SMALLER HAEMOPHILIA CENTRES PRESENTATION ST MARY'S HOSPITAL, PADDINGTON

Directors and staffing

- The directors of the Haemophilia Centre at St Mary's Hospital during 1970s-80s included Professor P L Mollison, Professor S N Wickramesinghe, and Dr Helen Dodsworth.
- 2. Professor Patrick L Mollison was director of the Centre from around 1968 to 1979. He was a Professor of Haematology and President for the British Society for Haematology in 1977. He was the lead author of the textbook, "*Blood Transfusion in Clinical Medicine*", eighth edition published in 1987.
- 3. Professor Mollison was a member of several committees relating to blood products and transfusions. During the 1970s, Professor Mollison was Chairman of the Medical Research Council's Blood Transfusion Research Committee.³ He was also Chairman of the Managing Committee for the Blood Products and Blood Group Reference Laboratories.⁴ In 1973, he was a member of a Committee constituted by the Department of Health and Social Security "to consider whether any change should be made in the present organisation of the blood transfusion service in England and Wales and to make recommendations".⁵ From 1978, Professor Mollison was a member of the Joint Management Committee DHSS/North West Thames Regional Health Authority for the Central Blood Laboratories. ⁶ He was also Chairman of a sub-committee of the Joint

¹ BSHA0000114

² NHBT0000114_054, NHBT0057339, NHBT0082928

³ MRCO000015_002. He regularly chaired meetings of the Research Committee including on 28 March 1972 [MRCO0005094] and 4 March 1975 [MRCO0000015_002]

⁴ MRCO0005269. He chaired meetings of the Managing Committee on 14 December 1972 [MRCO0005034] and 16 July 1974 [DHSC0002357_035]. A report of an ad hoc subcommittee on safety dated July 1974 is at MRCO0005047

⁵ DHSC0002175_071. The Committee met on three occasions on 18 July and 27 November 1973 and 30 April 1974: see NHBT0017077. It appears that Professor Mollison was not able to attend the meeting on 30 April and wrote a letter to Dr J J A Reid, Deputy Chief Medical Officer of DHSS, dated 19 April 1974: DHSC0003738_096

⁶ BPLL0008431_004 / BPLL0004826. The purpose of the committee was oversee the running of the Central Laboratories. Professor Mollison regularly attended meetings of the Joint Management Committee including on 13 December 1978 [First meeting CBLA0000872]; 21 February 1979 [2nd meeting CBLA0000912]; 31 August 1979 [Ad hoc meeting CBLA0000982]; 13 June 1979 [BPLL0008488]; 12 September 1979 [4th meeting DHSC0002195_028]; 19 December 1979 [5th meeting CBLA0001041]; 20 February 1980 [6th meeting

Management Committee, the Scientific and Technical Committee for the Central Blood Laboratories from 1979.⁷ Until 1979, he chaired the Central Laboratories Sub-Committee of the Central Committee for the NBTS before it was replaced by the Scientific and Technical Committee for the Central Blood Laboratories.⁸

- 4. Professor S. N. Wickramesinghe and Dr Helen Dodsworth were co-directors of the Centre from 1979 and during the 1980s. As recorded on 10 February 1998, "Dr Helen Dodsworth FRCP FRCPath (b. 1938) was Honorary Consultant Physician at St Marys Hospital Medical School, London, from 1970 to 1993 and Founder Member of the British Blood Transfusion Society in 1983. She was a Member of the British Society of Haematology from 1972 to 1993 and has published several papers on blood transfusion-related topics including: Dodsworth H. (1996) Blood transfusion services in the UK Journal of the Royal College of Physicians of London 30: 457-464. Gunson H H. Dodsworth H. (1996) 50 years of blood transfusion. Transfusion Medicine 6: 1-88." The 1996 journal article "Blood transfusion services in the UK" by Dr Dodsworth is at RCPH0000448.
- 5. In 1977, Dr Helen Dodsworth was a member of the Working Group on Trends in the Demand for Blood Products. The Working Group was appointed in January 1977 by the Department of Health and Social Security to "consider the likely trends in the demand for blood products over the next five to ten years, taking into account the practicalities of supply".

CBLA0001068]; 2 May 1980 [7th meeting DHSC0002325_037]; 9 July 1980 [8th meeting CBLA0001137]; 22 October 1980 [9th meeting CBLA0001190]; 6 February 1981 [10th meeting CBLA0001268]; 20 March 1981 [11th meeting CBLA0001315]; 19 June 1981 [12th meeting DHSC0002209_093]; and 23 October 1981. [13th meeting DHSC0002211_063]

⁷ The purpose of the committee was to advise on the scientific, technical research, and associated running and development of the Central Laboratories. Professor Mollison regularly chaired meetings of the Scientific and Technical Committee, including on 26 March 1979 [BPLL0008430_001]; 7 June 1979 [CBLA0000952]; 23 January 1980 [4th meeting CBLA0001052]; 23 April 1980 [Fifth meeting CBLA0001093]; 18 June 1980 [Sixth meeting CBLA0001119]; 17 September 1980 [Seventh meeting CBLA0001171]; 4 March 1981 [CBLA0001299]; 10 June 1981 [10th meeting CBLA0001374]; 24 November 1981 [11th meeting CBLA0001506]

⁸ Professor Mollison chaired meetings of the sub-committee on 24 November 1975 [DHSC0003743_008]; 9 February 1976 [DHSC0003743_009]; 18 November 1977 [DHSC0002185_038 / DHSC0003743_012]; 21 February 1978 [CBLA0000733], and attended meetings of the Central Committee on 24 February 1977 [MRC00005118_003] and 23 January 1978 [CBLA0000733]

6. Professor Wickramesinghe, co-Director of the Centre, displayed a particular interest in the study of HIV and the impact on bone marrow. She applied to the Medical Research Council for a project grant to study "the ultrastructural abnormalities affecting the bone marrow of patients with HIV infection". In 1979, she wrote to Dr Richard Lane of BPL explaining that she had been collaborating in "a small study into the possible effects of DDAVP on bone marrow function" and sought his views about DDAVP.

7. Other personnel at St Mary's Hospital included:

- a. Professor P E Crome, who later became Director of the Haemophilia Centre at Queen Mary Hospital, Roehampton, was at St Mary's Hospital during Professor Mollison's time as Director of the Centre. She attended a UKHCDO meeting on Professor Mollison's behalf on 1 October 1968.⁹
- b. Dr Paul Giangrade was an SHO in Endocrinology/Metabolic Medicine to Prof.
 V. Wynn at St Mary's Hospital from February 1982-July 1982.¹⁰
- c. Professor Christine Lee trained as a haematologist as a registrar under Consultant Dr Jack Field at St Mary's Hospital between 1974 and 1976. 11
- d. Dr Anthony Pinching, Immunologist. Dr Pinching was Scientific Secretary to the Medical Research Council Working Party on AIDS. ¹² The role of the Working Party was to review scientific knowledge and research on AIDS in the UK and abroad; to encourage contact and co-operation between research workers in the field; and to advise the MRC on the current state of knowledge in the field and on topics for research. He co-authored an important article published in The Lancet on Saturday 1 September 1984, "Prevalence of Antibody to Human T-Lymphotropic virus type III in AIDS and AIDS-risk patients in Britain". ¹³

⁹ HCDO0001013

¹⁰ Dr Paul Giangrande written statement dated 23 October 2020 [WITN3311003]

¹¹ WITN0644058 para 2. Oral evidence 20 October 2020.

¹² MRCO0000172 003

¹³ NHBT0000068_015

- e. Dr Diana Samson was Honorary Senior Registrar at Northwick Park Hospital and St Marys Hospital from 1973-1976.¹⁴
- f. Professor Howard Christopher Thomas, took up the role of departmental chair of medicine at St Mary's Hospital Medical School in 1987.¹⁵ Dr Thomas was Chair of the Department of Health Advisory Group on Hepatitis and Chair of the DH Steering group which helped develop the Hepatitis C Strategy for England.¹⁶ Witness statements from Professor Thomas are at WITN3824001 and WITN3824005.

Status of Haemophilia Centre, Relationship with other Haemophilia Centres and Regional Blood Transfusion Centre

- 8. The Haemophilia Centre at St Mary's Hospital was based at the Department of Haematology, St Mary's Hospital, Praed Street, Paddington, London W2 1NY. In 1970, St Mary's Hospital was one of 13 designated Haemophilia Centres in the London area.¹⁷
- 9. At a meeting of Directors of Haemophilia Centres in London on 15 October 1970, it was explained by Dr Lees of the Department of Health and Social Security (DHSS) that DHSS were considering whether a reappraisal of the pattern of Haemophilia Centres in the London area was necessary in view of the developments in the treatment of haemophiliacs. The Directors stated that most of the work with haemophiliac patients arose from minor bleeds and surgery. It was noted that Directors were prepared to refer patients requiring specialised treatment to those centres (such as the Royal Free Hospital) where considerable expertise in the subject had been developed, but did not think that any special designation of such centres was required. Several Directors said that patients preferred to be treated locally as they could more easily attend for minor

¹⁴ Dr Diana Samson Witness statement dated 10 December 2020 [WITN4673001]

¹⁵ WITN3824001 para 3

¹⁶ DHSC0015453. Dr Thomas' CV is at PRSE0002631

¹⁷ DHSC0100026_009 and OXUH0003597. The 13 designated Haemophilia Centres in the London area at that time were Guy's Hospital, St Mary's Hospital, King's College Hospital, Royal free Hospital, Hospital for Sick Children (Great Ormond Street), Lewisham Hospital, University College Hospital, Westminster Hospital, St Thomas' Hospital, The London Hospital, St George's Hospital, The Middlesex Hospital, Hammersmith Hospital.

¹⁸ OXUH0003597

bleeds and reach the centre early in a bleeding episode. It was recorded that the "pattern in the Home Counties was for all the centres to be in London". ¹⁹

- 10. St Mary's Hospital was part of the North-West Thames Region (Region 05). In 1976, Professor Ingram and Dr Dormandy were asked to be jointly responsible for the South-East Haemophilia Supraregion.²⁰ Dr Dormandy of the Royal Free Hospital and Professor Ingram of St Thomas' Hospital Haemophilia Reference Centres decided to split the Supraregion along the Thames. St Mary's Hospital, being in the northern half (comprising East Anglia Region (04), North-West Thames Region (05), and North-East Thames Region (06)), fell under the responsibility of Dr Dormandy.²¹
- 11. From 1976, NHS factor VIII concentrate was distributed through the Regional Blood Transfusion Centres. With some slight adjustments, it was said that this corresponded to the supply areas of the appropriate Blood Transfusion Centres at Brentwood, Edgware and Cambridge.²² The relevant Regional Blood Transfusion Service Centre for St Mary's Hospital was the North London Blood Transfusion Centre, Edgware.
- 12. The material was divided among the Regional Transfusion Centres proportionately to the number of different haemophiliacs treated in the Regions in 1974.²³ In 1976, the allocation of NHS factor VIII concentrate to the North West Thames Region, based on 1974 returns, was 160 bottles per month.²⁴ Specifically, 15 bottles per month were allocated to St Mary's Hospital.²⁵

¹⁹ OXUH0003597

²⁰ CBLA0000506. In 1976, the North-West Thames Region (05) included Westminster, St Mary's, Middlesex, Hammersmith, Lister (Stevenage), Luton & Dunstable, Bedford, Edgware, Hillingdon and Northwick Park (Harrow).

²¹ See also: CBLA0000533 minutes of meeting on 15 December 1976 where it is recorded that "Professor Ingram and Dr Dormandy, who were the reference Centre Directors for regions 04-08, had taken the Thames as a dividing line so that Professor Ingram would be mainly concerned with regions south of the Thames (07/08) and Dr Dormandy with regions north of the Thames (04, 05 and 06)."

²² CBLA0000506

²³ CBLA0000506

²⁴ CBLA0000510

²⁵ CBLA0000510. In 1976, NHS factor VIII concentrate was allocated to the North West Thames Region as follows: GOSH 62 bottles; Hammersmith 55 bottles; Middlesex 22 bottles; St Mary's 15 bottles; and Westminster 6 bottles.

- 13. At a meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres (Regions 04, 05 and 06) and Blood Transfusion Centres on 15 December 1976 (attended by Dr H Dodsworth on behalf of St Mary's Hospital), it was noted that the distribution area of the Regional Blood Transfusion Centre at Edgware did not coincide with Region 05 and that the NHS factor VIII supply had been adjusted to account for this.²⁶ In the North-West Thames Region (05), there were 5 Haemophilia Centres, 6 Associate Centres and one more proposed Associate Centre. Dr Cleghorn (North London BTC, Edgware) confirmed that he was prepared to handle and distribute NHS/commercial concentrate and to hold a reserve for the North-West Thames Region. However, he felt that the allocation of material must be up to the haemophilia experts. It was further noted that the number of Haemophilia Centres in Region 05 (and 04) was out of proportion to the number of patients and that some of these appeared to be unnecessarily close, that some designated Haemophilia Centres had fewer patients than the Associate Centres; and that Dr Mitchell of Charing Cross Hospital had asked if they could become an Associate Centre. After discussion, it was agreed to maintain the status quo and to recommend that Charing Cross Hospital should be added to the list of Associate Centres.²⁷
- 14. At a further meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres (Regions 04, 05 and 06) and Blood Transfusion Centres on 23 September 1977, Dr Dodsworth of St Mary's reported that 1,400 bags of cryoprecipitate had been used since the previous September. The Centre wanted to start 2 patients on home therapy so required an allocation of NHS concentrate. At the same meeting on 23 September 1977, it was noted that Dr Ardeman had asked everyone in the North West Thames Region what NHS concentrate was needed. The figures added up to 427 bottles per month against a supply of 360 bottles per month. He and Dr Davies had revised the allocations to fit in with the increased supply and also to reduce the reserve stock but there would still be a shortfall of 67 bottles per month.

²⁶ CBLA0000533

²⁷ CBLA0000533

²⁸ CBLA0000657

²⁹ CBLA0000657

15. It does not appear that Dr Dodsworth (or any other representative on behalf of St Mary's Hospital) attended a further meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres (Regions 04, 05 and 06) and Blood Transfusion Centres on 1 September 1978.³⁰ At that meeting, was recorded that Dr Ardeman had attended a meeting in April 1978 with Dr Dormandy, Dr Tuddenham, Dr Davies and Mrs Britten "to try and sort out the distribution of the 360 bottles per month of NHS concentrate allowed to North West Thames, bearing in mind that the requirements of the region were much more than this".³¹ It had been agreed that 360 bottles should be allocated to Centres for patients on home therapy, pro rata, on the basis of the returns for those patients treated in 1977.³² Furthermore, Dr Ardeman questioned the decision of the subcommittee that all 360 bottles received by North West Thames should be distributed each month so the Blood Transfusion Centre had no reserve stock. It was agreed at the meeting that Dr Cleghorn should maintain a stockpile at the North London Blood Transfusion Centre.³³

Numbers of patients registered and numbers of patients treated

- 16. In response to a request for information from the Department of Health and Social Security in December 1969,³⁴ Dr P E Crome of St Mary's Hospital indicated that for the year ending 30 September 1969:³⁵
 - a. There were 16 cases registered at the Centre;
 - b. There were 84 incidents of haemorrhage for which patients attended the Centre for treatment;
 - c. There were no haemophiliac patients not registered with the Centre who attended for treatment;
 - d. There were 2 incidents of severe bleeding in patients attending the Centre;
 - e. The were no major surgical operations undertaken in patients registered with the Centre during the year;

³⁰ CBLA0000838

³¹ CBLA0000838

³² CBLA0000838

³³ CBLA0000838

³⁴ DHSC0100026 009

³⁵ DHSC0100026_014

- f. No patients with incidents of severe bleeding or major surgical operations were transferred to the Special Treatment Centre at Oxford.
- 17. In November 1972, Professor Mollison responded to a survey, for the attention of Dr Maycock of the Blood Products Laboratory, in which he indicated that there were 13 patients treated regularly.³⁶
- 18. A list of Haemophilia Centres suggests that there were 11 patients with haemophilia A at St Mary's Hospital in around 1975.³⁷
- 19. In the following years, the numbers of patients registered and/or treated at St Mary's Hospital, Paddington from the available evidence were as follows:
 - a. <u>1976</u>: The Annual Returns for 1976 signed by Prof P L Mollison stated that there were 7 haemophilic patients and 2 Christmas disease patients treated at St Mary's during the year.³⁸
 - b. <u>1977</u>: The Annual Returns for 1977 signed by Prof Mollison reported 12 haemophiliac (haemophilia A) patients and 3 Christmas disease (haemophilia B) patients treated during the year.³⁹
 - c. <u>1979</u>: The Annual Returns for 1979, signed by Dr H Dodsworth, reported 9 haemophiliac patients and 4 Christmas disease patients were treated at St Mary's during the year.⁴⁰
 - d. <u>1980</u>: The Annual Returns for 1980 signed by Dr H Dodsworth, reported 12 haemophilia A patients and 1 patient with von Willebrand's disease were treated at St Mary's during the year.⁴¹ There were 5 patients treated with haemophilia B.

³⁶ BPLL0008111

³⁷ OXUH0000863 002

³⁸ HCDO0001118

³⁹ HCDO0001205

⁴⁰ HCDO0001373

⁴¹ HCDO0001470

- e. 1981: The Annual Returns for 1981 signed by Prof Wickramasinghe are very faint and difficult to read. 42 It appears that the Centre treated 9 haemophilia A patients, 2 carriers of haemophilia A, 1 von Willebrand's patient, and 3 haemophilia B patients. It appears that there were around 25-26 registered patients with haemophilia A, 7 registered patients with haemophilia B, and 1-2 registered patients with von Willebrand's disease. 43
- f. 1982: The Annual Returns for 1982 signed by Dr H Dodsworth state that 10 haemophilia A patients, 1 haemophilia A patient with factor VIII Antibodies, and 5 haemophilia B patients were treated during the year. 44 It appears that there were 29 registered patients with haemophilia A, 8 registered patients with haemophilia B and 4 registered patients with von Willebrand's disease. 45
- g. <u>1983</u>: The Annual Returns for 1983 signed by Dr H Dodsworth reports that the Centre treated 6 haemophilia A patients, 1 patient with von Willebrand's disease, and 3 patients with haemophilia B (Christmas disease).⁴⁶
- h. 1984: The Annual Returns for 1984, signed by Prof S Wickramesinghe and Dr H Dodsworth. record that the Centre treated 8 haemophilia A patients, 1 von Willebrand's patient, and 3 haemophilia B patients. Although the print is very faint, it appears that there were 31 registered patients with haemophilia A, 9 registered patients with haemophilia B, and 10 patients with von Willebrand's disease.
- i. 1985: The Annual Returns for 1985 signed by Dr H Dodsworth state that 9
 Haemophilia A patients and 3 Haemophilia B patients were treated during the
 year. 48 No patients with von Willebrand's disease were treated during that year.

⁴² HCDO0001574

⁴³ HCDO0001574

¹⁴ HCDO0001670

⁴⁵ HCDO0001670

⁴⁶ HCDO0001766

⁴⁷ HCDO0001860

⁴⁸ HCDO0001955

It appears there were 34 registered patients with haemophilia A, 9 registered patients with haemophilia B, and 10 registered patients with von Willebrand's disease.⁴⁹

j. 1986: The Annual Returns for 1986 signed by Prof S N Wickramesinghe and Dr H Dodsworth record that St Mary's treated 5 haemophilia A patients and 2 haemophilia B patients during the year. No patients with von Willebrand's disease were treated during that year. It appears there were 34 registered haemophilia A patients, 9 registered haemophilia B patients, and 12 registered von Willebrand's patients. St

k. 1987: The Annual Returns for 1987 signed by Prof Wickramesinghe states that the Centre treated 5 haemophilia A patients and 2 haemophilia B patients. No patients with von Willebrand's disease were treated during that year. There were 34 registered patients with haemophilia A, 9 registered patients with haemophilia B, and 12 registered patients with von Willebrand's disease. Sa

1. 1988: The Annual Returns for 1988 signed by Prof S N Wickramesinghe and Dr H Dodsworth record that 5 haemophilia A patients and 1 haemophilia B patient were treated at the Centre. No patients with von Willebrand's disease were treated during that year. There were 34 registered patients with haemophilia A, 8 registered patients with haemophilia B, and 13 registered patients with von Willebrand's disease. St

20. Data from St Mary's was contributed to published studies including: Jaundice and Antibodies Directed Against Factors VIII and IX in Patients Treated for Haemophilia or Christmas Disease in the United Kingdom by Rosemary Biggs, ⁶⁰ Haemophilia

⁴⁹ HCDO0001955

⁵⁰ HCDO0000325_003, HCDO0002050

⁵¹ HCDO0002050

⁵² HCDO0002139

⁵³ HCDO0002139

⁵⁴ HCDO0002231

⁵⁵ HCDO0002231. The Annual Returns for 1989 and 1990 are at HCDO0002324 and HCDO0002414 respectively.

⁶⁰ HCDO0000581

Treatment in the United Kingdom from 1969 to 1974 by Rosemary Biggs, ⁶¹ and Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976-80 by C R Rizza and Rosemary J D Spooner. ⁶²

21. According to the witness statement of Dr Michael Laffan, ⁶³ paediatric services were reconfigured in West London and paediatric haematology was located on the St Mary's hospital site. All paediatric haemophilia services at St Mary's Hospital later closed and paediatric patients were transferred to Great Ormond Street. ⁶⁴

Treatment policies and blood product usage

- 22. In response to a questionnaire for Dr Maycock, BPL, in November 1972, Professor Mollison indicated the preferred treatment for patients with haemophilia was not cryoprecipitate but freeze-dried concentrate. He estimated that he required 120 bottles of freeze-dried concentrate annually for the present treatment policy.⁶⁵
- 23. At a meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres and Blood Transfusion Centres on 15 December 1976 (at which Dr Dodsworth attended on behalf of St Mary's Hospital) it was agreed that priority for NHS concentrate should be given to patients who were allergic to cryoprecipitate and to those who were already on home treatment with NHS concentrate. 66 20% of the allocation of NHS concentrate for the Region would be set aside each month for emergency use. As part of a discussion on the distribution and allocation of NHS and commercial concentrate, it was agreed that the Directors of Blood Transfusion Centres for the North West and North East Thames Region should handle NHS factor VIII products and that, in principle, they should be asked to look into the feasibility of purchase, allocation and distribution of commercial factor VIII (as was already the case in East Anglia). 67

⁶¹ PRSE0004645

⁶² HCDO0000586

⁶³ WITN3089003 at para 6.3

⁶⁴ WITN3089003 para 6.3.12

⁶⁵ BPLL0008111

⁶⁶ CBLA0000533

⁶⁷ CBLA0000533

- 24. In <u>1976</u>, the Annual Returns show that St Mary's used 1,281 bottles/89,620 units of cryoprecipitate and 16 bottles/9,600 units of NHS Factor IX Concentrate.⁶⁸
- 25. At a meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres and Blood Transfusion Centres on 23 September 1977, Dr Dodsworth of St Mary's stated that 1,400 bags of cryoprecipitate had been used since the previous September. The Centre wanted to start 2 patients on home therapy so required an allocation of NHS concentrate.
- 26. In <u>1977</u>, the Annual Returns showed that the Centre used 1,216 bottles of cryoprecipitate, 42 bottles/8,990 units of NHS Factor VIII Concentrate (Elstree), and 43 bottles/25,200 units of NHS Factor IX Concentrate (Oxford).⁶⁹
- 27. In 1979, according to the Annual Returns, St Mary's used 865 bottles/69,200 units of cryoprecipitate, 161 bottles (40,260 units) of NHS Factor VIII Concentrate, 30 bottles/7,290 units of Armour Factor VIII Concentrate (Factorate), 139 bottles/34,335 units of Immuno Factor VIII Concentrate (Kryobluin) and 62 bottles/31,760 units of NHS Factor IX concentrate to treat patients with haemophilia or Christmas disease. To treat the one patient with von Willebrand's disease, the Centre used 10 bottles/800 units of cryoprecipitate.⁷⁰
- 28. In 1980, the Annual Returns showed that, to treat haemophiliac patients, St Mary's used 349 bags 24,430 units of cryoprecipitate in hospital, 14,332 units+11 bottles and 10,024 units+2 bottles of NHS Factor VIII Concentrate in hospital and at home respectively, 25,233 units+2 bottles and 12,963 units of Armour Factor VIII (Factorate) in hospital and at home respectively, 79,197 units+3 bottles and 32,656 units of Immuno Factor VIII (Kryobulin) in hospital and at home respectively. 10 bags of cryoprecipitate were used to treat one von Willebrand's disease patient in hospital. To treat 5 haemophilia B patients, the Centre used 40,965 units+31 bottles of NHS Factor IX Concentrate.

⁶⁸ HCDO0001118

⁶⁹ HCDO0001205

⁷⁰ HCDO0001373

- 29. In <u>1981</u>, it appears that the Centre treated its haemophilia A and von Willebrand's disease patients with cryoprecitate, NHS factor VIII concentrate, Armour factor VIII (Factorate) and Immuno Factor VIII (Kryobulin).⁷¹
- 30. In 1982, St Mary's treated its Haemophilia A patients with NHS Factor VIII concentrate (45,745 units in hospital and 31,679 units for home treatment), Armour Factor VIII (Factorate) (3,086 units for home treatment), and Immuno Factor VIII (Kryobulin) (30,745 units in hospital and 41,246 units for home treatment). It treated its von Willebrand's patients with 50 bags of cryoprecipitate, 2,735 units of NHS Factor VIII concentrate, and 5,665 units of Immuno Factor VIII (Kryobulin); all of which was provided in hospital. The one Haemophilia A patient with Factor VIII antibodies was treated with 50 bottles of cryoprecipitate. The haemophilia B patients treated at St Mary's received 27,600 units and 30,220 units of NHS Factor IX concentrate in hospital and for home treatment respectively.⁷²
- 31. In 1983, the Centre used around 421 bottles/105,250 units of NHS factor VIII concentrate and 21 bottles/12,390 units of Armour Factor VIII (Factorate) to treat haemophilia A patients. It is noted that it was not possible to distinguish from the records between the amount used in hospital and for home treatment. 5 bags/350 units of cryoprecipitate was used to treat 1 patient with von Willebrand's disease. Around 162 bottles/97,200 units of NHS factor IX concentrate was used by the Centre to treat haemophilia B patients in hospital. A handwritten summary of material used by Haemophilia Centres in the North West Thames Region in 1983 is broadly in line with this. In the North West Thames Region in 1983 is broadly in line with this.
- 32. In 1984, the Centre used 1,812,685 units of NHS factor VIII concentrate (an estimated 986,035 and 826,650 units in hospital and for home treatment respectively) and 8,350 units of Armour factor VIII (Factorate) for home treatment. It was noted that it was "very difficult to distinguish between in + out patient use". 75 98,682 units of NHS factor IX concentrate was used for home treatment of haemophilia B patients.

⁷¹ HCDO0001574. This document is very faint and difficult to read.

⁷² HCDO0001670

⁷³ HCDO0001766

⁷⁴ HCDO0000152 003

⁷⁵ HCDO0001860

- 33. In 1985, St Mary's used 51,220 units of NHS Factor VIII concentrate to treat Haemophilia A patients in hospital and 79,370 units of NHS Factor VIII concentrate to treat Haemophilia A patients at home. For Haemophilia B patients, 71,090 units of NHS Factor IX concentrate was used for home treatment. ⁷⁶ A list of haemophiliacs treated within NWT RHA with NHS heat-treated factor concentrate in April 1985 shows four patients under the care of Dr H Dodsworth at St Mary's Hospital. ⁷⁷
- 34. In 1986, the Centre used 6,495 and 108,775 units of NHS factor VIII concentrate for in-patient and home treatment respectively, 3,600 units of Alpha factor VIII (Profilate) for home treatment, 5,600 units of Armour factor VIII (Factorate) for home treatment, and 8,913 and 31,842 units of Immuno factor VIII (Kryobulin) for in-patient and home treatment respectively to treat haemophilia A patients. For haemophilia B patients, the Centre used 13,110 and 7,480 units of NHS factor IX concentrate for in-patient and home treatment respectively.⁷⁸
- 35. In <u>1987</u>, the Centre used 9,840 and 72,000 units of NHS factor VIII concentrate for inpatient and home treatment respectively, and 2,716 and 536 units of Immuno factor VIII (Kryobulin) for in-patient and home treatment respectively to treat haemophilia A patients. For haemophilia B patients, the Centre used 18,600 and 19,500 units of NHS factor IX concentrate to treat haemophilia B patients in hospital and at home respectively.⁷⁹

Knowledge of risk of hepatitis/AIDS and response to risk

36. Prior to becoming Director of St Mary's Haemophilia Centre, Dr Dodsworth attended a number of UKHCDO meetings in 1970s (and can thus be taken to be familiar with the matters discussed at those meetings) on behalf of Professor Mollison when he was Director, including on:

⁷⁶ HCDO0001955

⁷⁷ BPLL0010517 002

⁷⁸ HCDO0000325 003, HCDO0002050

⁷⁹ HCDO0002139. The Annual Returns for 1989 and 1990 are at HCDO0002324 and HCDO0002414 respectively.

- a. 5 April 1971,83
- b. 27 October 1972,84
- c. 1 November 1974,85
- d. 13 January 1977,86 and
- e. 24 October 1977.87
- 37. It does not appear that Professor Mollison attended any UKHCDO meetings himself.
- 38. On 12 February 1979, Professor Mollison chaired an ad hoc meeting at the Medical Research Council where there was a discussion about the non-parenteral/parental spread of non-A non-B hepatitis in Britain.⁸⁸
- 39. As co-Director of the Centre from 1979, Dr Dodsworth was a regular attendee at UKHCDO meetings (and can thus be taken to be familiar with the matters discussed at those meetings), including on:
 - f. 20 November 1979,89
 - g. 9 October 1981,⁹⁰
 - h. 17 October 1983,91
 - i. 17 March 1986,⁹²
 - j. 9 October 1986,⁹³
 - k. 16 June 1989,⁹⁴
 - 1. 9 October 1989, 95

⁸³ HCDO0001014

⁸⁴ HCDO0001015

⁸⁵ HCDO0001017

⁸⁶ PRSE0002268

⁸⁷ PRSE0001002

⁸⁸ PRSE0001960 / MRCO0000033_005

⁸⁹ CBLA0001028

⁹⁰ CBLA0001464

⁹¹ PRSE0004440

⁹² PRSE0001688

⁹³ PRSE0004317

⁹⁴ PRSE0002656

⁹⁵ HCDO0000015_035

- m. 21 September 1990,96 and
- n. 7 October 1991.97
- 40. At the meetings on 13 September 1982 and 21 October 1985, Dr Dodsworth sent her apologies. On 13 September 1982, Dr Saad Abdalla attended on her behalf on 13 September 1982, 98 and Dr B Bain attended on her behalf on 21 October 1985. 99
- 41. It does not appear that any of the Directors from St Mary's contributed to the Glasgow Symposium on Unresolved problems in Haemophilia in 1980, 100 or the Manchester Symposium on Current Topics in Haemophilia in 1982. 101
- 42. In 1985, a meeting of Directors of Haemophilia Centres supplied by NBTS Edgware (including Dr H Dodsworth of St Mary's Hospital) was arranged for 18 January 1985 to discuss the problems related to AIDS/HTLVIII in Haemophiliacs. ¹⁰² The topics to be covered included:
 - a. Brief general review of AIDS/HTLV 3 related problems in haemophilia in UK and USA;
 - b. Evidence regarding efficacy and safety of heat-treated concentrates;
 - c. Availability/cost of commercial products;
 - d. Problems at BTS: donor screening, product distribution
 - e. Problems at BPL Elstree: product availability;
 - f. Problems of anti-HTLV 3 screening in patients/families/staff;
 - g. Patient management and counselling;
 - h. Aspects of laboratory/clinical safety, and potential industrial problems;
 - i. Financial problems.

⁹⁶ HCDO0000015_021

⁹⁷ HCDO0000491 001

⁹⁸ CBLA0001619

⁹⁹ PRSE0001638

¹⁰⁰ RLIT0001242

¹⁰¹ DHSC0002221 003

¹⁰² CBLA0001975. The Directors of the following Haemophilia Centres supplied by NBTS Edgware were invited to the meeting: GOSH, UCH, Luton & Dunstable, Ashford, Bedford, Edgware, Middlesex, Hillingdon, Lister (Stevenage), and Charing Cross.

43. In 1993, Dr Dodsworth argued in the Lancet that all blood donor units should be tested for HTLV.¹⁰³

44. At a witness seminar on "Haemophilia: Recent History of Clinical Management" at the

Wellcome Institute for the History of Medicine on 10 February 1998, Dr Dodsworth

spoke briefly about the availability of factor VIII concentrate. 104 She said that

"[a]lthough the manufacturing process was discovered in the early 1950s, there was

never adequate provision for manufacture of factor VIII concentrate in this country

until the early 1970s". 105 In particular, "the facilities at Elstree were inadequate to

produce the quantities which were needed". 106

45. She further explained that, in 1976, she was asked to represent Pat Mollison on a

committee convened to advise the Department of Health on how much factor VIII

concentrate and albumen were needed to treat patients in the UK. Their spokesman, Dr

Tovey, the Director of the Bristol Transfusion Centre, had persuaded them that if they

wanted to treat their patients adequately, "it would be necessary to fractionate at least

80 per cent of the blood that was donated". She went on to say:

"At this point the Government decided that money was available for neither

extending the fractionation unit at Elstree nor for equipping the transfusion

centres to separate yet more plasma from donor units. So this is really why we

found ourselves buying large quantities of factor VIII concentrate from

America, and why we infected so many of our patients with HIV."107

Patients infected with hepatitis/HIV

46. Provisional UKHCDO data available to the Inquiry suggests that 3 patients at St Mary's

Hospital tested positive for HIV: 1 patient in 1984 and 2 patients in 1985. 108

¹⁰³ DHSC0004305 034

¹⁰⁴ RLIT0000022 internal p.29-30

¹⁰⁵ RLIT0000022 internal p.29-30 footnotes omitted

¹⁰⁶ RLIT0000022 internal p.30

107 RLIT0000022 internal p.30

¹⁰⁸ INQY0000250

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47. In 1990, Dr Dodsworth reported that there had been a case of hepatitis in a patient with von Willebrand's Disease. A letter from Miss RJD Spooner to Dr Heptonstall stated:

"The Quarterly Report Card for July-September 1990 from St. Mary's Hospital, London W2, was ticked to report that there had been a case of Hepatitis during the Quarter. On telephoning the Centre Dr. Helen Dodsworth (Co-Director) told me that the patient had von Willebrand's Disease and had received "buckets of cryo" plus some Factor VIII concentrate before he developed Non-B Hepatitis."

48. In 1993, a further case of hepatitis was reported by Dr Dodsworth. Another letter from Miss RJD Spooner to Dr J Heptonstall dated 24 May 1993 stated:

"The Haemophilia Centre at St Mary's Hospital, London has reported that one of their patients [redacted] became anti-Hep.C +ve in March 1993 (Event 93/14). Could you investigate, please? The event was reported by Dr Helen Dodsworth."

Treatment arrangements for HIV and HCV patients

49. At the UKHCDO meeting on 21 October 1985, it was noted that St Mary's Hospital, Paddington were organising AIDS counselling courses and their courses were well advertised. 109

50. At a later meeting of the Haemophilia Centre Directors AIDS Group on 2 July 1986 (at which there does not appear to have been a representative on behalf of St Mary's) it was noted that the Chair had received frequent complaints via the Haemophilia Society of "apparently appallingly low standards of counselling at some Centres." Specifically, at St Mary's:

"[t]he problems arising from the lack of understanding by the AIDS counselling experts at St Mary's Hospital of the special problems of haemophiliacs was

¹⁰⁹ PRSE0001638

discussed. It was agreed that this could give rise to very difficult situations regarding haemophiliacs and that St Mary's should not be involved in the AIDS Group's Counselling Day. It was pointed out that Heather George at St Mary's were already organising a Counselling Course for Haemophiliacs, to take place on 8th August, no Haemophilia Centre Directors were involved. It was agreed that the Chairman should write to Heather George to obtain details of the programme."

JENNI RICHARDS QC ANNABEL LEE

Inquiry Counsel Team

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