Witness Name: Dr Maurice Strevens
Statement No.: WITN3808005
Exhibits: 0
Dated: 13 May 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR MAURICE STREVENS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 28 January 2021.

I, Dr Maurice Strevens, will say as follows: -

Section 1: Introduction

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

1.1. My name is Maurice John Strevens. My address and date of birth is known to the Inquiry. My qualifications are MB BCh (Wales) FRCP FRCPath.

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. Pre-registration Medical House Officer
Bridgend General Hospital
South Wales
August 1969 - January 1970

2.2. Pre-registration Surgical House Officer
Cardiff Royal Infirmary

South Wales
February 1970 - July 1970

2.3. In relation to the above roles. Pre-registration jobs are designed to give basic experience in general medicine and surgery and if completed successfully leads to entry on the GMC register.

2.4. Senior Medical HO
Sully Hospital
South Wales
August 1970 - July 1971

2.5. Senior Medical HO
Bridgend General Hospital
South Wales
August 1971 - July 1972

2.6. Registrar in General Medicine
Portsmouth Royal Infirmary
Hampshire
August 1972 - July1974

2.7. The above posts gave experience in a range of medical disciplines and teaching towards gaining membership of the Royal College of Physicians. I achieved this while working in Portsmouth.

2.8. Specialist Registrar in Haematology
Aberdeen Royal Infirmary
Aberdeenshire
July 1974 - November 1975

2.9. The above was my first post in haematology. A lot of the time was spent in the haematology laboratory where I was introduced to microscopy of both blood films and bone marrows, the techniques of measurement in the general lab., techniques in coagulation and blood transfusion. The training was aimed at eventually passing the exams required to become a member of the Royal College of Pathologists.

2.10. Senior Registrar in Haematology
Sheffield Hospitals (Royal Infirmary, Hallamshire Hospital, Sheffield Children's Hospital) and The Sheffield Blood Transfusion Centre
November 1975 - November 1979

2.11. In relation to the above. I continued my training in both laboratory and clinical haematology. This included training and experience in the treatment of bleeding disorders. Sheffield was a Haemophilia centre for both adults and a separate unit for children at the Children's Hospital. I spent more time than was usual for senior registrars at the Children's Hospital because of personal interests. There was a lot of research taking place into bleeding disorders in Sheffield at that time. Professor Preston was particularly interested in liver disease associated with NonA nonB hepatitis in Haemophiliacs.

2.12. I spent 6 months in residence at the Sheffield transfusion centre. This gave me valuable insight into the workings of a regional transfusion Centre. This included my attendance as a medical officer at large donation sessions. I learnt about the careful selection process of blood donors and the belief that blood from unpaid regular volunteers was inherently safer than the American system of paying blood donors. Although both the UK and the USA tested blood for known blood borne pathogens, in the United Kingdom there was concern about pathogens which at that time could not be defined.

2.13. In 1979 I took and passed the final exam and became a member of the Royal College of Pathologists.

2.14. Notes on Haematology Training:

2.14.1. In 1969 there was no clinical haematology service at Bridgend General Hospital. The haematology laboratory was led by a general pathologist who just happened to have an interest in clinical haematology. In spite of this I still found myself involved in the treatment of patients with leukaemia and lymphoma in a general medicine setting.

2.14.2. In the 1960s a group of senior haematologists from various backgrounds felt that haematology services in the UK should be provided by doctors rigorously trained in all aspects of both clinical and laboratory haematology. At the end of

the training there was an exam leading to membership of the Royal College of Pathologists. One had to pass in all areas of haematology - membership of the college is an essential qualification for any consultant haematologist. At the time the combination of both laboratory and clinical skill in one doctor was very different to the splitting of the two discipline which occurred in most other countries

2.15. Consultant Haematologist for the Coventry hospitals (Various hospitals around Coventry including the Coventry and Warwickshire hospital and the Walsgrave Hospital)
December 1979 - June 2005

2.16. When I became a Haematology consultant in Coventry there were just two consultants, one senior registrar, a registrar who was working in both medicine and haematology and an SHO on the SHO medical rotation. With only two consultants there was no opportunity to specialize. However with two consultants we could provide 24 hour consultant cover which meant we could provide comprehensive care in the more specialist areas of haematology including acute leukaemia and haemophilia and because of my extended training at the Sheffield children's hospital this included the treatment of children as well as adults in both leukaemia and haemophilia. Because of the ethnic mix of Coventry residents there was also a need to provide services for patients with thalassaemia and sickle cell disease – once again both children and adults. The problem was how to provide expert care in such a wide range of specialised areas. This was possible because of the high level of collaboration between haematologists resulting in the development of effective networks in specialist areas. For leukaemia this was based around a national and international clinical trials structure with detailed programmes for the investigation and treatment of patients. In the UK most patients are entered into clinical trials which not only benefits research but also ensures a high level of care for individual patients. For haemophilia the formation and development of the UKHCDO ensured that all haemophilia care was developed and delivered by specialists in the field. All haemophilia directors meet regularly and were provided with timely updates. The collection and collation of data proved invaluable in the development of policy and the delivery of specialist care. Policy changes were discussed and approved at most UKHCDO meetings based on evidence presented at the meetings or following recommendation from expert sub-committees. This should be evident from the minutes of the meetings which I believe the Inquiry has full access to.

2.17. Government representatives came to our meeting and senior haematologists were able to meet and inform government representatives. It's important to remember that in the early 70s there was no internet.

2.18. Within the service for patients with haemophilia my duties were shared with my colleague (Dr NKS) He spent a lot of time on national and international committees and because of his commitments, he wanted to continue with his regular outpatient clinics for haemophilia patients and I would provide the emergency and day to day care for patients coming to the department and also provide care for patients coming into hospital for treatment in other specialties (dentistry, surgery - especially orthopaedic surgery etc.).

2.19. When I started in Coventry most patients with severe disease were being treated with factor eight concentrates (American products for adults and British (BPL) for children. The use of concentrates facilitated home treatment under the supervision of a senior haemophilia sister who visited them regularly at home. This service was well established when I started in 1979. Because patients were being seen less often at the hospital a computerised database was set up. This enabled us to maintain records of products issued, how and why they were used. These records enabled us to keep track of patients' progress and quickly identify specific issues (target joints etc.)These arrangement continued until the retirement of Prof NKS in 1991.

3. Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement. Please ensure your answer addresses your involvement with the UKHCDO.

3.1. Between 1969 and 2005 I have held the following positions:

3.1.1. Clinician in charge of the haematology lab

3.1.2. Clinical Director of Medicine and a member of the hospital trust board.

3.1.3. An examiner for the Royal College of Pathologists when final exams were held in Coventry and external examiner when the number of examination centres were reduced.

3.1.4. As haemophilia director I was a member of the UKHCDO and attended their meetings. I did not sit on any of their committees or hold any other position in the organisation.

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

4.1. I have previously been involved with this enquiry responding to criticism of aspects of my care relating to patients attending the Coventry centre. In one case I was able to demonstrate that the criticism related to my (deceased) colleague - not myself. In the second case I was unhappy with the evidence provided but was not able to review the patient's hospital records. The request to view the records was made via the IBI. The IBI person involved requested access for notes held at the Coventry and Warwickshire Partnership (dealing with community care) and written permission was given by the patient but the notes I required were his hospital records held at University Hospitals Coventry and Warwickshire. The records manager at UHCW confirmed that they were in possession of the records but that the consent I had was invalid. I believe that a new request for access was submitted to the person concerned but he failed to respond. As far as I was concerned the report submitted by the patient was not balanced and contained significant inaccuracies. My view was that it appeared to be based on an assumption of cover-up and conspiracy. The IBI invited me to submit a report based on my recollections but I felt this would be unwise as whatever I said could be carefully scrutinised in the light of the written records that his legal team had access to. I was unhappy with the alternative proposal to redact my name from his report but I felt it was the safest way to protect my reputation.

4.2. I have not been involved in any other enquiries.

Section 2: Decisions and actions of the Coventry and Warwickshire Hospital

5. Please describe the roles, functions and responsibilities of the Haemophilia Centre at the Coventry and Warwickshire Hospital ('the Centre') during the time that you worked there. Please provide an account of the Hospital's history, its establishment and its activities during this time.

5.1. As haemophilia services evolved, the Coventry Centre was designated as a 'Haemophilia Centre' with 'Comprehensive Care' being provided by Birmingham Queen Elizabeth Hospital for adults and the Children's Hospital for children.

5.2. I worked in close collaboration with the Birmingham centres. Where there were gaps in our service provision such as genetic counselling and more complex diagnostic analysis I was free to refer to the Birmingham centres but Birmingham was over 20 miles from Coventry and whenever possible I felt that it was better to offer services locally. If patients would prefer to go to the Birmingham centres I would be happy to refer although I do not remember this happening.

5.3. Surgery was an issue. According to our designation patients should be referred to the Comprehensive Care Centres in Birmingham. If patients required surgery I always discussed this with my Birmingham colleagues and the response was usually to proceed with the surgery in Coventry.

Roles and Responsibilities

5.4. Diagnosis of bleeding disorders. This was usually done in our own labs. Occasionally samples might be sent away for more complex analysis. FVIII inhibitors could be screened for and levels monitored in Coventry.

5.5. Counselling and education were provided by myself and the Haemophilia sister on an ongoing basis. Before home treatment patients and parents had to learn to recognise the early signs of bleeding and seek early intervention at the hospital. With home treatment they had to learn to administer factor eight and to learn how long to continue treatment. Advice and support was always available. With an experienced haemophilia nurse working in the community the whole process could run smoothly.

5.6. Patients were referred to Birmingham for specialist genetic counselling.

Coventry's Hospitals - History.

5.7. When I started in 1979 there were around five hospitals in Coventry. The services were coordinated with some hospitals providing general services and others more specialised. During the 80's most of these hospitals closed, their services becoming more centralized on two sites - the Coventry and Warwickshire Hospital near the centre of town and the relatively new Walsgrave Hospital around four miles from the city centre. The anachronism was that the A and E unit was at the C and W site while most of the specialist services (medicine, surgery, cardiology etc) were four miles away. The arrangement was far from satisfactory and eventually all services were moved to Walsgrave in the 1990s and the Coventry and Warwickshire Hospital closed.

6. If applicable, please explain the relationship between the Centre and:

a. Any Regional Transfusion Centre(s);

b. Any Regional Health Authority and its representative(s);

c. Other local haemophilia centres; and

d. BPL and/or PFL.

Please include in your answer the purpose, frequency and attendees of any meetings between the Centre and these organisations.

6.1. **A/B:** The Regional Transfusion Centre was in Birmingham where all blood supplies came from supplying the whole of West Midlands Region. As far as I can remember this included the distribution of factor eight products from BPL. After Trusts were established the supply of blood products remained unchanged. The funding of specialist blood products was an issue. Any Trust with a haemophilia centre would have to deal with serious financial risks. Trusts were expected to live within a budget but with so much expenditure focused on a handful of patients expenditure could vary widely from one year to another because of major problems occurring in one or two patients. The solution was that funding for haemophilia was retained at Regional level

6.2. An example. I had a patient who had antibodies to factor 8 so any major bleeding problem could be life threatening. A surgeon decided to 'band' his piles - a simple procedure for a 'normal' patient. The surgeon did not discuss it with me. The patient ended up requiring over 100 units of blood over a two month stay in the intensive care unit. Eventually he was allowed to die - we were unable to control his persistent bleeding. I kept the Regional officer controlling the haemophilia budget regularly

updated and my 'exceptional' expenditure that year was covered from the pooled regional budget. During my years in Coventry I never experienced any problems in the funding of specialist blood products. When I was clinical director for medicine I attended a six week business course at the Manchester Business School. Budget management and financial control modules proved to be very useful.

6.3. **C:** In clinical terms the Birmingham centres were very helpful in both developing local policies and giving advice relating to specific patients.

6.4. I think there were meetings between Birmingham centre directors and senior Regional Officers. I was not involved in those meetings but I would have been made aware of any decisions that affected the Coventry Centre (eg the practicalities of Regional funding)

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

7.1. Myself and Professor Keith Shinton (now deceased) were co - haemophilia directors. When Professor Shinton retired I became the sole director.

8. Please describe:
a. your role and responsibilities at the Centre and how, if applicable, this changed over time;
b. your work at the Centre insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.

8.1. This has mostly been described above. From 1979 -1991 I was a joint haemophilia director and from 1991 - 2005 I was the sole director so from 1991 I took on the responsibility for the haemophilia outpatient clinic. As well as the clinical responsibilities there was also the tasks of data collection and collation and supplying the UKHCDO with annual returns.

8.2. With regards patients with HIV - especially when effective treatments became available (HAART) I set up a new clinic with a genito-urinary medicine consultant with expertise in AIDS management to manage haemophiliacs with HIV. These patients were reluctant to go to a GUM clinic.

8.3. When HAART first became available a few patients were sent to Heartlands Hospital for urgent treatment.

8.4. HCV positive patients were monitored and some were given Interferon treatment as appropriate.

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

9.1. According to the UKHCDO stats for 1986 that have been supplied by the Inquiry it appears that we treated 24 patients with Haemophilia A, and 6 patients with Haemophilia B. I am sure that all these would have had severe disease. One patient with von Willebrand's disease was treated with DDAVP - probably to cover a minor surgical procedure. In addition to these we would had had many patients registered with minor bleeding problems who would carry a bleeding disorder card but would never have been reviewed. If any dentist or surgeon required further information then we would have the records and advise then accordingly. In summary we provided direct ongoing care for around 30 patients who almost certainly were on home treatment and regular prophylaxis. The number did not change significantly during my time in Coventry.

10. To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the Centre regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? In addressing this issue, please answer the following questions:

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

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

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

d. What if any involvement did you have?

10.1. The general principles of treatment were that all blood products should be avoided if possible. DDAVP or Cryoprecipitate should be used in preference to factor

concentrate if practical and safe. This would only be practical for patients with mild disease and especially if they had never been exposed to factor concentrates. UK concentrate should be used in preference to American products although this had to be tempered by the severely limited amount of UK concentrate relative to demand. Finally attempts would be made to limit the number of different suppliers of American products - subject to availability.

10.2. As far as I can remember all products were supplied from Birmingham (I think the transfusion centre). I think the Birmingham Centre directors devised the purchasing policy and I am confident that they would have been based on the principles outlined above.

10.3. In practice this meant that children were supplied with BPL products and adults received American products. Further information about the annual usage of factor products in Coventry would be available from UKHCDO annual returns records. As far as I can remember selection of products was done at a regional level. My colleagues in Birmingham would have been involved in the process.

10.4. Once a quality standard had been agreed I would not have thought that cost was a significant issue.

10.5. I believe there was a disagreement at one point when switching to recombinant blood products was being considered. Dr Frank Hill felt that there were delays in switching. The regional medical officer wrote to Dr Hill explaining they were awaiting an evaluation report. I believe that correspondence relating to this is covered later in my statement.

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

11.1. I cannot remember the details, but the Inquiry has provided details of my usage in 1986 and these indicate that two American products were used in 1986, Alpha and Armour.

11.2. Following the development of tests for HIV, the degree of contamination of concentrates became apparent and so we switched to heat treated products as quickly as possible. Then as genetically engineered products became available and

were shown to be safe and effective we switched to these products. All of this was done in the light of UKHCDO advice and implemented though our regional directors.

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

12.1. As far as I am aware the hospital had no involvement in the purchase of therapeutic materials. Neither did it have or exert any influence on purchasing decisions being made on the products we used.

12.2. Similarly neither myself nor my colleagues in the Centre were involved in the purchasing decisions being made with respect to the products we used.

12.3. Nevertheless representatives of pharmaceutical companies regularly sought meetings with staff at the centre. Personally such meetings were infrequent and not encouraged due to pressure of work.

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

13.1. I don't remember having any involvement in purchasing policy.

14. 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.

14.1. See above especially my answer to question 10.

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

15.1. In the 1970s, prior to factor eight concentrates, cryoprecipitate was the treatment of choice for bleeding episodes. Patients would need to come to the hospital and the frozen cryoprecipitate - around 4 - 8 bags had to be melted in a water bath. This was then infused into the patient. The issue was that the whole process would take at least an hour from the recognition of a bleed to the administration of the

cryoprecipitate. By that time the joint was often swollen and inflamed. Several days rest would be required together with repeat treatments. This often led to 'target joints' where repeated bleeds into the same joint eventually led to arthritis and lifelong disability. The big advantage of freeze dried concentrates was that the product could be at home by patient or parent which led to treatment being given far more quickly as a result, it quickly became apparent that target joints were much less common, patients were not getting arthritis and were able to live a much more normal life. Even before prophylaxis was introduced having a treatment before they undertook an activity that had a high risk of inducing a bleed was a sensible use of factor eight and eventually led to prophylaxis and the understanding that even small doses of factor concentrate could keep many patients bleed free and led to them being able to lead an almost normal life. I cannot emphasise enough the importance of the introduction of factor concentrates on the lives of patients with severe haemophilia.

15.2. I am aware that some patients in some centres used cryoprecipitate at home. I do not think this was a practical consideration for most patients.

15.3. The 'risk' of infection from concentrates was an emerging issue. The Inquiry has provided a letter from the UKHCDO dated 24th June 1983 following a meeting of the Reference Centre Directors. The fourth paragraph states that *"there is as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy but the situation will be constantly reviewed."*

15.4. In much of the practice of interventional medicine there is always a balance between risk and benefit. For example if a patient required a hip replacement and wanted to know the risk of dying, the risk of serious life changing infection etc. the surgeon can provide advice as there is data available. In 1983 there was very little data available about the size of the risks from concentrates confounded by the absence of tests to predict problems and so treatment was provided in this context.

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

16.1. See my answer to question 15.

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

17.1. As stated previously home treatment with concentrates was firmly established when I started working in Coventry and this naturally evolved into prophylaxis. Cryoprecipitate was never considered as an alternative to concentrates in the context of home treatment.

17.2. Cryoprecipitate was always considered the treatment of choice for patients with mild/moderate disease who required infrequent treatment of limited duration and non - life threatening severity. Whenever possible these treatment decisions would involve a consultant haematologist - day or night. This was regarded as particularly important for patients who had never previously received concentrate.

17.3. This policy did not change while I was at Coventry.

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

18.1. When I started in Coventry in 1979 the policy of home treatment was firmly established. It was felt that all patients should be offered home treatment as quickly as possible - especially in children, with a view to preventing the life changing arthritic complications, which inevitably followed hospital based treatments. Home treatment also meant that patients, especially children, could live a much more normal life. Please see my answer to question 15 for further detail.

18.2. When the high risk of HIV infection became clearly apparent in 1985 following the introduction of testing for HIV, the production of heat treated products quickly

followed although it took a little time to optimise the heat treatment process. As far as I can remember there was no change in home treatment policy at that time.

18.3. There was emerging evidence of a link between HIV infection and the use of factor concentrates throughout the early 80s. How this would translate into policy was always going to be difficult. Fortunately we had within the UKHCDO national / international experts who met to discuss these issues and offer guidance to Haemophilia directors like myself. Document HCDO 000270_004 is a good example of the guidance we were being given. We were of course free to take or reject the advice. It is always important to address the consequences of extreme actions like stopping all concentrate usage. As an 'older' haematologist I have vivid recollections of the consequences of inadequately treated haemophilia - something that is too easy to forget. As far as I can remember there was no significant change to home treatment policy.

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

19.1. I refer to my answer to question 15. As I stated the progression from home treatment to prophylaxis was almost a natural progression. What surprised me was how little treatment was needed to suppress the majority of bleeds. It was a virtuous circle - as bleeds were prevented, joints became healthier which led to lower prophylactic dose requirements. The concern was that factor requirements would rocket but as far as I remember that didn't happen.

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

20.1. As a general policy factor concentrates would always be avoided in children with mild or moderate disease and to reinforce this no factor concentrate was issued from the blood bank without the involvement of a haematologist.

20.2. The need for cover for a surgical procedure would need to be considered on a patient by patient basis - and if necessary I would seek advice from my Birmingham colleagues.

21. In the enclosed minutes of a meeting of the UKHCDO held on 30 September 1994 [page 5 of HCDO0000494], Dr Bolton-Maggs raised concern about the availability of funding for concentrate purchase, particularly regarding prophylaxis for children, recombinant products, and treatment for inhibitor patients. Was this ever your experience at the Centre? If so, please describe the consequences of any shortage of funding for concentrates, and any steps taken to remedy this situation.

21.1. As previously described funds for concentrates were held centrally and I was never aware of funding problems - for children or recombinant products.

Section 3: Knowledge of, and response to, risk

Hepatitis

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

22.1. When I started in Coventry in 1979, Hepatitis B was a clearly defined viral infection and donors and donations were screened for infection. Nevertheless Hepatitis B infection could still infect blood recipients and so all haemophiliacs were routinely immunised as soon as vaccines became available and preferably before they started regular treatment. My understanding of NANB hepatitis was that it was ill-defined and could be due to a number of different viruses or something else completely. It was generally regarded as less severe than Hep B but without a test for the virus(es) little could be said about the nature of the infection. With regards patients receiving concentrates it was recognised that soon after commencing treatment patients experienced what was often a mild illness with minor disturbance of liver function which sometimes settled but could also result in a persistent mild disturbance of liver function. Whether this was due to persistent infection or something else to do with the treatment was not clear. Most doctors did not regard it as a serious problem. However Dr Eric Preston (later Professor) in Sheffield where I trained became increasingly concerned and eventually took liver biopsies from some affected patients. I remember the results being presented at a UKHCDO meeting. The results

showed that some had serious, advanced liver disease. HIV infection was the major concern at the time and effective heat treated concentrate was subsequently introduced. When NANB hepatitis was identified as being due to Hepatitis C it was also found that the heat treatment for HIV also inactivated the Hep C virus. virus.

22.2. From my appointment in 1979 to Professor Shinton's retirement in 1991 he was in charge of the haemophilia outpatient clinic and it was Professor Shinton together with the Haemophilia sister who organised the testing and follow up for both HIV and HCV in the Coventry haemophilia patients. My knowledge of Hepatitis C came via communications from the UKHCDO, publications in the medical press and from colleagues.

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

23.1. Re questions 23 and 24: Once there was a test to demonstrate HCV infection, all patients who had received factor concentrates were tested for the virus and the significance explained to them together with information about the prevention of spread to others. All this was organised by my colleague Prof. Shinton who ran the haemophilia clinic. The further use of concentrates was not an issue since it had been demonstrated that the heat treatment introduced to inactivate HIV was also highly effective in inactivating HCV.

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

24.1. Please see answer to question 23.

25. 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?

25.1. Hepatitis B infection usually presented as an acute inflammatory condition of the liver which usually resolved in weeks, although occasionally it could progress to fulminant liver failure and death, but, by immunizing patients, infection and complications could be avoided. Hepatitis C usually caused a much milder hepatitis but most patients developed a low grade persistence of the infection, which in a small number of

patients led to progressive serious liver disease. Many patients with persistent infection would describe non-specific low grade symptoms - i.e. in a non-specific way they felt generally unwell.

HIV and AIDS

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

26.1. Cases of unusual immunodeficiency were first described in the USA in the early 1980s. One sign of a possible new problem was the increased demand for Pentamidine - a treatment for PCP pneumonia - an unusual exotic form of pneumonia. There was also an increase in an unusual cancer - Kaposi sarcoma. These conditions were found to be associated with immune deficiency and seemed to be occurring in gay men and IV drug abusers. There were early concerns that it could represent a blood borne infection and this suspicion was enforced when similar problems started to be seen in patients with haemophilia who were using recently introduced factor concentrates.

26.2. There was always concern in the UK about the use of American concentrates. The concern was of a non-specific nature - that is blood should be taken from healthy unpaid volunteers rather than paid donors some from dubious backgrounds and in poor health. The first potential case of immunodeficiency in a UK haemophilia patient was featured in a letter from the UKHCDO in 1983 to all Haemophilia centre directors and included advice about the use of concentrates **HCDO0000270_004**

26.3. From memory I thought the advice was balanced - the issue being the dramatic effect on haemophilia care if all concentrates were withdrawn at that stage.

26.4. It was only when the HIV virus was identified and testing was introduced, that the extent of infection in blood products and the transmission of infection to haemophilia patients became apparent.

26.5. I took over the haemophilia clinic when Prof. Shinton retired in 1991. At that time patients infected with HIV were being treated with AZT which was the only drug available at that time. It was my impression that it was not very effective and patients were deteriorating. When HAART first became available in UK it's use was restricted to certain specialist centres. In the West Midlands this was the infectious diseases unit at Heartland's Hospital in Birmingham. As HAART became more freely available I established a separate clinic for HIV patients in conjunction with a Genito-urinary medicine specialist for Haemophilia patients - they were very reluctant to attend the usual GUM clinics. It was gratifying to see the rapid progress these patients made. The GUM specialist was also delighted to be treating patients who without fail took the treatment regularly. Regimens were difficult at first but became less complex with time. Failure to take the drugs regularly as prescribed was known to cause drug resistance but because of their discipline in taking the drugs this was not a problem with the haemophilia patients.

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

27.1. From around 1982 there was concern that the syndrome of AIDs might be blood borne and that Haemophilia patients were being affected, at first in the US and then in UK, provoking the letter from the UKHCDO in 1983 to all Haemophilia directors.

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

28.1. As soon as a test for HIV became available, all haemophilia patients were tested. (Prof. Shinton was in charge of this.)

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

29.1. As far as I can remember most regular users of American factor eight concentrates were infected so it was only patients who had never received concentrate that were at risk and would not be given un-heat-treated products.

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

30.1. The UKHCDO letter from 1983 alerted us to the issue and in accordance with the advice given, patients continued to receive concentrates. It was in 1985 that the extent of the problem became clear.

30.2. In 1983 without a test it was impossible to judge what the extent of the risk was, although I believe at that time CD4 monitoring was being introduced. What was clear was that to withdraw concentrate and to terminate home treatment programmes would have a profound effect on the day to day lives of severe haemophiliacs taking us back to a time when severe disability was common and life expectancy was significantly shortened.

Response to risk

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

31.1. Prof. Shinton together with the Haemophilia sister organised the testing of patients for HIV and HCV infection. They would have been responsible for counselling patients.

31.2. As the infected patients entered a programme of regular monitoring with blood tests it would be surprising if they had not been aware of why they were being monitored. The one exception could have been children where parents may have kept the details from their children.

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

32.1. From the early days of concentrate usage there were some concerns about the use of American concentrates. The concern was not about known risks but the as yet unknown risks of the US policies of plasma donation. The difference of approach to blood donation in the UK v USA was emphasised to me during my six-month training at the Sheffield Blood Centre. Each year at the regular UKHCDO meetings we were presented with graphs of concentrate usage rising but the availability of UK concentrate increasingly failing to keep up.

32.2. In Coventry therefore patients would not be given concentrate if their condition could be adequately managed with cryoprecipitate but this was not the case for patients with severe haemophilia. Our treatment policies therefore did not change as a result of the 1983 advice. However our policies were constantly policed by blood bank staff and on-call haematologists (consultant or senior registrar)

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

33.1. No, please see my answer to question 32.

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

34.1. As far as I can remember heat treated concentrate was used as soon as it was available in the West Midlands. It was used for all severe haemophiliacs. I can see no reason for not using heat treated products as soon as it was available

35. Please explain which categories of patients were regarded as suitable for, and treated with, heat-treated concentrates, and why.

35.1. As far as I am aware, all patients requiring factor concentrate were given heat treated product as soon as it was available in the West Midlands.

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

36.1. None. We could only act on information that was available in the context of what products were available to us. Please see my previous answers including to questions 11 and 15.

37. Please consider the enclosed letter from Professor Griffiths to Dr Hill, copied to you [DHSC0033758]. Professor Griffiths refers to concerns surrounding the rollout of recombinant Factor VIII, in particular, with regard to funding and purchasing arrangements. As far as you are able to recall, please explain the concerns mentioned by Professor Griffiths, whether you agreed, and what steps if any were taken to remedy these concerns.

37.1. I am afraid I disagree with your interpretation of this letter. Professor Griffiths says that he is awaiting the evaluation of recombinant factor 8 from two expert groups before approving the switch to recombinant products. He also states that if there are exceptional circumstances in individual patients where delaying treatment pending the outcome of the evaluation would not be appropriate then a local funding arrangement could be made. The majority of patients were already HIV/HCV positive and receiving heat treated product. If there were individuals who were virus negative and requiring a 'safer' product then a 'special case' could be made as Prof. Griffiths alludes to.

Section 4: Treatment of patients at the Centre

Provision of information to patients

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

38.1. The number of new patients commencing factor concentrates in Coventry between 1979 and the suspicion/identification of the AIDS virus in concentrates would have been small. Advice given would have been on an individual basis. They would have been warned about Hepatitis B and they would have been offered vaccination prior to commencing therapy. Giving advice about HCV or HIV would have been difficult from around 1983 - 1985/6 when there were emerging suspicions of AIDS being transmitted via blood products and non A non B not being the benign infection it was once thought to be. Fortunately as far as I can remember we did not have to deal with this situation because of an absence of new patients.

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

39.1. The only alternative to concentrates was cryoprecipitate. This would have been workable for mild to moderate cases. Desmopressin could be considered for mild haemophilia where bleeds were not life threatening especially if patients had previously demonstrated a satisfactory response to the drug. If patients/parents had ever expressed a desire to use cryoprecipitate delivered in hospital I would have felt obliged to advise them of the significant consequences of that decision in the longer term as I have referred to previously, in particular in the answer to question 15. Fortunately I was never put in that position.

HIV

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

40.1. These discussions would have taken place in a clinic situation or possibly with the haemophilia sister in a home environment. I was not involved in the haemophilia clinic in Coventry from 1979 until 1991 when Prof. Shinton retired.

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

41.1. I am unaware of any patients or parents in Coventry raising these concerns. I am not sure that 'manage' is an appropriate term in this situation. It's a case of balancing risks and benefits which is very difficult when information/facts are limited. One would need to present the facts as they were at that time and discuss the issues related to any particular decision that is made. At the end of the day it is for the patient/parent to decide.

42. In the ensuing discussion, it was decided that treatment of patients with NHS or commercial concentrate should continue, rather than reverting to cryoprecipitate by home therapy, as the link between commercial concentrates and HIV/AIDS was unproven [page 10 of PRSE0004440]. Please explain whether you agreed with this recommendation, why or why not, and whether it was followed at the Centre.

42.1. I am not sure that 'decided' is the right word. There would have been a discussion at the meeting and a general consensus was arrived at. Any individual director could follow their own views but it's always useful to be aware of your colleagues views in this difficult situation. Personally although I can't remember this item I supported the recommendations set out in the letter HCDO0000270_004 There are many clinical situations where risk and benefit have to be balanced. Even if the link was proven there was still no information as to the size of the risk and for most haemophiliacs

they had already been exposed to that risk for a period of time. Clearly the balance of risk would be perceived differently for previously untreated patients.

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

43.1. Prof. Shinton organised the testing and I assume the testing was done shortly after tests became available. I cannot remember the figures, but my impression was that most regular users of American concentrates were infected. I do not know how many children who were taking BPL products were infected.

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

44.1. I have no information about the process. See my answer to question 43 above.

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

45.1. Please see my answer to question 43, I was not involved.

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

46.1. Please see my answer to question 43, I do not know

47. At a meeting of the British Society for Haematology held on 4 January 1985, Dr Preston stated that "Haemophilia Directors considered every patient who had been given Factor VIII concentrate should be considered as harbouring the AIDS virus." Was this your approach when interacting with patients under your care/the Centre's care? Please explain how this assumption may have affected how Haemophilia Directors interacted with patients.

47.1. My impression is that what he was saying was that before test results were available all patients who had received concentrate should be approached as if they were infected with HIV. I don't believe that this statement made any difference to how staff

approached patients since we were trained to approach all patients as an infection risk. I cannot think of any situation where 'extra' precautions would have been taken. I have seen a request from a patient dated 12th Aug 1985 and this did have a sticker attached warning of the danger of infection- but this was after a positive HIV test had been found. The period of time we are talking about here is shortly before results were available. If a needle stick injury occurred in a patient 'at risk' of HIV then advice would have been sought about management.

48. The minutes of a meeting of the UKHCDO held on 21 October 1985 record a discussion surrounding a shortage of funding for haemophilia centres, with particular regard to HTLV-III [page 3 of PRSE0001638]. In your capacity as Haemophilia Centre Director, did the Centre suffer from any such shortage of funding? If so, why, and what consequences did this have for the treatment of patients and/or HIV positive haemophiliacs?

48.1. I have read this paragraph carefully and I'm a little non-plussed. The statement specifically refers to 'funds to create a safe laboratory and clinical facilities for staff" All laboratories are equipped to handle potentially infectious samples similarly I am not aware of any special requirements for staff. Casual social contact with HIV positive individuals has never been regarded as a health risk so I could not make a case for extra funding. Of course Coventry was not a comprehensive care centre but all I can say is that Coventry did not suffer any financial problems resulting from HIV infection at that time.

NANB Hepatitis/Hepatitis C

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

49.1. I do not know.

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

50.1. Prof. Shinton would have organised the testing when testing became available. The haemophilia sister would have been heavily involved in that programme. I have no

specific information about how patients were given the results or by whom. I have knowledge of one patient who was tested for HCV (he claims secretly) in January 1991 when testing first became available. He claimed he was not informed of the positive result until October 1992 when he went to college in London. Prof. Shinton retired in mid 1991 and I had not reviewed the patient in the haemophilia clinic before he went to London. I assumed he had been made aware of his HCV status before he went to London. He was certainly being seen by the haemophilia sister who had asked me to write a letter of referral. She was taking samples to monitor his CD4 counts at three monthly intervals.

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

51.1. I was not involved in the roll out of HCV testing. This was organised by Prof. Shinton. I have seen results from January 1991. I have no knowledge of the pre and post-test counselling.

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

52.1. I cannot now recall but from the information regarding results I assume testing became available in Jan 1991. I have no information about the extent of the testing programme.

Delay

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

53.1. I have no first hand knowledge of how patients were notified of their results.

Consent

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

54.1. I was not involved in the routine review of patients until 1991 and so prior to 1991 I cannot comment on the details of this process since I was not involved.

54.2. My understanding is that routine monitoring would have commenced after positive test results. I suspect much of the monitoring of patients' infectious diseases was done in the patient's home. For HIV this would involve 3 monthly check of their CD4 count which was used as a trigger to commence AZT treatment. When I took over the clinic in 1991 several patients were already taking AZT. For HCV this would be a regular check of their liver function. When I took over the clinic a few were taking Interferon treatment.

54.3. It is normal procedure to explain to patients why blood samples are being taken and to inform them of the results and the significance of any change. If this was being done in the home by a nurse then the responsible consultant would also be involved in reviewing the results and deciding if the patient needed to come to a clinic for review.

54.4. The reasons for blood monitoring needs to involve the patient and consent would normally be implied. The collection, pooling and analysis of data at both local, regional and national level were essential tools in advancing the understanding of haemophilia and its complications and most patients understood this. As far as I am aware written consent was never recorded or stored.

55. Were patients under your care/under the Centre's care treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent to treatment? Was their consent recorded and if so, how and where?

55.1. All severe haemophilia patients in Coventry were already taking factor concentrates when I arrived in 1979. The majority were on home treatment. I feel the terms 'express and informed consent' may be appropriate for medicine in 2021 but would have been alien in the 1980s for the approach to patients presenting with newly diagnosed haemophilia. The situation would usually be parents with a young child. There would be a lot of time spent with such parents explaining the nature of the disease and its likely progression without active intervention including the use of blood products. I find it inconceivable that parents would refuse blood products in that situation when faced with the alternative. The discussion of theoretical risk prior to the recognition of HIV and HCV would have been very difficult for parents to follow.

55.2. With less severe forms of haemophilia the safety of the product does have a different risk profile and the decision on choice of product would be talked through with the patient.

55.3. I did not obtain formal written consent to treatment in patients with haemophilia.

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

56.1. If a patient was under my care and required a test for HIV or Hepatitis then they would have been given clear knowledge of and information about the testing proposed and the fact that they had blood taken would have been taken as implied consent. 'Routine' blood tests (a blood count etc.) would not necessarily be described in detail but would be referred to as 'routine' checks.

PUPS

57. Please 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).

57.1. In relation to questions 57 and 58: With heat treatment being used as a means of inactivating virus in plasma concentrates it was important to establish the effectiveness of any such process not just in the laboratory but also in haemophilia patients who had not been infected. I cannot remember anything about the patient referred to in Dr Rizza's letter. I suspect that this was the only patient I was involved with that entered into any PUP study.

57.2. The published report of the study indicated that informed consent was obtained in all cases (as well as local ethical committee approval) but I have no memory of this patient and the actual consent process that was followed.

57.3. The important things in gaining informed consent would be to:
a) confirm that the treatment was necessary.
b) provide the information to indicate that the treatment was safe.
c) talk through the post treatment testing that was to be done and to offer assurance that these are the sort of tests that would be done anyway.
d) offer assurance regarding the confidentiality of the data.

57.4. The results of the study are detailed in PRSE0000192. Essential the (small) study indicated that BPL 8Y did not transmit HCV infection.

58. The enclosed letter from Dr Rizza to you dated 10 August 1990 [OXUH0002130_010] indicates your involvement in a study titled 'NHS 8Y Virgin Patient Study'. In relation to this document, please explain:
a. the extent of your involvement in this study;
b. the reason for the use of 'virgin patients';
c. whether and how consent was obtained from patients involved in the study;
d. the findings/conclusions of the study.

58.1. See answer above.

Research

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

Please provide the same details in relation to any other studies in which you were involved or articles you have published other than as a consultant haematologist, insofar as relevant to the Inquiry's Terms of Reference.

59.1. Apart from the study as detailed in doc PRSE000192, as far as I can remember I was not involved with any research studies related to haemophilia or other bleeding disorders.

60. The enclosed 1992 article titled 'Confirmation of viral safety of dry heated factor VIII concentrate prepared by BPL' records that you participated in the study forming the basis of the article [page 1 of PRSE0000192]. Please explain the extent of your involvement in this study and the enclosed publication.

60.1. Please see my answer to question 57 and 58

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

61.1. Please see my answer to question 57, 58 and 59

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

62.1. Please see my answer to question 57, 58 and 59. Aggregated data was sent to the UKHCDO in the form of annual returns. Being aggregated it was anonymised. This process was without the express consent of patients or their parents.

63. Please consider the enclosed Clinical Trial Exemption Application, in which you are named as a potential participating physician [page 52 of OXUH0000608_002]. Did you participate in this trial? If so, please explain the nature of your involvement and that of any patients under your care, including whether and how patient consent was obtained.

63.1. Please see my answer to question 57, 58 and 59.

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

64. How was the care and treatment of patients with HIV/AIDS managed at the Centre? In particular:

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

b. What treatment options were offered over the years?

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

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

64.1. Until 1991 the haemophilia outpatient clinic was the responsibility of Prof. Shinton.

64.2. After 1991 it became my responsibility. When I took over many of the patients with HIV infection were taking AZT in response to falling CD4 counts. In spite of this it was clear that the disease was progressing until the mid 1990s when highly active anti-retroviral therapy (HAART) became available. At first supplies were limited so the treatment was restricted to major centres. In the West Midlands this was the infectious disease unit at Heartlands Hospital. The unit developed a priority list and

by then I had one or two patients desperately ill. I referred them and one was selected for immediate treatment. Not only was he given HAART therapy but they were able to identify and treat one of the exotic infections that patients with AIDS are susceptible to. He was treated for this and was also given immune boosting treatment. After two years of therapy he regained his weight and health was able to walk again. When HAART became more generally available in Coventry I established a joint clinic with a genito-urinary medicine specialist to treat the haemophilia patients who were extremely reluctant to attend the GU medicine clinic (mostly for patients with venerial diseases). It was gratifying to see the patients gradually respond to the treatment. At first the treatments were complex but with time they were simplified and became much easier for the patients to take. The GUM specialist was impressed with how haemophiliacs stuck to their treatment such that resistance was never a problem. As far as I am aware, after the introduction of HAART no haemophilia patient died with AIDS and even before HAART the numbers were very small.

64.3. With regards HCV infections it was generally felt that HIV accelerated the development of liver disease. At that time treatment options were limited and often failed to clear the virus. Several patients elected to try the various forms of interferon. The response was usually disappointing but pegylated interferon proved to be more effective than alpha interferon and was even more effective when ribavirin was added. I believe that several new antiviral drugs have been introduced since my retirement.

64.4. I cannot remember the details but I believe that all patients were aware of the risks and benefits of the treatments they were being given. All patients were routinely monitored in the clinic.

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

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

b. What treatment options were offered over the years?

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

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

65.1. Routine review was provided by the haemophilia sister at the patients' home with regular blood monitoring. Patients were seen in the clinic at the request of the patient / parent or the sister

65.2. A) Patients were not routinely followed in a specialist clinic but would be if specific issues needed to be addressed.

65.3. B) Various forms of interferon were the only treatments available while I was in Coventry.

65.4. C) The main risks discussed were of unpleasant side effects and the significant risk of failure. The major benefit of course was the eradication of the infection and the hope that there would be no further deterioration in liver disease and the reduced risk of liver cancer.

65.5. D) As stated above the patients were kept under regular review.

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

66.1. Support came mostly from staff in the department. If other forms of support was provided, I am not aware of it.

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

67.1. No

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

68.1. As far as I am aware there were no problems with funding of treatments for HIV or HCV.

69. What if any involvement did you or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

69.1. There was no involvement in trials of treatment for HIV (I cannot speak for patients treated at Heartlands hospital). Regarding HCV there was no involvent in trials to treat the disease.

Records

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

70.1. There was no departmental policy. As stated there were very few patients that died and none that I recall dying in hospital.

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

71.1. I don't know whether there was a policy regarding the retention of hospital records. I was pleasantly surprised to find that the UHCW medical records department could confirm the existence of medical records within minutes of an enquiry about a patient who died thirty years previously and also that they were in original form - not photocopies

Section 5: UKHCDO and other haemophilia centres

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

72.1. When I came to Coventry in 1979 I became a joint haemophilia director and thereby a member of the UKHDO

72.2. The UKCDO became invaluable in developing and maintaining my knowledge of haemophilia during very difficult times. The value of access to up to date information from world leading haemophilia experts at a time when there was no internet cannot be overstated. It also facilitated the establishment of a network of high quality diagnostic and therapeutic centres in the UK. I was not involved with any working parties or specialist groups

Treloar's

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

73.1. I was unaware of the existence of Lord Mayor Treloar college before I came to Coventry. My involvement related to one patient who went to the college after he had developed a form of haemophilia that was particularly difficult to treat (He had developed inhibitors which rapidly inactivated any factor eight treatment he was given). Lord Mayor Treloar enabled him to pursue his education with rapid access to treatment facilities on site. Whilst at Treloar he was started treatment attempting to induce 'immune tolerance' to factor eight treatment by regular infusions of factor VIII. When he came back to Coventry during the holidays I was asked to provide care and continuation of his immune tolerance therapy during the holiday which I did. This was my only involvement with the college.

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

74.1. I don't know whether his immune tolerance treatment was part of a research project or not but I don't think it was.

75. The enclosed letter to you from Dr Wassef dated 6 April 1984 [TREL0000335_011] indicates that over Easter 1984, you had arranged for the patient to be provided Armour Factorate. Without referring to anything that would identify the specific patient, please explain the circumstances in which it was decided that the patient would receive Factorate. What is the protocol that is being described? Who decided that the patient should receive Factorate? Had the patient previously been treated with factor concentrates? If not, why were they introduced at this point in time? If the patient had previously received factor concentrates, was any consideration given to alternative treatment given your knowledge of the risks of HIV/AIDS?

75.1. It was generally regarded as 'good practice' that once a patient had been started with a particular product they should continue with that product unless there was a good reason to change it.

75.2. I didn't think I was in any position to question what treatment he should receive at that time. The treatment was very important for him at that time since he was facing a life with severe haemophilia with no effective treatment. From memory he already had extensive joint damage and was confined to a wheel chair.

76. In the enclosed letter from you to Dr Wassef dated 25 June 1984 [TREL0000335_014], you discuss arrangements for the patient's treatment after he leaves Treloar Centre. Without referring to this patient in particular, please describe the process by which Treloar's patients came to be under your care after leaving the Centre.

76.1. After leaving Treloar college this patient was coming back to Coventry to live. The letter TREL000335_014 indicates that immune tolerance therapy had not worked and treatment options were discussed.

76.2. When this patient came back to Coventry I can't remember the discussion I had with him about his treatment but I do remember that he continued with regular factor concentrate but the basis was unclear. Clearly he had 'failed' immune tolerance therapy and yet regular factor 8 treatment did appear to be preventing major bleeding episodes.

77. The enclosed letter from Dr Wassef to Dr Hill copied to you dated 29 June 1983 discusses an AIDS investigation relating to a Treloar's patient. Please recount your knowledge of these investigations in as much detail as you are able to, including:

a. any personal involvement in AIDS investigations, whether at the Coventry and Warwickshire Hospital, Treloar's or elsewhere;

b. steps taken to obtain consent and inform patients of their findings; and

c. what was done with the information gained as a result.

77.1. I have no recollection of the letter (TREL0000335_0200) or its contents and I would not have been involved with any monitoring of patients at Treloar college. However, the letter refers to AIDS related tests and states that the results are enclosed but unfortunately the enclosure is not included. The test would not have been a test for the HTLVIII/ AIDS virus which was yet to be described. I suspect that his CD4 counts were being monitored.

77.2. With regards AIDS monitoring in Coventry, I had no involvement with monitoring until 1991 when I took over the clinic. However, prior to my involvement I believe that similar monitoring to that which I refer to above with respect to (TREL0000335_200) was being done in Coventry. I have seen a letter sent to the parents of one of our haemophilia patients in 1983 asking them to come to Walsgrave Hospital for blood tests to be taken. It states that it was in relation to possible HIV infection due to the use of factor 8 concentrate. It also included an appointment at the Haemophilia outpatient to discuss the results. It appears that this letter was being sent to all Coventry patients who had received factor 8 concentrate and that CD4 counts were being monitored on a regular basis. Monitoring the CD4 count would have provided useful information with regard to the progression of immunodeficiency associated with HIV infection and the timing of treatment when it became available and also to monitor the effectiveness of that treatment. The reason for the monitoring is stated in the letter and consent would have been implied (by undergoing the tests).

Section 6: Pharmaceutical companies/medical research/clinical trials

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

a. Providing advisory or consultancy services;

b. Occupying a position on any advisory panel, board, committee or similar body;

c. Receiving funding to prescribe, supply, administer, recommend, buy or sell a particular product;

d. Undertaking medical research for or on a company's behalf; or

e. Providing results from medical research studies to a company.

If you were involved in any of the arrangements described above, please provide details of your involvement and any incentives, financial or otherwise, you received.

78.1. I would like to say I was not involved with any of the activities described in 78 a, b, c, d or e but you have provided me with documentation with evidence of a meeting with a representative of Cutter who made Koate HT in 1986, I have no recollection of this.

78.2. As a general principle I tried to avoid meeting with pharmaceutical representatives as I was a busy hospital doctor.

78.3. As far as I can remember I was never involved in the process of selecting therapeutic materials but neither can I remember the process whereby products were selected - but I thought it was done at regional level. After Coventry became a Trust, although I had a nominal budget for therapeutic materials effectively it was a regional budget and I think it was Mick O'Donnell at the Region Health Authority who had effective control of the budget. Although the budget was nominal we were always credited with the amount spent.

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

79.1. The centre did not have any guidelines. There may have been hospital guidelines but if there were I do not know what they were. As stated above I had no involvement with any pharmaceutical companies.

80. 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?

80.1. I received no funding from pharmaceutical companies.

81. The enclosed document [BAYP0000009_052] is a letter dated 4 November 1986 to you from Anne Walton, Senior Sales Representative at Cutter Pharmaceuticals discussing the sourcing and screening of plasma and viral inactivation methods.

a. As far as you can recall, please explain the context of this letter, including the meeting mentioned in the letter. Why was the information contained within it provided to you and how was it used by you/the Centre?

b. How often and for what purposes did you meet with representatives from pharmaceutical companies? Other than Cutter, please identify the pharmaceutical companies with whom you corresponded, whether regularly or infrequently, in your capacity as Haemophilia Centre Director.

c. How were decisions made as to which pharmaceutical companies provided heat-treated concentrates to the Haemophilia Centre at the Hospital?

81.1. The letter detailed the presentation she made at a meeting I had with her. I have no recollection of that meeting. The information was not used in any way to promote the purchase of her company's products.

Section 7: Interaction with the financial assistance trusts and schemes

82. Please explain as fully as you can any involvement you have had in relation to any of the trusts or funds (the MacFarlane Trust, the Eileen Trust, the MacFarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund) which were set up to provide financial assistance to people who had been infected. Relevant involvement may include:

a. Occupying a formal position with any of the trusts or funds;

b. Providing any advice to any of the trusts or funds, including for the development of any eligibility criteria or policies;

c. Informing patients about or referring patients to the different trusts or funds;

d. Determining or completing any part of applications made by patients.

You may find it useful to refer to the enclosed documents [MACF0000110_008 & DHSC0003009_002] which indicate your involvement in the Macfarlane Trust. In your answer, please clarify the purpose and extent of the involvement demonstrated in these documents.

82.1. I had no involvement with the MacFarlane trust or similar bodies. Haemophilia patients were well aware of the organisations and seemed to know how to apply for assistance. My only involvement was in supplying supporting information about the patients as illustrated in documents MACF0000110_008 and DHSC0003009_002

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

83.1. I suspect that our Haemophilia Sister would have been very much involved in assisting patients and their families. She GRO-A was very much involved in accessing support services.

Section 8: vCJD

84. 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?**

84.1. I cannot recall when I first became aware of potential risks of blood products transmitting vCJD. I think it was 1997 when I was informed of people who had died with vCJD and who had previously been blood donors. At that time there were no reports of transmission through blood transfusion. It was also felt that transmission would be more likely if the transfusion had included white cells. However implicated donations had been used to make clotting factor concentrates and we were in a position to a identify the batches and b identify Coventry patients who had received material from those batches. One issue was should patients be informed. I remember receiving a letter from the department of health indicating that patients should not be informed. Minutes of a regional meeting of haemophilia directors indicate that my chief executive in Coventry had instructed me not to inform patients. I would not have been happy with this since I felt it was patronising and patients had a right to know. However I also felt that patients had a right not to know if they chose not to. The result was a convoluted letter sent to all haemophilia patients (who had received concentrate) offering them the opportunity to be told (BWCT000036). Because it was UK plasma it was BPL products involved so it was children who had received the materials. I spoke to several families and as far as I can remember they were very pragmatic about the situation. I don't know if the CE knew what I had done.

84.2. My letter contained as much information that was available at the time and patients responses were filed in the notes. No further counselling was offered

85. Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so, please answer the following questions:

a. What steps were taken/put in place a process at the Hospital for informing patients about the risks of or possible exposure to vCJD?

b. What steps were taken 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?

85.1. Please see my answer to question 83..

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

86.1. My recollection is that no other measures were put in place because there was insufficient information available to inform what action should be taken.

87. The enclosed minutes are from a meeting of the West Midlands Regional Working Party on the Treatment of Haemophilia held on 7 January 1998, at which you were present [BWCT0000036]. The minutes record that you spoke with parents of children at the Coventry Haemophilia Centre about nvCJD. Please describe the nature of these discussions, including their purpose and the information given to parents.

87.1. Please see my answer to question 83.

88. In the enclosed letter copied to you [DHSC0004596_010], Dr Lee describes various concerns relating to vCJD and the use of confidential patient information. Did you share these concerns? If so, please describe the basis for this and what steps, if any, were taken in response2.

88.1. Having read the detailed response from Dr Soldan (HCDO0000242) I feel that concerns about confidentiality were being appropriately considered.

Section 9: Look-back and tracing exercises

89. In as much detail as you are able to, please explain your knowledge and involvement in HCV look-back or tracing exercises involving patients at the Coventry Haemophilia Centre. In answering this question, you may find it useful to refer to the enclosed document which relates to this matter [NHBT0041435_003].

89.1. As far as I understand it HCV look-back was conducted by the National Blood Transfusion service and as such I had very little involvement with it.

89.2. The letter you refer to (NHBT0041435_003) however did involve a haemophilia carrier who was given factor 8 concentrate to cover an operation. It seems clear that she then developed Hepatitis C but subsequently managed to clear the virus. I

presume the repeat PCR test was negative and there was no further action to be taken.

89.3. I don't think I had any other involvement with the programme.

90. In as much detail as you are able to, please explain your knowledge and involvement in HTLV-III/HIV look-back or tracing exercises involving patients at the Coventry Haemophilia Centre. You may be assisted by the enclosed documents which relate to this matter [NHBT0046145_009, NHBT0018438_014 & HCDO0000132_009].

90.1. The HIV look back was run by the NBTS. My involvement was purely administrative. With respect to the surgical patient the surgeon was invited to see the patient him/herself or leave it to the NBTS to contact the GP. An infected batch of BPL factor 8 was given to haemophilia patients. These patients were already being dealt with in the Haemophilia Centre so needed no further action via the NBTS. The letter from Dr Rizza was about a haemophilia patient who according to UKHCDO data sero-converted between 1985 to 1986. I cannot remember the case so I am unable to give any further information.

Section 10: Other issues

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

91.1. Please see my answer to question 4.

91.2. In addition, the only 'complaints' / criticisms relate to this enquiry. The first was from the sister of a (deceased) haemophilic who said I was rude and off-hand during a consultation. I was able to demonstrate that it was my (deceased) colleague who she had the consultation with.

91.3. The second concerned a letter of referral I wrote when the patient moved to London to study music and I was transferring his care to a London centre. I had recently taken over the haemophilia clinic from my retired colleague, I had not had the

opportunity to review him in the clinic and the letter was written based on information we had on his computerised records. The letter included the information that he was HCV positive. When the patient went for his first O.P. appointment the doctor raised the issue of his positive HCV test and the patient claimed he knew nothing about this. I wanted to review his medical records but the patient failed to give his consent.

92. 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.

92.1. I have nothing more to add.

Statement of Truth

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

Signed: GRO-C

Dated: 13/05/2021

Table of exhibits:

Date	Notes/ Description	Exhibit number