Witness Name: Professor Sir John Stuart Lilleyman
Statement No.: WITN5095001
Exhibits: N/A
Dated: 10 February 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF JOHN STUART LILLEYMAN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 12 January 2021

I, John Stuart Lilleyman, will say as follows: -

Section 1: Introduction

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

1.1. Name and title: Professor Sir John Lilleyman
Address: GRO-C
GRO-C
Date of birth: GRO-C 1945
Professional qualifications: MB BS (Lond), DSc (Med, Lond),
MD (Hon, Sheff), FRCP (Lond and Edin), FRCPath, FRCPCH, F Med Sci.

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

2.1. Graduated from St Bartholomew's Hospital Medical College in 1968.

2.2. *Postgraduate training posts:*

(a) 1968 Hemel Hempstead General Hospital (pre-registration House Officer, medicine and surgery),

(b) 1969 St Bartholomew's hospital (post registration HO paediatrics),

(c) 1969 Senior House Officer in Pathology, United Sheffield Hospitals (rotating between haematology, microbiology, chemical pathology, histopathology),

(d) 1971 Registrar in Haematology, United Sheffield Hospitals,

(e) 1972 MRC Research Fellow (Haematology) (Senior Registrar grade) Welsh National School of Medicine Heath Hospital, Cardiff,

(f) 1974 Senior Registrar in Haematology, United Sheffield Hospitals,

2.3. Career grade posts:

(g) 1975 Consultant haematologist, Sheffield Children's Hospital.

(h) 1995 Professor of paediatric oncology, Barts and the London School of Medicine.

(i) 2004-7 Medical Director, National Patient Safety Agency (seconded).

(j) 2008 Non-Executive Director, Medicines and Healthcare Products Regulatory Agency.

(k) 2012 retired.

2.4. Other appointments:

(l) Inaugural Chief Executive, Clinical Pathology Accreditation (CPA) UK Ltd. 1991-1997

(m) President, Association of Clinical Pathologists. 1998-1999

(n) Member, Council for Professions Supplementary to Medicine. 1998-2001

(o) President, Royal College of Pathologists. 1999-2002

(p) Vice chairman, Academy of Medical Royal Colleges. 2000-2002

(q) Member, NHS Litigation Authority Professional Advisory Panel. 2001-2007

(r) Vice Chairman, Joint Consultants Committee. 2001-2002

(s) Member, Health Professions Council. 2001-2003

(t) President, Royal Society of Medicine. 2004-2006

(u) Strategic Adviser, NHS National Research Ethics Service. 2007-2009

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. Please ensure your answer addresses your involvement with the UKHCDO.**

3.1. I was an attending member of the UK Haemophilia Centre Directors from 1975-1995. I was a supporter of SHOT, the Serious Hazards of Transfusion Group. (I was awarded the James Blundell Award by the British Blood Transfusion Society in 2010 for my work on transfusion safety as medical director of the National Patient Safety Agency).

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

4.1. I have not provided evidence to or been involved in any other inquiries, investigations or litigation relating to HIV, HBV, HCV or vCJD.

Section 2: Work as a Senior Registrar

5. **With regard to your work under Professor Blackburn at the Royal Infirmary and Hallamshire Hospitals, please:**

a. **Describe your role and responsibilities in relation to the care of patients with bleeding disorders, and how they changed over time;**
b. **Describe the nature of your interaction with Professor Blackburn;**
c. **Your knowledge of any policies formulated by Professor Blackburn as regards the selection and use of blood products, the care and treatment of patients with bleeding disorders, and infections transmitted by blood products.**

5.1. My first experience of treating bleeding disorders came in 1970-71 when I was a senior House Officer progressing to a junior registrar in Sheffield under Professor Eddie Blackburn who was director of the North Trent regional

haemophilia centre. In- patient work at that time was at the old Sheffield Royal Infirmary, as the Hallamshire Hospital was not yet open for in-patients. There were four haematology trainees at different stages of training in his department and we all took turns to offer 24 hour cover for his patients (not all with bleeding disorders, others had leukaemia or other blood disorders). Professor Blackburn was an attentive head of department and well connected with professional colleagues all over the UK.

5.2. Haemophilia patients were regular customers and we all got to know them very well. In those days (1970-1971) painful bleeds in adults were usually treated by brief hospital admission and infusion of ABO group specific fresh frozen plasma, usually one, sometimes two litres. This was obtained by an individual emergency run from the Regional Blood Transfusion Service (in Sheffield) where the stocks were stored. Cryoprecipitate was available from the same source but this (then) rarer alternative was mostly saved for children because of the smaller volume.

5.3. Most 'routine' bleeds would settle with this approach. Occasionally a more serious bleed following an injury, or a planned or emergency surgical procedure would require a higher level of Factor VIII where the required volume of fresh plasma alone might put too great a strain on the cardiovascular system. Cryoprecipitate might be used in such circumstances but where this would be inadequate or sufficient units were not available (much higher levels of factor VIII required) there was also the occasional use of an early non-commercial Factor VIII concentrate.

5.4. I recall that this came from an academic laboratory in Oxford and was made from plasma from English blood donors via the Blood Transfusion Service. My recollection is that it was issued on a named patient basis to some Haemophilia Reference Centres and used chiefly in life threatening injury or to cover elective surgery. This novel material was issued at the request of a Consultant in charge of a Haemophilia Reference Centre (Professor Blackburn in Sheffield). I think there was a small stock available for emergencies kept in Professor Blackburn's laboratory.

5.5. The on- call for trainee haematologists to see haemophilia patients in Sheffield spanned both the Hallamshire Hospital (for adults) and the Children's Hospital

(for the under 16-year-olds). The (then new) consultant haematologist at the Children's Hospital at the time I was covering out-of-hours haemophilia emergencies was Dr Jeremy Guyer, whose primary interest was leukaemia, so the children with bleeding disorders were still ultimately the responsibility of Professor Blackburn.

6. **With regard to your training under Professor Bloom at the Welsh National School of Medicine Heath Hospital, please:**

a. **Describe your role and responsibilities in relation to the care of patients with bleeding disorders, and how they changed over time;**
b. **Describe the nature of your interaction with Professor Bloom;**
c. **Your knowledge of any policies formulated by Professor Bloom as regards the selection and use of blood products, the care and treatment of patients with bleeding disorders, and infections transmitted by blood products.**

6.1. After passing the first part of the examinations for Fellowship of the Royal College of Pathologists while in Sheffield (needed to be a consultant haematologist), I moved to Cardiff and the new Heath Hospital of the Welsh National School of Medicine to broaden my haematology training. I was an MRC Research Fellow at Senior Registrar grade, and the head of the department was Professor Allan Jacobs. Professor Arthur Bloom was head of the Haemophilia Reference Centre at the same hospital. Most of my time in Cardiff was spent on the management of various anaemias and haematological malignancies but sharing the on call with three other senior trainees we covered haemophilia patients out of hours as well. There were also junior registrars and House Officers forming the front line so my direct involvement with haemophiliacs was rather less than it had been in Sheffield. The use of fresh plasma and cryoprecipitate was much as in Sheffield as I recall. I cannot remember whether FVIII concentrate was used much – again, I rather think as in Sheffield on a named patient basis.

6.2. I recall Professor Bloom being an excellent teacher, but I had relatively little to do with his department on a day-to-day basis as I was primarily accountable to Professor Jacobs whose main interest at that time was iron metabolism. I do not recollect what Professor Bloom's specific policies on selection and use of blood products were for treating haemophilia, but, as he was Chairman of the

UKHCD, I would imagine his views were aligned with the consensus of the membership of that body.

6.3. My personal obsession at this time was to pass the FRCP examination as it had become apparent that to be a consultant haematologist in the 1970s you needed to be a qualified physician as well as a pathologist. I managed to achieve this while working in Cardiff and then had the opportunity in 1974 to return to Sheffield as a senior registrar under Professor Blackburn again to take the second examination for the FRCPath. After passing this I was seconded to the Children's Hospital as Dr Guyer left to return to London, and I was appointed to replace him as consultant haematologist in August of 1975.

Section 3: Decisions and actions of the Sheffield Children's Hospital

7. Please describe how the care of children with bleeding disorders was organised at Sheffield Children's Hospital during the time that you worked there. Please provide an account of the history of the provision of care of children with bleeding disorders, its establishment and its activities during this time.

7.1. As a consultant haematologist at the Children's Hospital, I had responsibility for the care of all children with any haematological disorder. Although I had some paediatric training, I was not an experienced paediatric physician, so I was partnered with Dr John Black, a well-known senior colleague, for the first two years of my consultancy. We did joint ward rounds and discussed some cases (mostly leukaemia), and I thus extended my limited paediatric training as a consultant. This arrangement fizzled out after the two years passed, when John Black obviously felt I was safe to be left alone.

7.2. The Haemophilia Reference Centre for the treatment of patients in the North Trent Region was based at the Sheffield Hallamshire Hospital under Professor Blackburn and, following his retirement, Professor Eric Preston. I became the paediatric wing of this service and we had regular meetings to discuss any matters pertaining to the care of bleeding disorders. It should be understood that the Hallamshire Hospital is about 200 yards from the Children's Hospital, so we all met at least once a week for Journal reviews and discussion of clinical problems.

7.3. Out of hours cover for haematological problems at the Children's Hospital (i.e the patients I was responsible for) was provided by the 4 senior registrar grade rotating trainees in haematology at the Hallamshire Hospital, each being seconded to my department full time for 6 months during their training. The one of the four on call would take calls from the on-site junior paediatrician, and often would pop across to the children's hospital to assess and advise on management. If consultant advice was needed, I was always on call unless I was away in which case I would ask one of my senior colleagues at the Hallamshire to provide cover. I lived within walking distance of the Children's Hospital.

7.4. Latterly (1985 or thereabouts) I was successful in gaining funding for a dedicated haemophilia nurse at the Children's Hospital, and we made an excellent appointment of Ms Vicky Vidler, who rapidly learned all about bleeding disorders and made immense improvements to the everyday quality of care for these patients.

8. Please identify senior colleagues at the Hospital concerned with the care of children with bleeding disorders and their roles and responsibilities during the time that you worked there?

8.1. Senior colleagues involved with the care of children with bleeding disorders during my time at the children's hospital other than myself included Professor Eric Preston and Dr Michael Greaves at the Hallamshire Hospital. They had no formal clinical roles but were always available for informed advice on management in my absence. In addition, Dr W Wagstaff, the director of the Regional Blood Transfusion Centre in Sheffield used to do a formal clinical session with me once a week, when he came to help with the leukaemia clinic. He was a useful contact for the supply of blood products, in particular cryoprecipitate.

9. Please describe:

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

b. your work at the Hospital 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.

9.1. My consultancy role at Sheffield Children's Hospital was to be responsible for the haematology laboratory and blood bank, and to supervise care for children with haematological disorders including bleeding disorders, bone marrow disorders, anaemias, white cell disorders, platelet disorders and coagulation disorders.

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

10.1. From the documents received from the Inquiry, I see the number of patients treated for haemophilia A at Sheffield Children's Hospital in 1983 was 17 of whom 3 had factor VIII inhibitors. One patient had Christmas Disease.

10.2. The number of patients treated for haemophilia A in 1986 was 14 of whom 3 had factor VIII inhibitors. Three patients had Christmas disease.

11. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the Hospital, 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:

11.1. The selection, obtaining and use of blood products for patients with bleeding disorders at the Children's Hospital was from 2 different sources these being:

11.1.1. Direct from the UK National Blood Transfusion Service for fresh plasma and/or cryoprecipitate at the request of a doctor (consultant or senior trainee) for a specific patient. Delivered to the haematology department and stored in the blood fridges.

11.1.2. The hospital pharmacy at the Children's Hospital would order Factor VIII concentrate via the pharmacy at the Hallamshire hospital. The Children's Hospital Pharmacy would then process the delivery notes and invoices, recording batch numbers, and then deliver the product to the Haematology Department to be stored in the Blood Fridges.

a. Who had responsibility for the selection and purchase of blood products?

11.2. The overall responsibility for selection and purchase of blood products would rest with **the** consultant haematologists responsible for the care of those patients they were prescribed for.

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

11.3. The decisions about the selection and purchase of blood products were made by **consultant** haematologists, based on their assessment of the perceived benefits and risks. What these were would be discussed at regular informal meetings between the consultants at the Hallamshire Hospital and the Children's Hospital, and also on the wider forum of the UK Haemophilia Centre Directors.

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

11.4. See 11(b).

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

11.5. Commercial considerations were seen as less important than efficacy and safety, though all other things being equal (they seldom were) the cost of one product over another would be considered.

e. What if any involvement did you have?

11.6. My personal involvement in deciding on which factor VIII concentrates to purchase was frequently to reiterate that for children who were small and required less Factor VIII per dose than adults, cryoprecipitate had many advantages and for most admissions for joint bleeds, bumps and scrapes, heavy bruises and minor surgery, was to be preferred since it only exposed patients to a very small number of UK donors and reduced the risk of viral transmission that was becoming a recognised problem with large pool fractionation processing.

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

12.1. I cannot give a detailed answer to exactly what products were used and when for treating patients at the hospital over my 20 years there as a consultant (1975-1995) since I have no relevant documentation to remind me of details.

12.2. In the early years the products would have mostly been Fresh Frozen Plasma (FFP, for both haemophilia and Christmas Disease), cryoprecipitate (for children with haemophilia), and occasionally an experimental non-commercial factor VIII concentrate fractionated in an academic laboratory in Oxford made available in small quantities to Haemophilia Reference Centres, also for haemophilia. These compounds covered most problems presented by 'straightforward' clinical events. There were other measures we could use for some types of bleeding (eg post dental extraction) such as the antifibrinolytic agents such as tranexamic acid (Cyklocapron) which would prevent delicate blood clots from breaking down.

12.3. A rarely used commercial product, FEIBA (Factor Eight Inhibitor Bypassing Activity) was also used, very infrequently, for the very few boys we cared for with Factor VIII antibodies. This was a plasma-derived product with the same potential risks of FVIII concentrate in terms of viral transmission. Like all plasma derived concentrates it was heat treated from the mid-1980s. We had no patients with Christmas Disease and Factor IX inhibitors.

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

13.1. I had no personal relationship of any kind with the pharmaceutical companies manufacturing or supplying blood products for the treatment of haemophilia or other bleeding disorders.

14. If applicable, please explain your involvement in making arrangements for the purchase of commercial products from pharmaceutical companies.

14.1. I only ever ordered commercial products through the hospital pharmacy, and usually only with the advice of my consultant colleagues at the Hallamshire Hospital.

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

15.1. I believe that the responsibility for the selection and purchase of blood products was carried by the Hallamshire hospital for the haemophilia centre patients at both the Hallamshire and the Children's Hospitals.

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

16.1. Cryoprecipitate is a processed blood product from fresh plasma which is cooled and centrifuged and this process captures the FVIII in the base of the container. It is a useful way to give large doses of FVIII in smaller fluid volumes than fresh plasma and exposes the recipient to fewer blood donors that fractionated FVIII concentrates. It remained the treatment of choice for haemophilia in my department at the Children's hospital for all but the most serious bleeds or surgery, particularly after the problems of viral transmission of NonA NonB hepatitis started to appear.

16.2. Antifibrinolytic agents such as tranexamic acid were useful for preventing clots from breaking down and were employed following surgery or dental extractions to reduce the FVIII required. For mild haemophiliacs and patients with von Willebrand's Disease Desmopressin (DDAVP) was also used since it can raise the factor VIII concentration in those whose FVIII production was not zero.

17. What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the Hospital 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?

17.1. The main point I would make here is that we in Sheffield realised pretty early on that there was a potential problem of virus transfer in blood products used for haemophilia since nonA-nonB hepatitis was already recognised as a problem following the observation that abnormal liver function tests were not an infrequent finding in both adults and young boys with severe haemophilia. We published a study from the Children's Hospital about this in 1980. (Mcgrath KM, Lilleyman JS, Triger DR, Underwood JC. Liver disease complicating severe haemophilia in childhood. Archives of Disease in Childhood, 1980, 55, 537-540)

18. What was the Hospital's policy and approach 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?

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

18.1. The study referenced in 17 above reinforced our view that cryoprecipitate was a safer product than FVIII concentrates until and unless large plasma pool products had been successfully treated for virus inactivation. We therefore used this product in preference to FVIII concentrate for routine treatment for all but major surgery in young boys.

19. What was the Hospital's policy and approach in relation to home treatment? Did the policy and approach change over time and if so how?

19.1. In the late 70s and early 80s, enthusiasm for home treatment with more widely available fractionated Factor VIII concentrate from pharmaceutical companies was gathering momentum. The obvious benefits of convenience, earlier treatment and less disruption were self-evident. But the early safety problems surrounding the commercial factor VIII concentrates, particularly those from the United States, meant that many haematologists were very reluctant to use them for home treatment, particularly for children. From the mid-1980s things changed as Factor VIII concentrates were being successfully heat treated to reduce viral contamination and home treatment became more attractive. The risks and benefits were still discussed but in the 1990s Factor VIII became virus free when it was manufactured using recombinant technology, the only considerations then were availability and cost.

20. What was the Hospital's policy and approach in relation to prophylactic treatment? Did the policy and approach change over time and if so how?

20.1. Prophylactic treatment was only ever considered in extraordinary circumstances early during my time in Sheffield. I recall treating one young man on the morning of his wedding. With more, safer, Factor VIII prolonged treatment at home to break a cycle of repetitive bleeds into target joints it could be useful.

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

21.1. Children with mild or moderate bleeding disorders would have been treated with DDAVP in many cases if faced with a minor injury or surgical procedure. Factor concentrates would be avoided if possible.

22. To what extent did you work with Professor Preston at the Royal Hallamshire Hospital in the treatment of patients with bleeding disorders? Did you formulate policies jointly, such as for the use of blood products and the response to risk of infection? Please describe the system of referring patients from under your care to the Royal Hallamshire Hospital, and any other interactions with Professor Preston insofar as relevant to the Terms of Reference.

22.1. Professor Preston, as head of the Haemophilia Reference Centre following Professor Blackburn's retirement, was the go-to colleague for advice and support with the treatment and investigation of bleeding disorders. With colleagues at the Hallamshire he did the seminal work on investigating liver disease in haemophiliacs and was well respected by his clinical colleagues. For support to me, at the Children's Hospital, he was always available. The formal referral of boys from the Children's Hospital to his care at the Hallamshire Hospital was usually at the age of 15-16.

23. What involvement, if any, did you have in the use of immunoglobulins in the treatment of patients?

23.1. I was not involved in the use of immunoglobulins in the treatment of patients. Indeed, I spent some time trying to dissuade colleagues from using the material where it was not essential. Particularly so in the treatment of Childhood Immune Thrombocytopenic Purpura, as indicated in my letter to The Lancet, Vol 344, October 1994, page 1155. My reluctance to use it was because I was aware of the problems of virus transmission in large pool plasma products and taking this into account an unnecessary use of immunoglobulin in a self-limiting disease with low morbidity should be avoided.

Section 4: Knowledge of, and response to, risk

Hepatitis

24. When you began work as a consultant haematologist at the Hospital, 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? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

24.1. When I began work as a consultant haematologist at the Children's Hospital on August 1st 1975 I was aware of transmitted disease as one of the hazards of transfusion, and that every donation was tested by the Blood Transfusion Service. Diseases screened for included syphilis and hepatitis B. By the time I left the Children's Hospital in 1995 the screening of each donation had expanded to include HIV, Hepatitis C and Hepatitis E.

25. What, if any, further enquiries and/or investigations did you and/or the Centre 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? (ULHT0000001 may be of assistance).

25.1. We were aware in the late 1970s that some adult patients with haemophilia had abnormal liver function tests (using a standard collection of biochemical measurements) and Professor Preston and colleagues at the Hallamshire Hospital had shown that when such patients had a percutaneous liver biopsy worrying evidence of persistent liver disease ranging from benign chronic persistent hepatitis to chronic aggressive hepatitis and established cirrhosis was evident. Led by Dr Kathy McGrath, an Australian junior doctor on secondment with us for 6 months, my colleagues and I found the same to be true of a small cohort of young haemophiliacs and published the results in 1980 (See ULHT0000001).

26. What, if any, actions did you and/or the Centre take to reduce the risk to patients of being infected with hepatitis (of any kind)?

26.1. Driven by these and similar studies, concern about the safety of fractionated FVIII concentrate being marketed by some commercial companies in the USA began to rise.

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?

27.1. My understanding of the nature and severity of the different forms of blood borne hepatitis was influenced by these studies, and the problem of symptomless progressive liver disease was better defined.

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 during your time working at the Hospital? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

28.1. My first inkling of HIV was at a childhood leukaemia meeting in London in 1981, where we learned of a rare lung infection called *Pneumocystis carinii pneumonia (PCP)* being found in 5 young, previously healthy gay men in Los Angeles. This was of interest because children on chemotherapy for acute leukaemia are also susceptible to this rare condition because of immunosuppression. By the end of 1981 there were 270 reported cases of severe immunodeficiency among gay men in the USA, and 121of them had died. In June of 1982, the disease was reported in American haemophiliacs. In September, the CDC used the term AIDS (acquired immune deficiency syndrome) to describe the disease.

28.2. The virus causing AIDS was not defined until April 1984 as a retrovirus called HTLV 111. In 1986 it was re-named HIV. By 1985 it was being screened for in all blood donations.

28.3. The big problem with HIV and haemophilia is that before the virus was defined and screened for in blood donations the virus could contaminate FVIII concentrates and thereby infect the recipients. This was particularly so for commercial factor VIII made in the USA where high risk paid blood donors were used as a source of plasma.

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

29.1. I first became aware of the association between AIDS and blood products around the time when the matter was raised at the UKHCDO in September of 1982. (See document CBLA0001619). It states there in the minutes that *'It appeared that there was a remote possibility that commercial blood products were involved'* after the report of the first three haemophiliacs to be diagnosed with the Acquired Immune Deficiency Syndrome in California.

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

30.1. I have no clear recollection of any specific action taken at that time other than to continue to avoid the use of commercial factor VIII concentrate from the USA for any patients and to stick to cryoprecipitate and (if needed) NHS/UK Factor VIII.

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

31.1. See 30, above.

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

32.1. To the best of my recollection at this time the Sheffield Children's Hospital only used NHS (UK) Factor VIII concentrate and only if cryoprecipitate was unavailable or unsuitable.

33. At a meeting of the UKHCDO dated 13 September 1982 at which you were present [CBLA0001619], Dr Craske stated that there was a remote possibility that commercial blood products had been involved in cases of HTLV-III in the United States, including three cases in haemophiliacs. Dr Craske instructed Haemophilia Centre Directors to report any cases in their patients. Did you ever make such a report to Dr Craske? As far as you are able to recall, how soon after this meeting did you become aware that HTLV-III could be transmitted by blood and/or blood products, and that this had occurred in the UK? If you are able to give precise dates, please do so.

33.1. I never made such a report to Dr Craske. I think I was aware around this time that the transmission of HTLV 111 by blood and blood products was possible, but I had no personal experience of such an event.

34. The enclosed document [PARA0000013] is a note titled 'Haemostasis Club' dated 8 March 1983 which discusses the known epidemiology of AIDS in the UK.

a. What was the context of this note?
b. Please recount your knowledge and experience of the Haemostasis Club, including its purpose, members, and your involvement.
c. Page 3 of the document refers to your research into immunological responses in children. Please describe as much as you are able to about this research, including:
i. Which patients were involved, and whether their consent was sought;
ii. Other individuals involved in this research;
iii. Any funding and/or ethical approval sought; and
iv. The aims, method and findings of the research.

34.1. This note appears to be an information sheet about AIDS from the 'Haemostasis Club' which, despite my being cited as "looking at" T4 and T8 cells in children with lymphoblastic leukaemia, haemophilia and 'normals', I have no recollection of. I have looked at my list of publications and cannot see any articles there relating to this idea. I am also embarrassed to say that I cannot remember what the Haemostasis club was and who was involved. My apologies. It was apparently registered as a Charity in 1979 and unregistered in 2009.

Response to risk

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

35.1. We at the Children's Hospital would have been frank and open with parents of children with bleeding disorders about the benefits and risks of therapy with blood products, and with their children as well, as appropriate.

36. Please consider the enclosed letter from Professor Bloom and Dr Rizza to the UKHCDO dated 24 June 1983 [HCDO0000270_004]. What steps, if any, were taken by you/the Hospital to comply with the treatment policy recommended by this letter? If applicable, please describe how this treatment policy differed from the approach that had previously been in place at the Hospital as regards the use of cryoprecipitate, commercial products, and alternative treatments.

36.1. It was reassuring to see that Professor Bloom and Dr Rizza were recommending reserving supplies of UK-made factor VIII concentrate (Cryoprecipitate and Freeze Dried) for children with bleeding disorders as that was already our policy and had been ever since we became concerned about transmission of hepatitis.

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

37.1. We had always used cryoprecipitate as first line therapy for children with haemophilia and used only BPL UK made FVIII concentrate when necessary. This was heat treated from 1985 as far as I recollect, and this was a useful virus protection.

38. The enclosed UKHCDO meeting minutes dated 21 October 1985 record that at the time of the meeting, most Centres were using heat-treated materials [page 6 of PRSE0001638]. When did the Hospital begin to use heat-treated factor products and for which categories of patients? Do you consider that heat-treated products should have been made available earlier? If not, why not?

38.1. These sources of factor VIII were used until recombinant FVIII was developed towards the end of the 1980s and, not being a blood product, effectively mitigated the risk of transmission of blood-borne viruses.

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

39.1. Because, dealing with children, we minimised the number of blood donors involved in the products we used regularly (cryoprecipitate), and secured the source of the donors (UK volunteers) for concentrate that we used when cryoprecipitate was not sufficient, it is hard to see what more we could have done without withholding treatment to prevent pain and disability.

39.2. It is important to point out that the UK National Blood Transfusion Service expanded an extensive donor testing system that from 1972 included Hepatitis B, from 1985 included HIV, and from 1991 included Hepatitis C.

39.3. Currently every unit of blood donated is tested for Syphilis, Hepatitis B, HIV, Hepatitis C, Hepatitis E and Human T-lymphotropic virus (HTLV).

40. 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?

40.1. It is easy with the sharp focus of hindsight to say that the problems of viral transmission in blood products was underestimated, but no-one saw HIV coming, and no-one recognised the complexity of the problem of viral hepatitis until it was established. It is hard to see what we, at the Children's Hospital, might have done differently. We were very keen to avoid using the American

Factor VIII once AIDS appeared in California, and I honestly do not recollect any boys with haemophilia under our care developing this condition up to the time I left the Hospital in 1995.

Section 5: Treatment of patients at the Hospital

Provision of information to patients

41. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at the Hospital 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.

41.1. Obviously in my time at the Children's Hospital I encountered several boys with haemophilia and became responsible for their treatment and welfare from this point of view. I would, in the first instance following a diagnosis, see the child and the parents together and explain what the problem is, what it means for the future and what we need to do about it. There would be several more such meetings and probably some with the parents alone, depending on the age of the child. I would always consider it to be my responsibility, as the consultant in charge of the patient, to keep the family fully informed about the need for treatment, the benefits, and the risks.

42. 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.

42.1. In the late 1980s I was able to get funding for a haemophilia nurse. This was a dedicated role to the care of children with bleeding disorders reporting to me. The incumbent, Mrs Vicky Vidler, was a great help in supporting the families and the patients and would sit in on any meetings or clinic attendances with me, getting to know the families very well. She would be an excellent conduit of information for me and for them. I am afraid that I lost contact with her when I left the Children's Hospital and moved to London.

HIV

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

43.1. As I recollect none of my haemophilia patients had HIV, at least up to the time I left in 1995, so any discussion would be simply to make the parents and patients aware of the potential problem and explain what we would be doing to avoid it – minimising the use of large pool blood products, preferring UK made concentrates and cryoprecipitate.

44. In the enclosed minutes of a meeting of the UKHCDO held on 17 October 1983 [page 10 of PRSE0004440], Dr Chisholm remarked that patients were refusing to take up commercial factor VIII concentrate because of the AIDS scare. Did any patients or parents of patients under your care at the Hospital raise this concern with you or your colleagues? If so, what steps were taken to manage these concerns?

44.1. I think we anticipated this concern and would reassure parents that we would avoid commercial factor VIII concentrate if possible. As far as home treatment is concerned, this was less of a problem for young boys, because the parents were uncomfortable about IV injections and the patients were too young.

45. In the ensuing discussion, it was decided that treatment of patients with NHS or commercial concentrate should continue, rather than reverting to cryoprecipitate by home therapy [page 10 of PRSE0004440]. Please explain whether you agreed with this recommendation, why or why not, and whether it was followed at the Hospital.

45.1. I think in 1983 I would have continued to have tried to avoid commercial factor VIII from the USA because of their donor pool and my fear of viral hepatitis transmission. I would have been happy with NHS concentrate.

46. How many patients at the Hospital were infected with HIV? How and when did you learn that patients under your care/the Hospital's care had been infected with HIV?

46.1. I have no access to hospital records at the Children's Hospital to support my recollection that we had no HIV arising in our patients with bleeding disorders during my time there, but I believe this to be true. I recall asserting that our efforts to avoid transfer of hepatitis (following our study of liver disease, see question 25 above) by avoiding large pool factor VIII concentrate and preferring to stick with cryoprecipitate wherever possible not only reduced the risk of liver disease but also the transfer of HIV.

46.2. We did however have a young teenage girl who came to us in February 1987 for investigation of a possible bleeding disorder. She was found to be HIV positive after several post-operative bleeding episodes at two London hospitals on two separate occasions. Her story is outlined in a letter I wrote on her behalf to the Department of Health to get financial support for her. This is in the document DHSC0006212_133. Without access to her hospital records I cannot recall whether we thought she had a bleeding disorder or not.

47. Please describe the Hospital's process for HIV testing, including pre-test and post-test counselling.

47.1. I think we did not rush to mass HIV testing for our patients who had only received cryoprecipitate or NHS Factor VIII. I cannot remember that we did. For any that wanted reassurance we would have agreed and discussed with the parents what the process involved and what a positive result could mean. But I cannot recall any positive results in our haemophiliac boys up to the time I left (1995).

48. How and when were patients told that they had been, or might have been, infected with HIV? What if any involvement did you have in this process?

48.1. The one patient I can recall with HIV (see Q 46 above) would have been referred on to colleagues more experienced in the management of HIV than me. There is a specialist centre at the Hallamshire Hospital.

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

49.1. Again, I would have left this to the experts.

NANB Hepatitis/Hepatitis C

50. How many patients at the Hospital were infected with hepatitis C?

50.1. We had no diagnostic tests for Hepatitis C, and the hepatitis C virus was not identified until 1989. I do not know how many children under my care would have had this disease. Our study of liver disease in boys with haemophilia (Document OXUH0001751_003 refers) would suggest that some did.

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

51.1. I cannot answer this. But if they had abnormal liver biopsies this would have been discussed with the parents at length and close follow up would have been carried out.

52. When did the Hospital begin testing patients for hepatitis C? Please describe the Hospital's process for HCV testing, including pre-test and post-test counselling. What involvement did you have in this process?

52.1. Testing for Hepatitis C began around 1990-1991, and screening of blood donations in 1991. Patients at the Children's Hospital would have been tested around this time.

52.2. I am sure parents and boys would have been counselled appropriately pre and post testing.

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

53.1. I cannot recall exactly when we started testing for hepatitis C, but I am sure that we would have tested all patients who had received blood products for any bleeding disorder and certainly if they had any abnormal liver function tests.

54. Were the results of testing for HIV and hepatitis C notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

54.1. All important test results would have been notified to parents and patients promptly, I am sure.

55. How often were blood samples taken from patients attending the Hospital 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?

55.1. Blood samples were taken from patients when there was a good reason for doing so in the patients' interests. What was being tested would have been explained to the patient and the parents. Blood samples would usually be discarded after testing.

56. Were patients under your care/under the Hospital's care 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?

56.1. In the 1970s fresh frozen plasma, cryoprecipitate and academically produced VIII concentrate from NBTS plasma were used and the patients and their parents would become familiar with them. Consent and an explanation of the products would be obtained in the beginning, but then for regular customers would be assumed on subsequent visits. Later, when commercial concentrates

appeared, if these were used, the same would apply. There would probably be no formal signed consent, but it would always be implicit. At that time, no one had any idea what was coming.

57. 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?

57.1. Consent was always sought from patients and/or parents for tests for HIV or hepatitis, with a full explanation of why they were being done.

58. At a meeting of the UK Haemophilia Centre Directors on 24 October 1977, it was noted that in relation to the provision of further information to the National Register, some clinicians expressed concern about the potential misuse of confidential patient data [p19 of PRSE0001002]. Did you share this concern? As far as you can recall, was the risk associated with including patient data in the National Register theoretical, or were you aware of any instances where confidential data was used inappropriately? If so, please explain any instances of data misuse you can recall, at the Hospital or elsewhere, during your time as a consultant haematologist.

58.1. I cannot find the relevant reference in document PRSE0001002, though I have looked carefully. There is no page 19 in that document – the page numbers only go up to 12. Nevertheless, I cannot say I am particularly concerned that there has been or would be a misuse of patient data by anyone in charge of any central registry of rare and difficult diseases, and I would be surprised and disappointed if this were to be the case. In paediatric practise it is a primary concern that patient data should always be protected by the professional staff involved.

59. Please describe your involvement with Lord Mayor Treloar College/Treloar's ("Treloar's") and/or with the care and treatment of boys attending Treloar's.

59.1. During my time we did have a few haemophiliac boys attend the Lord Mayor Treloar's School in Alton, Hampshire. I cannot remember how many, but it

would be very few and only those whose pattern of morbidity warranted living away from home where education could continue uninterrupted by frequent trips to hospital.

59.2. We would have had no control over their choice of therapeutic products. I think some of the original referrals from Sheffield were made by my predecessor, Dr Jeremy Guyer (now sadly deceased) as consultant haematologist before me. By 1980 I was becoming concerned about hepatitis and since I had no control on which products were used with Treloar's boys, they were more exposed to American factor VIII (Profilate). In 1976 this would not have been virally inactivated. Nevertheless, I see that I also used this product in a serious problem with one of their boys while at home on holiday, where there was a life-threatening head injury (see document TREL0000191_022).

59.3. The concept of a special residential school for boys with haemophilia was a brave and exciting experiment. It gave the pupils a greater chance of not missing school because of hospital trips and to mingle with peers who had similar problems.

60. Did you recommend that any children with bleeding disorders attend Treloar's and/or refer them to Treloar's? If so:

a. How many patients did you recommend and/or refer to Treloar's and over what period of time?
b. What prompted the recommendation or referral?
c. What involvement did you have in the arrangements for them to attend Treloar's?
d. What involvement did you have in the ongoing care and treatment of boys attending Treloar's?

60.1. The boys from Sheffield that went to Treloar's were all disruptively symptomatic with repeated serious disabling bleeding patterns. I certainly referred at least two (see TREL0000081_105 and TREL0000237_072). But by 1980 I was increasingly concerned about potential exposure to hepatitis viruses with large pool Factor VII concentrate, particularly American products, because of the demographics of their paid plasma donors. Treloar used to use more of these products than I did in Sheffield.

61. Please consider the enclosed letter dated 18 May 1976 [TREL0000237_064], regarding the treatment of a patient. Please clarify your approach to patient consent to treatment with Factor VIII concentrate, ensuring that your answer addresses the following questions:

a. The letter indicates that you thought it was unlikely consent would have been sought prior to treating this patient with Factor VIII concentrate. Is this an accurate conclusion? Was this approach to consent limited to treatment of patients at Treloar's, or did you also take this approach to consent when treating patients under your care at Sheffield Children's Hospital?

b. If so, please explain the basis for this position, and the circumstances in which consent to treatment with blood products would be sought, and when it would not be required.

61.1. The letter from me to Mr Copeland is clumsily written. The point I was trying to make was that with a child several hundred miles away in a boarding school, getting parental permission with signed consent for treatment of irregular but often frequent bleeds would be difficult and arguably unnecessary if the professional staff at Treloar's can act *in loco parentis*. This was the normal arrangement for other boys in the school as I understood it.

62. In the enclosed letter dated 7 June 1976 [TREL0000191_002], you express regret that a patient previously treated only with cryoprecipitate had been administered Factor VIII concentrate. This patient was part of the hepatitis study outlined on page 11 of the enclosed document [OXUH0003758_006].

a. Why was this approach necessary?

b. As far as you can recall, please explain the supply issues you mention. relevant were the supply issues to the decision to use factor concentrates?

c. Please clarify the meaning of the comment that the patient's treatment was "(for us) …pretty conservative management"?

62.1. I was always keen on reducing the risk of exposure to large pool blood products with their increased likelihood of viral contamination. It was my continuing determination in this respect that made me prefer the use of cryoprecipitate from local UK donors where 5 units would expose the recipient to 5 donors, whereas the Profilate 600 (manufactured by Alpha in the USA) would expose

the recipient to over 1000 donors. In the letter I was apologising for having to use Profilate since the supply of Cryoprecipitate was limited. In other words the amount of Factor VIII he needed could not be provided with cryoprecipitate alone.

62.2. 'Pretty conservative management' means that we were throwing the book at the problem in efforts to conserve the function of the affected joints.

63. Please describe any research and/or trials and/or experimental treatment that you are aware of involving pupils at Treloar's, including any involvement that you had in such research/trials/treatment.

63.1. I cannot recall being involved in any trials or experimental treatments at Treloar's, except for the hepatitis study that is referred to.

64. The enclosed document [TREL0000191_006] is a letter from you dated 12 September 1975 in which you volunteer to assist in a hepatitis study run by Dr Kirk. As far as you are able to recall, please explain your involvement in this study and the approach taken regarding consent by patients included in the study. You may find it helpful to consider the enclosed document which discusses Dr Kirk's hepatitis study [OXUH0003758_006].

64.1. The proposed Treloar hepatitis study was an attempt to look at the incidence of hepatitis in a cohort of boys who were restricted to one type of Factor VIII over a period of time to see whether the incidence and type of hepatitis differed from that of other cohorts restricted to other Factor VIII sources – that is different Factor VIII concentrates. My contribution was an offer to restrict our boys at home in Sheffield to cryoprecipitate for treatment with the proviso that we would obviously have to break protocol and give a concentrated form of Factor VIII for serious or life-threatening bleeds.

65. In the enclosed document [TREL0000295_315], Dr Aronstam of Treloar's writes to you regarding a patient with chronic hepatitis and HIV. Without referring to this patient in particular, please describe how the care of patients was shared between Treloar's and Sheffield Children's Hospital.

65.1. Care of haemophiliac boys at Treloar's was shared as it was necessary to look after them in Sheffield when they came home for holidays. It would be necessary to receive a summary of events and treatments from Treloar's, and then to send one in return when the holidays were over. The letter from Dr Aronstam to me describes a boy with some disturbing clinical features which would require careful observation and possibly further investigation.

PUPS

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

66.1. Most 'previously untreated patients' in the context of this inquiry would be young children referred to me between 1975 and 1995 at the Sheffield Children's Hospital with a history suggestive of a bleeding disorder. How they were treated would have depended on their severity, i.e. the frequency of bleeding episodes, what their specific diagnosis was (haemophilia, Christmas disease or some other problem), and the date on that 20 year timescale they presented.

66.2. From 1975-1985 those boys with severe Factor VIII deficiency who had painful bleeding episodes would have been treated in the first instance with cryoprecipitate, avoiding large pool concentrates for all but serious haemorrhage. This choice was to avoid virus contaminated material. From 1985 large pool factor VIII concentrate was heat treated and the risk of virus transmission was greatly lessened.

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

67. How was the care and treatment of patients with bleeding disorders and HIV/AIDS managed at the Hospital? 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 HIV?

67.1. We were fortunate in that we had no boys with HIV/AIDS during my time at the Children's Hospital as far as I can recollect. I did see a 14 year old girl who was referred with a possible bleeding disorder who had been multi-transfused following surgery on two occasions at different London Hospitals. (See document DHSC0006212). She was tested by me and found to be HIV positive. She was then referred to the appropriate specialist clinic at the Royal Hallamshire Hospital. Her transfusion history in London was quite extraordinary but I have no record or recollection whether she had a bleeding disorder.

67.2. For (a) we would refer all patients with HIV/AIDS to the appropriate expert colleagues at The Royal Hallamshire Hospital. The Children's Hospital, albeit a separate NHS Trust, is within strolling distance of the Royal Hallamshire, with close professional ties.

67.3. For (b) I cannot answer. I left Sheffield in 1995.

67.4. For (c) I cannot answer.

67.5. For (d) I cannot answer.

68. How was the care and treatment of patients with bleeding disorders and hepatitis C managed at the Hospital? 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?

68.1. Hepatitis C was not identified until 1989. The team that did so was awarded the Nobel Prize in 2020. The study of liver biopsies we carried out at the Children's Hospital in 1979-80 did identify 5 young boys with haemophilia who had evidence of chronic persistent hepatitis not associated with hepatitis A or B. While we had no treatment for an unrecognised condition, we concluded that exposure to FVIII concentrate made from large pool plasma should be minimised in such patients.

68.2. (a) These boys would have been referred to a physician for follow up.

68.3. 68(b) At that time there was no recognised therapy for Hepatitis C, but latterly effective treatment with interferon and ribarvirin has been available.

68.4. 68(c) Parents were told that the boys we had in our study would be carefully followed. They will all now be under the care of the Hallamshire Hospital, I hope.

68.5. 68(d) See 68(a)

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

69.1. Patients infected through blood products for treatment of bleeding disorders would have been referred to the relevant specialist clinic which would have had appropriate professional support.

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

70.1. Not at the Children's Hospital, but the AIDS clinic at the The Royal Hallamshire might have.

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

71.1. We did not have any difficulties with such funding during my time at the hospital.

72. 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.

72.1. Neither I nor my patients were involved with clinical trials in relation to HIV treatments or hepatitis treatments during my time at the hospital.

Records

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

73.1. I do not know what the hospital's policy was on information on death certificates of those with HIV or hepatitis. I was never involved in writing one.

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

74.1. I do not know what the retention policies of the Hospital were for medical records during the time I worked there.

Research

75. Please list all research studies that you were involved with as a consultant haematologist at the Hospital (or any other relevant positions of employment) insofar as relevant to the Inquiry's Terms of Reference, and please:

a. Describe the purpose of the research.
b. Explain the steps that were taken to obtain approval for the research.
c. Explain what your involvement was.
d. Identify what other organisations or bodies were involved in the research.
e. State how the research was funded and from whom the funds came.
f. State the number of patients involved.
g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent.
h. Provide details of any publications relating to the research.

Please provide the same details in relation to any other studies in which you were involved or articles you have published, insofar as relevant to the Inquiry's Terms of Reference, including the enclosed article [OXUH0001751_003].

75.1. Most of my research interests during my time at the Children's Hospital related to childhood leukaemia, and the National Medical Research Council therapeutic trials for children with these diseases.

75.2. The only research project I was involved in with boys with haemophilia was that reported in document OXUH0001751-003 where I was the corresponding author and the first author was Dr Kathy McGrath, a senior haematology trainee on a sabbatical from Australia on a six-month secondment to my department. We studied the histological changes in liver biopsies from 5 out of 18 boys with persistent abnormal liver function blood tests.

75.3.

75.4. Other co-authors were Dr D Triger, consultant hepatologist at the Royal Hallamshire Hospital, and Professor James Underwood consultant histopathologist at the Royal Hallamshire Hospital. The study would have had to have been approved by the local research ethics committee. Written informed consent was obtained from both parents of each child.

75.5. The purpose was to expand the study reported earlier by Professor Preston at the Royal Hallamshire Hospital, also with Dr Triger and Professor Underwood, where he reported persistent liver disease in adults with haemophilia.

75.6. The paper was published as:

McGrath KM, Lilleyman JS, Triger DR, Underwood, JCE, Liver Disease complicating severe haemophilia in childhood. Archives of Disease in Childhood, 1980, 55, 537-540,

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

76.1. No patients were involved in this research study without their consent and that of both parents.

77. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or shared with third parties without their express consent? If so, please explain what data was used, and how/why it was shared.

77.1. No patient data from this study was used for other research or shared with third parties.

Section 6: UKHCDO

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

78.1. I was an attending member of the UK Haemophilia Centre Directors by virtue of my clinical responsibilities treating haemophilia and allied disorders and attended meetings between 1975 and 1995. I may have been a member of the Paediatric Working Party but have no recollection of attending any such meetings, I am sorry.

79. Please consider the enclosed UKHCDO meeting minutes dated 30 September 1984 [HCDO0000494]. On page 7, the minutes record that you had asked Dr Colvin for clear guidance relating to the treatment of paediatric patients. What was the context of and reason for this request? Had clear guidance been previously absent, and to what products and types of patients did your request refer? What guidance, if any, was formulated as a result?

79.1. HCDO0000494 records the UKHCDO meeting of 30 September 1994, not 1984. This is an important difference because in between these dates the first synthetic (recombinant) factor VIII was approved by the US FDA, and UK blood donor testing for HIV and Hepatitis C had begun. I cannot recall the content of my letter to Dr Colvin on this occasion, but presumably it was to seek consensus on the optimal choice of therapeutic agents for children with haemophilia and how best to achieve home treatment for them. This meeting was 11 months before I left Sheffield, and I had no responsibility for bleeding disorders at St Bartholomew's Hospital – there I was responsible only for children with cancer and leukaemia.

Section 7: Pharmaceutical companies/medical research/clinical trials

80. Please describe the nature of your involvement with any pharmaceutical company involved in the manufacture and/or sale of blood products. Examples of such involvement may include:

a. Providing advisory or consultancy services;
b. Occupying a position on any advisory panel, board, committee or similar body;
c. Receiving funding to prescribe, supply, administer, recommend, buy or sell a particular product;
d. Undertaking medical research for or on a company's behalf; or
e. Providing results from medical research studies to a company.

80.1. I was not involved in any way with any pharmaceutical company involved in the manufacture or sale of blood products.

81. At the Hospital, what if any requirements and/or guidelines were in place concerning declaratory procedures for involvement with a pharmaceutical company? Did you follow these requirements and/or guidelines?

81.1. I cannot give a summary of the Hospital's requirements or guidelines on involvement with a pharmaceutical company because no involvement ever arose.

82. 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?

82.1. I never received funding from a pharmaceutical company while at the Children's Hospital.

Section 8: Interaction with the trusts and schemes

83. Please describe as fully as you can any involvement you have had in relation to any of the 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 assistance to people who had been infected. Relevant involvement may include:

a. Occupying a formal position with any of the trusts or funds;
b. Providing any advice to any of the trusts or funds, including for the development of any eligibility criteria or policies;
c. Informing patients about or referring patients to the different trusts or funds;
d. Determining or completing any part of applications made by patients.

83.1. I have not been much involved with any of the trusts and schemes set up to provide financial assistance to people who have been infected by blood products apart from one young girl who contracted HIV following multiple blood transfusions at different hospitals near London (see q85 below). I am aware of the Macfarlane trust, but cannot recall any dealings with them.

84. The enclosed minutes of a meeting of the UKHCDO held on 29 September 1988 discuss the establishment of the Macfarlane Trust [page 2 of BART0002329]. The minutes record that a register of those infected was needed. Haemophilia Centre Directors were asked to encourage patients to register with the Macfarlane Trust. What, if any, steps were taken by you/the Hospital to encourage patients to register?

84.1. Since as far as I can remember we had no HIV diagnosed in our haemophiliac patients, and in 1988 hepatitis C was not yet discovered, we took no particular steps that I can recall to encourage patients to register.

85. The Inquiry understands that you were involved in the Scheme of Payments for Those Infected with HIV through NHS Blood or Tissue Transfer. In answering this question, you may wish to refer to the enclosed documents which refer to patients under your care seeking assistance from this scheme [DHSC0006212_131, DHSC0006212_133 and DHSC0006212_134]. Without referring to any particular patient, please explain:

a. How this scheme functioned and your involvement with it;
b. How many patients under your care sought and/or received assistance from this scheme;
c. Your opinion as regards the functioning of this scheme. For instance, do you consider that it was well run? Did it achieve its aims? Are you aware of any shortcomings in its operation?

85.1. I have seen the documents you refer to and I have nothing to add. The patient came to me because it was thought she might have a bleeding disorder. Her history of bleeding during and after surgery would perhaps suggest this but I have no further information about her apart from the documents you have collected. It is an extraordinary story. The administration of 'fresh' blood from a walking donor is a risky procedure. I saw her some 2 years later. She was HIV positive.

85.2. Without access to her hospital records I cannot comment further. She would have been referred to the Hallamshire Hospital specialist clinic for further management.

85.3. I cannot say whether she benefitted from her application, how the scheme functioned, or whether it was well run.

Section 9: Later employment

86. Please outline your role as Medical Director at the NHS National Patient Safety Agency. In your answer, please also identify any issues or aspects of your work that are relevant to the Terms of Reference.

86.1. The National Patient Safety Agency (NPSA) was set up as an independent body of the Department of Health in 2001 to help the NHS in England and Wales to learn from its mistakes and become a safety conscious organisation. At the core of this ambitious brief was a demand that the Agency should establish a data collection system whereby all reports of adverse events in the service would be collected, collated, and analysed. This would, in turn, help understanding of common factors involved in repeated errors and allow the development of better designed systems and processes. I joined the NPSA as Medical Director in 2004 and was seconded by Barts and the London School of Medicine (my employers) as a pre-retirement position.

87. Please outline your role as Strategic Adviser at the NHS National Patient Safety Agency. In your answer, please also identify any issues or aspects of your work that are relevant to the Terms of Reference.

87.1. There were several areas of focus in the Agency's portfolio that I was involved in, from wrong-site surgery to drug delivery blunders and (perhaps relevant to the Terms of Reference) blood transfusion errors.

87.2. Amongst other things, I was also made responsible for oversight of the already established National Confidential Enquiries these being Perioperative Deaths (CEPOD), Maternal and Child Health (CEMACH), and Suicide and Safety in Mental Health (NCISH), together with the Central Office for Research Ethics Committees (COREC).

87.3. Then, as it was announced that the Agency would be phased out in the 'bonfire of the quangos', I decided to retire and left full time employment in 2007. In

retirement I was a non-executive director of the Medicines and Healthcare Products Regulatory Authority from 2007-2012.

Section 10: Other Issues

88. **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.**

88.1. I am not aware of any complaints made about me to any of my employers, to the General Medical Council, to the Health Service Ombudsman, or any other body that has a responsibility to investigate complaints.

89. **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.**

89.1. What happened to patients unwittingly infected by blood or blood products over the 20 years that I worked at the Children's Hospital is something that has saddened me greatly. I draw some comfort from the policies that I pursued which I hope minimised the risks as understood at the time. I was a great disciple of cryoprecipitate which exposed recipients only to very few local UK blood donors. Similarly, the early Factor VIII concentrates made in Oxford used only plasma from UK volunteer donors, albeit in much larger pools. The advent of HIV and Hepatitis C was tragic, until technology caught up and that stable door was closed – too late for too many.

Statement of Truth

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

Signed: GRO-C

Dated: 10 February 2021