Witness Name: Mark Winter

Statement No.: 1

Exhibits: 0

Dated: 6 August 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR MARK WINTER

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 24 January 2020. The numbers of each paragraph in this statement correspond to the numbers of the questions as set out in the Part 9 letter dated 24 January 2020.

I, Dr Mark Winter, will say as follows: -

Section 1: Introduction

1.1 Dr Mark Winter (my address is known to the Inquiry)

1.2 Date of birth GRO-C 1949

1.3 FRCP FRCPath

1.4 Haematologist and Haemophilia Centre Director 1983-2011

Kent and Canterbury Hospital Ethelbert Road Canterbury CT1 3 NG

2. Senior registrar in Haematology, Middlesex hospital 1976–1979.

Standardised Haematology training, under the aegis of the Royal College of Pathologists, culminating in the MRCPath examination.

Six month Secondments to a District General Hospital (Edgware) and a Regional Transfusion Centre (North London) whilst at the Middlesex.

My secondment to the North London transfusion centre did not involve any responsibility for blood products.

Senior registrar in Haematology, Guys Hospital 1979–1983

3. Member of UKHCDO 1983–2011

Medical trustee for the MacFarlane trust 1996-2009

Medical director of the National Haemophilia Alliance 1999–2005

4. I have previously given evidence to the Archer inquiry and to the Penrose inquiry.

This statement should be read in conjunction with my written and oral submissions to the Archer and Penrose inquiries.

I have reviewed my evidence to the Archer and Penrose inquiries and compared them to my draft submission to the current inquiry.

The only comment that I would make is that, on reading my written submission to Archer, whilst the process to switch to exclusively heat treated concentrate started in May 1984, it was not completed till the end of June 1984 because of supply issues.

From July 1st 1984, non heat treated concentrate was not used again in our centre (section 35.9 of my submission below).

Beyond that my submissions to Archer and Penrose still seem accurate.

Section 2: Your employment at Guy's Hospital

5. The director of the Haematology Department at Guys was Dr Percy Barkhan, an expert in vitamin K metabolism

6.1 There were only relatively few patients with haemophilia attending Guys Hospital for treatment as most patients resident in this area were registered with the major centre at Saint Thomas's Hospital, less than a mile away.

6.2 I do not recall any locally written protocols related to haemophilia management.

As far as I can remember we followed UKHCDO guidelines.

7.1 As a trainee I was not involved in any way in blood product procurement at Guys so cannot comment in detail on this question.

7.2 As far as I can recall we received an allocation of factor concentrate from the Blood Products Laboratory (BPL) at Elstree each month and any shortfall was covered by the purchase of commercial concentrates with which I was not involved.

8. As above, as a trainee I had no commercial contacts.

9. No other organisations were involved in the purchase of commercial concentrates.

Guys was an accredited Haemophilia treatment centre and followed UKHCDO guidelines.

10.1 Neither of the consultants had expertise in Haemophilia.

10.2 Haemophiliac patients were managed by the three Senior Registrars.

10.3 When the first reports of AIDS in patients with haemophilia emerged in 1982, we prioritised BPL concentrate for children, for newly diagnosed patients and for patients who required factor concentrate only rarely, following UKHCDO guidelines.

11. DDAVP, where clinically applicable.

Cryoprecipitate was available but not used as far as I can recall, see below

12. As far as I can recall we were able to treat all of our patients with some form of factor concentrate and did not choose to use cryoprecipitate because of the well described problems with this product as set out in paragraph 35.3 below.

13.1 By 1979, when I started at Guys, the benefits of home treatment were well documented:

- early treatment of bleeding at home
- no need for hospital treatment for most bleeds
- treatment could be self-administered at home, work and school
- greater independence

I therefore set out to establish a home therapy programme.

13.2 As set out above the number of severely affected adult patients was small, probably less than ten.

13.3 They were treated with a combination of BPL and commercial concentrate depending on the supplies that we had been receiving from Elstree.

13.4 As these were the days before the discovery of HIV, and before the significance of abnormal liver function test results became apparent, the information given to patients would have been strongly in favour of the expectation of a positive improvement in lifestyle.

14.1 We did not use long term prophylactic therapy for adults as this was not standard clinical practice at that time.

Short-term prophylaxis was recommended for adult patients who had target joints or who were recovering from surgery

14.2 The very small number of children with severe haemophilia were treated with prophylaxis if deemed appropriate.

15. Children with haemophilia were prioritised to receive treatment with BPL concentrate, supplies allowing.

16.1 Patients with mild haemophilia and Von Willebrands disease were treated with DDAVP.

16.2 Patients with moderate haemophilia were assessed for suitability for DDAVP treatment.

16.3 If they were not suitable they were treated wherever possible with BPL concentrate.

17.1 Home therapy was recommended for all patients with severe haemophilia if it was felt that they or a family member were capable of administering the concentrate in the home setting.

17.2 Children with severe haemophilia were started on home therapy from around the age of three years depending on the expertise of the parents in venous injection and depending on the state of the child's venous access.

A full comprehensive care program was introduced for patients with significant haemophilia including three monthly clinical reviews, physiotherapy and rheumatology assessments and laboratory supervision.

Section 3: Decisions and actions of the Kent Haemophilia Centre

18. I was the director of the Centre and ultimately responsible for all clinical and laboratory activities of the centre.

19.1 My responsibilities as Centre director were the same as in other comprehensive care centres.

19.2 There were two main areas of responsibility, firstly organising and providing the full range of clinical services appropriate for patients with hereditary bleeding disorders and secondly for maintaining an appropriate array of laboratory services in support of the clinical service.

The coagulation laboratory was managed by a senior scientist who was directly accountable to me.

19.3 My other main areas of responsibility were running a clinical and laboratory thrombosis service, running an anticoagulant clinic for three thousand patients, teaching, training, audit, appraisal, accreditation and research.

19.4 In due course, I was appointed as the nominated HIV physician for the East Kent area

20.1 When I started as haemophilia centre director haemophilia services in Kent were not well developed.

Many patients were travelling to London to be under the care of the major centre at Saint Thomas's hospital.

20.2 The only other haemophilia centre of any size or significance in Kent was the centre that I had been appointed to at Margate.

20.3 There were probably of the order of twenty patients with severe haemophilia attending the Margate centre when I started my consultancy.

20.4 Over the next ten years the centre grew very significantly, partly because of repatriation of patients who were travelling to London and partly because the centre developed expertise in HIV management.

20.5 By 1995 there were more than forty patients with severe haemophilia attending the Margate centre, many of whom lived more than thirty miles away.

20.6 As facilities in Margate were poor an application was made to the local health authority to relocate the centre into much better and more centralised facilities at the Kent and Canterbury Hospital.

20.7 The centre in Canterbury opened in April 1995 and shortly afterwards was designated as a comprehensive care centre by UKHCDO.

21.1 I have no further information concerning the system for purchasing coagulation factor concentrates in Margate before my appointment in 1983.

21.2 Patients were given a prescription by their GP for factor concentrate and took this prescription to a High Street chemist who then decided what form of factor concentrate to purchase.

No records of batch numbers appear to have been kept, which made it impossible to trace any potentially infected patients when in due course we were notified of contaminated batches.

22. See response to question 35.

23. a. I was fully responsible for all decisions relating to concentrate therapy in our centre, being the only consultant.

From the start of my consultancy in December 1983 to May 1984:

- supplies of BPL concentrate were limited and were not of sufficient quantity to allow all patients with haemophilia to be treated with this product, which would have been my treatment of choice, as it was derived from British plasma.

b. Supplies of commercial concentrate were available from several suppliers, predominantly American.

It was my responsibility to purchase enough commercial concentrate for all patients in the centre to receive appropriate clinical treatment.

c. As I believed that all of the available commercial concentrates were of equal clinical efficacy and safety my main responsibility was then to purchase coagulation factor concentrates at the most advantageous price.

24.1 Relationships with the pharmaceutical companies were seen as being generally symbiotic because the companies provided financial support for activities and projects which were not possible under the NHS.

This included support for patient education events, patient information documents, and haemophilia centre staff training programmes.

24.2 As an example, the companies funded the development of a Filofax style diary for use by children with Haemophilia.

The diary provided children with information concerning their haemophilia and the children were trained to input information into the diary, including blood product usage, on a daily basis.

This project was nominated for a BUPA communication award.

24.3 The companies also funded the development of a software program (ADVOY) which enabled haemophilia patients to capture haemophilia data In the home setting.

Children and teenagers with significant haemophilia were issued with a Palm pilot which they used at home and at school to capture concentrate usage.

This was absolutely invaluable in obtaining accurate figures of concentrate usage in the home setting

24.4 These projects would not have been funded by the NHS.

24.5 These relationships had no influence on the type of concentrate being used by the centre.

25. No other organisations were responsible for coagulation factor purchase in our centre, which was the ultimate responsibility of the local trust.

26. BPL concentrate was used for children if possible and also for infrequently treated adults prior to the switch to Heat-treated factor VIII and heat-treated factor IX which took place in May 1984.

27. Patients with mild haemophilia and with von Willebrand's disease were treated with DDAVP rather than coagulation factor concentrates, if the clinical situation allowed this.

28.1 DDAVP is a safe drug but can only be used in patients with mild haemophilia or von Willebrand disease.

28.2 Patients with severe or moderate haemophilia treated with DDAVP do not experience high enough levels of factor response for this treatment to be effective

29.1 Cryoprecipitate was not used in our centre because of the well described problems with its usage, particularly unsuitability for children, as compared to the use of coagulation factor concentrates

29.2 All patients with factor VIII deficiency were in any case treated exclusively with heat-treated concentrate from May 1984.

30.1 The centre was strongly in favour of home therapy where at all appropriate and this was strongly recommended for all suitable patients.

30.2 This policy, the strong promotion of home therapy, did not change over time

31.1 The centre was strongly in favour of prophylactic therapy for children with severe haemophilia and would start talking to parents about the possibility of introducing this treatment once the child had reached the age of about three.

31.2 The actual implementation of prophylactic therapy depended on the severity of the haemophilia and the ease of venous access.

31.3 At that time prophylaxis was only used for adults if they had developed a target joint or in the days and weeks following surgery

32.1 January to May 1984: BPL concentrate, supplies allowing

32.2 May 1984 to 1995: heat treated factor VIII and IX only.

32.3 1997 till today: recombinant factor VIII and IX only.

33.1 Patients with mild haemophilia and Von Willebrands disease were treated with DDAVP.

33.2 Patients with moderate haemophilia were assessed for suitability for DDAVP treatment.

33.3 If they were not suitable, they were treated wherever possible with BPL concentrate, till May 1984 when they were treated exclusively with heat- treated factor VIII concentrate

34. No patients attending the centre were infected with any viruses apart from HIV, HBV and HCV.

Section 4: Knowledge of, and response to, risk

35.1 By 1979, haemophilia clinicians had significant concerns that commercial concentrates were likely to have been contaminated by a third hepatitis virus, known as non-A, non-B, subsequently identified as hepatitis C.

These concerns were based on:

1. the finding of abnormal liver function tests in regularly treated patients;
2. studies in the late 1970s indicating the presence of abnormal liver histology, including cirrhosis, in regularly treated patients

35.2 By early 1984 it was apparent that there were even more significant concerns concerning the safety of the coagulation factor concentrates being used at that time to treat patients with haemophilia.

These concerns were based on the following observations, as above:

1. the previously held view that the abnormal liver function tests (believed at the time to be due to an as yet identified third hepatitis virus, subsequently identified as hepatitis C in 1989) detected in patients who were regularly treated with coagulation factor concentrates were not of any great clinical significance, as the patients were clinically well, had been shown to be untenable because of the data from the Sheffield haemophilia centre, and other centres, indicating that liver biopsies on patients with regularly treated haemophilia showed that many patients had significant chronic liver disease, including cirrhosis.
2. Furthermore, the report of American haemophiliac patients with AIDS in 1982, followed by the isolation of the HIV virus in 1983, indicated very strongly that AIDS had a viral aetiology and was therefore potentially present in the blood supply.

35.3 In trying to respond to this crisis two forms of therapy could be rejected as being unsuitable for severely affected patients:

1. Desmopressin (DDAVP) :
   - Not effective in patients with severe or moderate haemophilia;
   - Only leads to significant rises in factor VIII in patients with mild haemophilia.
   - Not effective in factor IX deficiency
2. Cryoprecipitate:
   - much less effective clinically than factor VIII concentrate
   - not effective in factor IX deficiency
   - extremely difficult and laborious to reconstitute
   - had to be stored in a deep freeze and was therefore not suitable for home treatment

- often caused side-effects
- could not be used in children because of the high volume
- was in any case in short supply

35.4 At this highly critical time there were therefore only three options for haemophilia clinicians:

Option one: suspend treatment

Not a good idea:

- most patients with severe haemophilia die of internal bleeding, particularly into the brain and gastrointestinal tract
- the life expectancy of untreated patients with severe haemophilia is of the order of twenty years only
- ten patients with severe haemophilia had died of cerebral bleeding in the UK in 1983

Option two: continue with BPL concentrate only

PRO

- Derived from voluntary donors in the UK
- Relatively cheap
- liked by patients

CON

Did not include any form of viral inactivation process

Option 3: switch to heat treated factor VIII and IX

CON

- derived from paid commercial donors in the US
- no full product license, available on a named patient basis only
- significantly more expensive
- not liked by patients

PRO

Did include a heat inactivation step in the manufacturing process which might in theory be effective in inactivating any viruses in the concentrate

35.5 My colleagues at Saint Thomas's Hospital, the Middlesex hospital and in Sheffield held the same view as myself that we ought to seriously consider the use of a heat-treated concentrate.

We were aware that Alpha therapeutics had obtained a full product licence in the US in February 1984 for the treatment of patients with haemophilia with a heat-treated factor VIII concentrate.

Heat treated factor IX concentrate was also available.

35.6 There was intense discussion and disagreement at UKHCDO about which treatment to use at this very sensitive time.

Many clinicians did not believe that British donor plasma carried any significant viral risk.

No British patients had been reported as having AIDS who had been treated exclusively with BPL concentrate.

There were very significant and understandable concerns that the heating inactivation process might alter the factor VIII molecule so that it might lead to the development of inhibitor formation

in the patient, a particularly serious event as it makes future treatment with concentrate very much less effective.

There was no proof at that time that heating inactivation worked because neither HIV or HCV had been isolated.

For these reasons many centres opted to continue with non heat-treated BPL concentrate until July 1985, by which time all haemophilia centres in the country did convert to the exclusive use of heat-treated product.

Heat treated concentrate was in any case in short supply till 1985.

35.7 By May 1984 I had managed to obtain funding for heat-treated factor VIII and factor IX and therefore made the decision to switch all of my patients with both factor VIII and factor IX deficiency to the heat-treated product.

I had obtained consent from my trust, and had completed the necessary paperwork to allow me to use a named patient product for each of my patients.

35.8 All patients on home therapy were summoned to the centre and asked to bring with them any residual supplies of unheated concentrate.

The situation was explained to them in and they were given the choice as to whether they would like to remain on unheated concentrate or move to the new heat-treated concentrate. They were instructed by the nursing staff as to how to administer the new product and were given supplies for home treatment.

All patients did agree to switch to heat treated concentrate in May 1984. If there had been any objectors we would have had to stock both heated and non- heat treated concentrate, which did not happen.

35.9 Together with the centres at Saint Thomas's, the Middlesex and Sheffield, the switch to heat-treated product occurred at the end of May 1984.

No patient since that time was infected by any virus in our centre.

35.10 It transpired that subsequent research indicated that heat treatment did indeed effectively inactivate HIV but that it had a much less significant impact on HCV.

The chances of being infected with HCV following concentrate treatment did not significantly diminish until the introduction of second and third generation concentrates a few years later.

35.11 I shall always remember this quite exceptionally difficult time as being the most complex and difficult decision that I ever had to make as a doctor

36. See question 35.

37. I supported a move towards self-sufficiency in blood products as I believed that voluntary donated plasma was likely to be safer than commercially donated plasma.

38. See question 35.

39. See question 35.

40. See question 35.

41. See question 35.

42. See question 35.

43. See question 35.

44. See question 35.

45. The patients were clinically well and were thriving on concentrate therapy. See also question 35.

46. See question 35.

47. See question 35.

48. See question 35.

49. See question 35.

50. See question 35.

51. I did agree, see question 35.

52. See question 35.

53. Conversations with my own patients and with patients from other centres attending residential haemophilia seminars.

54. The Haemophilia Society had written to the DOH, imploring them not to reduce or withdraw supplies of imported concentrate from the US.

Plus, conversations with patients.

55. I ran a series of public awareness lectures on AIDS across Kent and appeared on local media.

Patients were given substantial oral and written information about HIV and hepatitis and also had access to Haemophilia Society information.

56. I cannot recall the exact dates. HIV and hepatitis were always very extensively discussed at national haemophilia Society meetings and residential seminars because of the understandable level of concern amongst the patient group.

57. I have tried to outline in question 35 the complexities of the decision concerning any potential switch to heat treated products in 1984/1985.

The switch to heat-treated concentrates in May 1984 was based on theoretical concerns.

We had no evidence at the time that heat inactivation was actually effective and therefore I am not critical in any way of my colleagues who made a different decision at that time.

58. See question 35.

The heat-treated Alpha product was the only heat-treated product available until later in 1984.

It had only been licensed in the US in February 1984 and was therefore not available in the UK until the spring of that year, on a named patient basis only.

59. I did not revert to cryoprecipitate See question 35.

60.1 It is very frustrating to realise how close England came to being self-sufficient in blood products in 1977.

The Secretary of State, David Owen, was medically trained and understood very clearly the potential dangers of continuing to rely on imported commercial blood from the US.

The DOH seemed eventually to have made a decision to become self- sufficient, and the funding seemed to have been secured, they even held a press conference announcing the move.

60.2 At this critical moment, Dr David Owen was appointed Foreign Secretary and the political momentum towards self-sufficiency within the DOH appears to have been lost.

This was a highly critical moment in relation to the subsequent HIV epidemic amongst patients with haemophilia.

60.3 There was a degree of criticism of the DOH, the blood products laboratory at Elstree and the National blood transfusion directors.

It was the view of UKHCDO that these organisations did not show significant dynamism or enthusiasm for pushing for a move towards self-sufficiency, unlike in Scotland.

61. See above.

62. A major difficulty for haemophilia clinicians in responding to this unprecedented crisis was the lack of standardised and national advice on virological matters.

The expert advisory group on AIDS was not established until 1985.

It would been very helpful to us if it had been established by 1984 at the latest so that we could have received advice about HIV testing in particular.

63. See question 35.

64. See question 35.

65. See question 35.

No patients who received heat treated product were infected with HIV

66a This was a particularly serious incident as the hospital concerned was not a designated haemophilia centre and was therefore not accredited to treat patients with haemophilia.

As soon as I became aware of this incident, and the incident below, I took steps to ensure that no patient with haemophilia was ever treated at this hospital again.

Both the patient and the doctor concerned have now died; this matter is therefore closed.

66b This was a particularly serious incident as the hospital concerned was not a designated haemophilia centre and was therefore not accredited to treat patients with haemophilia.

As soon as I became aware of this incident, I took steps to ensure that no patient with haemophilia was ever treated at this hospital again.

Both the patient and the doctor concerned have now died; this matter is therefore closed.

66c These incidents happened at the William Harvey Hospital in Ashford. I am not able to provide further details about these incidents or the names of the doctors involved.

67. I do not recall the names of the doctors who expressed such a view.

Section 5: Treatment of patients at the Centre

68. New patients were at all times given written and oral information about the theoretical risks of viral infection with concentrate usage.

This information was regularly updated as greater knowledge about viral contamination became apparent.

All new patients were strongly encouraged to join the Haemophilia Society and were also introduced into the very active local Haemophilia Society group in Kent.

See also question 35

This information changed regularly, as patients were being treated with increasingly sophisticated concentrates, which were less likely to transmit viruses than heat treated concentrate.

HCV testing was not available until 1990/1.

69. Yes.

70. Information about desmopressin, for whom this drug might be suitable

71. A comprehensive home therapy induction program was run by senior nursing staff.

Patients or parents would be taught how to administer the concentrate in the home setting, how to keep records of concentrate usage, how to dispose of needles and how to store the product.

If a child was involved the school would be visited and written and oral information passed on to the school authorities

72. Early 1984.

73.1 By October 1984 an HIV antibody test have been developed by Dr Richard Tedder at the Middlesex hospital in London.

UKHCDO made an arrangement with Dr Tedder that all patients who had received factor VIII concentrate should have their blood sent to him for this test to be performed.

73.2 It was not the practice in our centre to store blood samples.

73.3 Patients were therefore recalled on an individual basis and told that they were having a blood test for the new virus performed and that it would be sent to London and that the results would be available in a few weeks.

74.1 From the time when it had first been established that hepatitis viruses were likely to be present in coagulation factor concentrate in the mid-1970s haemophilia clinicians had regarded it as their responsibility to monitor on a regular basis their patients for the presence of any such viral infections.

This was in addition to carrying out the other routine blood tests required by haemophilia patients, all of this being part of a comprehensive care package.

74.2 At the time it was not considered logical to ask the patient to give informed consent for blood testing any more than it was considered logical to ask for consent to administer intravenous treatments to them, which some patients were receiving up to three times every week.

Blood tests were often taken through the same needle at the time of concentrate administration

In hospital practice it was only prior to surgical procedures that patients were asked to provide written signed consent.

The concept of pre-test counselling did not exist in medical practice at that time.

It was the advent of HIV testing that change this practice because never before in clinical medicine had there been a situation where the patient could be affected by just having a blood test performed, whatever the result of that test.

A particular feature of HIV testing was that a patient having a negative test result might still end up paying increased mortgage and life insurance premiums.

75.1 On 26th of October 1984 I received the results of the blood tests that had been sent to Dr Tedder.

Thirty out of thirty one blood samples tested positive for HTLV III antibody in our centre.

Fifteen of these patients were children under 18 years of age.

75.2 It was very difficult in the first instance to interpret these results. What did the phrase HTLV – III antibody positive mean?

Antibodies to some viruses, such as chickenpox measles and mumps are associated with lifelong immunity whereas antibodies to other viruses can be associated with active infection.

Did the results mean that the patient had been exposed to a virus and was now immune or did the results mean that the patient had active virus?

The latter turned out to be true but at that time nobody knew.

It was therefore very difficult to work out exactly what to say to patients without unduly alarming them.

75.3 Patients were told their blood results, by myself, together with a nurse or counsellor and a relative in a clinical room.

I told each of the patients that they had tested positive for this new virus and I advised them about the possibility of transmission through sexual activity.

HIV testing and support was offered to their partners.

All patients and partners were offered counselling; the centre had a full-time counsellor.

We issued them with condoms if required.

They were advised of the importance of clearing up any blood spillages in the home setting.

75.4 I advised them that in time they might become unwell and that we would be monitoring them very closely including regular assessment of their immune function.

75.5 They were advised not to spread the result of their test too widely because of the widespread discrimination against HIV that was prevalent at the time.

The lack of standardised advice from a national virus authority was again absolutely critical at this time.

75.6 I became aware through my MacFarlane trust work of the very unsatisfactory way in which some patients in some centres had received their test results.

Some patients were told in corridors whilst some patients received a letter from the centre telling them that they had tested positive and that they should discuss the matter with their general practitioner.

75.7 There were especially complex problems concerning the question of whether children should be told.

Many centres chose not to tell children at that time.

My own view was that the children should be told and we therefore set about discussing this matter with the parents.

In the end it was decided that I should tell each child accompanied by the parents and a nurse or counsellor.

I therefore told all of our infected children in this manner apart from the youngest who was four year old at the time.

We told him a few years later when his parents felt that he was ready to understand the information.

For some of the children the news was not a surprise because they were aware that something very worrying was happening to them.

Their parents had started to become upset when they were visiting the hospital or when there were articles about HIV on the television.

75.8 Most of these children were on home therapy programmes and as it was the usual practice for mothers to be injecting the home treatment we therefore had to deal with what we called the "double guilt" of mothers, as they had inadvertently given the injection that had infected their child and had also passed on the gene that had caused the child's haemophilia.

These women required very intensive psychological support and counselling

75.9 There were further very complex issues at the schools where the infected children where attending.

Nearly all the schools told us that they could no longer accept the child because the child might bleed on the school bus or at lunch or during pottery classes and might then infect another child or a teacher.

One of the schools accepted the child eventually only after a nurse had been appointed who sat alongside the child through every class, wearing gloves and carrying a bottle of disinfectant.

76. All patients were advised of the possibility of sexual transmission and were offered condoms.

It was recommended that their wives/ partners should be tested for HIV although not all patients wished for this to happen.

The wife of one of our patients did turn out to be HIV positive. All patients and partners were offered counselling.

77. They were counselled at the same time as their haemophiliac husband/ partner.

78. Thirty out of thirty one blood samples tested positive for HTLV III antibody in our centre.

As far as I can recall. fifteen of these patients were children under 18 years of age.

79. See question 124. We did not undertake any work to try and identify the possible date of HIV seroconversion, as this type of study requires sequential and retrospective testing of stored blood samples, which we did not have. As far as I am aware, the only centre in the UK that was able to perform this type of study was the Royal Free Hospital.

80. Only one patient had been infected with Hepatitis B.

As he was also infected with HCV he received the same counselling and advice as other hepatitis C positive patients.

81. One.

82. It was not possible to inform patients of hepatitis C infection until the blood test for this virus became available in 1990/1991.

It had been suspected for many years that regularly treated patients were likely to have the virus previously known as non-A non-B hepatitis, subsequently known as hepatitis C.

These patients had therefore been receiving regular advise for a number of years before confirmation of the diagnosis.

They were informed that they had a chronic viral infection of the liver that was causing inflammation.

They were advised that they would need careful and specialised monitoring of liver function to make sure that they were not developing cirrhosis.

They were advised to have a low-fat diet and they were advised to drink as little alcohol as possible.

They were advised about the importance of good hygiene.

They were advised of the theoretical possibility of sexual transmission of HCV though, unlike HIV, there was very little data on this subject.

There was at that time no antiviral treatment for HCV.

83. New patients were advised of the possibility of hepatitis C infection.

Regularly treated patients until 1984 were in any case extremely likely to have been infected from the time of the first treatment with concentrate,

84. As soon as the HCV test became available ...1990 or 1991.

Patients were told of their result in person, in the clinic, together with a nurse or counsellor and a relative.

85. About fifty, I do not have precise figures.

86. Patients were told of the blood test results at the next clinic following availability of these results.

87. I gave each patient as much information as I had, whether this was part of public health information or not.

88. Patients were reminded on a regular basis that the history of concentrate therapy showed that every few years a new virus was identified.

89. see question 82.

90. see question 74.

The patients understood that their comprehensive care programme involved regular blood testing and which blood tests were being performed.

Consent was not requested. Blood samples were not stored.

91. As set out above it was not the practice to seek informed consent for any aspect of comprehensive care therapy until the mid-1990s onwards

92. see question 74.

93. All new patients (PUPs) were integrated into the comprehensive care programme as above.

A small number of PUPs were entered with the signed consent of their parents into concentrate evaluation studies.

94. During the years 1983 to 2011 I published around one hundred peer reviewed papers.

Please see my curriculum vitae for further information.

The centre at Canterbury was not heavily involved in clinical research because of the very intense clinical workload.

Research at Canterbury fell broadly into three categories:

1. laboratory based coagulation studies, in conjunction with two research scientists, on the subject of coagulation factor XII.

   These were laboratory studies only.

2. Multi-centre clinical studies on new forms of coagulation factor concentrate or post licensing surveillance studies on new coagulation factor concentrates.

3. Multi centre Medical Research Council studies on new forms of antiretroviral therapy...Concord, Alpha, Delta.

All research activity within the centre was carried out according to local ethical committee protocols and also to national ethical committee protocols if the studies were multicentre in nature.

As demanded by these protocols:

All research activity had formal approval from the local and/or national committee

All patients received extensive oral and written information concerning any study

All patients gave signed consent at the time of enrolment to any study

95. Ethical committee guidelines were followed at all times.

96. No

97. No, apart from the annual release of patient data to UKHCDO.

98. Yes, all Haemophilia centres provided such data to UKHCDO including name, date of birth, diagnosis, basal factor level etc.

Viral status was not disclosed.

This disclosure was strongly supported by the Haemophilia Society.

99. See response to question 94.

100. The situation at Canterbury was unusual in that I had become the HIV physician and was also looking after a number of patients who had acquired HIV infection through drug addiction or through sexual activity.

For this reason, patients had both their haemophilia and HIV infection managed within the centre by myself, with referral to other specialists clinics as deemed clinically appropriate, particularly to liver specialists once therapy for HCV had become available.

Eventually, I was replaced as HIV physician and at that time combined HIV clinics were carried out by myself and the new HIV clinician.

Patients were offered new antiretroviral therapy as and when it became available, alongside detailed discussion concerning potential benefits and side effects.

101. As above

102. As for HCV, only one patient with HBV.

103. As above

104. See question 100

Advice and information and treatment was provided by the Hepatologist.

105. See above

106. See question 100

107. The children were treated in the same way as adults

108. The major dynamic concerning coinfection with HIV and HCV is that the hepatitis virus tends to become more activated, and cause more pathological damage, if there is coinfection with HIV.

109. The centre had a full-time counsellor

110. Not that I can recall.

111. See 109.

112. AIDS was not a notifiable disease.

Because of the stigma surrounding this diagnosis it was not usual to use this term on a patient's death certificate as it had caused significant problems with the coroner, and with undertakers.

No such stigma surrounded patients dying of hepatitis.

113. We were obliged to follow the trust policy on medical records.

As far as I can recall there was a mandatory requirement to retain all medical records for at least seven years.

114. Like other haemophilia centres, our centre had a policy of having our own separate haemophilia records in addition to the patient's hospital notes.

This was because we were extremely concerned about losing critical clinical information, including usage and batch numbers of concentrates, if we relied upon hospital notes only, which often went missing.

115. No.

116. No.

Section 6: Treloar's

117. I had no connection with the haemophilia school at Lord Mayor Treloar's College which had closed by the time that I started my consultancy in late 1983.

A few of my more elderly patients had been patients at the school many years previously.

Section 7: Self-sufficiency

118. My understanding of the term self-sufficiency was that the country would be able to produce sufficient concentrate from its own voluntary donors without having to import any form of concentrate from overseas

As a trainee registrar I was not involved in any initiatives towards encouraging self-sufficiency

119. National usage of coagulation factor concentrates was collated by the Oxford haemophilia centre and subsequently by the UKHCDO database in Manchester.

They were able to provide annual figures on national usage of concentrate

I was not involved at any time in any estimation of blood product usage, which would have been the responsibility of the UKHCDO secretariat.

120. I am not able to answer these questions, which should be directed at the UKHCDO secretariat

121. See question 120.

122. The BPL plant at Elstree never produced enough factor VIII and factor IX for the country to become self-sufficient, unlike in Scotland.

See also question 60.

123. I do not agree.

Figures of national concentrate usage Increased every year during the 1970s and 1980s

UKHCDO made continued representations during the 1970s to DOH for the country to become self-sufficient

124.1 This is a very central and critical question.

Coagulation factor concentrates were derived from pools of around twenty thousand donors.

We now know that the incidence of HCV in US donor plasma in the 1970s was around 3%.

This means that a patient with haemophilia having commercial factor concentrate during the 1970s was presumably being infected with several hundred strains of HCV at the time of every injection.

Many patients were receiving thirty to fifty treatments every year.

It was therefore inevitable that a patient with haemophilia receiving commercial factor VIII in the 1970s would be infected with HCV.

124.2 There are two studies in the UK from the early 1980s indicating that the incident of HCV in British plasma was around 0.5-1.5%.

If therefore Dr Owen's initiative in 1976 had been successful in establishing self-sufficiency the chances of a haemophilia patient acquiring HCV from voluntary British plasma would still have been considerable as around one in a hundred out of the twenty thousand donors in each batch would still have been infected.

124.3 From this I conclude that the incidence of HCV infection would in fact not have been very significantly reduced by the establishment of self-sufficiency. The incidence of HCV infection did not really decrease until the introduction of second and third generation concentrates in the late 1980s.

The only exception to this would be the small number of patients with mild or moderate haemophilia who had to be treated with concentrate only occasionally.

124.4 The situation with HIV would appear to be different.

We know from the work of Dr Peter Kernoff at the Royal Free hospital using stored blood samples that HIV does not seem to have been detectable in British haemophilia patients until around 1980.

It also seems that the incidence of HIV was very much less in British donor plasma than in American plasma.

In Scotland, where there was self-sufficiency, hardly any patients treated with voluntary donated plasma acquired HIV infection, as compared with the 90% infection rate in England in regularly treated patients.

It is therefore tempting to speculate that if the country had indeed become self-sufficient from 1977 onwards that the number of patients with haemophilia infected with HIV would have been gratefully reduced.

This is retrospective speculation, I stress.

125. I do not recall, from UHCDO data, that the UK was ever self-sufficient in factor IX.

126. Yes, heat treated factor IX, from May 1984, till the advent of recombinant concentrate.

See also question 35.

Section 8: Blood services and BPL

127, 128,129,130. Interactions with BPL were very limited.

I was not using their products from May 1984 onwards when I began using exclusively commercial heat-treated concentrate and then subsequently recombinant concentrate

Section 9: UKHCDO

131. All haemophilia consultants are members of the UKHCDO.

I served on a number of working parties including HIV, Von Willebrands, centre reclassification and transfusion associated disease.

Major policy decisions were the responsibility of the UKHCDO executive, on which I did not serve.

132. UKHCDO has a Secretariat originally based at the haemophilia centre in Oxford but now based in Manchester.

Comprehensive care centre directors meet separately every quarter. There is an annual general meeting of all haemophilia doctors.

A major function of this organisation is the collation of clinical data concerning patients with haemophilia and related disorders.

UKHCDO working parties publish peer-reviewed guidelines to assist haemophilia clinicians in the management of patients.

As the representative body of clinicians, UKHCDO interact with the DOH. There are no formal commercial links.

Information was disseminated to members at the AGM, in writing, and in peer- reviewed publications.

The working parties on which I served, see above, produced guidelines which can be accessed from my curriculum vitae or from the UKHCDO website.

Apart from serving on these working parties, and the CCC committee, my only other relationship to UKHCDO was to provide annual data from my centre.

Section 10: Pharmaceutical companies l medical research clinical trials

133. Yes, detailed advice to all of the commercial companies over the duration of my consultancy.

134. Yes, I regularly gave teaching and training sessions to commercial companies and also served on medical advisory panels of commercial companies.

I received a fee for these professional services.

Under the terms of my NHS contract I was allowed to perform up to ten hours of private work each week. There are only about twenty comprehensive care centre directors in the country and they would all have been active to some extent in this sort of advisory work with commercial companies.

Over the period of twenty-eight years that I was centre director the companies changed names very regularly either because of amalgamation or because they had been taken over.

The medical advisory panels were informal and infrequent, of the order of one a year.

I do not have the dates of my membership to these panels but at the time of my retirement the main companies with whom I was interacting were Bayer, Baxter, Pfizer and Novo Nordisk.

I had no relationship with BPL as I had not used their products since 1984

Core activities of these medical advisory panels were:

- Planning of training days for Haemophilia centre staff
- Planning of training days for blood product company staff
- Writing of publications and information leaflets for Haemophilia doctors, nurses and patients
- Planning residential weekends for Haemophilia patients and families
- Evaluation of possible new blood products for future clinical usage
- Development of support mechanisms for Haemophilia patients and families such as electronic haemophilia diaries to capture home treatment usage

135. See 134.

136. No

137. No

138. No

139. My hospital trust was aware of my interaction with pharmaceutical companies as I was responsible for the purchase of commercial concentrates for the trust

140. Yes, Evaluation studies on new types of coagulation concentrate. See my curriculum vitae

141. As above

142. Yes

Section 11: vCJD

143. Through reading of the scientifically literature and through UKHCDO meetings.

I cannot remember the exact dates

144. Patients were given updated information concerning vCJD at the time of the clinical review.

They were also in receipt of Haemophilia Society literature.

145. See above. I do not recall the date

146. That there was a theoretical risk but that no patient with haemophilia had as yet developed the disease

147. Any patient who seemed unduly concerned was referred to the centre counsellor

Section 12: The Centre's involvement with the financial support schemes

148. I was able to make sure that all relevant patients attending my centre had access to the McFarlane trust and Eileen trusts as I was the medical trustee for these organisations.

Skipton fund leaflets and posters were displayed throughout the centre.

149. See above

150. The process was that a patient registered with the McFarlane trust could make an application for special assistance, in addition to their regular financial support from the trust.

The centre director where the patient was being treated would then be asked by the trust to provide medical information in relation to the patient's condition.

As medical trustee, I would then provide advice to the trust concerning this information.

151. Although I cannot recall the exact details, all Haemophilia centre directors must have provided in confidence a list of HIV and HCV positive patients to the respective Macfarlane and Skipton trusts

152. Applications for financial assistance were solely the responsibility of the trust

Section 13: Your involvement with the financial support schemes

153. I believe that I was appointed by the DOH as the medical trustee for the Macfarlane trust because I had also become an HIV physician.

The main functions of the medical trustee were to attend the board meetings of the trust and to provide medical advice, particularly concerning individual applications for financial assistance .

This involved liaising with the haemophilia centre medical staff where the patient was being treated.

I was also responsible in communicating Macfarlane trust matters of interest to my UKHCDO colleagues.

154. See 153. I had no interactions with the DOH following my appointment

155. Together with the other trustees I was responsible for formulating trust policy during the time that I was their medical advisor

156. See 153.

157. See 153.

158.1 I had initial concerns in the early years of my appointment because the board meetings of the trust seemed to spend more time discussing financial issues rather than discussing the needs of patients.

158.2 Subsequently, the trust executives seemed to follow a policy of providing generalised welfare support for patients, who were expected to be the passive recipients of this funding.

I knew from talking to patients that this is not what they really wanted which was instead to be able to rebuild their lives and to become financially independent.

I therefore formed a view that not enough was being done by the trust to promote patient independence.

These concerns were eventually addressed

I also did not believe that registered patients with the trust were receiving the level of financial support (via lump sums) to which they should have been entitled, considering the very serious viral infections that they had acquired through NHS treatment.

Financial support was significantly greater in other countries, such as in Ireland.

Finally, it was my belief that there was a particular problem with the treatment of widows.

As far as I can recall many of these women, who had given up their work to support their dying husbands, only received six months of financial support following the death of their husband.

This seemed wholly inadequate.

159. No, see 158.

The trust made regular applications to the DOH for increased financial assistance and also lobbied members of Parliament for their support

160. The issue was that patients who had acquired HIV through sexual activity could attend STD clinics on an anonymous basis where they were given a code.

This code was then used when they were being prescribed their antiretroviral therapy resulting in them having free prescriptions.

In contrast, patients with haemophilia, who had been infected by NHS treatment, were expected to pay the prescription charges in full.

As many patients were on several medications this was proving very expensive for them.

I contacted local regional and national pharmacological departments and also discussed this matter in detail with the MacFarlane trust and the DOH. Although all of the organisations I contacted agreed that the situation was completely unfair none of them were able to come up with a way of amending the existing exclusion criteria for prescriptions, which are in any case wholly irrational.

I eventually recommended to haemophilia centres that they should try and persuade their own pharmacy departments to accept prescriptions for haemophilia patients on a code, as in the STD clinic, which allowed the prescriptions to be issued free of charge.

161. I do not recall this conversation.

I was in support of registered patients becoming trustees of the McFarlane trust.

There was however a concern that such a trustee should not attend that part of the board meetings where we were discussing individual requests from other patients for financial support.

162. I can recall several meetings where representatives of the MacFarlane trust met with the health minister and asked for an increase in funding for patients registered with the trust.

My role was to provide medical advice.

I cannot remember the dates of these meetings nor the personnel involved. The outcome was usually pretty negative.

163. See 158.

164. The partnership group was an initiative of the chief executive of the trust.

I was not involved with the establishment of this group and do not recall attending their meetings.

165. I have no recollection of this meeting.

I think the dynamic was that the awareness of yet another possible infectious agent affecting people with haemophilia presented an opportunity for the trust to apply for extra funding.

166. The trust had no policy on assisted conception before I brought this matter to their attention.

My concern was that there were a number of wives and partners of patients with HIV positive haemophilia who had been infected themselves.

There was evolving scientific evidence that the chances of sexual transmission of HIV could be significantly reduced by the process of sperm washing.

This process was however expensive and a further complication was that the chances of success were only around 10% per cycle.

Many couples might therefore need five or six treatments before the wife/partner became pregnant.

The Macfarlane trust originally decided that they could not provide financial support for this treatment.

It then became apparent that a number of health authorities were prepared to provide funding for three cycles of sperm washing to be carried out .

My recollection is that the MacFarlane trust did eventually agree to provide funding for sperm washing for those couples who had failed to conceive after three courses but I have no records of this nor any figures for the number of patients treated.

My own health authority in Kent was supportive and a patient and his wife under my care had two healthy and uninfected children following these procedures.

167 - 171. As per Macfarlane trust

Unlike the McFarlane trust (1300 patients) the Eileen trust was very small with only around twenty to thirty patients.

172. No

173a I have no recollection of this.

173b I think the issue was that the original qualification for Skipton fund support stipulated that the patient had to be both hepatitis C antibody positive and have abnormal liver function tests.

As there are other causes of abnormal liver function aside from viral infection, alcohol for instance, we believed that it would be fairer if the criteria were amended to being hepatitis C antibody positive only.

174. See 158.

I was not involved with the Skipton fund.

Section 14: Haemophilia Society

175a I offered my services to the haemophilia Society when they were campaigning for the establishment of a financial support scheme for patients with haemophilia who had been infected with viruses through their treatment.

I provided medical advice to them, acted as media liaison and on a number of occasions accompanied Haemophilia Society officers to make presentations and to discuss matters with members of parliament.

175b-d These three committees overlapped and did not meet frequently.

Medical advice was given to Haemophilia society trustees .

Projects on patient information leaflets and publications were discussed. Future teaching and training requirements for haemophilia patients and families were discussed.

Section 15: Involvement with the National Haemophilia Alliance

176. By 1999 I had formed the view that one of the major reasons underlying the viral contamination of blood products was the lack of a unified political voice that represented the haemophilia community.

The Haemophilia Society had made their own representations to politicians whilst UKHCDO had been making independent representations to the Department of Health.

These different and unco-ordinated approaches had not resulted in a strong and coherent political voice, and we remained reliant on imported commercial blood products from paid donors.

At the UKHCDO AGM of 1999 I therefore proposed that we should establish a national haemophilia alliance comprising the following organisations:

- UKHCDO
- the Haemophilia Society
- the Haemophilia Nurses Association
- the Haemophilia physiotherapists Association
- the British Social Workers Association
- the Institute of Biomedical Scientists
- the Clinical Scientists group

Apart from representing the unified political voice of the haemophilia community, a major piece of work undertaken by the alliance was the publication of the first ever national service specification for patients with haemophilia.

This set out standards of care at all levels for patients with haemophilia wherever they were and was an attempt to respond to the variable levels of care that had been administered in the past.

This document was formally approved by the DOH.

Section 16: Other issues

177. By the mid-1990s most haemophilia clinicians were fully signed up to the concept of moving their patients away from plasma-derived blood products as soon as possible.

My recollection is that we used recombinant blood products as soon as they were clinically available.

178. Around 1997, as far as I can recall.

179. Clinical complaints were relatively few, particularly given the very complex nature of the work being undertaken at the centre.

All complaints were resolved by either talking to the complainant and/or by writing to them.

No complaints about my clinical activity were submitted to any other body.

180.1 **Medical practice in the 1980s**

Medical practice was very different in the 1980s, particularly in relationship to the issues of patient consent and of patient involvement in decision making.

Overall, there was a more paternalistic approach.

180.2 **Variability of care**

It has always been my view that the level of care offered to some patients in some centres was not what those patients had a right to expect, even by the standards of the day.

It was always very striking to hear at national haemophilia seminars of the very variable standards of care that patients were receiving.

I am particularly aware of the entirely inappropriate way in which some patients were informed of their HIV and hepatitis results and believe that those patients have a right to feel badly let down by their centres.

Relevant to this is that the nature of Haematology training changed in the mid-1970s.

Prior to this Haematologists had been trained in laboratories but under the new system Haematology training required postgraduate experience of general medicine and the passing of the Membership of the Royal College of Physicians exam.

When the viral contamination issues emerged, some centres were therefore being managed by doctors with very limited experience in breaking bad news and dealing with death and dying, unlike the later generation.

180.3 **Classification of haemophilia centres.**

Of particular concern was the way in which haemophilia centres were classified.

There were strict criteria in place, including regular inspection and triennial audit, for the designation of the twenty or so comprehensive care centres.

In addition to these centres, there were a very large number of so-called haemophilia treatment centres, many of which had less than ten patients registered with the centre.

Some of these centres were sited close to each other, and/or to comprehensive care centres.

It did not seem necessary to have so many of these smaller haemophilia centres who were in most regions not subject to regular audit and clinical inspection and where there were no doctors with particular expertise in haemophilia.

This may still be a significant issue which the inquiry may wish to address.

180.4 **Financial support**

As set out above, I have never believed that the level of financial support given to patients with haemophilia who were infected with HIV and hepatitis viruses through their NHS treatment was at all adequate, given the very significant level of physical and psychological suffering.

It is not too late for this serious issue to be addressed.

Statement of Truth

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

Signed ..... GRO-C

Dated 06/08/2023

Table of exhibits:

Date	Notes Description	Exhibit number