Witness Name: Dr Robert Cuthbert
Statement No.: WITN4105001
Exhibits: Nil
Dated: 12 March 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ROBERT CUTHBERT

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 17 November 2020.

I, Dr Robert Cuthbert, will say as follows: -

Section 1: Introduction

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

1.1

Name:	Dr Robert Cuthbert
Home address:	GRO-C
Work address:	Department of Haematology, Belfast City Hospital, Lisburn Road, Belfast BT9 7AB
Date of birth	GRO-C 1956
Professional qualifications	MD, FRCPath, FRCP

2. Please set out your employment history including the various roles and responsibilities that you have held throughout your career from qualification onwards, as well as the dates of any posts held or qualifications obtained. If you have retired, please provide the date of your retirement and details of the last position held.

2.1 Employment History:

(i) House Officer in Medicine and Surgery 1 August 1982-31 July 1983
Belfast City Hospital

Rotation through surgery and medicine to meet requirements for full registration with the General Medical Council.

(ii) Senior House Officer — 1 August 1983-31 July 1985
General Medicine Rotation

Rotation through internal medicine, cardiology, neurology, therapeutics and geriatrics. Successful completion of Membership of the Royal College of Physicians of Edinburgh, July 1985.

(iii) Senior House Officer — 1 August 1985-31 July 1986
Department of Immunology
Belfast City Hospital

Practical laboratory experience in the techniques of cellular and humoral immunity, complement function, autoimmunity and HLA typing. Clinical duties at the adult and children's immunology outpatient clinics.

(iv) Clinical Lecturer/Honorary Registrar — 1 August 1986-31 May 1989
Department of Haematology
Royal Infirmary of Edinburgh

Training in clinical and laboratory haematology. Study of the immunological consequences of HIV infection in haemophiliacs, and the immunology of factor concentrate transfusion in HIV seronegative haemophiliacs.

(v) Senior Registrar in Haematology — 1 June 1989-20 February 1994
City Hospital & Queen's Medical Centre, Nottingham,
Higher specialist training in clinical & laboratory haematology.

(v)(a) Locum Consultant Haematologist, Queen's Medical Centre, Nottingham September 1992 to August 1993.

This was undertaken during my senior registrar tenure in Nottingham. I resumed senior registrar status in September 1993 until my substantive appointment as a Consultant Haematologist at Altnagelvin Hospital, Derry in February 1994.

(vi) Leukemia/BMT Fellowship — 01 August 1991-31 July 1992
Division of Hematology
Vancouver General Hospital

Advanced training in the treatment of patients with acute leukaemias and in bone marrow transplantation. This was taken as a year of unpaid leave from my senior registrar post in Nottingham.

(vii) Consultant Haematologist — 21 February 1994–31 July 2000
Altnagelvin Hospital
Londonderry

Provision of clinical and laboratory haematology services for Altnagelvin Hospital Trust; visiting specialist Sperrin/Lakeland Hospitals Trust: Outpatient clinics at Altnagelvin Hospital and Erne Hospital, Enniskillen.

Head of the Department of Haematology: Feb 1994-Feb 1997. The position involved clinical leadership & management responsibility for the department staff & services budget, and the senior administrative role in the running, development and planning of the laboratory haematology service.

Clinical Director of Pathology Services: Feb 1997–March 2000. The position involved clinical leadership & overall management responsibility for the pathology directorate, which includes: histopathology, cytopathology, microbiology, clinical biochemistry, & laboratory haematology.

(viii) Consultant Haematologist — 01 August 2000-31 March 2018
Belfast City Hospital

Provision of clinical services for patients with malignant haematological disorders, and general haematological conditions. Participation in management of the laboratory service and accompanying consultative service. Head of the haematology laboratory service for Belfast HSC Trust April 2001- October 2017. Retired 31 March 2018

(ix) Locum Consultant Haematologist — 30 April 2018 to date
Belfast City Hospital

Provision of outpatient clinic services for patients with chronic myeloproliferative neoplasms.

3. Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement with them (for example, the holding of any office; board, committee or ordinary membership).

3.1 Membership of Committees, etc. relevant to the Inquiry: - None

4. Please confirm whether you have provided evidence to, or have been otherwise involved in, any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement; provide a complete list and copies of any statements or reports which you provided in the course of any such inquiry, investigation or litigation. You are not required to provide a copy of the statement referred to at point 1 of the list of documents above but should include reference to that statement in the list together with any other statements/reports given to the Penrose Inquiry.

4.1 Evidence to other inquiries, etc:

Statement to the Penrose Inquiry "Draft Medical Report [STHB0000756] dated 19th September 2011.

No others.

Section 2: Statement provided to the Penrose Inquiry

5. You provided a statement to the Penrose Inquiry which was titled 'Draft: MEDICAL REPORT' [STHB0000756]. Please confirm whether the contents of that statement are true and accurate. If there are any aspects of that statement which you do not consider to be true and accurate, please identify them and set out the extent to which they are not true and accurate, and why.

5.1 I can confirm that my statement to the Penrose Inquiry entitled "Draft: MEDICAL REPORT' [STHB0000756]" is true and accurate to the best of my knowledge and belief.

Section 3: Decisions and actions of the RIE and BCH

6. Please describe the roles, functions and responsibilities of (i) the Haemophilia and Thrombosis Centre at the RIE (ii) the Northern Ireland Haemophilia Comprehensive Care Centre and Thrombosis Unit at BCH and (iii) any other haemophilia centre at which you have been employed (together "the Centres") during the time that you worked at each of the Centres.

7. Please identify your senior colleagues at the Centres and set out their roles and responsibilities during the time that you worked there.

8. Please describe:

a. your role and responsibilities at the Centres and how, if applicable, they changed over time;

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

Questions 6-8

8.1 Roles, functions and responsibilities at:

(i) Haemophilia and Thrombosis Centre at the RIE:
Investigation and treatment of patients with primary bleeding disorders, including general aspects of management such as physiotherapy, social work support, etc.

8.2 My role was to provide clinical support for these patients at the level of registrar, under the supervision of a consultant haematologist (Dr - later Professor - Ludlam). This role was undertaken on a rotational basis, usually for 3-4 months at a time, also rotating to the malignant haematology service and to the clinical laboratory.

8.3 My research role at RIE involved laboratory-based studies of immune function and correlation of these findings with any clinical consequences of immune deficiency, arising in patients with and without HIV infection. I have included a copy of my MD thesis and the Inquiry has sight of the relevant scientific publications arising from this research. I believe the content of my MD thesis will provide the Inquiry with a useful account of the contemporary perspective of clinical investigation at the time.

8.4 Senior Colleague - Professor Christopher Ludlam – Haemophilia Director responsible for lead role in developing and managing the clinical service and supervision of registrars and senior registrars on rotation, as well as supervision of research projects within the department.

(ii) NI Haemophilia Comprehensive Care Centre and Thrombosis Unit at BCH: - Investigation and treatment of patients with primary bleeding disorders with a similar basis to that of the Edinburgh centre.

8.5 My role here was limited to the provision of an acute clinical service for any emergencies that may have arisen during the "out of hours" period when I was on-call at consultant level. My role was no different to that of any other consultants providing the on-call service.

(iii) Haemophilia Service at Queen's Medical Centre, Nottingham

8.6 Senior Colleague - Dr Alec French - Haemophilia Director responsible for lead role in developing and managing the clinical service and supervision of registrars and senior registrars on rotation. After his retirement Dr French was succeeded by Dr Gerry Dolan.

8.7 My role here was limited to the provision of an acute clinical service when I was on-call at senior registrar level, under the supervision of a consultant haematologist (Dr Alec French). This role was undertaken on a rotational basis, and was no different to that of any other registrars and senior registrars providing the on-call service.

8.8 My senior registrar job rotated on an annual basis between Nottingham City Hospital and Queen's Medical Centre. At QMC the haemophilia rotation was usually for 3-4 months at a time, also rotating to the malignant haematology service, paediatric haematology service and to the clinical laboratory.

8.9 From September 1992 to August 1993 I had a limited role at locum consultant level in providing a clinical service for any emergencies that may have arisen

during the "out of hours" period when I was on-call. My role was no different to that of any other consultants providing the on-call service.

8.10 **NB** - for (ii) and (iii)
My work at each of these centres was focussed solely on acute clinical bleeding problems. I did not have any clinical responsibility or involvement in decisions about blood products or the management of blood-borne infections.

9. Approximately how many patients with bleeding disorders were under the care of each of the Centres when you began working at them and over the years that followed? (If you are able to give exact rather than approximate figures, please do so.)

9.1 I do not have any precise information about how many patients with bleeding disorders were under the care of each of these Centres, although I am aware that the numbers would have been at least 60-70.

10. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the Centres regarding the importation, manufacture and use of blood products (in particular factor concentrates) during the times that you worked there? What if any involvement did you have in these decisions?

11. What responsibility, if any, did the Centres have for the selection and purchase of blood products, and what decisions were taken by them as to which products to purchase and use? In addressing this issue, please answer the following questions for each Centre:

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

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

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

d. What if any involvement did you have in these decisions and decision-making processes?

12. What particular products were used for treating patients at the Centres, over what period of time and for which categories of patients?

Question 10-12

12.1 RIE – My understanding is that the policy at RIE was to use SNBTS-derived factor concentrates in all patients as far as was possible. The aim was for Scotland to be self-sufficient in the provision of these products. I had no role in formulating these policies or decisions.

12.2 I do recall that one or two patients had to receive commercial concentrates, for example FEIBA, in order to manage inhibitor problems.

12.3 There was a card system held in the department giving details for each patient of the diagnosis – haemophilia A or B, von Willebrand's disease, etc, severity of haemophilia, current inhibitor status, the factor concentrate that should be used, or whether the patient was a previously untransfused patient (PUP), or whether the patient should be given DDAVP.

12.4 QMC – As far as I recall the aim was to provide NHS-derived factor concentrates as far as possible. I did not have sight of the actual policies at any time. I had no role in formulating them.

12.5 At BCH I believe the policy was very similar to that of QMC and RIE but again I did not have sight of the actual policies at any time. I had no role in formulating them.

13. What was the relationship between the Centres and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions of the Centres?

13.1 I have no knowledge of any relationship between the centres and the pharmaceutical companies producing blood products.

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

14.1 I have no knowledge of any responsibility for the selection and purchase of blood products being provided by any outside organisations.

15. How were decisions taken as to which products to use for individual patients? What involvement did you have in such decisions?

15.1 Decisions for individual patients were dealt with by the haemophilia director at each centre. I had no involvement in these decisions.

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

17. What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the Centres make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

18. What were the policies and approaches of the Centres regarding the use of cryoprecipitate for the treatment of patients with bleeding disorders?

Question 16 -18

18.1 Based on my experience at RIE. I cannot provide any such information for other centres:

18.2 DDAVP was available for some individuals with mild haemophilia A and for some patients with von Willebrand's disease. As far as I recall cryoprecipitate was available for some patients with von Willebrand's disease.

18.3 DDAVP has the advantage that it can raise factor VIII and von Willebrand factor levels enough to cover various invasive procedures or minor bleeds. Its disadvantage is that it has a limited duration of action and repeated doses lead to an ever-diminishing response. It is known to have an antidiuretic effect so that theoretically it can cause fluid retention, although I do not recall any cases in which this was of any clinical significance. There was also a theoretical risk that it might cause thrombosis but I had not observed this side effect.

18.4 It is known that cryoprecipitate is useful in mild/moderate haemophilia A but has a lower efficacy in severe haemophilia A as the volumes required to be effective were considered to be too high to provide any advantage over factor concentrate.

18.5 By the time I came to work at RIE in 1986 the combination of careful donor selection and heat-treatment of concentrates was considered to have eliminated the risk of HIV transmission and was, therefore, preferable to cryoprecipitate which could not be heat-treated. As far as I know there were no new HIV seroconversions following the introduction of heat treatment in late 1984. The intensity of heat treatment was later increased and I believe this also eliminated the risk of transmission of what was later to be identified as hepatitis C virus.

19. What were the policies and approaches of the Centres in relation to home treatment? Did the policies and approaches change over time and if so how?

19.1 Home treatment was available for patients with severe haemophilia at all the centres. At that time home treatment was used on a "on demand" basis so that patients could self-administer at the first symptomatic hint of a bleed with the aim of reducing the size and duration of the bleed and consequently reduce the long term damage, particularly to joints. There was no change in policies during my time working at these centres.

20. What were the policies and approaches of the Centres in relation to prophylactic treatment? Did the policies and approaches change over time and if so how?

20.1 I have had no direct knowledge of prophylaxis policies. I do understand that they were just developing in the childhood setting during the latter part of my specialist training but I had no involvement with this.

21. What were the policies and approaches of the Centres in relation to the use of factor concentrates for children? Did the policies and approaches change over time and if so how?

21.1 I have no knowledge of policies for use of concentrates in children as my role was limited to the adult setting.

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

22.1 I can comment on a limited basis only of my experience at RIE:
I do not have any knowledge concerning the use of concentrates in patients with mild haemophilia or von Willebrand's disease. I do recall, however, that concentrates were use rarely in moderate haemophilia, for example to cover major surgery or treat recurrent bleeding in a "target" joint.

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

23.1 I have no knowledge of any other infectious transmissions at any of these centres.

Section 3: Knowledge of, and response to, risk

General

24. When you first started working with people with bleeding disorders (please state when that was):

a. What did you know and understand about the risks of infection associated with blood and/or blood products?
b. What were the sources of your knowledge?
c. How did your knowledge and understanding develop over time?
d. 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?

24.1 I first started working with patents with bleeding disorders in August 1986 in Edinburgh, when I was appointed as a clinical lecturer/registrar in haematology at RIE.

24.2 **a.** I knew that there had been transmission of HIV to a group of patients with severe haemophilia A, and that the source of infection was thought to have been a donor contributing plasma to the production of factor VIII in Scotland.

24.3 **b.** I was briefed about this event prior to interview.

24.4 **c.** I learnt that heat treatment had reduced the risk considerably but that caution was still required. During my time in Edinburgh I learned about the high risk of transmission of NANB hepatitis even with heat treatment of concentrates, although it was not then clear of its significance for causing clinical disease. Later it was felt that more intense, prolonged dry heat treatment had led to elimination of the risk of transmission of NANB hepatitis.

24.5 **d.** I understood that the risks of infection from commercially supplied concentrates was much higher than those produced locally by SNBTS.

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

25.1 Based on my experience at RIE. I cannot provide any such information for other centres:

25.2 The policy at RIE was to consider all patients who had received concentrates to be in the "high risk" category whether or not they had been tested for HIV, HBV, or NANB (available only by measuring ALT levels at that time). There was an active policy to avoid labelling patients as, for example "HIV +ve", so that the generation of stigmatising influences could be avoided. My understanding is that the patients were advised to consider themselves as high risk and take appropriate precautions with their home treatment, eg with needles and bottles, and to use barrier contraception to minimise the risk of sexual transmission.

Hepatitis

26. When you first started working with people with bleeding disorders:

a. What was your knowledge and understanding of the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products?
b. What were the sources of your knowledge?
c. How did that knowledge and understanding develop over time?
d. Please specify, in answering this question, your role(s) at the Centres at the relevant times.

26.1 See also 24 above:
a-c. I knew that there had been an outbreak of HBV in Edinburgh in the 1970's and that blood transfusion including the use of concentrates was a potential source of transmission. However, by the 1980's a donor screening programme was in place and it was thought that the risk of HBV transmission was very low. Little was known about NANB hepatitis, although blood–borne transmission seemed likely.

26.2 Amongst the patients I encountered abnormal liver transaminases were observed in all patients who had received factor concentrates, but the

prevalence of overt liver disease was very low. At the time (1986-89) it was not known whether the observation of elevated, often fluctuating liver transaminases (see Fig. 3.1 of my thesis) would be associated with the later development of overt liver disease. My focus was to investigate clinical manifestations of HIV infection, and I noted at the time that there was no evidence of a higher rate of progression of liver disease in HIV positive compared with HIV negative patients (pp 65-68; 77-78, & Table 3.4 of my thesis).

26.3 **d.** My roles are outlined at 6-8 above.

27. What, if any, further enquiries and/or investigations did you/the Centres at which you were working at any relevant time carry out or cause to be carried out in respect of the risks of the transmission of hepatitis? What information was obtained as a result?

27.1 I have no additional knowledge about any such further enquiries and/or investigations.

28. What, if any, actions did you/the Centres at which you were working at any relevant time take to reduce the risk to patients of being infected with hepatitis (of any kind)?

28.1 Please see 25 & 26 above.

29. 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?

29.1 Please see 26 & 27 above.

HIV and AIDS

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

30.1 Please see 24 above.

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

31.1 This information was emerging in the early 1980's and was reported in the general medical journals such as NEJM and the Lancet. I learned a little more whilst studying for my MRCP examinations but this was very much "theoretical" knowledge. It was only when I began working in Edinburgh in 1986 that I became fully aware of the significance of HIV transmission in blood and blood products and the consequent risk of progression to AIDS.

32. What, if any, enquires and/or investigations did you and/or the Centres at which you worked at any relevant time 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?

32.1 This question relates directly to my research project in Edinburgh and is reported in my publications and best summarised in my MD thesis.

33. What, if any, actions did you and/or the Centres take to reduce the risk to your patients of being infected with HIV?

33.1 Please see 24 & 25 above.

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

34.1 Based on my experience at RIE. I cannot provide any such information for other centres:

34.2 SNBTS factor concentrates continued to be used at RIE. SNBTS factor concentrates were heat treated from December 1984 and were therefore thought to be associated with a lower risk of HIV transmission than single donor non-heated pooled products such as cryoprecipitate. Donor screening by self-exclusion and HIV antibody testing was thought to have further reduced the risk. Subsequently it was shown that risk of HIV transmission in factor concentrates had been eliminated. We also had the opportunity to investigate directly on the efficacy of heat treatment when a plasma donor was found to be HIV positive. This was reported in STHB0000159: Article entitled 'Efficacy of Heat Treatment of Factor VIII Concentrate' published in the journal *Vox Sanguinis* in May 1988.

Response to risk

35. Did you or your colleagues at the Centres take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps?

35.1 Based on my experience at RIE. I cannot provide any such information for other centres:

35.2 Please see 25 above.

35.3 With respect to being informed about their results I believe patients were invited to meet with Professor Ludlam to discuss this on an individual basis. I was not involved in this process, which preceded my time in Edinburgh.

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

36.1 Based on my experience at RIE. I cannot provide any such information for other centres:

36.2 At RIE heat treated factor concentrates were used for all patients assigned to concentrates. They had been introduced in late 1984/early 1985, before I arrived.

Section 4: Treatment of patients at the RIE & BCH

Provision of information to patients

37. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to:

a. patients with a bleeding disorder who were treated at the Centres about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing?

b. patients about alternatives to treatment with factor concentrates?

Please detail whether, and if so how, the information changed over time.

37.1 Based on my experience at RIE. I cannot provide any such information for other centres.

37.2 **a.** I can recall only one patient who was counselled before treatment, as all the others that I encountered were established on treatment before I arrived in Edinburgh. This patient was a PUP who was to start treatment during the latter part of my time in Edinburgh, so either 1988 or 1989. He was informed by Professor Ludlam that there was a theoretical risk of HIV but that this was highly unlikely to occur. He was informed that precautions in place included combination of donor screening by self-exclusion and HIV antibody and HBsAg testing, as well as now-proven effective heat treatment of concentrates. He was informed that there was a risk of NANB hepatitis but that risk had been substantially reduced, and hopefully eliminated, by more rigorous heat treatment of concentrates. I do not recall whether or not surrogate donor screening with ALT levels was in place at that time. HCV screening was not yet available. He was asked to participate in a PUP study especially to evaluate the efficacy of rigorous heat treatment in the elimination of NANB transmission. This would involve fortnightly assessment and blood testing for a period of time (the exact duration of which I do not recall).

37.3 As a recipient of factor concentrate he was informed that, despite these precautions, he would have to be considered as "high risk" and would therefore be subject to the general precautions of all such patients as outlined in 25 above.

37.4 **b.** I recall that patients with mild or moderate haemophilia A and von Willebrand's disease were considered for DDAVP depending on clinical circumstances but they were informed by Professor Ludlam that it was always possible that cryoprecipitate or factor concentrate might be required if DDVAP proved to be of suboptimal efficacy.

HIV

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

38.1 I would have first discussed HIV/AIDs with patients during my time at RIE. It was rarely discussed with asymptomatic patients, but would have been discussed with symptomatic patients as part of the explanation of their symptoms and clinical problems. Also when AZT (zidovudine) became available it was necessary to discuss HIV/AIDS with those patients who were candidates to receive it. At that time it would have been offered exclusively to symptomatic patients.

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

39.1 Please see 24 above.

40. What if any arrangements for pre-test counselling were made at any Centre at which you worked at a relevant time?

40.1 I was not involved in pre-test counselling. All the patients had first been tested before my time in Edinburgh. The only exception I can recall is the PUP mentioned at 37 above.

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

41.1 My understanding is that patients were informed by the haemophilia director, Professor Ludlam. I have no knowledge about how the information was given to individual patients.

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

42.1 I was not involved in giving this information to patients. Please see 41 above. However, I do know that patients were not told specifically to keep their information secret so much as to explain that they were "high risk" non-specifically, as outlined in 25 above.

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

43.1 I have no knowledge about partner or family member testing.

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

44.1 I had no role in advising partners or other family members. However, please see 25 above regarding general precautions.

45. What if any arrangements were made at the Centres for post-test counselling?

45.1 I had no role and have no knowledge about post-test counselling.

46. How many patients at the Centres 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. How many (if any) were children?

46.1 My information for this question is derived from Chapter 2, Table 2.1, page 44 of my MD thesis:

		Mild	Moderate	Severe
Haemophilia A				
n=86	HIV Ab +ve:	0	6	20
	HIV Ab-ve:	23	10	27
Haemophilia B				
n=26	HIV Ab +ve:	0	0	0
	HIV Ab-ve:	15	6	5

vWD n=21
HIV Ab +ve: 0
HIV Ab-ve: 21

46.2 One patient with severe haemophilia A was aged 17 during the period of my research. There were no others under the age of 18 years.

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

47.1 In Edinburgh, because there had been a long term policy to store patients' serum, it was possible to retrospectively test samples and examine the pattern of seroconversion. This work is reported in Chapter 2 of my MD thesis, summarised in Table 2.2 on page 45. Much of it was later published in the BMJ, based on information about the18 patients who were thought to have seroconverted as a consequence of receipt of a single batch of SNBTS factor VIII concentrate – please see PRSE0000836: Article entitled *"HIV Antigen and Antibody Detection: Variable Responses to Infection in the Edinburgh Haemophiliac Cohort*" published in the British Medical Journal in February 1988.

Hepatitis B

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

48.1 I do not recall any discussions with patients about HBV infection as I did not have any involvement of this process.

49. How many patients at the Centres were infected with hepatitis B?

49.1 I do not recall any of the patients having active HBV infection. I have discussed some aspects of liver disease in Chapter 3 of my MD thesis – pp 65-68. On Table 3.4, page 68 I have summarised clinical features of liver disease in my study. Approximately 90% of patients who had not received HBV vaccination had serological evidence of HBV exposure, but only 2/98 patients were HBsAg positive. Neither of these patients had active liver disease. There were 4 patients with mild to severe liver disease, all of whom were HBsAg negative.

NANB Hepatitis/Hepatitis C

50. Were patients infected with NANB hepatitis informed of their infection and if so, how and by whom? You may find the letter at [PRSE0000534] of assistance in answering this question.

50.1 I do not recall any discussions with patients about HCV infection as I did not have any involvement of this process.

50.2 PRSE0000534: Letter dated 1 October 1986 from myself to Dr McDougall is a copy of a clinic letter concerning the visit of one patient to a routine outpatient appointment. The letter does not refer to any information the patient may have been given about NANB hepatitis, which apparently developed in his case earlier in 1986, before I arrived in Edinburgh. The letter, therefore, does not provide any insight regarding what or how patients were informed about NANB hepatitis transmission.

51. What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management? What if any involvement did you have in this process?

51.1 I was not involved in counselling patients about NANB hepatitis.

52. When did the Centres begin testing patients for hepatitis C? How, when and by whom were patients informed of their diagnosis of hepatitis C? Were they told in person, by letter or by phone? What if any involvement did you have in this process?

52.1 I was not involved as HCV testing was not available until sometime after I left RIE.

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

53.1 I was not involved in counselling patients about HCV infection.

54. How many patients at the Centres were infected with hepatitis C?

54.1 I have no information about the prevalence of HCV infection per se. However, it was known that all patients who had received factor concentrates before 1985/86 developed evidence of NANB hepatitis manifested by elevation of liver transaminases. Please see 49 above and Ch 3 pp 65-68 of my thesis.

.

Delay/other information

55. 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.

55.1 I have no knowledge of when patients were notified about the results of HIV or hepatitis testing.

56. What information was provided to patients about the risks of other infections such as parvovirus?

56.1 I have no knowledge about information given to patients about the risks of other infections such as parvovirus.

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

57.1 Please see 25 above.

58. What actions or decisions were taken by the Centres to trace patients who may have been infected through the use of blood or blood products?

58.1 The Haemophilia Centre at RIE recorded the batch no. and no. of bottles issued to each patient for home treatment. Each patient on home treatment was then asked to record every dose of factor concentrate and the batch number from which it was derived. Thus each patient had a diary of bleeding episodes and corresponding self-administered treatment.

58.2 A similar record was kept in the centre itself for use for patients requiring in-hospital treatment. The two records could then be merged for regular review and long-term storage.

58.3 Please also see 47 above.

58.4 I have no knowledge of any other methods or decisions that may have been employed in tracing infected patients.

Consent

59. How often were blood samples taken from patients attending the Centres and for what purposes? Were such samples stored and if so for how long? What information was given to patients about the purposes for which blood samples were taken? Did the patients give informed consent to the storage and use of the samples?

59.1 Samples were taken at each visit wherever possible. Serum was separated, frozen and stored long term. Patients were informed that samples were taken for routine clinical monitoring and also for research purposes. This information was given verbally. I do not recall the use of written information or any requirement for signed consent. Consent was implied in that the patients collaborated in having the samples taken.

59.2 With respect to my role in seeking research samples: I explained that I was involved in evaluating immunity in haemophilia patients (i) receiving treatment with and without concentrates, and (ii) evaluating immunity in haemophilia patients with and without HIV infection. The purpose of the research was (i) to investigate the possibility of changes in immunity due to the actual administration of concentrates, and (ii) to develop techniques and strategies to evaluate and monitor immunity in the presence of HIV infection. This information was given verbally. I do not recall the use of written information or any requirement for signed consent. Consent was implied in that the patients collaborated in having the samples taken: The patients were told that we wanted blood samples for research. If they agreed (100% did) they offered their arm to put in a venous cannula and take the blood. My understanding is that this represents implied consent. That was pretty standard practice at the time. For example, when administering intensive chemotherapy to leukaemia patients, we explained likely benefits and side effects verbally and then got on with the treatment. The same principle applied for seeking consent for research.

60. Were patients under your care or under the care of your colleagues at the Centres treated with factor concentrates or other blood products without their express consent? If so, how and why did this occur? What was your approach to obtaining consent to treatment?

60.1 Patients were not given concentrates without their verbal/implied consent. It's over 30 years ago, but my memory suggests that the patients would always say something such as "Yes, that's ok. I will have the treatment, please". That's express consent. Even if they did not use some such words, they offered their arm for a venous cannula and watched the concentrate being infused.

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

61.1 Patients were not tested without their verbal/implied consent.

PUPS

62. Please detail all decisions and actions taken at the Centres by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS) or any similar such reference.

62.1 It was imperative to talk to the haemophilia director, Professor Ludlam, before treating a PUP. I have outlined my experience of the only case of treatment of a PUP that I can recall – please see 37a above.

Research

63. Your statement to the Penrose Inquiry makes reference to your MD thesis entitled 'Clinical and Immunological Studies on a Cohort of Haemophiliacs Infected with the Human Immunodeficiency Virus'. Please provide a copy of your thesis; and confirm where the clinical and immunological studies which formed the basis of your research were undertaken.

63.1 This work was undertaken at RIE August 1986 - May 1989. I shall forward a scanned copy of my thesis.

64. Please provide a complete list of all research studies that you were involved with during your time at the Centres, insofar as relevant to the Inquiry's Terms of Reference, including for the avoidance of doubt the studies which gave rise to the articles provided to you with this rule 9 request, and thesis above.
Please:

a. Describe the purpose of the research;
b. Explain the steps that were taken to obtain approval for the research;
c. Explain what your involvement was and identify any other persons involved;

d. Identify what other organisations or bodies were involved in the research;
e. State how the research was funded and from whom the funds came;
f. State the number of patients involved;
g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent.
h. Provide details of any publications relating to the research and identify the lead author in relation to each article.

64.1 **a.** The purpose of the research was (i) to evaluate immunity in haemophilia patients receiving treatment with and without concentrates, and (ii) to evaluate immunity in haemophilia patients with and without HIV infection. The aim of the research was (i) to investigate the possibility of changes in immunity due to the actual administration of concentrates, and (ii) to develop clinical strategies to evaluate and monitor immunity in the presence of HIV infection.

64.2 **b.** The project had been approved by the Edinburgh University ethics committee before I arrived at RIE.

64.3 **c.** My role was to evaluate patients regularly on a clinical basis to identify potential symptoms and signs of impaired immunity and to correlate any such findings with the associated laboratory investigations of immune function. Other participants in the study included Professor Ludlam, RIE virologists Drs Peutherer and Simmonds, and MRC immunologists Dr Steel and Ms Diane Beatson (based at the Western General Hospital campus).

64.4 **d.** The research was undertaken within the auspices of RIE and University of Edinburgh.

64.5 **e.** As far as I know the research was funded by the Scottish Home & Health Department and administered through the University of Edinburgh, based on research grants secured by Professor Ludlam.

64.6 **f.** Please see 46 above and Chapter 2, Table 2.1, page 44 of my thesis.

64.7 **g.** Please see paragraph 2 of 59 above.

64.8 **h.** As well as my MD thesis the publications related to this research are outlined in the articles that you have:

- PRSE0000836: Article entitled 'HIV Antigen and Antibody Detection: Variable Responses to Infection in the Edinburgh Haemophiliac Cohort' published in the British Medical Journal in February 1988. Lead author – Dr Peter Simmonds
- PRSE0004673: Article entitled 'HLA Haplotype A1 B8 DR8 as a risk factor for HIV-related disease', published in the Lancet in May 1988. Lead author Dr Michael Steel.

- STHB0000159: Article entitled 'Efficacy of Heat Treatment of Factor VIII Concentrate' published in the journal Vox Sanguinis in May 1988. Lead author – myself.
- PRSE0003612: Article entitled 'Human immunodeficiency virus detection: correlation with clinical progression in the Edinburgh haemophiliac cohort', published in the British Journal of Haematology in July 1989. Lead author – myself.
- PRSE0002039: Article entitled 'Five Year Prospective Study of HIV Infection in the Edinburgh Haemophiliac Cohort' published in the British Medical Journal in October 1990. Lead author – myself.
- HSOC0002665: Article entitled 'Determinants of HIV disease progression: six-year longitudinal study in the Edinburgh haemophilia/HIV cohort', published in the Lancet in November 1991. Lead author – Dr Peter Simmonds
- PRSE0002359: Article entitled 'Immunological studies in HIV seronegative haemophiliacs: relationships to blood product therapy', published in the British Journal of Haematology in March 1992. Lead author – myself.

65. In particular, were all of the patients comprising the 'Edinburgh cohort' referred to in the articles you co-authored (and provided to you with this rule 9 request):

a. aware they were being studied for research purposes? What, if any part did you have in providing them with this information?
b. aware of their HIV diagnosis at the time of the research being carried out? If not, when and by whom were they told of their diagnosis?

You may be aware of the allegations made by some of the Edinburgh Cohort, that they did not provide consent to be a part of the research study and were not told they were infected with HIV until some years after his information was published, see for example pages 15 and 16 of the Haemophilia Society's submission to the Penrose Inquiry [PRSE0004897] and [WITN2190001].

65.1 **a.** Please see paragraph 2 of 59 above.

65.2 **b.** It is possible that some patients who remained asymptomatic may not have been aware of their HIV results during the research period. My understanding is that all patients who had received concentrates prior to 1985 (when heat treatment was introduced) were told that they were at risk of having acquired HIV infection. It was necessary for each individual to discuss their own status with Professor Ludlam. It may be that not all patients took up this offer. Please see 25 and 35 above regarding this policy. Please also see Ch 2 pp 40-41 of my thesis.

65.3 Patients who had developed any clinical features of HIV infection would have been aware of their diagnosis as it would have been explained to them as the cause of their symptoms. Please also see 38 above.

65.4 With respect to the *Haemophilia Scotland* submission to the Penrose Inquiry concerning consent for research, I have explained my role in informing patients about our work at that time. Please see 59 above. However, it is possible that the patients were not informed about the actual publication of the results of research.

65.5 It is important to emphasise that this research was observational rather than interventional, and as such was not experimental.

66. Please provide the same details in relation to any epidemiological or similar studies in which you were involved, insofar as relevant to the Inquiry's Terms of Reference.

66.1 The same principles applied to the seroepidemiology study which identified the period of seroconversion using stored serum samples as outlined in 47 above.

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

67.1 Patients were not subjected to research without their consent. I have outlined the policy on consent in 59 above.

68. Was patient data (anonymised, de-identified or otherwise):

a. 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?

b. shared with third parties without their express consent? If so how, and why did this occur, and what information was provided to whom?

68.1 Patient demographic information was anonymised to protect their privacy. This was, and still is, in accordance with the standards required in conducting and publishing clinical research.

68.2 **a.** I do not recall specifically requesting consent to publish anonymised data.

68.3 **b.** I do not recall any occasions in which patient data was shared with any third parties but, of course, it was shared within the research group in Edinburgh.

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

69.1 As well as my MD thesis the publications related to this research are outlined in the articles that you have: Please see 64 g above.

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

70. How was the care and treatment of patients with HIV/AIDS organised at the Centres? In particular:

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

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

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

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

70.1 **a.** Specialist care for the management of HIV disease had not been established during my time in Edinburgh. Patients were managed at the haemophilia centre. Professor Ludlam collaborated with other haemophilia directors, virologists and other physicians in developing a system of care for the patients.

70.2 **b.** In 1987 AZT (zidovudine) became available. It was offered to symptomatic patients with more advanced features of HIV disease, but was not at that time used as prophylaxis in asymptomatic patients. Please see Ch 3 pp 72-73 of my thesis.

70.3 **c.** Patients were informed that AZT might provide benefit in reducing symptoms and complications of HIV disease. Because it was still at an early stage of development, it was not yet certain that there would be long-term benefit. The drug was thought to be well tolerated and associated mainly with minor side effects, although again information about potential long-term toxicity was limited.

70.4 **d.** Patients were followed-up at the centre with ongoing clinical monitoring, evaluation of CD4 lymphocyte counts and detection of HIV antigenaemia.

71. How was the care and treatment of patients with hepatitis B organised at the Centres? In particular:

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

b. What treatment options were offered over the years?

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

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

71.1 I was not involved in clinical management of HBV or any other manifestations of liver disease. My understanding is that Professor Ludlam collaborated with the Edinburgh hepatology specialists in managing liver disease.

72. What if any involvement did you and/or colleagues at the Centres have with any clinical trials in relation to treatments for HIV and Hepatitis C? Please provide details.

72.1 I have no information about clinical trials in the treatment of HIV or HCV. I had no involvement in these.

73. How was the care and treatment of patients with NANB hepatitis organised at the Centres? In particular:

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

b. What treatment options were offered over the years?

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

73.1 Please see 71 above.

74. How was the care and treatment of patients with hepatitis C organised at the Centres? In particular:

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

b. What treatment options were offered over the years?

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

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

74.1 Please see 71 above.

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

75.1 I have no information about arrangements for the care of children. I was not involved in paediatric haematology.

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

76.1 Counselling, psychological support and social work support were available as part of the comprehensive care programme of the centre. The haemophilia nursing staff were important in providing support supplemented by the work of an assigned social worker. There was also the possibility of referral to a psychiatrist who had a special interest in psychological aspects of physical disease.

77. Did the Centres receive government funding or funding from any other source to help with the counselling of patients infected with HIV? Please specify the government department(s), if any, from which funding was received.

77.1 I have no information about funding sources related to counselling of patients infected with HIV and/or HCV.

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

78.1 I have no information about funding sources related to counselling of patients infected with HIV and/or HCV.

79. What if any involvement did you or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

79.1 Please see 72 above.

Records

80. Please answer:

a. What was the policy at each of the Centres at which you worked, as regards the recording of information on death certificates when a patient had been infected with HIV or hepatitis?

b. What were the retention policies of the Centres with regards to medical records during the time you were practising there?

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

d. 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 Centres or the RIE/BCH? If so, why, what information did you keep, in what format, and where is that information held now?

e. 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.

80.1 **a.** I do not recall any specific policy about recording information on death certificates concerning patients with HIV or hepatitis. There were two AIDS-related deaths during my time in Edinburgh, but I do not have information about their death certificates. I know of no hepatitis-related deaths during my time in Edinburgh.

80.2 **b.** Clinical case-notes were held in the centre. I have no information about a policy for how long records were to be retained.

80.3 **c.** I did not have separate files for any individual patients. I had anonymised collective information about patients' laboratory research results and a brief summary of their HIV diseases status. Please see Appendix 3.1 pp 83-94 of my thesis.

80.4 **d.** I did not keep records or other information at home or elsewhere. Research details were held in the centre in secure filing.

80.5 **e.** I do not hold any other records or other information on these patients.

Section 5: UKHCDO

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

81.1 Just after starting at RIE I presented a short paper on my proposed research project to a UKHCDO seminar held in Edinburgh in September 1986. I have had no other involvement with UKHCDO.

Section 6: Pharmaceutical companies/medical research/clinical trials

82. Have you ever:

a. provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products?
b. received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products?
c. sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?
d. received any financial incentives from pharmaceutical companies to use certain blood products?
e. received any non-financial incentives from pharmaceutical companies to use certain blood products?

f. **received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?**

If so please provide details.

82.1 I have had no involvement with pharmaceutical companies concerning blood products.

83. **What regulations or requirements or guidelines were in place at the time of your employment at the Centres concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?**

83.1 I was not involved and have no knowledge of these matters.

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

84.1 I have not undertaken research for or on behalf of any pharmaceutical company involved in the manufacture or sale of blood products.

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

85.1 I have not provided results of medical research to any pharmaceutical company.

86. **If you did receive funding from pharmaceutical companies for medical research, did you declare the fact that you were receiving funding and the source of the funding to your employing organisation?**

86.1 I have not received funding for medical research from any pharmaceutical company.

<u>Section 7: vCJD</u>

87. **When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products?**

87.1 In the mid-late 1990's information about vCJD was emerging in the general medical publications such the lancet and NEJM.

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

a. **What steps were taken to put in place a process at the Centres for informing patients about possible exposure to vCJD?**

b. What steps were taken to tell patients of possible exposure to vCJD?

c. What steps were taken to provide information to patients about the risks of vCJD?

d. What steps were taken to arrange for counselling, support and/or advice to be offered to patients who were being informed that they might have been exposed to vCJD?

88.1 I had no involvement in decisions concerning information provided to patients about vCJD.

Section 8: The financial support schemes

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

89.1 I had no involvement with any such trusts or other funds.

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

90.1 I had no involvement with any such trusts or other funds.

Section 9: Other issues

91. 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.

91.1 No such complaints have been made about me.

92. Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.

92.1 I wish to quote my closing remarks in my 1989 MD thesis which I believe will provide the Inquiry with some further insight into the ambience of the time at which we undertook these studies in Edinburgh:

92.2 *One must pay tribute to the present generation of haemophiliacs. Many have seen the whole history of haemophilia treatment unfold during their own lifetime. Many have willingly taken part, in some cases repeatedly, in clinical trials of blood product therapy. Many have suffered the consequences of viral contamination of factor concentrates, usually with a stoical determined attitude to overcome, or at least come to terms with, their own disability and the problems inherent in its treatment.*

Statement of Truth

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

Signed GRO-C

Dated 12 March 2021