prentice, Dr George MacDonald and Dr Charles Forbes, Consultant, was also involved in the Centre. In addition to Dr G Lowe, there were various other registrars and SHOs in the Department of Medicine who would have treated Haemophiliac patients both as inpatients and out patients. Dr C Prentice dealt mainly with clinical matters and, Dr MacDonald with laboratory investigations and Dr John Davidson dealt with the Blood Bank and Blood Transfusion Departments.

In the RHSC in 1980, Dr Willoughby was the sole Haematology consultant. Other members of his

clinical staff included a Leukaemia Research Fellow, a haematology SHO or Registrar who rotated for 6-12 months through the unit from Adult Haematology (One of these was Dr Aileen Keele) as well as 2 other part time Clinical Assistants (GP sessions), Dr A Campbell (deceased) and Dr J Kelt who also worked as a GP in Stirling.

Dr I Hann replaced Dr Willoughby in, I think, 1983, and there was an expansion of consultant staff with the appointment of Dr Elaine Simpson (deceased) as Consultant oncologist (I cannot recall the date). When Dr Hann left to take up his post in Great Ormond St Hospital, he was replaced by Dr Brenda Gibson.

8. Please describe your role and responsibilities (a) at the Adult Haemophilia Centre and (b) at the RHSC and how those changed over the year

A) Although I held the title of Haemophilia SHO, my responsibilities in the Haemophilia Unit were in addition to my responsibilities as a medical SHO in the Department of Medicine. These included attending daily Consultant ward rounds, routine management of patients in Ward 3 including arranging investigation, following up results, supervising the JHO, assisting at the weekly General Medical Clinic and being included in the on call rota for acute Medical Receiving (when the unit was responsible for assessing acute medical patients in A&E, arranging admission or discharging as appropriate and managing acute admissions).

As stated in response to Q5, I joined the Haemophilia nurse after the morning ward round to asses any patients attending, take routine blood samples (Hep B markers, FVIII levels, Fbc LFTS) if required and administer treatment (nurses at this time, as far as I recall, were not qualified to administer treatment intravenously).

B) The RHSC. I refer to my response to Q2 of response to witness statement under Rule 9 of the Inquiry [WITN3527001]

and to my oral evidence to the Penrose Inquiry [PRSE0006020]

page 3 line 24-25

page 4 line 1-25

pages 7 and 8

page 9 lines 5-25

page 10 line 1-8

page 13 lines 15-25

page 14 lines 1-12

9. Approximately how many patients with bleeding disorders were under the care of (a) the Adult Haemophilia Centre and (b) the RHSC when you first started working at each and over the years that followed? Were all patients at the Adult Haemophilia Centre adults and all at the RHSC children? (If you are able to give exact rather than approximate figures, please do so).

I am unable with any accuracy to give these figures for either the Adult or the Paediatric Haemophilia Centres. I think that accurate figures may be available from other sources and I note that in Q 1 of the request for a written statement addressed to me from the Penrose Inquiry [PRSE0003995] it was stated that according to the UKHCDO in 1980 there were 55 patients treated at the RHSC for haemophilia.

The numbers at the adult centre remained fairly static with the addition of a small number of patients diagnosed in adulthood (these would generally be patients with mild haemophilia or VonWilliebrands Disease presenting at surgery or dental extraction) All patients at the adult centre were adults.

At the RHSC there would be a small number of patients each year, perhaps one or two, newly diagnosed and some children would be transferred to the adult unit. The age at which this occurred varied from individual to individual. In this respect, I refer to my written response to Q2 of the Penrose Inquiry [PRSE0003995].

10. What decisions and actions were taken, and what policies or standard operating procedures (written or otherwise) were formulated, (a) at the Adult Haemophilia Centre and (b) at the RHSC regarding the importation, manufacture and use of blood products (in particular factor concentrates) during the time that you worked there?

Policies in both units were decided by the Consultants.

- A) During my time at the Adult Centre, a folder pertaining to each patient was kept in a filing cabinet in the Haemophilia Unit and this stated what type of therapy each patient should receive. The blood products were ordered by the Blood transfusion and Blood Bank unit under the directorship of Dr J Davidson.
- B) In the RHSC there were no such written instructions but the practised policy was that newly diagnosed patients, and those with mild haemophilia, were treated with cryoprecipitate and those on Home Therapy and those frequently attending severely affected haemophiliacs not on home therapy would be treated with concentrate or cryoprecipitate depending on the severity of the bleeding episode.

In the RHSC the blood products were ordered by the senior chief technician Mr Jewell and purchase of commercial Factor VIII was dependent on whether or not adequate supplies of SNBTS Concentrate were available.

After the arrival of Dr Hann, his policy was to stop purchase of Commercial Factor VIII and use SNBTS concentrate and Cryoprecipitate and subsequently only heat treated concentrate. After Dr Hann's arrival, Scotland was approaching self sufficiency of Factor VIII concentrate and increased supplies of this were available.

I refer to my written response to Q1 of the Penrose Inquiry [PRSE0003995].

- 11. Who was responsible for the selection and purchase of blood products (in particular factor concentrates) for use (a) at the Adult Haemophilia Centre and (b) at the RHSC? What particular products were used for treating patients (a) at the Adult Haemophilia Centre and (b) at the RHSC, over what period of time and for which categories of patients? In addressing this issue, please answer the following questions: 1
- a. How, and on what basis, were decisions made about the selection and purchase of blood products?
- 1 In answering these questions you may find it helpful to review the transcript of evidence you gave to the Penrose Inquiry (PRSE0006020).
- b. What proportion of blood products used were from the Scottish National

Blood Transfusion Service (SNBTS), and did this change over time?

- c. What were the reasons or considerations that led to the choice of one product over another?
- d. What role did commercial and/or financial considerations play?
- e. What involvement if any did you have?

At the Adult Centre, the Co Directors and Dr J Davidson took the decisions regarding selection and purchase of Blood Products.

In the RHSC, initially Dr Willoughby and subsequently Dr I Hann and Dr Gibson took these decisions. Dr Willoughby delegated the task of ordering Blood Products to his Chief Technician, Mr Jewell.

During my time at the Adult Centre, the Blood Products used were cryoprecipitate, SNBTS Factor VIII and IX concentrates Commercial concentrate was purchased for use during Major surgery such as knee joint replacement. A commercial product FEIBA was used in those patients who had developed a Factor VIII inhibitor.

DDAVP was also used in patients with Von Williebrand's Disease and in some mildly affected Haemophiliacs for procedures such as dental extraction. In the RHSC, the products used were cryoprecipitate, SNBTS Factor VIII and Factor IX concentrate and Commercial Factor VIII concentrate (Armour) as well as DDAVP when appropriate.

I refer to:

My written response to Q1 addressed to me by the Penrose Inquiry [PRSE0003995] My oral response [PRSE0006020] - page 22 line 11-25, page 23 line 1-14.

- a) I was not involved in the decisions about the selection and purchase of blood products.
- b) I am unable, with any degree of accuracy, to give a figure for this but in the Preliminary report of the Penrose Inquiry (as quoted in Q8 addressed to me for my written response [PRSE0003995]) it was noted that the amount of Commercial Factor VIII concentrate used fell during 1982 with a larger drop in 1983 and a parallel increase in the amount of SNBTS Factor VIII concentrate used.
- c) I refer to my written response to Q1 addressed to me by the Penrose Inquiry [PRSE0003995] and my oral response [PRSE0006020] page 23 line 6-14.

As stated, in the RHSC newly diagnosed and infrequently treated mildly affected Haemophiliac patients would in general receive cryoprecipitate. However, if a child presented with a potentially fatal or severe bleeding episode (e.g. head injury and suspected intra cranial bleeding) they may have received Factor VIII concentrate, SNBTS if available or commercial if not, to achieve rapid and therapeutic levels of Factor VIII. Severely affected patients requiring frequent treatment may also have received Concentrate or cryoprecipitate. Those on Home Therapy were treated with concentrate. The choice of concentrate, whether SNBTS or commercial, would depend on what was available.

d) I was not aware of any commercial or financial considerations and was not aware as to the source of the budget for purchase of commercial concentrate.

- e) I had no involvement in the purchase of blood products and the Policy of treatment of Bleeding Disorders was decided by the Consultant.
- 12. What was the relationship between (a) the Adult Haemophilia Centre and the pharmaceutical companies manufacturing/supplying blood products, and (b) the RHSC and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions described above?

I was not aware of any such relationship in the Adult Centre.

In the RHSC, a representative from Armour visited the Haematology Department from time to time (as did other representatives from pharmaceutical companies supplying other products such as chemotherapeutic agents and IV antibiotics) but as far as I was aware, the relationship, such as it was, did not have any influence on the purchase of the product. The amount ordered was, as far as I was aware, the amount required to maintain an adequate supply of concentrate for the Home Therapy Programme.

I refer to:

My oral evidence to the Penrose Inquiry [PRSE0006020] page 29 line 10-24. page 30 line 4-12.

- 13. If the responsibility for the selection and purchase of blood products lay with an organisation other than the Adult Haemophilia Centre / RHSC, please specify which organisation and provide as much information as you can about its decision-making.
- a) In the Royal Infirmary, the responsibility for the purchase of blood products lay with the Blood Transfusion Unit, as far as I was aware.
- b) In the RHSC, I was not aware of any other organisation involved.
- 14. How were decisions (at each hospital) taken as to which products to use for particular patients? What role if any did you have in such decisions? Were patients given any choice, or involved in any discussions, as to which products to receive?

I refer to the response given to Q10 and Q11c.

The preference was to use SNBTS concentrate but in the early 80s, supplies of this were not reliable. Supply could not always meet demand and there was not, as far as I recall, a regular delivery of a set amount of SNBTS concentrate. If a certain amount of concentrate was requested, the amount sent from SNBTS would often be less than that amount.

The commercial product was more "user friendly" in that it dissolved (reconstituted) more quickly and each box, as far as I recall, would also contain the necessary supplies such as the butterfly needles solution for reconstitution and even child friendly medical plasters to cover the site of the injection. Parents administrating Home Therapy often expressed a preference for this. As previously stated, the policy for use of blood products would have been taken at Consultant level.

Where a child, who was normally treated with cryoprecipitate, received Factor concentrate as treatment for a bleeding episode requiring prompt control and higher levels of circulating Factor VIII, as previously described, the reason for this would be discussed with the parents. Moreover, when training for home therapy, the rationale for using Factor Concentrate as opposed to cryoprecipitate would be explained.

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

As stated in my response to Q11c and Q10 and to Q1 of my written evidence to the Penrose Inquiry [PRSE0003995], the alternative treatments to Factor Concentrate were DDAVP and Cryoprecipitate.

16. What were, in your view, the advantages and disadvantages of those alternative treatments? What use was made of such alternative treatments (a) at the Adult Haemophilia Centre and (b) at the RHSC? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

I refer to my response to Q10 and 11.

Cryoprecipitate was a blood product made from plasma and as such carried a risk of Hepatitis. It had to be stored frozen and thawed prior to use. It was usually 'pooled' so that one bag of 5 units would be obtained from 5 donors and in adults the dose was 5 to 10 bags so although exposed to less donors, patients receiving cryoprecipitate were still exposed to a number of donors.

Children would be treated with fewer bags depending on their weight-perhaps 1-5 bags and thus exposed to fewer donors but still exposed to at least 5 donors.

As mentioned, cryoprecipitate had to be thawed and this could take 20 minutes for one bag. The amount of Factor VIII varied from bag to bag and it was difficult to accurately assess if sufficient amount of Factor VIII had been administered to achieve adequate therapeutic levels without checking post treatment Factor VIII levels in the blood.

Infusion of cryoprecipitate could be associated with allergic and more serious anaphylactic reactions which could be potentially fatal. Larger infusions could lead to fluid overload and potentially cardiac failure. It was not practicable for home therapy.

I refer to my oral evidence given to the Penrose Inquiry [PRSE0006020] page 21 line 15-22.

DDAVP

Prior to its use for elective procedures such as dental extraction, a test dose of DDAVP had to be given to assess the response of the patient's Factor VIII levels prior to the infusion and if that would be adequate to maintain haemeostasis. The response to DDAVP was transient and it could only be used in mildly affected haemophiliacs who had reduced, but not absent, levels of Factor VIII. Infusion could lead to a lowering of blood sodium levels and to water intoxication. Patients had to

restrict fluid intake during infusion. It was not suitable for the treatment of severe bleeding episodes and only for very mild bleeding episodes in patients who had reduced but not absent levels of FVIII.

The main advantage of DDAVP was that it was not a blood product and thus free from the risk of infection but though used where appropriate, the circumstances in which it could be used were limited.

17. What was (a) the Adult Haemophilia Centre's, and (b) the RHSC's policy and approach as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and if so how?

I refer to my response to Q10 and Q11 and to my written response to Q1 of the Penrose Inquiry [PRSE0003995].

The policy for the use of cryoprecipitate in the Adult Centre did not change in the time I worked there.

In RHSC, after the arrival of Dr Hann in 1983 there was a clearer policy of treating newly diagnosed and those (mainly mildly affected) less frequently treated patients with cryoprecipitate or DDAVP where appropriate.

For severely affected Haemophiliac patients and for those less severely affected patients who would normally have received cryoprecipitate, for certain bleeding episodes such as GI bleeds, intracranial bleeds and intra oral bleeds, where it was important to achieve adequate levels of Factor VIII promptly, the difficulty in calculation of the dosage and the larger volume required along with the time taken to prepare the product would have led to concentrate being the preferred choice over cryoprecipitate in such circumstances. As previously stated, cryoprecipitate was not practicable for Home Therapy.

18. What was (a) the Adult Haemophilia Centre's and (b) the RHSC's policy and approach in relation to home treatment? When was home treatment introduced? Did the policy and approach towards home treatment change over time and if so how?

- a) Home Therapy had not been introduced in the Adult Centre at the time I worked there.
- b) I refer to my written response to Q1 of the Penrose Inquiry [PRSE0003995] and my written response to the request under rule 9 of this Inquiry section 3 other issues last paragraph [WITN3527001].

Home Therapy and Prophylactic Therapy were introduced by Dr Willoughby not only for psychosocial reasons, to help the children lead as normal life as possible including regular attendance at school, but also to prevent morbidity, particularly crippling haemophiliac arthropathy and mortality by prompt treatment of potentially bleeding episodes.

The policy did not change during Dr Willoughby's time but as far as I recall, very few children were commenced on home therapy from the arrival of Dr Hann until the supply of SNBTS was reliable and sufficient to cover Home Therapy needs and also until heat treated concentrate was available.

19. What was (a) the Adult Haemophilia Centre's and (b) the RHSC's policy and approach in relation to prophylactic treatment? Did that policy and approach change over time and if so how?

I refer to my response to Q18 above.

The rationale for Prophylactic Therapy, as put to me by Dr Willoughby, was that a twice weekly regular dose of Factor VIII would provide sustained though low levels of Factor VIII and this would be sufficient to prevent spontaneous bleeding episodes such as haemarthroses and allow more effective treatment of any bleeding episodes.

As far as I recall, several parents stopped Prophylaxis during 1983/84 when there was uncertainty about the role of Factor VIII concentrate in transmission of AIDS but some reverted back to prophylaxis. There was no policy introduced by the Consultants to stop prophylaxis.

- 20. What was (a) the Adult Haemophilia Centre's (if applicable) and (b) the RHSC's policy and approach in relation to the use of factor concentrates for children? Did that policy and approach change over time and if so how?
- a) not applicable
- b) I refer to my response to Q11c and Q16 above and to my written response to Q1 of the Penrose Inquiry [PRSE0003995].
- 21. To what extent, and why, were people with mild or moderate bleeding disorders treated at (a) the Adult Haemophilia Centre and (b) the RHSC with factor concentrates?
- a) I refer to my response to Q10.

SNBTS Factor VIII concentrate was used at the Adult Centre, but I cannot recall what the policy was in relation to which patients and in what circumstances it was used.

b) I refer to my response to Q 11c and to Q17 above and to my written response to Q1 of the Penrose Inquiry [PRSE0003995] and my oral evidence to the Penrose Inquiry:

page 18 line 16-23

page 22 line 18-25

page 23 line 2-14.

22. What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at (a) the Adult Haemophilia Centre and (b) RHSC in consequence of the use of blood products?

During the period I worked in Haemophilia, I was not aware of any other viruses transmitted to patients as a consequence of use of blood Products. HCV was not identified as the cause of non A non B (post transfusion) hepatitis until a month or so before my departure from the RHSC.

Section 3: Knowledge of, and response to, risk

General

23. When you began work at the Adult Haemophilia Centre as Haemophilia Senior House Officer in 1977, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time at the Adult Haemophilia Centre and at the RHSC?

In 1977 I was aware the risk of Hepatitis B and Post Transfusion Hepatitis (later NANB) associated with the use of blood and blood products. This knowledge would have been gained from my undergraduate teaching and from further study of Medical textbooks in preparation for sitting the MRCP examination.

During my time at the RHSC my understanding of the evolving natural history of Post Transfusion Hepatitis by then known as NANB Hepatitis, came from attending scientific meetings in the mid 1980s when the results of liver biopsies performed in Haemophiliacs and other patients thought to have NANB Hepatitis were presented. Until such studies, it was thought that the majority of patients thought to have NANB Hepatitis and displaying abnormal Liver Function tests remained asymptomatic.

Later I carried out a literature search in preparation for my presentation at the symposium "AIDS and Hepatitis in Haemophilia" in 1987.

The knowledge regarding the risks of the virus responsible for AIDS (HTLV3 and later HIV) from blood products was slow to evolve (this was pre the world wide web) and my knowledge would have been gained initially from discussions with colleagues, attending scientific meetings and later from regular updates in the "Morbidity and Mortality Report" from the US which I arranged to be sent to me from the Department of Epidemiology.

I refer to my oral evidence given to the Penrose Inquiry [PRSE0003995] - page 70, page 71 line 1-16.

24. What advisory and decision-making structures were in place, or were put in place, (a) at the Adult Haemophilia Centre and (b) at the RHSC and/or within the area covered by each hospital and/or nationally, to consider and/or assess the risks of infection associated with the use of blood and/or blood products?

This would have been out with my level of responsibility and I was not involved nor aware of such decision-making structures.

25. What was your understanding of the relative risks of infection from (i) the use of commercially supplied blood products and (ii) the use of NHS blood products?

My understanding was that any blood product carried a risk of Post Transfusion, later NANB Hepatitis whether NHS or commercial and that despite screening of donors, both paid and voluntary, Hepatitis B remained a risk but possibly more in commercial concentrate. Later, (1983/84) commercial concentrate was thought to carry a higher risk of infection with a putative

agent thought to be linked to the development of AIDS.

I refer to my oral evidence to the Penrose Inquiry [PRSE0006020]. page 37 line 23-25 page 38 line 1

26. What decisions and actions were taken by the Adult Haemophilia Centre, by the RHSC and by you to minimise or reduce exposure to infection?

I was not responsible for such decisions but for treatment of Haemophilia, there were no alternatives to treatment with blood or blood products (cryoprecipitate or concentrate) apart from DDAVP which was used if appropriate to do so.

27. Was any training or advice provided (and if so, what training or advice) to clinical staff at the Adult Haemophilia Centre and/or the RHSC in relation to advising patients of the risks of infection associated with the use of blood and blood products? If so, who provided this training or advice?

There was no official training at the Adult or RHSC Centres. One learned from one's seniors and that included advice to regularly monitor Liver Function Tests and Hepatitis B status and to advise patients why this was being done.

Hepatitis

28. When you began work at the Adult Haemophilia Centre, what was your knowledge and understanding of the risks of the transmission of hepatitis, including hepatitis B and NANB hepatitis (hepatitis C), from blood and/or blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time at the Adult Haemophilia Centre and then at RHSC?

I refer to my response to Q23 above.

When I was working in the Adult Centre, NANB Hepatitis was known as Post Transfusion Hepatitis. I was aware that some Haemophiliac patients had abnormalities of Liver Function Tests (LFTs) but at that time, the natural history of what was later known as NANB Hepatitis was not known.

As stated in my response to Q23, I gained knowledge of NANB Hepatitis as information about the natural history of the condition evolved.

29. What if any enquiries and/or investigations did (a) the Adult Haemophilia Centre and (b) the RHSC carry out or cause to be carried out in respect of the risks of transmission of hepatitis? What information was obtained as a result?

In both the Adult and the RHSC Centres, the patients' LFTs and Hepatitis B status would be checked at intervals, possibly 3-12 monthly in frequent attenders and those on Home Therapy. As previously stated, a number of patients were found to have abnormalities of LFTs but both at my

time at the Adult Centre and the RHSC there were no patients in whom these abnormalities progressed nor in whom symptoms of liver disease developed.

I refer to my oral evidence to the Penrose Inquiry [PRSE0006020] - page 20 lines 11-25, page 21 lines 1-10.

If a patient was found to become newly positive for Hepatitis B in the Adult Centre, SNBTS would be informed so that they could try to identify the donor responsible.

As far as I recall, we had no new sero-conversions to Hepatitis B during my time at the RHSC. Hepatitis B was also a notifiable disease in that the Public Health Authority had to be informed if a case arose to allow contact tracing and identification of the source of infection.

30. What, if any actions did (a) the Adult Haemophilia Centre and (b) the RHSC take to reduce the risk to patients of being infected with hepatitis (of any kind)?

I refer to my response to Q 26

After the introduction of a vaccine for Hepatitis B, all Haemophilia patients were offered and encouraged to have this vaccination which was administered by the Haemophilia Nurse. At that time, routine childhood immunisations were administered by the Haemophilia Nurse/Sister and not by the GP or Health Visitor in the Community.

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

During my time at the Adult Centre and initially at the RHSC I was aware that patients who received blood products were at risk of Hepatitis B and Post Transfusion Hepatitis, later NANB Hepatitis. As far as I recall at that time it was thought that few of these patients would develop chronic liver disease. However, around about the mid 1980s, I became aware of studies particularly in, I think, Sheffield, of liver biopsies in Haemophiliac patients who had abnormal LFTS. This demonstrated a risk of progression in some patients to chronic active and chronic persistent hepatitis and cirrhosis. It was not known what percentage of those patients developed chronic liver disease at that time. The virus responsible for NANB Hepatitis was discovered just a few months prior to my departure from the RHSC.

I knew that patients infected with Hepatitis B could develop an acute hepatitis or a chronic hepatitis and in the latter patients there was a risk of developing cirrhosis or liver cancer. Hepatitis B vaccine became available in the early 1980s (1982).

HIV and AIDS

32. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular of the risks of transmission from blood and blood products? How did your knowledge and understanding develop over time?

I refer to:

my written response to the Penrose Inquiry -Topic B5 further questions [PRSE0001126] 1 and 2 My oral evidence to the Penrose Inquiry [PRSE0006020] as follows: page 44 line 10-25 page 45 line 1-4

page 70 page 71 line 1-16.

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

I refer to my evidence written and oral to the Penrose Inquiry as referred to in Q32 above. There were reports of patients with haemophilia developing AIDS in the USA in, I think 1983 and the first case in a Haemophiliac in the UK was reported in, I think, 1984 and I would have been aware of that from discussions with seniors and colleagues.

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

I refer to my written response to topic B5 (b) directed to me by the Penrose Inquiry [PRSE0001126].

The transmissible agent responsible for AIDS was not isolated until 1984 by Gallo and Montagnier separately and when a reliable test for this virus (HTLV3 as it was known then) became available later that year, before we could inform and arrange testing in our patients, we received results of retrospective testing carried out by Dr Follet of the regional virology Laboratory. However, confirmatory testing was carried out after discussion with the parents and extended to all haemophiliac patients who had received blood products.

35. What if any actions did you and your colleagues take in light of your awareness of a possible association between AIDS and the use of blood products and/or to reduce the risk to your patients of being infected with HIV?

I refer to; my response to Q17 above my oral evidence to the Penrose Inquiry [PRSE0006020] page 32 line 5-18

my written statement in response to a request under Rule 9 of the Inquiry [WITN3527001] section 3 last paragraph.

After the arrival of Dr Hann in 1983, there was a change in practice to use SNBTS concentrate in preference to commercial concentrate. This change in part reflected the increase supply of SNBTS as a result of Scotland achieving self-sufficiency but also, as the evidence for a transmissible agent in blood products and in particular commercial concentrate was mounting, SNBTS concentrate was thought to carry less risk.

In addition, in 1983, the policy of treating newly diagnosed, less severely affected and infrequent attending patients with cryoprecipitate and the use of DDAVP where appropriate, was

strengthened. In addition, following the introduction of heat treated SNBTS Factor VIII concentrate in 1984, this was the sole concentrate used.

I refer to my oral evidence given to the Penrose Inquiry [PRSE0006020] - page 46 lines 5-12, page 48 lines 14-16.

36. Did you and your colleagues at the RHSC continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why, and which products did you use?

I refer to my response to Q35 above.

There may have been some, though much reduced, use of commercial Factor VIII in 1983 if there were insufficient supplies of SNBTS.

Response to risk

37. Did you or your colleagues at the Adult Haemophilia Centre and the RHSC take any steps to ensure that patients and/or the public were informed and educated about the risks of hepatitis and (in relation to the RHSC) HIV? If so, what steps?

As previously stated, parents/patients in both centres were aware of the risks of Hepatitis and were advised of those risks during initial counselling, training for Home Therapy and whenever blood were taken for LFTs and Hepatitis B.

There was no policy as to inform parents about the risks of HIV which were not identified until 1983/84 and the knowledge about the risks of transmission of a causative agent and the natural history of the disease evolved slowly (this was before the introduction of the internet and in contrast to the rapid increase in knowledge during the current Covid crisis). Initial discussions with parents were of the state of knowledge at the time and as knowledge evolved, parents would be informed.

I refer to:

my written response to topic B5 (a) of the Penrose Inquiry [PRSE0001126] my oral evidence given to the Penrose Inquiry [PRSE0006020] - page 45 lines 9-25, page 46 lines 13-19.

38. When did you begin to use heat treated factor products and for which categories of patients?

Heat Treated Factor VIII concentrate was introduced in late 1984 early 1985. It was then used as the preferred and, if I recall, the only concentrate given to those patients who were treated with Factor VIII concentrate.

39. Was the switch to heat treated factor products communicated to patients and their families, and if so how was this explained?

The parents/child would be informed that this was the preferred concentrate as heat treatment was

thought to inactivate the HTLV3 virus which by that time had been identified as the causative transmissible agent for AIDS. They were also informed that at that time it was not known if heat treatment inactivated the as yet unidentified causative agent for NANB Hepatitis.

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

I refer to:

my response to Q35 above my oral evidence given to the Penrose Inquiry [PRSE000020] - page 21 lines 11-25, page 22 lines 1-6.

41. Do you consider that your decisions and actions and those of your colleagues (a) at the Adult Haemophilia Centre and (b) at the RHSC in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

I followed the policies and advice of my senior colleagues. In the evolving situation, I am not sure if anything could have been done differently.

42. Was it the understanding at the RHSC that American factor products might carry a higher level of infection risk than domestically obtained products? If so, when was this understanding reached? What proportion of treatment was provided using American factor products at this time? Did this change, and if so when?

I refer to:

my oral evidence given to the Penrose Inquiry [PRSN0006020] as follows: page 32 line 5-18 page 37 line 23-25 page 38 line 1.

There was an awareness in the RHSC that American Factor VIII concentrate was obtained from paid donors and could carry more risk of infection particularly of Hepatitis B and later (1983/84) of an agent responsible for transmission of AIDS though it was also known that domestic Factor VIII was not free from such risks.

I cannot give, with any accuracy, a figure for the proportion of treatment provided using American Factor VIII at that time but as previously stated, that proportion fell from 1983 and these figures should be available from the Preliminary Report of the Penrose Inquiry.

43. Looking back now, what decisions or actions by (a) the Adult Haemophilia Centre and (b) the RHSC could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

The only decision that could have been taken to totally avoid the use of infected blood products

(domestic and commercial) would have been to stop treatment all together and that decision, with its implications for morbidity and mortality among the Haemophiliac population, could only be taken if evidence based and at a high level.

44. What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients with bleeding disorders? What, if anything, do you consider could or should have been done differently by these others?

Perhaps, with the benefit of hindsight, the Home Therapy programme at the RHSC introduced by Dr Willoughby was over reliant on commercial Factor VIII but this was before the appearance of AIDS and its association with the use of blood products and at a time when there were insufficient supplies of SNBTS Factor VIII.

As I stated in the last paragraph of my statement in response to a request under Rule 9 of the Inquiry [WIT3527001], "All clinical staff involved, like Dr Willoughby who instituted home therapy with Factor VIII concentrate, acted in what was thought to be the best interests of their patients"

Section 4: Treatment of patients at the Adult Haemophilia Centre and at the RHSC

Provision of information to patients

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

I refer to:

my oral evidence given to the Penrose Inquiry [PRSE0006020] - page 49 lines 14-25, page 50 My written response to Topic B5(a) [PRSE0001126]

Newly diagnosed patients/parents both at the Adult Centre and the RHSC would have been seen initially by the Consultant and, as well as an explanation of the nature of the clotting defect and the risk and types of bleeding episodes, the treatment available for treating bleeding episodes would be discussed. I cannot say with certainty how much emphasis was placed on the risks of treatment which were in 1977 and until 1983/84 Hepatitis B and Post Transfusion Hepatitis, later known as NANB Hepatitis.

Again, I cannot state with certainty but after the association between the use of concentrates and transmission of HIV was established this would also have been explained. However, until the introduction of heat treated factor VIII newly diagnosed children (usually babies) would not have received concentrate but would have been treated with cryoprecipitate.

46. What information did you provide or was, to your knowledge, provided by

others (a) at the Adult Haemophilia Centre and (b) at the RHSC to patients and their families about alternatives to treatment with factor concentrates? Please detail whether and if so how this changed over time.

- (a) In the Adult Centre, treatment with concentrates had already been introduced to some patients prior to my arrival and, as far as I recall, if patients normally treated with cryoprecipitate were treated with concentrate the reason for this would be explained. Patients for whom DDAVP was appropriate would be informed about this treatment. However, I cannot answer this question in relation to the Adult Centre with certainty.
- (b) As previously stated, in the RHSC, Home Therapy was established prior to my arrival but parents of children then and of those subsequently commenced on Home Therapy would be advised and themselves know (from their previous experience of their child being treated with cryoprecipitate) that cryoprecipitate was impracticable for Home Therapy. In this group of severely affected patients DDAVP would not have been appropriate therapy, and severely affected patients, not on Home Therapy, would generally be treated with cryoprecipitate; and if the alternative treatment in the form of concentrate was required for a specific bleeding episode, as previously stated, the reason for this would be given. In those patients where it would be effective as treatment, parents would be informed about its use. As the implication that commercial concentrate possibly carried greater risk of transmission of the putative infective agent for AIDS, parents were advised that SNBTS concentrate be used instead. Parents were later advised that Heat treated Factor VIII concentrate was the only concentrate in use.

47. What information did you provide or was, to your knowledge, provided by others (a) at the Adult Haemophilia Centre and (b) at the RHSC to patients and their families before they began home treatment?

- (a) There were no patients on Home Therapy or commenced on Home Therapy during my time at the Adult Centre.
- (b) At the RHSC, the discussion to commence Home Therapy was consultant led, I cannot say what information was given to the parents of the cohort that commenced Home Therapy prior to my arrival. Those subsequently commenced on Home Therapy would be trained by Sister Murphy and myself. This would involve training in reconstituting the concentrate, performing venipuncture and the administration of the concentrate via the butterfly cannula, as well as maintenance of record books and precautions for infection control such as wearing disposable gloves and a plastic apron and disposal of equipment and actions to deal with blood spillage. This would involve discussion as to why these measures were necessary due to the risk of Hepatitis B infection. These parents would also have been told, when blood specimens were taken from the children for routine monitoring of Hepatitis B status and sometimes for checking post infusion Factor VIII levels and blood count, that we also checked LFTs as we were aware that some haemophiliacs had abnormal LFTs which was possibly due to another type of hepatitis but the cause and course of that was not known (until later in the 1980s).

These families would usually be members of the Haemophilia Society; membership was encouraged by those working in the Unit, which published a book on Home Therapy written by Peter Jones and parents would be able to access that. I cannot recall any patients being commenced on Home Therapy when there were concerns regarding the possible transmission of the putative infective agent responsible for AIDS but if there were such patients, these concerns

would have been discussed with the parents.

48. Were patients given any choice, or involved in any discussions, as to the risks of prophylactic treatment?

Both the benefits, which were well documented, and the risks of treatment, would have been discussed but most families opted for prophylactic treatment. Some of these families had first-hand experience of the psychosocial and physical morbidity of haemophilia and saw for themselves the positive effect that it had in allowing their children to lead a more normal life and prevent the morbidity seen in older Haemophiliac patients.

HIV

49. When did you first discuss AIDS or HIV (HTLV-III) with any of the patients at the RHSC and their families? What did you tell them?

I refer to:

my written statement in response to the Penrose Inquiry [PRSE0001126] to Topic B5(a)-note the error in the date which should have read 1983/4- and topic B5 further questions 1 and 2. my oral evidence to the Penrose Inquiry [PRSE0006020] - page 45 lines 5-25, page 48 line 18.

50. Please describe how and when you learned that patients under the care of the RHSC had been infected with HIV. What tests were undertaken, where and over what period of time?

I refer to:

my written evidence to the Penrose Inquiry [PRSE0003995] in answer to Q15 and Q12 and Q13 my written response to topic B5 (b) [PRSE0001126] my oral evidence given to the Penrose Inquiry [PRSE0006020] as follows: page 35 line 1-17

page 55 line 24-25 page 56 line 1-25.

As stated in my oral evidence to the Penrose Inquiry as referenced, I cannot recall the date upon which confirmation of HTLV3 infection was received.

I note my letter to Dr Taylor in Inverness informing him that a patient transferred to his care from the RHSC had been found to be positive for HTLV3 was written by me on 17th May 1985. I do not think that after Dr Hann asking me to inform him I would have delayed imparting this important information. Also, I was on maternity leave from approximately the mid/ end of January 1985 until the beginning of May 1985 and I therefore deduce that the letter from Dr Follet detailing the result of his retrospective analysis was probably received at the beginning of May. Following receipt of these results, and after discussion with parents, further blood samples were taken from the patients to confirm the results of retrospective testing.

51. You gave evidence to the Penrose Inquiry that retrospective HTLV-III antibody testing of stored samples was initiated by Dr Follett, head of the regional virology laboratory, and Dr Hann received a letter from him, indicating the names of the children who had tested positive (Penrose statement p.2 para.12, [PRSE0006020]). Can you explain how you became aware of this, and what you learned about it? In answering this question, you may want to consider a letter dated 17 May 1985

from you to Dr Taylor at Raigmore Hospital which stated "Dr Follett of Ruchill has recently looked at samples stored from haemophiliacs over the years (these samples had been sent for HBsAg analysis) and found that several of our patients were HTLV3 AB POSITIVE, "[GMCO0001690_055].

I refer to the references to my evidence to the Penrose Inquiry as given in Q51 above and to my oral evidence to the Penrose Inquiry [PRSE0006020] - page 55 lines 15-20

52. What if anything was said to patients and their families before and after the retrospective HTLV-III testing took place?

After the discovery in 1984 of the virus HTLV3, thought to be responsible for the transmission of AIDS, parents were advised that when a reliable test for this virus became available their children could be tested. At that point, I was unaware, as I think was Dr Hann, that Dr Follett was going to test specimens retrospectively. When Dr Hann and I discussed the results of retrospective testing with the parents we told parents that Dr Follet had tested stored specimens, which had been taken for Hepatitis B analysis, and we had not been consulted about this beforehand. We also advised parents that confirmatory samples should be taken and tested.

53. What if any arrangements were made at the RHSC for pre-test counselling?

The concept of pre-test counselling for HIV had not been developed at this time and if it had been, as the testing was carried out without our knowledge retrospectively, we would have been unable to counsel pre testing.

54. A meeting of Haemophilia Directors and SNBTS representatives was held on 29 November 1984 (PRSE0002066) where it was reported that five out of 10 patients already tested at the RHSC were HTLV-III antibody positive. Were you aware of the meeting? What discussions can you recall taking place about this at the RHSC at the time?

I cannot recall that I was aware of that meeting nor can I recall specific discussion but I do remember that at that time there was considerable concern among clinicians in the Haematology Department, including myself, that some of our patients may have been infected with the HTLV3 virus. It may be that Dr Follett had communicated some preliminary anonymous results but I cannot say for certain.

55. How and when were patients and their families at the RHSC told that they had been, or might have been, infected with HIV? Were they told in person, by letter or by telephone? Were they seen individually or in groups? 3

I refer to:

my written statement in response to Q15 of the Penrose inquiry [PRSE0003995] my written statement in response to topic B5(c) to the Penrose Inquiry [PRSE0001126] my oral evidence [PRSE0006020] as follows:

page 57 line 3-25

page 58 line 1-22

page 59 line 21-25

page 60 and Page 61 page 67 line 7-21.

56. If parents were told without the patient present, what guidance were they given about when and how to inform their child about the diagnosis?

I refer to my written response to Q16 of the Penrose Inquiry [PRSE0003995]. In this instance, we did advise that particularly the older children should be informed of the diagnosis and that information could be given to the child by the parents or if they preferred, by the

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

I refer to:

clinical staff.

my written statement in response to a request under rule 9 of the Inquiry dated 28/6/2019 [WITN3527001] section 3 "Attitudes to HIV"

my written statement to the Penrose Inquiry in response to topic B5 (c) [PRSE0001126] my oral evidence [PRSE0006020] - page 60 lines 11-25, page 61 lines 1-25.

58. What were they told about life expectancy?

I refer to my answer to Q57.

59. What were they told about the source of the infection?

I refer to my written statement in response to Topic B5 of the Penrose Inquiry further questions 1 and 2 [PRSE0001126].

The parents were told that the infection had been transmitted through blood products and most likely through commercial concentrate.

60. What if any arrangements were made at the RHSC for post-test counselling? In answering this question you may wish to note your evidence to the Penrose Inquiry (p. 68-69 of PRSE0006020) that you could not recall RHSC parents being invited to a meeting in Edinburgh on 19 December 1984 to discuss HTLV-III testing, but you thought that a meeting had been held at the Glasgow Royal Infirmary to inform haemophilia patients about the situation regarding the transmission of AIDS through blood products.

I do recall that, as stated in the reference above, our patients were invited to such a meeting but my mistaken recollection was that it had been held in Glasgow as Dr Forbes was involved. Certainly if we had been informed of such a meeting, we would have encouraged our patients to attend.

In answer to the question regarding post test counselling, I refer to: my written statement in response to Q18 of the Penrose Inquiry [PRSE0003995] my written response no 2 to oral evidence given by Mrs C Leitch [PRSE0001462] my oral evidence to the Penrose Inquiry [PRSE0006020] as follows:

page 62 line 7-14 page 65 line 6-25 page 66 line 1-12.

61. Were you aware of any discussions among clinicians about whether they should or should not tell their patients of their HIV status? If you were aware of such discussions, when and where did they happen, and what reasons were considered and discussed for informing or not informing people that they had HIV?

Dr Hann's response was that parents should be informed of the results of testing as soon as practically possible.

62. What was the RHSC's policy in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were tests carried out?

The evidence at the time suggested that household contacts were not at risk but parents particularly of children on home therapy were advised to follow precautions for prevention of infection as previously stated and as given in my oral evidence to the Penrose Inquiry [PRSE0006020] - page 60 line 22-25, page 61 line 1-7

There was no policy at the RHSC for testing family members but pre-test counselling and testing could be arranged for those that requested testing. The situation in the RHSC differed from that in the Adult unit where testing of sexual partners would have had to be addressed.

63. What if any information or advice did the RHSC provide to partners or family members of people who were at risk of infection with HIV or were infected with HIV?

I refer to my answer and references to the evidence given to the Penrose Inquiry as in response to Q62.

- 64. How many patients at the RHSC were infected with HIV? Of those infected,
- a. How many had severe haemophilia A?
- b. How many had moderate haemophilia A?
- c. How many had mild haemophilia A?
- d. How many had haemophilia B or von Willebrand's disease?
- e. Were all of them children?

I am unable to give these figures with any degree of certainty.

- (e) some of the patients who had tested positive had already transferred to the Adult Unit.
- 65. Was work undertaken at the RHSC to establish the time period during which patients seroconverted? If so, please describe what work was done and what if any conclusions were reached.

I was not aware of such work at the time but this was later looked at and reported to the Penrose

Inquiry and I refer to the record of my oral evidence to that Inquiry [PRSE0006020] as follows: page 36 line 8-25 page and 37 line 1-14.

Hepatitis B

66. Were patients (a) at the Adult Haemophilia Centre and (b) at the RHSC who were infected with hepatitis B informed of their infection and if so, how?

I cannot recall any patients newly infected with Hepatitis B during my time at either Centre but with the implication for possible transmission to contacts such patients would have been informed. In addition, patients infected with Hepatitis B can present with an acute Hepatitis and this would require an explanation of the cause and likely outcome to be given.

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

I was not involved in such discussions.

68. How many patients (a) at the Adult Haemophilia Centre and (b) at the RHSC were infected with hepatitis B?

I cannot recall these figures with any certainty, but I recall one boy who was infected with Hepatitis B prior to my arrival and who was transferred to the Adult unit soon after.

NANB Hepatitis/Hepatitis C

69. Were patients (a) at the Adult Haemophilia Centre and (b) at the RHSC infected with NANB hepatitis informed of their infection and if so how?

(a) During the period that I worked in the Adult Centre, there was an awareness of Post Transfusion Hepatitis and patients were advised that LFTs were being monitored as these had been found to be abnormal in some Haemophiliacs and that this could possibly be due to a form of hepatitis whose cause and natural history was as yet unknown.

(b) At the RHSC I refer to:

my written response to a request under Rule 9 of the Inquiry 2019 [WITN3527001] section 3 Other Issues- blood Testing.

my oral evidence to the Penrose Inquiry [PRSE0006020]. page 53 Line 3-12.

Parents/patients were advised when routine blood were taken that these included blood specimen for analysis of LFTs and that it was known that some Haemophiliacs had abnormalities of liver tests and that the cause of this liver abnormality was not known nor was it known whether in these Haemophiliacs these abnormalities progressed to more severe liver disease. After the studies of liver biopsies in Haemophiliacs, they would be advised that in some patients these abnormalities could progress to more severe liver disease but the percentage that did so and the overall prognosis was not clear.

70. What information was provided to patients infected with NANB hepatitis

about the infection, its significance, prognosis, treatment options and management?

I refer to my answer to Q69 above.

The infective agent responsible for NANB Hepatitis (Hepatitis C virus) was identified just prior to my departure from the RHSC and at that time the blood test for Hepatitis C had not been introduced nor was there any treatments available. Liver biopsies were not carried out in our paediatric patients. This procedure was thought to carry too great a risk.

71. By the time of your departure from the RHSC in 1989, what was known about hepatitis C?

As far as I recall the Hepatitis C virus was identified just prior to my departure from the RHSC and as stated in the answer to Q70, testing for this virus had not been introduced.

72. How many patients at the RHSC were infected with NANB/hepatitis C?

I do not, nor did I ever, have this information.

Delay/public health/other information

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

I was not involved in notifying the parents of the results of Hepatitis C testing. I refer to:

my written response to Q15 directed to me by the Penrose Inquiry [PRSE0003995] my oral evidence to the Penrose Inquiry [PRSE0006020] as follows: page 56 line 15-24

page 57 line 12-25 page 58 line 1-9.

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

Hepatitis B was a notifiable disease and as such, Public Health would be notified of any new cases.

All blood specimens from patients with bleeding disorders who had been exposed to blood products (and indeed all the Haematology patients who had been exposed to blood products) were marked "High Risk" with a yellow sticker as was the practice at the time.

The practice nowadays is for all blood samples to be treated as high risk.

Sister Murphy and I visited the schools of those severely affected Haemophiliacs (with parental

consent) to advise the staff there not only about the nature of Haemophilia and the actions to be taken in the event of a bleeding episode but also precautions to be taken to prevent infection mainly concentrating on the risks of Hepatitis B. The General Practitioner was informed of any patient who had become Hepatitis B Positive.

As previously stated, parents or children administrating Home treatment were advised on precautions to be taken to prevent infection. As far as I recall these parents would have been advised to arrange Hepatitis B vaccination through their General Practitioner.

Initially because of the stigma and hysteria associated with AIDS and the concerns about maintaining confidentiality, the information regarding HTLV3 positivity was not disclosed to GPs or indeed wider family members.

I refer to my response to request under Rule 9 of the Inquiry 2019 [WITN3527001] section 3 Attitudes to HIV.

GPs may have been informed later with the agreement of parents. I recall from my time in General Practice that HIV positive patients could choose not to have the GP informed of the diagnosis.

I was not involved when discussions as to what information or advise to provide or treatment to offer patients with regards to Hepatitis C were taken.

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

I do not recall being aware of the risks of other infections at that time.

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

I refer to my previous responses where I stated the advice given to parents and the older children regarding prevention of infection.

Consent

77. How often were blood samples taken from patients attending the Adult Haemophilia Centre and the RHSC? For what purposes were samples taken? What information was given to patients about the purposes for which blood samples were taken? Did (a) the Adult Haemophilia Centre and (b) the RHSC obtain patients' informed consent (or in the case of children, the consent of their parents or guardians) to the storage and use of those samples?

I cannot give an accurate response as to how frequently samples were taken. I refer to:

my oral evidence to the Penrose Inquiry [PRSE0006020] - page 53 lines 1-16, page 52 line 8-25 my written response to a request under Rule 9 of the Inquiry [WITN3527001] Section 3: Other Issues paragraph 4 Blood Testing.

I was not aware that samples were stored.

78. Were patients under the care of (a) the Adult Haemophilia Centre and (b) the RHSC treated with factor concentrates or other blood products without their express and informed consent (or in the case of children, the consent of their parents or guardians)? If so, how and why did this occur? What was the approach to obtaining consent to treatment? If it is your position that patients (or their parents/guardians) did give express and informed consent to treatment with factor concentrates, please explain the basis for that position and set out the information that was provided to them.

Patients and parents of children with Haemophilia would have been informed at diagnosis of the nature and the effects of the clotting factor deficiency, the common types of bleeding episodes and the risks of morbidity and mortality. They would also have been informed about treatments available. As previously stated, this initial consultation would be consultant led. In children, the initial treatment would have been cryoprecipitate. Factor VIII concentrates were introduced prior to 1977 and were already in use both in the Adult Centre and the RHSC before I started working in Haemophilia. If a decision was taken to treat a child who normally received cryoprecipitate with concentrate, the reason for this would be explained to the parents. When home treatment was commenced the parents would be advised that concentrate would be used as cryoprecipitate was not practicable for Home Therapy use.

At that time, the concept of informed and written consent was not developed to the extent it is now and as was the practice at the time, consent was implied rather than actively obtained.

79. Were patients under the care of (a) the Adult Haemophilia Centre and (b) the RHSC tested for hepatitis or (in the case of the RHSC) HIV or for any other purpose without their express and informed consent? If so, how and why did this occur? What was the approach to obtaining consent for testing?

In the Adult Centre during my time there, patients were advised when blood was taken it would be sent to the lab for checking Hepatitis B status, sometimes for Factor VIII levels or full blood count and for monitoring of LFTs.

Similarly in the RHSC and, as already stated, parents were informed when bloods were taken for Hepatitis B and monitoring of LFTs or Factor VIII levels or FBC.

The initial testing for HTLV3 was retrospective as already explained but prior to confirmatory blood samples being taken for HTLV3, the reason for this would be discussed with the parents as would it be with those parents whose child had not been tested retrospectively and in whom testing was carried out.

PUPS

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

Decisions regarding treatment of previously untreated patients would have been taken by the Consultant. I cannot recall any discussions regarding PUPS.

Research

- 81. Please detail any knowledge you have of any research that could be relevant to the Inquiry's Terms of Reference that may have taken place at the Adult Haemophilia Centre and at the RHSC including, if known:
- a. The names of clinicians who were involved in or leading the research.
- b. The purpose of the research.
- c. The steps that were taken to obtain approval for the research.
- d. What your involvement was.
- e. What other organisations or bodies were involved in the research.
- f. How the research was funded and from whom the funds came.
- g. The number of patients involved.
- h. The steps taken to inform patients of their involvement and seek their informed consent.
- I. Details of any publications relating to the research.

The relevant research in which I was involved and the lead clinicians involved is listed in my CV [PRSE0002690].

DDAVP in Haemophilia: As I recall was a case study in the form of a letter to the Lancet and which reported hyponatraemia associated with DDAVP infusion given, I think, pre dental extraction in a patient with mild Haemophilia. The patient was aware that bloods were being taken for Factor VIII levels and blood sodium levels and his permission was gained prior to publication.

The Haemophiliac patient's self perception in change in health and lifestyle arising from self treatment:

My involvement in this study was to inform families that this study was proposed and if they wished to participate a full explanation would have been given by the lead investigator, Professor Marcova, prior to enrolment. I do not know the source of funding for this study.

Liver Dysfunction in Haemophilia:

I cannot recall this study and am unable to say how it was funded.

"Aids and Hepatitis in Haemophilia"

this was a presentation given by me at an international Haematology Update Meeting and was prepare from a literature search of current knowledge. The meeting was sponsored by Lederle.

82. To your knowledge, were patients (or in the case of children, their parents or guardians) made aware of their being involved in research? What was the approach taken with regards to obtaining their consent to such involvement?

I cannot recall any research involving Haemophiliac patients during my time at the Adult Centre or at the RHSC where patients/parents were not aware of their being involved in research and the object of any research in which they were involved would be fully explained and, at that time, involvement may have involved written consent.

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

Not to my knowledge.

84. Was patient data (anonymised, de-identified or otherwise) shared with third parties? If so how and why did this occur and what information was provided and to whom?

Not to my knowledge.

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

These are referred to in Q81.

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

- 86. How was the care and treatment of patients with HIV/AIDS managed at the RHSC? In particular:
- a. What steps were taken to arrange for, or refer patients for, specialist care?
- b. What treatment options were offered over the years to those infected with HIV?
- 4 For example, the curriculum vitae you provided to the Penrose Inquiry (PRSE0002690) included reference to the following:
- a. DDAVP in Haemophilia. Lowe GD, Pettigrew AF, Middieson S, Forbes CD, Prentice CRM, Lancet 1977, Vol. 21, p614
- b. The haemophiliac patient's self perception of change in health and lifestyle arising from self treatment. Marcova I, Forbes CD, Rowlands A, Pettigrew AF, Willoughby M. Int J Rehab Research 1983 6 (1) 11-18
- c. Liver Dysfunction in Haemophilia. Stevens MM, Small M, Pettigrew AF, Lowe GD, Sturrock RD, Follett EA, Forbes CD. Scottish Med J Vol 31, 1968 p103
- d. "AIDS and Hepatitis in Haemophilia" Proc. Of International Haematology update meeting. Glasgow, March 1987. Lederle Publications.
- c. What information was provided to patients and their families about the risks and benefits of specific treatments and about side effects?

I refer to:

My written response to a request under Rule 9 of the Inquiry 2019 [WITN3527001] to Q4 and Section 3: Other Issues paragraph 1 and 2 My oral evidence to the Penrose Inquiry [PRSE0006020] - page 40 lines 1-8, page 62 Line 7-14

(a) Those patients who were found to be positive for the then HTLV3 virus were referred to the specialist Infectious Disease unit which at that time was based in Ruchill Hospital. These specialists had experience of looking after patients with AIDS whereas there were few if any paediatricians in Scotland at that time who had experience of treating children who were positive for the HTLV3/HIV virus.

At that time in Glasgow, there was a significant problem with Intravenous Drug misuse and needle sharing and thus there were already a number of patients with AIDS attending Ruchill. There was

close liaison between Ruchill and ourselves and in addition, these boys were seen regularly at the Haemophilia clinic (which had been set up after Dr Hann's arrival and prior to the finding of HTLV3 positivity in these boys) and monitored for any sign of clinical progression and where any progress in the knowledge of AIDS could be discussed.

I particularly remember that the then consultant neurologist, Dr John Stephenson, joined Dr Hann and myself at the clinic on at least one occasion to demonstrate to Dr Hann and myself the appropriate neurological examination for these children so that we could clinically monitor for neurological symptoms and signs in addition to other clinical signs.

- (b) During my time at the RHSC, the only treatment which became available was AZT and one patient was commenced on this treatment by the specialists at Ruchill. I refer to my response to a request under Rule 9 of the Inquiry 2019 to Q4 as already referred to above.
- (c) I again refer to my response to a request under Rule 9 of the Inquiry 2019 to Q4 [WITN3527001].

Treatment would have been initiated by the Specialists at Ruchill who would have been responsible for providing information regarding risks, benefits and side effects of treatment. For the one patient whom I can recall receiving AZT during my time at the RHSC it is my recollection that for budgetary reasons, the drug had to be ordered through the pharmacy at the RHSC and then supplied to the Haematology department in the dose prescribed by Ruchill.

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

As per response to Q86.

- 88. How was the care and treatment of patients with hepatitis B managed (a) at the Adult Haemophilia Centre and (b) at the RHSC? In particular:
- a. What steps were taken to arrange for, or refer patients for, specialist care?
- b. What treatment options were offered over the years?
- c. What information was provided to patients and their families about the risks and benefits of specific treatments and about side effects?
- (a) I cannot recall being involved in the management of patients with Hepatitis B in the Adult Centre but I believe that such patients were referred to the Hepatologist/ Gastroenterologists at the Glasgow Royal Infirmary.
- (b) with regards to the patient at the RHSC who was Hepatitis B positive I think he was initially referred to the Infectious Disease Unit at Ruchill (at that time and up until the early 90s, the Infectious Disease Specialists at Ruchill dealt with Infectious Diseases in Paediatric patients).

That patient was asymptomatic and I only remember taking blood samples from him on at least one occasion to monitor his LFTs and Hepatitis B markers.

With regards to treatment options, I was not aware of any specific treatments for Hepatitis B other than treatment of acute Hepatitis.

With regard to information provided to patients about the risks and benefits of specific treatments, I was never involved in such discussions.

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

As per the response to Q88, in the one patient I recall, Hepatitis B markers and LFTs were monitored.

- 90. How was the care and treatment of patients with NANB hepatitis managed at (a) the Adult Haemophilia Centre and (b) the RHSC? In particular:
- a. What steps were taken to arrange for, or refer patients for, specialist
- b. What treatment options were offered over the years?
- c. What information was provided to patients and their families about the risks and benefits of specific treatments and about side effects?
- (a) During my time at the Adult Centre, the concept of NANB Hepatitis had not been fully established and as previously stated, patients were known to be at risk of Post Transfusion Hepatitis and had LFTs monitored.
- (b) At the RHSC, I commenced that practice of monitoring LFTS in Haemophiliacs.
- (a) As patients were asymptomatic and there were no patients in whom there was marked deterioration in LFTs during my time at the RHSC and prior to the discovery of the infective agent for what was by this time known as NANB Hepatitis, patients were not referred to any specialists.
- (b) During my time at RHSC and the Adult Unit, there was no treatment for NANB Hepatitis.
- (c) I was not involved in the treatment of patients for NANB Hepatitis.
- 91. What if any involvement did you and/or colleagues at RHSC have with any clinical trials in relation to treatments for HIV? Please provide details.

During my time at the RHSC, I was not involved, nor was I aware, of any colleagues being involved in any clinical trials in relation to treatment for HIV.

92. How did the arrangements made for the care and treatment of children infected with HIV and/or hepatitis differ (if at all) from the arrangements made for adults?

With regards to Hepatitis B, as stated, the child affected was referred to the Infectious Disease unit at Ruchill whereas adults were referred to the Hepatologist at the GRI.

For HIV, the arrangements were, as far as I know and bearing in mind I did not work in the Adult Centre at the time that patients were being referred, that adults and children were referred to the Infectious Disease Specialists at Ruchill hospital with close liaison between them and the Haemophilia Units.

93. What if any arrangements were made at or through RHSC to provide patients infected through blood products, or their families, with counselling,

psychological support, social work support and/or other support?

I refer to:

my written response to Q18 directed to me by the Penrose Inquiry [PRSE0003995]. my written statement given to the Penrose Inquiry following reading of the transcript of oral evidence given by Mrs.C Leitch to the Inquiry [PRSE0001462] paragraph 2.

my oral evidence to the Penrose Inquiry [PRSE0006020] as follows:

page 39 line 17-22

page 65 line 6-25

page 66 line 1-23

94. What (if any) difficulties did RHSC encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV?

I was not aware of any difficulties in that regard.

Records

95. What was the policy or practice of (a) the Adult Haemophilia Centre and (b) the RHSC as regards recording information on death certificates when a patient had been infected with hepatitis or (in the case of the RHSC) HIV?

There were no deaths from Hepatitis or HIV during the time I worked in the Adult and Paediatric Haemophilia Units and therefore I was not involved in recording information of such patients on death certificates nor was I aware of any policy for this.

96. What were the retention policies of the Adult Haemophilia Centre / RHSC in regards to medical records?

I presume that the policy for retention of medical records would have been as per National guidelines but I do not know what the policy was as this was an area in which I had no involvement and which was out with my level of responsibility.

97. Were families asked to return records / log books they had kept of blood factor treatments administered at home? If so, what happened to these records?

I refer to my oral evidence to the Penrose Inquiry [PRSE0006020] - page 40 line 25, page 41 lines 1-25, page 42 lines 1-32.

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

I think initially after confirmation of HTLV3 positivity in a number of our patients, because of the hysteria and stigma associated with AIDS at the time and in order to protect patient confidentiality, some information and letters specifically referring to HTLV3 status may have been kept in separate locked files in Dr Hann's office and I assume in time those would have been incorporated into hospital records. However, I cannot say with certainty if this was the case.

99. Did you keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere other than the

Adult Haemophilia Centre / RHSC? If so, why, what information and where is that information held now?

I did not keep any records about any of the patients at the RHSC or the Adult Centre at home or anywhere other than the Adult and Paediatric Units.

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

I do not hold any records or information about any of my patients.

Section 5: Other issues

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

In June 2003, I was informed by the GMC that a complaint from a former patient of the Haemophilia Unit had been received (GMC reference TCB/FPD/2003/1173). Unfortunately, I do not have a copy of the original letter of complaint but this complaint was that I had not informed the patient that he had been found to be HTLV3 positive and also that he had been treated with Commercial Factor VIII.

I enclose a copy of the response on my behalf from Dr Riaz Mohammed of the MDDUS and the letter sent to me by the GMC in April 2005 informing me of the final outcome of their investigation. No breach of Good Medical Practice was identified by the GMC

I note that among documents accompanying this request for a written statement under Rule 9 of the Inquiry rules, is included the letter I wrote to the Consultant, Dr Taylor, who was responsible for this young man's care following the relocation of the family to Inverness prior to the results of retrospective testing for HTLV3 becoming available.

102. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry.

The evidence definitively implicating the transmission of HIV through use of Factor concentrate evolved slowly. This is in contrast to the current pandemic of the Covid 19 virus in an age when scientific knowledge can be disseminated rapidly via Social Media and the Internet and DNA technology can more readily identify infectious agents. Such technology was not available to identify the infectious agent of AIDS or for NANB Hepatitis.

When transmission of AIDS through concentrate was confirmed, steps were taken to reduce the risks of transmission of infection by using cryoprecipitate and where appropriate DDAVP and for patients requiring treatment with concentrate, the use of SNBTS concentrate and only Heat Treated concentrate after it was available. As all blood products carried a risk of NANB Hepatitis there was little option for alternative treatments apart from DDAVP when appropriate.

Those involved in caring for patients with Haemophilia and particularly, those in Paediatric practice, built up a close relationship with patients and their families over the years. All clinical staff involved acted in what was thought to be in the best interests of their patients. When infection with HIV was confirmed in some of the children, there was an awful realisation that, in retrospect, the treatment

given in good faith had caused dreadful harm.

Statement of Truth

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

Signed		GRO-C	
Dated	301	august	2020

Table of exhibits:

Date	Nates/ Description	Exhibit number
	GMC complaint letters and outcome	WITN3527003
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