SMALLER HAEMOPHILIA CENTRES PRESENTATION

BRISTOL

Contents

Introduction

1. This note focusses on haemophilia care at the Bristol Children's Hospital ('BHC') and Bristol Royal Infirmary ('BRI') during the 1970s and 1980s. The Bristol Haemophilia Centre was located over the haematology departments of both hospitals, with adults and children treated separately.

Directors and other key personnel

2. At the BRI, Dr A B Raper was the Director from 1968 to 1976. His successor was Dr G L Scott, who held the position until the year 2000.[1]

3. At BCH, Consultant Paediatrician Dr David Burman was in post from 1978 until 1987.[2] He held joint haemophilia clinics with Dr Scott.[3] Both Dr Scott and Dr Burman were invited to UKHCDO meetings, although in practice usually one or the other would attend.[4]

4. Dr Helena Daly was Senior Registrar in the haematology department of the BRI during 1979-1985, with training rotation placements at the BCH and the Regional Blood Transfusion Centre. She also attended the joint haemophilia clinic with Dr Burman at BCH.[5]

Status of the Haemophilia Centre and relationship with other Haemophilia Centres

5. Bristol, along with Exeter, was one of the largest Haemophilia Centres in the South West Region, with other regional centres described as "associated centres".[6] However, they also sat within the Oxford Haemophilia Supraregion; see the minutes of the 2nd meeting of the Haemophilia Centre Directors and Blood Transfusion Centre Directors within the Oxford Haemophilia Supraregion on 19 June 1978, which was the first attended by Dr Burman and Dr Scott.[7] It appears that BHC was listed for the first time as an associate centre on this occasion, although it is more common to see the BRI and BHC collectively referred to as the Bristol Centre.

Facilities and staffing in the 1970s and 1980s

6. In February 1976, a directory of haemophilia centres noted the contact details for the Department of Haematology at the BRI, said to be contactable on weekdays 9am to 5pm ("*please ask for the Sister-in-Charge*"). Outside those hours, patients were directed to contact the Accident and Emergency Department.[8] By 1978, the directory

---

[1] WITN4685002
[2] WITN1574001 §6
[3] TREL0000243_039
[4] E.g., PRSE0004377
[5] WITN4685001 §2.3 & 6.2-6,3
[6] CBLA0009439
[7] OXUH0003765_020
[8] OXUH0003570_009

also listed separate contact details for BHC as follows: "*Children: Dr D Burman, Dr GL Scott, Casualty Department, Bristol Children's Hospital. (Children are treated in the Casualty Department; please telephone beforehand and ask for Dr Burman's house physician.)*"[9]

7. Dr Daly describes the "comprehensive 24 hour clinical and laboratory haematology service for the area" provided by the haematology department at the BRI during her time there (1979-1985):[10]

> "*A well-equipped Haematology laboratory which undertook a comprehensive range of investigations including coagulation.*
> *Inpatients were cared for in a ward shared within the professorial unit and on other general wards.*
> *There was a designated haematology day unit where patients attended for OP chemotherapy, procedures e.g. bone marrow biopsy, treatments of bleeding episodes.*
> *Formal OP clinics were held weekly in the OP Dept.*
> *Treatment of bleeding episodes outside routine hours was undertaken by the Pathology SHOs (on call rota) in the day unit on a demand basis*."

8. The staffing complement comprised one consultant haematologist (Dr Scott), two senior registrars (including herself), one registrar, and 2-3 rotating pathology SHOs. There was a full-time haematology day unit sister, several SRNs (state registered nurses) and several SENs (state enrolled nurses).[11]

9. In 1989 the Haemophilia Society agreed to fund a part-time physiotherapist[12] although it appears an appointment was not made until 1991.[13]

Numbers of patients registered and treated

10. In 1971 there were 27 patients treated at the BRI for haemophilia and Von Willebrand's disease.[14]

---

[9] HCDO0000138_007
[10] WITN4685001 §6.1
[11] Ibid
[12] HSOC0029690_010
[13] HSOC0029615
[14] CBLA0000083

11. In 1975 there were 15 patients with severe haemophilia and "a number of others who attend infrequently for treatment".[15]

12. The first available annual returns data are for 1976. They show that year the Bristol Centre treated 39 patients with haemophilia (i.e., haemophilia A), 7 with Christmas disease (haemophilia B), and 5 with Von Willebrand's disease, including adults and children.[16]

13. In 1977, there were 38 patients with haemophilia A, 9 with Christmas disease / haemophilia B and 4 with Von Willebrand's disease.[17] In 1978 there were 36 patients with haemophilia A, 6 with Christmas disease / haemophilia B, and 3 with Von Willebrand's disease.[18]

14. In 1979, the breakdown was separated into adults and children. At the BRI there were 20 adult patients with haemophilia A, 8 with Christmas disease and 2 with Von Willebrand's. At the BHC, there were 10 children who received treatment for haemophilia A and 1 with Von Willebrand's disease. [19]

15. By 1980, the data for adults and children was once again combined. There were 31 haemophilia A patients, 7 haemophilia B patients and 4 patients with Von Willebrand's disease.[20] In 1981, there were 35 haemophilia A patients, 10 haemophilia B patients and 6 patients with Von Willbrand's disease.[21] The following year, the annual returns data omitted the number of patients, save that there were 12 patients with haemophilia B.[22]

16. In 1983, the number of patients with haemophilia A had increased to 48, there were 11 patients with haemophilia B and 9 with Von Willebrand's disease.[23] In 1984 there were 37 haemophilia A patients, 9 haemophilia B patients and 9 von Willebrand's patients, as well as one patient with a factor XIII coagulation defect.[24] In 1985 there

---

[15] CBLA0005695
[16] HCDO0000023_002
[17] HCDO0001143
[18] HCDO0001238
[19] HCDO0001307
[20] HCDO0001402
[21] HCDO0001500
[22] HCDO0001603
[23] HCDO0001699
[24] HCDO0001795

were 47 haemophilia A patients, 8 haemophilia B patients and 6 Von Willebrand's patients, as well as 2 patients with factor XIII deficiency.[25] In 1986, there were 40 haemophilia A patients, 11 haemophilia B patients, 6 Von Willebrand's patients and 2 patients with factor XIII deficiency.[26] In 1987, there were 46 haemophilia A patients, 7 haemophilia B patients, 2 von Willebrand's patients and 2 patients with Factor XIII deficiency.[27]

17. Annual returns data for 1988 record there were 45 patients with haemophilia A, 6 patients with haemophilia B and 6 patients with Von Willebrand's disease.[28] In 1989, there were 34 patients with haemophilia A, 4 patients with haemophilia B, 8 von Willebrand's patients and 3 patients with factor XIII deficiency.[29] In 1990, there were 42 haemophilia A patients, 10 patients with haemophilia B, 4 with Van Willebrand's disease and 3 patients with factor XIII deficiency.[30]

Treatment policies and blood product usage

18. Dr Daly recalls that "The Haemophilia Centre Director Dr G L Scott was responsible for product selection at the BRI and I believe BCH".[31] Dr Scott produced an informal statement to assist Dr Daly in preparing her evidence for the Lindsay Tribunal in 2000.[32] He wrote:

> "*It was always my policy to use plasma-derived products from English and Welsh donors which were fractionated at the NHS-managed blood products laboratory at Elstree, in preference to commercial products... My belief was that the NHS products carried less risk of infection, particularly hepatitis and HIV than commercially derived products from the USA. Allocation of these products was determined by the amount of plasma which was collected by each regional blood transfusion centre, and as the Bristol centre serving the south west regional health authority had a very good record for plasma collection our allocation was above average. Nevertheless it was not sufficient*

[25] HCDO0001887
[26] HCDO0001983
[27] HCDO0002076
[28] HCDO0002165
[29] HCDO0002259
[30] HCDO0002350
[31] WITN4685001 §10.1.1
[32] WITN4685002

to cover our needs and therefore commercial blood products had to be purchased to make up the deficit. Priority for NHS products was given to children and adults who had previously received little treatment and were known to be hepatitis and HIV negative."

19. Dr Daly, who discussed product choices with Dr Scott in the early to mid-1980s, recalls similarly:

> "*I believe selection was based on a preference for UK donor plasma, single donor products for mild/moderately affected individuals or with no previous exposure and heat-treated concentrates from 1984.*"[33]

Early shortages

20. In 1971 the preferred treatment option was "*some cryoprecipitate and some freeze-dried concentrate*" (rather than solely one or the other, which were the other options on a survey questionnaire sent to Dr Raper). 730 single donor preparations of cryoprecipitate had been required in 1971. It was anticipated that in future 480 single donations of cryoprecipitate and 250 bottles of freeze-dried concentrate would be required annually. It appears that there was a shortage of factor VIII concentrate at this time; if not restricted by shortage, it was estimated that only 180 donations of cryoprecipitate but 1,000 bottles of freeze-dried concentrate would be used.[34]

21. By 1974, Bristol received factor IX concentrate from the PFL in Oxford; in a letter dated 27 March 1974, Dr Bidwell at PFL warned against using this for a patient with impaired liver function.[35]

22. The shortage of factor VIII concentrate continued. On 2 July 1975, Dr Scott wrote to Dr Maycock at BPL regarding supplies of factor VIII, copying to Dr G Tovey, Director of the South West Regional Blood Transfusion Centre.[36] He wrote:

> "*As I told you during our telephone conversation the other morning, we are encountering difficulties over the supply of Factor VIII material for the treatment of our patients with haemophilia....*

---

[33] WITN4685001 §11.3 & 11.9
[34] CBLA0000083
[35] CBLA0007517
[36] CBLA0005695

I have reviewed the treatment of each patient, and I am sure that the current usage of Factor VIII is justified, and that if it was to be reduced, then the standard of patient care would be seriously affected. With the current regime we are enabling most of the patients to continue in some form of employment, and to lead a reasonably acceptable, if restricted, life. Most of the patients agree that over the last couple of years a very high standard has been offered by this Centre and they would be reluctant to see this service lapse.

Our current usage of Cryoprecipitate is running at approximately l,000 units (i.e. material obtained from single donations) per month, and this is being provided by the Regional Blood Transfusion Centre at Southmead. In addition, we have been purchasing between 6 and 7 thousand units of Factor VIII in the form of concentrates from commercial sources, namely Hyland, and Immuno Products, and this has been used for home treatment programmes and to cover minor surgery. The current cost of this is in the region of 7 to 8 hundred pounds monthly, which is going to mean an increase in the drug bill to the District of between 8 and 9 thousand pounds in the current year. Quite obviously, the District Administrators are not anxious for this expenditure to continue, let alone to increase. I have been able to maintain a high standard of patient care, only due to the efforts of the Regional Blood Transfusion Centre in meeting our demands for Cryoprecipitate and to the understanding of the District Administrators who have allowed me so far to purchase commercial Factor VIII without question.

It now appears that the Regional Blood Transfusion Centre cannot guarantee me more than 800 units of Cryoprecipitate each month. As you are aware, they are faced with the dilemma of processing increasing amounts of plasma to produce Cryoprecipitate or supplying more plasma for fractionation by your Department. In addition, the high demands made by my Department over the past year has depleted the stock of cryoprecipitate previously held at the Transfusion Centre to meet any emergency demands at the B.R.I, or elsewhere in the region. I am writing to you, therefore, to ask whether you would find it possible to allow me a regular supply of Elstree Factor VIII concentrate to go some way towards meeting the difference between my requirements and that which the Regional Transfusion Centre can meet. I realise that you must

receive similar letters from almost every other Haemophilia Centre Director, but I think that it is probably fair to point out that the Bristol Transfusion Centre has provided significant amounts of plasma for fractionation and that in the past the demands made for the Elstree concentrate have been relatively slight.

I would be most grateful for any help that you are able to give towards providing a supply of Factor VIII so that I do not have to reduce the standard of service which I offer to haemophiliac patients in this area."

23. On 18 July 1975, Dr Tovey of the Regional Transfusion Centre wrote to Dr Maycock:[37]

> "*Dr. Scott has undertaken to restrict the amount of cryoprecipitate being transfused to haemophiliacs at the Bristol Royal Infirmary to a lower figure and to use more Hemofil in an emergency. As a result of this we are planning to step up the amount of fresh frozen plasma we send you to about 100 - 120 packs per quarter. This will be a minimal figure and if we can manage more before the additional equipment arrives we will certainly bear this in mind.*"

24. It appears therefore that the shortage of NHS factor VIII concentrate was addressed on this occasion by substituting commercial factor VIII for cryoprecipitate in order to free up more plasma supplies for BPL.

25. On 19 October 1976, Dr Tovey wrote to Dr Biggs at the Oxford Haemophilia Centre regarding:[38]

> "*… the sensible suggestion that the number of units of cryoprecipitate issued by us to the Bristol Royal Infirmary and Exeter, and the other associated centres, during 1975 might be used as a basis for distribution. In case this is of help the units issued are as under:-*
>
> *Bristol Royal Infirmary and Exeter - 11,000*
>
> *Associated centres - 5,280*

[37] CBLA0009063
[38] CBLA0009439

This suggests, therefore, that the additional requirement for Factor VIII in this Region for patients treated at the associated centres is likely to be about 50 per cent of that required by Bristol and Exeter combined. If this is accepted, I see that it approximates fairly closely to my estimate based on total population, i.e. about 100 bottles of AHG concentrate per month in all."

Relationship with the Regional Transfusion Centre

26. On 17 November 1976, Dr Maycock wrote to Dr Scott that while BPL had been sending the Bristol Centre 20 bottles of factor VIII concentrate per month, "*Now that a regular distribution to the regions is starting (it has already started in the South West Region), would you in future please obtain such BPL concentrate as you require from Dr. G. H. Tovey at the Regional Transfusion Centre.*"[39]

27. This appears to have become the practice from then on. Dr Daly recalls that BPL products were distributed via the Regional Blood Transfusion Service, while commercial concentrates were purchased by the BRI hospital pharmacy.[40]

28. Dr Daly further recalls:[41]

> "*BRI... had a close relationship with the Blood Transfusion Service which provided blood, plasma, platelet concentrate and cryoprecipitate for essential patient care. They also provided expert opinion when required. The Medical Director was also consultant haematologist at Southmead Hospital where I did part of my training, so I knew him well. I trained for six months at the Regional Blood Transfusion Centre. Many of the MLSOs in the SW Region did periods of training there also.*"

Annual returns data commencing in 1976

29. Over the course of 1976, the Centre used for the treatment of 39 haemophiliac patients: 442,680 units of cryoprecipitate; 132,800 units of NHS factor VIII concentrate; 10,836 units of Alpha Profilate; 60,240 of Armour Factorate; 11,200 units of Cutter Koate; 66,100 units of Hyland Hemofil; and 76,600 units of Immuno Kryobulin. Five patients with Von Willebrand's disease received: 16,890 units of

[39] CBLA0000487
[40] WITN4685001 §11.6
[41] WITN4685001 §98.1

cryoprecipitate; 8,000 units of NHS factor VIII; and 2,800 units of Immuno factor VIII. Seven patients with Christmas disease (haemophilia B) received solely NHS factor IX concentrate (170,400 units).[42]

30. During 1977, the usage of cryoprecipitate decreased and the amount of factor VIII concentrate, both NHS and commercial, increased. 38 haemophilia A patients received: 308,200 units of cryoprecipitate; 182,200 units of NHS factor VIII; 153,750 units of Cutter Koate; and 123,740 units of Hyland Hemofil. Dr Scott commented on the annual returns form, "*Most patients found that NHS concentrate unsatisfactory because of its insolubility*". The 9 patients with Christmas disease received 115,370 units of NHS factor IX concentrate. The 4 patients with Von Willebrand's disease used: 13,560 units of NHS factor VIII; 1,500 units of Cutter factor VIII; and 3,260 units of Hyland 13.

31. The complaint regarding poor solubility of NHC factor VIII concentrate was renewed by Dr Scott in a letter to Dr Tovey dated 21 February 1978:[43]

> "*We have had a number of complaints from Haemophiliacs on home treatment concerning the effectiveness of the Elstree Factor VIII concentrate. Some bottles of Batch No. HL 1390 were returned to us by one patient who found that he was getting little or no symptomatic relief using this material, although he obtained instantaneous relief from using a smaller number of units of Koate. We have assayed some units of this batch and, although we have found it contained the stated number of units, it has taken over 30 minutes for it, to go into solution completely, and that is using a roller mixer. I think it very likely that patients would use it before it was completely dissolved and thereby losing most of the Factor VIII activity.* ***Because of its insolubility I feel that I cannot use this material for home treatment any longer and this will mean a considerable increase in the amount of commercial Factor VIII which has to be purchased.*** *I thought that I ought to let you know this so that you could perhaps pass on my comments to Elstree. Talking to other Haemophilia Centre Directors I do not think that I am alone in finding the Elstree concentrate unsatisfactory.*"

[42] HCDO0000023_002
[43] BPLL0009270_006

(Emphasis added.)

32. This suggests that some of the usage of commercial factor VIII may have been due to preference rather than shortage of NHS material. There is evidence from this period that at least one patient was dispensed commercial concentrates for home treatment use.[44] However, Dr Tovey followed up with a letter to Dr Maycock in which he stated he had not "*received any similar comments from other haematologists in the Region to whom we send Elstree factor VIII concentrate*".[45]

33. In 1978, the trend away from use of cryoprecipitate and towards factor VIII concentrate continued. The 36 haemophilia A patients received: 158,480 units of cryoprecipitate; 269,116 units of NHS factor VIII concentrate; 462,800 units of Armour Factorate; 110,520 units of Cutter Koate; and 74,600 units of Hyland Hemofil. The 6 patients with Christmas disease used 129,632 units of NHS factor IX concentrate (an increase in per patient usage). The 3 patients with Von Willebrand's received 5,740 units of cryoprecipitate and 40,225 units of NHS Factor VIII.

34. In 1979, cryoprecipitate usage went up again, although this was partly explicable by the increase in number of patients treated: 256,970 units of cryoprecipitate were used for 20 adults and 20,304 units for 10 children with haemophilia A. Meanwhile, supplies of NHS factor VIII concentrate appear to have been prioritised for children: 111,720 units went to the 20 adult patients and 127,295 units to the 10 children. The adults received the following commercial concentrates: 47,775 units of Abbott Profilate, 107,950 units of Armour Factorate, 247,670 units of Cutter Koate and 64,400 units of Hyland Hemofil. The children received proportionately less, but still a significant amount of, commercial concentrate: 3,920 units of Abbott Profilate, 18,972 units of Armour Factorate, 75,250 units of Cutter Koate and 2,800 units of Hyland Hemofil. The 8 adult patients with Christmas disease used 252,915 units of NHS Factor IX concentrate. The two adult patients with Von Willebrand's disease received 7,896 units of cryoprecipitate and 19,645 units of NHS factor VIII. The child with Von Willebrand's received 5,264 of cryoprecipitate and 18,565 units of NHS factor VIII.[46]

---

[44] TREL0000145_019
[45] BPLL0009270_005
[46] HCDO0001307

Home therapy

35. During Dr Daly's time at BRI (1979-1985), home therapy was commenced by Dr Burman at BHC for children with severe haemophilia and regular bleeds from approximately 4 years of age, using BPL factor products.[47] Cryoprecipitate was considered impractical for home therapy.[48] Her evidence is that routine prophylaxis was never used, although sometimes a specific period of prophylaxis would be instituted for particular patients, e.g., for a troublesome joint.[49]

36. In 1980, the 31 patients with haemophilia A received 250,400 units of cryoprecipitate. This was all administered in hospital (whether inpatient or outpatient clinics) and none was used for home treatment. They received 65,650 units of NHS factor VIII in hospital and 227,550 units for home treatment. A small amount of Abbott Profilate was used in hospital, 2,940 units. The remainder of the use of commercial materials was for home treatment: 179,203 units of Abbott Profilate, 59,620 units of Armour Factorate, 66,990 units of Cutter Koate, 49,920 units of Immuno Kryobulin and 72,000 of Speywood Humanate. (Humanate had been licensed that year and Speywood's Director had written to Dr Scott to advertise it.[50]) The 4 patients with Von Willebrand's received 8,600 units of cryoprecipitate in hospital and 13,200 units of NHS factor VIII for home treatment. The 7 patients with haemophilia B used NHS factor IX, namely 130,130 units in hospital and 121,445 at home.[51]

37. In 1981, the 35 haemophilia A patients received: 256,700 units of cryoprecipitate in hospital and 5,100 at home; 20,373 units of NHS factor VIII in hospital and 452,647 units at home; 40,941 units of Abbott Profilate in hospital and 129,660 units at home; 2,790 units of Cutter Koate in hospital and 239,380 at home; 25,596 of Immuno Kryobulin at home and 86,000 units of Speywood Humanate at home. The 10 haemophilia B patients used 21,980 units of NHS factor IX in hospital and 145,475 units at home. The 6 patients with Von Willebrand's used 36,300 units of cryoprecipitate, 9,300 units of NHS factor VIII and 750 units of Cutter Koate in hospital, and 27,600 units of NHS factor VIII at home.[52]

---

[47] WITN4685001 §19.1.1
[48] WITN4685001 §36.6
[49] WITN4685001 §20.1
[50] IPSN0000333_024
[51] HCDO0001402
[52] HCDO0001500

Changes in product usage in response to risk of AIDS

38. In 1982, haemophilia A patients used 153,800 units of cryoprecipitate in hospital and 85,200 units of cryoprecipitate at home.[53] Dr Daly has noted in relation to cryoprecipitate that:[54]

> *"In BRI cryoprecipitate (cryo) was used to treat mild and moderate haemophilia (until DDAVP became available 1983), severe patients with haemophilia who attended the Centre for treatment and von Willebrand's disease. A lot of cryo was used at BRI when I first arrived. When reports of AIDS appeared some individuals preferred cryo because it was derived from UK plasma."*

39. Her recollection is therefore consistent with the increase in the use of cryoprecipitate in home therapy in 1982. However, it was also in January 1982 that one patient, Lee Turton, whose parents have given evidence to the Inquiry, was switched from cryoprecipitate to NHS factor concentrate, apparently because cryoprecipitate was not available.[55] In a note by K E Milne of the 13th meeting of UKHCDO on 13 September 1982,[56] it is stated that Dr Daly, who was attending on behalf of Dr Scott on that occasion, commented that "*special arrangements had been made to supply Cryo to three patients who particularly requested it, but that it might not be possible to continue the arrangement indefinitely*". Dr Daly herself does not recall this conversation, given the passage of time.[57]

40. Use of NHS compared to commercial concentrates also increased that year. Haemophilia A patients received: 87,794 units of NHS factor VIII in hospital and 562,956 units at home; 2,547 units of Abbott Profilate in hospital and 65,373 units at home; 18,980 units of Cutter Koate in hospital and 246,590 units at home; and 474 units of Immuno Kryobulin in hospital and 7,821 units at home. Patients with Von Willebrand's disease received 23,800 units of cryoprecipitate in hospital, 5,990 units of NHS factor VIII in hospital and 28,205 units of NHS factor VIII at home. The only commercial concentrate used by Von Willebrand's patients was 1,150 units of Cutter

[53] HCDO0001603
[54] WITN4685001 §18.1
[55] WITN1575012; WITN1574002; IBI 08.10.19 p.3
[56] DHSC0001313 p.3
[57] WITN4685001 §18.3

Koate used for home treatment. The haemophilia B patients continued to receive solely NHS factor IX (60,790 units in hospital and 157,935 units for home treatment).[58]

41. This pattern continued in 1983. Patients with haemophilia A received 176,195 units of cryoprecipitate in hospital and 118,955 units for home treatment, a significant increase. NHS concentrate use for these patients was 156,735 units in hospital and 437,890 units at home, slightly less than the previous year. Use of commercial concentrates fell sharply: just Cutter Koate was used, with 8,160 units administered in hospital and 155,620 units at home. This is in the context of a rise in patient numbers, to 48 with haemophilia A. The 9 patients with Von Willebrand's disease received 13,920 units of cryoprecipitate in hospital, 1,920 units of NHS factor VIII in hospital, 31,610 units of NHS factor VIII at home, and no commercial material. The 11 haemophilia B patients continued to receive NHS factor IX, 102,930 units in hospital and 72,540 units for home treatment.[59]

42. In a 1985 article in *British Jounral of Haematology* co-authored by Dr Daly and Dr Scott amongst others, it was noted that "*The total amount of treatment used at the Centre decreased in 1983. This is due to a growing reluctance by patients to use commercial concentrate*".[60]

DDAVP

43. Dr Daly has stated that DDAVP was used from 1983 "*for mild/moderate haemophilia A and von Willebrand's disease where a response had been previously demonstrated following a test dose and generally pre dental/other minor surgery/ non-life threatening bleeds. All newly diagnosed patients had a trial of DDAVP so their response would be known when they presented needing it. It avoided the need for blood products and risk of transfusion transmitted infection (TTI) from large plasma pools and for cryo*"; although it was not suitable for home therapy or major surgery.[61]

---

[58] HCDO0001603
[59] HCDO0001699
[60] GLEW0000677 p.3 - Daly, Palmer, Scott & Lee, 'Aids Surveillance in Haemophilia', *British Jounral of Haematology* 1985, 59, 383-390
[61] WITN4685001 §17.3

She sought advice from Dr Bloom on the usage of DDAVP and received a letter encouraging its use on 7 July 1983.[62]

Heat-treatment

44. Letters in March and April 1984 from R M Saunders, Department of Health and Social Security to S J Hince, Assistant Regulatory Affairs Manager at Armour Pharmaceutical Ltd, and from W J Tarbit at Armour, to the Department of Health and Social Security, show that Dr Scott entered the BRI into the trial of heat-treated Factorate.[63]

45. In relation to heat-treated products, Dr Scott later wrote in 2000: [64]

> "*In late 1984 heat treated commercial products became available but not in sufficient supply to provide our needs. The first heat treated products were received in the Bristol Haemophilia Centre in December 1984. There was discussion amongst haemophilia centre directors and also by the Haemophilia Society... about whether heat treated commercial products were preference to NHS products. The efficacy of heat treatment had not been fully established and it was believed by many physicians dealing with haemophilia that NHS concentrates although not heated were preferable.*
>
> *Heat treated NHS Factor VIII became available in March 1985 although our quota was not sufficient to meet our needs. It was the policy to give heat treated NHS concentrates to children and mildly affected adults who had not received much treatment previously. We continued to use non heat treated NHS protect and also heat treated commercial product.*
>
> *In August 1985 all the NHS product was heat treated. We were asked to return all non heat treated product. We did not keep a large stock nor did any patients but all the patients were asked to return their non heat treated product and it was replaced. The non heat treated product was returned to Elstree. Our allocation was still not enough to meet our needs and therefore commercial heat treated product was sued as well. In October 1985 the new NHS*

[62] WITN4685003
[63] ARMO0000314
[64] WITN4685001 §10.1.1

intermediate purity heat treated product VIIIY was introduced and from that time it became our major treatment produce and commercial Factor VIII was gradually withdrawn."

46. Dr Daly has confirmed that heat-treated NHS concentrate was first introduced in March 1985, and that all NHS concentrate was heat-treated by October 1985 when the 8Y product became available. Her evidence is that "*I wished to use heat products exclusively from late 1984 but this was not possible until late 1985*".[65] She has stated that:[66]

> "*When commercial heat-treated factor concentrates became available there was a move towards these (as heat treatment inactivated the HIV virus). However, the amount of commercial factor concentrates available was limited and there were cost issues. Some patients elected not to have heat treated commercial concentrates as these were manufactured from US plasma. Some patients remained with cryo although less convenient.*
>
> *I remember one patient attending the BRI was on home therapy with cryo due to allergy. He had deep freeze at home provided by the DHSS.*
>
> *Use of cryo decreased in 1985 with availability of heated commercial concentrates. When BPL heat treated concentrates became available, patients were moved to those and cryo was seldom used.*
>
> *This was a time of great uncertainty. No one knew what was best. There were times when individuals preferred cryo and other times when they avoided it and times when it was advised and times when it was not advised.*"

47. Dr Daly has stated that non heat-treated NHS product was considered as an alternative to heat-treated commercial period during the period before NHS heat-treated factor VIII was available, although she has not suggested Bristol adopted any decided policy on this issue:[67]

> "*In UK it was considered that commercial non heat treated products of US origin were more likely to transmit infection (HIV and/or NANBH) than*

[65] WITN4685001 §35.1.9
[66] WITN4685001 §18.1
[67] WITN4685001 §10.1.2-10.1.11

non-heat treated concentrates produced from plasma of UK non-remunerated donors because of the greater prevalence of HIV in the US, the greater size of plasma pools used by commercial companies, use of remunerated donors and because the epidemic presented in the US two years earlier that in the UK.

...

The advice changed several times in 1984-1985 until sufficient HT product was available to treat all patients. At all times doctors were encouraged to treat patients with the best available product rather than withhold treatment and risk life or limb threatening bleeding complications. This created a terrible dilemma for patients and their treaters. Some patients were reluctant to attend the Centre for treatment, some went without treatment and the total amount of Factor concentrate fell for the first time since its introductions. Patients and staff became more discerning in their use of products."

48. It appears that when heat-treated NHS product was made available in March 1985, the Centre was asked which patients to prioritise to receive the limited stocks. In a letter Dr Scott wrote to Dr Snape at BPL on 26 March 1985, he stated:[68]

"*I understand that I have to write to you with regard to supplies of heat treated Factor VIII concentrate. Attending this Centre there are a number of patients who I would like to treat with this material. In order of priority they are as follows:-*

Group I. Children

...

Group II. This Group are MILDLY affected F.VIII ADULTS

...

Group III. This Group are MODERATELY severe F.VIII ADULTS.

...

Group IV. ADULT patients with severe F.VIII deficiency who have received large amounts of commercial concentrates in the past, but who have not sero-converted for HTLV-III.

...

[68] BPLL0010572

As I do not know how much material we can expect, I cannot decide on the exact distribution of it at this stage. However, I would intend to allocate it in the order that I have given, starting with the children and mildly affected adults."

49. Dr Daly has further explained that heat-treated factor IX concentrate (the NHS product 9A) became available to BRI in October 1985.[69] Similarly, Dr Scott wrote in 2000:[70]

> "*NHS Factor IX has always been used in the Centre and the supply has always been adequate so that there has been no necessity to purchase commercial product. At the end of October 1985 heat treated Factor IX became available from Elstree, all non heat treated was withdrawn and patients were asked ot return their non heat treated material.*"

50. A notice dated 28 September 1989 under the Exemption from Licences (Clinical Trials) Order 1981, concerning a notification submitted by Dr Lane for 'Dried Factor VIII Fraction High Purity (heat treated, type 8Y)' manufactured at the BPL Elstree, lists both Dr Scott and Dr Burman as clinicians authorised to take part in the trial of this product.[71]

Annual returns data from 1984 onwards

51. During 1984, 37 haemophilia A patients received: 160,780 units of cryoprecipitate in hospital and 21,800 units at home; 70,695 units of NHS factor VIII in hospital and 504,655 units at home; 39,610 units of Cutter Koate in hospital and 173,980 units at home; and 20,000 units of Travenol Hemofil in hospital. The 9 von Willebrand's patients received: 91,420 units of cryoprecipitate in hospital and 400 units at home; 2,780 units of NHS factor VIII in hospital and 6,900 units at home; no commercial material was used. The 9 haemophilia B patients received NHS factor IX: 68,865 units in hospital and 54,680 for home treatment. The patient with a rarer factor XIII coagulation defect received plasma and factor XIII.[72]

---

[69] WITN4685001 §10.1.9
[70] WITN4685001 §10.1.1
[71] BPLL0003575 p.52
[72] HCDO0001795

52. In the 1985 data, it can be seen that the use of cryoprecipitate for home treatment tailed away once heat-treated material was available. 47 haemophilia A patients received: 56,460 units of cryoprecipitate in hospital and 3,100 units at home; 80,510 units of NHS factor VIII in hospital and 427,710 units at home; 1,620 units of Alpha Profilate in hospital and 11,610 units at home; 8,625 units of Armour Factorate in hospital and 55,305 units at home; 118,776 units of Cutter Koate in hospital and 292,130 units at home; and 580 units of Scottish factor VIII concentrate for home treatment. The 6 von Willebrand's patients used 18,000 units of cryoprecipitate in hospital, 2,450 units of NHS factor VIII for home treatment, 4,200 units of Cutter Koate in hospital and 10,520 units of Cutter Koate at home. The 8 haemophilia B patients received NHS factor IX: 31,080 units in hospital and 42, 040 units at home. The 2 patients with factor XIII deficiency received 8,810 units of factor XIII.[73]

53. In 1986, 40 haemophilia A patients received: 960 units of cryoprecipitate in hospital; 132,080 units of NHS factor VIII in hospital and 602,760 units at home; 11,310 units of Alpha Profilate in hospital and 2,860 units at home; and 57,290 units of Cutter Koate in hospital and 195,770 units at home. The 6 Von Willebrand's patients used: 4240 units of cryoprecipitate in hospital; 3,800 units of NHS factor VIII in hospital and 480 units at home; and 1,560 units of Cutter Koate in hospital and 17,210 units at home. The 11 haemophilia B patients received NHS factor IX concentrate – 43,615 units at hospital and 47,090 units at home. The 2 patients with factor XIII deficiency received 7,800 units of factor XIII.[74]

54. In 1987, no cryoprecipitate was used for haemophilia A patients and just 1,120 units for Von Willebrand's patients. The 46 haemophilia A patients received: 145,646 units of NHS factor VIII in hospital and 447,944 units at home; 3,000 units of Alpha Profilate in hospital and 4,400 units at home; and 11,840 units of Cutter Koate in hospital and 226,800 units for home treatment. The two Von Willebrand's patients also received: 2,600 units of NHS factor VIII in hospital and 2,010 units at home; 6,800 units of Alpha Profilate at home; and 16,460 units of Cutter Koate for home treatment. The 7 haemophilia B patients received NHS factor IX: 46,155 units in

[73] HCDO0001887
[74] HCDO0001983

hospital and 103,830 units at home. The 2 patients with Factor XIII deficiency received 22,615 units of Oxford factor XIII concentrate.[75]

55. In 1988, there was again limited use of cryoprecipitate; just 8,400 units administered to the 6 patients with Von Willebrand's disease. The 45 haemophilia A patients received: 95,285 units of NHS factor VIII in hospital and 659,845 units at home; 10,000 units of Alpha Profilate in hospital and 118,010 units at home; and 10,560 units of Cutter Koate in hospital and 106,480 units for home treatment. The Von Willebrand's patients also received: 10,035 units of NHS factor VIII in hospital and 30,660 units at home; 6,500 units of Alpha Profilate in hospital and 10,250 at home; and 12,640 units of Cutter Koate for home treatment. The 6 patients with haemophilia B received NHS factor IX concentrate: 21670 units in hospital and 105,950 units for home treatment). The 3 patients with factor XIII deficiency received 62510 units of Oxford factor XIII.[76]

56. In 1989, the records appear to be potentially incomplete. They state that 34 haemophilia A patients received 125,485 units of NHS factor concentrate in hospital and 876,570 units for home treatment, while 4 patients with Von Willebrand's disease received 15,600 units of NHS factor VIII in hospital and 92,745 units at home. Eight patients with haemophilia B received 27,597 units of NHS factor IX concentrate in hospital and 97,845 units for home treatment. No other types of material are recorded.[77]

57. In 1990, 42 haemophilia A patients received: 211,335 units of NHS factor VIII in hospital and 954,260 units at home; and 14,310 units of Cutter Koate in hospital and 10,800 units at home. The 4 patients with Van Willebrand's disease used solely NHS factor VIII: 55,260 units in hospital and 94,700 units at home. The 10 patients with haemophilia B received NHS factor IX: 33,165 units in hospital and 99,310 units at home. The 3 patients with factor XIII deficiency received NHS Factor XIII concentrate: 25,020 units in hospital and 42,500 units for home treatment.[78]

---

[75] HCDO0002076
[76] HCDO0002165
[77] HCDO0002259
[78] HCDO0002350

Knowledge of risk of hepatitis and response to risk

58. Dr Scott attended UKHCDO meetings on 1 November 1974, 13 January 1977, 13 November 1978, 17 October 1983, 21 October 1985, 17 March 1986, 25 September 1987, 29 September 1988, 9 October 1989, 21 September 1990, 17 January 1991, 7 October 1991, 18 September 1992, 8 February 1993 and 1 October 1998. He would therefore have been aware of the developing state of knowledge on hepatitis infection risks.

59. As well as submitting annual returns to Oxford regarding patients registered and products used, Dr Scott also participated in the hepatitis survey, reporting on cases diagnosed.[79] On one occasion he corresponded with Rosemary Spooner at the Oxford Centre regarding a patient who had contracted hepatitis followed by his wife also falling ill.[80] It was noted that a list of all the units of cryoprecipitate used by the patient had been sent to the Blood Transfusion Centre, presumably for further investigation.

60. On 10 May 1977, Dr Scott wrote to Dr Maycock at BPL regarding 'AHF Concentrate- Batch HJ 1196'.[81] He wrote: "*On checking through our records I see that this batch of AHF concentrate was given in all to ten patients with Haemophilia. As far as I am aware none of these patients have subsequently developed hepatitis or jaundice, although seven of them are severe haemophiliacs who have had serum hepatitis in the past.*" This demonstrates an example of tracing an implicated product batch for cases of suspected hepatitis.

61. On 11 January 1978, Dr Tovey at the South West Regional Blood Transfusion Service wrote to Dr Maycock at BPL about a patient diagnosed with post-transfusion hepatitis:

> "*I have received a report from Dr. Geoffrey Scott, Consultant Haematologist, Bristol Royal Infirmary, that this boy, a severe haemophilic under his care, has recently developed HbsAg positive hepatitis. During the past six months he has been injected with factor VIII concentrate from three bottles of Lister factor VIII (1337, 1362 and 1363) but at the same time has received*

[79] E.g. OXUH0000352
[80] HCDO0000262_008
[81] CBLA0004148

cryoprecipitate prepared at the RTC from 207 different patients. It is clearly going to be some time before we can decide whether any donor of the cryoprecipitate is a carrier but the necessary wheels have been put in motion. You will remember that you wrote to me about factor VIII, batch HL 1234, on 7th March 1977. As you will see, none of this batch was given to [the patient] and there has been no report of hepatitis from any other haemophilic patient in the Region to date."

62. On 26 July 1978, Dr Scott wrote to Dr Aronstam at Lord Mayor Treloar College regarding a patient:[82]

> "*Thank you for your enquiry about this boy with Haemophilia who is to attend the Lord Mayor Treloar College from next term.... He has had a variety of commercial Factor VIII concentrates and he had hepatitis in 1975. He is now Hb S Ag Negative.*"

63. The doctors at Treloar's also reported back on pupils who were registered as patients at the Bristol Centre, including on liver function test levels possibly indicative of hepatitis.[83]

64. A memorandum from Rosemary Spooner at the Oxford Centre dated 3 March 1983 encloses hepatitis survey forms completed by Dr Daly,[84] relating to a patient who tested positive for hepatitis A; his half-brother who received the same batch of concentrate was "*being checked out by Bristol*".

65. On 22 November 1985 Dr Daly completed hepatitis survey forms for a patient who developed "what appears to be acute non-A, Non-B Hepatitis" two weeks after using Armour Factorate for a scalp laceration.[85]

66. Dr Daly's duties in the later period of her tenure (up to 1985) included "monitoring for evidence of infection with hepatitis and HIV".[86] This in practice included monitoring of HBV markers and liver function tests ('LFTs'). Patients with raised

---

[82] TREL0000145_021
[83] TREL0000145_088; TREL0000243_015
[84] HCDO0000260_665, 667 & 670
[85] HCD0000256_035 and HCD0000256_036
[86] WITN4685001 §6.3

LFTs were advised to avoid alcohol. Patients not exposed to HBV were offered vaccination.[87] Her recollection is that:[88]

> *"I do know from patients I treated at the BRI that they were all aware of the risk of hepatitis and of risks to others if there was blood spillage, of the need to return needles, syringes etc. to the Centre (or other site where arrangements were made)."*

67. However, witnesses to this Inquiry have stated that they or their affected family members were not informed of the risks associated with the blood products that they were being given.[89]

Knowledge of risk of AIDS and response to risk

68. One of the first patients to die from AIDS in the UK was a Bristol patient, in August 1983. He became acutely ill in January 1982, at which time Dr Daly noted he had an 'acute viral infection ? related to factor concentrate'.[90] By May 1983, it was suspected that the illness was AIDS. Dr Daly undertook an investigation into all patients regularly attending the Bristol Centre, which was later published: Daly, Palmer, Scott & Lee, 'Aids Surveillance in Haemophilia', *British Jounral of Haematology* 1985, 59, 383-390.[91] 43 patients attending the Bristol Centre aged 13 to 78 years old were tested between May and October 1983. Of these, 31 patients were discovered to have abnormal T cell subsets or helper / suppressor rations, and 32 patients had hypergammaglobulinaemia.[92] (Further, nineteen also patients had elevated AST and GGT levels, and 29 were anti-HBs positive. Nine patients were seropositive for cytomegalovirus. [93]) It was concluded that "*Circumstantial evidence suggest that the development of AIDS in the index case was due to intensive exposure to commercial factor VIII concentrate in a short period*".[94]

---

[87] WITN4685001 §25.1
[88] WITN4685001 §46.2
[89] See for instance W1574001 (10), W2660001 (Section 4, paragraph 1)
[90] WITN4685001 §32.3
[91] GLEW0000677
[92] Ibid p.1
[93] Ibid p.2
[94] Ibid p.6

69. As noted in the section above, this resulted in concern about the safety of commercial concentrates, an increase in the use of cryoprecipitate and an alternative therapy and a reduction in levels of treatment overall.

70. Dr Scott wrote in a letter of 3 October 1983, apparently to a patient and his wife:[95]

> "*As I am sure you know one of the patients attending the Bristol Haemophilia Centre has recently died of AIDS. The cause of this condition is still unknown but there is evidence to suggest that it is due to an infection which can be transmitted by blood or blood products. There is reason to believe that the source of the infection in this case was imported Factor VIII concentrates but this is not proven and it cannot be said with certainty that these were the source of infection. I can understand that you are extremely worried that you have contracted a similar condition by using imported blood products. However, I would like to make it clear that the risk of this is extremely small. Thousands of Haemophiliacs in Europe and America have been treated with Factor VIII concentrates for over ten years and the number of reports of AIDS has been extremely small.*
>
> *As far as possible we are avoiding the use of imported Factor VIII concentrates but there is not enough NHS produced Factor VIII available at the moment to meet our needs so we will have to continue to use some commercial Factor VIII for the time being. The production of NHS concentrate is being increased and hopefully we shall be self-sufficient in the not too distant future. In the meantime I think that the dangers of refusing treatment if only commercial concentrate is available is greater than the danger of contracting AIDS. It is also the opinion of the Haemophilia Society which is set out in their latest bulletin.*
>
> *I hope that this allays your fears but if you have any further problems please feel free to discuss it with me or any of the other Medical Staff.*"

[95] HSOC0003486

71. At the 17 October 1983 meeting of the UK Haemophilia Centre Directors, Dr Scott gave details of the Bristol AIDS case to his fellow directors following a presentation by Dr Craske.[96]

72. In November 1983, Dr Daly and Dr Scott had a letter published in *The Lancet* entitled 'Fatal AIDS in a Haemophiliac in the UK' in which they wrote *"Hitherto the most serious infection to which haemophiliacs given clotting factor concentrates were thought to be at risk was hepatitis, but now attention has focused on acquired immune-deficiency syndrome (AIDS)... We report here a fatal case of AIDS in a haemophiliac who received intensive treatment with factor VIII (FVIII) concentrate of US origin."* They described how the otherwise fit 55-year-old patient had received commercial factor VIII cover for an operation in December 1981, and was subsequently admitted to hospital in January 1982 and discovered to have an atypical lymphocyte count. His range of developing symptoms over the next 18 months were described, culminating in fatal P carinii pneumonia. They concluded, *"It seems highly probable that the development of AIDS (and hepatitis B and non-A, non-B hepatitis) was related to this treatment. This case provides further evidence for a link between exposure to blood products and AIDS."*[97]

HLTV-III testing and informing of diagnosis

73. As noted above, Dr Daly's duties in the later period of her tenure (up to 1985) included "monitoring for evidence of infection with hepatitis and HIV".[98] Testing for HIV was available from 1984.[99] She recalls:[100]

> *"There was no formal pre-test counselling initially. I spoke with patients as I was monitoring them. I explained I was storing sera in the hope of a future test. No patient objected. They wanted to find out also. Later, after I received the results of the initial tests and when testing further patients, I did provide a form of pre-test counselling. I can't remember for certain if I recorded that in the clinical records in the BRI.*

---

[96] PRSE0004440
[97] PRSE0004509. See also MACK0000604_002
[98] WITN4685001 §6.3
[99] WITN4685001 §25.1.4
[100] WITN4685001 §49-51

To put this in context when I started working at the BRI specific informed consent was obtained only for surgery. I introduced informed written consent for (invasive) bone marrow examination

....

At the BRI, all patients with whom I was involved were informed in person, in private and usually by me initially. The Consultant Dr Scott, second senior registrar, registrar and SHOs also discussed this with patients subsequently. I led the process at the BRI."

74. She further explains that until 1986/1987, patients were given an uncertain prognosis as doctors were still optimistic that HIV seropositive patients would not necessarily develop AIDS.[101]

75. However, Colin and Denise Turton have given evidence that their son Lee while under the care of BCH was tested for HIV and found to be positive in March 1985, whereas they were not told tests were being done and they were not informed of the diagnosis until June 1985.[102] Dr Daly wrote to Dr Burman on 31 May 1985 about Lee and another child who had tested HLTV-III positive:[103]

> "*I would be grateful if you could see them and counsel them and their parents appropriately as they are so young the main problem with these patients will be in the injection of Factor VIII concentrate to them, which would put the parents or whoever the administrator is at slight risk of contamination and they obviously ought to wear gloves.*
>
> *If you want I can arrange for the parents of both these children to be tested. I am going to look through their records to see whether or not these children ever received commercial Factor VIII concentrate or whether they were, in fact, contaminated by British Factor VIII concentrate. I will let you know the results of this. I regret to have to give you what must really be tragic results in the light that these samples were taken prior to the commencement of heat-treated British Factor VIII concentrate.*"

---

[101] WITN4685001 §51
[102] IBI 08.10.19 p.6-8
[103] WITN1575008

76. On 14 June 1985, Dr Donaldson, senior registrar to Dr Burman, wrote to Lee Turton's GP:[104]

> *"I saw Lee's parents recently following a report from the laboratory that he is positive to HTLV-III virus. This retrovirus is, as you know, implicated in the cause of acquired immune deficiency syndrome, AIDS. Whereas a significant number of homosexual subjects who have raised antibodies in the HTLV-III virus go on to get clinical AIDS the risk appears to be far lower in the haemophilia population. To date there are 5,000 haemophiliacs in the UK, approximately 50 per cent of whom are antibody positive to HTLV-III. Only four cases of AIDS have been described in haemophiliacs in the UK and a comparable number in the USA. ... The chance of Lee developing AIDS is therefore extremely small and I stressed this to his parents.*
>
> *He has obviously met the virus through receiving human Factor VIII pooled from multiple donors, but from now on there should be no further exposure since the Factor VIII obtained is British not American and is heat treated."*

77. This is consistent with Dr Daly's evidence that the advice initially given to patients and their families regarding the risk of HLTV-III positivity leading to AIDS was, it later transpired, unduly optimistic.

Numbers infected with HIV and seroconversion dates

78. From May to October 1983, Dr Daly undertook a clinical and immunological review (immunoglobulin levels and lymphocytes subsets) of 43 patients regularly attending the centre.[105] Three patients had symptoms consistent with, but not considered to be diagnostic of, AIDS.

79. Later, anti-HLTV-III tests were carried out on stored sera. Dr Daly recalls that these showed the earliest seroconversion date was in 1981, the majority in 1982-1983 and one patient seroconverted later, between September 1984 and March 1985.[106] Provisional UKHCDO data available to the Inquiry suggests that 13 patients seroconverted in total between 1981 and 1986.

---

[104] WITN 1575010
[105] WITN4685001 §34.2 & GLEW0000677
[106] WITN4685001 §58.1

80. In Lee Turton's case, Dr Daly wrote in November 1988: "*It is almost certain that he acquired his HIV infection from one particular batch of NHS concentrate just prior to the introduction of heat-treating.*"[107]

Testing for HCV

81. Dr Daly has stated that:[108]

> "*Included in the monitoring for hepatitis, I arranged for serum to be stored in the public health laboratory in Bristol and the microbiology department at RCH-T. This was done because at that time we did not know the cause of abnormal LFTs and there was a lot of research going on to determine this. Samples were stored in the hope of a future test for NANBH. When a test for hepatitis C became available, these samples as well as more recent samples were tested for hepatitis C. These patients were regular attenders at the haemophilia centre and did not require tracing as such.*"

82. A number of individuals who gave evidence to the Inquiry concerning the manner in which their diagnosis was communicated recalled that they were given limited information about the infection.[109]

Treatment for HIV and HCV

83. Dr Daly recalls that the death of the Bristol patient "caused considerable anxiety among patients attending the Centre. I became involved in a great deal of 'counselling' and support of other patients attending the Centre. I undertook the initial 'counselling' of seropositive (and seronegative) patients with haemophilia. I undertook surveillance and immunological evaluation of patients at the Centre who had received the same

---

[107] WITN 1575006

[108] WITN4685001 §64.1

[109] See for instance W2401001 (Section 6, paragraph 2): 'I was not offered any information or support when I was informed I had contracted hepatitis C. The only advice offered was that I needed to inform my dentist. The same applied when I had a letter from the Royal Victoria Infirmary, Newcastle regarding the vCJD'; see also W1811001 (21) in relation to the comments of his GP, Dr Maendl: 'Adequate information was not provided to help me manage or understand the infection. All Dr Maendl said, was to see our doctors at the BRI. Dr Maendl didn't know much about the virus at all, or at least, that is what it seemed like. Nobody wanted to give me information or prepare me. Instead they were trying to cover their own backs'

blood products as the index patient."[110] She adds, "In BRI I set up an additional clinic in the day unit at which I reviewed a few patients per session in a private room. Each consultation lasted approx. 30 mins. Sometimes I was accompanied by a haemophilia nurse."[111]

84. However, a number of individual witnesses to the Inquiry recalled that there was no support offered.[112]

Consent

85. Various witnesses to the Inquiry have noted that they were treated or tested at Bristol without their knowledge or consent.[113]

86. In relation to consent for testing, Dr Daly recalls that all BRI patients would have blood samples taken at all routine review appointments (at least twice yearly for those with severe haemophilia). Testing included FBC, liver and renal function tests, hepatitis serology, and inhibitor assays. Patients were given "general information of the reason for blood tests". She also informed patients she was storing samples of sera in the hope that further tests would be developed in the future. However, she does not believe patients were asked to consent to the storing of sera, which was routine. Neither was consent sought for routine hepatitis testing, although she believes patients would have been aware this was being done. When HLTV-III testing became available, tests were conducted on stored sera without patient consent being sought, although her recollection is that patients were informed and "They wanted to find out also". Subsequently, patients were advised to be tested and consent was sought for testing.[114]

---

[110] WITN4685001 §6.4

[111] WITN4685001 §47.4

[112] W3137001 (13): 'There was absolutely no support offered. My father was told not to tell people and he was told they did not need to inform anyone. He initially refused treatment for his HIV, with my mother having to coax him into taking any of the drugs prescribed' and at paragraph 44: 'There was absolutely no counselling offered at all, although my daughter did later seek counselling to help with some of her problems which turned out to stem from my father's illness, and the effect of suppressing her grief'; W0862001 (17); W2396001 (Section 6, paragraph 15); W3629001 (31 – 32); W1574001 (32) and see also at paragraph 57: 'I have never been offered any help; no counselling or psychological support'

[113] See for instance W2401001 (Section 4, paragraphs 1 – 3).

[114] WITN4685001 §73-75

Other issues

87. A Bristol branch of the Haemophilia Society was established with the support of Dr Scott in 1974.[115]

88. In 1989, Dr Scott corresponded with the Macfarlane Trust to ensure all patients he could trace were registered with the Trust.[116]

JENNI RICHARDS QC

RACHEL BARRETT

Inquiry Counsel Team

June 2021

[115] HSOC0029671_028
[116] MACF0000175_017