Presentation Note on the Lord Mayors Treloar's School and Haemophilia Centre

Introduction

1. This note is intended to provide an overview of the Lord Mayor Treloar School ("the School") and the Haemophilia Centre ("the Centre") (together, "Treloar's") and its activities, based on the documents and statements received by the Inquiry. In addition to statements from people treated at the Centre, and from their relatives, there are statements from: Mr Alec MacPherson, Headmaster from 1974 to 1990[1]; Mr Ian Scott, Housemaster / Care Manager from 1981 to 2011[2]; Ms Amanda Beesley, a member of care staff from 1979 to 1981[3]; and Ms Helen Burton, Headmaster's Secretary from 1976 to 1997 and thereafter Admissions Officer until 2009[4]. Statements have also been received from clinicians from the Haemophilia Centre: Dr Roy[5], Dr Fowler[6] and Dr Painter[7], and from School Medical Officer Dr Tomlinson[8]. Dr Peter Kirk has declined to provide a statement. As he now lives in Canada, the Inquiry has no means to compel him to provide a statement.

Overview of the School

2. The Lord Mayor Treloar Cripples Hospital and College opened on 7 September 1908 with the first boys entering the college on 26 October 1908. At that time, the Hospital and College occupied two blocks of wooden buildings. The hospital passed into the control of the Ministry of Health in 1947 while the College remained independent. It became known as the Lord Mayor Treloar College.

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[1] WITN5561001

[2] WITN5314001

[3] WITN1090001. She also gave oral evidence to the Inquiry on 16.10.19

[4] WITN1128001

[5] WITN4149002

[6] WITN5278001

[7] WITN5277001

[8] WITN5578001

3. In 1953 the College moved to new premises in Froyle. In 1956 the September intake of pupils included three children with haemophilia for the first time.[9] The facilities in Froyle were described as "excellent", and included a swimming pool, games room and spacious grounds for outdoor activities.[10]

4. The Florence Treloar School for girls was built at Holybourne and opened in 1965. The schools merged to become co-educational in 1978 with the upper school based at Holybourne (subsequently called Lord Mayor Treloar College) and the lower school at Froyle (subsequently called Lord Mayor Treloar School). Both the School and College were operated through the Treloar Trust.[11]

5. In this presentation, the term "School" will be used to describe both the School and College, unless a specific distinction is required.

6. The School and College provided the usual educational provision alongside a full care staff. The prospectus in 1989 notes that even if a child was confined to bed for some days, teachers were timetabled to teach at the medical centre ensuring that the child would not fall behind.[12]

7. From at least 1981 there were a number of boarding houses: Burnham, Gasston, Pike and Jephason Houses. Gasston House was the junior house, for those aged 7-11. The other houses were for students from ages 11-16. Mr Scott records that pupils were allocated to house on the basis of age rather than as a result of having a particular disability.[13] In each house, there were dormitories for between two and four pupils. Meals were eaten in the boarding house.[14] Pupils with haemophilia were in boarding houses with others with different disabilities. However, they moved to the College site at the end of school year

[9] TREL0000517 at p.89. See also HSOC0022908

[10] HSOC0022843

[11] WITN1128001 §5 and WITN5314001 §§5-7.

[12] WITN5561002

[13] WITN5314001 §12 and §61.

[14] WITN5314001 §62.

nine (age 14), rather than school year eleven (age 16) when other students moved up, because that was where the Haemophilia Centre was located.[15]

8. Each boarding house had a housemaster, subsequently called Care Manager. Mr Scott has indicated that this role was a pastoral one with some necessary basic care elements, as well as arranging and ensuring "high quality care delivery" for the boarders in the house from care staff. The care staff were in turn supported by physiotherapists, occupational therapists, speech therapists and medical staff. Mr MacPherson has estimated that about forty qualified nurses and thirty therapists delivering physiotherapy, speech therapy and occupational therapy were employed by the Trust, managed by the College Medical Officer, Dr Pat Tomlinson.[16] Dr Tomlinson was the College Medical Officer from 1978 to 1994.[17] The focus was on utilising a multi-disciplinary approach to enable maximum independence for pupils.[18] When a pupil had received treatment at the Haemophilia Centre that was communicated back to residential staff, seemingly in writing though there are no records of this available to the Inquiry.[19]

9. In July 1964, a publication of the Haemophilia Society described the Lord Mayor Treloar College.[20] They noted that there was a total of 130 boys attending the College at that time, of whom 26 were boys with haemophilia, "the second largest group of boys suffering from the same disability". By 1965 there were 31 pupils with haemophilia.[21] By 1970 there were 40 pupils with haemophilia increasing to over 50 by 1974.[22] In 1975 it was noted that there were 39 boys with Haemophilia A, 5 boys with Haemophilia with inhibitors (it appears this was Haemophilia A) and 8 boys with Haemophilia B.[23]

10. The Local Education Authority usually applied on a pupil's behalf for admission to the School and thereafter paid the fees. Some pupils were jointly funded with a Social Services

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[15] WITN5314001 §13

[16] WITN5561001 §18

[17] WITN5578001

[18] WITN5314001 §19-22

[19] WITN5314001§49

[20] HSOC0022843

[21] TREL0000517 at p.90

[22] NHBT0107241 p.6 and TREL0000517 at p.90

[23] NHBT0107242

Department. A very small number of pupils were placed and paid for by their parents.[24] The School considered each child individually to assess their needs including the physiotherapy and medical care required.[25]

11. However, from the documents it is apparent that treating haemophilia clinicians were frequently involved in either recommending to parents that a child should be admitted to the School or seeking advice from the School about how this should arranged.[26] Sometimes the clinician also took the lead in making the relevant arrangements for a child's admission to the School with limited liaison with the Local Education Authority.[27] In other cases, the clinician wrote to the Local Education Authority to ask, even urge, them to arrange for a child to be given a place at the School.[28] The involvement of clinicians in the schooling arrangements accords with several witness statements from people who were infected and affected who describe the difficulties they, or their loved one, faced in attending mainstream school and that the treating clinician at their "home" Haemophilia Centre had recommended attendance at Treloar's.[29] Another witness describes how she received a letter stating that the School would like to offer her son a place, having never applied for it.[30] It might be inferred that the treating clinician, or the Local Education Authority, had made the relevant application without her involvement.

12. The expressed rationale of clinicians for the child to be admitted to Treloar's was varied. In some cases, the home situation was noted to be difficult, for example parents struggling to recognise a bleed or the social setting was challenging for other reasons.[31] In other cases, the home situation was very positive, but the child was missing a lot of schooling,[32] or the need to provide care was becoming too much for the parent.[33]

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[24] WITN1128001 §8 and WITN5561001 §13. See also a prospectus from sometime between 1969 and 1974: TREL0000545.

[25] WITN5561002

[26] TREL0000336_037

[27] TREL0000011_029

[28] TREL0000308_043

[29] Including WITN3044001 §10, WITN4641001 §22, WITN1055001 §9, WITN3648001 §12 and WITN1090001 §13

[30] WITN1428001 §8

[31] BHCT0001031

[32] TREL0000336_037 and TREL0000011_029

[33] TREL0000308_043

13. The Local Education Authority, at least in the late 1960s, remained involved after a pupil was admitted to Treloar's in assessing whether they would remain there. In one example, a parent was concerned that her son was unhappy at Treloar's, and the Senior School Medical Officer of the Borough Council wrote to Dr Rainsford to ascertain the situation.[34]

Overview of the Haemophilia Centre

14. Until 1978, haemophilia patients who were attending the School initially attended the college sick bay when they suffered a bleed. They were then transported to the Lord Mayor Treloar Hospital, based at Alton, for treatment with plasma if required.[35] In 1968, Dr Rainsford was appointed as a Research Fellow (on which see further below in the Research section) and with the appointment, there was an increase in the number of plasma transfusions given to pupils. These appear to have been given at the Lord Mayor Treloar Hospital.[36] A contemporaneous document, dated March 1969, suggests that "special arrangements" were in place at the School to enable immediate treatment.[37] It is unclear whether this was simply referring to the relative proximity, and ease of access, to the Lord Mayor Treloar Hospital or whether there was on-site treatment at that time.

15. Upon his appointment, Dr Rainsford established a coagulation laboratory for the first time at the Lord Mayor Treloar Hospital and established protocols for the treatment of people with haemophilia. This was a significant change to the situation prior to his appointment.[38]

16. In 1972 the Treloar Haemophilia Centre was established, under the Directorship of Dr Arblaster, based at the Lord Mayor Treloar Hospital,[39] funding having been agreed for the Centre in 1971.[40] Dr Aronstam was the Associate Director. At the same time, a haemophilia ward was established at the Lord Mayor Treloar Hospital. [41] During 1976, it appears that

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[34] TREL0000505

[35] TREL0000517 at p.90 and WITN1128001 §6

[36] TREL0000517 at p.90

[37] TREL0000504

[38] AMRE0000011_051

[39] TREL0000517 at p.91

[40] DHSC0100026_122

[41] TREL0000517 at p.91

Dr Aronstam went to Canada for one year during which Dr Kirk assumed his responsibilities. [42] In 1977 Dr Aronstam became Director of the Centre. [43]

17. In 1979 the Centre transferred to the Upper School at Holybourne.[44] Ms Trish Turk was employed as the Haemophilia Sister at around the same time.[45] The transfer was undertaken because the distance of six miles between the College and the Hospital was considered by Dr Aronstam to be too great, and if students were admitted as inpatients at the Hospital there were detrimental educational effects.[46] By 1981, Dr Aronstam noted that there was a ten bed sick bay unit at the College but that the haemophilia laboratory and secretarial support were located at the Lord Mayor Treloar Hospital. A consultant orthopaedic surgeon attended the Centre on a weekly basis and complex orthopaedic or bleeding problems were referred to the Oxford Haemophilia Centre or Nuffield Orthopaedic Centre.[47] A witness who was a student recalls a transfusion room at the school, along with its own lab. He recalls the Centre operated on an open-door policy basis.[48]

18. By 1981, Dr Aronstam, in his doctoral thesis, described the Centre as being staffed by himself as Director together with two full time medical officers. In the Upper School, there was a Sister and thirteen part-time nurses, of whom four were "dedicated to the treatment of haemophilia and are competent to transfuse haemophiliacs". [49] The School and College medical centres were staffed 24-hours a day, together with a doctor on call. Ms Burton recalls that Dr Wassef, one of the full time medical officers of the Centre, lived GRO-C GRO-C very close to the Centre.[50] She recalls that Dr Wassef was mainly based at the Centre, while Dr Aronstam and Dr Roy worked at the Basingstoke Hospital Haematology Department as well as seeing pupils at the Centre. She recalls that there was an agreement in 1978 that the NHS would reimburse the College for some of the staff who were formally

[42] TREL0000327_031

[43] TREL0000517 at p.91

[44] HHFT0001066_002 at p.1. Note that TREL0000517 at p.91 suggests it was in 1978

[45] WITN1128001 §6

[46] HHFT0001066_002 at p.1

[47] TREL0000517 at p.91

[48] WITN1243001 §26.

[49] TREL0000517 at p.91

[50] WITN1128001 §16

employed by the College, including the Haemophilia Sister, staff nurses and nursing auxiliaries. The doctors were employed by the NHS.[51]

19. Dr Tomlinson is clear in her witness statement that she had no involvement in the decision-making at the Centre: they operated independently of the medical centre at the School.[52]

20. There were dedicated drivers and vehicles to transport pupils, initially to the Lord Mayor Treloar Hospital and subsequently from the Lower School to the Haemophilia Centre at the Upper School.[53] This accords with the recollection of a witness who was a student who states that at the Lower School between 1980 and 1983 there were no doctors so that when he had a bleed, a van driver was called to transport him to the Upper School site to see a doctor and receive treatment. At the Upper School clinics were held where he would be reviewed twice a day until the bleed recovered. In addition, he attended for routine reviews, orthopaedic assessments, and blood tests.[54]

21. Mr MacPherson recalls that there was considerable communication between school staff, such as housemasters, teachers and care staff as well as himself, and the staff of the Haemophilia Centre. He notes that "We were always talking to the doctors and nurses caring for these boys" and such communication was "essential". However, he notes that he would not normally communicate with any other Haemophilia Centre, hospital or other clinician as this would be dealt with by the doctors.[55]

Key staff of the Centre

22. Dr Rainsford was a Research Fellow from 1969 and, as is noted above, effectively laid the ground-work for the Centre to be established. Dr Arblaster was the Director of the Centre from 1972 to 1976, during which time Dr Aronstam was the Associate Director. Dr Aronstam became Director of the Centre in 1977 and remained until May 1997.[56]

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[51] WITN1128001 §6

[52] WITN5578001

[53] WITN1128001 §6, WITN5561001 §30 and WITN5314001 §54

[54] WITN1541001 §11

[55] WITN5561001 §31-33 and §38

[56] HCDO0000280_009

23. Dr Aronstam has been described by one witness as "very much a hero to us haemo boys" who tried to stand up to the medical profession at the time. He recalls going to Dr Aronstam's house for tea and having a conversation in which Dr Aronstam said that "we probably have really f***** up" and reassured him and his friend that they were trying their best and that "I'll be there; we'll be there for you" with tears in his eyes.[57] The witness recalls Dr Aronstam saying that this had happened on "my watch" and that he felt guilty.[58]

24. Dr Mounir Wassef worked as the Senior Clinical Medical Officer at the Centre from October 1978.[59] It is somewhat unclear when he retired. The latest document available to the Inquiry is dated April 2003.[60]

25. Dr Peter Kirk worked at the Centre from July 1974 to June 1976. It is unclear whether he worked beyond that date at the Centre or at a different Centre, because he did not resign from the UKHCDO until March 1978 when he indicated that he had decided not to continue his career in haematology and was looking to move to general practice.[61] Unfortunately, Dr Kirk has declined to provide any answers to a Rule 9 request that was sent to him. He is now based in Canada and cannot therefore be compelled to answer. The documentation shows that Dr Kirk assumed Associate Director responsibilities in 1976 while Dr Aronstam was in Canada. Officially while Dr Aronstam was in Canada, it appears that Dr John Fowler was a "locum in administrative charge". However, Dr Fowler states that he had no involvement whatsoever with the Centre or in seeing any patients.[62]

26. Dr Painter worked as Senior Clinical Medical Officer at Hampshire Area Health Authority and Honorary Registrar in Haemophilia at the Centre between May 1977 and September 1978, working as Associate Director of the Centre in the later part of this time. Dr Painter had no experience in haemophilia prior to joining the Centre.[63]

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[57] WITN1243001 §47

[58] WITN1243001 §56

[59] TREL0000304_124

[60] TREL0000114_053

[61] HCDO0000545 p.1

[62] WITN5278001 §9

[63] WITN5277001 §9

27. Dr Ashok Roy worked as a haematologist at the Centre from 1986 to 1990. He was junior to both Dr Wassef and Dr Aronstam. He has stated that his role was to treat and look after bleeds in patients of the Centre. He had no managerial responsibility and was not involved in any decision-making processes.[64]

Treatment policies and use of blood products

Annual returns data

28. The annual returns for the Centre provide considerable insight into the use of blood products there.

29. In 1976, 78 patients with Haemophilia A were treated and 6 patients with Haemophilia B. The predominant product used was cryoprecipitate (605,150 units) followed by Kryobulin (558,867 units) and Hemofil (488,594 units). NHS Factor VIII concentrate usage was much more limited at 153,590 units. Only 13,000 units of Koate were recorded. All Factor IX concentrate was NHS concentrate (166,569 units).[65]

30. It appears that the use of Hemofil was significantly greater in 1976 than in 1975. This arose because seven boys had a severe anaphylactic reaction to Kryobulin in the Spring term of 1976 resulting in the decision being taken that they would not receive Kryobulin again.[66]

31. In 1977, the usage was:
    a. 468,100 units of cryoprecipitate;
    b. 480,440 units of Kryobulin;
    c. 568,170 units of NHS concentrate;
    d. 852,040 units of Hemofil.[67]

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[64] WITN4149002 §6

[65] HCDO0000045_003

[66] OXUH0003758_006

[67] HCDO0001131

32. There was limited usage of Factorate (86,370 units) and Koate (57,680 units). All Factor IX concentrate that was reported was NHS concentrate. The figures for the number of patients treated are unclear.

33. In 1978, 72 patients with Haemophilia A were treated and 6 with Haemophilia B. There was a very significant increase in Factor concentrate usage:
    a. 285,482 units of Koate;
    b. 293,527 units of Kryobulin;
    c. 464,420 units of Factorate;
    d. 586,130 units of NHS concentrate;
    e. 1,349,650 units of Hemofil.[68]

34. Just 11,560 units of cryoprecipitate were used. In relation to Haemophilia B treatment, 258,875 units of NHS concentrate were used.

35. In 1979 the number of patients had decreased to 62 patients with Haemophilia A and 6 patients with Haemophilia B. However, usage remained at similar levels:
    a. 228,533 units of Kryobulin;
    b. 274,442 units of Koate;
    c. 456,172 units of Factorate;
    d. 521,450 units of NHS concentrate;
    e. 1,232,395 units of Hemofil.[69]

36. Cryoprecipitate usage increased to 238,800 units. Usage of NHS Factor IX concentrate remained at a similar level (223,295).

37. In 1980 there were 67 patients with Haemophilia A and 5 patients treated with Haemophilia B. The records refer to products being used as home treatment, which appear to relate to patients who were not students at the School. The predominant product remained Hemofil with 950,520 units (756,872 at the Hospital and 193,648 as home treatment). Thereafter the usage was 414,674 units of Factorate; 348,882 units of Koate, 288,250 units of NHS

[68] HCDO0001224

[69] HCDO0001294

concentrate; 276,685 units of Kryobulin, 166,400 units of cryoprecipitate and 9840 units of Humanate. 264,691 units of NHS Factor IX were used.[70]

38. In 1981, 53 patients with Haemophilia A were treated. The significant increase in 1981 was in the use of Hyland. The figures for product usage for Haemophilia A treatment were as follows:
    a. 8400 units of cryoprecipitate;
    b. 231,597 units of Kryobulin;
    c. 526,506 units of Factorate;
    d. 599,614 units of NHS concentrate;
    e. 661,796 units of Hemofil;
    f. 830,925 units of Hyland.[71]

39. Porcine Factor VIII also appears to have been used for the first time (15,530 units). There were 4 patients treated with Haemophilia B. However, in 1981, the product usage was substantially lower than previously with just 159,869 units of NHS Factor IX concentrate recorded.

40. In 1982, 61 patients with Haemophilia A were treated and 6 patients with Haemophilia B. The products used for the treatment of Haemophilia A were:
    a. 9260 units of Koate;
    b. 271,380 units of Kryobulin;
    c. 711,516 units of NHS concentrate;
    d. 1,531,567 units of Factorate;
    e. 1,736,438 units of Hemofil.

41. Autoplex and Feiba usage is also recorded. In relation to Haemophilia B, 247,909 units of NHS Factor IX concentrate are noted.[72]

42. In 1983, 57 patients with Haemophilia A were treated with the following:

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[70] HCDO0001388

[71] HCDO0001487

[72] HCDO0001590

a. 7460 units of Profilate;
b. 322,860 units of Koate;
c. 325,815 units of Factorate A2;
d. 329,796 units of Kryobulin;
e. 497,379 units of Factorate;
f. 748,699 units of Hemofil, of which 14,400 were Hemofil T;
g. 858,581 units of NHS concentrate.[73]

43. FEIBA and Autoplex use is also recorded. In that year, the number of Haemophilia B patients treated reduced to 3 and the usage reduced slightly to 135,969 units of NHS Factor IX concentrate.

44. In 1984, 46 patients with Haemophilia A were treated and 5 patients with Haemophilia B. The usage figures for Factor VIII were:
    a. 76,946 units of Hemofil;
    b. 197,081 units of Kryobulin;
    c. 863,150 units of Koate;
    d. 1,462,763 units of Factorate;
    e. 1,993,566 units of NHS concentrate.[74]

45. In addition, 19 bags of cryoprecipitate and 10,080 units of Porcine Factor VIII were used for Haemophilia A patients. 304,164 units of NHS Factor IX were used.

46. In 1985, 60 patients with Haemophilia A were treated and 4 patients with Haemophilia B. Usage in relation to Haemophilia A treatment was:
    a. 3800 units of cryoprecipitate;
    b. 191,550 units of NHS Factor VIII;
    c. 326,050 units of Hemofil;
    d. 358,773 units of Kryobulin;
    e. 664,934 units of of Profilate;
    f. 690,591 units of Factorate;

[73] HCDO0001686

[74] HCDO0001782

g. 757,572 units of Koate.

47. 119,495 units of Porcine Factor VIII were also used. 1985 appears to be the first year in which commercial Factor IX was used: 257,260 units of NHS Factor IX, 70,060 units of Konyne and 4590 units of Profilnine.[75]

48. In 1986, 48 patients with Haemophilia A were treated. No cryoprecipitate was used. Porcine Factor VIII reduced substantially to 13,520 units. Other product usage was:
    a. 97,418 units of Kryobulin;
    b. 147,790 units of Hemofil;
    c. 269,860 units of Profilate;
    d. 485,698 units of Factorate;
    e. 573,007 units of NHS concentrate;
    f. 899,860 units of Koate.

49. 291,385 units of NHS Factor IX were used. No commercial Factor IX was recorded.[76]

50. In 1987, when treating 49 patients with Haemophilia A, the following products were used:
    a. 20,200 units of Monoclate;
    b. 62,120 units of Hemofil;
    c. 165,290 units of NHS Factor IX;
    d. 431,494 units of NHS Factor VIII;
    e. 555,970 units of Profilate;
    f. 1,249,100 units of Koate.

51. For the treatment of 5 patients with Haemophilia B, 314,000 units of NHS Factor IX were used.[77]

52. In 1988, 44 patients with Haemophilia A were treated and 3 patients with Haemophilia B. Product usage was:

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[75] HCDO0001875

[76] HCDO0001971

[77] HCDO0002064

a. 37,195 units of Monoclate;
b. 98,060 units of Factor IX;
c. 464,240 units of Koate;
d. 722,850 units of Profilate;
e. 852,166 units of NHS Factor VIII.

53. In addition, 139,140 units of Porcine Factor VIII were used. 375,235 units of NHS Factor IX were used for the treatment of patients with Haemophilia B.[78]

54. In 1989, 40 patients with Haemophilia A were treated with the following products:
a. 22,290 units of Koate;
b. 186,900 units of Monoclate;
c. 383,380 units of Profilate;
d. 1,864,063 units of NHS concentrate.

55. In addition, 4350 units of Porcine Factor VIII were used.

56. 5 patients with Haemophilia B were treated, using NHS Factor IX concentrate (187,175 units).[79]

57. In 1990, 36 patients with Haemophilia A were treated with:
a. 7200 units of Profilate;
b. 102,465 units of Monoclate;
c. 152,621 units of NHS Factor IX;
d. 1,740,180 units of NHS Factor VIII.

58. 15,240 units of Porcine Factor VIII were also used. 4 patients with Haemophilia B were treated with 290,710 units of NHS Factor IX.[80]

Cryoprecipitate and early use of concentrates

[78] HCDO0002153
[79] HCDO0002247
[80] HCDO0002338

59. It appears that even before the use of concentrates, the Centre tended to administer larger doses of cryoprecipitate to patients than did other centres.[81] This seems to have continued with the use of concentrates.

60. The earliest use of AHG concentrates appears to be in 1969: Dr Rainsford wrote thanking Dr Maycock for providing six bottles of dried concentrate. He noted that he felt "safer now that we have something in reserve for emergency purposes".[82] This timeframe, and its limited use initially, accords with several witness accounts. One witness, who attended the School between approximately 1969 and 1973, states that not all pupils received uniform treatment. He recalls that he received cryoprecipitate at Treloar's, rather than factor concentrates.[83] Another witness recalls receiving fresh frozen plasma from 1966 until he started to receive cryoprecipitate from 1970 until he left Treloar's in 1972.[84] A further witness who attended the School between 1969 and 1971 recalls receiving cryoprecipitate and FFP.[85]

61. Further witness evidence includes a witness who describes receiving factor concentrates as a new treatment during the years 1972 and 1973.[86] Similarly the widow of another pupil has obtained letters referring to a prophylactic trial of factor VIII in around 1973.[87] Some medical records suggest trial doses of Hemofil being given to a pupil in March 1973 when he was described as "not responding clinically to Cryoprecipitate".[88] Another describes starting treatment with Hemofil when he was 11 years old, in 1975.[89]

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[81] TREL0000059_008

[82] DHSC0100025_098

[83] WITN1096001 §7.

[84] WITN1379001 §6

[85] WITN5414001 §6

[86] WITN1245001 §8

[87] WITN1055001 §10

[88] TREL0000244_042

[89] WITN3130001 §7.

62. In relation to Factor IX, a witness recalls receiving a mix of cryoprecipitate and freeze-dried Factor IX when he joined the school in 1976 but within a year being moved to just freeze dried factor.[90]

Choice of factor concentrates

63. Firstly, in relation to mild haemophiliacs, it appears that Dr Aronstam's policy was to use DDAVP and cryoprecipitate in the late 1970s. In May 1979, Dr Aronstam was asked by Dr Craske to give NHS Factor VIII to mild haemophiliacs to establish whether it transmitted hepatitis.[91] Importantly, Dr Aronstam's reply is firm: "I totally disagree with this concept. I do not wish any of my mild haemophiliacs to develop hepatitis in any form and therefore adopt the policy of either using DDAVP or Cryoprecipitate".[92]

64. With regard to students with severe haemophilia, it does not appear that there was any specific policy in place as to which concentrates would be used. Some insight can be gained from a file note of a meeting between a pharmaceutical representative and Dr Aronstam dated 31 August 1978. The note records that Dr Aronstam's "first requirement is convenience of administration, since they can often have 15 infusions to give at a time". He preferred Hemofil and Factorate to Koate because of that. The note records that Dr Aronstam "was interested in the PE material and will look at it when available. He believes animal has a place in treatment, but has never used it."[93] Dr Painter recalls that Hemofil was the preferred option "because it went into solution more quickly than the others especially the "Lister" product which could take up to 20 minutes or more to dissolve".[94]

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[90] WITN1432001 §11

[91] HHFT0000916_003

[92] HHFT0000916_002. Thereafter Dr Craske wrote to clarify that he intended Dr Aronstam only to use concentrates where they were indicated, and if so to use NHS rather than commercial concentrates: HHFT0000916_001.

[93] IPSN0000331_008

[94] WITN5277001 §17

65. In addition, two witnesses, who are brothers, both attended Treloar's and had been told by their doctor at their "home" Haemophilia Centre that they were to receive only British factor products. This was reiterated in a letter from their mother to Dr Wassef and Dr Roy.[95] One of the brothers recalls informing Dr Roy of this and being told that American products were the same as British products and that it did not matter which they received.[96] Despite this, it appears that he was able to insist on receiving only British products.

66. One witness recalls that he received 1500 units of factor concentrates three times a week over a period of approximately 18 months after he had completed a course of immune tolerance for inhibitors. He believes that the product used was Armour. In addition, during his time at Treloar's, he states that he was given FEIBA, Factor VII Inhibitor Bypass Agent, Autoplex and Porcine Factor VIII. He recalls that when Dr Dasani attended Treloar's he was "very shocked at the number of batches that were in use at Treloar's. There appeared to be no attempt to limit any exposure to infected blood products". His impression was that there were issues of cost.[97]

67. Throughout the annual returns, the records indicate that individual pupils were given a variety of products. This is also evident from a number of the medical records of individuals, one of which noted that a pupil had received "a variety of products at school, sometimes three different products within 2 or 3 days".[98] The rationale for the variety of products appears to be "the difficulties we experience in supplying replacement material for 55 severe haemophiliacs".[99]

68. Another witness notes that "product brands were never mixed in a single dose, but different batches of the same brand could be used to obtain the correct number of units, so if 1200

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[95] TREL0000121_106

[96] WITN1078001 §8. See also WITN1623001 §10.

[97] WITN3044001 §12-14.

[98] TREL0000328_077. See also TREL0000056_014 and TREL0000286_006

[99] WITN1592011

units were required, we could use 2 x 500 units from one batch and 200 units from another batch".[100] A further witness states that he was given "many different brands of Factor concentrate during the six years I attended Treloar College".[101] Another witness, the widow of a Treloar's pupil, states that he was treated with Hemofil, Factorate, Koate, Lister and Kryobulin while at Treloar's.[102]

69. The medical records for one pupil show that in 1975 he was treated with cryoprecipitate and Kryobulin.[103] Later he was also treated with Lister Factor VIII, Factorate and Koate,[104] Hemofil and Interhem,[105] and Profilate.[106] The records for another show he received a course of prophylactic treatment with Hemofil in 1977.[107] Another was treated with Hemofil, Lister, Koate, Factorate and Kryobulin as well as cryoprecipitate between 1973 and 1979.[108] Another received Lister, Hemofil, Kryobulin and Koate as well as cryoprecipitate between 1975 and 1979.[109] The records of a pupil with inhibitors who attended Treloar's from 1979 to 1987 show that he received Autoplex,[110] Koate, Hyate C, Factorate,[111] FEIBA, Porcine 3150,[112] Inter Hem,[113] Profilate[114] and Factor IX.[115]

70. Even in relation to pupils who had previously only received NHS Factor VIII, the records suggest that their treatment was also changed to commercial concentrates. In relation to one pupil, his records show that prior to attending Treloar's, he had only received NHS Factor VIII and the plan was for that to continue,[116] but after suffering a reaction to Lister

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[100] WITN1541001 §14

[101] WITN1592001 §9

[102] WITN1353001 §8. See similarly WITN1202001 §14

[103] TREL0000319_023
[104] e.g. TREL0000324_048
[105] e.g. TREL0000319_021
[106] TREL0000319_024
[107] TREL0000074_020
[108] TREL0000225_003
[109] TREL0000064_004
[110] TREL0000167_016 & TREL0000170_033
[111] TREL0000170_002
[112] TREL0000170_003
[113] TREL0000170_018
[114] TREL0000173_027
[115] TREL0000173_061
[116] TREL0000242_012 & 013

material on two occasions in 1981 he was switched to commercial material.[117] Subsequently he received Kryobulin, Koate, Factorate and Hemofil.[118]

71. On 21 November 1978, Dr Rizza wrote to Dr Aronstam regarding other pupils at Treloar's who were under the care of the Oxford Haemophilia Centre when at home:[119]

> "Thank you for your letter of 10 November about the above boys who are interested in learning self therapy. I have not seen any of those boys for sometime now and providing you think they have grown to be sensible and responsible individuals, I see no reason why they should not go ahead to administer treatment themselves. On looking through our records I see that none of the boys has Hepatitis B antibody and that they have all been treated mainly with N.H.S. factor VIII although [named pupil] has had the occasional dose of Armour. I think if possible they should receive treatment with the N.H.S. material."

72. That named pupil, far from being restricted to NHS treatment at Treloar's, received Hemofil, Koate, Factorate and Kryobulin between 1977 and 1980, as well as Lister material.[120]

73. A further witness describes that pre-mixed doses were put on the tables in the treatment room, each labelled with a pupil's surname. If there was not a syringe ready with their name on, then they would simply be given someone else's dose.[121] The process changed in about 1983 when "they suddenly became incredible strict" with locks on fridges and the treatment was mixed by staff in front of the pupils. Record keeping was also "noticeably tighter" and pupils were no longer allowed to administer treatment unsupervised.[122]

74. In addition, the evidence does suggest that very large doses were used. In his doctoral thesis, Dr Aronstam recorded the number of transfusions used in relation to his study group over 1973 to 1977. He produced the following table:

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[117] TREL0000241_035; TREL0000242_011
[118] TREL0000242_041 & 035 & 033
[119] TREL0000175_090
[120] TREL0000036_004
[121] WITN1432001 §13
[122] WITN1432001 §15

Year	No. of Patients in each year studied	No. of Bleeding episodes	No. of Transfusions	No. of Transfusions / bleeding episode
1973	39	639	782	1.22
1974	43	708	873	1.23
1975	49	948	1359	1.43
1976	54	1249	1781	1.43
1977	51	1391	1931	1.39
TOTAL		4935	6726	1.36

75. In addition, he noted that "During the years of the study the amount of haemophiliac material used rose by a factor of 2.5 from 561,640 units of factor VIII in 1973 to 1,153,340 in 1977", which accords with the Annual Returns data.[123] Although the increase was said to be presumed to be because "the haemophiliacs entering the College towards the end of the period were more severely affected" and that the treatment policy had remained the same, Dr Aronstam's explanation of the "present policy at the College in treating elbow bleeds in pre or early adolescence" suggests a less conservative approach. Namely the policy was "to:

    a) treat these bleeds vigorously
    b) pay scrupulous attention to restoration of function
    c) give limited prophylaxis when recurrent bleeds occur
    d) develop a programme of physical treatment aimed at strengthening the muscles protecting the elbow joint."[124]

76. The policy of treating bleeds "vigorously" appears to contradict another part of his doctoral thesis that suggests that the lowest possible dose should be sought. Summarising and discussing literature, he said "As preparations of factor VIII became more freely available, so reports of undesirable side effects became more and more frequent, culminating in the realisation that widespread parenchymal liver disease appeared to be a direct consequence of transfusion therapy. … While no really convincing evidence has been presented to link the majority of undesirable side effects to the quantity of factor VIII transfused, it is logical to look for the lowest dose of factor VIII likely to be clinically effective… A scarce and

[123] TREL0000517 at p.105 and 106.
[124] TREL0000517 at p.112-113

potentially harmful preparation must be used rationally and the enormous benefits to the haemophiliac of adequate factor VIII make the sensible use of this preparation vital." [125]

77. It is notable that in a letter dated 21 March 1978, a treating "home" clinician wrote to Dr Maycock about a patient who he said they were having difficulties in gaining a rapport with. The issue was that he had returned to Plymouth after being a pupil at the School. He had been receiving 740 units of Hemofil every alternate day as part of the prophylaxis trial but this level of treatment could not be maintained at Plymouth due to the cost implications. It had proved difficult to persuade him to reduce the dosage by half and to switch to Elstree products. His parents were described as "rather resentful" and the patient "still fails to have confidence in our surveillance".[126] A further letter on 18 May 1979 similarly suggests that the Centre tended to use bigger doses of concentrate than other Centres were using at that time.[127] A letter from parents also raised concerns about whether the Centre sometimes over-treated their children.[128]

78. Importantly, in a report on the Centre in 1986, which appears likely to have been written by Dr Aronstam, it is noted that "The annual use of Factor VIII, which peaked in 1984, has decreased by one-third since then, although the number of bleeding episodes treated has not altered significantly.... We have, however, significantly reduced the average amount of Factor VIII given per transfusion. This is due to a combination of factors. Firstly, our intensive regimes in the early 1980s have improved joint and muscle states and bleeding episodes are less severe and less frequent, thus requiring less Factor VIII. We have also studied the responses to treatment over the years and learned the minimum doses which are needed in different situations".[129] He anticipated however, that costs would not be reduced due to the expense of highly purified materials.

Mechanics of supply

79. In 1969 Dr Rainsford wrote to Dr Maycock in relation to the provision of supplies. He stated that the needs of the School for AHG were "no heavier than what they would have

[125] TREL0000517 at p.86

[126] CBLA0003023

[127] TREL0000072_029

[128] TREL0000121_106

[129] HHFT0001073

been before I came here had the boys been adequately treated" and raised concerns about the limited supply of cryoprecipitate that he had been receiving. He noted that he received a maximum of 24 bags of cryoprecipitate twice a week from Dr Zeitlin, of the South London Transfusion Centre. [130] Dr Zeitlin's response reveals that he considered that Dr Rainsford's request for "the equivalent of 10,000 cryos a year" was excessive.[131]

80. NHS blood products were supplied to the Centre by the Wessex Regional Transfusion Centre at Southampton. [132] Initially it seems that Dr Aronstam had free rein in purchasing concentrates. However, subsequently at a meeting of the Haemophilia Centre Directors and Blood Transfusion Directors for the Oxford Supraregion on 19 June 1978, Dr Aronstam reported that the policy in relation to purchasing commercial concentrate had changed. He was now required to get it from his Regional Blood Transfusion Centre, having budgeted ahead in relation to how much he needed. [133]

81. By August 1978, a pharmaceutical representative noted that "All orders for the Wessex area are processed through the buying office in Winchester, but Aronstam makes the decisions, as he is by the far the biggest user".[134]

82. The supply was consistently considered to be too limited by Dr Aronstam.[135] However, it is notable that although in 1970 the use of AHG concentrates by Treloar's was at the lower end of the spectrum compared to other Centres, by 1973 they were the third highest user. Their usage remained broadly the same in 1974 while other Centres used significantly more. Nevertheless, their usage was still equivalent to the Royal Free where there were likely to be much greater patient numbers.[136]

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[130] DHSC0100025_098

[131] DHSC0100025_100

[132] OXUH0000652.

[133] OXUH0003765_020 at p.4-5

[134] IPSN0000331_008

[135] OXUH0000652. The need to "beg and borrow" from other centres is confirmed in a letter to the Lancet by Prof Biggs dated 29 June 1974: PRSE0002515

[136] DHSC0100005_159

83. In 1974 Dr Aronstam wrote to the Department of Health and Social Security to raise concerns that he had to "beg for materials from other transfusion centres: from the Lister Institute; from the Oxford Unit; from the Bristol and Edgware Transfusion Centres and from other Haemophilia Centres who have supplied me with material unofficially. I have also had to, when all else has failed, buy off the commercial market and have spent about £1,000 in the past year".[137] He sought a guarantee from Dr Waiter of the DHSS of the supply or the necessary funds. There appears to have been continuing difficulty in relation to shortages of supply: in a letter to Dr Aronstam, Dr Biggs noted that the DHSS seemed to believe "that the shortage of factor VIII is more in the minds of doctors than in reality". She noted that the Ministry was claiming that bills for Factor VIII had to be met within Regional drug bills which was "absurd".[138]

84. In July 1974 Dr Aronstam wrote to thank Dr Maycock for agreeing to provide him with five bottles of AHG per week.[139]

85. Interestingly in a letter dated 14 March 1978, Dr Aronstam wrote to Dr Stafford, Consultant Haematologist at Plymouth General Hospital, regarding a patient who had been receiving prophylactic treatment at the School. He recognised the difficulties Plymouth would have in maintaining that level of products for the patient and said, "We are obviously more fortunate than you in that the Wessex Region is supplying us with all the material we need for our admittedly enthusiastic programme".[140]

86. Despite this, at a meeting of the Haemophilia Centre Directors and Blood Transfusion Directors for the Oxford Supraregion on 19 June 1978, Dr Aronstam reported that "He did not think that he would be able to manage within his budget". Dr Smith, Wessex RTC, noted that the College was a "special case" and that he was awaiting the DHSS's reply to a request for official recognition of the situation. Other regions raised concerns that they were subsidising other locations and questioned whether the Centre should cross-charge regions from where the pupils had come from. Ultimately it was decided that this would be

[137] OXUH0000652. The need to "beg and borrow" from other centres is confirmed in a letter to the Lancet by Prof Biggs dated 29 June 1974: PRSE0002515

[138] OXUH0000645_001

[139] CBLA0000219

[140] CBLA0000745

too complex. Instead, a letter was to be sent to the DHSS about the continuing shortage of NHS concentrate.[141]

87. In a letter dated 19 November 1979, Dr Aronstam set out the avenues he had explored of "ways of conserving resources". He had sought to use cheaper concentrates, asking pharmaceutical companies to reduce their prices and asked School staff to be stricter to reduce the frequency of bleeds, much to his disappointment because this required curtailing the pupils' activities. He had also asked for a greater supply of NHS concentrate despite it being "much less convenient for us to use". However, this was also unsuccessful "because of a Regional directive to send more plasma to the Lister Institute to make NHS concentrate and there is, therefore, less available for locally produced cryoprecipitate … the two aims of a) using more cryoprecipitate and b) sending more plasma to the Lister Institute are not compatible".[142]

88. In April 1980, supply difficulties appear to have continued. Dr Aronstam wrote a letter to the Editor of the BMJ stating that in his experience the NHS could not "provide more than a fraction of my needs for the treatment of 70 severe haemophiliacs. The shortfall is made up by the purchase of expensive commercial concentrates and it has been made plain to me that there will be pressures to cut the amount made available and in the foreseeable future no prospect of any increase". Consequently, he advocated exploring the possibility of commercially successful private industries fractionating the material for the NHS.[143]

89. At the UKHCDO meeting of 30 September 1980, there was a lengthy discussion about the usage of concentrates in the UK and the availability of NHS material. Dr Walford stated that she anticipated the pro rata returns for plasma supplied system would be in place by April 1981. She indicated that Wessex would receive an additional allocation of Factor VIII above the pro rata entitlement because of the School.[144]

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[141] OXUH0003765_020 at p.4-5

[142] HHFT0001062

[143] DHSC0002197_084. Dr Bidwell, Head of Plasma Fractionation Laboratory Oxford, responded to Dr Aronstam rejecting the "misleading half-truths" in his letter: CBLA0001193. Dr Aronstam replied in turn: CBLA0001199.

[144] PRSE0003946. In 1981 memorandum addressing the pro rata distribution of blood products, the Centre was noted to require a system of special allocations with a certain number of units per pupil to be allocated: CBLA0001294. This was confirmed in April 1981: CBLA0001341.

90. In a newspaper article dated 4 February 1981, Mr MacPherson is recorded as calling on the Government to increase production of NHS concentrate after pupils suffered headaches and dizziness following the use of American concentrate.[145] Mr MacPherson recalls that he was asked to publicise the issue by Dr Aronstam.[146]

91. Witness evidence of pupils at the School about their awareness of supply problems varies. One witness describes receiving Hemofil throughout his time at Treloar's (1975-1983). He recalls that attempts were made to bring in British Factor VIII but there was not much available. He believes that he received BPL just before he left Treloar's.[147] By contrast, another witness recalls that during his time at Treloar's, in the early 1980s, there did not appear to be any shortage of Scottish or English Factor VIII when a trial of American Factor VIII was pursued. He recalls three fridges with Scottish Factor on the top shelf because it was deemed the safest, then the English Factor VIII and at the bottom the American Factor VIII. He had been told to start at the top when needing factor concentrate.[148] He recalls a new product being present from around September 1982.

Consent to treatment

92. The mother of a pupil who subsequently died recalls that she and her husband were not told anything about her son's treatment while at the School. As far as she was concerned, her son was still receiving cryoprecipitate. No consultations were held nor any updates on his treatment and condition provided.[149] She was never told or asked to consent to her son being given factor concentrates.[150]

93. The parents of two students who attended Treloar's have stated that they do not recall being asked to give their consent to their children being tested for HIV or hepatitis, nor of any

[145] TREL0000524

[146] WITN5561001 §65

[147] WITN3130001 §12

[148] WITN1243001 §33.

[149] WITN4641001 §24-25

[150] WITN4641001 §35

forms relating to medical treatment being signed when their children were admitted to the School.[151] This is reiterated by many other parents of pupils.[152]

94. Witnesses who were themselves pupils at Treloar's universally do not recall being asked to give their consent to either treatment or testing.

95. Within the documents, there are some consent forms that the School held from parents consenting to the pupil "receiving such medical, dental and surgical treatment as may be considered necessary and desirable, provided that in the case of serious illness or accident the Principal shall make all reasonable effort to notify me". [153] This accords with the recollection of staff, that the School held consent forms from parents to allow them to act in *loco parentis* for the children. Despite the indication on the consent form that parents would be notified of something serious, consent forms to operative procedures appear in some records to have been signed by the Headmaster.[154]

96. School staff recall that in addition to the generic consent form, if a child was unwell, then parents were informed.[155] What is less clear is whether this provision of information took place for haemophiliacs who had a bleed and whether this was treated as something in the normal course of events, rather than something that needed to be notified to parents.[156] At the end of each term, the pupil's "home" clinician was often provided with a record of the bleeds and treatment received but these documents do not appear to have been provided to parents as well on a routine basis.[157]

97. In 1973, it appears that consent was sought to trial some pupils with factor concentrates as part of research work to ascertain the correct dosages.[158] However, some letters to parents

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[151] WITN1077001 §16-18 and WITN1623001 §16-18.

[152] Including WITN2804001 §32

[153] An example of which is: TREL0000250_020

[154] TREL0000295_453

[155] WITN5314001 §49 and WITN1128001 §20

[156] By comparison, when two boys needed "special tests" on their blood necessitating a journey to the Oxford Haemophilia Centre, the parent was informed – albeit no consent was sought: TREL0000502. The reply agreed but sought an explanation for why the test was being carried out and the result: TREL0000186_025

[157] TREL0000075_099

[158] TREL0000277_010. Some parents subsequently wrote to withdraw consent: TREL0000065_015.

suggest that they were only informed subsequently about the changes and invited to then meet the clinicians to discuss it.[159] It has not been possible to identify, other than some consent for certain research (see further below), consent forms or letters indicating consent having been given in relation the changing of products. Indeed, one document suggests no parental contact about medical care throughout a term, despite the pupil having a significant number of bleeds and being given two courses of prophylactic treatment.[160]

98. Dr Painter has stated that he does not think any information was provided to parents in relation to risks of infection in consequence of treatment with blood products or about alternatives to factor concentrates.[161]

99. There is no documentary evidence of parents giving consent to testing for hepatitis or HIV in advance, nor in relation to retrospective testing of samples that appears to have taken place.

Prophylaxis

100. As noted below, various research trials were undertaken into prophylactic treatment. One witness states that he was one of six boys selected, it seems in 1973/4, to receive Factor VIII prophylactically for a year.[162] Thereafter prophylaxis appears to have been a significant feature in the treatment received. One witness describes the word "prophylaxis" being used a lot at the School and that "We would be given Factor VIII and sometimes this could be twice a day or twice a week. I have disagreed with it because I felt it hammers my veins. They would put you on it to try and calm [a target joint] down. They told us it was prophylaxis Factor VIII and they would give it even though I didn't want it. I used to argue with the doctor and say that I didn't want it".[163]Another witness confirms that there "was a drive for prophylaxis" in the school which was unwanted by the pupils.[164]

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[159] For example, TREL0000027_038, TREL0000057_007 and TREL0000056_021

[160] TREL0000108_010

[161] WITN5277001 §48 and §49

[162] WITN1482001 §4

[163] WITN0297001 §12

[164] WITN1243001 §44.

101. By 14 March 1978, Dr Aronstam was reporting that the Centre "now use prophylaxis routinely in many clinical situations, and we feel that it can be of positive benefit when some of our boys are going through difficult patches". As noted above, he described the programme at the Centre as "admittedly enthusiastic".[165] In a letter dated 14 November 1978, Dr Aronstam set out his policy on "the clinical indications for prophylaxis" as:

"(i) Frequency of bleeding and by this I am talking about 20-30 bleeds/100 days …
(ii) The covering of a "bad patch".
(iii) Cover for an extended course of physiotherapy and for invasive procedures.
I do not believe in extended prophylaxis in any other situation".[166]

102. Importantly, he notes his concerns about prophylaxis because "I am also becoming increasingly aware of, … the potential danger to our haemophiliac population of hyper-transfusion with blood products". He references an increased incidence of chronic aggressive hepatitis and high blood pressure. Consequently, he states that he is "increasingly wary of the indiscriminate use of blood products in our boys".[167]

103. However, witness evidence suggests otherwise. One witness recalls that in around 1979 the school "really started to push the use of prophylaxis treatment", despite resistance from the pupils.[168] A further witness has noted that in her father's medical records in a letter dated 26 June 1979, Dr Wassef wrote that her father had suffered a higher than average number of bleeds and that "because of his alarming frequency of bleeds we thought of putting him on prophylaxis to save material" but instead decided that "supplying him with the material and advising him to treat himself at the earliest sign of a bleed will very much help in reducing his material requirements".[169] These witnesses' evidence is corroborated

[165] CBLA0000745

[166] TREL0000332_068. This letter is in response to a letter from the home clinician raising concerns about a change in management of a patient: TREL0000333_023

[167] TREL0000332_068

[168] WITN1432001 §12.

[169] WITN1941001 §14

by the Inquiry's review of the Treloar's medical records in which "prophylaxis" is often given as the reason for administration in treatment record forms.[170]

104. Indeed by 1980, Dr Aronstam informed a parent that ongoing prophylaxis was not an option due to cost, rather than because of any concerns about hepatitis.[171]

105. When prophylaxis was used, the usual process appears to have been treatment on alternate days, compared to other Centres who treated twice weekly.[172]

106. In 1981, Dr Aronstam described the aims of prophylaxis as being primarily "to reduce the frequency of bleeding" with the "secondary effect of reducing bleeding is to reduce the incidence of chronic synovitis and ultimately of chronic joint changes".[173]

107. There is evidence that prophylaxis continued in 1983 and 1984.[174] With one pupil, he received prophylactic treatment for most of a term only stopping for 8 days "because of the changeover to heat treated factor VIII".[175] This might suggest that prophylaxis continued despite the lack of heat-treated material.

108. Similarly, by letter dated 19 March 1984, Dr Aronstam advised a "home" clinician, a Consultant Paediatrician, that due to difficulties with the elbow a pupil should receive a course of prophylactic treatment. He recommended treatment on alternate days, with the dose increasing if there was any breakthrough bleeding. The letter from the home clinician appears to have raised concerns about T cells, to which Dr Aronstam responded "I note your comment about factor VIII preparations affecting 'T' cells. This is a very worrying problem for all of us in haemophilia care. At present the general view is that while the disease is horrific, the numerical risk of it is nevertheless small and should not deflect us from the appropriate treatment"; which in this case was prophylaxis.[176]

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[170] E.g. TREL0000110_080
[171] TREL0000108_016
[172] TREL0000075_100
[173] TREL0000517 p.49
[174] TREL0000108_010
[175] TREL0000247_007
[176] TREL0000343_044

109. Only in a letter dated 16 July 1987, did Dr Aronstam inform a different clinician that a student's prophylactic treatment had come to an end: "The decision to terminate his prophylaxis was taken after careful consideration because of the recent increase in the number of published papers about the immuno-suppressive effects of Factor VIII concentrate, particularly in anti HIV positive haemophiliacs".[177]

Heat treated factor products

110. One witness recalls a conversation he had with a fellow pupil, now deceased, that in 1980 Dr Aronstam had attended a conference in South America where he expressed his concerns about the need to heat treat Factor concentrate. At the conference, it is said that Dr Aronstam introduced two German experts from Behringwerke, who gave a presentation advising that their company could heat treat Factor VIII.[178] It was this witness' understanding that Dr Aronstam thought that heat treated products could be introduced within 3 months of the 1980 conference. Moreover, the witness describes a conversation with Dr Aronstam in around 1991 in which "Dr Aronstam was quite exasperated and rather agitated. He explained to me that the PHLS had 'f***** him'. He said that he had done all he could and that he had done his best but did not understand why they did not listen to him and implement heat treated blood products when he suggested they do so. He believed that by 1981 or 1982 we would have all been on heat treated products and with this, he said that AIDS/HIV did not need to happen".[179]

111. The witness recalls that Dr Aronstam tried to do his own heat treatment by heating the water in the mixing machine to 28 degrees and not letting the factor out of the machine until after the 20 to 25 minutes reconstitution time. Even at home, he was told he must place the Factor concentrate in a bowl of warm water and make sure that it stayed at 28 degrees while mixing it. He recalls Dr Aronstam or Dr Wassef saying sometimes "don't worry boys we're going to warm it up. There will be no more yellow (hepatitis)".[180]

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[177] TREL0000092_132

[178] WITN1243001 §29.

[179] At §30.

[180] At §31.

112. From the documentary evidence, it appears that some pupils were provided with heat-treated Lister factor VIII as part of a trial in September 1984.[181] Other pupils who were on commercial concentrates were changed to heat treated factor VIII in late 1984, but those on the (presumably, unheated) Lister product were not.[182] A standard paragraph was inserted into letters to pupils' home treating consultants at the end of the Autumn term in December 1984 stating: "Lately we have changed to heat treated factor VIII (marked H on the computer sheet) for patients who were taking commercial factor VIII. Those who were on Lister remain unchanged."[183]

113. It appears therefore that Treloar's took the course of preferring non-heat-treated NHS material to heat-treated commercial material for patients who had not previously been exposed to commercial material. At some point, presumably as it became available, heat-treated NHS factor VIII was also provided. For example, a record shows "HT Lister" being transfused on 15 August 1985.[184]

114. It also appears that when heat-treated material was first introduced it was given to pupils who had tested negative for anti-HLTV-III as a priority. A letter of 27 December 1984 from Dr Aronstam to Dr Sweet in Guernsey regarding a Treloar's pupil registered with Dr Sweet states:

> "While [the pupil] was with us we took the opportunity of sending a blood sample to Colindale to check for the presence of antibody to HTLV 3 (the putative AIDS virus). I understand that the results are equivocal and they wish a further sample to be sent.
>
> I would not like to unnecessarily alarm the mother as the presence of this antibody occurs in almost all severe haemophiliacs. However, it is important to clarify the possibility that he might be negative in which case it would be essential that he be treated only with Heat Treated Factor VIII."[185]

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[181] TREL0000159_243

[182] TREL0000239_032 and TREL0000247_007

[183] TREL0000239_032

[184] TREL0000239_024

[185] TREL0000313_147

115. A further letter from Dr Aronstam to Dr Sweet on 5 June 1985 refers to the good news that the pupil had tested negative and was receiving heat-treated product.[186]

116. By contrast, a letter of 20 February 1985 from Dr Aronstam to Dr Snape at BPL gives a list of HLTV-III positive students eligible to receive heat-treated material; this appears to refer to a trial of some kind.[187]

117. By 27 December 1984, Dr Aronstam noted that "it is now pretty well accepted that haemophiliacs who are severe should be switched to Heat Treated Concentrate…"[188]

118. Pupils appear to have been transferred to heat-treated Factor IX in early 1985.[189]

119. At an RCD meeting on 9 January 1986, verbal reports from Holland that a patient had become anti-HTLVIII positive after receiving Armour heat-treated concentrate were discussed. Dr Aronstam indicated that he was seeing the doctor shortly and would seek a confidential written report on the case.[190] He reported at the HCD meeting on 27 January 1986 that the information was true and that the details would shortly be published in the Lancet.[191]

120. In 1986, it was the policy of the Centre to give 8Y to all pupils who were HIV negative.[192] There is an exchange of letters showing at least one pupil's parents were concerned that heat treated British blood (8Y) be used as the sole treatment. On 15 August 1986 they wrote to Dr Wassef to say "we do insist that [our son] is only given heat treated British blood (8Y). If there is any problem in getting this please let us know before giving any treatment."[193] His mother also rang his home treating consultant, Professor Hardisty at GOSH, who reported this to Dr Aronstam on 17 September 1986 as follows:

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[186] TREL0000313_145
[187] CBLA0002054
[188] TREL0000313_133
[189] TREL0000248_078
[190] PRSE0001281
[191] PRSE0001413
[192] TREL0000120_042
[193] TREL0000120_045

"This young man has recently started on his first term at the Lord Mayor Treloar. I am indeed very pleased that he has found a place there since I feel that he was not getting optimum treatment at home. His mother, who is an extremely anxious lady, rang me up recently to say that you were treating him with commercial Factor VIII concentrate and asked whether he might instead continue on 8Y material, which he has previously been receiving from us. I did my best to convince her that there is nothing to choose between commercial and NHS concentrate now that both are obtained from screened donors and subjected to heat treatment (though I was not able to refer specifically to the material you use since I do not know which it is). Although [the pupil's mother] said that you would treat [the pupil] with 8Y if we provided it, I frankly do not think that this is indicated nor indeed should we find it easy to provide you with sufficient from our current allocation. This letter is therefore really just to let you know that I have told [the pupil's mother] that she should rely entirely on the treatment which you provide."[194]

121. Dr Aronstam replied on 19 September 1986:

"Thank you very much for your letter about this young haemophiliac and the logistics of his Factor VIII treatment. We have in fact been giving him 8Y material, apart from one occasion when we were not able to provide.

Our policy is to give 8Y to all those who are negative for HIV and I have assured [the pupil's mother] about this, even though I certainly agree with your own view that all concentrates now are equally safe. The problem with [the pupil's mother] is that I do not think she really believes me and therefore, politically, a much easier road is to reserve 8Y for [the pupil]. We certainly have enough problems here without looking for more."[195]

122. It appears that the parents' intervention did therefore result in their son receiving heat treated NHS factor VIII, although the attitude of the doctors involved towards their concerns is jarring.

[194] TREL0000120_044
[195] TREL0000120_042

123. By 1988, the Wessex Region indicated that the aim was "to wipe out the Commercial Factor VIII budget for all hospitals except Lord Mayor Treloar. If supplies of Factor 8Y increased further, the LMT budget could then be reduced".[196]

High purity products and recombinant

124. At a meeting of the Wessex Regional Health Authority Regional Medical Advisory Committee meeting on 10 December 1992, Dr Aronstam argued for a decision of the Development and Evaluation Committee (DEC) to be overturned to allow him to use high purity products for haemophiliacs. He had produced a lengthy submission to the DEC on why the move should be made.[197] In the meeting, he argued that there was "accumulating evidence" such that "it was difficult not to justify its use". Three major issues were raised by the Committee:

"1 What is the scientific evidence of benefit?

2 How should this treatment be measured against the potential uses of the almost a million pounds extra cost?

3 In HIV+ haemophiliacs, can ring-fenced money be used to pay for this treatment? This was considered appropriate in view of the iatrogenic nature of HIV-infected patients."

125. Ultimately, the RMAC "agreed to overturn the DEC recommendation and recommend that HPFC be used in the treatment of HIV+ haemophiliacs only. The RMAC only supported the use of the AIDS ring-fenced money in the funding of this treatment, and requested that central policy on this should be investigated and questioned.[198]

126. In May 1993, the DEC reconsidered whether high purity products should be provided to all haemophiliacs. The conclusion was that this fell into the category of 'beneficial but high cost', qualified with the acknowledgement that prescribing high purity products for all haemophiliacs would be supported if costs fall.[199]

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[196] NHBT0111301

[197] HHFT0000005

[198] TREL0000531

[199] TREL0000533

127. As to recombinant, Dr Aronstam sought to persuade one Health Authority to review their decision not to fund recombinant products for a pupil because other health Authorities were doing so. Consequently, he noted that "we are not in the ridiculous situation that people I treat are receiving different levels of care according to where they live".[200] The Dorset Health Authority responded by letter dated 7 May 1997 stating that it had not agreed to fund recombinant for all patients and it was being considered on an individual patient basis.[201]

UKHCDO

128. Dr Rainsford attended the 1968 Haemophilia Centre Directors meeting[202] and was a regular attendee thereafter. Dr Aronstam was a similarly regular attendee from 5 April 1971.[203]

129. On 14 September 1981, the UKHCDO discussed whether the Treloar Haemophilia Centre should be a reference centre because the "Centre had very special and wide experience in the management of haemophilia in adolescents and played an important role in introducing the boys who attended the College to home therapy". It was ultimately decided that it would not because it did not have patients referred to it from wide areas and was closed during School holidays. However, it was agreed that Dr Aronstam would be invited to attend Reference Centre Directors meetings without the official designation of Treloar's as a reference centre.[204]

130. At the 12 February 1990 meeting of the Haemophilia Centre Directors AIDS Group, there was a discussion as to the difficulties of having an open discussion about issues with Dr Aronstam present because he was acting as an expert witness for the claimants. Dr

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[200] HHFT0001640_005

[201] HHFT0001640_003

[202] HCDO0001013

[203] HCDO0001014

[204] LOTH0000012_122 p.6 and p.7

Aronstam offered to resign from the group, but he was encouraged to await advice from the lawyers for the defendants.[205]

Knowledge of, and response to risk

Serum hepatitis and hepatitis B

131. The Centre participated in the Hepatitis Survey conducted by Oxford Haemophilia Centre from as early as 1969, providing information about hepatitis suffered by students.[206] For example, 10 students were noted to have developed hepatitis during the Autumn term of 1974, all of whom had been treated with a common batch of Hemofil.[207]

132. The risks of hepatitis from blood products were discussed at the 5 April 1971, 27 October 1972, 31 January 1974[208] and 1 November 1974 HCD meetings, all of which either Dr Aronstam or Dr Arblaster attended. At the 18 September 1975 meeting of HCDs, attended by Dr Aronstam, there was a detailed discussion of the incidence of hepatitis and Dr Biggs presented a draft of the six-year study which was eventually published in 1977 as "*Haemophilia treatment in the United Kingdom from 1969 to 1974*".[209]

133. Dr Craske gave detailed reports on the issue of hepatitis at the 30 September 1980 HCD meeting, which it appears Dr Aronstam attended, including that "[l]arge pool concentrates appeared to give higher risk of hepatitis than small pooled concentrates".[210]

134. Dr Craske again reported on hepatitis at the 9 October 1981 HCD meeting, which Dr Aronstam attended. Dr Craske made a number of recommendations and noted recent

[205] PRSE0004635

[206] TREL0000382

[207] NHBT0107241 p.2

[208] Held jointly with BTDs.

[209] British Journal of Haematology, 1977, 35, 487: DHSC0000303.

[210] PRSE0003946.

developments, including claims from commercial firms that a hepatitis-free factor IX concentrate was available.[211]

135. The medical records of one witness shows that he was being tested for hepatitis antibodies from 29 October 1974 and his blood samples were labelled "hepatitis risk" from October 1976. Another witness has found similar material in his records, with his pathology records noting "hepatitis risk" from 5 October 1977 and a further witness has noted blood request forms with "hepatitis risk" on from March 1982.[212]

136. Dr Kirk provided information in 1976 to the Bournemouth Department of Pathology about a pupil who was negative for HbsAg and HBsAb and had a presumptive diagnosis of non-B hepatitis "probably associated with the transfusion of Kryobulin".[213]

137. Dr Aronstam, in 1978, told a pharmaceutical representative that he believed hepatitis "is strictly a function of the number of doses given and said that 48 of his present patients at LMT have had it and it frequently recurs". He rejected any hepatitis issue particular to the Armour material.[214] This is in contrast to letters sent by Dr McHardy in 1974 to home clinicians that a particular batch of Hemofil had been identified as a batch that had caused hepatitis infection of a number of boys.[215]

138. However, this position appears to have shifted by 1981, because in his doctoral thesis, Dr Aronstam noted that "Hepatitis has always been a risk for the patient with haemophilia who required therapy with plasma or plasma products… but the risk increased markedly

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[211] DHSC0001312

[212] WITN1541001 §28

[213] TREL0000070_056

[214] IPSN0000331_008. See similarly a letter from Dr Painter to Dr Goldman noting abnormal liver function tests of a patient and that this was a "very common problem with our 55 haemophiliacs… inasmuch as probably half of them have SGOT's (AST) of two to even three times the normal limit. The significance of this is not readily apparent, and we are currently looking into this matter with some urgency".

[215] Including TREL0000027_035 and TREL0000142_049. There was subsequently some uncertainty about whether it was Hepatitis A and B: HHFT0000931_001, DHSC0100018_107, DHSC0100018_174 and DHSC0100018_182

with the introduction of pooled concentrated preparations of factor VIII." [216] This understanding of the risks of factor concentrates appears to have extended beyond just Dr Aronstam as a witness describes that from around 1977 or 1978 some boys did not return to school after the holidays because they were recovering from Hepatitis B. The witness asked one of the doctors, in around 1978 or 1979, why the boys were getting sick and she told him that the donors were paid donors which meant that "drug addicts gave blood to buy more drugs and the drug addicts may have carried diseases".[217]

139. The severity of serum hepatitis was also known to both Dr Painter and Dr Aronstam. In a letter to a home clinician dated 7 March 1978, Dr Painter wrote that parents of a pupil had raised concerns about their son's condition. He noted that "it seems that they have not been put in the picture concerning the state of his liver, and this is an oversight for which I offer my most profound apologies…It is pretty certain that he does have chronic hepatitis… If they are liable to repeated bouts of jaundice or if their general condition deteriorates, then we consider a trial of steroids. At the moment [X]'s clinical condition is very good, … I did explain this, as best as I could, to his parents, but I told them that one could not predict the future in these cases, particularly as it seems that haemophiliacs do not follow the usual pattern of events when it comes to chronic hepatitis. I did warn them, however, that the future might be rather grim, but that this was something we would discuss with them more fully should circumstances change."[218]

140. Furthermore, in 1981, Dr Aronstam described acute hepatitis as one of the hazards of treatment and defined acute hepatitis as being a "clinical syndrome characterized by jaundice, gastro-intestinal symptoms and pyrexia, associated with transfusions and of presumed viral etiology. It may rarely be due to type A or short incubation hepatitis. It is often due to type B hepatitis and is recognised increasingly frequently as being due to a type or types of hepatitis which are neither A nor B."[219] He noted that chronic hepatitis

[216] TREL0000517 at p.72

[217] WITN3130001 §11

[218] TREL0000257_044

[219] TREL0000517 at p.72

included both chronic persistent hepatitis (CPH) and chronic aggressive hepatitis (CAH) and "post-necrotic cirrhosis and probably primary hepatocellular carcinoma may occur as sequelae" as well as associated immune complex diseases. [220]

141. The number of pupils infected with Hepatitis B at the Centre was significant. A chart of testing for a research study from 1970 to 1973 indicates that very many students were testing positive.[221] Lists of the results of testing in 1987 shows that the majority of those tested were positive.[222]

142. Despite this, one witness recalls that his parents "constantly asked the doctors if the blood that was being given to me and my brother was safe. My parents were assured everything was fine. I would be brought into the same room every day where they would stick a needle in my arm [for prophylaxis] and send me on my way."[223]

HIV and AIDS

143. Dr Aronstam attended the 13 September 1982 HCD meeting, during which Dr Craske provided an update on behalf of the hepatitis working party and provided the following information on AIDS: "The Reference Centre Directors had asked Dr. Craske to look into the report from the United States of this syndrome mainly in homosexuals but including three haemophiliacs. It appeared that there was a remote possibility that commercial blood products had been involved. Dr. Craske asked the Directors to let him know if they had any cases of the syndrome. The Working Party was considering the implications of the reports from the U.S.A."[224]

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[220] TREL0000517 at p.74-5

[221] HHFT0000054

[222] HHFT0001486_001

[223] WITN2942001 §7

[224] PRSE0004807

144. On 24 January 1983 Dr Aronstam attended a meeting between Immuno, HCDs and others at London Airport to discuss hepatitis-reduced factor VIII and factor IX concentrates. The notes of these meetings have been considered by the Inquiry on a number of occasions.[225] The information presented by Dr Craske on AIDS was that up "*to December 1982, some 800 people had been reported as suffering from the AIDS, and there was a 45% mortality*". Ten haemophiliacs in the USA had been affected and five had died. All had had prolonged treatment with factor VIII, though without implicating a particular batch or product. There had also been other cases involving blood and blood product transmission. In the UK, "*so far only one or two cases* [had] *been reported from the communicable diseases centre*". It was noted that infectious precautions were being taken in the USA, including "*unspecified measures to screen out*" certain donors and, and measures were being considered by the UKHCDO's Hepatitis Working Party. Reference was made to two articles on the editorial in the New England Journal of Medicine which indicated that the T4/T8 ratios among haemophiliacs receiving factor VIII were greater among those who had been "*exposed to concentrates than those exposed to cryoprecipitate only"*. However, cryo in the US came from "*volunteer unpaid donors*" who were "*presumably well motivated people*." Further discussion was had about proposed trials to test the effect of Immuno's inactivation procedures, which were aimed in particular at NANB hepatitis. This included that *"young children could not be used for trials as neither they nor their parents could give consent*".

145. On 14 February 1983 Dr Aronstam attended a meeting of RCDs.[226] The agreement reached with Immuno about clinical trials was taken forward and Professor Bloom addressed the issue of AIDS: "*Professor Bloom said that the Syndrome would be discussed at the Stockholm meeting of the World Federation of Haemophilia. Reports from the United States indicated that the incidence of AIDS was higher than at first thought and there was some concern that the haemophiliac population of the U.K. who had received American concentrates might be at risk. Dr. Craske summarised the latest information from the United States and said that approximately 10 cases of AIDS are thought to have occurred*

[225] PRSE0002647 and DHSC0001800.

[226] HCDO0000411.

in non-haemophiliacs in London, one in Glasgow and one in Manchester." A reporting system was discussed and subsequently put in place.[227]

146. On 24 June 1983 Professors Bloom and Rizza wrote to all HCDs regarding AIDS.[228] They noted that so far one possible case of AIDS had been reported to UKHCDO which conformed to the CDC definition but could not be considered a definite case. The letter then set out "*general recommendations*" agreed at the 13 May RCD meeting.

    a. First, considering treatment with DDAVP for mildly affected patients with haemophilia A or von Willebrand's disease and minor lesions. It was noted that that this was the usual practice of many HCDs, given the "*increased risk of transmitting hepatitis by means of large pool concentrates in such patients.*"
    b. Second, reserving supplies of NHS concentrates (cryo or freeze-dried) for treatment of children or mildly affected patients or patients unexposed to imported concentrates.

147. The letter added that the RCDs had agreed there was "insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy" but the situation would be constantly reviewed.

148. A witness recalls Dr Aronstam dropping a vial of Factor VIII on the floor which broke and he commented on the time he spent cleaning the mess up off the floor, to which Dr Aronstam replied that "we had to be very careful because this is the stuff which carried all the infections".[229]

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[227] HCDO0000517_001.

[228] HCDO0000270_004.

[229] WITN1512001 §21: no date is given for this conversation so it may relate to hepatitis rather than HIV.

149. One witness recalls that after one lunchtime, all haemophiliacs were asked to go to a classroom. They were told that they were to phone home to ask their parents if they had particular batch numbers at home. If they did, they were to tell them to return them to the hospital and not use it. He estimates that this took place in around 1981/2. The witness rang home and discovered that he had one of the batch numbers.[230] The significance of this was never explained to the witness.

150. It appears that pupils were being tested for their T-cell count by January 1983.[231] There is evidence in the medical records of pupils being routinely monitored for signs which might indicate ARC or AIDS such as swollen lymph nodes, weight loss, rashes etc from early 1983.[232]

151. This monitoring is referred to in the termly summary letters sent to pupils' home consultants from June 1983 onwards, usually using a phrase to the effect that the pupil exhibited none of the stigmata of ARC or AIDS.[233]

152. By letter dated 7 June 1983, Professor Bloom wrote to Dr Aronstam to inform him that one of the pupils at the School had received some of the factor VIII from the same batch as "one used for our suspect AIDS patient. Although our patient may not be suffering from AIDS I nevertheless thought that you should know."[234] In response, Dr Aronstam told Professor Bloom that he had reviewed the T cell sub-sets of all the boys earlier that year and was repeating it at that time in June 1983. The particular pupil "exhibits none of the stigmata of AIDS".[235]

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[230] WITN0297001 §17-21

[231] TREL0000108_006

[232] E.g. TREL0000267_028 p.4, TREL0000173_004 p.31

[233] TREL0000239_037

[234] TREL0000145_065

[235] TREL0000145_066

153. Also in June 1983, Dr Aronstam wrote to a GP in relation to a different pupil informing him that the pupil had lost movement in both elbows and shoulders which "appears to be a direct result of his reluctance to treat himself adequately because of the current hysteria about AIDS. I have explained the very small risk numerically of him acquiring the disease, but he is adamant and is, I am afraid, retreating very much into himself. It is worrying in this respect as he has lost some weight, we have found a few lymph nodes and his T lymphocytes are showing the same sort of inverted ratio that characterizes the illness".[236] Given the reassurance about the use of blood products, it does not appear that Dr Aronstam informed the pupil about his concerns that he was showing signs of AIDS.

154. At the end of June, Dr Wassef wrote a series of letters to home clinicians setting out the treatment received that term, together with laboratory results and orthopaedic information. In each letter a specific heading was included on AIDS. Results of "AIDS related tests" were provided to the home clinician and a note of whether pupil did or did not exhibit any of the "stigmata of AIDS".[237] There is no indication of whether these results were provided to the pupils or their parents.

155. By letter dated 7 July 1983, Dr Wassef wrote to a home clinician informing them about a pupil who was on a "tolerance inducing protocol" but that this appeared "to have run out of steam". He went on that "While we have supplied [X] with enough material to see him through the summer holidays, I have my own reservations as to whether it is ethically right in the current climate". Dr Wassef stated that he was happy to "fall in" with any decision that the home clinician made. It does not appear that these concerns were communicated by Dr Wassef to the pupil or his parents, as the home clinician subsequently informed Dr

[236] TREL0000143_058

[237] For example, see TREL0000108_033 and TREL0000062_229

Wassef that the "AIDS implications" had been discussed and it had been decided to probably stop the "desensitisation".[238]

156. It does not appear that these concerns were necessarily shared by Dr Aronstam because, as noted above, by letter dated 19 March 1984 he recommended a course of prophylactic treatment to a home clinician noting the risks of AIDS but stating that "the numerical risk of it is nevertheless small".[239]

157. This is despite testing for anti-HLTV-III antibodies taking place from 1984. There is a positive test result in one pupil's medical records dated 18 December 1984,[240] and reference to an earlier test on 13 January 1984, which must have been a retrospective test on a sample from that date[241]. There is a letter from Dr Wassef regarding another pupil stating that he was tested for anti HLTV-III for the first time on 23.01.84 and found to be positive.[242] Other pupils tested HLTV-III antibody positive on 11 January 1984 [243] and 12 January 1984; this must be a reference to retrospective testing.[244]

158. In a report to the Wessex Region in 1986, Dr Aronstam recorded that 43 of the Centre's patients were HIV antibody positive. Retrospective sampling had shown that two seroconverted in 1980, five in 1981, ten in 1982, eleven in 1983 and five in 1984. The remaining ten had been sero positive for at least three years. He noted that "Many of our patients are now showing clinical evidence of HIV disease. Seventeen have persistent generalised lymphadenopathy and seven are thrombocytopenic. Two cases have now progressed to full-blown AIDS." T-cell monitoring showed a "downward trend … with increasing length of exposure to the virus".[245]

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[238] TREL0000248_094

[239] TREL0000343_044

[240] JPEA0000001_037

[241] TREL0000239_105, p.9

[242] TREL0000241_ 016

[243] TREL0000173_004 p.52, and see TREL0000173_051

[244] TREL0000267_089

[245] HHFT0001073 p.1

Hepatitis C

159. In 1979, Dr Craske provided Dr Aronstam with some results of hepatitis screening tests of a pupil. He noted that "It appears that one type of N/A, N/B hepatitis is associated with Hemofil and possibly other American concentrates. The second type of short incubation of N/A, N/B hepatitis appears to be associated with transfusions of NHS concentrate or Kryobulin, manufactured by Immuno Limited. Since we know that Immuno acquires much of this plasma from one of the American drug companies, it appears unlikely that the association of the two types of N/A, N/B hepatitis with different products can be related to difference sources of donor plasma. It appears much more likely that it is due to different methods used in the preparation of American and European concentrate". Consequently, Dr Craske recommended that Dr Aronstam "try and maintain patients who have received only Kryobulin and, or NHS material in the past on one or other of these products …"[246]

160. In 1981, Dr Aronstam noted that non-A, non-B hepatitis existed and stated that "Whatever the nomenclature, this form of hepatitis is as likely to progress to chronic hepatitis as the hepatitis B variety … and is therefore at least as important".[247] He noted other publications showing that the incidence of liver function abnormalities increased with age and suggested that this was "presumably" therefore with increasing exposure to factor VIII.[248]

161. He noted that NANB would still be capable of inducing chronic liver damage and "the addition of a further chronic disabling disease to the lot of patients already suffering from severe haemophilia is a therapeutic catastrophe and will be a major concern to those concerned with the transfusion therapy of haemophiliacs for some time to come".[249]

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[246] HHFT0000909

[247] TREL0000517 p.77

[248] TREL0000517 at p.79

[249] TREL0000517 at p.78-79

Communication with and treatment of patients

Hepatitis

162. One witness describes waking up one morning in or around 1975/6 and seeing that his best friend in his dormitory had turned bright yellow. A group of ten boys were then diagnosed with Hepatitis B and told it would take six months to recover. The rest of the boys "were told that there were two forms of Hepatitis – the fatal kind and the non-fatal kind" and that the boys with Hepatitis B had the non-fatal kind. Nevertheless, they were required to have a red mark on their plates and to hand them in personally to be sterilised.[250] Another witness, the sister of a pupil at Treloar's, recalls that her brother's crockery and cutlery were marked because he was infected with hepatitis.[251]

163. Another witness describes being informed that he was infected with Hepatitis B along with a group of other pupils. They were told that "because we were Haemophiliacs we would get over it unlike other people". He does not believe that his mother was ever told of his infection or that he was being tested for any infections.[252]

HIV and AIDS

Informing patients of their diagnosis

164. One witness states that the school "never really addressed the rumours surrounding AIDS; it was just haemophiliacs getting ill".[253] Another witness recalls his roommate becoming gaunt and withdrawn. He did not return to school after half term and his death was noted in an assembly. Pupils started to ask what had happened and were told "there may be something like a virus in the factor but we were not to worry until more information

[250] WITN1800001 §9

[251] WITN0085001 §12

[252] WITN3224001 §9 and §14

[253] WITN1432001 §18

was known and, that we would be looked after".[254] A further witness recalls a newspaper being left out in the TV room in around May 1983 with the article "Killer Blood". He states that the staff member who left the paper had their employment terminated shortly thereafter.[255]

165. There appears to have been a meeting with pupils at some point regarding AIDS. One witness describes a meeting with the doctors at Treloar's at which "they told us 'don't worry, only two people in the United Kingdom with haemophilia have AIDS. Thousands have haemophilia, don't worry'. I believe it was Dr Aronstam that told us and I was reassured by that".[256] This appears to correspond to the meeting that took place when a mother was visiting her two sons at Treloar's. She recalls that the boys were called into the hall, without her, for a meeting. One of her sons, now deceased, told her afterwards "It was about AIDS mum and haemophiliacs in America. They said we were not to worry. We won't have it here". She has questioned why as a parent present at the school she was not invited to the meeting or informed of the concern.[257] Another witness recalls that Dr Aronstam reassured pupils about the safety of Factor VIII after they had seen a television programme referring to it being contaminated.[258]

166. In the Minutes of the Governing Body meeting on 24 June 1985 under the heading AIDS, it is recorded that "…a letter has been written by Dr Tomlinson (with the assistance of Dr Aronstam) to all parents concerning this problem … some parents and children were rightly worried about this subject, but with increasing knowledge this concern was decreasing. He reassured Governors that the College was enforcing very stringent hygiene precautions, as recommended by Dr Aronstam".[259] To date, the Inquiry has not been able to locate a copy of this letter.

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[254] WITN1243001 §42

[255] WITN1243001 §38.

[256] WITN3130001 §14

[257] WITN1154001 §11. The mother of another pupil recalls her son telling her about a similar meeting the day before he was informed of his own infection: WITN2804001 §21

[258] WITN1490001 §9: the witness ties this to the Cook report but giving the dates, it seems that it was likely to be a different television programme.

[259] TREL0000360

167. In relation to informing pupils of their infection with HIV, the recollections of pupils, not surprisingly, differ.

a. One witness recalls being told, at about age 16, at the same time as one other pupil.[260] This is echoed by another pupil who recalls being told together with a class mate.[261] He describes being told in a manner that was "all very matter of fact. From what I can remember Dr Wasseff said 'You have HIV. We are not sure of the implications but what we can say is that it is incurable and we cannot guarantee that you will be alive in 6 to 12 months'....[we] looked at each other in disbelief and then we laughed (through shock)."[262] It was left to him to tell his parents on his next home visit.[263]

b. Another recalls being told in a group of up to five students at a time whenever test results were received, with repeat testing over a period of six months until testing became more reliable.[264] He notes that children were told before their parents knew and without their parents being present, requiring him to tell his parents of the test results.[265] Telling pupils in groups of five is recalled by a further witness as well who described it as "a surreal but relaxed atmosphere as the staff wanted us to maintain our kinships and keep the camaraderie up".[266] He recalls it being explained that hepatitis and other viruses had contaminated the supplies and that factor concentrate was "not as clean as it should be". Thereafter, Dr Aronstam went round the room and said, "you haven't, you have, you have, you haven't" and so on. They answered a pupil's question about how long the boys had, answering that it was two to three years but maybe more, and explained about T-cells. They were told not to tell anyone else about their statuses because of the media interest in the School that had already arisen. The witness is the only remaining survivor from his group of five. He was not critical of how he was informed of his infection but considers that

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[260] WITN3044001 §16.

[261] WITN1723001 §11

[262] At §11

[263] At §13

[264] WITN1231001 §12.

[265] At §13.

[266] WITN1243001 §49-52

the School should have immediately told his mother of it, rather than waiting for a year.[267]

c. A widow of a pupil at the School has described her late husband's recollection of "being seated in a big room at Treloar's with a lot of his friends while the staff went around the room saying "yes, no, yes, no" to indicate whether they were HIV positive…This really upset him as he was left to tell his mother on his own".[268] No information was given to him as to how to manage the infection or how to avoid infecting others. A similar account is provided by other witnesses recording what they were told by those infected.[269]

d. Another witness recalls being called into a room with Dr Aronstam and being questioned about why he had never asked about his infected status. The witness asked if he was positive and was told that he was. He was told that the life expectancy was no more than 10 years at which point "Being told this was the first and last time I have ever felt a physical reaction to words; it was like being punched in the face, I remember clearly rocking back in my chair".[270] He believes that doctors knew of his infection years before he was told and he was only told because he had a girlfriend.[271] His mother was not told directly of his HIV infection. She found out one day when he returned from the School and his haemorrhagic status card fell on the floor stating that he was HIV positive. The School had broken up for the summer holidays so there was no one she could speak to until the September. She discovered that the father of her son's girlfriend had been told of his infection before her. The Consultant at Treloar's apologised, bluntly, when she spoke to him in the September that she had found out about his infection in that way. She states that she was not given adequate information about how to manage his infection or how it could be transmitted.[272]

e. Another witness recalls being called to a meeting in Easter 1986 to be told that he had tested positive for HIV. He was told by Dr Aronstam, together with a nurse. However, since reviewing his medical records, they indicate that his summer term

[267] WITN1243001 §78.

[268] WITN1180001 §6

[269] WITN1206001 §6 and WITN2912001 §9

[270] WITN1512001 §10

[271] WITN1512001 §10 and §14-15

[272] WITN2804001 §14-19

assessment on 29 June 1983 states "AIDS on 10.3.83" and a letter to his "home" centre on 30 June 1983 confirms that AIDS related investigations were carried out. There is regular reference thereafter to monitoring of his lymph nodes and a positive HTLV-III test is recorded as being on 12 January 1984. His UKHCDO records state that he was first recorded as HIV positive on 6 September 1983.[273] The witness cannot remember whether he then told his father about his infection or whether Treloar's told him.[274]

f. Another witness recalls that on one occasion when his mother visited him at Treloar's, she "called me into a room with two staff from the school and told me that I had HIV. She was upset and did not quite understand what she was telling me."[275] The witness describes how he was told of his infection as "absolutely shocking" and says that they should have been told in a private room and given information about the infection and how to deal with it.[276] He notes that the way in which he was told of his infection was very different from other pupils at Treloar's who were told in groups. His mother recalls being called by the school and asked to attend, then being told by staff members.[277] She recalls being given very little information.

168. Not all pupils or parents were told by the Centre. One mother recalls receiving a telephone call from the local "home" haemophilia centre asking her to attend. She was informed that her son was HIV positive and was asked for her permission for the school to inform him of his diagnosis.[278] However, having received her deceased son's medical records, she has discovered that she was informed four years after he had tested positive. She had not given consent to his testing, nor been informed of it.[279]

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[273] WITN1541001 §20-21

[274] At §24

[275] WITN1406001 §13

[276] At §15.

[277] WITN1406002 §13-16

[278] WITN1428001 §14

[279] WITN1428001 §24

169. The wife of a man who had been a pupil at Treloar's was unaware that he was HIV positive until his sudden death. When she spoke to his parents, they were also unaware that he was infected, despite him having been told of his infection when he was a teenager.[280]

170. This witness evidence accords with the evidence of staff members. The Housemaster was not involved in informing pupils or their parents about their diagnosis.[281] Mr MacPherson states that Dr Aronstam, or one of his assistant doctors, was responsible for telling pupils and their parents/guardians of their infection. Mr MacPherson does not know when or what information was provided in this regard.[282]

171. The documentary evidence suggests that there were delays in informing pupils and/or parents as to the diagnosis of HIV, or the suspicion of it. By letter dated 27 December 1984, Dr Aronstam wrote to a home clinician stating that the results of HTLV-III testing for a pupil were "equivocal" and further testing was being undertaken. He stated that "I would not like to unnecessarily alarm the mother as the presence of this antibody occurs in almost all severe haemophiliacs".[283] By letter dated 22 March 1985, Dr Wassef informed a home clinician that a pupil was HTLV-III positive.[284] In response, the home clinician stated that he "felt it only right to let his parents know that he was positive for HTLV3. We plan that [X] himself should not be informed".[285] In December 1985, Dr Wassef stated, in relation to a different pupil, that his mother had asked about his HTLV-III status and he had then told her that he was positive. He stated that "She most probably anticipated my answer and was not over worried about it".[286] It does not appear that there were plans proactively to inform her.

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[280] WITN2830001 §2-4

[281] WITN5314001 §71

[282] WITN5561001 §47-49

[283] TREL0000313_133

[284] TREL0000240_173

[285] TREL0000240_171.

[286] TREL0000159_229

172. The medical records of one pupil indicate that he may have first tested anti-HLTV-III positive on 13 January 1984,[287] although the test result itself is not included in the medical records the Inquiry has for him. There is a test dated 18 December 1984 recording him to be HLTV-III antibody positive. There are letters in November and December 1985 between Dr Rizza of the Oxford Centre and his father and GP informing of his HLTV-III antibody positive results.[288] These suggest that results were not given by Treloar's but were given by the Oxford Centre while he was a patient at Treloar's. His brother was tested for anti-HLTV-III for the first time on 23 January 1984 and found to be positive.[289] This raises a question as to when he and his family were informed, as his father in his statement recollects being told of the HIV diagnosis by the Oxford Centre in 1988.

173. However, it appears that the manner of informing pupils that they were HTLV-III positive may have changed by 1988. The minutes of the Governing Body meeting held on 20 June 1988 states that "… all haemophiliacs were informed whether or not they were HV positive. This would normally be done by, or with the consent of the parents, but in the last resort [Miss Kershaw, Assistant in Charge of the Haemophiliac Centre] or Dr Aronstam would undertake the responsibility". [290] Similarly, in a letter dated 13 December 1988, Dr Wassef informed a home clinician that a pupil had wanted to know if he was HTLV-III positive. Dr Wassef had "discussed this matter with his mother on the telephone… and we came to the conclusion that [X] should now be told the facts in full".[291]

Treatment provided

174. Recollections vary in relation to whether counselling was provided to pupils who were diagnosed as HTLV-III positive. Mr MacPherson states that "Lots of support was or was made available to assist pupils, their parents and guardians following their having received an adverse diagnosis. This ranged from informal discussion with a member of staff to a formal appointment with our Counsellor or with our Consultant Psychiatrist. The Care Staff

[287] TREL0000239_105, p.9
[288] JPEA0000001_030, JPEA0000001_031, JPEA0000001_032 and JPEA0000001_033. See also JPEA0000001_027.
[289] TREL0000241_016
[290] TREL0000356
[291] TREL0000159_210

and Nurses bore the heaviest load as they were readily available and accessible."[292] Ms Burton recalls that there was a team of counsellors at the School. She "kept the log for students to be seen by [them] but I do not recall there being a structured or organised arrangements for all haemophiliac students to be seen as a matter of course. Any member of staff could refer a student to a counsellor. Alternatively, a student could request counselling such as this service and was just part of what Treloar's offered".[293]

175. The Housemaster, Mr Scott, was not aware of any counselling being provided to pupils or parents.[294] Moreover, he states that with the benefit of hindsight there was a lack of training for staff in relation to supporting those with HIV and/or AIDS: "Clinical staff from the Treloar Haemophilia Centre attended to explain medical information as regards HIV/AIDS to staff, such issues as its means of transmission, safe disposal of clinical waste and in particular care that had to be taken around blood, so we did receive some useful instruction, but there was a lack of training which would have enabled staff to offer psychological support to infected students". Consequently, he found himself ill equipped to address individual concerns.[295]

176. In a report in 1986 to the Wessex Region, Dr Aronstam noted that "The bare facts [of HIV infection at Treloar's] do not reveal the cataclysmic impact of the AIDS/HIV problem on our Haemophilia Centre. The patients, their families, the Haemophilia Centre staff and the community around us are all profoundly affected and will continue to be so for many years to come". He noted that they had devised a "multi-faceted strategy" in response:

a. Counselling: he recorded the fear and prejudice affecting adults and parents of children infected, as well as the need for support for the dying and the bereaved. He stated that he was providing the counselling together with a nursing sister because "The specialised nature of the haemophiliac condition makes it impossible to win the trust of the patient unless you are seen to have a thorough understanding of the primary illness. For this reason I do not see a role for the injection of specialised counsellors into our Unit". Dr Aronstam stated that he would continue to play a "major role" in counselling.

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[292] WITN5561001 §55

[293] WITN1128001 §30

[294] WITN5314001 §78

[295] WITN5314001 §42-43

b. Medical surveillance: follow up at regular intervals to be aware of the stage of development of their illness.
c. Immunological surveillance: he considered it "essential" to monitor T cell markers and had developed capability in their laboratory to run the tests.
d. Treatment: only AZT was available at that time.
e. Blood products: as well as noting the existence of highly purified Factor VIII concentrate that was coming on stream, Dr Aronstam also noted "significant reductions in the Centre's use of Factor VIII".[296]

177. One witness recalls that at some point in the mid to late 1980s pupils were told that there was "an issue with some of the product given" and thereafter pupils with haemophilia were segregated from the rest of the school population. For those who had tested positive for HIV, he describes them being quarantined and "treated like lepers".[297] He describes a 6-inch rule being enforced and being required to use paper sheets, paper plates, glasses and plastic cutlery that was burned after use. He states that if they were in a classroom, then they were required to wear plastic gloves and some people wore face masks.[298] A witness, not herself a person with haemophilia but who attended Treloar's, also recalls the 6-inch rule.[299] None of the other witnesses state that this took place. Mr MacPherson states that there was no segregation of pupils with HIV[300] and Mr Scott does not recall any changes to the practices of the staff in how they related to the pupils other than being aware of the risks.[301]

178. Another witness states that he started a relationship with a girl at the school and the teachers informed her parents about it and that he had haemophilia. He was pressured to tell her about his HIV infection. Her family removed her from the School but they kept in touch and subsequently married.[302]

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[296] HHFT0001073

[297] WITN1231001 at §21

[298] At §7.

[299] WITN3439001 §14

[300] WITN5561001 §57

[301] WITN5314001 §82

[302] WITN1406001 §25-30

179. When considering the medical records of pupils, an entry in one pupil's medical notes on 5 November 1987[303] states:

> "He is aware of his Hepatitis status and is rather reluctant to know his HIV status because he is already taking precautions re sex and blood spillage etc. He has no girlfriend at present and Mr Maddox will let us know if and when this happens. Mr Maddox has a very good relation with [the pupil] and can communicate easily with him. There is no urgency re [the pupil's] sex education re HIV infection as he is already aware of the same precautions being HBsAG carrier. J Kershaw will continue counselling [the pupil] and presumably before the end of this term he will be aware of his HIV status."

180. Later Sister Jane Kershaw at Treloar's wrote on 20 September 1989 of the same pupil after he had left the College:

> "[The pupil] is fully aware of his HIV status and all its implications, many discussions have taken place on the subject of HIV and AIDS and also regarding relationships and related emotional issues. Overall I would describe [the pupil] as well adjusted to the problem, but harbours quite a lot of anger about the situation aggravated by some negative experiences. I have had some contact with [the pupil's] parents, but they have tended not to want to talk about HIV/AIDS unless necessary, but like many parents were happy for me to discuss aspects such as sexual relationships, etc. "[304]

181. In the same letter Sister Kershaw described the situation of another pupil who was aware of his HIV status but had not been informed that it had progressed to a diagnosis of AIDS:

> "[The student] is now almost 17 years old and as you will be aware, his overall health has declined. He has been taking Zidovudine tablets for the past 14 months and is also on Fluconazole. As you can appreciate, the whole family are under a lot of pressure and have found it very difficult to come to terms with [the pupil's] HIV status particularly

[303] TREL0000222_147
[304] TREL0000222_033

because [the pupil's] need for Factor VIII concentrate has been so infrequent. For a long time [the parents] did not want to inform [the pupil] of his HIV status…

[The pupil] was prescribed Zidovudine therapy and was diagnosed as having AIDS. It is not difficult to understand the magnitude of the problem. [The pupil] is aware of his low T4 count and that it is because his immune system is not functioning properly because of HIV. He is also aware that his oral and oesophageal candida are related to this. But [the parents] have insisted that [the pupil] does not know that the diagnosis of AIDS has been made. Even though I have talked at length about issues of HIV/AIDS, relationships, blood spillage etc. [The pupil] has never asked me if he has AIDS but I have made it quite clear to the family if he did then I would tell him the truth. [The family] are a very close loving family but are functioning under a considerable strain as you will appreciate. I do hope your social worker will be able to offer this lovely family the kind of support they so desperately need."

182. Mr MacPherson notes in his statement that although the College Medical Officer, Dr Tomlinson, did not normally treat haemophilia, she "played a significant role in both the medical care and the pastoral care given to the students and staff. … When it became clear that haemophiliacs were suffering from the effects of hepatitis and AIDS she became the 'clear head' who explained to all those concerned the risks involved and how the students could still interact in a healthy way, without drama or rumour."[305] He goes on to note that Dr Tomlinson sought to manage risk, engaging with all staff in order to do so.

183. A standard "package" of three drugs appears to have been used for pupils whose T-cell ratios dropped, namely Zidovudine, Fluconazole (to safeguard against oral thrush) and nebulised Pentamadine or oral Septrin.[306]

184. The Governing Body minutes of 24 February 1986 indicate that there was no change in how pupils who were HTLV-III positive were treated within the School. However, a three-stage plan was put in place for when a pupil was "actually suffering from AIDS". Initially, they would not be asked to leave the School and information would be kept confidential; when they were suffering from an opportunistic illness they would be nursed in the sick

[305] WITN5561001 §49

[306] TREL0000062_165

bay but would be transferred to their home or hospital for permanent nursing care when they became "so weak as to be unable to benefit from further teaching (but not before)".[307]

Hepatitis C

185. One witness recalls being informed by Dr Wassef that he was infected with hepatitis C in 1988 and that this had been detected in the early 1980s.[308] He was told that he should continue his Factor IX treatment as usual and that the hepatitis C infection would kill him but that Dr Wassef was not sure when this would happen.

186. Another witness states that his parents were called into a meeting at Treloar's and informed that he had been infected with Hepatitis C and says that they were told very little about the infection: "the general gist was 'your son will be fine' and to get on with life'".[309] He believes that Treloar's knew of his infection for some time before his parents were told. He was told by his parents subsequently.[310] His parents had no idea that he was being tested for infections.[311]

187. A further witness states that he was informed of his hepatitis C infection in 1993/4, despite the first positive test result in his medical records dating from 1990.[312] When he was told of his infection, he recalls simply being told that he had hepatitis C, but not being given any information about routes of transmission.

188. In the medical records of one student, there is a positive test result for HCV antibodies in May 1990.[313] His clinical notes also refer to him being HCV positive on 19 March 1991.[314] He was advised of his diagnosis on 20 June 1991[315] at a general review where he

[307] TREL0000365

[308] WITN1507001 §7: it seems likely that this would have been non-A, non-B rather than Hepatitis C at this time.

[309] WITN2942001 §9-11

[310] WITN2942001 §9-11

[311] At §19

[312] WITN1079001 §8 and §9

[313] TREL0000313_074

[314] TREL0000313_027 p.1

[315] Ibid p.6

had happened to ask about the condition of his liver. He was given an article from the Bulletin about HCV/viral hepatitis at this appointment and his mother was advised of the diagnosis by telephone around the same date. Therefore, there appears to have been a delay of approximately a year between diagnosis and notification.

189. This appointment was also described by Dr Wassef in a letter of 12 July 1991.[316] The letter states: "We will be seeking advice regarding management of this condition following the recent publications on the value of Interferon in some cases of HCV infection." Dr Wassef wrote about this student again on 26 March 1992,[317] stating that his liver measured 6cm and his gamma GT and alkaline phosphatase levels were raised. Dr Wassef noted that on the available knowledge at the time, the presence of antibodies to Hepatitis C did not imply immunity, nor did it guarantee absence of future chronic liver disease.

190. Arrangements for patients with hepatitis C to be seen by a hepatologist do not appear to have been made until late 1995. The letter available to the Inquiry addresses the situation of a patient of the Centre but not of the School. However, it includes the note that Dr Wassef was "aware of the ongoing dialogue between yourself and Dr Aronstam regarding arrangements to see all our Haemophilia patients with antibodies to HCV sometime in the near future…"[318]

Impact on pupils

191. All the statements from pupils at the School who attended the Centre speak of the enormous impact that the infections had on them.[319] The pupils with haemophilia are described by one witness as being a tight knit group: "We shared dormitories, fell in, fell out, fell over, did school, understood bleeds and began training in how to self-infuse Factor 8 and Factor 9 .. and of course all the other normal kid's stuff was in full flow…".[320]

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[316] TREL0000313_066
[317] TREL0000313_062
[318] TREL0000137_046
[319] WITN1078001 §15 and §16; WITN1079001 §22
[320] WITN1243001 §26-27.

192. Many speak of suffering from survivor's guilt.[321] One statement speaks of the pact that he made with four of his closest friends that whoever survived was to fight to get to the bottom of what was unfolding: he is the sole survivor.[322] Numerous statements indicate that they have tried to put that part of life behind them as a coping mechanism because of the very many losses they have suffered.[323]

193. One witness speaks powerfully of phoning a Treloar's' friend each year and saying to each other "that's another" year that they had survived. In 1998, when he attended the funeral of his friend it was a huge shock.[324]

194. Parents, siblings and spouses of pupils at the School also speak of the enormous impact on them. In relation to parents, they speak of the fear that they had that their children would be found to be infected with HIV.[325] For some parents, this meant that they insisted on the children coming home at weekends.[326] The stigma of HIV impacted families across the board particularly because of the connection that people made between the School and HIV. The Inquiry has heard moving evidence already from those infected and affected with a connection to the School.

Record keeping

195. Mr MacPherson has stated that the application for a place at Treloar's included details of the pupil's disability. These were kept in a locked cupboard. Their medical notes were held by the relevant Medical Centre; by this, in relation to pupils with haemophilia, it appears to refer to the Haemophilia Centre.[327] Ms Burton recalls that NHS notes and medical records were kept separately from school records.[328] Dr Tomlinson states that

[321] Including WITN1243001 §118

[322] WITN1432001 §17

[323] Including WITN1512001 §24

[324] WITN1096001 §67.

[325] WITN1077001 §22.

[326] WITN1077001 §24.

[327] WITN5561001 §23

[328] WITN1128001 §13

separate medical notes were kept by the Haemophilia Centre and she is unaware of the arrangements for storage of them.[329]

196. It appears that by 1982 the Centre had stopped recording all of the batch numbers of products that the pupils were receiving: in a letter dated 3 November 1982 to Peggy Britten at the Royal Free Hospital, Dr Aronstam stated "We had stopped recording all the batch numbers of the transfusions because of the enormous amount of work this entailed for all our boys three times a year".[330] It is unclear whether this was only in relation to the letters sent to home clinicians or more generally. However, it is clear from subsequent medical records that some batch numbers were recorded.[331]

197. Witnesses have had difficulties obtaining medical records subsequently. One witness sought his medical records from Treloar's and was told that they had been destroyed. More recently, he was told that they had been found in a cupboard at Basingstoke and he was provided with them.[332] However, he notes that the records are missing any information about HIV or the testing that was carried out for that.[333] Another witness experienced similar difficulties in relation to his records, initially being told that they had been destroyed then subsequently being found at the back of a cupboard. However, the documentation, when received, was limited.[334]

Research

Funding and projects

[329] WITN5578001 §11

[330] TREL0000116_139

[331] CBLA0000010_193

[332] WITN1432001 §20

[333] WITN1432001 §72

[334] WITN1723001 §8

198. A Research Fellowship in Haemophilia was established at the College by the National Fund for Research Into Crippling Diseases in 1968.[335] In her support of the continuation of the grant, Professor Biggs noted that "The collection of 49 haemophilic patients at the Alton school makes this a unique opportunity to study the disease".[336] On 2 July 1970, Dr Rainsford wrote to D. Guthrie at the National Fund for Research Into Crippling Diseases,[337] providing an update. At that point the research being undertaken was as follows:

a. Project 1 was an investigation into seasonal variation in the tendency to bleed;
b. Project 2 was an investigation into rheumatoid arthritis in haemophilic joints;
c. Project 3 was related to abnormal Immunoglobulins and Inhibitors to Factor VIII;
d. Project 4 was an investigation into the incidence of Antibody to Australia Antigen in cases of Christmas Disease and Haemophilia.

199. Following the initial grant (which was for £10,000), Treloar's was awarded a further three-year grant in January 1971 of £15,000. An application was made for continuation funding between 1974 and 1977 of £24,000.[338]

200. There is an undated document headed 'Proposed Research Programme'[339] apparently written in the mid-1970s in support of a funding request (possibly the one mentioned in the above paragraph). It states:

> "Lord Mayor Treloar College is a unique establishment since there are more than fifty boys suffering from various coagulation defects (namely Haemophilia, Christmas Disease and von Willebrand's Disease) in residence at the College for approximately 264 days each year. These boys usually come to the College at the age of eleven and leave at the age of sixteen to eighteen years of age. They are, therefore, under continual medical supervision for nine months of e ach year and often for many years.
>
> …
>
> It will be seen from the foregoing that the College lends itself to a specific type of research into haemophilia and other coagulation disorders, namely to study the relationship between recognised laboratory findings and clinical observations in these somewhat uncommon conditions. It is also the only establishment in the United

[335] AMRE0000011_006
[336] AMRE0000012_004
[337] AMRE0000011_066
[338] AMRE0000007_002
[339] AMRE0000011_021

Kingdom which can provide the opportunity and the facilities for extensive clinical trials of various kinds of treatment. This type of research cannot, at present, be conducted anywhere else."

201. This highlights what was perhaps perceived as the advantages of Treloar's as a research subject population.[340] The document refers to the Research Fellowship in place since 1968 and notes that "meticulous medical records are maintained". It also notes that there was a close collaboration with the Oxford Haemophilia Centre and with the MRC Research Unit at Oxford, which were expected to continue.[341]

202. Completed projects at that time were:

a. A four-year study on the incidence of jaundice and the presence of Australia antigen and antibody in boys being frequently transfused with blood products, in cooperation with the Virus Reference Laboratory, Public Health Laboratory Service, Colindale.

b. Plasma Cortisol Levels and the frequency of bleeding in haemophilia. The incidence of platelet antibodies in boys subjected to frequent transfusions with blood and blood products in co-operation with the MRC Blood Group Reference Laboratory, London. No platelet antibodies were detected in any of fifty boys over a period of one year. This study was published as Plasma Cortisol Levels and the Frequency of Bleeding. Clinica Chimica Acta 53 (1974) P.351-354 Rainsford, Richardson and Stuart Shaw.

c. A Three —Year Study of Adolescent Boys Suffering from Haemophilia and Allied Disorders British Journal of Haematology, 1973, 24, P.539-551 Rainsford and Hall.

d. Platelet Coagulant Activities and Clinical Severity in Haemophilia Thrombosis et Diathesis Haemorrhagica, Vol XXIX 28.VI.1973, p.722-729 Walsh, Rainsford and Biggs.

e. Tranexamic Acid in the Control of Spontaneous Bleeding in Severe Haemophilia Thrombosis et Diathesis Haemorrhagica, Vol XXX 1.11.1973, P.272-279 Rainsford, Jouhar and Hall.

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[340] It was repeated by Dr Aronstam in his justification in 1979 for a Haemophilia Centre to be established at the School: HHFT0001066_002

[341] This may tally with a supportive letter from Dr Biggs at the Oxford Haemophilia Centre to Mr Guthrie dated 29 November 1973 - AMRE0000007_013

203. Ongoing projects at that time were:

a. A prophylactic trial, to determine whether a prophylactic transfusion of factor VIII administered at weekly intervals would reduce the frequency of bleeding in haemophilia (as to which, see further below).

b. A research project to determine whether there is a relationship between immune arthritis and factor VIII antibodies in the joints of haemophiliacs with the MRC Haemophilia Research Unit, Oxford and the Nuffield Orthopaedic Centre, Oxford.

204. Proposed future projects were:

a. Measurement of platelet activity and its relationship to factor VIII related protein.

b. To determine whether the post transfusion levels of factor VIII and its related antigen had a bearing on the frequency of bleeding.

c. Further work on fibrinolysis and tranexamic acid.

d. To determine whether the antithrombin or anti-Xa had any influence on clinical severity, i.e. the frequency of bleeding.

e. To determine the relationship of antitnrombin-3 complex to the incidence of deep vein thrombosis in patients under treatment with Heparin and undergoing hip replacement surgery.

205. Funding was also provided by the Sir William Coxen Trust Fund and reports on progress were made on 20 April 1974[342] and 1 January 1976[343].

Prophylaxis studies

206. On 19 August 1972, Dr Arblaster wrote to the DHSS to request a research grant for a prophylactic trial in haemophilia to be conducted by the Treloar Haemophilia Centre.[344] This funding was granted[345] and at a Haemophilia Centre Directors meeting held at Oxford on 27 October 1972, it was unanimously agreed that a double-blind clinical trial to evaluate

[342] SWCX0000003_002
[343] OXUH0003758_007
[344] DHSC0100026_146
[345] TREL0000521

prophylactic therapy in the treatment of haemophilia should be carried out at Treloar's.[346] A note by one of the participants at the meeting suggests that no individual Haemophilia Centre would be able to organise the proposed trial of prophylactic therapy due to ethical concerns but the Lord Mayor Treloar College would be able to undertake it.[347]

207. A proposal document for this trial suggests that the boys and parents or guardians were to be asked for informed consent.[348]The trial commenced in the Summer term of 1973.[349] In a letter likely to be associated with the commencement of this trial, Dr MacGregor at Warwick Hospital wrote to Dr Aronstam on 25 April 1973[350] regarding a pupil registered with him: "During these holidays I have had an opportunity to discuss the research project using Factor VIII concentrates with [a pupil] and his mother and they have agreed to cooperate…it is very much to be hoped that the new preventative treatment will bring his coagulation under better control". This does appear to show consent being requested, although not formally documented.

208. An interim report was presented to the HCD meeting on 31 January 1974.[351] During the Summer term of 1974, 5 students were included in the prophylaxis trial; by the Autumn term, this had reduced to 3.[352] In a meeting of Haemophilia Centre Directors held on 18 September 1975,[353] Dr Aronstam stated that he had encountered difficulty in organising the trial and felt that an extension of the trial should not include a placebo dose.[354]

209. In Dr Aronstam's PhD thesis, 'Bleeding Episodes in Severely Affected Adolescent Haemophiliacs and Their Management with Replacement Therapy', it is noted that no cases of hepatitis developed during this first trial, HbsAg testing having been conducted on a termly basis.[355]

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[346] AMRE0000007_019; HCDO0001015
[347] MRCO0000065_022
[348] DHSC0100026_147
[349] AMRE0000007_019
[350] TREL0000318_012
[351] CBLA0000187
[352] NHBT0107241
[353] OXUH0003735
[354] See also MRCO0000065_005
[355] TREL0000517 p.122 & 126

210. The study results informed the paper Aronstam, A., Arblaster, P. G., Rainsford, S. G., Turk, P., et al. 1976. Prophylaxis in Haemophilia: A Double-blind Controlled Trial. *British Journal of Haematology*, 33, 81.[356]

211. The second trial looking at prophylaxis in haemophilia A was undertaken following the results of the first trial.[357] Its findings were published in Aronstam, A., Kirk, P. J., McHardy, J., Culver-James, J. W., McLellan, D. S., et al. 1977. Twice weekly prophylactic therapy in haemophilia A. *J. Clin. Path.*, 30, 65-67.

212. The authors sought to establish the lowest dose of Factor VIII concentrate that could be given while still providing a beneficial therapeutic effect. For this trial, twice-weekly infusions of Factor VIII-containing material (cryoprecipitate and Kryobulin) were given to four boys, each of whom were on the first trial. Each boy was randomly allocated to a different dose schedule, one to raise their Factor VIII levels to 15% or one to raise them to 30% of average normal. The authors of the second trial stated that at the beginning of each trial term, screening of inhibitors and hepatitis B surface antigen took place. The authors reported that their results broadly confirmed the results of their last trial (1976). They state that a 24-hourly prophylactic administration of a dose of Factor VIII (to raise Factor VIII levels to 30%) would reduce bleeding frequency by 90%. Due to constraints of financial resources and therapeutic material making this near impossible to achieve, the authors concluded that further work is required to research the possible benefits of limited periods of prophylaxis: "The possibility that a badly affected joint might improve on short-term prophylaxis and reduce the bleeding frequency in the long term appears the most fruitful line to be evaluated" (p3)[358].

213. On 8 July 1976, the MD of Immuno Ltd wrote he was pleased to hear from Dr Kirk at Lord Mayor Treloar Hospital that Birmingham Children's Hospital were collaborating

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[356] NHBT0000091_036

[357] Aronstam, A., Kirk, P. J., McHardy, J., Culver-James, J. W., McLellan, D. S., et al. 1977. Twice weekly prophylactic therapy in haemophilia A. *J. Clin. Path.*, 30, 65-67 [RLIT0000084]

[358] Ibid

during the holidays in the Prophylactic Treatment Trial for a Treloar's student, and would provide Kryobulin for this purpose free of charge.[359]

214. The third trial of prophylaxis treatment for individuals with severe haemophilia A was undertaken at Treloar's to assess the benefit of short term prophylactic Factor VIII on reducing bleeding frequency,[360] following the results of their previous two trials. During 1976 and 1977, prophylaxis was administered twice weekly to five boys and three times weekly to 13 boys. The therapeutic material used for this trial included cryoprecipitate (supplied by the Wessex Regional Transfusion Centre), NHS Factor VIII, or commercial Factor VIII.

215. At a Haemophilia Centre Directors meeting held on 13 January 1977, Dr Kirk provided an update on the "third trial of prophylactic treatment at Alton".[361] He explained that prophylactic doses were given on alternate days and they were calculated to give a rise of 30% in Factor VIII, compared to "on demand" doses, which aim to raise Factor VIII levels to 20%. It was remarked that two boys (who were showing the best results from prophylaxis treatment) wanted to stop, however the others wanted to continue. Following a comment from Professor Stewart that prophylaxis should not be widely used, Dr Rainsford commented that "the prophylactic trial was aimed to provide information for the future and not with the intention of immediate implementation".

216. The results were published in Aronstam, A., McLellan, D. S., & Turk, P. 1979. Transfusion requirements of adolescents with severe haemophilia A. *Journal of Clinical Pathology*, 32, 927-930.[362] The authors stated that during 1976 and 1977, there was a one-quarter increase in the overall use of Factor VIII as a result of providing prophylactic therapy to the boys at Treloar's. The boys who were on prophylaxis consumed four times more Factor VIII per bleed on average than boys who were not on prophylaxis. Receiving prophylaxis twice a week resulted in a 30% reduction of bleeds and those on thrice weekly

[359] TREL0000280_067
[360] Aronstam, A., McLellan, D. S., & Turk, P. 1979. Transfusion requirements of adolescents with severe haemophilia A. *Journal of Clinical Pathology,* 32, 927-930 [RLIT0000093].. See also the unpublished report at OXUH0003758_004.
[361] PRSE0001665 p13
[362] RLIT0000093

prophylaxis resulted in a 60% reduction of bleeds. When on thrice weekly prophylaxis, the boys consumed a 77% increase in Factor VIII compared to those not on prophylaxis.

217. From the published articles of each of the trials, it is clear that a mixture of therapeutic material was used: cryoprecipitate, NHS Factor VIII and commercial (foreign) Factor VIII. It is unclear whether the risk of contracting hepatitis through the use of blood products was communicated with either the students or their parents/guardians prior to their consenting to taking part in the trials.

The Hepatitis Survey

218. There is a report titled 'The Incidence of Australia Antigen and Antibody in Boys Suffering from Coagulation Disorders Report of a Study at the Lord Mayor Treloar College' detailing a study which was conducted over 10 terms (Summer 1970 to Summer 1973).[363] It involved observation of 81 students, of whom 20 attended throughout the duration of the survey. Transfusion material was screened from the Spring term in 1971, which resulted in a reduction in the rate of conversion to antibody positivity. There was a loose association between those who had received least transfusions and testing antibody negative. Thirty-five to forty per cent of the students were antibody positive at all stages of the study, indicating previous exposure to serum hepatitis.

219. A witness has noted that in his medical records they may indicate that a blood sample was taken to provide to Dr Craske for research in December 1969.[364]

220. Two witnesses have found that in their medical records they were given a dose of treatment of "Travenol/Hyland/Hemofil FVIII" as part of "Dr Craske's research work" in 1974.[365]

221. In September 1975, a protocol was produced by Dr Peter J Kirk titled 'Hepatitis in Haemophilia Associated with the Use of Factor VIII Concentrates: A Prospective

[363] HHFT0000053_001. See also the interim report at HHFT0000332 and summary diagram at HHFT0000054.
[364] WITN1379001 §6 and WITN1620001 §38
[365] WITN1245001 §26

Survey'.[366] Dr Kirk first presented the pilot protocol at a meeting of Haemophilia Centre Directors in Glasgow on 18 September 1975 [367]. He invited other Directors to take part in the study stating that a requirement for participation was that a patient receive only one type of material and that samples must be collected and sent for virology testing.

222. Pupils enrolled in this study were restricted to a particular type of Factor VIII material for 18 months; cryoprecipitate, Kryobulin, Hemofil, Elstree concentrate or Oxford concentrate. From Treloar's, 21 boys were restricted to cryoprecipitate, eight were given only Kryobulin, six were given Hemofil, one Profilate, four Lister/Elstree concentrate and five Factor IX.[368] Patients with Factor VIII antibodies or mild haemophiliacs who were not on regular replacement therapy were not included.

223. The protocol stated "All patients or their parents/guardians must give their informed consent". [369] However, the evidence of this in practice is lacking; the template letter informing parents of the study simply states "If you have any queries concerning this survey I would be happy to discuss the matter with you."[370] W1202 states in their witness statement that although they have seen evidence that they were involved in the Hepatitis study, they have been unable to "find a consent form from my parents indicating that they consented to my taking part in such a study".[371]

224. For the pupils at Treloar's who took part in the study, during the holidays, arrangements were made with their home centres to ensure they were still receiving the material they were allocated. In a letter from Dr Mann to Dr Kirk dated 12 September 1975, Dr Mann confirmed that she would be pleased to help with Dr Kirk's study and that they already used only cryoprecipitate on their patients with haemophilia[372]. (By contrast, on 15 April 1977, Dr Swinburne wrote that she had to treat a pupil over the holidays with Kryobulin

[366] CBLA0000312; see also OXUH0001589_002
[367] OXUH0003735
[368] 'Haemophilia and other coagulation defects amongst boys resident at Lord Mayor Treloar College and Florence Treloar School: Autumn Term 1975 and Spring Term 1976' dated 20 April 1976 [OXUH0003758_006]
[369] CBLA0000312
[370] TREL0000225_048
[371] WITN1202001
[372] TREL0000280_074

due to a bad bleed and she was "sorry if this will interfere with your hepatitis trial. However, I feel that he has had so much joint damage that everything possible should be put in train to control this"). [373]

225. On 2 April 1976, Dr Kirk wrote to Dr M.C. Peard of Horsham Hospital regarding a student on the hepatitis study.[374] He appeared to be developing hepatitis which was probably associated with an infusion of factor VIII concentrate (Hemofil B) on 15 February 1976. His HBsAb and HBsAg had been negative on 1 March 1976. It was possible his developing hepatitis may be of the B or non-B type.

226. A report written by Dr Kirk and Dr McHardy dated 20 April 1976[375] summarises the trial. Dr Kirk and Dr McHardy state that three boys had developed hepatitis during the study. One pupil in particular entered the study on 20 October 1975 with normal liver function tests, and was restricted to only Kryobulin for treatment. He was reported to be unwell with tiredness, anorexia and nausea for most of the Autumn term. He was then diagnosed as having anicteric non-B hepatitis.

227. In one pupil's records, there is a direction from Dr Kirk at the Oxford Haemophilia Centre that he was only to be transfused with cryoprecipitate as he was involved in "a national prospective hepatitis study". The card has an entry detailing a transfusion on 15 May 1976.[376]

228. One witness has found in his medical records a note that he was part of a Hepatitis study using trials of Kryobulin. In particular, there is a letter from Dr Kirk to Dr Lilleyman.[377] He has not found any record of his parents providing consent to his participation in the study.[378]

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[373] TREL0000211_022
[374] TREL0000103_018
[375] 'Haemophilia and other coagulation defects amongst boys resident at Lord Mayor Treloar College and Florence Treloar School: Autumn Term 1975 and Spring Term 1976' dated 20 April 1976 (OXUH0003758_006).
[376] TREL0000064_017; and see also TREL0000250_016
[377] WITN1202007
[378] WITN1202001 §30.

229. On 1 April 1977, Dr Kirk wrote[379] that:

"'We have been conducting the Hepatitis Survey for some 19 months and are almost in a position to have a significant result. All the cases of clinical hepatitis and almost all the cases of asymptomatic hepatitis were confined to the patients restricted to commercial concentrates. There were no significant differences between the cases restricted to Hemofil and Kryobulin. In the next stage of the Study, I am proposing to restrict patients to either commercial concentrates as a group or Cryoprecipitate or Lister Concentrate as I understand that all commercial Factor VIII concentrates are being made from North American plasma including Kryobulin."

230. There is an ethical consideration as to whether, having established that commercial concentrates all bore a higher hepatitis risk, the study ought to have continued with some students being placed in the commercial concentrates group.

231. On 7 October 1977, Dr Craske wrote to Dr Aronstam to confirm that Dr Kirk was writing up his results from the hepatitis study[380]. He highlighted his keen interest in continuing the project as he wanted to establish the aetiology of non-B hepatitis, associated closely with commercial freeze-dried Factor VIII preparations, and he stated that it would be valuable to take serum samples from the Treloar's boys so that he could try out new tests, "particularly those thought to give a good correlation with chronic liver damage".

232. At the first meeting of the Haemophilia Centre Directors' Hepatitis Working Party on 14 December 1977, Dr Kirk discussed the results of the "prospective survey on hepatitis"[381]. Dr Kirk stated that the boys from Treloar's who were treated with freeze dried products were found to have consistently abnormal liver enzyme tests compared to those who were treated with cryoprecipitate. They appeared well and had no clinical evidence of chronic liver disease. However, it was reported by Dr Kirk that two pupils did have clinical symptoms and signs consistent with chronic active hepatitis and these were both associated with the use of Hemofil. These findings resulted in a discussion of problems associated with the interpretation of abnormal liver function tests and liver disease in haemophiliacs.

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[379] CBLA0000590
[380] HHFT0000925_001
[381] HCDO0000544

233. An application for a Research Grant titled 'Studies of the epidemiology and chronic sequelae of Factor VIII and IX associated transfusion hepatitis in the United Kingdom' was made in April 1978 by Dr Craske.[382] When explaining the background of and motivation for the project, Dr Craske referenced the Hepatitis Study, and provided a summary of the results that Dr Kirk had presented at the meeting on 14 December 1977. Namely, that 15/45 boys from Treloar's had consistently elevated serum enzyme levels for over six months or more, which illustrated an association with the use of freeze dried Factor VIII concentrate, that ten out of 13 boys examined had evidence of hepatosplenomegaly and that two boys had evidence of chronic active hepatitis.

Double-Blind Studies of Different Doses of FVIII

234. The following studies conducted at Treloar's investigated the optimum dosage of Factor VIII required to treat a bleed in an individual with haemophilia:

a. Aronstam, A., Wassef, M., Choudhury, D. P., Turk, P. M. & McLellan, D. S. 1980. Double-blind controlled trial of three dosage regimens in the treatment of haemarthroses in haemophilia A. *The Lancet*, pp 169-171[383]; also published as Aronstam, A., Wassef, M., Hamad, Z. & McLellan, D. S. 1981. The effect of bleeding patterns on the response of haemophiliac haemarthroses to different doses for Factor VIII. *Clin. lab. Haemat.* 3, pp 107-112.[384]

b. Aronstam, A., Wassef, M., Hamad, Z., Cartlidge, J. & McLellan, D. 1983. A double-blind controlled trial of two dose levels of Factor VIII in the treatment of high risk haemarthroses in haemophilia A. *Clin. lab. Haemat.* 5, pp 157-163.[385]

235. According to Dr Aronstam in his PhD thesis, 46 boys who attended Treloar's in 1978 and 1979 were studied. It is stated that consent was obtained from their parents and the boys themselves.[386]

[382] CBLA0000756
[383] RLIT0000198
[384] RLIT0000098
[385] RLIT0000111
[386] TREL0000517 p.135

236. On 23 May 1978, the mother of a student wrote to Dr Aronstam and Dr Painter saying "thank you for your recent letter concerning the higher dosage of Factor VIII. Whilst I agree to the first part of your programme (the higher dosage) I do not feel I can give my permission to your other suggestion concerning the 'other substance; you mention. Before agreeing to anything like this I would like to know a lot more about this 'other substance' and for it to be tested at length, so I would ask you not to include my son; in your programme".[387]

237. A letter from another parent to Dr Aronstam and Dr Painter, dated 24 May 1978, stated that "we are not happy about our son...being included in an investigation conducted as you describe. We are anxious that the total amount of Factor VIII he receives should be kept to a minimum".[388]

238. A letter from Dr Peard to Dr Aronstam dated 17 September 1980 confirms that Dr Aronstam did obtain consent from a pupil's local Haemophilia Centre to participate in one of these studies (likely the second)[389] Dr Peard stated "it is important that research should continue into the best treatment for haemophilia, and I would support your request to the parents that Andrew be included in the anticipated double-blind controlled trial of the new preparations of Factor VIII". By contrast, when on 14 October 1980, Dr Aronstam wrote to Dr Swinburne as he wished a student registered with him to participate,[390] he received a cautious reply, asking for more information.[391] This tends to suggest that Dr Aronstam's willingness to test treatment hypotheses amongst the student population was not always met with approval.

The Survival Characteristics of VIII:C Ag

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[387] TREL0000105_040. See also TREL0000147_018 and TREL0000070_027 from other parents in response to the same request, and Dr painter's response at TREL0000147_019.

[388] TREL0000070_027
[389] TREL0000075_086
[390] TREL0000327_005
[391] TREL0000327_007

239. In an outline protocol titled "Factorate IIB Plasma Half-Life/Recovery" that has both Dr Jones (Newcastle Haemophilia Centre) and Dr Aronstam (Lord Mayor Treloar Hospital) named, it states that "this study forms Stage I of a proposed investigation into the potential benefits of High Purity Factorate".[392] The aim of this study was to compare the 'in vivo' survival of factor VIII procoagulant antigen (VIII:C Ag) with VIII procoagulant VIII:C survival data.

240. The protocol says that all patients will provide informed consent, unless they are under the age of 16 and then it will be obtained from the parents. There are two undated forms signed by parents who consented to their sons taking part in a "trial of a new Factor VIII product as explained by Dr Aronstam" which appear to be relevant.[393]

241. The results were published in McLellan, D. S., Pelly, C., McLellan, H. G., Jones, P. and Aronstam, A. 1982. The 'In Vivo' Survival Characteristics of Factor VIII Procoagulant Antigen (VIII:C Ag) in Haemophilia A Subjects. *Thrombosis Research*, 25, pp 33-39.[394]

242. The materials used for this study were two commercial concentrates, Hemofil and Factorate. Hemofil was from Hyland, Travenol and Factorate, a high purity concentrate, from Armour. In a letter from Dr Lott, Head of Medical Services at Armour Pharmaceutical Company Limited, to Dr Jones, Director of the Newcastle Haemophilia Centre, dated 23 December 1980, modifications to the protocol of the study were discussed illustrating the relationship with Armour and the influence Armour had on the clinical trial.[395]

The Autoplex trials

243. A report on the use of Autoplex was published in Aronstam, A., McLellan, D. S., Mbatha, P. S. & Wassef, M. 1982. The use of an activated factor IX complex (Autoplex) in the management of haemarthroses in haemophiliacs with antibodies to factor VIII. *Clin. lab. Haemat.* 4, pp 231-238.[396]

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[392] HHFT0001201_004
[393] TREL0000012_113, TREL0000108_158
[394] RLIT0000104
[395] HHFT0001201_003
[396] RLIT0000110

244. There was no mention in the published study as to whether informed consent was obtained from the patients, parents and/or guardians. Nor was there mention of the possible risks of infection associated with the use of products made from pooled human plasma.

245. A further clinical trial into the use of Autoplex was conducted under the UKHCDO Inhibitor Working Party. [397] At a meeting of the United Kingdom Factor VIII Inhibitor Working Party, held in October 1983, it was expressed that the Working Party wanted to continue the trial of Autoplex versus Factor VIII until February 1984, when the certificate for the trial material expired.[398] The minutes of the meeting state that "concern was expressed as to whether AIDS [HIV] might be introduced into UK haemophiliacs" and Travenol Laboratories were asked to inquire as to whether there had been any such cases in the United States.

The DDAVP study

246. On 26 June 1978, Dr Painter at Treloar's wrote to the mother of a student:

> "I understand from [the student] that you are interested to know more about the drug which we are proposing to use for a Trial in the near future. It is a form of anti-diuretic hormone which is produced in the body and is responsible for helping to regulate the amount of fluid that the body retains. It has been discovered to increase the F.VIII level in mild haemophiliacs, but is not affected in severe cases such as [the student]. However, as far as we are aware, no-one has tried the effects of this drug with a dose of F.VIII and it is this which we were interested in looking into in case the combination had the effect of making the F.VIII longer lasting.
>
> We would be doing this on a very limited scale initially but if the results were encouraging then it would be hoped that we would be able to extend the trial and thus gain more information.
>
> I hope this information is of help to you."[399]

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[397] United Kingdom Haemophilia Centre Directors: Inhibitor Working Party, Autoplex clinical trial - patient consent form (HHFT0001161)
[398] OXUH0000447_002
[399] TREL0000327_022

247. This letter may well relate to a planned DDAVP trial. The letter does not mention parental consent being required, although it is possible that it was sought and this was what had prompted her to ask her son to find out more information.

248. There appears to have been a trial involving "a new Factor VIII product" that another pupil participated in, with the consent of his mother, though the nature and extent of the consent is unclear.[400] This appears to have been suggested in 1979 but did not take place until 1980 because manufacturers did not produce stocks of the material in time.

249. Handwritten notes show the participation of Treloar's pupils in a three-stage DDAVP trial conducted in May to July of 1982.[401]

250. This study was published in McLellan, D. S., Knight, S., McLellan, H. G., Wassef, M. & Aronstam, A. 1985. The influence of D.D.A.V.P on the survival of factor VIII in severe haemophiliacs. *Thrombosis Research*, 40, pp 113 -119.[402]

251. As reported in the published report, phase one was a baseline study where only Factor VIII was infused, no DDAVP. In phase two, DDAVP was administered immediately after Factor VIII was infused and in phase three DDAVP was given 24 hours after the Factor VIII infusion.

Inhibitors study

252. A number of students with inhibitors appear to have been involved in a European Group Study commenced in 1982,[403] trialling a "tolerance inducing protocol" with gradually increasing dosages of high potency Factorate.[404] There is evidence in the medical notes of one student that consent was sought from his parents for this.[405] On 7 July 1983, Dr

[400] WITN1090001 §15-21
[401] TREL0000110_004, TREL0000110_135, HHFT0001430
[402] RLIT0000124
[403]TREL0000173_004 p.27 and see TREL0000173_082; TREL0000248_026; TREL0000006_003 and see TREL0000007_003; TREL0000173_084.
[404] TREL0000173_004 p.32
[405] TREL0000173_083

Aronstam expressed concern that it was "possibly wrong" to expose one student to factor VIII at this level, but this does not appear to have resulted in him being removed from the study.[406] By 3 February 1984, this student's inhibitors had reduced sufficiently for him to benefit clinically from human-derived Factor VIII.[407]

253. A later letter of 17 December 1993[408] from Dr Wassef regarding a pupil with inhibitors noted "Inducing protocols are now coming to the fore again as treaters are encouraged by the safety of the materials"; which could be taken as a comment on the safety of the materials used under the tolerance inducing protocol previously.

Other evidence relating to students involved in research

254. Evidence of these projects and others can be found in correspondence and medical records relating to the students at Treloar's.

255. On 6 January 1969, Dr Ingram wrote to ask permission from his home clinician for a student at Treloar's to participate in a trial. The letter explains the proposed trial of Tranexamic acid including details of known side effects including nausea and haematuria.[409] Further correspondence shows that the student's and parental consent was also sought.[410]

256. However, when a parent wrote to Dr Rainsford on 26 November 1969[411] with a concern about "a new type of tablet for the treatment of haemophilia", stating "When I signed the form for permission to treat [my son] I thought it referred to Cryo Precipitate", Dr Rainsford replied[412] that it was "a new preparation which is being used for the treatment of haemophilia. This will not cure the condition but it is though to that it may redunce the tendency to haemorrhage and thereby may reduce the need for transfusion". He did not seek consent for the change.

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[406] TREL0000173_004 070
[407] TREL0000173_004 p.35, and see also TREL0000173_019
[408] HHFT0000145_002
[409] TREL0000386_010
[410] TREL0000386_007, TREL0000386_006
[411] TREL0000376_010
[412] TREL0000376_011

257. On 19 January 1970, Dr Rainsford at Treloar's wrote to Dr Patel at St Mary's Hospital regarding a fibrinolytic agent prescribed for a student registered with him.[413] It states: "Unfortunately, this preparation cannot at present be obtained in this country and we have only been given a supply by the Manufacturers in order to try it out on haemophilia. Unless our trial showed definite results it is doubtful whether this preparation will be available in future. Out trial should be completed by the end of this term and, if you like, I will then let you know what our findings have been."

258. A standard letter was sent out to parents in 1974[414] reading:

> "I am very glad to tell you that the Lord Mayor Treloar Trust has obtained a grant from the National Fund for Research into Crippling Diseases which has enabled them to appoint Dr. S.G. Rainsford to the staff of the College and to equip a laboratory for his use at the Hospital. Dr. Rainsford will be concerned with the welfare of boys suffering from Haemophilia, Christmas Disease and other similar diseases, and will co—operate with and advise the staff of the Hospital regarding their treatment. He will work under the direction of Dr. Rosemary Biggs of the Oxford Haemophilia Centre. The boys will continue to receive treatment at Lord Mayor Treloar Hospital, Alton, where Dr. Rainsford will use his laboratory to check the potency of the materials used and the response to treatment. During the course of his work he will collect information regarding the incidence of joint and muscle haemorrhages.
>
> The study may involve dividing the boys into groups receiving somewhat different treatment. It must be emphasised that equal care will naturally be given to every boy; the difference will involve only minor modification of treatment. I am sure that the new medical arrangements are very much in your son's interest and that you will welcome this development."

259. The medical records of several students contain an undated consent form giving parental consent for an un-named trial "as explained by Dr Aronstam".[415] Most have

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[413] TREL0000376_001

[414] TREL0000020_023

[415] TREL0000242_ 034

provided this consent, although there is one refusal.[416] Possibly related to this unnamed trial, there are trial stamps and references to "trial doses" in the medical notes of several pupils for November 1978[417] – although it is not clear what the trial is.

260. In relation to consent, a template consent form was used to elicit parents' consent for the School Medical Officer to provide such treatment as necessary in an emergency, and also to sanction their child to be vaccinated.[418] However, such consent would not include blanket consent for the child to participate in research trials.

Pharmaceutical companies and research

261. One witness describes being part of an 8-month trial with American Plasma from Speywood Laboratories, along with 50 other boys. The witness has struggled to reconcile this "risky trial" with Dr Aronstam's stance on heat treatment. The witness believes that every boy on the trial at Treloar's got HIV.[419]

Pharmaceutical companies

262. As can be seen in the research section above, there was considerable interaction with pharmaceutical companies supplying products to the Centre for the purposes of trials and studies. Documents also show contact between pharmaceutical companies and Dr Aronstam in relation to the price of products and other advertising matters, seeking to persuade him to use them.[420] Moreover, in the minutes of a Cutter Laboratories Ltd Board Meeting dated 16 December 1980, the following was recorded:

"It was agreed that full investigation should go into the promises made by Carroll Jones and Sidney Pugh to the Alton Centre where Doctor Aronstam had been promised some form of financial support for a research fellowship and had put in a great deal of time and

[416] TREL0000327_037
[417] e.g. TREL0000326_105 p. 13, TREL0000276_076 pp.2-6
[418] TREL0000165_053, filled out on 8 September 1976
[419] WITN1243001 §32.
[420] Including IPSN0000331_001

effort putting forward a representation to the Company. However, nothing materialised and it seems that this was causing the Alton Centre to have nothing to do with Cutter whatsoever. It was agreed that this should now be looked into again with a view to the Company being in a position to offer some form of financial support for such a fellowship."[421]

263. No further record in relation to this issue has been traced.

264. One witness recalls that over the Christmas holidays in 1982, the Centre had been refurbished and extended considerably. He recalls a new consultation room, a communal room and two new offices, together with a mini-lab and new isolation wing. The witness questions the proximity of this building work with the trial of US plasma that took place.[422] The same witness recalls Dr Aronstam walking two people, that he understood to be American pharmaceutical company representatives, out of the Centre saying "don't come selling your s*** to us again."[423]

265. This witness recalls pharmaceutical companies leaving gifts which were passed on to pupils as incentives to take treatments or when they were well behaved. These gifts included chronograph watches, pyramid clocks, stationary kits (Bayer Filofax and pens), back packs and other branded goods.[424] Another witness, someone who attended Treloar's but was not a pupil with haemophilia, recalls seeing the boys with haemophilia and they "talked about what they had received additional goodies like watches. I saw them with free pens and backpacks and we didn't. I didn't get them. I was jealous."[425]

Haemophilia Society

266. Dr Aronstam contributed several articles to the Haemophilia Society publications and spoke at several meetings. In 1981 he is reported as being involved in the Group Seminar Proceedings discussing his research into the correct dose of Factor VIII to give.[426] In 1984

[421] BAYP0000021_063 p.5
[422] WITN1243001 §35.
[423] WITN1243001 §36
[424] WITN1243001 §43.
[425] WITN3439001 §5
[426] PRSE0003316 p.3

he spoke at the Group Seminar on the "Expectations of the Haemophiliac"[427], and in 1987 on "Growing Up".[428]

267. More significantly, Dr Aronstam is recorded as participating in the "most helpful introduction to AIDS" given by Professor Bloom to the Haemophilia Society Council meeting on 8 October 1983.[429]

268. In addition, Sister Turk wrote a lengthy article about the work at the School with pupils with haemophilia. This set out the benefits of Treloar's including the extensive facilities and accommodation available to pupils. She noted that substantial research was undertaken there and the extensive use of prophylaxis.[430]

269. The Centre appears to have benefited from some funding support from the Society for wheelchairs, a microscope and some other small funding.[431] A request for the funding of a registrar position was refused.[432]

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JUNE 2021

[427] HCDO0000279_012

[428] HCDO0000276_042

[429] HSOC0019923_006

[430] HSOC0022908 p.4-5

[431] HSOC0029476_002, HSOC0019508, HSOC0016116_029 and HSOC0029671_030.

[432] HSOC0029691_098 and HSOC0029691_089