WESSEX REGIONAL TRANSFUSION CENTRE 1970-1990: PRESENTATION

Contents

Introduction

1. This note focuses on the Wessex Regional Transfusion Centre ('RTC') from its establishment in September 1970[1] under the directorship of Dr Donald Smith, until 1990 when Dr Frank Boulton was appointed as Director. The period from then onwards will be covered by Dr Boulton's evidence.

The work of Wessex RTC

Remit

2. The Wessex RTC was set up and funded by the Wessex Regional Health Board in 1970; the region had previously obtained blood supplies from Bristol and South London. In 1980, it served a population of 2.14 million (it did not cover the entirety of the population served by the Regional Health Board).[2] By 1987, this had risen to 2.3 million[3] and in 1989 it was suggested that a better estimate was 2.8 million.[4] Based in Southampton, it covered a region which included Hampshire, the Isle of Wight, Dorset, and part of Wiltshire.[5] By 1984, it served 11 district blood banks, namely:

    (1) Basingstoke District Hospital
    (2) Royal Victoria Hospital, Boscombe, Bournemouth
    (3) Dorset County Hospital, Dorchester
    (4) Royal Naval Hospital, Haslar
    (5) Southampton General Hospital
    (6) Salisbury General Infirmary
    (7) St Mary's Hospital, Newport, I o W
    (8) Poole General Hospital
    (9) Queen Alexandra Hospital, Portsmouth

[1] NHBT0108704
[2] NHBT0110056
[3] NHBT0112745
[4] NHBT0003372
[5] NHBT0010821_009

(10) Royal Hampshire County Hospital, Winchester

(11) Lord Mayor Treloar's Hospital, Alton.[6]

3. The blood banks were supplied directly by Wessex RTC with whole blood, plasma reduced blood, platelet concentrates, white cell poor blood, white cell concentrate, washed red cells, fresh frozen plasma (for local use) and cryoprecipitate.[7]

4. In addition, Wessex RTC supplied the Blood Products Laboratory ('BPL') with fresh frozen plasma ('FFP'), time expired plasma and specific plasmas which were processed to produce factor VIII concentrate amongst other products. In return, BPL sent Wessex RTC factor VIII, plasma protein fraction ('PPF') and other blood products such as anti-D, for issuing to the district blood banks.[8]

Staffing and facilities

5. In 1980, the key staff at the Wessex RTC included: Dr Smith, Medical Director, Mr F Allison, Senior Chief Medical Laboratory Scientific Officer ('MLSO'), Dr RM Barnes, Deputy Medical Director, Mr DJ Duddridge, Regional Donor Organiser, and Mr B Grundy, Administrator.[9] A February 1984 report adds that the Nursing Officer was Mrs A Burnett and there were two Chief MLSOs, Mr D Dyball and Mr N Northcott.[10] When Dr Boulton joined in 1990, the staffing complement included the CEO, two consultants, two associate specialists, six donor session medical doctors, two clinical scientists, one principal medical laboratory scientist, three deputy principal medical laboratory scientists, five chief medical laboratory scientists, several senior medical laboratory Scientists, other medical laboratory scientists and trainees.[11]

6. In the Regional Transfusion Directors meeting on 17 March 1976, it was noted that:

> "*Dr Smith confirmed the offer made by Dr Barnes on his behalf that RTC Wessex would have washing and sterilizing facilities that could be used by*

[6] NHBT0010821_009
[7] NHBT0010821_009
[8] NHBT0010821_009
[9] NHBT0110056
[10] NHBT0010821_009
[11] WITN3456002 §124-126

other RTCs but added that the centre had not yet been inspected by Medicines Act Inspectorate."[12]

7. A Mobile Donation Centre was commissioned and had its first session on 1 September 1980.[13] At that time, it was noted that the "*increase in blood collection and handling has exerted considerable pressure on the space available in the Transfusion Centre*".[14] Two small extensions had been carried out and a further two-storey extension was planned for 1981/82.

8. A January 1982 report, 'Clinical Work at the Wessex Regional Transfusion Centre', stated that:

> "*We now have no difficulty in recruiting nursing, administrative and scientific staff, but medical staffing at Clinical Assistant grade remains a problem. We are fortunate in having two full-time Associate Specialist posts filled~ but the part-time Clinical Assistant posts have not been fully staffed during the year.*
>
> *We hope to appoint a third Consultant in March 1982. This vacancy has been unfilled for twelve months now.*"[15]

9. A 1984 report states that the Wessex RTC laboratories at that time covered four areas of work: grouping and testing collected blood; hepatitis testing; plasma processing ("*responsible for extracting plasma from whole blood and certain processing eg cryoprecipitate*") and grouping reagents.[16] To that, a quality control department was added in 1988.[17]

10. Dr Smith stepped down in 1989 but remained at the Wessex RTC in the role of Locum Medical Manager[18] until 30 April 1990 to facilitate the appointment of his successor, Dr Boulton.

---

[12] NHBT0016478
[13] NHBT0110056
[14] Ibid
[15] NHBT0110055
[16] NHBT0010821_009
[17] NHBT0006264
[18] NHBT0006264

11. Following an audit visit to Wessex RTC carried out by Dr Moore, deputy director of the National Directorate, on 19 July 1989, it was noted:

> "*Director Jim Smith (at present Grade 16), said that the RHA intend to adopt a structure for the RTC in which he as Business Manager, manages all items except medical. At best Dr. Herborn would be appointed Medical Director, but with limited power. According to Jim Smith, Dr. Herborn is not highly regarded either by RHA or by Jim Smith himself. When I met Dr. Herborn and Jim Smith together, there was an uncomfortable feeling of not knowing who was in charge.*"[19]

12. It should be noted that at §177 of his witness statement, Dr Boulton comments on this evidence:

> "*Mr Moore's report that Mr Jim Smith had said that Dr Herborn was not highly regarded by the RHA (and that Mr Smith shared that alleged opinion of Dr Herborn) is a sad reflection of the dysfunction of the WBTC with the retirement of the previous Director, Dr Don Smith, in 1987-8. Mr Smith might have assumed that as Dr Herborn had not been appointed by the RHA to succeed Dr Smith as Director, he (Dr Herborn) might have been 'not highly regarded' by the RHA; but these allegations should be taken in the context that Mr Jim Smith was found by the RHA in late 1991 to be inadequate as a 'General Manager' and was redeployed within the RHA. Dr Herborn was hard-working and conscientious: as the sole medical consultant in the Centre at the time it would not have been fair to expect him to develop active policies around the donor apheresis strategy as there was so much else going on.*"[20]

Blood collection sessions

13. In 1980, it was noted in the Wessex RTC's annual report that responding to an increased need for Factor VIII and plasma protein fraction production would involve

[19] NHBT0003372
[20] WITN3456002

moving from 16 sessions per week to 18 in 1982/83 and more thereafter. The limiting factor was said to be processing capacity at BPL.[21]

14. In the January 1982 report, 'Clinical Work at the Wessex Regional Transfusion Centre', it was noted that:

> "*It was hoped that from 1st April, 1982, we would obtain the necessary finance from the Regional Health Authority so that 18 blood collection sessions could be done each week and 1,000 packs of fresh frozen plasma sent to the Blood Products Laboratory for preparing Factor VIII concentrate, Plasma Protein Fraction and immunoglobulin. However, it now appears unlikely that we shall be able to bring this plan into operation until October 1982, and this will then bring about a much more satisfactory intake of Factor VIII concentrate and P.P.F. to Wessex~ with considerable cash savings.*"[22]

15. By February 1980, the Wessex RTC was operating 18 donor sessions per week.[23]

16. The process of a blood collection session was described following an inspection in February 1990:

> "*A small apheresis suite operates within the Centre for clinical apheresis and the collection of some hyperimmune plasmas, principally anti-D from boosted donors, but the vast majority of donations are collected at mobile sessions. A visit was made to a session held at the Civic Centre in Southampton.*
>
> *Donor records are not computerised, the 101 card system being used. The cards for all called donors are brought to the session. At the clerking table, when a donor has completed the consent form, a set of 6 bar-code labels is issued. One label is stuck onto the donor's record card and another onto the Session Sheet. Known donors and new donors are differentiated by using different bar-code series, thcse for new donors having green edges. In*

[21] NHBT0110056
[22] NHBT0110055
[23] NHBT0010821_009

addition, a white Session Sheet is used for known donors, while new donors' details are recorded on a green Session Sheet."[24]

Armed forces and prison donors

17. Blood was collected from naval donors. It was noted at the Executive Committee of the Haemophilia Society meeting on 9 December 1971:

> "*Dr. Kuttner had had a most interesting visit to Dr. Smith, Director of the new Wessex Blood Transfusion Centre in Southampton which supplies cryoprecipitate to both Dr. Leslie's and Dr. Stern's treatment units. Dr. Smith had been very pleased at the interest shown in what he was doing. The crews of many ships are volunteering as blood donors.*"[25]

18. On 27 June 1984, Dr Smith wrote in an internal memo:

> "*Please could you ask the team clerks, particularly at Naval sessions to enquire if there is any history of jaundice even if the donor has previously donated. Anyone with a history of jaundice will not be accepted but I wall always write to them and explain that they can go on our research panel.*"[26]

19. It was noted at the Regional Directors Meeting of 11 July 1984 that, "*The Army would continue their association with Wessex.*"[27]

20. Blood was also collected at Camp Hill Prison on the Isle of Wight. A letter of 9 May 1972 from Dr Smith describes an incident where a prisoner donor tested HAA (hepatitis associated antigen) positive but a decision was taken not to inform him. In a letter written to all RTCs he stated as follows:

> "*This donor attended one of our blood collection sessions at Camp Hill Prison on the Isle of Wight. Our routine tests showed that he had a positive H.A.A. test and this was confirmed by the Portsmouth Public Health Laboratory. These facts were then communicated to the Governor of the Prison and the*

[24] NHBT0006264
[25] HSOC0029691_142
[26] NHBT0108948
[27] BPLL0007665_004

Prison Medical Officer who decided that for medical reasons (personality difficulties) it would be inadvisable to let [the patient] know these results. Liver function tests were normal.

I asked the Prison Medical Officer to let me know when this man would be discharged and he has now been in touch with me to say that he will be going under the care of the probation officer, Borough High Street, London, S.E.1. I regret that we do not know the donor's address.

I thought I would let you have this information so that you will be warned if he attends one of your blood collection sessions."[28]

21. On 22 June 1972, Dr Maycock, in his role as consultant adviser to the DHSS, wrote "*Have you the information easily available to show the incidence of prisoners and Forces donors? Unless Wessex has an unusually high prison population I think 4 positives indicates a fairly high incidence.*" Dr Smith replied that there were 3 Au antigen positive armed forces donors out of 2401, 6 positive prison donors out of 1676 and 9 out of 42,675 from the general public. He commented, "*It looks to me as if we shall lose our prison population of donors eventually.*"[29]

Plasmapheresis

22. In 1987, the Wessex RTC had a panel of 46 plasmapheresis donors.[30] There was preference for manual rather than machine plasmapheresis as this was thought to pose a lower risk to the donor, and take less time.[31]

Regulation and inspection

23. The Wessex RTC was inspected by the Medicines Inspectorate of the DoH from 26 to 28 February 1990. The summary conclusion was:

> "*The Inspector acknowledged that, since the last inspection, there had been a number of improvements, notably the establishment of a QC Department and*

[28] DHSC0100020_045
[29] NHBT0108717_003
[30] NHBT0112745
[31] NHBT0110055

the introduction of automated sampling into Transfusion Microbiology. However, in spite of a small amount of extra computerisation, many procedures were still exceedingly manual and the need for a fully integrated complete computerised system was identified." [32]

Output of the Wessex RTC

24. On 19 September 1973, Dr Smith wrote to Dr Maycock at DHSS a letter regarding *"Supply of fresh frozen plasma for preparation of factor VIII concentrate"*, in which he set out the costs estimate for setting up a new deep freeze room necessary to prepare FFP.[33]

25. On 10 July 1974, Dr Barnes wrote in an internal memo to Dr Smith:

> "*Mr Jackson, Department of Health, telephoned me yesterday afternoon. Mr. Mitchell, M.P., Southampton Itchen, has raised a Parliamentary question to the effect that he has been informed locally that some blood used in local hospitals has been imported from America under the auspices of a firm called Fenwal. Is this correct, and if so has there been any local shortage of blood necessitating such a step?*
>
> *I assured Mr. Jackson that*
>
> *(1) On no occasion had we imported blood from America or elsewhere, and*
>
> *(2) Apart from the three-day working week (which we rode pretty successfully [sic] there was absolutely no shortage of blood in Wessex.*
>
> *I also pointed out that what might have happened here was that a patient or patient's relative might well have seen a Fenwal pack and jumped to the conclusion that the pack, complete with blood, had been imported from the*

[32] NHBT0006264
[33] DHSC0002175_042

States, i.e. that the informant might well have confused the container with the contents… Mr. Jackson agreed and also pointed out that a concentrated A.H.G., a product derived from human blood, was indeed imported via Travenol under licence."[34]

26. On 8 May 1975, Dr Smith wrote to DHSS:

> "*We have now had a look at the costing figures for the facilities required for increased plasma production for the preparation of Factor VIII concentrate, as requested at the last meeting, and with some misgivings we have reluctantly reduced the expenditure as follows:..*
>
> *…*
>
> *To send the 9,500 donations mentioned in column 6, Appendix 1, we would still require most of the £26,000 mentioned in our original return for capital equipment and revenue.*
>
> *In conclusion, we believe the source figures and analysis should be collected and treated in a standard fashion, otherwise the final league table gives an incorrect impression of regional costs and cannot be used to draw comparisons as a basis for the allocation of any money which is available for this project.*
>
> *If the money is made available to use for this project, we shall be able to start within three months and we would try to reach the target figure by six months.*"[35]

27. On 13 October 1975, Dr Smith wrote to DHSS "*I should like to confirm that we can meet our target figures for the production of fresh frozen plasma for Factor VIII Concentrate according to the chart that you produced.*"[36]

28. In the Wessex RTC's 1980 annual report, it was noted that:

---

[34] NHBT0112221
[35] DHSC0002177_026
[36] DHSC0002179_018

"*There has been a continuous increase in demand for blood and blood products, which is now being led by the need for plasma to produce Factor VIII a.h.f, and plasma protein fraction... the total number of donations collected in 1980 was 86,926 with the plasma from about 38,000 going to Factor VIII and Plasma Protein Fraction production.*"[37]

29. On 14 March 1980, representatives of Wessex RHA met with Dr. R. Lane and Dr. J.K. Smith of BPL and Dr. E. Bidwell of PFC. Dr Smith's account of the meeting was that the Wessex attendees "*were told that Oxford were unable to increase their handling of plasma to 600 per week and that they were not entirely happy to process 500. Dr. Lane stated that even if we increased our plasma supply to B.P.L. in 5 litre pools, there could be no pro rata increase of Factor VIII, but in due course we would receive some P.P.F. back.*"[38]

30. On 1 April 1980, Dr Smith wrote to Dr Lane at BPL:

> "*In consultation with the Wessex R.H.A., we have decided not to increase our blood collection sessions and bring the planned extra team into operation in the financial year 1980/81. As you could not be certain that we would get the Factor VIII concentrate back from you with increased fresh frozen plasma collection, we have decided to wait until you let us know that you will be able to deal with our extra fresh frozen plasma and the present production of 500 packs a week will continue. When your plant has the required capacity to deal with our plasma, particularly in single transfer packs, please would you let me know and we will make the necessary administrative arrangements with the Wessex R.H.A. to increase our sessions.*
>
> *This, of course, has been a great disappointment to us and the money that we have saved by not having an extra team will now have to go towards the purchase of commercial Factor VIII. We hope that by the time you can go ahead the R.H.A. will have the necessary money to make available. Let us hope that the general economic situation improves, because I think it would be*

[37] NHBT0110056
[38] CBLA0001198

a great shame if we have to rely upon imported Factor VIII to treat British patients.

Regarding our present-production, we are sending 500 units of fresh frozen plasma each week, and from our calculations we should receive about 380 x 250 i.u. vials a month. We would of course appreciate any extra that you can provide from the national pool for the patients in Alton.

We would also like to request an increase in the amount of Plasma Protein Fraction sent to us each month. At the moment we are receiving 420 units of P.P.F. and 100 bottles dried plasma. Last year we sent 2,323 litres of time-expired plasma to you and we calculate that this should yield 276 bottles P.P.F. each month. The 500 units of fresh frozen plasma we are sending each month should also yield about 522 bottles P.P.F., the total being 798 bottles of P.P.F., so. it would appear that we are about 200 bottles of P.P.F. down each month and if you can increase our monthly allowance we would very much appreciate it.

I understand that we shall be sending a member of our scientific staff to study your R.I.A. method and this will be most valuable as we can then make the necessary administrative arrangements to obtain capital and revenue for the apparatus."[39]

31. Dr Lane replied:

"Thank you for your letter of 1st April concerning the difficulties with supply and processing of factor VIII which we are currently experiencing. I have forwarded your letter to the Department so that they will be aware of this particular instance of discrepancy between central and regional planning. It is my continuing hope that we shall soon know about the future plans for BPL but in the meantime, we shall do our best to provide the factor VIII pro-rata

[39] CBLA0001088

from the plasma received at Oxford and to augment this where possible from the other national supplies.

We agree, that you are not receiving as much plasma protein factor as you would normally receive on a pro-rata basis, but I would remind you that the question of pro-rata supply, while receiving active consideration, has not to my knowledge received formal approval at this time. Hopefully, pro-rata supply will be approved in the near future so that centres that are doing well shall have the incentive to continue this trend…."[40]

32. However, Dr JK Smith from BPL also responded:

> "*… may I point out that our inability to take an increased plasma supply from Wessex is related to the single-pack problem. BPL could take any reasonable amount of 5 litre packs, but in our present difficulty with freeze-drying, we could not guarantee that the extra factor VIII would be returned immediately to back your financial case.*"[41]

33. This issue prompted Dr Aronstam of Treloar to write a letter to the BMJ, published on 20 September 1980, arguing:

> "*The Wessex Regional Transfusion Service has recently offered to increase the supply of plasma to the Lister blood products laboratory, only be told that there was not the capacity to handle the extra plasma. I think it most important that the repetitive cry for increased plasma does not obscure the very real need for adequate fractionation potential in England today.*"[42]

34. Dr Aronstam's letter prompted a rebuttal from Dr Bidwell of PFL,[43] which in turn elicited a letter from Dr Smith defending Dr Aronstam's characterisation of the issue.[44]

---

[40] CBLA0001090
[41] CBLA0012012
[42] RLIT0000667
[43] CBLA0001193
[44] CBLA0001198

35. On 3 December 1980, Dr Smith wrote to Dr Lane at BPL:

> *"We are now in a position to send to you at B.P.L., Elstree, 12 x 5 litre pools of fresh frozen plasma weekly. We can actually increase this amount in April 1981. Our new Class 1 Clean Room is now in use and with a little extra effort we can send you this additional fresh plasma, but we would of course wish to be assured that we will receive Factor VIII Concentrate and P.P.F. pro rata. If you can agree to this we will proceed in the near future with the above arrangements.*
>
> *Thank you for supplying the HBsAg reagents, and as you know we have bought the nuclear counter, and we are most grateful for your help."*[45]

36. Dr Lane replied:

> *"I am pleased that you will be able to increase the supply of fresh frozen plasma to the BPL, despatching this material in 5L pools.*
>
> *As you know, the arrangements for pro-rata supply of finished products are not due to commence until 1 April 1981, and I would hesitate to anticipate that date with any private arrangement. However, after that date I assure you that we would be able to return your finished product on the basis of a pro-rata agreement. I will await your response because I imagine that you will wish to make your main input of raw material after April 1981."*[46]

37. On 6 March 1981, Dr Smith wrote to Dr Lane:

> *"We could now send to you at B.P.L., London, 8 x 5 litre pools of Fresh Frozen Plasma weekly for processing to Factor VIII concentrate. We would, of course, like to be assured that in due course we would receive the concentrate back, but we will of course not expect any Plasma Protein Fraction for the time being.*

[45] BPLL0000916
[46] BPLL0000916

Subject to your agreement, we would like to send the first pool on Friday, 10th April, 1981, and then at fortnightly intervals. We will of course continue to send 500 single plasma packs to Oxford each week.

I mentioned this matter to Dr. Jim Smith at the end of this meeting and he agreed that the above amount of plasma could be dealt with and returned pro rata in due course.

Our long term plan is to increase this amount of F.F.P. to the total equivalent of 1,000 single packs of F.F.P. each week from April 1982, and we would appreciate a comment about this as it will need another blood collection team on the road and we will be required to make the necessary arrangements with the R.H.A."[47]

38. Dr Lane replied:

"*I confirm that we can accept the extra plasma that you describe and add that pro-rata supply of factor VIII will commence on the 1st April. I note with interest your plans to increase FFP supply by April 1982 and... I believe it would be advantageous by then to receive this additional material.*"[48]

39. In further correspondence, these arrangements were confirmed.[49] On 2 December 1981, Dr Smith wrote to BPL:

"*All being well, from the 1st April, 1982, we hope to be collecting the previous Oxford plasma into the new international Travenol pack at the rate of 500 each week. That will then come to you, and Oxford will no longer be concerned with supplying Factor VIII and Albumin to us. After April, whenever Dr. Lane wishes, instead of sending the 200 in 5 litre plasma pools, we will send this in single units in the new plasma pack.*

Provided we receive the necessary finance from the Wessex R.H.A., and we anticipate that this will be from November 1982, we will then be sending a

[47] BPLL0000901_004
[48] BPLL0000901_003
[49] BPLL0000901_002, BPLL0000901_001

total of 1,000 packs of plasma each week to Elstree for fractionation. This will meet the initial Trends document regarding plasma production."[50]

40. On 6 January 1982, Wessex RTC's Administrator, Mr Grundy, wrote to the Wessex Regional Health Authority, setting out the following points amongst others:[51]

    - The service had expanded to meet its production target "*so that, if the appropriate revenue allocation is made for 1982/83, we shall be sending some 9000 kg of plasma to BPL for processing in 1983/84*".

    - The plan was to remove plasma for fractionation from some 51% of the units supplied. He noted, "*There is little need seen for increasing significantly the amount of blood collected for red cell requirements in the near future.*"

    - The system in operation produced a yield of some 25% of FVIII available in the plasma. It was believed that could be improved on by collection into heparin. It was suggested this would be done for plasma collected by plasmapheresis.

41. On 20 October 1988, Dr Smith circulated a memo with estimates of future clinical usage of factor VIII within the Haemophilia Centres supplied by Wessex. He noted:

    "*The aim would be, in the first instance, to wipe out the Commercial Factor VIII budget for all hospitals except Lord Mayor Treloar. If supplies of Factor 8Y increased further, the L.M.T. budget could then be reduced.*

    If there is no further increase in demand for Factor VIII, we should be self-sufficient by December, 1988: (1534 vials per month).

    The R.T.C. stock of Factor 8Y was 1,210 units on 26.9.88. The Commercial stock of Factor VIII was 619 vials on 30.9.88."[52]

42. A statement of objectives for the 1988/89 year included the following aims:

---

[50] BPLL0000878_005
[51] NHBT0110055
[52] NHBT0111301

"1.1 Total Blood Donation Collection = 110,000 by Mobile Teams. Funding for additional 2 sessions work each week (from 18-20 weekly blood collection sessions).

1.2 To send 20.7 tonnes of Fresh Frozen Plasma to BPL for chemical fractionation.

1.3 Plasma target for other specific immunoglobulins

Anti-Tetanus 150 L.

Anti-Hepatitis B 40 L.

Anti-Varicella Zoster 5 L.

1.4 Commercial Factor VIII Budget to be reduced to £200,000.

1.5 Anti-D plasma production for immunoglobulin production to be 120 L. Recruit and immunise donors. Purchase/ lease additional plasmapheresis machine."[53]

43. At a visit to the Centre undertaken by Dr Moore in July 1989, it was noted that:

"Current plasma output is... 7.3 tonnes per million (not 9.13 as we had thought). Currently they are on target to meet their predictions (+ 1% for 1st quarter). Apheresis is only used for Anti-D and some other specific plasmas. The machines and staff are greatly underutilised.

Have made great efforts to reduce the amount of whole blood issued. Estimated that 80% of donations are now used for plasma of which 70% SAG(M). They consider there is a possibility of increasing SAG(M) slightly (2%) and reducing the 8000 units of therapeutic FFP used."[54]

[53] NHBT0144478
[54] NHBT0003372

44. The plan for the future was to increase production by increasing the number of blood collection sessions from 18 to 20 sessions per week. However, the small building was a limiting factor.[55]

Allocation of blood and blood products

45. A document dated 12 February 1976 compiles responses to a query from Wessex RTC as to future requirements for blood and product products in the hospitals it supplied. The hospitals were: Royal Hampshire County Hospital, Winchester, Basingstoke General Hospital, Royal Naval Hospital, Haslar, Royal Victoria Hospital, Boscombe (Hospital and Haemophilia Centre), Southampton, General Infirmary, Salisbury, Poole General Hospital, and St Mary's General Hospital, Portsmouth. Generally, no significant changes were anticipated save that Dr Stern from the Haemophilia Centre in Boscombe noted that they were doing more dental and orthopaedic surgery on haemophiliacs and required larger doses of cryoprecipitate and concentrate.[56]

46. On 27 February 1976, Dr Smith sent a memo to all Haemophilia Centre Directors in the Wessex area warning that:

> *"The new document HC(76)4, February 1976, "Arrangements for the Care of Persons Suffering from Haemophilia and Related Conditions", mentions that the management of patients undergoing surgery has become easier as a range of therapeutic materials have become more readily available and it may no longer be necessary to refer patients to the Reference Centre at Oxford for major surgery.*
>
> *Unfortunately, in Wessex our cryoprecipitate, 18,466 units annually, is at maximum production and we are also trying to produce 11,000 units of fresh frozen plasma for the British Factor VIII concentrate. I have no news of when we shall receive Factor VIII freeze dried concentrate from the Blood Products*

[55] NHBT0003372
[56] NHBT0112213

Laboratory, and it may well be another six months at least before any is available.

In view of this, may I request that if surgical procedures are contemplated, as you have previously done, you keep us informed, and as Appendix 2 paragraph 7 suggests, it will still be possible and may well be advisable, to consult the Reference Centre at Oxford about the further availability of therapeutic materials if we are unable to help you."[57]

47. On 7 May 1976, Dr Smith wrote to Dr Chisholm, at the Southampton Haemophilia Centre:

> *"I thought I would draw to your attention that we have had to supply more than our usual amount of Cryoprecipitate to you during the last month. We try to produce for Southampton 130 units of Cryoprecipitate each month, and during April we sent you 190.*
>
> *I regret that due to all the demands made for Cryoprecipitate elsewhere, when we have supplied you with 130 per month, we shall not be able to supply any more. I will try to let you have a few bottles of Factor VIII Concentrate if you require it. We are still not receiving a supply from the Blood Products Laboratory in London, and it may be necessary for you to buy some commercial concentrate to book our own requirements.*
>
> *I am sorry about this, but as soon as we receive some Factor VIII Concentrate I will let you have it."*[58]

48. She replied on 12 May 1976 giving monthly totals of units of cryoprecipitate used and explained:

> *"As you can see for the first three months of the year our requirements were below average but, unfortunately in April we had a patient who required*

[57] NHBT0107767
[58] NHBT0111665

cryoprecipitate three times weekly for a fortnight to control a chronic haemarthrosis and this pushed up our total for that month.

In your letter you say that you produce 130 units of cryoprecipitate each month for Southampton and it would seem that we use approximately half of that on average. You did not of course send 190 units to us during April - this must have been the total amount put out for Southampton use.

It looks as though May is also going to be a heavy month and much as I would like to restrict our use of cryoprecipitate I am afraid it is usually beyond my control. If you do have a few bottles of factor VIII concentrate you could let me have I would be very grateful. Our last bill for commercially available factor VIII concentrate was £360!"[59]

49. Dr Smith followed up with an internal memo stating:

"*Subject to availability, we would like to send 60 unite of Cryoprecipitate and 5 units of Factor VIII Concentrate monthly direct to the Royal South Hants Hospital for Dr. Chisholm.*

On Thursday, 1st July, 1976, and thereafter monthly, please send 60 unites of Cryoprecipitate direct to the Children's Ward Laboratory at Southampton General Hospital."[60]

50. Dr Smith attended the meeting of Haemophilia Centre Directors, Regional Transfusion Directors and Regional Scientific Advisors on 26 July 1976. The minutes record:

"*Dr. Smith said that he supplied cryoprecipitate to hospitals in Newport, Dorchester, Salisbury and Winchester. These are not Haemophilia Centres but Dr. Smith felt confident that the patients were well cared for at these hospitals. Dr. Smith said that he would ask at the next Regional Haematology meeting to see if the centres should be listed and designated as Associate Haemophilia*

[59] NHBT0111664
[60] NHBT0111663

Centres. The view was expressed by Dr. Rainsford and Dr. Scott that it is not generally desirable for patients to be treated at hospitals which were not haemophilia centres."[61]

51. Dr Kirk from Treloar College wrote to Dr Smith the following day:

> "*As a result of the meeting yesterday, it would seem that Haemophilia Centres are responsible for the treatment and training at associated Centres.*
>
> *As we have several Centres in the Region, it will be necessary to identify those places which treat haemophiliacs and determine whether or not they wish to become associated Centres: Furthermore to determine which Centre they wish to become associated with.*
>
> *It would seem that as you supply Cryoprecipitate to places other than the designated Centres, it might be best if you could write to the various Hospitals for their views on association. This way it would not appear as if the established Centres were plying for custom.*"[62]

52. On 30 July 1976, Dr Maycock followed up in a letter to Dr Smith:

> *"... we are now trying to work out an allocation of concentrate for each haemophilia "super region". I still feel, perhaps even more so after the meeting at Oxford, that the final distribution to haemophilia centres, although it is actually made through RTCs must be organised locally in conjunction with the reference centres... If there is ever unlimited concentrate and cryoprecipitate, all these problems will, of course, disappear.*"[63]

53. On 17 November 1976, Dr Maycock, in his role as Director of BPL, wrote to St Mary's Hospital Portsmouth, advising that in future they should obtain their usual

[61] CBLA0000391
[62] NHBT0107773_002
[63] CBLA0000400

supply of 10 bottles of factor VIII concentrate per month from Wessex RTC, "*now that general distribution of concentrate is beginning*".[64]

54. On 17 March 1977, Dr Smith wrote to Dr Mayock:

> "*I thought you would like to have sight of the approximate amount of Factor VIII that is being used in Wessex at the moment. We may be going on to supply commercial Factor VIII from the Transfusion Centre to Haemophilia Centres, and this is how the exercise started.*"

55. He gave the following figures:

Supplier	Travenol	Immuno	Armour
Alton/Basingstoke	1. 409,000 2. 193,500	1. 260,500 2. 317,500	
Southampton	1. 9,500 2. 6,750	1. 4,250 2. 7,500	6,750
Bournemouth	225,000		
Total	843,750	589,750	6,750

56. Dr Smith calculated that Wessex RTC would receive 528,000 units of factor VIII from BPL and obtain 1,440,250 units of commercial factor VIII. He added:

> "*Assuming that there are 60 haemophilia patients per. million population in Wessex, plus another 50 in residence at Alton, we have a total of 170 patients who are each receiving 17,860 units annually.*
>
> *It is interesting that the Scottish Transfusion Service forecast that 10,000 units per patient per year should be satisfactory during the next few years, and the Swiss experience is that 20,000 units per patient per year are required for moderately severe and severe patients.*"[65]

[64] CBLA0004553
[65] CBLA0000583

57. Dr Maycock replied on 22 March 1977:

> *"Figures like these point to 50m iu p.a. which is now most often quoted. My calculation assumes 3000 haemophiliacs.*
>
> *I think it will be very difficult for UK to produce this quantity in the form of concentrate which the clinicians seem to want."*[66]

58. In the Wessex RTC's annual report for 1980, it was stated that:

> *"The amount of Factor VIII a.h.f, which is provided by the Blood Products Laboratory is insufficient to meet the Regional needs. The reason for this is the existence of the Lord Mayor Treloar Haemophilia Centre at Alton. Consequently, some 3.1 million units of commercial a.h.f. will have been purchased in the current financial year. It is hoped that our plans for expanding our plasma collection will make significant reductions in this."*[67]

59. At some point in 1981 the Advisory Committee to the NBTS carried out a survey of the issue of Factor VIII at RTCs to establish which of them operated a central supply system for their region. Wessex disclosed that it did hold Factor VIII supplies which were paid for by the RHA. The comments provided state:

> *Encountered difficulties in coping with Haemophilia Centre Directors' individual preferences for particular brands of Factor VIII and getting Haemophilia Centre Directors to operate within their budgets.*[68]

60. By October 1983 Wessex RTC appear to have increased its supply of cryoprecipitate such that Dr Chisholm at a meeting of the Haemophilia Centre Directors stated that she could get unlimited amounts of cryoprecipitate (but struggled to get large amounts of commercial concentrates).[69]

---

[66] CBLA0000585
[67] NHBT0110056
[68] CBLA0001456
[69] PRSE0004440

61. On 20 July 1987, Dr Smith wrote to all consultant haematologists and senior hospital pharmacists in the Wessex area:

> *"We have had a further reduction in the amount of Plasma Protein Fraction being sent to us from the Blood Products Laboratory, London.*
>
> *Although the new Fractionation Plant will be in operation shortly, I think it is unlikely that there will be an improvement in the supply of P.P.F. until April, 1988, and I would advise that commercial albumin (P.P.F.) solutions are obtained at your hospital to meet clinical use.*
>
> *Below is a list of manufacturers who may be able to help you by supplying P.P.F"*[70]

62. He recommended Biotest (UK) Ltd, Travenol Laboratories Ltd, Immuno Ltd and Hoechst UK Ltd.

Pro-rata system

63. At the meeting of UK Haemophilia Centre Directors on 30 September 1980, it was minuted that:

> *"Dr. Walford replied that she hoped that by April 1981 pro rata returns of factor VIII concentrate would be made to the Regions with a few exceptions in the case of Regions with extra responsibilities, such as Wessex where the Lord Mayor Treloar College was situated and which would receive an additional allocation of F.VIII above the pro rata entitlement."*[71]

64. A draft paper for the Advisory Committee on the NBTS, headed 'Pro-Rata Distribution of Blood Products', was produced on 1 February 1981. It recognised the special position of Wessex RTC due to the need to supply Treloar College within its area:

[70] NHBT0111307
[71] PRSE0003946

"*With the agreement of Transfusion Directors, BPL... proposes to aim for an initial target of returning to RTCs 80% of the notional gross yield. This equates roughly with current production levels. The 80% target will be closely monitored and may be increased in the light of experience. The remaining Factor VIII will be used to build up one month's reserve stock of Factor VIII and will also allow for special provisions for the Lord Mayor Treloar Hospital and certain other users described below.*

...

The Committee's views are sought on

a. whether a special allocation should be made to Wessex RHA because of the Lord Mayor Treloar Hospital...

b. if so, how might that allocation be assessed."[72]

65. Correspondence from Dr Lane on 10 March 1981 suggested that pro-rata supply of factor VIII would commence on 1 April 1981.[73] He wrote on 24 April 1981 to DHSS: "*I believe it is now agreed that the only special provisions for factor VIII distribution are as follows:- a) Lord Mayor Treloar College b) Channel Islands.*"[74]

66. An internal BPL memo from Mr Pettet dated 21 January 1982 objected to what he saw as preferential treatment in the proposed allocation to Wessex RTC.[75] His counter-proposal was adopted.[76]

67. The pro-rata system was in place in May 1989, when Dr Chisolm explained in correspondence:

"*Andrew [Herborne, Wessex RTC] tells me that the annual delivery of plasma to BPL from the Wessex Region is 20.7 tons which gives us a credit of £800,000 but the use of Factor VIII alone is well over £1,000,000. In order to reduce the shortfall it may be that the region will increase the amount of*

[72] CBLA0001294
[73] BPLL0000901_003
[74] CBLA0001341
[75] CBLA0001537
[76] CBLA0001538

plasma reduced blood it issues; this currently is 77% of the total and so could be increased."[77]

Cross-charging

68. Planning for a cross-charging system in Wessex commenced from at least early 1984, when a consultancy report by Price Waterhouse Associates was obtained.[78] Wessex was one of three RTCs which trialled the new system.[79] These trials were conducted in March 1985.[80]

69. Dr Smith recounted in a letter of 6 April 1989 to all consultant haematologists, regarding 'cross-accounting arrangements between the Blood Products Laboratory and Wessex RTC':

> "*From 1st April, 1989 we shall be charged for the Therapeutic materials supplied to us by the Blood Products Laboratory, London for regional use. In turn the fresh plasma we recover from blood donations and by plasmapheresis will be bought from us by BPL.*
>
> *It is likely that we shall have to charge D.H.A's for albumin preparations which in the last 12 months have largely, in the case of 4.5% albumin solution, (PPF), been obtained commercially by the Pharmacy Departments of D.H.A's. We have no Regional budget at our Centre for albumin products and it is for this reason that I draw this to your attention at the start of the financial year.*
>
> *Regarding Factor VIII-Y we shall supply this to Haemophilia Centres free of charge and the shortfall in NHS supply for 1989/90 will be purchased commercially within our budget for the L.M.T. College at Alton.*
>
> *Specific immunoglobulins supplied by the P.H.L.S. will be free and human anti-tetanus Immunoglobulin supplied from our Centre to Pharmacy Departments will also be free.*

---

[77] NHBT0111305_002
[78] NHBT0010821_009. See also NHBT0111545 and NHBT0010821_002
[79] CBLA0001836
[80] NHBT0010822

At the moment we have no news about cross-charging R.T.C. to D.H.A's for anti-D Immunoglobulin but we will keep you informed. We are barely self sufficient with the supply of anti-D Immunoglobulin.

Because there is plasma stock-piled at BPL from our Centre, we will try to reduce the cost as much as possible but we may have to charge you, later in the year, for albumin products."[81]

Relationship with Treloar College

70. A key feature of the Wessex RTC's remit was that it supplied the Lord Mayor Treloar College and Haemophilia Centre at Alton.

71. Before the establishment of the Wessex RTC, on 20 March 1969, Dr Zeitlin of the South London RTC wrote to Dr Maycock at BPL regarding the supply of cryoprecipitate by his service to Lord Mayor Treloar College; he noted that Dr Rainsford of Treloar felt "*100 bags of cryo a week is a ridiculous output for the whole region. In point of fact the whole region (Wessex) is not producing any!*"[82]

72. On 30 April 1974, Dr Aronstam of Treloar wrote to the DHSS:

"*During 1973 this Centre used 900,000 units of Factor VIII in the treatment of haemophilia. We used approximately 650,000 units of Factor VIII as Cryoprecipitate, 50,000 units as Fresh Frozen Plasma and about 200,000 units as Human and Animal Concentrate.*

Our official supply from the Wessex Regional Transfusion Centre at Southampton is the equivalent of 10,000 bags of Cryoprecipitate or 182 bags per week throughout the year. I have been repeatedly told by Dr. Smith that this is the absolute maximum production he is able to make available for me.

The excess material we have used is the equivalent of another 77 bags of Cryoprecipitate a week or 5,000 units of Concentrate per week. I have had to obtain these extra materials from a variety of sources often at very short

[81] NHBT0111299
[82] DHSC0100025_100

notice and at great difficulty to both myself and the sources... This situation is quite impossible."[83]

73. Dr Smith was consulted regarding decisions at Treloar, for example in correspondence regarding the pros and cons of the Treloar Haemophilia Centre being based at the hospital or college.[84] Dr Aronstam of Treloar was the Secretary of Wessex RTC's quarterly Consultant Haematologists meeting, at which the supply of Factor VIII was regularly discussed[85]

74. On 14 March 1978, Dr Aronstam was more positive about the service provided by Wessex RTC; he wrote to Dr Stafford, Consultant Haematologist at Plymouth General Hospital:

> "*We are obviously more fortunate than you in that the Wessex Region is supplying us with all the material we need for our admittedly enthusiastic programme.*"[86]

75. However, at an Oxford Haemophilia Supraregion Meeting on 19 June 1978, which Dr Smith attended, it was noted:

> "*It had been stated publicly by the DHSS that the United Kingdom should be self- sufficient in F. VIII concentrate by 1977 and from then on would not require to purchase commercial F. VIII. This was not proving to be the case.*
>
> *Dr. Aronstam said that he was encountering problems because of the change of policy over ordering commercial F. VIII. Initially he had ordered the commercial F. VIII on prescription directly from the Commercial firms, but now he had to get it via his Regional Blood Transfusion Centre and budget ahead for how much he would need. He did not think that he would be able to manage within his budget. Dr. Smith said that he did not think there was any problem in the Wessex Region apart from the one at Alton, which was a special case because of the large number of haemophilic boys at the College.*

[83] OXUH0000652
[84] NHBT0107239
[85] CBLA0001198
[86] CBLA0000745

He was awaiting the DHSS's reply to a request for official recognition of the special situation at Alton."[87]

76. A sales person for Hyate noted after a meeting with Dr Aronstam on 25 August 1978:

> "*All orders for the Wessex area are processed through the buying office in Winchester, but Aronstam makes the decisions, as he is by the far the biggest user. His first requirement is convenience of administration, since they can often have 15 infusions to give at a time. The six months study of all commercial concentrates last year showed Hemofil and Factorate to be better than Koate in this respect. In his opinion, solubility is slower with our product. It is worth going back, if we can provide evidence to the contrary.*"[88]

Knowledge of risk and response to risk - HBV

Donor selection and exclusion

77. A system was in place from at least 1970 whereby Medical Officers in the Wessex region reported to Dr Smith any cases of 'infective hepatitis' where the patient or a family contact of theirs was a registered blood donor, for example after a health visitor saw a child with hepatitis, whose parent donated blood.[89] The policy applied by Wessex RTC was that close contacts would be excluded from further donating for a period of 6 months.[90] Donors who themselves contracted hepatitis were permanently withdrawn from the donor panel.[91] However, they might be asked to donate for the purposes of producing anti-HAA serum for testing purposes.[92] An example of a letter notifying a donor, dated 3 August 1976, read:

[87] OXUH0003752_005
[88] IPSN0000331_008
[89] NHBT0108678. See e.g. NHBT0108544, NHBT0108546
[90] See e.g. NHBT0108542
[91] See e.g. NHBT0108548
[92] See e.g. DHSC0100019_127 and NHBT0107885_003

"Your family doctor has very kindly let me know that you have recently become unwell and developed jaundice. I do hope that this will clear quickly and you will feel better in yourself soon.

May I take this opportunity of thanking you for the donation which you gave on 21st July, 1976, and the many other occasions that you have helped our Service and patients in hospital.

As you probably know, regretfully we shall now have to withdraw you as a donor, due to the jaundice, but once again many thanks for all your valuable assistance."[93]

78. Donors would also be excluded if their serum bilirubin level was high enough to indicate jaundice; although the cut-off threshold above which blood would not be accepted was raised in 1973.[94]

79. On 13 June 1975, Dr Maycock wrote to Dr Smith:

> *"One of the recommendations of the Advisory Group on hepatitis antigen testing will be that it will no longer be necessary to exclude donors with a history of hepatitis or who have antibody, providing, they have not had an attack of hepatitis within the previous year or been transfused and that their blood is negative for antigen by RPH."*[95]

80. This change had not yet been implemented by August 1976, when an enquiry as to hepatitis notification requirements[96] elicited the following reply from Dr Smith:

> *"...for some time now we have had an informal arrangement in certain areas of Wessex that we are told by the M.O.H. of cases of infective hepatitis who are blood donors. Usually the Health Visitor enquires if other members of the family are donors and we arrange not to call the contacts to one of our blood*

[93] NHBT0108941
[94] NHBT0107248; NHBT0109077, NHBT0108874
[95] NHBT0109112 in response to Dr Smith's query at NHBT0108957_006
[96] NHBT0108670_003

collection sessions until six months has elapsed. The patient is withdrawn as a donor.

Now that we have a sensitive haemagglutination test for Au. (Hepatitis associated antigen), which causes the majority of cases of post-transfusion hepatitis, I think the above arrangements can be discontinued...

At the moment we are not bleeding donors with a history of jaundice (other than neonatal) or donors who have been in contact with a case of hepatitis during the last six months, but eventually (W.H.O. recommendation) we shall not exclude donors with a history of jaundice, provided the Au. antigen test is negative and the donor has not suffered from hepatitis or jaundice during the previous 12 months.

... It would be helpful, however, to ask Health Visitors to tell close contacts of cases of hepatitis that they should not volunteer to donate for at least 6 months."[97]

81. On 4 January 1977, this anticipated policy change was implemented. Dr Smith sent an internal memo directing that:

> "*We are now able to accept persons who have previously had jaundice as donors, provided they have not had hepatitis or jaundice during the last twelve months. This is because of the sensitive test for hepatitis which has been developed.*"[98]

82. An example of a letter sent to a donor under this revised policy on 30 March 1979 said:

> "*Thank you for letting me know that have had mild hepatitis, and I hope by you are feeling much better.*
>
> *If you would like to continue donating, in 12 months' time we could take a small sample of blood for a special test and if the result is negative you would*

[97] NHBT0108670_002
[98] NHBT0108668 p.9. See also NHBT0108667_002

then be able to continue as a normal donor. Perhaps you could let me know if you would like us to arrange this."[99]

83. An internal memo dated 18 December 1981 provided:

> "*With effect from 1st January, 1982, the practice of taking "samples only" from these donors will cease, instead they will be regarded as ordinary donors and will be dealt with in exactly the same way as new donors, both at donor sessions and in the laboratories.*
>
> ...
>
> *Donor selection will remain as it is, i.e. reject if a history of jaundice or hepatitis within the previous twelve months, or a history of close contact within the previous six months.*"[100]

84. The impact of this policy can be seen in the case of a donor whose donation was potentially implicated in a case of post-transfusion hepatitis who was allowed to donate again with an HAA negative test.[101] A letter from Dr Maycock to Dr Smith dated 30 September 1971 shows it was recognised that "*of course, an Australia antigen negative test does not mean that the agent of serum hepatitis is absent*".[102]

85. Guidance for doctors at donor sessions was updated in November 1976 to extend the period of exclusion for donors recently returned from tropical areas, from 8 to 12 weeks, and to add:

> "*Pyrexia of unknown origin in persons who have visited the tropics.*
>
> *The possibility has to be kept in mind that such pyrexias might result from Lassa fever or other dangerous viruses. In view of this blood or blood products should not be used from such patients until 3 months have elapsed following resolution of the pyrexia.*"[103]

---

[99] NHBT0112218
[100] NHBT0144439
[101] NHBT0108934_005
[102] NHBT0107106
[103] NHBT0201969

Testing donations

86. Testing for HAA ('Hepatitis Associated Antigen' or 'Australia antigen') was an issue under consideration from the outset. On 17 May 1971 Dr Smith wrote on a memorandum concerning estimates of initial capital and annual costs of reagents to test for HAA:

> "*Hepatitis Associated Antigen*
>
> *Since the Wessex Transfusion Centre was opened in September 1970 we have been testing all donations sent to the Renal Dialysis Unit at Portsmouth. From April 5th we have also been testing all the cryo and fresh frozen plasma which has been used.*
>
> *Dr. Cliff of the Wessex Regional Hospital Board has recently presented a report to the board about the dangers and problems of transmitting serum hepatitis. As a result of this Dr. Revens asked Mr. Coxon to set in touch with us about the finance necessary to get this testing service going on as many donors as possible.*
>
> *We have now completed an estimate of the initial capital cost together with the annual cost of reagents. As you will see, the most expensive annual cost is that of antibody. Up to now we have always used free donations, and this will be our policy in the future, but there may be occasions when we shall have to consider using commercial sera if the anti-sera available free comes in short supply or is unsatisfactory. I personally think that we shall not be calling upon this money or only a small amount of it will be necessary for commercial anti-sera each year.*
>
> *Mr Kavanagh and I have been doing these tests, but before allowing any other technical members of the staff to perform them we shall require, for safety reasons, the negative pressure ventilated cabinet. One Junior Technician and*

one Technician will also be needed before we can test all donations of blood."[104]

87. On 19 October 1970, Dr Smith had written to Abbot Laboratories in California asking for "*for details, including price, of your Au-HAA tests for Australia antigen*".[105] He received a response dated 5 November 1970 explaining that the AUS-Test kit could be ordered directly from California.[106] He went on to request funding from the Wessex Regional Health Board for "*the financing of the apparatus*" for "*the screening of blood for H.A.A.*".[107]

88. On 25 May 1971, Dr Smith wrote to the City of Portsmouth Department of Public Health, "*Towards the end of this year we hope to start testing all our donors for the presence of Hepatitis Associated Antigen*", and that he hoped that would enable him to discontinue the system of health visitors notifying cases of hepatitis.[108]

89. In line with this effort, an internal memo dated 23 June 1971 read, "*We shall be receiving from the Blood Products Laboratory by passenger train 10 vials of anti-H.A.A. serum for routine testing.*"[109] In a letter to Dr Brueton dated 9 August 1971, Dr Smith noted of a donation potentially implicated in a case of post-transfusion hepatitis, "*Blood donation number 31422 taken on the 14th September 1970 was sent for plasma. We were not, at that time, doing Au antigen tests.*"[110] The implication appears to be that by August 1971, HAA / Au antigen testing of donations was being undertaken, to some extent.

90. Universal testing commenced from 4 October 1971. A letter from the Lister Institute on 11 November 1971 noted that "*We have been testing all Winchesters of plasma received from Southampton since S441 for Australia antigen*", and asked for information about a particular plasma pool.[111] Dr Smith's reply was:

---

[104] NHBT0108704
[105] NHBT0108712_006
[106] NHBT0108712_001
[107] NHBT0108709_002
[108] NHBT0108678
[109] NHBT0108698_001
[110] NHBT0108694_001
[111] NHBT0107890_005

> *"Since the 4th October 1971 all donations of blood have been tested for Hepatitis Associated Antigen at the Wessex Transfusion Centre. Apparently the pool sent to you, which you found H.A.A. positive, was one sent from donations taken before the 4th October 1971.*
>
> *I should like to confirm that all Winchesters are from ten donor pools and we would, in no circumstances, knowingly send you plasma from a donor who is known to have a positive H.A.A. test."*[112]

91. By the time of the Regional Directors' Meeting on 6 October 1971, Wessex was one of four RTCs (along with Sheffield, Edgware and Cardiff) able to say that they were testing all donations for HAA.[113]

92. The testing was initially undertaken by an electro-immunodiffusion method which took 2 hours[114] using reagents derived from HAA positive donors.[115] In response to a query from his deputy, Dr Barnes, as to whether blood could henceforth be labelled as HAA tested, Dr Smith replied on 13 December 1971:

> *"Until the testing of blood donations for H.A.A. becomes more accurate and specific I do not think we should alter the fresh blood group labels in any way. The test at the moment is only 40 per cent effective and I would not like the clinicians to believe that a patient could not contract transfusion hepatitis after being given H.A.A. negative blood using our present test."*[116]

93. On 29 April 1974, Dr Smith wrote an internal memo regarding possible introduction of a haemagglutination test:

> *"Since we have been testing our donors for the presence of the Australia (Au) antigen which causes transfusion hepatitis, we have managed to obtain the reagents, without direct charge, from donors who already have either the antigen or antibody in their plasma. The electroimmunodiffusion test that we*

[112] NHBT0107890_004
[113] NHBT0015758_001
[114] NHBT0108997_005
[115] NHBT0109167_005
[116] NHBT0108997_001

use has been known not to pick up all carriers of the Au antigen and the stage has now been reached where more sensitive tests have been evolved and evaluated. We are shortly to receive expert advice through the D.H.S.S. that the test we should move on to is the haemagglutination technique using red cells coated with antibody to Au antigen. This test is now available commercially from Burrough Wellcome, a large ethical pharmaceutical company, and the cost for each test will be about 10p, ...

Probably the most sensitive test available is the radio-immunoassay one, but this is time-consuming with a liability to give false positives, and the cost would be in the region of 70/80p a test."[117]

94. As noted above, in a letter dated 18 August 1976, Dr Smith mentioned that "*Now... we have a sensitive haemagglutination test for Au. (Hepatitis associated antigen), which causes the majority of cases of post-transfusion hepatitis*".[118] In another letter dated 7 December 1976, he indicated this testing had been implemented 2 years previously, commenting that, "*The revenue which was required to perform the Burroughs Wellcome haemagglutination test was granted to us most quickly by the Wessex R.H.A.*"[119]

95. An internal memo notes that from 13 December 1976, a 5 ml blood sample was to be taken from every donor on each occasion giving blood for Au antigen and VDRL (syphilis) testing; "*We are required to do this for safety reasons.*"[120]

96. On 5 March 1979, Dr Smith wrote to Dr Jenkins at the North East Thames RTC:

> "*At the moment we are using the Burroughs Wellcome haemagglutination test when testing donors for Au antigen and we are wondering which third generation test to use in the future. Obviously if there is a recommendation from your committee to use R.I.A., we will do so.*

[117] NHBT0109143_001
[118] NHBT0108670_002
[119] NHBT0108669
[120] NHBT0108668 p.14

For some weeks now we have been using the Hepanostika microElisa method on a trial basis with new donors and it is claimed that this is extremely sensitive. We are now wondering whether to extend our test to cover all new donors by this method.

I would very much welcome your views about this matter as we are anxious to make the correct move for the future."[121]

97. Dr Jenkins replied that "*Hepanostika are currently visiting all centres promoting the microElisa technique, which is being considered alongside RIA by the Department's Advisory Group.*"[122] Dr Smith subsequently attended a meeting with a sales manager to discuss the new test[123] and on 6 December 1979 wrote to Dr Lane at BPL:

> "*We welcome any news about KIA testing for Au antigen. It appears to me that it would be most convenient to go to your test in due course.*
>
> *If there is an opportunity to try the procedure in Wessex, we would welcome this.*"[124]

98. On 2 April 1981, Dr Smith wrote to Dr Lane at BPL complaining about the cost of reagents for a new BPL radioimmunoassay HbsAg test, which he described as "*an excellent and sensitive test*". He stated:

> "*On the 1980 figures, this will cost us (Wessex R.H.A.) in the future £21,600 per annum if this money can be made available. As I have emphasised before, locally for the safety of the patient we must use the most sensitive technique; any litigation involving a patient with post-transfusion hepatitis when a less sensitive test is used would be extremely expensive without taking into consideration patient care.*"[125]

---

[121] NHBT0108661_002
[122] NHBT0108661_001
[123] NHBT0108660_002
[124] CBLA0006099
[125] CBLA0001330

99. Dr Lane replied that the price had been set by the DHSS.[126]

Donors who tested positive

100. Once testing was in place, the issue arose as to how to handle donors whose donations tested positive for HAA. A report of the Hepatitis Advisory Group to the Wessex Regional Hospital Board in March 1973 states that:

> "*All blood donations are now screened for HAA at the Wessex Regional Blood Transfusion Centre and it is therefore the established practice to only supply screened blood to hospitals in the region.*
>
> ...
>
> *Positive HAA donors are traced and excluded from the donor panel, and arrangements are made to contact the general practitioner of such a donor with a view to arranging referral to a Consultant to investigate the liver function tests.*"[127]

101. There are various examples to show that donors who tested positive were notified by letter, asked to provide their GP's contact details, and follow-up tracing was conducted.

- In an example from August 1971, a donor whose prior donation had been potentially implicated in a case of post-transfusion hepatitis was screened for HAA on his next donation visit. He tested positive and was asked to provide contact details for his GP, who undertook to carry out liver function tests. The information was also notified to Dr Maycock at DHSS.[128]

- A handwritten note from a donor on 8 September 1971 replied "*Thanking you for the information, I shall refrain from donating any further blood.*"[129]

- Another donor wrote on 19 May 1972:

---

[126] CBLA0001339
[127] NHBT0202116. Dr Smith was a member of the Advisory Group; NHBT0110059_008
[128] NHBT0107885_008, NHBT0107885_012
[129] NHBT0109016

"Thank you for your letter dated 17th May, informing me of the outcome of a recent test done on my blood in connection with hepatitis.

I am sincerely sorry that my name has to be withdrawn from your active panel of donors, but understand that this is very necessary. I only hope that this condition was found out in time to prevent any transmission of hepatitis to a patient. I would add that I have been totally unaware of the position until I received your letter, although it does explain a few 'symptoms' I have had at times.

I agree that my doctor should be made aware of this finding; his name and address are as follows:-...

If you feel there is any further action I should take, no doubt you will let me know."[130]

Tracing donations

102. From the time the RTC was established, it can be seen that efforts were made by the Wessex team to trace possibly implicated donations where there was later evidence of jaundice or hepatitis.

- In one example where a donor developed post-transfusion hepatitis, on 1 January 1971, Dr Brueton, director of the South West RTC, wrote to Dr Smith regarding donor tracing for bottle number 83745:

  "*This bottle of blood was issued to you during the week commencing 16th November.*

  A previous donation from the same donor was one of three bottles of blood transfused to a patient who developed hepatitis.

[130] NHBT0109010 p.1

Could you please trace what has happened to bottle No. 83745? If it has gone into a plasma pool, please let know the reference number of the batch. I think that Dr. Maycock should then be informed either by you or me."[131]

Dr Smith followed up to trace whether the donation had been issued to a particular patient or sent out.[132]

- In an example in March 1971 where a donor suffered jaundice three days after donating, the implicated donation was traced to Southampton General Hospital where it had been transfused to a patient. The hospital clinician and the patient's GP were informed.[133]

103. As noted above, HAA testing of donations was established in 1971. There is subsequent evidence to show that a positive HAA test led to previous donations from the same donor being traced and where possible withdrawn.[134]

104. Haemophilia centres also reported cases of post-transfusion hepatitis to the Wessex RTC.[135] The correspondence indicates contemporary concerns about the safety of factor products. On 21 March 1974, a letter from the DHSS to Dr Smith responded to his notification of cases at Lord Mayor Treloar Hospital; the author wrote "*The list of transfusion fluids used was not enclosed. Was Hemofil concerned?*" [136] On 20 June 1974, Dr Dilling at the Bournemouth Haemophilia Centre reported, "*I think this patient has been infected with serum hepatitis but the evidence seems to suggest that Hemofil rather than cryoprecipitate is the infectious agent.*"[137] On 19 November 1974, she wrote again regarding a patient who tested HAA positive, "*I am sending you a list of all cryoprecipitate given this year, though it is possible the*

[131] NHBT0108673_013
[132] NHBT0108673_010, NHBT0108673_007
[133] NHBT0108680_007
[134] See e.g. NHBT0107886 p5 and 7, NHBT0109087, DHSC0100020_045
[135] See e.g. TREL0000205_201
[136] DHSC0100018_142
[137] DHSC0100018_041, DHSC0100018_042

Hemofil may be the cause."[138] Dr Craske had sent Dr Smith an account of the outbreak of hepatitis associated with Hemofil at Bournemouth.[139]

Staff testing

105. Wessex RTC staff were also tested for HAA. On 29 March 1971, Dr Smith wrote to Dr John Guthrie, Chair of Division of Pathology, Southampton General Hospital:

> "*At various times we have had discussion about Au antigen testing of laboratory staff and safety precautions in the laboratory.*
>
> *We have recently written to the Wessex Regional Hospital Board and they have referred this matter to D.H.S.S. about the position of a member of the staff who was found to be a carrier of Au antigen.*"[140]

106. The policy adopted was that antigen positive staff could continue working for the RTC but not handling "open" blood or blood products.[141]

107. In January 1974, it was noted that following testing the previous May, medical staff were to be offered voluntary testing every 6 months.[142]

Vaccination

108. Hepatitis B vaccinations were made available to at-risk staff in November 1982.[143] Dr Smith attended the meeting of the Western Division of National Blood Transfusion Service Consultants on 11 January 1983, where it was "*warned that there could be a 25% incidence of serum sickness reaction with the new vaccine and that it only protected against hepatitis B. Its use should be for carefully selected individuals who were at definite risk.*"[144] Dr Smith received a letter dated 27 October 1983 from Professor Ralph Wright, University of Southampton enclosing a memo for staff about

[138] NHBT0108913 p5
[139] NHBT0108915
[140] NHBT0109140_007
[141] NHBT0109159
[142] NHBT0109166
[143] NHBT0111685, NHBT0111682
[144] NHBT0098755_009

the vaccine, which addressed an unjustified concern that the vaccine could transmit AIDS.[145]

Knowledge of risk and response to risk – NANBH / HCV

Knowledge of NANBH

109. NANBH is mentioned in the documents from at least 1976, when Dr Kirk at Treloar College wrote to Dr Smith:

> "*I enclose details of two patients whom I have reported to Oxford as cases of non-B hepatitis almost certainly associated with the use of Factor VIII concentrates.*"[146]

110. In his letter of 6 January 1982, Wessex RTC's Administrator, Mr Grundy, noted that:

> "*The present level of spending on commercially-produced FVIII a.h.f, is £350,000 in Wessex. This, if our 1982/83 proposals are approved, will reduce to some £274,000 in 1983/84 - with a further proviso that present levels of usage are maintained…. The cost of commercially acquiring the additional FVIII a.h.f, represented by 11,300 kg of plasma would be £191,000 at the present price of 7P per i.u. plus VAT. There is of course the increased risk of hepatitis transmission to consider, particularly Non A and Non B with imported Commercial Blood Products. Further dependence on commercial sources would undoubtedly bring about a rise in cost. The World Health Organisation recommends each nation to be self sufficient in blood products.*"
> [147]

111. In his 1987 article "*The appropriate use of diagnostic services: a guide to blood transfusion practice*", Dr Smith wrote:

---

[145] NHBT0144320
[146] TREL0000100_109
[147] NHBT0110055

> *"Post-transfusion hepatitis (PTH) occurs after approximately 10% of transfusions in the USA; it has been estimated that up to 90% of cases are due neither to hepatitis A not B (non-A, non-B hepatitis). In the UK it is believed that non-A, non-B viruses play a smaller part as a cause of PTH. Persons with a history of jaundice are accepted as donors provided this occurred at least a year ago."*[148]

Testing donations

112. In the same 1987 article, Dr Smith noted that some centres in the USA were indirectly screening donated blood by looking at ALT and anti-HBc. [149] He did not give an opinion as to whether the UK should follow suit. No evidence has come to light to date to show that surrogate testing had been used at Wessex RTC.

113. On 6 December 1989, Dr Smith wrote an internal memo about HCV testing:

> *"The test that the South Western RGM is referring to is a new one for detecting Hepatitis C virus which is one of the viral causes of non-A non-B hepatitis. The incidence of non-A non-B post-transfusion hepatitis in the United States is as high as I0~, but in the U.K. it is much less of a problem and we may see about one case a year in our Region. National studies are being made now to find out the incidence but so far we have no instructions to do this testing from the National Directorate at Manchester.*
>
> *The technique which is an Enzyme linked immune-assay produced by Ortho Diagnostics costs £1.00 per test, so in our Region where we need to test about 100,000 donations, it would be quite expensive and we have mentioned the possibility of this having to be done in next years [sic] Budget which you will not yet have seen. The budget is in the final stages of preparation.*
>
> *I expect that National negotiations and purchase by a National Contract could bring the cost down but at the moment there is only one supplier. HIV2 testing*

[148] DHSC0032167_083
[149] DHSC0032167_083

of selected donors (West African residents and travellers) is still taking place, free of charge, by the Central P.H.L.S. at Colindale."[150]

Knowledge of risk and response to risk - HIV

AIDS leaflet

114. Dr Smith attended the meeting of Regional Transfusion Directors on 15 May 1983 at which possible steps to address the risk of HIV were discussed. Two options, questioning of donors at sessions and discontinuing sessions in areas of high risk donors, were rejected. It was decided that a pamphlet explaining AIDS to donors should be developed.[151]

115. In April 1984 the RTDs reported on their experience with the AIDS leaflet, and in particular the method they had used to distribute it, how many they had used, and what the impact was on donor attendance. The entry for Wessex RTC makes it clear that the leaflet was initially sent with the call up cards (August 1983 – February 1984) but was then made available at sessions. Wessex RTC had used 71,700 leaflets. It was judged to have had no effect on donor attendance.[152]

116. On 24 January 1985, Dr Smith wrote to Dr Alison Smithies at DHSS:

"Thank you for your letter about Preventative Action against Transmission of AIDS. We display a poster at our blood collection sessions together with a notice at the Team Clerk's desk and in addition we have altered the NESTS form 110 to draw attention to AIDS.

I think a national poster would be very useful and when the new AIDS leaflet arrives we intend to send this to all our donors with their call-up letter."[153]

---

[150] NHBT0144310
[151] CBLA0001707
[152] CBLA0001820
[153] DHSC0101658_014

117. She replied that his approach seemed very comprehensive.[154]

118. At the Regional Transfusion Directors meeting on 13 April 1988, it was recorded in the minutes that:

> *"Dr. Smith asked to whom comments should be made for any revision of the Aids leaflet and was advised to contact Dr. Hilary Pickles. Dr. Smith also asked for advice about how to deal with a positive blood donor who declined to come forward for a confirmatory sample and counselling. It was felt that if a registered letter failed to produce results, it would be appropriate to call on the donor at home. A refusal to discuss the matter in those circumstances would have to be regarded as conclusive.*
>
> ...
>
> *Dr. Smith drew attention to a phone call which he had had from an Insurance Company requesting information about the HIV status of a donor who was taking out an Insurance Policy. It was agreed that this information could only be released with the donor's written consent."*[155]

119. In October 1989, Dr Smith wrote a letter to Dr Gunson outlining the steps he had taken in response to AIDS, in order to inform the HIV litigation then in progress:

> *"From our records, our leaflet about high risk donors was distributed with call-up cards and given to new donors, and available to donors to pick up, at our blood collection sessions in September, 1983. At this time, we were involved in nerve shattering Television, Radio and Newspaper publicity. The memo about high risk donors to all establishments 'Collecting blood for Transfusion', Food & Drug Administration, U.S. Dept. of Health & Human Services, was dated March 24th, 1983 (Petriccianni J.C. 1983).*
>
> *I had an informal meeting with the Medical Secretary of the Gay Society and he offered to publicise information on AIDS and provide advice (R.T.D. 188*

[154] DHSC0101658_013
[155] CBLA0002409

Minutes 18th May 1983). General instructions were issued to the Staff at Wessex R.T.C. about AIDS and Blood Transfusion at this time."[156]

Viral inactivation

120. On 12 December 1984, Dr Smith wrote to the Treasurer of the Wessex Regional Health Authority:

> "*Thank you for your letter about the cost effect of heat treating Factor VIII. We have already had a look at this and an allowance has been made in our budget proposals 1985/86 in our Annual Plan (copy enclosed).*
>
> *In the introduction of our plan we talk about the loss of yield in Factor VIII when the Blood Products Laboratory starts to heat treat in April 1985 and we will be keeping a close eye on the possible cost of this in the future. I hope this letter provides the answers you require.*"[157]

121. On 29 October 1985, Dr Smith wrote to DHSS:

> "*As you know we are only using heat treated Factor VIII for the treatment of haemophilia and I have mentioned to our local haematologists the problems that might be present with intravenous IgG immunoglobulin.*"[158]

Testing donations

122. In February 1985, Dr Smith along with other RTC Directors signed a letter to the Lancet arguing that further consideration should be given before introducing HTLV-III antibody tests due to: the risk of false positives; leading to unnecessary stress for donors; with possible consequences for supply of blood; and the need to prioritise available tests for high risk groups.[159]

123. However, by 5 August 1985, Dr Smith had decided in favour of testing. He wrote to DHSS:

---

[156] NHBT0020661
[157] NHBT0110058_001
[158] DHSC0002285_013
[159] PRSE0002407

"There will be no difficulty at all in meeting the suggested deadline of October for HTLV3 antibody testing.

We will now go ahead to make preparations to introduce routine screening of blood donations collected in Wessex."[160]

124. The national commencement date for testing was 14 October 1985. Dr Smith confirmed to DHSS:

"Our stocks in the Centre and in the hospital blood banks were all negative for the [HTLVIII] antibody on the 14th October 1985. This includes fresh frozen plasma and cryoprecipitate."[161]

125. When it came to Anti-HIV 2 testing, Dr Smith wrote on 22 March 1988:

"We have been sending donor samples since the beginning of February, 1988. So far 13 have been sent, all with negative results."[162]

Look-back

126. On 26 September 1985, Dr Jayaswal, Consultant Haematologist at Wessex RTC, responded rather dismissively to a look-back request from BPL. She wrote:

"Thank you for your letter and details of the Factor VIII batches. Logistically it is going to be impossible for us to scrutinize 1,500 donors from so long ago, and both Dr. Smith and I agreed that we would ensure any of our HTLVIII a/b positives do not include the donors mentioned by checking prospectively. It would seem that the donors of plasma for 8 CRV1526 are due for a donation again within the next few months and hopefully they will be cleared as they come along. I am sure that you will appreciate that it is very difficult to clear them otherwise."[163]

---

[160] DHSC0002275_030
[161] DHSC0002285_013
[162] NHBT0003697
[163] CBLA0000010_227

127. The request was chased up by Dr Lane on 20 October 1988, who noted "*The batches of factor VIII in question are now the subject of an enquiry by a clinician concerning an HIV sero-conversion in a young haemophiliac*".[164]

128. Dr Smith replied on 26 October 1988, saying:

> "*Regarding your letter about the follow-up action concerning donors who contributed to the above batch, we will check our records to see if any of our HIV1 antibody positive donors were implicated.*
>
> *I understood that Dr. Jayaswal was doing this but she has now left us to work as Associate Director of the Brisbane Transfusion Centre.*
>
> *Unfortunately, we now cannot trace the sheets which Dr. Snape provided with the list of single packs. Please could I have another copy of the sheets and I will be in touch with you again as soon as possible. Sorry about this.*"[165]

HIV contamination incident

129. In late September / early October 1984 a blood donor was admitted to Bournemouth Hospital with a "*skin rash consistent with Kaposi's sarcoma, leukopenia and anaemia.*"[166] The indication was that he had AIDS. The donor was a gay man and had given blood on a number of occasions, including several days before his admission in early October. The donor's blood had been used in the production of batch no. HL3186 of factor VIII and distributed to patients.

130. This section of this Note addresses the evidence the Inquiry has received about batch no. HL3186. It examines: (i) the initial investigation into batch no. HL3186; (ii) the notification to haemophilia centre directors; (iii) the donor and his donations; (iv) the progress of the recall; (v) Dr Craske's investigation; and (vi) a consideration of who received the infected batch.

[164] CBLA0000010_229
[165] CBLA0000010_230
[166] CBLA0000010_183

Initial investigation

131. On 2 October 1984 BPL produced an internal memo about the donor's admission to Bournemouth hospital. It stated: "*[d]onor admits to homosexual activity but was VDRL negative when he donated blood several days ago.*"[167] The memo noted that the donor had given blood on 27 March 1984 and that that blood was dispatched to BPL on 6 April 1984. This blood was part of the pool from which batch no. HL3186 of factor VIII was produced. Batch no. HL3186 was distributed to Wessex RTC on 10 August 1984 in the form of 485 vials. 400 vials had gone to Cardiff RTC on 15 August 1984.

132. In addition to his March 1984 and September 1984 donations, the donor had also given blood on 21 November 1982 and 7 September 1983. However, the November 1982 and September 1983 donations were not used to supply plasma to BPL.[168] In addition to the production of factor VIII batch no. HL3186, "*fraction V was recovered*" and was "*held as L938 and L939.*"[169] These were secured and relabelled by BPL so that they were not used.

133. On 2 October 1984 Dr Smith of the Wessex RTC was notified by telephone of the donor's presentation and '*asked to recall all vials including any held by patients for home therapy.*'[170] Dr Smith was also asked to report any plasma from this donor dispatched to BPL or PFL within the last 5 years[171] and to determine whether the donor had '*a history of attendance at local special clinics for venereal disease.*'[172]

134. It was noted that Dr Tedder of Middlesex had been consulted but that he did not want to receive samples of plasma fractions "*since he did not feel test methods presently in use were appropriate.*" Dr Tedder did request to receive a sample from the donor's most recent September 1984 donation. Dr Craske, PHLS Manchester, was

---

[167] CBLA0000010_183
[168] §4 pf CBLA0000010_183
[169] §2 of CBLA0000010_183
[170] CBLA0000010_183
[171] The same BPL memo records that Dr Napier at Cardiff RTC was unavailable but Mr Booth, Senior Chief MLSO at Cardiff, was informed by telephone on 3 October 1984 and asked to recall all vials of HL3186. This was followed up in writing the same day: CBLA0000010_208 On 8 October 1984 Dr Napier confirmed in writing to Dr Snape that Cardiff had '*instituted recall arrangements.*' CBLA0000010_212
[172] §4 of CBLA0000010_183

consulted and he asked to be supplied with a list of haemophilia centres who had been supplied with HL3186 in order to initiate follow-up studies on patients treated with this batch.

135. On 2 October 1984 Dr Barnes, the Deputy Medical Director of the Wessex RTC, telephoned BPL late in the evening and stated that the donation of 21 November 1982 was taken at Leeds. Time expired plasma from this donation was sent to BPL in pool number C3162TE.[173]

136. On 3 October 1984 Dr Snape of BPL wrote to Dr D Smith of the Wessex RTC to put in writing a telephone conversation between them the same day.[174] The letter is headed "*Factor VIII Batch HL3186: Possible Risk of AIDS.*" Dr Snape requested that unused vials were recalled and that recovery of unused vials should be extended to those issued to individual haemophiliacs on home treatment.

Notification to haemophilia centres

137. On 4 October 1984 a notification letter was sent by Dr Barnes[175] to the haemophilia centre directors in the Wessex region regarding batch no. HL3186.[176] The letter stated that:

> *"With further reference to Mr Allison's telephone call to your Blood Bank Chief MLSO yesterday, asking for the above quoted batch of Factor VIII to be recalled and returned to us.*
>
> *The reason for this is that one of the donors whose plasma was incorporated in this pool is now thought to be suffering from AIDS. Investigations are being carried out and the diagnosis should be settled, one way or the other, within the next week or two. In the meantime, may I confirm Mr. Allison's request and ask for all unused ampoules of this batch to be recalled and returned to this Centre.*

[173] §8 of CBLA0000010_183
[174] CBLA0000010_207
[175] Dr Barnes was covering for Dr D S Smith who was on holiday at this time: CBLA0000010_180
[176] DHSC0002247_090. The consultant haematologists at Treloar's, Bournemouth, Portsmouth, Southampton, Salisbury, Winchester, Dorchester and Newport

In order to prevent undue worry to your patients, may I ask for your discretion here and, for the time being at least, to keep this news to yourself. When any definite information does become available, either Dr Smith or myself will let you know."

138. The instructions at this stage therefore were that patients should not be told about the infected batch in order to avoid "*undue worry*".

139. On 16 October 1984 Dr Barnes informed all haemophilia centre directors in Wessex that he was "*extremely sorry to have to tell you that the diagnosis of AIDS has now been confirmed.*"[177] It appears Dr Barnes had managed to confirm the donor's diagnosis with some haemophilia centre directors the previous day by telephone. Dr Barnes stated that both Dr Snape of BPL and Dr Craske would be in touch regarding "*the follow-up of your patients.*" Dr Barnes stated that he had been "*asked to suggest that a policy of discrete surveillance be pursued.*" It is unclear what "*discrete surveillance*" was meant to entail.

140. On the same date Dr Barnes also informed Surgeon Commander Buchanan at the Royal Naval Hospital, Haslar that blood had been sent to his hospital, which was now known to be from a donor who was suffering from AIDS:

"presumably has been transfused into a patient. Details are:

Group O plasma reduced blood. Pack No. 003 358 S9. Taken 27 March 1984. Sent to R.N. Hospital, Haslar, 2 April 1984."[178]

The donor and his donations

141. On 4 October 1984 Dr Barnes wrote to Dr Snape to confirm the following details of the donor's known donations:[179]

[177] DHSC0002247_093
[178] DHSC0002247_094
[179] CBLA0000010_209

(i) 21 November 1982 at Cottingham, Leeds RTC. This donation was not used. Time expired plasma pooled and sent to BPL on 11 January 1983 under batch no. C3162.

(ii) 7 September 1983, Bournemouth. This whole blood donation was sent to a Portsmouth hospital and not returned.[180]

(iii) 17 March 1984, Bournemouth. FFP sent to BPL on 6 April 1983. The plasma reduced blood was sent to a Portsmouth hospital. Batch No. S/F 4333, Pack No. 003 358 S8.[181]

(iv) 25 September 1984, Bournemouth. This was still at the RTC.[182] The red cells were destroyed and the plasma separated and frozen. Red cells were destroyed. 10 ml plasma aliquot was sent to Dr Tedder.

142. Dr Barnes stated in relation to the second and third of these donations: "*we are not getting in touch with the clinicians involved until the diagnosis is confirmed.*"[183]

143. There was also a "*possibility*" of a donation prior to November 1982 in the same region and attempts were being made to trace that donation. Dr Barnes subsequently confirmed in a letter to Dr Craske on 5 November 1984 that records had been searched back to 1977 and no further donations were found.[184]

144. An undated document, with no stated author, states that the donor's blood type was Group O Rh(D) positive.[185] This document suggests that between the period 26 August 1983 to 10 February 1984 "*all regular donors [at Wessex RTC] sent AIDS leaflet.*" The document states that "*An AIDS leaflet was received by the donor in early 1984.*" It is not known when precisely he received it, whether the donor read this leaflet and, if so, what he thought about it. The contents of that leaflet, and the

[180] An undated, unauthored document describes this second donation as "*whole blood donation transfused. Further information from Dr Ala*": DHSC0004180_050
[181] Dr Lane explained in his draft proof of evidence for the HIV litigation that the third donation was sent to BPL was expired plasma and that "*this would have been used to manufacture albumen which was heat treated and for this reason we did not take any steps to follow-up this product.*" §61 of CBLA0000072_032
[182] See draft of Dr Lane's proof at §52: CBLA0000072_032
[183] CBLA0000010_209
[184] DHSC0001690
[185] DHSC0004180_050

question of whether the language of the leaflet was sufficient to deter high risk donors, has already been explored in Inquiry hearings.

145. The same undated document refers to a donation by the donor on 14 February 1983 at Birmingham RTC. This purported donation does not feature in the other documents which record the donor's donations. It is not presently known whether this is an error.

146. On 12 October 1984 Dr Barnes confirmed to Dr Lane that a biopsy of the donor showed early Kaposi's sarcoma and that the plasma sample which had been sent for testing was HTLV III positive.[186] By this time, the donor had contracted pneumocystis pneumonia. Dr Lane later wrote "*the indications were that the infection had probably been contracted some two years before in the United States.*"[187] The source of that suggestion is unknown.

147. The donor sadly died in November 1984.[188]

Progress of the recall

148. On 8 October 1984 Dr Barnes updated Dr Snape, following a telephone call on 5 October 1984, of the progress made with returning of vials of Batch HL3186:[189]

Haemophilia Centre	No. Sent	No. Returned
County Hospital, Dorchester	25	5
General Infirmary, Salisbury	70	0
Royal Hants County Hospital, Winchester	10	0
Lord Mayor Treloar, Alton	200	33
Royal Victoria Hospital, Bournemouth	60	40

[186] §58 of CBLA0000072_032
[187] §58 of CBLA0000072_032
[188] DHSC0004180_050
[189] CBLA0000010_211

General Hospital, Southampton	60	1
Queen Alexandra Hospital, Portsmouth	50	10
St Mary's Hospital, Newport, Isle of Wight	10	10
Total	485	99

149. On 8 October 1983 Professor Bloom wrote to Dr Snape stating that he had recalled all the bottles and "*spoken to as many patients as I can personally. Only one student in London has not yet been seen by me but he has not used any of the material.*"[190]

150. On 11 October 1984 Dr Barnes sent 95 vials to Dr Snape.[191]

151. On 17 October 1984 it was confirmed by Dr Barnes to Dr Snape that 20 more vials of batch no. HL3186 had been received from Royal Victoria Hospital, Bournemouth. Therefore, 60 out of 60 vials had been returned.[192]

152. On 25 October 1984 Dr Smith at Wessex RTC sent Dr Snape a further 72 vials from HL3186 which had come from Treloar's.[193]

153. Dr Snape compiled a report about batch HL3186 on 23 October 1984.[194] The following breakdown was given about the Wessex locations of infected vials:[195]

	No. of vials sent	**No. of vials recovered**

[190] CVHB0000002_022
[191] CBLA0000010_214
[192] CBLA0000010_217. A copy of this letter was also sent to Dr Craske, haemophilia centre directors, Dr Smith at Wessex and Dr Rizza at Oxford "for inclusion in the Haemophiliac Centre Director's [sic] statistics": CBLA0000010_221
[193] CBLA0000010_220
[194] DHSC0001111
[195] No table in the original but data put into tabular format with a percentage total added. For Cardiff, a total of 338 vials out of 400 vials had been recovered. 9 patients in total received the batch

Dorchester County	25	5
Salisbury	70	0
Winchester	10	0
Lord Mayor Treloar's	200	105
Bournemouth	60	60
Southampton	60	1
Portsmouth	50	6
Newport, Isle of Wight	10	10
Total	485	187
Total as a percentage	100%	37.94%

154. The number of Wessex patients who received the batch was not set out in this report.

155. For the donation received by BPL on 6 April 1984, which was pooled for fractionation on 17 May 1984 and issued for clinical use on 10 August 1984, the timetable was noted to be "*consistent with the five week period presently supportable for fresh frozen plasma and six to eight week delay from pooling plasma to release factor VIII concentrate for clinical use.*" The report then stated:

> *"Enforcement of a three month quarantine period would not in this instance have avoided the loss of resource resulting from the plasma pool being compromised by a single donation; it would almost certainly have avoided patient exposure to the product however.*

Enforcement of a six month quarantine period would have prevented release of the batch for clinical use; it would also have allowed the donation to be excluded before pooling, thus avoiding a very expensive reject situation.

This incident must be an extremely cogent argument for the establishment of cold—storage facilities capable of supporting a six— month quarantine of fresh frozen plasma.

The appearance of this donor at three different Centres within two years clearly underlines a fundamental problem when carrying out follow—up of donor incidents of this sort. Surely central co ordination of donor records is unavoidable.'[196]

156. It appears that a copy of this report was sent to the DHSS on 24 October 1984 by Dr Snape.[197]

Dr Craske's investigation

157. On 20 November 1984 Dr Craske wrote to the haemophilia centre directors in Wessex and Wales, in addition to Dr Rizza of the Oxford haemophilia centre, Dr Lane and Dr Snape of BPL, Dr McKee at Wessex RHA and Dr Smith of Wessex.[198] Dr Craske explained that he had "*responsibility for the epidemiological follow-up of recipients of this batch to confirm whether any hazard exists and to assist in the investigation of patients where required.*" It was Dr Craske's "*hope that we can obtain the maximum information from this unfortunate incident, and devise methods for the prevention of the disease.*" Dr Craske explained that previous studies on the products transfused in relation to AIDS cases in Cardiff and Bristol suggested that it was not possible to identify specific batches of factor VIII in retrospective studies. Dr Craske stated that "*only a proportion of the patients transfused with an infected batch are likely to contract HTLV-3 infection.*" Dr Craske outlined a strategy for investigation:

---

[196] DHSC0001111
[197] PRSE0001658
[198] CBLA0000010_188. A version of this letter was sent to the Scottish BTS and others on 23 October 1984: HCDO0000273_066

"(a) Identify all patients who have received batch no. HL3186: if a serum specimen taken before the date of transfusion of factor VIII HL 3186 is available, then this should be tested for HTLV-3 antibody. This will identify persons already exposed to infection. If no specimen is available then a specimen of serum (2.0 ml) should be collected as soon as possible to exclude the possibility of prior HTLV-3 infection.

(b) Follow up of patients: Patients identified should be followed up at least at four monthly intervals for 6 years. Further review should be undertaken if a patient becomes ill to exclude the possibility of an AIDS related illness. A control patient who has not received batch number HL3186 should be selected for each index patient. These should be matched as far as possible for age, severity of disease and transfusion history.

(c) A set of simplified forms[199]... should be completed and returned to me... Follow up should be carried out even if a patient is found to be positive for HTLV-3 antibody in the first specimen tested. This will assess whether exposure to more than one batch of factor VIII contaminated with HTLV-3 has any effect on the chance of contracting AIDS.

(d) Four monthly review: Forms JC1, JC2 and JC3 should be completed and sent to Dr Craske at Manchester PHL. The history and medical examination should be designed to exclude AIDS related disease. Laboratory investigations should include haemoglobin, E.S.R., white count, absolute lymphocyte count and differential, white platelet count, and total serum IgG, IgA and IgM estimations. Blood should be taken for hepatitis B, and other viral antibodies as appropriate. Two mls of serum should be retained for HTLV-3 antibody tests and sent to Dr Craske at Manchester PHL."

158. Dr Craske set out two different "*strategies*" for the follow up of patients. The first depended on whether the individual was informed of the risk associated with batch no. HL3186. If they had been informed, Dr Craske proposed that testing could be

[199] Comprising of patient data and clinical features, laboratory investigations for haematology, immunology and virology

carried out on each specimen obtained at a four monthly review. Dr Craske advised that any spouse should be informed that they are at risk of contracting HTLV III as a result of sexual contact. A test of HTLV III antibodies could be offered at the time of follow up. Dr Craske's view was that follow-up could be arranged through the centre director or in collaboration with the GP "*as thought necessary*".

159. Dr Craske also outlined "*an alternative strategy*" where the patient was not told of the risk. In such cases, the clinician should observe the patient at regular four month clinical reviews and collect specimens for testing at Manchester. Such specimens would not be examined until 2 years after the initial exposure or until the patients develop symptoms which are suggestive of AIDS or a director requests testing. Dr Craske set out "*the ethical problems*" with these 2 strategies in a separate appendix.[200] Dr Craske described the first option as "*the only tenable one on moral and ethical grounds*". It was Dr Craske's view that "*ideally*" the patient should be told but that this would:

> "*depend on many factors, including the amount of anxiety concerning AIDS there is already present at the Centre, and the degree to which the patient is capable of understanding the situation. Every effort should be made to encourage the patient to discuss the problem with his spouse and help them to face the problem together. The General Practitioner should also be informed by letter.*"

160. Investigation of spouses was left to the "*discretion of the Haemophilia Centre Director and will depend upon whether it is decided to inform the index patient of the possibility that the batch of factor VIII was contaminated with HTLV-3 virus...*"

161. At the Penrose Inquiry on 10 June 2011 Professor Ian Hann, of Royal Hospital for Sick Children, Yorkhill, was asked about the ethics of the strategies proposed by Dr Craske and said:[201]

---

[200] Appendix entitled "Ethical Problems Associated with HTLV-3 Infection In Haemophiliacs": CBLA0000010_188

[201] PRSE0006031 pages 28 – 30 of the transcript

"*We had lots of discussions about this at the time and this was one of many. I think it helped to crystallise the situation ... and I tended to agree with him, whereas quite a few others didn't.*"

162. A template letter from Dr Snape, dated 24 October 1984, referred to the amount of information that should be disclosed to patients.[202] He stated:

> *"Whilst the decision on how much information to give to individual affected patients is clearly yours to make, I believe that Dr Craske may be able to advise on the balance of known factors which will determine the risk of infectivity from treatment with the batch. It is perhaps important to realize that the donor in question was one of approximately 7,000 donors in the pool - a significantly higher dilution factor than obtained with some commercial concentrates which have arguably been involved in AIDS transmission to haemophiliacs."*

163. On 20 November 1984 William McKee, the Regional Medical Officer of the Wessex Regional Health Authority, set out his views about communication with those potentially infected in a letter addressed to 'Doctor'.[203] He wrote:

> "*I have discussed the subject of AIDS with two members of the Working Party and feel that in the first instance it would be strongly advisable for the patients who received Batch No. HL 3186 of Factor VIII concentrate, or their parents, to be told, with the emphasis that the benefits of treatment by Factor VIII far outweigh the small risk of the patient developing AIDS. I hope you will agree to do this now and let me know thereafter.*
>
> *The public interest in this matter will almost certainly lead to further Press enquiries in Wessex before long. I would like to be able to say that all patients have been informed and that the situation is being closely monitored.*"

[202] CBLA0000010_181
[203] HHFT0001026_004

164. On 24 January 1985 Dr Snape wrote a letter to haemophilia centre directors[204] and noted that Dr Craske had received a "*very poor response to requests for details of patients treated with this batch, and an even less satisfactory response to requests for samples of patients' sera.*"[205] Dr Snape urged the haemophilia directors to give Dr Craske "*your complete support in the identification of patients treated with this batch, and in the clinical follow-up notified in Dr Craske's letter of 20 November 1984.*"

165. Dr Snape also requested to be supplied with a list of patients treated with batch no. HL3186.

166. One centre director, Dr P J Green of Portsmouth, objected to the tone of Dr Snape's letter.[206] He wrote to Dr Snape on 2 February 1985 in the following terms:

> "*I object to the tone of your letter. I intend to follow up the patients affected by the transfusion of HL3186 and I reserve the right to do this in my own time and in my own way. If you had taken the trouble to enquire from Dr Craske you would know that he is in possession of samples from some of my patients and in due time he will be in receipt of samples from all of them. It has taken him 7 weeks to supply me with the results of the tests he does and I only then got them by 'phoning him. Things I dare say will work out in their own time.*"

167. In around October 1985 it was recorded at the UK AIDS Group meeting, in a note written by Dr Craske, that in relation to HTLV III infections associated with batches of factor VIII "*especially HL3186*" he, Dr Snape and Rosemary Spooner of Oxford planned:[207]

> "*to review the latest information regarding possibly affected batches at Manchester shortly. A short report will be presented at the Oxford meeting. There appear to be 5 identifiable batches of factor VIII associated with HTLV-3 infection. Our preliminary impression, however, is that the*

[204] Other than Dr Hamblin at Bournemouth and Dr McAndrews at Isle of Wight
[205] CBLA0001997
[206] CBLA0000010_196
[207] HCDO0000271_097

seroconversion rate related to any one batch is in some cases unexpectedly low."

168. It appears that Dr Craske's investigation into this issue never produced a formal report. Dr Lane later described the follow up as "*not comprehensive*".[208]

169. On 30 August 1988 Dr Lane wrote to Dr Craske asking for a copy of a final report due to the possibility of litigation by those seeking compensation for HIV infections.[209] On 23 September 1988 Dr Craske replied to Dr Lane that a follow up "*in the formal sense*" had not been carried out.[210] Dr Craske attributed this to the conduct of haemophilia centre directors:

> "*The follow-up we were doing eighteen months ago of this incident was bedevilled at that time by the reluctance of Haemophilia Centre Directors to cause, what they considered to be, an unnecessary worry to their patients,*"

170. Dr Craske stated that he had written a paper for publication in 1987[211] which used an analysis of the implicated batches "*as a way of defining criteria for a further investigation of incidents of this sort.*" Dr Craske stated that Dr Lane's letter had prompted him to reopen this enquiry to know the outcome for patients who had been exposed to this batch: "*I will consult my files and let you have a report as to what is known at the present. It should be easy enough to identify where the recipients are now who received this and other batches which may have been infected.*" However, he outlined one problem:

> *"One problem is that most of the batches of material followed-up had only one or two patients where one could be certain that HIV infection was likely to have been associated with the suspect batch. This is due to the fact that in many cases antibody test results are only available after the suspect batch was transfused. It is, therefore, possible that a patient could have been infected prior to receiving the one under investigation and could have been antibody*

[208] §69 of CBLA0000072_032
[209] CBLA0000010_200
[210] CBLA0000010_202
[211] The Inquiry has been unable to find this 1987 paper but a study by Dr Craske dated 10 September 1986 is at: DHSC0001039

positive for say one or two years prior to this event. We do, however, have good data for one batch and this combined with the investigations in Edinburgh will give us a consistent picture and will go in some way to establishing the likely outcome in terms of risk of seroconversion after receiving a batch contaminated with HIV.

171. Dr Craske's plan was to discuss this matter with Dr Rizza at the annual meeting in Dublin in the following week. There is no reference to any such discussion between Dr Craske and Dr Rizza recorded in the minutes of that meeting.[212]

Who received the infected batch?

172. On 30 October 1984 Dr Buchanan of the Royal Naval Hospital, Haslar wrote to Dr Barnes and stated that a patient had received Group O plasma reduced blood, which had been donated by the donor on 27 March 1984.[213] Dr Buchanan stated:

> "*Further follow up investigation of this patient has revealed that he has a mild iron deficiency anaemia with a normal white count and no evidence of lymphopenia. RIA for anti HTLV-3 was undertaken by Dr Tedder at the Middlesex Hospital and has been found to be positive.*"

173. Dr Craske had been informed of the findings and it was noted that the individual's GP had "*undertaken to interview the patient*".[214]

174. On 5 November 1984 Dr Barnes wrote to Dr Craske to confirm the names and personal information of two patients in Wessex who received blood transfusions from donations from the donor.[215] The first was transfused in September 1983 with whole blood from the donor donated on 7 September 1983. In an undated document, which has no named author, it is stated that "*later anti-HTLVIII [was] found in serum*" and that this patient died in 1984 from "*neoplasm of rectum*".[216]

---

[212] BART0002329
[213] DHSC0004180_058
[214] DHSC0004180_058
[215] DHSC0001690
[216] DHSC0004180_050

175. The second transfused patient received blood as a consequence of a bleeding peptic ulcer. It was noted that the patient had "*mild iron deficiency anaemia and anti-HTLV III detected in his serum early [in] November 1984.*"[217]

176. A total of 29 transfused in Wessex were exposed to batch no. HL3186. The distribution is set out in the below table:[218]

Director	**Haemophilia Centre**	**No. of patients transfused**
	Newport, Isle of Wight	0
Dr Gilliver	Dorchester	4
Dr Parry	Salisbury	3
Dr Mavor	Winchester	1
Dr Aronstam	Lord Mayor Treloar's	8
Dr Ozier	Boscombe	0
Dr Chisholm	Southampton	8
Dr Green	Portsmouth	5
Total		29

177. On 29 January 1985 Dr Bell, locum consultant haematologist, confirmed to Dr Snape the names of the exposed patients from Southampton.[219] All 8 of the patients had been told of the issue and sera from 7 of the patients had been sent to Dr Craske. The remaining patient was being followed up by Dr Aronstam at Treloar's.

[217] DHSC0004180_050
[218] DHSC0004180_050
[219] CBLA0000010_194

178. On 28 January 1985 Dr Aronstam of Treloar's wrote to Dr Snape confirming that 6 students had received batch no. HL3186.[220] This list is at variance with an earlier letter dated 3 December 1984 from Dr Aronstam which said two patients shared between Southampton and Treloar's were treated with batch no. HL3186.[221] One name in the 3 December 1984 letter does not appear on the 28 January 1985 list. The likely reason for this is that that individual was being followed up by Southampton.[222] The Inquiry has received witness evidence from one of the people on this list; the other named individual is his brother.[223] Both contracted HIV. The witness describes being told about receiving the batch in the following terms:

> *"17. I remember an occasion in Treloar and we had just had dinner around 12 o'clock on our regular tables. Prayers were said. I was 13 or 14 years old at the time (I left when I was fifteen and a half). There was a tap on the glass to get our attention and Dr Wassif [sic] came to the centre of the room and said, can all haemophiliacs go to such and such a classroom. This is how I remember being told I had been infected.*
>
> *18. I had to go to classroom 2A. There were about ten or eleven of us in this particular age band. The nurse and Dr Wassif came in and said have you all got a pen and paper. He then told me personally, if you have such and such a batch number, and he read the numbers out. He said you have permission from the headmaster and I need you all now to use the public phone outside our dormitory's office and ask your parents to check if they have that batch number at home. Not to use it but to return it to your hospital. That batch number that was read out was at home, we had got it from Southampton General. Dr Wassif then left the room. I remember getting off the seat walking down to our dorms and we were all lined up in a row outside our dormitory to see our dorm master, Mr Eggins. He knew why we were there.*

[220] CBLA0000010_193
[221] TREL0000110_040.
[222] CBLA0000010_194
[223] WITN0297001

19. I rang home and learned that I had one of the batch numbers at home. I spoke to my Dad. They didn't tell us why we had to check these batch numbers. It was a long time ago but looking back, the first part I can actually remember. I left college and went to my hospital to see Dr Chisum."

179. Both the witness and his brother had received the batch HL3186.

180. The Inquiry has seen records of material given to another child at Treloar's. He received batch no. HL3186 for 6 instances of "*stomach*" bleeds on 11, 12, 13, 14, 15, and 16 of September 1984. He then received the same batch on 20 and 29 September 1984 for left ankle bleeds.[224]

181. On 13 February 1985 B E Gilliver of Dorset AHA wrote to Dr Aronstam at Basingstoke District Hospital about a pair of brothers whose care was shared between Dr Aronstam and Wessex.[225] One of the brothers was noted to be positive "*before exposure to Batch HL3186.*"

182. A letter from Dr S Al-Ismail at Moriston Hospital to Professor Bloom at Cardiff dated 16 July 1986 refers to two patients who received batch no. HL3186, who had sero-converted and a third who had been exposed to batch no. HL3186.[226] On 18 December 1986 Dr Al-Ismail wrote to Dr Rizza at the Oxford haemophilia centre sending the details of treatment a patient had had since September 1984.[227] The patient had been exposed to batch no. HL3183. He further wrote: "*three of our haemophiliacs who were recipients of that batch sero-converted to HIV positive, and in one of the patients [redacted] the sero-conversion occurred between June 1985 and March 1986 i.e. 9 months to 18 months after exposure.*" The specific details on the quantity of factor VIII could not be determined as the treating hospital in Carmarthen had not kept details of the bottles used. In his oral evidence to the Inquiry on 17 November 2020, Dr Al-Ismail confirmed that 3 or 4 of his patients were exposed to this batch.[228]

---

[224] TREL0000143_095
[225] TREL0000077_073
[226] CVHB0000004_126
[227] HCDO0000132_039
[228] INQY1000074

JENNI RICHARDS QC

KATHARINE SCOTT

RACHEL BARRETT

TAMAR BURTON

Inquiry Counsel Team

January 2022