Witness Name: Dr Helena Mary Daly
Statement No.: WITN4685001
Exhibits: WITN4685002 – WITN4685007
Dated: 22/3/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR HELENA MARY DALY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 18 November 2020.

I, Dr Helena Mary Daly, will say as follows: -

Section 1: Introduction

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

1.1. Name: Dr Helena Mary Daly, of an address known to the Inquiry

1.2. Date of birth: 1951

1.3. Professional Qualifications:

1.3.1. MB BCh BAO UCD 1975

1.3.2. MRCPI 1978

1.3.3. MRCPath 1982

1.3.4. FRCPath 1994

1.3.5. HDip Healthcare (Risk Management) 2000

1.3.6. FRCPI 2005

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. I qualified as a doctor from University College Dublin in 1975.

2.2. I commenced Haematology training as a medical SHO at St James Hospital, Dublin in 1978. My work involved haemophilia care. This was followed by SHO & Registrar posts in Clinical & Laboratory Haematology at the Meath Hospital, also in Dublin.

2.3. In 1979 I moved to Bristol UK to the South West Regional Health Authority senior registrar training scheme based at the Bristol Royal Infirmary (BRI), which incorporated the Bristol Haemophilia Centre, rotating to Southmead & Frenchay Hospitals, Bristol Children's Hospital & Regional Blood Transfusion Centre. In Bristol I trained in all aspects of haematology, including malignant & non-malignant haematology, bleeding disorders, laboratory work and blood transfusion and studied for the MRCPath examination. Under consultant supervision, I took on day to day clinical care of haemophilia. In my latter years I also attended the Haemophilia Clinic at Bristol Children's Hospital.

2.4. At the request of Professor I J Temperley, Professor of Haematology and National Haemophilia Centre Director and on the advice of the SW Regional Committee for Higher Specialist Training, I undertook a locum Consultant post at Ireland's National Haemophilia Centre (St James and National Children's Hospitals) July-September 1985. This is a large Centre at which 300-400 patients were registered. My main responsibilities were paediatric haematology and haemophilia care. This involved clinical management of inpatient bleeding episodes, (ward) day attenders, providing advice, from a haematology perspective, in relation to surgical procedures (general and dental) and both paediatric and adult outpatient sessions (combined with dental, orthopaedic and social services). Soon after my arrival I was provided with the results of HIV

tests. I set about informing patients with haemophilia of their HIV status and 'counselling' them of the implications (HMD to Mr D Fitzpatrick 1/10/85 [MACK0000394]). My work during this period resulted in my participation in the Lindsay Tribunal 2000.

2.5. In 1986, I was appointed consultant haematologist at Royal Cornwall Hospital Treliske, Truro, Cornwall, and worked there until September 1992. I was involved in all aspects of haematology including malignant & non-malignant haematology, bleeding disorders, haemophilia care of adults and children, laboratory work and blood transfusion. I, together with the paediatrician service, was also involved in shared care of childhood haematology and cancer with Bristol Children's Hospital.

2.6. Royal Cornwall Hospital Trust was the designated Haemophilia Centre for Cornwall and I was appointed Haemophilia Centre Director in December 1987 and managed care of children and adults. At a later point, I held and managed the budget for blood products relating to the Haemophilia Service. I was involved in selection of blood products for treatment of patients with inherited coagulation disorders and surveillance of side effects particularly blood borne infection. I have not been actively involved in haemophilia care since I left in 1992.

2.7. I returned to Ireland in 1998 and have done locum consultant haematology and research posts since that time. I had no further involvement in haemophilia care.

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. Committee membership

AIDS Action Group	1988-1992	I was involved in formulating and co-coordinating the District AIDS Policy and allocating the AIDS budget.
AIDS designated physician	1989-1992	I was nominated AIDS designated physician for Cornwall in 1989 and co-ordinated management of (the small number) HIV infected patients. I was appointed because of my experience in management of HIV infected patients with haemophilia in Bristol and Dublin and experience in treating opportunistic infection in immuno-compromised patients.
Hospital Transfusion Committee	1990-1992	I set up and organised meetings of the Transfusion Committee.
UK Regional Haemophilia Centre Director's Committee SW Regional Representative	1990-1992	

a) The Inquiry is aware of your involvement with the "South West Haemophilia Treaters Group". Please outline the purpose of this group and your involvement with the group. The minutes from the meeting held on 10 May 1991 are attached as a memory aid [TSFT0000001_026].

3.2. South West Haemophilia Treaters Group

3.2.1. The purpose of this group was improvement in haemophilia care within the region. I was one of the initiators of the group and was Chair at one stage.

3.2.2. The regional consultant haematologists met twice a year to discuss matters. There were 8-9 designated Haemophilia Centres in the South West Region including the Regional Haemophilia Centre at Bristol Royal Infirmary/Bristol Children's Hospital. Each had a Haemophilia Centre Director. Each Director also covered laboratory, benign and malignant haematology, blood transfusion and some paediatrics. Where there were two consultant haematologists in a district, one tended to take a lead in haemophilia care and be Director. Sometime in mid-1989, a few of us set up a treaters group within the region to discuss important topics as they emerged.

3.2.3. I found a list of audits undertaken by this group in an old CV from 2001.

June 1989	Truro Care of Haemophilia in the SW Region
Sept 1990	Exeter Haemophilia care in SW Region
May 1991	Bristol Liver disease in Haemophilia
July 1992	Plymouth Care of Haemophilia in SW Region

3.2.4. This reflects the discussions during that period together with a report from the UKHCDO and discussion on product selection. There were similar subgroups for leukaemia and lymphoma care.

4. Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in

relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports which you provided.

4.1. I participated in the Tribunal of Inquiry into the infection with HIV and Hepatitis C of persons with haemophilia and related matters in Ireland 2000-2001 (The Lindsay Tribunal).

4.2. I provided written statements:

4.2.1. Statement of Dr Helena M Daly 18/2/2000

4.2.2. Dr Helena M Daly Supplementary statement Response to Terms of reference 7a) and 8 and to the testimony of patients with haemophilia and their relatives 2/4/2001

4.2.3. Dr Helena M Daly Second supplementary statement – response to extracts from medical records (24 Irish patients) 12/4/2001

4.3. and gave oral evidence based on those written statements on 14 & 15/9/2000 and 3 & 4/5/2001.

4.4. These witness statements were provided to The Lindsay Tribunal in confidence. I do not consent to their disclosure.

4.5. The Inquiry team already has a transcript of my oral evidence 14 & 15/9/2000 No [LIND0000329].

5. **Please consider the evidence that you gave to the Lindsay Tribunal, which is attached to this letter [LIND0000329]. Please confirm whether the contents of the above transcript of oral evidence are true and accurate. If there are any matters contained in the oral evidence that you provided to the Lindsay Tribunal that you do not consider to be true and accurate, please explain what they are.**

5.1. LIND0000329 includes a transcript of my oral evidence to the Lindsay Tribunal 14-15/9/2000 (Phase I relating to the work of the (Irish) Blood Transfusion Board Service Board (BTSB) and decisions they took).

5.2. (Please note: Pages 18-top of 27 and pg. 54-top of pg. 55 of this document relate to the evidence of another witness.)

5.3. I gave evidence under oath which I believed and believe to be accurate.

5.4. There are multiple typographical errors in the transcript included in LIND0000329.

5.5. I do not agree to disclosure of this transcript. The transcript so far as this refers to named individuals should be redacted.

The questions below focus, as appropriate, on your time as a senior registrar in Haematology at the Bristol Royal Infirmary ("BRI") between 1979 and 1985 and Consultant Haematologist, and ultimately, Director of the Truro Haemophilia Centre ("Truro") between 1985 and 1995.

<u>Section 2: Decisions and actions of those treating patients with bleeding disorders at the BRI and Truro and your decisions and actions</u>

6. In relation to your work at the BRI as a Senior Registrar in Haematology please:

a) describe the facilities, organisation, roles, functions and responsibilities of the BRI during the time that you worked there and how they changed over time:

6.1.

Facilities	A well-equipped Haematology laboratory which undertook a comprehensive range of investigations including coagulation.

	Inpatients were cared for in a ward shared within the professorial unit and on other general wards. There was a designated haematology day unit where patients attended for OP chemotherapy, procedures e.g. bone marrow biopsy, treatments of bleeding episodes. Formal OP clinics were held weekly in the OP Dept. Treatment of bleeding episodes outside routine hours was undertaken by the Pathology SHOs (on call rota) in the day unit on a demand basis.
Organisation	Staff included one consultant haematologist, 2 senior registrars, one registrar and 2-3 rotating pathology SHOs. There was a full-time haematology day unit sister, several SRNs and SENs.
Role, Functions & Responsibilities of the BRI	The Haematology department provided a comprehensive 24 hour clinical and laboratory haematology service for the area.

b) describe your role and responsibilities and how they changed over time;

6.2. I did my senior registrar training in the SW Regional Health Authority based at the Bristol Royal Infirmary and rotating to:

Sept 1979 - Dec 1979	Bristol Royal Infirmary

Jan 1980 - Feb 1981	Southmead and Frenchay Hospitals
Feb 1981 - Mar 1981	Bristol Children's Hospital
Apr 1981 - Sept 1981	Regional Blood Transfusion Centre
Oct 1981 - Nov 1983	Bristol Royal Infirmary
Dec 1983 - Jan 1985	Southmead Hospital & BRI
Feb 1985 (secondment)	Honorary Senior Registrar Royal Postgraduate Medical School Hammersmith Hospital London
Mar 1985 - Jun 1985	Bristol Royal Infirmary
Jul 1985 - Sept 1985	National Haemophilia Centre Dublin
Oct 1985 - Jun 1986	Bristol Royal Infirmary

6.3. My responsibility was shared with a second senior registrar and included clinical and laboratory haematology, an on-call service, training junior staff and teaching medical students. As I became more senior, I took on more of the day to day care of haemophilia - investigation and management of patients with inherited coagulation disorders including monitoring for evidence of infection with hepatitis and HIV. I commenced attending Haemophilia clinics with Dr Burman at the Bristol Children's Hospital (BCH) towards the end of my SR rotation.

c) describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products:

6.4. In 1983, one of the patients with haemophilia in Bristol died from AIDS (Daly HM and Scott GL Fatal AIDS in a Haemophiliac Lancet 1983 ii 1190 [PRSE0004509], Carne CA, Tedder RS, Smith A, Sutherland S, Elkington SG Daly HM, Preston FE and Craske J Acute encephalopathy coincident with seroconversion for anti HTLV III Lancet 1985 ii 1206-1208 [SHTM0000645]). He was one of the first patients with haemophilia to do so in the UK. This caused considerable anxiety among patients attending the Centre. I became involved in a great deal of 'counselling' and support of other patients attending the Centre. I undertook the initial 'counselling' of seropositive (and seronegative) patients with haemophilia. I undertook surveillance and immunological evaluation of patients at the Centre who had received the same blood products as the index patient.

d) identify senior colleagues involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products, and their roles and responsibilities during the time that you worked there.

6.5. The Bristol Haemophilia Centre Director was the late Dr G L Scott together with Dr David Burman Consultant Paediatrician at Bristol Children's Hospital (BCH).

7. In relation to your work as a Consultant Haematologist and Director at Truro please:

a) describe the facilities, organisation, roles, functions and responsibilities of Truro during the time that you worked there and how they changed over time;

7.1.

Facilities	A well-equipped haematology laboratory opened in 1986 which undertook a comprehensive range of investigations. There were 25 MLSOs accountable to a laboratory manager. Independent beds were available on an acute medical ward (8 beds including 5 isolation cubicles) for inpatients. One house physician and one SHO provided day to day care for these patients. Many of the nurses had extended training in Haematology. All out-patient activities, including haemophilia care, were held in a purpose-built Haematology Oncology Unit adjacent to the laboratory funded by locally raised funds. The unit was run as a day treatment centre and incorporated an outpatient transfusion room, plasma exchange room, procedure room, treatment room, cytotoxic preparation suite and consultant and nursing offices. Patients attended daily for blood and platelet transfusions, chemotherapy, bone marrow biopsies, factor replacement therapy etc.
Organisation	There were two general Haematology clinics (50 patients) per week, staffed by two Consultants, one staff grade, two clinical assistants and one SHO. Nursing staff included a Clinical Nurse Specialist, Sister, SRN, SSEN, and two SENs.

Role, Functions & Responsibilities	The department provided a comprehensive clinical and laboratory service for a population of 275,000.

b) describe your role and responsibilities and how they changed over time:

7.2. I was appointed as a second Consultant Haematologist at the Royal Cornwall Hospital Treliske Truro in July 1986 to provide a 24 hour clinical and laboratory haematology service. I was appointed Haemophilia Centre Director in December 1987. I took on shared care management of paediatric haemato-oncology with the professor at Bristol Children's hospital together with local consultant paediatricians

c) describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products:

7.3. I developed the Haemostasis/Thrombosis service with a weekly clinic and took on the care and management of children (together with the Paediatricians) and adults with haemophilia including supervision of administration of treatment and monitoring of infection hepatitis B, NANBH and HIV.

7.4. I reorganised the Haemophilia centre. I set up a Coagulation Clinic to investigate all new cases of suspected haemostatic or thrombotic disorders. All severely affected patients or their parents were already trained in self-administration and home therapy.

7.5. After a few years as Haemophilia Centre Director (1988) I was involved in selection of blood products for treatment of patients with inherited coagulation disorders and managed the budget for blood products relating to the Haemophilia Service. I undertook ongoing surveillance of side effects particularly blood borne infection.

d) identify senior colleagues involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of blood or blood products, and their roles and responsibilities during the time that you worked there.

7.6. Dr J S Murrell was head of department until he retired in early 1992 and Haemophilia Centre Director until 1988. He continued to be involved in haemophilia care when on call.

8. In relation to Truro, please refer to the Contract for Provision of Haemophilia Care from April 1991 - Cornwall and Isles of Scilly Health Authority dated 13 March 1991 prepared by you and presented to Mr A Blane [HSOC0017729]. Please confirm what the purpose of this document was. Was a similar document prepared each year and if so please provide copies of earlier and later versions? In the covering letter, you request that Mr Blane confirm whether the policy is acceptable to the "purchasers as well as the providers". Please explain who you were referring to? Why did the policy have to be acceptable to the purchasers as well as the providers?

8.1. I am reminded by the document itself.

8.2. The Haemophilia Society undertook a survey on the provision of haemophilia care proposed by Haemophilia Centres from April 1991.

8.3. In response to their survey, I summarised the care provided at Royal Cornwall Hospital Treliske at that time in accordance with the guidelines of the organisation of Haemophilia Centres (1989). No change was anticipated.

8.4. During my tenure, I believe this was a once off survey. It relates to 29 years ago and I have no such copies.

8.5. The Unit Business Manager represented the provider (in this case the hospital/Trust) and needed to confirm acceptance of the proposed arrangements and to understand the totality of care provided rather than

solely the cost of factor concentrate. I believe the purchaser was the District Health Authority. The purchaser funded the care provided.

9. Approximately how many patients with bleeding disorders were under the care of (a) the BRI and (b) Truro 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).

9.1. BRI

9.1.1. I have no records of the number of patients. The centre was larger than that at Truro and smaller than Ireland (300-400 registered).

9.1.2. In 1984 there were, at least, total 35 patients (28 severe and moderate haemophilia A and severe von Willebrand's disease, 10 mild haemophilia and moderate von Willebrand's disease and 5 patients with haemophilia B) [GLEW0000677].

9.1.3. I don't remember a newly diagnosed patient with severe haemophilia when at BRI but they would have presented to the BCH. A few severely affected patients moved to the area to attend College.

9.1.4. There were many new mild and moderate haemophilia and von Willebrand's disease e.g. in 1983 eleven patients with von Willebrand's disease (Vwd), five with mild haemophilia A, three with moderate haemophilia A and two with mild haemophilia B were identified (total 21). (Daly HM and Wakerley G Experiences in a Coagulation Referral Clinic in Bristol Bristol Medico-Chirugical Journal 1985 1 18-20). In my evidence in 2000 I said there were c. 80 patients in Bristol (pg. 118 [LIND0000329]).

9.2. Truro

9.2.1. I do not know. There were c. 10 severely affected (all haemophilia A) and others with mild/moderate haemophila and Vwd.

9.2.2. One or two children with severe affected haemophilia A were diagnosed when I was Director and one moved to the area from elsewhere. Most new patients had mild or moderate haemophilia or von Willebrand's disease.

10. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by (a) the BRI and (b) Truro, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? What if any involvement did you have in the formulation and application of these policies?

10.1. BRI

10.1.1. The Haemophilia Centre Director Dr G L Scott was responsible for product selection at the BRI and I believe BCH. His policy is described in his letter to me of 29/6/2000 in relation to the Lindsay Tribunal (Letter Dr G L Scott to Dr H Daly 29/6/2000) [WITN4685002]. In my final years at the BRI I discussed products with him particularly heat treatment.

10.1.2. In UK it was considered that commercial non heat treated products of US origin were more likely to transmit infection (HIV and/or NANBH) than non-heat treated concentrates produced from plasma of UK non-remunerated donors because of the greater prevalence of HIV in the US, the greater size of plasma pools used by commercial companies, use of remunerated donors and because the epidemic presented in the US two years earlier that in the UK.

10.1.3. At the HCDO meeting on 17 October 1983 [PRSE0004440] it was advised there was no need to change home therapy to cryo but to continue with BPL and commercial concentrate.

10.1.4. The situation changed when HIV results returned autumn 1984.

10.1.5. In October 1984 the Centre of Disease Control (CDC) recommended a change to heat treated (HT) products and in late 1984 the UK Haemophilia Reference Centre Directors recommended the use of HT products for Haemophilia A but not for Haemophilia B (AIDS Advisory Document 14/12/84 [HCDO0000270_007]).

10.1.6. Some UK Haemophilia Centre Directors felt they should wait until sufficient BPL (UK) HT concentrates were available, stopped using non-HT BPL concentrates in late 1984 and purchased commercial FVIII and/or FIX concentrate of US origin. Some UK patients and doctors were reluctant to use products of US origin even when HT as they had been the cause of the earlier cases of HIV infection in the UK. Experience with HT products was at that time limited.

10.1.7. 1985 was a time of great uncertainty in the haemophilia world with the advent of HIV and possibility of infected concentrates in stock or in use. UK Haemophilia Centre Directors were aware that non-HT factor concentrates were potentially infected with HIV. It was known that HIV was eliminated by HT at temperatures greater than 60°C (Lancet 1985 I 271-2 Rouzioux [SHPL0000371_036]). It was fortuitous that HIV was heat sensitive and that technology being developed to deal with NANBH could be rapidly introduced to inactivate HIV. Cost and uncertainty of the consequences of NANBH had been factors preventing its introduction in the UK prior to that time. Publicity of the widespread concern that HIV could cause AIDS, which was lethal, led to its rapid introduction. Prior to this time, the UK

was self-sufficient in FIX concentrate but not in FVIII concentrate. The deficit was made up by purchase of commercial concentrate of US origin.

10.1.8. In 1985, in UK HT concentrate was considered optimal for all patients with haemophilia. There was a delay in changeover to exclusive use of HT products due to uncertainty, cost and availability. Initially previously untreated patients (PUPS), children and HIV negative patients were prioritised to receive HT products. Some argued HIV positive patients should receive HT to reduce further HIV exposure. The remaining patients were treated with commercial HT concentrate, cryoprecipitate, or non-HT BPL concentrate as there were global supply problems with HT commercial factor VIII concentrate.

10.1.9. BPL introduced heat treated FVIII concentrate in March 1985 and all BPL concentrate was HT by Oct 1985 when the intermediate purity concentrate 8Y (80°C x 72 hrs) became available. HT FIX concentrate (9A) was available at BRI in October 1985. It was introduced later as there was some concern re potential thrombogenicity of heat-treated FIX concentrate.

10.1.10. In June 1985 it was concluded that use of cryoprecipitate and non-HT concentrate was no longer justified (Bloom et al BMJ 1985 290 1901-2 [PRSE0001917]) and that use of cryo could be revisited when HIV donor screening was introduced (October 1985).

10.1.11. The advice changed several times in 1984-1985 until sufficient HT product was available to treat all patients. At all times doctors were encouraged to treat patients with the best available product rather than withhold treatment and risk life or limb threatening bleeding complications. This created a terrible

dilemma for patients and their treaters. Some patients were reluctant to attend the Centre for treatment, some went without treatment and the total amount of Factor concentrate fell for the first time since its introductions. Patients and staff became more discerning in their use of products.

10.2. Truro

10.2.1. Dr J S Murrell, Consultant Haematologist, was Haemophilia Centre Director at Truro when I took up post in 1986. I believe he had made an early decision to change to heat treated commercial factor concentrates prior to availability of UK HT factor VIII concentrates. Only two patients were HIV positive. In view of this he continued with BPL heat treated FVIII concentrate (from April 1985) where available and for children and commercial HT concentrates as insufficient BPL. In October 1985 BPL intermediate purity HT concentrate 8Y became available and this was preferred particularly for children, mildly affected patients who required concentrate and those with no previous exposure to prevent NANBH. In 1990 or 1991 some highly purified monoclonal FVIII concentrate was used. I believe there was no patient with severe haemophilia B at Truro. There was one child with, I believe, moderate FIX deficiency, who needed occasional treatment with heat treated BPL FIX concentrate.

11. Who had responsibility at (i) the BRI and (ii) Truro for the selection and purchase of blood products, and what decisions were taken at each as to which products to purchase and use? In addressing this issue, please answer the following questions:

11.1. BRI

11.1.1. Dr G L Scott

11.2. Truro

11.2.1. Dr J S Murrell. Although I became Haemophilia Centre Director at the end of 1987, I did not select products initially. I believe I commenced doing so in late 1988. I do remember being involved in discussions regarding monoclonal (high purity) FVIII concentrate. As head of Department, Dr Murrell would still have been involved.

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

11.3. I believe selection was based on a preference for UK donor plasma, single donor products for mild/moderately affected individuals or with no previous exposure and heat-treated concentrates from 1984. Subsequently HT BPL (8Y), when available, and later monoclonal FVIII concentrate of increased purity was selected to prevent NANBH. Once all products were heat treated to inactivate HIV the emphasis changed to prevention of NANBH.

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

11.4. Efficacy and safety from infection risk.

c) Where were the products sourced? From where were they purchased?

11.5. I don't know.

11.6. BRI

11.6.1. I believe BPL products were ordered directly from BPL by the blood transfusion department and distributed via the Regional Blood Transfusion Service. Commercial concentrates were purchased by Pharmacy.

11.7. Truro

11.7.1. I believe BPL products were ordered and distributed via the Regional Blood Transfusion Service Bristol. Commercial concentrates were possibly purchased by the laboratory.

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

11.8. Cost vs. other health care costs was always an issue but did not compromise safety or dominate the physician's choice.

e) What involvement did you have?

11.9. As above. In BRI limited to discussion with my Consultant. In Truro sometime after 1988 I was involved with, and later responsible for, selection.

12. What particular products were used for treating patients at (a) the BRI and (b) Truro, over what period of time and for which categories of patients?

12.1. I do not remember brand names.

13. What was the relationship between (a) the BRI and (b) Truro, and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions referred to above?

13.1. I am not aware of any relationship at either Centre with any pharmaceutical company manufacturing/supplying blood products.

14. If the responsibility for the selection and purchase of blood products at the BRI or Truro lay with an external organisation, please specify which organisation and provide as much information as you can about its decision-making.

14.1. Not that I am aware of.

15. How were decisions taken at (a) the BRI and (b) Truro as to which products to use for individual patients? What involvement did you have in such decisions, as Senior Registrar, then as Consultant Haematologist and

finally as Director? To what extent, if at all, were patients offered a choice as to which products to use?

15.1. As far as I remember decisions were made on broad disease categories unless a patient had had an allergic reaction to a specific product.

15.2. As senior registrar I discussed it with Dr Scott 1984-85. As consultant haematologist Truro I chose the type of therapy e.g. DDAVP, cryo, concentrate and as Haemophilia Centre Director Truro as described in answer to Q10 and 11 above.

15.3. Treatment was discussed with patients. If a patient expressed a particular view that was accepted where possible. Such views tended to be re commercial vs. UK plasma derived product.

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

16.1. Haemophilia A: 1970s – Cryoprecipitate,

16.2. 1980s – Cryoprecipitate & DDAVP for mild/moderate haemophilia & Vwd (1983). I sought treatment advice from Prof A Bloom on 7/7/83 [WITN4685003].

16.3. Haemophilia B: none other than (frozen) plasma which was impractical.

17. What were, in your view, the advantages and disadvantages of those alternative treatments? What use was made of them at (a) the BRI and (b) Truro? 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. DDAVP: It was useful for mild/moderate haemophilia A and von Willebrand's disease where a response had been previously demonstrated following a test dose and generally pre dental/other minor surgery/ non-life threatening bleeds. All newly diagnosed patients had a trial of DDAVP so their response would be known when they presented

needing it. It avoided the need for blood products and risk of transfusion transmitted infection (TTI) from large plasma pools and for cryo.

17.2. Greater use of DDAVP was made at Truro where I tested all relevant new patients routinely.

17.3. Yes, where possible it was used in preference to concentrates/blood products but DDAVP, or indeed cryo, was impractical for home therapy or severely affected patients or when a guaranteed level of FVIII was rapidly required although the response with cryo was more predictable. It wasn't suitable for major surgery as tachyphylaxis occurred after a few days.

18. What was the policy and approach at (a) the BRI and (b) Truro as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?

18.1. BRI

18.1.1. In BRI cryoprecipitate (cryo) was used to treat mild and moderate haemophilia (until DDAVP became available 1983), severe patients with haemophilia who attended the Centre for treatment and von Willebrand's disease. A lot of cryo was used at BRI when I first arrived. When reports of AIDS appeared some individuals preferred cryo because it was derived from UK plasma.

18.1.2. When commercial heat-treated factor concentrates became available there was a move towards these (as heat treatment inactivated the HIV virus). However, the amount of commercial factor concentrates available was limited and there were cost issues. Some patients elected not to have heat treated commercial concentrates as these were manufactured from US plasma. Some patients remained with cryo although less convenient

18.1.3. I remember one patient attending the BRI was on home therapy with cryo due to allergy. He had deep freeze at home provided by the DHSS.

18.1.4. Use of cryo decreased in 1985 with availability of heated commercial concentrates. When BPL heat treated concentrates became available, patients were moved to those and cryo was seldom used.

18.1.5. This was a time of great uncertainty. No one knew what was best. There were times when individuals preferred cryo and other times when they avoided it and times when it was advised and times when it was not advised.

18.2. Truro

18.2.1. When I took up post in July 1986 heat treated commercial and BPL concentrates were in use and very little cryo used except Vwd with bleeding.

a) Did that policy and approach change over time and if so how? In answering this question in respect of Truro, you might wish to refer to your statement regarding the use of cryoprecipitate at the 13th meeting of UKHCDO on 13 September 1982 [CBLA0001619 and DHSC0001313]

18.3. I do not see any statement by me referred to in the minutes of the 13th meeting of the UKHCDO 13/9/1982 [CBLA0001619] when I was working at the BRI and not in Truro. I have no recollection of the 'comment' attributed to me in a conversation, or of that conversation with Mr K Milne outside of that meeting 38 years ago [DHSC0001313].

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

18.4. The policy and approach to treatment of haemophilia changed several times during 1983-1992 as new information became available in publications and at the UKHCD meetings.

19. What was the policy and approach at (a) the BRI and (b) Truro in relation to home treatment? Did the policy and approach change over time and if so how?

19.1. BRI

19.1.1. At approx. 4 years children with severe haemophilia and regular bleeds were commenced on home therapy with factor concentrates with parental agreement. I believe this was intended to be with BPL factor concentrates. Home therapy in children was commenced at Bristol Children's Hospital under the care of Dr D Burman Consultant Paediatrician. I do not remember any patient commencing home therapy when I worked at the BRI.

19.2. Truro

19.2.1. Patients with severe haemophilia in Cornwall had been commenced on home therapy by Dr J Murrell prior to my arrival. They had been treated early with heat treated concentrate of US origin. I do not remember initiating home therapy for any patient while working at Truro. Two newly diagnosed severely affected children were diagnosed while I worked there but were too young to commence home therapy.

20. What was the policy and approach at (a) the BRI and (b) Truro in relation to prophylactic treatment? Did the policy and approach change over time and if so how?

20.1. Routine prophylaxis was not undertaken at either Centre where treatment was demand led. In 1991, evidence was emerging from Sweden of the long term benefits of prophylaxis. I have never instituted routine prophylaxis. Occasionally in an individual patient with a troublesome joint a period of specific prophylaxis was used.

21. What was the policy and approach at (a) the BRI and (b) Truro in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?

21.1. Factor concentrates were avoided in very young children with severe haemophilia where single donor product was preferred unless there was difficulty with the volume required when factor concentrate might be used.

21.2. When home therapy commenced for severe haemophilia after 4 years, factor concentrates were used.

21.3. BPL concentrates (UK Plasma) were used in preference for children.

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

22.1. Factor concentrates were not normally used to treat mildly affected individuals whose treatment was usually prophylaxis pre procedure/surgery/dental. Cryoprecipitate was used and later DDAVP.

22.2. In moderately affected individuals with few bleeds concentrates were avoided. In the occasional moderately affected individual with many bleeds factor concentrate might have been used and for major surgery when a predicted post infusion level was required at a defined time.

23. What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at (a) the BRI and (b) Truro in consequence of the use of blood products?

23.1. None that I am aware of.

Section 3: Knowledge of. and response to. risk

General

24. When you began work as a Senior Registrar in Haematology at the BRI, what did you know and understand about the risks of infection associated

with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

24.1. As an intern I was aware of the Edinburgh outbreak of acute hepatitis B in a dialysis unit in the early 1970s. Many staff and patients were infected and both patients and medical staff died. This raised awareness of clinical staff to hepatitis B which at the time was considered the most serious form of hepatitis. Donor plasma was screened for hepatitis B to prevent transfusion transmitted hepatitis. Individuals with a history of jaundice were excluded as blood donors.

24.2. I was aware of a risk of hepatitis B and non-B hepatitis and abnormal liver function associated with blood and/or blood products in patients with haemophilia when I began work as a Senior Registrar Haematology at the BRI.

24.3. The source of my knowledge was a retrospective chart review I undertook of results of liver function tests and markers of hepatitis B infection in patients with haemophilia in Ireland. I was aware of reports of patients with asymptomatic abnormal liver function where liver biopsy had shown chronic liver disease. Consequently, I was aware that mildly affected patients who only need occasional treatment should receive single donor treatment rather than concentrate therapy.

24.4. In 1982 I became aware of AIDS in homosexual men with multiple partners in the USA and subsequently in IV drugs users, Haitians, persons with haemophilia and recipients of blood and platelet transfusion. In 1983, a patient with haemophilia was diagnosed with AIDS in Bristol. In 1984 this was shown to be due to HIV infection. The full clinical significance of AIDS did not become clear until after I left Bristol in 1986.

24.5. In 1984-1986 I became aware of the potential for serious liver disease due to NANBH, later identified as hepatitis C in 1989, which had previously not been considered serious.

24.6. Initially we knew that some patients with haemophilia had abnormal liver function tests (LFTs) not attributable to hepatitis B. This was referred to as NANBH, was usually asymptomatic and not thought to have serious sequelae. In the 1980s evidence emerged that some asymptomatic patients with haemophilia with persistently elevated transaminases who underwent liver biopsy had chronic active hepatitis and cirrhosis. It became clear that NANBH was not innocuous in the long term. It was shown that >95% of patients who received large pool concentrates were probably infected by a transfusion transmitted virus although the serious consequences of this infections were not fully realised.

24.7. It was found that heat treatment (HT) reduced the incidence of NANBH and efforts to produce virally inactivated concentrates were developed (initially heat treatment). When HIV emerged the potential serious consequences were more obvious. Heat treatment was rapidly introduced as the technology was already developed.

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

25.1. The practice at both BRI and Truro included:

25.1.1. Monitoring of hepatitis B markers and liver function tests.

25.1.2. Liver function tests were routinely monitored for all patients regularly receiving blood products (not only patients with haemophilia). Patients with abnormal LFTs were advised to limit/avoid alcohol. Patients not exposed to hepatitis B were offered vaccination.

25.1.3. Storage of serum for subsequent testing should further knowledge of aetiology be acquired.

25.1.4. Testing for HIV when that test became available in 1984.

25.2. Later in Truro samples were tested for Hepatitis C I think in 1991. I do not remember if I had those results before I left Truro.

26. 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?

26.1. I understood the risk was likely to be greater with commercial concentrates because they were derived from the larger plasma pools and remunerated donors than NHS concentrates which were derived from much smaller plasma pools donated by non-remunerated donors. I was unaware of certain risks associated with those donors (prisoners, IV drug users) until much later 1984-1985. Until 1983 I thought those risks were mainly theoretical and unavoidable.

26.2. When HIV infection emerged because of its greater prevalence in the US and because the epidemic presented in the US two years earlier than the UK this was a further increased risk.

Hepatitis

27. When you began work as a Senior Registrar in Haematology at the BRI, what was your knowledge and understanding of the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

27.1. See answer to Q 24 above.

28. What, if any, further enquiries and/or investigations did you carry out or cause to be carried out in respect of the risks of the transmission of

hepatitis? What information was obtained as a result? In answering this question you may find it helpful to refer to the letter from you to all Haemophilia Centre Directors in the South West Region dated 11 November 1990 [TSFT0000001_011 and TSFT0000001_012],

28.1. As Regional representative of UKHCDO I wrote to all Haemophilia Centre Directors in the SW Region 11/11/90 [TSFT0000001_011 and TSFT0000001_012] regarding

28.1.1. Criteria for liver disease in haemophilia and how it should be monitored

28.1.2. enclosed a copy of the report of the Working Party on Chronic Liver disease in Haemophilia. I do not know the date of this or have a copy.

28.1.3. referred them to 4 publications

28.1.4. a proposed agenda for next meeting of the haemophilia treaters group/sub-Committee due to take place 10/5/1991

28.1.5. The latter documents my intention to circulate a survey to the Regional Directors of details of (liver functions test (LFTs) and serological markers of hepatitis including hepatitis C and to arrange a guest lecture by an expert in liver disease at the same meeting (a consultant at the BRI).

28.2. My intention was to assess the extent of liver disease – overt and occult where possible. I believe I presented the results of that survey in Bristol May 1991. I do not have a copy of the results.

28.3. I don't know what meeting in September I was referring to. It might have been a meeting of the haemophilia treaters group/sub-Committee.

29. What, if any, actions did you, or the Centres at which you worked, take to reduce the risk to patients of being infected with hepatitis (of any kind)?

29.1. Avoidance of commercial concentrate of US origin (hepatitis B) – not fully possible due to limited UK derived concentrate.

29.2. Avoidance of concentrates (US and UK) in mild/moderately affected patients and vWD (non B hepatitis). This was ineffective as virtually all products were subsequently shown to transmit NANBH from c.1985.

29.3. Avoidance of concentrates in children less than 4 years where possible.

29.4. I participated in the study group of the UK Haemophilia Centre Directors on surveillance of transmission of NANBH to determine the risk of NANHB with BPL 8Y which ultimately confirmed that dry heat at 80°C for 72 hours reduced the risk from c. >90% to <10%.

30. 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?

30.1. Hepatitis B– acute infection could be acute symptomatic (icteric) hepatitis or asymptomatic seroconversion (anicteric). Most developed anti HBs and cleared the HBsAg but a persistent chronic HBsAg positive carrier (infectious) state developed in a minority. The acute hepatitis could rarely be fatal. Chronic hepatitis B could cause cirrhosis, liver failure and liver cancer but we thought this was exceedingly rare.

30.2. NANBH - was considered innocuous as the acute infection was silent. This was wrong.

30.3. From 1985 - 1986, there was growing concern that asymptomatic abnormal LFTs may reflect significant underlying liver disease. Following identification of the hepatitis C virus (HCV) and the development of an antibody test (Choo et al, 1989 [NHBT0000097_010]), it was recognised that HCV was the principal cause of non-A, non-B hepatitis, that the majority of patients with haemophilia treated with coagulation factor concentrate before the introduction of heat-treatment had been exposed to the virus and subsequently tested positive for anti-HCV antibody.

Hepatitis C infection is now known to be far the commonest cause of chronic liver disease and liver cancer among patients with haemophilia in developed countries.

30.4. I did not look after a patient with haemophilia with symptomatic chronic liver disease.

30.5. I identified two cases of acute icteric transfusion transmitted hepatitis A in 1985 (Hepatitis A Transmission by Factor IX Concentrates Vox Sanguinis 1996; 71; 126-128, E Lawlor, S Graham, F Davidson, PL Yap, C Cunningham, H Daly, IJ Temperley [HSOC0026857]).

31. What liver function tests and/or other forms of monitoring were undertaken at (a) the BRI and (b) Truro and how did that change over time? What was the purpose of such testing and monitoring?

31.1. LFTs included Bilirubin, Alanine aminotransferase (ALT), Aspartate transaminase (AST), alkaline phosphatase (ALP) and Gamma-glutamyl transferase (GGT). Hepatitis serology included (HbSAg, HBeAg, anti HBs and storage of serum. Later, in Truro, hepatitis C serology (anti HCV) was added.

31.2. To determine hepatitis B status, detect asymptomatic infection and need for hepatitis B vaccination.

31.3. To look for evidence of liver disease, to determine concentrate safety and later the cause of abnormal LFTs by documentation of hepatitis C.

HIV and AIDS

In answering the following questions, you may find it helpful to refer to the letter that you co-authored with Dr G Scott 'Fatal AIDS in a haemophiliac in the UK' published in the Lancet on 19 November 1983 [PRSE0004509] together with the correction 'Fatal AIDS in a UK haemophiliac' published in the Lancet on 7 January 1984 [MACK0000604_002] and your oral evidence to the Lindsay Tribunal on 15 September 2000 [LIND0000329].

(Note: A further letter Haemophilia and AIDS in the UK MB McEvoy and NS Galbraith Lancet Dec 10 1983 pg. 1371 [PRSE0004506] is relevant to the above.)

32. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular of the risks of transmission from blood and blood products during your time working at (a) the BRI and (b) Truro? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

32.1. I first heard of AIDS in the Morbidity and Mortality Weekly Reports (MMWR) prepared by the Centers for Disease Control and Prevention (CDC) in late 1982. I followed the USA and UK literature over the following years.

32.2. Following the death from AIDs of one of our haemophilia patients in August 1983, 18 months after intensive treatment with commercial concentrate of US origin, I believed there was a definite risk that this was in some way due to factor concentrate.

32.3. At the time of his acute illness in Jan 1981, having excluded other causes, I thought it was an 'acute viral infection ? related to factor concentrate'. In May 1983, we suspected AIDS. My consultant identified a histopathologist who was immune to hepatitis B and who kindly agreed to do a post mortem which confirmed the diagnosis. Subsequently my consultant had to insist on the report being published in the Lancet after it was initially rejected.

32.4. By end of 1984 we had results of HIV tests on patients at the BRI and learned that many of our patients, mainly those who have been heavily treated, were HIV positive. At that time, they were well and we still hoped that most HIV positive patients with haemophilia would not develop AIDS. The pattern of infection in patients with haemophilia (PCP Pneumonia) was different from that of homosexual patients in USA who developed Kaposi sarcoma and had considerable wasting.

32.5. It appeared likely that HTLV III infection was transmitted by blood and factor concentrates in patients with haemophilia. Initially we thought by large pool commercial concentrates of US origin but as cases were reported from European countries, we suspected it could be true of any concentrate from any country. I don't remember when I first knew of a patient in the UK who developed HIV infection and had received BPL products only.

32.6. Initially we thought that anti HTLV III antibodies might be protective. In Truro a consultant microbiologist told me this was unlikely as anti HTLV III was not a neutralising antibody but a marker of infection. By then we knew HIV had contaminated the global blood supply, donor testing for HIV had been introduced and factor concentrates were heat treated to inactivate HIV. The risk of contracting HIV infection from blood and blood products had mainly ceased but the clinical progression to AIDS had yet to become apparent.

32.7. From when we first read a report of AIDS in a patient with haemophilia in the USA we were concerned but did not understand the mechanism. When the index patient became ill after intense treatment with factor concentrate we became suspicious of AIDS. When AIDS was confirmed after death we concluded this provided evidence for a link between exposure to blood products and AIDS. We still did not know the mechanism which was later found to be due to HIV infection. The diagnosis in the index patient was subsequently confirmed by retrospective HIV testing in late 1984.

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

33.1. From MMWR reports in late 1982 when AIDS and Pneumocystis Carinii pneumonia were reported in patients with haemophilia and blood transfusion recipients in USA. My report in the Lancet in Nov 1983 concluded that this provided further evidence for a link between exposure to blood products and AIDS [PRSE0004509].

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

34.1. In the BRI, I reviewed the blood products received by the index patient and identified which other patients had received the same batches. I did not find one batch that appeared to be infected. In retrospect I believe all three batches were probably all infected.

34.2. In May-October 1983 I undertook a clinical and immunological review (immunoglobulin levels and lymphocytes subsets) of 43 patients regularly attending the centre (those regularly receiving treatment). This was published in the British Journal of Haematology Feb 1985 (GLEW0000677).

34.3. The index patient died of PCP. Three other patients had clinical features consistent with, but not diagnostic of, prodromal AIDS (wt. loss, thrombocytopenia, lymphadenopathy). No patient had symptomatic liver disease.

34.4. The most significant finding was profound T helper cell depletion with a corresponding reduction in the helper/suppressor ratio in 7 of 43 patients (16.2%) including the index patient and another with clinical features of prodromal AIDS. Profound helper cell depletion is a features of AIDS. We concluded that most of the immunological abnormalities (hypergammaglobulinemia and abnormal T helper/suppressor ratios due to increased suppressor T cell) may be due to repeated antigenic exposure in factor concentrates and that only profound lymphopenia due to T helper cell depletion, rare in asymptomatic patients, is likely to be of prognostic significance for AIDS.

34.5. The first death from AIDS of a haemophilia in the country caused considerable anxiety. The total amount of treatment used at the centre decreased due to reluctance of patients to use commercial concentrate.

35. What, if any, actions were taken at (a) the BRI and (b) Truro to reduce the risk to patients of being infected with HIV?

35.1. BRI

35.1.1. See [WITN4685002].

35.1.2. Preference for plasma derived products from UK donors rather than commercial concentrates.

35.1.3. Priority for NHS products for children, those with little previous treatment, hepatitis and HIV negative.

35.1.4. Commercial heat-treated concentrate introduced Dec 1984.

35.1.5. Heat treated NHS FVIII concentrate available from March 1985 was prioritised for children and those with little previous exposure together with heat treated commercial concentrate of US origin until October 1985 when intermediate purity NHS 8Y became available and the main treatment.

35.1.6. Reduction in use of commercial concentrate where possible.

35.1.7. Avoidance of concentrates in mild/mod/Vwd, children, those with little previous exposure.

35.1.8. Use of Cryo & DDAVP where possible.

35.1.9. I wished to use heat products exclusively from late 1984 but this was not possible until late 1985.

35.1.10. The total amount of treatment used at the Centre decreased in 1983 [GLEW0000677].

35.2. Truro

35.2.1. In Truro all patients received heat treated concentrates (BPL or commercial).

35.2.2. Very little Cryo was used.

35.2.3. DDAVP (& tranexamic acid) use increased.

36. Did (a) the BRI and/or (b) Truro continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why, and which products were used?

36.1. BRI: Yes See [WITN4685002].

36.2. Truro - I was not in Truro at the time. I believe that commercial heat-treated factor concentrates were used early.

36.3. It was not certain that factor concentrates were infected. The advice was to continue to treat patients to avoid the risk of life or limb threatening haemorrhage. If use of concentrates had ceased without alternate treatment people would have died from bleeding. I believe the reason factor concentrate continued to be used lay in the balance of risks and available alternatives. A study conducted at the BRI provides insight into pre-treatment days (Learning about Haemophilia: An alternate source of information C Kendrick Bristol Medico-Chirugical Journal Dec 1986 132-133 [WITN4685004]). I saw many patients similarly affected when an SHO in St James's Hospital Dublin in the late 1970s.

36.4. If the blood supply was infected with HIV that included the UK supply. At that time blood, platelet concentrate, FFP and Cryo were not donor screened. Any of which could have been, and we now know were, infected with HIV. Use of blood and platelet transfusions did not cease also.

36.5. There was a move away from commercial concentrate but there was insufficient BPL concentrate to treat all.

36.6. Cryo was considered impractical for home therapy. I don't know if there would have been enough Cryo.

Response to risk

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

37.1. Yes.

37.2. Patients were aware of a risk of hepatitis, mainly hepatitis B, particularly in the context of transmission through administration of treatment. I discussed this with any new patient. I screened all patients for hepatitis B and arranged hepatitis B vaccination where appropriate.

37.3. From 1985-1986 I started to discuss NANBH more as we became more concerned of its significance. I monitored LFTS regularly and explained why I was doing this.

37.4. AIDS was discussed from when I became aware of it in 1983 particularly with regard to risk of sexual transmission of infection and through administration of treatment. I provided increasing information as I acquired it. Initially we were optimistic that only few patients would develop AIDS but this was wrong and the delay was due to the latent period of the virus. I was not much involved with parents at that time but when I was I provided whatever information I had.

37.5. In Truro all patients were informed of screening for hepatitis and NANBH and why. By then all patients were receiving heat treated concentrates. However, it was known that I had some experience with HIV infection in haemophilia and patients and some parents wanted to discuss it in general particularly in the early years.

38. When did you begin to use heat treated factor products and for which categories of patients? From where did you obtain heat treated products? Did you experience difficulties in obtaining such products?

38.1. Commercial heat-treated factor VIII concentrate was obtained in December 1984, BPL heat treated FVIII concentrate April/October 1985,

BPL heat treated FIX concentrate end October 1985 for patients with severely affected haemophilia A and B. Children were prioritised for BPL concentrate.

38.2. I was not involved in obtaining the products in BRI. I believe the commercial concentrates were ordered through pharmacy and the BPL concentrates were ordered directly from BPL and distributed via the BTS. In Truro I think commercial concentrates may have been ordered by the laboratory staff. I am aware there was insufficient BPL heat treated concentrates and commercial concentrates were required.

38.3. I believe heat treated commercial factor VIII concentrate was more expensive but from December 1984 non heat-treated commercial concentrate was no longer considered acceptable.

38.4. By 1990 I believe we were using some high purity commercial monoclonal FVIII concentrate in Truro.

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

39.1. If it was known that HIV caused AIDS, that heat treatment inactivated the causative agent HIV and that concentrates could be safely heat treated then heat-treated concentrates should have been made available earlier. However, it was not known. As soon as it was known, there was a move to heat treatment. It was fortuitous that heat treatment, being developed for NANBH, was effective in inactivation of HIV.

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

40.1. I did not select treatment at the BRI.

40.2. All patients were not transferred to Cryo. I do not know if there would have been sufficient Cryo to do this. More Cryo was used for patients attending for hospital treatment.

40.3. In general home therapy continued with factor concentrate as Cryo was considered less practical. The amount of concentrate used decreased after 1983 mainly due to reduction in use of commercial concentrates.

40.4. I do not think an overall change to Cryo would have significantly altered the situation regarding NANBH.

40.5. In Truro a change was made to heat treated concentrates.

41. Do you consider that your decisions and actions, and the steps taken at (a) the BRI and/or (b) Truro, 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.

41.1. Yes I believe we did our best to keep up to date and follow the most recent advice given our knowledge at the time.

41.2. BRI

41.2.1. I did not select treatment at the BRI.

41.2.2. I believe the trial of heat-treated BPL FVIII (8Y) and FIX (9A) which I supported and participated in was an appropriate response to reduce/eliminate the risk of NANBH.

41.3. Truro

41.3.1. I believe the early change to heat treated factor VIII concentrate probably limited HIV infection and confirmation that heat-treated BPL FVIII (8Y) and FIX (9A) limited risk of NANBH was a significant benefit.

41.3.2. We used little Cryo mainly for Vwd.

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

42.1. Much earlier, in 1979, I should have 'shouted louder' about my concerns arising from a retrospective chart review I undertook of results of liver function tests in patients with haemophilia. The view that patients with haemophilia have abnormal LFTs should not have been accepted uncritically. It was the canary in the mineshaft. However, there was no alternate treatment at the time.

42.2. I was in my first haematology post as SHO. I presented the information at a scientific meeting attended by haematologists and blood transfusion scientists. No one questioned it.

42.3. Commercial concentrates of USA origin made from plasma derived from remunerated donors with 'high risk' life styles should never have been used to treat UK, or any other, patients with haemophilia. However, I did not know about those donors until late 1984. Much of the hepatitis B, NANBH and HIV infection had occurred before we became aware of the risk due to asymptomatic infection.

42.4. It would have been better if it had been possible to treat all UK patients with haemophilia with UK derived concentrates both non heat-treated and heat treated and at an earlier time.

42.5. 'Life can only be understood backwards but must be lived forwards' Søren Kierkegaard.

43. 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?

43.1. I believe I am a witness of fact and describe matters relating to me alone. I am not an expert. I cannot answer for others. I believe the aim of this Inquiry is to answer the above question.

Section 4: Treatment of patients at the BRI and at Truro

Provision of information to patients

44. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at (a) the BRI and (b) Truro about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing? Please detail whether, and if so, how this changed over time.

44.1. As a witness of fact I describe matters relating to me alone.

44.2. BRI

44.2.1. I discussed the possibility of transmission of hepatitis, mainly hepatitis B, as I knew it, the need to monitor LFTs, need for hepatitis B vaccination, the emerging concern relating to AIDS/HIV infection and in the latter years NANBH with patients receiving any product for the first time.

44.3. Truro

44.3.1. I discussed the possibility of transmission of hepatitis, both hepatitis B and NANBH, the need to monitor LFTs, need for hepatitis B vaccination and subsequently hepatitis C testing with patients receiving any product for the first time.

44.3.2. I believe there was only one child who commenced heat treated BPL factor concentrate (hospital based) when I was there. I discussed the risk of infection with his mother.

44.3.3. The above was not exclusively, or indeed mainly, prior to commencement of factor concentrate therapy as most of the patients were already on home therapy when I started working

at the BRI and Truro. I explained we were using DDAVP to avoid risk of infection from blood products.

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

45.1. I did not provide information to families. I did not discuss patients with families or partners unless specifically asked to do so by the patient. I don't remember being asked to speak with a family member. Sometimes patients attended with a partner but not often. In the case of minors, I spoke with the parents(s) usually the mother.

45.2. The situation changed over the years

45.2.1. Severe haemophilia – Avoidance of commercial non heat-treated concentrates.

45.2.2. Increased use of Cryo for hospital based treatment.

45.2.3. Preference for commercial heat-treated concentrates.

45.2.4. Preference for heat treated BPL factor concentrate.

45.2.5. Mild/moderately affected were offered Cryo or DDAVP (late 1983).

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

46.1. I do not believe I started any patient on home therapy in the UK.

46.2. I do know from patients I treated at the BRI that they were all aware of the risk of hepatitis and of risks to others if there was blood spillage, of the need to return needles, syringes etc. to the Centre (or other site where arrangements were made).

46.3. I believe this information was provided to the patients or parent and not to family members.

HIV

In answering the following questions you might find it helpful to refer to your letter of 31 May 1985 to Dr Burman regarding two haemophilic children infected with HIV through British factor VIII concentrate [WITN1575008][1] and two letters from Dr Scott to you dated 21 November 1988 [WITN1575006][2] and 24 April 1989 [WITN1575004][3].

(NB These documents refer to an identified deceased former patient and have been sent because they contain generalised comments based on particular patients. I understand I am not asked about specific patients and therefore do not require written consent from next of kin before I can discuss further.
WITN1575008 - I do not know what product infected these children or the identity of one. It appears they were infected before heat treated BPL factor VIII concentrate was available.)

47. When did you first discuss AIDS or HIV (HTLV-III) with any patients or their families? What did you tell them?

47.1. I did not discuss patients with families or partners unless specifically asked to do so by the patient.

47.2. I did speak with the wife of the index patient as his illness progressed and the likely diagnosis became apparent.

47.3. From 1983 onwards AIDS was a concern for patients at the BRI, particularly those heavily treated and regularly attending, who became aware that one of their group was ill and subsequently died GRO-A 1983).

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1 The patient's name has been redacted and is not necessary to answer the questions.

2 The patient's name has been redacted and is not necessary to answer the questions.

3 The patient's name has been redacted and is not necessary to answer the questions.

I discussed it whenever they attended if they wished. I told them what I knew at the time and as I learnt it.

47.4. I undertook surveillance of patients attending the Centre. In BRI I set up an additional clinic in the day unit at which I reviewed a few patients per session in a private room. Each consultation lasted approx. 30 mins. Sometimes I was accompanied by a haemophilia nurse.

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

48.1. I first learned when I received the result of the HIV test of the index patient verbally from Dr J Craske Consultant Virologist of the PHL Manchester at a Haemophilia meeting I believe in Cardiff in late 1984. Subsequently I received the results of other patients tested from my consultant and, I believe, the PH Laboratory Bristol.

49. What if any arrangements were made for pre-test counselling?

49.1. There was no formal pre-test counselling initially. I spoke with patients as I was monitoring them. I explained I was storing sera in the hope of a future test. No patient objected. They wanted to find out also. Later, after I received the results of the initial tests and when testing further patients, I did provide a form of pre-test counselling. I can't remember for certain if I recorded that in the clinical records in the BRI.

49.2. To put this in context when I started working at the BRI specific informed consent was obtained only for surgery. I introduced informed written consent for (invasive) bone marrow examination.

49.3. By the time I worked in Truro all patients were routinely advised they would have regular hepatitis and HIV serology at review appointments.

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

50.1. At the BRI, all patients with whom I was involved were informed in person, in private and usually by me initially.

50.2. The Consultant Dr Scott, second senior registrar, registrar and SHOs also discussed this with patients subsequently. I led the process at the BRI.

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

51.1. I raised the topic in general with reference to media reports which were frightening, moved on to tests done earlier in the year and to the patient's result. Most patients in the BRI knew they had been tested although some were unaware. I informed patients of their HIV result and 'counselled' regarding its implications in general, to patients with haemophilia specifically, for treatment, risk of infection re blood spillage and sexual transmission to the best of my knowledge at that time. I also advised on the risk of vertical transmission to a baby and avoidance of pregnancy until the situation and risk to partner and infant became clearer. Centre Directors began counselling on 'safe sex'. I referred to Dr P Jones's book (AIDS and the blood A practical guide) and gave them a copy. It was easy to read, covered the main points and provided some factual information to refer to.

51.2. In general patients were concerned about what they had read and heard in the media and welcomed the opportunity to discuss the matter in confidence with someone who had some knowledge of the problem in relation to haemophilia. These patients attended regularly for treatment or clinical review and further advice was given as and when information became available.

51.3. I tried to discuss the issue of HIV with every patient with haemophilia I met whether seropositive or negative, tested or not yet retested. All needed to be informed of their results and counselled or needed to be tested and to receive 'pre-test counselling'. This initial 'medical

counselling' was the start of a process. Patients required on going counselling. We did not understand the complexity of the issue until we commenced counselling.

51.4. Initially we were optimistic as even HIV positive patients were well. We firmly believed that there was some co-factor accounting for the higher prevalence and different clinical expression of HIV/ AIDS among homosexual men with multiple partners who developed AIDS defining illness first in particular Kaposi's sarcoma (co-infection with Herpes virus HHV8).

51.5. By 1985 I knew that many patients with haemophilia had contracted HIV but few had developed AIDS.

51.6. Haemophilia Centre Directors still hoped and believed that many, if not most, HIV seropositive patients would not necessarily develop AIDS (Carne et al Lancet 30/11/85 [SHTM0000645], P Jones 1985 [RLIT0000046]). In retrospect, this view was wrong and unduly optimistic. It resulted from the long incubation or latent period between infection and development of clinical disease. It was wondered if the antibody conferred immunity, was it a neutralising antibody? Age at seroconversion also proved to be an important factor in development of AIDS.

51.7. We told patients we didn't know the prognosis. Giving news of uncertainty is worse than giving bad news. Most had antibodies but were not ill. We compared it to hepatitis which all patients with haemophilia were aware of, where one had an antibody but was not ill. This continued as the general view probably up to 1986/1987.

51.8. At that time there was, and indeed still is, an aura of secrecy about HIV. This made the situation more difficult. Many patients did not initially wish me to inform their GP. I respected this request for confidentiality therefore clinical letters were on occasion brief or did not specifically reveal a patient's HIV status although this was recorded in their medical records.

51.9. This was a time of great secrecy, ignorance, fear and perceived stigma. It was a harrowing experience for patients and their carers. I had treated and cared for these patients for some time. I knew them well and had to give bad news. I shared their fear, uncertainty and concern. As others working with haemophilia at that time, I had no specific training in counselling. As a haematologist I was experienced in treating and caring for patients with life threatening diseases and I had experience of being the bearer of bad news.

51.10. In the early days some doctors felt we shouldn't tell patients their HIV results as it would frighten them. I didn't agree with that. So I asked patients if they benefited from the talk and the overwhelming majority said they did. It was a relief to many that they could discuss this taboo subject in a straightforward manner. That (not telling patients a diagnosis) was not unique to HIV infection. Some held that view in relation to childhood leukaemia/cancer, TB. There were medical euphemisms for all over the years – malignancy/neoplastic, Koch's disease, Lues.

51.11. I have never heard of patients being told to keep their infection a secret.

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

52.1. There was no written policy.

52.2. Patients were asked if they wanted a partner tested in 1985 when sexual transmission became apparent. I offered to test parents administering treatment to children (my letter to Dr D Burman 31/5/1985 WITN15750008). We did not routinely test other family members.

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

53.1. I am not aware of any partner infected by HIV when I worked at BRI or Truro. If a patient asked me to speak with a partner I did. Otherwise this matter was bound by doctor-patient confidentiality and advice was given to the patient only.

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

54.1. From 1983-1986 I was in discussion with patients throughout including after their HIV test as indicated above and provided 'medical counselling'. There was no formal post-test counselling with a Counsellor.

55. The Inquiry is aware of your involvement in counselling services of patients infected with HIV and their families during your time at St James's Hospital during 1985 [MACK0000394]. In your letter to Mr Fitzpatrick, you indicated that there were plans for the UK Government to institute a nationwide AIDS counselling service for patients with haemophilia which was to take place at St Mary's Hospital, Paddington and you requested that Mr Fitzpatrick find out whether St Mary's Hospital would be prepared to take persons from the Haemophilia Centres in the UK and advise them regarding counselling. Please explain what the outcome of this request was?

55.1. I was never part of a 'counselling service' at any hospital. I undertook what was later described as 'medical counselling' of patients under my care wherever I worked.

55.2. (NB As to MACK0000394 The IBI advised the cover page is a summary of the document provided and authored by the Material Provider. It is not part of my letter: the country is Ireland and not Southern Ireland; and The blood transfusion service in Ireland was known in 1985 as the Blood Transfusion Service Board in contrast with that in the UK (National Blood Transfusion Service).

55.3. In my letter I referred to an article I read in the Medical Laboratory Service Gazette 1985. I believe the UK Government intended to set up

a nationwide AIDS counselling service and to provide funds for a training course for AIDS counsellors at St Mary's Hospital for staff caring for persons with AIDS. That course and the proposed nationwide counselling service related to persons with AIDS and not only patients with haemophilia.

55.4. I wrote that letter on 1/10/1985 when I finished my locum post at the National Haemophilia Centre Ireland. I made a recommendation not a request. I believe this does not fall within the terms of reference of this Inquiry.

56. In your letter to Mr Fitzpatrick you stated that "in Ireland there has not been an organised attempt to educate the medical staff or the general population with regard to the problem of HTLV-III infection." What is your view on how the UK handled this problem in comparison?

56.1. At that time, 1985, I don't know if there had been an organised attempt to educate medical staff or the general population in the UK either. There was a proposal for a government funded nationwide AIDS counselling service and funding for a training course for AIDS counsellors.

56.2. However, the UK is a bigger country. There are more haemophilia centres, more people involved in haemophilia care and the UKHCDO provided leadership. There was a dedicated social worker at the Royal Free Hospital for counselling patients with haemophilia.

56.3. In our department at the BRI we had the index patient and all haematology staff (doctors, nurses and laboratory staff) were interested and aware but there was no organised education programme.

56.4. The nurses and young doctors administered treatment and laboratory staff performed coagulation assays using what was shown to be (potentially) infected control material (1985).

57. How many patients at (i) the BRI and (ii) Truro 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?

57.1. BRI

57.1.1. I do not know.

57.1.2. There were significant numbers

57.1.3. Most had severe haemophilia A

57.1.4. The index patient had moderate haemophilia A

57.1.5. I don't remember if there was anyone with mild haemophilia A.

57.1.6. I believe there were no patients with haemophilia B

57.1.7. I believe there was one patient with severe, homozygous von Willebrand's disease

57.1.8. I believe there were two children both with severe haemophilia A

57.2. Truro

57.2.1. Two patients with severe haemophilia A. One died before I took up post (1986) and one with severe haemophilia A was asymptomatic until I left (1992). Another child with severe haemophilia A, whom I had met in Bristol, moved from Bristol to Truro in 1989.

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

58.1. BRI

58.1.1. Yes. In some cases several anti HTLV III tests were done on stored sera which showed date of last negative and first positive result giving an estimate of time of seroconversion. The index patient seroconverted during his acute illness in Jan 1982 (Carne et al 1985 (SHTM0000645)). I think the earliest at the BRI was 1981, most seroconverted in 1982-1983 but I don't remember for certain. I know one patient seroconverted later (between Sept 1984 and March 1985).

58.2. Truro

58.2.1. Not that I am aware of.

Hepatitis B

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

59.1. Other than the index patient whom I informed, I do not remember another patient seroconverting for hepatitis B while under my care. Most were already seropositive for hepatitis B and aware of it.

59.2. Patients were informed of a risk of transmission from administering concentrate, of sexual transmission, of possible development of chronic liver disease and need to monitor LFTs.

60. How many patients at (a) the BRI and (b) Truro were infected with hepatitis B?

60.1. I don't remember.

60.2. Of 43 patients studied at the BRI in 1983-1984, 31 of 43 (72%) had previous exposure to hepatitis B (29 anti HBs positive and two had developed a persistent carrier state).

NANB Hepatitis/Hepatitis C

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

61.1. I informed patients that I was monitoring their LFTS for evidence of 'hepatitis'. If their LFTs were abnormal, I discussed the likely causes with them including the possibility of NANBH. Initially I looked for evidence of hepatitis B and if this was negative considered NANBH. Later it was recognised that both could, and likely did, co-exist. Initially we thought NANBH was innocuous. In the late 1980s evidence emerged that abnormal liver function tests in patients with haemophilia may reflect chronic (asymptomatic) liver disease, - chronic persistent and chronic active hepatitis and cirrhosis and may be due to an as yet unidentified form of hepatitis – termed non- A non- B hepatitis (NANBH). I informed patients that heat-treated concentrates would likely reduce, if not eliminate, the risk of NANBH. I did not have any patient with symptomatic liver disease.

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

62.1. HCV was isolated from the serum of a patient with non-A, non-B hepatitis in 1989 (Choo et al [NHBT0000097_010]).

62.2. In 1991 an antibody test for hepatitis C became available and patients were tested for this. This was initially done in research laboratories. I believe Dr R Tedder at Dept. of Microbiology Virology Section Middlesex Hospital and University College Medical School London first had the hepatitis C test in UK. I can't remember when we in Truro first had access to the test for current or stored samples. I don't remember seeing any positive hepatitis C result. Consequently, I do not believe I informed anyone of a diagnosis of hepatitis C.

62.3. When the hepatitis C test became available it was shown that hepatitis C was very common in the general population and UK blood donors also tested positive. Consequently, hepatitis C was transmitted by red blood cells and all blood products manufactured in England as well as US commercial concentrates. Hepatitis C was more common than HIV.

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

63.1. Not applicable.

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

64.1. Included in the monitoring for hepatitis, I arranged for serum to be stored in the public health laboratory in Bristol and the microbiology department at RCH-T. This was done because at that time we did not know the cause of abnormal LFTs and there was a lot of research going on to determine this. Samples were stored in the hope of a future test for NANBH. When a test for hepatitis C became available, these samples as well as more recent samples were tested for hepatitis C. These patients were regular attenders at the haemophilia centre and did not require tracing as such.

65. How many patients at Truro were infected with hepatitis C?

65.1. I do not know.

66. Please refer to the correspondence between you and Miss Spooner regarding patients who developed NANB Hepatitis at the BRI [HCD00000256_035 and HCD00000256_036][4]. Please describe:

66.1. (NB HCDO0000256_035 is a covering letter from me to Ms R Spooner Oxford Haemophilia Centre enclosing HCDO0000256_036 (C1 and C2 hepatitis survey form) dated 22/11/85 reporting one patient with hepatitis following commercial concentrate (July 1985))

a) What steps would have been taken by you/the Centre to investigate these matters, and what was the standard process for tracing infected batches?

66.2. I did not initially investigate this case. I was in Ireland July-October 1985. Standard practice for tracing an infected batch included reviewing the recent treatment history, informing the manufacturer and reporting it to the hepatitis survey. In this case it appears I knew the infected batch.

b) whether the patients, generally, would have been told that they were being monitored for NANB Hepatitis?

66.3. Yes, patients knew their LFTs were monitored for hepatitis. This patient presented with jaundice and knew he was being investigated.

c) whether the patients, generally, would have been notified of their NANB Hepatitis diagnosis and if so whether they would have been told immediately?

66.4. This patient had icteric hepatitis and knew he had hepatitis. I believe the detail would have been explained to him. If anicteric and detected on routine LFTs he would be told at his next visit unless a result was very abnormal or some other significant change.

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4 The patient's name has been redacted and is not necessary to answer the questions.

d) whether the patients, generally, would have been told that their personal information was being shared with other people such as Miss Spooner?

66.5. Personal information was not being shared with 'other' people.

66.6. Annual returns were submitted to the National Haemophilia Centre.

66.7. Details of adverse events were submitted to the relevant survey collated by Ms R Spooner a senior, valued and experienced member of the National Haemophilia Centre staff.

e) whether such patients would have been offered counselling by the Centre. If not why?

66.8. No not for NANBH in 1985. I do not believe that was standard practice. The diagnosis would have been explained and discussed.

f) whether you/the Centre would have notified the pharmaceutical company who manufactured the infected batches of the fact that a patient had been infected shortly after having been treated with their product?

66.9. I believe that should have been done in July 1985. I do not know if it was.

g) the reason why this information was being sent to Miss Spooner?

66.10. See response to (d) above.

67. Please refer to the correspondence between you and Miss Spooner regarding patients who developed Hepatitis at Truro [HCD00000370_004 and HCD00000370_005][5]. Please describe:

67.1. (NB HCDO0000370_005 is a letter from Ms R Spooner Research Assistant Oxford Haemophilia Centre dated 15/4/87 requesting further details in response to my submission with the Annual returns for Truro Haemophilia Centre for, I believe, 1986.

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5 The patient's names have been redacted and are not necessary to answer the questions.

67.2. HCDO0000370_004 is my response dated 29/4/1987 to Ms Spooner's letter of 15/4/87 providing the requested information in particular relating to one patient with icteric hepatitis post cryo (1979).)

a) What steps would have been taken by you/the Centre to investigate these matters, and what was the standard process for tracing infected batches?

67.3. This occurred 7 years before I took up post at the Centre. I did not investigate it.

b) whether the patients, generally, would have been told that they were being monitored for Hepatitis?

67.4. See response to Q 66 (b) above.

c) whether the patients, generally, would have been notified of their Hepatitis diagnoses and if so whether they would have been told immediately?

67.5. See response to Q 66 (c) above

d) whether the patients, generally, would have been told that their personal information was being shared with other people such as Miss Spooner?

67.6. See response to Q 66 (d) above

e) whether such patients would have been offered counselling by the Centre. If not why?

67.7. No not for jaundice in 1979. I do not believe that was standard practice. The diagnosis would have been explained and discussed.

f) whether you/the Centre would have notified the pharmaceutical company who manufactured the infected batches of the fact that a patient had been infected shortly after having been treated with their product?

67.8. I believe the implicated product was cryo produced by the Blood Transfusion Service. I do not know if it was notified

g) the reason why this information was being sent to Miss Spooner?

67.9. See response to (d) above.

Delay/public health/other information

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

68.1. Patients were informed of their hepatitis and HIV results promptly on the basis of medical need and at their next outpatient review.

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

69.1. By public health implications I refer to risk of transmission.

69.2. I informed patients (or parent of) with haemophilia, with or without HIV/AIDS and/or hepatitis B, of the risk of cross contamination on exposure to their blood when administering home therapy, disposing of equipment and at dental treatment. I advised those seropositive for HIV/AIDS and hepatitis B of the risk of sexual transmission and the risk of vertical transmission to a baby when the latter became known in 1985.

69.3. I was not aware of a similar transmissible risk with NANBH until hepatitis C was identified. I do not remember caring for a patient with confirmed hepatitis C.

69.4. My responsibility was not confined to patients only. I had an obligation to my GP and dental colleagues to ensure they were not subjected to unnecessary risk. I advised HIV positive patients that I would like to inform their GP and dentist (if they were attending a private dentist) of their status. Most patients agreed to this in confidence. A few did not. I

advised GPs/Dentists to ensure they used universal precautions when treating patients with haemophilia. By 1985 universal precautions was becoming standard practice.

69.5. Re: what treatment to offer patients The IBI advised this refers to things like vaccinations; preventative treatment; post exposure treatment and whether to change factor concentrates or move to cryoprecipitate.

69.6. Hepatitis B vaccination is included in answer to Q25.

69.7. I do not remember a patient with haemophilia requiring post exposure treatment for hepatitis B or HIV exposure.

69.8. Whether to change factor concentrates or move to cryoprecipitate is included in answer to Q 29 and Q35 above.

70. What information was provided to patients and their families about the risks of other infections?

70.1. The IBI advised this refers to parvovirus, CMV etc.

70.2. I did not provide information about parvovirus or CMV Infection.

70.3. I do not remember being aware of documented reports of transfusion transmitted parvovirus B19 infection in patients with haemophilia at that time. The papers I have seen are from the late 1990s and early 2000s.

70.4. I do not remember being aware of documented reports of transfusion transmitted CMV infection in patients with haemophilia at that time.

71. What information was provided to patients and their families about the risks of infecting others?

71.1. See answer to Q 69 above.

72. What actions or decisions were taken at any of the hospitals at which you worked to trace patients who may have been infected through the use of blood or blood products?

72.1. At the BRI and Truro any patient under my care who may have been infected through the use of blood or blood products was regularly attending the department and on regular follow up. If they failed to attend an appointment a reminder was sent.

Consent

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

73.1. At both BRI and RCH-T blood samples were taken at all routine review appointments i.e.at least twice per year for severely affected patients and once per year for mild/moderate, more frequently for those under surveillance, those who were seropositive or had abnormal LFTs for the purpose of patient care. Patients also frequently had blood samples taken for pre- and post- infusions factor levels.

73.2. Patients attending for review had routine blood tests (FBC, liver and renal function tests, hepatitis serology, and inhibitor assays) taken by the nurses/phlebotomist before they were seen by a doctor. Patients were given general information of the reason for blood tests and give their results by a doctor.

73.3. I don't think patients were asked to consent to storage of sera. I advised patients I intended storing sera in the hope of future tests. I believe PHL stored sera for repeat/subsequent testing in the case of seroconversion for any virus on an almost routine basis.

73.4. As with all consent at that time this was verbal not written consent and was not specifically recorded. See answer to 49 above re (invasive) bone marrow examination.

74. 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?

74.1. No if treatment with factor concentrate/cryo was needed the patient was so advised and generally accepted the advice. In general treatment was for bleeding episodes. More severely affected patients were fully aware of what they needed and often told the doctor. Patients who required less treatment (e.g. mild haemophilia) might have had questions which were discussed with them.

74.2. As with all consent at that time this was verbal not written consent and was not specifically recorded. That was standard of care.

75. 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?

75.1. See answer to Q 49 above.

75.2. Informed consent was not sought for routine hepatitis testing although patients were told it was being done. That was standard care at the time and considered routine. I do not member but more explicit consent may have been sought for hepatitis C testing in 1991.

75.3. In 1984 a test for HIV became available. In BRI sera, in many cases stored sera, from the PH virology dept. was sent to the Middlesex Hospital possibly via Manchester PH. Specific consent for HIV testing was not sought from patients at that time. I told patients as I was

monitoring them that I was having sera stored in the PHL in the hope of a future test. No patient objected. They wanted to find out also.

75.4. Tests were performed in batches. At the BRI the Haemophilia Director was advised of results in late 1984. Subsequently, patients were advised to be tested and agreed to testing. I commenced a form of pre-test counselling. I can't remember for certain if I recorded that in the clinical records in the BRI.

75.5. By the time I worked in Truro all patients were routinely advised they would have regular hepatitis and HIV serology at review appointments.

75.6. In later years written consent was advised and recorded in medical records. This ceased to be a requirement when HIV testing became the norm, treatment became available and the prognosis improved.

PUPS

76. 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) including, but not limited to, the 'Surveillance of previously untreated patients for possible virus transmission by BPL factor VIII and IX concentrates 8Y and 9A' study [DHSC0001084] and the "NHS 8Y 'Virgin Patient' Study" which is the subject of your letter to Dr Rizza dated 5 December 1990 [OXUH0002128_003][6].

76.1. I believe the terms previously untreated patients (PUPS) and 'virgin patients' both referred to patients who had no previous exposure to factor concentrate, cryoprecipitate or plasma. They were therefore either newly diagnosed patients and if needing factor concentrate likely to be severely affected children or mild/moderately affected patients undergoing surgery.

6 The patients' names have been redacted and are not necessary to answer the questions.

76.2. From 1985, I was aware of the high incidence of NANBH in patients receiving all factor concentrates. BPL were working to develop a severely heat-treated concentrate to eliminate risk of viral transmission. When available this had to be confirmed in human subjects. The tests used were liver transaminases as surrogate markers of NANBH.

76.3. Dr Smith at BPL conducted a 'pilot study'. I submitted results from one patient who received 8Y (factor FVIII concentrate) and one who received 9A (factor IX concentrate) as described in DHSC0001084 (Surveillance for evidence of NANBH transmission by BPL concentrates 8Y and 9A dry heated 80°C 72 h Dr J K Smith) and PRSE0000044 (Colvin BT, Rizza RC, Hill GH, et al Effect of dry-heating of coagulation factor concentrates at 80°C for 72 hours on transmission of non-A, non-B hepatitis. Study Group of the UK Haemophilia Centre Directors on Surveillance of Virus Transmission by Concentrates. Lancet 1988; 2 (8615): 814-6).

76.4. The marked reduction in evidence of transmission of NANBH justified a more formal prospective clinical trial in accordance with ICTH guidelines co-ordinated by Dr C Rizza and Dr P Kernoff. (PRSE0000192). I submitted results from, I believe, another patient who received 8Y (factor FVIII concentrate). The study confirmed the previous findings that severe dry heating of factor VIII concentrate at 80°C for 72 hours reduced the risk of transmission of hepatitis C from 90% to 0-11% (Confirmation of viral safety of dry heated factor VIII concentrate (8Y) prepared by Bio Products Laboratory (BPL): a report on behalf of the UK Haemophilia Centre Directors Brit J Haematol 1991 84 269-272 PRSE0000192).

76.5. I believe the NHS 8Y 'Virgin Patient' Study referred to in my letter to Dr Rizza 5/12/90 (OXUH0002128_003) is the above confirmatory study.

Research

77. Please list all research studies that you were involved with during your time at the BRI, Truro and St James's Hospital that could be relevant to the Inquiry's Terms of Reference, and please:

a) Describe the purpose of the research.

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

c) Explain what your involvement was.

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

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

f) State the number of patients involved.

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

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

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

77.1. My work at St James's Hospital Dublin does not fall within the terms of reference of the UK infected blood inquiry as the patients were not treated by the NHS.

77.2. Publications:

77.2.1. The following are case reports:

77.2.1.1. Daly HM and Scott GL Fatal AIDS in a Haemophiliac in the UK Lancet 1983 ii 1190 (letter) and Lancet, 7 January 1984 (PRSE0004509, MACK0000604_002)

77.2.1.2. Carne CA, Tedder RS, Smith A, Sutherland S, Elkington SG Daly HM, Preston FE and Craske J Acute encephalopathy coincident with seroconversion for anti HTLV III Lancet 1985 ii 1206-1208 (SHTM0000645)

77.2.1.3. Daly HM and Hadden ME Clinical experience with a pasteurised human plasma concentrate in Factor XIII deficiency Thrombos Haemostasis 1988 59 171-174 [WITN4685005]

77.2.1.4. Daly HM, Carson PJ and Smith JK Intracerebral haemorrhage due to acquired FXIII inhibitor - successful response to factor XIII concentrate Blood Coagulation and Fibrinolysis 1991 2 507-514 [WITN4685006]

77.2.2. The following are research studies:

77.2.2.1. Daly HM, Palmer R, Scott GL and Lee G AIDS Surveillance in Haemophilia Brit J Haematol 1985 59 383-390 (GLEW0000677)

77.2.2.2. Daly HM and Wakerley G Experiences in a Coagulation Referral Clinic in Bristol Bristol Medico-Chirugical Journal 1985 1 18-20 [WITN4685007]

77.2.2.3. Surveillance for evidence of NANBH transmission by BPL concentrates 8Y and 9A dry heated 800C 72 h Dr J K Smith 1987 (DHSC0001084)

77.2.2.4. Effect of dry heating of coagulation factor concentrates at 800C for 72 hours on transmission of Non-A, Non-B hepatitis Study Group of the UK Haemophilia Centre Directors on Surveillance of Virus transmission of concentrates Lancet 1988 ii 814-816 (PRSE0000044)

77.2.2.5. Confirmation of viral safety of dry heated factor VIII concentrate (8Y) prepared by Bio Products Laboratory (BPL): a report on behalf of the UK

Haemophilia Centre Directors Brit J Haematol 1991 84 269-272) (PRSE0000192)

77.2.2.6. [See Annexure 1]

77.3. No epidemiological or other studies.

78. The Inquiry understands that a number of studies were undertaken in which your patients may have been enrolled or information about them studied, including the following:

a) 'Surveillance of previously untreated patients for possible virus transmission by BPL factor VIII and IZX concentrates 8Y and 9A' [DHSC0001084] published in the Lancet on 8 October 1988 as 'Effect of Dry-Heating of Coagulation Factor Concentrates at 80C for 72 hours on Transmission of Non-A, Non-B Hepatitis by the Study Group of the UK Haemophilia Centre Directors on Surveillance of Virus Transmission by concentrates' [PRSE0000044],

b) "AIDS surveillance in haemophilia", Daly, Palmer, Scott and G Lee, British Journal of Haematology, 1985, 59, 383 - 390 [GLEW0000677]

c) "Acute encephalopathy coincident with seroconversion for anti-HTLV-IM", Came C.A, Tedder R.S, Smith A, Sutherland S, Elkington S.G, Daly H.M, Preston F.E, Craske J [SHTM0000645]

d) "Fatal AIDS in a haemophiliac in the UK" *Lancet ii,* 1190, Daly, H.M & Scott, G.L [PRSE0004509] and the correction to this publication "Fatal AIDS in a UK

Haemophiliac", *Lancet* (7 January 1984), Daly, H,M & Scott, G [MACK0000604_002]

e) 'Confirmation of viral safety of dry heated factor VIII concentrate (8Y) prepared by Bio Products Laboratory (BPL): a report on behalf of the UK Haemophilia Directors' [PRSE0000192]

f) "Hepatitis A Transmission by Factor IX Concentrates" Vox Sanguinis 1996; 71; 126-128, Lawlor, Graham, Davidson, Yap, Cunningham, Daly, Temperley

g) "Treatment of Haemophilia in the UK 1981 -1996" [HSCC0023510]

78.1. I believe report 'f' above does not fall within the terms of reference of the UK infected blood inquiry as the patients were not treated by the NHS.

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

79.1. Of the above list only a, b and e were research studies.

79.2. No I discussed each study with the relevant patient(s)/parent. I don't remember if verbal or written consent was obtained. When ethical approval was obtained informed written consent was obtained.

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

80.1. See answer Q77 (vi).

80.2. Anonymised data was used for the study Experiences in a Coagulation Referral Clinic in Bristol (Daly HM and Wakerley G Bristol Medico-Chirugical Journal 1985 1 18-20). I also used anonymised data for audit studies which were presented locally and in the region. These were service evaluation to assess care. No change to care or intervention was involved.

80.3. I submitted annual returns for Truro 1986-1991which included name, d.o.b., diagnostic information, inhibitor and HIV status [HSOC0023510] . In the event of an adverse reaction to a blood product (e.g. abnormal liver function, seroconversion for hepatitis) details of the event were reported to the manufacturer of the product where known so the batch could be withdrawn and the event investigated. Both situations were standard of care at the time.

80.4. During that time patient consent for data collection or service evaluation was not sought and was not standard practice.

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

81.1. See answer to Q 66d and Q 80 above.

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

82.1. See answer to Q77 above.

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

83. How was the care and treatment of patients with HIV/AIDS managed at (i) the BRI and (ii) Truro? 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 and their families 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?

83.1. BRI

83.1.1. Haemophilia patients with HIV/AIDS were managed by the Haematology team.

83.1.2. One symptomatic patient was referred for bronchoscopy for diagnosis of pneumonia. A second patient was referred for lymph node excision biopsy

83.1.3. One patient was treated for opportunist fungal infection (PJP).

83.1.4. Index patient was too ill. I discussed his illness with his wife.

83.1.5. Frequent follow up at 1-3 monthly intervals depending on state of health.

83.2. Truro

83.2.1. Haemophilia patients with HIV/AIDS were managed by the haematology and paediatric teams.

83.2.2. Joint care with two specialists

83.2.3. Only zidovudine (AZT) was available at the time

83.2.4. Treatment with AZT was commenced at BCH and risk/benefit discussed there

83.2.5. Symptomatic – at least monthly more often if necessary. Asymptomatic – 3-4 monthly.

84. How was the care and treatment of patients with hepatitis B managed at (i) the BRI and (ii) Truro? In particular:

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

b) What treatment options were offered over the years?

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

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

84.1. BRI

84.1.1. No symptomatic patients and none referred. I suggested referring asymptomatic patients for liver biopsy in early 1980s but it wasn't accepted.

84.1.2. N/A

84.1.3. N/A

84.1.4. Regular non-invasive LFTs

84.2. Truro

84.2.1. N/A

84.2.2. None

84.2.3. N/A

84.2.4. Regular non-invasive LFTs

85. How was the care and treatment of patients with NANB hepatitis managed at (a) the BRI and (b) Truro? In particular:

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

b) What treatment options were offered over the years?

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

85.1. BRI & Truro

85.1.1. None. No symptomatic patients

85.1.2. None

85.1.3. N/A

86. How was the care and treatment of patients with hepatitis C managed at Truro? In particular:

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

b) What treatment options were offered over the years?

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

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

86.1. I do not remember when the results of hepatitis C tests became available. I do not remember any patient being diagnosed with hepatitis C when I worked at Truro.

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

87.1. I provided what was later described as 'medical counselling' to all patients at risk of HIV, and later proven to be HIV positive, at BRI and

RCH-Treliske. This was detailed, frank, truthful and repeated. There was no designated psychological support at that time.

87.2. Social work support was provided at both centres and in particular at Truro but I think was mainly, invaluable, practical support.

88. Did (a) the BRI and/or (b) Truro receive funding from any external source to help with the counselling of patients infected with HIV? If so please provide details.

88.1. I don't know.

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

89.1. I had to make a case for high purity FVIII concentrate as with any new treatment.

90. What if any involvement did you or your colleagues at (a) the BRI and (b) Truro have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

90.1. I had no involvement in clinical trials of treatments for HIV or hepatitis.

Records

91. What was the policy at (a) the BRI and (b) Truro with regards to recording information on death certificates when a patient had been infected with HIV or hepatitis?

91.1. I do not know of a specific policy for HIV and/or hepatitis. To my knowledge it was the same as for any other diagnosis. It tended to be the ward based doctors who wrote the death certificates.

91.2. I put the clinical diagnosis or post mortem diagnosis where applicable. In the BRI there was a high autopsy rate in the early 1980s. For the index patient there was a limited autopsy which confirmed the diagnosis.

91.3. One patient under joint care of haematologists and paediatricians died in Truro. He died at home. I believe the GP may had signed the death certificate.

92. What were the retention policies of (a) the BRI and (b) Truro with regards to medical records during the time you were practising there?

92.1. I do not know how long records of deceased NHS patients were retained. Records of deceased patients were often stored off site. I have had need to obtain information from the medical records of deceased patients a long time after the event. The information was stored on microfiche.

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

93.1. No I don't believe so. Patients on home therapy submitted regular treatment returns but I think these were stored in their medical records.

94. 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 at the hospital at which you worked? If so, why, what information and where is that information held now?

94.1. No.

95. What was the system at (a) the BRI and (b) Truro for keeping records of the blood or blood products that were used?

95.1. I believe blood transfusion records were kept for 30 years. This is now a legal requirement (EU) but even at that time was the norm.

95.2. I don't know where they were stored. In the 1970-1980s laboratory records were handwritten in ledgers and not computerised and therefore some were not of good quality. In the late 1980s these were computerised.

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

96.1. No.

Section 5: UKHCDO

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

97.1. I believe I first attended on behalf of Dr G L Scott in Manchester 1982.

97.2. Once I became Haemophilia Centre Director in Truro in 1988, I attended as Director. I believe I attended each year 1988-1992 inclusive.

97.3. These were day long meetings with presentations on *inter alia* general demographic aspects, hepatitis, inhibitors, HIV infection and deaths.

97.4. The existence of the database was fundamental to the development of knowledge of haemophilia and improvement in haemophilia care in UK. It was an excellent organisation. At the meeting where was a lot of networking and informal discussion in addition to the formal presentations.

97.5. In 1990-1992 I was SW Regional Representative on the UK Regional Haemophilia Centre Director's Committee of the UKHCDO. I was asked to lead a group which aimed to encourage individual directors to submit their returns. Most directors did but some didn't. I was asked to improve matters

97.6. I was involved with the Study Group of the UK Haemophilia Centre Directors on Surveillance of Virus Transmission by Concentrates through my submission of data on 2 patients. (See PRSE0000044).

Section 6: Blood services and BPL

98. Please describe the relationship between (a) the BRI and (b) Truro and (i) the blood services and (ii) BPL over the years in which you worked at the respective Centres?

98.1. Both BRI and Truro had a close relationship with the Blood Transfusion Service which provided blood, plasma, platelet concentrate and cryoprecipitate for essential patient care. They also provided expert opinion when required. The Medical Director was also consultant haematologist at Southmead Hospital where I did part of my training, so I knew him well. I trained for six months at the Regional Blood Transfusion Centre. Many of the MLSOs in the SW Region did periods of training there also.

98.2. Bio-Products Laboratory was the national fractionation centre and produced factor concentrates from plasma donated by volunteer non-remunerated donors in England and Wales as convenient treatment for patients with haemophilia A and B and other rare coagulation deficiencies. The BRI received both FVIII and FIX concentrate from BPL. I knew of Dr J Smith from UKHCDO meetings. I contacted him when I needed FXIII concentrate to treat 2 young children (BCH). FXIII was available on a named patient basis from Bio Products Laboratory. [HSOC0023510: Treatment of Haemophilia in the UK 1981-1996 pg. 353].

99. Please outline the interactions and dealings you had with the blood services, whether on a regional or national level, and/or with BPL during the time that you worked at (a) the BRI and (b) Truro. In answering this question, you might wish to refer to your letter to all Haemophilia Centre Directors of the South West Region dated 23 March 1991 [TSFT0000001_016].

99.1. (NB - TSFT0000001_016 - I only have the first page of this correspondence so I am without the entire document which I understand

is no longer available. I reserve the right to add to / amend my response should the 2nd page become available.)

99.2. My contact with the Blood Transfusions Service was on a Regional level at both BRI and Truro. I did 6 months training in blood transfusion in the Regional Blood Transfusion Centre at Southmead Hospital and therefore knew many of the staff.

99.3. I was a consultant haematologist in Truro in receipt of blood and blood products from the Regional Centre on a constant routine and occasional emergency basis. They never let us down even though Truro was the furthest city from a Blood Transfusion Centre in the UK and our catchment included the Scilly isles.

99.4. As a member of the study group of the UKHCD on surveillance of virus transmission of NANBH, I was involved in studies of BPL heat treated factor VIII and FIX concentrates (8Y and 9A) with Dr J Smith. At Truro I also had patients with anti-thrombin III and protein C deficiency. I believe I obtained protein C concentrate and advice from Dr J Smith at BPL to treat a patient with protein C Deficiency during labour and also to treat a patient with an exceedingly rare acquired FXIII inhibitor with BPL FXIII concentrate. On each occasion they were extremely helpful. I have joint publications with BPL staff.

99.5. I was SW Regional Representative on the UKHCDO and co-ordinated the haemophilia treaters group.

99.6. TSFT0000001_016 is the first page of a letter from me to the Haemophilia Centred Directors in the SW region and Dr I Fraser Medical Director Regional BTS 23/3/1991. In it I refer to a visit to me from the BPL representative re BPL (high purity) Monoclonal FVIII concentrate which was now available in sufficient amounts for our needs and due to be authorised 1/4/1991. As a licensed product it would be preferred in line with the recommendation of the UKHCDO.

99.7. I refer to the production process, costing and indicate that I am likely to use it by inference in preference to the use of a commercial monoclonal product already in use because it was a national product, derived from UK non-remunerated donors, licensed and we needed a balance between RBCs, platelets and plasma obtained in the region.

100. Please refer to your letters to Dr Snape, the then Head of Quality Control at the Blood Products Laboratory ("BPL") regarding one of your patients [BPLL0010527 and BPLL0010525[7]] and answer the following questions:

a) Were patients, generally, notified of the fact that their liver function was being monitored regularly?

100.1. Yes patients knew their LFTs were monitored for hepatitis. Please see answer to Q 61 and Q 66.

b) why was information of this nature being provided to BPL? Were patients told that their personal information was being shared with BPL? If not, why not?

100.2. BPLL0010527 This is an initial report (Dec 1985) , and BPLL0010525 a follow up report, of an important adverse event (NANBH) following heat treated BPL FVIII concentrate to Dr T Snape Head of Quality Control at BPL.

100.3. Please see answer to Q 66 and Q 81 above.

100.4. In the event of an adverse reaction to a blood product e.g. abnormal liver function, seroconversion for hepatitis, details of the event were reported to the manufacturer of the product where known so the batch could be withdrawn and the event investigated. Both reflected the standard of care at the time.

7 The patient's name has been redacted and is not necessary to answer the questions.

100.5. I cannot remember if I told this boy's parent, but it is likely I did. In general, I explained to patients/parents that it was important to report such events to prevent another patient becoming infected. Most patients were in favour of this.

Section 7: Pharmaceutical companies/medical research/clinical trials

101. Have you ever:

a) provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products?

101.1. No.

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?

101.2. No.

c) sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?

101.3. No.

d) received any financial incentives from pharmaceutical companies to use certain blood products?

101.4. No.

e) received any non-financial incentives from pharmaceutical companies to use certain blood products?

101.5. No.

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

101.6. No.

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

101.7. No.

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

101.8. No.

101.9. I did not have close contact with Pharmaceutical companies.

If so, please provide details.

101.10. As senior registrar I was funded by Armour Pharmaceuticals to attend the XVII World Federation of Haemophilia World Congress June 8-13 1986 Milan where I presented a poster on FXIII deficiency. I cannot remember what was involved. I think my flights and my accommodation in a Pension were paid.

101.11. I also attended a funded dinner in Amsterdam at a World Federation of Haemophilia World Congress in the 1980s.

102. What regulations or requirements or guidelines were in place at the time 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?

102.1. N/A

103. 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?

103.1. N/A

Section 8: Involvement with the financial support schemes

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

104.1. The only Trust I recognise is the Macfarlane Trust.

104.2. My memory is very vague.

104.3. I think I was asked to sign a form(s) on behalf of a patient(s) by the hospital Social Worker to support assistance such as nutrition and/or heat in which case(s) I did so.

Section 9: Other Issues

105. 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.

105.1. None that I am aware of.

106. 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.

106.1. The questions above to relate to haemophilia. I also treated two children in Bristol with congenital FXIII deficiency with a BPL pasteurised FXIII concentrate (Daly HM and Hadden ME Clinical experience with a pasteurised human plasma concentrate in Factor XIII deficiency Thrombos Haemostasis 1988 59 171-174 [WITN4685005]) and a patient in Truro with an acquired inhibitor to FXIII with the same concentrate (Daly HM, Carso PJ and Smith JK Intracerebral haemorrhage due to

acquired FXIII inhibitor - successful response to factor XIII concentrate Blood Coagulation and Fibrinolysis 1991 2 507-514 [WITN4685006]).

Statement of Truth

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

Signed: GRO-C

Date: ……22/3/2021……

Table of exhibits:

Date	Notes/ Description	Exhibit number	Section
2000	Letter Dr G L Scott to Dr H Daly 29/6/2000	WITN4685002	2
1983	Letter Prof A L Bloom to Dr H Daly 7/7/1983	WITN4685003	2
1986	Learning about Haemophilia: An alternate source of information C	WITN4685004	3

Date	Notes/ Description	Exhibit number	Section
	Kendrick Bristol Medico-Chirugical Journal Dec 1986 132-133		
1988	Clinical experience with a pasteurised human plasma concentrate in Factor XIII deficiency Daly HM and Hadden ME Thrombos Haemostasis 1988 59 171-174	WITN4685005	4
1991	Intracerebral haemorrhage due to acquired FXIII inhibitor - successful response to factor XIII concentrate Daly HM, Carson PJ and Smith JK Blood Coagulation and Fibrinolysis 1991 2 507-514	WITN4685006	4
1985	Experiences in a Coagulation Referral Clinic in Bristol Daly HM and Wakerley G Bristol Medico-Chirugical Journal 1985 1 18-20	WITN4685007	3

ANNEXURE 1

	a) purpose of research	b) steps taken to obtain approval	c) what your involvement was	d) other organisations/ bodies involved	e) how funded	f) No. of patients involved.	g) details of steps taken to inform patient & seek informed consent	h) details of publication
Case reports								
1	Not research. Report of 1st case.	N/A	I, among others, cared for the patient & wrote the report	None	N/A	1	N/A	See 1 above
2	Not research. Case report	N/A	I, among others, cared for the patient	Virology Dept Middlesex Hosp	Med Research Council	3	N/A	See 2 above

	a) purpose of research	b) steps taken to obtain approval	c) what your involvement was	d) other organisations/ bodies involved	e) how funded	f) No. of patients involved.	g) details of steps taken to inform patient & seek informed consent	h) details of publication
			& wrote the report					
3	Clinical experience with a new pasteurised FXIII concentrate	N/A	I supervised administration & monitored results	Bristol Children's Hosp/ BPL	N/A	2	Consent was obtained from parents.	See 3 above
4	Case report	N/A	I investigated & treated patient	BPL	N/A	1	I discussed initial Rx with patient	See 4 above

	a) purpose of research	b) steps taken to obtain approval	c) what your involvement was	d) other organisations/ bodies involved	e) how funded	f) No. of patients involved.	g) details of steps taken to inform patient & seek informed consent	h) details of publication
				Dept of Medicine St James's Hosp Leeds				
Research								
5	AIDS Surveillance in Haemophilia	Approved by Ethical Committee Bristol & Weston Health Authority	I undertook the research & wrote it up	Southmead Hosp Bristol	Bristol District Medical Research Committee grant	43	Informed consent was obtained from patients.	See 5 above

	a) purpose of research	b) steps taken to obtain approval	c) what your involvement was	d) other organisations/ bodies involved	e) how funded	f) No. of patients involved.	g) details of steps taken to inform patient & seek informed consent	h) details of publication
					(project) No. 426			
6	Need for a coagulation referral clinic	N/A	I initiated the clinic	None	N/A	99	N/A Service evaluation	See 6 above
7	Effect of dry heat of factor concentrate at 80^0C x 72 h on	I don't remember	Submitted data on 2-3 patients	Study group of the UKHCDO on surveillance of virus transmission by concentrates	I don't know	2-3 of 32	Informed consent obtained from parent/patient.	See 7 above

	a) purpose of research	b) steps taken to obtain approval	c) what your involvement was	d) other organisations/ bodies involved	e) how funded	f) No. of patients involved.	g) details of steps taken to inform patient & seek informed consent	h) details of publication
	transmission of NANBH							
Treatment of haemophilia in the UK 1981-1996 Pg. 350 for the period covered by this report (1981-1996), patient consent for data collection was not sought and was not required by law.								
Service Evaluation. Designed and conducted solely to define or judge current care within a single service - no measure against a predetermined standard. No change/intervention to care.								