SMALLER HAEMOPHILIA CENTRES PRESENTATION
GREAT ORMOND STREET HOSPITAL (GOSH)

Directors, staffing and facilities

1. The Directors of the Haemophilia Centre at Great Ormond Street Hospital (GOSH) during the 1970s-80s included Professor Roger Hardisty and Professor Ian Hann. Professor Hardisty was Director of the Centre from around 1968 to 1987. He was President of the British Society for Haematology in 1982.[1] It appears that Professor Hann was Director of the Centre from 1987 onwards.

2. Professor Ian Hann has provided a written statement dated 19 August 2020.[2] Professor Hann was Consultant Haematologist and latterly Professor of Paediatric Haematology and Oncology and Head of Department and Clinical Director at the Hospital for Sick Children, Great Ormond Street, London and University College London / Institute of Child Health.[3] Dr Hann stated that throughout his career, he strongly advised families to join the Haemophilia Society and the majority did so.[4]

3. Dr Lynne Ball has provided a written statement dated 21 March 2021.[5] Dr Ball was Honorary Senior Registrar (Paediatrics Haematology/BMT) at Hospital for Sick Children, Great Ormond Street, London, from March 1986 to March 1988.[6] She explained her role, her colleagues, and the facilities at GOSH in more detail at paragraph 6 of her written statement:[7]

> *"During my appointment as senior registrar at GOSH which extended over the period from 1-03-1986 to 31-03-1988 I was assigned for one year to provide day to day in patient and out patient care for children with coagulopathies. This included but not exclusively those children aged 0-18 years with haemophilia.*

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[1] BSHA0000114
[2] WITN3497005. Professor Hann gave oral evidence to the Inquiry on 8 December 2020 [INQY1000082]
[3] WITN3497005 para 3
[4] WITN3497005 para 130
[5] WITN4739001
[6] WITN4739001 para 2
[7] WITN4739001

I worked under the direct supervision of Professor Dr. Roger Hardisty and later Prof Dr Ian Hann. I worked also with a dedicated haemophilia specialist nursing sister(s) and we had a dedicated treatment area, on-site specialist laboratory diagnostic facilities and weekly outpatient clinics attended by Prof Hardisty and myself together with the haemophilia sister. Children were regularly reviewed and monitored according to standard practice for inhibitors, hepatitis B and HIV…

Having completed one year in this capacity I was then superseded by Dr Elaine Simpson who assumed similar responsibilities. I was then assigned to co-ordinate and execute the care of children undergoing stem cell transplantation, which was a continuation of my training in paediatric oncology and stem cell transplantation. However, I maintained my involvement with children with coagulopathies requiring acute care as necessary in a 1:2 out of hours rota shared with Dr Simpson as well as continuing the support group and my involvement in the zidovudine trial, only discontinuing these involvements on taking up my appointment as consultant at Alder Hey in January 1989."

4. Other personnel at GOSH included:

   a. Dr Colin A Sieff, who represented Professor Hardisty at a UKHCDO meeting on 13 November 1978;[8]

   b. Dr Una Callaghan, who represented Professor Hardisty at a UKHCDO meeting on 9 October 1981;[9]

   c. Dr Jane Evans, Lecturer in Haematology, who attended a UKHCDO meeting on 21 October 1985 on behalf of Prof Hardisty.[10]

[8] HSOC0010549
[9] DHSC0002339_048 and CBLA0001464
[10] PRSE0001638

d. Dr A Rankin, who attended a meeting of regional Haemophilia Centre Directors and Blood Transfusion Centre Directors on 1 September 1978 on behalf of Professor Hardisty.[11]

5. In the 1990s, GOSH was later designated as a Comprehensive Care Centre (CCC) and the haemophilia team consisted of:[12]

> "*Dr Ian Hann – Haemophilia Centre Director*
> *Kate Khair – Haemophilia Clinical Nurse*
> *Sue Chillingworth – Physiotherapist*
> *Sue Trickett – Social Worker*
> *Dr Ri Liesner – Senior Registrar*"

6. In response to a rule 9 request for documentation, the Inquiry received a letter dated 10 September 2018 from Dr R Liesner, Haemophilia Centre Director, and Dr Peter Steer, Chief Executive,[13] stating that they were "*unable to locate any stored relevant documentation from 1970/80's except individual patient hospital records...*" and that the "*physician in charge of the haemophilia centre in the 1970's and 1980's – Professor Roger Hardisty – is deceased and there is no personal paperwork from that time to be found in storage*".[14] The Inquiry has received a witness statement from CEO Matthew Shaw of GOSH setting out what searches were carried out in response to the Inquiry's rule 9 request.[15]

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

7. The Haemophilia Centre at Great Ormond Street Hospital, formally known as the Hospital for Sick Children (HSC), was based at the Department of Haematology, Great Ormond Street Hospital, Great Ormond Street, London WC1N 3JN. Guidelines

[11] CBLA0000838
[12] HSOC0017396
[13] WITN3774003
[14] WITN3774003
[15] WITN4650001

produced by GOSH and the Institute of Child Health for Haemophilia and Bleeding Disorders in 1995 provides some information about the background of GOSH:[16]

> "*Since opening in 1852, Great Ormond Street Hospital has earned itself a national and international reputation as a centre of excellence. Children requiring very specialised care can be looked after by specialists in many fields: cardiac surgery, intensive care, plastic surgery, haematology/oncology, to name but a few, all on one site...*"

8. In around 1970, GOSH was one of 13 designated Haemophilia Centres in the London area.[17] In a letter to Dr Obank of DHSS dated 23 December 1969,[18] Professor Hardisty referred to a joint memorandum from Dr Dormandy, Dr Ingram and himself regarding the organisation of haemophilia care in London. A document authored by Dr Dormandy, Professor Hardisty and Dr Ingram, which appears likely to be the joint memorandum,[19] sets out their view as to the "*need to improve existing facilities for the care of patients with haemophilia and related disorders in and around London*".[20] It states that:[21]

> "*With the increasing availability of cryoprecipitate, a much more active approach can and should be taken to the treatment of minor bleeding episodes. The concept of an adequate therapeutic service has therefore altered radically during the last few years, and the provision of such a service now demands much greater resources of both staff and therapeutic materials than formerly.*"

9. On 11 February 1970, a meeting of 3 London Haemophilia Centre Directors (Professor Hardisty of Great Ormond Street Hospital, Dr Dormandy of the Royal Free Hospital, and Dr Ingram of St Thomas' Hospital) took place with officials at the Department of

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[16] HSOC0017396
[17] DHSC0100026_009 and OXUH0003597. The 13 designated Haemophilia Centres in the London area at that time were Guy's Hospital, St Mary's Hospital, King's College Hospital, Royal Free Hospital, Hospital for Sick Children (Great Ormond Street), Lewisham Hospital, University College Hospital, Westminster Hospital, St Thomas' Hospital, The London Hospital, St George's Hospital, The Middlesex Hospital, Hammersmith Hospital.
[18] DHSC0100026_011
[19] DHSC0100026_026
[20] DHSC0100026_026
[21] DHSC0100026_026

Health and Social Security (DHSS) to discuss the organisation of haemophilia care in London.[22] At an office meeting, prior to the arrival of the 3 London Haemophilia Centre Directors, it was agreed as DHSS policy that GOSH would be treated separately:

> "*It was agreed that the Department's policy should be aimed at a reduction in the number of centres in London, possibly by insistence that only 1 of the "Todd pairs" of London Teaching Hospitals should undertake haemophiliac work. Great Ormond Street Hospital would be excluded from the pairing as it dealt exclusively with children. The Lewisham Centre should also remain as it was the only RHB Centre in London.*"

10. At the meeting with the 3 Haemophilia Centre Directors, it was recorded that, from the perspective of Professor Hardisty and GOSH:[23]

> "*Professor Hardisty explained that at Great Ormond Street the emphasis was on early treatment of minor bleeds in children to prevent crippling. The increase in workload derived from the larger number of treatments being given per patient rather than an increase in the number of patients. At his centre, some 30% of the 69 registered patients attended frequently or fairly often. Professor Hardisty also spoke of the need to assay the anti-haemophiliac material and thought that the recruitment of a Technician would relieve his 2 Senior Registrars of the routine part of their present duties.*"

11. After discussion, it was agreed that:[24]

> "*It seemed likely that St Thomas' and the Royal Free would in time naturally evolve as the main Haemophilia Centres. Great Ormond Street should also remain in view of its special nature and possibly Hammersmith…*"

[22] DHSC0100026_084
[23] DHSC0100026_084
[24] DHSC0100026_084

12. Professor Hardisty attended a meeting of Directors of all Haemophilia Centres in London on 15 October 1970 at which the organisation of Haemophilia Centres in London was further discussed.[25]

13. 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 Hardisty.[26] 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. GOSH, being north of the Thames, fell under the responsibility of Dr Dormandy.[27] It appears from that letter that Professor Hardisty was listed under Region 06 i.e. North-East Thames Region.[28]

14. However, a document dated 6 December 1976 showing an allocation of NHS factor VIII concentrate to regional blood transfusion centres and haemophilia centres based on 1974 returns shows GOSH as part of the North-West Thames Region.[29] Based on 1974 returns, the North-West Thames Region was allocated 160 bottles per month.[30] Specifically, 62 bottles per month were allocated to the Hospital for Sick Children (GOSH).[31]

15. The minutes of a meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres (Regions 04, 05 and 06) and Blood Transfusion Centres on 15 December 1976 suggests that GOSH was treated as part of Region 05 (North-West Thames Region).[32] It is recorded that Professor Hardisty attended the meeting. He pointed out that his

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[25] OXUH0003597

[26] CBLA0000506

[27] 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).*"

[28] CBLA0000506

[29] CBLA0000510

[30] CBLA0000510

[31] 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.

[32] CBLA0000533

patients attended from all four regions (05-08) and raised the issue of the allocation of factor VIII concentrate:

> *"Professor Hardistry [sic] said that (a) all his patients on home treatment were on commercial F.VIII for which the Hospital for Sick Children had a special allocation from the DHSS, and (b) patients came from any of the 4 regions 05-08 and that if a different system of allocating concentrate for each region had to be used, this would become very complicated and therefore dangerous. As far as he was concerned, it was only feasible to supply concentrate to the patient or his parents or to the hospital concerned with the care of the patient.*
>
> *Dr Jenkins pointed out that patients registered at the Hospital for Sick Children who lived in the Brentwood parish might well require emergency treatment with blood or blood products at any time, and it would be in the patient's best interest for the RBTC to have his full records.*
>
> *The Chairman pointed out that the Hospital for Sick Children was in a unique situation because it was a supra-regional children's hospital. He asked if it could be accepted in principle that the Hospital for Sick Children should retain its individual status, and this was agreed.*
>
> *It was also agreed that a record of patients living 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."*

16. It can be seen from the minutes that GOSH was seen as being in a unique position, treating children from across the region, and was treated as a special case when it came to the allocation and distribution of factor VIII concentrate.

17. Professor Hardisty and Dr C A Sieff sent their apologies for a further meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres (Regions 04, 05 and

06) and Blood Transfusion Centres on 23 September 1977.[33] However, it is recorded in the minutes that a letter from HSC (Hospital for Sick Children) was read aloud by Dr Dormandy which indicated that there was a shortfall of NHS concentrate and that it was necessary for GOSH to purchase commercial concentrate:[34]

> "*Despite their allocation of 30 bottles NHS conc./month they had needed to buy more commercial conc. from January to August 1977 (235 u) than over the same period in 1976 (185,000 u).*"

18. Professor Hardisty sent his apologies for a further meeting of Directors of Haemophilia Centres/Associate Haemophilia Centres (Regions 04, 05 and 06) and Blood Transfusion Centres on 1 September 1978,[35] although it is recorded that Dr A Rankin attended in his stead. Dr Rankin again raised the issue of a shortage of factor concentrates for home therapy which led to patients being transferred to other Centres:[36]

> "*Dr Rankin commented that their allocation had been reduced from 100 to 65 bottles. This was enough to treat only half their patients on home therapy, hence they had started transferring their patients to other Centres at a much younger age, e.g. to Professor Ingram and the Royal Free Hospital. She also made the point that, as the children were growing, their concentrate requirements increased steadily.*"

19. It was noted that this created knock-on problems for other Centres:[37]

> "*Dr Kernoff felt that this did not solve the problem – it merely passed to someone else; it increased the Royal Free's use of concentrates and they were already overrunning their budget. The problem needed to be dealt with at a regional, supra-regional and national levels. Only 20% of the Royal Free's requirements were being met with NHS concentrate at present. Despite this, and in accordance with the Reference Centre Directors' recommendations, it was*

[33] BART0000689 / CBLA0000657
[34] BART0000689 / CBLA0000657 p. 3
[35] CBLA0000838
[36] CBLA0000838 p. 5
[37] CBLA0000838 p. 5

the intention to switch home treatment patients from cryoprecipitate to concentrate. Half the home treatment patients at the Royal Free were still using cryoprecipitate and this was felt to be an unacceptable state of affairs. If NHS concentrate was not available then commercial concentrate would have to be bought. In fact, the extra cost might not be very great since the cost of cryo to the Royal Free was not inconsiderable and, taking into account the unitage, it worked out at almost the same price as commercial concentrates."

20. On 24 November 1978, Colin Sieff wrote to Dr Richard Lane explaining that they were experiencing a shortage of supply:[38]

> "*Although our monthly quota of 60 bottles of PPF comes from the Edgware Blood Transfusion Centre, you can see that the North West Thames Region contributes only approximately one quarter of the NHS patient load. More than twice this number of patients comes from other Thames regions with fewer hut still significant numbers from further outlying regions. Although the figures are for discharges and deaths, most of the PPF is used post-operatively. However, these figures reflect fairly accurately the numbers of operations performed on patients from these regions.*
>
> *I wonder therefore whether it would be possible for us to receive an allocation of PPF from some of the other regions as this would considerably ease our problem. As the numbers of operations being performed by the unit is steadily increasing and there is still a 2-year waiting list, our requirements will soon be at least twice what we are getting at the moment. If we cannot increase our supplies through your help, we will have to attempt to find resources to buy it commercially, or else reduce the numbers of operations performed at this hospital.*"

[38] BPLL0000929_001

21. On 10 December 1984, Dr J Evans, Lecturer in Haematology at GOSH, wrote to Mr N Pettit of the Blood Products Laboratory regarding shortages in supply of NHS factor VIII and the possibility of clinical trials involving small donor pools:[39]

> "*Further to our telephone conversation, I am writing to you about supply of National Health Service factor VIII for the haemophilia children at GOS. As you are aware my initial reason for contacting you was because of the difficulties in obtaining a sufficient amount of NHS concentrate to treat our patients this month.*
>
> *On reviewing the records of our patients we have four patients who have never received any commercial concentrate but who are currently receiving regular treatment with NHS factor VIII concentrate…*
>
> *We discussed the possibility of treating these patients with either a small pool plasmapheresis factor VIII concentrate or alternatively a small pool heat treated concentrate. We would be interested and willing to co-operate in a clinical trial of these products in these particular patients…*
>
> *As you are well aware, our reason for approaching you initially is that we would really like to treat all the children with NHS concentrate. In addition to the possible advantages of using these new products, it would also result in more NHS concentrate for use by our other patients. I am sure it will come as no surprise to you that many of the parents of the children we treat here are very anxious about the use of commercial concentrates in use by their offspring… I have discussed all this with Professor Hardisty who is the Director of the Haemophilia Centre.*"

22. On 8 May 1985, Sarah Johnson, Haemophilia Sister of GOSH, wrote to Mr Pettit with a list of "*most of our severe haemophiliacs requiring concentrate who we would like to have Heat Treated Lister*".[40] She stated that:

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[39] CBLA0001945
[40] CBLA0002160

"*Our present supplies from Edgeware and Brentwood certainly do not seem enough for our needs at the moment.*"

23. It appears therefore that GOSH was supplied with products from the Regional Blood Transfusion Centres at both Edgware and Brentwood who largely supplied the North-West and North-East Thames Regions respectively.

24. On 31 December 1985 Dr Marcela Contreras of the Regional Blood Transfusion Service wrote to Professor Hardisty to improve record keeping of units of blood received.[41]

Numbers of Patients Registered and/or Treated at the Centre

25. In response to a request for information from the Department of Health and Social Security in December 1969,[42] Professor Hardisty indicated that for the year ending 30 September 1969:[43]

    a. There were 89 cases registered at the Centre;
    b. There were 527 incidents of haemorrhage for which patients attended the Centre for treatment;
    c. There were 5 haemophiliac patients not registered with the Centre who attended for treatment;
    d. He found it impossible to answer the question of how many incidents of severe bleeding in patients attending the Centre, "*owing to the imprecision of the word 'severe'.*"[44] He stated that "*The severity of a bleeding episode obviously depends not only on the amount of blood lost from the circulation, but also on the anatomical site and the length of time which has elapsed between the onset of bleeding and the initiation of treatment. The great majority of incidents which we have treated here are hemarthroses or muscle bleeds following minor*

[41] NHBT0105294
[42] DHSC0100026_009
[43] DHSC0100026_011
[44] DHSC0100026_011

trauma or arising spontaneously, but some of these could certainly be classed as 'severe'. If the question is intended to refer to episodes of major accidental trauma, then our reply for the year in question is nil".[45]

e. There were no major surgical operations undertaken in patients registered with the Centre during the year;

f. No patients with incidents of severe bleeding or major surgical operations were transferred to the Special Treatment Centre at Oxford.

26. The joint memorandum authored by Dr Dormandy, Professor Hardisty and Dr Ingram in late 1969,[46] provides some information about the number of patients treated at their respective Centres. Table 1 shows that there were approximately 90 patients under supervision at Great Ormond Street and 61 patients treated.[47] The number of treatments was 894 which was an average of 14.6 treatments per patient treated.[48] As explained in the memorandum, their view was that the "*total number of patients under care at a Centre is not a very precise measure of the work load, because of the volume of work will depend on the proportion of cases who are severely affected... We suggest that the most reliable measure of work load is the average number of treatments given per annum...*"[49] It was further explained that at Great Ormond Street:[50]

> "*The number of patients registered has increased from about 60 to 90 during the last 5 years, despite the referral of patients to adult hospitals (Royal Free Hospital or St Thomas' Hospital) on attaining the age of about 12-13 years. Although figures for the number of treatments in past years are not readily accessible, it can be confidently stated that the availability of cryoprecipitate has led to a very great increase in this respect during the last 2-3 years.*"

[45] DHSC0100026_011
[46] DHSC0100026_026
[47] DHSC0100026_026 p. 4
[48] DHSC0100026_026 p. 4
[49] DHSC0100026_026 pp. 2-3
[50] DHSC0100026_026 p. 6

27. At around the end of 1972, Professor Hardisty responded to a survey, for the attention of Dr Maycock of the Blood Products Laboratory, in which he indicated that there were 49 patients treated regularly.[51]

28. A list of Haemophilia Centres suggests that there were 45 patients with haemophilia A at GOSH in around 1975.[52]

29. An article published in the British Medical Journal in 1977 shows the spread of patients in the North-East Thames Region.[53] Table II shows the numbers of patients cared for at each centre and treated at home according to type of haemophilia and preparation. At GOSH, no patients with haemophilia A were treated at home with cryoprecipitate, 5 haemophilia A patients were treated at home with factor VIII concentrate, and 1 haemophilia B patient was treated at home with factor IX concentrate.[54] It was recorded that "*The Hospital for Sick Children, which cares for 33 of the region's haemophiliacs, also has extensive external commitments*".[55]

30. In the following years, the numbers of patients registered and/or treated at GOSH from the available evidence in the annual returns were as follows:

    a. 1976: The Annual Returns for 1976, signed by Prof Hardisty, record that the Centre treated 38 patients with haemophilia A and 12 patients with Christmas disease.[56] There were 38 registered patients with haemophilia A, 12 patients with Christmas disease, and 4 patients with von Willebrand's disease.[57]

    b. 1977: The Annual Returns for 1977, signed by Prof Hardisty, show that the Centre treated 40 patients with haemophilia A, including 1 patient with factor VIII antibodies, 10 patients with Christmas disease, and 4 patients with von Willebrand's disease.[58]

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[51] CBLA0008794
[52] OXUH0000863_002
[53] HSOC0022537
[54] HSOC0022537 p. 4
[55] HSOC0022537 p. 4
[56] HCDO0001077
[57] HCDO0001077
[58] HCDO0001160

c. 1978: The Annual Returns for 1978, signed by Prof Hardisty, indicate that the Centre treated 41 patients with haemophilia A, including 1 patient with factor VIII antibodies, 12 patients with Christmas disease, and 3 patients with von Willebrand's disease.[59]

d. 1979: The Annual Returns for 1979, signed by Prof Hardisty, show that the Centre treated 36 patients with haemophilia A, including 1 patient with factor VIII antibodies, 7 patients with Christmas disease, and 1 patient with von Willebrand's disease.[60]

e. 1980: The Annual Returns for 1980, signed by Prof Hardisty, indicate that the Centre treated 29 patients with haemophilia A, 2 patients with von Willebrand's disease, and 7 patients with haemophilia B.[61] There appear to have been around 87 registered patients with haemophilia A, 23 registered patients with haemophilia B, and 7 registered patients with von Willebrand's disease.

f. 1982: The Annual Returns for 1982, signed by Prof Hardisty, record that the Centre treated 43 patients with haemophilia A, 2 patients with von Willebrand's disease, 3 haemophilia A patients with factor VIII antibodies, and 5 haemophilia B patients.[62] There appear to have been around 94 registered patients with haemophilia A, 25 registered patients with haemophilia B, and 9 registered patients with von Willebrand's disease.[63]

g. 1983: The Annual Returns for 1983, signed by Prof Hardisty, show that the Centre treated 36 patients with haemophilia A, 2 haemophilia A patients with factor VIII antibodies, 2 patients with von Willebrand's disease, 4 patients with haemophilia B, and 1 carrier of haemophilia B.[64] There appear to have been around 80 registered patients with haemophilia A, 19 registered patients with

[59] HCDO0001257
[60] HCDO0001324
[61] HCDO0001421
[62] HCDO0001620
[63] HCDO0001620
[64] HCDO0001717

haemophilia B, 1 registered carrier of haemophilia B, and 9 registered patients with von Willebrand's disease.[65]

h. 1984: The Annual Returns for 1984, signed by Professor Hardisty, recorded that the Centre treated 37 patients with haemophilia A, 5 patients with von Willebrand's disease, 4 haemophilia A patients with factor VIII antibodies, 9 haemophilia B patients.[66] It appears there were around 79 registered patients with haemophilia 1, 16 registered patients with haemophilia B, 1 registered carrier of haemophilia B, and 9 registered patients with von Willebrand's disease.

i. 1985: The Annual Returns for 1985, signed by Professor Hardisty, show that 36 patients with haemophilia A, 3 patients with von Willebrand's disease, 5 haemophilia A patients with factor VIII antibodies, 2 haemophilia B patients were treated at the Centre.[67] There appear to have been around 80 registered patients with haemophilia A, 15 registered patients with haemophilia B, 1 registered carrier of haemophilia B, and 8 registered patients with von Willebrand's disease.[68]

j. 1986: The Annual Returns for 1986, signed by Professor Hardisty, indicate that 23 patients with haemophilia A, 4 haemophilia A patients with factor VIII antibodies, 3 von Willebrand's patients, and 5 patients with haemophilia B were treated at the Centre.[69] There appear to have been 78 registered patients with haemophilia A, 14 registered patients with haemophilia B, 1 registered carrier of haemophilia B, 9 registered patients with von Willebrand's disease, and 5 registered patients with platelet defects.[70]

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[65] HCDO0001717
[66] HCDO0001812
[67] HCDO0001905
[68] HCDO0001905
[69] HCDO0002001
[70] HCDO0002001. The annual returns for 1987 signed by Dr I Hann are at HCDO0002090. Further data from around 1996 is contained in HCDO0000277_009 which forms part of a report by the South East Institute of Public Health into Haemophilia Services in South Thames 1996: HCDO0000277_001

31. Data from GOSH was contributed by Prof Hardisty 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,[71] "*Haemophilia Treatment in the United Kingdom from 1969 to 1974*" by Rosemary Biggs,[72] and "*Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976-80*" by C R Rizza and Rosemary J D Spooner.[73]

Treatment policies and blood product usage

32. In response to a questionnaire for Dr Maycock, BPL, in late 1972, Professor Hardisty indicated the preferred treatment for patients with haemophilia was cryoprecipitate or freeze-dried concentrate.[74] He estimated that he required 930 single donor preparations of cryprecipitate annually for the present treatment policy or 1,700 bottles of concentrate.[75] The covering letter to the form dated 21 November 1972 explained that:[76]

> "*Our present usage of cryoprecipitate is not restricted by shortage/but is undoubtedly excessive, since we have to compensate for the low potency of the material we receive, (4-6 units per pack on average during the last few months). For this reason it would presumably be economical of material if we were to switch to Factor VIII concentrate, and I should certainly prefer the latter material for its significantly greater reliability. On the other hand, since we treat most of our haemophiliacs as outpatients, it is important that we should be able to administer replacement therapy by syringe rather than by drip; for this reason cryoprecipitate of reliable potency would presumably be preferred.to the Factor VIII concentrate supplied at present, since it could be given in a smaller volume. Ideally, I should certainly much prefer to be able to use concentrates with a higher potency than those at present made, and perhaps the yield in this case would not be significantly less than in the cryoprecipitate we are currently receiving.*"

[71] HCDO0000581
[72] PRSE0004645
[73] HCDO0000586
[74] CBLA0008794
[75] CBLA0008794
[76] CBLA0008794

33. In around 1974, Professor Hardisty signed a statement saying "*I agree that a British Standard for Factor VIII should be made available for use at Haemophilia Centres after supplies of the current 4th Standard are exhausted.*"[77] The context for the statement appears to be that, on 14 June 1974, Rosemary Biggs wrote to all Haemophilia Centre Directors warning that the National Institute for Biological Standards and Control would discontinue the preparation of a British Standard for VIII after the current 4th Standard. She expressed that "*We [Professor Blackburn and I] feel that a British Standard is essential for the efficient running of our Haemophilia Centres and that some attempt must be made to ensure that an alternative source of supply is available once the Institute ceases to prepare a Standard*".[78]

34. According to the available evidence in the annual returns, the blood products used by GOSH were as follows:

    a. 1976: To treat 38 patients with haemophilia A, the Centre used a variety of products, including 3,276 bottles / 229,320 units of cryoprecipitate, 1 bottle / 215 units of NHS factor VIII concentrate, 10 bottles / 3,309 units of Abbott Factor VIII (Profilate), 381 bottles / 95,222 units of Armour Factor VIII (Factorate), 1 bottle / 280 units of Cutters Factor VIII (Koate), 124 bottles / 32,638 units of Hyland Factor VIII (Hemofil), 435 bottles / 100,220 units of Immuno Factor VIII (Kryobulin).[79] To treat patients with Christmas disease, the Centre used 240 bottles / 162,293 units of NHS factor IX concentrate[80]. To treat 4 patients with von Willebrand's disease, the Centre used 333 bags of cryoprecipitate.[81]

    b. 1977: To treat 40 patients with haemophilia A, the Centre used 957 bags / 66,990 units of cryoprecpitate, 374 bottles / 67,626 units of NHS factor VIII concentrate, 294 bottles / 86,116 units of Armour Factor VIII (Factorate), 852 bottles / 22,3546 units of Cutters Factor VIII (Koate), 271 bottles / 102,108 units

[77] OXUH0003865_032
[78] OXUH0003865_053
[79] HCDO0001077
[80] HCDO0001077
[81] HCDO0001077

of Hyland Factor VIII (Hemofil), and 12 bottles / 6,032 units of Immuno Factor VIII (Kryobulin).[82] For home treatment of haemophilia A patients, the Centre used 30,436 units of NHS factor VIII, 67,100 units of Armour Factor VIII (Factorate), 166,618 units of Cutters Factor VIII (Koate), and 25,830 units of Hyland Factor VIII (Hemofil).[83] To treat 10 patients with Christmas disease, the Centre used 393 bottles / 235,800 units of NHS factor IX concentrate.[84] For home treatment of Christmas disease (haemophilia B) patients, the Centre used 100 bottles / 58,280 units of NHS factor IX concentrate.[85] To treat 4 patients with von Willebrand's disease, the Centre used 148 bags / 10,360 units of cryoprecipitate and 540 units of Cutters Factor VIII.[86] According to a letter 24 April dated 24 April 1978 from Dr Ardeman to Dr Lane setting out the amounts of Commercial Factor VIII used in the North West Thames Region during 1977,[87] GOSH used 457,744 units of commercial factor VIII.[88] This did not include amounts used for patients living in the North East Thames Region.

c. 1978: To treat 41 patients with haemophilia A, the Centre used 695 bags / 48,650 units of cryoprecipitate, 813 bottles / 173,765 units of NHS factor VIII concentrate, 1,870 bottles / 473,674 units of Armour Factor VIII (Factorate), and 75 bottles / 27,540 units of Cutters Factor VIII (Koate).[89] To treat 1 haemophilia A patient with factor VIII antibodies, the Centre used 1 bottle / 530 units of Cutters Factor VIII (Koate). It was noted that the patient was registered at Oxford and transferred there for further treatment. To treat 12 patients with Christmas disease, the Centre used 388 bottles / 193,211 units of NHS factor IX concentrate.[90] To treat 3 patients with von Willebrand's disease, the Centre used 80 bags of cryoprecipitate.[91]

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[82] HCDO0001160
[83] HCDO0001160
[84] HCDO0001160
[85] HCDO0001160
[86] HCDO0001160
[87] CBLA0000761
[88] CBLA0000761
[89] HCDO0001257
[90] HCDO0001257
[91] HCDO0001257

d. 1979: To treat 36 patients with haemophilia A, the Centre used 896 bags / 62,720 units of cryoprecipitate, 661 bottles / 159,675 units of NHS factor VIII, 1,811 bottles / 463,441 units of Armour Factor VIII (Factorate), 5 bottles / 1,590 units of Cutters Factor VIII (Koate), 180 bottles / 144,410 units of bovine/porcine factor VIII, and 43 bottles / 21,500 units of FEIBA.[92] Of that amount, 81 bottles / 18,080 units of NHS factor VIII, 43 bottles / 12,040 units of Armour Factor VIII (Factorate), 4 bottles / 1,060 units of Cutters Factor VIII, 180 bottles / 144,410 units of porcine factor VIII and 43 bottles / 21,500 units of FEIBA were used to treat 1 patient with factor VIII inhibitors.[93] To treat 7 patients with Christmas disease, the Centre used 222 bottles / 136,259 units of NHS factor IX concentrate.[94] To treat 1 patient with von Willebrand's disease, the Centre used 164 bags / approximately 1640 units of cryoprecipitate, and 4 bottles / 900 units of NHS factor VIII (Elstree).[95]

e. 1980: To treat haemophilia A patients in hospital, the Centre used 327 bags / 22,890 units of cryoprecipitate, 17,668 units of NHS factor VIII, 18,134 units of Armour Factor VIII (Factorate), and 9,164 units of Immuno Factor VIII (Kryobulin). For home treatment of haemophilia A patients, the Centre used 111,251 units of NHS factor VIII, 414,192 units of Armour Factor VIII (Factorate) and 107,713 units of Immuno Factor VIII (Kryobulin). To treat 2 patients with von Willebrand's disease in hospital, the Centre used 75 bags of cryoprecipitate.[96] To treat 7 patients with haemophilia B, it appears that the Centre used around 64,495 units of NHS factor IX in hospital and 58,155 units of NHS factor IX for home treatment.[97]

f. 1982: To treat haemophilia A patients in hospital, the Centre used 266 packs / 18,620 units of cryoprecipitate, 95,158 units of NHS factor VIII, and 415,145 units of Armour Factor VIII (Factorate). For home treatment of haemophilia A patients, the Centre used around 110,190 units of NHS factor VIII, 924,719

[92] HCDO0001324
[93] HCDO0001324
[94] HCDO0001324
[95] HCDO0001324
[96] HCDO0001421
[97] HCDO0001421

units of Armour Factor VIII (Factorate) and 35,599 units of Hyland Factor VIII (Hemofil). For 3 haemophilia A patients factor VIII antibodies, the Centre used 2 bottles / 430 units of NHS factor VIII and 75 bottles / 15,435 units of Armour Factor VIII (Factorate). To treat 2 patients with von Willebrand's disease in hospital, the Centre used 41 packs / 2,870 units of cryoprecipitate and 17,780 units of NHS factor VIII.[98] To treat 5 patients with haemophilia B, the Centre used 4,910 units of NHS factor IX concentrate in hospital, and 90,410 units of NHS factor IX for home treatment.[99]

g. 1983: To treat haemophilia A patients in hospital, the Centre used 246 packs / 17,220 units of cryoprecipitate, 590 bottles / 143,672 units of NHS factor VIII, and 299 bottles / 63,355 units of Armour Factor VIII (Factorate). To treat haemophilia A patients at home, the Centre used 274,795 units of NHS factor VIII, 353,160 units of Armour Factor VIII (Factorate), 33,120 units of Cutters Factor VIII (Koate).[100] For 2 haemophilia A patients with factor VIII antibodies, the Centre used 37 bottles / 8,050 units of Armour Factor VIII (Factorate). To treat 2 patients with von Willebrand's disease in hospital, the Centre used 65 packs / 4,550 units of cryoprecipitate.[101] For haemophilia B patients, the Centre used 37,037 units of NHS factor IX in hospital, and 101,860 units of NHS Factor IX for home treatment.[102] To treat 1 carrier of haemophilia B, the Centre used 5,950 units of NHS factor IX.[103]

h. 1984: To treat haemophilia A patients in hospital, the Centre used approximately 710 bags of cryoprecipitate and 107,141 units of NHS factor VIII. For home treatment of haemophilia A patients, the Centre used 322,925 units of NHS factor VIII, 52,500 units of Armour Factor VIII (Factorate), and 22,770 units of Cutters Factor VIII (Koate). It is noted in manuscript that 9,600 units of Armour Heat-Treated was also used.[104] To treat 5 patients with von

[98] HCDO0001620
[99] HCDO0001620
[100] HCDO0001717
[101] HCDO0001717
[102] HCDO0001717
[103] HCDO0001717
[104] HCDO0001812

Willebrand's disease in hospital, the Centre used 39 bags of cryoprecipitate.[105] For 4 haemophilia A patients with factor VIII antibodies, the Centre used 26 bags of cryoprecipitate, 20,250 units of NHS factor VIII, and 2,400 units of Armour Heat Treated. To treat 9 patients with haemophilia B on home treatment, the Centre used 64,600 units of NHS factor IX concentrate.[106]

i. 1985: To treat haemophilia A patients in hospital, the Centre used 220 packs / 15,400 units of cryoprecipitate, 116,045 units of NHS factor VIII, 43,465 units of Armour Factor VIII (Factorate)and 12,825 units of porcine factor VIII (Hyate C). For home treatment of haemophilia A patients, the Centre used 386,725 units of NHS factor VIII, and 180,000 units of Armour Factor VIII (Factorate).[107] Specifically, to treat 5 haemophilia A patients with factor VIII antibodies, the Centre used 28,735 units of NHS factor VIII, 6,460 units of Armour Factor VIII, 12,825 units of porcine factor VIII, and 55,860 units of Profiline Factor IX.[108] To treat 3 patients with von Willebrand's disease in hospital, the Centre used 148 packs / 10,360 units of cryoprecipitate.[109] To treat 2 patients with haemophilia B at home, the Centre used 37,660 units of NHS factor IX and 24,840 units of commercial factor IX (Profiline).[110] A list of haemophiliacs treated within NWT RHA with NHS heat-treated factor VIII in April 1985 lists 5 patients under the care of Professor Hardisty at GOSH.[111]

j. 1986: To treat haemophilia A patients in hospital, the Centre used 3 bags of cryoprecipitate, and 151,470 units of NHS factor VIII. For home treatment of haemophilia A patients, the Centre used 540,990 units of NHS factor VIII and 14,800 units of Armour Factor VIII (Factorate).[112] To treat 4 haemophilia A patients with factor VIII antibodies, the Centre used 22,180 units of NHS factor VIII, 71,480 units of NHS factor IX, and 16,620 units of commercial factor IX (Profiline) in hospital. For home treatment of haemophilia A patient with factor

[105] HCDO0001812
[106] HCDO0001812
[107] HCDO0001905
[108] HCDO0001905
[109] HCDO0001905
[110] HCDO0001905
[111] BPLL0010517_002
[112] HCDO0002001

VIII antibodies, the Centre used 13,965 units of NHS factor VIII and 14,355 units of NHS factor IX.[113] To treat 5 patients with haemophilia B, the Centre used 170,530 units of NHS factor IX for home treatment.[114] No products were used to treat haemophilia B patients in hospital. By letter dated 15 April 1987, R J D Spooner raised a few queries regarding the Annual Returns for 1986.[115]

35. According to a survey by the Haemophilia Society in 1986, the majority of severely affected patients were dealt with by nurses at 19 centres including the Hospital for Sick Children, London.[116] More than 20% of severely affected patients had seen a physiotherapist at the Hospital for Sick Children, London.[117] More than 75% of severely affected patients were on home therapy at 20 centres including the Hospital for Sick Children.[118]

36. The Inquiry has received several written statements from individuals and/or their family members who were treated at GOSH, for example, Mark Ward, who was diagnosed with severe haemophilia A at GOSH when he was a child;[119] an anonymous witness with severe haemophilia A;[120] Amanda Patton, whose brother, Simon Cummings, was diagnosed with severe haemophilia as a toddler and treated at GOSH;[121] Della Ryness-Hirsch, whose late twin son Nicholas (Nick) was treated at GOSH,[122] and Amanda Beesley, whose late husband Andrew Beesley was referred to GOSH.[123]

37. Mr Ward was treated at GOSH between 1972 and 1983.[124] He stated that he "*spent more time in the hospital or in the back of an ambulance*"[125] than he did at home. He suffered from nosebleeds and almost bled to death on a number of occasions, and

[113] HCDO0002001
[114] HCDO0002001
[115] HCDO0000374_004
[116] HCDO0000276_032 p. 9 para 6.5
[117] HCDO0000276_032 p. 10 para 6.8
[118] HCDO0000276_032 p. 10-11 para 6.10
[119] WITN1591001 and WITN1591002. Mr Ward gave oral evidence to the Inquiry with Mr Richard Nicholas Dudley-Smith on 17 October 2019 [INQY1000043].
[120] WITN0125001
[121] WITN0042001 para 4
[122] WITN0282001. Mrs Ryness-Hirsch gave oral evidence to the Inquiry on 9 May 2019 [INQY1000007]
[123] WITN1090001. Mrs Beesley gave oral evidence to the Inquiry on 16 October 2019 [INQY1000042]
[124] WITN1591001 para 4
[125] WITN1591001 para 4

describe "*some really dark times*".[126] He described that "*Staying in GOSH as an inpatient, I often woke up to find another child had died in the night*".[127]

38. Regarding his treatment at GOSH, Mr Ward explained, "*Whenever I went to GOSH with a bleed they tried all manner of different things on my arm to improve it. They would trial all different methods and equipment, treating me as a guinea pig*".[128] When asked in oral evidence "*Do you know which Factor VIII products you received?*", Mr Ward replied:[129]

> "*A. Oh, anything that was going. Probably scraped it off the road, I don't know. It was all the suspects we've seen, the Alpha, you know, the normal ones, the Armour.*
> *Q. So your understanding is you received the commercial pharmaceutical company products. We know at one stage, and we will come on to that, you received Scottish NHS product. As far as you know, did you also receive the BPL Factor VIII, the Lister product?*
> *A. Yes…*"

39. Mr Ward explained that, in 1983, "*it was decided by GOSH that I needed a knee operation*".[130] His care was then transferred to the Royal Free Hospital where he received Scottish Factor VIII and diagnosed with HIV.[131]

40. Ms Patton's brother, Mr Cummings, spent a lot of his childhood at GOSH where he was initially treated with whole blood, which was later replaced with cryoprecipitate.[132] Ms Patton recalled that there were no creche facilities or separate rooms for other children and siblings so she would be with her brother when he had these transfusions.[133] Mr Cumming's haemophilia care later transferred from GOSH to St

[126] WITN1591001 para 8
[127] WITN1591001 para 9
[128] WITN1591001 para 14
[129] INQY1000043 p. 61
[130] WITN1591001 para 16
[131] WITN1591001 para 17
[132] WITN0042001 para 5
[133] WITN0042001 para 5

Thomas' hospital, and he was also treated at the Bristol Royal Infirmary, Churchill Hospital in Oxford, Treloar's College, and Basingstoke Hospital.[134]

41. Mrs Beesley's late husband, Andrew Beesley, was diagnosed with severe haemophilia A in or about February 1969 following a referral by his GP to Great Ormond Street.[135] Mr Beesley was given both cryoprecipitate and factor VIII blood products.[136] His notes record that in August 1972, his treating physicians at GOSH suggested that he be temporarily treated prophylactically with cryoprecipitate two or three times per week by his GP or at Mr Beesley's local hospital in Crawley.[137] The notes from GOSH record that Andrew's GP was willing to try giving him the prophylactic treatment and that his mother was also learning how to give injections with home treatment to start in September.[138] On 25 September 1980, Dr Gorman at GOSH confirmed that Mr Beesley had been using "*dried Factor VIII concentrate rather the Cryoprecipitate and we should by [sic] happy if he is trained in one of these concentrates*".[139]

42. An anonymous witness treated at GOSH obtained his records showing all the treatments he received including cryoprecipitate and British factor VIII concentrate.[140] He narrowed down the source of his infection to treatment with factor VIII concentrate in either 1984 or 1985.[141] He started home treatment in 1984.[142] He believed that the factor VIII which infected him with HIV was administered by his mum from a batch they had in the fridge at home.[143]

43. Mrs Ryness-Hirsch's son, Nick, was transferred to GOSH in the summer of 1976. In her statement, Mrs Ryness-Hirsch thought "*GOSH was the best children's hospital in*

[134] WITN0042001 paras 6, 20, 23 and 27
[135] WITN1090001 para 6
[136] WITN1090001 para 6, WITN1090003
[137] WITN1090001 para 9, WITN1090004
[138] WITN1090001 para 10, WITN1090005
[139] WITN1090001 para 24, WITN1090016
[140] WITN0125001 para 8
[141] WITN0125001 para 9
[142] WITN0125001 para 11
[143] WITN0125001 para 12

the world".[144] She stated that they met a young doctor, Dr Colin Sieff, "*who explained haemophilia to us*".[145] She stated that:

> "*Dr Sieff explained Nick's haemophilia and we thought we'd just have to deal with it. We were given enough information at the time but we didn't really understand the implications then. It was Dr Sieff who informed us about the Haemophilia Society.*"[146]

44. Mrs Ryness-Hirsch described an incident in the summer of 1976 when a deck chair collapsed "*and hit Nick on his face causing quite a bruise*".[147] She stated that they "*rushed off to Great Ormond Street*" where they "*gave him his first injection*".[148] Mrs Ryness-Hirst described that "*It was an intravenous injection and Nick screamed the place down*".[149] Mrs Ryness-Hirst later requested information about the provenance of products being used to treat Nick. She explained in her written statement:[150]

> "*I asked at GOSH during a routine visit if Nick was receiving any American treatments and was clearly told "No" and that his treatment came from Cryoprecipitate. I asked Dr Sieff about Factor products and he said it was a new form of treatment that would revolutionise how haemophiliacs were treated but that all the children would be moved onto it when they reached the age of 4. I told him then and later that we would not want Nick to receive American products.*
>
> *I told Dr Sieff I'd lived in America and didn't think I'd like US blood regardless of whether it was treated or screened. In the US people can sell their blood, so blood is collected from drug addicts and we heard later, even from prisoners. My friend sent me articles, which I just gave to the doctors at GOSH.*

[144] WITN0282001 para 9
[145] WITN0282001 para 9
[146] WITN0282001 para 10
[147] WITN0282001 para 12
[148] WITN0282001 para 13
[149] WITN0282001 para 13
[150] WITN0282001 paras 20-24

Unfortunately I didn't photocopy them. I now know this was an error, but it didn't occur to me at the time.

By the time GOSH came to change Nick's treatment from cryoprecipitate to Factor products treatment there was nothing in the papers about contaminated blood (although since that time, I have seen reports and evidence that it was well known at that time that the treatment was contaminated). On the day that Dan and I were told by Nick's doctors that his treatment would switch to "Factor VIII treatment" (around about 1980), I informed them that I would not allow him to be given this treatment.

I kicked up bloody murder. I told the medics to keep Nick on Cryoprecipitate and was told that there was not enough available. I was told that there was some cryoprecipitate in Elstree but the supply was not sufficient.

Dr Sieff assured me that any factor products given to Nick were perfectly safe and were coming from UK donors. Eventually we had no choice and had to agree to Nick receiving Elstree only Factor VIII instead of Cryoprecipitate. Apparently, there just wasn't the availability of Cryoprecipitate and Nick needed treating. The first dose was administered on 3 November 1980 following an injury to Nick's right knee. He was administered 280 units..."

45. On 21 January 1985, Mrs Ryness-Hirst read an article in the Guardian newspaper titled "*AIDS and a caring society*".[151] She stated that she was so concerned that she wrote a letter to the paper explaining her family issues and the problem with American Factor products.[152] She was worried about identifying Nick so the letter was published on 23 January under her sister-in-law's name.[153]

46. Mrs Ryness-Hirst then received a phone call from Professor Hardisty at GOSH requesting that she and Dan come for a meeting.[154] She stated that, at the meeting, she

[151] WITN0282001 para 28. WITN028010
[152] WITN0282011
[153] WITN0282012
[154] WITN0282001 para 29-34

was scolded by Professor Hardisty and was told that all the children in the GOSH blood unit had been tested and "*Nick was the only one that had not showed signs of the HIV virus*".[155] She added that, "*We had never been asked for permission to test and as the testing had been done some months earlier, they certainly had not asked us and then in the event of the results – not informed us*".[156]

47. Mrs Ryness-Hirsch then described the discussion for Nick's future treatment:

> "*A discussion ensued about how to continue to treat Nick Professor Hardisty told us that new heat treated products would be available some months further and asked if we wished Nick to come into GOSH to basically stay on a ward and in bed until that happened (to protect against bleeds). We thought that not feasible and I asked to think about it overnight. By the morning I had realised that we knew (since Nick had no HIV virus as shown by the test) that all the batches we had had from Elstree where some treatment was left in the bottle (this happened regularly as doses were calculated by weight of the person being treated and sometimes there would be half a bottle here and there returned unused.*
>
> *I wondered whether since we all knew that all the 'left overs' would be virus free (because they had tested Nick and he was negative) if Elstree would have retained these 'ends of bottles'. It turned out they had (or so we were told) and this treatment was returned to us and was sufficient for Nick to use until he went on to heat-treatment in the January as Prof Hardisty had told us.*"[157]

48. Regarding Nick's treatment, Mrs Ryness-Hirsch confirmed:

> "*Nick only ever had Elstree treatment. Great Ormond Street kept him on cryoprecipitate until November 1980 when he went onto NHS Factor products. The Royal Free agreed he would only have Elstree treatments...*"[158]

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[155] WITN0282001 para 29-34
[156] WITN0282001 para 29-34
[157] WITN0282001 para 29-34
[158] WITN0282001 para 42

49. Following their meeting Professor Hardisty then wrote a reply to the 23 January letter which was published on 31 January 1985.[159] An earlier draft of the proposed letter was sent to Dr Lane at BPL on 25 January 1985.[160] Mrs Ryness-Hirsch described:

> "*I felt his published response was somewhat disparaging of Dan and I as parents. As a result I wrote to Professor Hardisty directly on 4 February 1985 putting him right as to the reason for my original letter to the Guardian (WITN0282014). After this we always felt the relationship between our family and GOSH staff was difficult*".

50. Mrs Ryness-Hirsch described difficulties in obtaining Nick's medical notes when his treatment transferred from GOSH to the Royal Free Hospital.[161]

51. Dr Ball was not involved in the decision-making process as to which products to use but described which products were used at GOSH during her time:[162]

> "*9. I was not involved in the decision-making process or choice of product at GOSH but we used heat treated concentrate, including 8Y and porcine derived products as well as cryoprecipitate and DDAVP based on the recommendations and availability of products at the time. Other blood products were supplied from regional BTS according to standardised protocols and availability, screened in accordance with National policies*"

52. Dr Ball explained:[163]

> "*17. The choice of alternatives was a national recommendation communicated to all heads of departments at a time when I was in training at GOSH and Dr Simpson and I were instructed by Prof Hardisty to follow this recommendation*

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[159] WITN0282013 / MDIA0000039. Professor Hardisty had also written to The Sun by letter dated 9 April 1975 regarding an article concerning another patient: CBLA0012748
[160] BPLL0004754
[161] WITN0282001 paras 35-37
[162] WITN4739001para 9
[163] WITN4739001 para 17

to the letter. Any deviation from his recommendation had to be discussed with him beforehand and only he could authorise any deviation from the protocol. To my knowledge this never occurred. He was also an expert in coagulation and platelet disorders and actively involved in the elucidation of different forms of Von Willebrands disease so his knowledge and teaching of the use of DDAVP in selected cases of haemophilia and platelet aggregation disorders was very cutting edge at the time. I had a very good working relationship with Prof Hardisty and his successor Prof Ian Hann and they were invaluable sources of support."

53. Regarding the policy for home treatment, Dr Ball stated:[164]

"*Home treatment was the standard aim at GOSH and teaching of parents and children was established by the haemophilia sister assigned to the unit. I cannot recollect what proportion of children were successfully assigned to home treatment programmes*."

54. Regarding the treatment of mild or moderate haemophilia, Dr Ball stated:[165]

"*At GOSH, mild or moderate haemophilia would have been treated according to the severity and clinical indications as previously discussed, in line with the recommendations at that time. I cannot comment on what decisions were made in relation to treatment prior to my tenure or subsequent to my departure.*"

55. Dr Ian Hann appears to have been more actively involved in the selection of blood products for patients. His written statement at para 24 explains:[166]

"*During my 20 years at GOSH our policy was always to use British pathogen – treated products initially and when they were available. However, within a relatively short time we were able to take part in pioneering studies with the new and inherently safer recombinant products. Thereafter we were able to*

[164] WITN4739001 para 18
[165] WITN4739001 para 20
[166] WITN3497005

institute recombinant concentrate prophylaxis for all eligible patients, as one of the first places in the world to achieve this comprehensive approach. Our aim was to reduce spontaneous bleeds to less than one per year in non- inhibitor patients, and we achieved that high bar."

56. Dr Hann further described in detail his relationship with pharmaceutical companies supplying blood products in his written statement at paras 131-140:[167]

"*131.During my time at the RHSC and GOSH I met infrequently with representatives of all blood product Pharma companies including Bayer, Centeon, Novo-Nordisk, Pfizer, and Baxter. This was for the purpose of exchanging information within ABPI (Association of the British Pharmaceutical Industry) rules with regard to progress being made with therapies, timescales etc. In particular, we needed to inform them of what was required and we needed to know about vital developments such as pathogen reduction modalities, their efficacy and safety, progress with development, supply and trials with recombinant products, and longer lasting factor concentrates. I did not provide consultancy services in any other way.*

132. Prior to my retirement from clinical medicine I did not receive any pecuniary gain from blood product companies. Following my departure in 2006, I worked as Medical Head of Haematology for Bayer UK for four years and was salaried throughout from that source. My role was to assist with development of longer acting factor concentrates, develop antifibrinolytic compounds and develop one of the new oral anticoagulant drugs.

133. At some stage after the development of recombinant products, Bayer set up an International Board which I think was called the Paediatric Haematology Network or 'PedNet', Membership involved Paediatric Comprehensive Care Centre Directors from around Europe and Scandinavia. Other than sponsorship to attend the international venues my memory is that we did not receive honoraria for such attendances, although I am not certain on this point. Such

[167] WITN3497005

payment would not in any case have breached ABPI guidelines. The meeting carried on until I stepped down as Director and my successor took over. It was a highly successful and vital scientific support to paediatricians who often are not involved in the adult treaters communications and experiences, which are in any case different.

134. I have never received financial incentives to use blood products.

135.I have never been offered, and neither did I ever take, non-financial incentives to use certain blood products

136. I have never received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from Pharma whilst I was in clinical medicine.

137. I always was aware of the ABPI guidelines and the GMC (General Medical Council) guidance on the subject of involvement with Pharma. I always complied and was never the subject of a complaint to either body.

138. I was not involved with Pharma blood product studies at the RHSC. We began recombinant factor studies as soon as the products became available to GOSH. Initially this was with Bayer and subsequently with Pfizer and Baxter as products became available. These were approved by the Ethics Committee, the R & D Office and with fully informed consent.

139.Vide supra – The trials performed were regulatory in nature and thus the anonymised data was collected by the companies for presentation to the regulators.

140.Any funding through trials at GOSH was monitored and approved by the R & D Office (jointly GOSH and ICH) and the office of the CEO via the clinical directorships; the latter because of other potential resource implications and the potential to be locked-in to ongoing costs once the product was marketed."

57. It appears from correspondence that Professor Hardisty also met with pharmaceutical representatives, including Linda A Frith, Sales Development Manager to Professor Hardisty, "*to discuss Koate HT, Factor VIII concentrates and Gamimune, intravenous gamma globulin*".[168] Ms Frith stated, "*The price of Koate HT is 12 pence per International Unit. I would be pleased to supply you with Koate HT for any of your boys that do not tolerate other products*."

58. Dr Ian Hann confirmed that some patients were entered into clinical trials of new products including 'previously untreated patients' (PUPS). He stated in his written statement at paragraph 94:[169]

> *"At GOSH, many of our newly diagnosed PUP's were entered into trials of the new recombinant products, which proved a Godsend."*

59. A memo from J K Smith to Marnie Quinn, Commercial Department at BPL dated 18 March 1991 suggests that a clinical trial of 8Y was carried out involving children at GOSH. It states:[170]

> "*In 1985, BPL adopted (without publicising it) the policy of ensuring the limited supply of 8Y would go first to HIV-negative and previously untreated patients. Many of these were children attending Haemophilia Centres at Great Ormond Street and Birmingham Children's hospital. These children were invaluable to BPL's clinical proof that 8Y does not transmit HIV or hepatitis...*
>
> *Supplies to these two hospitals, and to other centres with patients in the first trial, were guaranteed by delivery via PFL, which was given this allocation "for support of clinical trial". When it became clear that someone would have to pay for the product, both centres (Dr Hann and Dr Mill) wished to continue the arrangement, on the understanding that BPL would "transfer charge" their RHA. That is what my "Transfer" stamp means.*

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[168] BAYP0000007_104
[169] WITN3497005
[170] BPLL0006105

When supplies of 8Y became adequate in about 1990, I asked again whether they wished to revert to assured direct supplies from BPL, and they preferred that the existing system should not be disturbed until they let me know positively...

As you will appreciate, these understandings have not been documented but I will do my best to recall distant events if controversy threatens..."

60. However, Dr Hann had no recollection of a clinical trial for 8Y domestic concentrate.[171]

Knowledge of risk of hepatitis/HIV and response to risk

61. Professor Hardisty was a regular attendee at UKCHDO meetings, including on 5 April 1971,[172] 27 October 1972,[173] 31 January 1974,[174] 18 September 1975,[175] 13 January 1977,[176] 24 October 1977,[177] 20-21 November 1979,[178] 13 September 1982,[179] 17 October 1983,[180] 17 March 1986,[181] and 9 October 1986.[182]

62. He also sent his apologies on occasions, including on 1 October 1968,[183] 1 November 1974,[184] and 30 September 1980.[185] On other occasions, he was represented by a colleague at GOSH, including at the UKCHDO meetings on:

    a. 13 November 1978, Prof Hardisty was represented by Dr C A Sieff;[186]
    b. 9 October 1981, Prof Hardisty was represented by Dr Una O'Callaghan;[187]

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[171] WITN3497005 para 95
[172] HCDO0001014
[173] HCDO0001015
[174] CBLA0000187
[175] OXUH0003735
[176] PRSE0002268
[177] PRSE0001002
[178] CBLA0001028
[179] CBLA0001619
[180] PRSE0004440
[181] PRSE0001688
[182] PRSE0004317
[183] HCDO0001013
[184] HCDO0001017
[185] PRSE0003946
[186] HSOC0010549
[187] DHSC0002339_048 and CBLA0001464

c. 21 October 1985, Prof Hardisty was represented by Dr Jane Evans;[188]

d. 25 September 1987, Prof Hardisty was represented by Dr I M Hann.[189]

63. As described above, Mrs Ryness-Hirsch stated that she raised the issue of the risk of imported factor concentrates with Professor Hardisty at GOSH in the early 1980s but felt that her concerns were not taken seriously. At paragraph 89 of her written statement, she said:[190]

> "*…the more I tried to inform GOSH of the dangers of American products the worse our relationship with the medical staff became. This was in terms of the way they were insisting on treating Nick with products that we felt were detrimental to his health. GOSH failed to take my concerns serious about the products being given to haemophiliacs. As far as the American newspaper articles, which I had been sharing with the unit were concerned, these products were not free from contamination and when I questioned their processes we were subjected to unjustified criticism by the head of the Haemophilia Centre.*"

64. Mr Ward gave evidence that no warnings were given to his mother about the possible risk of infection to her:[191]

> "*Nobody ever warned my mother about the possible risks of infections to her. With a really bad nosebleed mum would be drenched in my blood. If I was in bed, the bath, etc she came into contact with my blood whilst helping me to clean it up. We did not realise that I was a risk to her and no one warned her that I was. This was not only reckless but they were playing with my parents' lives as much as they were with mine and it is a miracle that she was never infected.*"

65. In September 1986, in response to another patient's mother expressing concern about receiving commercial factor concentrates, Professor Hardisty wrote to Dr Aronstam at

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[188] PRSE0001638
[189] HCDO0000485
[190] WITN0282001
[191] WITN1591001 para 26

Treloar's, expressing his view that, by that time, there was no difference between commercial and NHS concentrate:[192]

> "*His mother, who is an extremely anxious lady, rang up recently to say that you were treating him with commercial Factor VIII concentrate and asked whether he might instead continue on 8Y material, which he has previously been receiving from us. I did my best to convince her that there is nothing to choose between commercial and NHS concentrate now that both are obtained from screened donors and subjected to heat treatment (though I was not able to refer specifically to the material you use since I do not know what it is). Although Mrs [redacted] said that you would treat [redacted] with 8Y if we provided it, I frankly do not think that this is indicated nor indeed should we find it easy to provide you with sufficient from our current allocation.*
>
> *This letter is therefore really just to let you know that I have told Mrs [redacted] that she should rely entirely on the treatment you provide…*"

66. Professor Aronstam replied to Professor Hardisty by letter dated 19 September 1986 confirming that he "*certainly agree[d] with your own view that all concentrates are now equally safe.*"[193]

67. Regarding the risks of hepatitis and HIV, Dr Lynne Ball stated in her written statement that:[194]

> "*25. When I began work at GOSH, I was aware of the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products as previously described. That is why all children were offered routine vaccination against hepatitis B at GOSH as well as staff regularly handling blood products. Children with haemophilia were also regularly monitored for infections at six monthly intervals. This was not*

[192] TREL0000120_044
[193] TREL0000120_042
[194] WITN4739001

undertaken at Alder Hey but was one of the protocols that I as Haemophilia Director introduced as well as vaccination to reduce the risk of hepatitis B

26. I was aware of the acute and chronic nature of hepatitis B and non A non B hepatitis but until reliable serological determination and treatment options were available for hepatitis C only supportive care could be offered…

27. I think the processes at GOSH were consistent with the knowledge base and recommendations at the time but the standard of care at Alder Hey up to my appointment in relation to the overall care of children with haemophilia fell below the standards I had experienced during my tenure at GOSH. I think nationally there was no self-sufficiency of blood products that left physicians no choice other than to use imported commercial concentrates. Prior to the recognition of severe viral complications these had been life transforming for patients. Many mothers I met and listened to who had experienced brothers with severe debilitating haemophilia and had chosen to have children based on the relatively "normal" life injection of factor concentrates allowed. Hepatitis B vaccinations at GOSH and this was introduced as standard of care at Alder Hey from 1989.

28. Initially there was a general consensus that HIV was the most life-threatening risk to patients with haemophilia treated in the 1970/1980's and that effective vaccination against hep B was sufficient to protect against the worse risk of hepatitis. The liver dysfunction associated with chronic hepatitis C I feel was initially underestimated in light of the urgency of the HIV problems but was later recognised as yet another blood borne disease that would have life altering consequences in long-term survivors of recipients of contaminated blood and blood products. All efforts were made to screen donors and patients, but the early antibody tests were unreliable. As with HIV, once reliable testing became available this was offered to patients but the natural history of the infection, especially in children surviving to adulthood, would take time to manifest and there were no national or international studies to determine interventions which might prevent or ameliorate the worst of hepatic dysfunction at the time I was in charge of the haemophilia care.

30. No action I could have individually taken would have prevented the transmission of HIV from contaminated blood products as I was not in any consequential position when these were introduced. I cannot comment on hep C as I am not aware if any new patients developed hep C as a result of contaminated blood products after I was appointed to Alder Hey. Again, most of the boys I treated after 1989 had already received numerous doses of factor concentrate. I established good medical practice standards of care following the recommendation at the time and with the product availability at the time. My positions both at GOSH and Alder Hey were ones of caring for the consequences of previous treatments and trying to improve services directed at the care for children and families with haemophilia and life-threatening infection. This also required not only direct medical care but psycho-social support in a time when nationwide fear and stigmatisation were rampant and supportive care requirements were sadly lacking.

31. When I chose to specialise in paediatric haemato-oncology there was no recognised training programme and very few specialists who had completed any form of specialist attachments which gave insights into the care of children with haemophilia. HIV was a new and relatively unknown infection as was hepatitis C and as such there was also a lack of awareness as to the clinical trajectory of infections in these children. At GOSH, Prof Hardisty had developed a unit striving to provide the recognised high standard of care but even he was unable to prevent the unpreventable in children requiring massive doses of life saving factor 8 as this was HIV contaminated at source. Alder Hey failed because there was insufficient staffing and attention to detail by those charged with the care of these patients…"

68. Dr Hann described his knowledge and response to risk whilst GOSH in his written statement at para 30:[195]

"*From 1987 until 2006 at GOSH the risks and benefits of therapies and pathogen reduction measures developed apace. It was always my goal, and that*

[195] WITN3497005

of all other treaters, to be able to manage our patients with recombinant products with no risk of TTI. The understanding of Hepatitis C (Hep C) risk developed rapidly after 1990 and thankfully by then we had concentrates shown at last to be effectively treated for pathogen reduction, plus the development of recombinant products. It became clear that Hep C was a chronic serious disease which required major therapeutic intervention, but initially the drug therapies were very limited and largely ineffective."

69. It does not appear that Professor Hardisty contributed to the Glasgow Symposium on "*Unresolved problems in Haemophilia*" in 1980,[196] or the Manchester Symposium on *"Current Topics in Haemophilia*" in 1982.[197] On 27 April 1989, a national symposium on "*Paediatric HIV Infection*" was held at the Royal College of Physicians and Surgeons in Glasgow by the Haemophilia Society and GOSH, attended by Dr Lynne Ball.[198]

Testing patients for HTLVIII and informing them of diagnosis

70. Mrs Ryness-Hirsch believed that her son Nick was tested for HIV without his knowledge or consent. Her written statement at paras 44-45 provides:

> "*I now believe Nick was being tested at GOSH for both HIV and Hepatitis. I new they were taking blood samples but we thought they were just routine samples to check his haemophilia levels. We didn't know they suspected he could have been infected with something so serious and weren't telling us. To be honest had they bothered to ask us we would have agreed but we were just not consulted.*
>
> *After we had the argument with Professor Hardisty at GOSH I remember he told us directly that they had tested all the boys on the unit for HIV and only Nick had come back negative. This was the only time we were informed of any*

[196] RLIT0001242
[197] DHSC0002221_003
[198] RHAL0000111

testing being conducted, it was in the heat of an argument so we didn't really take it in…"

71. An anonymous witness also described being tested for HIV at GOSH although he was not aware of it at the time:[199]

> "*I have obtained my records showing when I was tested for HIV from the UK Haemophilia Centre Doctors Organisation's National Haemophilia Database (the "Database") [WITN0125002]. These records show that I was tested on 15 December 1984 and that this was my last negative test result. I was tested again on 30 September 1985; this was the date I first tested positive for HIV. I don't know about my brothers being tested. They probably were, but I cannot confirm this. My parents were not aware of me being tested for HIV. They are aware of another patient at GOSH who was diagnosed with HIV at the same time as me, suggesting there was systematic testing of patients going on at the time.*"

72. The anonymous witness's parents were contacted by telephone and asked to come into the hospital:[200]

> "*I understand from them that my parents received a phone call from someone at the hospital asking them to come and see them. They said that there was an issue with one of our results. My dad was working away in Liverpool and flew straight back down to London. My mum has said that she knew immediately that this issue would be with my result, as my glands were often swollen as a child. They were informed at the hospital. I was not present.*
>
> *When I was diagnosed my parents were told that I would be lucky to see my tenth birthday…"*

73. The witness also described learning of his HIV diagnosis:[201]

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[199] WITN0125001 para 7
[200] WITN0125001 paras 18-19
[201] WITN0125001 paras 21-23

"*21. In the summer of 1993, before I started secondary school, I went to GOSH for a haemophilia check-up. It was not uncommon for us to have our check-ups in the school holidays to avoid us taking time off from school. On this occasion my dad also came with us to the hospital. This was unusual as he did not generally attend our appointments.*

22. [redacted] was with us and he and I were left in the waiting room with my dad while my mum disappeared. I was then taken into a room with my parents and [redacted] Di Gibb, one of my doctors, was there with my nurse Kate Khair. That is when they told me I was HIV positive.

23. By the age of 12 when I was told, I knew a bit about HIV as it had been in the news. The people I saw on television were always really ill. Hearing that I was infected with HIV was devastating. I broke down in tears. When I composed myself the first thing I said was "Am I going to die?" for a 12-year-old boy, that was a pretty big thing to face."

74. The witness also added:[202]

"*After I was aware that I was HIV positive I saw my hospital notes from GOSH when I was collecting them to take them to an appointment. Inside they stated "HIV PATIENT UNAWARE" and this was highlighted and marked so it could not be missed. This was probably a year or two after my being told.*"

75. The witness felt that he had been supported when he was told of his diagnosis and described the information that he was provided with:[203]

"*27. My parents had discussed how to tell me of my diagnosis with the hospital and I felt very supported on the day I was told. Afterwards, I just had to get on with it.*

[202] WITN0125001 para 26
[203] WITN0125001 para 27-28

28. I was never told what I could or couldn't do as a result of being infected by HIV. I don't think a doctor or a nurse ever had a conversation with me about the possibility of sexual transmission of HIV. I learned about it in sex education at school. Having the diagnosis meant that I was interested in the subject and read articles relating to HIV. Having haemophilia meant that I probably matured a little earlier than some due to having to manage my condition. Being diagnosed with HIV added to this."

76. Dr Ball was not in tenure when patients were informed of their HIV status and could not comment as to the timing of information being provided to patients and families. She did not know what the policies were regarding informing children of their test results when initially diagnosed because she was not involved in their care at those specific times.[204] There was no specific policy as far as Dr Ball could remember but "*in line with all practice at that time parents would be informed, and a discussion would be undertaken as to how and when the children would be informed.*"[205]

77. With regard to testing and diagnosis of HIV, Dr Hann also had limited information. According to his written statement at paragraph 74(e):[206]

"*How and when patients seroconverted at GOSH is an issue about which I have only very vague memories. As far as I can remember look back studies were going to be carried out through public health auspices, but I am not certain. As far as I recall, all seroconversions happened before 1983.*"

78. However, Dr Hann acknowledged that there were some issues regarding consent for testing at GOSH:[207]

"*75. By the time that I had arrived at GOSH, I and many others had realised that consent processes were not adequately applied. We instituted fully informed consent for all transfusions and all testing procedures which basically*

[204] WITN4739001 paras 53-54
[205] WITN4739001 para 55
[206] WITN3497005
[207] WITN3497005

consisted of an explanation of what was happening, why it was happening and the risks of such. Much of that had been in existence for many years but there were gaps e.g. the consent to test stored samples, consent to proceed with straightforward procedures such as essential blood and platelet transfusions etc."

Numbers infected with HIV

79. Dr Ball could not remember the accurate figures of HIV infected children with haemophilia but estimated that it was 6 boys at GOSH.[208] She stated that they were all aged under 16 years of age and she did not "*recollect any attempt to document the moment of sero-conversion either at GOSH or Alder Hey and to my knowledge there were no stored serum samples to retrospectively analyse this time point*".[209] She stated that during her "*tenure at GOSH there were no deaths related to HIV or Hepatitis*".[210]

80. According to provisional data received by the Inquiry from UKHCDO, it appears that 11 patients were infected with HIV at GOSH in total: 1 tested positive in 1984, 8 tested positive in 1985, and 2 tested positive in 1987.[211]

Testing for HCV and numbers infected

81. The Inquiry does not currently have precise information as to the number of patients at GOSH infected with HCV. The written statement of Dr Ball provides at para 46-47:[212]

> "*46. I have no documentation or recollection as to any cases of hepatitis C so I am unable to answer this request*

[208] WITN4739001 para 42
[209] WITN4739001 para 43
[210] WITN4739001 para 81
[211] INQY0000250
[212] WITN4739001

47. When did (a) GOSH or (b) Alder Hey begin testing patients for hepatitis C? I have no documentation or recollection as to the definitive date. At GOSH, the testing would have started after my tenure ..."

82. Dr Hann recalled that some of his patients were confirmed to have hepatitis C. His written statement at paras 81-85 provides:[213]

"*During my time at GOSH no patient acquired a significant TTI. A number of patients did have persistent transaminitis of unknown cause and most were aware of that. Approximately three years later we were able to confirm Hep C in some of the patients that I inherited. Extensive efforts were made to inform them pre and post testing about all of the consequences. This was carried out by two clinical nurse specialists, myself, the infectious diseases team and social work / psychology support teams.*

82. GOSH began testing for Hepatitis C, immediately after validated tests became available, which I believe was in 1990. Following counselling, all patients with haemophilia were tested over a period of a few months starting with those who had persistent transaminitis of unknown cause. In this instance, and unlike HIV, our patients were informed why the test was being done and that they would be called back to clinic or day care appointments. It was, as before, not thought good practice to inform such complex information by letter or telephone.

83. As before, the clinical science behind Hep C was still uncertain by 1990 and therapies were unproven and initially unsatisfactory. Accurate prognostication was impossible, but we did know by then that a proportion of affected people, after a number of years, did develop very serious liver disease, and the families were fully informed and expertly followed up.

84. Pre and post test counselling at GOSH is described in full above.

[213] WITN3497005

85. I cannot recall how many patients with haemophilia were Hep C infected. My memory is that some were and that no new cases appeared during my time."

83. There is some correspondence in 1991 between Dr Hann and Dr Duncan Thomas/Dr Richard Lane of the Blood Products Laboratory regarding apparently positive HCV tests in two haemophiliac boys who had been treated with 8Y. A letter dated 28 March 1991 from Dr Hann to Dr Lane at BPL stated:[214]

> "*I am concerned that we appear to have had two children who have developed Hepatitis C infection whilst being treated with this batch [8Y]. I thought I should make this clear so that you can urgently review its status.*"

84. The issue was apparently resolved following correspondence culminating in a letter from Dr Hann to Dr Duncan Thomas dated 13 June 1991.[215] A handwritten note on the letter, apparently by Dr Duncan Thomas, appears to read "*spoke on the 'phone 13/06/91 Told him that PHLS believed this to be old infection, which was now being detected by more sensitive antibody tests.*"

Treatment arrangements for HIV and HCV patients

85. An anonymous witness described his experience at GOSH after being diagnosed with HIV:[216]

> "*When I went to GOSH I would always see two doctors; a haemophilia doctor and another doctor. She was very nice but I didn't know why I was seeing her. That was Dr Di Gibb. I now know that she was a HIV doctor. She used to come from Mortimer Market to GOSH to run a special clinic for boys with HIV. I later learned Dr Lynne Ball fought tooth and nail for children such as myself to get treatment for HIV at GOSH. Dr Lynne Ball was the haemophilia doctor at the time.*"

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[214] BPLL0016112_011. See also BPLL0016112_008, BPLL0010481, BPLL0016112_007, BPLL0016112_006, BPLL0005767_002, BPLL0016112_005
[215] BPLL0016112_002
[216] WITN0125001 para 34

86. The witness described taking different drug treatments for HIV including DDI and 3TC,[217] and taking part in drug trials at GOSH.[218] He described how his "*body would become resistant to the medications but more dedications were becoming available to try*".[219] He described having an overall positive experience of treatment:[220]

> "*71. All the treatment which I received was provided on the NHS... We did not have access to private health care. The NHS infected me, but otherwise the treatment it has provided to me has been incredibly good. I wish others had been as fortunate as me.*
>
> *72. If it were not for the doctors fighting for Di Gibb to come and hold HIV clinics at the hospital, I don't know where I would be. I was treated at the best children's hospital in the world.*"

87. The patient's treatment later transferred from GOSH to University College Hospital and the Royal Free Hospital.[221]

88. Regarding the treatment arrangements for HIV and HCV patients at GOSH, Dr Ball explained in her written statement that:[222]

> "*70(a) In the 1980s, there were no specialist in AIDS care for children with haemophilia. As discussed in previous answers, I consulted with other paediatric specialists including haematologists, immunologists as well as pulmonologists, infectious disease specialist, gastroenterologists, dermatologists, neurologists. I also actively sought support from specialist caring for young adult HIV patients. The children had complex multi system complaints and as there was very little general knowledge in this field there was no expert so I, like most paediatricians caring for these children, was guided by*

[217] WITN0125001 paras 43-44
[218] WITN0125001 para 73
[219] WITN0125001 para 46
[220] WITN0125001 paras 71-72
[221] WITN0125001 para 74
[222] WITN4739001

best practice, This was difficult especially in a field where epidemiologists were publishing that AIDS related symptoms in children where rare when at that time they were considering new borns and vertical transmission as we were being confronted with symptomatic children unfortunately dying of AIDS.

70(b) During my tenure, apart from supportive care including psycho-social support, the only available treatment specifically directed against HIV was Zidovudine, which required careful dosing and monitoring.

70(c) All available information was provided to patients and their families but this was limited as few children had been treated in the 1980's, which was one of the motivations for undertaking a limited study at GOSH to determine the pharmacokinetics and to document any immunological improvements. However, this was a small observational study and it would be many years before advances in knowledge and treatment options evolved, by which time I was no longer involved in the direct management of these children"

89. Dr Ian Hann described the various treatments available for HIV, hepatitis C, and hepatitis B, in his written statement at paras 101-110.[223] In summary, after Dr Hann "*started at GOSH and not before, possible specific therapies for HIV gradually became available and specialist counselling and diagnostic services were provided in collaboration with the infectious diseases and immunology teams*".[224] After hepatitis C was discovered, "*the Infectious Diseases Team again made arrangements to jointly manage all such patients with us*".[225] He further explained:

> "*Initially the only treatment for HIV was prophylactic Co-trimoxazole as stated above, along with symptomatic management of infections and other sequelae, none of which occurred during my time. After a short time at GOSH, trials of antiretroviral therapy, initially I believe with AZT, became available and thereafter the Infectious Diseases Teams managed that therapy in appropriate patients. After 1990, and in patients with established Hep C and indications for therapy, trials of interferon and other therapies were managed by that team and we managed their coagulation problems.*

[223] WITN3497005
[224] WITN3497005 para 101
[225] WITN3497005 para 101

c. Information for families about therapeutic trials came via the Infectious Diseases Team, using the written patient information leaflets approved by the Ethics Committee. They also provided regular expert counselling which covered all aspects such as toxicities of therapy.

d. The difference between management of children and their families versus adults is a very big subject and is the basis for much of paediatric care. It involves the age specific written and verbal communication for the children and the varying dosages and toxicities in the paediatric age groups.

102. Follow-up management and monitoring of HIV infected patients was jointly with the Infectious Diseases and Haemophilia Teams, who had access to specialist advice e.g. social work/immunology/family therapy/psychology / psychiatry / hepatology."

90. As far as Dr Hann was aware, they did not have patients with hepatitis B but if they had, they would have been jointly managed at GOSH with Infectious Diseases.[226] Once hepatitis C was diagnosable, the patient would be jointly managed with Infectious Diseases at GOSH and transitioned for treatment. Dr Hann explained:[227]

> "*Hep C patients were offered entry in clinical trials as therapies became available and the indications for therapy were extant. This was in the early years difficult to manage and not very successful, using mainly interferon and then ribavirin and combinations. Later on drugs such as sofosbuvir/ledipasvir became available. All required expert Paediatric Infectious Diseases management.*
> *c. Information about risks and benefits of Hep C therapy was supplied orally by the infectious diseases team, by supplied literature and Ethics committee approved information leaflets.*

[226] WITN3497005 para 103
[227] WITN3497005 para 105

d. Information especially directed for the level of child's understanding of Hep C was developed along with appropriate level discussion."

91. Dr Hann also added that wider support was "*much easier at GOSH as we already had on-site access to world-class paediatric infectious diseases, clinical nurse specialists, trained dedicated counsellors and hepatologists, for instance*".[228] He stated that there was good access on site to expert psychology and psychiatric help, and that although it took years of effort to solve the problem of a lack of dedicated space at GOSH, "*they now have world-class facilities*".[229]

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June 2021

[228] WITN3497005 para 109
[229] WITN3497005 para 109