

**SMALLER HAEMOPHILIA CENTRES PRESENTATION**  
**THE MIDDLESEX HOSPITAL**

**Directors, staffing and facilities**

1. The directors of the Haemophilia Centre at the Middlesex Hospital during the 1970s-80s included Professor J W Stewart and Dr Samuel J Machin. Professor Stewart was Director of the Centre until April 1984 when Dr Machin took over as Director.<sup>1</sup> Professor Stewart and Dr Machin were both active members of the British Society for Haematology and attended committee meetings on 5 October 1978,<sup>2</sup> 16 November 1978,<sup>3</sup> 24 January 1979,<sup>4</sup> 25 April 1979,<sup>5</sup>
2. Other personnel at the Middlesex Hospital (but not specifically at the Haemophilia Centre) included Dr Richard Tedder. Dr Tedder co-authored a publication in the British Medical Journal in 1985 which contained a study of HTLV-III in patients with haemophilia who had received factor VIII treatment.<sup>6</sup> Dr Tedder sent his apologies for UKHCDO meetings on 21 October 1985,<sup>7</sup> and 9 October 1986.<sup>8</sup> On both of those occasions, Dr Machin was in attendance on behalf of the Middlesex Hospital.

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

3. The Haemophilia Centre at the Middlesex Hospital was based at Mortimer Street, London W1N 8AA.
4. In 1970, the Middlesex Hospital was one of 13 designated Haemophilia Centres in the London area.<sup>9</sup> Professor Stewart attended a meeting of Directors of Haemophilia

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<sup>1</sup> HCDO0000168\_008

<sup>2</sup> BSHA0000186\_055

<sup>3</sup> BSHA0000186\_054

<sup>4</sup> BSHA0000186\_053

<sup>5</sup> BSHA0000186\_052

<sup>6</sup> WITN3089007

<sup>7</sup> PRSE0001638

<sup>8</sup> PRSE0004317

<sup>9</sup> DHSC0100026\_009 and OXUH0003597. The 13 designated Haemophilia Centres in the London area at that time were Guy's Hospital, St Mary's Hospital, King's College Hospital, Royal Free Hospital, Hospital for Sick

Centres in London on 15 October 1970 at which the organisation of Haemophilia Centres in London was discussed.<sup>10</sup>

5. On 29 November 1976, Dr Dormandy of the Royal Free Hospital wrote to all Haemophilia Centre Directors in Regions 04 (East Anglia), 05 (North-West Thames) and 06 (North-East Thames) including Professor Stewart.<sup>11</sup> At that time, Professor Ingram of St Thomas' Hospital and Dr Dormandy of the Royal Free Hospital, both Haemophilia Reference Centres, were asked to be jointly responsible for the South-East Haemophilia Supraregion. Dr Dormandy and Professor Ingram decided to split the Supraregion along the Thames. The Middlesex Hospital, being in the northern half (comprising East Anglia Region (04), North-West Thames Region (05), and North-East Thames Region (06)), fell under the responsibility of Dr Dormandy.<sup>12</sup> It appears from the list of who the letter was sent to that Professor Stewart (and therefore the Middlesex Hospital) was part of Region 05, i.e. the North-West Thames Region.
  
6. From 1976, NHS factor VIII concentrate was distributed through the Regional Blood Transfusion Centres. With some slight adjustments, it was said that this corresponded to the supply areas of the appropriate Blood Transfusion Centres at Brentwood, Edgware and Cambridge.<sup>13</sup> The relevant Regional Blood Transfusion Service Centre for the Middlesex Hospital was the North London Blood Transfusion Centre, Edgware.
  
7. The material was divided among the Regional Transfusion Centres proportionately to the number of different haemophiliacs treated in the Regions in 1974.<sup>14</sup> In 1976, the allocation of NHS factor VIII concentrate to the North West Thames Region, based on

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Children (Great Ormond Street), Lewisham Hospital, University College Hospital, Westminster Hospital, St Thomas' Hospital, The London Hospital, St George's Hospital, The Middlesex Hospital, Hammersmith Hospital.

<sup>10</sup> OXUH0003597

<sup>11</sup> CBLA0000506

<sup>12</sup> See also: CBLA0000533 minutes of meeting on 15 December 1976 where it is recorded that "*Professor Ingram and Dr Dormandy, who were the reference Centre Directors for regions 04-08, had taken the Thames as a dividing line so that Professor Ingram would be mainly concerned with regions south of the Thames (07/08) and Dr Dormandy with regions north of the Thames (04, 05 and 06).*"

<sup>13</sup> CBLA0000506

<sup>14</sup> CBLA0000506

1974 returns, was 160 bottles per month.<sup>15</sup> Specifically, 22 bottles per month were allocated to the Middlesex Hospital.<sup>16</sup>

8. Professor Stewart attended a meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres (Regions 04, 05 and 06) and Blood Transfusion Centres on 15 December 1976.<sup>17</sup> At this meeting, Professor Stewart stressed the importance of not jeopardising the supply of factor VIII concentrates:<sup>18</sup>

*“Professor Stewart stressed the importance of not agreeing to any changes in the present arrangements unless it was quite certain that the new proposal would not jeopardise the supplies.”*

9. It does not appear that Professor Stewart attended a further meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres (Regions 04, 05 and 06) and Blood Transfusion Centres on 23 September 1977,<sup>19</sup> but Dr Machin did attend a further meeting on 1 September 1978 on Professor Stewart’s behalf,<sup>20</sup> at which the distribution of factor VIII concentrates was discussed.

10. As part of the North-East Thames Region, Dr Machin appears to have been a member of the Association of Haematologists in North East Thames Region Haemophilia Working Party. It is recorded that he attended a meeting of the working party on 25 June 1986,<sup>21</sup> and sent his apologies for meetings on 9 November 1983,<sup>22</sup> and 13 December 1984.<sup>23</sup>

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<sup>15</sup> CBLA0000510

<sup>16</sup> CBLA0000510. In 1976, NHS factor VIII concentrate was allocated to the North West Thames Region as follows: GOSH 62 bottles; Hammersmith 55 bottles; Middlesex 22 bottles; St Mary’s 15 bottles; and Westminster 6 bottles.

<sup>17</sup> CBLA0000533

<sup>18</sup> CBLA0000533

<sup>19</sup> BART0000689 / CBLA0000657

<sup>20</sup> CBLA0000838

<sup>21</sup> BART0000673

<sup>22</sup> BART0000678

<sup>23</sup> BART0000676

11. In January 1985, a meeting of all haemophilia centres supplied by NBTS Edgware was arranged to discuss problems related to AIDS/HIV, which Dr Machin was invited to attend on behalf of the Middlesex Hospital.<sup>24</sup>
12. According to the written statements of Dr Machin, between 1980 and 1990, the Middlesex “*Medical School combined with University College London (UCL) and the hospital with UCH to become UCLH*”.<sup>25</sup> The Inquiry understands that this merger happened in 1987 and that the Middlesex Hospital closed in 2005.

### **Number of Patients treated and/or registered at the Centre**

13. In response to a request for information from the Department of Health and Social Security in December 1969,<sup>26</sup> Professor Stewart indicated that for the year ending 30 September 1969:<sup>27</sup>
  - a. There were 45 cases registered at the Centre;
  - b. There were 25 incidents of haemorrhage for which patients attended the Centre for treatment;
  - c. There were 3 haemophiliac patients not registered with the Centre who attended for treatment;
  - d. There were 4 incidents of severe bleeding in patients attending the Centre;
  - e. There were 2 major surgical operations undertaken in patients registered with the Centre during the year;
  - f. 1 patient was transferred to the Special Treatment Centre at Oxford.
14. In around January 1973, Professor Stewart responded to a survey, for the attention of Dr Maycock of the Blood Products Laboratory, in which he indicated that there were 21 patients treated regularly.<sup>28</sup>

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<sup>24</sup> CBLA0001975

<sup>25</sup> WITN3090001 para 2 and WITN3090002 para 2

<sup>26</sup> DHSC0100026\_009

<sup>27</sup> DHSC0100026\_015

<sup>28</sup> BPLL0008111

15. A list of Haemophilia Centres suggests that there were 18 patients with haemophilia A at the Middlesex Hospital in around 1975.<sup>29</sup>

16. In the following years, the numbers of patients registered and/or treated at the Middlesex Hospital from the annual returns were as follows:

- a. 1976: The Annual Returns for 1976, signed by Prof Stewart, indicate that the Centre treated 9 patients with haemophilia A, including 1 patient with factor VIII antibodies, and 1 patient with Christmas disease.<sup>30</sup>
- b. 1977: The Annual Returns for 1977, signed by Prof Stewart, show that the Centre treated 8 patients with haemophilia A, including 2 patients with factor VIII antibodies, 5 patients with Christmas disease, and 5 patients with von Willebrand's disease.<sup>31</sup> No carriers of haemophilia A or Christmas disease were treated. Of the 5 patients with Christmas disease, 1 patient was on regular home therapy. No haemophilia A patients or von Willebrand's patients were on regular home therapy.<sup>32</sup>
- c. 1978: The Annual Returns for 1978, signed by Prof Stewart, show that the Centre treated 16 patients with haemophilia A, including 2 patients with factor VIII antibodies, 4 patients with Christmas disease, and 4 patients with von Willebrand's disease.<sup>33</sup> Of the 16 patients with haemophilia A treated at the Centre, it appears that 5 patients were on regular home therapy. 2 of the 4 patients with Christmas disease were on regular home therapy.
- d. 1979: The Annual Returns for 1979, signed by Prof Stewart, show that the Centre treated 8 patients with haemophilia A, 1 patient with Christmas disease, and 5 patients with von Willebrand's disease.<sup>34</sup> Of the 8 haemophilia A patients

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<sup>29</sup> OXUH0000863\_002

<sup>30</sup> HCDO0000095

<sup>31</sup> HCDO0001187

<sup>32</sup> HCDO0001187

<sup>33</sup> HCDO0001284

<sup>34</sup> HCDO0001353

treated, it appears that 1 patient was on regular home therapy. 1 patient with Christmas disease was also on regular home therapy.

- e. 1980: The Annual Returns for 1980, signed by Prof Stewart, indicate that the Centre treated 16 patients with haemophilia A, 7 patients with von Willebrand's disease, 1 patient with factor VIII antibodies, and 1 patient with haemophilia B.<sup>35</sup> It appears there were around 44 registered patients with haemophilia A, 6 visitors with haemophilia A, 10 registered patients with haemophilia B, 8 registered patients with von Willebrand's disease, and 1 registered carrier of haemophilia A. It appears that 4 haemophilia A patients received home treatment, as well as 1 haemophilia B patient.
  
- f. 1981: The Annual Returns for 1981, signed by Prof Stewart, show that the Centre treated 18 patients with haemophilia A, 2 carriers of haemophilia A, 7 patients with von Willebrand's disease, 2 patients with factor VIII antibodies and 1 patient with haemophilia B.<sup>36</sup> It appears there were around 53 registered patients with haemophilia A, of whom 5 were on home therapy. There appear to have been 10 registered patients with haemophilia B, 3 registered carriers of haemophilia A and 19 registered patients haemophilia B plus 1 visitor.<sup>37</sup>
  
- g. 1982: The Annual Returns for 1982, signed by Prof Stewart, record that the Centre treated 16 patients with haemophilia A, 2 carriers of haemophilia A, 2 patients with von Willebrand's disease, 1 patient with factor VIII antibodies, and 1 patient with haemophilia B.<sup>38</sup> There appear to have been around 60 registered patients with haemophilia A (including 1 visitor from Liverpool and 1 transfer from Newcastle). There appear to have been 10 registered patients with haemophilia B, 5 registered carriers of haemophilia A, and 19 registered patients with von Willebrand's disease.

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<sup>35</sup> HCDO0001450

<sup>36</sup> HCDO0001551

<sup>37</sup> HCDO0001551

<sup>38</sup> HCDO0001650

- h. 1983: The annual returns for 1983, signed by Prof Stewart, show that the Centre treated 16 patients with haemophilia A, 1 patient with factor VIII antibodies, 9 patients with von Willebrand's disease and 2 patients with haemophilia B.<sup>39</sup> There appear to have been around 58 registered patients with haemophilia A (of which 7 patients received home treatment), 11 registered patients with haemophilia B, 5 registered carriers of haemophilia A, and 29 registered patients with von Willebrand's disease.
- i. 1984: The Annual Returns for 1984, signed by Dr Machin, show that the Centre treated 22 patients with haemophilia A, 4 haemophilia A patients with factor VIII antibodies, 4 patients with von Willebrand's disease, and 2 patients with haemophilia B.<sup>40</sup> It appears there were around 62 registered patients with haemophilia A, 11 registered patients with haemophilia B, 5 registered carriers of haemophilia A, and 33 registered patients with von Willebrand's disease.
- j. 1985: The Annual Returns for 1985, signed by Dr Machin, show that the Centre treated 18 patients with haemophilia A, 2 haemophilia A patients with factor VIII antibodies, 4 patients with von Willebrand's disease, and 1 patient with haemophilia B.<sup>41</sup> There appear to have been around 65 registered patients with haemophilia A, 11 registered patients with haemophilia B, 5 registered carriers of haemophilia A, 36 registered patients with von Willebrand's disease.
- k. 1986: The Annual Returns for 1986 report that the Centre treated 18 patients with haemophilia A, 1 haemophilia A patient with factor VIII antibodies, 3 patients with von Willebrand's disease, and 1 patient with haemophilia B.<sup>42</sup>

17. Shelagh O'Shea and Luke O'Shea Philips have provided written and oral evidence to the Inquiry.<sup>43</sup> Mrs O'Shea explained that she "*signed Luke up with the Middlesex*

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<sup>39</sup> HCDO0001747

<sup>40</sup> HCDO0001841

<sup>41</sup> HCDO0001934

<sup>42</sup> HCDO0000353\_002

<sup>43</sup> WITN0043001 and WITN1696001 respectively. Mrs O'Shea and Mr O'Shea Philips gave oral evidence to the Inquiry on 4 June 2019.

*Hospital, now the University College London (UCL) Haematology Department” when they moved to London where he was under the care of a Professor from 1984.<sup>44</sup>*

18. Data from the Middlesex Hospital was contributed by Professor Stewart to published studies including: Jaundice and Antibodies Directed Against Factors VIII and IX in Patients Treated for Haemophilia or Christmas Disease in the United Kingdom by Rosemary Biggs,<sup>45</sup> Haemophilia Treatment in the United Kingdom from 1969 to 1974 by Rosemary Biggs,<sup>46</sup> and Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976-80 by C R Rizza and Rosemary J D Spooner.<sup>47</sup>

### **Treatment policies and blood product usage**

19. In response to a questionnaire for Dr Maycock, BPL, in January 1973, Professor Stewart indicated the preferred treatment for patients with haemophilia was some cryoprecipitate and some freeze-dried concentrate. He estimated that he required 1000 single donations of cryoprecipitate and approximately 50 bottles of freeze-dried concentrate annually for the present treatment policy. If supply of cryoprecipitate and/or concentrate were not restricted by shortage, Professor Stewart estimated that he would require 1,500 single donations of cryoprecipitate and 70 bottles of freeze-dried concentrate annually.<sup>48</sup>

20. The blood products used by the Middlesex Hospital according to the annual returns were as follows:

- a. 1976: To treat 9 haemophilia A patients, the Centre used 3,475 bottles of cryoprecipitate, 156 bottles of Hyland Factor VIII (Hemofil), and 27 bottles of Immuno Factor VIII (Kryobulin).<sup>49</sup> To treat 1 patient with Christmas disease, the Centre used 96 bottles of NHS factor IX.<sup>50</sup>

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<sup>44</sup> WITN0043001 para 2

<sup>45</sup> HCDO0000581

<sup>46</sup> PRSE0004645

<sup>47</sup> HCDO0000586

<sup>48</sup> BPLL0008111 p. 28

<sup>49</sup> HCDO0000095

<sup>50</sup> HCDO0000095



- b. 1977: The total amount used to treat 8 haemophilia A patients was 1,086 bottles / 76,020 units of cryoprecipitate, 22 bottles / 4,950 units of NHS factor VIII, and 7 bottles / 3,500 units of Immuno Factor VIII (Kryobulin). To treat 2 patients with factor VIII antibodies, the Centre used 35 bottles / 2,450 units of cryoprecipitate and 14 bottles / 3,150 units of NHS factor VIII.<sup>51</sup> It was noted in manuscript that 1 of the two patients with factor VIII antibodies “*was transferred to the Royal Free Hospital for further treatment*”.<sup>52</sup> To treat 5 patients with von Willebrand’s disease, the Centre used 732 bottles / 3,660 units of cryoprecipitate, and 3 bottles / 750 units of Hyland Factor VIII.<sup>53</sup> To treat 5 patients with Christmas disease, the Centre used 114 bottles / 63,840 units of NHS factor IX.<sup>54</sup> For home treatment of 1 patient with Christmas disease, the Centre used 79 bottles / 44,240 units of NHS factor IX.<sup>55</sup>
- c. 1978: To treat 16 patients with haemophilia A, the Centre used 3,390 bottles / 237,300 units of cryoprecipitate, 310 bottles / 77,500 units of NHS factor VIII, and 75 bottles / 18,000 units of Hyland Factor VIII (Hemofil) in total. For 2 patients with factor VIII antibodies, the Centre used 58 bottles / 14,500 units of NHS factor VIII concentrate and 47 bottles / 11,750 units of Hyland Factor VIII (Hemofil) in hospital; and 7 bottles / 1,750 units of NHS factor VIII and 3 bottles / 750 units of Hyland Factor VIII (Hemofil) for home therapy. To treat 4 patients with Christmas disease, the Centre used 200 bottles / 120,000 units of NHS factor IX. For 4 patients with von Willebrand’s disease, the Centre used 320 bottles of cryoprecipitate.<sup>56</sup>
- d. 1979: To treat 8 patients with haemophilia A, the Centre used 3,217 bottles / 225,190 units of cryoprecipitate, 59 bottles / 15,340 units of NHS factor VIII, 2 bottles / 450 units of Armour Factor VIII, and 44 bottles / 20,600 units of Hyland Factor VIII (Hemofil) in total. To treat 1 patient with Christmas disease, the Centre used 34 bottles / 21,160 units of NHS factor IX. To treat 5 patients with

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<sup>51</sup> HCDO0001187

<sup>52</sup> HCDO0001187

<sup>53</sup> HCDO0001187

<sup>54</sup> HCDO0001187

<sup>55</sup> HCDO0001187

<sup>56</sup> HCDO0001284

von Willebrand's disease, the Centre used 557 bottles / 38,990 units of cryoprecipitate.<sup>57</sup>

- e. 1980: To treat haemophilia A patients in hospital, the Centre used 4,000 bags of cryoprecipitate, 2,000 units of NHS factor VIII, and 20,000 units of Hyland Factor VIII (Hemofil). For home treatment of haemophilia A patients, the Centre used 12,000 units of NHS factor VIII and 14,700 units of Hyland Factor VIII (Hemofil). For treatment of 7 von Willebrand's patients in hospital, the Centre used 760 bags of cryoprecipitate. For treatment of 1 patient with factor VIII antibodies in hospital, the Centre used 4 bottles / 1,000 units of Hyland Factor VIII (Hemofil) and 21 bottles of FEIBA. For treatment of 1 patient with haemophilia B, the Centre used 7,000 units of NHS factor IX in hospital and 7,000 units of NHS factor IX for home treatment.<sup>58</sup>
- f. 1981: To treat haemophilia A patients, the Centre seemingly (as the figures are difficult to read) used in total 83,130 units of plasma, 759 bags of cryoprecipitate, 10,000 units of NHS factor VIII, 20,000 units of Cutters Factor VIII (Koate), 2,000 units of Hyland Factor VIII (Hemofil), 56,000 units of Immuno Factor VIII (Kryobulin), 18,720 units of Speywood Factor VIII (Humanate) and 21,000 units of FEIBA in hospital; and 16,500 units of NHS factor VIII and 7,000 units of Immuno Factor VIII (Kryobulin) for home treatment. For 2 patients with factor VIII antibodies, the Centre used 254 bags / 17,780 units of cryoprecipitate, 2,000 units of NHS factor VIII, 11,000 units of Immuno Factor VIII (Kryobulin), 18,720 units of Speywood Factor VIII (Humanate), and 21,000 units of FEIBA. To treat 2 carriers of haemophilia A, the Centre seemingly used 8,950 units of plasma and 55 bags of cryoprecipitate. To treat 7 patients with von Willebrand's disease, the Centre used 38,850 units of plasma and 508 bags of cryoprecipitate. To treat 1 patient with haemophilia B, the Centre used 5,150 units of NHS factor IX in hospital.<sup>59</sup>

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<sup>57</sup> HCDO0001353

<sup>58</sup> HCDO0001450

<sup>59</sup> HCDO0001551

- g. 1982: In total, the Centre used 151 bags / 10,570 units of cryoprecipitate, 50,480 units of NHS factor VIII, 64,430 units of Cutters Factor VIII (Koate), 5,572 units of Immuno Factor VIII (Kryobulin), and 8,000 units of FEIBA to treat haemophilia A patients in hospital. For home treatment of haemophilia A patients, the Centre used 50,000 units of NHS factor VIII, 9,300 units of Cutters Factor VIII (Koate), 6,000 units of Immuno Factor VIII (Kryobulin), and 7,000 units of FEIBA in total. 8,000 units of FEIBA were used in hospital and 7,000 units of FEIBA for home treatment of 1 patient with factor VIII antibodies. To treat 2 carriers of haemophilia A in hospital, the Centre used 10 bags / 700 units of cryoprecipitate and 6,102 units of NHS Factor VIII. To treat 2 patients with von Willebrand's disease in hospital, the Centre used 97 bags / 6,770 units of cryoprecipitate and 510 units of NHS factor VIII. To treat 1 haemophilia B patient, the Centre used 20,180 units of NHS factor IX in hospital and 10,000 units of NHS factor IX for home treatment.<sup>60</sup>
- h. 1983: In total, the Centre used 350 bags / 24,500 units of cryoprecipitate, 105,005 units of NHS factor VIII, and 10,230 units of Cutters Factor VIII (Koate) to treat haemophilia A patients in hospital; and 148,115 units of NHS factor VIII and 20,000 units of FEIBA to treat haemophilia A patients at home. 20,000 units of FEIBA were used to treat 1 patient with factor VIII antibodies. 220 bags / 15,400 units of cryoprecipitate was used to treat 9 patients with von Willebrand's disease in hospital. To treat 2 haemophilia B patients in hospital, the Centre used 5,120 units of NHS factor IX.<sup>61</sup>
- i. 1984: The total amount used to treat haemophilia A patients in hospital was 24,800 units of cryoprecipitate, 80,500 units of NHS factor VIII, 51,940 units of Alpha Factor VIII (Profilate), 15,600 units of Armour Factor VIII (Factorate), 31,000 units of FEIBA and 43,840 units of factor IX concentrate. For home treatment of haemophilia A patients, the Centre used, in total, 104,000 units of NHS factor VIII and 49,000 units of factor IX concentrate. To treat 4 patients with von Willebrand's disease in hospital, the Centre used 8,800 units of NHS factor VIII. For haemophilia A patients with factor VIII antibodies, the Centre

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<sup>60</sup> HCDO0001650

<sup>61</sup> HCDO0001747

used 6,400 units of cryoprecipitate, 11,250 units of NHS factor VIII, 14,000 units of Alpha Factor VIII, 43,840 units of NHS factor IX, and 31,000 units of FEIBA in hospital. For home treatment of haemophilia A patients with factor VIII antibodies, the Centre used 49,000 units of NHS factor IX. To treat 2 patients with haemophilia B, the Centre used 12,920 units of NHS factor IX in hospital, and 13,600 units of NHS factor IX for home treatment.<sup>62</sup>

- j. 1985: To treat haemophilia A patients in hospital, the Centre used 15,755 units of NHS factor VIII, 312,150 units of Alpha Factor VIII (Profilate), 12,950 units of Armour Factor VIII (Factorate), 38,500 units of FEIBA, and 81,060 units of Alpha Factor IX. For 4 haemophilia A patients with factor VIII antibodies, the Centre used 81,060 units of Alpha Factor IX and 38,500 units of FEIBA. To treat 4 patients with von Willebrand's disease, the Centre used 10 bags of plasma and 16,000 units of cryoprecipitate. To treat 2 patients with haemophilia B in hospital, the Centre used 2,720 units of NHS factor IX and 13,000 units of Alpha Factor IX.<sup>63</sup>
- k. 1986: To treat haemophilia A patients in hospital, the Centre used 163,000 units of NHS factor VIII, 593,000 units of Alpha Factor VIII (Profilate), 22,360 units of Procine factor VIII, and 97,000 units of Factor IX. To treat 2 haemophilia A patients with factor VIII antibodies in hospital, the Centre used cryoprecipitate, 97,000 units of Alpha Factor IX and 22,360 units of FEIBA. To treat 3 patients with von Willebrand's disease in hospital, the Centre used 27,000 units of cryoprecipitate. To treat 1 patient with haemophilia B, the Centre used 2,900 units of NHS factor IX and 6,000 units of Alpha Factor IX.

21. Dr Machin wrote to Mr Snape on 4 February 1985 requesting heat treated factor VIII for certain categories of named patients.<sup>64</sup> A list of haemophiliacs treated within NWT RHA with NHS heat-treated factor concentrate in April 1985 shows 8 patients under the care of Dr Machin at the Middlesex Hospital.<sup>65</sup>

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<sup>62</sup> HCDO0001841

<sup>63</sup> HCDO0001934

<sup>64</sup> CBLA0002015

<sup>65</sup> BPLL0010517\_002

22. It appears that Dr Machin met with a representative of Cutter in 1986 to discuss the purchase of blood products. In a letter dated 14 November 1986, Linda A Frith, Sales Development Manager, wrote to Dr Machin:<sup>66</sup>

*“Thank you for your intention to buy Koate HT. I can offer you a price of [18] pence per International Unit for the sale of 250,000 IU Koate HT. We currently hold in stock 250 IU, and 500 IU vial sizes. 1000 IU vial size will be available shortly. If you wish, a specific lot of material can be reserved for you to offtake as you require. However, you may wish to take delivery of your order all at one time. We delivery by courier which will be the same day if urgent and the following day if routine. Home Treatment packs are also available. Please let us know how many you require when ordering Koate HT.”*

23. Ms Frith further added:<sup>67</sup>

*“I would like to confirm that Cutter will be able to provide funds to your department of £5,000. I would like to do this in one payment before the end of this year. Would you be able to provide me with a letter saying what the funds would be used for, e.g. to help support a research project or a researcher. etc.”*

24. Mrs O’Shea gave evidence that her son Luke was treated on three occasions, including twice at the Middlesex Hospital:<sup>68</sup>

*“2.1. Luke was treated on three separate occasions. On the 15th May 1985, Luke was treated at the Middlesex Hospital following an injury to his mouth. He was treated again on the 21st December 1987 following a nosebleed. On the 24th November 1989, Luke received treatment at the Shrewsbury Hospital after a trauma to his knee. On those occasions he was given Factor VIII blood products and subsequently was infected with Hepatitis C.*

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<sup>66</sup> BAYP0000009\_063

<sup>67</sup> BAYP0000009\_063

<sup>68</sup> WITN0043001 para 2.1-2.3

2.2. *I know from Luke's medical notes that the injury to his mouth was intermittently bleeding for 3 days. An infusion DDAVP had not controlled it and so Luke received 1,680 units of Alpha heat treated FVIII concentrate. The notes do state that Luke received propylate list number 360210, lot number A6-0311. At this time, Luke was under the care of Professor Machin.*”

25. Dr Machin explained in response to paragraph 2.2 of Mrs O’Shea’s statement:<sup>69</sup>

*“After his mouth bleed in May 1985 Luke was first treated with infusions of a licensed chemical DDAVP. He did not respond to this therapy and therefore standard care at that time involved progression to providing a F.VIII concentrate to control his bleeding.”*

26. Mr O’Shea further gave evidence which indicates that he was referred for a clinical trial of heat treated factor VIII concentrate:<sup>70</sup>

*“11. In a letter dated 12.06.1985 Professor Machin wrote to Dr Kernoff at the Royal Free Hospital and referred to my treatment with Factor VIII concentrate. In this letter he confirmed I was treated with 1,680 units of alpha heat treated Factor VIII concentrate and that I was a virgin haemophiliac (ie. I had never previously received blood products). The letter confirms that I received Profilate List Number 360210, Lot Number A6-0311 and that I was to be followed up fortnightly for liver function tests, blood count and virology. He finished by saying "I hope they will be suitable for the heat treated trial." A copy of this letter is now shown to me marked WITN1696004.*

*12. The heat treated trial was not discussed with me or my mother. I also note that this letter was copied to Ian Marshall at Alpha Therapeutics. As more evidence and knowledge about the scandal became clear to me this letter for the first time became very relevant to me, about 6 months ago. I obtained copies*

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<sup>69</sup> WITN3090001

<sup>70</sup> WITN1696001

*of my records in 2004 however until further information came to light much of my records meant little to me. I've been in the dark for years."*

27. Dr Machin explained:<sup>71</sup>

*"There was a study being organised by Dr. P. Kernoff, lead haemophilia consultant at the Royal Free Hospital (now deceased) to assess the incidence of acute post infusion NANBH and other viral transmissions in a commercial F.VIII concentrate from Alpha Therapeutic UK Ltd. It was to this study Luke was recruited. This would have been discussed with his mother, although I acknowledge that standards of consent in the 1980's was quite different to what it is now. The nature of the study and the reasons for wishing to use the concentrate would have been explained to his parents and consent to follow-up obtained. The main focus of this study was to establish if the use of this particular heat treated F.VIII reduced the incidence of NANBH, which the study conformed it did (see. British Journal of Haematology, 1987, 67, 207-211 entitled "Reduced risk of non-A, non-B hepatitis after a first exposure to 'wet heated' factor VIII concentrate."*

28. Dr Machin specifically responded to paragraph 11 of Mr O'Shea's witness statement as follows:<sup>72</sup>

*"In 1985 there was widespread national and international issues for haemophiliacs receiving all forms of F.VIII concentrates, in that the risk of post-infusion NANBH in patients receiving a first exposure F.VIII concentrate approached 100%. By using a wet heated sterilised commercial concentrate, it was hoped that the incidence of NANBH would be reduced. The purpose of the study would have been explained to Luke's mother, but not specifically to a young boy."*

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<sup>71</sup> WITN3090002

<sup>72</sup> WITN3090002

29. Dr Machin added that, “*Mr Ian Marshall was the trial coordinator for Alpha Therapeutics*”.<sup>73</sup> He also responded to Mrs O’Shea’s statement with the following:<sup>74</sup>

*“The results of the study Luke was recruited into were subsequently published in the 16. British Journal of Haematology, 1987, 67, 207-211 entitled “Reduced risk of non-A, non-B hepatitis after a first exposure to ‘wet heated’ factor VIII concentrate.” and the lead author was P.B.A. Kernoff (now deceased). The results of this paper led to the widespread use of this concentrate in the UK between 1987-1990 to reduce significantly the incidence of NANBH. It is unfortunate that Luke contracted Hepatitis C despite receiving a heat treated F.VIII product that was proven by this study to give a lower risk of hepatitis C than the standard F.VIII provided at that time.”*

#### **Knowledge of risk of hepatitis/HIV and response to risk**

30. Professor Stewart was a regular attendee at UKHCDO meetings, including on 1 October 1968,<sup>75</sup> 5 April 1971,<sup>76</sup> 27 October 1972,<sup>77</sup> 31 January 1974,<sup>78</sup> 1 November 1974,<sup>79</sup> 18 September 1975,<sup>80</sup> 13 January 1977,<sup>81</sup> 24 October 1977,<sup>82</sup> 13 November 1978,<sup>83</sup> and 20-21 November 1979.<sup>84</sup>

31. On other occasions, Dr Machin attended UKHCDO meetings on behalf of the Middlesex Hospital, either as Director of the Centre or in place of Professor Stewart or Dr Tedder, including on 9 October 1981,<sup>85</sup> 13 September 1982,<sup>86</sup> 17 October 1983,<sup>87</sup>

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<sup>73</sup> WITN3090002 para 13(e)

<sup>74</sup> WITN3090001. The same is stated at WITN3090002 para 16

<sup>75</sup> HCDO0001013

<sup>76</sup> HCDO0001014

<sup>77</sup> HCDO0001015

<sup>78</sup> CBLA0000187

<sup>79</sup> HCDO0001017

<sup>80</sup> OXUH0003735

<sup>81</sup> PRSE0002268

<sup>82</sup> PRSE0001002

<sup>83</sup> HSOC0010549

<sup>84</sup> CBLA0001028

<sup>85</sup> CBLA0001464

<sup>86</sup> CBLA0001619

<sup>87</sup> PRSE0004440



21 October 1985,<sup>88</sup> 17 March 1986,<sup>89</sup> 9 October 1986,<sup>90</sup> 25 September 1987,<sup>91</sup> 29 September 1988,<sup>92</sup> 16 June 1989,<sup>93</sup> and 9 October 1989.<sup>94</sup>

32. It does not appear that Professor Stewart or Dr Machin contributed to the Glasgow Symposium on Unresolved Problems in Haemophilia in 1980,<sup>95</sup> or the Manchester Symposium on Current Topics in Haemophilia in 1982.<sup>96</sup>

33. Dr Machin co-authored several academic articles including:

- a. An article in the Lancet in 1985 titled “*Wet Heating for Safer Factor VIII Concentrate?*”;<sup>97</sup>
- b. An article in the British Journal of Haematology in 1985 on “*HTLV-III antibody and T-cell subset ratios in haemophiliacs and their spouses*”;<sup>98</sup>
- c. An article in the Journal of Haematology in 1987 on the “*Reduced risk of non-A, non-B hepatitis after first exposure to ‘wet heated’ factor VIII concentrate*”.<sup>99</sup>

34. Mrs O’Shea gave evidence that:<sup>100</sup>

*“2.3. At the time Luke was given the Factor VIII product, there were no discussions with me about the risk of him being exposed to infections. It was just a matter of course that Luke will need FVIII and that is what they will give him. There was absolutely no discussion about the product being dangerous. Had that been the case, I would have gone away and had a discussion with Luke’s Dad and my mother. His injury was not life threatening, so I would not have put Luke through something that would have endangered his life. He was 3 years*

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<sup>88</sup> PRSE0001638

<sup>89</sup> PRSE0001688

<sup>90</sup> PRSE0004317

<sup>91</sup> HCDO0000485

<sup>92</sup> BART0002329

<sup>93</sup> PRSE0002656

<sup>94</sup> PRSE0001175

<sup>95</sup> RLIT0001242

<sup>96</sup> DHSC0002221\_003

<sup>97</sup> RLIT0000186

<sup>98</sup> RLIT0000127

<sup>99</sup> NHBT0042403

<sup>100</sup> WITN0043001

*old. He is my only child. There was no discussion. It was just a process; he is bleeding and the next day it was FVIII. That is what it was.”*

35. Dr Machin responded to paragraph 3 of Mrs O’Shea’s statement as follows:<sup>101</sup>

*“It would be normal practice for all such patients in 1984-5 to have discussions about the dangers of infections, particularly HIV, hepatitis B and other forms of hepatitis from any blood products provided. I would expect for this to have occurred with Ms O’Shea, although not necessarily directly with me. It is unfortunate that she has no recollection of this occurring and Luke’s records fail to ascertain if any documented discussions took place.”*

#### **Testing patients for HTLVIII and informing them of diagnosis**

36. It appears that early HIV testing centred at the Middlesex Hospital and that stored samples from other Haemophilia Centres were sent to Dr Tedder at the Middlesex Hospital for HIV testing. According to an interview with Professor Christine Lee in June 2015, stored samples were sent from the Royal Free Hospital to Dr Tedder at the Middlesex Hospital for HIV testing.<sup>102</sup>

*“And then towards--, the HIV virus was not identified until I think May or June of ‘84 and we didn’t have a test until the November of ‘84 and we had access in a research capacity, and I mean now it’s horrific what we did but it was okay at that time--, I can’t even remember--, we must--, yeah, we used gloves, but we actually decanted from our stored specimens--, because we had 600 patients we didn’t know who was positive and who was negative, and we decanted the stuff into little test tubes and sent them down to Richard Tedder at the Middlesex Hospital for testing and then we knew that we had 111 people who were actually infected.”*

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<sup>101</sup> WITN3090001

<sup>102</sup> THOM0000001

37. Professor Lee confirmed in oral evidence that, “*as a matter of fact, patients at the Royal Free, all the patients at the Royal Free, were tested for HIV without their knowledge and consent*”, was correct.<sup>103</sup> Other haemophilia clinician witnesses referred to samples being sent from their centres to Dr Tedder at the Middlesex Hospital for HIV testing, for example:

- a. Dr Mark Winter stated in oral evidence, “*Dr Richard Tedder who was a virologist at the Middlesex Hospital and it was not being advertised to any of the hospitals because everybody suddenly wanted this test. But the UKHCDO came to an arrangement with Dr Tedder that haemophilia centres could send him blood samples on their patients for that test to be done*”.<sup>104</sup> In response to a question from the Chair, “*your memory is that your tests conducted by the Middlesex came back to Thanet sometime the end of October/beginning November. Is that about right?*”.<sup>105</sup> Dr Winter stated “*... on this list of authors is Dr Tedder from the Middlesex, he was a virologist, and it was his test that was made available to the haemophilia directors ...*”<sup>106</sup> Dr Winter also stated, “*I was taught by my professor at the Middlesex always a good idea to take an extra vial of blood and store it. You never know what it might be useful. He did with that all of his patients*”.<sup>107</sup>
- b. Dr Brian Colvin stated in oral evidence, “*Well, of course, the testing has only really just started. This almost certainly comes from Richard Tedder and, interestingly enough, it might come mainly from his centre because the Middlesex has a number of people with haemophilia in it, it's not a big centre but it may well be that the -- and this is pure speculation now, but it might be that the people in the Middlesex centre might be tested quite quickly by Dr Tedder, because he is in that area and, if that was the case, then it wouldn't perhaps be surprising that not so many of them are anti-HTLV-III positive because they are not big treaters.*”<sup>108</sup>

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<sup>103</sup> Transcript 21 October 2020 INQY1000066

<sup>104</sup> Transcript 1 October 2020 INQY1000059

<sup>105</sup> Transcript 2 October 2020 INQY1000060

<sup>106</sup> Transcript 2 October 2020 INQY1000060

<sup>107</sup> Transcript 2 October 2020 INQY1000060

<sup>108</sup> Transcript 7 October 2020 INQY1000062

- c. Dr David Bevan was asked in his oral evidence, “*Now if we come to the question of the testing and informing patients of their test results, your understanding is that Professor Flute had sent samples in the early part of 1985 to Dr Tedder at the Middlesex Hospital. And is this right, that was not on stored samples because St George's didn't maintain a bank of stored samples? Is that right?*”<sup>109</sup> Dr Bevan responded, “*I cannot say for certain that none of them were stored samples but I know that we had no bank of stored samples. So I guess it was -- when I said he would have started sending them to Richard Tedder's lab in -- when he wrote that letter to Dr Snape in December 1984, and that process of sending samples to the Middlesex may well have occupied several months of 1985 before all the samples he could get were there. I believe that the agreement by Professor Tedder to test samples for British haemophiliacs put considerable load -- so he wasn't able to test them all at once. There was a kind of a queue and a backlog, which was eventually resolved.*”<sup>110</sup>

### **Numbers infected with HIV**

38. It appears from provisional data received by the Inquiry from UKHCDO that 1 patient at the Middlesex Hospital tested positive for HIV in 1985.<sup>111</sup>

### **Testing for HCV**

39. Mrs O’Shea gave evidence that due to Luke’s age at the time, her consent would have been required for any treatment or testing.<sup>112</sup> She explained in her evidence that:<sup>113</sup>

*“...Luke was being tested from the 13th November 1984 without my consent or knowledge. I refer to his medical notes where there is an entry dated 13*

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<sup>109</sup> Transcript 12 January 2021 INQY1000086

<sup>110</sup> Transcript 12 January 2021 INQY1000086

<sup>111</sup> INQY0000250

<sup>112</sup> WITN0043001 para 4

<sup>113</sup> WITN0043001 para 4-4.4

*November 1984 which records 'blood sample for haemophilia — mild' and 'urgent test for HIV/HB. Has received no blood products'.*

*4.1. I was under the impression that Luke was being tested just for haemophilia and had no idea of any other tests taking place. We were called back for other blood tests over a period of about a year and then Luke had his first bleed.*

*4.2. I have seen in Luke's medical notes a letter dated 12th June 1985, from Dr. Machin to a Doctor at the Royal Free Hospital. The letter is dated after Luke received treatment on the 15th May 1985 for his mouth injury. The letter mentions Dr. Machin having treated "two 'virgin' haemophiliacs with Alpha heat treated FVIII". It then gives the details of the two patients, one being Luke.*

*4.3. The letter states 'both patients will attend for fortnightly follow up blood samples, for liver function tests, blood count and virology. I hope they will be suitable for the heat treated trial.' This letter was copied to a male possibly working for Alpha Therapeutics.*

*4.4 I have also seen in Luke's medical notes a letter dated the 22nd June 1993 from Dr. Machin to a Doctor of the Ealing Health Authority. In this letter he discusses Luke and says that 'he has been under his care since March 1985 when a diagnosis of mild haemophilia A was made. 'Since that time he has required treatment with high purity Factor VIII concentrate on only one or two occasions per year. You will be pleased to hear that he is fortunately HIV negative and he has completely normal liver function tests. On examination everything is completely within normal limits, including a complete range of muscle and joint movements. Obviously any bleeding episode should be treated by an infusion of Factor VIII concentrate. For this he attends my clinic here at the University College Hospital and apart from that I only see him annually to review his progress.'"*

40. Dr Machin responded as follows:<sup>114</sup>

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<sup>114</sup> WITN3090001. The same is stated at WITN3090002 para 14

*“In relation to consent, all Luke’s blood tests from 1984 onwards would have been obtained with parental approval. However I recognise that the standard level of consent process in the 1980s may not have involved specifically discussing the precise laboratory tests to be conducted on the blood sample obtained. It was routine practice at the Middlesex Hospital to label all blood test tubes and laboratory request forms from all haemophiliacs as (danger of infection) on yellow stick on forms.”*

41. Dr Machin added that:<sup>115</sup>

*“Having carefully read Ms O’Shea’s statement of 31.10.18 I have several specific factual comments concerning the clinical events which followed. Generally in 1984/5 all haemophilia patients, after a first exposure to conventional F.VIII concentrates had a very high incidence of NANBH with a transitory rise in some liver function tests, particularly the enzyme ALT. To eliminate such possible contamination concentrates were being sterilised by several novel methods, usually involving some form of heating. It was then becoming accepted that evidence of product safety could only be reliably prospectively evaluated by using such first exposure virgin patients. From 1984 all patients would have been routinely tested for their F.VIII level, absence of any inhibitor and for markers of HIV and Hepatitis B infection. The 3 latter tests were all clear and negative in Luke. Consent for such tests would have been obtained from his parents before testing.”*

42. Mr O’Shea gave evidence that:<sup>116</sup>

*“8. I first received Factor VIII on 15.05.1985 following a mouth bleed. My mother did not receive any information about the products that were being used on me nor was there a discussion about the potential risk of infections.*

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<sup>115</sup> WITN3090001. The same is stated at WITN3090002 para 15

<sup>116</sup> WITN1696001

9. *It is clear from my records that I was tested for HIV (then HTLV ill) in early June 1985, shortly after I was given Factor VIII. The results are now shown to me marked WITN1696002. Fortunately I tested negative but again, neither my mother nor I were informed that I was being tested and consequently we were not informed of the result either.*

10. *It also appears that I was tested for a number of viruses before I received any Factor VIII treatment. There is now shown to me marked WITN1696003 pathology results dated 13.11.1984. It should be noted that the reason for the tests is listed as "URGENT, Haemophilia. Has received no blood products."*

43. In relation to testing for HIV, Dr Machin stated:<sup>117</sup>

*"Luke had regular HIV tests or equivalent tests, which were all negative, as was standard practice with all haemophiliac patients prior to transfusions or any specific therapy."*

44. By letter dated 21 June 1991, Professor Tedder wrote to Dr Rizza at the Oxford Haemophilia Centre:<sup>118</sup>

*"I am faced with increasing problems over counselling patients found to be infected with HCV who wish to know of the risk of transmitting this to their spouses. We have talked in the past about the early results in the Oxford population and unfortunately with John Craske being away on leave I cannot pursue this any further at the moment.*

*It concerns me that we do not know what the transmission rate is and therefore although this laboratory has generated some rather weak evidence in favour of sexual transmission of hepatitis C in genito-urinary medicine clinics, I find it almost impossible to know what to say to the infected patient. I expect you have*

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<sup>117</sup> WITN3090002 para 13(f)

<sup>118</sup> OXUH0001863\_002

*the same problem. Would it therefore not be sensible to reexamine this whole matter with some urgency?*

*For our part, I am fairly happy with the available serological testing and would be prepared to underwrite the cost of a preliminary survey. This would not include HCV RNA assays on all samples though we would of course undertake some PCR estimations on a cross-sectional basis. It would include such confirmatory testing as is required to get the truth on transmission rates, I realize that with John on leave and myself away from this evening there is little that can be done immediately. Can we try and pursue this in a few weeks time? If problems arise in the meantime my colleagues here, Moya Briggs and Jeremy Garson, will help I am sure.”*

45. Dr Rizza responded to Professor Tedder by letter dated 25 June 1991.<sup>119</sup>

*“Thank you for your letter of 21 June 1991. As I mentioned to you on the telephone the other day, I am very anxious to find out to what extent there has been sexual transmission of HCV to the spouses of HCV positive haemophiliacs. As you know, one of the early serological methods revealed a rate of transmission approaching 20% in our group. Given the uncertainties of method I have found it extremely difficult to know what to say to the couples. They are aware of the tests that are becoming available and many wish to know what a positive result means. I am very keen therefore to pursue the problem as quickly as possible and welcome your offer of help.”*

### **Treatment arrangements for HIV and HCV patients**

46. Mr O’Shea was treated for infection with HCV by Dr Laffan at the Hammersmith Hospital.<sup>120</sup> The Inquiry currently has limited information available about the treatment arrangements for HIV and HCV patients at the Middlesex Hospital.

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<sup>119</sup> OXUH0001863\_001

<sup>120</sup> WITN1696001 para 17



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June 2021