Witness Name: Dr John Tucker

Statement No.: WITN3532002

Dated: 18 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR JOHN TUCKER

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 10 September 2020

I, John Tucker, will say as follows: -

Section 1: Introduction

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

Name : Dr John Tucker
Address (since 2006) GRO-C
Date of birth : GRO-C 1951

Professional Qualifications:
BSc Hons (Med Sci) 1972. Edinburgh University
MB,ChB 1975. Edinburgh University
MRCP (UK) 1978

MRCPath 1984
FRCP (London) 1996
FRCPath 1996

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.**

Preregistration House Officer in Medicine, Royal Infirmary of Edinburgh for 6 months, 1975-1976

Preregistration House Officer in General Surgery, Leith Hospital for 6 months,1976

Senior House Officer in Royal Hospital for Sick Children in Edinburgh for 6 months in 1976-1977

Senior House Officer in Medicine, Royal Infirmary of Edinburgh for 6 months in 1977

Senior House Officer in Medicine at Deaconess Hospital Edinburgh for 9 months in 1977- 1978. In this general Medical post I passed the 1st part of MRCP(UK).

Registrar in Medicine, Leith Hospital 1978-1980. This role involved my supervision of the junior Medical Team, and allowed me the clinical experience to complete the MRCP (UK) examination.

Registrar and Senior Registrar in Haematology based at Royal Infirmary of Edinburgh from 1st January 1980 - April 1985. I had 6 month attachments to the SNBTS based in the Royal Infirmary, plus the Western General Hospital and the Royal Hospital for Sick Children in Edinburgh.

In this role I studied all aspects of Clinical and Laboratory Haematology under the supervision of the 2 Consultants in the Department, Dr A C Parker, Head of Department, and Dr C A Ludlam, Haemophilia Director. This included specialist training in Haematological malignancies and both acquired and congenital bleeding problems including Haemophilia. Under the direction of Dr (later Professor) Ludlam, the Haemophilia Centre expanded from a side room in Ward 23 to a standalone unit with specialist Nursing Sister and clerical and support staff.

During my time as a trainee I passed all the parts of the MRCPath Examination and gained the CCST. I was able to teach Medical and Nursing Students and write some scientific papers.

April 1985-April 1988 Research Fellow in Imperial Cancer Research Fund Department of Medical Oncology as St Bartholomew's Hospital London.

In this post I furthered my knowledge and experience of Haematological Neoplasms, and published some research papers.

April 1988- January 2001 Consultant Haematologist, Good Hope Hospital Birmingham

Here I developed a busy Clinical Haematology practice, with supportive colleagues. We were strong supporters of the Medical Research Council sponsored clinical trials. I encouraged appropriate patients to participate in these schedules in order to offer the latest treatments within a rigorous scientific scrutiny. It should be noted that in these days informed consent to participate was verbal, and only later in the 1990's was written consent required.

January 2001 - May 2011. Consultant Haematologist and subsequently Head of Service at Borders General Hospital Melrose. In this post I worked with colleagues to provide a comprehensive Clinical and Laboratory Haematology service. There was close collaboration with Lothian Haematologists especially for more specialised services e.g. bleeding disorders and bone marrow transplantation. After my official retirement in 2011 I worked part time for a further 18 months and then as an occasional locum until I voluntarily resigned from the GMC register on 1st Feb 2014.

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.**

I was an ordinary member of the British Society of Haematology 1982-2002
I was not involved in any other group relevant to the Inquiry.

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.**

   As Consultant Haematologist at Borders General Hospital, Melrose, I was aware of the Penrose Inquiry. I recall being requested to provide some data regarding recipients of certain blood and blood products. From my memory most of the recipients had died from their original diagnosis e.g. cancer. Very few were still alive, and I have no memory of any of them developing possible blood transmitted illnesses.

   I have no record of this activity.

5. **It is the Inquiry's understanding that your haematology career has involved positions as Registrar and Senior Registrar in Haematology at Royal Infirmary of Edinburgh ("the Infirmary") between 1980-1985, as Consultant at Good Hope Hospital Birmingham ("Good Hope"), and Consultant (and possible Director for a time) at Borders General Hospital Melrose ("Borders General"). The questions below refer, as appropriate, to these locations, but the principal focus is your time at the Infirmary. If you have information concerning the other hospital(s) relevant to the period or issue to which the question relates, please include that in your response; likewise, if you had no involvement at (say) Good Hope with the treatment of patients with bleeding disorders, or the care of patients infected with HIV or hepatitis, please say so.**

   The Inquiry has correctly summarised my Haematology career. For accuracy please note that from April 1985-April 1988 I was Research Fellow in ICRF Dept of Medical Oncology at St Bartholomew's Hospital in London.

   After I left the Royal Infirmary of Edinburgh in April 1985, I had no direct professional involvement with patients suffering from congenital bleeding disorders, and did not care for patients infected with HIV or hepatitis.

   As Consultant at Good Hope Hospital, Birmingham, I referred any cases to Dr J Wilde, Haemophilia Director at Queen Elizabeth Hospital, Birmingham.

As Consultant at Borders General, all patients with Haemophilia and allied disorders were under the care of Professor C. A. Ludlum in Edinburgh.

Section 2: Decisions and actions of those treating patients with bleeding disorders at the Infirmary, Good Hope and Borders General and your decisions and actions

6. **In relation to your work at the (a) Infirmary, (b) Good Hope and (c) Borders General please:**

   a. Describe the facilities, organisation, roles, functions and responsibilities (insofar as relevant to the Inquiry's Terms of Reference) of the hospital/centre during the time that you worked there, and how they changed over time;

   Please note that my responses relate to my time in post at the Edinburgh Royal Infirmary. In my work in Good Hope and Borders General Hospitals I had no remit to manage patients with congenital bleeding disorders.

   When I started as Haematology Registrar at Edinburgh Royal Infirmary there were 2 Consultants. Dr AC Parker was Head of Department, and Dr CA Ludlam was Haemophilia Director. Under the direction of Dr Ludlam, the Haemophilia Centre expanded from a basic side room in ward 23 to a spacious stand alone unit, with specialist Nursing and clerical support staff. The patient notes were stored in the Haemophilia Centre.

   Haemophilia outpatients were seen on a walk in basis, and attended to by the Duty Registrar. Bleeding episodes were treated immediately with infusions of blood products, according to the treatment plans devised by Dr Ludlam.
   Inpatient care was under the direction of Dr Ludlam
   Ward and Unit nurses supervised infusions.

b. Identify senior colleagues at the hospital/centre (insofar as relevant to the Inquiry's Terms of Reference) and their roles and responsibilities during the time that you worked there;

Dr Ludlam as explained above was in clinical charge of patients with Haemophilia and allied disorders.

Dr B McLelland was Blood Transfusion Director, with his office located in the Infirmary. All products for Haemophilia patients including home treatment was requested by the Haematology staff and despatched by the Blood Transfusion Dept (SNBTS).

c. Describe your role and responsibilities at the hospital/centre and how those changed over the years.

When I began my Specialist training, I spent time in the various laboratories. I was then introduced to the clinical work.

I was promoted from Registrar to Senior Registrar in October 1980, and continued my training in the various aspects of Haematology.

I was aware that Dr Ludlam and fellow Haemophilia Directors were in frequent discussion regarding optimal treatment strategies, and he kept colleagues appraised.

7. **Approximately how many patients with bleeding disorders were under the care of (a) the Infirmary, (b) Good Hope and (c) the Borders General 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).**

From memory there were approximately 100 registered patients at the Infirmary. Patients with severe Haemophilia numbered approximately 30, and were the most frequent users of the service.

8. **What decisions and actions were taken, and what policies were formulated, at (a) the Infirmary and (b) Good Hope 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 and how did those decisions change over time?

I understood that decisions at Edinburgh Royal Infirmary regarding selection and purchase of blood products were made jointly by Dr Ludlam and Dr McLelland.

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

I have no information.

c. Where were the products sourced? From whom were they purchased?

Products were mainly sourced from Scottish BTS.

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

I have no information.

e. What involvement did you have?

I had no involvement.

9. **What blood products were used for treating patients at (a) the Infirmary and (b) Good Hope, over what period of time and for which categories of patients? How were decisions taken at the hospital/centre as to which products to use for individual patients? What involvement did you have in such decisions? Were patients given any choice, or involved in any discussions, as to which products to receive?**

When I started at Edinburgh Royal Infirmary in 1980, most outpatient bleeding episodes were treated with Cryoprecipitate, but there were frequent allergic reactions requiring premedication with Antihistamine and hydrocortisone.

SNBTS intermediate purity Factor 8 concentrate was also available at this time and was less prone to cause acute reactions. It was needed to treat inpatients with large bleeds and in association with surgery. As patients were increasingly educated in home treatment, this was the product provided.

I had no direct involvement in these decisions.

10. **What was the relationship between (a) the Infirmary and (b) Good Hope and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions referred to above?**

The Infirmary was supplied by SNBTS. I have no information about Pharmaceutical companies.

11. **If the responsibility for the selection and purchase of blood products at the hospital/centre lay with an external organisation, please specify which organisation and provide as much information as you can about its decision-making.**

See my answer to Q10.

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

As stated in Q9, Cryoprecipitate was widely used before the gradual change to SNBTS Factor 8.

Patients with Von Willebrand's Disease could respond to IV hormone DDAVP.

13. **What were, in your view, the advantages and disadvantages of those alternative treatments? What use was made of them at (a) the Infirmary and (b) Good Hope? 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?**

Cryoprecipitate is prepared from a small donor pool, which reduced the risk of any transmission of infection. However, it produced acute allergic reactions and the factor 8 increment was unpredictable.

Factor 8 concentrate is produced from a large donor pool, with increased risk of contamination from a single donor. The response is more predictable, with fewer acute allergic reactions.

14. **What was the policy and approach at (a) the Infirmary and (b) Good Hope 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?**

See my answer to Q9.

15. **What was the policy and approach at the Infirmary in relation to home treatment? So far as you are aware, when was home treatment introduced? Did the policy and approach change over time and if so how?**

Home treatment became more common, as there was in post a specialist Sister who was able to educate patients. I have no information about a specific start date.

16. **What was the policy and approach at the Infirmary in relation to prophylactic treatment? Did the policy and approach change over time and if so how?**

Prophylaxis treatment was as far as I recall limited to inpatients undergoing surgery or other high risk procedure e.g. joint manipulation. I was aware that some Centres adopted prophylactic home treatment but this was not policy at the Infirmary.

17. **What was the policy and approach at the Infirmary in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?**

Factor concentrate was preferred to Cryoprecipitate due to volume considerations, as large volume infusions could cause heart failure. I am not sure if this policy changed over time.
I have no other recall in this area.

18. **To what extent, and why, were people with mild or moderate bleeding disorders treated at (a) the Infirmary and (b) Good Hope with factor concentrates?**

People with mild or moderate bleeding disorders would be unlikely to receive factor concentrates. Hormonal treatment with desmopressin (DDAVP) was sometimes used for to treat menorrhagia in women with Von Willebrand's Disease.

19. **What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at (a) the Infirmary, (b) Good Hope and (c) the Borders General in consequence of the use of blood or blood products?**

I have no information in this area.

20. **Please provide, insofar as you have not already done so above, a full account of Professor Ludlam's policies, decisions and actions during the time that you worked with him, as regards the use of factor concentrates, the risks of infection, the treatment of patients and the provision of information to patients.**

Professor Ludlam took up his post in January 1980, and took a great interest in his patients, and devoted a lot of time and energy into their care. He soon appointed a Specialty Sister, and organised relocating the Centre to a far superior accommodation.

He made great use of the Coagulation Laboratory, where the performance of factor assays became far more routine than previously.
I recall that he was thoughtful in the use of factor concentrate on a case by case basis.
In Edinburgh we were reassured that our factor 8 was sourced from Scottish donors.

The risks of any blood borne infection was thus thought to be low.
The risk of uncontrolled bleeding was considered as a greater concern.
I became aware that some of the Haemophilia patients had tested positive for the newly available HIV assay in October 1984, when I was on secondment to the Western General Hospital in Edinburgh. I believe that Professor Ludlam personally informed people of the results, at a meeting which I did not attend.

Section 3: Knowledge of, and response to, risk

General

21. When you began work at the Infirmary, 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?

When I joined the Haematology Department, I was worried about the abnormal blood liver function tests (LFTs) commonly seen in the patients with severe Haemophilia. I was informed that this was due to non-A, non-B hepatitis. In Edinburgh there had been an outbreak of Hepatitis B in the renal dialysis unit some years previously, with patient and staff deaths, thus it was obviously a worry that a different strain of hepatitis due to an, as yet, unidentifiable virus was prevalent. Identification of the Hepatitis C virus was finally achieved in 1989.

The emerging reports of AIDS in patients with Haemophilia were a cause of increasing concern amongst the patients and their professional staff. Scottish derived Factor 8 was sourced from volunteer donors. This was intuitively considered to be a purer product than that obtained from paid donors. In Edinburgh we continued to use this product where clinically indicated.

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

I was aware of Consultant level discussions between Haematology and BTS but was not party to them.

23. **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?**

I was aware that commercially derived blood products imported from USA and other countries was sometimes sourced from paid donors. This could result in impurities and blood borne transmission, less of a risk in the BTS products.

Hepatitis

24. **When you began work at the Infirmary, 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?**

See Q21.

25. **What, if any, further enquiries and/or investigations were carried out at (a) the Infirmary and (b) Good Hope in respect of the risks of the transmission of hepatitis? What information was obtained as a result?**

I was not aware of any investigation in this area.

26. **What, if any, actions did you, the Infirmary or Good Hope take to reduce the risk to patients of being infected with hepatitis (of any kind)?**

There was no specific action available other than to restrict the use of factor 8 to clinically indication.

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

As a Consultant at Good Hope I became aware of the identification of Hepatitis C, and the emergence of treatment. I was not directly involved in this area as previously explained.

HIV and AIDS

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

I learned from the literature and colleagues that patients with Haemophilia were developing HIV. This was attributed to contamination of factor 8 by an infectious agent. In Edinburgh we had no cases, and were confident that SNBTS products were safe. So it was a dreadful shock when a group of patients tested positive for HIV in October 1984.

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

From memory I became aware of this possible association in 1983, via the literature.

30. What, if any, enquiries and/or investigations were carried out at the Infirmary in respect of the risks of transmission of HIV or AIDS? What was your involvement? What information was obtained as a result?

It became apparent that patients with Haemophilia who seroconverted to HIV positive after receiving an accidentally contaminated batch of SNBTS factor 8 were more heavily pretreated than those who also received the same batch and did not become

HIV antibody positive. This finding was consistent with other studies by colleagues in the Infirmary which showed an association between abnormal T lympocyte subsets and the total exposure to factor 8.

I undertook a small study published as a letter in the Lancet demonstrating a similar reduction in cutaneous skin test responses in heavily treated patients. This study was performed before any HIV testing of our patients took place.

31. **What, if any, actions were taken at the Infirmary to reduce the risk to patients of being infected with HIV?**

With the dreadful discovery of contamination of a batch of SNBTS factor 8, there was an urgent response to heat treat products.

32. **Did you and your colleagues at the Infirmary continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? Why?**

The policy at the Infirmary was to use factor concentrate as clinically indicated. There was a tension between the immediate bleeding episode and a possible long term complication of uncertain significance. Once we had definite proof of HIV positive patients in our practice, we used heat treated products wherever possible.

Response to risk

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

As a trainee I was not involved with patient information or education.

34. **When did the Infirmary begin to use heat treated factor products and for which categories of patients? From where did the Infirmary obtain heat treated products? Did the Infirmary experience difficulties in obtaining such products? Did the Infirmary return non-heat treated products or continue to use them?**

As far as I recall the SNBTS urgently implemented a supply of heat treated factor 8 in response to the discovery of a batch contaminated with HIV. I have no knowledge of difficulties in the supply chain.

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

In retrospect earlier provision of heat treated products would probably have reduced the risk to patients. I was not party to these discussions.

36. Did the Infirmary 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 have no memory of patients being treated with Cryoprecipitate after the discovery of contamination of pooled factor products.

37. Do you consider that your decisions and actions, and the steps taken at the Infirmary, 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.

As a trainee I had no role in policy decisions. My understanding was that as the Infirmary was provided with previously HIV free SNBTS products, the risks were considered to be low. The situation changed dramatically with the discovery of HIV contamination, and as far as I could tell, the subsequent steps taken were adequate and appropriate.

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

I cannot in retrospect suggest anything which could have been done differently given the reality of the situation.

39. **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?**

I am unable to comment on these matters due to my lack of information in these areas.

Section 4: Treatment of patients

Provision of information to patients

40. **What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at (a) the Infirmary and (b) Good Hope 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.**

See Q33.

41. **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.**

See Q33.

42. **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?**

See Q33.

HIV

43. When did you first discuss AIDS or HIV (HTLV-III) with any of the patients at the Infirmary? What did you tell them?

See Q33.

44. Please describe how and when you learned that patients under your care/the care of the Infirmary had been infected with HIV. What tests were undertaken where and over what period of time?

My understanding was that in October 1984 Dr Ludlam arranged for a small number of stored serum samples from the Haemophilia clinic to be analysed with the newly available HIV test at the laboratory of Dr Richard Tedder in Middlesex Hospital, London. Much to his dismay some patients tested positive. This unexpected and deeply distressing finding was subsequently confirmed in additional patients.

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

I was not aware of any pre-test counselling.

46. 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?

I had no direct involvement in the reporting of results to patients. My understanding was that Dr Ludlam organised an open meeting with the local Haemophilia community, many of whom were related to each other given the hereditary nature of their illness. I believe that individuals were then invited to make separate appointments to discuss their own situation.

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

I have no information.

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

See Q47.

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

I seem to remember that trainees were advised by Dr Ludlam to refer any questions of this nature to him for his attention.

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

See Q49.

51. How many patients at the Infirmary were infected with HIV? Of those infected,

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

f. How many were children?

If patients at Good Hope and/or the Borders General were infected with HIV in consequence of the use of blood and/or blood products, please provide details of the numbers infected and the circumstances of their infection.

I have no access to this data.

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

As serum samples were taken for long term storage when patients attended the Infirmary, it was possible to identify the time frame of seroconversion. This was subsequently attributed to the administration of a specific batch of SNBTS factor 8.

Hepatitis B

53. 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?

I cannot recall any Haemophilia patients who developed Hepatitis B at the Infirmary.

54. How many patients at the Infirmary were infected with hepatitis B?

I cannot recall any Haemophilia patients who developed Hepatitis B at the Infirmary.

NANB Hepatitis/Hepatitis C

55. Were patients at the Infirmary 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 had no knowledge or input in this area.

56. Did you have any involvement at Good Hope with the testing and/or diagnosis of patients for hepatitis C? If so, please answer the following questions:

a. 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 was your involvement in this process?

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

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

d. How many patients at Good Hope were infected with hepatitis C?

See Q5.

Delay/public health/other information

57. 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.

See Q33.

58. 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?

See Q33.

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

See Q33.

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

See Q33.

Consent

61. How often were blood samples taken from patients attending the Infirmary 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?

Blood samples were taken from patients about 3-6 monthly. We explained that this was for routine monitoring and for possible later testing. Verbal consent was obtained before venepuncture.

62. In paragraph 9 of the witness statement you have previously provided the Inquiry, you state that routine blood tests were taken from all haemophilia patients attending the Infirmary, and serum was placed in long term storage. You add that this was part of a monitoring scheme established by Professor Ludlam as part of "his comprehensive care pathways for all patients attending the Haemophilia Centre". In relation to this, please answer the following questions:
a. Please provide full details of the monitoring scheme established by Professor Ludlam, when testing under this scheme began and the purpose for which it began.

From memory Dr Ludlam organised routine testing for Haematology, Biochemistry, and Virology for all his patients, when he started in post in 1980.

b. What was your involvement in the monitoring scheme and what did routine blood testing involve?

As a trainee I was expected to comply with this programme. Patients were generally happy to participate.

c. What information was provided to patients when such testing took place?

Patients were informed that the tests were routine.

d. What was the Infirmary's approach in relation to obtaining consent for such testing?

Verbal consent was the norm in the 1980's. This also applied to for example patient participation in MRC trials of chemotherapy for acute leukaemia etc.

63. Were patients under the care of (a) the Infirmary and (b) Good Hope treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur?

All treatment with blood products was as clinically indicated, with patient consent.

64. What was the approach of the Infirmary in relation to obtaining consent to treatment? Was consent recorded and if so how and where?

Verbal consent was obtained from all adult patients for every treatment episode. Parents would take this role for any minors.

65. Were patients under your care, or the care of (a) the Infirmary and (b) Good Hope, tested for HIV or hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur?

As per Q44 I have no knowledge of consent being obtained for this analysis.

PUPS

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

I seem to recall that some previously untreated patients were offered treatment as clinically indicated with recombinant factors. I have no more details.

Research

67. Please list all research studies that you were involved with during your time at a) the Infirmary and (b) Good Hope and (c) Borders General 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 epidemiological or similar studies in which you were involved, insofar as relevant to the Inquiry's Terms of Reference.

At the suggestion of Dr Ludlam, I was first author of a case report in the Lancet of one Haemophilia patient who developed a glandular fever-like illness at the time of seroconversion to HIV. He was a recipient of the batch of SNBTS factor 8 which was subsequently found to be contaminated with HIV. There was an input from Dr Tedder's Laboratory. The patient as I understand was aware of the anonymous case report, but I was not involved with this communication.

There was no specific funding for this paper.

This is the extent of my research as relevant to the Inquiry.

68. The Inquiry understands that you contributed a study published in the Lancet August 1985: "Human T-lymphotropic Virus Type III (HTLVI III) Infection in Seronegative Haemophiliacs after Transfusion of Factor VIII" Please set out what you recall of this research study, and the involvement you had in it.

This paper was published after I left the Infirmary. I was included as an author in recognition of the clinical care I had given to some of the patients. I didn't take part in the writing. This was a detailed account of the seroconversion phenomenon linked with a batch of SNBTS factor 8. The patients who unfortunately became HIV positive had previously received more doses of factor, and there was some evidence of a dosage effect attributed to the offending batch of factor 8.

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

I cannot make any blanket response in this area. I would however make the point that some of the scientific papers published about the so called Edinburgh cohort were in effect detailed case reports and audits. There was no initial hypothesis or scientific question to answer, rather there was the need to communicate with the Haemophilia community the experience of our centre.

70. Please describe and provide details of any research undertaken at the Infirmary that you are aware of, involving patients with bleeding disorders.

I have no list of publications from the Infirmary.

71. 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?

I do not know the answer to this question.

72. 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?

See Q71.

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

See Q67 and Q68.

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

74. How was the care and treatment of patients with HIV/AIDS in consequence of infection from blood or blood products managed at (a) the Infirmary and (b) Good Hope and (c) Borders General? 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?
d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?

I had left the Infirmary in April 1985, before any HIV treatment programme was in place for the Haemophilia clients.

75. How was the care and treatment of patients with HBV in consequence of infection from blood or blood products managed? 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 B?

I was not involved in this area.

76. How was the care and treatment of patients with NANB hepatitis in consequence of infection with blood or blood products managed at (a) the Infirmary and (b) Good Hope? 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?

See Q75.

77. How was the care and treatment of patients with hepatitis C in consequence of infection with blood or blood products managed at the (a) Good Hope and (b) Borders General? 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?

See Q75.

78. What arrangements were made at (a) the Infirmary and (b) Borders General for the care and treatment of children infected, in consequence of blood or blood products, with HIV or hepatitis? How did those arrangements differ (if at all) from the arrangements made for adults?

See Q75.

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

See Q75.

80. **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.**

See Q75.

Records

81. **What was the policy at (a) the Infirmary and (b) Good Hope and (c) Borders General with regards to recording information on death certificates when a patient had been infected with HIV or hepatitis?**

I have no information on this topic.

82. **What were the retention policies of a) the Infirmary and (b) Good Hope and (c) Borders General in regards to medical records during the time you were practising there?**

I have no information on the policy at the Infirmary.

83. **Did Professor Ludlam maintain separate files for some or all patients? If so, why and where were those files located?**

I think Professor Ludlam kept files of patient treatment, so he could monitor usage.

Section 5: Scottish National Blood Transfusion Service

In your statement to the Inquiry, you note you took part in a 6 month attachment to the Scottish National Blood Transfusion Service (SNBTS) based in the Infirmary. In relation to your experience at SNBTS, please provide the dates of the attachment and answer the following questions insofar as you are able to.

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

From memory my 6 month attachment to SNBTS was in 1982.

As a trainee I had no involvement in any relevant decisions or actions.

85. What discussions or meetings or interactions did you have with SNBTS in relation to:

a. the risk of infection with hepatitis from blood products;

b. the risk of infection with HIV/AIDS from blood products;

c. the steps to be taken to reduce the risk of infection?

See Q84.

<u>Section 6: Pharmaceutical companies/medical research/clinical trials</u>

86. Have you ever:

a. provided advice or consultancy services to any pharmaceutical

company involved in the manufacture and/or sale of blood products?

b. received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the

manufacture or sale of blood products?

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

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

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

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

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

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

If so, please provide details.

No.

Section 7: vCJD

87. **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?**

vCJD was first reported in 1996, when I was at Good Hope. Due to the possibility of transmission by blood transfusion the BTS informed Haematologists and Blood Banks that they planned leucodepletion of blood and products, implemented in 1999.

Following a case report in 2003 of probable transfusion transmitted vCJD (by which time I was at Borders General) I was aware that the SNBTS was seriously concerned, but were hampered by the lack of any donor screening techniques.

88. **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 (a) Borders General and (b) Good Hope 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?

As far as I recall recipients of blood transfusion were not given any specific information about vCJD, in line with national practice.

89. **What measures were put in place at (a) Good Hope and (b) Borders General from a public health perspective, in relation to the care and treatment of patients?**

There were no patients in either hospital with vCJD.

Section 8: The financial support schemes

90. **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 through blood or blood products?**

I have no knowledge of these trusts or funds.

91. To what extent, during your time at (a) Good Hope and (b) Borders General, did staff (including you) inform patients about the different trusts or funds?

I have no knowledge of these trusts or funds.

92. Did (a) Good Hope and (b) Borders General have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

I have no knowledge of these trusts or funds.

93. What kind of information did (a) Good Hope and (b) Borders General provide to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?

I have no knowledge of these trusts or funds.

94. Did (a) Good Hope and (b) Borders General, 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.

I have no knowledge of these trusts or funds.

95. Was (a) Good Hope and (b) Borders General 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.

I have no knowledge of these trusts or funds.

96. 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 have no knowledge of these trusts or funds.

Section 9: Other Issues

97. 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.

When at Good Hope there was a formal complaint made about me by a relative of my patient who developed acute myeloid leukaemia after a prolonged period with Primary Thrombocythaemia. This proceeded under the "3 wise men" structure, and it was concluded that I acted appropriately.

No other formal complaints were made against me in my working career.

98. 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.

I have nothing to add.

Statement of Truth

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

Signed GRO-C

Dated 18th November 2020.