SMALLER HAEMOPHILIA CENTRES PRESENTATION

SOUTHAMPTON

Contents

Introduction

1. This note focusses on the Southampton Haemophilia Centre from the 1970s to the early 1990s.

Directors and other key personnel

2. The Centre Director was Dr John Leslie from at least 1972[1] until 1975. He was succeeded by Dr Morag Chisholm in 1975. Dr Chisholm wrote to the Department for Health and Social Security shortly after her appointment:

> *"I have recently been appointed Consultant Haematologist in this hospital and shortly before taking up my appointment spent four weeks at Oxford Haemophilia Centre. My predecessor, Dr. John Leslie was the Director of the Southampton Haemophilia Centre and I would like to be appointed to continue*

[1] HCDO0001015

this work in this area. Dr. Charles Rizza suggested I should write to you and find out if this could be arranged and suggested you might contact him if further discussion was necessary."

3. Dr Chisholm remained in this role until she retired in 1998[2] and was succeeded by Dr Denise O'Shaunessey.

4. Other staff involved in the relevant period included Locum Consultant Haematologist Dr Andrew Bell, Professor R Wright and Dr Colin Smith.[3]

Status of the Haemophilia Centre and relationship with other Haemophilia Centres

5. The Southampton Haemophilia Centre was originally based in Royal South Hants Hospital, Southampton;[4] it had moved to Southampton General Hospital by 1984.[5] It was one of the smaller centres in the Wessex Region. It did not have reference centre status.

6. There was an ongoing relationship between the Southampton Centre and Lord Mayor Treloar College, as patients registered at Southampton and attending Treloar's would divide their time and treatment between the two. See, for example, the letter of 6 December 1979 from Dr Aronstam of Treloar's to Dr Chisholm, informing her that one of her patients was now trained in self-therapy.[6] On at least one occasion, Treloar's also relied on the Southampton Centre in case of emergency care during a school trip. Dr Painter of Treloar's wrote to Dr Chisholm on 20 June 1978:[7]

"The Treloar Schools are organising a camp in the New Forest from the 29th August to 5th September 1978. Amongst the potential campers, there are three haemophiliacs. I am enclosing some details on them so that if they do have a bleed and are brought to your Centre, you will have some information available."

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[2] HCDO0000497
[3] DHSC0041319_005
[4] HSOC0022718
[5] DHSC0002247_090; DHSC0041319_005
[6] TREL0000325_013
[7] TREL0000075_103

Relationship with Regional Transfusion Centre

7. The Southampton Centre received NHS factor VIII from the Wessex Regional Transfusion Centre.[8]

Facilities

8. In 1972, the Haemophilia Society made a grant of £130 to the Centre "to purchase a Shandon immuno-electrophoresis apparatus to be used for diagnosing haemophilia carriers and patients with von Willebrand's disease."[9]

Numbers of patients registered and treated

9. Annual returns data shows the following numbers of patients were registered and treated at the Centre:

    a. In 1976, 22 patients with haemophilia A, two patients with haemophilia B (then called Christmas disease) and one patient with Von Willebrand's disease.[10]

    b. In 1977, 16 patients with haemophilia A, two patients with haemophilia B and one patient with Von Willebrand's disease.[11]

    c. In 1979, 31 patients with haemophilia A, two patients with haemophilia B and one patient with Von Willebrand's disease.[12]

    d. In 1980, 29 patients with haemophilia A, two patients with haemophilia B and two patients with Von Willebrand's disease.[13]

    e. In 1981, 29 patients with haemophilia A, four patients with haemophilia B and three patients with Von Willebrand's disease.[14]

[8] E.g. DHSC0002247_090
[9] HSOC0022718
[10] HCDO0000021_003
[11] HCDO0001203
[12] HCDO0001371
[13] HCDO0001468
[14] HCDO0001570

f. In 1982, 34 patients with haemophilia A, four patients with haemophilia B and one patient with Von Willebrand's disease.[15]

g. In 1983, 33 patients with haemophilia A, one carrier of haemophilia A, two patients with haemophilia B and one patient with Von Willebrand's disease.[16]

h. In 1984, 27 patients with haemophilia A, five patients with haemophilia B and two patients with Von Willebrand's disease.[17]

i. In 1985, 27 patients with haemophilia A, four patients with haemophilia B and three patients with Von Willebrand's disease.[18]

j. In 1986, 27 patients with haemophilia A and two patients with Von Willebrand's disease.[19]

k. In 1987, 29 patients with haemophilia A and three patients with haemophilia B.[20]

l. In 1988, 30 patients with haemophilia A, six patients with haemophilia B and one patient with Von Willebrand's disease.[21]

m. In 1989, 25 patients with haemophilia A and four patients with haemophilia B.[22]

n. In 1992, 23 patients with haemophilia A and four patients with haemophilia B.[23]

Treatment policies and blood product usage

10. The Inquiry does not have witness evidence from any staff member, and there is no document now available setting out any overarching policy approach to product choice.

11. Annual returns data show that in 1976, one patient with Von Willebrand's disease received 18 units of cryoprecipitate. The 22 patients with haemophilia A received:

[15] HCDO0001667
[16] HCDO0001763
[17] HCDO0001857
[18] HCDO0001952
[19] HCDO0002047
[20] HCDO0002136
[21] HCDO0002228
[22] HCDO0002321
[23] HCDO0002411

46,620 units of cryoprecipitate; 22,500 units of NHS factor VIII; 6,750 units of Armour Factorate; 16,750 units of Hyland Hemofil; and 9,500 units of Immuno Kryobulin. Two patients with haemophilia B received 14,400 units of NHS factor IX concentrate.[24]

12. In 1977, the patient with Von Willebrand's disease received 5,000 units of NHS factor VIII concentrate (if this was the same patient as was treated the previous year, they had switched over from cryoprecipitate). The 16 patients with haemophilia A received: 5,740 units of cryoprecipitate (a steep decrease); 95,750 units of NHS factor VIII; 4,760 units of Armour Factorate; 7,830 units of Cutter Koate; 500 units of Hyland Hemofil; and 900 units of Immuno Kryobulin. Two patients with haemophilia B received 32,400 units of NHS factor IX concentrate.[25]

13. In 1978, Dr Chisholm also expressed an interest in using factor VII concentrate. On 9 February 1978, Dr Chisholm wrote to Dr Bidwell at the Plasma Fractionation Centre in Oxford:[26]

> *"Following our discussion at the recent Haemophilia Directors meeting I am writing to ask if it would be possible for you to let me have a supply of Factor VII concentrate. Recently a patient on Warfarin died from a subdural haematoma because we were unable to correct the prothrombin time completely. In addition we would like to have a supply of Factor VII to treat the bleeding complications in patients with severe liver disease, where other methods have failed. The use of Factor VII concentrate to correct the coagulation defect in patients prior to liver biopsy was discussed at some length at the Oxford meeting recently and I feel this may be a further area in which Factor VII could be useful to us."*

14. Dr Bidwell replied on 13 February 1978:[27]

> *"As you are aware we have recently developed a factor VII concentrate for therapeutic use. We have not yet applied for a product licence for this material as you will appreciate the Committee on Safety of Medicines requires a greet*

[24] HCDO0000021_003
[25] HCDO0001203
[26] BPLL0004249_002
[27] BPLL0004249_001

real of supporting data as well as a lot of paper work before such an application would be considered. It has been used in a few patients with congenital factor VII deficiency under the provision for the treatment of named patients but I am uncertain whether the regulations would permit us to supply it for un-named patients. As you are probably aware, this laboratory is a subsidiary of the Blood Products Laboratory and I am therefore sending your letter to Dr. Maycock for his decision."

15. Dr Maycock followed up on this correspondence by letter of 23 February 1978 to Dr Bidwell:

> *"I am writing about the correspondence you have had with Dr. Chisholm (letters of 9th and 13th February, 1978). I have discussed this matter with Dr. John Holgate. He feels that in the case of coagulation factor preparations of a rather unusual kind, it would be in order to release them in a limited way to users like Dr. Chisholm on condition that they submitted reports of the results of infusion in all instances. This procedure would in sense be as though the preparation were personally prescribed for each patient. Dr. Holgate felt that until we had collected more information about clinical effects of this preparation, it would be pointless to go to the trouble of submitting a licence application. I would like to discuss this procedure with you when you are back. It is not the intention of Medicines Division that the material should be broadcast to all who might request it. It should be distributed to selected users."*

16. In 1979, one patient with Von Willebrand's disease received 2,250 units of cryoprecipitate and 245 units of NHS factor VIII concentrate. The 31 patients with haemophilia A received: *nil* cryoprecipitate; 167,555 units of NHS factor VIII; 9,400 units of Armour Factorate; 9,635 units of Hyland Hemofil; and 30,080 units of Immuno Kryobulin. Two patients with haemophilia B received 24,000 units of NHS factor IX concentrate.[28]

17. In 1980, two patients with Von Willebrand's disease received cryoprecipitate and NHS factor VIII concentrate (the quantities are unclear on the page of the annual returns form). From this date onwards, the annual returns forms distinguish between usage in

[28] HCDO0001371

hospital (both inpatient and outpatient) and use for home therapy. The 29 patients with haemophilia A received: 650 bags of cryoprecipitate, administered in hospital; 33,605 units of NHS factor VIII in hospital and 108,100 units dispensed for home treatment; 27,750 units of Armour Factorate in hospital and 32,500 units used for home treatment; and 6,500 units of Immuno Kryobulin in hospital. Two patients with haemophilia B received 23 bottles of NHS factor IX concentrate, of which 13 were administered in hospital and 10 dispensed for home treatment.[29]

18. In 1981, three patients with Von Willebrand's disease received 88 bags of cryoprecipitate and 8,685 units of NHS factor VIII concentrate, all administered in hospital. The 29 patients with haemophilia A received: 550 bags of cryoprecipitate, administered in hospital; 25,855 units of NHS factor VIII in hospital and 122,735 units dispensed for home treatment; 39,962 units of Armour Factorate for home treatment; 18,720 units of Cutter Koate for home treatment; 2,176 units of Hyland Hemofil in hospital and 12,512 units for home treatment; and 2,450 units of Immuno Kryobulin in hospital and 19,919 units for home treatment. Four patients with haemophilia B received 21,725 units of NHS factor IX concentrate, of which 9,725 were administered in hospital and 12,000 dispensed for home treatment.[30]

19. In 1982, the patient with Von Willebrand's disease received 1,260 units of cryoprecipitate and 6,975 units of NHS factor VIII concentrate, all administered in hospital. The 34 patients with haemophilia A received: 31,920 units of cryoprecipitate, administered in hospital; 14,537 units of NHS factor VIII in hospital and 132,580 units dispensed for home treatment; 4,140 units of Armour Factorate in hospital and 16,165 for for home treatment; 1,500 units of Cutter Koate in hospital and 6,700 for home treatment; 2,320 units of Hyland Hemofil in hospital and 9,280 units for home treatment; and 8,286 units of Immuno Kryobulin in hospital and 82,440 units for home treatment. Four patients with haemophilia B received 32,910 units of NHS factor IX concentrate administered in hospital and 4,880 units dispensed for home treatment.[31]

20. In 1983, 33 patients with haemophilia A were treated, one carrier of haemophilia A, two patients with haemophilia B and one patient with Von Willebrand's disease. The

[29] HCDO0001468
[30] HCDO0001570
[31] HCDO0001667

haemophilia A patients received: 578 bags of cryoprecipitate administered in hospital (a later annotation appears to show this was 40,370 units); 52,335 units of NHS factor VIII in hospital and 133,790 for home treatment; 52,597 units of Armour Factorate, all used for home treatment; 12,952 units of Hyland Hemofil in hospital and 16,976 units of Hemofil for home treatment. The haemophilia A carrier received 1,800 units of Armour Factorate in hospital. The Von Willebrand's disease patient received 12 bags of cryoprecipitate in hospital. The two haemophilia B patients received 16,860 units of NHS factor IX concentrate in hospital and 9,955 units for home treatment, and no other materials.[32]

21. On 17 October 1983, Dr Chisholm attended the 14th Meeting of UK Haemophilia Centre Directors. The minutes record:[33]

> *"Dr. Chisholm raised the problem of patients refusing to take up commercial factor VIII concentrate because of the AIDS scare. She wondered in view of the worry of the patients whether the Directors could revert to using cryoprecipitate for home therapy. Professor Bloom replied that he felt that there was no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. Dr. Chisholm pointed out that there was a further problem in her region because of problems in getting large amounts of commercial concentrates whereas she could get unlimited supplies of cryoprecipitate. Other Directors reported that they had the same problems. After discussion it was agreed that patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in their usual way."*

22. Dr Chisholm appears to have followed this advice, despite her misgivings. Cryoprecipitate was not prescribed for home therapy at the Southampton Centre. The annual returns data for 1984 show 27 patients with haemophilia A were treated, five patients with haemophilia B and two patients with Von Willebrand's disease. The haemophilia A patients received: 237 bags of cryoprecipitate administered in hospital; 47,355 units of NHS factor VIII in hospital and 168,250 for home treatment; 815 units

[32] HCDO0001763
[33] PRSE0004440

of Armour Factorate in hospital and 71,190 units used for home treatment; 18,760 units of Cutter Koate in hospital and 18,240 units for home treatmen; and 3,600 units of Travenol Hemofil for home treatment. The Von Willebrand's disease patients received 15 bags of cryoprecipitate in hospital. The two haemophilia B patients received 38,190 units of NHS factor IX concentrate in hospital and 48,960 units for home treatment, and no other materials.[34]

23. Dr Chisholm expressed an interest in participating in trials of heat-treated factor concentrates in 1984. On 11 April 1984 she wrote to Dr Rizza at the Oxford Centre:[35]

> "*The recent memo sent out to all UK Haemophilia Centre Directors about trials about Hepatitis reduced Factor VIII asked for a list of available patients to evaluate the hepatitis risk of various Factor VIII concentrates. It is not entirely clear from the memo but am I right in saying that only patients who have not been previously exposed to a blood product would be eligible for entry to the Trial. I do not know of any such patients on my list at present, but should any arise, what would you wish me to do?*"

24. Dr Rizza replied on 30 April 1984:[36]

> "*Thank you for your letter of 11th April, 1984 which I received on my return from holiday. You are asking questions about the recent memorandum sent round to the U.K. Directors concerning trials of hepatitis reduced factor VIII. The ideal patients are those who have never refused any transfusions of blood products but those patients may be hard to come by and I think we may have to make use of patients who have received some material in the past. Providing they have not received blood products within the previous year, we should be able to obtain valuable information from them. With regard to the last question in your letter, should a previously untransfused patient require surgery I wonder if you could let Miss Spooner know details of the patient and in particular which blood product you plan to use in him or her. If all of the directors keep us informed we shall be able to see whether or not one blood*

[34] HCDO0001857
[35] OXUH0001890_002
[36] OXUH0001890_001

product is being tested in preference to others. It would be nice with our colleagues collaboration to be able to arrange for all the various blood products to be tested in a reasonably standardised way and so get information which will help us all when deciding which product is safest."

25. It is not known to what extent patients at the Southampton Centre were subsequently involved in such trials.

26. On 19 February 1985, Dr Andrew Bell, Locum Consultant Haematologist at the Southampton Centre wrote to Dr Snape at BPL regarding heat-treated NHS material:[37]

> "*Thank you for your letter regarding the allocation of heat-treated Factor VIII concentrate. I enclose a list of patients registered at the Southampton Haemophilia Centre who I would wish to receive this product when it becomes available. I should add that it may not be possible to supply all the information you have asked for on these patients because of the way in which we operate here but we will do our best to oblige.*"

27. This was followed by a list of names of "*patients likely to require heat-treated factor VIII concentrate*"; the criteria applied are not known.

28. Later in 1985, the Southampton Centre was alerted to possible contamination of a batch of heat-treated commercial factor VIII supplied by Armour Pharmaceutical Ltd. C R Bishop of Armour wrote to Dr Bell on 10 May 1985:[38]

> "*CONFIRMATION OF TELEPHONE ADVISE 10th MAY 1985 HEATED TREATED FACTORATE BATCH No. Y69402*
> *As a result of the on-going United States surveillance programme, we have been advised that one donor, whose plasma was incorporated into pools from which our Antihaemophilic Factor, FACTORATE I, was produced, has developed acquired immune deficiency syndrome (AIDS). When this donor was giving plasma, we exerted our strict routine screening, the donor showed no indications of ill-health, stated he was not a member of any risk group associated with AIDS, and was on active military duty. Only one batch in the*

[37] CBLA0011568
[38] ARMO0000379

United Kingdom is implicated. Fortunately this is a heat treated batch No. Y69402. This small, heat treated batch was distributed in December 1984 and January 1985 to a few centres only, of which yours is one, and we anticipate that the product has already been used. If you should still hold any of this batch, kindly notify us so that we can arrange for its return. We shall effect reimbursement or replacement as you choose. Do not hesitate to contact me, should you require any further information."

29. This was followed on 4 June 1985 by a further letter from R B Christie at Armour to Dr Bell:[39]

> "*RE: HEAT TREATED FACTORATE BATCH NO. Y69402*
> *Further to Mr. Bishop's letter of 10th May, we have been advised by the Department of Health that they would be very interested if all patients who have received this batch of material could be followed up for HTLV-III antibody conversion and/or any clinical or haematological signs of AIDS or pre-AIDS symptomology. They would also like to know the numbers of patients who received this particular batch of material. It would be extremely helpful if you could assist in this matter in the following way: (i) Provide the number of patients who received Factorate batch Y694Q2, the dose and the number of separate occasions that the product was administered to individual patients. (ii) If known, the HTLV-III antibody status of these patients prior to receiving Y694G2. (iii) The patient's clinical condition and immunological status prior to receiving Y69402. (iv) The patient's current HTLV-III antibody status, and clinical condition, T4 T8 lymphocyte ratio, etc., and then a follow-up at approximately six month intervals for two years. All information will be treated in the strictest confidence and it is not necessary to identify patients by name.*
> *I realise that this request imposes an additional burden on your unit, but it is an unusual opportunity to assess the effectiveness of heat treatment in rendering a batch of Factor VIII safe which was known to contain plasma from a donor who has developed AIDS. Your kind assistance would be much appreciated. If*

[39] ARMO0000398

we can help in any way, please let me know. We are making a similar request to the other centres who received the batch in question."

30. It is not known whether Dr Bell complied with this request.

31. In 1985, 27 patients with haemophilia A were treated, four patients with haemophilia B and three patients with Von Willebrand's disease. The haemophilia A patients received: 556 bags of cryoprecipitate administered in hospital; 31,135 units of NHS factor VIII in hospital and 154,945 for home treatment; 47,005 units of Armour Factorate in hospital and 134,800 units used for home treatment; 7,080 units of Cutter Koate in hospital and 18,900 units for home treatment. The Von Willebrand's disease patients received 190 bags of cryoprecipitate in hospital. The four haemophilia B patients received 12,955 units of NHS factor IX concentrate in hospital and 11,190 units for home treatment.[40]

32. The Centre treated 27 patients with haemophilia A in 1986, and the materials used for their treatment were: 180 bags of cryoprecipitate administered in hospital; 247,955 units of NHS Factor VII in hospital and 201,185 units provided for home treatment; 71,570 units of Armour Factorate in hospital and 59,765 units at home; 21,950 units of Cutter Koate in hospital and 19,200 units at home; 58,780 units of Travenol Hemofil in hospital and 45,920 units at home. Two patients with Von Willebrand's disease received 60 bags of cryoprecipitate and 440 units of NHS Factor VIII, all in hospital.[41]

33. The Centre treated 29 patients with haemophilia A in 1987, and the materials used for their treatment were: 299 bags of cryoprecipitate administered in hospital; 50,445 units of NHS Factor VII in hospital and 112,370 units provided for home treatment; 25,250 units of Alpha Profilate in hospital and 44,580 units for home treatment; 5,280 units of Cutter Koate at home; 52,420 units of Travenol Hemofil in hospital and 124,170 units at home. No patients with Von Willebrand's disease were treated that year. Three patients with haemophilia B received 34,975 units of NHS factor IX concentrate at hospital and 12,800 units for home treatment.[42]

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[40] HCDO0001952
[41] HCDO0002047
[42] HCDO0002136

34. The Centre treated 30 patients with haemophilia A in 1988, and the materials used for their treatment were: 53 bags of cryoprecipitate administered in hospital; 293,750 units of NHS Factor VII in hospital and 226,570 units provided for home treatment; 189,180 units of Alpha Profilate in hospital and 40,050 units for home treatment; and 720 units of Travenol Hemofil in hospital. One patient with Von Willebrand's disease received 6 bags of cryoprecipitate. Six patients with haemophilia B received 86,860 units of NHS factor IX concentrate at hospital and 27,180 units for home treatment.[43]

35. On 25 May 1989, Dr Chisholm wrote to Dr R D Hyde, Manager of the Department of Haematology and Blood Transfusion, Southampton General Hospital.[44] She referred to the recent use of factor products as follows:

> "*In response to your recent letter asking about coagulation product usage in the Southampton Haemophilia Centre, I have checked our records and been in touch with the BPL and Andrew Herborne. The small table lists the average usage of Factor VIII and Factor IX over the past three years which should give a reasonable estimate of our budgeting requirements. It appears there is still some stock of plasma at BPL which will enable us to have a continuing supply for a limited period of Factor VIII and possibly Factor IX free of charge. Neither the BPL nor Andrew were certain about the Factor IX but I could continue to order this directly from BPL for the time being and we will wait to see if we are to be charged for this.*
>
> *With regard to the other Factors (VII, XI, XII, anti-thrombin III) I have not had to use these products in recent years so it is not possible to budget for these.*
>
> *Andrew tells me that the annual delivery of plasma to BPL from the Wessex Region is 20.7 tons which gives us a credit of £800,000 but the use of Factor VIII alone is well over £1,000,000. In order to reduce the shortfall it may be that the region will increase the amount of plasma reduced blood it issues; this currently is 77% of the total and so could be increased. Apparently France has a 100% production of plasma reduced blood. The question of albumin is one*

[43] HCDO0002228
[44] NHBT0111305_002 & 003

that needs to be addressed; this is the second biggest item on the Southampton Hospitals' drug expenditure(approximately £114,600 per annum) and I have suggested to Dr. Saunders, who writes the Southampton Newsheet, that an article on albumin, if not already written, would be worth doing."

36. She appended to the letter a table showing average usage of factor VIII and factor IX in the Southampton Centre between 1986 and 1988. In 1986, 27 patients used 400,695 units of factor VIII (mean of 14,840 units per patient) and 3 patients used 31,235 units of factor IX (mean of 10,412 per patient).[45] In 1987, per patient usage of factor VIII declined slightly; 29 patients used 414,515 units, giving a mean of 14,294 units per patient. The usage of factor IX by 3 haemophilia B patients increased to 47,775 units (mean of 15,925 per patient). In 1988, usage of factor VIII increased. 30 patients used 483,650 units, giving mean usage of 16,122 units per patient. There were 6 patients who required factor IX that year and they used 86,860 units, giving a mean of 14,477 units per patient.

37. Looking again at the annual returns data, the Centre treated 25 patients with haemophilia A in 1989, and the materials used for their treatment were: 21 bags of cryoprecipitate administered in hospital; 107,080 units of NHS Factor VII in hospital and 440,095 units provided for home treatment; 33,120 units of Alpha Profilate in hospital and 12,480 units for home treatment. No patients with Von Willebrand's disease were treated that year. Four patients with haemophilia B received 22,490 units of NHS factor IX concentrate at hospital and 28.050 units for home treatment.[46]

38. The Centre treated 23 patients with haemophilia A in 1990, and the materials used for their treatment were: 195,400 units of NHS Factor VII in hospital and 376,755 units provided for home treatment. No patients with Von Willebrand's disease were treated that year. Four patients with haemophilia B received 16,035 units of NHS factor IX concentrate at hospital and 38,260 units for home treatment.[47]

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[45] These figures do not match exactly the annual returns data; it is not possible to ascertain the reason for the discrepancy.
[46] HCDO0002321
[47] HCDO0002411

Knowledge of risk of hepatitis and HIV and response to risk

39. On 18 July 1975, Dr Kirk wrote to Dr Chisholm regarding one of twelve patients who were treated at Royal South Hants Hospital with a batch of Kryobulin factor VIII concentrate found to carry HBV:

> "*Within the last few days it has come to my attention that twelve patients treated at this Centre have been given a material which has proved to be HBsAg positive by radio-immunoassay testing. - The above patient received the material (Kryobulin factor VIII concentrate Nr. 09M6575) on 23rd June 1975. This patient on previous testing has no antibody to hepatitis B and there is a real possibility of him developing jaundice over the next few weeks. In this event would it be possible to receive two 10ml. samples of clotted blood for antibody and antigen tests?*"

40. The Inquiry does not have a record of her reply, but this shows that the risk of hepatitis infection from factor concentrates would have been recognised. Dr Chisholm also submitted data for the Hepatitis Survey conducted from the Oxford Centre. See, for example, correspondence in October to November 1977, in which Rosemary Spooner chased for completed hepatitis forms for one patient following the submission of annual returns data that year.[48]

41. A further form submitted in 1982 relates to a patient who received Kryobulin, Lister Factor VIII and a blood transfusion. He developed hepatitis in late February 1982 with symptoms including jaundice and raised LFTs. He tested negative for HBsAg.[49]

42. Another form submitted in 1983 concerns a patient who was diagnosed with asymptomatic hepatitis following a routine liver function test in October 1982. He had previously received Immuno Kryobulin, Armour Factorate and Lister factor VIII. He was noted to be HBsAg positive on three successive tests from October 1982 to February 1983.[50]

[48] HCDO0000021_003 &HCDO0000021_002
[49] HCDO0000260_362
[50] HCDO0000260_362

43. Treloar's monitored its students for hepatitis, including by regular liver function tests, and this information was passed back to the Southampton Centre in respect of its patients. See, for example, a termly update from Dr Wassef of Treloar's regarding one student sent to Dr Chisholm on 12 December 1979:[51]

> *"Biochemically during the past ten months his S.G.O.T. has been persistently raised, total proteins have been mostly raised and Gamma G.T. only recently raised."*

44. Dr Chisholm first attended a UKHCDO meeting on 17 October 1983 (discussed above) at which the risk of AIDS was discussed.[52] Thereafter she attended the annual meetings in 1988, 1989, 1992, 1995, 1996 and 1997. It may reasonably be assumed that she would have received copies of minutes of UKHCDO meetings during her time as director and would through that means have become aware of the discussions of risk taking place at the meetings; she would also have received the communications from Dr Craske/Dr Rizza/Professor Bloom in March and June 1983.

45. A number of witnesses to this Inquiry have noted that they, or their relatives, were not informed of the risks connected with the blood products that they were receiving.[53]

HLTV-III testing and informing of diagnosis

46. As noted above, Dr Chisholm raised the problem of patients refusing to take up commercial factor VIII concentrate because of the 'AIDS scare' at the UKHCDO meeting on 17 October 1983.[54] On 4 October 1984, a notification letter was sent from the Wessex Regional Transfusion Centre to a number of haemophilia centres, including to Dr Chisholm at the Southampton Centre.[55] It warned:

> *"B.P.L. Factor VIII Batch No. H.L.3186*

[51] TREL0000073_025
[52] PRSE0004440
[53] WITN1885001 (6 – 7); WITN1962001 (5 – 6); WITN0080001 (4.1)
[54] PRSE0004440
[55] DHSC0002247_090

With further reference to Mr. Allison's telephone call to your Blood Bank Chief MLSO yesterday, asking for the above quoted batch of Factor VIII to be recalled and returned to us. The reason for this is that one of the donors whose plasma was incorporated in this pool is now thought to be suffering from AIDS. Investigations are being carried out and the diagnosis should be settled, one way or the other, within the next week or two. In the meantime, may I confirm Mr. Allison's request and ask for all unused ampoules of this batch to be recalled and returned to this Centre. In order to prevent undue worry to your patients, may I ask for your discretion here and, for the time being at least, to keep this new to yourself. When any definite information does become available, either Dr. Smith or myself will let you know."

47. It appears that eight patients at the Southampton Centre were potentially affected.[56] Two were students at Treloar's: Dr Andrew Bell, Locum Consultant Haematologist at Southampton, wrote to Dr Aronstam at Treloar's on 3 December 1984:[57]

> "*These two brothers were issued with NH Batch No. HL3186 Factor VIII from the Southampton Haemophilia Centre recently (10 bottles on 22. 8.84 and a further 3 bottles on 29. 8.84). I understand from the notes that you are keeping them under review and as far as I can tell there are no arrangements to follow them up in Southampton. If this is not the case, perhaps you could let me know*."

48. A follow up letter was sent by Dr Snape of BPL on 24 January 1985 to a distribution list including Dr Chisholm:[58]

> *"Follow – up of Patients Treated with Factor VIII Batch HL3186*
> *In October 1984 you were informed by Dr. D.S. Smith, Director of Wessex RTC, of the need to recover and return to BPL all unused vials from batch HL3186, following confirmation of the inclusion, in the plasma pool from which the batch was manufactured, of plasma from a confirmed AIDS sufferer. With your assistance this recall was completed promptly and effectively. As you know, the follow-up of patients treated with batch HL3186 is being co-ordinated by Dr.*

[56] CBLA0000010_194
[57] TREL0000110_040
[58] CBLA0001997

John Craske, PHLS, Manchester. I understand from Dr. Craske that he has received very poor response to requests for details of patients treated with this batch, and an even less satisfactory response to requests for samples of patients' sera. I would urge you to give Dr. Craske your complete support in the identification of patients treated with this batch, and in the clinical follow-up outlined in Dr. Craske's letter of 20th November, 1984. BPL has no direct role in clinical follow-up, but I am required to furnish a report on the effectiveness of the recall procedure and the extent of treatment with this compromised batch. To this end I would be grateful if you would supply me with a list of patients treated with batch HL3186 (with a copy to Dr.Craske if you have not already supplied this information to him)."

49. Dr Bell responded on behalf of the Southampton Centre on 29 January 1985:[59]

> "*Thank you for your letter of the 24th January regarding follow up of patients treated with Factor VIII Batch HL3186. All eight patients exposed to this batch at Southampton have been informed of the problem and sera from seven of these patients have been sent to Dr. John Craske. One of the eight patients* [name supplied] *is being followed up by Dr. A. Aronstam at Lord Mayor Treloar College, Alton, although he was supplied with Factor VIII from this Centre. The names of the eight patients are as follows*: [names provided]."

50. It appears therefore that despite the initial request for 'discretion', in order "*to prevent undue worry to your patients",* the Southampton Centre took the approach of informing potentially affected patients, although it is not known what if anything they were told about the provision of sera to Dr Craske.

51. On 12 February 1986, Dr Chisholm wrote to the GP of one of her patients:[60]

> *"... this lad with severe haemophilia is in reasonable condition ... He continues to be worried by the HTLVIII positivity and I tried to reassure him as best I can. His full blood count is normal and he is well but clearly there are social problems which are disturbing both to him and perhaps more so to his mother*."

[59] CBLA0000010_194
[60] TREL0000110_026

Numbers infected with HIV and seroconversion dates

52. The Inquiry does not have data on the number of seroconversions amongst Southampton patients. A standard form relating to one patient, enclosed with a note dated 8 January 1987, lists his anti-HIV negative and positive test dates, the approximate date of his first dose of heated factor VIII, a list of the types of factor VIII concentrate he was exposed to in the 12 months before sero-conversion, the batch numbers and dates of the usage of each. This patient seroconverted between February and October 1985. He had received Koate, Armour and Lister material.[61]

Testing for HCV

53. A number of witnesses to the Inquiry recalled that they or the infected individuals were tested without their consent or knowledge. One infected witness recalled that they "*did not sign anything to give my consent for a hepatitis C test*" and that they believed that "*they must have had that positive result on their system for so long. I think that they were frightened to tell everyone and that they thought that ignorance was bliss*"[62].

54. Various witnesses recalled that the method or manner in which the medical professionals or institutions adopted to communicate the diagnosis to them was inappropriate. One witness recalled:

> "*In 1994 I attended a routine check-up with my haematologist at the Southampton Hospital haemophilia centre. At the end of the appointment I got up to leave the room, I had my hand on the door handle and was just going to open the door when my consultant told me that he needed to tell me something. He said that it was his last day in the job before he retired and this was the last time that I would see him. He told me that I had hepatitis C and said that he needed to tell me because he did not want it on his conscience. He advised me to go and enjoy the rest of my life.*
>
> *I sat down again and asked him what he meant. He said again that I had hepatitis C. He told me that it was a blood borne virus that potentially can kill you, he told me to go and enjoy the time I had, and I should go to Disneyland.*

[61] HCDO0000132_035
[62] WITN1885001 (20)

This appointment had been late in the day on a Friday which meant that I had all weekend to think about it before being able to speak to my doctor. The only thing I could think of was that hep C was exactly the same as HIV. I told my wife to go and find someone else so that she could enjoy her life. We had just had a baby boy; I was looking at him and just could not stop thinking about what was going to happen and about what he would do without me. I felt that I could not touch my child; I could not touch my wife. Every minute felt like a day."[63]

55. Another individual who was infected with HCV (by blood transfusion rather than through treatment at the Centre), recalled how they were informed by letter from the blood transfusion service at Southampton and that the "*letter was very basic; it simply stated that Hepatitis C had been picked up in the donation that I had given. There was a lot of emphasis in the letter that it was only Hepatitis C and that no other serious infections had been found. I guess they were saying that HIV had not been detected. The letter requested that I phone to make an appointment*". This individual goes onto note that "*it was very wrong to just send a letter in the post informing me that I had Hepatitis C. I was extremely distressed on reading the letter, I read it over and over again. I just could not take the information on board I thought it must be a mistake*". This witness then saw a Consultant Haematologist at the Haematology unit at Southampton General Hospital and after some discussion was informed that the blood transfusions "*I had received in 1988 were the most likely route of my Hepatitis C infection. I felt that the seriousness of the infection was played down*".[64]

56. A common experience that was felt by a number of witnesses was that they received limited information at the time of their diagnosis by the medical practitioners involved.[65]

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[63] WITN1885001 (11 – 13)

[64] WITN1974001 (6 – 7)

[65] See for instance WITN1885001 (17) who noted: 'I do not believe that I was given adequate information to help me manage and understand the infection. My diagnosis was very poorly communicated to me. The most information I got was from the Haemophilia Society in London'; see also WITN1962001 (19 – 21)

Other issues

57. On 31 July 1989, Dr Chisholm wrote to John Williams of the Macfarlane Trust:[66]

> "*Thank you for your recent note listing the 10 patients registered with the Southampton Haemophilia Centre who have registered with the Trust. In addition to those there is one further patient, the girl friend of a haemophiliac who died last year, who I believe has registered independently with the Trust. I am not sure if her circumstances enable her to have equal claim on the Trust. I would appreciate clarification of this issue.*"

58. On 9 October 1989, Dr Chisholm attended the 21st meeting of Haemophilia Centre Directors. The minutes record that when the topic of HIV litigation was discussed, "*Dr. Chisholm asked about cost to the patients of taking action and what the Directors could do to help them. Dr. Jones said the patients were now being asked to put down £7,000.*" Later in the meeting, she also requested a future discussion regarding management of patients with inhibitors.[67]

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[66] MACF0000175_036
[67] HCDO0000015_035