Witness Name: Dr Elizabeth Mayne
Statement No. WITN0736009
Exhibits: **WITN0736010** to **WITN0736014**
Dated: 4 February 2021

INFECTED BLOOD INQUIRY

SIXTH WRITTEN STATEMENT OF DR ELIZABETH MAYNE

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

0.2 I, Dr Elizabeth Mayne, will say as follows: -

Preliminary Remarks

0.4 In making this statement, my sixth Rule 9 response, I have endeavoured to address the issues raised in the Rule 9 request to the best of my ability.

0.5 However, I should I indicate at the outset that I am relying on my recollection of events and details that took place up to 50 years ago from the 1960s, through to the late 1990s. I am an octogenarian and I suffer from serious health issues which are known the Inquiry. I have considerable difficulty with both sight and hearing. My ability to read contemporaneous clinical notes is impaired. There is inevitable fading of memory with the passage of time, and the preparation of this statement has been challenging. There are aspects of the Rule 9 request that I have not been able to deal with as comprehensively or with the detail I would have liked. However, notwithstanding these limitations, I have answered the questions to the best of my ability; I would like to point out to the Inquiry that it is not easy to rejuvenate the elderly brain.

Insofar as I have addressed some of these issues in my earlier statements and there are differences in my recollection, I would have greater confidence in what is stated in this statement.

Section 1: Introduction

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

1.1 My name is Dr Elizabeth Emily Mayne. My address is known to the Inquiry. My date of birth is known to the Inquiry.

1.2 I hold the following qualifications:-

MB BCh BAO	1962 The Queen's University of Belfast
MD (by thesis)	1968 The Queen's University of Belfast
MRCPath (by examination)	1970
FRCPath	1982
MCRP (Glas)	1984
FRCP (Glas)	1986
FFP (RCPI) (by invitation)	1995
FRCP (Edin)	1998
FRCP (Lon)	1998
FRCP (Ireland)	2002

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 have held the following positions as a Haematologist and specialist:-

- Senior Registrar, Clinical Pathology (Haematology), Royal Victoria Hospital, Belfast, 1968-1972.
- Consultant Clinical Haematologist (with a special interest in bleeding and clotting disorders), Royal Victoria Hospital, Belfast, 1972-1999.
- Director, Northern Ireland Haemophilia Reference Centre, Royal Victoria Hospital, Belfast, 1978–1999.

2.2 I retired in 1999.

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 I have been a member of the following Committees or groups:-

- Member of the Standing Commission of Human Rights (NI) 1979-1985.
- Member of the Committee on the Safety of Medicines 1987-1989.
- Member of the United Kingdom Haemophilia Centre Directors' Organisation 1967-1999.
- Chairman of the United Kingdom Haemophilia Centre Directors' Organisation 1990-1993.
- Trustee of the Macfarlane Trust (Department of Health) 1991-1996.
- Trustee of the Eileen Trust 1993-1996.
- Chairman of the Research Ethics Committee of the Queen's University of Belfast (1995-1999).
- Honorary Lecturer in Haematology at the Queen's University of Belfast 1983-1991.
- Honorary Reader in Haematology 1991-1999.
- Member of the Association of Clinical Pathologists 1968-1999.
- Association of Clinical Pathologists Broadsheet Editor, Technical Methods Committee 1987-1989.

- Member of the British Society of Haematology 1973–2001.
- Member of the British Society of Haematology, Thrombosis and Haemostasis Task Force 1978-1986.
- Member of the Sub-Committee of Thrombosis and Haemostasis Task Force: Thromboplastin Standardisation Monitoring Committee 1981-1984.
- Member of the UK Haemophilia Society Medical Advisory Panel 1982-1994.
- Member of the United Kingdom Haemophilia Reference Centre Directors AIDS Working Party 1983-1999.
- Member of the International Society for Haemostasis and Thrombosis 1971-2000.
- Member of the World Federation of Haemophilia 1980-2003.
- Vice-President of the World Federation of Haemophilia 1996.
- Member of the Scottish and Northern Ireland Haemophilia Centre Directors Committee 1988.
- Haemophilia Directors Scottish and Northern Ireland Coagulation Working Party 1988–1999.
- Royal College of Pathologists (Haematology) Board of Clinical Examiners 1981-1999.
- Royal College of Pathologists (Haematology) Senior Examiner 1993-1996.
- Honorary Life Member of the Ulster Society of Obstetricians and Gynaecologists for services to women with acquired and inherited bleeding disorders 1992-date.
- President of the Northern Ireland Medico-Legal Society 2006-2007 – Address: History of Haemophilia entitled 'Drawing Blood'.
- President of the Ulster Medical Society 2003-2004 – Address: 'Haemophilia – The Gender Trap'.
- First female Chairman of the Medical Staff Committee of the Royal Victoria Hospital, Belfast 1997-1999.
- Reviewer of Papers for Medical Journals:

- Haemophilia
- British Journal of Haematology
- Blood Coagulations and Fibrinolysis
- Diabetologia

- Journal of Pathology and Bacteriology
- Ulster Medical Journal.

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 that you provided.

4.1 I prepared an expert report for the HIV litigation in England and Wales in 1990. A copy of that report is included in the Inquiry's database (CBLA0000072_024).

4.2 I am aware that three patients commenced civil litigation against the Eastern Health and Social Services Board in respect of HCV infection. I was invited to submit appropriate medical reports. I did not receive any official notification of the outcomes, although I did learn that one claim had been withdrawn. I presumed that the others were settled out of Court. I was not invited to provide oral evidence or attend Court.

Section 2: Decisions and actions of the Northern Ireland Haemophilia Centre

5. Please describe the roles, functions and responsibilities of the Haemophilia Centre in Belfast ("the Centre") during the time you worked there, both before it became a Reference Centre in 1980 and after.

5.1 In 1963 after completing my pre-registration year, I attained a Senior House Officer post in the then designated department of Clinical Pathology under Professor (then Dr) M G Nelson, Consultant Haematologist, After a period of training in routine haematology I undertook two years of research. In 1967 I returned to the Department as one of four Registrars.

5.2 At that time Dr Nelson suggested that I undertook the organisation and development of the relocated coagulation laboratory as an appropriate follow-up to my research. In addition, he suggested I develop a special interest in the management of Haemophilia and allied disorders.

5.3 The late 1960s was a special time for Haemophilia. Cryoprecipitate, the first really effective treatment had been discovered by Pool and Shannon in 1965.

5.4 My fellow registrar, Dr Brian Otridge, initially, was responsible for preparing 'in house' cryo within the hospital Blood Bank. He took up a consultant post in Dublin in 1968. I took over his mantle until the preparation of cryo was transferred to the Northern Ireland Blood Transfusion Service (NIBTS) for production on a larger scale.

5.5 During the 1960s the Hospital had been designated as the Treatment Centre for Haemophilia in Northern Ireland. Due to the small patient numbers, it was affiliated to the major centre in Oxford. Dr Charles Rizza acted as specialist advisor. If necessary planned surgery would be undertaken there. The Centre in Belfast had no physical presence as one would understand it today.

5.6 Patients attended the department on an ad hoc basis. They were examined within Dr Nelson's rooms. The Fracture Clinic provided plaster casts for immobilisation as and when necessary. Fresh frozen plasma (FFP) was administered to patients in whichever Medical ward had bed availability – not an ideal situation.

5.7 During the next thirty years plus the Centre developed, albeit slowly, along several lines. Physical space was obtained for both outpatient and inpatient facilities. Over time funding was obtained to provide appropriate Centre staffing levels, medical, nursing, secretarial, technical and ancillary personnel were appointed.

5.8 The Inquiry may be assisted by a report written by me on the activity of the Centre for the year 1991/92 as a contemporaneous record for that time. See WITN0736010 '1991 Report of Activity of the Northern Ireland Regional Centre for

Hereditary Haemorrhagic Disorders, also incorporating Hereditary Thrombotic Disorders'

5.9 At the time of my retirement in May 1999 the Centre was due to move to new purpose built accommodation within the Belfast City Hospital. It would be overseen by my successor and all the staff would be transferred, namely:

- One Specialist Haemophilia Senior Nurse.
- One Senior Staff Nurse/Sister.
- 1 E grade Staff Nurse.
- One fully trained Nurse who had a dual role of a fully trained Aromatherapist/Reflexologist.

- The Director: A part time Consultant Haematologist.
- One full time non Consultant staff grade Doctor.
- A Registrar rotating sixth monthly through the Haematology unit.
- House Physician from inpatient unit.
- Dedicated Dental Consultant on site.
- Visiting Consultant Orthopaedic Surgeon (attending Centre)
- Visiting Consultant Hepatologist (attending Centre)

- Two full-time secretaries.
- Receptionist.

- One Chief MLSO and three MLSOs.
- One Senior Research Bio-scientist.

- A Physiotherapist
- A Social Worker

5.10 The above staff enabled the Centre to provide an appropriate comprehensive range of treatment and support to those with inherited bleeding and clotting disorders and a dedicated phone line for help and advice.

5.11 Finally, over several decades prior to the described relocation, educational seminars, tutorials and lectures took place on the Royal Victoria Hospital site to promote the understanding of Haemophilia. Patients were seldom annoyed by the ignorance of members of the general public, but they despaired at the lack of knowledge shown by some of the medical profession. I had never seen let alone examined a haemophiliac when I qualified in 1962.

5.12 The job description for my successor was for a full time Director of the Centre.

6. Please:

a. Explain the relationship between the Centre and the Eastern Health and Social Services Board and where decision-making responsibility lay between the two as regards to any matters falling within the Inquiry's Terms of Reference.

6.1 The relationship between the Centre and the Eastern Health and Social Services Board was cordial and supportive. Responsibility for clinical decision-making lay with the Centre.

6.2 Responsibility for administrative and funding decisions lay with the Board. There was no official timetable for meetings. Discussions were held as and when deemed necessary. On a routine basis a report on the Centre's activities was presented to the Board.

6.3 Meetings were convened from time to time to discuss the financial implications involved in the purchase of Factor Concentrates. Northern Ireland had a proportionately higher number of Inhibitor patients than the rest of the UK. These patients had to be treated with products such as FEIBA and porcine Factor VIII which were very expensive.

6.4 At all times, the Board was reasonable and had constructive advice to offer. I recall providing guidance and advice to the Board relating to the assessment of haemophiliac patients for social benefits such as Attendance Allowance. The Board doctors found this acceptable. There was no problem in seeking funds.

b. Identify any other board or body which had responsibility for the Centre during the period that you worked there and explain where decision-making responsibility lay in relation to that board or body as regards to any matters falling within the Inquiry's Terms of Reference.

6.5 No other body had responsibility for the Centre during the period I worked there.

7. Please describe your role and responsibilities as director of the Centre.

7.1 In November 1972 I was appointed as Clinical Haematologist to the Royal Victoria Hospital, with a special interest in bleeding and clotting disorders.

7.2 My prime duty was to provide an accurate diagnostic service for all patients with haemophilia and allied disorders. This service included a comprehensive care/treatment facility for all patients diagnosed as having an inherited bleeding disorder. The largest group comprised those males suffering from Haemophilia A or B, also both sexes affected by the Von Willebrand Syndrome. It also included a small group of patients with other single Factor deficiencies and a few with rare platelet conditions.

7.3 As time went by new diagnoses of inherited thrombotic disorders came to the fore. They also had to be accommodated for on a diagnostic, emergency and planned treatment basis.

7.4 Despite the time required to fulfil the aforesaid duties, it seems appropriate to indicate that I was also responsible for providing a general haematological service to the site. I was responsible for the hospital's anti-coagulant control service; likewise I had to ensure that advice was available for the management of serious acquired abnormal bleeding problems in ICU and across other specialties.

7.5 ICU provided a particular challenge in relation to total clotting failure – it was not uncommon to be collecting the bleeding in buckets – it was often wrongly described as acquired haemophilia. It was caused by the release of pro clotting substances from bomb blasted/multiple gunshot injuries to the tissues as a result of 'civil conflict'. The release of these substances triggered clotting in the micro circulation, depleted the clotting factors, especially Factor VIII hence the misnomer. It occasionally led to the administration of concentrate incorrectly. Factor replacement had to be carried out under cover of anticoagulant therapy associated with the appropriate tissue/organ repair. After some experience, suitable protocols were established. I am told they remain in use today.

7.6 The Inquiry may be wearied by the detail, but it seemed important to indicate the considerable overlap which existed between duties directly related to the Centre and the wider field. I have spared the Inquiry from any further details of teaching, meetings and the like.

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

8.1 The original register of haemophilia patients which I received in the 1960s contained 44 names. The most recent documented figures I have are contained in the Annual Report of 1991, which is the only one remaining in my possession. At my retirement, the haemophilia and bleeding disorder register contained 300 names.

9. What decisions and actions were taken, and what policies were formulated, by you and by the Centre, regarding the manufacture, importation and use of blood products (in particular factor concentrates) during the time that you were director?

9.1 See 10 below.

10. What responsibility did the Centre, and you as its director, have for the selection and purchase of blood products? In addressing this issue, please answer the following questions:

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

10.1 In the 1970s, apart from myself no other individual was concerned with the selection and purchase of Factor Concentrate. Cryoprecipitate remained the treatment of choice for children. The then Paediatric Haematologist, rightly, declined involvement in discussing the selection of products for adults.

10.2 The first use of concentrate in Belfast was in November 1971. A haemophilic was admitted with severe intestinal bleeding. Copious amounts of 'cryo' were ineffective. It was impossible to stop the bleeding. He had developed a High Responding Inhibitor. It negated the effect of his treatment.

10.3 Earlier that month, I had returned from USA having spent time there doing platelet research at Browne University, Rhode Island, under Professor Mario Baldini. Later, in Boston, I saw the new Factor VIII concentrate being used most effectively to treat haemophilic bleeding. I was impressed and brought this information home. Thus, my senior colleague Dr John Bridges recalling this information suggested that I speak to my colleagues in the USA to see if any of the new concentrate could be procured for this young man who was exsanguinating. I duly made contact. I arranged for a consignment of "Hemofil" (manufactured by Travenol Laboratories Ltd) to be sent to Belfast. Coincidentally on that very day Prof Isley Ingram from St Thomas's in London had an identical problem. The company agreed to double the consignment to the UK. The product arrived in Belfast that evening. After treatment, the bleeding stopped and the patient remained well until discharge. Thereafter, Hemofil was the only commercial concentrate in use in Belfast for the next three years.

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

10.4 Kryobulin (Immuno Ltd Vienna) was chosen as the most suitable product for Home Treatment (HT) patients for a variety of reasons.

10.5 Firstly, the packaging had been well thought out by the company. It was eminently suitable for all patient requirements to enable an injection to be prepared and administered with ease. All components were available and presented with clear instructions - right down to the Mister Men plasters! The latter amused the adults. The company personnel were business-like and efficient.

10.6 The only concentrate in use in the Centre previously was Hemofil. That company had no Home Treatment (HT) package and did not wish to increase their commitment to Northern Ireland.

10.7 Therefore the Centre's treatment policy was as follows:

1. Cryoprecipitate for children
2. Hemofil for all non HT patients
3. Kryobulin for all HT patients

thereby attempting to minimise donor exposure in each group. There was no cross over of usage between groups. This is a most relevant point.

10.8 Furthermore, the number of companies that would need to be dealt with was also minimised, just in case of any mishap or complication that might occur. Always I had concerns regarding the repeated injections of IV material in relation to the risk of as yet unknown viruses being transmitted.

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

10.9 It was difficult in the early days to estimate the quantities of concentrate required, particularly for home treatment patients. I came to the conclusion that these patients would require amounts double or even treble after their first year of treatment. It seemed likely that patients would change from using treatment to stop a

bleed when it occurred to taking treatment to prevent a bleed occurring. Each patient would develop a particular pattern of prophylaxis to suit his lifestyle. This scenario did occur. The expected increase in demand for concentrate developed. Therefore, it became necessary to meet frequently with both companies to plan and adjust standing orders to obtain discounts for the increased quantities in use and to ensure continuity of availability.

10.10 During the late 1980s, a third product had to be introduced due to increased demands for Kryobulin creating a significant shortage. Armour Pharmaceuticals made a successful tender and became the provider of the third product.

d. In the document entitled 'A Synopsis of Haemophilia', you state that a "Policy was adopted in 1977" which concerned the usage of commercial factor VIII material. Please explain precisely what this policy was, the rationale for the policy, the considerations that were taken into account in formulating the policy and how the policy changed or developed over time.

10.12 Please refer to the response to 10 (b) and (c) above.

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

11.1 The relationship which existed between the Centre and the pharmaceutical companies was business-like and professional. Please see section 8 dealing with pharmaceutical companies.

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

12.1 To the best of my recollection, responsibility for the selection and purchase of blood products lay with the Centre during my time as Director. However, my

attention has been drawn to an Eastern Health & Social Services memo dated 25 October 1984 which indicates that from 1 December 1984 all blood products listed in a schedule to the memo were to be obtained from NIBTS. I would accept the memo as correctly representing the situation post December 1984. See BHCT0000501.

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

13.1 A number of treatments other than concentrates were and are available. These included: -

a) Fresh Frozen Plasma (F.F.P.)
b) Russell's viper venom (STYPVEN)
c) D.D.A.V.P (D-amino vasopressin)
d) CRYOPRECIPITATE
e) Epsilon amino caproic acid (E.A.C.A) Tranexamic acid (CYCLOKAPRON)

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

14.1 At the outset, it is necessary to state that meaningful discussion of advantages and disadvantages of alternative treatments raises a range of complex issues. Effective treatment of bleeding disorders is patient specific and must take account of individual circumstances. Evaluation of treatments other than concentrates cannot be done in isolation. The fact that, once they became available, concentrates offered many advantages, cannot be ignored.

14.2 I have already outlined the Centre's approach to different treatment options for haemophilia; however, I consider it sufficiently important to expand on what I have already said in the context of how treatment evolved over time.

Cryoprecipitate

14.3 When planning for home treatment with concentrates, I was anxious and apprehensive about repeatedly injecting patients with any material, particularly over periods of weeks and months via the intravenous route. Therefore, I decided that all children should remain on treatment with cryoprecipitate. This was early in the 1970s and Dr John Bridges, the paediatric haematologist, was happy with the decision. Later in 1982, his newly appointed successor, Dr SI Dempsey, was even more enthusiastic about using cryo in this way than myself. However, we agreed an exception should be made in respect of a very limited category of patient.

14.4 In addition to the two severely affected paediatric patients already on home treatment, it was decided that patients with brain injuries or those who required major surgery should have definitive amounts of Factor VIII concentrate to guarantee the achievement of 100% VIII C levels. Fortunately, the situation never arose and concentrates were never used in those circumstances during my time.

Why cryoprecipitate for Children?

14.5 Due to their diminutive size, children did not require large doses of cryoprecipitate to be effective. This reduced the likelihood of allergic reactions which were common in adult patients who did require larger doses. There are a number of problems associated with using cryoprecipitate in large doses.

Disadvantages of cryoprecipitate

14.6 Firstly, the inability to make reliable dose calculations. This was a very significant problem. Factor VIII C clotting activity has a wide physiological variation. It can increase (along with other clotting factors) four-fold during the third trimester of pregnancy. Likewise, it is raised taking the oral contraceptive pill. It is also increased at ovulation, the point mid-cycle of the menstrual period. This is probably designed, physiologically, to aid ovulation. Thereafter the level falls again prior to the onset of

menstrual bleeding. Exercise, particularly circuit running, is also associated with doubling or trebling the Factor VIII clotting activity on a temporary basis. It is likely due to increased blood flow through the spleen which then releases its Factor VIII clotting activity from its normal pool. Thus there is wide variation in the VIII C activity from batch to batch of cryoprecipitate, dependent on the status of the donor.

14.7 Secondly, there is a purity issue due to the presence of 'incidental' material. During the time I was involved in the preparation of cryo, technicians, including myself, noticed packs which had an odd iridescent green colour, while others noticed that during sunny summer periods it often showed a distinct orange, almost red, colour. It transpired that the first change was caused by the donor using the oral contraceptive pill. The second was caused by donors using self-tanning sprays and lotions.

14.8 Thirdly, allergic reactions occurred in some patients. Reactions were mild – such as an itchy rash, but others were more alarming clinically with temperature rises and rigors often lasting several hours.

14.9 Fourthly, its preparation for use and its administration are relatively time consuming and inconvenient. A fridge freezer is necessary for safe storage. Generally patients prefer other forms of treatment.

14.10 Fifthly, like all untreated blood products it carries the risk of viral infection.

Antifibrinolytic agents and DDAVP

14.11 Antifibrinolytic agents and DDAVP were, and are, used frequently and regularly especially at the time of dental extractions. They are also valuable for the treatment of menorrhagia in haemophilia carrier patients or, those with the Von Willebrand Syndrome or Hereditary Telangiectasia.

Concluding remarks

14.12 All treatments have advantages and disadvantages. They each have their appropriate time and place. However, that time and place may change with expanding knowledge and experience.

15. What was your/the Centre's policy as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? How did that policy change over time?

15.1 See 14 above.

16. In the document entitled 'A Synopsis of Haemophilia', you stated that "it was felt important to try and treat all children with locally prepared Cryoprecipitate in the first instance to avoid hepatitis". When did you decide that it was important to treat children in this way? To what extent did you, in accordance with this decision, treat children with locally prepared cryoprecipitate rather than with other products?

16.1 See 14 above.

17. In your expert report dated May 1990, you referred to the use of cryoprecipitate for "mildly affected haemophiliac patients, children and patients with the von Willebrand syndrome" being advocated by the UKCDO in June 1983 and stated that "many centres already operated such a policy". Did your Centre already operate a policy of using cryoprecipitate for patients within those categories? If not, why and did the Centre change its policy in or after June 1983?

17.1 As described above, the policy of using cryoprecipitate for treating mildly affected patients and children was adhered to but, at times, proved in practice to be much more complex than expected.

17.2 Cryoprecipitate, DDAVP and antifibrinolytic agents were, and are, used for the management of Von Willebrand's syndrome. Further information is included at 20 below.

18. What was your/the Centre's policy and approach in relation to home treatment and prophylactic treatment?

18.1 The policy of the Centre towards home treatment and prophylaxis treatment has already been addressed at 10 above.

19. What was your/the Centre's policy and approach in relation to the use of factor concentrates for children?

19.1 The Centre's policy and approach in relation to children was to use cryoprecipitate. Concentrates would only be used where a child developed a severe skull or brain injury or indeed required major surgery such as cardiac intervention. In those situations, it would not be ethically appropriate to cover them solely with cryoprecipitate. It would be vital to achieve 100% haemostasis. Fortunately, such a situation never arose in my time.

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

20.1 As already stated, effective treatment of bleeding disorders is patient specific and needs to take account of individual circumstances. Occasionally, it was necessary to use concentrates for patients whose bleeding disorders were classified as mild or moderate. I can best illustrate circumstances in which this situation arose by reference to specific examples.

20.2 Mildly affected patients with haemophilia attended the Centre sporadically, often following trauma or when requiring dental extractions. Occasionally, problems arose within a family. In one case, Factor VIII clotting levels of two brothers always were found to be in excess of 30% of normal. One might say a "typical" level for a mildly affected patient. However, clinically the brothers were much more severely affected. Appropriate doses of cryoprecipitate proved totally ineffective.

20.3 After some time I decided to check their Factor VIII clotting activity myself using two completely different techniques. My senior MLSO in the blood coagulation laboratory undertook the same tests in parallel. The results coming from both of us were identical. The two stage techniques gave results of only 3 to 5% clotting activity but the conventional modern one stage method revealed 30 to 40%. These results were confirmed by colleagues in Oxford.

20.4 Unfortunately, my colleagues in Oxford had no help to offer in terms of management of treatment of the patients but did suggest that probably we would have to resort to concentrates. Eventually the problem was resolved by mutational analysis in 2008.

20.5 The second example concerns two related families. One family was clearly clinically and laboratory-wise, severely affected and they went on to a home treatment programme with Kryobulin. The other family (cousins of the first family) was clinically and laboratory-wise not so severely affected. After some time, possibly two to three years, I decided to do their Factor VIII clotting levels via two different techniques. Once again, my senior MLSO performed the tasks in parallel. Both sets of results were the same. The old-fashioned two-stage technique indicated clotting factor of 3 to 5%. The conventional modern one stage method revealed the usual 30 to 40% of Factor VIII activity.

20.6 Following this investigation, the two-stage results were used as the levels to monitor treatment. The brothers were treated with calculated doses of concentrate. Theoretically, I would have advocated the use of much larger doses of cryoprecipitate, but by the time these results were available the patients had become used to concentrate and rejected cryoprecipitate.

20.7 I have gone into these cases in some detail to explain that classification of bleeding disorders as 'mild' or 'moderate' in vivo activity is not always straightforward nor is it a reliable indication of patients' clotting Factor VIII. Limiting treatment to, for example, cryoprecipitate is, in practice, not always as easy as it might seem in theory.

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

21.1 I do not recall any other viral infections occurring in the Centre patients, but I do recall in approximately 1999, one patient's viral screening showed that at some time he had been exposed to CMV. The latter is more commonly transmitted by a cellular type of infusion – i.e. whole blood or platelets. I know of no other infections.

Section 3: Knowledge of, and response to, risk

General

22. When you became a consultant haematologist in 1972, what did you know and understand about the risks of infection associated with blood and/or blood products? How did your knowledge and understanding develop over time?

22.1 The possible transmission of viral hepatitis through blood transfusion, plasma infusion or the infusion of plasma derived products has been well known for a long time. I first learned of it as an undergraduate in the 1950s.

22.2 It would seem appropriate at this stage to point out to the Inquiry that in order to attain the examination of MRCPath in Haematology it is necessary to spend time within the Blood Transfusion Service. During this time, in my case the topic of transmission induced infection was dealt with in detail. Later, the topic was kept under review, both formally by postgraduate courses eg the Hammersmith summer course for Consultants, and informally with NIBTS and virologist colleagues.

22.3 Between the late-1970s and the mid-1980s, there was increasing evidence that NANB hepatitis was not as benign as had been thought but could progress from

chronic persistent hepatitis to cirrhosis. It is important to stress that it was an evolving picture.

23. What advisory and decision-making structures were in place, or were put in place (i) at the Centre, and (ii) in Northern Ireland to consider and assess the risks of infection associated with the use of blood and/or blood products?

23.1 There was no formal advisory and decision-making structure at the Centre or in Northern Ireland. I suspect it was deemed unnecessary as excellent advice was available from Professor John Connolly, Virologist and from the UKHCDO and the WHO.

24. What was your understanding of the relative risks of infection from (i) the use of commercially supplied blood products, and (ii) the use of NHS blood products?

24.1 I was aware there was a higher prevalence of NANB infection associated with commercial concentrate compared to NHS concentrate but the latter also presented a significant risk of viral infection. An important factor in transmission is the potential size of the donor population in each category.

25. What decisions and actions were taken by the Centre and by you to minimise or reduce exposure to infection?

25.1 The Centre consulted with NIBTS and the University Department of Virology and followed UKHCDO recommendations.

25.2 The Centre continued to pursue its treatment policies and have regard to national and world opinions. I had many informal discussions with colleagues in the USA, Australia and Italy.

Hepatitis

26. When you became a consultant haematologist at the Centre in 1972, 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? How did that knowledge and understanding develop over time?

26.1 By 1972 my knowledge of the viral transmission of Hepatitis B and NANB (later C) was incomplete as it was with all my colleagues.

26.2 Hepatitis B transmission remained a constant risk. Thankfully, in reality, in the haemophiliacs in Northern Ireland it was almost non-existent. To the best of my recollection only two sub-clinical cases were ever detected in Centre patients. However, it was necessary to maintain vigilant testing.

26.3 My attention has been drawn to an article in the Ulster Medical Journal (April 1989) entitled Hepatitis B Virus infection in Northern Ireland 1970 – 1987. I note it refers to 11 Haemophiliacs in whom acute infections occurred between 1972 and 1982 after receiving blood transfusions, cryoprecipitate or Factor VIII, and one patient died aged 51 years. Plainly, this conflicts with my recollection. (WITN3082021)

26.4 In respect of NANB, the situation remained perplexing for almost twenty years. This was evidenced by the persistence of abnormal liver function in treated patients. Although one knew there was ongoing virological research on a worldwide basis, the lack of identification of a causative agent was a constant worry. Not all colleagues expressed an equal degree of concern. It was suggested that I stop testing if it was so upsetting. I took the opposite view and continued.

26.5 Gradually, knowledge progressed, liver histology was identified and in 1991 Hepatitis C was identified. It has proved to be a complex and deadly virus, possibly in keeping with its long prodromal phase.

26.6 WITN0736011 is an extract from a medico-legal report that I wrote in 2000 or 2001 and it may be of assistance to the Inquiry insofar as it demonstrates my understanding of hepatitis and its impact upon patients with haemophilia at that time.

27. What, if any, 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?

27.1 In response to questions 27, 28 and 29, I would feel a measure of satisfaction if I could inform the Inquiry that I undertook an innovative and extensive programme of investigation into the viral transmission of Hepatitis and its prevention. Sadly I cannot. The problems were complex, not least because the infecting agents were unknown at the time.

27.2 However, all my Haemophilia medical colleagues were in the same situation. The UKHCDO Hepatitis Working Party was tireless in its research efforts. The Scottish Haemophilia Directors and I formed a small group which met once a month at the height of the HIV epidemic. I think we continued to meet at that interval to discuss all those inter-related issues of safer concentrates and self-sufficiency for Scotland and Northern Ireland.

27.3 Usually some 100 plus haemophiliacs were treated annually in Northern Ireland. The provision of a dedicated plasma fractionation facility was not feasible in terms of economics or specialist personnel. Therefore, an agreement was reached between NIBTS here in Northern Ireland and SNBTS in Edinburgh.

27.4 Plasma donated in Northern Ireland would be sent to Scotland and in return Northern Ireland would receive Scottish Factor Concentrates, The system proved to be mutually satisfactory, thus, increasing the safety profile for the patients.

28. What, if any, actions did you take to reduce the risk to patients of being infected with hepatitis (of any kind)?

28.1 See 27 above.

29. What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?

29.1 Already I have alluded to the rarity of transmission of Hepatitis B in Northern Ireland. I recall that in the USA in the mid-1990s the prevalence varied from 50% to 80%. I believe I remember this because it was, in my view, so unexpectedly high.

29.2 Originally, it was thought that Hepatitis A could not be transmitted by concentrates but again the unexpected happened in the 1990s, although not in Northern Ireland.

29.3 As time passed, Hepatitis D came to my notice. One patient showed evidence of past infection on his routine screening test. The Virologist informed me that the infection was a subtype or sequela to his sub-clinical HBV. No action was required as he was well and would not be a future blood donor.

29.4 I think the last prevalence figure I remember for the UK in respect of HCV transmission was around 60%. These figures may be remembered incorrectly. Lastly, in the late 1990s Hepatitis E made its appearance. I have memory failure about its clinical significance. It did not present any problem for the Centre patients. It was of academic interest at the time.

HIV and AIDS

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

30.1 The immune deficiency syndrome, which later became known as HIV/AIDS first came to my notice during an informal lunchtime discussion with three colleagues. They were the late Arthur Bloom, Virologist John Craske and the late Peter Kernoff.

30.2 John Craske was describing the content of a paper just published, to the best of my recollection in the Lancet, but with the passage of time I cannot be more specific. It described an account of an immune condition which had occurred in homosexual males in San Francisco. I enquired as to the relevance to haemophilia. He reminded us that the individuals cited in the paper were known to maintain their lifestyle by being paid blood donors, as was documented in the World in Action (1975) programme. Whilst the revelations of that were horrific, I was unprepared for the shock of the news of a possible future infection which could affect those in receipt of plasma derived concentrates, namely, the Haemophiliac population.

30.3 Gradually, over time the tragedy unfolded, it seemed unbelievable that the treatment which had transformed lives for the better could now transform them for the worse and could be fatal.

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

31.1 See 30 above.

32. What steps did you then take in light of that awareness?

32.1 HIV/AIDS caused mayhem locally, nationally and internationally. The actions taken locally will be considered under the following headings:

a. Review of Treatment Policy.
b. Alternative Treatment.
c. Dissemination of Information.
d. Patient/Staff Testing.
e. Additional facilities/staff for Centre.

f. Liaison with colleagues in other departments.
g. Social health matters.
h. Research.

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

33.1 In answering this question, I will expand on the categories listed at 32 above. In reference to (a) and (d), 15 patients tested positive. Data was derived from the three meetings described later in this statement. Eight patients had received only one product. Seven patients had received two.

33.2 HIV patients had used the most Factor during the preceding year and, therefore, had the greatest number of possible Virus exposures. If earlier testing had been available, it might have been possible to pinpoint the introduction of the second product as being causative.

33.3 I expected the greatest users to become positive, but what was surprising was the fact that after the first testing no more patients became positive.

33.4 The concentrates had not become safe overnight, therefore had the patients developed some form of immunity? I do not know.

33.5 The treatment policy was kept under review. Discussions and many conversations took place with the patients. A return to cryoprecipitate was offered. It was turned down. Patients were asked to reduce their usage if possible.

33.6 Further to (d) at the outset it was decided to offer testing to staff. If they wished a blood sample would be taken and laid down in Virology. It would only be tested in the event of illness. All staff of the Centre accepted and complied with this policy.

33.7 Regular patient testing continued and where appropriate the testing of partners was carried out after counselling and obtaining consent. One spouse tested positive.

33.8 The dissemination of information was time consuming but necessary. There were many misconceptions, mostly related to the 'stigma' of a positive diagnosis. There was the erroneous idea that positivity was solely linked to drugs, homosexuality and promiscuous heterosexuality.

33.9 I spoke on radio, television and attended meetings varying from the WI to the Armagh Diocesan Synod in order to offset and counteract incorrect rumours regarding the mode of infection of HIV.

33.10 The staffing levels in the Centre were augmented by an E grade nurse, a full-time secretary and a scientific officer. The latter was to help with the laboratory side of the situation and possible future research.

33.11 Measures were taken to liaise with colleagues from other disciplines as and when necessary. A Dermatologist, a Neurologist, and an Infectious Disease expert were all briefed, and were willing to and did attend patients in the Centre. In respect of general assistance, a liaison was also formed with the Sexually Transmitted Disease Department. They had many more HIV patients.

33.12 A mutually beneficial association was created which was also helpful for the nurses and social workers of both departments.

34. In the document entitled 'A Synopsis of Haemophilia', you state that in June 1983 general recommendations on treatment policy were sent out to all Haemophilia Centres in the UK. What were those recommendations? Were you involved in formulating them? What steps did you take in light of the recommendations? (I enclose a copy of the minutes of a special meeting of Haemophilia Reference Centre Directors on 13 May 1983 at which treatment policy was discussed).

34.1 As a member of the UKHCDO, I would have been involved in compiling recommendations on treatment policy which were sent out to all Haemophilia

Centres in the UK. I do not remember the detail of the recommendations but accept the minutes of the meeting as an accurate record.

35. What, if any, actions did you take to reduce the risk to your patients of being infected with HIV?

35.1 I followed the recommendations issued by UKHCDO in June 1983 which reflected my existing practice in any event.

36. Did you continue to use blood products to treat patients, after becoming aware of the possible risks of infection of HIV? Why?

36.1 Within my response to Q33 I have indicated that I continued to use concentrates. Even with the benefit of hindsight, I cannot envisage otherwise. In reality, the choice was stark – stop treatment with concentrates with all the risks and disruption that would entail for patients or continue with treatment in light of the information then available.

36.2 In my 1990 report regarding the HIV litigation (See CBLA0000072_024) I say that at a special meeting of the Reference Centres, it was agreed that there was insufficient concrete evidence to warrant changing the type of concentrate use to treat *severely* affected patients. After prolonged discussion it was felt that the immense benefits of treatment precluded change. That meeting resulted in the recommendations issued in June 1983 referred to at 35 above.

Response to risk

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

37.1 I do not think I can expand usefully to answer this question other than as already answered previously.

38. At a special meeting of Haemophilia Reference Centre Directors on 13 May 1983, it was suggested that there was a need for Haemophilia Centre directors to "discuss what should be done with regard to the surveillance and reporting of suspected cases and the management of patients". What decisions or actions did you take following that meeting, with regard to the surveillance and reporting of suspected cases and the management of patients?

38.1 Regrettably I cannot recall details of the above meeting. I can say that my practice and management of all patients continued unchanged.

39. What consideration did you give to the use of heat-treated products prior to the meeting (attended by you) of Haemophilia Reference Centre Directors on 10 December 1984? Did you (a) agree with and (b) follow the recommendations made at that meeting, including the recommendation to use heat-treated concentrates? (A copy of the notes of the meeting of Haemophilia Reference Centre Directors on 10 December 1984 and of the recommendations dated 14 December 1984 is enclosed).

39.1 Viral inactivation of concentrate was pivotal to discussions following the isolation of HIV. A multiplicity of techniques was considered, including solvent/detergent, exposure to ultraviolet light, gamma irradiation, wet (pasteurisation) and dry heat. A plethora of expertise and information was amassed. There was lengthy debate on the potential risks and difficulties associated with each technique. Not all transmissible viruses were eliminated equally well by all of the treatments. It does not seem particularly helpful to document the different properties of the possible transmissible viruses, namely, HBV, HIV, HCV, CMV and Parvovirus. Finally, it was agreed that the use of dry heat treatment seemed to provide the safest option to achieve viral inactivation.

39.2 The safety of the processing was uppermost in the minds of all the Centre Directors. Factor VIII is composed of a large protein molecule. The Inquiry will be very familiar with the effects of heat on protein, e.g. egg protein. Depending upon the temperature, the duration and type of heat, the egg protein undergoes alteration from

a liquid, to lightly boiled, to hard boiled, to inedible. These changes take place within a matter of minutes.

39.3 Therefore, the doctors considered what might happen to the large protein molecule of Factor VIII if it was exposed to an incorrect, too high or too low or too wet or too dry, treatment. It might become altered or denatured in a subtle fashion, which would render it as foreign protein to the patient receiving it. An inappropriately treated Factor VIII molecule ultimately could behave as if it was an antigen causing the production of an antibody or inhibitor to the infusion of Factor VIII.

39.4 By December 1984, Northern Ireland was being supplied with NHS concentrate from PFC in Edinburgh. I think it was around this time, or not much later, that PFC began producing heat treated Factor VIII. Following the Reference Centre Directors meeting in December 1984, heat treated concentrates, both commercial and NHS, began to be used as they became available.

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

40.1 I do not believe heat-treated products could have been made available earlier. I described above what happens if protein is heated and the potential implications if the molecule becomes altered or denatured. The risk of heat treated product giving rise to inhibitors was of great concern. I can best illustrate the point by recounting the experience of having had to observe the heart rending tragedy of watching a young haemophilic bleed to death because he had a high responding inhibitor and at the time in question there was no treatment to overcome the inhibitor.

40.2 I feel that the Centre Directors showed some degree of wisdom in proceeding cautiously in relation to heat treatment.

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

41.1 The two words "could" and "should" often suggest that today, with the benefit of hindsight, it may cause alteration of decisions or changed actions. Like everyone else, I wish that none of my patients had been infected as a result of blood products. However, after careful appraisal I remain convinced that the course of action pursued by both myself and my colleagues was measured and appropriate for that time in light of the information and the state of knowledge at the time.

42. What decisions or actions by you and/or by the Centre could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

42.1 See 41 above.

43. In the document entitled 'A Synopsis of Haemophilia' you stated that "During 1983/84 there were suggestions in the literature that a reversal to treatment with cryoprecipitate might be appropriate for the safety of patients". Did you revert to treatment with cryoprecipitate for some of your patients? If so, how did you decide which patients would be offered a return to cryoprecipitate and which would not? If not, why not?

43.1 Theoretically, a return to using cryoprecipitate would have been appropriate for some patients. However, it was neither a practical nor realistic option. Following lengthy explanatory discussions, during which the possibility of reverting to cryo was raised, I was greeted by an emphatic refusal from the patients concerned. Patients had become used to carrying their concentrate/pack with them to school, to college or their workplace. The presence of that pack had become life changing. A return to being dependent on the availability of a fridge freezer and to the lengthy process of thawing and preparing cryoprecipitate was just not acceptable to them.

44. 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?

44.1 I do not feel able to comment on the actions, decisions or policies of others.

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

45.1 I believe that greater efforts are likely to have achieved greater results. However, I would refer to my answers at 39 and 40 above. Viral inactivation raised a range of significant issues and knowledge of the effects of inactivation techniques was limited. Once again, I am not sure how useful it is, with the benefit of hindsight, to speculate on what might, or might not, have been achieved because bleeding does not stop while expert political decisions are in the process of being made.

Section 4: Treatment of patients at the Centre

Provision of information to patients

46. What information did you provide or cause to be provided to patients with a bleeding disorder (and to patients who did not have a bleeding disorder but were treated with blood products for other conditions) 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.

46.1 No local leaflets/printouts were available. Discussions with patients were held if and when possible. Each patient was provided with information provided by the national Haemophilic Society. There were few occasions when concentrate was given to patients other than those with Haemophilia or allied disorders. I recall rare incidents when concentrates were given to counteract the excessive effects of Warfarin anti coagulation. It was also used for patients with advanced liver disease.

In my view, there were instances when concentrates were used erroneously on an emergency basis within the ICU (see question 7).

47. In your expert witness report dated May 1990, you asserted that "the patients themselves became aware of the risks of hepatitis during the mid 1970s". What is the factual basis for your assertion? What discussions did you have with patients about these risks in the mid 1970s? What opportunity did you give patients to take informed decisions as to the risks and benefits of treatment?

47.1 An annual meeting for patients, relatives and members of staff was held as part and parcel of the activities of the Northern Ireland Group of the National Haemophilia Society. Over time, a multiplicity of experts was invited to be speakers. Each gave an opening talk on aspects of haemophilia and then the afternoon was open to patients and their relatives to ask questions of the experts - questions about treatment, about the risks, about advances in therapy, changes in scientific research etc. Over the years speakers included:- Prof Arthur Bloom, Dr Reuben Mibashin, Dr Charles Forbes, Dr Peter Jones, Prof Christopher Ludlam and Dr Geoff Savage.

47.2 Discussions were routinely held at all clinic appointments. They were also initiated by patients in need of advice. Furthermore, the patients' own branch of the Haemophilia Society also held meetings which disseminated useful information and on occasion were able to bring experts who could answer patient questions.

47.3 Patients also had their own magazine/journal, originally started by me but then passed on to the patients. A severely affected and greatly disabled haemophilic became its editor and production manager. It was entitled "CLOTT". The odd title was mine, hopefully from the haemophiliac point of view the eventual goal for treatment would be the taking of a tablet; "tablet" is represented by the second capital 'T' of the title. The magazine gave patients the opportunity to request information from the National Society, write articles, invite medics or other people for interviews, arrange holidays etc.

47.4 Therefore, the patients in the 1970s onwards would have been aware of all aspects of haemophilia treatment and research, if they attended their local society and read its magazine.

48. What information did you provide or cause to be provided to patients about alternatives to treatment with factor concentrates? Please detail whether, and if so, how this changed over time.

48.1 Possibly the question refers or relates to the use of DDAVP and the anti-fibrinolytic agents – if so; this matter has been addressed in an earlier section.

49. What information did you provide or cause to be provided to patients before they began home treatment/home therapy?

49.1 It is important to point out to the Inquiry that commencement of a patient on HT occupied a minimum of 4 hours. The time was taken up with practical instruction but mainly providing information on a Q&A basis. The initial appointment often took place in the patient's own home.

49.2 All members of the family shared in the experience. In respect of young people, their school teacher was invited to be present and always the GP was present. In rural areas, several district nurses joined in the gathering. After the initial meeting, the patients and the person administering the injection would be given trial treatment. The family was required to phone as soon as the injection had been administered, to report progress or problems. One week later a second meeting took place. It was organised to allow time to develop within the family to see if they had any questions in relation to the product, the process, or any other matter which might have occurred to them. A third meeting took place 3 weeks later. If there were no problems, supplies were provided for one month's treatment. Additionally the secretarial aspects were addressed in detail. Each patient had to complete a dedicated form giving details of the product used and entering volume and units used. A copy was sent to me and the patients retained a copy for their personal records. At all times patients were advised regarding the risks of disease, any then-

known risk of using concentrate, and were encouraged to have discussions any time they had a problem.

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

50.1 At this distance in time, I cannot recall the details but I have no doubt I had informal discussions with the patients at clinical appointments. The minutes of the UKHCDO meeting in December 1984 have been brought to my attention. I note that I attended; however, I cannot recall attending or the meeting itself. I assume that the decision to hold the 1985 meetings was influenced by this meeting. It was then decided to have formal meetings. I arranged for three meetings to take place in early 1985. These meetings are described in my Rule 9 Response to Witness WITN2340 dated 20 May 2019.

51. Please describe how and when you learned that patients under your care had been infected with HIV.

51.1 I have set out previously that I arranged a number of special meetings in 1985 with the patients. At that meeting they were invited to be tested. Their express consent was invited for that testing and prior to such testing I had no knowledge of whether a patient was infected with HIV. I only became aware after the test results were received.

52. The document entitled 'A Synopsis of Haemophilia' states that when patients' results were available, they were entered into a confidential notebook which you retained and kept in a locked filing cabinet drawer in your office. What happened to that notebook? If you have the notebook, or a copy, please provide it to the Inquiry.

52.1 The notebook was destroyed before my retirement. No other information was recorded.

53. How and when were patients told that they had been, or might have been, infected with HIV? What information was given to them about the significance of a positive diagnosis? Did you tell patients to keep their infection a secret?

53.1 The topic of HIV/AIDS arose naturally at routine appointments and was discussed. Thereafter it was decided to hold more general, formal meetings to enable the global situation to be presented and discussed by a wider audience of patients and their relatives (see question 54.)

53.2 Patients were told their results in private on a one to one basis. The majority had been tested at the Group meetings. On that occasion some had expressed a wish that they receive their results by mail. That sentiment alerted me to the possibility that the full implication of a positive result had not been understood. The suggestion was rejected.

53.3 At the results session information on infectivity was presented and how the result would affect each patient's lifestyle. By this time, a degree of panic had, not surprisingly, developed. It was not helped by some of the media coverage.

53.4 Depending on age to some degree, it was explained that day to day household activity was unchanged; schooling, shopping, eating in restaurants, going to work and going to mass/church were all unaffected. How each had become infected led on to the explanation that it had happened by "doing what the Doctor ordered" namely through their treatment. The latter would continue in the meantime but would be constantly reviewed.

53.5 If appropriate, sexual transmission was discussed. This would be addressed in more detail at counselling visits.

53.6 Lack of knowledge within the general population and the limited experience of many individuals led me to suggest that patients should not publicise their results unnecessarily.

Counselling

53.8 Patients were given information on what was meant by counselling and how it could help/work for them. It would be available as and when they felt they needed to talk. It would be provided, in the main, by myself and our Social Worker. However, in an emergency Sister Farrell or Sister McAfee would be available.

53.9 I felt that something more was needed. After a two week pondering period, appropriate steps were taken and a fully qualified nurse who had specialised in Aromatherapy and Reflexology joined the staff. She did her sessions at the same time as patients came for counselling. The spouses/accompanying relatives had their session during the counselling and the patients themselves went before or afterwards. I believe the above was more beneficial than all my talk. All affected individuals availed themselves of these sessions.

54. Please provide full details of a group meeting or series of such meetings held with patients at the Centre to discuss HTLV-III (in 'A Synopsis of Haemophilia' you state that during December 1984 plans were laid to interview all patients attending the Centre and that meetings took place over the following months; your statement to the Inquiry reference WITN0736001 suggests that these meetings began in January 1985). What was the purpose of the meeting(s)? Who was invited to attend? What is your recollection of what happened at the meeting(s)? What information was provided to individuals?

54.1 When the HIV/AIDS tragedy was evolving in the 1980s, to be told of a positive HIV test was in essence a death sentence. There was no treatment. Patients were terrified. Likewise, relatives and friends were bewildered and frightened. I gave much thought to the planning of how to achieve the essential HIV testing. Finally, I agreed to have group meetings, three in total. All patients who had been treated were invited to attend with the exception of the paediatric patients who were looked after by their haematologist.

54.2 The prime aim of the meetings was to provide information about the global situation, and secondly, to inform patients of the local situation. In particular, the

mode of transmission from person to person and its effect on the day to day living of those concerned. Information about care was given to friends and relations. It was suggested to be careful as the general public was not well informed about modes of transmission and infectivity. Finally, there was a need to address confidentiality, lack of which gave great concern to the patients.

54.3 The format of the meetings was that I gave an introduction. Thereafter, there was time for an informal chat over a cup of tea and finally the testing would take place. My sources of information regarding HIV infection were multiple; the UKHCDO AIDS working party, chaired by Dr Charles Rizza, provided copies of all publications as and when they appeared. This information was invaluable. Secondly, information gained through combined monthly meetings with colleagues in Scotland and, thirdly, in an informal manner through conversations with my colleagues with whom I had worked in the USA, Australia and Europe. In a different context, I also had regular discussions with my STD colleagues.

54.4 Furthermore, from time to time I went to London for meetings organised by the British Council. These meetings were convened to disseminate knowledge to individuals and groups other than haemophiliacs. Also, I attended meetings of the London Lighthouse to learn how those affected through sexual transmission were coping with the tragic situation.

54.5 To return to the format of the meeting, I presented and explained to patients and relatives the characteristics of the HIV virus. Inside the body cavity in the blood stream, it was lethal. However, outside the body the virus was extremely vulnerable. It could be destroyed by a simple wipe of bleach and certainly, heat treatment removed its activity (see future "heat treated concentrates"). Therefore, apart from IV, i.e. through treatment, blood transfusion, dirty needles between drug users, there was no way that it could be transmitted except by sexual intercourse. It was easier to transmit it by what could be described as vigorous sexual intercourse.

54.6 After my introduction, the patients were offered testing. At this point in time, testing was not mandatory. Patients could say yes or no. I had anticipated that most people would accept the opportunity to be tested. They all did. The reason for

couching the invitation for testing in this manner was to permit patients to be in full control of their lives - circumstances which, sadly, would change radically if the tests proved to be positive. They were told that no names would be used, that a coding system would be applied and that for confidentiality purposes the results would be logged into a confidential notebook. They were asked if they wished to know their result. Contrary to my expectations one patient declined to hear the result. His response posed a problem. Rapidly, I had to consider the action I would take if this particular patient tested positive. It was recognised that all patients who tested positive would require a confirmatory test. Apart from taking his routine treatment, sexual transmission was the only other means of transmission. Therefore, a short delay before his confirmatory test would not constitute a public health issue.

54.7 After the testing was completed, I then had a concluding address with the patients. I was acutely aware of the difficulty of imparting unpleasant news to patients. I had been much involved in telling individuals that either they, or their close relative was suffering from acute leukaemia and all the problems associated with chemotherapy. I well knew from experience that the audience for this type of introductory session would perhaps remember as much as 25% of what they were told, and it was unlikely that they would remember more than 50%. Therefore, it seemed important to me to reiterate to them exactly how their lifestyle might change in the future if they had experienced transmission of the virus. I also asked them to refrain from sexual activity before they came back for their results. They were aghast, and there was some laughter at this, but the purpose was to protect spouses and partners and the general public.

55. In 'A Synopsis of Haemophilia', you state that "Patients, following counselling, were asked if they wished to be told the result. If they did not wish to be told, it remained confidential to the three people mentioned previously [i.e. you, the Chief MLSO in the Haemophilia Laboratory and your personal secretary] until such time, in the future, when it became vitally necessary to interview and inform patients of the results".

a. What counselling was provided to patients before they were asked if they wished to be told the result?

b. You decided to tell patients their test results only if they wished to be told. In reaching that decision what consideration did you give to the risk to partners and families, and to the broader public health implications, from not informing a patient of a positive test result?
c. How many patients decided that they did not wish to be told the result?
d. In what circumstances did you envisage that it might become "vitally necessary" to inform patients of the results?

55.1 See response to question 54 above.

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

56.1 Following the confirmation of a positive result spouses/partners were tested by mutual agreement.

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

57.1 All relevant information was relayed to patients and their relatives either in the Centre or at home during a home visit.

58. How many patients at the Centre were infected with HIV?

58.1 There were fourteen patients with haemophilia A, one patient with Haemophilia B, one spouse and no children. The figures did not change through time.

58.2 There were two paediatric patients on home treatment but they did not seroconvert.

59. In your statement WITN0736001, you stated that you wished to address "the occurrence in Northern Ireland of the lowest infection rate in the United Kingdom within the Haemophiliac population of the Province". Please do so.

59.1 I have addressed this in my fourth statement to the IBI dated 21 February 2020.

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

60.1 No patient attending the centre had clinical Hepatitis B. During routine viral testing at clinic appointments, one patient was found to have a high titre of Hep B antibody denoting a sub clinical infection. Please see also the response to Q26.

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

61.1 One. See above.

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

62.1 Yes, patients infected with NANB hepatitis were informed of the existence of their abnormal liver function tests. At the time the condition was termed Non-A Non-B. At that time although patients had raised liver function tests they were otherwise well.

62.2 It was not possible to inform patients of active hepatitis C infection until the specific blood test for this virus became available and was obtained by the Belfast Trust.

62.3 It had been suspected for many years that regularly treated patients were likely to have the virus previously known as Non-A Non-B hepatitis, subsequently known as hepatitis C. Patients had been attending the Centre regularly for many years and receiving advice before the confirmation of their diagnosis. They were informed that they had a chronic viral infection of the liver that was causing inflammation.

62.4 Further, they were advised that they would need careful monitoring of liver function to make sure that they were not developing cirrhosis. They were advised to have a low-fat diet and they were advised to drink as little alcohol as possible. They were advised of the theoretical possibility of sexual transmission of HCV though, unlike HIV, there was little substantial information available.

62.5 There was no antiviral treatment available at the time.

63. When did the Centre begin testing patients for hepatitis C? How were patients informed of their diagnosis of hepatitis C? What information was provided to patients infected with hepatitis C about their infection, its significance, prognosis, treatment options and management?

63.1 The Centre began testing patients for Hepatitis C in 1993 when the test became available.

63.2 All patients were routinely assessed for liver function and for unknown viruses, up until the definitive test for active Hepatitis C became available in 1993. Prior to that time it had been noted that from the commencement of the HT programme that all patients in receipt of concentrates developed abnormal liver function test results. They remained clinically well. On clinical examination there was no evidence of any possible liver disease. Patients were surprised at the clinical examination but the abnormal test results were explained, they were told they did not have Hepatitis B, a condition of which patients were well aware. Likewise, they knew they did not have any symptoms of Hepatitis A, therefore they were not surprised when they were told that they probably had a condition called Non-A Non-B hepatitis. They were not impressed by the originality of the scientific name of the diagnosis. However they accepted regular tests being carried out at routine visits on the understanding that if

anything untoward occurred clinically or if the test results became more abnormal, they would be referred to a liver specialist. For many years, it was assumed that NANB hepatitis was a relatively benign asymptomatic condition. Throughout many years of NANB existence, tests for all forms of known hepatitis were routinely undertaken. I was unwilling to carry out liver biopsies on clinically well patients with Haemophilia A or B, despite the presence of abnormal liver function tests. I felt the risk of abnormal bleeding was unpredictable. I did not think it would be an ethical procedure to undertake. However, I acknowledge the results of the liver biopsies undertaken by the Sheffield Group were an important development. It was concerning to learn of the presence of abnormal liver histology, while not knowing its cause and having no treatment available

63.3 Some 3-4 years prior to 1993 tests for Hepatitis C antibody became available. That test, if positive, only indicated that the individual had met the virus at some time. In a similar way, adults, if tested, would show the presence of anti-measles antibody although of course they had no clinical evidence of the condition. During discussion with patients they found it difficult to understand the explanation of having HCV antibody. Some were worried that I was keeping secrets from them.

63.4 When the specific tests became available in 1993, the results indicated in many cases active disease. Even in 1993 it was difficult, even impossible, to give any precise prognosis or details of how the diagnosis might play out in time. As developments progressed viral load testing became capable of the estimation of infection. Likewise, different subtypes of the virus were accurately diagnosable. At this time a special liver clinic was established. The procurement of a Consultant Hepatologist who had the willingness to come to terms with the nature of haemophilia was difficult. Eventually a suitable consultant joined the staff and a regular clinic was held in the Centre.

63.5 I maintained my links with Professor Reuben Mibashin in Kings College Hospital, London. We cooperated in providing a venue for liver transplantation patients as and when that became necessary. Before my retirement two such patients went to London for surgery.

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

64.1 In excess of 100.

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

65.1 The results of the HIV tests were provided to the patients as soon as was practicable after being received. The laboratory process dictated the interval between testing and results being available.

65.2 Early viral testing is often fraught with laboratory technical difficulties. Limitations of the early test meant that confirmatory testing was required. The seriousness of the test result necessitated a confirmatory test in all cases.

65.3 With regard to HCV, the tests were done in batches to facilitate the effective management of the laboratory. The patients were informed at their next routine clinic visit. That may have been some time later.

65.4 It is important to state that a positive antibody test required no action at this time. Positivity merely showed that, at some time in the past, the patient had been exposed to the virus, and his immune system had responded. I personally had hoped that the antibody might have indicated some immunity to HCV, but such hopes were dashed when the same individual, at a later date, demonstrated the presence of HCV RNA particles. A possible explanation could be that he had been re-infected by a different subtype or mutant strain.

65.5 The antibody tests were explained to patients at the next routine visit. The timing of routine reviews depended on the severity of the patient's condition. Those on Home Treatment or severely affected were seen on a monthly basis. The moderately severe were seen theoretically on a six monthly basis – I say theoretically because if they had no problems they would cancel for perhaps a further 3-6 months. The very mildly affected were seen annually.

65.6 At a later date from late 1993 onwards, if their definitive test showed active disease the patient was contacted and seen as soon as possible. Then management would proceed, after discussion, to the Liver Clinic and possible treatment with alpha interferon.

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

66.1 I would like to point out to the Inquiry that public health implications were to the forefront of my practice at all times. Consideration and advice was given in regard to risk of infection to partners, friends, relations and the general public.

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

67.1 All appropriate information was relayed to patients, their relatives either in the Centre or in their place of residence.

67.2 Risk of infection via personal relationships, day to day contact, family life, associating with the general public were all explained.

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

68.1 The risks regarding common daily living situations were addressed. Risks in relation to spouses, family members, extended relatives and in day to day contact with the general public, and relating to school work, public places and in general employment were all considered.

Consent

69. In 'A Synopsis of Haemophilia' you stated that "as often as possible, it had been customary to take a blood sample from the patient when he attended the Haemophiliac Follow-up Clinic". Was it the normal practice at the Centre to take samples at every appointment? What information was given to patients about the purposes for which blood samples were taken? Did you obtain patients' informed consent to the storage and use of those samples?

69.1 The customary practice of the NI Haemophilia Centre was to check patients' blood at every visit. I must stress that many patients attended at widely spaced intervals, at times six months to a year apart for those that were mildly or moderately affected. Those that were severely affected or were involved in the programme of home treatment were seen and checked more frequently. The patients on home treatment (HT) had a system of forms that they returned every week to indicate how much concentrate they had used and if they had any problems.

69.2 Thereafter, they were seen at monthly intervals. It was in my view imperative that their bloods were checked to ensure that they had not developed any haematological problems such an anaemia, unduly excessive bleeding or the development of inhibitor that would negate the efficacy of their concentrate and finally, to check on their liver function tests and hepatitis status.

69.3 Patients were well versed in this practice and accepted the information given to them about the blood testing and the purposes for which they were being taken. They seemed happy to consent to these arrangements.

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

70.1 All patients attending the Centre were happy to receive treatment with factor concentrates.

70.2 In the early days of treatment with concentrates, it was not the practice at the time to obtain written informed consent. Patients, to put it mildly, were overjoyed at receiving concentrate treatment. As the HT programme progressed, some severely affected patients felt left out and contacted the Centre to request the opportunity of participating in the HT programme.

70.3 Everyone was told of the risk of viral infections associated with all blood and blood products.

71. The Inquiry has heard from witnesses who say that they were not in a position to give informed consent to treatment with factor concentrates, because they were not given sufficient (or any) information about the risks of treatment or about alternatives to treatment. Do you accept this? If not, explain the basis on which you say that your patients did give informed consent to treatment with factor concentrates.

71.1 For the purpose of clarification, at the instigation of concentrate therapy, all matters pertaining at that time in respect of risk were conveyed to patients before they commenced on HT. Discussions included comparison of treatment with cryoprecipitate and treatment with concentrates. No figures were mentioned but patients understood that concentrates came from a large number of donors in comparison to cryoprecipitate. However, the prospect of their lives being revolutionised, the ease of injection, and the ability to undertake reliable dose calculations precluded any obvious reservations about the treatment. No patient ever expressed any reservation to myself or any other member of staff in respect of their treatment.

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

72.1 Absolutely not. In all cases I obtained verbal consent from the patient.

Research

73. Please detail all research studies that you were involved with during your time as a consultant at, or director of, the Centre. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, please:
a. Describe the purpose of the research.
b. Explain the steps that were taken to obtain approval for the research.
c. Explain what your involvement was.
d. Identify what other organisations or bodies were involved in the research.
e. State how the research was funded and from whom the funds came.
f. State the number of patients involved.
g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent.
h. Provide details of any publications relating to the research.

73.1 Always I believed that Consultant led Medical Practice should be a blend of therapeutic management allied to a percentage of educational clinical research. (I suppose I mean both the Art and the Science).

73.2 I undertook 2 years of full time research in 1965. My remit was to determine the role of blood platelets and the blood coagulation system in the development of the vascular complications of Type One Diabetes Mellitus.

73.3 I maintained my interest in matters relating to blood platelets up to and including November 1971. At which time I had completed a period of platelet research in the Departments of Professor Mario Baldini, Browne University, Rhode Island and Dr Shirley Ebbe, Tufts University, Boston, Massachusetts.

73.4 On my return to Northern Ireland I realised that I was more suited to the challenge of day to day patient care than the world of academic research.

73.5 Despite my preference I found that from 1972 onwards there was little if any time or opportunity to carry out meaningful research. Primarily this was due to my not being a full time Director and to having responsibilities elsewhere. However, a little minor and later more substantive research was carried out; the latter in collaboration with my Scottish colleagues and the SNBTS in Edinburgh.

73.6 Minor research:

73.7 Two papers were published in the Ulster Medical Journal. They were intended to apprise my medical colleagues of the plight of the Haemophilia population in respect of the effects of the HIV epidemic (WITN3082020: Human immunodeficiency virus infection in Northern Ireland 1980-89) and to illustrate altered skin sensitivity in those who were HIV positive as a marker of altered immunity (WITN0736012: Immune response to multiple skin test antigens in haemophiliacs).

73.8 To my surprise all the patients (20) were pleased to take part and gave verbal consent willingly.

73.9 The more substantive research concerned the studies undertaken to achieve higher purity of NHS Scottish Concentrate.

73.10 To achieve maximum accuracy and to fulfil all the appropriate written consents and give adequate opportunity to the patients for discussions a full time medical Registrar was appointed. The funding was provided by either SNBTS or the Scottish Home and Health Department – I cannot recall which.

73.11 The appointee was Dr Orla McNulty who proved to be invaluable. She became a permanent member of the Centre staff funded by the Eastern Health & Social Services Board.

73.12 A list of the studies is as follows:

- Highly Purified Porcine Factor VIII in Haemophilia A with Inhibitors to Factor VIII (Exhibit WITN0736013).

- Multicentre Prospective Cohort Study comparing immune function in patients treated with either SNBTS high-potency Factor VIII concentrate or with monoclonally immunopurified Factor VIII concentrate.
- Clinical trial to assess the tolerability of high purity Factor VIII concentrate manufactured by SNBTS in previously untransfused non-HIV infected patients with Haemophilia A.
- Clinical trial to assess the tolerability of high purity Factor VIII concentrate manufactured by SNBTS in patients with Haemophilia A who possess antibodies to HIV.
- Clinical trial to assess the tolerability of high purity Factor VIII concentrate manufactured by SNBTS in patients with Haemophilia A.
- Clinical trial to assess the efficacy of continuous infusion of high purity Factor VIII (Liverate) compared to conventional intermittent bolus infusion.
- A study of the safety, economy and efficacy of Replenate (BPL high purity Factor VIII) by continuous infusion.
- MRC Concorde Trial: The use of Zidovudine therapy in HIV.
- Clinical trial to examine the safety and efficacy of a new high purity Factor IX product produced by ion exchange chromatography in patients with Haemophilia B.

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

74.1 My understanding of ethical principles that should guide research developed through a number of stages which I would describe as:

- Awareness.
- Realisation.
- American Perspective.
- Economic/business perspective.
- Academia.

74.2 The above denote stages in the development of my understanding of all aspects of the ethical principles of medical research.

74.3 I first became aware of them as an undergraduate. Then as a postgraduate in full time research I was taught about them comprehensively by my senior Consultant supervisors. Thereafter in the USA I gained the American perspective, similar, but with different emphasis.

74.4 My term on the CSM revealed the situation as it pertained to the economic world of the pharmaceutical industry; more stringent in some ways. The world of 'conflict of interest' was revealed.

74.5 The wheel came full circle when I took over on the Chairmanship of the University Research Ethics Committee.

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

75.1 No.

76. Was patient data (anonymised 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?

76.1 No.

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

77.1 All patients attending the Centre were aware of the existence of UKHCDO.

77.2 They were aware that the secretariat collected and compiled stats on an annual basis relating to their treatment and they realised the procedures were necessary in order to estimate changes in treatment product availability year by year. In those circumstances it was a matter of implied, rather than express, consent.

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

78.1 There are no further publications relating to the Centre's activity.

PUPS

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

79.1 There were no PUPS.

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

80. How was the care and treatment of patients with HIV/AIDS managed at the Centre? What steps were taken to arrange for, or refer patients for, specialist care? What treatment options were offered over the years to those infected with HIV? What information was provided to patients about the risks and benefits of specific treatments and about side effects?

80.1 The Centre provided a comprehensive programme of treatment for all patients infected with HIV/AIDS. A full complement of specialists was available for expert advice concerning complications which developed in relation to the HIV infection. This was easy to arrange as the other major activity of the Haematology Department was the establishment and operation of a bone marrow transplant unit. The complications of post bone marrow transplant are very similar and in parallel to those

of an immune-compromised patient. The cause is different. One is due to ablative chemotherapy and the other is due to the virus infection.

80.2 Therefore, specialists in infectious diseases, dermatology, urology and hepatology were available at appropriate times to offer advice and treatment. Thereafter, all patients had open access to the Haemophilia Centre at all times. They were either given my phone number or that of one of two senior nurses in the Centre. They had regular appointments with the social worker, although at times she became overwhelmed by the burden of the problems associated with the HIV infection and from time to time it was difficult to sustain a constant social service person. The service of a social worker was always available.

80.3 Also, facilities were made available for either the patients or their relatives to indulge in sessions of aromatherapy and reflexology on a weekly basis. When retroviral therapy became available patients were informed of all details and complications and were offered treatment which was monitored closely. Thankfully out of the 16 patients who originally were diagnosed, three benefited and maintained normal lifestyles following retroviral treatment. Sadly, the others had died before treatment was available.

80.4 The article published in the Ulster Medical Journal in April 1991 of which I was a co-author may assist the Inquiry to gain an overall impression of how patients with HIV/AIDS (not only haemophiliacs) in Northern Ireland were managed (See WITN3082020)

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

81.1 The follow up and monitoring has already been addressed in question 80, however, I reiterate that if the patients were unable to attend the Centre, the social worker, Sister Farrell, Sister McAfee or myself paid home visits to ascertain what help could be provided. Patients were also encouraged to keep in touch with the Haemophilia Society and to apply, as and when appropriate, to the Macfarlane Trust for help in financial constraints.

82. How was the care and treatment of patients with hepatitis B managed at the Centre? What steps were taken to arrange for, or refer patients for, specialist care? What treatment options were offered over the years? What information was provided to patients about the risks and benefits of specific treatments and about side effects?

82.1 The care and treatment for patients with Hepatitis B was not a feature of the Centre. During my time as Consultant there were no cases of active Hepatitis B amongst the patients. Two patients indicated that they had suffered from sub-clinical Hepatitis B at some earlier times. However, I have already acknowledged that my recollection appears to conflict with the article published in the Ulster Medical Journal in 1989 entitled "Hepatitis B virus infection in Northern Ireland 1970 – 1987" (See 26 above). That said, the article does illustrate that there was no complacency about the risk of Hepatitis B. The subject of Hepatitis B was constantly discussed with all patients as the risk remained constant despite the advent of HIV and other liver problems.

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

83.1 See 82 above.

84. How was the care and treatment of patients with NANB hepatitis managed at the Centre? What steps were taken to arrange for, or refer patients for, specialist care? What treatment options were offered over the years? What information was provided to patients about the risks and benefits of specific treatments and about side effects?

84.1 My approach to the treatment of patients with NANB hepatitis was as follows:

a. At the outset of the HT programme I incorporated liver function tests as part and parcel of the monitoring. Why? Because I had a feeling of unease about repeated injections via the intravenous route. At the time Hepatitis B was the

most well-known of the viral infections that could be transmitted by blood or blood products. Therefore, I decided to check the LFTs as an indicator of possible problems occurring.

b. Abnormal tests occurred with sustained regularity. They persisted but did not progress in severity over decades. The patients were well. Many colleagues thought it totally benign, others like myself more circumspect. Even with hindsight, would I have done anything differently? I considered liver biopsy but rejected such a risk of bleeding in a clinically well patient. Later, I felt the same even after the publication of the Sheffield paper revealed the histological findings of cirrhosis.

c. I repeatedly advised patients regarding diet and intake of alcohol – advice that was not always received sympathetically.

d. The sequence of vital testing continued. The different phases were experienced. Clinical symptoms seem to have occurred in patients who had had abnormal LFTs for 25 to 30 years. The first sign was often intolerable fatigue.

   In or around this fatigue becoming manifest, patients were referred to a liver specialist. Dr Michael Callendar became our Hepatologist and came once a week to the Centre.

   Treatment with alpha interferon was given as and when required with appropriate monitoring of viral load. It had excellent results in some but had unbearable side effects in others.

84.2 I understand better treatments are now available. I remain convinced that the HCV infection can be a deadly condition, yet I am at a loss to see what more could have been done sooner given the state of knowledge and the absence of an effective test.

85. How was the care and treatment of patients with hepatitis C managed at the Centre? What steps were taken to arrange for, or refer patients for, specialist care? What treatment options were offered over the years? What information was provided to patients about the risks and benefits of specific treatments and about side effects?

85.1 See 84 above.

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

86.1 The follow up and monitoring of patients with Hep C was comparable to that for patients with HIV. The other speciality clinicians came to the clinic to provide a 'one stop shop' for all aspects of haemophilia care.

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

87.1 There were no children affected with HIV and if they were infected with hepatitis it had not yet come to my notice before I had retired. I am unaware of the number of children infected by hepatitis. This was and is under the care of the paediatric department of the Royal Belfast Hospital for Sick Children.

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

88.1 The arrangements for counselling etc. for patients with HIV problems consisted of access to me personally and to the social worker. This counselling occurred in two hourly sessions. Also, the social worker or myself or other members of staff would visit the patient's home. Further facilities were provided with both aromatherapy and reflexology for periods of half an hour to one hour, before or after counselling. Similar arrangements were in place for both those with HIV and HCV.

Records

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

89.1 This question highlights a very difficult and thorny problem which affected all doctors in managing HIV deaths. I took the decision not to put HIV as a primary cause of death after a meeting of the HCDO at which the issue was discussed at considerable length and taking into account the great sensitivity surrounding the matter for families in Northern Ireland, especially in rural communities.

89.2 There were a number of local religious reasons not to include HIV on the Death Certificate and there were also the paramilitaries who could use the information to exploit a family or individual. While HIV was not given as the primary cause of death, death certificates were filled in, in accordance with all rules and regulations. The primary cause of death, for example, pneumocystis pneumonia was stated. What was omitted was the secondary or tertiary cause of that pneumonia. However, all GPs and undertakers/funeral directors were personally informed that the death related to HIV so that all personnel involved with treating the body after death would be aware of the diagnosis. I am unaware of the policy relating to hepatitis as I was fortunate enough not to be associated with a haemophilic death due to that cause.

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

90.1 All medical records for the patients were retained in the filing system for the Centre in full accordance with the retention principles of the medical records department of the hospital. The records could be retrieved at any time because patients would attend the Centre at any hour of the day or night on a 24/7 basis. I felt it was vital that their records would be available. The Medical Records department were content with this arrangement. I am unaware of the specific document retention policy.

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

91.1 See 92 below.

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

92.1 No separate files were kept for any patient. The patients' files were all kept in one filling system although for a period of time all diagnoses of HIV status were kept in a separate book. This was to ensure confidentiality. If anyone needed to know, there was only one point of access. When a patient died, the medical records were eventually completed with a final diagnosis and were filed. Due to the passage of time, I cannot confirm if this is absolutely accurate, however, it is the best information I can provide.

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

93.1 No.

Section 5: Self-sufficiency

94. In your expert report dated May 1990 you state that from 1969 onwards UK Haemophilia Centre Directors "reflected on and discussed constantly the need for self-sufficiency of United Kingdom Factor VIII production". What discussions and reflections were there about self-sufficiency over the period of your involvement with UKCHDO?

94.1 In the early to mid-1970s discussion rotated around the financial and practical difficulties in upgrading the facilities at Elstree and at Oxford but I do not remember precise details.

94.2 From and around this time self-sufficiency was a constant item on the agenda. However, it seemed to me that haemophilia generally and self-sufficiency in particular was a low priority for Government. As soon as the representative from the Department of Health became knowledgeable and was sympathetic towards the problems of haemophilia, they seemed to be deployed elsewhere.

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

95.1 I remember the announcement at the time. I regret that, with the passage of time, I am unable to recall any further information. My only memory was that the sum in question was insufficient for the need.

96. What did you understand the term "self-sufficiency" to mean in 1974/1975? In particular, did you understand it to mean self-sufficiency in providing Factor VIII blood products prophylactically, or solely in response to bleeding incidents?

96.1 In 1974/1975 "self-sufficiency" in Northern Ireland would have been understood as referring to cryoprecipitate.

96.2 The term "prophylaxis" would not have been used in those days.

96.3 Supply of factor concentrates became the issue once they became commercially available. In order to meet the Centre's need for Factor VIII I endeavoured to procure as much NHS concentrate as possible. There were three

sources of NHS concentrate – BPL at Elstree, Oxford Fraction Centre, and SNBTS Edinburgh.

96.4 In 1982 it was arranged that plasma from NI donors be sent to Edinburgh SNBTS. An appropriate reciprocal amount of NHS concentrate would be returned to Belfast. Doing the best I can to recall, initially the NHS supply of concentrate was in the order of 10% of the amount used. Over time this increased significantly, but I am unable to be precise. It is true to state that Northern Ireland never became self-sufficient in NHS concentrate. The aforesaid arrangements were put in place as it was unrealistic to establish a plasma fractionation unit in Northern Ireland.

96.5 The Inquiry may be assisted by two documents which have been brought to my attention. Both were prepared by me in the 1980s and include some details of concentrate usage as well as useful background information. One dated 1 August 1985 is headed "Northern Ireland Reference Centre Factor VIII Usage" (BHCT0000503); the other dated 25 March 1988 is entitled "A Profile of the Management of Haemophilia in Northern Ireland" (WITN0736014). I cannot be absolutely sure at this time, but I think these documents were prepared in connection with funding issues.

97. Did your understanding of what "self-sufficiency" meant change at any time? If so, when and why?

97.1 My understanding was, and remained, that self-sufficiency meant the availability of adequate supplies of Factor VIII concentrate to look after all aspects of haemophilia.

98. What was your understanding of how others defined "self-sufficiency"? Please answer (to the extent that you are able to) by reference to (i) those involved in the supply of plasma, (ii) those involved in the production of blood products, (iii) clinicians prescribing blood products, (iv) patients using blood products (and their families), and (v) those responsible for managing relevant health authorities and bodies.

98.1 It is difficult to comment meaningfully on how others defined "self-sufficiency". At this point, I do not recall much about others' views on the subject within the groups mentioned. I do not believe that patients were concerned with, or considered the meaning of self-sufficiency. They were receiving treatment that enabled them to live a normal life and I believe that that is what was of paramount importance to them at the time.

98.2 I recall that most of the time the Board accepted my advice on what blood products were required. I provided data on who was being treated with what. As stated, it was my view that self-sufficiency meant adequate supply to provide treatment for all aspects of haemophilia. This was accepted by the Board. A small number of patients needed treatment with FEIBA which was enormously expensive. The Board complained that I was the most expensive clinician they had. They asked me to come and meet them to discuss this financial burden. I think the documents I mentioned at Q96 above may well have been prepared in connection with such meetings. However, the Board never refused funding.

99. What, if any, efforts were made to ensure that all of the groups mentioned in the previous question shared a common understanding of what "self-sufficiency" meant?

99.1 I believe different groups had different ideas and concerns about self-sufficiency. A common understanding was difficult to achieve. UKHCDO made efforts through their bulletins and communications to convey information, but it was inefficient and I feel there was no direct effort made to keep people informed adequately about the issues at that time.

100. Insofar as it is within your knowledge and experience, how were estimates made of how much Factor VIII blood product would be required for use, (i) in Northern Ireland, (ii) in England and Wales and/or (iii) in the United Kingdom. In particular:

a. What was your role in making such estimates, and how did this changeover time?

100.1 I prepared the estimates for how much product would be required for use in Northern Ireland each year. It took approximately one week of intensive work each year to achieve this. The estimates were based on previous years' figures and trends arising therefrom. The estimates would also depend on local issues. For example, if it was envisaged that more orthopaedic surgery was scheduled to happen in the following year then this would be factored into the estimate.

b. What was the role of the UKHCDO and how did this change over time?

100.2 I understood the role of the UKHCDO was to collate information from the various Centres in order to project future UK requirements. To my knowledge, that role did not change.

c. What assumptions would underpin the estimates (including assumptions as to how the blood products would be used)?

100.3 Considerations included:

- how many new patients entered into your register,
- what was the severity of their condition,
- what was their clinical profile,
- were they likely to require elective surgery,
- were they candidates for home treatment and prophylaxis?

100.4 One had to apply common sense and expect that unpredictable things would happen. It was always necessary to have a surplus. I would consider the annual increase in demand over the previous 10 years and use that as a starting point. I then made allowance for anticipated further increase in demand.

d. How would the estimate be made (e.g. by whom were they made, when and through what process)?

100.5 See (c) above.

e. How were the estimates shared with other interested parties?

100.6 The annual return was prepared by me and returned to Oxford every year.

f. How did any of these processes change over time?

100.7 There was no change of note in the processes during my time.

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

a. What was your role in providing such figures, and how did this change over time?

101.1 Every issue of concentrate that left the hospital blood bank was identified by barcode in duplicate. One was entered into the patient's chart and one into blood bank records. No concentrate was issued for home treatment without forms being provided which had to be returned to the blood bank before any further issue was made. The amounts used and the purpose for which they were used were scrutinised by myself. Action was taken if too much was being used by contacting the patient and bringing forward their clinical appointment for assessment. The profile of the individual patient was closely monitored. It was for the patient to keep an accurate record of their home treatment. This record would be closely audited by me.

b. What was the role of UKHCDO and how did this change over time?

101.2 There was no change in the role.

c. How would the calculations be made (e.g. by whom were they made, when, through what process and using what data)?

101.3 Calculations were made as described in my answer to question 100 above.

d. How were those figures broken down geographically (e.g. by Country, region or any other unit)?

101.4 As Northern Ireland was and is such a small jurisdiction there was no distinction made for geographical breakdown.

e. How were the figures shared with other interested parties?

101.5 They were sent to Oxford by me in the course of annual returns.

f. How did any of these processes change over time?

101.6 These processes did not change over time.

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

102.1 I do not believe that there was, at any time, any significant discrepancy between estimates and actual use.

103. It may be suggested that England and Wales never achieved self-sufficiency of Factor VIII blood products, in the sense that clinicians were always reliant on commercially imported products to meet the demand of patients for such products.
a. Is this correct, to the best of your knowledge?
b. If so, why, in your opinion, was self-sufficiency never achieved?
c. If, in your view, self-sufficiency was achieved, when was it achieved and why was it not achieved earlier?

103.1 To the best of my knowledge the requirements for concentrate were ever increasing. Due to the effectiveness of treatment, increasing patient expectations and ensuring the wellbeing of the patients generally, more concentrate was required. I would suggest it was not possible to achieve full self-sufficiency for the large number of patients in England and Wales. It was not achieved.

104. To what extent do you consider Northern Ireland achieved self-sufficiency in blood products (accepting that the plasma was fractionated in Scotland rather than Northern Ireland)?

104.1 Northern Ireland was self-sufficient in the supply of cryoprecipitate at all times. However, supplies of NHS concentrate were never sufficient to meet demand. We received limited quantities of concentrate from Elstree and Oxford, although this was largely on the basis of the good relationship I had with Dr Lane and Drs Bidwell and Grant respectively. From 1982, Northern Ireland had an arrangement with SNBTS for the supply of NHS concentrate from PFC. The amount of NHS from PFC increased in the following years. I am unable to say at this time what proportion of concentrate used in the Belfast Centre was NHS concentrate. The remainder was from commercial concentrates. I would add that I believe that NHS suppliers did an excellent job with the limited resources that they had.

105. It may be suggested that a significant contributory factor to not achieving self-sufficiency (or not doing so earlier) was a failure by haemophilia clinicians to provide timely and accurate estimates of future demand for Factor VIII blood products. In particular, it may be suggested that haemophilia clinicians failed to identify the foreseeable increase in use of such products once they became available. How would you respond to these suggestions?

105.1 I disagree with this statement. I think it is difficult for those not involved at the time to appreciate fully appreciate the monumental task of providing estimates. The difficulty of doing so and keeping your own clinical work going was great. I do not believe that I, or other clinicians, could have done more. I consider that the estimates

were as good as they could be given the variables that inevitably arise in the treatment of haemophilia.

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

106.1 Any views expressed on this issue are largely speculative. For my own part, I doubt that self-sufficiency in Factor VIII products would have made a huge difference. Cryoprecipitate was regarded as virtually sacrosanct and safe, but patients still contracted HCV and HIV from it, not withstanding that in Northern Ireland we were entirely self-sufficient in the production of cryoprecipitate. Self-sufficiency in the production of concentrates may have reduced the numbers infected but it would not have eradicated the problem of viral infection. It is important to remember that there was a great difference in clinical manifestations. It is attractive to suggest that there would have been a reduction in HIV infection but I am by no means certain that this would be the case, given the variable nature of viral behaviour. By way of illustration, I am aware that one patient in Northern Ireland received doses of HIV-contaminated product, but did not seroconvert, while on the other hand, one donor in Edinburgh was sufficiently virulent to contaminate a batch that went on to infect 29 patients.

Section 6: Northern Ireland Blood Transfusion Service

107. Please set out the interactions and dealings you had with the Northern Ireland Blood Transfusion Service ("NIBTS") or its predecessor(s), in your capacity as the director of the Centre, insofar as relevant to the Inquiry's Terms of Reference.

107.1 The relationship between the Centre, NIBTS and myself was cordial. Consultations took place as and when required. There was no formal timetable for meetings, but we met regularly to discuss matters relating to the teaching of:

(a) MLSOs and Junior Doctors
(b) Viral transmission and programmes of vaccination against Hepatitis B for both blood donors, members of laboratory staff and hospital personnel.
(c) Supplies and availability of cryoprecipitate.

107.2 An important question arose when it was envisaged that patients might return to usage instead of the concentrates. Assurance of availability was given but the need did not materialise.

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

108.1 The supply of cryoprecipitate was maintained. There was an ample supply available if patients had agreed to return to its use. They did not. I recall they were emphatic about this, because of the inconvenience of usage and the necessity for fridge freezer availability.

109. What discussions or meetings or interactions did you have with NIBTS, its predecessor or any other blood service in relation to:
a. The risk of infection with hepatitis from blood products.
b. The risk of infection with HIV/AIDS from blood products.
c. The steps to be taken to reduce the risk of infection?

109.1 See 110 below and responses to Qs 22-26.

110. What involvement did you have with any decisions or actions taken by NIBTS or its predecessor in response to the risks arising from blood and blood products?

110.1 As stated, there was good ongoing contact with NIBTS. The situation in relation to risk of viral infection was reviewed, to the best of my recollection, roughly every six months. However, it was an evolving situation. Belfast continued to support the UK centres who were concerned with plasma fractionation and the manufacture of NHS concentrate.

111. What system was followed for keeping records of the blood or blood products used in Northern Ireland (both in relation to source and use)?

111.1 See 101(a) previously

Section 7: UKHCDO

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

112.1 The UKHCDO grew out of various earlier Ministry of Health and Medical Research Council Committees. The latter had met during the 1950s with a view to improving the care of haemophilia patients. Various individuals were concerned at the tragic and severe problems experienced by such patients. There was at that time a unanimous view that the medical practitioners of the day had limited knowledge about haemophilia. I suspect they were like me when I qualified in 1962, in that they had never seen or even met a patient suffering from haemophilia, let alone known how to cope with their problems in the absence of any specific treatment,.

112.2 The inaugural meeting of the newly formed UKHCDO took place in 1968 in Oxford under the Chairmanship of Professor EK Blackburn of Sheffield. I attended that meeting representing Northern Ireland. Thereafter during the 1970s when I became the Director of the Northern Ireland Haemophilia Centre I became a full member of the organisation and in my own right attended all meetings. The aims and objectives of the organisation were straightforward - to improve the standard of care and treatment for all patients with haemophilia and allied disorders; to disseminate this message of improvements and the needs for new treatments for all

medical practitioners. To members of the Haemophilia Society and through our colleagues and the Society the information would be disseminated right down to the patient.

112.3 I believe the aims of the AIDS Working Party were threefold; to monitor the number of infected UK patients, their treatment and progress. Secondly, to disseminate updated information regarding the AIDS epidemic as it evolved on the global stage to the members, who in turn would keep all Centres informed. Finally, the Working Party evaluated the new treatments and management strategies. Looking back there was reasonable success in all those aspects.

112.4 In the 1990s, I was elected Chairman. During my chairmanship the new UK treatment document for recommendations of haemophilia management was published in cooperation with the Department of Health (see HCDO0000269_062).

112.5 Cross regional annual audit was introduced across the UK. It followed on from a successful pilot scheme between Scotland and Northern Ireland. It aimed to create a uniform standard of care for all. The audit had a disadvantage. It had no powers of enforcement and it was agreed that from time to time peer review was ineffectual. However, it was helpful and is still in operation in 2020.

112.6 The establishment of a Constitution for the UKHCDO was undertaken, drawn up, adopted and approved. Financial arrangements were modified within the secretariat and charitable status was established for the organisation.

113. During the period that you were involved with UKHCDO, please outline:
a. The purpose, functions and responsibilities of UKHCDO, as you understood them.
b. The structure, composition and role of its various committees or working groups.
c. The relationships between UKHCDO and pharmaceutical companies.
d. How decisions were taken by UKHCDO.
e. How information or advice was disseminated by UKHCDO and to whom.

f. Any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to:
- the importation, purchase and selection of blood products;
- the manufacture of blood products;
- self-sufficiency;
- alternative treatments to factor products for patients with bleeding disorders;
- the risks of infection associated with the use of blood products;
- the sharing of information about such risks with patients and/or their families;
- obtaining consent from patients for the testing and storage of their blood, for treatment and for research;
- heat treatment;
- other measures to reduce risk;
- vCJD exposure; and
- treatments for HIV and hepatitis C.

113.1 I am unable to add to the information provided at 112 above.

Section 8: Pharmaceutical companies/medical research/clinical trials

114. Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products? If so, please list the names of the companies and give details of the advisory or consultancy services that you provided.

114.1 I have never provided advice or consultancy services to any pharmaceutical company.

115. Have you ever 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? If so, please provide details.

115.1 I have never received any pecuniary gain as I have never provided such advisory or consultancy services to pharmaceutical companies.

116. Have you ever sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details of your involvement and of any financial or other remuneration you received.

116.1 I have never sat on any advisory panel, board, committee, or similar body of any pharmaceutical company.

117. Have you ever received any financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

117.1 I have never received any financial incentives from pharmaceutical companies to use certain blood products.

118. Have you ever received any non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

118.1 I believe that it became known throughout the pharmaceutical industry that I was unreceptive to gifts, that if sent or left with my secretarial staff they would be, and they were, returned. If a company product was in use, or if a pharmaceutical company so desired, educational gifts for the Centre or extra accessories for the patients were acceptable i.e. slides, pamphlets and books.

118.2 I was pleased to seek and receive sponsorship for the Killyhelvin Hotel meeting on Hepatitis C. That seemed appropriate.

118.3 Funding was accepted for travel to scientific meetings, either to present a paper or take part in discussion groups.

119. Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?

119.1 I have never received any funding of this nature from a pharmaceutical company.

120. 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?

120.1 I followed the principles and guidelines as applicable to members of the then Committee on the Safety of Medicines. I would like to add that there were no factor concentrate manufacturers in my investment portfolio. I mention this because my holdings were shown to the general public through a BBC Panorama programme with my name attached and no consent having been obtained.

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

121.1 I always had an interest in pig platelets from the time of my research into the vascular complications of Type I Diabetes Mellitus. Pig platelets have almost identical properties to human platelets. Therefore, I became interested in the work of a Dr Johnston who worked for Speywood Laboratories.

121.2 He was studying the characteristics of porcine Factor VIII as a potential treatment for patients who had developed high responding inhibitors. I received no remuneration, apart from a glass model pig manufactured by Wedgewood. It was given to me for using the product for the first time (1981). The treatment was successful. The product was good, but some patients developed allergic reactions and eventually most developed anti-porcine antibodies. Alternative treatment had to be sought. All five patients involved gave full informed consent to the new treatment.

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

122.1 I have not provided a pharmaceutical company with results from medical research studies that I have undertaken.

123. 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?

123.1 I never received funding for medical research from any company.

Section 10: vCJD

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

124.1 The entity of CJD infection first came to my notice during proceedings of the Committee on Safety of Medicines during the years 1991 to 1993. Thereafter, I was aware there was a theoretical risk it could be transmitted to humans via factor concentrates or any product derived from bovine sources or any product of a bovine source.

124.2 It was not until the year before my retirement in 1998 that I received information about one patient who had been given concentrate prepared from a donor who subsequently developed vCJD. The patient was duly informed personally by me. However, already he had complications of a medical nature unrelated to his haemophilia and sadly he died. CJD was not a contributing factor to his demise.

124.3 I understand that since that time more steps have been taken in relation to CJD, but at that time there appeared to be no reason for me to burden patients with potentially distressing information the reliability and value of which remained unclear. I believe that guidance was subsequently issued indicating that patients should be

informed about the theoretical risk of vCJD, but it wasn't appropriate in my time to do so.

125. What if any steps did you take:
a. To put in place a process at the Centre for informing patients about possible exposure to vCJD?
b. To tell patients of possible exposure to vCJD?
c. To provide information to patients about the risks of vCJD?
d. To arrange for counselling, support and/or advice to be offered to patients who were being informed that they might have been exposed to vCJD?

125.1 See response to 124. I would add that these events coincided with my retirement.

Section 11: The Centre's involvement with the financial support schemes

126. To what extent, during your time as director of the Centre, did the Centre and its staff inform patients about the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust and the Caxton Foundation) which were set up to provide financial support to people who had been infected?

126.1 The patients were made fully aware of the availability of funding from the MacFarlane Trust.

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

127.1 Patients were encouraged to apply through our social worker or personally. I was happy to help, and many were helped. Given the social and political context in Northern Ireland at the time, there was some difficulty occasionally with interference from paramilitary groups seeking to intercept benefits for financial gain. In those instances I had to visit the post offices to prevent interception of the payment and

ensure the widow received it - a situation which I imagine was not a problem for the rest of the UK.

128. What kind of information did the Centre provide to the trusts and funds about, or on behalf of patients who were seeking assistance from the trusts and funds?

128.1 There was complete confidentiality between the information provided by the social worker to the Trust as the patient had agreed to its submission. No application was refused.

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

129.1 There were sixteen individuals affected; therefore, only a small number of applicants. There was no question of acting as a gateway and neither I nor any member of the Centre staff did so. All patients were eligible to apply to the Macfarlane Trust and they did so through the social work or secretarial staff. Requests for assistance discussed at the Trust meetings were anonymised. I would not have known whether people from my Centre had applied or not. I encouraged all to apply for whatever assistance they felt was necessary but I was not involved in the promotion or rejection of any application by individuals.

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

130.1 Neither the Centre nor its staff was involved in determining applications for assistance. It should be stated that during my period as a Trustee, I left applications from the Belfast Centre in the capable hands of both the nurses and the social worker.

Section 12: Your involvement with the financial support schemes

131. In your statement WITN0736001 you state that you were a Trustee of the Macfarlane Trust from 1991 to 1996. Please explain:

a. How you first came to be appointed as a Trustee.

131.1 I was appointed as a Trustee in 1991 by the then Secretary of State for Health. Then, as now, I presumed it was because I was at that time the Chairman of the UKHCDO.

b. The functions that you carried out and the responsibilities that you held in this capacity.

131.2 I feel that my function was to aid the non-medical members of the Trust as far as my experience permitted in medical aspects of applicants' requests.

132. Please describe as fully as you can your involvement in assessing and approving or rejecting applications for assistance. In particular, please explain:
a. The criteria used for approving or rejecting applications for grants at the Case Review sessions at Trustees' meetings (see, e.g., MACF0000002_35 and MACF0000013_041 which are enclosed) and who drew up those criteria.
b. How the regular payments system operated and how the levels of payments were determined and revised.
c. If there was a policy on reducing assistance to those beneficiaries perceived to mismanage their finances (see MACF0000013_13, enclosed) and, if so, how that policy operated.

132.1 These are dealt with within the details from the MacFarlane Trust Handbook of 1995.

132.2 The following extract sets this out:

Trust Activities

There have been no major changes in Trust policies or activities during the year. The main new activity has been the survey of members' needs. This has taken longer to complete than we had hoped and the Trustees felt that it would be a mistake to make any policy changes until the results became available.

Financial Help

The sum paid out during the year to April 1994(?) March 1995 was £2,169,191 which was a once again a slight increase on the previous year. Full details of the current system of payments in Part 2 of the Handbook. The emphasis continues to be on the monthly seasonal payments which allow Individuals to decide their own priorities in the use of Trust help.

The total sum was made up as follows:

Single payments: Nearly 600 payments were made, totalling £345,227. The emphasis continues to be in support of those who are sick and on help at the time of bereavement.

Regular payments: These payments are made at rates which vary according to financial need. At the beginning of the year 850 people receiving regular payments and at the end of the year this had fallen to 787. The overall total was £1,481,464. Of this approximately £120,000 was the special supplement paid to those whose health is most vulnerable (about a quarter of the people registered).

Winter payments: These are flat rate of £500 to those who have HIV, whether registered persons or partners. The total this year was £341,500.

A graphical comparison with previous years' expenditure is shown on page 7 together with a breakdown of the expenditure showing the main types of payment made.

Advice, Guidance and Information

As with the financial help there has been no change of policy in this part of the Trust's work. Efforts have continued to Improve the service provided, both in the number of people helped and in the standards of information and advice available.

Details of the services are covered in Part 2 of the Handbook, but in general terms they fall into one if the categories listed below.

- *Applications and negotiations for DSS and Local Authority benefits*
- *Housing and Mortgages*
- *Equipment for disability*
- *Community care*
- *Money management including investment and taxation*
- *Legal, including Wills and estates*
- *Health (general information - we do not presume to cover individual cases)*

133. At a meeting of Trustees on 9 September 1993 (see MACF0000013_041) you presented a paper (Annex B to the minutes of the meeting on 9 September 1993 and enclosed) entitled Review of Regular (And Other) Payments. You provided to the Trustees, as a series of annexes to that paper, a qualitative analysis of the "Extra costs of living with HIV", together with case examples and financial estimates.

a. Please provide (if you have them) copies of this qualitative analysis, including the case examples and financial estimates, that was shared with Trustees.

133.1 I do not have copies of the documents sought.

b. Please explain, to the extent that you are able to, how this analysis was undertaken.

133.2 Regrettably I am unable to provide any adequate data that would be helpful to the Inquiry in this respect.

c. The minutes of the meeting on 9 September 1993 record that you and Ms Harrington agreed to make proposals on a system of objective and fair assessment. What proposals were subsequently made?

133.3 Regrettably, I have no recollection.

d. Please describe how the special supplement to the regular payment was implemented by the Trust and any feedback that you were aware of from beneficiaries.

133.4 Regrettably, I have no recollection.

134. Please set out any involvement you had in advising the Macfarlane Trust and/or in formulating the Trust's policy or approach and/or in assessing applications to the Trust, in relation to payments towards reduced-risk or assisted conception. In answering this question, please consider the enclosed letters from the Macfarlane Trust dated 21 December 1995, 3 April 1996, 11 April 1996 and 6 June 1996 and the enclosed letter to the Macfarlane Trust dated 16 April 1996 and address the following questions:
a. Why (and when) the Trustees decided on a policy of not giving any financial assistance with conception (having previously made payments to couples, according to the letter of 3 April 1996).
b. What further enquiries you undertook, as referred to in the letter of 21 December 1995.
c. What advice you provided to the Trust as its "medical Trustee" on this issue.

d. How and why the Trust then settled on a policy of contributing towards the cost of private assisted reproduction treatment, but only if it was approved by the Human Fertilisation and Embryology Authority and available from the NHS (according to the letter of 3 April 1996).
e. Why Trustees had "reservations" about providing any financial assistance with sperm washing and were "reluctant to be involved with anything experimental" (according to the letter of 11 April 1996).
f. Why (see the letter of 6 June 1996) the Trustees were "not prepared to appear to endorse this mode of treatment".
g. Why the letter of 6 June 1996 stated that "one call on Trust resources that has never been accepted is for medical treatment of any kind", whilst the letter of 3 April 1996 stated that Trustees had settled on a policy allowing contributions towards the cost of private assisted reproduction treatment.

134.1 The details of the applicant's request are not fresh in my memory but I recall that it constituted a complex issue relating to IVF (In Vitro Fertilisation). I sought and accepted advice from Sir Colin Campbell. He had succeeded Baroness Mary Warnock as Chairman of the In Vitro Fertilisation and Embryology Committee. They both were familiar with me through the University Research Ethics Committee. I welcomed their input. I believed it to be fair to the applicant and to future applicants who might make similar requests.

135. In the Third Deed of Variation for the Trustees of the Macfarlane Trust (see MACF0000003_022) it is recorded that you were a party to the Second Deed of Variation in 1996 as a DHSS Trustee. Please clarify what was meant by this, whether this constituted a change to your role over the years and if so how, whose interests you were representing in your role as a DHSS Trustee, whether you received any instructions from the DHSS or elsewhere as to how to perform your role (and if so what instructions) and whether you had any reporting obligations to the DHSS.

135.1 I do not remember any second Deed of Variation. I do not recall whatever discussions took place relating to the second Deed of Variation. I am unable to clarify what was meant. I never received any instructions from DHSS on how to

perform the role and had no reporting obligations to them. It would, therefore, be misleading to characterise my role as that of a "DHSS Trustee". My role was that of Trustee independent of Government and related to my chairmanship of the UKHCDO.

136. In your statement WITN0736001 you state that you were a Trustee of the Eileen Trust from 1993 until 1996. Please explain how you came to be appointed as a Trustee, whether this was also as a DHSS Trustee and what this entailed, as well as the functions that you carried out and responsibilities that you held in this capacity.

136.1 I was appointed as a Trustee to the Eileen Trust by the Secretary of State. As with the Macfarlane Trust it would be misleading to characterise my role as that of a DHSS Trustee. My role was that of Trustee independent of Government and related to my chairmanship of the UKHCDO. My function as a Trustee was similar to the Macfarlane Trust, but drew on my wider experiences as a Physician and someone who had blood transfusion experience other than that related to Factor concentrates and inherited bleeding disorders e.g. in relation to the development of open heart surgery, and trauma associated with the Northern Ireland civil unrest.

137. In your statement WITN0736005 at 2.14.2 you state that "following a vigorous campaign involving myself and many others in the UK we achieved lump sum payments to be made to affected individuals. I was involved with the Macfarlane Trust to provide help for those who were affected over and above the original lump sum payment. The Eileen Trust was also set up in parallel to aid those infected through receiving blood transfusions in the UK." Please explain what the "vigorous campaigning" entailed and outline who else was involved.

137.1 Thirty years ago I had abundant energy. Locally I appeared on BBC Northern Ireland television. I spoke on Ulster Radio. I urged the NI BBC to make an episode of its documentary programme 'Spotlight', which would be the local equivalent of the UK television programme 'Panorama'. They agreed. It took a great deal of time to organise patients and staff to do a full day's filming at the hospital. Permission at all

levels had to be obtained, this included the written consent of patients and they had to be happy to talk to camera about their experiences including HIV.

137.2 A photograph of the venue was taken before arrival of television production engineers and their team. Facilities were provided for complete confidentiality and appropriate facilities for catering etc. The programme was duly completed. I received a phone call the next day from the producer. It was not going to be used. It was completely non-controversial. No patient had anything but reasonable comments to make. They would send me the video for the Centre to use and a contribution to the NI branch of the Haemophilia Society. The video arrived, and may well be held in the Centre. It was accompanied by a cheque for £30.00.

137.3 I met as often as possible with members of the National Haemophilia Society in London. We talked to the Press. I remember particularly a difficult Daily Mail journalist who was clearly hostile to the needs of haemophiliac population. Further we lobbied MPs and I have to give a special thanks to the support given by Frank Field. I also met with Rt Hon. Ken Clarke.

138. Do you consider, from your perspective as a Trustee, that the Macfarlane and Eileen Trusts were well run? Do you consider that they achieved their purposes? Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

138.1 During my lifetime I have sat on many committees, a number of which can be accurately described by this excerpt from an anonymous ditty:

'Oh, give me your pity, I'm on a committee which means that from morning til night
We attend and amend and contend and defend without a conclusion in sight.'

138.2 However, the Macfarlane and Eileen Trusts were far removed from the sentiments of that ditty in their operation and character. I considered them to be well run. I will now refer particularly to the Macfarlane Trust as it was the larger and I felt possibly it had a more difficult role due to numbers of applicants.

138.3 I felt that the Trust was meticulously administered by the late John Williams and his staff. Likewise the meetings were quietly and competently chaired by the late Reverend Prebendary Alan Tanner. Clifford Grinstead supplied serious and careful financial advice. All members were allowed to have their opinions and views expressed.

138.4 In the eyes of the patients the Trustees were unable to do everything to their satisfaction. The applicants' problems were complex and difficult. One vociferous patient group found us lacking on many occasions. I remember it was called 'The Birchgrove Group'.

138.5 Occasionally I was chided for being too "emotional." However after the first London Roadshow my critical colleague waxed eloquent and I could not resist suggesting that since being on the Roadshow he had become a little too "emotional". This highlighted a difficulty for members who were not used to meeting the applicants face to face. It showed that perhaps a few Trustees were too remote from the situation on "the ground". My memories indicated that the Trust performed a difficult task with integrity and hard work.

139. To the extent that you have not already done so, please explain as fully as you can any involvement you have had in relation to any of the trusts or funds, including:
a. Any involvement you had in relation to the development of any criteria or policies relating to eligibility for financial assistance.
b. Any involvement you had in providing advice to any of the trusts or funds.
c. Any involvement you had in assessing applications to the trusts or funds.

139.1 I have no further helpful comments to contribute.

Section 13: Haemophilia Society

140. Please provide details of your involvement with the Haemophilia Society's Medical Advisory Panel, explaining what the function of the Panel was and your role and responsibilities as a member of the Panel.

140.1 I was appointed to the Medical Advisory Panel in 1982. It involved attending Panel meetings and providing a conduit for processing the flow of information from the UKHCDO to the Society and thence on to the patients.

140.2 The latter was achieved through the medium of their regular Journal or by generation of appropriate leaflets/booklets. At the time I assumed I had been appointed in recognition of the degree of progress that had occurred in Northern Ireland during the preceding decade. A Northern Ireland group of the Society was flourishing, and in a mundane yet important business sense it was providing a significant income to the Society.

140.3 Local members were disappointed that the funds so eagerly raised went to London. However, they were pleased when the Society funded their own dedicated physiotherapist – the first they had been able to experience.

140.4 During my time I was privileged to meet and work with many haemophiliacs. I am unable to recall all their names, but I do wish to mention the late John Prothero. He encapsulated all that is fine and courageous in so many severely affected patients that I have had the privilege to know, especially in connection with the Society.

Section 14: Other Issues

141. 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.

141.1 Those witnesses to the Inquiry, known as the 'infected and affected' have quite rightly presented their heart-breaking stories and had their voices heard. No-one could fail to be moved by these personal accounts, and I wish to express my

deepest sympathy and regret for the enduring and devastating mark which contaminated blood products has left on their lives.

141.2 In preparing this statement for the Inquiry, I have encountered the challenges to the memory which the passage of years inevitably presents; however, whilst some clinical and historical details have eluded me, the memory of the harrowing deaths of some patients – who I also considered to be friends, through years of getting to know them and their loved ones as I treated and counselled them - is as stark as if it happened yesterday. For me, it was absolutely devastating to witness the unfolding horror of the harm caused by factor concentrates, where once there had been great hope. I feel that the term 'affected' must also include those Centre staff members – doctors, nurses, social workers and others - who were profoundly affected by the tragedy and are to this day still mourning the untimely loss of so many.

Statement of Truth

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

GRO-C

Signed:

Dr. Elizabeth Mayne

Date: 4/2/21