Witness Name: Dr Robert Carr
Statement No.: WITN4677001
Dated: 17th November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ROBERT CARR

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 24 September 2020

I, Robert Carr, will say as follows: -

Section 1: Introduction

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

   Name: Robert Carr
   Address: GRO-C London GRO-C
   Date of birth: GRO-C 1951

   Professional qualifications:

   BSc. MBChB (Edinburgh)
   Member (by professional examination) Royal College of Physicians (Edinburgh), Royal College of Pathologists

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

   August 1977 - January 1978 House Officer
   Adult & Paediatric Infectious Diseases,
   City Hospital, Edinburgh

February - July 1978	House Officer General Surgery, Queen Elizabeth Hospital, Gateshead, Tyne & Wear
August 1978 - July 1979	Senior House Officer, Paediatric Haematology, Royal Hospital for Sick Children, Edinburgh.
August 1979 - July 1980	Registrar Rotation in General Medicine, Royal Infirmary, Edinburgh
August 1980 - July 1983	Registrar Rotation in Adult and Paediatric Haematology, Department of Haematology, Edinburgh Royal Infirmary, and Royal Hospital for Sick Children, Edinburgh
August 1983 - July 1991	Senior Registrar Rotation in Haematology Department of Haematology, Royal Liverpool Hospital. Mersey Regional Blood Transfusion Centre, Walton General Hospital, Liverpool Alder Hey Children's Hospital, Liverpool
August 1991 to Present	Consultant in Haematology Guy's & St Thomas' Hospital, London. Senior Lecturer United Medical and Dental School of Guy's & St Thomas' Hospital, Reader in Haematology, King's College London.

Role and Responsibilities at Guy's & St Thomas' Hospital:

1991-2001: Clinical lead for haematological Malignancy: Leukaemia, Lymphoma, Myeloma.
Laboratory lead for diagnostic haem-oncology.
2001-2016: Clinical lead for Leukaemia
2013 to present: Clinical Lead for Young Adult Cancer, Guy's & St Thomas' and SE London.

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.**

Membership of Professional Societies

British Society for Haematology
American Society of Haematology

Other relevant institutional / national roles

2001 – 2011 Member of the St Thomas' Hospital Research Ethics Committee;
From 2008 - 2011 I was the Committee Chairman.
2011 – 2016 Member of the Health Research Authority Confidentiality Committee (HRA CAG)

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

I have not been involved in any other enquiry into blood borne diseases.

5. **It is the Inquiry's understanding that your haematology career has involved positions as Junior Haematology Registrar at Royal Infirmary of Edinburgh ("the Infirmary"), as Senior Registrar in Haematology at Alder Hey Children's Hospital ("Alder Hey"), in the Department of Haematology at Royal Liverpool Hospital ("Royal Liverpool") and as Consultant Haematologist at Guy's and St Thomas' Hospital ("Guy's and St Thomas'"), where you now lead the young adult cancer service. Please confirm if that is correct; if incorrect, please set out the correct position. The questions below refer, as appropriate, to these locations, but the principal focus is your time at the Infirmary. If you have information concerning the other hospital(s) relevant to the period or issue to which the question relates, please include that In your response; likewise, if you had no involvement at the other hospital(s) with the treatment of patients with bleeding disorders, or the care of patients infected with HIV and hepatitis, please say so.**

My employment history, as stated on p4 of the Rule 9 request, is correct.

Section 2: Decisions and actions of those treating patients with bleeding disorders at the Infirmary, Alder Hey, and Royal Liverpool, and your decisions and actions

6. In relation to your work at the (a) the Edinburgh Royal Infirmary, (b) Royal Liverpool Hospital, and (c) Guy's and St Thomas' Hospital please:

a. describe the roles, functions and responsibilities (insofar as relevant to the Inquiry's Terms of Reference) of hospital/centre during the time that you worked there (insofar as relevant to the Inquiry's Terms of Reference), and how they changed over time.

Edinburgh Royal Infirmary (abbreviation: RIE)

I address my time in Liverpool and London first for reasons of clarity, as in neither place did I have any involvement with the management of haemophilia patients

b. please identify senior colleagues at the hospital/centre involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and /or HIV in consequence of infected blood or blood products and their roles and responsibilities during the time that you worked there.

Royal Liverpool Hospital, Walton General Hospital, Alder Hey Children's Hospital

Patients with inherited bleeding disorders were managed in Liverpool by Dr A. McVerry at the Royal Liverpool Hospital.

From August 1983 to July 1984 I was posted at Walton General Hospital, Liverpool, which did not see or treat patients with haemophilia. From August 1984 to March 1985 I undertook training in blood transfusion at the Mersey Regional Blood Transfusion Centre. I had no involvement in the preparation of blood products.

At the Royal Liverpool Hospital, from April 1985, my work was primarily focused on the management and diagnosis of general medical and malignant haematological conditions. At that time Senior Registrars were expected to concentrate their training on their particular areas of interest, in my case this was malignant and paediatric haematology.

While I would have been involved in looking after congenital bleeding disorder patients admitted to the haematology ward with acute bleeds, under the direction of the coagulation consultant, I have no recollection of policies, what blood products were used, nor was I involved in any way in the policies or out-patient support of patients with inherited coagulation disorders.

At the Alder Hey hospital my work was exclusively related to the diagnosis and clinical management of children with general haematological conditions and those with leukaemia and lymphoma. I do not remember seeing any patients with haemophilia, Christmas disease, or von Willebrand disease while working at the Alder Hey.

c. describe your role and responsibilities at the hospital/centre and how, if applicable, this changed over time;

Guy's & St Thomas' Hospital, London

At St Thomas' Hospital, patients with congenital bleeding disorders are managed within the Regional Haemophilia Centre (then Director Dr Geoff Savage) which, from before my arrival in 1991, was completely separate from the Department of Haematology. Consequently I had no contact or involvement with this patient group.

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

All answers below apply only to my time in Edinburgh

Q6a-d: Edinburgh Royal Infirmary (RIE) 1980 -1983

The clinical and laboratory service, as relating to congenital bleeding disorders, was led by a single consultant, Dr Christopher Ludlam, assisted by a designated registrar on a rotating basis. This structure was constant during this period. Patients who developed hepatitis would have clinical input from Dr Niall Finlayson, consultant hepatologist. There was no HIV infection during these years, the period of my employment at RIE. The registrar rotated between the haematology sub-specialties. The registrar was responsible for the day to day clinical care of in-patients as well as seeing outpatients in clinic or attending the hospital on an ad hoc basis. Clinical management of haemophilia and other congenital bleeding disorders was dictated by departmental policy, with regular, usually daily, discussion between the consultant (CL) and registrar regarding more complex patients. This structure was constant during this period and applied across the department's sub-specialties. Registrars and more junior staff all felt well supported.

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

   I do not know the total number of patients with bleeding disorders registered with the department of Haematology in Edinburgh at that time.

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

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

   At the Edinburgh Royal Infirmary there was a strict policy of treating congenital bleeding disorder patients with blood products exclusively prepared from Scottish blood donations. This practice was initiated by Dr Ludlam's predecessor, Dr Howard Davies, and continued by Dr Ludlam. Patients were treated with either cryoprecipitate or Factor VIII concentrate prepared from Scottish blood donations at the Scottish National Blood Transfusion Service (SNBTS), or SNBTS Factor IX concentrate for those with Christmas disease.

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

   See Q8a.

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

   The policy was not influenced by commercial considerations.

   d. What if any involvement did you have?

   The practice was well established before I joined the department, hence I had no role in deciding this policy. It follows from the above that there was no commercial consideration in this practice.

9. **What particular products were used for treating patients at (a) the Infirmary and (if relevant) (b) Royal Liverpool, over what period of time and for which categories of patients?**

   Haemophilia A: Cryoprecipitate or Factor VIII concentrate prepared from Scottish blood donations at the Scottish National Blood Transfusion Service (SNBTS), Haemophilia B (Christmas Disease): Cryoprecipitate or SNBTS Factor IX concentrate. Von Willebrand Disease: Cryoprecipitate. During my time in Edinburgh DDAVP also came into use for vWD patients with bleeds. My memory is that it was not being used in haemophilia patients.

10. **What was the relationship between (a) the Infirmary and (if relevant) (b) Royal Liverpool and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Infirmary's decisions and actions?**

    None. No commercial products were used at the RIE at this time.

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

    Not applicable.

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

    My memory is that patients treated exclusively in hospital were given cryoprecipitate. Those on home treatment were, of necessity, given Factor concentrate to keep and use at home. They might also have some cryoprecipitate if attending hospital for treatment of a bleed.

13. **What alternative treatments to factor concentrates were available in the 1970s and 1980s for people with bleeding disorders?**

    Cryoprecipitate.

14. **What were, in your view, the advantages and disadvantages of those alternative treatments? What use did (a) the Infirmary and (if relevant) (b) Royal Liverpool make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?**

The principal objective reason for the avoidance of commercial factor concentrates prepared from American paid donors, during my time at the RIE, was that there was known to be an increased risk of these concentrates being contaminated with what was then known as non-A/non-B Hepatitis virus for which, at that time, there was no screening test. In summary, clotting factor concentrate and cryoprecipitate prepared exclusively from Scottish donor blood was considered safer as it was less likely to be contaminated with non-A/non-B hepatitis virus. And cryoprecipitate was used frequently to preserve limited stocks of Scottish Factor concentrate. The policy did not change during my time working in Edinburgh.

15. **What was the policy and approach at (a) the Infirmary and (if relevant) (b) Royal Liverpool as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?**
a. Did that policy and approach change over time and if so how?

No

b. How, if at all, was the policy and approach informed by discussions had with external parties?

The policy and reasoning behind the policy in Edinburgh is described above.
It is not possible for me to answer these questions in relation to my time in Liverpool (qv. P3, 6b). However, I was aware that in Liverpool many, and maybe all, patients were receiving commercial concentrates.

16. **What was the policy and approach at (a) the Infirmary and (if relevant) (b) Royal Liverpool in relation to home treatment? Did the policy and approach change over time and if so how?**

The policy did not change during the time I worked in Edinburgh (See Q12).

17. **What was the policy and approach at (a) the Infirmary and (if relevant) (b) Royal Liverpool in relation to prophylactic treatment? Did the policy and approach change over time and if so how?**

I do not remember how many, if any patients were on prophylactic treatment in Edinburgh

18. **What was the policy and approach at (a) the Infirmary and (if relevant) (b) Royal Liverpool in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?**

I do not remember a specific policy for the treatment of children in Edinburgh.

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

I am reasonably certain that those with mild haemophilia, and hence very infrequent bleed, were treated with cryoprecipitate only.

20. **What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at (a) the Infirmary and (if relevant) (b) Royal Liverpool in consequence of the use of blood products?**

In Edinburgh: Hepatitis C ('non-A/non-B hepatitis') was a known infection causing disturbed biochemical indicators of liver function, but at that time there was no specific blood screening or diagnostic test.

There was high awareness in Edinburgh of the dangers of Hepatitis B as a consequence of the 1969-1970 Hepatitis B outbreak amongst renal failure patients on haemo-dialysis, during which a number of dialysis patients and staff members died. By the 1980s all blood for transfusion and preparation of blood products was screened for Hepatitis B, and work was in progress within the SNBTS to develop an effective screening test for Hepatitis C.

During the period in question, early 1980s (pre-1984) prior to the characterisation of HTLV-III, I believe there were no cases of transfusion acquired Hepatitis B, and there were no cases of the transmissible agent responsible for the syndrome described as AIDS.

I believe new cases of liver transaminitis, likely due to Hepatitis C, did occur but I do not have access to records to confirm or refute this.

21. **Please provide, insofar as you have not already done so above, a full account of Professor Ludlam's policies, decisions and actions during the time that you worked with him at the Infirmary, as regards the use of factor concentrates, the risks of infection, the treatment of patients and the provision of information to patients.**

To summarise: policies, information and overall treatment of patients with coagulation disorder at the RIE.

There was a high level of awareness of the risk of viral infections carried by blood products, for this reason Dr Ludlam continued his predecessor's policy of using non-commercial blood products exclusively from Scottish donors. By the nature of the condition all the patients were well known to the department and, being a heritable disease, we often knew several members of the same family. There was a policy of close monitoring for evidence of non-A/non-B hepatitis (deranged liver

test) and keeping them informed. The Edinburgh Haemophilia community was well informed about the emerging condition of immunodeficiency in the USA, via the Haemophilia society as well as discussion during medical consultations. It was a matter of concern for both patients and doctors.

I enjoyed working with Dr Ludlam. His attention to the overall wellbeing of this 'family' of individuals who were under his long-term care was exemplary. On a personal level, he was one of the two senior colleagues who, during my years of training, taught me the importance of not just good medicine, but holistic care of the whole patient.

Section 3: Knowledge of, and response to, risk

22. When you began work as a Registrar at the Infirmary, what did you know and understand about the risks of infection associated with blood and/or blood products, in particular hepatitis (of all kinds)? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

It was known that Hepatitis B virus was transmitted in blood and that infection was associated with significant mortality. The recent history of the hepatitis B outbreak in renal dialysis patients in Edinburgh ensured that this was core medical education during my undergraduate training.

I became aware of the importance of 'non-A/non-B' hepatitis principally when I became a haematology registrar and involved in treating congenital bleeding disorder patients. The Edinburgh blood transfusion service had an ongoing programme to identify the agent and develop a specific diagnostic/screening test for use in the blood transfusion service. I knew that this virus was not uncommon in donated blood, it caused hepatic transaminitis (disturbed biochemical markers of liver function) but was not immediately life threatening. I cannot remember whether it was, at that time, known that this infection could predispose to later liver cirrhosis.

Recognition and understanding of the new Syndrome of AIDS (Acquired Immunodeficiency Syndrome) and its transmission by transfused blood and blood products unfolded during my time as a haematology registrar in Edinburgh.

23. What advisory and decision-making structures were in place, or were put in place at (a) the Infirmary and (if relevant) (b) Royal Liverpool, to consider and assess the risks of infection associated with the use of blood and/or blood products?

All blood and blood products were already being screened for Hepatitis B by the time I became a haematology registrar at the Edinburgh Infirmary.

Congenital bleeding disorder patients were being regularly screened for deranged liver tests, as a marker of non-A/non-B Hepatitis. There were close links and regular discussion about this infection between the Scottish Blood Transfusion and the RIE Haematology Department.

The evolving response to the newly described syndrome of AIDS and the evolving evidence that it was transmissible by blood I describe elsewhere.

24. 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?

In the Haematology Department at the RIE I understood that there was significant risk of transmission of Hepatitis B by commercial products, which is why it was not used in any patient. It was considered that blood and blood products prepared from Scottish blood donors were safer due to the effective screening process by the SNBTS. It was believed that there was relatively less likelihood of Scottish blood products transmitting non-A/non-B hepatitis than commercial factor concentrate manufactured from pooled donations from paid donors in the USA.

25. What, if any, further enquiries and/or investigations did you and/or (a) the Infirmary or (if relevant) (b) Royal Liverpool 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?

I was not personally involved in any risk management activities. Blood donations were being screened for hepatitis B. There was work in progress to develop a test to identify the agent causing non-A/non-B hepatitis.

26. What, if any, actions did you and/or (a) the Infirmary or (if relevant) (b) Royal Liverpool take to reduce the risk to patients of being infected with hepatitis (of any kind)?

This is outlined above. In summary, avoidance of commercial factor concentrates; use of blood products made exclusively from Scottish donor blood; ongoing work to develop a diagnostic test for non-A/non-B hepatitis.

27. 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?

This is described in detail in my answer to Q22.

HIV and AIDS

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

The emerging information about cases of opportunist infections in homosexual men was first reported in the Centres of Disease Control and Prevention (CDC) 'Morbidity and Mortality Weekly Reports' in June 1981. This was widely reported in the medical press, and also by national daily newspapers. The CDC, through their surveillance and reports, was the international source of information about this new disease. It was a rapidly unfolding story during my time as Haematology Registrar at the Edinburgh Royal Infirmary.

This reported syndrome was not formalised as the new disease entity of Acquired Immunodeficiency Syndrome (AIDS) until the summer of 1982. It was not until January 1983 that epidemiological evidence from CDC's investigations confirmed that the likely cause was a transmissible agent that could also be transmitted in blood. The evidence was that AIDS was occurring in transfusion recipients with no risk factors for the new syndrome and also in some haemophiliacs who had received American Factor VIII concentrate. Furthermore, the epidemiology of AIDS was similar to that of hepatitis B. The American National Hemophilia Foundation (NHF) issued a statement about preventing transfusion transmitted AIDS in January 1983.

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

The developing story and evidence of the link between AIDS and an infectious agent likely transmitted in blood was a topic of great important to Dr Ludlam and myself. We kept abreast of the developments as they were reported.

30. What, if any, enquiries and/or investigations did you and/or the Infirmary 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?

There was, I believe, discussion between Dr Ludlam, the Scottish National Blood Transfusion Service and infectious disease experts regarding the source of blood used for cryoprecipitate and factor concentrate, and whether there were any reports of AIDS in the Scottish donor population. It was believed that there had been no reports of an AIDS-like illness in any who had donated blood. It was this evidence that led Dr Ludlam to devise the study of lymphocyte profiles in the Edinburgh haemophilia patients who were, to our knowledge, AIDS-free.

The Edinburgh haemophilia patients continued to be treated with blood products exclusively from Scottish donors.

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

This is addressed by my answer to Q30.

32. Did the Infirmary continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? Why?

As I remember there was not change in the policy of using exclusively SNBTS products, both Factor concentrates and Cryoprecipitate, for the reasons outlined in the answer to Q30.

Response to risk

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

I know that there was much discussion within the haematology department and with patients about the emerging AIDS infection. I do not remember if this was formalised in any way. However, I do remember that the haemophiliac patients were well aware of the emerging AIDS story.

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

SNBTS clotting factors were not being heat treated during my time in Edinburgh (to summer 1983), I believe because there had been no cases of AIDS in Scottish blood donors up to that time. Subsequent events suggest this was correct. In late 1984, 24 haemophiliacs were found to be anti-HTLVIII positive, traced to a single batch of factor concentrate given to patients in the spring of 1984. No previous blood donations to the SNBTS have been linked to transmission of AIDS.

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

No for the reasons outlined in Q34.

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

I cannot remember whether some patients reverted to cryoprecipitate. I do not remember any patients who were on home therapy, hence using concentrate, ceasing to treat themselves at home and attending hospital for cryoprecipitate instead.

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

I believe that the decision to continue using cryoprecipitate and factor concentrates made from Scottish donors by the SNBTS was correct and appropriate. The belief that blood and blood products supplied by the SNBTS were safe, in that there was no evidence of risk specifically from HIV contamination, was confirmed retrospectively, in that there were no cases of blood borne AIDS during the time I was working as a haematology registrar in Edinburgh (up to July 1983). That this belief was correct was tragically confirmed in 1984 by the AIDS outbreak resulting from a single HTLV-III infected donation contaminating a batch of SNBTS FVIII.

38. **Looking back now, what decisions or actions by you and/or by the Infirmary and (if relevant) (b) Royal Liverpool could and/or should have avoided, or brought to an end earlier, the use of infected blood products?**

Looking back I believe that Dr Ludlam and the SNBTS acted rationally and appropriately in the light of the evidence at the time. I think that this is borne out by the evidence that no case of blood / blood product transmitted HTLV-III occurred in Edinburgh prior to 1984.

39. **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?**

Given my level of knowledge at the time and now, I consider that the policy in Edinburgh was both appropriate and showed some foresight.
I am in no position to comment more widely.

Section 4: Treatment of patients

Provision of information to patients

40. **What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at (a) the Infirmary and (if**

relevant) (b) Royal Liverpool with a bleeding disorder about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing? Please detail whether, and if so, how this changed over time.

Discussions with patients about commencing factor replacement therapy, alternative therapies and home treatment were not appropriate for my role as a junior haematology registrar. These discussions would all have been done by Dr Ludlam.

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

See Q40.

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

See Q40.

HIV

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

The causative agent of AIDS, HTLV-III / HIV-I, was identified by the Pasteur Institute in Paris during 1983, and convincing evidence that this virus was the causative agent of AIDS demonstrated, by the National Institute of Health in America, in 1984.

I finished working in Edinburgh and moved to a Senior Registrar post in Liverpool during the summer of 1983, before the virus was identified and specific testing available. Hence discussion with patients about a specific causative agent and testing for it was not possible.

I am not able to provide answers to Q 44 through to Q 52 as I had left Edinburgh and had no subsequent involvement in the care of patients with congenital bleeding disorders.

44. **Please describe how and when you learned that patients under your care/the care of the Infirmary had been infected with HIV.**
See Q43.

45. **What if any arrangements were made at the Infirmary for pre-test counselling?**

See Q43.

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

See Q43.

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

See Q43.

48. **What was the 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?**

See Q43.

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

See Q43.

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

See Q43.

51. **How many patients at (a) the Infirmary and (if relevant) (b) Royal Liverpool 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?
    e. How many had von Willebrand's disease?
    f. How many were children?

See Q43.

52. Was work undertaken at (a) the Infirmary and (if relevant) (b) Royal Liverpool to establish the time period during which patients seroconverted? If so, please describe what work was done and what if any conclusions were reached.

See Q43.

Hepatitis B

53. 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?

I cannot remember any patients being newly infected with Hepatitis B during my time in Edinburgh. I think it unlikely there were any cases as all blood donations were screened for the hepatitis B virus.
If there were any cases it would not have been within my role to break this news.

NANB Hepatitis/Hepatitis C

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

A specific test for this virus was not available during my time at the RIE, although I remember work was going on within the SNBTS to develop a test. However, blood samples were regularly taken to monitor biochemical parameters of liver function as a surrogate for identifying new NANB hepatitis infections. This would also provide evidence of a silent Hepatitis B infection, though unlikely as all blood products were screened. Blood was regularly taken from all haemophilia patients for this purpose during routine reviews.

I was not involved in discussing new hepatitis infections with patients. I therefore do not remember if any hepatitis infections occurred during my time working with Dr Ludlam

55. Did you have any involvement with the testing and/or diagnosis of patients for hepatitis C? If so, please identify at which hospital and answer the following questions:
I would have been involved in testing insofar as I would be taking the blood samples for liver function tests, and explaining what the blood sample was being used for.

a. 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?

Patients with newly deranged liver tests would be seen by Dr Ludlam and not by myself, as junior registrar. The information would only have been given in face to face consultations.

b. What information was provided to patients infected with hepatitis C about their infection, its significance, prognosis, treatment options and management?
See Q55a.

c. When a test for HCV became available, what if any steps were taken to ensure that all patients who had received blood products were traced and invited to be tested?

There was not a specific test for Hepatitis C during my time in Edinburgh.

Delay/public health/other information

56. 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.

As explained in my previous answers, infection with hepatitis viruses was taken extremely seriously in Edinburgh. I was not involved in informing patients of a new infection. As part of the comprehensive and holistic care provided for haemophilia patients at the RIE, they would have been seen by Dr Ludlam who would explain to them the implications for themselves and others.

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

I have discussed this extensively in my answers in previous sections.

58. What information was provided to patients about the risks of other infections?
This patient group was very well informed about the risks of blood products. I am sure this was in large part because of the former Hepatitis B outbreak in renal dialysis patients in Edinburgh. They received information from Dr Ludlam, Haematology medical staff including myself and the Haemophilia Society.

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

They would have been informed of the risks of blood borne infections and to take appropriate precautions regarding the disposal of syringes, needles, etc.

Consent

60. How often were blood samples taken from patients attending (a) the Infirmary and (if relevant) (b) Royal Liverpool and for what purposes? What information was given to patients about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of the samples? Was their consent recorded and if so how and where?

It was part of routine medical care to take regular blood samples from inherited blood coagulation disorders for the purposes of monitoring their haemoglobin (checking for occult blood loss, eg. bleeding into the gut), liver enzymes (used as a surrogate indicator of hepatitis, as described above in Q54), Factor VIII or Factor IX levels (to assess responses to treatment, and for the purpose of monitoring for the development of a 'inhibitor'). All patients were fully aware of this monitoring and were naturally interested in, and informed of the results. My memory is that the surplus plasma remaining from samples sent to the coagulation lab were stored (frozen) as part of routine clinical and laboratory practice. These might be used to look back if a patient developed an inhibitor.

Patients are not asked for *explicit* consent every time blood is taken, then or today. That they bare their arm for a needle to be inserted is adequate *implied* consent.

61. Were patients under your care or under the care of your colleagues at (a) the Infirmary and (if relevant) (b) Royal Liverpool treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent to treatment? Was their consent recorded and if so how and where?

No patient was treated with factor concentrate or any blood products without their consent. As above, it would be impossible for this to happen. When a new patient was to be started on factor replacement therapy this would be discussed with them by Dr Ludlam. Consequently, I do not know whether signing a formal consent document was part of this process.

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

The causative agent of AIDS (HIV) was unknown while I was working at the RIE.
Routine monitoring for hepatitis is addressed in Q54.
The issue of consent is addressed in Q60.

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

The management of previously untreated patients who were to be initiated on clotting factor therapy was not within my responsibility, as describe in Q61.

Research

64. Please list all research studies that you were involved with during your time at (a) the Infirmary and (if relevant) (b) Royal Liverpool insofar as relevant to the Inquiry's Terms of Reference, and please:

The only research study that I was involved in at Edinburgh Royal Infirmary was the study of lymphocyte immunity, published in the Lancet, first as a letter and then as a formal scientific paper. The Inquiry is aware of these publications, copies of which were sent to me as part of the Rule 9 request.

a. Describe the purpose of the research.

The purpose was to find out if lymphocyte (immune cells) abnormalities, associated with the development of the new syndrome of AIDS, but also observed in some homosexual men as well as in some healthy haemophiliac patient in the USA, were present in Edinburgh haemophiliacs who we believed had not been exposed to the new, as yet unidentified, AIDS agent. It was later confirmed that our premise, that the Edinburgh haemophiliacs were AIDS-free, was correct.

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

Approval for the research. This is an important subject which I address in general and in relation to the Edinburgh AIDS Study on pages 34-35, under the heading Research Governance.

c. Explain what your involvement was.

My involvement was principally collecting the blood samples for the project and making sure that they reached the haematology laboratory for processing and forwarding to Dr Steel's laboratory where the lymphocyte subsets were assessed. While this was Dr Ludlam's idea, I was given responsibility for the logistics of the study and, as a haematologist in training and with a particular interest in research

and immunology, I was pleased to be encouraged to take some ownership of the work.

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

The immunological analyses, measurement of lymphocyte subsets, were performed by Dr Michael Steel in his MRC funded laboratory at the Western General Hospital. Samples were also sent to the microbiology laboratory of Dr Peutherer.

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

The clinical component of the study, ie. obtaining blood samples, incurred no significant cost and had no funding. I believe, but do not know, that Dr Steele did his analyses within his core funding from the MRC.

f. State the number of patients involved.

Forty-seven patients.

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

The process by which I informed patients of the study and obtained blood samples, with their consent, is described in section 68, paragraph 2.

h. Provide details of any publications relating to the research.

i. Disordered immune regulation in haemophiliacs not exposed to FVIII. Ludlam CA, Carr R, Veitch SE. Lancet May 23, 1983, p1226.

ii. Abnormalities of circulating lymphocyte subsets in haemophiliacs in an AIDS-free population. Carr R, Edmond E, Prescott RJ, Veitch SE, Peutherer JF, Steel CM. Lancet June 30, 1984, pp1431-1434.

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.

I was and have not been involved in any other studies relating to coagulation disorders or affected patients.

65. The Inquiry understands that you contributed a study published in the Lancet in May 1983: "Disordered immune regulation in haemophiliacs not exposed

to commercial factor VIII" with a more detailed report published in June 1984: "Abnormalities of circulating lymphocyte subsets in haemophiliacs in an AIDS-free population" [PRSE0001303, OXUH0002842] Please set out what you recall of this research study, and the involvement you had it in.

This is addressed in my answer to Q64.

66. **In the enclosed letter from yourself to Professor Ludlam dated 9 January 2006 [MDUN0000006_047], you stated that you have no memory of the consent process around this study, and that it was practice to store down plasma from each haemophiliac, and that you remember saying to patients "an extra tube for Dr Ludlam's store today," or some such.**

a. What instructions, if any, did you receive from Dr Ludlam regarding collecting these extra samples? Were you aware of what he was using them for?

This is largely answered in para 64c. The term 'instructed' is misleading. As described above, I considered myself a partner in this investigation, though under Dr Ludlam's leadership. I was of course fully aware of the rationale for the study, where the blood samples were going and the analyses being performed. Without this knowledge it would not have been possible of me to discuss the study, rationale and process, with the individual patients while taking their study blood samples.

b. Were patients informed as to what the "extra tube" for Dr Ludlam's store was for?

I believe that my comment concerning 'an extra tube for Dr Ludlam's store' was not related to this study, as the nature of the tests meant that they had to be performed on fresh, not 'stored', ie. frozen samples. There were no other research projects ongoing, as I can remember, but it was considered important for clinical reasons to develop a 'library' of frozen plasma samples, for example for inhibitor assessment (as described above) and evidence, and timing, of past infection by, for example, NANB hepatitis once a diagnostic test became available. This was good clinical practice; not research.

c. Was the "extra tube" used just for this study, or for other purposes as well?

As above, I believe that my comment regarding an "extra tube" did not relate to the immunity study.

d. What instructions, if any, did you receive from Dr Ludlam regarding the information to be provided to patients surrounding these "extra tubes" and whether consent was to be sought?

See Q66c.

67. In the same letter, you state that "patients, at the time, would have been well informed about the cases of the newly described Acquired Immunodeficiency Syndrome in American haemophiliacs."

a. Was this information provided to patients from the Infirmary or from external sources? What information was provided?

This 'expert' patient group were very aware and increasingly well informed about the developing 'AIDS' epidemic in the United States. They received information from the haemophilia society and it was discussed during their hospital visits. Discussion with patients about AIDS was part and parcel of their holistic care during this period. It was driven not by protocol but by good clinical practice.

b. Did patients ask about the risk of AIDS, and if so what was the procedure or policy regarding answering these questions?

See Q67a.

c. What instructions were provided by Dr Ludlam in terms of addressing patient concerns about risk of infection?

There was no 'instruction' to me from Dr Ludlam. Openness and honesty about difficult subjects, whether diagnosis of life threatening haematological malignancies or a new infection threat, was part of medical culture in Edinburgh and has remained with me throughout my career.

68. In the transcripts of the oral evidence of Professor Ludlam from the Penrose Inquiry [PRSE0006035, page 42 onwards], there is reference to request forms labelled "AIDS study" that were requested by yourself in 1983 [See WITN2190010 for a sample of these types of forms].

'AIDS Study' request form.

An example of one of these forms has been sent to me. I confirm that it is my writing. This is the request form that accompanied study blood samples to the laboratory. They were labelled thus so that the haematology staff knew to do an expanded lymphocyte cell count, and then send the blood to the MRC Unit for lymphocyte subset analysis.

I was responsible for taking many of these blood samples. In those days there were no phlebotomists. Blood test sample were almost exclusively taken by junior doctors. My practice was to write these forms when with the patient, while explaining to them what the blood was being used for, ie this specific investigation relating to AIDS and immunity. The label 'AIDS' was a shorthand for identifying the samples as needing specific processing when they reached the laboratory, invariably delivered by myself. The fact that I was using AIDS, in large letters, to label the blood samples is evidence of the openness about why they were being taken. Taking the blood samples myself, which could only be done with their consent, together with the explicit form, provided the opportunity for me to discuss the study with the patients and answer any questions that they might have had.

a. What was the procedure for processing these request forms?

Described above.

b. What instructions were given to you from Dr Ludlam?

There was no 'instruction' from Dr Ludlam (see Q67c).

c. Were these request forms the same samples collected as the "extra tube" mentioned in your letter to Professor Ludlam in 2006?

I believe that blood samples for this study were probably not related to the extra tube for storage (see Q66).

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

No.

70. 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?

No.

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

No.

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

I did write and invited review on 'AIDS and haemophilia' in a journal called Biomedicine and Pharmacotherapy in 1985, vol.39, p347. I no longer have a copy of this paper.

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

73. How was the care and treatment of patients with HIV/AIDS managed at (a) the Infirmary, (if relevant) (b) Royal Liverpool and? 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?

There were no cases of Hepatitis B in the haemophiliac population during my time working as a haematology registrar in Edinburgh, as far as I can remember. HIV was not identified until after I left Edinburgh in 1983, and the first cases of AIDS/HIV infection in Edinburgh haemophiliacs occurred in 1984.

74. How was the care and treatment of patients with hepatitis B managed at (a) the Infirmary, (if relevant) (b) Royal Liverpool? 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?

I have no information to comment on this.

75. How was the care and treatment of patients with NANB hepatitis managed (a) the Infirmary, (if relevant) (b) Royal Liverpool? 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?

Cases of presumed NANB Hepatitis / Hepatitis C were referred to the consultant hepatologist at the RIE, Dr Niall Finlayson, for advice and clinical management.

76. How was the care and treatment of patients with hepatitis C managed at the (a) the Infirmary, (if relevant) (b) Royal Liverpool? 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?

See Q75.

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

I do not think any children were diagnosed as having hepatitis B or NANB Hepatitis while I was working as a haematology registrar in Edinburgh.

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

Not applicable, as stated above.

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.

While in Edinburgh there were no clinical trials related to hepatitis, nor cases of presumptive HIV infection, as described above. HTLV-III had not been identified.

80. What was the Infirmary's policy with regards to recording information on death certificates when a patient had been infected with HIV or hepatitis?

I do not know.

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

I do not know.

82. Did Professor Ludlam maintain separate files for some or all patients? If so, why and where were those files located?

To my knowledge Dr Ludlam did not keep a parallel set of medical, ie clinical, records on any patient.

There will have been research records, that is the results of the T-lymphocyte subset studies undertaken by Dr Steel, as is essential for any research study. These records were not part of clinical care (the clinical significance of these studies was unknown) therefore it would have been inappropriate to file them in the patient's case records.

I do not have a visual memory of these records, but I would have used them to write the research letter and Lancet paper, together with Dr Ludlam.

Research records kept separate from clinical case notes was standard good medical and research practice then as it is today.

Section 5: Pharmaceutical companies/medical research/clinical trials

83. 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?

g. undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products?

h. provided a pharmaceutical company with results from medical research studies that you have undertaken?

If so, please provide details

The answer to all questions (Q83 a-h) is never.

Section 6: Other Issues

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

I have never had any complaint made about me to my employer, to the GMC, or Health Service Ombudsman.

85. **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.**

Examination of research process and governance is an important component of this Inquiry. With my experience of research ethics at both institutional and national levels over a period of fifteen years, I believe that some commentary on this subject is relevant to the current Inquiry. See below.

A Reflection on Research Process, Governance and Consent

It would be inappropriate to judge the conduct of clinical research during the 1980s in the light of today's formalised research governance framework.

History

In England and Scotland the first formal Research Ethics Committees were starting to be established at an institutional level in the mid-1980s. The haematology department at Edinburgh Royal Infirmary was research active and I was involved in 'recruiting' patients into national leukaemia trials at both the Royal Infirmary and the Royal Hospital for Sick Children in Edinburgh. There were no institutional governing bodies overseeing these trials and I do not remember asking patients/families to sign consent forms at either institution, though they were verbally informed about the research, which in adults and children involved randomisations between different treatments.

I do remember when I moved to Liverpool, as a senior registrar, and starting my own research projects, attending the local Research Ethics Committee to gain approval for a study that involved additional very small blood samples being collected from preterm babies. My recollection was this was one of the first such committees in the UK.

Conducting research is part of good clinical practice

This is a central tenet of medicine. Medicine advances by investigating clinical phenomena that are not understood. The immune assessment and monitoring study in haemophiliacs that I was involved in with Dr Ludlam was a good example. The new syndrome of altered immunity in homosexuals and haemophiliacs in the USA was believed to be due to an agent transmissible in blood. It had been reported that similar immune alterations had been observed in some haemophiliacs in the USA who, it was believed, had not been infected but there was no certainty. It was important to know if such immune alterations were exclusively a consequence and marker of 'AIDS'. If so, this could be a surrogate diagnostic test, analogous to liver dysfunction indicating infection by NANB hepatitis.

The haemophiliac population in Edinburgh were unique in that there had been no recorded case of AIDS in Scottish blood donors, and the haemophiliacs had exclusively received Scottish blood products. Hence there was an opportunity to discover if these immune alterations were present haemophiliacs not exposed to the AIDS agent. This was research that might directly benefit the study population.

Research and Consent

The formalised process of consent by research subjects developed during the 1980s. While patients joining clinical trials or participating in observational research would be informed, there had been no formalised process of written consent. With regard to the Edinburgh haemophiliacs AIDS study, it was conducted according to good research practice at that time. The patients were informed, they agreed to have their blood taken, there was no information sheet, but this was not covert as demonstrated by the blood form with "AIDS study" clearly written on it.

Current research governance

All research must be approved by a Research Ethics Committee. Interventional research, for example those testing new treatments, requires detailed information sheets explaining the rationale for the study and potential risks to and benefits for the participant. For observational studies, as the Edinburgh study would today be considered, patients must always be fully informed about the purpose and must give their consent to participate. However, it is increasingly accepted that verbal consent is adequate for observational studies where there is no treatment being tested.

How would a Research Ethics Committee view the Edinburgh AIDS Study today? It was scientifically sound, would advance understanding of a condition that was important, it carried no risk, and raised no ethical issues for the patient or researcher.

It would be considered appropriate for 'Fast Track' approval, usually by the Chair and one other member of the committee. While verbal consent is gaining acceptance for non-interventional studies, this study related to a new disease causing concern for patients and doctors, therefore written/signed consent would be more appropriate. A brief information sheet, explaining the rationale and process for the study ensures consistency in what the participant is told. It also ensures that the participant fully understands the research purpose and practical details, and which they can refer to for discussion with their family.

In summary, the study was ethical by today's research standards and the process of providing information and consent was consistent with research practice in the 1980's.

Statement of Truth

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

Signed

GRO-C

Dated 17th November 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number