PRESENTATION NOTE ON SIX ENGLISH REGIONAL TRANSFUSION CENTRES

This presentation note provides an overview of, and a summary of some of the relevant documentation in relation to, the following six Regional Transfusion Centres ("RTCs") in England: the South London/South Thames RTC (Tooting/Lewisham); the North East Thames RTC (Brentwood); the South West RTC (Bristol); the North Western RTC (Manchester/Lancaster); the East Anglian RTC (Cambridge); and the West Midlands RTC (Birmingham).

Earlier presentation notes on the Blood Services in the UK focused on: the organisation and history of the Blood Services [INQY0000307, INQY1000159]; the work of Professor John Cash [INQY0000308, INQY1000160, INQY1000161]; the work of Dr Harold Gunson [INQY0000309, INQY1000161, INQY1000162]; the Wessex RTC [INQY0000325, INQY1000182]; and the Yorkshire RTC [INQY0000326, INQY1000183].

The particular RTCs covered in this presentation note have not previously been the main focus of oral evidence or an oral presentation[1]. The Inquiry has, of course, already received and heard evidence in relation to the Belfast RTC in Northern Ireland (see the statements and oral evidence of Dr Morris McClelland [WITN0892001, WITN0892006, INQY1000179]) and the Cardiff RTC in Wales (see the statement and oral evidence of Dr Tony Napier [WITN6915001, INQY1000163, INQY1000164]). In relation to other English RTCs the Inquiry has already examined evidence regarding: the North London RTC (see the statement and oral evidence of Professor Marcela Contreras [WITN5711001, INQY1000165, INQY1000166], Dr Patricia Hewitt [WITN3101006, WITN3101009, INQY1000170, INQY1000171] and Professor John Barbara [WITN6989001, WITN6989013, INQY1000176]); the Oxford RTC (see the statement and oral evidence of Dr Colin Entwistle [WITN6917001, INQY1000167]); the Mersey/North Wales/Liverpool RTC (see the statement and oral evidence of Dr Vanessa Martlew [WITN4034001, INQY1000174]); the Trent RTC (see the statement and oral evidence of Dr Bill Wagstaff [WITN6988001, INQY1000175]); the Wessex RTC (see the statement and oral evidence of Dr Frank Boulton [WITN3456002, INQY1000181]); the Newcastle RTC (see the statement and oral evidence of Dr Huw Lloyd [WITN6935001, WITN6935037, WITN6935039, INQY1000182, INQY1000183]; and the West Midlands RTC (see the statement and oral evidence of Dr Gamal Gabra [WITN5495001], [INQY1000180].

A similar presentation note is being prepared in relation to the Scottish RTCs which have not already been considered in the Inquiry's oral hearings.

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[1] The Inquiry has heard oral evidence from Dr Lorna Williamson regarding the East Anglian RTC, but she did not take up her post there until 1988 [WITN0643001, WITN0643010, INQY1000169]; it also heard oral evidence from Dr Vanessa Martlew regarding Manchester RTC in the mid-1980s but she was not the centre director [WITN4034001, INQY1000174]. Further information about the East Anglian and Manchester RTCs is therefore set out within this presentation note.

South Thames Regional Transfusion Centres at Sutton, Lewisham and Tooting

An overview

1 The South Thames Regional Transfusion Centre (STRTC) was formed in 1990 by the merger of the South London Regional Transfusion Centre (established in 1946, originally based in Sutton, but from 1970 based in Tooting) and the South East Thames transfusion unit in Lewisham at the Hither Green hospital - **NHBT0097060_001**. STRTC will be used in this presentation to refer to both the pre and post 1990 arrangements.

2 The Regional Transfusion Directors (RTDs) were Dr R Zeitlin between 1947 and 1970, Dr Keith Rogers between 1970 and 1991 and Ms Belinda Phipps between 1991 and 1994.

3 STRTC was funded by two Regional Health Authorities - South West Thames Regional Health Authority ('SWTRHA') and the South East Thames Regional Health Authority ('SETRHA'). STRTC's geographical boundaries incorporated South London, Surrey, Kent, Sussex and North East Hampshire. It served 57 hospitals - **NHBT0105407_124**.

4 STRTC appears to have had an 'overlap area' with the North West Thames Regional Transfusion Centre at Edgware (NWTRTC), and in August 1984 Dr Rogers wrote to Dr Contreras stating that the RHA was keen for STRTC to hand over responsibility for supply to the overlap area, to NWTRTC - **SBTS0000673_157**. Responsibility for some but not all hospitals were transferred in 1988 - **NHBT0105407_197**. By 1991 NWTRTC were supplying all of the hospitals in their geographical area except for the Royal Marsden in Fulham, which was still being supplied by STRTC - **NHBT0105407_093**. There had however been no corresponding transfer of the relevant donor catchment areas. It was therefore suggested by Dr Contreras that from 1 January 1992, NWTRTC should take over collections in Chelsea, Fulham, Hammersmith and Kensington. This appears to have happened later on during that year - **NHBT0105407_120**.

5 Prior to 1990, SWTRHA was concerned with the Tooting site, and the SETRHA with the Lewisham site. The lack of co-ordination between the two RHAs and their apparent inability to jointly manage STRTC was seen as dysfunctional (see for example a report from February 1985 which stated that '*a properly coordinated service would regard blood collected by either Lewisham or Tooting as Regional resource..... Various proposals can be prepared jointly by Tooting and Lewisham but such efforts are pointless unless and until the two RHAs agree to treat transfusion as an enterprise which will be managed as a co-ordinated whole on behalf of the two RHAs*' - **DHSC0046036_017**).

6 Further problems experienced at SWTRHA are set out in a document entitled 'Discussions with Dr Rogers (Tooting) January 1986' by an unknown author, in which it is said that:

a. Dr Roger's colleagues do not accept him as director, and '*in no sense report to him (Chaos!)*'

b. He has *'lacked'* contact from the RHA, despite the recent Christmas crisis.

SBTS0000673_141

At around this time it appears that there was a struggle for management control of STRTC, with the RHA wishing to put a non-medically qualified General Manager in charge, and this being the subject of much concern by members of the medical profession - **SBTS0000673_118**.

7 By June 1988 staff shortages at STRTC were so acute that services had to be curtailed - **NHBT0086548_003**.

8 An inspection of STRTC some time between March 1987 and 1991 said as follows:

a. It is situated at the rear of St George's hospital in Tooting. It incorporates a small sub-centre in Kent which has storage facilities and '*issue function*'.

b. It employs 340 staff and serves a population of 6.5 million people

c. It collects 240,000 donations per annum.

NHBT0006256.

9 There was another somewhat critical inspection of STRTC in 1990, which concluded that it was underfunded, by which time a proposal had been made to merge STRTC with the Lewisham Blood Transfusion Unit - **NHBT0006254**. A feasibility study was undertaken in September 1989 by Deloitte, Haskins and Sells. The Inquiry does not have a copy of this study.

10 There was an audit of STRTC by, amongst others, Dr Roger Moore, in May 1990 - **NHBT0009651_001.**

11 An informal visit from the Medicines Inspectorate in June 1992 led to the decision being made to close the Lewisham/Hither Green site. Works were done to extend the facilities at Tooting - **DHSC0006854_003** and **NHBT0105407_102**.

12 There was a quality audit of STRTC in July 1993 - **NHBT0089967_001**.

13 In 1974, 1976 and again in a paper in February 1977, a proposal was put forward by STRTC to the RHA for a frozen blood centre to be set up at the STRTC - **DHSC0100038_001**. This was not supported by the DHSS - **DHSC0100037**.

Blood Collection and Targets

Whole blood and red cells

14 When it was first built, STRTC issued 200,000 red cell units from the Tooting site. By 1992 it issued 420,000 products from the same site - **DHSC0006854_003**.

15 On 20 March 1969 Dr Zeitlin of STRTC wrote to Dr Maycock about the request from Dr Rainsford for *'10,000 cryos a year'* for Lord Treloars school. The letter goes on: *'This together with our other quite heavy commitments is quite out of the question, and one wonders what happened to the Treloar cases before he took over.'* **DHSC0100025_100.** In his reply Dr Maycock stated that '*The products of 10,000 donations a year for one relatively small school seems to me quite heavy*' - **DHSC0100025_099**.

16 In 1980, Dr Rogers stated that he expected to bleed 260,000 donors that year – **CBLA0007185_001**.

17 On 20 December 1985 there were press reports of blood shortages in London and the South East of England. This was said to have arisen for two reasons – a drop off in donors around the Christmas period, and the high level of demand for blood for use in complex operations in and around London. It was reported that as well as a national campaign for more donors, Dr Rogers had brought the issue to the attention of the press. The London Regional Transfusion Centres (RTCs) were also said to be getting blood from other parts of the country - **DHSC0002163**.

18 In January 1986 it was said that Lewisham collected 40,000 donations, with a total number of donations for the area being around 290,000. However it was also noted that there was no co-ordination between the two teams (Tooting and Lewisham) and they often set up shop in each other's localities - **SBTS0000673_141.**

19 Prior to December 1986 the blood donor panel was 250,000 strong, with 83% of donations coming from mobile sessions, and 17% from workplace sessions - **NHBT0006757**.

20 In October 1987 Dr Ed Harris was reporting that in one hospital, surgical lists had to be cancelled because STRTC could not supply the blood - **DHSC0002382_106**. In 1987, 30,000 units had to be imported from other Centres - **DHSC0046036_037**.

21 In a letter in March 1990 to Dr Gunson, Dr Rogers described the services provided to donors at STRTC to be less than adequate - **NHBT0009858_002**.

22 The blood shortages in the area continued and there is correspondence dated June 1990 between Dr Gunson and STRTC which illustrates that there were ongoing shortages of blood at STRTC requiring ad hoc deliveries of blood from other centres- **NHBT0008837** and **NHBT0008836**.

23 In September 1990 Dr Rogers wrote to a donor explaining that STRTC had always provided blood to private hospitals but this represented only 5% of their output - **NHBT0003807**. He also made it clear that they charged the private hospitals for the blood to cover their costs,

24 It would seem from correspondence in 1992, that Scottish centres provided STRTC with emergency supplies of red blood cells - **SBTS0000467_018**.

Plasma

25 In November 1973 Dr Rogers wrote to Dr Maycock to inform him that in order to extend the amount of plasma STRTC could provide to Elstree, they would need to spend approximately £35,000 on building works- **DHSC0002357_002**.

26 On 4 April 1974 Dr Rogers wrote to Dr Maycock stating that the use of freeze dried plasma in the region had increased by 30% in 1973 compared to 1972. As the consumption was exceeding the amount that was being sent for freeze drying, Dr Rogers asked whether this could be tolerated or whether they would have to reduce their consumption - **DHSC0100041_003**.

27 The target for the year ending December 1976 was 36,000 donations to be made available for AHG - **DHSC0002179_015**.

28 In July 1980 the SETRTHA asked DHSS to set out as a matter of urgency how many donations they should be allocating to PPF and Factor VIII - **DHSC0002197_116**.

29 At a meeting in March 1981 of the Joint Working Group on Blood Transfusion Services SE/SW Thames RHAs, it was stated that an April 1979 assessment of the region made it

clear that there was an adequate supply of transfusible red cells, but in order to meet the Government's policy of '*developing services at the Elstree laboratory and of producing a very much larger amount of blood products centrally and in particular Factor VIII concentrate'* there needed to be a very '*considerable expansion*' of blood collection. For the SE and SW Thames region this would need to rise to about 420,000 donations per annum – an increase of 100,000 donations. It was thought that it would be *'very difficult'* to achieve this kind of expansion in the number of donors. It would also lead to a surplus in red cells which they considered would be '*a very real Public Relations problem*'. Consideration was given to the use of a panel of regular plasmapheresis donors to make up the increase. It was estimated that the panel would only need to be 4,000 strong. Another advantage of going down this route would be a reduction in the risk of undetected hepatitis carriers contaminating the whole batch of Factor VIII due to the small size of the panel. They therefore recommended a trial of a plasmapheresis programme at either Lewisham or Tooting - **DHSC0001466** and **DHSC0001972**.

30 At that meeting the attendees (from the two RHAs) concluded that the cost to the regions of commercial blood products was probably equal to the cost of running a machine plasmapheresis programme. However, an economic case to invest in a plasmapheresis programme needed to be made out, and at present it was unknown how much product would be made available from Elstree and whether this would be charged for.

31 In a note dated 14 August 1989 Dr Gunson set out the plasma targets for STRTC as follows:

a. The plasma target was set at the same as the previous year, the unknown factor being what has been collected at Lewisham. It was agreed this was too low, and the combined target for Tooting and Lewisham was reset at 50 tonnes. This was still only 7.7 tonnes per million.
b. 75% of whole blood was separated into SAG(M) but 40% of this was used for platelets, leaving only 220ml of plasma per donation.
c. There were eight plasmapheresis machines available at the RTC, with only six being operational. The plasmapheresis centre was open 5 days a week. 1,200 donors were on the plasmapheresis panel with 2.5 tonnes collected in this way at both Tooting and Lewisham.
d. Management and co-ordination of SE and SW Thames still continued to cause problems and financing from the two RHAs continued to be a source of disappointment. **NHBT0003371.**

32 At an internal meeting of STRTC in 1990 it was noted that the cost of running the plasmapheresis clinic was more than the £100,000 per annum they received from BPL for the plasma - **NHBT0000189_029**.

AIDS leaflets

33 Dr Rogers set out his views to Dr Wagstaff about the approach to take to AIDS donor leaflets in June 1983 as follows: '*I believe we need a high key approach but I believe that approach should be passive rather than active. In other words, we want to put up information which is going to be seen and acted on by donors but I am not sure that there is any mileage in asking our staff to actively question or examine donors to try and exclude potential AIDS carriers.*' He expressed some doubt about the leaflet being produced in Edgware and suggested that the route to deterring risky donors was through the gay media - **NHBT0039762_045**

34 He also set out his views on the AIDS pamphlet to Dr Walford in the same month. He thought there should be some indication as to what was meant by promiscuity. His concern was that having a pamphlet that just addressed AIDS, made it very much more difficult for someone who has picked it up, to walk out of the session (as it would be obvious why they were leaving). He favoured including, on a poster, AIDS amongst a lot of other reasons (not stigmatised) as to why a person should not donate (recent surgery, active hay fever, recent treatment by antibiotics etc), so that if a person left the session, no one would know which of the criteria had persuaded him/her to leave the session - **NHBT0039762_046**.

35 By March 1984, STRTC had issued 16,000 AIDS leaflets (approximately 3,500 per month) and had a stock of 41,000. All new donors were receiving a copy of the leaflet with their certificate book, and they were on display on tea tables and chairs at sessions. Most donors seemed uninterested in the leaflet, and left them at the sessions. There had been no impact on donor attendance - **DHSC0002239_050**.

36 From January 1985 STRTC were handing out a 'Dear Donor' letter to all donors at donor sessions. Donors were given sufficient time to read it before being called to be bled, and were then asked whether they had indeed read it. Dr Rogers made it clear that it would not be possible to send these letters to donors at the time they were being called up, as call

up was done by postcard, and it would not in any event be possible to ensure that all donors in industrial sessions would receive the letter.

37 The Dear Donor letter said as follows:

> *'The most likely carrier of AIDS are men who participate in homosexual practices, even if only infrequently; drug addicts; prostitutes; people who have visited Haiti; any woman who has a sexual relationship with a bi-sexual or a haemophiliac man.'*

38 The letter also set out a mechanism by which a potential donor could signal to the collection team that (s)he may be at risk of AIDs without having to inform them that they were in an at risk group – that was by telling the team that they were *'unwell'* – this would result in the donor not being called to future sessions - **DHSC0002257_057**.

Screening donations for infections

HBV

39 In a letter from Dr Rogers to Dr Maycock dated 11 February 1975 he stated: '*Has it become accepted national policy that all Centres will adopt R.P.H.A as a method of screening for Australia antigen? If this is so then the information has bypassed me and I would be grateful if you could quote its source to me. I have no plans at present for adopting this test and it will be impossible ....for at least six months to a year after we have been granted the £18,000 per annum revenue that would be required to finance this test on all our donors.'* **DHSC0002359_029**

40 In 1981, STRTC started to use the BPL RIA test for HBs Ag testing - **CBLA0007185_001** and **CBLA0004677**.

41 In June 1993 STRTC wrote to Dr Gunson stating that they were able to start Anti-HBc testing after 4 October 1993 - **NHBT0018429**.

42 On 5 September 1994, Ms Phipps wrote to the NBA stating that about a year ago when Anti-HBc testing was being discussed, STRTC was keen to introduce it, and that they remained keen to implement it (along with ALT testing) but understood they were not able to introduce it unilaterally. The letter went on to state '*as a result of not introducing this test, we may have infected a number of people during the last year. As you know the Transfusion Service has no organised means of collecting adverse reactions (unlike the drug industry which at least has the yellow card system), so accurate information on post transfusion infection is unavailable'* - **NHBT0005723**.

HIV

43 In a letter to the DHSS on 3 September 1985, Dr Rogers expressed concern about the focus of the SETRHA and SWTRHA on the laboratory aspects of the HIV testing programme rather than ensuring that those who wanted to be tested knew how to go about it. He reported that the STRTC had been getting some phone calls which led them to believe that people who wanted HTLV-III tests were waiting for screening to be introduced by the blood transfusion service before coming forward to donate. He concluded that an active national and local publicity campaign was required to point people away from the blood service, to testing in the community. He was however concerned that if testing was to be done in 'special clinics' it would deter some from using them - **DHSC0002121** (see also **DHSC0002123** and **DHSC0002122**).

44 SWTRHA issued a press release on 23 September 1985 informing people of the community donor testing and warning them not to give blood to get themselves tested - **DHSC0002279_019**.

45 On 2 September 1985, Dr Rogers informed the DHSS that both the Tooting and the Lewisham site would be ready to begin HLTV-III screening by 14 October 1985- **DHSC0101855**.

46 In a letter to all Haematologists from Dr Rogers dated 2 October 1985, he said as follows:
'After 14th October it is our intention to try and ensure that all 'fresh' blood and products issued by this Centre will have been tested for HTLV III antibodies before issue. There may be some problems with platelet preparations, particularly early in the week, but we hope these problems can be solved.

As far as possible, would you please try and make sure, that by the 14th October 1985, you have used all fresh blood and fresh products made from donations taken before Monday September 30th, 1985.This does not apply to fractionated products produced at Elstree…… - but only to red cells, fresh frozen plasma, cryoprecipitate etc, nor does it apply to cryoprecipitate or fresh frozen plasma leaving this Centre on or after Friday 4 October 1985.

Hospitals who themselves take blood from donors will need to think about their arrangements to ensure that these donations are adequately screened for HTLV-III antibodies.' **DHSC0002489_143**.

47 In a letter dated 29 October 1985 to Dr Smithies at the DHSS, Dr Rogers stated that STRTC stopped issuing untested blood and blood products *'early in the week'* commencing 7 October 1985 and that they had previously asked hospitals to get rid, by 14 October 1985, of any blood issued prior to 27 September 1985. The plan with FFP and cryoprecipitate was to take steps to recall any untested product stating '*Most hospitals are not using it anyway*'. There was no plan to recall it for testing - **DHSC0002285_014**.

48 Tooting used the Wellcome test while the Lewisham site used the Organon one - **NHBT0004410**.

49 In 1985 two donors were found to be HTLV-III positive - **NHBT0019474_001**. By 3 September 1986 STRTC had found six HTLV-III positive donors - **NHBT0019456**. Between October 1986 and March 1990, another seven were identified - **NHBT0019479**.

HCV

50 In January 1991, STRTC estimated that because of the need to re-organise the laboratories, it was unlikely they would be in a position to start HCV testing until June 1991 - **NHBT0116001**.

51 Dr Gunson was informed in December 1991 that both the SETRHA and the SWTRHA had devolved enough funding to the District Health Authorities to cover 90% of the costs of HCV screening - **NHBT0000075_074**.

52 Some of the recommendations as to whether donors Dr Tedder had been involved in testing could be re-admitted or removed from the donor panel can be seen at **NHBT0053769**.

Archive samples

53 By 1994, archive samples from all blood donations were being kept for two years - **JPAC0000040_100**.

Donor Counselling

54 The procedure in place at the end of October 1991 for a donor found to be HCV positive, was to write to them to inform them of the result. The donor was provided with a leaflet (presumably on HCV), and the GP was informed of the results - **NHBT0028266.** Donors were not counselled at STRTC, instead they were seen by their GP and/or referred on to a liver specialist by the GP - **NHBT0000075_074**.

Communication regarding infections and lookbacks

Hepatitis

55 There are various examples of STRTC being involved in look back exercises with the relevant hospitals when donors tested positive for infections, or where recipients of donations from STRTC tested positive for infections. See for example **NHBT0019840** and **NHBT0055889**.

56 There is evidence of communication between Dr Maycock and STRTC, and STRTC and the various hospitals in the region, about serum hepatits – see for example **DHSC0100011_109** which shows the steps being taken to trace the recipients of implicated donations in 1951; and **DHSC0100017_002** which sets out the tracing undertaken from a donor thought perhaps to be infected with hepatitis in 1965.

57 There is evidence of Dr Rogers reporting potential infections from cryoprecipitate and factor VIII to Dr Maycock - **HCDO0000255_053**. There is also evidence of communication with BPL over possible transmission of HCV - **NHBT0000060_008**.

58 When a donor was implicated in an infection, there was a temporary suspension of that donor from the panel while the investigation was carried out - **NHBT0019344** and **NHBT0019841**. Donors were notified of this by letter - **NHBT0019841**.

59 On 26 June 1990 Dr Rogers wrote to Dr Gunson explaining that when a blood donation was associated with a case of possible transfusion transmitted hepatitis , then all the implicated donors were written to and asked to provide a blood sample for repeat testing. All the samples were then sent to PHLS to enable STRTC to '*clear the case one way or another*' - **NHBT0005380**.

60 In January 1995 STRTC estimated that their HCV look back would be well underway by February 1995 - **NHBT0019947**.It would appear from a memo dated 1 February1995 that it was well underway by then, as it was reported by STRTC that they had found 376 HCV positive donors at Tooting and Hither Green, with 2,500 donations to chase - **NHBT0019914**.

HIV

61 In January 1986 Dr Rogers agreed to increase the track-back on any previous donations given by a donor found to be positive for HTLV-III from five to six years, at BPL's request - **BPLL0010775**.

Arrangements for distribution of blood products

62 In November 1976 STRTC kept ¼ of the product received by BPL for emergencies, distributing the remaining ¾ to the haemophilia centres in the area in proportion to the number of people with haemophilia treated at those centres - **CBLA0000503**. Decisions about the allocation of Factor VIII products between patients were made by Professor Ingram - **CBLA0000704**.

63 In 1977 there was a reallocation of 20 bottles of BPL Factor VIII concentrate a month from North Thames RTC to STRTC - **CBLA0000608**.

64 At a meeting in March 1981 of the Joint Working Group on Blood Transfusion Services SE/SW Thames RHAs it was noted that SW Thames RHA had spent £127,000 on commercial blood products during the year 1979/1980 and for the year 1978 over £347,000 had been spent on like products in the SE Thames region - **DHSC0001972**.

65 As at July 1981, STRTC did not purchase or distribute commercial blood products for the region – they were bought by hospitals - **DHSC0002209_050.**

66 By the time BPL were providing heat treated Factor VIII, STRTC were unable to provide this to clinicians without the authority of BPL - **CBLA0002121**.

Miscellaneous

67 There is correspondence between STRTC and Dr Rejman about patients who had applied to the DHSS for payments from the Scheme of Payment for 'Those Infected with HIV Through Blood or Tissue Transfer', see **EILN0000016_001**, **DHSC0004084_088** and **DHSC0004084_087**, concerning the gateway criteria for being accepted as a beneficiary of the Eileen Trust.

North East Thames Regional Transfusion Centre at Brentwood

The NETRTC – An overview

1 The directors of the North East Thames Regional Transfusion Centre (NETRTC) were Dr W John Jenkins from 1955 – 1981 and Dr Jean Harrison from 1981 – 1995. The Inquiry has a witness statement from Dr Harrison [**WITN7046001**], and this part of the written presentation draws heavily on her statement.

2 In a letter Dr Jenkins wrote to Dr Maycock in September 1973 he described the resources as being so stretched that they had no room for sickness, holidays or failure of apparatus. He described the working conditions as 'poor' and set out the requirements for additional staff, equipment and building works to be able to meet the 1975 targets - **DHSC0002175_043**.

3 Dr Harrison states that when she first came to the NETRTC, she was the sole (junior) haematological consultant, and had to get cover from consultants in other centres/hospitals to cover her when she took leave. The centre was described at the point that Dr Harrison took over as Centre Director, in a report by Dr John Cash dated 19 March 1986, as '*a sick centre*' [**SBTS0000618_160**, page13]. A report entitled 'Visitor to Brentwood' authored at about the time Dr Harrison took over as director gives a snapshot of NETRTC in 1980 – it had three medical consultants, seven teams collecting 1.9 million donations a year – **BAYP0000010_003**.

4 During her tenure as director (see paragraph 14 of her statement [**WITN7046001**]) there were 275 members of staff, including Dr Borelessa, another consultant haematologist, who was appointed as Dr Harrison's deputy. By July 1987 there was a regional haemophilia coordinator on the staff of the NETRTC (initially Sister Davies and then Sister George)– this post is described in **NHBT0010587** as follows:

> *'This Nursing Officer is on the staff of the Regional Transfusion Centre, but currently has her office at the Royal Free Hospital, where there is a major Haemophilia Centre. She travels throughout the North East Thames Region, giving advice and nursing care to haemophiliacs and their families in their homes. She also attends haemophilia clinics and works with the Transfusion Service and the Haemophilia Centres to coordinate the supply of NHS Factor VIII concentrate within the Region.'*

A more detailed description of the role is set out in the article written by Dr Colvin and others entitled 'Regional Co-ordinator for Haemophilia in Domiciliary practice' in the BMJ 1977 2, 814 - 815 - **HSOC0022537**. See also **BART0000690** for some of the teething difficulties posed by the fact that this nurse was providing intravenous therapy for patients in their own home.

5 Dr Harrison appears to have had a reasonably close relationship with the funding Regional Health Authority (RHA), stating in paragraph 15 of her statement [**WITN7046001**], that she liaised with the Regional Medical Officer, as well as meeting with the administrator and treasurer.

6 Paragraph 16 of Dr Harrison's statement states that the NETRTC had an annual budget of £11 million, but that requests for additional funds could be made on an ad hoc basis to the RHA.

7 It is clear from paragraph 8 of Dr Harrison's statement [**WITN7046001**], that there were a number of committees in place during the 80s and early 1990s attended by her as director of the NETRTC, namely the North East Thames Regional Transfusion Committee and the North East Thames Regional Association of Haematologists. Her statement also refers to the North East Thames Region Association of Haematologists Haemophilia Working Party which met to discuss a number of important issues such as screening for HIV and HCV (see for example **BART0000675** and **BART0000677).**

8 An inspection in September 1990 of NERTC by the Medicines Inspectorate found that the operating conditions and procedures were not of a standard expected to meet any future licensing requirements [**NHBT0006247**].

9 During 1995 the NBA went out to consultation on plans which included a decision to amalgamate NETRTC with the North West Thames RTC at Colindale [**NHBT0000236_014** page 6]..

10 As well as acting as a Regional Transfusion Centre (RTC), NETRTC also provided a Reference Laboratory and a Reagents Laboratory to the North East Thames region. According to a July 1987 report, between 40 and 50 samples were sent daily from hospitals in the region to NETRTC for grouping and investigation. Some of the services provided included genotyping, investigation of haemolytic disease, cross- matching and investigation of a range of issues with antibodies [**NHBT0010587** page 16 and 17]. By

1984 NETRTC was one of only four frozen blood banks - **DHSC0002245_002**. By1990, the frozen blood bank at NETRTC had closed and been transferred to the centralised frozen blood-bank at Birmingham RTC **NHBT0006247**.

Blood collection

11 Along with other RTCs, NETRTC had two principal targets to achieve – it had to meet the needs of its local hospitals for whole blood, red cells and other components such as platelets, and it had to achieve the target set for it by the Department of Health and Social Security for plasma to be sent to BPL with a view to achieving self-sufficiency in blood products in the UK.

12 A report on NETRTC and the North West Thames RTC by Dr John Cash dated 19 March 1986 [**SBTS0000618_160**] suggested serious problems with the blood supply in London noting that:

a. There were blood shortage problems in London almost daily and genuine clinical need was often not met, with some hospitals resorting to the media to call in donors directly to their hospitals.

b. NETRTC had not responded to the increasing demand for blood, the blood collection programme having steadily declined since 1981.

13 It appears that it was not until NETRTC entered into an agreement with the Oxford RTC for a regular supply of blood that this abated (see **DHSC0003993_022, NHBT0118872_002**).

Finding donors

14 By July 1987 it was reported that NETRTC, which served a population of 3.4 million, collected 137,000 donations out of the 2 million donations made in England and Wales [**NHBT0010587**]. An inspection report dated September 1990 noted that the centre collected 155,000 donations per annum against a target of 160,000 [**NHBT0006247**].

15 Dr Harrison's statement makes it clear that the NETRTC did have a problem in attracting sufficient donors. This was, she states, largely to do with the donor population, big

swathes of which, for cultural and socio-economic reasons, were not blood donors. This shortage of donors was compounded as sessions in factories and at work places reduced.

16 A report by Dr Gunson in which he compared the 1985 blood collection data of five RTCs of a similar size (including NETRTC), shows NETRTC collecting the least - **DHSC0002441_043**.

17 Dr Harrison speaks in some detail in her statement of the efforts made to increase donor numbers by mounting publicity campaigns and by sending its caravan around the streets. She also states at paragraph 66 of her statement [**WITN7046001**] that the NETRC undertook research to show that it was safe to donate blood between the ages of 65 and 70, and their findings (that it was safe) were published and accepted by the National Directorate (paragraph 312).

18 An RTD meeting in October 1971 attended by Dr Jenkins noted that all RTCs collected donations from prison, borstals or equivalent institutions - **NHBT0015758_001**. It appears from **NHBT0008628_001** that in September 1983 NETRTC had a donor session in a 'Military Corrective' but it is asserted in that document that '*the donors were all fit young men, well vetted by their supervisors*'. Dr Harrison in her statement, states that blood was not collected from prisons during her tenure.

Donor targets

19 Initially during Dr Harrison's tenure, donor collection sessions were led by doctors, however there was a problem with recruiting sufficient numbers of doctors. She therefore proposed training nurses to lead sessions. This proposal was opposed not only by her fellow Regional Transfusion Directors, but also the CMO, who was asked for an opinion (see paragraphs 37 - 45 of Dr Harrison's statement [**WITN7046001**]). It was, however, agreed that a trial should be set up. This was a success [**BPLL0007206**] and at an RTDs' meeting in 1984 Dr Harrison is recorded as stating that she was now ready to move over completely to nurse-led sessions -**DHSC0002245_002** (see also **CBLA0001905).** Dr Harrison's view as expressed in her statement is that this improved the quality of the service as nurses had no clinical freedom, so had to follow the guidance, and were better at explaining to donors why they could not donate. An account of this is given in the article by Dr Harrison published in the Lancet in November 1987 entitled 'Nurses in the Transfusion Service' (**SBTS0004256_114**).

20 According to Dr Harrison's statement [**WITN7046001**] at paragraph 28, the NETRC processed all the blood it collected on the day that it was collected, which necessitated the employment of laboratory staff to work in the evening.

Donor selection processes

21 **DHSC0100027_440** is a letter from Dr Jenkins to Dr Maycock from 1966, having received a copy of the 'Memorandum on the Selection, Medical Examination and Care of Blood Donors', seeking advice on whether to circulate this to hospitals, expressing concern on the one hand that in doing so it would appear to give approval to the bleeding of donors in hospitals, while on the other acknowledging the widespread bleeding of donors in hospitals thus making the point that *'it might be expedient to keep them fully informed on matters affecting the safety of donors'.* Further correspondence on the issue is at **DHSC0100027_441** and **DHSC0100027_443**.

22 Paragraph 434 of Dr Harrison's statement suggests that the NETRTC was providing donors with leaflets about AIDS prior to the National leaflet being published on 1 September 1983 (**BPLL0007247**). Paragraph 233 of Dr Harrison's statement provides as follows:

> *'Before there were national leaflets for HIV, we decided at NETRTC that there would be new leaflets every 6 months. These leaflets would carry the nationally agreed text listing risk groups, but as the leaflet looked different each time a donor attended, we felt that repeat donors would be more likely to read the new leaflet even if they had seen the previous ones.'*

The Inquiry has not been able to locate one of these NETRTC leaflets.

23 The survey undertaken of the first six months of experience distributing the AIDS leaflet suggests that NETRTC had the leaflets available at sessions with a sign saying 'Please Take One', and that of their 60,000 stock, 20,000 had been taken. NETRTC reported no impact on donor attendance - **CBLA0001820**.

24 **NHBT0039762_088** suggests that from 1 February 1985, once the DHSS had mandated that AIDS leaflets must be given to each donor, each donor was handed a leaflet at a donor session. From March 1985 however, this practice changed, and instead leaflets were sent out with call up cards. Thus from March 1985 leaflets were only handed to walk-in donors during sessions.

25 Paragraph 232 of Dr Harrison's statement provides as follows: '*Potential donors were then asked to sign a document to confirm that they understood the leaflets, that the restrictions did not apply to them, that they consented to the microbiological and blood group tests and agreed to donate blood.*'

26 In a letter from Dr Smithies to the chair of the Joint Consultants Committee of the British Medical Association of 15 October 1986, it is reported that the practice at NETRTC was that where there was any doubt about whether a donor was in an at risk group, they would not be bled, but referred to the NETRTC for advice. As at October 1986, Dr Harrison had noted that many donors had taken this course, rather than seek advice during the donor session where there 'may be little opportunity for privacy' - **BMAL0000024**. Indeed, it is clear from paragraphs 429 - 432 of Dr Harrison's statement that sessions were not equipped with private booths to give donors complete privacy when being questioned. Accordingly she states that staff were instructed to ask donors whether they fell within any at risk groups, rather than explicitly ask them about their sexual practices.

Plasma for concentrates

27 **DHSC0002177_062**, **DHSC0002179_020** and **DHSC0002179_038** is correspondence between the DHSS and NETRTC in October 1975 which reveals that NETRTC had estimated they could provide 43,500 donations to BPL per annum, but in fact (due to a five month delay in building works being undertaken at the centre) were significantly behind.

28 A letter from Dr Jenkins to the North East Thames Regional Health Authority dated July 1978 sets out some of the problems with the arrangements for providing plasma to BPL – namely that while plasma was provided to BPL '*in vast quantities*' from the region, the finished products was distributed in proportion to patient needs throughout the country, meaning that NETRTC was subsidising some areas of the country which did not produce much plasma. This letter also sets out the amount of commercial product required during the year in the region - **DHSC0002187_117**.

29 As to the plasma targets, a letter from Dr Harrison to DHSS dated 29 April 1985 [**DHSC0002269_017**] states that the NETRC target for 1985 was 25,000 litres with a target for 1986 of 30,000 litres of plasma per annum. Of note in this letter is the reference

to the drop in donor attendance during the beginning of 1985 due to fears that donating blood gave rise to a risk of contracting AIDS.

30 By 1989 the plasma targets were said to be 31,000 Kgs as set out in a memo from Dr Roger Moore of the DHSS [**NHBT0003370**]. The memo goes on to state that it was Dr Harrison's plan to collect 35,000 Kgs in 1990/1991.

31 Dr Harrison took the view that plasmapheresis was not an economical way to collect plasma - **NHBT0003370**. NETRTC instead focussed on increasing yields of recovered plasma and trying to increase donor numbers in order to meet its targets for sending plasma to BPL. At paragraph 89 of her witness statement Dr Harrison states that in order to try and increase the amount of plasma that could be sent to BPLs she would go '*around hospitals in order to attempt to persuade doctors not to use whole blood and use red cells in SAGM instead as a source of red cells for transfusion.*'

32 By 1985 NETRTC was able to obtain an average of 200 mls of plasma from each donation it collected. By November 1988 Dr Harrison was reporting that NETRTC was issuing virtually no whole blood at all, and this had been accepted by clinicians in the region - **NHBT0009593**. Paragraph 99 of Dr Harrison's statement says this:

> *'...it appears that in 1985 we collected 27,000 litres of plasma for Elstree from 136,000 full donations of blood with an average of 200mls plasma from each donation. In 1987, we had to provide 53,000 units of platelet concentrate. It appears we provided 24,000 litres of recovered plasma to Elstree from 136,000 donations, so then an average of 177mls of plasma was sent to Elstree for every donation of blood collected by the Brentwood Centre. '*

33 The relationship between BPL and NETRTC went both ways, plasma was supplied by NETRTC and BPL products were then returned back to them for onward distribution. **CBLA0000533** makes it clear that from 1 December 1976 concentrates from BPL were provided to the RTCs to distribute to Haemophilia Centres according to the number of patients they were treating. **RFLT0000002** sets out the arrangements for the purchase and distribution of Factor VIII from NETRTC (dated 3 August 1979). This states that NHS Factor VIII was to be reserved for home treatment, with Haemophilia Centres giving cryoprecipitate and commercial products. **CBLA0000444** is an example of Dr Jenkins negotiating with BPL for more Factor VIII to meet the needs of those patients on

home treatment. There are also documents which show a shortfall in the region of NHS Factor products – see for example **CBLA0000722**.

34 In her witness statement at paragraph 165 Dr Harrison states that NETRTC did not distribute commercial products to either hospitals or haemophilia centres. Accordingly, the only blood products that NETRTC supplied to the region were the NHS/BPL ones.

35 At a meeting of the North East Thames Region Association of Haematologists Working Party on Haemophilia on 8 September 1989 (**BART0000667** - page 2) Dr Harrison made the point that NETRTC received £1 million per annum from BPL for the plasma they provided, but charged them £3 million per annum for the products they received back. In her statement at paragraphs 114 - 115 Dr Harrison explains that this was a problem for NETRTC which she tried to solve by charging hospitals for their use of BPL product. Ultimately this problem was not solved until cross-charging was introduced.

36 The kind of difficulties this led to can be seen in a letter from the North East Thames Regional Health Authority to BPL dated May 1990 (**NHBT0097035_023**) which states that Dr Harrison was unwilling to sign the contract with BPL setting the price for their products for the region, on account of the uncompetitive prices being offered by BPL. The Inquiry has been unable to find the follow up correspondence on this issue.

37 BPL factor products were provided on a pro rata basis to each of the RTCs. In turn NETRTC provided each haemophilia centre in the area with a 'free allocation' of factor products. Any BPL product required by the centre over and above that allocation could be purchased from NETRTC as long as it was available - **RLHO0000001_017**. The details of which BPL product was provided to which hospital was kept in a log book at NETRTC, but this was destroyed during the re-organisation within the NBA London and South East zone - **BPLL0016082_024.**

38 According to both **BPLL0016082_024** and Dr Harrison's witness statement, by the 1990s, BPL were providing their products directly to hospitals.

NETRTC - Blood components and products to local hospitals

Blood components

39 NETRC not only produced and supplied blood to hospitals, but also cryoprecipitate as well as fresh frozen plasma, platelets and granulocyte concentrates. The documents reveal the following:

a. Under Dr Jenkins some patients within the geographical boundary of NETRTC were receiving cryoprecipitate and factor concentrates direct from NETRTC for home treatment - **HCDO0000033_011.**

b. At least in 1976, NETRTC were to be informed if patients in their area were treated with commercial products, and the NETRTC would have a list of patients living in their area: **CBLA0000533**.

c. By July 1987, the NETRTC was supplying 35 hospitals with blood and blood products [**NHBT0010587**].

40 The hospitals served by NETRTC appear to have changed during the years. Prior to 1989/1990 three of the hospitals in the NETRTC area were being supplied by the Northern Thames Regional RTC (see for example paragraph 21 of Dr Harrison's statement [**WITN7046001**] and **SBTS0000618_160**, see also **DHSC0002193_028** for some of the problems that this gave rise to.) This had changed by 1989/1990 once the NETRTC's processing capacity had increased. This was achieved when NETRTC built a new extension (completed in 1987).

41 In 1981 Dr Harrison was proposing a reduction in the production of cryoprecipitate at NETRTC in order to be able to send more plasma to BPL [**BART0000681**]. By July 1987 3,000 donations were being processed for cryoprecipitate [**NHBT0010587**]. In her statement, Dr Harrison stated that had NETRTC been asked to increase their production of cryoprecipitate, they would have been able to do so quickly, albeit she did not think that they would have been able to meet the prophylactic treatment needs of all the haemophilia population in the region in this way, even if they had put all their plasma into it, stating at paragraph 199: '*The patients might have to accept that they only had treatment when they had bleeding and not prophylactic treatment'.*

NETRC and Cross Charging

42 In a letter dated 27 September 1982 from Dr Harrison to the RHA, she stated that it was not only her view that the proposals for cross-charging were an excellent way to fund BPL, but that the proposals should be extended to cover all the products produced by NETRTC to ensure (i) that clinicians did not turn away from the charged for BPL

products (such as factor VIII) to the 'free' products made by the NETRTC such as cryoprecipitate and (ii) to encourage a more judicious use of blood by hospital colleagues - **DHSC0101509** (see also **BART0000679)**. In her statement at paragraph 134 Dr Harrison states that she considered that cross-charging should also have encompassed commercial products.

43 Dr Harrison gives an account of the changes that arose from cross-charging in **RLHO0000001_017.** In this letter to the Tower Hamlets Health Authority, she set out the way in which BPL factor products were provided and allocated prior to cross-charging:

a. NETRTC received a pro rata allocation of factor VIII dependent upon the amount of plasma provided to BPL.

b. Each haemophilia centre in the region had an allocation of free BPL product, if they required any additional BPL product (assuming there was some available), they were charged for it.

The document went on to set out the detail as to how funding worked post cross-charging, and shows that there after the first year the cost of buying the BPL products gave NETRTC a shortfall of approximately £1 million. The RHA therefore decided to top slice the budgets of the districts in the region to pay this shortfall.

Screening for viruses

HBV

44 On 10 February 1975 Dr Jenkins wrote to Dr Maycock setting out his view that RIA testing was required to test for HB Ag as it was more sensitive than testing by reverse passive haemagglutination. He noted that a decision as to this was awaited from the hepatitis committee - **DHSC0002359_027**. In November 1979 Dr Jenkins wrote to Dr Lane offering NETRTC to evaluate the BPL RIA test, stating that they used the Abbot Austria II technique for all donations, and had done so for several years - **CBLA0001031**. The preliminary report of the evaluation can be seen at **CBLA0007179**. By January 1980 it looks as though NETRTC had switched to using the BPL RIA test - **CBLA0001048.**

45 There is some evidence of NETRTC being informed by clinicians when their patients developed HBV - **HCDO0000259_149. DHSC0100017_166** is a letter from 1966 which set out the steps taken when NETRTC were informed that a recipient of a blood transfusion had developed serum hepatitis. It can be seen that the key factor in deciding whether to defer them as donors was a history of jaundice.

NANB

46 One of the donor cards shows NETRTC sending plasma from a donor to Professor Zuckerman as early as 1979 for testing for potential NANB - **NHBT0009121.**

47 At a meeting of the Association of Haematologists (North East Thames Region) in December 1979, there is reference to a 'Regional Study of Post Treatment Hepatitis' which revealed that up to 70% of severe haemophiliacs had abnormal liver function tests with NANB 'types of hepatitis' being the most common - **BART0000682** (see also **BART0000685)**.

HIV

48 NETRTC began screening for HIV on 14 October 1985 (paragraph 455 of Dr Harrison's witness statement).

49 Where a donation tested positive in the RTC, on the advice of Dr Zuckerman:

a. The donation was subject to a further test at the RTC, and if this was negative, the sample was not sent to the reference centre for confirmation.
b. Such a donor was then re-tested six months after the initial positive tests and re-admitted if both the screening test and confirmatory test was negative. [**NHBT0009201**]

50 In August 1985, the Terrence Higgins Trust wrote to Dr Harrison stating that prior to HIV testing '*donors should be specifically and individually informed that their blood will be tested, together with a brief explanation of what this means*', and that '*appropriate counselling*' was required, as '*It is not necessarily sufficient to refer him/her to his/her G.P.*' [**NHBT0039762_134]**. Dr Harrison's statement explains that donors were told in their call up letter that such testing would be undertaken (see paragraphs 253 and 457) and they were asked to sign a declaration at the session making it clear that they understood this.

51 As for what the NETRTC did about the components that had not been tested for HIV but were in stock post 14 October 1985 Dr Harrison says this at paragraph 460 of her statement (emphasis added):

> *'I am sure any fresh blood in stock would have been tested from the samples. Blood samples for frozen blood* ***could*** *be tested before such blood was issued for use. I*

cannot recall the position in relation to blood that had already been issued to hospital and not yet used. '

HCV

52 In a letter written by Dr Harrison to Professor Allain in July 1991 she stated that she was unable to start screening for HCV as she had neither the funding nor the equipment, and her staff had still not been trained. She also expressed some concern that there was a risk of litigation arising from the fact that testing had not started as soon as the test was available - **NHBT0000075_007.**

53 According to Dr Harrison's statement, NETRTC started HCV testing on the nationally agreed date (paragraph 496). Paragraph 510 of Dr Harrison's statement provides that NETRTC needed to move into a new microbiological laboratory and recruit more staff before beginning HCV screening and so would have struggled to begin in April 1991, albeit this would have been possible.

54 Dr Harrison was not entirely sure what had happened to the components/products that had not been screened but were still in stock post 1 September 1991. In paragraph 505 of her statement she stated: '*I am sure that blood in stock would have been tested from the samples. Blood samples for frozen blood* ***could*** *be tested before such blood was issued for use. In relation to blood that had already been issued to hospital and not yet used, I would have expected that hospitals would identify any blood in stock but not yet transfused. Such donations would have been placed in quarantine until they had been tested.'* (Emphasis added).

Procedure once a donor was identified as being infected with HIV or Hepatitis

HIV

55 According to Dr Harrison's statement, once HIV testing was introduced, a donor who tested positive would be asked to come into the centre by letter, where (s)he would be seen by a transfusion doctor together with a doctor from the donor's local hospital. At that meeting the donor would be informed of their results 'and offered support' (see paragraphs 234 – 243). Further blood samples would be taken to confirm the diagnosis, a referral to a specialist service made, authority sought to inform the donor's GP of the diagnosis and advice given to encourage the donor to inform sexual partners of the diagnosis.

56 Dr Harrison can be seen to be trying to ensure that there were appropriate specialists to refer donors who tested positive for HIV to, for both treatment and counselling in the letter she wrote to Dr Sibellas of the DHSS on 16 September 1985 - **DHSC0002279_046**.

Hepatitis

57 **NHBT0000192_132** is a letter from Dr Harrison to GPs informing them of the plans to start screening donations for HCV, that donors would be asked for permission for the results of a positive test to be shared with their GP, and giving the GPs names of specialists to refer any positive donors to.

58 Dr Harrison's statement makes it clear at paragraphs 261 - 265 that they sought advice from Professor Zuckerman as to both how to deal with donors with liver disease, as well as on the HCV look back. She also states that because of their links with Professor Zuckerman they could move more quickly than some other centres in introducing the HCV screening test. It is not entirely clear what this means.

59 Dr Harrison's statement at paragraphs 245 – 246 also states that all the previous donations from a positive donor would be tested, by testing stored samples. If there were any that tested positives, those hospitals who had received the donation would be informed. The statement also sets out the procedure for tracing a donor who might be infected, when informed by a hospital that a patient had received a blood transfusion from a donor who had a diagnosis of HCV.

Record keeping and sample storage

60 Initially records were kept on '101' cards. Some records were computerised in 1984 (**NHBT0010587** page 35), with donor records being computerised in or around 1989 **NHBT0006247**. Records were kept for 30 years (para 317 of Dr Harrison's witness statement).

61 A serum sample was kept from each donor at each donor session, frozen, and kept for three years (para 318 of Dr Harrison's statement).

South Western Regional Transfusion Centre at Bristol

Overview

1 The South Western Regional Transfusion Centre (SWRTC) in Bristol was set up in 1948. The Regional Transfusion Directors (RTDs) of the SWRTC were Dr Geoffrey Tovey 1948 – 1979, Dr Ian Fraser 1979 – 1992 and Dr Tim Wallington 1992 – 1995.

2 The following details emerge from an inspection report of the centre from 1989:

a. The centre was in a purpose built building in the grounds of Southmead Hospital in Bristol. It was extended in 1985. There was a sub-centre in Plymouth.

b. It served a population of 3.4 million. It provided products to 17 hospitals. It collected 190,000 donations a year and employed nearly 300 staff.

c. There was a plasmapheresis clinic at the centre with 12 machines.

d. Donor records were not yet computerised, but this was planned to occur in the next 2 years. Records were still being held on the 101 system.

NHBT0006267. See also the earlier report in 1984 - **NHBT0105932_002**.

3 A later inspection in 1992 makes it clear that there were by then two hospital transfusion committees, one in Exeter and one in Gloucester. Staff from SWRTC would attend the meetings - **NHBT0009747**.

4 Senior staff at SWRTC attended a number of other meetings:

a. Internal meetings such as the Senior Staff Administration Meetings (see for example **NHBT0092744_009**).

b. External local meetings such as the South-West Haemophilia Treaters Group (see for example **TSFT0000001_026**).

c. Regional meetings such as the Western Division Consultants meetings (for example **NHBT0094257_001**).

d. National meetings such as the Regional Directors meetings, the Advisory Committee of the NBTS (for example **DHSC0001136)**, the Central Blood Laboratories Authority Central Committee for Research and Development in Blood Transfusion meetings (for example) **PRSE0002741**) and the CBLA working group on AIDS on 27 January 1984 (for example **CBLA0001799)**.

Targets

Whole blood and red cells

5 At a meeting of the Cossham and Frenchay Hospital Management Committee on 11 September 1962 the rapidly increasing use of whole blood was noted in a letter from Dr Tovey. This provides that there had been an 8% rise in 1960, a 1% rise in 1961 and the first five months of 1962 was showing a 28% rise. The minutes record a plea from Dr Tovey that requests for blood are kept to the minimum required for the patient's safety - **GLOA0000024.**

6 It would seem that when SWRTC was short of donations, they obtained red cells from other RTCs in England and Wales and sometimes even from Glasgow RTC - **SBTS0000027_046**.

7 A letter written by Dr Fraser in May 1990, describes there being a low stock of 'O' blood, which had led to a hospital in Exeter having to cancel a number of operations due to '*lack of blood*' - **NHBT0097017_003.**

Cryoprecipitate

8 The amount of cryoprecipitate produced in 1992 was said to be 2000 units - **NHBT0001571**.

Plasma

9 In July 1975 SWRTC were said to be planning to increase the number of packs of plasma they were to provide to BPL to the previous level of 100 – 120 per quarter. This was to be achieved by a haematologist at the Bristol Royal Infirmary - Dr Scott - agreeing to restrict the amount of cryoprecipitate being infused, and to use more haemofil in an emergency - **CBLA0005695, CBLA0009058, CBLA0009063** and **BPLL0003754.**

10 There is correspondence between the DHSS and the South Western Regional Health Authority (SWRHA) in 1981/1982 about the plasma targets for the region. In a letter dated 18 December 1981, (which the Inquiry cannot at present trace) the DHSS suggested a target of 30,000 Kg, but the SWRHA refused to fund this, stating that the plasma target for the regions was '*inflated to an unreasonable degree by the expectations of the directors of the haemophilia centres'* and that a more appropriate target for the region (and one they would fund) was 20,000 Kg - **DHSC0002215_017** and **NHBT0098757**.

11 In August 1984 Dr Fraser wrote to the SWRHA to explain that he could not expand the plasma programme via SAG(M) because of a lack of staff and a diminished budget - **NHBT0098683_001**. In November 1984 the SWRHA produced a memo on the plasma targets set by the DHSC. It noted as follows:

a. Current funded level of production was 15,000 litres of plasma per annum.
b. The DHSC target for 1987/1988 was 30,000 litres per annum.
c. A costed action plan to increase the amount of plasma obtained to this level was set out. Two sources were considered for increasing the plasma - plasmapheresis and SAG(M).
d. The authors of the report considered that once the region was producing 30,000 litres of plasma it would be self-sufficient, so would not need to buy in commercial product (said to be at a cost of £100,000). It was therefore recommended that the cost of achieving the increase in plasma should be top sliced from District allocations '*to allow this Ministerial directive and matter of national importance to proceed'*.

NHBT0098681

12 Something slightly different is stated in a document for an SWRHA meeting held on 10 December 1984. It states that SWRTC plasma production was 12,500 litres per annum, and that a rise to 15,000 litres would make the region self-sufficient in everything but Factor VIII.

'However the target set by the DHSS for the SWRHA is the production of 30,000 litres of plasma by 1987/1988. This target is based on the relative population of the South West and was not derived from the Region's projected requirement for blood products.

In practical terms, because the SWRHA has a much lower than average need for Factor VIII relative to population, our share of the national production target will require an investment greater than our marginal return. However, unless the Blood Products Laboratory receives sufficient plasma to operate, then the full benefits of national self-sufficiency (NHS £40m per annum – SWHRA £800,000 per annum) may not be realised.'

Despite this, the meeting concluded with a recommendation that the monies should be spent to reach the 30,000 litre target - **NHBT0098796**. See also **NHBT0098790** and **NHBT0098792**.

13 By April 1985 it was clear that the SWRTHA had not yet approved the budget to increase the plasma targets to that requested by the DHSS - **DHSC0002265_022**. The plasma

targets set out for SWRTC from 1985 – 1988 show an increase from 18,000 Kgs in 1985 to 32,000 Kgs in 1988. It was anticipated that the SWRHA would fund these targets.

14 At a Senior Staff Administrative meeting on 1 July 1985 the annual plasma target was said to be 20,000 litres, but that donations were 10% down – **NHBT0105952**.

15 In July 1989 SWRTC was said to be on target to meet its 90/91 plan – **NHBT0003374_001**.

16 By 1992 SWRTC was expecting to provide over 39,000 Kgs of plasma to BPL (mainly through recovered plasma), with an additional just under 1,000 Kgs of specialized plasmas - **NHBT0003273**.

Selection of Donors

High risk donors

17 SWRTC stopped collecting donations from prisons in January 1984. The reasons given to the prison governors for this was the '*extremely high incidence of hepatitis carrier status*' amongst the population and the relationship between a high hepatitis carrier status and AIDS - **NHBT0091997**.

AIDS

18 In May 1983 Dr Fraser sent information to all the sessional doctors about AIDs, explaining what it was, how it was transmitted, who was at highest risk, and what the symptoms were – **NHBT0099867**.

19 On 20 March 1984 the SWRTC informed the DHSS that after the first 6 months of using the national AIDS leaflet, they had used 28,000 leaflets and had 18,000 in stock, giving a rate of usage of 4,000 every month. It was reported that a leaflet was offered to every donor before they 'sign in'. Initially nearly all the leaflets were taken away from the sessions by donors, but by March 1984 this had dropped to a quarter (the leaflets being left behind on the seats). SWRTC had noted no effect on donor attendance, with no feedback from donors of any kind - **DHSC0002239_054**.

20 In an unsigned statement of Dr Fraser's (which may have been for the HIV litigation,[2]), Dr Fraser stated that leaflets were sent to donors when their call up cards were sent to them - **NHBT0019638**. Of note, in this statement Dr Fraser explained that *'Although in 1982 it was becoming apparent that there could be a link between blood and the development of AIDS, it was clear that by 1983 there was a definite link'* (para 18).

21 In a letter to Dr Wagstaff, director of the Trent Regional Transfusion Service, Dr Fraser said this regarding questioning donors to establish whether they may be infected with HTLV III: '*We still do not support the idea of asking donors, on the questionnaire, if they have night sweats, weight loss or lymph gland enlargement. As far as our region is concerned there is nowhere where a private discussion can be held between the medical office and the donor. ..... We do not support the idea of handing out the AIDS pamphlet to all donors, this would slow the session down anyway. However we feel the pamphlets should be on prominent display.'* **NHBT0039762_049**

22 At a Senior Staff Administrative meeting on 1 July 1985 Dr Fraser requested that an additional sentence saying 'I have read and understood the AIDS leaflet' be added to form 110 – **NHBT0105952**.

23 In an audit report of SWRTC in 1993, one of the issues of concern was that donors were not being asked to read the AIDS leaflet - **NHBT0009640**.

BPL

24 There is evidence of communication between SWRTC and BPL in respect of donors who had been diagnosed with, or suspected as having developed infections – see for example **DHSC0001488** in the case of a patient who had developed the signs and symptoms of HIV in July 1985. See also **CBLA0008722** which is a letter from BPL to SWRTC informing them of a batch of BPL product provided to SWRTC that had been associated with NANB.

Donor Screening

HBV

25 On 15 May 1974 Dr Tovey wrote to Dr Maycock stating that SWRTC would be pleased to take part in the proposed haemagglutination test screening for HBV, and would screen 2,400 donations per week - **CBLA0007128**.

[2] Dr Fraser was certainly being kept abreast of the HIV litigation - NHBT0100559 and NHBT0100921

26 On 2 February 1976, Dr Tovey wrote to Dr Maycock to inform him that he had almost completed testing the 5,000 samples by both RPH (reversed passive haemagglutination) and CIE (counter immunoelectrophoresis) and anticipated the RPH would be in use as routine within the next seven days - **DHSC0100001_029** and **DHSC0100001_028**.

AIDS

27 By August 1985 SWRTC were reporting to the DHSS that as a result of the RHA agreeing to fund the screening kits, additional staff and the equipment required (and space not being an issue), SWRTC were in a position to start screening in October 1985 - **DHSC0002275_038**. However, by mid-September 1985 the situation had changed, as Dr Fraser had been told that he was no longer able to recruit the additional staff he needed to implement the AIDS screening. He therefore informed the DHSS that while he would be able to begin the screening in mid-October, he would have to curtail some of the other services that had previously been provided to the region - **DHSC0002277_055**.

28 In fact, SWRTC started screening on 30 September 1985 and by 14 October '*all blood donations, fresh frozen plasma and cryoprecipitate and products from fresh blood had been tested*'. Blood banks were asked to send back any products issued to them prior to 30 September and Dr Fraser reported to the DHSS that the changeover had gone well - **DHSC0002285_027**.

29 By January 1998, no positive donors had been identified at SWRTC - **MRCO0000500_023**. However, two positive donors were found in the South West of England, both members of at risk groups - **NHBT0004704**.

NANB

30 There are various examples of Dr Tovey reporting cases of homologous serum jaundice to Dr Maycock throughout the 1950s, 1960s and 1970s, see for example **DHSC0100012_015** and **DHSC0100012_067**.

31 It is clear from the correspondence that Dr Cash and Dr Fraser were in correspondence in 1986 and 1987 about the question of the introduction of NANB surrogate screening – see for example **PRSE0002109**, **PRSE0001973** and **PRSE0003936**. It would appear that Dr Fraser was in favour of carrying out a study using surrogate testing.

32 In October 1986 Dr Fraser wrote to Dr Smithies of the DHSS informing her that it had been agreed by the RTDs that there should be a multi-centre prospective study to establish the incidence of core antibody and raised ALT levels in donations in various parts of England. The plan was to test 10 – 12,000 donations in England in four centres, including SWRTC, and two centres in Scotland. Dr Fraser was of the view that the study would require central funding - **PRSE0003348**.

33 SWRTC was part of a multi-centre trial of surrogate screening using ALT and anti HBc testing (see for example minutes from the steering group such as **NHBT0000187_024, NHBT0000076_037** and **NHBT0000187_029**). In a letter of March 1990, Dr Fraser reported that of 3,009 donors screened, there had been 8 abnormal results - **NHBT0000077_093**. This study was written up in Transfusion Medicine in 1992 - **NHBT0000103_003**.

34 In a letter to Dr Gunson in October 1991, Dr Fraser stated that HBc testing was carried out only on plasmapheresis donors donating for anti –D and Rh(D), and ALT testing was carried out on plasmapheresis donors at 6 monthly intervals. The letter also sets out the level at which ALT was considered to be abnormal and their practice when an abnormal result was seen - **NHBT0000077_081**.

Hepatitis C

35 Having been asked by Dr Gunson in January 1991 when SWRTC would be able to begin HCV screening, Dr Fraser thought that the optimum time would be July 1991 as they had to employ more staff - **NHBT0000073_035**. SWRTC was ultimately provided with sufficient staff and funding by SWRHA to carry out HCV screening - **NHBT0000075_078**.

36 There is correspondence in April 1991 when Dr Fraser wrote to SWRHA informing them that the date to commence HCV screening had been put back, and stating that his haematologist colleagues were therefore expecting a reduction in the price of blood and its products to reflect this - **NHBT0000191_132**.

37 At a meeting of the Western Division of Consultants on 30 July 1991 it was recorded that SWRTC were using the UBI ELISA test, and then relying on their Public Health Laboratory (PHL) to do the 'alternative' test (it is presumed this means the confirmatory

test)- **NHBT0094257_001** and **NHBT0090710**. On 31 July 1991 Dr Fraser reported that SWRTC had been using the UBI kits for the last two months and were relatively impressed with them - **NHBT0090778_009**.

38 In September 1992 Dr Wallington wrote to a clinical colleague complaining that as a consequence of a woman who was seeking treatment by IVF, being advised by a doctor (presumably in a fertility clinic) to give blood in order to establish her virological status, she had indeed come and given blood. The letter goes on to state: '*It is worrying that blood donors should come forward for this reason. It is especially worrying that they should have been advised to do so from within the medical profession. The safety of our blood supply is dependent on donors being of the lowest possible risk and an important element of that is that they should be true volunteers without any motivation beyond the simple desire to give their blood. Otherwise we fear that medical questions might not be answered with complete truthfulness.*' **NHBT0004786**

39 In 1994 a paper entitled 'Hepatitis C (HCV) positive blood donors in South-West England: A case control study' was published in Transfusion Medicine which concluded that the current donor policies were ineffective at excluding those with a history of intravenous drug abuse, and consideration should be given to introducing direct confidential questioning about risk factors for all donors - **DHSC0032377_084**.

Donor Counselling

Arrangements for donors with HBc and raised ALT levels

40 According to a letter written by Dr Fraser to Dr Gunson in October 1991:

a. There was an arrangement for all donors with a positive HBc test or raised ALT levels in Devon and Cornwall to be seen in Exeter by a Senior Registrar, with positive donors in the rest of the region being seen in Bristol by a named consultant and a senior registrar.
b. There were agreements throughout the region with haematology departments allowing them to speak in confidence to donors and if necessary carry out examinations.
c. There were arrangements in place to refer donors on for further counselling, testing and treatment after this initial counselling.

- NHBT0000077_081.

Hepatitis

41 At a meeting of the Western Division Consultants on 30 July 1991 attended by Dr Fraser, it was said that most of the centres were planning to refer HCV positive donors to their GPs for counselling due to the heavy workload RTC based counselling would involve - **NHBT0094257_001**. It is not clear if this included SWRTC, but given that an audit report from February 1992 makes it clear that counselling of any donors found to be infected with HBV, HCV and syphilis was undertaken at the centre by either a consultant or a staff grade physician, it seems unlikely - **NHBT0009747**.

42 There is evidence of SWRTC finding named clinicians to whom they were able to refer HCV positive donors to for treatment - **NHBT0075690**.

HIV

43 In an audit report from February 1992 it was said that if a donor was found to be infected with HIV, (s)he was counselled by the director and counselling was arranged at the hospital close to the donor. It would be routine for them to see an HIV counsellor that day - **NHBT0009747**.

Arrangements for the purchase, supply and distribution of factor VIII

44 In an unsigned statement of Dr Fraser's (probably for the HIV litigation) it was said that:

a. SWRTC was supplying cryoprecipitate from 1967 and BPL Factor VIII from 1977.
b. SWRTC was not involved in the purchase of commercial Factor VIII.
c. During the late 1970s, SWRTC was receiving only half the amount of BPL Factor VIII it required to treat all those with haemophilia in the region.

NHBT0019638.

45 Prior to November 1976 BPL was providing Factor VIII to hospitals in the South West region directly (see for example **CBLA0005691**). From that point on, a regular distribution was made of Factor VIII to SWRTC and so hospitals obtained their supplies from the centre - **CBLA0000487**. As to the allocation of Factor VIII to SWRTC, this may have been based on the amount of cryoprecipitate the various Haemophilia Centres received from SWRTC - **CBLA0000471**.

46 There is correspondence from 1976 and 1977 from Dr Tovey to Dr Biggs at the Oxford Haemophilia Centre asking for an increase in the allocation to the South West Region of Factor VIII. This was because half of those treated in the region were treated at associate centres, but the region's allocation was based only on the number of patients treated in Exeter and Bristol - **OXUH0000686_004, CBLA0000467, OXUH0000686_002** and

HCDO0000023_005. See also **DHSC0100006_179** for the rationale behind the national policy of distribution between regions.

47 In 1977, SWRTC and Wessex RTC agreed that SWRTC should supply the hospitals in Bath with products (despite Bath being within Wessex RTC's catchment), thus BPL were asked to increase SWRTC's allocation of Factor VIII and reduce Wessex's - **CBLA0000578**.

48 There is correspondence in 1978 which shows Dr Maycock getting directly involved in agreeing how many bottles of Factor VIII a particular patient could receive - **CBLA0000828**.

49 As to the position with the purchase and supply of commercial products:

a. There are figures for the commercial products purchased by the South West Region (it is not clear whether this was by the District Hospitals or by SWRTC for the region) in 1979 - **DHSC0002193_063** and **DHSC0002193_064**.
b. As at July 1981, BPL Factor VIII was held by SWRTC, but the District General Hospitals purchased their own commercial products, paid for out of the hospital pharmacy budget - **DHSC0002209_042**.

50 In a letter to all consultant haematologists in the area, Dr Fraser wrote on 4 January 1985 to inform them that BPL were going to provide about 1/3 of their allocation in heat treated products, and that these would be distributed by SWRTC 'equally' through the region – **NHBT0091986**.

51 There then appears to have been some confusion later on in the year as to how heat treated Factor VIII product from BPL was to be distributed. In a letter from SWRTC to BPL, Dr Wallington expressed dismay that BPL would be deciding how to allocate the product rather than this being done by SWRTC - **BPLL0010624**.

52 On 13 December 1985 Dr Fraser wrote to his colleagues to explain the impact on supplies in the South West arising from the delay in the building works being done at BPL – in short there would not be the increase in Factor VIII that had been anticipated until October 1986 at the earliest, and there might even be a cut in allocation - **NHBT0091975.**

53 In 1990, following the introduction of cross charging, SWRTC suggested that a regional contract should be entered into with BPL for all products, with SWRTC co-ordinating the supply - **NHBT0010036_009**.

Look back

HIV

54 SWRTC provided information to haematological colleagues in the area some time after HIV screening was introduced, explaining that they would need assistance in identifying any recipients of infected blood donations, and setting out the reasons why such investigations were so important - **MACK0001136_006**.

55 In January 1986 Dr Fraser informed Dr Ala (Birmingham RTC) when a donor found to be infected with HIV had also donated at Birmingham, so as to enable an investigation to be undertaken in respect of previous donations - **NHBT0045768**.

Hepatitis

56 The standard operating procedure for investigating a case of post transfusion hepatitis as at 1990 is set out at **NHBT0005384.**

57 SWRTC took part in the national HCV look back, see for example **MODE0004549** and **NHBT0024506_006**. Results from the look back are at **NHBT0005815**. 164 donors were identified as HCV positive with 264 components issued (discounting what was sent to BPL). There is also correspondence which shows SWRTC making arrangements (via the Regional Director of Public Health) to ensure that any patients identified in the look back as having been infected with hepatitis C had recourse to specialist advice and treatment - **NHBT0088416**.

North Western Regional Transfusion Centre at Manchester and Lancaster

Overview

1 The North Western Regional Transfusion Centre (NWRTC) was made up of two centres, one in Manchester and one in Lancaster. The directors of NWRTC were Dr F Stratton between 1948 and 1980, Dr Harold Gunson between 1980 and 1988 and Dr Douglas Lee between 1988 and 1995.

2 The position prior to Dr Lee taking up his post as Regional Transfusion Director (RTD) of NWRTC has been covered in an earlier presentation on Dr Gunson - **INQY0000309.** This note therefore covers the period between 1988 and 1995.

3 An undated advert for a consultant post at NWRTC (but most likely in October or November 1988) provides as follows:

a. The Manchester Centre had three teaching hospitals within its boundaries, 17 district hospitals and 3 private hospitals.[3]
b. In excess of 110,000 donations were collected each year, by four mobile teams and the permanent donor collection centre.
c. The apheresis centre handled 45 donors a day, which was due to increase to 70 a day in 1989.
d. The centre at Lancaster collected 55,000 donations per annum.
e. There were three consultant posts.

NHBT0020510_022

4 As well as providing blood and components to district general hospitals, and plasma to BPL, NWRTC also acted as a reference centre for the district general hospitals, providing specialist tests and advice- **NHBT0115888_002**.

5 Information about the Manchester centre can be gleaned from a Medicines Inspectorate report of July 1990 (**NHBT0006277_002**):

a. Since 1984 the Manchester Centre had been based in the south east of the city in an old ICL computer factory. This was close to the Manchester Royal Infirmary.
b. The Centre had a plasmapheresis suite that handled 55 – 60 donors a day.

[3] There were no military hospitals in the area covered by NWRTC - NHBT0002985.

c. It served a population of 3.4 million, employed over 300 staff and collected over 100,000 donations annually.

6 Further information about the Manchester centre can be found in the report of the Medical Audit which took place in February 1992 - **NHBT0009743_001**:

a. A monthly meeting was held between the Manchester and the Lancaster Centres.
b. A consultant was always on call between the Manchester and Lancaster centres.
c. The RTC counselled in person any donor who tested positive for HIV, HBV or HCV.
d. The medical staff aimed to visit each hospital in the region annually.
e. Two hospitals within the area served by the Manchester Centre had transfusion committees, with a third due to establish one shortly. A consultant from NWRTC attended the meetings (see for example a report by Dr Love of a hospital transfusion committee meeting - **NHBT0203494)**.

7 Dr Lee's support for hospital transfusion committees can be seen in a letter he wrote to all hospital consultant haematologists in the region in March 1991, encouraging them to set up transfusion committees, and providing them with information about the role and purpose of such committees and sample terms of reference -**NHBT0203705**.

8 Information about the Lancaster Centre can be gleaned from the Medicines Inspectors report of December 1990 - **NHBT0006280_002**:

a. The Centre was based in the Lancaster Moore Hospital.
b. The Centre employed 132 staff and collected 155,000 donations per annum.
c. It had an apheresis suite with 12 machines.

The report concluded: '*This Centre is housed in an old building which is really too small and was not designed as a Transfusion Centre, resulting in a severe shortage of storage space and cramped conditions in a number of other areas. However conditions in terms of organisation and cleanliness are such that the facilities can operate to an acceptable standard at present.'*

9 Further information about the Lancaster centre can be found in an inspection of the Lancaster Transfusion Centre of September 1992 – the executive summary provides that:

a. There was a full-time consultant haematologist, another consultant haematologist who also worked at the Manchester centre, a clinical assistant and part-time senior registrar
b. Manchester and Lancaster operated almost autonomously.

c. Seven hospital blood banks were served by the Centre, and one had an active Transfusion Committee with a BTS consultant as a member.

d. The auditing team was '*impressed with the enthusiasm and dedication of the medical staff, the high quality of their work and their commitment to the concept of medical audit as a means of maintaining and improving standards.*'
NHBT0009741

10 A number of other inspections and audits of both centres were undertaken over the years:

a. A Quality Audit in April 1990 - **NHBT0009621**.

b. A quality audit of the Lancaster RTC in October 1990 - **NHBT0009616_001** and July 1991 – **NHBT0009615_001**.

c. A quality audit of Manchester in September 1991 - **NHBT0009616_001**.

d. An external audit was undertaken of the Lancaster Centre in 1995 as part of the National Blood Authority programme of reform - **NHBT0009733_003**.

11 On 12 September 1994 the NBA released a consultation document setting out plans for the future of the blood services – **NHBT0000236_014**. One of the changes they were consulting on was the amalgamation of the Manchester, Lancaster and Liverpool RTCs by closing the Lancaster and Liverpool cites. Dr Lee's response to this is at **DHSC0004351_059**.

12 In October 1995 Dr Lee wrote to Sir Colin Walker, the Chief Executive of the NBA, informing him that 20 out of the 42 posts at the Lancaster Centre were empty and urging the NBA to make clear its plans for Lancaster so that either the centre could stem the loss of staff (should there be a reprieve for the Centre), or let the changes take place in an ordered way - **NHBT0009734**.

13 In January 1996, it was agreed that the Lancaster Centre should relocate to the Lancaster Royal Infirmary - **DHSC0004530_063**.

Provision of plasma to BPL

14 NWRTC had regular plasma supply group meetings which considered the usage of components and products in the region such as Factor VIII, platelets and cryoprecipitate - **NHBT0203623** and **NHBT0203747**.

15 The 1989/1990 targets were 8.39 t.p.m (tonnes per million population). In a note of a visit to NWRTC by Dr Moore in August 1989, he noted that the use of SAG(M) was currently

below 60% which had contributed to a shortfall in the collection of plasma. There was also a shortage of donors, contributed to by the fact that 20% of plasmapheresis donors had failed to attend their appointments. The region was said to be 16% below target, with a likely annual shortfall of 10% or 3,800 Kgs. There were plans for two new apheresis centres in Bolton and Preston - **NHBT0003377**.

16 NWRTC set its own plasma targets for 1991/1992:

a. Manchester – for recovered plasma – 23,500 Kgs and apheresis – 6,000 Kgs.
b. Lancaster - for recovered plasma – 10,800 Kgs and apheresis – 4,000 Kgs

This was a 2.3% increase from the previous year - **NHBT0003352**. See also **NHBT0003332**.

17 In March 1991 Dr Lee agreed to revise the amounts of specialised plasma NWRTC would provide to BPL, but expressed concern at the 'stop go' approach to this issue making it difficult to plan - **NHBT0003331**.

18 The targets for 92/93 were set at 34,400 Kg for recovered plasma and 9,300 Kg for apheresis. This was said to be the same level as the year before - **NHBT0003251** - but that does not accord with **NHBT0003352**. The targets for specialist plasma targets in 93/94 were set out in **NHBT0003278**.

ALT and HBc testing

19 NWRTC took part in the multi-centre study for surrogate markers for NANB reported in Transfusion Medicine in 1992 - **PRSE0001695**.

20 On 12 February 1990 NWRTC wrote to the North Western Regional Health Authority (NWRHA) costing out ALT testing on plasma- **NHBT0101258**.

21 Dr Lee wrote to Dr Gunson in October 1991 to inform him that NWRTC was not routinely carrying out HBc testing, but was testing for HBc as part of the follow up for a case of post transfusion hepatitis and where a donor was being counselled because they were HCV positive. This letter also stated that ALT testing was not being carried out routinely, although AST testing was performed, and if this was consistently raised, ALT testing might be undertaken. A result greater than 60 would be abnormal. '*If we find a raised ALT in a plasma donor, we would seek to link it with one or more of the factors*

known to predispose. If we cannot do this, and if the finding is persistent, we would continue to bleed the donor with regular monitoring. Where the result is persistently greater than 90, we would refer the donor to the gastroenterologist for advice about liver function.' **NHBT0000193_051.**

22 In June 1993, Dr Lee informed Dr Gunson that NWRTC could begin HBc screening on 1 October 1993 - **NHBT0018435**.

Screening for HIV

23 On 18 May 1989 Dr Lee wrote to the NWRHA in the following terms: '*It has become clear to me from experience both here and in Lancaster and from comments made by the Directors of other Centres that we can no longer regard apheresis donors as an 'accredited panel' in the context of HIV infection. I say this because several episodes have come to light of apheresis donors either belonging to risk groups or being active sexual partners of members of risk groups. I have therefore given instructions that no untested products should be issued from either Centre.'* **NHBT0086417_023**.

24 By November 1989, 11,018,424 donations had been tested for HIV, and 145 had been found positive (1 in 76,000). The majority of donations during November were tested with the Wellcome kit, but a small number of donations were tested with the Abbott and the Du Pont kit - **NHBT0032831**.

Screening for HCV

25 There is evidence from 1989 that NWRTC was asking Dr Craske to carry out early HCV testing of donation samples in respect of donations made to patients who had been transfused and diagnosed with NANB - **NHBT0054310_026**.

26 By July 1990 NWRTC had undertaken an evaluation of the Abbot system for HCV testing - **NHBT0000189_189** and **NHBT0000189_191**.

27 In February 1991, Dr Lee told Dr Gunson that the earliest the NWRTC could commit to beginning testing for HCV would be 1 June 1991. Confirmation as to whether the DH were going to pay for this or '*confirmation of instructions from the Department to Regions to release the necessary money'* was requested by Dr Lee - **NHBT0000073_042**.

28 NWRTC used the Abbot kit - **NHBT0090777_005** and **NHBT0090778_002**. In March 1991 there were discussions about the confirmatory test that would be available. From

NHBT0113626 it looks as though the PHLS at Withington (which was to be the local reference centre) was to use the RIBA-II test with Ortho. See also **NHBT0112572**. The Lancaster Centre would send any reactive sample to their Abbot test to PHLS Withington, who would do a RIBA-II on the sample - **NHBT0113674**.

29 Dr Lee estimated the money that he would require over the period 1991/92 to pay for HCV screening, with a start date of 1 September 1991, at £381,166 - **NHBT0113661**.

30 In a letter to the NWRHA in July 1991, Dr Lee stated that NWRTC would begin screening for HCV on 1 September 1991 - **NHBT0203663**.

31 In October 1991, Dr Lee expressed an interest in being included in a national contract for purchasing HCV testing kits if it resulted in a significant reduction in the price of kits - **NHBT0113648_003**.

32 On 17 December 1991, NWRTC reported that it had received financial support for routine screening and confirmatory testing, but (i) no account had been taken of the need for counselling donors which was being undertaken by a Consultant Haematologist; (ii) nor had account been taken of the need for follow up, which was said to be posing some problems for Dr Warnes who was seeing all the positive donors from the Manchester Centre - **NHBT0000075_081**.

33 In July 1992, Dr Lee wrote to Dr Moore making out a case to retain Anti-D plasma not fractionated before December 1992 on the basis of financial considerations, the ethical duty not to waste donations and because most of those donors would now have been tested for HCV and so (it was argued) it must have been possible to formally document that retrospective testing and carry out a similar exercise to that undertaken in relation to the plasma stockpile when HIV testing was introduced - **NHBT0000060_037**.

34 Where a donor tested positive and RIBA-II indeterminate, but PCR negative, the donor could be reinstated to the panel if they subsequently become anti-HCV negative by an HCV screening test - **NHBT0033886**.

35 In June 1993, Dr Lee expressed his concern at being asked to implement a donor questionnaire for all donors, given the significant increase in staff this would require - **NHBT0006684**.

Counselling HCV positive donors

36 Dr Lee wrote to Dr Gunson in October 1991 to inform him of the plans for counselling HCV positive donors – the plan was to see donors and counsel them at NWRTC if their donation tested positive after testing by Dr Craske using the RIBA test. NWRTC did not intend to wait for the PCR tests before counselling. Where the results were indeterminate, the results would be left on the lab file and counselling would be deferred until another donation had been made - **NHBT0000193_051**.

37 In a letter dated 11 October 1995, Dr Love informed Dr Robinson that while in most cases, counselling was undertaken by NWRTC, 'in a surprising number of cases' the GP or even Consultant Physician insisted on undertaking the counselling, or agreed to do so for geographical reasons. They had found this counselling to have been poorly performed and in some cases met with a refusal to fill in the green forms - **NHBT0002722**. Information about both the counselling, the confirmatory testing and referrals for specialist treatment were provided by Dr Love to the relevant clinician undertaking the counselling - **NHBT0099313_025**.

38 An example of a letter written by NWRTC to a GP in respect of an HCV positive donor who was counselled by NWRTC can be seen at **NHBT0058226_005**.

Research projects

39 **NHBT0113621** contains a suite of documents for a study by Dr Lee (as part of a multi-centre trial) of the prevalence of HCV in the North Western Hospital population. The study retrospectively HCV tested samples taken from patients who were transfused in July and August 1991. The suite of documents includes letters to potential participants (asking for a sample of their blood) and an information leaflet. - **NHBT0112570_001**, **NHBT0113654_004** and **NHBT0115881**.

Arrangements for the distribution of blood products

40 In November1989 Dr Lee put in a bid for any surplus 8Y to be provided to his area, on account of the fact that the amounts received from BPL were significantly less than was required - **NHBT0033661**. It is clear from this and other correspondence (such as **NHBT0097035_036** and **UHMB0000006_014**) that NWRTC received and distributed BPL products for the region. Examples of the orders put into BPL from NWRTC can be seen at **NHBT0054295_007** and **NHBT0054295_004**.

41 In early 1990, the Director of the Manchester Haemophilia Centre at the Manchester Royal Infirmary and Dr Lee at NWRTC joined forces to press the North Western Regional Health Authority for more money to fund increased provision of Factor VIII - **NHBT0018289** and **NHBT0018288**.

42 Hospitals sourced commercial supplies of factor products independently of NWRTC - **NHBT0002183**.

HIV look back

43 In 1992 NWRTC was asked by Dr Gunson to provide the details of any donors who had tested positive for HIV, along with their donation numbers and the details of where those donations went - **NHBT0092320**. Some research on this appears at **NHBT0092301**.

44 There is evidence of NWRTC reporting those donors found to be HIV positive to CDSC - **NHBT0115743_001**.

Hepatitis C Lookback

45 NWRTC participated in the national HCV look back programme in 1995.

a. An example of a letter written to one of the hospitals that had received components from a donor with an HCV infection is at **NHBT0102851**.

b. There is evidence of NWRTC sharing information about HCV positive donors discovered during the look back in 1995, that had a history of donating in other RTCs - **NHBT0009970**.

c. There is also evidence of NWRTC being asked to counsel donors in its area who were identified by other RTCs as part of the national look back programme - **SBTS0003069_215** and **SBTS0003069_214**.

d. The results of the HCV look back in Manchester are at **NHBT0092375**. 628 donations were identified, 445 donations were traced,176 replies were received, 21 patients were found to be positive, and 27 recipients were counselled.

Miscellaneous

46 There is correspondence between NWRTC and Dr Rejman about patients who had applied to the DHSS for payments from the Scheme of Payment for Those Infected with HIV Through Blood or Tissue Transfer', see **EILN0000016_001, NHBT0092327, NHBT0098178** and **NHBT0103071**.

47 There is also evidence of NWRTC informing treating clinicians of the existence of the Eileen Trust at the time that it started to operate, informing them of their patient's right to obtain compensation - **NHBT0092313**.

East Anglia Regional Transfusion Centre at Cambridge

Background

1 The East Anglia Regional Transfusion Centre (EARTC) was established in 1946. Its Regional Transfusion Directors (RTDs) were:

a. Dr Jack Darnborough from 1969 to 1990.

b. Professor John-Pierre Allain from 1991 to1992. He has provided a witness statement to the Inquiry - **WITN3599001**.

c. Dr S M McDougall from 1992 to 1995.

d. Dr Lorna Williamson who was there from September 1988 as a senior registrar and was a caretaker director in 1995 for a few months before the centre was incorporated into the National Blood Authority. She has provided both written and oral evidence to the Inquiry.

2 The Inquiry has also received written evidence (**WITN6917001**) and heard oral evidence from Dr Colin Entwistle who was deputy director of the EARTC between 1968 – 1974.

3 This presentation addresses the period up to when Dr Williamson took up her post at EARTC as a senior registrar in haematology in September 1988.

4 In May 1982 EARTC served 12 hospitals and 2 armed services hospitals - **DHSC0101582**. Dr Entwistle told the Inquiry in his oral evidence that by the time he was at EARTC there were no donor sessions in prisons.

5 A medicines inspection of EARTC in 1990 reveals the following:

a. EARTC was in the grounds of Addenbrookes Hospital in Cambridge. It served a population of 1.9 million, employed 180 staff and collected over 90,000 donations annually.

b. It had a plasmapheresis suit which had about 120 – 150 donors per week.

c. The procedures at EARTC were computerised, and were based on the Cardiff RTC system.

d. About 48,000 units of plasma were provided to BPL for fractionation.

NHBT0006237

6 Senior members of staff were attendees at a range of local and national meetings, including the East Anglia Regional Health Authority Regional Working Party on AIDS - **CAMA0000075**.

Targets and production

Blood donations

7 In the first six months of 1973, EARTC had collected 34,141 donations - **DHSC0002175_039**.

8 In May 1974 Dr Darnborough wrote a letter to the Lancet entitled 'What price blood?' in which he stated that there was no shortage of blood. In making this statement he relied on the fact that 20% of blood was returned unused from hospitals. He went on to assert that EARTC could if required increase its collections by 20% fairly quickly - **DHSC0100024_124**.

Cryoprecipitate

9 In 1972 over 2000 units of cryoprecipitate were issued by EARTC to the hospitals in their region - **DHSC0100026_038, DHSC0100026_039** and **DHSC0100026_035**.

10 In September 1973 2,273 donations had been made into cryoprecipitate - **DHSC0002175_039**.

Plasma

11 In September 1973 Dr Darnborough wrote to the DHSS setting out the EARTC costs for the proposed expansion of Factor VIII production. This provided that in the first six months of 1973, 1,232 donations had been sent to BPL as FFP for fractionation - **DHSC0002175_039**.

12 In February 1975 Dr Darnborough appears to have been recommending that 180mls of plasma should be removed from each donation - **DHSC0100006_020**. However, by July 1975, red cells were prepared by removal of at least 200 ml of plasma, and usually more like 250 ml - **CBLA0000289**.

13 On 12 May 1975 Dr Darnborough wrote to the DHSS in relation to the plan to increase the plasma supply for the production of Factor VIII. Building works needed to be carried out at EARTC before this could begin, and so he estimated that it would not be until

March 1976 that EARTC would be able to produce 6,000 extra units, and the summer of 1976 before they could build up to 10,500 units - **DHSC0002177_030**.

14 On 9 October 1975 Dr Darnborough informed the DHSS that EARTC would be able to meet its target of 167 donations of plasma per month in September 1976 - **DHSC0002179_014** and **DHSC0002179_009**. However by July 1976 Dr Darnborough was pressing Dr Maycock as to when Factor VIII concentrate would be made available to EARTC, given that EARTC had reached their plasma targets- **CBLA0000383**.

15 In November 1980 Dr Darnborough informed Dr Lane that EARTC would be able to contribute their fair share to the 30 million additional units required between mid 1981 and mid 1982 - **BPLL0000917**.

16 In March 1983 an Operational Research Study of the Blood Transfusion Service was undertaken by a study group which included Dr Darnborough. This was to determine the future requirements (the next 15 – 20 years) for the region for blood and blood products. The report provides as follows:

a. In East Anglia they were hoping to be self-sufficient in Factor VIII by the end of August 1983. At the time of writing the report 30% of Factor VIII was purchased from commercial suppliers.
b. The report anticipated a rise in demand for red cells between 1982 and 1992 in the region of 19 – 24%.
c. The report anticipated a rise in the use of Factor VIII from 800,000 international units in 1982 to 1 million units in 1992.
d. This would require expansion to the current EARTC. Options for this were set out in the report.

17 It would appear that EARTC did not quite make their target for providing plasma to BPL in 1983. As at October 1984 the long term target for EARTC was to provide BPL with 17,000 Kg of plasma by 1993/1994 - **DHSC0002247_068**.

18 On 20 March 1985 Dr Darnborough informed DHSS that EARTC was undertaking two phases of building works which were highly relevant to their plasma procurement targets. The amount of plasma that could be supplied in 1985 was said to be 7680 Kgs (or litres), rising to 9,000 in 1986 following completion of phase 1 of the building works, 11,200 in 1987 following phase 2 of the building works, reaching 16,800 in 1988 - **DHSC0002263_029**.

Donor Selection Policies

Hepatitis B

19 In November 1971 Dr Darnborough wrote to Dr Maycock asking for advice as to whether EARTC ought to reconsider its policy of not removing donors who tested positive for serum hepatitis (instead just endorsing the infected donor's card with a code and only removing them if they '*were involved with transmission of serum hepatitis on the second occasion'*). Dr Darnborough thought this was the same policy adopted in all RTCs - **DHSC0100019_346**.

AIDS

20 In June 1983 Dr Darnborough expressed his views as to the approach to take in bringing information about AIDS to the attention of donors, stating his preference was for leaflets to be made available at sessions, but having 'no great objection' to them being sent out with call out cards and/or being handed out at sessions. He was of the view that donors should not however be directly questioned at sessions - **NHBT0021392.**

21 On 15 March 1984 EARTC reported to DHSS that they had a current stock of 70,000 leaflets and had issued just 5,000 giving a rate of usage of 1,000 per month - **DHSC0002239_081**. There had been a positive response to the leaflet in that a handful of men had written to say that they did not think they should be donors. There had been no negative comments. A local leader from a local campaign group for Homosexual Equality was however confused about the meaning of the phrase on the leaflet of 'many different partners' - **DHSC0002239_081**.

22 On 5 February 1995 Dr Darnborough wrote to Dr Smithies informing her that the first AIDS leaflets were displayed prominently at sessions, but since the revised leaflet and Health Circular were distributed they had 'stiffened up the routine' in line with the memo provided to all the donor panel clerks. This memo required:

a. Leaflets to be sent with call up cards for the next 12 months.
b. The organiser for sessions at firms and in the forces to be asked to provide a leaflet to all volunteers.
c. New donors and those who had not been invited by card to have the leaflet handed to them at registration.
d. All donors to be asked directly if they had read the leaflet.

NHBT0021395 and **NHBT0021396**.

Screening for infections

HBV

23 Dr Entwistle told the Inquiry in both his written (**WITN6917001**) and oral evidence that he devised an electropheresis system for detecting hepatitis B antigen, and used this personally on donations 6 months before hepatitis testing was introduced at EARTC. Infected donations were removed from circulation, the donor informed that they had picked up an infection and were then referred to their GP. As far as Dr Entwistle could recall, this test was the only test used at EARTC until he left in 1974.

24 In January 1971 Dr Darnborough expressed his concern that some centres might be starting routine screening for hepatitis B. It was his view that mass screening should not be introduced except on a national scale, as piecemeal introduction of the test would lead to considerable medico-legal complications - **DHSC0100004_119**.

25 Some of the results of Dr Entwistle's testing can be seen in **DHSC0100019_298**, which reports that by October 1971 he had found 8 Au antigen positives out of 10,000 donations, with 5 antibody positive, while 40 donors known to have been involved in post-transfusion hepatitis had been tested with two having been found to be antigen positive. By May 1972 he had tested 27,350 donations with 18 being antigen positive and 21 being antibody positive - **DHSC0100020_043**.

26 On 29 November 1972 Dr Darnborough wrote to all pathologists in charge of blood banks to explain that for a while a high proportion of all donations had been tested for Au Antigen and antibody, but that over the past few weeks, all donations had been screened, so from 4 December 1972 it could be said that all donations (save for very fresh blood of fractions issued within 2 to 3 hours) would have been tested and found negative for Au antigen - **DHSC0100020_163**.

27 In January 1982 EARTC changed from using Hepatest to RIA for screening for HBV - **CBLA0001493**. It was not however until August 1982 that EARTC were able to guarantee that all plasma pools sent to BPL would be 100% RIA tested - **CBLA0001598**.

HIV

28 An issue arose in August 1985 when the United States Air Force stated that from 16 August 1985 they only wished to receive blood that had been screened for HTLV-III. Dr Darnborough was advised by the DHSS that rather than refusing to supply blood on this basis prior to the national screening process beginning on 14 October 1985, he should provide the donations screened - **NHBT0004235**.

29 As at 30 August 1985 EARTC was doing its own evaluation of the Wellcome and Organon test kits, and although they had not yet recruited the Senior MLSO and MLSO required to carry out the HTLV-III screening they were confident they would be able to meet the deadline of 14 October 1985 - **NHBT0000186_043**.

30 According to Dr Darnborough, EARTC started screening for HTLV-III on 27 September 1985, so that by 14 October 1985 *'little if any of the blood on the shelves here or in the hospital banks was untested'*. A letter was sent by EARTC to all haematologists in charge of the blood banks in the EARTC area on 14 October 1985 asking them to return any fresh frozen plasma and blood issued before 27 September 1985 - **DHSC0002285_004**.

31 In October 1985 Dr Darnborough informed Dr Smithies that he was acceding to the request of the United Air Force to inform them of any of their donors who tested positive for HTLV-III - **DHSC0002283_052**.

32 In January 1986 Dr Darnborough reported what was thought to be EARTC's first donor with HTLV-III who *'happens to be an RAF serviceman'* - **DHSC0002475_012**. According to Professor Allain's statement, this was the only positive donor identified prior to 1992 (**WITN3599001**).

33 In 1987, due to restricted deep freeze storage space, material that had been untested could not be 'totally' segregated from material to be sent for despatch to BPL and PFC, and occasionally 'material has been sent in error' although this had always been picked up by BPL upon receipt of material - **BPLL0010788**. This may indicate that as late as 1987 there were untested stocks of product at EARTC.

34 **NHBT0006797** is an example of the work done by EARTC in 1988 to identify how a donor who was found to be HIV positive had got through the screening process, and the steps taken to trace all previous donations.

Arrangements for purchase, supply and distribution of NHS and commercial blood products to the region

35 On 3 August 1976 Dr Darnborough expressed alarm at the plans for NHS Factor VIII to be distributed on a supra-regional basis, thus lumping EARTC in with the London centres. He also stated that he would refuse to have anything to do with commercial preparations, and did not consider it appropriate for RTCs to be distributing this material - **CBLA0000410**. Dr Maycock's response is at **CBLA0000417**. By 26 August 1987 Dr Darborough describes himself as having been persuaded by Dr Maycock to organise the purchasing and distribution of the 'dirty' concentrate. Part of the reason for this change of heart was because of the discovery that one of the haematologists in the region was purchasing large quantities of commercial Factor VIII - **CBLA0000431** and **CBLA0000435**.

36 By December 1976 there was agreement as to how cryoprecipitate, NHS and commercial concentrate was to be distributed through the region by EARTC. In a letter to Dr Dormandy he explained the need for the RTCs to *'perform a monitoring function related to achieving present and future targets for NHS 'free' concentrate'* - **CBLA0000508**.

37 In 1978 the amount of Factor VIII used in the region was 84,750 i.u. - **DHSC0103341_194**.

38 In response to a letter dated 10 July 1981 from the DHSS, Dr Darnborough stated that the RTC held all the supply of Factor VIII for the region, and had done so since 1 April 1977. He also stated that the budget for commercial products came out of the BTS budget - **DHSC0002209_037** and **DHSC0002211_012**.

39 There is evidence that Dr Darnborough met with representatives from the pharmaceutical firms selling commercial products – for example **BAYP0000025_071**. From other correspondence it looks as though there was a regional contract for the supply of Factor VIII at least in 1982 and 1983 - **BAYP0000028_034**.

40 On 16 February 1990 Dr Moore wrote to all RTDs suggesting a national contract with BPL for the purchase of plasma and sale of products to RTCs – **NHBT0097053_045**. In response, Dr Darnborough expressed his concern about BPL selling their products directly to the user given the years of experience EARTC had as purchasers and distributers of commercial products - **NHBT0097035_071**.

WEST MIDLANDS REGIONAL TRANSFUSION CENTRE IN BIRMINGHAM

1 The Directors of the West Midlands Regional Transfusion Centre in Birmingham (WMRTC) were Dr Bird from 1967 to 1982 and Dr Ala from 1982 to 1996.

2 As the Inquiry has received both written and oral evidence from Dr Gamal Gabra who took up a post as a consultant at WMRTC in 1992 and was then appointed its deputy director -[**WITN5495001], [INQY1000180**] - this part of the presentation focuses on the evidence the Inquiry has about WMRTC up until 1992.

3 WMRTC was inspected by the Medicines Inspectorate in May 1988. The following information can be gleaned from that report:

a. WMRTC served a population of 5.2 million and 22 District Hospitals.

b. Just under 200,000 donations were collected annually, of which approximately 33% were used to prepare platelets.

c. About 200 staff were employed at the Centre, with another 100 employed as part of the eight donor session teams. The deputy director at this point was Dr R Ibbotson (whose son Nicholas Ibbotson has provided a statement to the Inquiry - **WITN0982001**). There was also another consultant haematologist in place– Dr Koster.

d. There was a permanent donor centre in Birmingham City Centre which had three plasmapheresis machines

NHBT0006270.

4 WMRTC's business plan dated November 1991 sets out the following information:

a. WMRTC was the second largest RTC in the UK, serving a regional population of approximately 5.2 million, approximately 20 District Health Authorities and 50 major hospital blood banks supporting over 200 hospitals.

b. It collected 235,000 blood donations and 15,000 plasma donations per annum.

c. Over 90% of the blood collected was processed into component parts.

d. There were two fixed sites, the blood donor centre in Birmingham City Centre and the Laboratory/Distribution base in Edgbaston.

NHBT0097052_001

5 A medical audit visit of WMRTC was undertaken by (the then) Dr Marcela Contreras and Dr Napier on 15 January 1992. This provides as follows:

a. The West Midlands area had several very active tertiary care facilities as well as approximately 50 main NHS hospitals and 6-7 private hospitals.

b. WMRTC was understaffed with only two consultant posts.

c. A Regional Transfusion Committee met approximately twice a year. The membership included the Regional Scientific Officer, the Regional Medical Officer or his representative, a Consultant from the Regional Virus Reference Laboratory, a Haematologist with haemophilia responsibilities and either a surgeon, an anaesthetist or an obstetrician. WMRTC was represented by the Director.

NHBT0009745

Blood and plasma targets

6 On 4th March 1975 Dr Maycock wrote to the RTDs setting out their provisional targets for sending plasma to BPL for fractionation. The suggestion for WMRTC was that they should divert over 18,000 donations away from cryoprecipitate, and send this instead to BPL- **DHSC0002359_041**.

7 In his response to Dr Maycock, Dr Bird made the point that:

'Haematologists in this Region are strongly against a reduction in cryoprecipitate production, which at present is at an optimal level, because they fear them may not get a fair share of the AHG concentrate.'

DHSC0002359_044. (See also **DHSC0100006_018** in which similar views are expressed).

8 In May 1975 Dr Bird stated as follows regarding the DHSS plans for Anti Haemophilic Globulin Concentrate:

'The DHSS costed this project on the basis that 6,200 additional donations will be required in this region. This is not in fact correct. If we are to maintain full supplies of cryoprecipitate to Regional Hospitals (the demand is escalating rapidly) and also supply raw material for the preparation of anti-haemophilic globulin concentrate during the interim period, we shall need 28,200 additional donations. For this, we shall need a whole blood colleting team..... and processing equipment and laboratory staff in proportion. The interim period is predicted to be six months; I think this is an underestimate.'

DHSC0002177_016

9 In October 1975, Dr Bird wrote to the DHSS about the plasma targets that had been sent for WMRTC confirming what the West Midlands RHA had already said to the DHSS - namely that whether or not WMRTC would meet the targets set for them for provision of plasma to BPL, was dependant on laboratory reconstruction, and so no *'firm predictions'* could be made - **DHSC0006899_024** and **DHSC0002179_030.**

10 By September 1976 WMRTC was collecting 160,000 donations of which 42,000 were separated. Most of the cryoprecipitate made by WMRTC was going to a recognised haemophilia centre. The deputy director, Dr Ibbotson, had two sessions per week treating people with haemophilia - **CBLA0010165_003**.

11 In October 1977, Dr Maycock wrote to Dr Bird stating that the intention for the region was that it would increase its donations for fresh frozen plasma from 26,000 donations (current target) to 40 – 50,000 donations (by the early 1980s) - **BPLL0007842_002**.

12 At a meeting of the West Midlands Regional Health Authority's Working Party on the Treatment of Haemophilia in December 1978 attended by Dr Bird, concern was raised about the fact that although WMRTC was sending 3.7 million units per annum of plasma to the Lister Institute, they were only receiving in return 1.4 million units per annum. This was because other regions had to be subsidised - **CBLA0000882**.

13 In January 1985 Dr Ala wrote to the RHA to warn them of the loss of yield as a result of the fact that Factor VIII was being heat treated. This of course gave rise to a corresponding need to increase plasma collection- **NHBT0046174**.

14 In April 1985 Dr Ala wrote to the DHSS in the following terms regarding the proposed rate of Fresh Frozen Plasma production (FFP):

'It now seems likely that the Regional Health Authority will support the costs of enhanced production, although we have yet to obtain final permission for employing the requisite additional staff.

Assuming that no difficulty is encountered in this connection, we plan to achieve a monthly FFP production level of 2750 Kg. by April 1986, rising to 3500 Kg. per month by April 1987.'

DHSC0002269_011

15 At a meeting of the West Midlands Regional Health Authority Working party on the Treatment of Haemophiliacs in October 1986 it was said that at present WMRTC produced 22.4 tonnes of plasma which should increase to 40 tonnes at the end of 1987.

'This means that if 200 units Factor VIII are produced per litre by Elstree pro rata distribution to West Midlands would be 8 million Factor VIII units, achieving self sufficiency. The committee viewed with disquiet the report by Dr Ala that in view of a budget deficit within the B.T.S.; money for plasma procurement had been vired to cover the overspend, thus curtailing any expansion of the 22.4 tonnes in the foreseeable future. This would culminate in a continuing reliance on commercial Factor VIII which was produced from U.S. plasma with all its inherent drawbacks.'

SHIN0000019.

16 In August 1989 Dr Ala met with Dr Moore of the National Directorate to discuss plasma supply:

a. The target that had been set of 45,000 Kg of recovered and 6,000 Kg of apheresed plasma had assumed that a new apheresis centre in Central Birmingham would be operational early in the year. It would not however be so until December 1989. Thus the 6,000 Kg was revised down to 2,500 Kgs.

b. *'Dr Ala kept insisting that West Midlands would meet their target and it took me some time to realise that he was not talking about the 51,000 Kg target he gave us early in the year, but his new 47,500 tonnes target.'*

c. For 90/91 the target was set at 57.5 tonnes, which included a total of 12.5 tonnes of apheresed plasma.

d. Further into the future a new Coventry centre with 12 apheresis machines was expected to enter into production in 91/92 which could increase productions by a further 12.5 tonnes.

NHBT0003375_001

17 The 1992/1993 recovered plasma target for WMRTC was 51 Kg, up from 47 Kg from the previous year (although see **NHBT0016104** which suggests that in 91/92 the plan was to provide 45.7 t of recovered plasma and 6.1 t from apheresis). The apheresis target was 5.8 tonnes, giving an overall target of 56.8 t - **NHBT0003249**.

Use of blood

18 It is clear from correspondence from 1971 (**DHSC0100028_094 and DHSC0100028_095**) and 1972, that the use of blood in different hospitals was being monitored by WMRTC – see for example **DHSC0100028_107 and DHSC0100028_108.**

19 Work done by Dr Bird on trying to increase the use of red cell concentrates in the area can be seen in the minutes of the meeting of the West Midlands Regional Health Authority's Working Party on the Treatment of Haemophilia on 18 December 1978 - **CBLA0000940**.

20 In 1985, Dr Ala wrote in the following terms to the Administrators at 9 local hospitals:

'The level of unused blood returned from your hospital has been very high. Clearly, your surgeons and anaesthetists are over-ordering. This is a wasteful practice and causes unnecessary work for your own laboratory staff and needles sequestration of blood units for cases that are unlikely to require blood transfusion.

I would strongly recommend the introduction of a "Maximum Surgical Blood Ordering Schedule".....

I would also suggest that you endeavour to pass on unused blood which is in-date to your local NHS District General Hospital..... the larger ones will be well able to ensure that the blood is not wasted..... in future, a handling charge will be instituted for returns, even when they are still in-date.'

DHSC0041318_118. One of the responses to this letter is at **DHSC0041318_119** and sets out the percentage of issued blood being returned to WMRTC unused, from a number of hospitals, which ranges from 45% to 76%.

21 On 31 July 1989, Dr Ala wrote to Dr Gunson in the following terms:

'I do not think I am alone amongst RTDs in finding that Frozen Fresh Plasma is overused and misused in District Hospitals.

There are a variety of reasons for suggesting that the genuine indications for FFP should be limited

i) It is wasteful –.....

iv) It can transmit HCV; HBV; HIV-1 and HIV -2.

Extrapolating from our own estimates in the West Midlands it is likely that between 20 and 30 tonnes of FFP in England and Wales could be diverted from the clinical sector to plasma fractionation. This would naturally require an effort ie persuasion of anaesthetists and surgeons that the ritual adherence to "formula" prophylaxis when stored blood is used at operation is inappropriate etc, etc. Yet it would probably be worthwhile if we are collectively failing to meet our plasma targets'.

NHBT0001606

22 In June 1990, Dr Ala wrote to the RHA asking them for comments on the paper he had drafted setting out the objectives for a Hospital Blood Transfusion Committee. One of the reasons for his renewed call to set these up in the region (having first raised it in 1983) was the need for 'more appropriate blood product utilisation' - **NHBT0016083_002**.

23 In a medical audit visit of WMRTC undertaken by (the then) Dr Marcela Contreras and Dr Napier on 15 January 1992 it was noted that '*the Director and medical staff at the Centre are recognised to have made notable contributions towards the advancement of*

transfusion medicine and this can be expected to continue when the third Consultant takes office during 1992'. WMRTC was the first to promote the concept of the Hospital Transfusion Committee through Dr Ala. Three such committees dated from 1983. More recently the total had increased to 8 out of a possible 25. These committees met between monthly and three monthly intervals.

NHBT0009745

Arrangements for the obtaining, supply and use of blood products and blood components in the region

24 A list of the hospitals to whom WMRTC issued cryoprecipitate in 1973 is set out at **DHSC0100026_062**.

25 At a meeting of Haemophilia Centre Directors, Regional Transfusion Directors and Regional Scientific advisors from the Supra regional Territory on 26th July 1976 attended by Dr Bird, it was agreed that unless there were 'overriding reasons' NHS concentrates should be distributed via RTCs - **CBLA0000391.**

26 There is evidence in 1980 of WMRTC being asked for Factor VIII by local clinicians to cover operations to be performed on a patient with haemophilia. WMRTC in turn requested extra product from BPL. BPL provided less than the amount asked for out of their stock, and set it against further monthly issues of product due to be sent to WMRTC - **BPLL0002097**.

27 In January 1981, Dr Bird was asked by S Godfrey (DHSS) to set out what the arrangements for the purchasing, supply and distribution of factor products were in the region - **DHSC0002203_017**. In his reply Dr Bird stated as follows:

'I confirm that this Centre holds regional stocks of commercial factor VIII concentrate purchased by the RHA on the basis of calculated regional requirements less what is expected from the BPL.

..... The Transfusion Service arranges the direct purchase of commercial factor VIII in consultation with the RHA and its Treasurer.'

28 In 1985, when heat treated Factor VIII was being supplied on a named patient basis, WMRTC were provided with the names of patients that the Haemophilia Directors wanted to treated with such product, this was presumably because WMRTC was obtaining the product from BPL - **BPLL0002375_004**.

29 There is evidence that Dr Ala met with representatives from pharmaceutical companies such as Cutter - **BAYP0000010_151**.

Relationship with PFC

30 In 1980, WMRTC explored the idea of PFC fractionating some of its plasma - **SCGV0000001_091** and **BPLL0004348**. This was not progressed.

High Risk Donors

31 From May 1983 WMRTC was giving out leaflets to donors asking certain groups not to donate because of the risk of passing on AIDS - page two of **NHBT0046177**. The leaflet says this about AIDS:

Can it be transmitted by Blood Transfusion?

It appears it can. .....

We want to ask people who may be at risk from the disease to avoid giving blood until we have a suitable screening test. ……..

.... we would ask the following groups to refrain from donating blood:

1) Homosexual men.
2) Women who continually have multiple sexual partners.
3) Partners of bisexual men.
4) Anyone who abuses drugs.
5) Anyone who has been in contact with a case of AIDS.

32 WMRTC was said to be the first RTC in England to issue such a warning - **DHSC0002231_010** and **NHBT0020751,** this being more than three months before the National AIDS leaflet was published by the DHSS - **BPLL0007247.** In June 1983, Dr Ala told Dr Wagstaff that this leaflet was '*prominently displayed at sessions but was not pressed upon every donor'* - **NHBT0039762_041**.

33 Dr Ala took also part in two or three radio shows early on, to deter high risk donors - **NHBT0020751**.

34 In April 1984, WMRTC informed the DHSS that in the first six months of its use of the National AIDS leaflet:

a. It had a current stock of 51,000.

b. 99,000 leaflets had been issued or taken with a rate of useage per month of 16,500.

c. The leaflets were handed to donors at collection sessions, and there had been no effect on donor attendance.

d. In terms of feedback from donors, it was said to be very little '*some donors have withdrawn of their own accord'*.

DHSC0002241_005.

35 On 27 September 1985, Dr Ala wrote to all MLSOs at WMRTC stating that if, once HTLV-III screening started, they were approached by members of high risk groups who wanted to know their HTLV-III status, they were to refer the potential donor to ward 19 at Birmingham General Hospital '*where confidentiality is strictly maintained and they have experience of sexually transmitted disease.*' For those potential donors who were not in a high risk group but wanted to be tested in any event, they should be referred to their GP for testing as it was thought not be appropriate for them to be referred to a G.U.M. clinic - **NHBT0046152**.

<u>Screening for blood borne viruses</u>

HBV

36 In May 1974 Dr Bird agreed to take part in the Haemagglutination Test for Detection of HB AG. The plan was to screen 3,200 donations per week - **CBLA0008423_001.**

37 Donors who tested positive for HBV were informed by letter, and asked for permission for their GP to be informed of their diagnosis - **NHBT0044926**. Counselling of HBV positive donors was then handled '*by a letter to General Practitioners'* - **NHBT0009745** and **NHBT0044878**.

38 In 1987, 199,651 donors were bled. Of those 11 were confirmed as HBsAg positive, of whom 8 were first time donors. The test used was the Wellcozyme ELISA - **NHBT0080252**.

39 In December 1989 WMRTC carried out a small Anti HBc Trial in which they performed 4921 tests, 17 of which were initially reactive. Of those 14 were repeatedly reactive - **NHBT0000188_145**.

HTLV-III

40 In May 1985 Dr Ala set out the cost of HTLV-III testing to the RHA, explaining that all seropositive tests would be retested twice more with the same test. Those donations that were positive in two out of three of those tests would be rejected, and subject to immunofluorescence confirmatory testing, with the residual positives being sent to Dr Flewett for testing by Western Blot - **NHBT0046167**.

41 In July 1985 WMRTC tried the Abbott, Organon and Wellcome test kits. They planned to evaluate the Pateur kit in September. They took on additional staff and equipment to facilitate the screening programme. Dr Ala undertook the counselling training at St Mary's Hospital in London. Professor Geddes at the East Birmingham Hospital was identified as the Infectious Disease specialist to whom infected donors would be referred. Community testing was set up in the General Hospital in Birmingham and the Regional Virology Reference Laboratory was the site for confirmatory tests- **DHSC0002277_016**.

42 By 1 August 1985, WMRTC had tested roughly one quarter of their total blood intake for HTLV-III. This was to be built up in September so that by 1 October they were hoping to be in a position to be able to screen all donations - **DHSC0002277_016**. In fact by the 14 October 1985 *'virtually all stocks of products at B.T.S. and peripheral hospitals had already been tested.'* - **DHSC0002285_015.**

43 By 29 October 1985, WMRTC had tested over 24,000 donations without finding a positive case. This led Dr Ala to tell Dr Smithies at DHSS that he thought that:

'the public and Parliamentary concern is exaggerated and misplaced. Much greater funds and concern should be invested in the more difficult area of influencing attitudes and behaviour rather than allowing them to be dissipated and assuaged in the area of blood transfusion.'

DHSC0002285_015.

44 By the end of 1986, WMRTC had found three HIV positive donors. The first, Dr Ala suspected, had donated to find out his HIV status, the second was a woman who was *'genuinely unaware of any risk factor'* despite having been infected by a bisexual drug-addict, and the third was a married man, who had just had his first homosexual relationship - **NHBT0004469**.

45 By February 1991, WMRTC had come across seven HIV positive donors- **NHBT0019460**. Infected donors were reported to the National Directorate in Manchester - **NHBT0019464**.

46 For those donors who informed WMRTC that they were self-excluding because they were in a high risk group, Dr Ala appears to have written to them to check the veracity of this statement because it was the practice of WMRTC to go back and test their previous donations in order to carry out look backs - **NHBT0045736**.

47 Counselling was delivered by WMRTC consultant staff. It was delivered after the donor had been sent a '*non-committal request for interview'* - **NHBT0009745**.

Hepatitis C

48 In a letter to a consultant haematologist at a local hospital, Dr Ala said as follows about this trial:

'We have carried out a limited trial of the prevalence of anti-HCV amongst 5,000 blood donors in the West Midlands, using the new ELISA test based upon the Chiron Corp. Recombinant Antigen. We have 14 repeatable positives (an incidence of 0.28%), and these are mostly established, middle-aged blood donor with a roughly equal sex ratio. There is no confirmatory test available as yet; a positive anti-HCV status correlates imperfectly with surrogate tests such as ALT and anti-HGC, and it is not certain that sero-positivity necessarily implies infectivity.'

Dr Ala went on to provide the details of the blood products received by that hospital from the sero-positive donors identified in the study, and asked for the names and GP details of the recipients of those products to enable Dr Aala to obtain their blood samples to carry out anti-HCV (ALT and anti-HBc testing).

NHBT0201473

49 In February 1990 Dr Ala wrote to a local GP in the following terms:

'I have recently carried out a limited trial of the new anti-Hepatitis C Test.... On some 5,000 blood donors. It is unlikely that the screening test will be adopted as part of our routine work until June or July of this year. .....

Your patient has received a transfusion derived from one of our seropositive donors, and I am very anxious to determine whether or not seroconversion for anti-HCV and supportive evidence of overt or subclinical post-transfusion hepatitis has occurred.'

NHBT0046049. See also **NHBT0045150_001** in which a different GP was advised to refer the patient to the Queen Elizabeth Hospital hepatology department for counselling and treatment.

50 On 24 January 1991 Dr Ala wrote to Dr Gunson stating that WMRTC could start routine screening of blood for HCV by April 1991, however, despite the fact that development funds granted to RHAs had been devolved to Districts, he did not think that the Districts '*will collectively be able to provide us with the 0.6 million pounds required to finance this exercise'*. **NHBT0000073_032**.

51 On 15 February 1991 Dr Ala in his role as Chairman of the Western Division of RTDs, wrote to all the RTDs in the Western Division about HCV testing in the following terms:

'In our particular case, the full year cost of anti-HCV testing with be £728,620. As a percentage of our total BTS base income, that represents 10.5%! Our Region is quite adamant that they will not support this screening test, and that Districts have been given control of all development monies.'

52 Dr Ala wrote to Dr Lloyd of the Northern RTC when Dr Lloyd decided to start screening for HCV before the National date on 8 May 1991 as follows:

'I am afraid your decision to commence testing before everyone else has come at a very inopportune moment, for it will seriously undermine the whole concept of establishing a National Service precisely at the time when this proposal is being submitted for reconsideration by the Department of Health……

Your view that to defer screening is "indefensible" in the light of product liability legislation cannot be taken seriously, nor is there any evidence of HCV prevalence sufficient to justify your precipitate decision on epidemiological and scientific grounds.'

NHBT0000074_020. Dr Lloyd's response is at **NHBT0000192_043**.

53 WMRTC used the Ortho ELISA test, with repeat reactives being retested by the Wellcome test, and then the RIBA-2. PCR testing was only carried out on RIBA indeterminates - **NHBT0000077_082**.

54 RIBA-2 positives and highly suggestive RIBA-2 indeterminates were called in for counselling at WMRTC by Dr Ala and then referred to a hepatologist at the Queen Elizabeth Hospital in Birmingham who carried out anti-HBc and ALT testing - **NHBT0000077_082.**

55 The RHA in the West Midlands did *'after some gnashing of teeth'* provide support for the first seven months of anti-HCV screening and supplementary testing. However, from April 1992, the users were expected to *'defray the estimated £800,000 annual costs'* - **NHBT0000193_083**.

56 In 1993, 100 of 34,012 new donors reacted to the ELISA test and there were 26 new donors with confirmed HCV antibody. In the same year, 100 of 107,812 established donors previously negative by the HCV ELISA screening test reacted by ELISA. In 1994, 63 of 31,150 new donors reacted to the ELISA test with 18 new donors confirmed with HCV antibody. In the same year, 88 of the 118,220 established donors reacted to ELISA - **NHBT0007769**.

57 Counselling was delivered by WMRTC consultant staff. It was set up following a letter with a *'non-committal request for interview'* - **NHBT0009745**.

Look back and product recall

58 In an undated (but likely to have been sent in mid 1987) Dear Doctor letter from Dr Ala, he said as follows:

'Within the Transfusion Service we feel that we have an obligation to trace all patients who have received blood that might have infected them with HIV. They belong to a 'high risk group' as yet largely unidentified. They need counselling and help in common with other high risk groups. ..... The NBTS cannot know of those infected donors who gave blood before screening was introduced, but who have not donated again, perhaps as a result of the publicity the subject was given. We would like to identify as many of these people as possible and, consequently the patients they may have infected. In order to do this, we are making a co-ordinated effort throughout the country and this letter is going to all appropriate specialists to ask for their help.

.....

Would it be possible:

- *To ask patients under your care you know to be HIV-antibody positive if they have given blood since 1979.*
- *If so, where and approximately when.'*

NHBT0129525, NHBT0129526

59 There is evidence that WMRTC (or at least the centre in Birmingham which was now part of the NBA) took part in the national HCV look back - **NHBT0038696**.

60 There is evidence of WMRTC sharing information with BPL about infected donors **-DHSC0001485.** There is also evidence of WMRTC informing BPL about incidents with their products, and BPL asking WMRTC to recall any unused product, and ask Haemophilia Directors to give the names of the patients treated with the recalled product, to Dr Craske '*in order that agreed follow-up may take place*' - **HCDO0000256_018** and **HCDO0000256_016**.

Other

61 There is evidence of other RTCs sharing information with WMRTC about HIV infected donors to ensure they did not donate elsewhere - **NHBT0045061**.

62 There is evidence of clinicians providing information to WMRTC about their patients who had been diagnosed with NANB, and had had transfusions, providing details of the transfusions so that investigations could be instigated by WMRTC - **NHBT0044356_003**.

63 There is evidence of WMRTC sharing information about infected donors with hospitals that had received previous donations from that donor - **NHBT0045967_002.**

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December 2022