

SMALLER HAEMOPHILIA CENTRES PRESENTATION

ESSEX GROUP:

(1) HARLOW

(2) COLCHESTER

(3) GRAYS (ORSETT)

(4) CHELMSFORD (BROOMFIELD)

(5) WESTCLIFFE-ON-SEA (SOUTHEND)

Directors, Facilities and Staffing

1. During the 1970s-1980s, the Directors of the Haemophilia Centres at:
 - a. Harlow included Dr D Carmichael (from 1976 until approximately 1980); and Dr Vernon Oxley (from approximately 1981 to at least 1995). Dr Carmichael was a member of the British Society for Haematology in 1974/5,¹ and 1979/80.² Dr Oxley was a member of the British Society for Haematology in 1979/80.³
 - b. Colchester included Dr J W Nicholas (from 1976 until approximately 1981); and Dr Margaret Anne Boots (from 1981 until at least 1991).⁴ Dr Boots was a member of the British Society for Haematology in 1979/80.⁵
 - c. Grays included Dr John S Oakey (from 1976 until at least 1986).
 - d. Chelmsford included Dr Olive Hazel Anne Baugh (from 1976 until at least 1991). Dr Baugh has provided a written statement to the Inquiry dated 2 April 2021.⁶ She was a member of the British Society for Haematology from 1975 to

¹ BSHA0000138

² BSHA0000114

³ BSHA0000114

⁴ See minutes of the UKHCDO meeting on 9 October 1981 where Professor Bloom welcomed 'Dr M A Boots who had succeeded Dr Nicholas as Director of the Colchester Haemophilia Centre ": CBLA0001464 p. 7

⁵ BSHA0000114

⁶ WITN5316001

2007,⁷ and a Consultant Haematologist at the Broomfield Hospital (previously Chelmsford and Essex Hospital) from 1975 to 2007.⁸

- e. Westcliffe-on-Sea (also known as Southend) included Dr Mills (from approximately 1981 to at least 1991). Dr Eden and Dr Traub⁹ were also based at the Haematology Department at Southend.

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

2. The Haemophilia Centres were based at:¹⁰

- a. Harlow: Department of Haematology, Princess Alexandra Hospital, Hamstel Road, Harlow, Essex, CM20 1QX. The designated Haemophilia Centre number was 097.
- b. Colchester: initially at the Department of Haematology, Essex County Hospital, Colchester, Essex;¹¹ then at the Department of Haematology, District General Hospital, Turner Road, Colchester, Essex, CO4 5JL.¹² The designated Haemophilia Centre number was 098.
- c. Grays: Orsett Hospital, Nr Grays, Essex. The designated Haemophilia Centre number was 099.
- d. Chelmsford: initially based at the Department of Pathology, Chelmsford and Essex Hospital, London Road, Chelmsford, Essex;¹³ then at the Department of Haematology, Broomfield Hospital, Broomfield, Chelmsford, Essex, CM1

⁷ WITN5316001 para 3.1

⁸ WITN5316001 para 2.2.7

⁹ According to Dr Colvin INQY1000062 p. 41

¹⁰ HCDO0000138_007 as at July 1978 (Southend was not yet a Centre); BPLL0010509 as at 8 August 1984; DHSC0002263_005 as at 15 February 1985 and HSOC0017344 as at February 1991 (Grays was not listed as a Centre). HCDO0000119_138 and HCDO0000602.

¹¹ HCDO0000138_007 as at July 1978; BPLL0010509 as at 8 August 1984

¹² DHSC0002263_005 as at 15 February 1985 and HSOC0017344 as at February 1991.

¹³ HCDO0000138_007 as at July 1978; BPLL0010509 as at 8 August 1984; DHSC0002263_005 as at 15 February 1985

5ET.¹⁴ The designated Haemophilia Centre number was 100. According to Dr Baugh, the move to the Broomfield site took place in 1984 and “*over time acquired eight inpatient beds, a five day treatment ward, two outpatient clinics a week, two very large anticoagulation clinics weekly and treatment of outpatients in the oncology treatment centre... Although the haematology service expanded the associate haemophilia centre, in view of the small number of patients, remained essentially a treatment unit*”.¹⁵ Her role as Haemophilia Centre Director was to provide “*an on-demand service for patients with bleeding or thromboembolic disorders*”.¹⁶ She was assisted “*from 1982 by an associate specialist whose training was in histopathology and cytology*”.¹⁷ She further described the arrangements at the Chelmsford Centre as follows:¹⁸

*“There were no designated areas for consultations or treatment other than the consultant’s office or a small area in the laboratory at the Chelmsford and Essex Hospital. Patients at risk of adverse reactions, for example on DDAVP or cryoprecipitate, were initially treated on one of the medical wards. After the move to Broomfield hospital in 1984 a waiting area and designated treatment rooms were available. My small number of patients were all registered with a reference haemophilia centre. The Royal London Hospital mainly or The Royal Free Hospital on a shared care basis. The major centre directors at the time were Dr Brian Colvin and Dr Peter Kernoff. I had no haemophilia outpatient clinic: patients were seen on demand.”*¹⁹

- e. Westcliffe-on-Sea: Southend Hospital, Prittlewell Chase, Westcliffe-on-Sea, Essex, S50 0RY. The designated Haemophilia Centre number was 101.

¹⁴ HSOC0017344 as at February 1991

¹⁵ WITN5316001 para 2.2.7

¹⁶ WITN5316001 para 5.1.2

¹⁷ WITN5316001 para 5.1.2

¹⁸ WITN5316001 para 5.1.2

¹⁹ The Chelmsford Haemophilia Centre closed in 2001: see HCDO0000012_170 and WITN5316001 para 5

3. In November 1976, Harlow, Colchester, Grays and Chelmsford were proposed Associate Centres in the North-East Thames Region (Region 06).²⁰ All four Centres were newly designated late in 1976 and formed part of the Royal Free Supraregion (together with the Royal Free, Cambridge, Hammersmith, Middlesex, St Mary's, Westminster, Great Ormond Street, London Hospital, UCH, Stevenage, Luton, Bedford, Edgware, Hillingdon, Northwick Park and Charing Cross Hospital).²¹ Southend had not yet been designated as a Centre.
4. By letter dated 29 November 1976, Dr Dormandy of the Royal Free Hospital wrote to all Haemophilia Centre Directors in the North East Thames Region (Region 06) including Dr Carmichael (Harlow), Dr Nicholas (Colchester), Dr Baugh (Chelmsford) and Dr Oakey (Grays).²² Dr Dormandy of the Royal Free Hospital and Professor Ingram of St Thomas' Hospital had decided to split responsibility for the South-East Haemophilia Supraregion along the Thames. Harlow, Colchester, Chelmsford and Grays, all being in the northern half (as part of the North East Thames Region), fell under the responsibility of Dr Dormandy at the Royal Free.
5. An article published in the British Medical Journal in 1977 provided some information about Haemophilia Centres in the North East Thames Region at that time.²³ The Region comprised 4 Haemophilia Centres: Royal Free Hospital, the London Hospital, the Hospital for Sick Children (Great Ormond Street) and University College Hospital; and 4 Associate Centres: Colchester, Harlow, Chelmsford and Grays (Orsett). The article stated that:²⁴

“...the “newly formed North-east Thames Regional Health Authority, in appraising the immediate requirements of the region, became aware of the need to expand facilities for home treatment of patients with severe haemophilia...

To ascertain how best to meet these requirements the chairman of the Association of Haematologists in the region convened a working party to

²⁰ CBLA0002956_005

²¹ OXUH0000863_002

²² CBLA0000506 p. 2

²³ HSOC0022537

²⁴ HSOC0022537 p. 2

consider the region's policy for organising haemophilia care and, especially, expanding home treatment facilities. Every haematologist in the region was invited to attend the first meeting, held in October 1975. Representatives attended from the region's four haemophilia centres (the Royal Free Hospital, the London Hospital, the Hospital for Sick Children, and University College Hospital) and from three hospitals which also cared for severe haemophiliacs (Harlow, Colchester, and Orsett)."

6. The article further stated that, "*As part of the working party's plan for haemophilia care, four associate centres have now been set up at Colchester, Harlow, Chelmsford, and Orsett with the help of the co-ordinator*".²⁵
7. Southend was designated as a new Associate Centre in 1981.²⁶
8. Dr Kernoff and Dr Colvin produced a paper on "*Haemophilia Services in the North East Thames Region: 1983*" which described the arrangements between regional Centres:²⁷

"There are Associate Haemophilia Centres at Chelmsford, Colchester, Harlow, Orsett and Southend. These Centres do not separately register patients or organise home treatment programmes and are not staffed or equipped to manage serious clinical problems, undertake major surgery or offer genetic counselling. Their main role is to offer local support to patients who are mainly managed at the RFH or London Hospitals."

9. There appear to have been regular regional meetings attended by Directors of the Essex Centres, including:
 - a. Dr Carmichael (Harlow), Dr Nicholas (Colchester), and Dr Oakey (Grays) attended a meeting of Directors of Haemophilia/Associate Centres and Blood Transfusion Centres, RHAs 04, 05 and 06 on 15 December 1976.²⁸ Immediately

²⁵ HSOC0022537 p. 3

²⁶ CBLA0001464

²⁷ BART0002284 p. 6

²⁸ CBLA0000533

following, Dr Oakey (Grays), Dr Carmichael (Harlow) and Dr Nicholas (Colchester) attended a meeting of the Association of Haematologists (NETR) Working Party in Haemophilia on 15 December 1976.²⁹ Dr Carmichael chaired the meeting and Dr Nicholas was Secretary.

- b. Dr Oakey (Grays), Dr Carmichael (Harlow) and Dr Nicholas (Colchester) attended a meeting of the Association of Haematologists (NETR) Working Party in Haemophilia on 15 July 1977.³⁰ Dr Carmichael chaired the meeting and Dr Nicholas was Secretary.
- c. Dr Baugh (Chelmsford), Dr Carmichael (Harlow), Dr Nicholas (Colchester), and Dr Oakey (Grays) attended a meeting of Directors of Haemophilia/Associate Centres and Blood Transfusion Centres in RHAs 04, 05 and 06 on 23 September 1977.³¹ Dr Carmichael chaired the meeting.³²
- d. Dr Oakey (Grays), Dr Carmichael (Harlow) and Dr Nicholas (Colchester) attended a meeting of the Association of Haematologists (NETR) Working Party in Haemophilia on 1 February 1978.³³ Dr Baugh (Chelmsford) sent her apologies. Dr Carmichael chaired the meeting and Dr Nicholas was Secretary.
- e. Dr Carmichael (Harlow), Dr Baugh (Chelmsford), and Dr Oakey (Grays) attended a meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres (Regions 04, 05 and 06) and Blood Transfusion Centres on 1 September 1978.³⁴ Dr Carmichael chaired the meeting.³⁵
- f. Dr Baugh (Chelmsford), Dr Carmichael (Harlow), and Dr Nicholas (Colchester) attended a meeting of the Association of Haematologists (NETR) Working

²⁹ BART0000691

³⁰ BART0000690

³¹ BART0000689

³² BART0000689, p. 1

³³ BART0000687

³⁴ CBLA0000838

³⁵ CBLA0000838 p. 2

Party in Haemophilia on 29 November 1978.³⁶ Dr Baugh was Secretary at the meeting. Dr Oakey (Grays) sent his apologies.

- g. Dr Baugh (Chelmsford), Dr Carmichael (Harlow), and Dr Nicholas (Colchester) attended a meeting of the Association of Haematologists (North East Thames Region) Haemophilia Working Party on 4 April 1979.³⁷ Dr Oakey (Grays) sent his apologies.
- h. Dr Baugh (Chelmsford) and Dr Carmichael (Harlow) attended a meeting of the Association of Haematologists (North East Thames Region) Haemophilia Working Party on 1 August 1979.³⁸ Dr Baugh was Secretary at the meeting. Dr Oakey (Grays) sent his apologies.
- i. Dr Nicholas (Colchester) and Dr Baugh (Chelmsford) attended a meeting of the Association of Haematologists (North East Thames Region) Haemophilia Working Party on 12 December 1979.³⁹ Dr Baugh was Secretary at the meeting. Dr Carmichael (Harlow) and Dr Oakey (Grays) sent their apologies.
- j. Dr Baugh (Chelmsford), Dr Oxley (Harlow) and Dr Boots (Colchester) attended a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 22 April 1981.⁴⁰ Dr Baugh was Secretary at the meeting. Dr Nicholas (Colchester) sent his apologies.
- k. Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Carmichael (Harlow) and Dr Traub (Southend) attended a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 9 February 1983.⁴¹ Dr Baugh was Secretary at the meeting.

³⁶ BART0000686

³⁷ BART0000685

³⁸ BART0000683

³⁹ BART0000682

⁴⁰ BART0000681

⁴¹ BART0000679

- l. Dr Baugh (Chelmsford) and Dr Oxley (Harlow) attended a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 9 November 1983.⁴² Dr Baugh was Secretary at the meeting.
- m. Dr Baugh (Chelmsford), Dr Boots (Colchester) and Dr Oxley (Harlow) attended a meeting of the Association of Haematologists North East Thames Region Haemophilia Working Party on 9 May 1984.⁴³ Dr Baugh was Secretary at the meeting. Dr Mills (Southend) sent his apologies.
- n. Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Mills (Southend), Dr Oakey (Grays), and Dr Oxley (Harlow) attended a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 13 December 1984.⁴⁴ Dr Baugh was Secretary at the meeting.
- o. Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Mills (Southend) and Dr Oxley (Harlow) attended a meeting of the Association of Haematologists North East Thames Region Haemophilia Working Party in Haemophilia on 22 May 1985.⁴⁵ Dr Baugh was Secretary at the meeting.
- p. Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Mills (Southend) and Dr Oxley (Harlow) attended a meeting of the Association of Haematologists North East Thames Region Haemophilia Working Party in Haemophilia on 27 November 1985.⁴⁶ Dr Baugh was Secretary at the meeting.
- q. Dr Baugh (Chelmsford) and Dr Oxley (Harlow) attended a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 25 June 1986.⁴⁷ Dr Baugh was Secretary at the meeting. It is recorded that Dr Boots (Colchester), Dr Mills (Southend) and Dr Oakey (Grays) sent their apologies.

⁴² BART0000678

⁴³ BART0000677

⁴⁴ BART0000676

⁴⁵ BART0000675

⁴⁶ BART0000674

⁴⁷ BART0000673

- r. Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Mills (Southend) and Dr Oxley (Harlow) attended a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 12 November 1986.⁴⁸ Dr Oakey (Grays) sent his apologies.
- s. Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Mills (Southend), and Dr Oxley (Harlow) attended a meeting of the North East Thames Region Association of Haematologists Haemophilia Working Party on 18 September 1989.⁴⁹ Dr Baugh was Secretary at the meeting.
- t. Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Mills (Southend) and Dr Oxley (Harlow) attended a meeting of the North East Thames Region Association of Haematologists Haemophilia Working Party on 9 October 1990.⁵⁰
- u. Dr Baugh (Chelmsford), Dr Boots (Colchester) and Dr Oxley (Harlow) attended a meeting of the North East Thames Region Association of Haematologists Haemophilia Working Party on 6 February 1992.⁵¹ Dr Baugh was Secretary at the meeting.

10. Harlow, Colchester, Grays, Chelmsford (and later Southend), as part of the North East Thames Region, were supplied with blood products by the Regional Transfusion Centre in Brentwood.⁵²

11. At a meeting of Directors of Haemophilia/Associate Centres and Blood Transfusion Centres in Regions 04, 05 and 06 on 15 December 1976, Dr Jenkins of the Brentwood Regional Transfusion Centre expressed a wish “*to be wholly involved with the supply, allocation and distribution of FVIII to Haemophilia Centres and Associate Centres in the Brentwood Parish and to all patients on home treatment in his Parish whichever Haemophilia Centre they were under*”.⁵³ It was agreed “*that a record of patients living*

⁴⁸ BART0000671

⁴⁹ BART0000667

⁵⁰ BART0000666

⁵¹ BART0000585

⁵² CBLA0000533, HCDO0000061_004

⁵³ CBLA0000533 p. 3

*in the Brentwood parish should be kept at the RBTC and that Dr Jenkins should be informed if commercial concentrate was being issued directly from any of the Haemophilia Centres”.*⁵⁴

12. At a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 22 April 1981, attended by Dr Baugh (Chelmsford), Dr Oxley (Harlow) and Dr Boots (Colchester),⁵⁵ it was recorded that: “

“It was felt unnecessary to maintain a reserve supply of Factor VIII concentrate at Brentwood for emergencies or major operations. All Associate Haemophilia Centres are advised to maintain a stock of at least 5,000 units of Factor VIII and it was agreed that further supplies of Factor VIII concentrate could be transferred from the major Haemophilia Centres or be obtained from the commercial suppliers at short notice...”

13. In her written statement to the Inquiry, Dr Baugh described the regional arrangements as follows:⁵⁶

“The major centres, the reference haemophilia centres, provided comprehensive care, including registration, information, management of serious bleeding problems, dental and surgical care, counselling, physiotherapy and social care, selection of blood products, selection and training of patients for home treatment and provision of their treatment. The directors gave advice and help freely when requested. Patient treatment regimes were discussed and advice given on product usage. The blood products used were cryoprecipitate, fresh frozen plasma or NHS Factor VIII and Factor IX concentrate, (and later, heat treated Factor 8y and factor 9A) which were obtained from the Blood Transfusion Laboratory, Brentwood on a by name patient basis. We held no commercial concentrates and had no access to any blood products other than NHS fresh frozen plasma, cryoprecipitate or concentrates obtained from the Brentwood Blood Transfusion Laboratory.”

⁵⁴ CBLA0000533 p. 4

⁵⁵ BART0000681

⁵⁶ WITN5316001 para 5.1.3

Number of Patients Registered and/or Treated at the Centres

14. A list of Haemophilia Centres in around 1975 shows that there were no patients at Harlow, Colchester, Grays or Chelmsford.⁵⁷ All four Centres were marked with an asterisk (*) indicating a “*New Associate Centre/New Centre designated late in 1976*”.⁵⁸
15. In a table enclosed under cover of letter dated 19 December 1977 from Dr Rizza to Dr Maycock, there were in 1976:⁵⁹
- a. 13 patients with haemophilia A, 0 carriers of haemophilia A and 1 patient with von Willebrand’s disease at Harlow;
 - b. No clear data was provided for Colchester;
 - c. 1 patient with haemophilia A, 0 carriers of haemophilia A and 0 patients with von Willebrand’s disease at Grays; and
 - d. 0 patients at Chelmsford.
16. The arrangements for Annual Returns in the North East Thames Region were discussed at a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 22 April 1981, attended by Dr Baugh (Chelmsford), Dr Oxley (Harlow) and Dr Boots (Colchester):⁶⁰

“Dr Kernoff suggested that it would be helpful if Associate Centres seeing and treating patients registered with either the London Hospital, the Royal Free Hospital, University College Hospital, or the Hospital for Sick Children, Great Ormond Street, would make regular returns at three or six monthly intervals to the Haemophilia Centre with which the patient is registered. This would enable the major Haemophilia Centres to monitor the progress of such patients and to be aware of any problems or complications which may occur. At present returns for Home Treatment patients are made by the major Haemophilia Centres with

⁵⁷ OXUH0000863_002

⁵⁸ OXUH0000863_002, CBLA0000699

⁵⁹ CBLA0000699 p. 6

⁶⁰ BART0000681 p. 2

whom each patient is registered. Associate Centres make returns for patients not on Home Treatment.”

17. Under cover of letter dated 27 April 1984, Dr Kernoff of the Royal Free Hospital enclosed “Returns for Colchester, Chelmsford and Southend relating to Royal Free patients treated at these places during 1983”.⁶¹

18. In a letter dated 30 April 1984, Dr Colvin of The London Hospital (Whitechapel) wrote to Miss Spooner setting out the arrangements for Annual Returns:⁶²

“As you may know the North East Thames Region has decided to centralise its data collection and I therefore have the information for my patients treated at Basildon, Colchester, Harlow and Southend but I don’t seem to have any details from Chelmsford. This policy will be reviewed at the next Regional Haemophilia Working Party. Obviously it is important to make sure that we are not duplicating data and I will be sending copies of everything I send you to the District General Hospitals involved.”

19. The number of patients registered and/or treated at each Centre according to the Annual Returns and other evidence received by the Inquiry is set out below.

Harlow

20. A letter dated 9 August 1977 from G S Davis, Haemophilia Co-ordinator at the North East Thames Regional Transfusion Centre in Brentwood, to Miss Spooner at the Oxford Haemophilia Centre described the arrangements at Harlow as follows:⁶³

“As you probably know, Harlow is only an associate Haemophilia Centre and do not actually register patients themselves. This poses quite a few problems when filling in these returns.

⁶¹ HCDO0000184_008

⁶² HCDO0000177_008

⁶³ HCDO0000061_004

The amount of cryo used is quite clear cut but I have run into problems when calculating the amount of concentrate used. This is because the home treatment patients that visit Harlow, really use it as a supply for picking up supplies but send all their home treatment records directly to their Main Centre. Therefore the problem that arises is have the Main Centres included in their returns the concentrate supplied to these patients by Harlow? Harlow merely record what they have issued; they do not have copies of the home treatment sheets.

Another problem is that there are other patients...

These are all home treatment patients and collect their NHS concentrate directly from me at the Blood Transfusion Centre at Brentwood. All seven are registered at either the Royal Free Hospital or the London Hospital. None of them have ever attended Harlow but I thought you might be interested in them in case they are not accounted for in either the Royal Free Hospital or the London Hospital returns.

Two other patients...

These are both "London" patients who pick up their concentrate from Black Notley and Chelmsford & Essex Hospitals respectively and send their returns to the London. Black Notley and Chelmsford & Essex Hospitals are both supplied from the Blood Transfusion Centre, Brentwood.

Occasionally if any of the other home treatment patients in the North East Thames Region are in any difficulties, I deliver supplies directly from the Blood Transfusion Centre, adding further to the problems of recording it on these returns. This applies for both concentrate and cryo."

21. According to information contained in the Annual Returns, the numbers of patients registered and/or treated at Harlow were as follows:

- a. 1976: The Annual Returns for 1976,⁶⁴ which name Dr Carmichael as Director of the Centre, show that Harlow treated 13 patients with haemophilia A,⁶⁵ including 1 patient with factor VIII antibodies, 0 patients with Christmas disease and 1 patient with von Willebrand's disease.⁶⁶
- b. 1977: The Annual Returns for 1977, which name Dr Carmichael as Director of the Centre, show that Harlow treated 10 patients with haemophilia A, and 0 patients with Christmas disease.⁶⁷ It appears that 5 patients were on regular home therapy: 2 patients were on regular home therapy from the Royal Free Hospital, 2 patients were on regular home therapy from the London Hospital, and 1 patient was on regular home therapy from the Royal Infirmary, Sheffield.
- c. 1978: The Annual Returns for 1978, which name Dr Carmichael as Director of the Centre, show that Harlow treated 10 patients with haemophilia A, and 0 patients with Christmas disease.⁶⁸ It appears that 5 patients were on regular home therapy.⁶⁹
- d. 1979: The Annual Returns for 1979, which name Dr Carmichael as Director of the Centre, show that Harlow treated 10 patients with haemophilia A, and 0 patients with Christmas disease.⁷⁰ It appears that 5 patients were on regular home therapy.⁷¹
- e. 1980: The Annual Returns for 1980 show that Harlow treated 9 patients with haemophilia A, and 0 patients with von Willebrand's disease.⁷²
- f. 1981: The Annual Returns for 1981, which name Dr Oxley as Director of the Centre, show that Harlow treated 12 patients with haemophilia A, 0 patients

⁶⁴ HCDO0000061_004

⁶⁵ HCDO0001081

⁶⁶ HCDO0001081

⁶⁷ HCDO0001163

⁶⁸ HCDO0001260

⁶⁹ HCDO0001260 p. 2

⁷⁰ HCDO0001328

⁷¹ HCDO0001328 p. 2

⁷² HCDO0001424

with von Willebrand's disease and 2 patients with haemophilia B.⁷³ It was noted that 1 haemophilia B patient was "*registered at Chelmsford*".⁷⁴

- g. 1982: The Annual Returns for 1982, which name Dr Oxley as Director of the Centre, show that Harlow treated 11 patients with haemophilia A, 1 patient with von Willebrand's disease, and 1 patient with haemophilia B.⁷⁵
- h. 1983: The Annual Returns for 1983, which name Dr Colvin / Dr Oxley as Director of the Centre, show that Harlow treated 3 patients with haemophilia A, 0 patients with von Willebrand's disease, and 0 patients with haemophilia B.⁷⁶
- i. 1984: The Inquiry does not have Annual Returns for Harlow in 1984.
- j. 1985: The Annual Returns for 1985, which name Dr Oxley as Director of the Centre but notes "*Return completed by Dr P Kernoff*",⁷⁷ show that Harlow treated 1 patient with haemophilia A, and 0 patients with von Willebrand's disease.⁷⁸
- k. 1986: The Inquiry does not have Annual Returns for Harlow in 1986 but a handwritten note dated 21 August 1987 records that some data regarding Harlow was "*entered on computer sheet*".⁷⁹

Colchester

- 22. A memo from Dr Bidwell to Dr Maycock dated 12 March 1976 reported that there were 2 patients with Christmas disease treated at Colchester during 1974-1975.⁸⁰

⁷³ HCDO0001524

⁷⁴ HCDO0001524 p. 3

⁷⁵ HCDO0001625

⁷⁶ HCDO0000142_003 p. 2

⁷⁷ HCDO0001909

⁷⁸ HCDO0001909

⁷⁹ HCDO0000377_002

⁸⁰ BPLL0007892_001

23. According to information contained in the Annual Returns, the number of patients registered and/or treated at Colchester were as follows:

- a. 1976: The Annual Returns for 1976, which name Dr Nicholas as Director, show that Colchester treated 7 patients with haemophilia A and 2 patients with Christmas disease.⁸¹ It was noted that one haemophilia A patient was on regular home therapy “*from GOS*” (presumably Great Ormond Street Hospital).⁸² Both patients with Christmas disease were on regular home therapy.⁸³
- b. 1977: The Annual Returns for 1977, which name Dr Nicholas as Director, show that Colchester treated 16 patients with haemophilia A, including 1 patient with factor VIII antibodies, and 2 patients with Christmas disease.⁸⁴ It was again noted that one haemophilia A patient was on regular home therapy at “*GOS*” (presumably Great Ormond Street Hospital),⁸⁵ and another haemophilia A patient was on regular home therapy “*from Nov*”.⁸⁶ Both patients with Christmas disease were on regular home therapy.⁸⁷
- c. 1978: The Annual Returns for 1978, which name Dr Nicholas as Director, show that Colchester treated 13 patients with haemophilia A, including 1 patient with factor VIII antibodies, and 5 patients with Christmas disease, including 1 patient with factor IX antibodies.⁸⁸ Colchester also treated 1 patient with von Willebrand’s disease.⁸⁹ It appears that 3 haemophilia A patients were on regular home therapy.⁹⁰ 2 patients with Christmas disease were on regular home therapy.⁹¹
- d. 1979: The Inquiry does not have Annual Returns for Colchester in 1979.

⁸¹ HCDO0001070

⁸² HCDO0001070 p. 2

⁸³ HCDO0001070 p. 3

⁸⁴ HCDO0001151

⁸⁵ HCDO0001151 p. 4

⁸⁶ HCDO0001151 p. 3

⁸⁷ HCDO0001151 p. 7

⁸⁸ HCDO0001248 p. 5

⁸⁹ HCDO0001248 p. 9

⁹⁰ HCDO0001248 p. 2

⁹¹ HCDO0001248 p. 11

- e. 1980: The Annual Returns for 1980, which name Dr Nicholas as Director, show that Colchester treated 12 patients with haemophilia A, 2 patients with von Willebrand's disease and 6 patients with haemophilia B.⁹²
- f. 1981: The Annual Returns for 1981, which name Dr Boots as Director, show that Colchester treated 11 patients with haemophilia A, 0 patients with von Willebrand's disease and 3 patients with haemophilia B.⁹³
- g. 1982: The Annual Returns for 1982, which name Dr Boots as Director, show that Colchester treated 16 patients with haemophilia A, 1 patient with von Willebrand's disease and 2 patients with haemophilia B.⁹⁴
- h. 1983: The Annual Returns for 1983, which name Dr Boots as Director, show that Colchester treated 23 patients with haemophilia A, 4 patients with von Willebrand's disease and 3 patients with haemophilia B.⁹⁵ A covering letter dated 20 February 1984 from Dr Boots to Miss Spooner provided some explanation for the figures.⁹⁶

“... At a Regional level it was decided that annual returns should be done by our reference centres to whom we send all records of treatment given at associate centres. Therefore the majority of my patients will be included in the London and Royal Free figures. I have only given materials used in patients not registered at either of those centres who received treatment at ECH [Essex County Hospital].”

- i. 1984: The Annual Returns for 1984, which name Dr Boots as Director, show that Colchester treated 11 patients with haemophilia A, 3 patients with von Willebrand's disease and 4 patients with haemophilia B.⁹⁷ These figures should

⁹² HCDO0001413

⁹³ HCDO0001511

⁹⁴ HCDO0001613

⁹⁵ HCDO0001710. See also HCDO0000210_016 and HCDO0000210_017

⁹⁶ HCDO0001710 p. 1

⁹⁷ HCDO0001805

be read in light of a covering letter dated 22 February 1985 from Dr Boots to Miss Spooner:⁹⁸

“As last year I am reporting on the computer form all the patients I have actually treated and the type of materials that they have received. As most of my patients are registered at either the Royal Free Hospital or The London those two Centres will be reporting the actual amounts of treatment used. I am only reporting the amount of treatment that I have used on patients not registered at the London or the Royal Free but treated by me at Colchester in 1984.”

- j. 1985: The Annual Returns for 1985 name Dr Boots as Director of the Centre but note *“forms returned by Dr P Kernoff”*.⁹⁹ They show that Colchester treated 4 patients with haemophilia A, 1 patient with von Willebrand’s disease and 1 patient with haemophilia B.¹⁰⁰
- k. 1986: The Annual Returns for 1986, which name Dr Boots as Director of the Centre, show that Colchester treated 8 patients with haemophilia A, 0 patients with von Willebrand’s disease and 2 patients with haemophilia B.¹⁰¹ As explained in a covering letter dated 9 February 1987 from Dr Boots to Miss Spooner:¹⁰²

“As in previous years, I am reporting on the Computer Form all the patients I have actually treated and the type of materials that they have received. As most of my patients are registered at either the Royal Free Hospital or The London Hospital, those two Centres will be reporting the actual amounts of treatment used.”

Grays

⁹⁸ HCDO0001805 p. 4

⁹⁹ HCDO0001897

¹⁰⁰ HCDO0001897

¹⁰¹ HCDO0000350_002. See also HCDO0001993. The Annual Returns for 1987 are at HCDO0002083; 1988 are at HCDO0002175 and covering letter at HCDO0002175; 1989 are at HCDO0002269; and 1990 are at HCDO0002359

¹⁰² HCDO0000350_005

24. According to information contained in the Annual Returns, the number of patients registered and/or treated at Grays were as follows:

- a. 1976: The Annual Returns for 1976, which name Dr Oakey as Director of the Centre, show that Grays treated 1 patient with haemophilia A.¹⁰³ A covering letter dated 6 October 1977 from Dr Oakey to Miss Spooner noted:¹⁰⁴

“1) Although we make the initial diagnosis, new cases are referred to a Haemophilia Centre in this Region for confirmation, registration and genetic counselling. Therefore all new cases in the Region will appear in returns from those centres.

2) Most cases in our District, as in others, are on home treatment and these are monitored by a Co-ordinator, Sister G Davis, who works from the N.B.T.S. Brentwood and it would seem practical for returns of Factor VIII used in home treatment to be submitted by her.”

- b. 1977: The Annual Returns for 1977, which name Dr Oakey as Director of the Centre, show that Grays treated 5 patients with haemophilia A, 0 patients with Christmas disease and 1 patient with von Willebrand’s disease.¹⁰⁵ It appears that 1 haemophilia A patient was on regular home therapy.¹⁰⁶
- c. 1978: It appears that Grays treated 4 patients with haemophilia A, 0 patients with Christmas disease and 1 patient with von Willebrand’s disease.¹⁰⁷
- d. 1979: The Annual Returns for 1979, which name Dr Oakey as Director of the Centre, show that Grays treated 3 patients with haemophilia A.¹⁰⁸

¹⁰³ HCDO0000025_002 p. 2

¹⁰⁴ HCDO0000025_002 p. 1

¹⁰⁵ HCDO0001192

¹⁰⁶ HCDO0001192 p. 3

¹⁰⁷ HCDO0001228

¹⁰⁸ HCDO0001325

- e. 1980: The Inquiry does not have Annual Returns for Grays in 1980.
- f. 1981: The Annual Returns for 1981, which name Dr Oakey as Director of the Centre, show that Grays treated 6 patients with haemophilia A, 2 patients with von Willebrand's disease and 1 patient with haemophilia B.¹⁰⁹
- g. 1982: The Inquiry does not have Annual Returns for Grays in 1982. However, patient records indicate that Grays treated around 7 patients with haemophilia and von Willebrand's disease in 1982.¹¹⁰
- h. 1983: A version of Annual Returns for 1983, which name Dr Colvin / Dr Oakey as Director of the Centre (which may indicate that this version includes patients also registered at the London Hospital), show that Grays treated 1 patient with haemophilia A, 0 patients with von Willebrand's disease¹¹¹ and 0 patients with haemophilia B.¹¹² Another version of the Annual Returns for 1983, which name Dr Oakey as Director of the Centre, show that Grays treated 2 patients with haemophilia A, 1 patient with von Willebrand's disease¹¹³ and 0 patients with haemophilia B.
- i. 1984/1985: The Inquiry does not have Annual Returns for Grays in 1984 or 1985.
- j. 1986: The Annual Returns for 1986, which name Dr Oakey as Director of the Centre, show that Grays treated 1 patient with haemophilia A, 3 patients with von Willebrand's disease and 0 patients with haemophilia B.¹¹⁴

Chelmsford

¹⁰⁹ HCDO0001521

¹¹⁰ HCDO0001621

¹¹¹ HCDO0000224_004

¹¹² HCDO0000224_006

¹¹³ HCDO0001719

¹¹⁴ HCDO0000375_006

25. Dr Baugh explained that when she was first appointed, “*there were no known patients with bleeding disorders in the district*”.¹¹⁵ The first patient was diagnosed in late 1976.¹¹⁶ Her best estimate was that there was a maximum number of 6 patients with severe haemophilia A.¹¹⁷

26. According to information contained in the Annual Returns, the number of patients registered and/or treated at Chelmsford were as follows:

- a. 1976: The Annual Returns for 1976, which name Dr Baugh as Director of the Centre, show that Chelmsford treated 0 patients with haemophilia A and 1 patient with Christmas disease.¹¹⁸ As noted in a letter (undated) from Dr Baugh to Miss Spooner, “*1976 was early days for us as an Associate Centre and we did not fully start to treat patients until 1977. The patient listed... is from another Area, in fact he was visiting a relation in hospital when he started to have a knee bleed...*”¹¹⁹
- b. 1977: The Annual Returns for 1977, which name Dr Baugh as Director of the Centre, show that Chelmsford treated 3 patients with haemophilia A and 0 patients with Christmas disease.¹²⁰
- c. 1978: The Annual Returns for 1978, which name Dr Baugh as Director of the Centre, show that Chelmsford treated 4 patients with haemophilia A and 1 patient with Christmas disease.¹²¹
- d. 1979: The Annual Returns for 1979, which name Dr Baugh as Director of the Centre, show that Chelmsford treated 5 patients with haemophilia A and 0 patients with Christmas disease.¹²²

¹¹⁵ WITN5316001 para 8.1

¹¹⁶ WITN5316001 para 8.1

¹¹⁷ WITN5316001 para 8.1

¹¹⁸ HCDO0000079_003

¹¹⁹ HCDO0000079_005

¹²⁰ HCDO0001149

¹²¹ HCDO0001245

¹²² HCDO0001314

- e. 1980: The Annual Returns for 1980, which name Dr Baugh as Director of the Centre, show that Chelmsford treated 8 patients with haemophilia A, 3 patients with haemophilia B and 0 patients with von Willebrand's disease.¹²³
- f. 1981: The Annual Returns for 1981, which name Dr Baugh as Director of the Centre, show that Chelmsford treated 7 patients with haemophilia A, 2 patients with haemophilia B and 3 patients with von Willebrand's disease.¹²⁴
- g. 1982: The Annual Returns for 1982, which name Dr Baugh as Director of the Centre, show that Chelmsford treated 6 patients with haemophilia A, 3 patients with haemophilia B and 2 patients with von Willebrand's disease.¹²⁵
- h. 1983: The Annual Returns for 1983, which name Dr Baugh as Director of the Centre, appear to show that Chelmsford treated 8 patients with haemophilia A, 3 patients with haemophilia B and 1 patient with von Willebrand's disease.¹²⁶
- i. 1984: The Annual Returns for 1984, which name Dr Baugh as Director of the Centre, show that Chelmsford treated 13 patients with haemophilia A, 2 patients with haemophilia B and 2 patients with von Willebrand's disease.¹²⁷
- j. 1985: The Annual Returns for 1985, which name Dr Baugh as Director of the Centre but note "*Return completed by Dr P Kernoff*", show that Chelmsford treated 2 patients with haemophilia A, 1 patient with haemophilia B and 0 patients with von Willebrand's disease.¹²⁸

¹²³ HCDO0001410

¹²⁴ HCDO0001508

¹²⁵ HCDO0001610

¹²⁶ HCDO0000218_003 pp. 2 and 4, although p. 1 appears to show that the Centre treated only 1 patient with haemophilia A.

¹²⁷ HCDO0001802

¹²⁸ HCDO0001894

- k. 1986: The Annual Returns for 1986, which name Dr Baugh as Director of the Centre, show that Chelmsford treated 9 patients with haemophilia A, 3 patients with haemophilia B and 0 patients with von Willebrand's disease.¹²⁹

Southend

27. According to information contained in the Annual Returns, the numbers of patients were registered and/or treated at Southend were as follows:

- a. 1981: The Annual Returns for 1981, which name Dr Mills as Director of the Centre, show that Southend treated 2 patients with haemophilia A and 1 patient with von Willebrand's disease.¹³⁰
- b. 1982: The Annual Returns for 1982, which name Dr Mills as Director of the Centre, show that Southend treated 3 patients with haemophilia A and 2 patients with von Willebrand's disease.¹³¹
- c. 1983: The Annual Returns for 1983, which name Dr Mills as Director of the Centre, show that the Centre treated 0 patients with haemophilia A and 3 patients with von Willebrand's disease.¹³² However, another version of the Annual Returns which name Dr Colvin / Dr Mills as Director of the Centre (which may indicate that this version includes patients also registered at the London Hospital), show that the Centre treated 5 patients with haemophilia A and 1 patient with von Willebrand's disease.¹³³ Miss Spooner wrote to Dr Kernoff in a letter dated 22 May 1984 querying the Annual Returns for Southend in 1983:¹³⁴

"I am a bit puzzled by the A(1) form for Southend. The only patient noted on your computer print-out as having also received treatment at

¹²⁹ HCDO0000292_002. The Annual Returns for 1989 are at HCDO00002266.

¹³⁰ HCDO0001571

¹³¹ HCDO0001668

¹³² HCDO0001764 p. 1. See also HCDO0000212_006, HCDO0000212_007, HCDO0000212_008 and HCDO0000212_009

¹³³ HCDO0001764 p. 2

¹³⁴ HCDO0000184_007

Southend was... but the A(1) form states that 3 von Willebrand's disease patients were treated there. I am wondering who the other 2 patients are and also which type of material (cryo or DDAVP)... received at Southend? I have not yet received any returns for 1983 from Dr Mills, so cannot cross-check that way..."

- d. 1984: The Annual Returns for 1984, which name Dr Mills as Director of the Centre, show that Southend treated 7 patients with haemophilia A, 6 patients with von Willebrand's disease and 1 patient with haemophilia B.¹³⁵
- e. 1985: The Annual Returns for 1985, which name Dr Mills as Director of the Centre, show that Southend treated 4 patients with haemophilia A and 5 patients with von Willebrand's disease.¹³⁶
- f. 1986: The Annual Returns for 1986, which name Dr Mills as Director of the Centre, show that Southend treated 5 patients with haemophilia A and 2 patients with von Willebrand's disease.¹³⁷ No haemophilia B patients were treated at Southend during 1986.¹³⁸

28. A List of Centres with Patients under 19 years of age includes the following Essex Centres and Directors which suggests that children may have been treated there:¹³⁹

- a. Dr Oxley, Department of Haematology, Princess Alexandra Hospital, Hemstel Road, Harlow, Essex CM20 1QX;
- b. Dr Boots, Department of Haematology, District General Hospital, Turner Road, Colchester, Essex CO4 5JL;¹⁴⁰

¹³⁵ HCDO0001858

¹³⁶ HCDO0001953

¹³⁷ HCDO0002048. See also HCDO0000294_004, HCDO0000294_005, HCDO0000294_006, HCDO0000294_007, HCDO0000294_008 and HCDO0000294_009

¹³⁸ HCDO0000294_006. The Annual Returns for Southend in 1987 are HCDO0002137, 1988 are at HCDO0002229; 1989 are at HCDO0002322 and 1990 are at HCDO0002412.

¹³⁹ HCDO0000013_269

¹⁴⁰ HSOC0017344 also states that children were treated at the Colchester Centre.

- c. Dr Baugh, Department of Haematology, Broomfield Hospital, Court Road, Broomfield, Chelmsford, Essex CM1 5ET; and
- d. Dr Eden, Haematology Department, Southend Hospital, Prittlewell Chase, Westcliff-on-Sea, Essex. SS0 0RY

29. Data was contributed to “*Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976-80*” by C R Rizza and Rosemary J D Spooner, including by:¹⁴¹

- a. Dr Baugh of Chelmsford and Essex Hospital, Chelmsford;
- b. Dr Nicholas of Essex County Hospital, Colchester;
- c. Dr Oakey of Orsett Hospital, Essex; and
- d. Dr Oxley and Dr Carmichael of Princess Alexandra Hospital, Harlow

Treatment policies and blood product usage

30. In a letter dated 16 May 1973 from the Regional Blood Transfusion Centre in Brentwood to Dr Maycock at DHSS, cryoprecipitate was issued “*to the following hospitals in the Region in 1972*” including Chelmsford, Colchester, Harlow, and Southend.¹⁴²

31. The regional distribution of NHS factor VIII, purchase of commercial concentrates and consumption of cryoprecipitate was discussed at a meeting of Directors of Haemophilia/Associate Centres and Blood Transfusion Centres in RHAs 04, 05 and 06 on 23 September 1977.¹⁴³ The positions of Dr Carmichael (Harlow), Dr Oakey (Grays), Dr Nicholas (Colchester) and Dr Baugh (Chelmsford) were set out as follows:¹⁴⁴

“Dr Carmichael: Those Princess Alexandra patients who were on HT had NHS conc. supplied directly to them by the Regional Coordinator. As the patients

¹⁴¹ HCDO0000586

¹⁴² DHSC0100026_058. In response to Dr Maycock’s letter dated 10 May 1973: DHSC0100026_049

¹⁴³ BART0000689

¹⁴⁴ BART0000689, p. 3

were all registered at one of the Haemophilia Centres the hospital did not have an allocation of its own. No commercial conc. had been needed or purchased. Cryo was used for patients who attended the hospital. He was satisfied with the arrangements.

Dr Oakey (Orsett): the same applied and he was satisfied.

Dr Nicholas (Essex County): the same applied but he would like more NHS conc. for his inhibitor patients. He received 4,000-5,000 u commercial conc./month from Prof. Hardisty for HT patients shared with HSC [Hospital for Sick Children].

Dr Baugh (Chelmsford & Essex): cryo. Was used for patients treated at the hospital but, like Dr Carmichael, she received NHS conc. from the Regional Coordinator for HT patients who were shared between her hospital and the Haemophilia Centre of the London Hospital.”

32. The funding of commercial factor VIII concentrates was discussed at a meeting of the Association of Haematologists (North East Thames Region) Haemophilia Working Party on 1 August 1979.¹⁴⁵ It was recorded that:¹⁴⁶

“Dr Carmichael had suggested that the need to rationalise the purchase of commercial Factor VIII concentrate in the NETR must be restated and that a position paper should be prepared...”

In the meantime, Dr Carmichael stressed that the Haemophilia Centres must demonstrate the best use of available resources. In the present financial situation, there could be no point in competing with other medical groups equally stressed by shortage of funds. He repeated that ‘good housekeeping’, active decisions when not to treat patients, using cryoprecipitate where ever possible, and cutting out expensive elective surgery, for example remedial

¹⁴⁵ BART0000683. See also BART0002487

¹⁴⁶ BART0000683 p. 1

orthopaedic surgery, would all demonstrate a careful and responsible use of available funds.”

33. It was agreed at the meeting:¹⁴⁷

“1. To no longer maintain the Brentwood reserve stocks of 30-40 bottles. Associate Centres with small reserves of Factor VIII concentrate are advised to buy-in at least 5,000 units of Commercial Factor VIII concentrate to cover unexpected urgent demands, and those known to have patients with Factor VIII inhibitors should maintain appropriately higher reserves.

2. That all NHS Factor VIII concentrate should be allocated to Home Treatment patients as a first priority, and that the presently available 370 bottles of Factor VIII concentrate per month should be allocated to the London and Royal Free Hospitals in proportion to the numbers of Home Treatment patients at each Centre...

3. Wherever possible, Hospital patients (including out-patients visiting for treatment) should be treated with cryoprecipitate or Commercial Factor VIII concentrate, the exception being Home Treatment patients previously exclusively treated with NHS Factor VIII concentrate.

4. To allow associate centres to hold a box of NHS Factor VIII concentrates (10 bottles each of 230 units), to facilitate supplies to known Home Treatment patients in their area.

Dr Kernoff agreed to supply Associate Centres with the recommended 5,000 units of Commercial Factor VIII concentrate. The Associate Centres must arrange to refund the costs but could take advantage of the cheaper price available to the major Haemophilia Centres. He suggested 8p/unit (plus VAT) as a likely figure.

¹⁴⁷ BART0000683 pp. 2-3

Dr Carmichael agreed to look into arrangements to obtain Factor VIII supplies through hospital pharmacies or alternatively a system of regional cross-accounting if supplies were obtained via the major Haemophilia Centres...

34. A paper was subsequently produced on “*Proposed changes in the arrangements for distribution and purchase of factor VIII concentrate in NETR*” dated 3 August 1979.¹⁴⁸ It was reiterated that “*the Directors of the RFH Centre are prepared to supply the Associate Centres at Chelmsford, Colchester, Harlow and Grays with commercial concentrate from RFH stocks at cost price*”.¹⁴⁹
35. At a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 22 April 1981, attended by Dr Baugh (Chelmsford), Dr Oxley (Harlow) and Dr Boots (Colchester),¹⁵⁰ it was recorded that:

“...In-patients who require prolonged or intensive treatment should receive cryoprecipitate or commercial Factor VIII concentrate. However young children who react to cryoprecipitate may receive NHS Factor VIII concentrate and should be considered as Home Treatment patients for the purposes of allocation of NHS Factor VIII concentrate to the four major Haemophilia Centres.

Brentwood Regional Transfusion Centre wishes to decrease production of cryoprecipitate so that more of the available plasma can be sent to the Blood Products Laboratory, Elstree, as Fresh Frozen Plasma. Brentwood would continue to produce some cryoprecipitate and would be prepared to set aside cryoprecipitate on request for planned cases. Centres should be prepared to use commercial Factor VIII concentrate for in-patients, (and out-patients visiting the Haemophilia Centre) in place of cryoprecipitate. It was accepted that this may involve certain Centres in greater expense, but it is hoped that this will be offset by increased supplies of Factor VIII concentrate from Elstree. (Commercial products may be obtained at a cheaper rate per unit via the Royal

¹⁴⁸ RFLT0000002

¹⁴⁹ RFLT0000002 p. 2

¹⁵⁰ BART0000681

Free Hospital which has a Regional Contract with nominated commercial firms).”

36. At a meeting of the Association of Haematologists North West Thames Region Working Party in Haemophilia on 9 November 1983, “*Dr Kernoff reviewed the current allocation of NHS Factor VIII Concentrate in the NETR*” and Sister Tubridy would “*review the numbers of home treatment patients managed by each Haemophilia Centre to ensure that the supply of 221,000 units of NHS Factor VIII is allocated as fairly as possible*”.¹⁵¹ It was noted that “*Additional Factor VIII Concentrate supplied by the BPL, Elstree will attract a charge, the cost to be met from revenue at present allocated for Commercial Factor VIII Concentrate*”,¹⁵² and that “*Haemophilia Centres using the Commercial Factor VIII Concentrate may still obtain supplies at a competitive price per unit via the Royal Free Hospital who have a ‘bulk buy’ contract with the commercial firms*”.¹⁵³

37. At a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 12 November 1986, attended by Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Mills (Southend) and Dr Oxley (Harlow), it was “*noted that NHS Factor VIII concentrates provides only 25% of Factor VIII requirement in the N.E.T.R. and is at present distributed to the Haemophilia Centres pro rata to the number of Home Treatment patients cared for by each Centre*”.¹⁵⁴ It was “*agreed that some NHS product should be available to Associate Haemophilia Centres for previously untreated patients and those previously treated with cryoprecipitate*”.¹⁵⁵

38. By letter dated 5 November 1996, Dr Colvin wrote to Dr Oxley (Harlow), copying Dr Boots (Colchester), Dr Baugh (Chelmsford) and Dr Eden (Southend), stating that “*It*

¹⁵¹ BART0000678 p. 1

¹⁵² BART0000678 p. 1

¹⁵³ BART0000678 p. 2

¹⁵⁴ BART0000671 p. 1. The criteria for inclusion in the list of “home treatment” patients used for calculation in the “pro rata” NHS factor VIII concentrate allocations dated 12 November 1986 is at BART0000672. A further iteration dated 28 March 1989 is at BART0000670.

¹⁵⁵ BART0000671 p. 1

*is now our policy to give recombinant factor VIII to patients who are being treated for the first time”.*¹⁵⁶

39. The blood products used by each Centre according to the Annual Returns and other evidence received by the Inquiry are set out below.

Harlow

40. The medical records of a patient show that he was frequently treated with cryoprecipitate at Harlow in 1972.¹⁵⁷ It was noted that the patient was “*Registered with G.O.S Hospital, but has been under care of Princess Alexandra Hospital, Harlow – who state that he has been having frequent bleeds, with transfusions four times a week*”.¹⁵⁸

41. In a letter dated 26 September 1972, W J Jenkins of North-East Metropolitan Regional Blood Transfusion Centre in Brentwood wrote to Dr Maycock at the Department of Health setting out issues of cryoprecipitate in 1971.¹⁵⁹ It was reported that 2,068 units were issued to the London Hospital, 4,372 units were issued to Harlow Hospital and 831 units to other Regional Hospitals.¹⁶⁰ W J Jenkins wrote, “*You may be surprised to see that Harlow Hospital is taking about twice as much cryoprecipitate as the London Hospital. Dr George Jenkins is fully informed on the situation*”.¹⁶¹

42. According to data contained in the Annual Returns, Harlow used the following blood products:

¹⁵⁶ BART0002287

¹⁵⁷ TREL0000027_013

¹⁵⁸ TREL0000027_013 p. 22

¹⁵⁹ DHSC0100026_032

¹⁶⁰ DHSC0100026_032 p. 1. A further letter dated 16 May 1973 sets out other hospitals in the Region to which cryoprecipitate was issued including Chelmsford, Colchester, Harlow, and Southend: DHSC0100026_058

¹⁶¹ DHSC0100026_032 p. 2. Dr Maycock’s response dated 10 May 1973 is at DHSC0100026_049

- a. 1976: To treat 13 patients with haemophilia A, Harlow used 3,295 packs of cryoprecipitate and 133 bottles of NHS factor VIII.¹⁶² To treat 1 patient with von Willebrand's disease, Harlow used 5 packs of cryoprecipitate.¹⁶³
- b. 1977: To treat 10 patients with haemophilia A, Harlow used 1,689 bags of cryoprecipitate and 6 bottles of NHS factor VIII.¹⁶⁴
- c. 1978: To treat 10 patients with haemophilia A, Harlow used 2,182 bags of cryoprecipitate and 360 bottles of NHS factor VIII.¹⁶⁵
- d. 1979: To treat 10 patients with haemophilia A, Harlow used 1,802 bags / approximately 1980,200 units of cryoprecipitate, 105,805 units of NHS factor VIII, and 9 bottles / 2250 units of Armour Factor VIII (Factorate).¹⁶⁶
- e. 1980: To treat 9 patients with haemophilia A, Harlow used 264 packs of cryoprecipitate and 15,162 units of Immuno Factor VIII (Kryobulin) in hospital; and 1,590 packs of cryoprecipitate, 135,350 units of NHS factor VIII, 31,466 units of Armour Factor VIII (Factorate) and 22,080 of Immuno Factor VIII (Kryobulin) for home treatment.¹⁶⁷
- f. 1981: To treat 12 patients with haemophilia A, Harlow used cryoprecipitate and Immuno Factor VIII (Kryobulin) in hospital; and plasma, cryoprecipitate, and NHS factor VIII for home treatment.¹⁶⁸ It was noted that one haemophilia A patient received "*his supply from ? Brentwood direct, not through us*".¹⁶⁹ To treat 2 patients with haemophilia B, Harlow used NHS factor IX.¹⁷⁰

¹⁶² HCDO0000061_004 p. 3

¹⁶³ HCDO0000061_004 p. 8

¹⁶⁴ HCDO0001163 p. 1

¹⁶⁵ HCDO0001260 p. 1

¹⁶⁶ HCDO0001328

¹⁶⁷ HCDO0001424 p. 1

¹⁶⁸ HCDO0001524 p. 1

¹⁶⁹ HCDO0001524 p. 1

¹⁷⁰ HCDO0001524 p. 3

- g. 1982: To treat 11 patients with haemophilia A, Harlow used 28,800 units of cryoprecipitate, 28,604 units of NHS factor VIII and 17,468 units of Immuno Factor VIII (Kryobulin) in hospital; and 89,800 units of cryoprecipitate, and 142,450 units of NHS factor VIII for home treatment.¹⁷¹ To treat 1 patient with von Willebrand's disease, Harlow used 1,600 units of cryoprecipitate in hospital.¹⁷² To treat 1 patient with haemophilia B, the Centre used 6 units of NHS factor IX.¹⁷³
- h. 1983: To treat 3 patients with haemophilia A, Harlow used 165 packs of cryoprecipitate, 55,298 units of NHS factor VIII and 968 units of Immuno Factor VIII (Kryobulin) in hospital. No products were used for home treatment.¹⁷⁴
- i. 1984: The Inquiry does not have Annual Returns for Harlow in 1984.
- j. 1985: To treat 1 patient with haemophilia A, Harlow used 500 units of NHS factor VIII in hospital. It appears that no commercial products were used either in hospital or for home treatment.¹⁷⁵
- k. 1986: The Inquiry does not have Annual Returns for Harlow in 1986.¹⁷⁶

Colchester

43. The Inquiry has received evidence from an anonymous witness, whose son was diagnosed as a haemophiliac just before his first birthday at Colchester Hospital.¹⁷⁷ To begin with, his son was treated with frozen bags of cryoprecipitate at Colchester. The witness described that his son “*was one of the first children to go on home treatment*”.¹⁷⁸

¹⁷¹ HCDO0001625 p. 1

¹⁷² HCDO0001625 p. 1

¹⁷³ HCDO0001625 p. 2

¹⁷⁴ HCDO0000142_003 p. 2

¹⁷⁵ HCDO0001909

¹⁷⁶ By letter dated 21 July 1995, Miss Spooner wrote to Dr Oxley requesting the Quarterly Report Card for January – March 1995 [HCDO0000112_058]

¹⁷⁷ WITN0995001

¹⁷⁸ WITN0995001 para 6

However, his son experienced anaphylactic shock from the cryoprecipitate and, as a result, was switched to factor VIII treatment at the age of 6. The witness' son continued to receive factor VIII at Colchester and was later transferred to Great Ormond Street Hospital where he was diagnosed with severe haemophilia.

44. A table enclosed with a memo from Dr Bidwell to Dr Maycock dated 2 March 1976 reported that Colchester used 0 bottles of Factor IX in 1972, 64 bottles in 1973, 126 bottles in 1974 and 126 bottles in 1975.¹⁷⁹ A further memo from Dr Bidwell to Dr Maycock dated 19 March 1976 noted that there was considerable variation of bottles of factor IX given per patient “*from 142 at Plymouth, 97 at Bristol, 83 at Windsor, 76 at Wolverhampton, to a middle group around 40 to 50 or thereabouts at St Thomas, Hull, Q.E. Birmingham, the London and Colchester, down to apparently more modest users of 10 to 20 per patient*”.¹⁸⁰

45. Correspondence dated 20 July 1983 shows that a patient at Colchester was treated at home with factor VIII in 1983.¹⁸¹

46. According to data contained in the Annual Returns, Colchester used the following blood products:

a. 1976: To treat 7 patients with haemophilia A, Colchester used 192 bottles / 13,440 units of cryoprecipitate, 12 bottles / 3,000 units of NHS factor VIII, and 4 bottles / 1,132 units of Armour Factor VIII (Factorate).¹⁸² To treat 2 patients with Christmas disease, Colchester used 143 bottles / 85,800 units of NHS factor IX.¹⁸³

b. 1977: To treat 16 patients with haemophilia A, Colchester used a range of products including commercial concentrates:¹⁸⁴

i. 1,210 bottles / 84,700 units of cryoprecipitate;

¹⁷⁹ CBLA0005850_005

¹⁸⁰ BPLL0007891

¹⁸¹ TREL0000116_132

¹⁸² HCDO0001070 p. 1

¹⁸³ HCDO0001070 p. 1

¹⁸⁴ HCDO0001151 p. 1

- ii. 3,396 units of Armour Factor VIII (Factorate);
 - iii. 4,689 units of Cutters Factor VIII (Koate);
 - iv. 8,250 units of Hyland Factor VIII (Hemofil); and
 - v. 400 units of Immuno Factor VIII (Kryobulin).
- c. To treat 2 patients with Christmas disease, Colchester used 181 bottles / 108,600 units of NHS factor IX.¹⁸⁵
- d. 1978: To treat 13 patients with haemophilia A, Colchester used 525 bottles / 36,750 units of cryoprecipitate and 43 bottles / 10,750 units of NHS factor VIII.¹⁸⁶ To treat 5 patients with Christmas disease, Colchester used 133 bottles / 79,800 units of NHS factor IX.¹⁸⁷ To treat 1 patient with von Willebrand's disease, Colchester used 12 bottles / 840 units of cryoprecipitate.¹⁸⁸ It does not appear that any commercial concentrates were used by Colchester in 1978.
- e. 1979: The Inquiry does not have Annual Returns for Colchester in 1979.
- f. 1980: To treat 12 patients with haemophilia A Colchester used 277 packs of cryoprecipitate, 278 bottles / 43,260 units of NHS factor VIII, and 2,010 units of Cutters Factor VIII (Koate) in hospital.¹⁸⁹ For home treatment of haemophilia A patients, Colchester used 18 packs of cryoprecipitate and 260 bottles / 38,850 units of NHS factor VIII.¹⁹⁰ To treat 2 patients with von Willebrand's disease, Colchester used 70 bottles / 4,900 units of cryoprecipitate in hospital.¹⁹¹ To treat 6 patients with haemophilia B, Colchester used 50 bottles / 28,660 units of NHS factor IX in hospital and 106 bottles / 66,055 units of NHS factor IX for home treatment.¹⁹²

¹⁸⁵ HCDO0001151 p. 1

¹⁸⁶ HCDO0001248 p. 5

¹⁸⁷ HCDO0001248 p. 5

¹⁸⁸ HCDO0001248 p. 9

¹⁸⁹ HCDO0001413 p. 1

¹⁹⁰ HCDO0001413 p. 1

¹⁹¹ HCDO0001413 p. 1

¹⁹² HCDO0001413 p. 3

- g. 1981: To treat 11 patients with haemophilia A in hospital, Colchester used:¹⁹³
- i. 379 packs / 26,530 units of cryoprecipitate;
 - ii. 24,400 units of NHS factor VIII;
 - iii. 9,300 units of Armour Factor VIII (Factorate); and
 - iv. 9,600 units of Immuno Factor VIII (Kryobulin).
- h. For home treatment of haemophilia A patients, Colchester used 2,500 units of NHS factor VIII.¹⁹⁴ To treat 3 patients with haemophilia B, Colchester used 166 bottles / 98,100 units of NHS factor IX for home treatment.¹⁹⁵
- i. 1982: To treat 16 patients with haemophilia A in hospital, Colchester used:¹⁹⁶
- i. 199 bags / 13,930 units of cryoprecipitate;
 - ii. 3,060 units of NHS factor VIII;
 - iii. 56,012 units of Immuno Factor VIII (Kryobulin); and
 - iv. 34,000 units of FEIBA.
- j. To treat 1 patient with von Willebrand's disease, Colchester used 12 bags / 840 units of cryoprecipitate in hospital.¹⁹⁷ To treat 2 patients with haemophilia B, Colchester used 91,640 units of NHS factor IX in hospital and 91,840 units of NHS factor IX for home treatment.¹⁹⁸
- k. 1983: To treat 24 patients with haemophilia A in hospital, Colchester used 109 bags of cryoprecipitate and 1,120 units of NHS factor VIII in hospital.¹⁹⁹ It was noted that "*the material used for all patients registered at Royal Free Hosp & London Hosp (as well as Colchester) will be included in RFH & London Hosp*

¹⁹³ HCDO0001511 p. 1

¹⁹⁴ HCDO0001511 p. 1

¹⁹⁵ HCDO0001511 p. 3

¹⁹⁶ HCDO0001613 p. 1

¹⁹⁷ HCDO0001613 p. 1

¹⁹⁸ HCDO0001613 p. 3

¹⁹⁹ HCDO0001710 p. 2

returns".²⁰⁰ These figures should be read in light of the covering letter dated 20 February 1984 from Dr Boots to Miss Spooner.²⁰¹

- l. 1984: To treat 11 patients with haemophilia A in hospital, Colchester used 34 bags of cryoprecipitate and 1,020 units of NHS factor VIII.²⁰² Again, these figures should be read in light of the covering letter dated 22 February 1985 from Dr Boots to Miss Spooner.²⁰³

- m. 1985: To treat 4 patients with haemophilia A in hospital, it appears that Colchester used:²⁰⁴
 - i. 1,880 units of NHS factor VIII;
 - ii. 10,000 units of FEIBA;
 - iii. 28 units of DDAVP;
 - iv. 26,010 units of Alpha Factor IX Concentrate; and
 - v. 41,315 units of NHS Factor IX Concentrate.

- n. For home treatment of haemophilia A patients, it appears that Colchester used 6,120 units of Alpha Factor IX Concentrate and 62,520 units of NHS factor IX concentrate.²⁰⁵ To treat 1 patient with von Willebrand's disease, Colchester used 12 bags of cryoprecipitate and 20 units of DDAVP in hospital.²⁰⁶ To treat 1 patient with haemophilia B, Colchester used 12,200 units of NHS factor IX for home treatment.²⁰⁷

- o. 1986: No figures are provided for products used to treat haemophilia A, haemophilia B or von Willebrand's disease patients at Colchester in 1986.²⁰⁸ As

²⁰⁰ HCDO0001710 p. 2

²⁰¹ HCDO0001710 p. 1

²⁰² HCDO0001805

²⁰³ HCDO0001805 p. 5

²⁰⁴ HCDO0001897 p. 1

²⁰⁵ HCDO0001897 p. 1

²⁰⁶ HCDO0001897 p. 1

²⁰⁷ HCDO0001897 p. 3

²⁰⁸ HCDO0000350_002

explained in a covering letter dated 9 February 1987 from Dr Boots to Miss Spooner:²⁰⁹

“As most of my patients are registered at either the Royal Free Hospital or The London Hospital, those two Centres will be reporting the actual amounts of treatment used.

In 1986 the only treatment used on patients not registered at these two Centres was for ... an acquired Haemophilia A patient registered at your Centre, on which I used NHS Factor IX concentrate as reported on form A7.”

47. In June 1990, an “*Update on Guidelines to Treatment of Haemophilia*” was produced for Colchester.²¹⁰ The Guidelines contained the following warning:²¹¹

“Many of the severe Haemophiliacs have been treated in the past with commercial concentrates. They must, therefore, be treated as HIGH RISK CASES.”

48. Further “*Guidelines on Treatment of Haemophilia*” for Colchester dated January 1994 1994 carried the same warning.²¹²

Grays

49. Records of a haemophilia patient treated at Orsett General Hospital between 1952-1956 (aged up to 4 years) show that he received 3 pints of fresh blood for a lip cut.²¹³

50. According to limited data contained in the Annual Returns, Grays used the following blood products:

²⁰⁹ HCDO0000350_005

²¹⁰ ESNE0000001_034

²¹¹ ESNE0000001_034. Further guidelines authored by Dr Boots, particularly in relation to two patients, dated June 1990 are at ESNE0000001_034, p. 2.

²¹² ESNE0000001_033

²¹³ TREL0000386_012

- a. 1976: To treat 1 patient with haemophilia A, Grays used 30 bottles / 2,100 units of cryoprecipitate.²¹⁴ These figures should be read in view of the covering letter dated 6 October 1977 from Dr Oakey to Miss Spooner.²¹⁵
- b. 1977: To treat 5 patients with haemophilia A, Grays used 356 bottles / 21,360 units of cryoprecipitate.²¹⁶ To treat 1 patient with von Willebrand's disease, the Centre used 170 bottles / 10,200 units of cryoprecipitate.²¹⁷
- c. 1978: To treat 4 patients with haemophilia A, Grays used cryoprecipitate.²¹⁸ To treat 1 patient with von Willebrand's disease, Grays used 207 bottles / 12,420 units of cryoprecipitate.²¹⁹
- d. 1979: Grays used cryoprecipitate to treat 2 patients with haemophilia A and Kryobulin to treat 1 patient with haemophilia A.²²⁰
- e. 1980: The Inquiry does not have Annual Returns for Grays in 1980.
- f. 1981: To treat 6 patients with haemophilia A in hospital, Grays used 35,820 units of cryoprecipitate, 3,500 units of NHS factor VIII, and 1,000 units of Immuno (Kryobulin).²²¹ To treat 2 patients with von Willebrand's disease in hospital, Grays used 4,800 units of cryoprecipitate.²²² No products were used to treat patients with haemophilia B.²²³
- g. 1982: The Inquiry does not have Annual Returns for Grays in 1982. However patient records indicate that Grays used cryoprecipitate and factor VIII

²¹⁴ HCDO0000025_002 p. 2

²¹⁵ HCDO0000025_002 p. 1

²¹⁶ HCDO0001192 p. 2

²¹⁷ HCDO0001192 p. 6

²¹⁸ HCDO0001228 p. 1

²¹⁹ HCDO0001228 p. 8

²²⁰ HCDO0001325 p. 2

²²¹ HCDO0001521 p. 1

²²² HCDO0001521 p. 1

²²³ HCDO0001521 p. 2

concentrate to treat around 7 patients with haemophilia and von Willebrand's disease.²²⁴

- h. 1983: On one version of the Annual Returns for Grays in 1983, to treat 1 patient with haemophilia A in hospital, Grays used 26 packs of cryoprecipitate.²²⁵ On another version of the Annual Returns, to treat 2 patients with haemophilia A, Grays used 166 packs of cryoprecipitate in hospital. To treat 1 patient with von Willebrand's disease, the Centre used 23 packs of cryoprecipitate.²²⁶
- i. 1984/1985: The Inquiry does not have Annual Returns for Grays in 1984 or 1985.
- j. 1986: To treat 3 patients with haemophilia A in hospital, Grays used 122 bags / 8,540 units of cryoprecipitate.²²⁷ To treat 3 patients with von Willebrand's disease in hospital, Grays used 111 bags / 7,770 units of cryoprecipitate.²²⁸

Chelmsford

51. Dr Baugh confirmed in her written statement that “*Apart from patients treated with cryoprecipitate or DDAVP, the decisions were made on behalf of their registered patients by the reference haemophilia centre directors*”.²²⁹ Furthermore, that “[a]dvice was given by the reference haemophilia centre directors on which products should be used for patients with moderate or mild haemophilia, children, new patients and those minimally treated.... It was recognised that commercial factor concentrates were needed to meet the shortfall in the larger centres”.²³⁰ Dr Baugh stated that she “*played no part in selection of concentrates*”²³¹ and “*had no involvement in these decisions*”.²³²

²²⁴ HCDO0001621

²²⁵ HCDO0000224_004

²²⁶ HCDO0001719

²²⁷ HCDO0000375_006 p. 1

²²⁸ HCDO0000375_006 p. 1

²²⁹ WITN5316001 para 9.1

²³⁰ WITN5316001 para 9.7

²³¹ WITN5316001 para 9.8

²³² WITN5316001 para 89.10

52. According to data contained in the Annual Returns, Chelmsford used the following blood products:

- a. 1976: To treat 1 patient with Christmas disease, Chelmsford used 3 bags of FFP.²³³
- b. 1977: To treat 3 patients with haemophilia A, Chelmsford used 201 packs of cryoprecipitate and 22 bottles of NHS factor VIII.²³⁴
- c. 1978: To treat 4 patients with haemophilia A, Chelmsford used 48 bags / 3,360 units of cryoprecipitate and 41 bottles / 10, 250 units of NHS factor VIII.²³⁵ These figures should be read in light of the covering letter dated 26 January 1979 from Dr Baugh to Miss Spooner which explained that she could only give full details of material used to treat 2 patients and that the material used to treat 2 patients on home treatment would be sent by the patients direct to Dr Colvin at the London Hospital.²³⁶
- d. 1979: To treat 5 patients with haemophilia A, Chelmsford used 22 bags / 1,540 units of cryoprecipitate and 32 bottles / 7,535 units of NHS factor VIII.²³⁷
- e. 1980: To treat patients with haemophilia A in hospital, Chelmsford used 93 packs of cryoprecipitate, 6 bottles of NHS factor VIII, and 2,174 units of Immuno Factor VIII (Kryobulin).²³⁸ For home treatment of haemophilia A patients, Chelmsford used 127 bottles of NHS factor VIII.²³⁹ To treat 3 patients with haemophilia B, Chelmsford used 15 bottles of NHS factor IX in hospital and 28 bottles of NHS factor IX for home treatment.²⁴⁰

²³³ HCDO0000079_003

²³⁴ HCDO0001149

²³⁵ HCDO0001245

²³⁶ HCDO0001245 p. 4

²³⁷ HCDO0001314

²³⁸ HCDO0001410 p. 1

²³⁹ HCDO0001410 p. 1

²⁴⁰ HCDO0001410 p. 2

- f. 1981: To treat patients with haemophilia A in hospital, Chelmsford used 12 packs / 840 units of cryoprecipitate, 7,900 units of NHS factor VIII, 2,678 units of Armour Factor VIII (Factorate) and 4,348 units of Immuno Factor VIII (Kryobulin).²⁴¹ For home treatment of haemophilia A patients, Chelmsford used 51,400 units of NHS factor VIII.²⁴² To treat 3 patients with von Willebrand's disease, Chelmsford used 36 packs of cryoprecipitate.²⁴³ To treat 2 patients with haemophilia B, Chelmsford used 26,446 units of NHS factor IX in hospital and 36,410 units of NHS factor IX for home treatment.²⁴⁴
- g. 1982: To treat patients with haemophilia A in hospital, Chelmsford used 9 packs of cryoprecipitate, and 3,240 units of NHS factor VIII.²⁴⁵ For home treatment of haemophilia A patients, Chelmsford used 58,370 units plus 10 bottles of NHS factor VIII.²⁴⁶ To treat 2 patients with von Willebrand's disease in hospital, Chelmsford used 32 packs of cryoprecipitate.²⁴⁷ To treat 3 patients with haemophilia B, Chelmsford used 24,215 units of NHS factor IX in hospital and 86,650 units of NHS factor IX for home treatment.²⁴⁸
- h. 1983: To treat patients with haemophilia A in hospital, Chelmsford used 54 packs / 3,780 units of cryoprecipitate, 4,710 units of NHS factor VIII and 6,125 units of Armour Factor VIII (Factorate).²⁴⁹ For home treatment of haemophilia A patients, Chelmsford used 68,870 units of NHS factor VIII.²⁵⁰ To treat 1 patient with von Willebrand's disease in hospital, Chelmsford used 44 packs / 3,080 units of cryoprecipitate.²⁵¹ To treat 3 patients with haemophilia B, Chelmsford used 43,520 units of NHS factor IX in hospital and 46,385 units of NHS factor IX for home treatment.²⁵²

²⁴¹ HCDO0001508 p. 1

²⁴² HCDO0001508 p. 1

²⁴³ HCDO0001508 p. 1

²⁴⁴ HCDO0001508 p. 2

²⁴⁵ HCDO0001610 p. 1

²⁴⁶ HCDO0001610 p. 1

²⁴⁷ HCDO0001610 p. 1

²⁴⁸ HCDO0001610 p. 2

²⁴⁹ HCDO0000218_003 p. 2

²⁵⁰ HCDO0000218_003 p. 2

²⁵¹ HCDO0000218_003 p. 2

²⁵² HCDO0000218_003 p. 4

- i. 1984: To treat patients with haemophilia A in hospital, Chelmsford used 25 packs / 1,750 units of cryoprecipitate, 2,890 units of NHS factor VIII and 3,460 units of Armour Factor VIII (Factorate).²⁵³ For home treatment of haemophilia A patients, Chelmsford used 86,535 units of NHS factor VIII.²⁵⁴ To treat 2 patients with von Willebrand's disease in hospital, Chelmsford used 34 packs / 2,380 units of cryoprecipitate.²⁵⁵ To treat 2 patients with haemophilia B, Chelmsford used 26,550 units of NHS factor IX in hospital and 25,650 units of NHS factor IX for home treatment.²⁵⁶

- j. 1985: To treat patients with haemophilia A in hospital, Chelmsford used 2,000 units of NHS factor VIII.²⁵⁷ To treat 1 patient with haemophilia B, Chelmsford used 22,060 units of NHS factor IX in hospital.²⁵⁸

- k. 1986: To treat patients with haemophilia A in hospital, Chelmsford used 17,242 units of NHS factor VIII.²⁵⁹ For home treatment of haemophilia A patients, Chelmsford used 142,625 units of NHS factor VIII and 5,720 units plus 12 vials of Alpha Factor VIII (Profilate).²⁶⁰ To treat 3 patients with haemophilia B, Chelmsford used 28,240 units of NHS factor IX in hospital.²⁶¹

Southend

53. An Inquiry witness recalled being treated with cryoprecipitate at Southend. He stated:²⁶²

²⁵³ HCDO0001802 p. 1
²⁵⁴ HCDO0001802 p. 1
²⁵⁵ HCDO0001802 p. 1
²⁵⁶ HCDO0001802 p. 4
²⁵⁷ HCDO0001894 p. 1
²⁵⁸ HCDO0001894 p. 2
²⁵⁹ HCDO0000292_002 p. 1
²⁶⁰ HCDO0000292_002 p. 1
²⁶¹ HCDO0000292_002 p. 4
²⁶² WITN0361001 para 121

“When I had cryoprecipitate provided, it was provided in a large yellow capsule. It was freezing cold. Administering it was a slow process that took several minutes. The health care practitioners at Southend Hospital would rush this, unaware that the process should be slow.”

54. The witness also received factor VIII concentrate, including porcine factor VIII.²⁶³
55. Another witness received factor VIII (BPL) in 1989 and Oxford factor VIII in 1991 at Southend Hospital.²⁶⁴ He was also treated at Great Ormond Street, the London Hospital, Derby Hospital, the Royal Free Hospital and at Oxford.²⁶⁵ The witness’ mother stated that she *“was not provided with any information from any of the doctors at the above hospitals beforehand about the risk of [her son] being exposed to infection when using FVIII”*.²⁶⁶
56. According to data contained in the Annual Returns, Southend used the following blood products:
- a. 1981: To treat 2 patients with haemophilia A, Southend used cryoprecipitate and NHS factor VIII concentrate in hospital.²⁶⁷ To treat 1 patient with von Willebrand’s disease in hospital, Southend used cryoprecipitate.²⁶⁸
 - b. 1982: To treat 3 patients with haemophilia A in hospital, Southend used 64 bags / 4,480 units of cryoprecipitate and 4,530 units of NHS factor VIII concentrate.²⁶⁹ To treat 3 patients with von Willebrand’s disease in hospital, Southend used 16 bags / 1,120 units of cryoprecipitate.²⁷⁰
 - c. 1983: One version of the Annual Returns, which name Dr Mills as Director of the Centre, show that the Centre treated 3 patients with von Willebrand’s disease

²⁶³ WITN0361001 para 122 although it is unclear whether this was at Southend or elsewhere.

²⁶⁴ WITN1401001 para 5

²⁶⁵ WITN1401001 para 5

²⁶⁶ WITN3258001 para 9

²⁶⁷ HCDO0001571. The document is faint and the precise figures are difficult to make out.

²⁶⁸ HCDO0001571. The document is faint and the precise figures are difficult to make out.

²⁶⁹ HCDO0001668 p. 1

²⁷⁰ HCDO0001668 p. 1

in hospital using 44 bags / 3,080 units of cryoprecipitate.²⁷¹ Another version of the Annual Returns which name Dr Colvin / Dr Mills as Director of the Centre (which may indicate that this version includes patients also registered at the London Hospital), show that the Centre used 123 packs / 8,610 units of cryoprecipitate, 3,000 units of NHS factor VIII, and 1,518 units of Immuno Factor VIII (Kryobulin) to treat haemophilia A patients in hospital; and 12 packs / 840 units of cryoprecipitate to treat von Willebrand's patients in hospital.²⁷² As noted above, Miss Spooner wrote to Dr Kernoff in a letter dated 22 May 1984 querying the Annual Returns for Southend in 1983.²⁷³

- d. 1984: To treat 7 patients with haemophilia A in hospital, Southend used 142 bags of cryoprecipitate, 2,640 units of NHS factor VIII concentrate, and 1,250 units of Cutters Factor VIII (Koate).²⁷⁴ To treat 6 patients with von Willebrand's disease in hospital, Southend used 98 bags of cryoprecipitate.²⁷⁵ To treat 1 patient with haemophilia B in hospital, Southend used 1,270 units of NHS factor IX.²⁷⁶
- e. 1985: To treat 4 patients with haemophilia A in hospital, Southend used 57 bags / 3,990 units of cryoprecipitate and 460 units of NHS factor VIII concentrate.²⁷⁷ To treat 5 patients with von Willebrand's disease in hospital, Southend used 173 bags / 12,110 units of cryoprecipitate and 210 units of NHS factor VIII.²⁷⁸
- f. 1986: To treat 5 patients with haemophilia A in hospital, Southend used 6 bags / 420 units of cryoprecipitate, 21,124 units of NHS factor VIII concentrate and 1,380 units of Alpha Factor VIII (Profilate).²⁷⁹ To treat 2 patients with von Willebrand's disease in hospital, Southend used 790 units of Alpha Factor VIII (Profilate).²⁸⁰

²⁷¹ HCDO0001764 p. 1

²⁷² HCDO0001764 p. 2

²⁷³ HCDO0000184_007

²⁷⁴ HCDO0001858 p. 1

²⁷⁵ HCDO0001858 p. 1

²⁷⁶ HCDO0001858 p. 2

²⁷⁷ HCDO0001953 p. 1

²⁷⁸ HCDO0001953 p. 1

²⁷⁹ HCDO0002048

²⁸⁰ HCDO0002048

Knowledge of risk of hepatitis and response to risk

57. It is apparent that some Directors of the Essex Centres attended various UKHCDO meetings. It is recorded that:

- a. Dr Oxley (Harlow) attended on 9 October 1981,²⁸¹ 21 October 1985,²⁸² 7 October 1991,²⁸³ 30 September 1994,²⁸⁴ 3 October 1996,²⁸⁵ and 30 September 1999.²⁸⁶
- b. Dr Nicholas (Colchester) attended on 13 January 1977.²⁸⁷ Dr Boots attended on 9 October 1981,²⁸⁸ 13 September 1982,²⁸⁹ 17 October 1983,²⁹⁰ 27 September 1984,²⁹¹ and 25 September 1987.²⁹²
- c. Dr Oakey (Grays) attended on 13 January 1977,²⁹³ 24 October 1977,²⁹⁴ and 13 September 1982.²⁹⁵

²⁸¹ CBLA0001464

²⁸² PRSE0001638

²⁸³ HCDO0000491_001

²⁸⁴ HCDO0000494

²⁸⁵ HCDO0000015_003

²⁸⁶ HCDO0000499

²⁸⁷ PRSE0002268

²⁸⁸ CBLA0001464

²⁸⁹ CBLA0001619

²⁹⁰ PRSE0004440

²⁹¹ PRSE0003659

²⁹² HCDO0000485

²⁹³ PRSE0002268

²⁹⁴ PRSE0001002

²⁹⁵ CBLA0001619

- d. Dr Baugh (Chelmsford) attended on 13 January 1977,²⁹⁶ 24 October 1977,²⁹⁷ 13 November 1978,²⁹⁸ 9 October 1981,²⁹⁹ 13 September 1982,³⁰⁰ 17 October 1983,³⁰¹ 9 October 1986,³⁰² 21 September 1990,³⁰³ and 18 September 1992.³⁰⁴
- e. It does not appear that Dr Mills (Southend) or Dr Eden attended any UKHCDO meetings in person. Dr Traub attended on 9 October 1981.³⁰⁵

58. Dr Baugh stated that she was “*aware of the risk of transmission of HBV in blood following my blood transfusion training...*”³⁰⁶ Furthermore, “[*b*]y the late 1970s or possibly early 1980s, I believe I was aware from discussion with colleagues and journal articles of the risk of other viral transmission in blood products including non A/non B hepatitis in treated patients”.³⁰⁷ Dr Baugh also stated that she “*was aware probably by the early 1980s from reports in journals and discussion with colleagues, that non A /non B hepatitis associated with abnormal fluctuating LFTs led, in some patients, to a significant risk of developing chronic liver disease leading to cirrhosis and possibly hepatoma...*”³⁰⁸

59. The risk of hepatitis from factor VIII concentrates was discussed at a meeting of the Association of Haematologists (North East Thames Region) Haemophilia Working Party on 4 April 1979, attended by Dr Baugh (Chelmsford), Dr Carmichael (Harlow), and Dr Nicholas (Colchester).³⁰⁹ The minutes of the meeting record:³¹⁰

“HEPATITIS RISK WITH FACTOR VIII CONCENETRATES

²⁹⁶ PRSE0002268

²⁹⁷ PRSE0001002

²⁹⁸ HSOC0010549

²⁹⁹ CBLA0001464

³⁰⁰ CBLA0001619

³⁰¹ PRSE0004440

³⁰² PRSE0004317

³⁰³ BART0002382

³⁰⁴ HCDO0000248_013

³⁰⁵ CBLA0001464

³⁰⁶ WITN5316001 para 17.1

³⁰⁷ WITN5316001 para 17.2

³⁰⁸ WITN5316001 para 17.3

³⁰⁹ BART0000685

³¹⁰ BART0000685

Dr Kernoff reported the increased recognition of Non A/ Non B Hepatitis as a risk of Factor VIII concentrates.

He suggested that until a diagnostic reagent is available, sera from all vulnerable patients should be stored, together with an aliquot of the concentrate used for the retrospective study.

Dr Jenkins suggested that all sera from possible post-transfusion hepatitis could at present be examined at Brentwood Regional Transfusion Centre for Hepatitis B.

Dr Colvin said that Haemophilia patients on regular Factor VIII concentrate treatment may have abnormal liver function tests, and that three groups have been identified:-

- 1. No abnormality*
- 2. Temporary disturbance of LFT's*
- 3. Permanent disturbance of LFT's.*

He suggested that there should be an attempt to evaluate treated patients.

It was agreed that regular testing for Hepatitis B, LFT's, and storage of sera for the retrospective study for NonA/NonB Hepatitis should be arranged. However the question of liver biopsy was problematical. It was important to assess liver changes on treatment, but the question of costs and ethics was also involved.

The Associate Haemophilia Centre Directors present agreed that they would not be prepared to undertake investigative liver biopsies. Drs Kernoff and Colvin agreed to present a working paper on the feasibility of liver biopsies and a rough draft proforma for a Regional Haemophilia Hepatitis survey.

It was agreed to set out:-

- a. *A Regional Policy for investigation of Home Treatment Patients for treatment induced liver disease.*
- b. *A Regional Policy outlining the indication for liver biopsy.*
- c. *A Regional Proforma to follow-up patients new to Factor VIII (or IX) concentrate therapy.”*

60. Dr Kernoff and Dr Colvin subsequently produced “*Guidelines on the screening and investigation of hepatic disease in patient with congenital coagulation disorders*” for the NETR Association of Haematologists: Haemophilia Working Party dated 16 May 1979.³¹¹ The Guidelines stated:³¹²

“Of possible particular relevance to chronic liver disease in haemophiliacs is transmission by factor concentrates of the agents responsible for non-A non-B hepatitis. This group of disorders has recently come under close scrutiny because of the realisation that the majority of cases of post-transfusion hepatitis in some parts of the world – in particular, the U.S.A. – are not due to hepatitis A or B viruses or any other recognised infective agent. At present, there is no specific laboratory tests available for non-A non-B hepatitis: and it seems likely that many cases are sub-clinical, or at least non-jaundiced. Recognition of the disease may therefore necessitate serial liver function tests being carried out after transfusion of possibly infectious material. For practical reasons, this could only be undertaken in patients at particularly high risk. Amongst haemophiliacs it seems likely that one risk factor is previously infrequent transfusion, since the patient will have been less likely to develop immunity to the disease. Another is probably a change from one type of concentrate to another. Whether commercial concentrates pose a greater risk than NHS material is uncertain. It is known that both commercial and NHS factor VIII and factor IX concentrates may transmit the disease.

Despite the general mild nature of acute non-A non-B hepatitis it seems very possible that there may be serious long-term sequelae and the acute disease

³¹¹ BART0000684

³¹² BART0000684 p. 1

*may sometimes be fatal. It is particularly for these reasons that closer monitoring of patients than has hitherto been the case is now being advocated.”*³¹³

61. The Guidelines recommended that:³¹⁴

“Patients considered to be at high risk of developing non-A non-B hepatitis (see above) should, where practicable, have blood samples for LFTs taken before and then at weekly intervals for 6 weeks after transfusion of the high risk material. The incubation period of non-A non-B hepatitis in haemophiliacs often seems to be short and it is highly desirable that developing hepatitis be recognised at an early stage by changing LFTs. Serial serum samples for hepatic immunology are also needed for retrospective analysis and use in research studies (see below). Samples of faeces may also be needed if developing hepatitis is demonstrated...”

62. At a meeting of the Association of Haematologists (North East Thames Region) Haemophilia Working Party on 12 December 1979, attended by Dr Nicholas (Colchester) and Dr Baugh (Chelmsford), the preliminary findings of the Regional Study of post-treatment Hepatitis were discussed:³¹⁵

*“Preliminary findings of the Regional Study of Hepatitis were discussed. Up to 70% of severe Haemophiliacs have abnormal liver function tests at some time, with a wide spectrum of histological abnormalities.
The Non A/Non B types of hepatitis appear to be most common.
All types of Concentrate constitute a risk. There is, as yet, no evidence that imported Concentrates are more dangerous.”*

63. The safety of heat treated concentrate was discussed at a meeting of the Association of Haematologists North East Thames Region Haemophilia Working Party in

³¹³ Footnotes omitted

³¹⁴ BART0000684 p. 2

³¹⁵ BART0000682 p. 2

Haemophilia on 22 May 1985, attended by Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Oxley (Harlow) and Dr Mills (Southend):³¹⁶

“Factor VIII Concentrate: Heat Treatment and Supply

The requirement that all Factor VIII Concentrate should be heat treated means that more commercial product is being used than before with the attendant risk of Hepatitis B and Non A/Non B Hepatitis transmission.

The pilot samples of NHS Heat Treated Factor VIII Concentrate were effective with good post infusion Factor VIII levels but was generally difficult to make up due to poor solubility.

The new NHS dry heat treated Factor VIII product (F.VIIIY) is reported by trial users to be highly satisfactory, with high purity, good solubility and good Factor VIII post infusion levels. When sufficient is available this product will be the first choice for all newly diagnosed patients, children and others not yet exposed to the HTLV III virus and will replace cryoprecipitate as the preferred [sic] treatment in appropriate cases.

The U.S.A. experience confirms that cryoprecipitate has caused less Hepatitis and HTLV III antibody sero-conversion, related to the small pool donations and the fact that cryoprecipitate is prepared from the plasma of volunteer donors unlike the large pool Commercial Factor VIII concentrate which is chiefly from paid donations.

Dr Colvin proposes to replace the use of Cryoprecipitate by NHS(HT)F VIII Y concentrate as soon as possible. In the meantime patients requiring infrequent treatments should continue on DDAVP and Cryoprecipitate.”

64. By letter dated 29 July 1986, Anne Walton wrote to Dr Baugh at Chelmsford enclosing a paper by Dr J P Allain which “*details the results of a study conducted in Paris on the*

³¹⁶ BART0000675

infectivity rate with respect to non-A, non-B hepatitis and LAV/HTLV III of Koate HT".³¹⁷

Knowledge of risk of AIDS and response to risk

65. Dr Baugh stated that she “*was aware of AIDS cases in the USA from the Lancet Article in 1981 with reports of a new immunodeficiency disease in the gay population, but remained unaware of possible HIV blood transmission until around 1982-83 when haemophiliacs in the USA were reported to have AIDS symptoms, presumed following use of commercial paid-donor Factor VIII concentrate...*”³¹⁸

66. In relation to advice and decision-making, Dr Baugh stated, “*Advice was disseminated from the reference centres by the RLH and RFH directors, and via the NETR Haematologists meetings*”.³¹⁹

67. The minutes of a meeting of the Association of Haematologists North East Thames Region Working Party in Haemophilia on 9 November 1983 record that Dr Kernoff “*advised all Haemophilia Centres should remain alert for possible cases*” of AIDS and:³²⁰

“It was suggested that blood samples from suspected or possible AIDS cases should be handled as for hepatitis B; that the use of blood products in the treatment of mild haemophilia should be avoided and that DDAVP and tranexamic acid should be used whenever possible.”

68. An update on AIDS was provided at a meeting of the Association of Haematologists North East Thames Region Haemophilia Working Party on 9 May 1984 attended by Dr Baugh (Chelmsford), Dr Boots (Colchester) and Dr Oxley (Harlow).³²¹ It was recorded that:³²²

³¹⁷ BAYP0000008_315

³¹⁸ WITN5316001 para 17.4

³¹⁹ WITN5316001 para 18.2

³²⁰ BART0000678 p. 2

³²¹ BART0000677

³²² BART0000677 p. 2

“...Heat treating concentrate has been tried but reported to cause loss of potency. It was suggested that until a positive test for AIDS and/or a vaccine is developed it should be policy to avoid use of blood products except for essential treatments and to use cryoprecipitate or plasma instead of FVIII Concentrate whenever possible.”

69. At a meeting of the Association of Haematologists North East Thames Region Haemophilia Working Party on 13 December 1984, attended by Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Mills (Southend), Dr Oakey (Grays), Dr Oxley (Harlow) and Dr Traub (Southend), it was recorded that an interim treatment policy in response to the risk of AIDS was agreed:³²³

“Update on AIDS

The American experience suggests that the risk of AIDS in treated Haemophiliacs is 1:300. It appears to be less than 1:800 in treated patients in the UK.

A recent survey of 1,000 treated Haemophiliacs in England and Wales shows that 30% are [HTLV-III] antibody positive. (The percentage may be higher in some centres – exposure to Commercial FVIII concentrate in the last 2 years may be a significant factor).

The clinical significance to those found to have HTLV-III antibody is not yet known, although it appears that the HTLV-III virus carrier state is for life.

The BPL Elstree hope to have heat treated FVIII Concentrate available from April 1985. Heat treated Factor IX should be available later in the year. There is some concern that Factor IX concentrate may be damaged by heat treatment with a risk of thrombosis or DIC to the recipients. The risk of seroconversion to

³²³ BART0000676 p. 2-3. See also the transcript of Dr Colvin’s oral evidence to the Inquiry on 7 October 2020 [INQY1000062 pp. 38 – 47]

HTLV-III antibody positive on Factor IX concentrate is not yet known. Smaller numbers of patients are involved and most have been maintained on a home-produced product. There is hope that the method of fractionation of FIX concentrate may reduce the risk of transmission of the HTLV-III virus.

In the meantime it was agreed that:-

- i. Emergency stocks of Commercial Factor VIII concentrate held by Associate centres should be exchanged for a Heat Treated product, (via the RFH Haemophilia Centre).*
- ii. Heat Treated material should be used whenever possible (with the exception of NHS FIX concentrate for the time being).*
- iii. All new patients, and mild haemophiliacs with injuries requiring maintenance of high levels of FVIII should be treated with Heat Treated NHS FVIII concentrate or small pool FVIII concentrate pro tem if treatment with cryoprecipitate or DDAVP is not possible.*
- iv. Family members who assist in home treatments, wives of haemophiliacs and hospital staff who treat haemophiliacs should not volunteer as blood donors for the time being.*
- v. Elective surgery should be delayed until the position is clearer and the efficacy of heat treatment proven.”*

70. By letter dated 16 April 1985, Dr Colvin wrote to Dr Boots (Colchester), Dr Mills (Southend), Dr Baugh (Chelmsford), Dr Oxley (Harlow) and Dr Oakey (Grays) enclosing a “*local set of rules for handling high risk samples in the laboratory in the light of the DHSS AIDS document*”, “*a set of guidelines for the management of haemophilia in general*”, and “*a new set of home treatment rules together with some counselling on the AIDS problem*”.³²⁴ The guidelines for the management of haemophilia in general treated all samples from patients with haemophilia as being “*High Risk*”.³²⁵

³²⁴ BART0000535_001. The guidelines for management of haemophilia in general can be found at BART0000535_002. The Inquiry does not have a copy of the other enclosures.

³²⁵ BART0000535_001

71. In further correspondence dated 22 August 1985, Dr Colvin stated that he had “*made arrangements to supply selected children with a single batch of 8Y concentrate*” and that he was “*reluctantly recommending that we change from cryoprecipitate to heat treated concentrate for the treatment of patients with mild haemophilia A...*”.³²⁶ The letter also stated that Dr Colvin would be “*grateful for a chance to discuss previously untransfused patients who might be suitable for prospective studies of concentrate safety*”.³²⁷

72. A further update on AIDS was provided at a meeting of the Association of Haematologists North East Thames Region Haemophilia Working Party in Haemophilia on 22 May 1985, attended by Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Oxley (Harlow) and Dr Mills (Southend).³²⁸

Testing patients for HTLVIII and informing them of diagnosis

73. By letter dated 16 April 1985, Dr Colvin wrote to Dr Boots (Colchester), Dr Mills (Southend), Dr Baugh (Chelmsford), Dr Oxley (Harlow) and Dr Oakey (Grays) regarding haemophilia treatment and the risk of AIDS.³²⁹ The letter stated:

“I now have anti HTLV III results from any of the home treatment patients but I am reluctant to give the list wide circulation because of doubts about the meaning of the test and the sensitive nature of the information. By no means all the patients who are positive have been told the result of their test though I have not hidden the information from those who wish to know. If you need to talk to any of them about the AIDS problem perhaps you could give me a ring to discuss the latest position.”

³²⁶ BART0000540

³²⁷ BART0000540

³²⁸ BART0000675

³²⁹ BART0000535_001

74. In further correspondence dated 22 August 1985, Dr Colvin stated that he had made arrangements for selected children to be supplied with NHS heat treated 8Y concentrate and that:³³⁰

“Before the first treatment with this batch of 8Y a sample should be taken for LFTs to be performed locally and a small aliquot of serum should be sent to me through the post for viral studies. Blood should then be taken at each attendance for treatment for LFTs and viral studies, the viral sample being sent to me at The London...”

75. By letter dated 27 August 1985, Dr Colvin enclosed “a confidential list of patients who are under our joint care and whose anti HTLV III results are known to me” in relation to patients at Southend, Harlow, Chelmsford, Colchester and Grays (Orsett).³³¹ The list indicated that:

- a. Southend: 6 patients tested negative between 1983 and 1985;
- b. Harlow: 1 patient tested positive in 1984, 6 patients tested positive in 1985, and 2 patients tested negative in 1985;
- c. Chelmsford: 4 patients tested positive in 1984/5, and 1 patient tested negative in 1985;
- d. Colchester: 4 patients tested positive in 1984/5, and 7 patients tested negative in 1984/5; and
- e. Grays (Orsett): 2 patients tested positive in 1984/5 and 3 patients tested negative in 1984/5.

76. Testing for HTLVIII was discussed at a meeting of the Association of Haematologists North East Thames Region Haemophilia Working Party in Haemophilia on 27

³³⁰ BART0000540

³³¹ BART0000509

November 1985, attended by Dr Baugh (Chelmsford), Dr Boots (Colchester), Dr Mills (Southend) and Dr Oxley (Harlow).³³² The minutes record.³³³

“HTLVIII Antibody Positivity

It was stressed that informed consent should be obtained before patients are tested for HTLVIII antibody and wherever possible counselling should be offered prior to testing.

All results should be held in strict confidence and revealed only to medical or dental attendants who require the information in order that correct precautions should be taken.

All patient treatments should be conducted with precautions suitable for HTLVIII antibody positive status.

At present it is not recommended that Hospital Staff should be routinely tested, although all incidents should be recorded in the accident book and serum samples securely held in a -70°C deep freeze for future reference (compensation claims may be involved in the future) ...”

77. In a letter dated 25 March 1987 to Miss Spooner, Dr Baugh confirmed that there were “no new cases of Hepatitis B or HIV Positive during 1986” at Chelmsford.³³⁴ All newly diagnosed patients had been “registered with the London Hospital via Dr Brian Colvin”.³³⁵

78. In a letter dated 6 January 1987, Dr Colvin wrote to Dr Baugh at Chelmsford setting out “a new list of anti HIV positive patients and the counselling they have received”.³³⁶ Dr Baugh stated that she had “no knowledge of the consent obtained or the extent of pre

³³² BART0000674

³³³ BART0000674 p. 3

³³⁴ HCDO0000292_003

³³⁵ HCDO0000292_003

³³⁶ BART0000577_002

or post-test counselling of patients or the information they were given at the reference centre apart from Dr Colvin's letter of 1987".³³⁷ Similar letters dated 6 January 1987 was sent to Dr Boots at Colchester,³³⁸ Dr Mills at Southend,³³⁹ and Dr Oakey at Grays.³⁴⁰

Numbers infected with HIV

79. According to provisional data provided to the Inquiry by UKHCDO regarding the number of patients infected with HIV:³⁴¹

- a. Colchester: 1 patient tested positive in 1985 and 1 patient tested positive in 1986 (2 patients tested positive in total);
- b. Chelmsford: 0 patients tested positive;
- c. Southend: 0 patients positive;
- d. No data provided for Grays or Harlow.

80. A report of the North East Thames Regional Health Authority, April 1st 1992 – March 31st 1993, gives a wider picture of the situation in the North East Thames Region at that time.³⁴²

Testing for HCV

81. There is limited evidence available in relation to the testing arrangements for HCV at Harlow, Colchester, Grays, Chelmsford or Southend.

82. Dr Baugh stated that "*Testing for HIV or hepatitis was carried out by the patients' reference centre*".³⁴³

³³⁷ WITN5316001 para 38.1

³³⁸ BART0000577_004

³³⁹ BART0000577_003

³⁴⁰ BART0000577_001

³⁴¹ INQY0000250

³⁴² SHTM0002548

³⁴³ WITN5316001 para 51.1

83. In a letter dated 21 September 1979, Dr Tuddenham at the Royal Free Hospital wrote to Dr Nicholas at Colchester regarding a patient whose AST was elevated.³⁴⁴ Dr Tuddenham wrote that *“Our policy is to check LFTs 6 monthly in any patient whose AST is above 20 and below 50 i.u. Above 50 i.u. we start checking them weekly and are rather disturbed to find that the number of patients who appear to have some kind of chronic hepatitis is rising”*.³⁴⁵

84. The Inquiry has received evidence from a witness who was treated at Colchester, initially by Dr Boots, then Dr Woods and then Dr Mohan.³⁴⁶ The witness underwent a dental clearance operation at Colchester in 1986 where the anaesthetist, Dr Griffin, gave the witness factor VIII concentrate pre-surgery. Following the surgery, the witness described feeling *“more unwell than I had previously been”* and she became jaundiced.³⁴⁷ Her health deteriorated and she was diagnosed 6 years later with hepatitis C. The witness described being told of her diagnosis at Colchester as follows:³⁴⁸

“My diagnosis came about as a result of the intervention of a Dr Woods at Colchester who caused me to undergo a liver biopsy in an effort to resolve my declining health. Following the biopsy, the consultant, a Mr Roger Motson told me the result in person, that I had Hepatitis C. He apologised to me, then said that my condition was fatal and that I may only have had six months thereafter to live.

I was provided with some information about the disease, directly following the diagnosis, something which couldn't have happened any sooner.”

85. The witness was referred to the Royal Free Hospital for HCV treatment.³⁴⁹

86. Another Inquiry witness, who was diagnosed with haemophilia, underwent an operation at Southend Hospital and also at the London Hospital in Whitechapel where he received

³⁴⁴ TREL0000015_021

³⁴⁵ TREL0000015_021

³⁴⁶ WITN0404001 para 29

³⁴⁷ WITN0404001 para 31

³⁴⁸ WITN0404001 para 34-35

³⁴⁹ WITN0404001 para 51

factor VIII concentrate.³⁵⁰ He was later informed by Dr Colvin in 1982 that he had been infected with HCV.³⁵¹ His wife was subsequently tested for HCV at Southend:³⁵²

“My wife went to Southend Hospital to get tested. She told me that they put a poison sticker on the tubes, and everyone else sitting outside could see what was going on. There was no consideration for privacy.

We waited a couple of weeks and then my wife received a letter informing her that she was not infected with HCV and therefore our children were not either.”

87. A note dated 14 May 1986 discusses a patient of Dr Boots at Colchester who was a carrier of Christmas disease.³⁵³ It was stated that *“In 1980 she had treatment with Factor IX concentrate and following this developed what was apparently an attack, of non-A non-B Hepatitis”*.³⁵⁴ Furthermore, the patient was more recently *“treated with two packs of Fresh Frozen Plasma... and she again became jaundiced with an apparent further attack of non-A non-B Hepatitis”*.³⁵⁵

Treatment arrangements for HIV and HCV patients

88. There is limited evidence available regarding the treatment for HIV and HCV at Harlow, Colchester, Grays, Chelmsford or Southend.

89. Dr Baugh stated that *“Patients with hepatitis C were managed and referred for specialist care by their reference centre”*.³⁵⁶ In relation to the care and treatment of patients with bleeding disorders and HIV/AIDS, Dr Baugh stated, *“Management, referrals and follow-up monitoring were carried [out] by the patients’ reference centre”*.³⁵⁷

³⁵⁰ WITN0361001

³⁵¹ WITN0361001 para 9

³⁵² WITN0361001 paras 32 -33

³⁵³ NHB0025026_004

³⁵⁴ NHB0025026_004 p. 1

³⁵⁵ NHB0025026_004 p. 1

³⁵⁶ WITN5316001 para 55.1

³⁵⁷ WITN5316001 para 53.1

90. In a note dated 10 August 1992, Dr Boots described a patient who was first seen at Colchester and diagnosed with mild Christmas disease.³⁵⁸ The patient was treated with factor IX concentrate in 1982, 1984, 1985, 1988, 1989 and 1992 when he was found to be HCV positive. In relation to his treatment for HCV, the notes described, “*At this stage, the patient was referred for advice to the Royal Free Hospital and it was decided to start him on a Interferon 3 mega units three times a week to try and improve his liver function*”.³⁵⁹

91. A regional Report of North East Thames Regional Working Party in July 1985 made recommendations for Regional and District Action for the Prevention and Management of HTLVIII infection including AIDS.³⁶⁰

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³⁵⁸ DHSC0006861_210

³⁵⁹ DHSC0006861_210

³⁶⁰ PHEN0001031