Witness Name: Dr Derek King
Statement No.: WITN4535001
Dated: 26 October 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR DEREK KING

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 6 August 2020

I, Derek King, will say as follows: -

Section 1: Introduction

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

Dr Derek John King

GRO-C

Date of Birth: GRO-C 1951

Qualifications: 1973 - B Med Biol with Commendation, University of Aberdeen

1976 - MB ChB with Commendation, University of Aberdeen

1979 - MRCP(UK)

1985 - MRCPath(Haematology)

1993 - FRCP (Edin)

1995 - FRCPath

Retired 31.3.2015

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.**

1.8.76 – 31.7.77 Resident House Officer, Aberdeen Royal Infirmary

1.8.77 – 31.7.78 Temporary Lecturer in Pathology, Department of Pathology, University of Aberdeen

1.8.78 – 30.9.79 Senior House Officer in General Medicine, Grampian Health Board

1.10.79 – 30.6.82 Registrar in General Medicine/Haematology, Grampian Health Board

1.7.82 – 30.6.84 Resident 4 and 5 (Senior Registrar equivalent), Residency Training Programme in Haematology, McMaster University Medical Centre, Hamilton, Ontario, Canada

1.7.84 – 31.10.86 Lecturer in Medicine (Honorary Senior Registrar), Department of Medicine, University of Aberdeen

1.11.86 – 1.6.94 Consultant in Haematology and Oncology to Grampian Health Board (then Aberdeen Royal Hospitals NHS Trust)

1.6.94 – 31.3.2015 Consultant Haematologist and Service Clinical Director for Laboratory Haematology to Aberdeen Royal Hospitals NHS Trust, then Grampian University Hospitals Trust, now NHS Grampian.

In both these consultant posts my main area of patient responsibility was at the Royal Aberdeen Children's Hospital (RACH) including malignant and non-malignant haematology, and oncology services.

From 1996 – 1999 Head of Service for Clinical Haematology in Medical Directorate (adult service).

Sept 2011 – March 2015 Clinical Lead for Governance and Quality Assurance for the Managed Service Network for Children and Young People with Cancer in Scotland.

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.**

British Society for Haematology – 1985 – present. Ordinary member.

Scottish Haemophilia Directors Organisation 1986 – 1996 when Dr HG Watson took over.

Grampian Hospital Transfusion Committee - 1986 to retiral. Representing RACH.

Joint Aberdeen Haemophilia Centre Director with Dr NB Bennett – 1986 – 1996 when Dr HG Watson took over.

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.**

I have not provided evidence to any other Inquiries.

5. **The questions below focus on your work at Royal Aberdeen Children's Hospital. The Inquiry understands that you have also provided haematology services at Aberdeen Royal Infirmary. Please provide details of your work at the Royal Infirmary. If you have information concerning Aberdeen Royal Infirmary relevant to the period or issue to which the questions below relate, please include that in your response.**

1986 – 1996 Along with Dr AA Dawson and Dr NB Bennett I provided the clinical haematology service at Aberdeen Royal Infirmary (ARI). This included the management of in-patients and out-patients with haematological diseases.
If not requiring inpatient care, patients with bleeding disorders were seen either as ward attenders or at the day case area.

After 1996 I did not undertake any in-patient care at ARI. My out-patient clinics were related to on-going monitoring of adolescents and young adults after treatment for cancer, and care of long-term patients with malignant and non-malignant haematological diseases.

I did not take part in the service for patients with bleeding disorders at ARI other than handover of patients transitioning from the service at RACH.

Section 2: Decisions and actions of the Hospital

6. **Please describe the roles, functions and responsibilities of the Hospital (insofar as relevant to the Inquiry's Terms of Reference) during the time that you worked there.**

Royal Aberdeen Children's Hospital (RACH) provides secondary and tertiary care for the paediatric population of Grampian and the Orkney and Shetland Islands, and tertiary care for some patients from Highland.

While there is the potential for blood and blood products to be transfused to any patient, the services particularly involved are the haematology service, including the regional haemophilia service, and the oncology service.

RACH is one of the recognised centres in the UK Children's Cancer and Leukaemia Group (previously United Kingdom Children's Cancer Study Group). RACH is on the same site as Aberdeen Royal Infirmary, Aberdeen Maternity Hospital, the SNBTS Regional Transfusion Centre and the University of Aberdeen Medical School.

7. **Please identify senior colleagues at the Hospital involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in**

consequence of infected blood or blood products and their roles and responsibilities during the time that you worked there.

For the majority of my career I was the only haematology consultant at RACH with some support from colleagues at Aberdeen Royal Infirmary – Dr AA Dawson, Dr NB Bennett and Dr HG Watson.

From 2008 to 2013 Dr V Neefjes was my co-consultant and had training in haematology and oncology.

Dr WM Bisset, Consultant Gastroenterologist would have been involved in the care of any patients who developed viral hepatitis.

8. **Please describe:**

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

My role as consultant haematologist included responsibility for care of children with all types of malignant and non-malignant haematological diseases and those with solid tumours, giving advice to clinical colleagues on investigation and management of patients as required.

I represented RACH on the Hospital Transfusion Committee.

Changes over time were moving from the "old" Children's Hospital to the new Children's Hospital in 2004, both on the Foresterhill site, and a change in the age of admission from up to 14 years to up to 16 years of age in 2012.

b. your work at the Hospital insofar as it involved the treatment of patients with bleeding disorders, the treatment of other patients with blood products and/or the care of patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.

Patients with bleeding disorders:

When appointed I wrote a haematology-oncology manual for use by staff at RACH. This included the management of patients with bleeding disorders and the management of blood transfusion.

In relation to bleeding disorders there was detailed information on type of blood product or drug to be used, calculation of dose, method of administration. In particular I emphasised the use of DDAVP in patients with moderate and mild Haemophilia A and most types of von Willebrand's disease.

All patients with bleeding disorders had open access to the Medical Ward in the old RACH and either the A&E Department or Paediatric Assessment Unit in the new RACH. I was informed of all attendances to review the patient and decide management.

Venous access can be difficult in children and only experienced paediatric junior staff were allowed to perform venepuncture. When appropriate parents then patients were trained in venous access. This was essential for home treatment then prophylactic treatment.

For patients with severe disease it was common to insert a Portacath (an indwelling intravenous device) to allow easier venous access. This required liaison with the paediatric surgeons and anaesthetists including arranging appropriate factor cover for the procedure.

Out-patient clinic every 3 months for review; when home treatment was introduced, review of bleeding episodes and use of factor concentrate.

For dental care, patients could be reviewed by the hospital dental department or their own dentist, with any treatment requiring factor cover being done in hospital.

Availability of a Haemophilia Sister who worked at both ARI and RACH including attendance at out-patient clinic.

Other patients requiring blood products:

The haematology-oncology manual had a section on transfusion of red cells and platelets including the calculation of volumes to be transfused in relation to the size of the child. Most of the transfusions would be for patients under my care, or latterly with

other consultants in the Haematology-Oncology Service and would follow the advice in the manual or be decided on ward rounds.

For other patients who might be considered for transfusion I emphasised to colleagues that there were potential risks in transfusion, and they should always ask if the transfusion is really necessary.

Later in my career, in conjunction with the Aberdeen Transfusion Centre, I was involved in writing protocols for transfusion in children, transfusion in neonates and management of massive transfusion in children.

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

The number of patients in any year varies depending on births of children with bleeding disorders, movement of families into and out of Grampian, and teenagers moving up to the adult service. There is also the impact of the change in age range that meant patients remained for longer in the service at RACH.
Prof HG Watson kindly provided these figures from registry data.
Representative numbers are:

	1985	1996	2015
Haemophilia A severe	3	7	8
Haemophilia A mild/moderate	4	3	9
Haemophilia B severe	0	1	1
Haemophilia B mild/moderate	0	0	2
Von Willebrand's Disease	5	3	9

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

In Scotland the Scottish National Blood Transfusion Service (SNBTS) was responsible for the provision of the supply of blood and blood products including clotting factor concentrates for the majority of my career.

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

Blood products were supplied on a national level by SNBTS. Decisions on the selection of products were made in discussion between the Scottish Haemophilia Centre Directors Organisation and SNBTS.

When cryoprecipitate was the main factor product each region received supplies proportionate to their blood donor population and Grampian was relatively "self-sufficient" because of a high number of donors. This reduced the need to use imported plasma.

SNBTS produced Factor VIII and Factor IX concentrates and distribution in Scotland was in a similar way to cryoprecipitate. The majority of the patients in Grampian were treated with product derived from Scottish plasma and there was little use of commercial product.

The main commercial product used was FEIBA (Factor Eight Inhibitor Bypass Activity) for patients with Haemophilia A and an inhibitor.

Discussions between SHCDO and SNBTS resulted in the decision to produce "High Purity FVIII concentrate" (Liberate) in Scotland using Scottish plasma and with improved viral inactivation steps. This was to address on-going concerns about transmission of viral infection.

When recombinant factor concentrates became commercially available SHCDO proposed to the Scottish Government that there should be a national contract for the purchase of this product then it could be distributed to the centres.

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

For recombinant FVIII concentrate there was a decision to purchase the product from two manufacturers to try to ensure continuity of supply in case of production problems with one supplier.

I was not aware of the financial considerations.

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

As far as I am aware, these matters were undertaken by the Scottish Government, SNBTS and the joint chairmen of SHCDO.

d. What if any involvement did you have?

I attended SHCDO committee meetings and was involved in some of the discussion. I fully supported the need to have recombinant concentrates for patients in Scotland.

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

Over my working career there were significant changes in the management of patients with bleeding disorders.

Patients with severe disease: factor concentrates. Initially those produced by SNBTS then recombinant concentrates.

Haemophilia A with inhibitor: FEIBA. Later recombinant Factor VIIa plus immune tolerising therapy.

Patients with moderate/mild Haemophilia A and majority of VWD: DDAVP. Possible use of cryoprecipitate or factor concentrate depending on assessment of severity of bleeding.

Haemophilia B: Factor concentrate. Initially SNBTS product then recombinant concentrate.

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

As the products were provided on a national basis there was no direct relationship between either RACH or ARI and the pharmaceutical companies in terms of direct contracting.

The companies did provide useful educational material for patients/families to help with adjustment to diagnosis, how to administer factor concentrate, how to manage bleeding episodes.

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

SNBTS as described.

14. How were decisions taken as to which products to use for individual patients? What involvement did you have in such decisions? To what extent, if at all, were patients offered a choice as to which products to use?

The choice of treatment for an individual patient would have been by me as treating consultant and dependent on the products available from SNBTS.

In mild or moderate Haemophilia A, Desmopressin (DDAVP) would be used unless the severity of bleeding required the use of cryoprecipitate or factor concentrate.

When HP Factor VIII concentrate first became available it was offered in the context of a clinical study.

When recombinant FVIII concentrates became available patients were given one of the two products available with the aim of only using the same product for an individual patient.

In relation to the choice of product the majority of discussions would be with parents although older patients could be involved as their understanding developed. The reliance on SNBTS products did mean that there was often only one product available in a particular situation and the option of using products from other sources may not have been discussed although much of this would have been before my appointment.

With the HPVIII study there was appropriate discussion and informed consent obtained.

When recombinant Factor VIII concentrates were introduced there was full discussion about the anticipated benefits of the new products and there would have been the option to remain on plasma based products although I do not remember any parents wishing to do this. Two recombinant products were available and were introduced so that approximately half of the patients were on one and half on the other. Parents concerned about the choice had this discussed.

Possibly one of the more difficult choices was in patients with mild disease where the options were to use DDAVP or cryoprecipitate. Even after full discussion of the risks of transmission of infection by blood products some parents preferred cryoprecipitate, feeling the more complicated and time-consuming administration of DDAVP and the possible side-effects were less acceptable. The first preparations of DDAVP had to be given by a longer infusion than cryoprecipitate and more monitoring.

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

Cryoprecipitate
DDAVP
Fibrinolytic inhibitors

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

The advantage of DDAVP is that it is a drug, not a product derived from plasma, therefore does not carry the risk of transmission of blood born infections. It is useful in mild/moderate Haemophilia A and most types of von Willebrand's Disease. There are side-effects from the drug, and it may not produce a consistent effect in terms of raising clotting factor levels. For the individual patient it is important to know if they have a satisfactory response to DDAVP. If DDAVP is used frequently over a short period of time it can lose effect.

Fibrinolytic inhibitors, such as tranexamic acid, can be used in superficial bleeding such as nosebleeds. These were used when clinically appropriate and might avoid or reduce the need for plasma-derived products.

Cryoprecipitate has the advantage of raising the Factor VIII level more rapidly than DDAVP and results in exposure to a much lower pool of donors than concentrates but is still a plasma product.

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

When cryoprecipitate was the only product it was used for patients with severe Haemophilia A and selectively in those with milder disease depending on severity of bleeding.

The advent of concentrate allowed patients with severe disease to transfer to that product as it allowed for home treatment and later prophylactic therapy.

When recombinant concentrate became available it was used initially in PUPs then other children as supplies were confirmed.

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

The only external parties involved were clinical colleagues in SHCDO and SNBTS. This related to availability of products rather than decisions on an individual patient. When recombinant concentrates became available patients were allocated to one of the two products purchased at the time and continued to use that product provided

supplies were maintained. As improvements were made in the products patients could be changed after discussion with parents and assurance of supplies.

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

RACH supported the use of home treatment when suitable products became available – Factor VIII concentrate that could be stored at home and reconstituted for use.

Parents would be trained in venepuncture technique, but it will be appreciated that in children venous access can be difficult. It is only when both child and parents are confident that it can be consistently undertaken.

When children were older, they were trained in venepuncture technique and reconstitution and administration of factor concentrate. This is important in allowing more independence for the patients.

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

RACH supported the use of prophylactic treatment when studies showed that this reduced both the incidence of bleeding episodes and the risk of long term joint damage. The availability of factor concentrates that could be stored and administered at home was essential for this to occur.

The ability to administer prophylactic therapy 2 or 3 times per week depends on the issues of venous access described above. As it is started in very young children is was often necessary to insert Portacaths to ensure reliable venous access.

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

Where possible treatments avoiding use of factor concentrates were used. These would include DDAVP and fibrinolytic inhibitors.

The decision to use factor concentrates would depend on clinical assessment on the severity of bleeding or the risk of bleeding e.g. if surgery or dental extraction was required.

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

I am not aware of any other infections transmitted by blood products.

Section 3: Knowledge of, and response to, risk

General

22. When you began work as a Consultant Haematologist at the Hospital, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

In 1986 the recognised viral infections transmitted by blood and blood products were HBV and HIV. There were possible risks of transmission of malaria and bacterial infection from product such as red cells and platelets, depending on the history of the donor.

It was known that patients could have biochemical changes in their liver function tests after transfusion that were not due to HBV but this Non-A, Non-B hepatitis had not had a causative agent identified.

Knowledge developed from training including time in blood transfusion, reading and attendance at educational meetings.

23. What advisory and decision-making structures were in place, or were put in place at the Hospital, to consider and assess the risks of infection associated with the use of blood and/or blood products?

These were discussed at the Hospital Transfusion Committee where I represented RACH.

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?

For NHS blood products such as cryoprecipitate the relative risk was lower because of much lower donor exposure e.g. a dose of 4 units of cryoprecipitate was from only 4 donors.

For products such as FVIII concentrate the risk was potentially higher due to the plasma being pooled from a large number of donors but the risk would also depend on the type of testing of donors and the treatment of the product to reduce viral contamination.

My understanding is that in the early days of commercial products the plasma frequently came from paid donors and possibly prisoners with a higher risk of being contaminated with viruses thus increasing the risk to patients.

Hepatitis

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

In 1986 the recognised viral infections transmitted by blood and blood products were HBV and HIV.

It was known that patients could have biochemical changes in their liver function tests after transfusion that were not due to HBV but this Non-A, Non-B hepatitis had not had a causative agent identified.

The recognition of HCV was in 1989.

Knowledge developed from training including time in blood transfusion, reading and attendance at educational meetings.

There were regular discussions at the Hospital Transfusion Committee and SHCDO.

26. 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?

At SHCDO we had information from SNBTS with regular updates on the testing of donors and products for viral infection.
I do not remember any specific enquiries or investigations at Centre level.

At ARI in 1995 Dr Dawson, Dr Brunt (Consultant Gastroenterologist) and Dr Molyneaux (Consultant Virologist) established a clinic to assess patients with possible HCV infection.

27. 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)?

In any patient I encouraged clinicians to balance risks of transfusion with risk of not transfusing plus consideration of alternatives. At RACH I was available for discussion on any decision about transfusion.

Use of DDAVP and fibrinolytic inhibitors when clinically appropriate.

28. 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?

Hepatitis B is a less severe disease in adults with the majority making a full recovery and a small proportion developing chronic hepatitis. It can be a more severe disease in children with a higher proportion developing chronic hepatitis.

By the time of my appointment there was effective testing of donors/donated blood for HBV and a vaccine was available to immunise patients likely to be exposed frequently to blood products.

Until the identification of HCV as the causative agent for most of NANB hepatitis it was difficult to know the significance of the hepatitis. As knowledge developed it was

reported that about 20% of patients would clear the virus and the others could develop chronic infection with, in the longer term, risk of cirrhosis and in a small proportion hepatocellular carcinoma.

HIV and AIDS

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

In 1986 it was known that HIV infection could be transmitted by blood and blood products. Knowledge developed from training including time in blood transfusion, reading and attendance at educational meetings.

After the virus was identified there was a rapid increase in knowledge about HIV and the disease it caused leading to screening of blood products and how infection risk could be reduced.

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

In the early 1980s during my training in Canada as reports in medical literature were published.

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

I cannot remember specific enquiries or investigations at RACH but when a reliable test was available it was introduced into testing of patients after discussion with parents.

In relation to children no cases of HIV infection were identified.

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

As discussed before a conservative approach to the use of blood products to limit exposure.

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

This was before my appointment as consultant.

Response to Risk

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

The risks would have been discussed with parents.

35. **When did the Hospital begin to use heat treated factor products and for which categories of patients?**

I think these products were made available by SNBTS in 1985 and all children would have been transferred to these products where appropriate.

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

I was not involved in any of the discussions about heat-treatment of factor concentrates and I do not know enough about the timing of this to give a valid opinion.

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

I am not aware of any decisions before my appointment, but I think there would have been discussion at SHCDO.

38. Do you consider that your decisions and actions, and those of the Hospital 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.

I cannot comment on any decisions made before my appointment. From my knowledge of the consultants in Aberdeen they would have had the best interests of patients in any decisions.

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

It is difficult to comment as heat-treated concentrates were available by the time I was appointed.

40. What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients with bleeding disorders? What, if anything, do you consider could or should have been done differently by these others?

From what I understand the development of factor concentrates in the USA offered patients with severe bleeding disorders the opportunity of a significant change in lifestyle. This included the convenience of home treatment with the benefits of early treatment of bleeding episodes and subsequently prophylactic treatment. There was understandable pressure from patients as they became aware of this development.
I am not aware of the discussions at the time to introduce factor concentrates and to what extent the potential risks were assessed against the apparent benefits.

41. 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?

I do not feel qualified to comment on this.

Section 4: Treatment of patients at the Hospital

Provision of information to patients

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

In discussion with parents at the time of diagnosis I outlined the problems their child faced depending on the exact diagnosis and severity of disease. This would include sites of bleeding, situations of risk, methods of treatment including pharmacological and blood products, other measures such as good dental care to reduce risk of extractions, other supportive care such as physiotherapy.

The risk of transmission of infection by blood products was discussed and was balanced against risk of not treating episodes of bleeding. This included the use of DDAVP in mild disease as a way of reducing the risk of using blood products.
The type of information about transmission of viral infection in particular changed over time as knowledge developed of HBV, NANB hepatitis/HCV and HIV, then nvCJD.

43. 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.

The main alternatives to factor concentrates are DDAVP and fibrinolytic inhibitors.
It would be unusual to suggest alternative treatments in severe disease as it is important to control bleeding quickly to reduce the risk of long term damage such as to joints.

In mild or moderate disease, the use of DDAVP was recommended but for an individual patient it would have to be shown that it was effective.

The use of fibrinolytic inhibitors in superficial bleeding was discussed. All these discussions included the importance of clinical assessment of severity of bleeding and how quickly treatment was needed.

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

The discussions had already taken place about the most appropriate form of treatment. Parents were taught how to recognise bleeding, e.g. in a joint, and the children were asked to report to their parents when they sustained an injury or had the sensation of a joint bleed developing. This depended on the age of the child.

The parents were given information about storage of factor concentrate at home, reconstitution and calculation of dose. As the child grew the dose was recalculated. Record sheets were provided to document factor concentrate use and, before the use of prophylactic therapy, to ensure any bleeding episodes were controlled. Later there were phone apps to record usage.

They were trained in venepuncture although this could be difficult in smaller children. They had contact details at RACH if they were having difficulties.
When prophylactic therapy was introduced the same discussion were had with the parents, frequently adding training in the use of a Portacath.

HIV

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

These discussions started after the identification of HIV in the early 1980s. Parents were informed of the potential risks and testing was done after this and with consent

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

During my time as a consultant none of the children under my care were diagnosed with HIV infection.

47. What if any arrangements were made at the Hospital for pre-test counselling?

As above discussion of the risk of HIV infection had already taken place. At the time of testing I spoke to parents for consent and indicated the impact of a positive test.

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

If any patient had tested positive the diagnosis would have been discussed in person with the parents and I would have done this.

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

Not applicable.

50. What was the Hospital'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?

I cannot remember if there was a definite policy.

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

If necessary, appropriate information and advice would be provided.

52. What if any arrangements were made at the Hospital for post-test counselling?

If it had been necessary infectious diseases specialists would have been involved at local or national level.

53. How many patients at the Hospital were infected with HIV? Of those infected,

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

None.

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

Not applicable but the records of SNBTS and the local virology department would have been used.

Hepatitis B

55. 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? What if any involvement did you have in this process?

No patients with bleeding disorders were diagnosed with HBV during my time as a consultant.

One patient with a different condition, not a bleeding disorder, developed HBV which was traced to a platelet transfusion. This was diagnosed in the Royal Hospital for Sick Children, Glasgow. Information was given to the parents at that time.

56. How many patients at the Hospital were infected with hepatitis B in consequence of treatment with blood or blood products?

This is the only patient I know of.

NANB Hepatitis/Hepatitis C

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

I was not aware of any patients diagnosed with NANB hepatitis before the advent of HCV testing.

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

I cannot remember the exact dates, but it would have been in the early 1990s. The first tests were not accurate, and it was probably in the mid-1990s that clinically useful tests were available.

One patient with a bleeding disorder was diagnosed with HCV by an antibody test. I discussed this in a direct meeting with the parents.

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

Any discussions and information giving would have been in consultation with appropriate specialist in infectious disease and liver disease. The initial discussions were at a time when the clinical implications of a positive HCV test were not clear, particularly in relation to the long term outlook.

The patient was transferred to the adult service during the time he was being assessed for the HCV infection and subsequently was seen at the joint clinic set up by Dr Dawson.

60. 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?

When a test became available it was incorporated into the monitoring of patients with bleeding disorders who were receiving blood products. This was discussed with parents.

61. How many patients at the Hospital were infected with hepatitis C in consequence of treatment with blood or blood products?

I am only aware of one other patient who developed HCV – a patient with a condition requiring multiple transfusions of blood and blood products.

Delay/public health/other information

62. 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.

The patient was diagnosed in Glasgow and I am not aware of any delays.

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

Information was supplied to parents about management of their child in relation to risk of transmission, dealing with bleeding episodes.
Specific treatments were not used.

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

If this relates to viral infection, HBV and HIV were discussed.

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

Parents were informed of the risks particularly if the child had any bleeding episodes.

Consent

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

Parents of children with bleeding disorders were informed of the need to monitor for the possibility of acquiring viral infection depending on when we had knowledge of particular infections and a test was available. After discussion verbal consent was obtained.

The frequency depended on severity of disease and if they had received blood products with the most frequent monitoring being of children with severe disease. Usually every 3-6 months.

During the HPVIII Study written consent to participation in the study, including virology testing, was documented.

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

I am not aware of any such episodes but in extreme emergency and in the absence of parents it might be necessary to transfuse a child if clinically indicated.

In any patient who might require transfusion of blood products e.g. bleeding disorders, treatment of malignant disease it was my practice to discuss the likely need for and purpose of the transfusions and potential risks at the time of diagnosis. I documented my discussions in the case notes and for most of my career the consent was not in writing. Each time a transfusion was indicated it would be discussed with the parents, usually on a ward round.

Latterly more formal consent procedures for transfusion were in place.

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

No.

PUPS

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

I am not sure what this question means.

In a PUP, after the diagnosis was established, there was detailed discussion with the parents to explain the diagnosis and its implications for the child and family. The options for treatment were described including potential risks. Due to the inherited nature of these diseases the discussion often included how treatment had changed and, latterly, the importance of the change to recombinant concentrate in hopefully removing the risk of blood borne viral infection.

The treatment advised would be what was regarded as the safest at the time of diagnosis.

High purity and recombinant products

70. In a letter dated 19 November 1990 ([SBTS0000706_223], attached), Professor Ludlam wrote to Mr D McIntosh of SNBTS about the manufacture of high purity factor VIII, stating that the 'top priority is that the product must be safe particularly from virus transmission' . You were copied into this letter. You may also be aided by [PRSE0003536].

a. Please set out your involvement in the debate about the need for and/or use of high purity products for HIV positive patients? Did you use such products for HIV positive patients at the Hospital?

I attended the SHCDO meetings when this was discussed but do not remember the details.

There were no children with HIV infection at RACH.

b. Please explain your involvement with efforts to obtain recombinant products for patients with haemophilia. What difficulties were encountered and why?

I attended the SHCDO meetings when this was discussed and supported the efforts to obtain recombinant products.

I was not involved in the discussions with Scottish Government and cannot remember what difficulties were encountered.

c. In your view, should recombinant blood products have been made available to all patients with haemophilia earlier than they were? If so, why, and when?

I cannot remember the time scale of the discussions in relation to the availability of these products to adequately comment. It was important to be reassured that there was continuity of adequate supplies to allow consistency of treatment for individual patients.

d. When were recombinant products available to patients treated at the Hospital?

Mid-1990s

Research

71. Please list all research studies that you were involved with during your time as a Consultant at the Hospital. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, please:

As RACH was a UK Children's Cancer and Leukaemia Group (previously UK Children's Cancer Study Group) centre I had an extensive portfolio of clinical trials and studies for children with malignant disease to provide the most up to date treatment options for the majority of patients. These included Medical Research Council leukaemia trials, and national and international trials for solid tumours.

The only research study related to bleeding disorders was for the SNBTS HPVIII product.

a. Describe the purpose of the research.

The HPVIII study was primarily a safety study in relation to transmission of infection and efficacy of the product. The study was stopped when recombinant concentrates became available.

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

Application to national and Grampian Research Ethics Committee.

c. Explain what your involvement was.

I made the local application and was responsible for identifying patients for the study, obtaining consent from parents and managing the study.

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

SNBTS and SHCDO.

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

I think it was through SNBTS

f. State the number of patients involved.

I cannot remember.

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

Parents of children suitable for the study had full discussion of the reasons for the trial explaining the production method used in the product and the aim to reduce the risk of

transmission of viral infection. Written information was provided, and written consent obtained.

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

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

I am only aware of one paper related to this study.

Ludlam CA, Lowe GDO, Mayne EE. A pharmacokinetic study of an ion-exchange solvent-detergent-treated high purity factor VIII concentrate. Transfusion Medicine 1995: 5; 4: 289-292

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

No. Consent given by parents.

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

No.

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

No.

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

None.

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

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

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

b. What treatment options were offered over the years to those infected with HIV?

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

No patients with bleeding disorders identified with HIV infection. If there had been, care would have been in liaison with the infectious disease services in RACH and ARI and linking with national service.

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

This would have been according to local/national advice.

78. How was the care and treatment of patients with hepatitis B managed at the Hospital? In particular:

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

b. What treatment options were offered over the years?

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

No patients with bleeding disorders identified with HBV infection. If there had been, care would have been in liaison with the gastroenterology service in RACH and linking with national service.

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

If there had been patients the on-going care and monitoring would have been with the gastroenterology service locally plus national service.

80. How was the care and treatment of patients with NANB hepatitis managed at the Hospital? In particular:

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

b. What treatment options were offered over the years?

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

One patient with a bleeding disorder was identified with HCV infection as noted in Answers 58 and 59.

As noted he was transferred to the adult service but if necessary care would have been in liaison with the gastroenterology service in RACH and linking with national service.

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

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

b. What treatment options were offered over the years?

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

As noted previously a multidisciplinary clinic was in operation at ARI for adult patients. No specific service was in place at RACH.

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

I did not take part in the clinic at ARI so am not aware of the arrangements.
At RACH no specific arrangements were in place.

83. Did the arrangements made at the Hospital for the care and treatment of children infected with HIV or hepatitis differ from the arrangements made for adults at the Royal Infirmary and if so how?

If it had been necessary discussion would have taken place with clinicians at ARI.
Within paediatrics many national services with MDTs have been established and the specialist care of patients with HBV, HCV and HIV would have co-ordinated through these.

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

As both the patients infected with hepatitis were under my care because of their underlying condition the patient and family had support from the service including social work support.

85. Did the Hospital receive funding from the government or from any other source to help with the counselling of patients infected with HIV?

I am not aware of any specific funding.

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

I have no information about this.

87. 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.

None.

Records

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

I cannot remember any policy for this.

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

I cannot remember the specific policy, but I think there was a policy for patients with malignant disease for relatively long term retention.

For patients with bleeding disorders the records of patients under active care would be available.

Records of patients who had died were kept but I do not know for how long.

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

No.

91. 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 Hospital? If so, why, what information and where is that information held now?

No.

92. 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.

No.

Section 5: UKHCDO

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

I relied on the SHCDO for getting appropriate information for management of the service at RACH. Initially this was by personal attendance at meetings and subsequently via Prof Watson.

I did not attend any meetings of UKHCDO or have involvement in any of its working parties or other groups. Relevant information was shared at the SHCDO meetings.

94. 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:

i. the importation, purchase and selection of blood products;

ii. the manufacture of blood products;

iii. self-sufficiency;

iv. alternative treatments to factor products for patients with bleeding disorders;

v. the risks of infection associated with the use of blood products;

vi. the sharing of information about such risks with patients and/or their families;

vii. obtaining consent from patients for the testing and storage of their blood, for treatment and for research;

viii. heat treatment;

ix. other measures to reduce risk;

x. vCJD exposure; and

xi. treatments for HIV and hepatitis C.

Other than helping in providing registry data to the UKHCDO I had no active involvement in the organisation.

Section 6: Pharmaceutical companies/medical research/clinical trials

95. 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.

No.

96. 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.

No.

97. 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.

No.

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

No.

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

No.

100. Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.

No.

101. 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?

Not applicable.

102. 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.

No.

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

No.

104. 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?

Not applicable.

Section 7: vCJD

105. 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?

I became aware of this about 2005 when a small number of reports suggested this possibility. This would have been from medical literature and discussion at meetings of hospital transfusion committee and SHCDO.

106. 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 put in place at the Hospital for informing patients about possible exposure to vCJD?

b. What steps were taken to tell patients of possible exposure to vCJD?

c. What steps were taken to provide information to patients about the risks of vCJD?

d. 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?

Dr Watson and Haemophilia Sister identified all local patients from the UKHCDO and circulated information about nvCJD in 2004 and 2006.

For children the information was sent to parents.

The content of the information was as suggested by UKHCDO.

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

All patients and parents were given the offer to discuss the issues related to nvCJD.

Section 8: The financial support schemes

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

I think one of the patients I looked after had help from the Macfarlane Trust.

109. To what extent, during your time at the Hospital, did staff (including you) inform patients about the different trusts or funds?

I cannot remember.

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

I do not remember a specific policy.

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

If requested appropriate information would have been provided with patient/parent consent.

112. Did the Hospital, or any of their 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.

No.

113. Was the Hospital 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.

Not that I was aware of.

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

I do not have sufficient knowledge to comment.

Section 9: Other Issues

115. 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.

I am not aware of any complaints made about me to any of the bodies mentioned.

116. 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.

In the provision of the clinical haematology service in Aberdeen I worked with Dr Audrey Dawson and Dr Bruce Bennett in a number of roles. I was resident house officer in the ward providing the service and this included the treatment of ward attenders with episodes of bleeding. As registrar then senior registrar in haematology I was involved in both in-patient and out-patient care of patients with all types of haematological diseases including those with bleeding disorders. As consultant I worked alongside both of them as colleagues again looking after a full spectrum of patients with haematological diseases.

Throughout my career they were both very supportive colleagues initially in terms of great help to me as a house officer, then during my haematology training and it is fair to say I would not have specialised in haematology without their support and guidance. As a consultant they provided advice and cover at RACH as I developed the service as my main specialist area.

I found that both Dr Dawson and Dr Bennett were totally committed to patient care and the development of a comprehensive service at a time of rapid change in the management of patients with bleeding disorders as well as those with leukaemia and lymphoma. They always had the best interests of patients foremost in their decision making about treatment and worked long hours to achieve the best outcomes.

It should be recognised that Dr Bennett made significant academic contributions to the basic understanding of haemophilia and von Willebrand's disease in terms of the clotting factors involved, the genetic implications including carrier assessment, and responses to treatment, in his work with Dr Oscar Ratnoff in Cleveland, Ohio.

I had also done a final year student elective with Dr Dawson encouraged by her enthusiasm for haematology.

Statement of Truth

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

Signed GRO-C

Dated 26.10.20