SMALLER HAEMOPHILIA CENTRES PRESENTATION

TRURO

The Centre

1. The Royal Cornwall Hospital was the designated haemophilia centre for Cornwall and was based at Treliske, Truro ("the Centre").[1] The Centre treated both adults and children.

The Directors

2. Dr J. S. Murrell was the Centre's Director from around 1977 until 1987. He remained working at the Centre after 1988.

3. From December 1987 to 1992 Dr Helena Daly was Director of the Centre. In July 1986 she had been appointed as the second consultant haematologist for the Centre. She was a member of the AIDS Action Group from 1988 to 1992. From 1989 to 1992 she was the AIDS designated physician for Cornwall. From 1990 to 1992 she set up and organised meetings of the Hospital Transfusion Committee. Dr Daly was also the chair of the South West Haemophilia Treaters Group. She has provided two statements to the Inquiry.[2]

Other staff members

4. Dr A. R. Kruger worked at the Centre from around the 1990s.

Facilities and staffing at the Centre in 1970s and 1980s

5. The Centre provided care and laboratory services for a population of 275,000.

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[1] From around 1977 the Centre was one of 12 new centres or associate haemophilia centres: OXUH0003765_020

[2] WITN4685001 and WITN4685008

6. Dr Daly has told the Inquiry that a '*well-equipped haematology laboratory opened in 1986 which undertook a comprehensive range of investigations.*'[3] There were eight beds, including five isolation cubicles, available for inpatients on an acute medical ward. One house physician and one SHO provided day-to-day care. Dr Daly has stated that '*many of the nurses had extended training in haematology*'.

7. Dr Daly's evidence is that there were two general haematology clinics (of around 50 patients) per week staffed by two consultants, one staff grade, two clinical assistants and one SHO. Nursing staff included a clinical nurse specialist, sister, SRN, SSEN and two SENs.[4]

8. Dr Daly further states that:

> '*All out-patient activities, including haemophilia care, were held in a purpose-built haematology oncology unit adjacent to the laboratory funded by locally raised funds. The unit was run as a day treatment centre and incorporated an outpatient transfusion room, plasma exchange room, procedure room, treatment room, cytotoxic preparation suite and consultant and nursing offices.*'[5]

9. In April 1990 the Haemophilia Society gave a grant of £2,5000 to the Centre '*to help with integration of haemophilia patient records to a standard compatible with the rest of the hospital.*'[6] In February 1992 the Haemophilia Society agreed to fund Dr Daly's application for £1,533 to cover the costs of employing a physiotherapist for three hours per week.[7] In 1993 the Haemophilia Society minutes referred to a request by Dr Kruger for a grant of £1,080 towards the sessional cost of a physiotherapist: '*this application was approved in the light of the staffing problems at the Truro haemophilia centre and the inability to secure local funding through the hospital Trust.*'[8]

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[3] §7.1 of WITN4685001
[4] §7.1 of WITN4685001
[5] §7.1 of WITN4685001
[6] DHSC0002472_103
[7] HSOC0010377
[8] HSOC0023737

Blood Transfusion Centre

10. The local blood transfusion service was the Regional Blood Transfusion Service based at Bristol ("BTS").[9]

11. In 1973 the transfusion service was supplying cryoprecipitate to 16 hospitals, including the Royal Cornwall Hospital.[10]

12. Dr Daly has described '*a close relationship*' between the BTS and the Centre. She describes that the Centre was '*in receipt of blood and blood products from the Regional Centre on a constant routine and occasional emergency basis. They never let us down even though Truro was the furthest city from a Blood Transfusion Centre in the UK and our catchment included the Scilly isles.*'[11] The BTS:

    '*provided blood, plasma, platelet concentrate and cryoprecipitate for essential patient care. They also provided expert opinion when required. The Medical Director was also consultant haematologist at Southmead Hospital where I did part of my training, so I knew him well. I trained for six months at the Regional Blood Transfusion Centre. Many of the MLSOs in the SW Region did periods of training there also.*'[12]

13. Dr Daly describes the relationship with BPL in the following terms:

    '*Bio-Products Laboratory was the national fractionation centre and produced factor concentrates from plasma donated by volunteer non- remunerated donors in England and Wales as convenient treatment for patients with haemophilia A and B and other rare coagulation deficiencies. The BRI received both FVIII and FIX concentrate from BPL. I knew of Dr J Smith from UKHCDO meetings. I contacted him when I needed FXIII concentrate to treat 2 young children (BCH). FXIII was available on a named patient basis from Bio Products Laboratory.*'[13]

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[9] §11.7.1 of WITN4685001
[10] DHSC0100026_061
[11] §98.3 of WITN4685001
[12] §98.1 of WITN4685001
[13] §98.2 of WITN4685001

South West Haemophilia Treaters Group

14. Dr Daly was one of the initiators of this group where the 8-9 designated haemophilia centre directors in the South West region meet twice a year to discuss haemophilia-related matters.[14] The group was set up in mid-1989. Haemophilia clinicians from Bristol, Taunton and Somerset, Devon and Exeter, Barnstaple, Torquay, Plymouth and Cheltenham hospitals were invited to join.[15]

15. The Group carried out a series of audits, including in June 1989 '*Truro Care of Haemophilia Care in the SW Region*'.[16]

Numbers of patients registered and numbers of patients treated

16. As the Centre only became a UKHCDO designated centre in the late 1970s the first annual return available is from 1977. The available annual returns completed by Dr Murrell demonstrate that the only commercial product he used from 1977 was Kryobulin.

17. Due to the Centre's location, the Centre often treated haemophiliacs on holiday. Clinicians from Treloar's School wrote to Dr Murrell about boys attending camping trips near the Centre. In a letter dated 16 September 1977, Dr Murrell was given information about boys' conditions and told that commercial factor VIII would be sent with them.[17]

18. The annual return from 1977 states that 28 haemophilia A patients were treated that year .[18] The products used were cryoprecipitate and NHS factor VIII. Next to Immuno's Kryobulin the words '*data not available*' are written but it appears from the rest of the document that around five patients received some Kryobulin. No deaths were recorded.

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[14] §3.2.2 of WITN4685001
[15] TSFT0000001_001
[16] §3.2.3 of WITN4685001
[17] TREL0000046_015
[18] HCDO0001213

19. The Inquiry does not have an annual return for 1978.

20. The annual return for 1979 states that 14 haemophilia A patients were treated that year.[19] Of those 14, five patients were noted to be on home treatment. The products used were cryoprecipitate, NHS factor VIII and Immuno's Kryobulin. No deaths were noted for the year. Although no haemophilia B patients are recorded on the front of the return, some factor IX was administered during the year.

21. The annual return for 1980 states that there were 20 haemophilia A patients and two patients with von Willebrand's treated at the Centre that year.[20] The products used were cryoprecipitate, NHS factor VIII and Immuno's Kryobulin. There is no information supplied about any patients with haemophilia B.

22. The annual return from 1981 states that there were 23 haemophilia A patients and one patient with von Willebrand's treated at the Centre that year.[21] The products used were cryoprecipitate, NHS factor VIII and Immuno's Kryobulin. The Centre's four patients with haemophilia B were treated with NHS factor IX.

23. The annual return from 1982 states that there were 20 haemophilia A patients and no patients with von Willebrand's treated at the Centre that year.[22] The products used were cryoprecipitate, NHS factor VIII and Immuno's Kryobulin. Two patients with von Willebrand's were treated with NHS factor IX.

24. The annual return from 1983 states that there were 21 haemophilia A patients and no patients with von Willebrand's treated at the Centre that year.[23] The products used were cryoprecipitate, NHS factor VIII and Immuno's Kryobulin. One haemophilia A patient with antibodies was treated with cryoprecipitate, NHS factor VIII, Kryobulin and 6 litres of HPPF during plasma exchange. There was one patient with haemophilia B, who was treated with NHS factor IX.

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[19] HCDO0001380
[20] HCDO0001582
[21] HCDO0001582
[22] HCDO0001677
[23] HCDO0001774

25. The annual return from 1984 states that there were 27 haemophilia A patients and one patient with von Willebrand's treated at the Centre that year.[24] The products used were cryoprecipitate, NHS factor VIII and Immuno's Kryobulin. The one patient with haemophilia B was treated with NHS factor IX.

26. The annual return for 1985 states that there were 15 haemophilia A patients and one patient with von Willebrand's treated at the Centre that year. [25] The products used were cryoprecipitate, NHS factor VIII and Immuno's Kryobulin. The one patient with haemophilia B was treated with NHS factor IX. The annual return contrasts with a letter written by Dr Murrell to BPL on 24 May 1985 where he listed eight patients '*on regular treatment.*'[26]

27. The annual return from 1986 states that there were 17 haemophilia A patients and one von Willbrand patient treated that year.[27] The von Willebrand patient received DDAVP. Plasma, cryoprecipitate, NHS factor VIII and Immuno's Kryobulin were used. One patient with haemophilia B was treated and they received NHS factor IX.

28. Dr Daly, who joined the Centre in 1986, recalls that there were around 10 severely affected, haemophilia A patients and others with mild or moderate haemophilia and von Willebrand's disease.[28] Dr Daly's recollection was that there was no patient with severe haemophilia B at the Centre.[29]

Treatment policies and blood product usage

29. In her role as Director, Dr Daly '*held and managed the budget for blood products relating to the Haemophilia Service.*' From around 1988[30] she was '*involved in selection of blood products for the treatment of patients with inherited coagulation disorders and surveillance of side effects particularly blood borne infection'*.[31]

[24] HCDO0001868
[25] HCDO0001963. Patients with other various coagulation defects were also treated.
[26] BPLL0010549
[27] HCDO0002057
[28] §9.2.1 of WITN4685001
[29] §10.2.1 of WITN4685001
[30] §7.5 of WITN4685001
[31] §2.6 of WITN4685001

30. Prior to this Dr Murrell had *'made an early decision to change to heat treated commercial factor concentrates prior to availability of UK HT factor concentrates.'*[32] Dr Daly states that from April 1985 he used BPL heat treated factor VIII concentrate '*where available*' and commercial heat-treated products when BPL heat-treated material wasn't available.

31. From October 1985 the Centre used 8Y which was preferred '*particularly for children, mildly affected patients who required concentrate and those with no previous exposure to prevent NANBH.'*[33]

32. Dr Daly states that upon her arrival in 1986 the Centre's patients were already on home treatment and she does not recall initiating home treatment for any patient while working at the Centre.[34] Her recollection is that she did not initiate a programme of routine prophylaxis.[35]

33. Dr Daly states that in 1990 or 1991 highly purified monoclonal factor VIII concentrate was used.[36]

Knowledge of risk of hepatitis and response to risk

34. When Dr Daly was an intern she was aware of the Edinburgh outbreak of hepatitis B in the dialysis unit in the early 1970s.[37] She has told the Inquiry that she was therefore aware of the risk of hepatitis and non-B hepatitis and abnormal liver function when she began work as a senior registrar in haematology at the Bristol Royal Infirmary in 1979.[38]

35. Dr Murrell attended the UKHCDO meeting on 24 October 1977 held in Oxford where Dr Peter Kirk presented Dr Craske's report on hepatitis and there was a discussion about the use of liver biopsies in haemophiliacs.[39] Annual returns from

[32] §10.2.1 of WITN4685001
[33] §10.2.1 of WITN4685001
[34] §19.2.1 of WITN4685001
[35] §20.1 of WITN4685001
[36] §10.2.1 of WITN4685001
[37] §24.1 of WITN4685001
[38] §24.2 of WITN4685001
[39] PRSE0001002

the late 1970s referred to patients with jaundice. It is reasonable to assume that he was aware of the potential relationship between blood borne viruses and haemophiliacs.

36. Dr Daly has told the Inquiry that in 1984 to 1986 she became aware of the potential for serious liver disease due to non-A non-B hepatitis.[40] Dr Daly states:

> *'Initially we knew that some patients with haemophilia had abnormal liver function tests (LFTs) not attributable to hepatitis B. This was referred to as NANBH, was usually asymptomatic and not thought to have serious sequelae. In the 1980s evidence emerged that some asymptomatic patients with haemophilia with persistently elevated transaminases who underwent liver biopsy had chronic active hepatitis and cirrhosis. It became clear that NANBH was not innocuous in the long term. It was shown that >95% of patients who received large pool concentrates were probably infected by a transfusion transmitted virus although the serious consequences of these infections were not fully realised.'*[41]

37. In April 1987 Dr Daly wrote to Miss Spooner at the Oxford Haemophilia Centre and made reference to a mild haemophilia A patient who had had '*an episode of jaundice following cryoprecipitate in 1979.*'[42]

38. In 1990 Dr Daily wrote to haemophilia centre directors in the South West region in relation to the issue of, and criteria for, liver disease in haemophiliacs.[43] She wrote in the following terms: '*After the meeting in September, I thought I would try and find out specifically what is meant by liver disease in haemophiliacs and it has not been easy.*'

39. She enclosed a copy of the working party report on chronic liver disease in haemophiliacs as well as some academic literature. The plan was for a discussion at the next Haemophilia Treaters Group in Bristol on 10 May 1991.

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[40] §24.5 of WITN4685001
[41] §24.6 of WITN4685001
[42] HCDO0000370_004. Dr Daly was responding to this letter from Miss Spooner: HCDO0000370_005
[43] TSFT0000001_011

Knowledge of risk of AIDS and response to risk

40. Dr Daly states that in 1982 she became aware of AIDS in certain groups, including haemophiliacs. Specifically, she became aware of AIDS from reading MMWR reports in late 1982 '*when AIDS and Pneumocystis Carinii pneumonia were reported in patients with haemophilia and blood transfusion recipients in USA.*'[44]

41. In 1983 a patient at Bristol, where Dr Daly worked, was diagnosed with AIDS.[45] Her evidence to the Inquiry is that she believes she first considered the possibility that the Bristol patient had or was developing AIDS in May 1983.[46] She states:

> '*Following the death from AIDS of one of our haemophilia patients in August 1983, 18 months after intensive treatment with commercial concentrate of US origin, I believed there was a definite risk that this was in some way due to factor concentrate.*'[47]

42. From May to October 1983 Dr Daly undertook '*a clinical and immunological review*' of 43 Bristol patients.[48] Dr Daly's report of the Bristol patient was published in the Lancet in November 1983.[49]

Arrangements for testing patients for HTLV III and informing them of their diagnosis

43. Testing was available for HIV in 1984.[50] Dr Daly states that at Truro '*all patients were routinely advised they would have regular hepatitis and HIV serology at review appointments.*'[51]

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[44] §31.1 of WITN4685001
[45] §24.4 of WITN4685001
[46] WITN4685008
[47] §32.2 of WITN4685001
[48] §34.2 of WITN4685001. This research was published in the British Journal of Haematology in February 1985.
[49] §31.1 of WITN4685001
[50] §25.2 of WITN4685001
[51] §49.3 of WITN4685001

Numbers infected with HIV

44. Dr Daly's recollection is that two patients at the Centre were infected with HIV.[52]

45. The provisional data provided to the Inquiry by UKHCDO suggests that four patients tested positive for HIV in Truro in 1985.[53]

Treatment arrangements for HIV

46. Dr Daly states that patients with HIV at the Centre were prescribed with zidovudine (AZT).[54]

47. Dr Daly was a member of the AIDS Action Group from 1988 to 1992. From 1989 to 1992 she was the AIDS designated physician for Cornwall. She was involved in coordinating the management of HIV-infected patients.[55]

48. The parents of Lee Turton have provided evidence to the Inquiry. Lee tragically died of AIDS in 1992 aged just 10. In 1989 the family moved to Cornwall and came under the care of the Centre, where he continued to be treated with AZT.[56] His family have raised concerns about the toxicity of AZT for such a young child.

Testing for Hepatitis C

49. Dr Daly attended the UKHCDO meeting on 7 October 1991 where the recommendation from the Working Party was that '*all haemophiliacs should be tested for hepatitis C. All those tested by 1st generation tests should be retested using 2nd generation tests.*'[57]

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[52] §10.2.1 of WITN4685001
[53] INQY0000250
[54] §83.2.3 of WITN4685001
[55] §3.1 of WITN4685001
[56] WITN1574001
[57] HCDO0000491_001

50. Dr Daly's recollection is that samples were tested for HCV in around 1991.[58] In relation to the issue of consent for the storage of blood samples she states:

'I don't think patients were asked to consent to storage of sera. I advised patients I intended storing sera in the hope of future tests.'[59]

51. She further states:

'I can't remember when we in Truro first had access to the test for current or stored samples. I don't remember seeing any positive hepatitis C result. Consequently, I do not believe I informed anyone of a diagnosis of hepatitis C.'[60]

52. The Inquiry has received evidence from infected individuals and their family members that is critical of the way that patients were informed of their diagnoses at the Centre. For example, the affected children of a mild haemophilia A sufferer describes that their father was informed of his diagnosis with HCV when a junior doctor '*announced the news in a casual manner, thinking that my father already knew.*'[61] She states that their father did not know what HCV was. The junior doctor told him that he might only have 10 years to live.[62] The family are critical that their father was told in an off hand manner in the middle of the ward in the hearing of other patients.[63]

53. A von Willebrand's sufferer has described to the Inquiry that he was informed by Dr Kruger that he was HAV, HBV and HCV position when he was about 18 or 19 years old. He was only informed of his infections when he asked Dr Krueger why he was having so much blood taken. He describes Dr Krueger as being '*surprised*' that the patient was unaware of his infections.[64]

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[58] §25.2 of WITN4685001
[59] §73.3 of WITN4685001
[60] §62.2 of WITN4685001
[61] WITN1453001
[62] WITN1453001
[63] WITN1611001
[64] WITN1492001

Number of patients with HCV and treatment

54. The precise number of patients infected with HCV at the Centre is not known.

55. An audit document, dated March 1996, headed from the South West Haematologists' Group states that 41 patients currently registered at the Centre had received cryoprecipitate or large-pool coagulation factor concentrates.[65] Of these, 38 patients were noted to be positive. One patient was untested. 31 of these patients were noted to have undergone serial liver function testing, 15 had normal LFTs and 13 had intermittently abnormal LFTs, three patients had persistently abnormal LFTs. Two patients had undergone liver biopsies. Testing for partners was noted to have taken place '*once*'. No patients were noted to have died from liver disease in the last 10 years. No patients were also infected with HIV, nor had any patients undergone a liver transplant. Four patients had been treated with alfa-interferon. As at that date, no patients had been given ribavirin or other anti-HCV treatment.

JENNI RICHARDS QC

TAMAR BURTON

INQUIRY COUNSEL TEAM

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[65] TSFT0000002_031