Witness Name: Dr Peter Hamilton

Statement No.: WITN4197005

Exhibits: N/A

Dated: 9th October 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR PETER HAMILTON

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 4th August 2020.

Section 1: Introduction

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

1.1 Peter John Hamilton MA BM,BCh,FRCP FRCPath.

GRO-C

Date of birth GRO-C 1942

1.2 Professional Qualifications
(BM,BCh Oxford) August 1968; M.R.C.P (UK) 1971:M.R.C.Path. 1974; F.R.C.P. 1983;
F R C.Path 1987

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 1st Jan 1978 Consultant Appointment as Haematologist to Royal Victoria Hospital Newcastle upon Tyne
16th Oct 2002 Retirement from all Clinical Work

2.2 I was appointed Consultant Haematologist and Co-Director of the Haemophilia Centre in Newcastle after registrar and senior registrar training in Aberdeen in General Medicine, Gastroenterology and Hepatology and training in Clinical and Laboratory Haematology. For the first 3 months of my appointment I was seconded to Cardiff' Haemophilia Centre for further laboratory training and the Oxford Haemophilia Centre for further clinical experience. After 5 years or so on the retiral of Professor Walker I came to be in Administrative Charge of the Haematological Laboratory and Hospital Blood Bank**. I had no administrative or budgetary responsibility for the Regional Haemophilia Service.** I had as a Consultant in Haematology at the Royal Victoria Infirmary, an extensive clinical remit looking after patients with haematological malignancies and was involved, along with a colleague, in setting up a bone marrow transplant service. I provided a second opinion for difficult clinical and laboratory diagnostic problems for The Northern Regions district hospitals particularly in the areas of aplastic anaemia, acquired haemophilia (a rare condition quite separate from Haemophilia A/B and vonWillebrands) and difficult clotting problems. In addition to being involved with general haematological diagnostic work as Director of Diagnostic Haematological Laboratory Services and Blood Banking I developed the Haemostasis and Thrombosis Service for the RVI and Associated Hospitals Trust, overseeing anticoagulant clinics and dealing with thrombophilia patients. After successfully integrating two major hospital laboratories with 47 technical staff and planning a rebuild for the department, I stood down to allow the new three hospital trust to plan laboratory services for the new millennium. I continued as senior consultant to provide managerial cover for the laboratory at the RVI. I had teaching responsibilities for medical students and those junior staff in our training programmes. I was also involved in clinical support and cover for the Director of the Newcastle Haemophilia Centre and his team of nurses, physiotherapist, social worker and the secretariat. With the support of the Nurse Specialist I ran a weekly outpatient session for Haemophiliacs, in particular reviewing those with HIV and Hepatitis C at 4 monthly intervals. Once a month I ran a general bleeding investigative Clinic. I usually attended the weekly Haemophilia Team review when clinical and social problems of the Centre's patients and their families were reviewed. In April 2000 the Director of the Haemophilia Centre retired and in addition to my general haematological duties I was interim director looking after adults and children until his replacement assumed his responsibilities in January 2001. I was able to establish a Joint Clinic with a newly appointed Infectious Disease Consultant who had a special interest in HIV and Hepatitis C in 2000. In 2002 I myself retired from all clinical practice.

2.3 *Senior Registrar in Medicine* 1976-1978
Clinical Lecturer in Medicine
Forresterhill and Associated Hospitals, Aberdeen
Training in Acute General Medicine, Gastroenterology including Hepatology

Lecturer in Pathology (Haematology) 1974-1976
University of Aberdeen
Training in Haematology and Blood Transfusion

Registrar in General Medicine 1971-1974
Forresterhill and Associated Hospitals, Aberdeen
Rotational Training in General Medicine

Senior House Officer (Neurology) 1970-1971
Department of Neurology, Churchill Hospital Oxford

Pre-Registration House Surgeon and Physician 1969-1970
Radcliffe Infirmary Oxford

Intern in Pathology 1968-1969
Johns Hopkins Hospital Baltimore Maryland USA
Autopsy and General Histopathology Training with attachment at Medical Examiners Office

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.*

3.1 United Kingdom Haemophilia Centre Directors Organisation 1978-2002(I played a supporting role for Dr Jones and had no role in any sub-committees.)

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, reports or documents that you provided.*

4.1 I have not been involved with or provided any evidence to any criminal investigations associated with the diseases listed. Two years after I retired I was the subject of a Professional Practice Investigation by the General Medical Council (see Para 152). I have provided in the past, but not for over 15 years, medical reports as requested by solicitors acting for either the litigant or defendant in medical negligence actions. I have not kept any records of my opinions and remember no details of such opinions. Such reports related inter alia to needle stick injuries, the likely origins of transmission of some of the diseases listed, and the appropriateness of treatments administered.

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

5. *Please describe the roles, functions and responsibilities of the Centre during the time that you worked there.*

5.1 The Newcastle Northern Regional Centre provided Comprehensive Care for those diagnosed with Bleeding Disorders from throughout the Northern Region and for a few patients from further afield. This included establishing a diagnosis and treatment with appropriate safe therapeutic concentrate and putting in place arrangements for rapid access to 24 hour

availability of nursing and medical care. The patient and their families need to know how to access the Centre at any time. Attending a local A&E department must be resisted because of the need for prompt treatment of bleeds with appropriate factor concentrates associated with monitoring of factor levels not available in local hospitals so liaison with emergency ambulances should be in place. Each Comprehensive Centre will have their own protocols in place for regular monitoring and support for Patients and Families with regard to detection of unwanted side effects of treatment including checks for inhibitors. The importance of physiotherapy assessment and the identification of so called target joints is vital. In children immunisation schedules should not be overlooked; inoculations should not be given intramuscularly. Regular dental checks are encouraged; in Newcastle there were good relations with practitioners at the dental hospital next door. Close liaison with Specialist services needs putting in place; orthopaedics, general and neurological surgical services- with patients or their relatives given a 'what to do' after head injury leaflet. In the case of HIV and Hepatitis C patients it is necessary to identify and discuss with surgeons willing to operate on infected patients. Carriers need identifying and counselled carefully. Pregnant carriers who can have subnormal factor 8 levels are linked with a named Obstetrician. Fertility services were available in Newcastle, particularly relevant when dealing with HIV and Hepatitis C patients and their spouses. Prenatal testing was provided in Newcastle. Pain relief needs to be addressed as aspirin and related drugs are contraindicated in Children and Adults with bleeding disorders. The most effective form of pain relief for bleeds into a joint is rapid treatment with factor and checking that haemostatic levels are maintained. But the most important aspect of the Haemophilia Centre is the recruitment of caring and supportive staff with the time to deal with worries and concerns of the patient and their families. Young mothers are especially vulnerable and need the support of dedicated councillors/social workers. The problems of getting Haemophiliacs into schools and work places needs attention. Good communication is vital. The most challenging task for the junior doctor is to listen to the patient: they will inevitably know more about their condition than you. Further responsibilities of the Director of the Haemophilia Centre include administrative and budgetary responsibilities along with maintaining standards; the continual monitoring of activities, listening and dealing with complaints, ensuring educational needs of patients and staff are addressed. The maintenance of staff and patient and family morale which was severely tested in our dealing with the HIV and Hepatitis C epidemics is also pertinent. Most patients and their families acted with quiet dignity and fortitude. However, there was a small cohort who lost confidence in the Haemophilia Centre staff. They vented their understandable frustration and anger at being infected by blaming staff for getting them into their horrendous predicament. These patients were very difficult to manage and very upsetting for all the staff. Some of these patients sought and were provided with care at the infectious disease unit at the General Hospital.

6. *How and when was the Northern Regional Haemophilia Service established and what were its roles, functions and responsibilities?*

6.1 I do not know when the Newcastle Haemophilia Centre was established. It was already an active and widely regarded Centre when I was appointed Consultant Haematologist in 1978.

7. *Please identify senior colleagues at the Centre and their roles and responsibilities during the time you worked there.*

7.1 The founder of the centre and medical director was Dr Peter Jones. He was trained as a paediatrician and responsible for the care of all the registered Haemophilia patients, children and adults from throughout the Northern Region of England-a population of about 1 million. His books Living with Haemophilia were practical guides for the families with Haemophilia and were eagerly received by the Haemophiliac community in the UK and wider afield. He was ably supported by Mrs Maureen Fearns as Clinical Nurse Specialist who was involved from the inception of the Centre. She was supported by a team of enthusiastic caring nurses. She was the key to Dr Jones's Home Care for Haemophilia. The founding Social worker was Mrs Jean Lovie who moved sometime in the late 1980's or 1990 to a Senior position at Newcastle Council involved with HIV services in the Community. She was replaced by Mrs Pat Latimer who worked tirelessly to support patients and their families. The MLSO in charge of the Hospital Coagulation Laboratory the late Mr Alan Oxley was instantly available when needed. There were sessions of dedicated physiotherapy services provided by the late Mrs Brenda Buzzard. A key member of the staff was the Senior administrative Assistant and Dr Jones secretary, Mrs Linda McBride. Mrs McBride provided me with secretarial support. (My own personal secretary was not involved with any of my work for the Haemophilia Centre). Mrs MacBride was very knowledgeable about our patients and their families and always capable of finding patients records and the only person capable of managing our dedicated computer.

8. *Please describe your role and responsibilities as consultant haematologist and co-director at the Centre and how, if applicable, this changed over time. Please include a description of the respective roles and responsibilities undertaken by you and those undertaken by Dr Peter Jones.*

9. *Please describe your work at the 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.*

9.1 I was the first trained Clinical and Laboratory Haematologist to be appointed in Newcastle. The Haematology Laboratory was directed by Prof Walker who had a Paediatric background and was an expert in Rhesus Haemolytic Disease of the newborn and a gifted morphologist. Money was tight; I had no dedicated microscope and no secretarial support for at least a year. We had a Senior Registrar in Haematology. There were no junior medical staff in the Haemophilia Centre. It took several years to obtain funding for a registrar in general haematology. Prof Walker asked me to run and develop the Coagulation Laboratory which was an important support arm of the separately administered Haemophilia Centre which had no laboratory of its own. Adult Clinical Haematological services were run by two very senior general physicians who were close to retirement. Along with a newly appointed senior lecturer we had to develop a 'modern' clinical haematology service and introduce a bone marrow transplant service. I had been given the title of Co-Director of the Haemophilia

Centre and my first priority was to develop the Coagulation Laboratory. I played no part in the administrative or budgetary running of the Haemophilia Service which was gaining a national if not international reputation at the forefront of a successful home therapy programme. As time went on I was able to provide clinical cover and support for the Clinical Director and his team of dedicated staff and develop a clinic enabling the centre to provide closer attention to the needs of the adult patients who were infected with HIV and Hepatitis and their families by drawing on my training in general adult medicine, gastroenterology and hepatology. A couple of years before my retirement I was able to establish a Joint Clinic in the Haemophilia Centre with a newly appointed Infectious Disease Physician who had a special interest in HIV/AIDS and Hepatitis. I wish to stress that although called Co-Director I never saw myself as Co-equal in the management of the Centre itself which was running very effectively and efficiently. I saw myself as a clinician supporting Dr Jones in the care of his patients and families, contributing to the care of the patients he and the nurse specialist had been looking after for many years. My commitment to the centre was not fixed, other than establishing one clinic per week drawing on my adult general medical, gastroenterological and hepatological training. I also provided a general diagnostic bleeding clinic once a month. I provided cover for any inpatient. My commitments probably never accounted for 3 of my nominal eleven session contract. Obviously when Dr Jones was away or on sick leave I provided extra support to the centre as I did on his retirement when I became interim director for 9 months. On his retirement my duties increased but I never did more than provide clinical consultations and was not involved in changing the day to day organisation of the Haemophilia Centre or its treatment programmes which had worked well over many years.

10. *Approximately how many patients with bleeding disorders were under the care of the Centre when you first started working there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so). What proportion were children and what proportion adults?*

10.1 I cannot remember these figures and cannot hazard meaningful guesstimates. I began working in Newcastle in 1978 and one or two new cases of haemophilia would be diagnosed each year with the occasional patient joining who came to live and/or study in Newcastle or leaving to live/or study away from the Northern Region. Tragically over the years 1985 to approx 1995 we lost over 70 patients to the scourge of HIV/AIDs and a few to liver disease, usually associated with alcohol driven Hepatitis C.

11. *What decisions and actions were taken, and what policies were formulated, by you and by the Centre, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you were there? In addressing this question please answer, to the extent that you are able to, the following questions:*

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

b. *What were the reasons or considerations that led to the choice of one product over another?*
c. *What particular products were used for treating patients, over what period of time and for which categories of patients?*
d. *From where were the factor concentrates used at the Centre sourced?*
e. *What role did commercial and/or financial considerations play?*
f. *What involvement did you have?*

11.1 I was not responsible for the provision selection or purchase of therapeutic substances at the Centre. When I was appointed in 1978 the Centre was fully established and had been running for several years. The over-riding principles were that an individual patient should be allocated a single source of concentrate and there should be at least two different concentrates available at any one time to ensure in the case of disruptions in supply we had stock available to cover any acute requirements. As far as I remember concentrate for home therapy was dispensed from the centre itself ensuring that the patient attended frequently for monitoring and the chance to provide increased support to families.

12. *What was the relationship between the Centre/you and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Centre's and your decisions and actions?*

12.1 I was not responsible for the decisions involved with choice of which concentrate for which patient and the administration of such products, I had my office a good ten minutes away from the centre so my interaction with pharmaceutical representatives was limited. When I was Interim director for the year following Dr Jones's retirement and the appointment of his replacement and I was asked by the Pharmacist about the new yearly contract after consultation with the Nurse Specialist I asked that contracts be rolled over for the year.

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

13.1 Dr Jones with input from the Nurse Specialist was responsible in conjunction with the Hospital Pharmacy for selecting ordering and providing therapeutic concentrate.

14. *The 6 February 1984 letter from Dr Peter Jones to a number of colleagues (including you) recorded that "Haemophilia Centre Directors believe that the present arrangements [for the purchase and distribution of commercial factor VIII] work well and should not be changed" [OXUH0000898]. Was that your view and, if so, why? Did you agree with the position as set out by Dr Jones in this letter?*

14.1 I had no experience with regard to the purchase of therapeutic blood products. I had every confidence in Dr Jones an acknowledged authority in the efficacy and effectiveness of the different therapeutic concentrates that the existing arrangements were working well.

15. *The enclosed letter dated 17 February 1986 from Dr Jones (copied to you) to Dr Wright, Public Health Laboratory Services [DHSC0002295_009], suggests that a shortfall of Factor VIII in all regions resulted in widespread use of various American products. Is that correct, in your view? Did a shortfall of NHS Factor VIII in your region result in increased use of American products? (Please also address your comments as reported in The Journal on 12 August 2000 that "Doctors had no choice but to rely on American blood products to treat their patients") [HSOC0003838].*

15.1 The need for safe effective treatment and the ready availability of therapeutic blood product for treating patients with blood disorders is self-evident. If there is not enough home-grown product then it is necessary to obtain product from wherever, subject to the necessary licencing supervision. Given the practice of American companies sourcing their products from paid donors and using penal institutions to garner blood, in my opinion reliance on USA products was not a good idea.

16. *How did you decide which products to use for particular patients? To what extent, if at all, were patients offered a choice, or given a say, as to what products would be used?*

16.1 The choice of safe effective treatment would have been made by Dr Jones in conjunction with the nurse specialist. My role was to ensure that the monitoring of factor levels was carried out by the laboratory correctly and quality assurance was satisfactory.

17. *What alternative treatments to factor concentrates were available for people with bleeding disorders in the 1970s and 1980s? What were, in your view, the advantages and disadvantages of those alternative treatments? What use did you 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 choice of therapeutic concentrate is governed in the first instance by the diagnosis and the need to obtain and maintain satisfactory haemostatic levels in the blood of the patient to allow healing whilst minimising any side effects. I was not involved in treating patients with blood disorders in the 1970's and I had no responsibilities in the 1980's for selecting appropriate treatments for Dr Jones' patients.

18. *What was your policy and approach at the Centre in relation to home treatment for patients with bleeding disorders? Did that policy and approach change over time and, if so, how?*

18.1 I was not responsible for the initiation or supervision of home therapy in patients.

19. *What was your policy and approach at the Centre in relation to prophylactic treatment for patients with bleeding disorders? Did that policy and approach change over time and, if so, how?*

19.1 I was not responsible for prophylactic treatment of patients which depended on the individual requirement of the patient at the time.

20. What was your policy and approach at the Centre as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and, if so, how?

20.1 I was not involved in formulating a policy for the use of Cryoprecipitate in Haemophiliac patients. The treatment options for an individual patient were the responsibility of the physician in charge of the patient, Dr Jones. As a general haematologist there was sometimes a need to use this treatment in low fibrinogen states associated with disseminated intravascular coagulation (DIC).

21. To what extent, and why, were patients with mild or moderate bleeding disorders treated at the Centre with factor concentrates?

21.1 Patients with mild and moderate Haemophilia will occasionally bleed spontaneously or suffer trauma requiring treatment. Levels of factor 8 in mild and often in moderate factor 8 deficient haemophiliacs will usually respond to Desmopressin supplemented by an antifibrinolytic if there is no haematuria. Levels have to be checked to ensure adequate response has occurred and in patients requiring repeat doses there is need for close monitoring for fluid retention as fitting may occur. Such an approach is not always sufficient and factor concentrate is required. Tongue bleeding can sometimes be a nuisance and direct application of thrombin coupled with local pressure is often appropriate.

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

22.1 If I remember correctly I had one patient with AIDS transferred to the Newcastle Haemophilia Centre from another centre who developed a cytomegalovirus infection, possibly associated with blood transfusion.

Section 3: Knowledge of, and response to, risk

General

23. At the time you took up your position as consultant haematologist at the Centre (and please state when that was), what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

23.1 I was appointed Consultant Haematologist in Newcastle in 1978, spending the initial 3 months in Cardiff and Oxford to expand my laboratory knowledge regarding coagulation tests and widen my clinical experience of Haemophilia. I understood from my haematological training that blood products had a small but definite risk of transmitting infections, in particular Hepatitis B which could become chronic, and so called Hepatitis. At that time HIV was not known about and hepatitis was thought to be 'a minor irritant' with the occasional transfused patient having a limited if unpleasant attack of acute hepatitis from which the patient recovered with no further sequelae. In my 24 years of Consultant practice in Newcastle I never witnessed an acute infection with Hepatitis B or nonA/nonB hepatitis- subsequently called Hepatitis C. When the HIV epidemic abated it was increasingly apparent that the received wisdom that nonA/nonB hepatitis was no more than a minor transient irritant was not true and it caused continuing often cryptogenic liver damage marked by aberrant liver function tests. Over the years the complications of such continuing infection including liver decompensation, cirrhosis, portal hypertension carcinoma and ultimately the need for liver transplantation became manifest. Through my position as Consultant in Charge of the Hospital blood bank in tracing the notes of patients involved in look back exercises mounted by the local blood transfusion service I came to realise that Hepatitis C was probably more widespread in the community than previously thought. During my time working in association with the Haemophilia centre only one patient seroconverted to HIV positivity-he was extensively investigated by Dr Jones. All the patients with AIDs had become infected with HIV before 1978.Toward the end of my career there was also concern that variant CJD might be transmitted by blood product. From my general leukaemic work I also knew that patients could have septicaemia as a consequence of transfusion most often with platelet concentrate.

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?

24.1 The UK Transfusion service uses voluntary carefully screened and unpaid volunteers as the source for the blood products they dispense. Whilst screening has improved over the years the risk of transmission of infection from blood products has always been low although statistics are no comfort to the occasional infected patient. The provenance and safety of commercially paid blood products is a complicated one, but suffice to say experience has shown particularly in the years before I was appointed (1978) that the incidence of HIV and Hepatitis C infection was worryingly high following administration of such therapeutic concentrates.

25. What advisory and decision-making structures were in place, or were put in place at the Centre and and/or within the area covered by the Northern Regional Haemophilia Service, to consider and assess the risks of infection associated with the use of blood and/or blood products.

25.1 I was not responsible for policy matters relating to advisory and decision making structures relating to the safety of blood concentrates at the Haemophilia Centre. As far as general hospital usage of blood and FFP I relied on the Blood Transfusion Service to have such structures in place and provide us with safe products

Hepatitis

26. At the time you took up your position as consultant haematologist at the Centre, what was your knowledge and understanding of the risks of the transmission of hepatitis, including HBV and NANB hepatitis (HCV), from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

26.1 In 1978 when I was appointed Consultant in Newcastle it was the received wisdom that although blood transfusion was safe there was a very small chance of transmissible disease with Hepatitis B-very rarely as units could be screened for the virus and discarded. NonAnonB hepatitis did occur at what was considered an inevitable but acceptable low level but was not thought to cause any long-term problems. These potential problems were very much reduced after blood was no longer collected from British jails in the early 1970's, donor screening became more thorough and screening for viruses instituted. Hepatitis B screening of blood was in place, and screening blood for Hepatitis C in the mid 1980's .The introduction of solvent detergent and Heat treatment of factor concentrates further diminished the chance of transmission of NonANonB Hepatitis. The delayed introduction of synthetic genetically engineered coagulation factors ultimately solved the problem of contaminated therapeutic concentrates blood products.

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 I do not remember ever having to think about this as no fresh cases of Hepatitis developed in our Haemophiliac patients or their families and Hepatits B was not a problem. Obviously the ability to detect the Hepatitis C virus antibodies in a patient's blood and recognise the different genotypes to aid treatment schedules with Interferon were advances. I retired before the modern virus clearing therapies were developed so avoiding the very real side effects seen with interferon therapy.

28. The Haemophilia Society Northern Branch Newsletter from August 1980 contains an article by your co-director, Dr Peter Jones, which states, in relation to NANB hepatitis, that "the risk of infection, which is almost always a very mild one, is therefore still present" [HSOC0021600]. Was it your view at that time that NANB hepatitis was "almost always … very mild"? If so, what was that view based on?

28.1 I suspect Dr Jones is referring to the continued risk of Hepatitis being transmitted by blood products and that there was an increasing awareness that although patients after an acute bout of infectious jaundice suffered no apparent ill health after recovery some were continuing to have low grade abnormalities of liver enzyme in their blood identified on routine monitoring whose significance was unknown at this time. Indeed the significance of low grade liver enzymes circulating in Haemophiliacs and in members of the healthy general population was not known at this time and the idea of persistent low grade viraemia with Hepatitis widely discounted.

29. *The same article referred to you "very carefully monitoring the progress of everybody receiving transfusions at [your] Tuesday morning liver clinic" and suggests that "we will be in a position to discuss his results with you in the not too distant future". Please provide details of the liver clinic which you ran and describe the monitoring that you carried out. What were the results of your monitoring, were they shared with patients and, if so, when?*

30. *What if any enquiries and/or investigations did the Centre and/or you carry out or cause to be carried out in respect of the risks of the transmission of hepatitis? What, if any, information was obtained as a result?*

30.1 You are asking me to discuss events that happened over 30 years ago. As a newly appointed Haematologist who had trained in Aberdeen I would have been slowly trying to establish myself and get to know staff and patients who had been together for many years and bridge cultural differences. The establishment of a clinic (attended usually by Sister Fearns) to begin to get to know the patients and staff seemed sensible. The unknown significance of the finding of low grade abnormalities in liver enzymes in the blood of Haemophiliacs which were found on routine monitoring offered an excuse for me to start this process and begin to contribute to care and understanding of the Haemophilia patients and their families at the centre. The clinic would be run weekly seeing a few patients at a time and conducting a full clinical history and clinical examination. I would have arranged for general blood screening and assess the Hepatitis B status of those attending and checked their clotting factors. Patients and their families requiring Hepatitis B immunising would be offered it. The major difficulty was the inability to perform liver biopsies to assess what was going on in the liver. There were reports of patients with Haemophilia who had had liver biopsies running into difficulties with bleeding. The clinics were useful in dealing with lifestyle problems and with alcohol abuse. All requests for laboratory investigations would have been discussed with patients and at follow up the results discussed. No evidence of symptomatic complaints relating to underlying liver damage was detected at this time. Control measures put in place centred upon avoidance of alcohol and trying to modulate high opiate pain relief.

31. *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)?*

31.1 Dr Jones was extremely active in trying to ensure the safest product was available for use. Attention to personal hygiene and not sharing razors or toothbrushes and the safe disposal of needles and safe sex would have been emphasised.

32. *The Group Seminar Proceedings publication by the Haemophilia Society [HCDO0000279_012], following a Group Seminar in March 1984 in which you participated, records you as saying that "Very few haemophiliacs actually die with hepatitis – only once since 1975". What was the basis for your statement that there had only been one death since 1975? The publication also suggested that "control" was "possible" in relation to hepatitis – what did you mean by that?*

32.1 I do not remember this group seminar that took place 36 years ago. I do however remember an anecdote concerning a patient likely to have been infected with NonANonB hepatitis who was a publican who died with liver cancer long before I was appointed to Newcastle in 1978. As far as Control of Hepatitis is concerned avoidance of alcohol is the main way of slowing the progression of liver damage in patients with Hepatitis and preventing the possibility of reinfection by using the safest blood products available.

HIV and AIDS

33. 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?

33.1 Before 1982 I had no knowledge of AIDS whatsoever. During 1982 and 1983 press reports and general awareness resulted in a realisation AIDS was a problem in the USA for Homosexuals , those with Haemophilia and Haitians. In 1983 the HIV virus was identified for the first time by both a French and American virologist and it was realised that this virus was the cause of AIDS. During late 1983 and 1984 the disease became a scourge amongst UK Haemophiliacs and if you had HIV for which there was no cure, your life expectancy was of the order of 3 years or less. AZT was introduced as a way of combating the virus causing AIDS in 1987 but by 1993 it was shown to not prolong life. The situation fortunately improved in 1995 with the introduction of so called Highly active antiretroviral therapy (HAART) which reduced the death rate by getting on for an half. Further refinements in drug therapy have resulted in almost normal life expectancy and suppression of the virus to levels not associated with infection of others.

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

34.1 1983 or 1984 following reports from the USA and a growing realisation that HIV/AIDS was being increasingly recognised in the UK in Haemophiliacs who were not homosexuals.

35. What steps were taken by you and/or at the Centre in light of that awareness?

35.1 I do not remember anything about the specific steps taken at the centre over 35 years ago. Dr Jones and Sister Fearns were in charge of everyday management of the centre and drawing up and updating protocols. When the HIV test was available in Newcastle, all patients would have been tested and the test offered to spouses and other family members. All those tested would have been counselled by Dr Jones.. This included dealing with and reassuring patients and their families that Haemophilia services would continue and anyone sick would be attended to either in the centre or if needs be in the Haematology ward. There was considerable alarm amongst our Haemophiliacs that they should not be considered homosexuals and that they would not be social pariahs. These fears were addressed by all staff at different times.

36. What, if any, enquiries and/or investigations did you and/or the Centre 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?

36.1 I did not take part in any retrospective look back exercise involving the Centre's patients. Constant monitoring, follow up and physical examination was conducted and on one occasion an HIV sero-conversion was detected by Dr Jones. This was extensively investigated by him and in the interests of patient confidentiality, specific details were not discussed with me.

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

37.1 I do not remember specific details regarding dealings with any patients , either those cared for in the Haemophilia Centre or my Haematology patients other than specifically emphasising the need for 'safe sex' , the careful disposal of needles (for which sharp boxes would be provided), general personal hygiene, dealing with cuts and spillages of blood and not sharing razors and toothbrushes.

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

38.1 The need to treat Haemophiliac bleeds which if left untreated could be very painful and lead to crippling necessitated continuing treatment with the safest concentrate available. The concerns of patients and their families would have been addressed directly and it would have been explained that subsequent to 1978 or earlier no evidence of HIV infection had occurred in patients at the centre using concentrate.

39. What steps were taken by you and/or the Centre following your attendance at a special meeting of Haemophilia Reference Centre Directors on 13 May 1983 [HCDO0000003_008]?

39.1 I do not know. I apologise but my mind is a complete blank with regard to my actions and thoughts at this time, now 37 years ago.

40. The enclosed memorandum dated 30 May 1983 from Dr Boulton to Dr McClelland [PRSE0003709] describes a conversation between Dr Boulton and Dr Jones on the subject of AIDS. Dr Boulton stated that Dr Jones "claimed that there is a lot of doubt about the diagnosis of all the AIDS cases in the UK, and in particular the haemophiliacs" and "felt he [Dr Jones] was still being somewhat less than cautious in his attitude, but this is not unexpected given his interests etc." What discussions did you and Dr Jones have following the meeting of Haemophilia Reference Centre Directors on 13 May 1983? Did Dr Jones share with you his view (as reported here) that there was "a lot of doubt" about the diagnosis of AIDS cases in the UK?

If so, did you agree with him? What do you understand by the reference to Dr Jones' "interests"?

40.1 I do not remember who Dr Boulton and Dr McClelland were. I cannot recall any discussions I had with Dr Jones at this time and do not recall what problems with AIDs diagnoses in the UK that were troubling Dr Jones or what Dr Jones's 'interests' might refer to.

41. The enclosed article in The Journal dated 14 August 2000 [HSOC0003838] quotes you as saying "When Aids first appeared in America there were concerns but the link to blood transfusions caused little more than a few raised eyebrows. It was not until 1984 when it was obvious that it was being transmitted in US concentrates that we became really worried". Does this accurately reflect your views at the time? Why was it in 1984 that you became "really worried"?

41.1 By 1984 there was increasing evidence that AIDS was becoming a problem in the USA (There is close connectivity of doctors internationally in the Haemophilia world) and that the pandemic would necessarily spread to those countries who had used American sourced blood product within the previous 5-10 years which was the time that HIV infection progressed to AIDS. It may have been at this time that Newcastle had its first case- a young man with probable cerebral toxoplasma infection who was transferred back to his home in Scotland for terminal care. I think Wales reported a number of AIDS patients at this time. There was every reason to fear that what had happened in the USA would cause problems here because of the use of American sourced concentrate. In 1984 the epidemic was not increasing in the UK particularly rapidly but the implications of the Population study from the Northern Region published in August 1985 reported HIV positivity in 81 of 120 patients tested who had received American concentrates. This was truly alarming.

Response to risk

42. On 24 January 1983 you attended a meeting with representatives of Immuno at London Airport [PRSE0002647], along with a number of other haemophilia centre directors and Professor Zuckerman. Please set out your recollection of that meeting and how it came about. Did you participate in any of the clinical trials proposed at that meeting (see the sub-heading in the notes "Clinical Trials Design") and if so please provide details? What can you recall about the discussion of AIDS that took place at the meeting? Did you share any of the information discussed at the meeting with your patients? If so, what information did you share? If not, why not?

42.1 I have no recollection of attending this meeting which occurred over 37 years ago.

43. Did you or the Centre take any steps to ensure that patients (or their parents) and/or the public were informed and educated about the risks of hepatitis and HIV? If so, what steps?

43.1 Dr Jones is and was a great communicator and was very involved in raising HIV awareness in the public at large as well as with patients and their families.

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

44.1 Dr Jones was responsible for recommending treatment at the Centre. I do not remember any discussion about treatment with Cryoprecipitate usage.

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

45.1 Dr Jones would be able to answer this question. I cannot remember when heat treated product became available (I could speculate it was possibly around Dec 1984) but I do know he was very involved and active in trying to urge people to provide heat treated products.

46. What if any consideration did you give to the use of heat-treated products prior to the meeting of UKHCDO Reference Centre directors on 10 December 1984 [HCDO0000394_117]? Did you (a) agree with and (b) follow the recommendations made at the meeting, including the recommendation to use heat-treated concentrates?

46.1 Dr Jones was responsible for decisions regarding the use of products.

47. Do you consider that heat-treated products should have been made available earlier? Please explain your reasons.

47.1 I was not party to the problems of providing heat treatment of products. As a practicising clinician I would have wished to have available the safest product as soon as possible.

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

48.1 This question should be addressed to Dr Jones and the clinical nurse specialist who were involved with providing continuous care at the Centre. I do not remember having any doubts as to their dedication in providing the safest treatment of their patients as was possible.

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

49.1 As per previous paragraph.

50. 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?

50.1 I cannot answer this question meaningfully. It should be remembered that I was appointed as a consultant in 1978 a couple of years before AIDS became the dreadful scourge it did in our patients. The infection with HIV which resulted in AIDS would have occurred 5 to ten years earlier and I had no knowledge of how such patients had been managed at this time.

51. Do you consider that greater efforts should have been made to inactivate viruses in blood or blood products prior to 1980? If so, who should have made or coordinated those efforts and what steps should have been taken and when? If not, why?

51.1 This is a question which requires specialist knowledge (which I do not possess) to answer.

Section 4: Treatment of patients at the Centre

Provision of information to patients

52. What information did you provide or cause to be provided and/or what information was (to your knowledge) provided by others at the Centre, to patients with a bleeding disorder:

a. about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates), prior to such treatment commencing?
b. about alternatives to treatment with factor concentrates?
c. before they began home treatment/home therapy?

Please detail whether and if so how the information provided to patients changed over time.

52.1 I do not remember what information was provided to patients at the Centre.

HIV

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

53.1 I do not remember the specific timing of going public about HIV at the Centre. There was a swirl of information in Haemophilia circles, the media and general public from 1984 onwards.

54. Please describe how and when you learned that patients under your care had been infected with HIV. How was the testing of patients arranged and by whom was it undertaken?

54.1 Dr Jones was very early in taking the HIV pandemic extremely seriously from the earliest time it was recognised in 1984 that we had a real problem about to engulf us. He undertook

the initial counselling very seriously. I do not remember when the first definitive testing became available in Newcastle.

55. *How, 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 telephone? Were they seen individually or in groups?*

55.1 I was not involved in informing patients at the Haemophilia Centre whether they were HIV positive or negative. My recollection is that sensitive information was not communicated to Patients or their relatives by letter or telephone. Patients and their relatives would have been told individually and in person.

56. *What information was given to them about the significance of a positive diagnosis? Were they told to keep their infection a secret? What information was provided about the infection, prognosis, treatment options and management?*

56.1 I do not have this information

57. *What, if any, arrangements were made for pre-test counselling and for post-test counselling?*

57.1 I did not perform pre or post test counselling. I do not remember what arrangements were in place to perform this.

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

58.1 I did not provide information to partners or family about HIV and I cannot remember what Dr Jones' policy about this was.

59. *What, if any, information or advice did the Centre provide to partners or family members of people that were at risk of infection with HIV or were infected with HIV?*

59.1 I do not remember what information or advice the Centre ie Dr Jones and Sister Fearns provided to partners or families at the Centre.

60. *How many patients at the Centre 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?*

60.1 I do not have these figures.

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

61.1 I did not take part or have knowledge of any look back exercise undertaken at the Centre to try and establish when sero-conversion occurred.

62. To the best of your knowledge, how many partners (or other family members) of patients became infected with HIV? (The enclosed letter from Dr Jones dated 13 February 1987 [HSOC0004704] suggests that as at that date the Centre was aware of three female partners becoming infected).

62.1 I was not involved with contact tracing of patients attending the centre who had received potentially contaminated product along with their families and sexual partners. I have no reason to dispute Dr Jones's figures.

Hepatitis B

63. Were patients infected with HBV informed of their infection and if so how? What information was provided to them about the infection, its significance, prognosis, treatment options and management?

64. How many patients at the Centre were infected with hepatitis B?

64.1 All infections with Hepatis B occurred in the Haemophilia Centre's patients before I was appointed in 1978. It is my understanding that whenever a patient was found to have Hepatitis B they would have been informed of their infection and immunisation of family members and sexual partners offered. Very few of the Centre's patients were infected with Hepatitis B and I do not remember managing any.

NANB Hepatitis/HCV

65. Were patients infected with NANB hepatitis informed of their infection and, if so, how? What information was provided to them about the infection, its significance, prognosis, treatment options and management?

65.1 Patients with NonA nonB hepatitis had all become infected before my appointment in 1978. During the years of my appointment I was not aware of any patient who became infected with what was later identified as Hepatitis C. My understanding is that at the time of acute infection if they were symptomatic they would have been counselled and told of the diagnosis. Many would have been asymptomatic and only learnt of their diagnosis when the

problem of abnormal liver function began to be addressed in the mid 1990's after the HIV epidemic had settled and we had a treatment for the HIV virus (1995 and later).

66. *When did you begin testing patients for HCV? How, when and by whom were patients informed of their diagnosis of HCV? Were they told in person, by letter or by phone?*

66.1 The HCV virus was first isolated in 1989 and it took several years before reliable testing was established in Newcastle. Anyone found to be Hepatitis C positive would have been counselled before the test was carried out and the positive test discussed with them in person at a follow up consultation. No staff were authorised to communicate sensitive information by telephone.

67. *Please describe the process of testing patients for HCV. 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?*

67.1 I do not remember the details of going through the records of those who had received therapeutic concentrates at the Centre but all details pertaining to the use of concentrates would have been stored in the Centre's computer data base. I do remember one patient who had only received one treatment many years previously that he had forgotten about. After the patient had been asked to attend the centre by letter, counselling would have occurred and blood taken for sending to the virology laboratory after they had given their consent.

68. *What information was provided to patients infected with HCV about their infection, its significance, prognosis, treatment options and management?*

68.1 Once a patient had been identified with Hepatitis C they would be contacted and seen in clinic with a nurse in attendance. It would have been explained that the reason for the consultation had resulted from identification of some abnormal blood results involving liver function and that I was concerned these may have been caused by infection from a blood product. There would be a complete medical history obtained and a full clinical examination. It would be pointed out that the progression of abnormal liver function tests would not necessarily result in overt liver problems for many years and particularly so if they abstained from or at least drastically decrease their alcohol intake. Interest was taken in drug histories and any abuse detected addressed. It was emphasised that there was need for sustained follow up and as treatments for elimination of the virus with interferon and ribaverin became available the chance of success in the light of the different strain of Hepatitis C found to be present discussed. Follow up appointments every 4 months were instigated. Because of the risk of transmission by sexual intercourse the use of condoms was recommended and testing would be available for partners if they wished.

69. *How many patients at the Centre were infected with HCV?*

69.1 I do not know how many patients were infected with Hepatitis C.

Delay/public health/other information

70. 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.

70.1 As far as I remember the results were notified to patients at their follow up consultation when the results would have been discussed. All results returned on patients were reviewed by nursing staff and problems identified for dealing with medical staff if appropriate. If an abnormal result was identified the patient would if necessary be recalled to an earlier clinic than scheduled. At times there were difficulties at the laboratory end when early viral identification and viral load tests were being developed and evaluated. This led to inevitable delays but such delays would be discussed with patients and communicated to them when available.

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

71.1 All patients with these viral infections were counselled about safe sex (condoms were provided), patients were advised not on any account to share needles. They were counselled about needle exposure and disposal in provided sharps boxes which should be returned to the Centre when full but not to overfill. Patients were asked not to share razors or toothbrushes. These messages were constantly reiterated along with the need for scrupulous personal hygiene. The nursing staff provided advice and help with regard to accidental needle stick injuries of family members, blood or concentrate spills and the disposal of blood soiled material and they were always available for advice. Questions about fertility were addressed and close liaison with obstetricians maintained . An orthopaedic and general surgeon was identified who would be willing to advise and operate on infected patients. Immunisations as appropriate were administered subcutaneously by experienced nursing staff. (Intramuscular injections in Haemophiliacs are contraindicated.) A liaison psychiatrist was also available.

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

72.1 Patients with AIDS can be plagued by Candida (thrush) herpes and chronic diarrhoea in addition to a wasting state often associated with atypical mycobacteria. Dietary advice is needed . There is great need to be careful in handling young children and gloves would be provided on occasion. Any pregnant family member needed specialist surveillance and attention paid to the possibility of vertical transmission to the child and advice about breast feeding. This was undertaken by Dr Snow the Infectious Diseases physician.

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

73.1 Both HIV and Hepatitis C are transmitted by sexual intercourse, both anal and vaginally. As such counselling about safe sex and the willingness of the centre to provide intermittent viral assessment of partners was offered. There is a possibility of transmission by oral sex and this practice had to be carefully explored . The sharing of needles and concentrates were specifically prohibited .

Consent

74. How often were blood samples taken from patients when attending the Centre and for what purposes? What information was given to them about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of those samples? Was their consent recorded and, if so, how and where?

74.1 Blood samples were taken as necessary with a laboratory form filled in by the requesting doctor. The reasons for testing would be varied, such as establishing a primary diagnosis or monitoring of response to therapy or monitoring disease progression. The reason for undertaking the investigations would be discussed with the patient and the blood taken by the nursing staff who always checked for consent and sent to the relevant laboratory. No blood was ordered by me to be stored in the department. If the nurse was concerned that proper consent to testing had not been clearly obtained the requesting doctor was summoned to put things right. I cannot remember where details of consent were recorded.

75. Were patients under your 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?

75.1 No. I do not remember specific instances relating to treatment of patients but it was always my policy to discuss the needs for treatments with patients and what such treatments would be and obtaining their consent before starting treatment. Records of consent would be in the patient's record.

76. 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?

76.1 No. The nursing staff were responsible for taking blood from our patients. They were meticulous in ensuring patients who gave specimens for HIV and Hepatitis diagnosis and monitoring and liver function tests for instance gave their consent as per protocol. I would expect they recorded such in the nursing record. I myself would always tell patients why we

were taking blood- this was particularly relevant with regard to checking alcohol levels from time to time.

PUPS

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

77.1 I dislike the use of the term PUPs which to my mind objectifies patients. I was not involved in the selection of Factor therapy for any previously untreated patient.

78. Did you use the term PUP or PUPS when speaking about or referring to any of your patients? If so, what did you mean by the use of the term?

78.1 No.

Treatment of patients who had been infected with HIV or Hepatitis

79. How was the care and treatment of patients with HIV/AIDS managed at the Centre? 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/their parents 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?

79.1 Surprisingly perhaps for what was such a horrendous experience I can remember nothing about my involvement with caring for and treatment of HIV/AIDS as managed at the Newcastle Haemophilia Centre in the years 1984 to the early 1990s.. The major burden of caring for the upwards of 80 horrendously ill patients and the support needed for their families would have been shouldered primarily by Dr Jones the Nursing staff and the Social worker although I am sure I did contribute.

80. The Inquiry understands that in 1987 a Clinical Care Group was set up by Dr Jones and Dr Mike Snow (a consultant physician), involving monthly meetings of clinicians involved with the care of patients with HIV infection and AIDS in the Newcastle District Health Authority area. Please set out what you can recall about this group.

80.1 I do not remember meetings of a Clinical Care group in 1987. Cooperation with Dr Snow who worked at the Newcastle General Hospital some 15 minutes across town was close . He and his staff were even busier than we were .I suspect that the Group was mainly concerned with the mechanics of setting up participation in the Concorde trial.

81. *The enclosed letter dated 17 February 1986 from Dr Jones (copied to you) to Dr Wright, Public Health Laboratory Services, [DHSC0002295_009] refers to a third case of lymphoma in one of the Centre's immunosuppressed haemophilic patients that year and states that "the extent of the disease here is now so great that we can no longer cope, in the sense that we have no time to do the fundamental work necessary to try to find out why we have proved so vulnerable". Please set out what you can recall about the extent of the disease at the Centre and the effect on the Centre's ability to cope. What was your understanding of Dr Jones' reference to "the fundamental work necessary to try to find out why we have proved so vulnerable"? Was this "fundamental work" carried out and, if so, what did you find out?*

81.1 I do not remember reading this letter. The excerpt captures the overwhelming sense of despair the tsunami of HIV was causing in the Haemophilia Centre. I do not know what fundamental work Dr Jones is referring to.

82. *How was the care and treatment of patients with HBV managed at the Centre? 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/their parents 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 HBV?

82.1 I do not remember having any Hepatitis B patients.

83. *How was the care and treatment of patients with NANB hepatitis managed at the Centre? 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/their parents 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 NANB hepatitis?

83.1 The care and treatment of NonA NonB Hepatitis is considered in the next paragraph as this condition is caused by Hepatitis C. The Hepatitis C virus was discovered in 1989 and it came to be recognised that this virus was the cause of NonA NonB Hepatitis which was, after recovery from the initial infectious phase of acute jaundice usually completely asymptomatic and diagnosed presumptuously by the recognition of persistent abnormal liver function tests. The infection of our patients with Hepatitis C occurred before I was appointed in 1978 and there was no evidence of acute Hepatitis C infection occurring after that date. I remember entries into the notes documenting in patient care on the general medical ward which later became the dedicated Haematological ward for management of

acute jaundice. It took a few years before the Newcastle Public Health laboratories had developed a reliable means of identifying the virus in our NonA NonB patients .

84. *How was the care and treatment of patients diagnosed with HCV managed at the Centre? 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/their parents 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 HCV?*

84.1 I undertook the management of patients with Hepatitis C at the Centre calling on my gastroenterological colleagues for advice where appropriate. I do remember managing an episode of liver decompensation with Dr Mansfield one of the hospitals gastroenterologists in our outpatient setting. About two years before my retiral I was able to establish a joint clinic with a newly appointed Infectious Disease Physician with special interest in HIV and Hepatitis C infection who came across town from his hospital to the Centre once a week. One patient was referred to Freeman Hospital for consideration of a liver transplant and one to Birmingham for a liver transplant. The mainstay of treatment for Hepatitis C infection is to slow disease progression by emphasising to patients the catastrophic effects of alcohol upon disease progression. Alcohol consumption was certainly a problem in many of our patients. The other finding was a high incidence of dihydrocodeine and Tramadol usage (both opiates) which needed addressing. The use of Interferon and Pegylated interferon and ribaverin in attempts to clear the virus was undertaken in several patients with limited success and unfortunately several instances of failure associated with horrendous reactions. One of the unexplained features of interferon therapy in our Haemophiliacs was their propensity for side effects of treatment which was usually tolerated by our Haematology patients well. Indeed I remember arranging at the patient's request a liver biopsy in one Haemophiliac in the radiology department so we could establish the severity of his liver disease in order for him to come to an informed decision about undertaking therapy. Hepatitis C patients were followed up on a 4 monthly rolling programme unless there were problems when they could attend the Centre directly. The risks and benefits of using interferon based treatments always explained at length by me and our caring nursing staff. I retired in 2002 before any other eradication treatments became available.

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

85.1 I do not remember being involved in the care of children with HIV or Hepatitis C.

86. *What involvement did you, or patients at the Centre, have with clinical trials in relation to treatments for HIV and/or HCV? Please provide full details. Please include (a) a discussion of*

the trial referred to in the enclosed letter from Dr Jones to Dr Weller dated 7 December 1988 [MRCO0000346_096] and (b) a discussion of your involvement in the Concorde trial of Zidovudine.

86.1 Although I was a named investigator for this trial I do not remember anything about it although as outlined in the letter I obviously participated. I do not remember discussions about trials for AIDS and remember nothing about the mechanics of the Concorde trial other than we at the Centre participated. I do remember the sense of utter dismay when attending the meeting in London in 1993 (I think) when the negative results of the trial were presented.

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

87.1 I think there may have been delay in receiving approval for using Pegylated interferon for HCV patients.

88. The enclosed letter from Dr Jones dated 13 February 1987 [HSOC0004704] suggests that work needed to be undertaken to Ward 13 to create additional facilities for patients. The letter states that the consultants would raise the finances required if they were not available through the NHS and that if they had to go to public appeal "we would go to appeal for immune-compromised or bone marrow failure patients, not AIDS patients". Please set out what you can recall about this, whether the funding for this work was available through the NHS, whether the consultants had to raise funding separately and, if so, what steps had to be taken to raise the funds.

88.1 I do not remember the letter or specific circumstances alluded to. I do remember that through my contacts with British Nuclear fuels at Seascale I was able to accept a substantial donation of £60,000 from their charitable trust and furnish a cubicle on our haematology ward for bone marrow failure patients which could be used for AIDs patients if needed.

89. What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support? What kind of counselling, if any, was made available to patients at the Centre?

89.1 I do not remember the formal arrangements for counselling, psychological support or social work support. If I identified a need during a patient consultation I would with their consent discuss the need at the Wednesday morning review meeting or mention it directly to the Social Worker.

90. How did the Centre use the £60,000 that was allocated by the Department of Health and Social Security to each Haemophilia Reference Centre to help with counselling of patients infected with HIV?

90.1 I remember nothing about this grant or how it was used.

91. The enclosed BMJ paper (co-authored by you) entitled 'AIDS and haemophilia: morbidity and mortality in a well-defined population" (published on 14 September 1985, [WITN3901009]) stated that "The resources devoted to counselling and laboratory support in centres treating people at risk and their families need to be urgently reassessed". Did any such urgent reassessment of resources take place and, if so, what was its outcome?

91.1 I remember nothing about this urgent reassessment.

Research

92. Please list the research studies that you were involved with during your time as consultant/director at the Centre. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, 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 (or their parents) informed consent; and
h. provide details of any publications relating to the research.

92.1 I cannot remember the different research studies undertaken at the Centre and have kept no record of any of the papers published.

93. What do you understand to be the ethical principles that should guide research? Did you apply those principles to the research studies referred to above and if so, how? If not, why?

93.1 The National Institutes of Health sets out seven main principles to guide the conduct of ethical research: Social and Clinical value, scientific validity, fair subject selection, favourable risk-benefit ratio, independent review, informed consent and respect for participants. As I cannot remember the different research studies I cannot comment further.

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

94.1 Clinicians involved with Clinical research have always I hope had respect for patients. The rights of patients who did not wish to participate in research studies would have been respected. I do not remember whether Consent was specifically asked for, granted or recorded.

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

95.1 I have no knowledge to be able to answer this question.

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

96.1 I was not involved with providing patient data to the UKHCDO or Oxford Haemophilia Centre. I cannot remember sharing any patient data with any third parties.

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

97.1 See above Para 92.

98. The enclosed BMJ paper (co-authored by you) entitled 'AIDS and haemophilia: morbidity and mortality in a well-defined population" (published on 14 September 1985, [WITN3901009]) refers to a study of 143 multi-transfused patients. Please explain how this study was undertaken and whether the patients were aware of, and had consented to, their involvement.

98.1 I remember nothing about the planning, collection of data, the writing of this paper or the need for consents. I do not know if the Newcastle Ethical Committee had been involved with the study.

Records

99. What was the Centre's policy or practice as regards recording information on death certificates when a patient had been infected with HIV or hepatitis? At the 8th meeting of the UK Regional Haemophilia Centre Directors Committee on 10 February 1992 [HCDO0000443], you are recorded as stating that there were "good relationships with the Coroner in the Newcastle area; they never put HIV on the certificate but they made sure that the Coroner knew about it". Please explain the practice that you were referring to, how you "made sure that the Coroner knew about it", why you never put HIV on the certificate and what discussions were held with the families of deceased patients about this issue.

99.1 The death certificate is a public record. Because of the considerable stigmatisation of patients with Haemophilia and acutely in those with HIV and its association in the public mind with Homosexuality it is my recollection that Dr Jones had come to an accommodation with the Newcastle Coroner to refrain from writing HIV/AIDs on the Death Certificate. It was made clear that there was further information available to the Coroner if he/she wanted it by ticking an appropriate box. I seconded such an approach. In all cases I dealt with the way the death certificate was handled meant that the grieving relatives were consulted as to what we proposed to record. Not all coroners allowed this practice without discussion. On one occasion It took some persuasion I remember not to open an inquest in to the death.

100. What were the retention policies of the Centre in relation to medical records during the time you were director?

100.1 The Trust will have had a policy with regard to record storage and retention. Our administrative assistant would have been familiar with it.

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

101.1 I did not keep separate files on patients.

102. Did you keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere other than the Centre? If so, why, what information and where is that information held now?

102.1 I did not keep patient records at home. I would take patient records from the Centre to my office in the Haematology Department for dictation which would then be returned with a tape to the Haemophilia Centre.

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

103.1 No. I do not currently hold any information regarding patients.

Section 5: Treloar's

104. *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.*

104.1 I had no involvement.

105. Did you recommend that patients under your care attend Treloar's? If so:

a. How many patients did you recommend or refer to Treloar's?
b. What prompted the recommendation(s)?

c. *What involvement did you have in the arrangements for them to attend Treloar's?*
d. *What involvement did you have with the ongoing care and treatment of boys attending Treloar's?*

105.1 None.

106. 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.

106.1 I do not know of any.

107. As far as you are aware, were the pupils at Treloar's treated differently to other people with bleeding disorders? If so, in what respects and why?

107.1 I do not know.

Section 6: Self-sufficiency

108. In December 1974 the Department of Health announced additional funding with the primary aim of making the NHS self-sufficient in Factor VIII blood products within two to three years. Were you aware of this announcement at that time? What role, if any, did you play in any arrangements made at the Centre or within the northern region, in response to that announcement?

109. What did you understand the term "self-sufficiency" to mean? In particular, did you understand it to mean self-sufficiency in providing Factor VIII blood products prophylactically, or solely in response to bleeding incidents? Did your understanding of what "self-sufficiency" meant change at any time? If so, when and why?

110. What was your understanding of how others defined "self-sufficiency"? Please answer by reference to (i) those involved in the supply of plasma, (ii) those involved in the production of blood products, (iii) clinicians prescribing blood products, (iv) patients using blood products (and their families), and (v) those responsible for managing relevant health authorities and bodies. What, if any, efforts were made to ensure that all of the groups mentioned above shared a common understanding of what "self-sufficiency" meant?

111. How were estimates made of how much Factor VIII blood product would be required for use in England and Wales?

a. *What was your role in making such estimates, and how did this change over time?*
b. *What was the role of UKHCDO and how did this change over time?*

c. *What assumptions would underpin the estimates (including assumptions as to how the blood products would be used)?*
d. *How would the estimate be made (e.g. by whom were they made, when and through what process)?*
e. *How were the estimates shared with other interested parties?*
f. *How did any of these processes change over time?*

112. *How were annual figures derived for how much Factor VIII blood product had been used over the course of a year?*

a. *What was your role in providing such figures, and how did this change over time?*
b. *What was the role of UKHCDO and how did this change over time?*
c. *How would the calculations be made (e.g. by whom were they made, when, through what process and using what data)?*
d. *How were those figures broken down geographically (e.g. by country, region or any other unit)?*
e. *How were the figures shared with other interested parties?*
f. *How did any of these processes change over time?*

113. *Were there significant differences between the estimates that were made and actual use? If so, why?*

114. *To what extent, if at all, did England and Wales (in your view) achieve self-sufficiency of Factor VIII blood products? Why, if this is your view, was self-sufficiency not achieved? Do you consider that more could have been done to achieve self-sufficiency and if so what?*

115. *Do you consider that there was a failure by haemophilia clinicians to provide timely and accurate estimates of future demand for Factor VIII blood products and/or a failure by haemophilia clinicians to identify the foreseeable increase in use of such products once they became available?*

116. *If self-sufficiency had been achieved in Factor VIII products, what, in your view, would have been the effect on the numbers of patients infected with (i) HBV, (ii) HCV, and (iii) HIV. Please comment on when self-sufficiency would have needed to be achieved (in your view) in order for any material difference to have been made in respect of each of these viruses.*

117. *To the best of your knowledge, did England and Wales achieve self-sufficiency in respect of Factor IX blood products?*

118. *If self-sufficiency in respect of Factor IX blood products was achieved, did you nonetheless use commercially produced products in preference to domestically produced products? If so, why?*

118.1 I was not involved in Haemophilia Care before 1978 and have no knowledge of the intricacies of self-sufficiency.

119. *Enclosed is a 1981 letter from Dr Lane of BPL to you and other reference centre directors [BPLL0002079] which referred to a meeting in Glasgow at which doubts having been expressed*

about BPL's "ability, capacity and intent to make up lost production caused by a difficult period of refurbishing" and referring to an anticipated "second period of disruption in order that capacity to manufacture factor VIII will be doubled by the end of November 1981". Please set out what you can recall about this issue. Did you have concerns about BPL's capacity and, if so, what?

119.1 I do not remember this letter and I knew nothing about the inner workings of BPL.

120. You attended a joint meeting of representatives of Haemophilia Directors, Blood Transfusion Service Directors and DHSS on 15 September 1981 [CBLA0001448]. What can you recall about that meeting and, in particular, the discussions about requirements for cryoprecipitate?

120.1 I do not recall attending this meeting or discussing cryoprecipitate requirements.

Section 7: Blood services

121. Please outline the interactions and dealings you had with the blood services, whether on a regional or national level, in your capacity as director of the Centre.

121.1 As a Consultant Haematologist in administrative charge of the Haematology Department I was responsible for the hospitals blood bank and transfusion services. My role as a Haemophilia Centre Co- director did not include any further responsibilities or contact with transfusion centres.

122. What if any consideration was given to increasing production of cryoprecipitate, or producing a product with lower risk, in response to the risks associated with factor products, and what, if any, involvement did you have with any blood service (regionally or nationally) in relation to this?

122.1 I cannot remember being involved in any discussions relating to the increasing production of cryoprecipitate or any other product to lower risk.

123. What if any discussions or meetings or interactions did you have with any blood service (regionally or nationally) in relation to: the risk of infection with hepatitis from blood products; the risk of infection with HIV/AIDS from blood products; and the steps to be taken to reduce the risk of infection?

123.1 I do not remember any discussions, meetings or interactions with the blood transfusion services about the risks of potential/actual risk of infectivity of blood products.

124. What if any involvement did you have with any decisions or actions taken by any blood service (regional or national) in response to the risks arising from blood and blood products?

124.1 I was involved in several of the BTS's look back exercises where the local BTS provided us with numbers of individual blood product supplied to our laboratory. We had to identify patients in the hospital who had received the product from inspection of the laboratory transfusion records and the patients hospital notes. The results of such searches were transmitted to the local BTS who were then responsible for dealing with it.

125. Please consider the enclosed letter dated 11 November 1993 from you to Mr Bradbeer [NHBT0005291_002]:

a. What were your roles and responsibilities as the "Consultant in Administrative Charge of Blood Bank" at Victoria Royal Infirmary and over what period did you undertake this role?

b. What if any involvement did you have as regards the transfusion of blood (as distinct from blood products) to patients at the hospital?

c. In this letter you stated that "although there is a 'test' which could improve the safety of the blood issued in my name it appears that for financial reasons in this country it has been decided not to use it". Please explain the concerns which led you to write this letter and how, if at all, they were resolved.

125.1 I became Consultant in administrative charge of the Hospital Blood bank when Professor Walker the previous head of the Haematology retired circa 1983. I relinquished the role circa 2000.My role was that of Clinical Governance ensuring satisfactory quality assurance and that the laboratory staff operated to the established protocols. I was assisted in this role by an experienced Clinical Staff Grade, Dr Vona Ellis. After she retired Dr Joan Fitzgerald a BTS Consultant provided the Infirmary with two sessions per week worked for several years. After she moved on, the BTS provided a named liaison consultant Dr Catherine Chapman. We were then able in the late 1990's to develop through a Transfusion Committee a Maximum Blood Order Schedule for different users of Blood Products . This was aimed at establishing with the different clinical services throughout the Hospital what were agreed reasonable maximum amounts of blood to be crossmatched and provided for different procedures undertaken. This action resulted in more effective use of blood throughout the hospital and reduced wastage. The Hospital Blood Bank issued compatible blood for Transfusion, issued Frozen Fresh plasma and cryoprecipitate as required per the request of the clinician ordering it. All such products were supplied by the BTS who were responsible for its safety. The blood bank was not involved with the issue of Factor Concentrates. The letter cited to Dr Bradbeer enclosed a letter from Dr Hugh Lloyd the chief executive of the local blood transfusion centre telling me that the Blood Transfusion Service was not testing for Hepatitis Core antibody on instruction from the department of health during 1993/4. As such blood for transfusion was being issued that was not as safe as it could be. As Consultant in administrative charge of the blood bank I was charged with issuing safe blood product for the hospital which I could no longer guarantee.

126. *In February 1995 you wrote to Dr Robinson of the National Blood Authority [NHBT0006070]) referring to your "agitation to have blood as safe as possible for donors". Please explain what prompted that letter and the nature of your concerns.*

126.1 This letter would suggest that the Blood Transfusion service was still not testing for Hepatitis B core antibody in 1995 being prevented from doing so by central authority. The transfusion Service was not testing for HTLV-1 and there had been concerns that the Transfusion Service had delayed introduction of Hepatitis C testing.

127. *In November 1997 you wrote to Dr Robinson of the National Blood Authority [NHBT0007029] about viral safety issues, in which you wrote that "There is no way the Purchasers are going to bail us out and the only answer is to buy the cheapest products which of course come from abroad. We will be sticking with old-fashioned FFP too as no Purchaser here is convinced that the extra expense is worth the health gain of using 'newer safer products'". Please explain what prompted that letter and the nature of your concerns. Did you consider that Dr Robinson's response of 22 December 1997 [NHBT0000731] sufficiently addressed your concerns? Please explain your answer.*

127.1 I have no recollection of writing to Dr Robinson in 1997 and the letters cited are muddled up. However, reading the letters it is clear that as a budget holder I am concerned that the BTS is unable to provide blood products that are cheaper than similar commercial products. I mention that because of the Purchaser/provider split in the health service and that in view of the hospital overspend, the purchasers who fund our hospital are only interested in purchasing the cheapest products which unfortunately come from abroad. Her response to me that as a non-profit organisation that they have to balance their books. As such they cannot compete with the costs of multinational corporations manipulating the market for blood products.

Section 8: UKHCDO

128. *Please describe your involvement with UKHCDO (including any of its working parties, committees or groups) and the dates of your involvement.*I was a member of the UKHCDO from 1978 to 2002.

128.1 I was not as I remember a prominent contributor to the meetings and played no role in any working parties or sub groups.

129. *During the period that you were involved with UKHCDO, please outline:*

a. the purpose, functions and responsibilities of UKHCDO, as you understood them;
b. the structure, composition and role of its various committees or working groups;
c. the relationships between UKHCDO and pharmaceutical companies;

d. *how decisions were taken by UKHCDO;*
e. *how information or advice was disseminated by UKHCDO and to whom;*
f. *any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to: the manufacture, importation, purchase, selection or use of blood products; alternative treatments to factor products for patients with bleeding disorders; self-sufficiency; the risks of infection associated with the use of blood products; the sharing of information about such risks with patients and/or their families; obtaining consent from patients; heat treatment and other measures to reduce risk; vCJD exposure; and treatments for HIV and HCV.*

129.1 I do not remember the purpose functions and responsibilities of the UKHCDO and in particular the relationship between UKHCDO and the pharmaceutical companies. I do not remember how decisions were taken; how information or advice was disseminated. I do not remember being involved in any decisions made by the UKHCDO.

130. 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 your answer to any of the above questions is Yes, please provide details.

130.1 I do not remember providing any advice or consultancy services to any pharmaceutical company involved in manufacture or sale of blood products nor have I ever received financial incentives to use, prescribe supply administer recommend buy or sell any particular blood product. I have not undertaken medical research for or on behalf of such companies.

131. What regulations or requirements or guidelines were in place during your employment concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take to comply with them?

131.1 I do not remember any declaratory procedures in place in my hospital.

132. 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?

132.1 I did not receive funding from pharmaceutical companies to fund medical research.

Section 10: vCJD

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

133.1 I would have been made aware of vCJD potential contamination of concentrates in 1997 when Sister Fearns discussed the problem with me.

134. How and by whom were decisions taken as to the information that should be provided to patients about vCJD and as to any steps which should be taken in relation to patients and their care and treatment?

134.1 I do remember that advice from the Lothian Ethical Committee was that patients should not be informed that the product had been recalled for this reason (vCJD). Both Sister Fearns and myself were very unhappy about this advice because it was our policy to be honest and open with our patients. I wrote to several people expressing my concerns.I am afraid I do not now remember why The Lothian Health Board were involved at that time.

135. What was the process at the Centre for informing patients about possible exposure to vCJD?

135.1 In the centre, against our better judgement, we followed the advice issued which was to be economical with the truth in telling the patients why the product was being recalled.

136. How and when were patients first told of possible exposure to vCJD? What subsequent notifications were provided to patients?

136.1 I remember having to deal with patients concerned about being infected with vCJD in or about January 2001. When I went into the Haemophilia Centre I was told that the telephone had been ringing non-stop, with queries about whether any Newcastle Centre patients had received the implicated concentrates which might transmit vCJD. I wrote a letter to all patients explaining the situation. (NTHT0000006-002) and they were invited to attend the Centre and discuss the possible problem with myself and Sister Fearns in attendance.

137. What information was provided to patients about the risks of vCJD?

137.1 I remember I was given a letter listing the products and the 48 patients who had been treated with the previously recalled therapeutic concentrate. That letter does not seem to have been found by the Enquiry. As far as I remember this letter also advised that this information was being sent out by the Chief Medical Officer in the interests of transparency, for information. It did not contain any advice as to the significance of the potential contamination for the patients or their families. The letter emphasised that there was no way of detecting the infectious agent or prion in the potentially contaminated units of concentrate nor in the recipient who may or may not therefore have been contaminated.

138. What counselling, support and/or advice to be offered to patients who were informed that they might have been exposed to vCJD? (You may wish to refer to the enclosed letter dated 22 January 2001 from you to patients [NTHT0000006_002]).

138.1 The urgency of dealing with extremely worried patients and their families demanding they be told if they had been potentially contaminated was obviously acute and very stressful for all our Centre Staff. In consultation with the nurse specialist Sister Fearns, I decided that we would not tell patients by phone whether they had received the batches or not. We were determined to avoid potentially stigmatising patients. Instead anyone who contacted the Centre was offered a consultation with Sister Fearns and myself, whether they had received one of the contaminated units or not to discuss their worries. It was emphasised to all centre staff that the results should not be communicated by phone and a letter would be sent out arranging the consultation (NTHT000000-002).There was no concrete information available to either Haemophilia Staff or for patients at this time and the Hospital Control of Infection who were contacted on several occasions had no useful information either. Patients do not like uncertainty and the importance of dealing with potentially devastating news in the Haemophiliac population who had already had to deal with HIV and Hepatitis C presented an interesting challenge. No definite facts were available and there was no test available to determine whether a patient was incubating vCJD in their body or whether the implicated units were actually infected. As far as I remember (the story may have changed later) there was no evidence that vCJD had ever developed in a potentially contaminated patient who had received blood from a donor who subsequently went on to develop encephalopathy. Furthermore In preparing blood products from donor blood the white cells likely to contain the prion in highest concentration are removed . I had also consulted the internet and found a couple of papers which suggested that the fraction of blood processed to make therapeutic concentrate was unlikely to contain the prion. Because vCJD is a risk for the whole British population who had ever eaten beef we have all been living with the threat of developing vCJD so it came down to a question of relative risk. I thought at this time the relative risk of being contaminated by the blood concentrate was low. There was no need for Haemophiliacs to change their life style (they were already excluded from being blood donors because of their Haemophilia) as they were not infectious to anyone else and somehow they had to accept that this was no more than another nightmare to put behind them. Because all such information was confusing all those counselled were offered a follow up appointment with our nurse specialist.

139. What measures were put in place, from a public health perspective, in relation to the care and treatment of patients?

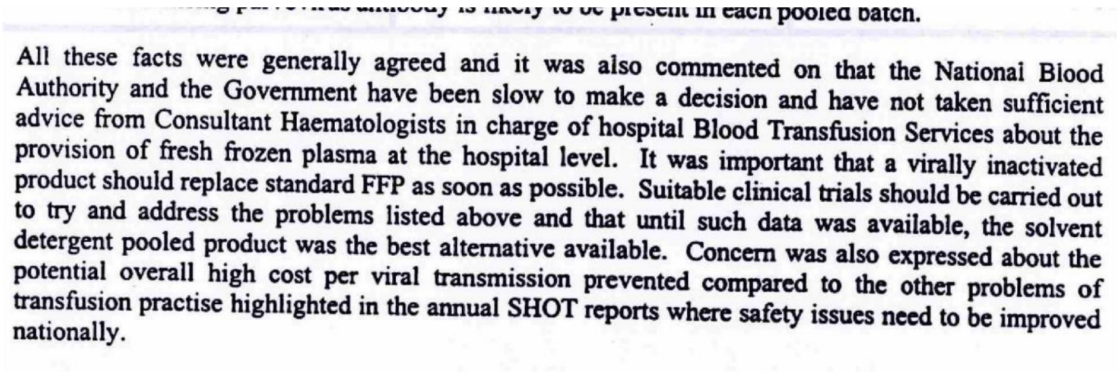
139.1 At this stage no measures regarding public health regarding the care and treatment were put in place. Indeed we were advised this exercise was advisory and in the interests of transparency. The Hospital Control of Infection convened but wanted to see what the National Committees would recommend. It was reported that a Committee arranged by the Department of Health would convene and discuss the matter and issue instructions and advice. This had not materialised before I retired in Autumn 2002.

140. The enclosed letter dated 4 November 1997 from Maureen Fearns to the Haemophilia Society [NTHT0000005_001] expressed concerns about the information to be provided to patients about a product recall (related to vCJD). The letter stated that you were not happy about advice received from BPL. Please set out what you can recall about this issue, what your concerns were and the steps that you took. What information was provided to patients about the product recall, and what was the policy and approach of the Centre generally regarding notification to patients about product recalls?

140.1 I cannot recall at the specific steps I took 23 year ago other than I wrote several letters expressing my disquiet at having to suppress information about possible contamination. Sister Fearns dealt with product recall and would have been open and honest with them about any previous recalls and why the recall was taking place and I know she was very uneasy about dealing with the recall on this occasion.

141. Please describe your involvement in a meeting on 14 January 1999 with other consultant haematologists to discuss the provision of FFP in England and Wales and your involvement in the production of a statement [NHBT0091964] to the effect that a virally inactivated product should be used at all times and that British plasma should not (because of doubts over vCJD transmission) be used for the provision of FFP.

141.1 I do not remember my attendance at this meeting. The statement to which I agreed, appended below, would have had my informed consent.



...is likely to be present in each pooled batch.

All these facts were generally agreed and it was also commented on that the National Blood Authority and the Government have been slow to make a decision and have not taken sufficient advice from Consultant Haematologists in charge of hospital Blood Transfusion Services about the provision of fresh frozen plasma at the hospital level. It was important that a virally inactivated product should replace standard FFP as soon as possible. Suitable clinical trials should be carried out to try and address the problems listed above and that until such data was available, the solvent detergent pooled product was the best alternative available. Concern was also expressed about the potential overall high cost per viral transmission prevented compared to the other problems of transfusion practise highlighted in the annual SHOT reports where safety issues need to be improved nationally.

Section 11: Involvement with the financial support schemes

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

142.1 The Social Worker dealt with all applications to the McFarlane Trust and the other funds mentioned. She would ask me for any form filling and signatures needed. I did not have any direct dealings with the trusts mentioned.

143. To what extent did the Centre and its staff (including you) inform patients about the different trusts or funds?

143.1 I would not have discussed applications and disbursement of funds to individuals. The Social worker was very knowledgeable about trusts and funds.

144. Did the Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

144.1 None that I remember. Problems identified would have been referred directly to the Social Worker who attended the weekly Haemophilia Centre staff meeting and was always available in the centre for contact.

145. What kind of information did the Centre (whether through you or otherwise) provide to the trusts and funds about or on behalf of patients who were seeking assistance from the trusts and funds?

145.1 Our social worker was very adept at identifying support schemes for our patients.

146. The Macfarlane Trust wrote to you asking for up-to-date health information in relation to applicants seeking financial assistance (see the enclosed letters to you from the Macfarlane Trust dated 1 October 1996 and 13 May 1998 and the document headed 'Doctor's report', [MACF0000259_086, MACF0000259_106, MACF0000259_107]). How often, typically, were you asked to provide such information to the Macfarlane Trust? The letters stated that the information provided by doctors would not be shared with the patient concerned – did you tell patients that you were providing this information to the Macfarlane Trust? Did you seek your patients' consent to provide the information? Did you provide patients with copies of the information you sent to the Trust?

146.1 I cannot remember how often I was asked to provide up-to date health information to the McFarlane trust. Any letters sent to me by the McFarlane Trust would have been handed to

the Social worker to deal with and she would get me to fill in the form which I would then sign and return to her. Because the social worker was dealing with the applications I was not otherwise involved with the patient's application. All dealings with the McFarlane Trust were then dealt with by the Social worker who was scrupulous about obtaining patients informed consent.

147. *Did the Centre, or any of its staff (including you), act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.*

147.1 This was the social workers responsibility.

148. *Was the Centre or any of its staff (including you) involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.*

148.1 The social worker did all the applications.

149. *In December 1999 you wrote the enclosed letter to Baroness Masham [MACF0000082_008], drawing attention to the impact of co-infection with HCV on the quality of life of the HIV positive haemophiliac. What was your purpose in writing this letter? What, if any, response did you receive?*

149.1 I cannot remember writing this letter or the response if any.

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

150.1 I do not remember any dealings with any trusts or funds of the Haemophilia Centre. These questions should be addressed to the Social Worker and the Nurse Specialist.

Section 12: Other issues

151. *In July 2001 you raised a concern with Karin Pappenheim, of the Haemophilia Society, about prescription charges for haemophilia patients (copy enclosed, [HSOC0013263]). Please explain what prompted you to raise this issue and how (if at all) it was resolved. The letter and her reply are self explanatory.*

151.1 I have no knowledge of whether the long term medical conditions alliance was successful in this campaign.

6. *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. (The Inquiry is aware that complaints were made to the GMC by* GRO-A GRO-A GRO-A

152.1 For the record Mr GRO-A was not one of the Complainants involved with the GMC Complaint regarding my fitness to practice. Mr and Mrs GRO-A on one occasion complained about the phrasing of one of my consultation letters. A meeting with them and the Medical Director was arranged which centred on their objection to my use of the word 'Mission' to describe a visit to a European destination. Otherwise I do not remember any other official complaints.

7. *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.*

153.1 No further observations.

Statement of Truth

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

Signed GRO-C

Dated: 9th October 2020 9th October 2020