

Tuesday, 9 November 2021

(10.00 am)

**SIR BRIAN LANGSTAFF:** Yes, Ms Scott.

**MS SCOTT:** Today is the start of the blood services hearings and this morning I'm going to be giving a presentation about the structure and history of the blood services in England, Wales, Northern Ireland and Scotland and then this afternoon we're going to hear from Ms Fraser Butlin who is going to give a presentation on early look-back.

We will be having presentations for the remainder of this week. Ms Richards will be starting a presentation on Professor Cash tomorrow and we will finish the week with a presentation on Dr Gunson, and next week we will have some oral witnesses.

**Presentation by Counsel to the Inquiry on the Structure and History of the Blood Services**

**MS SCOTT:** I'm going to start this presentation looking at the case, looking at the history and structure of the English blood services but much of what I say in this part of the talk applies also to Wales and that will become clear, I hope, as I go through this part of the presentation. Then I will give a separate part of the presentation on specifically Welsh parts, the Welsh history and structure.

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that there was proper procedures for taking of the blood, the equipment was clean, and so on -- and for the psychological effects of giving blood to a sick person in hospital. So, for example, the regulations suggested or stated that the donor shouldn't be taken to a ward full of sick patients in order to give blood.

Moving on, then, to the outset of the Second World War, Dr Janet Vaughan, who was a haematologist at the Hammersmith Hospital in London, drawing on experiences in the Spanish Civil War, advanced a plan to supply blood for transfusion to civilians in London. This involved the creation of blood depots and in 1939 the Ministry of Health approved the establishment of four blood depots to treat London civilians. These blood depots were managed by the Medical Research Council on behalf of the Ministry of Health. So this is the first involvement of Government in blood services.

It's also the beginning of blood banking on a large scale, which was possible because of the use of sodium citrate solution, which is an anticoagulant that allowed blood to be stored outside the body without clotting.

In 1940, in response to a lack of provision

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So the early days of blood transfusion, I'm going to start in 1921 with a gentleman called Percy Lane Oliver who established a civilian voluntary blood donation panel and by 1926 the Red Cross Society had become fully responsible for that service.

The panel arranged blood donors to a number of London hospitals to meet emergencies requiring blood transfusion and all the donations on that panel were voluntary and unpaid. There were other panels operating outside London on a similar basis but the information that the Inquiry has seen relates that there was more information in relation to the London panel and so, primarily, that's what I'm going to speak about.

Transfusions at this stage were person to person so, in other words, the donor was called up by the panel, having been notified by the clinician in hospital that they required blood, and they went off to the hospital and stood by the patient and the blood went from one to the other.

So this -- as a result of some bad experiences that some of the donors had, Mr Oliver drew up some regulations to protect the donor and these regulations address both the physical process of blood donation -- so, for example, to safeguard the donor to make sure

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outside London, regional blood depots were established throughout the country and they were established close to large district hospitals in major cities. These depots were set up in Newcastle, Leeds, Nottingham, Cambridge, Birmingham, Oxford, Manchester, Liverpool, Cardiff and, later, Belfast. So initially there were nine and then with Belfast there were ten.

These depots, along with some others, and we'll come on to in due course later, became known as Regional Transfusion Centres. These Regional Transfusion Centres outside London were managed by the emergency medical service, as opposed to the Medical Research Council who was managing the depots in London.

In 1943, it was agreed between the managers of the London depots, the Ministry of Health and the Medical Research Council that the blood supply had reached such a scale that national management was required and in 1946, September 1946, the National Blood Transfusion Service for England and Wales was created by the Ministry of Health.

That encompassed the London depots, the four depots were reduced to two. The Regional Transfusion Centres, by now there were 12 of those and they were joined in 1955 by Brentwood and in 1969 by Wessex,

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1 which was based in Southampton, making 14, and that's  
2 the number we usually see referred to in  
3 documentation.

4 The Regional Transfusion Centres, sometimes  
5 referred to as RTCs, were managed and run by Regional  
6 Transfusion Officers who then became known as Regional  
7 Transfusion Directors. They were medically qualified.  
8 These Regional Transfusion Directors -- I'm going to  
9 refer to them as that throughout this presentation --  
10 the Regional Transfusion Directors met regularly with  
11 the Ministry of Health who was responsible for  
12 managing the service.

13 The meetings were chaired by Dr William Maycock  
14 who later became Sir William Maycock, who had been  
15 appointed as Consultant Adviser on Blood Transfusion  
16 to the Chief Medical Officer of the Ministry of  
17 Health.

18 The purpose of the Regional Transfusion Director  
19 meetings was to advise the Consultant Adviser,  
20 Dr Maycock, so that he in turn could advise the  
21 Ministry of Health.

22 The next event is the creation of the National  
23 Health Service in 1948 and that led to the formation  
24 of 12 regional hospital boards in England and Wales  
25 and they became responsible for administering

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1 hospitals and specialist services in their areas, and  
2 the management of Regional Transfusion Centres was  
3 transferred from the Ministry of Health to the  
4 Regional Health Boards. So there is a period between  
5 1946 and 1948 where there is management by Central  
6 Government of the Blood Transfusion Service in England  
7 and Wales but by 1948 that has been devolved out to  
8 the regions to the regional hospital boards.

9 By 1953 the UK had more than 500,000 donors on  
10 its national panel and, in addition to this, it's  
11 important to remember that many hospitals had their  
12 own donor panels, and that remains the case during the  
13 1970s and 1980s in the period that the Inquiry is  
14 primarily concerned with. That will be something  
15 that -- an issue that will come up in the hearings  
16 that are in the next weeks and months.

17 **SIR BRIAN LANGSTAFF:** Can you help, was there a national  
18 panel as such and, if so, how did that fit with the  
19 system whereby the Regional Health Boards administered  
20 specialist services in each of the regions separately?

21 **MS SCOTT:** My understanding is that there was no national  
22 panel, as such.

23 **SIR BRIAN LANGSTAFF:** There was no national panel.

24 **MS SCOTT:** So each of the Regional Transfusion Centres had  
25 their own panels.

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1 **SIR BRIAN LANGSTAFF:** So when you said a moment or two ago  
2 that there were 500,000 people on the national panel  
3 what you meant was if you added together all the  
4 regions --

5 **MS SCOTT:** Indeed.

6 **SIR BRIAN LANGSTAFF:** -- and the nation we are talking  
7 about is England --

8 **MS SCOTT:** England and Wales.

9 **SIR BRIAN LANGSTAFF:** -- and Wales, so two nations?

10 **MS SCOTT:** Yes.

11 Regional Transfusion Centres were responsible  
12 for a range of services, including and most obviously,  
13 the collection of blood from voluntary donors, the  
14 processing of that blood and the testing of blood  
15 donations, the supply of blood to hospitals within  
16 their area and, on some occasions, they also supplied  
17 blood to other hospitals and bodies outside their  
18 area, and the supply of some blood products to  
19 hospitals in their area (so, for example,  
20 cryoprecipitate).

21 **SIR BRIAN LANGSTAFF:** Cryoprecipitate you would define,  
22 for purposes of this presentation, as a blood product?

23 **MS SCOTT:** Yes.

24 **SIR BRIAN LANGSTAFF:** Even though, in a sense, it is just  
25 part of blood, nothing has been done to it except

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1 getting rid of what else isn't cryoprecipitate?

2 **MS SCOTT:** Yes. I do define it as a blood product in this  
3 presentation, sir, yes.

4 **SIR BRIAN LANGSTAFF:** So when we talk about blood, we're  
5 not talking about cryoprecipitate, we're talking about  
6 red blood or --

7 **MS SCOTT:** Exactly.

8 **SIR BRIAN LANGSTAFF:** Where does plasma fit?

9 **MS SCOTT:** Yes, and red cell concentrate. There is  
10 a continuum between what sometimes is referred to as  
11 whole blood and getting on for blood products but  
12 I was differentiating -- in the early days the  
13 Regional Transfusion Centres were really only  
14 providing, pretty much, whole blood and then, as we go  
15 through the history, the product, if you like, from  
16 the Regional Transfusion Centre changes.

17 There are procedures that are carried out to the  
18 whole blood to turn them into what I am referring to  
19 as products, although, as you say, it is simply  
20 removing plasma, for example, to concentrate red cells  
21 or making cryoprecipitate or products of that nature.

22 **SIR BRIAN LANGSTAFF:** Thank you.

23 **MS SCOTT:** The Regional Transfusion Director -- I think  
24 I have already mentioned this -- was medically  
25 qualified and, importantly, was appointed by and

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1 accountable to the Regional Health Board. Each  
2 Regional Transfusion Centre was autonomous and this  
3 led to a divergence in practice between them, and  
4 that's a theme that we will develop as we go through  
5 the presentation.

6 In 1949, Dr Maycock was appointed the  
7 Superintendent of the Lister Institute Laboratories at  
8 BPL and, in 1954, BPL was established at Elstree,  
9 although its history goes back to 1943. Plasma  
10 supplied by the Regional Transfusion Centres was  
11 fractionated at BPL to produce blood products as the  
12 Regional Transfusion Centres did not have their own  
13 fractionation facilities. So they were able to make  
14 some blood products or some products, like  
15 cryoprecipitate, red cell concentrates, but they  
16 weren't able to fractionate blood into blood products  
17 such as Factor VIII, Factor IX, and so on, and so they  
18 provided plasma to BPL.

19 I'm going to move on now then to 1970, where  
20 there were efforts to restructure the NHS generally  
21 and, of course, the Blood Transfusion Service was  
22 affected by those proposed changes. Can we go,  
23 Soumik, please to NHBT0017065. This is a minute of  
24 a special meeting held on 16 April 1970 at the  
25 Regional Transfusion Centre in Cambridge of Regional

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1 Transfusion Directors, to discuss the Green Paper on  
2 the future structure of the National Health Service.

3 We can see the attendees. We have Dr Maycock,  
4 who is the chair. We've got attendees from the  
5 Department of Health and Social Security, we've got  
6 all of the Regional Transfusion Directors and we've  
7 got an attendee from the Blood Group Reference  
8 Laboratory.

9 We can see on that first page:  
10 "Green Paper on the Future Structure of the  
11 National Health Service.

12 "The Chairman recalled that, following  
13 an informal discussion of the Green Paper with a few  
14 Directors, he had written to all directors on 6 March,  
15 setting out what seemed to be the alternative ways of  
16 administering and organising NBTS and that at RTD  
17 meeting [Regional Transfusion Directors meeting]  
18 11 March it had been decided to hold a special meeting  
19 to discuss the Green Paper."

20 If we could turn over the page to the bottom of  
21 the second page, what the Regional Transfusion  
22 Directors then do is set out the potential  
23 organisational -- the potential options for  
24 organisational change for the Blood Transfusion  
25 Service. They consider regional health councils and

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1 they then consider area health boards and central  
2 administrations.

3 I'm just going to read from those two parts of  
4 the minute:

5 "Area health boards.

6 "Likewise the meeting agreed unanimously that  
7 administration of a regional transfusion centre by an  
8 Area Health Board was unlikely to be satisfactory.  
9 There would inevitably be difficulties, particularly  
10 financial difficulties, if a regional centre were  
11 administered by an Area Health Board because the  
12 latter was designed to provide services to its own  
13 area and not to a group of Area Health Boards. The  
14 Area Health Board concerned would have to adopt  
15 a regional outlook, with regard to the regional  
16 transfusion centre and it was to be expected that,  
17 while some Boards would succeed in doing this, others  
18 would not. The position of a transfusion director in  
19 such an administrative scheme would be difficult."

20 **SIR BRIAN LANGSTAFF:** Implicit in this is that the term  
21 "area" is describing a smaller area of land than  
22 a region.

23 **MS SCOTT:** Yes, I think that must be right.

24 **SIR BRIAN LANGSTAFF:** Otherwise this wouldn't make sense.

25 **MS SCOTT:** Yes.

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1 **SIR BRIAN LANGSTAFF:** So area health boards, and there  
2 might be a number in a region and, indeed, their  
3 boundaries might not be exactly with -- coincident  
4 with what had been the region.

5 **MS SCOTT:** Indeed.

6 **SIR BRIAN LANGSTAFF:** So you'd end up with a system of  
7 Regional Transfusion Centres to serve a region getting  
8 its money from a number of different area health  
9 boards within the region.

10 **MS SCOTT:** Yes.

11 **SIR BRIAN LANGSTAFF:** Yes, I see.

12 **MS SCOTT:** Then they go on to discuss central  
13 administration:

14 "The meeting agreed unanimously that  
15 the opportunity presented by the proposed  
16 reorganisation of NHS could be seized to reintroduce  
17 a National Blood Transfusion Service in the true sense  
18 of that name and unanimously proposed that the  
19 Regional Transfusion Centres should be centrally  
20 administered and financed. Since the administration  
21 of the service had been decentralised in 1948, it had  
22 become clear that development of the regional centres  
23 had been uneven and that many difficulties had arisen  
24 from the fact that administration and financing of the  
25 service were the responsibility of 13 different

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(3) Pages 9 - 12



1 authorities.  
 2 "A centrally administered and financed service  
 3 could be planned nationally" --  
 4 **SIR BRIAN LANGSTAFF:** So at this stage there were just  
 5 the 13.  
 6 **MS SCOTT:** 13, yes.  
 7 **SIR BRIAN LANGSTAFF:** Wessex came later, did it?  
 8 **MS SCOTT:** I think that's right, yes:  
 9 "A centrally administered and financed service  
 10 could be planned nationally in an effective manner and  
 11 run more efficiently than a service with decentralised  
 12 administration and financing. For example it would be  
 13 simpler to provide for the performance of certain  
 14 functions which need to be done in only one or a few  
 15 centres ..."  
 16 And then a number of different examples are  
 17 given of those functions.  
 18 The meeting then goes on to discuss what the  
 19 centralised service might look like. If we could just  
 20 go down the page then to 5, "Advisory committees",  
 21 there's another unanimous agreement at the meeting  
 22 that:  
 23 "... whatever the form of administration finally  
 24 adopted, the Regional Transfusion Directors' Meeting  
 25 should be retained. It was suggested that

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1 volume -- whatever the right word is -- smaller, the  
 2 regions remain for the purposes of blood transfusion.  
 3 **MS SCOTT:** Yes, and equally, looking at it from the other  
 4 way, if it's to go to a centralised administration, so  
 5 to be centrally administered and financed, the  
 6 proposal then is, even in those circumstances, the  
 7 Regional Transfusion Director meetings would still  
 8 remain. They must have been thinking, well, even with  
 9 a centrally financed and administered service, you  
 10 would still need transfusion centres in the region  
 11 responding to local demand and so you would require  
 12 meetings of the Regional Transfusion Directors.  
 13 **SIR BRIAN LANGSTAFF:** Yes. So either it was going to stay  
 14 as it was or it's going to go big.  
 15 **MS SCOTT:** Yes.  
 16 The Department of Health and Social Services  
 17 rejected -- sorry, Social Security rejected the  
 18 proposals of the Regional Transfusion Directors, and  
 19 we can see that at NHBT0016117.  
 20 This is another Regional Transfusion Directors  
 21 meeting on 25 October 1972, so two and a half years  
 22 later, and we can see again similar  
 23 attendees: Dr Maycock in the chair, Regional  
 24 Transfusion Directors, we've got an attendee from the  
 25 Scottish Home and Health Department and from the

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1 consideration should be given to making this  
 2 a statutory committee."  
 3 You can take that down, Soumik.  
 4 So that was the unanimous agreement of the  
 5 Regional Transfusion Directors and, it seems, from the  
 6 minute of that meeting, the other attendees, so from  
 7 the Department of Health and Social Security, that  
 8 there should be central administration of blood  
 9 services.  
 10 **SIR BRIAN LANGSTAFF:** Just looking at that last  
 11 recommendation for a moment, the supposition is that  
 12 although the Blood Transfusion Service had been  
 13 organised on a regional basis -- sorry, could we have  
 14 it back up, Soumik?  
 15 **MS SCOTT:** It's page 5 if you go down.  
 16 **SIR BRIAN LANGSTAFF:** If you are going to retain the  
 17 regional transfusion directors' meeting, if it makes  
 18 any sense, there still has to be a job for Regional  
 19 Transfusion Directors to do, which means the regions  
 20 must still exist as such so far as the Blood Service  
 21 is concerned.  
 22 **MS SCOTT:** Yes.  
 23 **SIR BRIAN LANGSTAFF:** So although the rest of the Health  
 24 Service was moving away from regions into areas,  
 25 perhaps smaller groups, smaller areas, smaller

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1 Scottish National Blood Transfusion Association, we've  
 2 got an attendee from the Northern Ireland Blood  
 3 Transfusion Service, and we've got attendees from the  
 4 Department of Health and Social Security.  
 5 If we can turn to page 4, please, of that minute  
 6 we can see, under paragraph 3:  
 7 "The NBTS in the revised National Health Service  
 8 "The Chairman referred to the report,  
 9 Organisation of National Blood Transfusion Service,  
 10 prepared by a Working Group and approved unanimously  
 11 by the RTD meeting, which had been given to the [Chief  
 12 Medical Officer] on 1 September 1971. Subsequently  
 13 two meetings had been held in the Department [that's  
 14 the Department of Health and Social Security].  
 15 Mr Gidden [from the Department of Health and Social  
 16 Security, we can see from the attendee list] had come  
 17 to inform the meeting of the present position.  
 18 "Mr Gidden said that as Directors knew, the  
 19 Government's White Paper on NHS reorganisation left  
 20 the responsibility for the provision of a blood  
 21 transfusion service with the Regional Health  
 22 Authority."  
 23 So, just pausing there, we've moved from  
 24 Regional Hospital Boards to Regional Health  
 25 Authorities.

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(4) Pages 13 - 16



1 "In general it had been decided that the  
2 functions of the RHAs, although extended to include  
3 present local health authority functions, should  
4 remain the same as those of Regional Hospital Boards  
5 now. Nevertheless, the Department recognised that  
6 the BTS [Blood Transfusion Service], although a vital  
7 component of the hospital service, was unlike any  
8 other component, and that a degree of central  
9 co-ordination in its operation was highly desirable if  
10 not essential. This existed in an important measure  
11 already through the meetings of the RTDs, which,  
12 however, had an informal and not a formal basis.  
13 "In the reorganisation of the Health Service it  
14 was envisaged that a much more thorough going planning  
15 procedure would be adopted, which would allow the  
16 Department to monitor the plans of health authorities  
17 on a continuing basis. This should help to ensure  
18 that important requirements of the BTS were not  
19 neglected. This was a deliberately new feature of the  
20 administrative arrangements, and the staff of the  
21 Department is to be very substantially increased to  
22 deal with individual regions."  
23 So that's the case put forward by the Department  
24 of Health and Social Security as to why there isn't  
25 a centralised service.

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1 disregarded regionally. Was the Department in future  
2 likely to try to ensure that all RHAs carried out  
3 centrally accepted advice?"  
4 Sir, pausing there that's a theme that we see  
5 repeated again and again over the years that arises  
6 with this regional structure:  
7 "Mr Gidden pointed out that the Department alone  
8 could decide what weight should be given to advice  
9 tendered by the RTD meeting."  
10 Sir, you may wonder whether that is an answer to  
11 the rather tricky question posed there by the Regional  
12 Transfusion Directors.  
13 "b. Implementation of policy by RHAs. Mr Gidden  
14 explained that the proposed planning cycle described  
15 in 'Management Arrangements for the Reorganised NHS'  
16 would enable the Department to exercise much closer  
17 scrutiny of the work of RHAs. For example, it was  
18 unlikely that failure by an RHA to provide for capital  
19 developments in an RTC would go unnoticed."  
20 Again, sir, it's not clear precisely what that  
21 means but that is something that we will be  
22 considering as we go through the hearings.  
23 **SIR BRIAN LANGSTAFF:** On the face of it there may be  
24 a difference between the idea that the regions have  
25 control of their regions and the idea that

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1 If we go over to the next page, we can see the  
2 reaction to that from the Regional Transfusion  
3 Directors:  
4 "The meeting expressed the greatest  
5 disappointment at the Department's rejection of its  
6 proposals for a centrally controlled service and  
7 criticised the delay of more than a year between the  
8 presentation of the proposals and this meeting. In  
9 the discussion the following points were raised:  
10 "a. Regional Transfusion Directors (i) Would  
11 this become a statutory advisory committee? Mr Gidden  
12 said that it would not; the only statutory committees  
13 were those of the Central Health Services Council; it  
14 would not be possible to form such a committee which  
15 could replace the RTD meeting."  
16 So that's no to the other unanimous agreement  
17 from that minute we looked at in 1970.  
18 "(ii) The RTD meeting was the only body that  
19 could give informed professional and technical advice  
20 to the Secretary of State about the running of NBTS.  
21 Did the Department propose to take measures to ensure  
22 that the advice given by the RTD meeting and accepted  
23 by the Department was applied uniformly and  
24 effectively in the regions? Hitherto advice, although  
25 apparently accepted by the Department might be

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1 the Government has control of the regions.  
2 **MS SCOTT:** Yes.  
3 **SIR BRIAN LANGSTAFF:** It's difficult to see how both can  
4 co-exist easily.  
5 **MS SCOTT:** Indeed.  
6 Soumik, you can take that down.  
7 So the plan as of 1974 is the management of  
8 Regional Transfusion Centres moves from Regional  
9 Hospital Boards to Regional Health Authorities but  
10 with greater departmental scrutiny, as set out in that  
11 document.  
12 It was recognised that the NBTS required some  
13 form of central co-ordination, as we have seen in the  
14 minute of that meeting, and so the Central Committee  
15 for the National Blood Transfusion Service was formed  
16 in 1975 to co-ordinate the work of the Regional  
17 Transfusion Centres. It was charged with keeping  
18 under review the operation of the National Blood  
19 Transfusion Service, including BPL and the Blood Group  
20 Reference Laboratory in England and Wales and advising  
21 the Government on the development of the Service.  
22 **SIR BRIAN LANGSTAFF:** Where exactly did that leave the  
23 meetings of the Regional Transfusion Directors because  
24 that's, what you told me earlier, was what they were  
25 doing?

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(5) Pages 17 - 20

1 **MS SCOTT:** So those continued and one of the criticisms of  
2 the central committee was that there was no formal  
3 liaison or relationship between the meetings of the  
4 Regional Transfusion Directors and the central  
5 committee and, ultimately, the central committee was  
6 abandoned and was replaced by a different kind of  
7 committee.

8 **SIR BRIAN LANGSTAFF:** Yes.

9 **MS SCOTT:** So it might be helpful to look at the first  
10 meeting minute of the central committee. We can see  
11 that at MRCO0000060\_023. We can see that that's the  
12 minutes of the meeting held on 19 June 1975, and the  
13 members of the committee included two Regional  
14 Transfusion Directors, the Consultant Adviser to the  
15 Chief Medical Officer, Dr Maycock, representatives  
16 nominated by the Royal Colleges, and other members in  
17 various specialties of medicine, the Department of  
18 Health and Social Security, and it was chaired by  
19 Dr Beddard who was a Deputy Chief Medical Officer.

20 You can take that down. In fact -- hang on,  
21 sorry, can we turn to page 2 of that document. Yes,  
22 if you just enlarge that so we can actually see it.  
23 If we go four lines down:

24 "Referring to paragraph 14 of the Report, [it]  
25 stressed that the Committee should concern itself with

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1 aspects of the NBTS which had national rather than  
2 regional significance and not with details which were  
3 purely of local interest.

4 "Turning to paragraph 21 of the Report the  
5 Chairman said that central financing could be  
6 contemplated in only very exceptional circumstances  
7 since to do otherwise would be to detract from the  
8 prerogative of Regional Health Authorities to  
9 determine, within the financial allocations made to  
10 them by the Department, their own priorities according  
11 to regional needs."

12 Then missing out the next paragraph -- next  
13 sentence:

14 "Development of the NBTS would be largely  
15 dependent on efficient operation by redeployment of,  
16 rather than addition to, resources; what was chiefly  
17 wanted from the Committee were recommendations, advice  
18 and ideas to this end."

19 Then the next paragraph:

20 "Professor Scott said that the Regions suffered  
21 from [I can't read that word] to finance developments  
22 in the policy formulation of which they had no say; he  
23 agreed that the committee would have to be circumspect  
24 in any advice it offered" --

25 **SIR BRIAN LANGSTAFF:** I think it's "having", "having to

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1 finance developments in the policy formation of which  
2 they had had no say ..."

3 **MS SCOTT:** Yes:

4 "... he agreed that the Committee would have to  
5 be circumspect in any advice it offered to the  
6 Department which had financial implications. In  
7 answer to Professor Stewart the Chairman said that the  
8 Department would, of course, consider carefully any  
9 advice tended by the Committee; if the advice was  
10 accepted it would be conveyed to RHAs in the same way  
11 as guidance was given on other aspects of the NHS.  
12 Mr Brooking said that Regions would welcome this."

13 So you can all already see the difficulties.  
14 You have got a central committee, which is considering  
15 issues of national importance not regional ones but  
16 with no budget, that is advising a Regional  
17 Transfusion Centre funded regionally.

18 We can see by 1974 concerns being raised about  
19 the structure of the blood service from outside  
20 organisations and, in particular, raising concerns  
21 about the impact on the drive for self-sufficiency.  
22 We can look at an example of that. So  
23 DHSC0100024\_126.

24 This is an editorial in the BMJ. We can see at  
25 the bottom of that page it is 27 July 1974. If we go

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1 to the second -- it's called "Blood Donors and the  
2 transfusion service", and if we go over to the second  
3 column of that, there is, in the top paragraph, about  
4 halfway down that paragraph, in the middle, it starts  
5 "Finally":

6 "Finally, there is no evidence to" --

7 The editorial has been discussing the fact that  
8 self-sufficiency has not been met and says:

9 "Finally, there is no evidence to support the  
10 conclusion that the failure of the Blood Transfusion  
11 Service to meet the increasing demands rests at the  
12 feet of the voluntary blood donor. Indeed the  
13 evidence suggests that there is no shortage of  
14 voluntary donors in Britain prepared to come forward  
15 and contribute to local and national needs. The  
16 problem rests on the quality of management (or lack of  
17 it) which has led to a steady decline in the British  
18 Blood Transfusion Service since the late 1950s. There  
19 has been no effective national planning; the regional  
20 and protein fractionation centres now lack sufficient  
21 staff, accommodation, equipment and the basic  
22 organisational units to do the job. Moreover, the  
23 medical staff in the centres are often geographically  
24 and administratively isolated from the care of  
25 patients. The remedy, then, is not for a topping-up

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(6) Pages 21 - 24

1 exercise with donors offered theatre tickets or nylon  
 2 stockings but for an urgent appraisal (for the first  
 3 time) of a national policy for the procurement and  
 4 eventual distribution of a natural resource which,  
 5 unlike oil, will be still readily available in  
 6 100 years' time."

7 Can we also look at PRSE0000598, which is also  
 8 the British Medical Journal, and we can see if we turn  
 9 over to page 3 of that that this article, "The blood  
 10 transfusion service and the National Health", is  
 11 written/authored by John Cash, National Medical  
 12 Director of the SNBTS. If we go back to the first  
 13 page, he says, in the second paragraph down:  
 14 "The sustained failure of the transfusion  
 15 services in England and Wales, known as the National  
 16 Blood Transfusion Service, over the past two decades  
 17 to meet the needs of the National Health Service  
 18 extends far beyond the provision of factor VIII  
 19 concentrates. In London and the home counties there  
 20 are chronic and occasionally serious shortages of  
 21 blood, which have an appreciable impact on both the  
 22 NHS and a large uncontrolled private sector."  
 23 If we go to the bottom of that column:  
 24 "Many general managers of regional health  
 25 authorities must view their regional blood transfusion

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1 inappropriate for modern blood transfusion practice;  
 2 it is both wasteful and dangerous."

3 Then if we go over to the right-hand column to  
 4 the bottom of that section called "A foundation for  
 5 change", we see a third of the way through that last  
 6 paragraph:  
 7 "The only option that will provide the quality  
 8 of service the health services in England and Wales  
 9 need, and the one that will give the blood donors  
 10 an assurance that their gifts are appropriately used,  
 11 is the creation of an integrated National Blood  
 12 Transfusion Service, which is removed from direct  
 13 regional health authority funding and managed by a new  
 14 and separate health authority which includes the Blood  
 15 Products Laboratory."  
 16 So that's the rather strongly expressed view of  
 17 Professor Cash about the English service.  
 18 **SIR BRIAN LANGSTAFF:** Now, he was expressing that from  
 19 a Scottish perspective.  
 20 **MS SCOTT:** Indeed.  
 21 **SIR BRIAN LANGSTAFF:** When he talks about "the creation of  
 22 an integrated National Blood Transfusion Service" is  
 23 he talking about a service for England and Wales or  
 24 England, Wales, Scotland and Northern Ireland.  
 25 **MS SCOTT:** My understanding is that it's for England and

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1 centres with some concern. These centres continue to  
 2 produce the therapeutic products against no nationally  
 3 agreed specifications, yet are within nine months of  
 4 new legislation on product liability. They are aware  
 5 of severe shortages in adjacent regions but have no  
 6 mechanism to give or receive help."

7 Then if we go down that column to what went  
 8 wrong and, halfway down that paragraph there -- sorry,  
 9 "What went wrong?" Yes, so halfway down the  
 10 paragraph, we start:  
 11 "The National Blood Transfusion Service is  
 12 a fragmented and disorganised shambles. Thus it has  
 13 been possible, and on many occasions, for severe  
 14 shortages of blood to arise in one part of the country  
 15 while less than 10 miles away (in another region) the  
 16 regional health authority is dismantling part of its  
 17 blood collection programme because of sustained  
 18 excesses."  
 19 Then going down to the last whole sentence in  
 20 that paragraph:  
 21 "Somehow the concept of the 'gift relationship'  
 22 of the voluntary donor and the needs of the patient  
 23 have been lost by a service which in truth is a series  
 24 of tight compartments with little or no facility to  
 25 work together. This system of management is wholly

26

1 Wales, rather than for a truly national service and if  
 2 we turn to the very end of that article it may give us  
 3 some insight into that:  
 4 "Many good friends and colleagues in England and  
 5 Wales may take exception to criticisms of the [NBTS]  
 6 by the national medical director of its wee sister in  
 7 Scotland. Undoubtedly my critique is partly based on  
 8 'self' interest: the continued decline of the [NBTS]  
 9 is now having a destabilising effect on the Scottish  
 10 service. Nevertheless, the overriding reason for this  
 11 cri de coeur is my belief that unless the vital  
 12 importance of the blood transfusion services to the  
 13 well being of the health services in the UK is better  
 14 understood, and the decline in performance arrested,  
 15 then within the next decade the consequences will be  
 16 grave."  
 17 I am not sure that does give us any more insight  
 18 but he is referring throughout to the National Blood  
 19 Transfusion Service and has made it clear that that is  
 20 the England and Wales service. So I had read it as  
 21 referring to the England and Wales service, rather  
 22 than a cry for a fully-integrated UK service.  
 23 **SIR BRIAN LANGSTAFF:** Yes. Well, he appears to be saying  
 24 that the Scottish service is doing rather better than  
 25 he sees the NBTS is doing.

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(7) Pages 25 - 28



1 **MS SCOTT:** Yes. In May 1977, the NBTS, together with the  
 2 director of BPL, submitted the National Blood  
 3 Transfusion Service -- submitted a document, which we  
 4 should, I think, look at. It's CBLA0000612. If we go  
 5 over to the second page, we can see it's a document  
 6 called:  
 7 "The National Blood Transfusion Service  
 8 "Its present Status and Proposals for  
 9 Reorganisation  
 10 "A submission prepared for consideration by the  
 11 Royal Commission on the National Health Service."  
 12 **SIR BRIAN LANGSTAFF:** So this is ten years before the  
 13 article you have just shown me?  
 14 **MS SCOTT:** Indeed.  
 15 If we go back to the first page we can see in  
 16 the letter from Dr Gunson to the Royal Commission  
 17 enclosing the document it's said that:  
 18 "This document represents the consensus of  
 19 opinion of the Directors of Regional Transfusion  
 20 Centres in England and Wales and the Director and  
 21 Director designate of the Blood Products Laboratory,  
 22 Elstree."  
 23 That's the basis upon which the document's been  
 24 authored. Then if we go over the page to page 3, we  
 25 can see the summary of the report. I'm going to pick

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1 "Blood Products -- Factor VIII and ... IX  
 2 concentrates, dried plasma, plasma protein fraction,  
 3 normal and specific immunoglobulins."  
 4 Then:  
 5 "Reagents for use in blood group serology and  
 6 for quality control."  
 7 Then regional functions are the:  
 8 "Supply of whole blood an concentrated red  
 9 cells.  
 10 "Supply of blood components ... platelets and  
 11 leucocytes. The short life of such components, ie  
 12 less than 72 hours, limits their supply to within  
 13 a Region", and tissue-typing and specialist regional  
 14 services.  
 15 Then it goes on to say:  
 16 "The present organisation which exists in the  
 17 Transfusion Service limits the development of the  
 18 national aspects of the service."  
 19 At the bottom of that paragraph:  
 20 "The Central Committee is only advisory to the  
 21 DHSS and, on national or any other aspects of the  
 22 Transfusion Service, the DHSS is not in a position to  
 23 instruct regions on the allocation of finance to RTCs.  
 24 Finally, the RHAs are not involved in national  
 25 policy-making for the NBTS, although ..."

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1 it up at (c):  
 2 "During recent years, the Transfusion Service  
 3 has assumed an increasing national role, which has  
 4 served from constraints arising from regional  
 5 development [sic], inadequate central co-ordination  
 6 and financing and a poor integration of the activities  
 7 of the Regional Transfusion Centres."  
 8 Then at (d):  
 9 "Proposals are put forward for improving the  
 10 national commitment of the Transfusion Service by  
 11 allocation of central finance and management through  
 12 the a statutorily constituted executive committee and  
 13 the appointment of a National Medical Co-ordinator.  
 14 Proposals are made ... for the retention of  
 15 flexibility of Regional Transfusion Centre functions  
 16 within Regions."  
 17 Then (e):  
 18 "It is essential that the Regional Transfusion  
 19 Centres are provided with adequate resources ...  
 20 accommodation", et cetera.  
 21 Then if we go over the page to page 10, they set  
 22 out there the different functions that the Regional  
 23 Transfusion Centres perform and we can see it has been  
 24 split into national functions and regional functions.  
 25 National functions are said to be:

30

1 **SIR BRIAN LANGSTAFF:** "... these policies ..."  
 2 **MS SCOTT:** Thank you.  
 3 "... these policies may commit RHAs to the  
 4 allocation of extra funds from the regional budgets to  
 5 finance development at RTCs."  
 6 So pointing out there that the structural  
 7 problems arising -- the problems arising from the  
 8 structure.  
 9 The next event that happens is that Dr Geoffrey  
 10 Tovey succeeds Dr Maycock as the Consultant Adviser in  
 11 Blood Transfusion to the Chief Medical Officer. That  
 12 happens in 1978, and Dr Tovey establishes three  
 13 divisions of the Regional Transfusion Centres, the  
 14 Eastern Division, the Western division and the  
 15 Northern Division, and they have area -- divisional  
 16 meetings, so groupings of Regional Transfusion Centres  
 17 getting together to create supra regions and  
 18 discussing issues that apply to their regions, and  
 19 they were tasked -- those regional meetings were  
 20 tasked by Dr Tovey with discussing National Blood  
 21 Transfusion Service policy ahead of Regional  
 22 Transfusion Director meetings were encouraged to  
 23 advance policy proposals.  
 24 So we now have -- the Regional Transfusion  
 25 Directors are meeting in two different forums: all

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(8) Pages 29 - 32

1 together in Regional Transfusion Director meetings and  
 2 then in these divisional meetings.  
 3 We understand that by March 1979 the Department  
 4 of Health and Social Security had not been convinced  
 5 by the proposal we have just looked at to centralise  
 6 the Blood Transfusion Service and so Dr Tovey drafted  
 7 a report in February 1980 entitled "Proposed Plan for  
 8 Reorganisation of the NBTS", which I don't think we  
 9 need to go to, but for those who want to look at it  
 10 it's DHSC0002197\_089. In that report, he stated that  
 11 there was a general appreciation within the service  
 12 that the major defects within the service were  
 13 unlikely to be overcome in the absence of a national  
 14 managed authority with statutory powers, but he noted  
 15 that such a policy was not going to be implemented  
 16 immediately, and so he made a number of interim  
 17 suggestions to try to improve the co-ordination  
 18 amongst Regional Transfusion Centres and for closer  
 19 links with the Scottish National Blood Transfusion  
 20 Service.  
 21 One of the suggestions he made was the  
 22 introduction of a central co-ordinating committee for  
 23 the National Blood Transfusion Service, due to the  
 24 perceived failure of the central committee to carry  
 25 out that co-ordinating role. That was adopted by the

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1 Department of Health and Social Security in 1980 by  
 2 replacing the central committee with a new advisory  
 3 committee on the National Blood Transfusion Service.  
 4 That committee was chaired by the Department of Health  
 5 and Social Security and it was made up of: a Regional  
 6 Health Authority representative -- so understanding  
 7 where the finances for the Regional Transfusion  
 8 Centres come from, there is now Regional Health  
 9 Authority representative on that national -- on that  
 10 advisory committee -- Regional Transfusion Directors  
 11 representatives; a director of BPL; the Consultant  
 12 Adviser to the DHSS, at that time Dr Tovey; and  
 13 observers from the Department of Health and Social  
 14 Security; from the Scottish National Blood Transfusion  
 15 Service, usually Dr or Professor Cash; Dr Doyle from  
 16 the Welsh Office; and Dr Acton from the DHSS in  
 17 Northern Ireland.  
 18 The terms of reference for that committee were  
 19 to advise the DHSS and the Welsh Office on the  
 20 co-ordination and work of Regional Transfusion Centres  
 21 and the Central Blood Laboratories in England and  
 22 Wales and to advise on the co-ordination of the  
 23 Regional Transfusion Centres and Central Blood  
 24 Laboratories with that of Scotland and Northern  
 25 Ireland.

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1 So, as I understand it, that's the first time  
 2 there was a formal brief, if you like, for looking at  
 3 co-ordinating the blood services in England and Wales  
 4 with those in -- with that in Scotland, albeit it was  
 5 through an English and Welsh committee.  
 6 I'm going to move now to February 1985 to  
 7 a document DHSC --  
 8 **SIR BRIAN LANGSTAFF:** When you tell me it's to advise, it  
 9 is to advise who: the Minister?  
 10 **MS SCOTT:** To advise, yes.  
 11 **SIR BRIAN LANGSTAFF:** So the power to do something about  
 12 what the advice suggests is left with the minister?  
 13 **MS SCOTT:** Yes, the Welsh Office and the Department of  
 14 Health and Social Security.  
 15 So moving on now to February 1985,  
 16 DHSC0002259\_037.  
 17 By now we have -- Dr Gunson is now  
 18 the consultant adviser in blood transfusion to the  
 19 Chief Medical Officer. He has replaced Dr Tovey.  
 20 Here we have a document being sent by Dr Fraser  
 21 on behalf of Dr Gunson to the Deputy Chief Medical  
 22 Officer, Dr Harris, at the DHSS:  
 23 "... requesting that the DHSS consider the  
 24 options available to achieve a nationally co-ordinated  
 25 transfusion service in England and Wales."

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1 So here we have Dr Gunson making similar  
 2 representations to those that had been made by others  
 3 before him.  
 4 If we turn over the page, we can see the title  
 5 "Regional Transfusion Directors' Committee  
 6 Organisation of the Blood Transfusion Service", and  
 7 the document sets out -- if we go over to page 2 -- so  
 8 we have there the title, "Regional Transfusion  
 9 Directors' Committee Organisation of the Blood  
 10 Transfusion Service", and the document sets out the  
 11 background and the functions of the regional  
 12 transfusion centres.  
 13 Then if we go on to the next page, page 3, I'm  
 14 going to look at paragraph 5. This part of  
 15 the document they are concerned with the problems of  
 16 the current structure and setting out some of  
 17 the problems. I just draw your attention to the part  
 18 on plasma supply:  
 19 "Plasma supply for the preparation of  
 20 fractionated products has highlighted the difficulties  
 21 of co-ordinating the activities of regional centres.  
 22 Whilst certain RHAs have agreed to increase plasma  
 23 collection in line with national targets others have  
 24 only agreed in principle without specifying a time  
 25 scale and may not exceed the plasma required to attain

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(9) Pages 33 - 36

1 regional self-sufficiency. One RHA has not responded  
2 to the request for additional plasma.  
3 "There are, again, RTCs who will find it  
4 difficult, or impossible, to achieve a level of plasma  
5 connection for regional self-sufficiency whilst others  
6 have the potential to supply in excess of their  
7 regional needs."

8 Then over the page Dr Gunson sets out the  
9 particular advantages of a nationally co-ordinated  
10 committee, co-ordination with the work of the regional  
11 blood transfusion centres. At paragraph 7:

12 "7.1. A coordinated national blood collection  
13 programme making the maximum use of the donor base  
14 throughout the country.

15 "7.2. A more effective co-ordination of the  
16 activities of the Central Blood Laboratories with the  
17 Regional Transfusion Centres.

18 "7.3. Planned activities at certain RTCs for  
19 special services and plasma connection for certain  
20 products could be based on a national programme and  
21 need not be reduplicated at each RTC ...

22 "7.5. Rationalisation of blood collection and  
23 labile product production could lead to significant  
24 revenue savings ...

25 "7.6. A nationally co-ordinated Service would

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1 If we go to page 6, at paragraph 5 they say:  
2 "On the question of organisation we suggest that  
3 there are 3 options available for the future of  
4 the BTS. The implementation of the recommended  
5 information system is crucial to each."

6 So they had identified that there was not  
7 sufficient reliable management information to allow  
8 effective management of the Regional Transfusion  
9 Centres. And so, briefly, the three options are --  
10 and the first one is, effectively, leave the  
11 organisational structure as it is but introduce  
12 reliable management information and continuing  
13 financial constraints to allow for more co-ordinated  
14 and effective management.

15 The second option is that -- to tackle the  
16 question of the relationship between the Central Blood  
17 Laboratories Authority and the Blood Transfusion  
18 Centre and the problems with lack of co-ordination  
19 between regions. So the second option is said to  
20 tackle that:

21 "... by raising the profile of the existing  
22 Regional Transfusion Directors Committee and the  
23 Advisory Committee on the Blood Transfusion Service  
24 and by introducing a new co-ordinating committee for  
25 CBLA and the BTS. Under this option the committees

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1 avoid the anomalies which exist at present in a number  
2 of regions where a District Hospital is more  
3 appropriately served by a Regional Transfusion Centre  
4 outside its own region."

5 The paper finishes at paragraph 9 with a request  
6 from the Regional Transfusion Directors:

7 "... that the DHSS consider the options  
8 available to achieve a nationally co-ordinated  
9 Transfusion Service for England and Wales."

10 And requested that a working party is  
11 established in order to do just that.

12 In 1986 it was agreed that the Department of  
13 Health and Social Security Central Management Services  
14 would carry out an investigation into the organisation  
15 of the National Blood Transfusion Service, and they  
16 carry out -- their report is dated October 1987.

17 It's CBLA0002392. We can see there, "An  
18 organisational study", and at the bottom we can see it  
19 is "NHS Management Consultancy Services", and that's  
20 October 1987.

21 It's a lengthy piece of work which involved  
22 visiting a number of Regional Transfusion Centres and  
23 considering in detail the work undertaken by the  
24 centres and differences in practice that they came  
25 across during their investigations.

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1 would have no executive power as this option envisages  
2 that the BTS would remain a regionally managed and  
3 funded service. However by formalising the role of  
4 the committees it is suggested that greater cognisance  
5 may be taken of their views and decisions."

6 So effectively sort of power up the existing  
7 committees and structures.

8 Then the third option they identify is the  
9 creation of a special health authority to centrally  
10 manage and fund the Blood Transfusion Service. It  
11 "could also be responsible for CBLA" if that were  
12 considered to be appropriate.

13 In 1988 the Department decided to adopt the  
14 second recommendation made, it's set out in this  
15 report, i.e. to continue regional executive management  
16 but with further central co-ordination. And they did  
17 this by forming the national directorate on  
18 28 July 1988.

19 We can see what they say about that in the press  
20 release issued, and that is DHSC0004764\_060.

21 "National management structure for Blood  
22 Transfusion Service.

23 "Edwina Currie, Parliamentary Secretary for  
24 Health, today announced that new management  
25 arrangements would be made to provide a formal

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(10) Pages 37 - 40



1 national management structure for the National Blood  
 2 Transfusion Service (NBTS). Replying to  
 3 a Parliamentary questions ... Mrs Currie said:  
 4 "We have decided that new management  
 5 arrangements are needed for the supra regional and  
 6 national dimension of the National Blood Transfusion  
 7 Service (NBTS).  
 8 "We therefore intend that operational  
 9 responsibility at the national level for the NBTS and  
 10 the Central Blood Laboratories Authority (CBLA) will  
 11 be exercised on behalf of the Health Ministers for  
 12 England and Wales by the NHS Management Board and  
 13 undertaken by its Director of Operations, in  
 14 consultation in respect of Wales with the Director,  
 15 NHS Wales. Day to day implementation of the national  
 16 strategy will be delegated to a new National Director  
 17 of the NBTS and a small supporting staff.  
 18 "The key objective will be:  
 19 "a) to implement a cost effective strategy for  
 20 ensuring an adequate supply of blood throughout  
 21 England and Wales;  
 22 "b) to implement a cost effective strategy for  
 23 the supply of plasma to the blood products laboratory  
 24 of the CBLA;  
 25 "c) to co-ordinate the activities of the NBTS

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1 Management Committee took place on 1 December 1988.  
 2 The committee was attended by the director and deputy  
 3 director of the National Directorate and a number of  
 4 Regional Transfusion Directors, including the heads of  
 5 the three divisions that Dr Tovey created.  
 6 The terms of reference were: to consider matters  
 7 of importance in relation to the work of the NBTS and  
 8 to advise the national director; to bring forward to  
 9 the committee matters of national importance to the  
 10 work of the NBTS; to receive reports from the NBTS and  
 11 the CBLA liaison committee; meetings of the head  
 12 laboratory scientists, nurse, donor service managers  
 13 and administrators and managers, *ad hoc* working  
 14 parties and the national publicity subcommittee, so in  
 15 order to receive the reports from all the various  
 16 different working groups and committees; and to report  
 17 to the divisions the decisions reached by the National  
 18 Directorate -- so information coming both ways.  
 19 Also at that time a month later, in  
 20 January 1989, the National Blood Transfusion Service  
 21 and Central Blood Laboratory Authority Liaison  
 22 Committee was established. That was a formal  
 23 committee, a committee in which there was formal  
 24 liaison between the two.  
 25 Also in January 1989, the Regional Transfusion

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1 and the CBLA;  
 2 "d) to promote the efficiency of the NBTS."  
 3 So this body, the national directorate, was  
 4 directly funded by the Department. Dr Gunson was  
 5 appointed as the national director and reported to the  
 6 director of operations of the NHS management board.  
 7 Mr Roger Moore, a civil servant at the  
 8 Department, was appointed the deputy director, but  
 9 management of the individual Regional Transfusion  
 10 Centres remained with the Regional Health Authorities,  
 11 and Dr Gunson, in his statement for the hepatitis  
 12 litigation, described the National Directorate as  
 13 operating via persuasion rather than executive power.  
 14 Where National Directorate policy required  
 15 the use of additional resources by regional  
 16 transfusion centres, this created difficulties because  
 17 there was no national budget to effect any those  
 18 policies. Regional Transfusion Centres' budgets  
 19 remained controlled by regional health authorities,  
 20 and we'll explore in the coming weeks and months  
 21 whether there are any exceptions to that in terms of  
 22 particular policies for testing blood donations and so  
 23 on.  
 24 The first meeting of the National Directorate of  
 25 the National Blood Transfusion Service National

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1 Director meetings came to end. So that's the full  
 2 meetings of all the Regional Transfusion Directors.  
 3 The meetings of the divisional directors  
 4 continued, so the three divisions continued to meet,  
 5 but there was no longer the regular meetings between  
 6 all of the Regional Transfusion Directors.  
 7 **SIR BRIAN LANGSTAFF:** Which of the divisions dealt with  
 8 London?  
 9 **MS SCOTT:** The Eastern, I believe. Let me just check.  
 10 Yes, Eastern: north London, Brentwood, South London  
 11 and Cambridge.  
 12 The Western division was Oxford, Bristol,  
 13 Southampton, Birmingham and Cardiff.  
 14 And Northern was Newcastle, Manchester,  
 15 Sheffield and Leeds.  
 16 The minute of that last Regional Transfusion  
 17 Director meeting in January 1989 records that the only  
 18 formal contact now remaining between Scotland and  
 19 England was between Dr Gunson and Dr Cash. The reason  
 20 for that was that the Scottish directors would attend  
 21 those meetings and that may have been the driver for  
 22 the creation of the Liaison Committee between the two  
 23 blood services which was formed in June 1990.  
 24 So, following the cessation of the Regional  
 25 Transfusion Director meetings, which of course were

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(11) Pages 41 - 44

1 also attended by the Department, the remaining  
2 channels of communication between the Department of  
3 Health, as it now was, and the NBTS were direct  
4 contact between Dr Gunson and Department officials and  
5 doctors, via the Management Board Co-ordinating  
6 Committee and by the annual report submitted by the  
7 National Blood Transfusion Service.

8 Despite the creation of the National  
9 Directorate, there were continuing calls for  
10 centralisation of the English and Welsh Blood  
11 Transfusion Service. Dr Gunson continued to make  
12 proposals for a move towards a national service and,  
13 in 1991, Department of Health went out to consultation  
14 on the future of the Blood Transfusion Service and, in  
15 particular, on plans to combine the Central Blood  
16 Laboratory Authority and the National Blood  
17 Transfusion Service.

18 Ultimately, the final structure of what became  
19 the National Blood Authority was determined by the  
20 technical working group, the National Blood Authority  
21 technical working group, who met over a period of  
22 time, finally reporting in July 1992.

23 Can we turn to that. It's SBTS0000466\_008.

24 We can see there the:

25 "Report of the technical working group on

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1 operational aspects of the National Blood Authority."

2 If we turn to page 16, we can see there "Terms  
3 of reference" and "Membership".

4 "... Terms of reference ...

5 "In light of the general support for the  
6 principle of establishing an influential National  
7 Blood Authority for England ..."

8 Note, just England.

9 "... and Ministers' acceptance of that

10 principle, the Technical Working Group is asked to  
11 reconsider the operational mechanisms for the NBA and  
12 make recommendations. In particular the Group should  
13 examine:

14 "- the proposed role of the NBA as the central  
15 [co-ordinator (*sic*)] for blood supplies to hospitals;

16 "- its proposed role in the allocation of  
17 capital to the Regional Transfusion Centres;

18 "- the composition required for the NBA to  
19 provide a satisfactory balance of interests between  
20 users, the RTCs and the BPL and which could take  
21 proper account of donor interests."

22 In framing its recommendations, the Working  
23 Group should take full account of the established  
24 policy in relation to self-sufficiency and the need  
25 for the NBA to and respond to developments within the

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1 EC."

2 Then we can see the list of members of the  
3 working group, who include Dr Gunson, Dr Wagstaff, who  
4 was a Regional Transfusion Centre director,  
5 representatives from regional health authorities, and  
6 from the Welsh Office and from the Department of  
7 Health.

8 We can see the summary of recommendations at  
9 page 4:

10 "Summary of Recommendations.

11 "... Role of the NBA.

12 "The NBA should be given the authority and means  
13 to achieve the national objectives for the blood  
14 supply ..."

15 The second issue is something that they had gone  
16 out on consultation as to whether or not it should be  
17 a central contractor, and that was rejected.

18 "The NBA should operate as a strategic authority  
19 to plan and implement a national strategy for the  
20 blood services.

21 "The NBA should approve key aspects of the RTCs'  
22 business plans and monitor their output ...

23 "The NBA should control the transfer of plasma  
24 to BPL for contract fractionation at agreed  
25 quantities, quality and handling charges ..."

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1 So you can see there, sir, that the  
2 RTC structure is to remain but with the NBA sitting  
3 above it controlling certain aspects and approving  
4 business plans.

5 Then if we go to page 10, at paragraph 2.5:

6 "Control of blood services.

7 "2.5. The Group concluded that the NBA should  
8 therefore be set up as the strategic authority for the  
9 blood services. It would plan and implement through  
10 the RTCs and BPL a National Strategy designed to  
11 ensure that the required volume and range of blood and  
12 blood products were obtained as economically and  
13 efficiently as possible consistent with quality,  
14 safety and efficacy.

15 "2.6. The NBA would co-ordinate the activities  
16 of the thirteen RTCs and of BPL in support of the  
17 National Strategy, promote good practices in relation  
18 to quality and efficiency and influence sensible  
19 development of the RTC network and of BPL in  
20 accordance with the National Strategy.

21 "2.7. The NBA should be given the right to  
22 approve key aspects of the business plans of the RTCs  
23 and to agree target production quantities for each, as  
24 well as to agree the level of handling charges. They  
25 would monitor out-turn and have the right to intervene

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(12) Pages 45 - 48

1 if have quantity or quality were not as agreed. There  
2 would be a managed market rather than a 'free for all'  
3 and NBA would develop a protocol, in conjunction with  
4 RTCs, to guide hospitals who wished to change the RTC  
5 from which they purchased their services."

6 If we go over the page, we see how the RHA, the  
7 Regional Health Authority, fits into this structure at  
8 paragraph 3.3:

9 "The RHAs are the line managers of the RTCs the  
10 introduction of the NBA as the strategic body, or  
11 Special Health Authority for the blood supply would  
12 limit the scope for RHAs managing their RTCs from  
13 a purely local perspective. However, the Group  
14 envisaged that the RHAs would be represented on the  
15 National Blood Authority ... and so contribute to the  
16 formulation of the National Strategy. The Regions  
17 would be brought in should disputes arise between the  
18 NBA and individual RTCs."

19 So a slightly complicated arrangement where the  
20 RHAs and RTCs retain a relationship but the NBA also  
21 has some say. It's clearly an attempt to deal with  
22 the problems of self-sufficiency, and so on, by giving  
23 the NBA power to control quantities and quantity and  
24 quality of, presumably, blood collection and plasma  
25 production to BPL.

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1 existence with the Regional Transfusion Centres  
2 operating through the Regional Health Authorities.  
3 That came to an end on 1 April 1994.

4 Probably the easiest place to understand how  
5 that looks is to look at the presentation, which is  
6 INQY0000307 at page 28. What we have done there is  
7 set out the functions of the NBA at paragraph 87. So  
8 the initial functions -- if we can go down to the  
9 bullet points, the initial functions that were  
10 contained within the 1993 -- that were exercised by  
11 the NBA in 1993 were:

12 "the provision of laboratories for the  
13 manufacture of blood products ...

14 "... for therapeutic, diagnostic and other  
15 purposes;

16 "research and development in plasma protein  
17 fractionation for other purposes;

18 "the manufacture of blood grouping re-agents and  
19 other related re-agents;

20 "the supply of blood products prepared or  
21 manufactured under sub-paragraph (b) [which is  
22 actually preparation of plasma fractions] for the  
23 purposes of the health service ..."

24 Then if we go down to the footnote, we can see  
25 that, in addition, it had paragraph (f):

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1 Sir, I note the time. I've got probably  
2 another, sort of, five or ten minutes on England  
3 before I turn to the other blood services.

4 **SIR BRIAN LANGSTAFF:** I think we'll come to that, shall we  
5 then, at 11.45. So 11.45.

6 (11.16 am)

7 (A short break)

8 (11.45 am)

9 **MS SCOTT:** Sir, we have arrived at 1 April 1993 with the  
10 Department of Health establishing the National Blood  
11 Authority. It established a Special Health Authority,  
12 called the National Blood Authority. We've looked at  
13 the recommendations of the working group and the NBA's  
14 role was to monitor the operation of the Regional  
15 Transfusion Centres and to provide advice as to the  
16 co-ordination of their respective activities.

17 Shortly after the National Blood Authority was  
18 established, the order establishing it was  
19 significantly amended. So from 1 April 1994 -- so  
20 a year into its existence -- the NBA took over direct  
21 responsibility for the collection, screening and  
22 processing of blood and its constituents and supply of  
23 blood and blood products for the NHS. So there was  
24 a hybrid position, if you like, of a year between  
25 1 April '93 and 1 April '94 where you had the NBA in

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1 "... 'the monitoring of the operation by  
2 Regional Health Authorities of the transfusion  
3 service, and the provision of the advice to the  
4 Secretary of State in connection with that service'  
5 and '(g) the provision of advice to Regional Health  
6 Authorities as to the co-ordination of their  
7 respective activities in connection with the  
8 transfusion service, with a view to securing and  
9 maintaining an adequate supply of blood and plasma for  
10 the purposes of the health service'."

11 **SIR BRIAN LANGSTAFF:** What has been set out in 87 is the  
12 1994 position, not the 1993 position.

13 **MS SCOTT:** Indeed.

14 **SIR BRIAN LANGSTAFF:** So the footnote, no doubt, is  
15 accurate. What I think you said was "in addition".

16 **MS SCOTT:** So the position in 1993 was that those  
17 provisions in bullet points and the two provisions in  
18 the footnote were in place. The provision in 1994,  
19 the two bullet points -- sorry, the two footnotes (f)  
20 and (g) came out and, if we go back to paragraph 87  
21 (aa) was inserted, so the bullet points remaining in  
22 '93 and '94. In '94, (aa) was added, which makes the  
23 NBA responsible directly for:

24 "... collection, screening and processing blood  
25 and its constituents and supplying blood plasma

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1 [et cetera] for the purposes of the health  
 2 service ..."  
 3 So that was added in in 1994.  
 4 **SIR BRIAN LANGSTAFF:** I see, so the black bullet points on  
 5 the screen were there from the beginning --  
 6 **MS SCOTT:** Indeed, and remained there.  
 7 **SIR BRIAN LANGSTAFF:** -- and (aa) was added --  
 8 **MS SCOTT:** It was, and --  
 9 **SIR BRIAN LANGSTAFF:** -- and, in order to make way for  
 10 (aa), the provision of advice and the monitoring of  
 11 the operation were removed.  
 12 **MS SCOTT:** Indeed, and if we go over the page, also added  
 13 in '94 was (h), which is:  
 14 "... the promotion, by advertisement and  
 15 otherwise, of the giving of blood and its constituents  
 16 for the purposes of the health service, with a view in  
 17 particular to maintaining an adequate number of  
 18 persons who are willing to give blood or its  
 19 constituents for these purposes ..."  
 20 **SIR BRIAN LANGSTAFF:** So previously was it a matter for  
 21 the individual regions how they advertised whether you  
 22 should come and give blood?  
 23 **MS SCOTT:** Indeed, it was, yes.  
 24 **SIR BRIAN LANGSTAFF:** And it would follow what you are  
 25 told about the process of donation and how it was

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1 centres increasingly were treated parts of the whole  
 2 institution, rather than distinct institutions  
 3 operating around the country."  
 4 Now, Dr Gunson was initially appointed as the  
 5 first national director of the National Blood  
 6 Authority when it was formed in April '93, but he  
 7 retired in May '94 and was replaced by Dr Angela  
 8 Robinson. In September '94, the NBA issued a document  
 9 called "Proposals for the Future Blood Service", which  
 10 was a consultation document, which was a synopsis of  
 11 a 777-page review called the Bain Report, and that  
 12 consultation proposed centralising management into  
 13 a single small unit, consolidating testing facilities  
 14 and putting cost-saving proposals into effect, whilst  
 15 securing the future blood supply in terms of quantity  
 16 and safety.  
 17 The NBA received a large number of responses to  
 18 that consultation, primarily from those areas --  
 19 regions rather -- where their Regional Transfusion  
 20 Centre was being considered for amalgamation with  
 21 other centres.  
 22 Following that consultation, the NBA created  
 23 three administrative zones in London and the South  
 24 East, in the Midlands and the South West, and the  
 25 Northern Zone, with an administrative centre in each.

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1 organised?  
 2 **MS SCOTT:** Yes.  
 3 **SIR BRIAN LANGSTAFF:** Soumik, can we go to WITN672006 --  
 4 WITN0672006.  
 5 **MS SCOTT:** This is a statement of Dr Gail Mifflin on behalf  
 6 of the NBTS. If we could go to page 92 of that  
 7 statement, she sets out what she understands that 1994  
 8 order actually meant. She says this, at  
 9 paragraph 272:  
 10 "On 1 April 1993, the National Blood Authority  
 11 ... the predecessor to NHSBT, was established as  
 12 an SHA [a Special Health Authority]. At that time the  
 13 NBA was responsible for BPL and the International  
 14 Blood Group Reference Laboratory."  
 15 So that's the 1993 position:  
 16 "On 1 April 1994, the NBA then became  
 17 responsible for the RTCs. I understand that from that  
 18 date the regional health authorities no longer managed  
 19 the RTCs. The name of the RTCs was changed to blood  
 20 centres (BCs)."  
 21 It goes on to say in paragraph 273:  
 22 "Referring to the documents I have been  
 23 provided, it would appear that the [blood centres] and  
 24 their functions became assimilated into the [National  
 25 Blood Authority] as a single national service. The

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1 It is administrative centre was in London and the  
 2 South East was North London, Midlands and the South  
 3 West was Bristol, and the Northern Zone was in Leeds.  
 4 They amalgamated now the Lancaster Regional  
 5 Transfusion Centre with the Manchester one, Bristol  
 6 with Plymouth and Oxford with Birmingham.  
 7 The National Blood Authority was abolished on  
 8 1 October 2005 and replaced by the establishment of  
 9 the NHS Blood and Transplant NHSBT, a Special Health  
 10 Authority in England and Wales.  
 11 So the current position is that NHSBT is the  
 12 health authority with responsibility for managing  
 13 blood services in England -- and I will come on to  
 14 explain why that doesn't include Wales in a moment --  
 15 and it has responsibility for managing services  
 16 including transplantation services in relation to stem  
 17 cells, human tissue and human organs in the UK.  
 18 I'm now going to move on to Wales. Before  
 19 I start I hope it will have been clear that much of  
 20 what I said in the previous part of the presentation  
 21 applied to Wales, so this is just the Welsh-specific  
 22 issues that I'm dealing with here, and I should also  
 23 say that there is currently less detailed information  
 24 available to the Inquiry about the history of Wales --  
 25 of the Welsh Blood Service, but that's something that

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(14) Pages 53 - 56

1 we will continue to investigate and it may be that  
 2 more information comes as a result of oral evidence.  
 3 So NBTS (Wales) was made up of a single Regional  
 4 Transfusion Centre in Cardiff, which served the  
 5 hospitals in south and mid-Wales. The Regional  
 6 Transfusion Centre in Cardiff was established in 1940  
 7 and following the establishment of the NHS in 1948 it  
 8 was managed by the Welsh Regional Health Board. In  
 9 1974, NBTS (Wales), effectively the Cardiff Regional  
 10 Transfusion Centre, became the responsibility of the  
 11 Welsh Office.  
 12 In 1982, responsibility was delegated by the  
 13 Welsh Office to the South Glamorgan District Health  
 14 Authority and in 1991 responsibility for NBTS (Wales)  
 15 was delegated to the Welsh Health Common Services  
 16 Authority. NBTS (Wales) did not become part of the  
 17 National Blood Authority when it was formed in 1993.  
 18 That was just for the Regional Transfusion Centres in  
 19 England. This change prompted consideration as to the  
 20 future management of the Welsh blood transfusion  
 21 services.  
 22 If we can look please at SCGV0000053\_013. So we  
 23 can see from this page here that this is a letter --  
 24 a covering letter, dated 14 November 1994, to R Ponton  
 25 in NHS Scotland and it is from a P Davenport of the

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1 and mission of NBTS (Wales), which appears below. The  
 2 vision is:  
 3 "To be the acknowledged Centre of Excellence  
 4 for blood transfusion and transplant immunology  
 5 services in Wales'.  
 6 "... Mission  
 7 "Through the generosity of donors and the  
 8 valued contribution of staff, to provide quality blood  
 9 transfusion and transplant immunology services for the  
 10 treatment of patients in Wales'.  
 11 If we then go on to page 8, paragraph 4.3, we  
 12 can see what prompted the report:  
 13 "The establishment of the [NBA] to take over  
 14 direct managerial control of the Transfusion service  
 15 in England from April 1994, and the outcome of the  
 16 Bain review into transfusion services, has resulted in  
 17 amalgamation of the former regional services within  
 18 England into three zones. Managerial and support  
 19 services will be centralised within each zone and  
 20 certain laboratory functions will be reorganised on  
 21 a supra-regional basis, thus allowing a small number  
 22 of English Regional Centres to be closed (this  
 23 includes the Mersey Centre)."  
 24 I will come onto why that is significant in  
 25 a moment.

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1 Health Services Division of the Welsh Office, and it  
 2 says:  
 3 "Future Management Arrangements for the National  
 4 Blood Transfusion Service (Wales) ...  
 5 "I promised to let you have a copy of the  
 6 recommendations for future management arrangements for  
 7 [NBTS (Wales)]."  
 8 Then if we turn over we can see the document  
 9 itself, "Recommendations for Future Management  
 10 Arrangements for the National Blood Transfusion  
 11 Service (Wales)", and then the date is October 1994.  
 12 Then if we turn over to page 4, we can see the  
 13 contents of that report, and page 6 we can see the  
 14 objective of the report:  
 15 "The objective of this report is to recommend  
 16 the chosen option for future management arrangements  
 17 for the National Blood Transfusion Service (Wales) ...  
 18 following receipt of a direction from the Secretary of  
 19 State for Wales indicating that Welsh Health Common  
 20 Services Authority ... should cease to maintain  
 21 managerial control of [NBTS (Wales)]."  
 22 It sets out what happened in 1991, that  
 23 managerial control was transferred to them from South  
 24 Glamorgan Health Authority.  
 25 It's then probably worth looking at the vision

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1 "The ethos behind these changes is to achieve  
 2 greater efficiency and a higher quality service. The  
 3 situation in Wales should therefore seek to mirror and  
 4 support these initiatives, and particularly move  
 5 towards a largely cohesive United Kingdom Transfusion  
 6 Service."  
 7 If we go over the page to -- sorry, if we go  
 8 over to page 11, we can see that there are a number of  
 9 shortlisted options that the report recommends, at  
 10 paragraph 8, section 8:  
 11 "The following are therefore the shortlisted  
 12 options worthy of further consideration ...  
 13 "A. Do minimum ([NBTS (Wales) becomes  
 14 a] Special Health Authority).  
 15 "B. Incorporation into the NBA as a fifth  
 16 Transfusion Centre within the South West Zone.  
 17 "C. [NBTS (Wales)] as a fourth zone within NBA.  
 18 Then if we go back to page 9, we can see what  
 19 "do minimum" means. That's paragraph 7.1, if we go  
 20 down to 7.1:  
 21 "This is taken to assume that formation of  
 22 a Special Health Authority for [NBTS (Wales)] alone as  
 23 opposed to, at present, being within the managerial  
 24 control of a Special Health Authority. This option  
 25 would be robust against all external influences and

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1 would maintain the unique identity of the Welsh  
2 Transfusion Service."  
3 Then missing out the next sentence:  
4 "It is recognised that this option will probably  
5 best serve the need for accountability to the  
6 Secretary of State for Wales and potentially could  
7 also lead to a co-operative co-existence with the  
8 National Blood Authority and also the Scottish and  
9 Irish Transfusion Services."  
10 Then if we go over the page to page 10, we can  
11 see a bit more detail at 7.4 about the option of  
12 incorporating it as the fifth transfusion centre  
13 within the South West Zone:  
14 "This option would embrace entirely the ideals  
15 of the NBA although further evaluation is necessary to  
16 examine the ability to retain overall accountability  
17 to the Secretary of State for Wales. It must be  
18 recognised that all strategic planning within the  
19 [NBA] has already taken place and the zonal planning  
20 is now well advanced. The timescale for incorporation  
21 of Wales as a potential fifth Centre within the South  
22 West Zone, therefore, could mean that professionals  
23 within the Welsh service would have little influence  
24 regarding already decided strategy and policy.  
25 However, because this option provides the support and

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1 document to page 38, we can see what the ultimate  
2 recommendation of this report was:  
3 "In making a recommendation, it is recognised  
4 that Option B: Incorporation into the NBA as a fifth  
5 Transfusion Centre within the South West Zone should  
6 be discarded, on the basis of poor satisfaction of  
7 quality financial evaluations.  
8 "In examining the remaining two options,  
9 Option A: Do minimum (NBTS(W) Special Health  
10 Authority) and Option C: NBTS(W) as four zone within  
11 the NBA, it has been clearly shown that Option A far  
12 outweighs Option C as far as satisfaction of quality  
13 criteria, there being little difference in the  
14 financial evaluations.  
15 "It is therefore recommended that the option of  
16 choice, based on quality criteria, is ...  
17 "... Do minimum ...  
18 "This would best serve the needs of the people  
19 of Wales in offering good stewardship of capital  
20 assets, effective service delivery and maintenance of  
21 accountability to the Secretary of State for Wales."  
22 So that was the proposal. In fact, it appears  
23 that that was not taken up because the service  
24 continued to be managed within the Welsh Health Common  
25 Services Authority, so a Special Health Authority was

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1 guidance of a large organisation with the same overall  
2 service objectives, it is retained for further  
3 evaluation."  
4 Then over the page we see a bit more detail  
5 about the third proposal, which is "[NBTS (Wales)] as  
6 a fourth zone within NBA":  
7 "This option, whilst embracing the ideals of the  
8 NBA, would offer an initial consideration greater  
9 opportunity for maintaining accountability to the  
10 Secretary of State for Wales and deserves further  
11 evaluation. However, the difficulties regarding  
12 strategic planning are also to be recognised and there  
13 could be some difficulty in engrafting Wales as  
14 a fourth zone subsequent to any formation of the NBA.  
15 It is assumed that this option, despite that fact that  
16 [NBTS (Wales)] has substantially lower annual  
17 collection volume than the equivalent English zones,  
18 would enable Wales to have similar status to  
19 an equivalent English zone. This would be reflected  
20 in the Managing Director of [NBTS (Wales)] being  
21 a member of the NBA Management Executive, and there  
22 being a Welsh member on the NBA Board. This option is  
23 therefore retained for future *[sic]* evaluation."  
24 **SIR BRIAN LANGSTAFF:** "... for further evaluation."  
25 **MS SCOTT:** I'm sorry. Then if we go lastly on this

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1 not, in fact, at that stage established.  
2 Now, initially, the Blood Transfusion Service in  
3 Wales reported to the Ministry of Health and then the  
4 Department of Health and Social Security, and then  
5 from 1965 it reported to the Welsh Office. The Welsh  
6 Blood Service was formed in 1999 and reported to the  
7 Senedd. Also, in 1999 responsibility for NBTS, for  
8 the Welsh Blood Service transferred over to the  
9 Valindre NHS Trust, pursuant to the Valindre National  
10 Health Service Trust Establishment Amendment  
11 Order 1999.  
12 Now, the director of the Cardiff Regional  
13 Transfusion Centre was Dr Napier from 1978 to 1998 and  
14 he also held the position of as part-time medical  
15 director of the Welsh Blood Service from 1999 to 2002,  
16 and we'll be hearing oral evidence from him next week.  
17 So that, sir, is the position of the Welsh Blood  
18 Service, insofar as it -- and, sir, you will have  
19 noticed that I've only made mention of South and  
20 Mid-Wales.  
21 The position in relation to North Wales was  
22 different. So hospitals in North Wales were served by  
23 the Regional Transfusion Centre in Liverpool, hence  
24 why it was significant that that Regional Transfusion  
25 Centre was being merged by the NBA.

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1 That position continued to be the case after the  
2 formation of the NBA in 2003. So when there was  
3 a split between England and Wales on 1 April 2003 with  
4 the establishment of the National Blood Authority, the  
5 hospitals in North Wales continued to be serviced by  
6 the Liverpool Regional Transfusion Centre. So they  
7 effectively went over to the NBA and formed part of  
8 the National Blood Authority.

9 In 2005 when NHSBT was formed as a Special  
10 Health Authority it was a Special Health Authority for  
11 England and Wales because it incorporated the  
12 hospitals in North Wales, or the services for the  
13 hospitals in North Wales, I should say.

14 So the NHSBT took responsibility for those  
15 county boroughs in North Wales that had historically  
16 been served by the Liverpool Regional Transfusion  
17 Centre and had formed part of the English service. It  
18 was not until 2016 that management of the provision of  
19 hospitals in North Wales transferred to NHSBT to the  
20 Welsh Blood Service. So it was not until 2016 that  
21 there was a unified Welsh Blood Service.

22 It's perhaps unsurprising in those  
23 circumstances, ie one Regional Transfusion Centre in  
24 Wales and the fact that North Wales was serviced by  
25 an English Regional Transfusion Centre, that the Welsh

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1 Regional Transfusion Director -- and for the period of  
2 time the Inquiry is concerned with that was  
3 Dr Napier -- was part of the same committees, groups  
4 and decision-making forums as the English Regional  
5 Transfusion Directors.

6 So we see Dr Napier attending Regional  
7 Transfusion Director meetings in England, we see  
8 Cardiff as being part of the western, south western  
9 zone of Regional Transfusion Centres, as created by  
10 Dr Tovey, and we see Dr Napier attending or at least  
11 being invited to attend those meetings, and we see,  
12 occasionally on minutes of meetings for advisory  
13 committee and central committee, and so on, Welsh  
14 representatives, but the question as to how -- as to  
15 the extent to which Wales was represented on  
16 decision-making bodies and advisory forums is an issue  
17 to be explored at the hearings.

18 Sir, I'm now going to move on to Northern  
19 Ireland and in common with the position in Wales,  
20 there is at present not much information available to  
21 the Inquiry about the history of the Northern Irish  
22 Blood Transfusion Service and, again, that is  
23 something that we continue to investigate and it may  
24 be that more evidence comes to light during the oral  
25 hearings.

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1 In 1948, the Northern Irish service became the  
2 responsibility of the Northern Ireland Hospitals  
3 Authority and in 1953 a new headquarters was  
4 established in Belfast which later became the Belfast  
5 Regional Transfusion Centre.

6 Also in 1953, the Service started to use  
7 a mobile donation unit, which was the first of its  
8 kind in the United Kingdom.

9 At this stage, the blood transfusion  
10 laboratories were at the Royal Victoria Hospital in  
11 Belfast. In 1961 they moved to Belfast City Hospital,  
12 but in 1970 the laboratories and the blood donor  
13 organisation were brought together in one building and  
14 amalgamated into a single organisation.

15 In Northern Ireland, the NHS was merged with  
16 the broader social care system in 1973 and called the  
17 Health and Personal Social Services and later the  
18 Health and Social Care system.

19 Between 1972 and 1999, the health system of  
20 Northern Ireland was managed by the UK Government via  
21 the Northern Ireland office.

22 So until 1999, public and social policy  
23 decisions appear to have been taken at Westminster and  
24 communicated through the Secretary of State within the  
25 Northern Ireland office, who answered directly to the

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1 UK Government.

2 During this period of direct rule, 1972 to 1999,  
3 it appears that the default position in terms of  
4 reform and the development of policy and strategy in  
5 health and social services was to mirror English  
6 policy decisions.

7 During this time, the service came under  
8 the remit of the Eastern Health and Social Services  
9 board.

10 On 1 June 1994, a special agency came into -- it  
11 was established. A special -- sorry, a special health  
12 and social care agency was established. The Personal  
13 Social Services (Special Agencies)(Northern Ireland)  
14 Order enabled the establishment -- sorry, sir, I've  
15 got that rather muddled. Let me start that again.

16 On 1 June 1994, an order came into operation  
17 which enabled the establishment of a special health  
18 and social care agency to which the Department of  
19 Health and Social Services could delegate its  
20 functions.

21 Also on 1 June 1994, the Northern Ireland Blood  
22 Transfusion Service special agency was established,  
23 established as a special health and social care agency  
24 pursuant to the order that allowed such agencies to be  
25 established.

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1 On the same date, directions came into force  
 2 which set out what the functions of the Northern  
 3 Ireland Blood Transfusion Service were, and those  
 4 directions required it to ensure that all hospitals  
 5 and other clinical units in Northern Ireland are  
 6 provided with adequate supplies of blood and blood  
 7 products.  
 8 In 1995, the Northern Ireland Blood Transfusion  
 9 Service moved to a purpose-built facility on the City  
 10 Hospital site in Belfast, and this remains their  
 11 headquarters.  
 12 The service had one Regional Transfusion Centre  
 13 in Belfast. The first director of the service,  
 14 between 1969 and 1980, was Colonel TE Field, followed,  
 15 from June 1980 to May 1994, by Dr Morris McClelland,  
 16 who was also the Regional Transfusion Director of the  
 17 Belfast Regional Transfusion Centre.  
 18 From June '94 and the creation of the Northern  
 19 Ireland Blood Transfusion Service,  
 20 Dr Morris McClelland's title became that of chief  
 21 executive and medical director, and he stepped down  
 22 in 2009.  
 23 **SIR BRIAN LANGSTAFF:** So he served for 29 years, from  
 24 1980?  
 25 **MS SCOTT:** Yes.

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1 We can see from the minutes of the meetings that  
 2 we have that a representative of the Northern Ireland  
 3 Blood Transfusion Service attended English and Welsh  
 4 Regional Transfusion Director meetings from the 1960s  
 5 through to 1989, when the meetings were abolished.  
 6 We can also see that Dr Morris McClelland was  
 7 invited to attend the Scottish National Blood  
 8 Transfusion Directors' meetings and the co-ordinating  
 9 group meetings from the end of 1982, and we can also  
 10 see that the Northern Ireland Office, via  
 11 a representative of the Department of Health and  
 12 Social Services, Northern Ireland, attended meetings  
 13 of the advisory committee of the National Blood  
 14 Transfusion Service.  
 15 Again, the extent to which there was  
 16 representation in decision-making forums for the  
 17 Northern Ireland Blood Transfusion Service is  
 18 something we will explore in the forthcoming hearings.  
 19 It's just worth noting before leaving Northern  
 20 Ireland that the service had had its plasma  
 21 fractionated by BPL, but in the early 1980s it appears  
 22 that it began sending its plasma to Scotland for  
 23 fractionation at PFC.  
 24 **SIR BRIAN LANGSTAFF:** The "early 1980s" can cover a wide  
 25 variety of years.

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1 **MS SCOTT:** It can.  
 2 **SIR BRIAN LANGSTAFF:** Some of which are of great  
 3 significance in this Inquiry. When?  
 4 **MS SCOTT:** My recollection is it was 1982 to -- about  
 5 1982, 1983. Let me just check that that is correct,  
 6 that my recollection is correct.  
 7 Perhaps, sir, I can get back to you on the  
 8 specific date.  
 9 **SIR BRIAN LANGSTAFF:** It may be a slowly developing  
 10 process over a period of time, I appreciate, but it  
 11 would be useful to know when it started and when  
 12 effectively it became the complete picture.  
 13 **MS SCOTT:** Yes.  
 14 Sir, then I come last but not least, of course,  
 15 to Scotland. So Scotland originally had a walking  
 16 blood donor panel established in Edinburgh by  
 17 a Mr Jack Copland at the Edinburgh Royal Infirmary.  
 18 There were initially 12 volunteers on the panel  
 19 and they would be collected and taken to the patient  
 20 when blood was required.  
 21 **SIR BRIAN LANGSTAFF:** So when they are described  
 22 as a "walking", they are collected?  
 23 **MS SCOTT:** That's what I understand.  
 24 Once it looked like there was going to be an  
 25 outbreak of war, the Second World War, the Department

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1 of Health set up a transfusion subcommittee and this  
 2 recommended that stores of blood should be made  
 3 available in various centres. So by the beginning of  
 4 World War II there were blood banks at the Royal  
 5 Infirmary in Edinburgh and at Stobhill Hospital in  
 6 Glasgow.  
 7 In 1940 the Scottish National Blood Transfusion  
 8 Association, a charitable body, was formed to run the  
 9 Blood Transfusion Service. At this stage, the  
 10 Scottish Blood Transfusion Service consisted of five  
 11 regional blood transfusion centres: the Edinburgh  
 12 Regional Transfusion Centre served Edinburgh and the  
 13 south east of Scotland; there was a centre in Glasgow  
 14 that served Glasgow and the west of Scotland; a centre  
 15 in Dundee that served Dundee and the east of Scotland;  
 16 in Aberdeen, served Aberdeen and the north-east of  
 17 Scotland; and in Inverness serving Inverness and north  
 18 Scotland.  
 19 Each transfusion centre had a transfusion  
 20 director and, in addition, there was from  
 21 the beginning a national organiser. Initially this  
 22 was Mr Copland.  
 23 By 1944, the centres combined had 57,000 donors,  
 24 and in 1948, of course, we know that the National  
 25 Health Service was created, and at that stage the

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1 blood service became the responsibility of the  
 2 Secretary of State for Scotland. So whereas  
 3 the position in England was that, on the establishment  
 4 of the National Health Service, that was devolved to  
 5 the regions, in Scotland it remained with Central  
 6 Government, the responsibility.

7 The Scottish National Blood Transfusion  
 8 Association continued as a charitable body which  
 9 managed the blood service through its Executive  
 10 Committee, but the Secretary of State for Scotland  
 11 took over all its premises, equipment and staff.

12 **SIR BRIAN LANGSTAFF:** Can I just understand that.  
 13 Was did taking over its premises, equipment and  
 14 staff consist of and where were the lines drawn  
 15 between that and management, which you say remained  
 16 with the charity?

17 **MS SCOTT:** Sir, I don't have --

18 **SIR BRIAN LANGSTAFF:** Or isn't it clear?

19 **MS SCOTT:** It's not clear to me and it may be something  
 20 that we can explore as we go through the hearings.  
 21 But when one looks at the meeting minutes, it's clear  
 22 that Regional Transfusion Centre directors are having  
 23 to make bids for improvements to accommodation for  
 24 equipment and so on to Central Government, and so it  
 25 seems that the funding was centrally -- was with

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1 Central Government, but quite what the role of the  
 2 SNBTA was in terms of management is not clear to me at  
 3 the moment.

4 **SIR BRIAN LANGSTAFF:** So in addition to premises,  
 5 equipment and staff, one could add financing or  
 6 funding, could one?

7 **MS SCOTT:** Yes, that's my current understanding but  
 8 I suspect that more will come clear as we progress  
 9 through the hearings.

10 **SIR BRIAN LANGSTAFF:** It might. I mean, if it's a charity  
 11 then it may well have drawn its money from other  
 12 sources.

13 **MS SCOTT:** Yes. And we see as well that it survives  
 14 various -- it effectively ends up as a donor  
 15 organisation, the SNBTA, surviving changes to the  
 16 structure of the service.

17 Can we look at PRSE0001217. This is a circular  
 18 dated 3 November 1972 entitled "Health Service  
 19 Reorganisation Scotland", and it was a circular issued  
 20 by the Scottish Home and Health Department. We can  
 21 see that on page 5 at the bottom there, Scottish Home  
 22 and Health Department.

23 Then if we go back, please, to the first page we  
 24 can see it's entitled:  
 25 "Sir

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1 "COMMON SERVICES AGENCY  
 2 "INTRODUCTION  
 3 "1. This circular indicates the likely form and  
 4 functions of the Common Services Agency and describes  
 5 the intended initial steps towards setting it up."  
 6 Sir, this was issued by the Scottish Home and  
 7 Health Department, and we can see what the purpose of  
 8 the CSA was if we go to page 2, paragraph 5:  
 9 "The CSA's prime role will be to act as an agent  
 10 for the health boards in providing them with important  
 11 supporting services of a kind likely to be best  
 12 organised centrally. The broad policies and questions  
 13 of broad resource allocation in respect of these  
 14 services will be decided by the Secretary of State on  
 15 the advice of the Planning Council, as appropriate, in  
 16 the light of the needs of the health boards and of the  
 17 Department for the services being [funded (*sic*)] for  
 18 them."  
 19 Then if we go to annex A, which we find at  
 20 page 6, we see "Proposed functions of the common  
 21 service agency", and if we go down to "A. Services",  
 22 we can see at (iii) that -- sorry, (iv), rather, it  
 23 includes Blood Transfusion Services.  
 24 So the proposal is for the creation of this  
 25 common service agency to which the functions of the

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1 blood service would be transferred. And we can see  
 2 that the central organisation -- if we go back to  
 3 page 2, the central organisation, the structure of the  
 4 CSA, at paragraph 6:  
 5 "The CSA will be operating a range of disparate  
 6 services and this fact will determine its basic  
 7 organisation. The main responsibility for the day to  
 8 day running of each service within the allocated  
 9 expenditure and in accordance with the broad policies  
 10 will fall to the chief officer or director of that  
 11 division of the CSA; and he will in most cases be  
 12 directed responsible to the Management Committee or to  
 13 any sub-committee which may be set up for the  
 14 particular service."  
 15 Then if we go over the page to paragraph 11  
 16 under "Policies", page 3, paragraph 11:  
 17 "It is envisaged that the broad policies within  
 18 which most divisions of the CSA will work will have  
 19 been laid down by the Secretary of State having regard  
 20 to the needs and priorities of those for whom the  
 21 service is provided and to any advice from the  
 22 Planning Council. Each division will operate within  
 23 its predetermined budget expressed as an earmarked  
 24 allocation by the Department to the CSA in the light  
 25 of budget estimates submitted annually through the

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(19) Pages 73 - 76



1 Management Committee."  
 2 So the proposal is for a very much centralised  
 3 structure, centrally funded, centrally managed, of the  
 4 blood services within this common service agency.  
 5 On issue of this circular, there was some  
 6 significant concern on the part of the Regional  
 7 Transfusion Directors about the plan. Their concerns  
 8 were not only that there was no detail about precisely  
 9 how the transfer was going to work but also that it  
 10 would be an overly bureaucratic structure. And so  
 11 they set out their views in a number of documents, but  
 12 I'm just going to look at one of those. It's an  
 13 PRSE0004463.  
 14 It's a letter written to NA Milne, Hon  
 15 Secretary, in Edinburgh, and if we go to the second  
 16 page of the document we can see it's signed by  
 17 a number of Regional Transfusion Centre Directors,  
 18 including director Dr John Cash, who was the director  
 19 of Edinburgh at the time, and Mr John Watt, who was  
 20 the first scientific director of PFC.  
 21 If we go back to the first page, we can see that  
 22 the subject of the letter is "Health Service  
 23 Reorganisation, Scotland - The Blood Transfusion  
 24 Service", and it starts:  
 25 "1. Following a meeting of the Regional

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1 Agency, but also calls into question the choice of  
 2 this Agency as the organisation best suited to  
 3 undertake the management of the Blood Transfusion  
 4 Service in Scotland. In particular it is stressed  
 5 that far reaching changes in the Clinical, Scientific,  
 6 Technical and Organisational spheres of blood  
 7 transfusion practice have emerged since the present  
 8 proposals were first considered. They appreciate that  
 9 detailed information about the intentions of the  
 10 Common Services Agency may not be available to either  
 11 the Scottish National Blood Transfusion Association or  
 12 the Scottish Home and Health Department  
 13 representatives. If this is so, it reinforces the  
 14 need to delay implementation of [the circular].  
 15 "4. As the professional group directly  
 16 responsible for the operation of the Blood Transfusion  
 17 Services in Scotland, they therefore consider it their  
 18 duty to make the following proposals:-  
 19 "(i) That arrangements for the transfer  
 20 responsibility for the Blood Transfusion Service to  
 21 the Common Services Agency be held in abeyance, in  
 22 order to allow full and urgent discussions to take  
 23 place between the Medical and Scientific Directors,  
 24 the Scottish National Blood Transfusion Association,  
 25 the Central Consultative Committee and Senior

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1 Directors and the Scientific Director of the Protein  
 2 Fractionation Centre, held in the Regional Blood  
 3 Transfusion Centre at Edinburgh ... on 9 January 1974,  
 4 I have been requested to convey to you their unanimous  
 5 opinion and constructive suggestions regarding the  
 6 future arrangements for the management of the Blood  
 7 Transfusion Service in Scotland.  
 8 "2. They desire to express their alarm and deep  
 9 concern that the Scottish National Blood Transfusion  
 10 Association has indicated its intention to transfer  
 11 its responsibilities to the Common Services Agency on  
 12 April 1st 1974, solely, as it appears to the  
 13 Directors, on the basis of Circular HSR(73)C40."  
 14 Which is the circular we just looked at.  
 15 "They wish to convey in the strongest possible  
 16 terms that they consider the proposals for the  
 17 transfer of these responsibilities as set out in [the]  
 18 circular to be totally inadequate as a basis on which  
 19 to judge whether the immediate and future commitments  
 20 to the Health Service can be effectively discharged.  
 21 "3. In view of the imminent changes in the  
 22 scope and function of the Blood Transfusion Service,  
 23 it is their considered opinion that the lack of detail  
 24 not only renders the document unacceptable as  
 25 a formula for their transfer to the Common Services

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1 Representatives of the Scottish Home and Health  
 2 Department.  
 3 "(ii) That the Scottish National Blood  
 4 Transfusion Association be asked to continue in office  
 5 in its present form, with the addition of the National  
 6 Medical Director and the Administrative Officer with  
 7 supporting staff, until such time as an acceptable  
 8 solution for the effective management of that Blood  
 9 Transfusion Service in Scotland has been agreed."  
 10 So despite this request from the transfusion  
 11 directors, in April 1974 the Blood Service was  
 12 reorganised and placed administratively within the  
 13 newly formed Common Service Agency of the Scottish  
 14 Health Service, in a division of the CSA called  
 15 Scottish National Blood -- the Scottish National Blood  
 16 Transfusion Service.  
 17 The CSA was overseen by the Scottish Home and  
 18 Health Department and its successors, namely the  
 19 Scottish Executive Health Department and the Scottish  
 20 Government Health Department.  
 21 The Scottish Home and Health Department and its  
 22 successors were administered prior to devolution by  
 23 the Scottish Office, Department of the Secretary of  
 24 State for Scotland. And since devolution in 1999, the  
 25 Common Services Agency has been administered through

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(20) Pages 77 - 80

1 the relevant minister, currently called the Minister  
 2 of Health and Social Care, who is answerable to the  
 3 Scottish Parliament.  
 4 The functions of the CSA were initially set out  
 5 in the National Health Service (Functions of the  
 6 Common Services Agency) (Scotland) Order 1974, and  
 7 required the CSA to supply human blood for the  
 8 purposes of carrying out blood transfusion and related  
 9 services including the production of blood fractions.  
 10 Its functions also included the donor services  
 11 previously administered by the SNBTA which continued  
 12 as a charitable body to represent blood donors.  
 13 So I think, sir, in answer to your question,  
 14 I think that may be the answer to the question:  
 15 the SNBTA was concerned with donor services and the  
 16 transfer of the equipment, personnel and accommodation  
 17 was in relation to the other services of the Blood  
 18 Service.  
 19 In October 1976, the Transfusion Directors sent  
 20 the Scottish Home and Health Department a paper  
 21 setting out their views on the future of the Blood  
 22 Transfusion Service, and we can see that at  
 23 PRSE0001535.  
 24 We can see the covering letter is to the  
 25 Scottish Home and Health Department, Dr McIntyre, and

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1 or available to, it, such independent specialist and  
 2 other advice as was available within its predecessor,  
 3 the Executive Committee of SNBTA. This lack of  
 4 professional expertise and clinical user involvement  
 5 is considered by the Transfusion Directors to be  
 6 a retrograde step in the management of the service.  
 7 "5. For some years before 1974 it had been  
 8 planned that a small BTS Headquarters should take over  
 9 the duties of the part-time officers of SNBTA and the  
 10 medical secretary and administrative officer provided  
 11 by SHHD. In the event the headquarters was not  
 12 established until nearly 1974 at the time of transfer  
 13 to CSA, when a CSA headquarters office was also  
 14 established, apparently to undertake on behalf of CSA  
 15 Divisions duties hitherto carried out within the  
 16 Divisions themselves. The resultant duplication of  
 17 effort, made worse by the recruitment of inexperienced  
 18 staff to CSA headquarters, has been expensive,  
 19 unrewarding to all concerned and detrimental to  
 20 effective management. The Transfusion Directors are  
 21 now in no doubt that the appropriate place for BTS  
 22 central administration is in its own headquarters  
 23 aided by financial and management containing and  
 24 internal audit. This arrangement would be cost  
 25 effective. Interposing CSA headquarters as a tier

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1 it says:  
 2 "You will remember the discussion at the BTS  
 3 Directors' meeting on 1 July at which it was agreed  
 4 that a paper concerning medical staffing and the  
 5 future of blood transfusion should be submitted to  
 6 you."  
 7 Then the middle of the next paragraph:  
 8 "I am accordingly enclosing a draft discussion  
 9 paper on future management of BTS which has been  
 10 agreed all by BTS Directors."  
 11 Then we get to the paper itself on page 2, and  
 12 it's called "Future management of the Blood  
 13 Transfusion Service in Scotland". Paragraph 1:  
 14 "This paper sets out, as a basis for discussion,  
 15 the consensus views of Scottish Transfusion Directors  
 16 on the future management of the Blood Transfusion  
 17 Service in Scotland."  
 18 Paragraph 4:  
 19 "The position in 1976  
 20 "The anxiety expressed during these meetings has  
 21 been realised."  
 22 It's referring to the anxiety expressed by the  
 23 directors as it's gone over the history of the  
 24 development of the CSA:  
 25 "The Management Committee does not have within,

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1 between the Directors of CSA Divisions and the  
 2 Management Committee to which they are accountable has  
 3 been most unfortunate."  
 4 Then it goes on at paragraph 6, over the page,  
 5 after the quote there:  
 6 "After [two and a half] years' experience and  
 7 following careful consideration it is the view of the  
 8 Transfusion Directors that BTS should be administered  
 9 as a National Service and that its nature renders it  
 10 unsuited to management by a committee composed  
 11 entirely of Health Board members and officers and  
 12 officials of SHHD within the framework of CSA."  
 13 Then the proposal that's made for the future is  
 14 set out at paragraph 7:  
 15 "It is suggested that the service should  
 16 transfer to a Management Committee responsible to the  
 17 Secretary of State and having the following  
 18 membership:  
 19 "Chairman, appointed by Secretary of State ...  
 20 "Transfusion Service National Medical  
 21 Director ...  
 22 "Transfusion Directors ...  
 23 "Donor interest ...  
 24 "User interest ...  
 25 "Health Board interest ..."

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(21) Pages 81 - 84

1 And:  
 2 "... Observers [from the Home and Health  
 3 Department] (Medical, Executive and Finance) ...  
 4 "[And] The secretary to the Committee should be  
 5 the National Administrator of the [Blood Transfusion  
 6 Service].  
 7 "The Committee would assume the executive  
 8 authority presently exercised by the CSA Management  
 9 Committee and there would be no further need for the  
 10 present Co-ordinating Group of Transfusion Directors;  
 11 the Directors' professional meetings are however  
 12 essential and should continue. It is hoped that the  
 13 Secretary of State would continue to receive advice  
 14 from the Blood Transfusion/Advisory Group to the  
 15 Planning Council."  
 16 The response to this we can see at PRSE0002319,  
 17 and it's dated 2 December 1976, to Ms Corrie, who sent  
 18 the paper we've just looked at. It's the second  
 19 paragraph:  
 20 "The paper [which is the paper we have just  
 21 looked at] is being circulated within the Department  
 22 and I am not yet in a position to sent you any formal  
 23 reply. It is only fair to say however that the SNBTS  
 24 is now formally a part of the NHS and can therefore  
 25 only be administered in the existing health service

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1 Committee with the remit 'to examine and report to the  
 2 Management Committee on the management arrangements  
 3 for the Blood Transfusion Service within the Common  
 4 Services Agency'. It was now urgent that the  
 5 management arrangements for the Blood Transfusion  
 6 Service be resolved, and he had therefore called  
 7 a special meeting of the Management Committee to  
 8 consider the report of the *ad hoc* Committee. A letter  
 9 had been received from Dr JD Cash on behalf of all the  
 10 Regional Directors of the Blood Transfusion Service  
 11 confirming that they accepted the recommendations of  
 12 the *ad hoc* Committee. The Chairman expressed his  
 13 appreciation."  
 14 We can see over the page what that looks like.  
 15 "After a full and frank discussion, the  
 16 Management Committee accepted the recommendations of  
 17 the *ad hoc* Committee on management arrangements in the  
 18 Blood Transfusion Service and agreed:  
 19 "(i) to establish a Sub-Committee of the  
 20 Management Committee specifically to deal with matters  
 21 relating to the Blood Transfusion Service to be known  
 22 as the Blood Transfusion Service Sub-Committee;  
 23 "(ii) that the Blood Transfusion Service  
 24 Sub-Committee should have the terms of reference set  
 25 other ion Appendix 1 ..."

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1 framework."  
 2 It goes on to say that that has been made clear  
 3 to the directors on a number of occasions.  
 4 Undeterred by this, the directors continue to  
 5 press their point that the current structure is  
 6 expensive and, frankly, in their view, doesn't work.  
 7 And an agreement is reached in June 1977.  
 8 We can see that recorded in a document at  
 9 PRSE0000108.  
 10 This is a minute of a special meeting of the  
 11 management committee of the Common Services Agency  
 12 held on 26 April 1978. If we go down to the bottom of  
 13 this page, at 681, "Matters arising from these  
 14 minutes":  
 15 "(i) Minute 648(i) - Management Arrangements in  
 16 the Blood Transfusion Service.  
 17 "There was submitted the report of the *ad hoc*  
 18 Committee on management arrangements in the Blood  
 19 Transfusion Service. Presenting the report, the  
 20 Chairman recalled that in 1977, the Blood Transfusion  
 21 Service Regional Directors had asked to meet the  
 22 Secretary of State to express their concern at  
 23 management arrangements in the Blood Transfusion  
 24 Service. The Management Committee, at their meeting  
 25 on 15 June 1977, had agreed to establish an *ad hoc*

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1 We can see that at page 5 of this document:  
 2 "There shall stand referred to the Blood  
 3 Transfusion Service Sub-Committee:  
 4 "(1) The review of the operational activity of  
 5 the Blood Transfusion Service to ensure that the  
 6 services provided are efficient and economic and  
 7 within approved financial allocations.  
 8 "(2) The formulation of proposals for the  
 9 development and improvement of the services ...  
 10 "(3) Liaison with other authorities on  
 11 developments in the [Service].  
 12 "(4) The review of complaints ...  
 13 "(5) The control of the establishment of staff  
 14 within the [Service] and the appointment and dismissal  
 15 of staff ...  
 16 "(6) The application to staff ... of nationally  
 17 approved terms and conditions of service ...  
 18 "(8) The provision of medical and operational  
 19 equipment required ...  
 20 "(9) The preparation of capital programme ...  
 21 "(10) The appointment of such *ad hoc* advisory  
 22 committees and working parties as may be necessary to  
 23 advise on specific matters relating to the service  
 24 provided by the Blood Transfusion Service."  
 25 So those are the terms of reference of the

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(22) Pages 85 - 88



1 subcommittee. Then if we go back to page 2, it sets  
 2 out the constituents -- the constitution, rather, of  
 3 the Blood Service Subcommittee at subparagraph (iii)  
 4 there:  
 5 "Six members of the Management Committee (one of  
 6 whom would be Convener) -- including the Chairman and  
 7 Vice-Chairman as ex-officio members in terms of the  
 8 Standing Orders of the Agency, Two specialists in  
 9 clinical medicine, Two specialists in laboratory  
 10 medicine, One medical officer from the Scottish Home  
 11 and Health Department, One representative of Donor  
 12 Interests."  
 13 Then we see at (v):  
 14 "... that the National Medical Director should,  
 15 as a matter of course, receive the agenda and  
 16 supporting papers for each meeting of the Blood  
 17 Transfusion Service Subcommittee and attend or be  
 18 represented and [over the page] that the other  
 19 Directors within the Blood Transfusion Service should  
 20 also receive copies of the agenda and supporting  
 21 papers of each meeting and, subject to the agreement  
 22 of the Convener, attend if they so wished ..."  
 23 So that was the agreement that was reached in  
 24 June 1977, and so what then happened was that that  
 25 subcommittee, in turn, set up a working party in which

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1 Social Security on co-ordination of the English and  
 2 Welsh and Scottish Blood Transfusion Services.  
 3 The first joint committee between the Scottish  
 4 and the English services was the formation of the  
 5 SNBTS/NBTS liaison committee in June 1990.  
 6 We can also see from the minutes that there was  
 7 regular attendance by Professor Cash at Regional  
 8 Transfusion Director meetings in England, that Dr Cash  
 9 attended the Advisory Committee on the NBTS formed in  
 10 December 1980, although that Committee was dealing  
 11 only with matters concerning England and Wales, and  
 12 there was often an English director or  
 13 a representative of the National Directorate, once  
 14 that had been formed, at Scottish Regional Transfusion  
 15 Director meetings.  
 16 In 1990, the Scottish National Blood Transfusion  
 17 Service created a General Manager position and that  
 18 position was then renamed National Director in 1996,  
 19 and the National Medical Director, who was  
 20 Professor Cash, became the National Medical and  
 21 Scientific Director.  
 22 So the regional directors and the PFC director  
 23 became managerially accountable to the General  
 24 Manager, who then became known as the National  
 25 Director, and professionally accountable to the

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1 representatives of the -- in which the transfusion  
 2 directors participated.  
 3 There were further legislative changes in 1978,  
 4 which had the effect of reconstituting the CSA, and so  
 5 members of the management committee of the CSA were  
 6 appointed by the Secretary of State and that structure  
 7 remained largely unchanged, following the appointment  
 8 of Professor Cash in 1978 as the National Medical  
 9 Director. Again, the extent to which the regional  
 10 services retained autonomy through the period will be  
 11 an issue that we will -- sorry, the extent to which  
 12 the individual Blood Transfusion Centres retained  
 13 autonomy through this period will be explored within  
 14 the hearings.  
 15 We can see from the minutes that are available  
 16 to us that, through the late 1970s and 1980s the  
 17 Scottish National Blood Transfusion Service  
 18 Co-ordinating Group met on a regular basis, as did the  
 19 SNBTS directors. I've already mentioned, when I was  
 20 doing the presentation on England, that the first  
 21 formal liaison, if you like, between Scotland and  
 22 England and Wales came when the advisory committee to  
 23 the National Blood Transfusion Service in England was  
 24 formed in December 1980, and there was -- part of the  
 25 remit was to advise the Department of Health and

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1 National Medical and Scientific Director.  
 2 The SNBTS management board at that stage  
 3 compromised (sic) the General Manager, the National  
 4 Medical and Scientific Director, the five Transfusion  
 5 Centre Directors the Director of PFC, a National Donor  
 6 Services Manager, Director of Human Resources,  
 7 a Director of Finance, and a Director of Quality.  
 8 Following a strategic review in 1998-1999, SNBTS  
 9 was restructured to move away from regional structure  
 10 towards a national structure and, since that time, all  
 11 blood donor services have been managed nationally.  
 12 A directorate for operations was created to manage  
 13 donor services, manufacturing and logistics and the  
 14 number of blood processing and testing units was  
 15 reduced to two.  
 16 A national quality directorate was formed along  
 17 with other national support services and hospital  
 18 blood banking and related clinical and laboratory  
 19 functions remained distributed within the Regional  
 20 Transfusion Centres. The Regional Transfusion  
 21 Directors became clinical directors.  
 22 In 2002 to 2003, the Common Services Agency  
 23 underwent a strategic review and, once again, the  
 24 clinical directors of Scottish National Blood  
 25 Transfusion Service expressed their dissatisfaction

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(23) Pages 89 - 92

with the CSA, as being not qualified to manage the performance of the SNBTS, and a report authored at that time concluded that there was some justification for those concerns because of the lack of a developed system of clinical governance in the CSA and a lack of clarity about the role and purpose of the board and a lack of clarity about how the CSA and its divisions add value to each other's activities.

Following that review, the governance arrangements were strengthened. The SNBTS national director became an executive director of the CSA board and the CSA board adopted the governance structure of other health boards, including a clinical governance committee and a centralisation of some of its support services.

On 1 October 2008, the National Health Service Functions of the Common Services Agency Scotland Order removed the production of blood fractions from the functions of the CSA. The CSA remained responsible for the provision of supplies of human blood for transfusion and related services, and there was a period of wider organisational structural change in 2012-2013 resulting in consolidation of a number of CSA divisions, often called strategic business units, and the centralisation of support services, but the

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SNBTS was considered of sufficient size and specialty to retain its own identity.

In 2013, there were changes to the name. The SNBTS Board was renamed Senior Management Group and was chaired by the SNBTS national director. The medical and Scientific Committee was renamed the Clinical Governance and Safety Group and the posts of clinical directors were removed and SNBTS was organised into a number of national directorates led by associate directors. Those were donor and transport (*sic*) services, blood manufacturing, patient services and strategy planning and performance.

There's been no significant further change to structure since that time.

It appears from the documentation that the Inquiry has that the SNBTS was funded centrally from the Scottish Government's central budget rather than from region health budgets as was the case in my England and Wales, that until 2002/2003 the Scottish Home and Health Department provided the CSA with a ring-fenced budget for the blood service but, after this time, there was no ring-fenced budget so it was left to the CSA to allocate a budget to the SNBTS as part of its internal business planning.

So, sir, that brings me to the end of the

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presentation on the history and structure of the Blood Transfusion Services. The presentation is accompanied -- supported by a written presentation, which has been disclosed to Core Participant through their legal representatives and will be made available on the website, and that has more detail and references to other documents that, for reasons of time, I haven't been able to go to.

**SIR BRIAN LANGSTAFF:** Yes. Well, thank you very much. So that concludes, just before 1.00, the first part of today's business. So we will meet again at 2.00. Then it's Ms Fraser Butlin, is it, we will hear from at that stage?

**MS SCOTT:** Yes.

**SIR BRIAN LANGSTAFF:** Yes, thank you very much.  
(12.59 pm)

(Luncheon Adjournment)

(2.00 pm)

**SIR BRIAN LANGSTAFF:** Yes.

**MS FRASER BUTLIN:** Thank you.

Sir, before I start the second presentation for today, looking at early look-back processes, one question which arose earlier in Ms Scott's presentation was about plasma from Northern Ireland and when that was processed by PFC in Scotland. That

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was something that was picked up in the Belfast haemophilia centre presentation, the official request for it to be dealt with by PFC rather than BPL was in May 1981 and it was expected at that point that the first plasma would reach PFC in October 1981. All the referencing for that point can be found on the website in the Belfast presentation.

**SIR BRIAN LANGSTAFF:** Thank you.

**Presentation by Counsel to the Inquiry relating to early look-back processes**

**MS FRASER BUTLIN:** Sir, the second presentation for today, as I've said, is looking at early look-back processes. Perhaps it's worth starting by explaining that the purpose of this presentation is twofold. Firstly, it's to put a selection of the documents that the Inquiry has identified into the public domain for those who have not had access to the full set of documents that has been provided to the Core Participants.

Secondly, it's to set the scene and to provide the backdrop for subsequent witness evidence. This presentation seeks to set out what had been done previously in relation to look-back processes, albeit often informally, so that we can then explore in much more detail with the relevant witnesses what happened

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(24) Pages 93 - 96

1 with the hepatitis C look-back process.  
 2 Before I start the substance of the  
 3 presentation, it's worth just dealing with one point  
 4 of terminology. In the presentation, I will be  
 5 talking about both look-back and reverse look-back.  
 6 Look-back, or sometimes called targeted look-back, is  
 7 where a donor is identified as being positive for,  
 8 say, hepatitis B or HTLV-III and the recipients of any  
 9 transfusions are then traced. Reverse look-back is  
 10 where a recipient of a blood transfusion or -- tests  
 11 positive or was identified as suffering from jaundice  
 12 in the early days, and the donor is then traced.  
 13 Both of those processes form part of this  
 14 presentation. I am going to address three parts,  
 15 three points, in the presentation. The first thing we  
 16 will look at through the documentation is matters  
 17 we've identified dealing with early jaundice  
 18 enquiries, the investigations that were undertaken and  
 19 the extent of the tracing of donors that took place  
 20 when jaundice was suffered by a recipient of a blood  
 21 transfusion; secondly, we will look at hepatitis B  
 22 look-back processes; and, thirdly, we will look at the  
 23 HTLV-III look-back process.  
 24 So starting off then with early jaundice  
 25 enquiries, we've been unable to identify a precise

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1 "Dr Maycock reported that during the last  
 2 18 months or so, 78 cases of haematogenous hepatitis  
 3 had been reported to the Ministry, of which some  
 4 25 per cent had died, but there was no record of the  
 5 outcome of about half of the remaining cases. In view  
 6 of the importance of collecting as much accurate  
 7 information as possible of cases of haematogenous  
 8 hepatitis, he [Dr Maycock] had prepared a report form  
 9 for completion in such cases, which was submitted and  
 10 approved by the meeting with the exception of  
 11 a particular paragraph ..."  
 12 So we see Dr Maycock seeking to establish  
 13 a clearer reporting system.  
 14 We have a copy of a report form. It's not  
 15 exactly the same as what was discussed at the  
 16 January 1948 meeting but it appears to be the form  
 17 that was in use by October 1949.  
 18 That is at DHSC0100011\_006.  
 19 On that form, we can see, at points 5 and 6,  
 20 a note of the primary disease or injury, in this case  
 21 post partum haemorrhage and shock, and, 6, the reason  
 22 for the transfusion: haemorrhage and obstetric shock.  
 23 We then see notes at the bottom of this page.  
 24 Under point 8, records dealing with the subsequent  
 25 development of jaundice and what exactly happened for

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1 date when there was a requirement on regional  
 2 transfusion offices to report cases of post  
 3 transfusion jaundice to the Ministry of Health but, as  
 4 we will see, reports were certainly being made from  
 5 1947, so from a very early stage.  
 6 The documentation we have identified suggests  
 7 that notification of post-transfusion jaundice was not  
 8 always straightforward or complete, and if we could go  
 9 to DHSC0100009\_103, please, we have a letter from  
 10 a regional transfusion officer to Dr Maycock in the  
 11 Ministry of Health, dated 1 December 1947, reporting  
 12 a case of jaundice after a transfusion of plasma.  
 13 Then if we go to the second page, the officer  
 14 notes:  
 15 "I have been making enquiries around the  
 16 hospitals and talking to RSO, but in spite of the fact  
 17 that I have told them many times that we wish to have  
 18 cases of jaundice reported to us I fear that quite  
 19 a number in this area have not been reported ..."  
 20 We then have a set of minutes of a meeting of  
 21 Dr Maycock and the Regional Blood Transfusion Officers  
 22 at DHSC0100054, please.  
 23 The meeting took place on 14 January 1948, and  
 24 if we go to the bottom of the page we can see minuted  
 25 that:

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1 the patient.  
 2 If we go back up to point 7 on the same page, we  
 3 see a note which explains that two pints of plasma had  
 4 been given:  
 5 "Transfusion was given in the middle of the  
 6 night at the patient's home. Unfortunately numbers of  
 7 bottles were not kept, in the excitement of the  
 8 moment."  
 9 **SIR BRIAN LANGSTAFF:** Just the reference to the plasma  
 10 there, my eyes noticed, when you went to the very  
 11 first document you showed us, from 1 December 1947,  
 12 that's DHSC0100009\_103 --  
 13 **MS FRASER BUTLIN:** Yes.  
 14 **SIR BRIAN LANGSTAFF:** If we just go back there.  
 15 **MS FRASER BUTLIN:** DHSC0100009\_103.  
 16 **SIR BRIAN LANGSTAFF:** And if we go over:  
 17 "... the general impression I have gained ..."  
 18 It's the last five lines:  
 19 "... is that the officers who have been in the  
 20 hospitals for sometime consider the Canadian plasma  
 21 has been the cause of the [problem]."  
 22 Do we know anything about the use of plasma from  
 23 Canada?  
 24 **MS FRASER BUTLIN:** Sir, no. That's something that we also  
 25 noted as we were preparing for this presentation, and

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1 it's something that the team is looking at further.  
 2 **SIR BRIAN LANGSTAFF:** It may have been something which  
 3 originated during wartime.  
 4 **MS FRASER BUTLIN:** Indeed.  
 5 **SIR BRIAN LANGSTAFF:** But it would be just interesting to  
 6 know a bit more about it.  
 7 **MS FRASER BUTLIN:** Indeed, sir. I'm afraid it's not  
 8 something I can assist with today but it is certainly  
 9 something that's on our radar.  
 10 **SIR BRIAN LANGSTAFF:** Very well. Thank you.  
 11 **MS FRASER BUTLIN:** So we don't need to go back to it,  
 12 Soumik, but looking at the report form from 1949 we  
 13 can see that there is a note that on this occasion  
 14 batch numbers weren't recorded, and we have a similar  
 15 note of the failure to record batch numbers in  
 16 a separate report from Wales.  
 17 If we could turn to -- sorry, just one moment.  
 18 Yes, if we could have DHSC0100008\_054.  
 19 My apologies, sir, I've just noticed we're taking this  
 20 out of chronological order. We're going back to 1944.  
 21 We should have looked at it earlier. Apologies.  
 22 But this a letter that also flags up issues  
 23 around batch numbers. It's a letter from the regional  
 24 blood transfusion officer to Dr Pantom of the Ministry  
 25 of Health, highlighting that they were "asked to see

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1 a case of delayed transfusion Jaundice" that day.  
 2 There's then a description of the clinical details of  
 3 the patient and a note that she was given both plasma  
 4 and whole blood.  
 5 The point I want to note from this document is  
 6 on the second page, and that is the regional  
 7 transfusion officer recording that:  
 8 "Unfortunately the surgeon did not record the  
 9 batch number of [the] bottle of plasma. We have the  
 10 identity of the donors. Do you want any blood from  
 11 the patient. Also is it worth while our trying to  
 12 contact the donors? They are apt to be a bit touchy  
 13 when questioned."  
 14 Which is something else that we will pick up  
 15 during the presentation, the issues being raised about  
 16 how to approach donors when jaundice has been  
 17 identified.  
 18 **SIR BRIAN LANGSTAFF:** It's obviously not the first time  
 19 then that donors have been asked to help where it is  
 20 thought that the blood which they gave may well be the  
 21 source of a subsequent infection.  
 22 **MS FRASER BUTLIN:** Indeed. So, even in 1944, we can see  
 23 that this appears to be a relatively well-established  
 24 process, although we've been unable to give a more  
 25 definitive date for you.

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1 **SIR BRIAN LANGSTAFF:** Yes, thank you.  
 2 **MS FRASER BUTLIN:** Staying with the reporting system and,  
 3 apologies, returning to the forms that were used, we  
 4 have another example of a form which is helpful to see  
 5 which is from Wales, dated 15 August 1950,  
 6 DHSC0100011\_011. You'll see it's very similar to the  
 7 form we looked at just a moment ago. We can see again  
 8 at point 6 -- 5 and 6, the primary disease or injury  
 9 and the reason for the transfusion, in this case  
 10 haemorrhage and shock following a prostatectomy.  
 11 We then see at point 7, the date of the  
 12 transfusion and we can see that, on this form, there  
 13 is a record of the number for the bottle whole blood  
 14 and batch numbers for the plasma and, again, sir,  
 15 you'll notice that, against the plasma, it says "CAN",  
 16 which is something else, again, in relation to Canada  
 17 that we've noted and will explore.  
 18 We can also see here the notes in brackets after  
 19 the batch numbers and the whole blood numbers. "Donor  
 20 has not had jaundice", so that donor appears to have  
 21 been identified and communicated with but, in relation  
 22 to the second bottle of whole blood, on 23 March 1950,  
 23 they have recorded "Donor did not reply to letter".  
 24 **SIR BRIAN LANGSTAFF:** But they obviously haven't been able  
 25 to make any enquiries about the Canadian plasma if it

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1 was the Canadian plasma which was responsible.  
 2 **MS FRASER BUTLIN:** Indeed. There's no note at all of what  
 3 happened in relation to those products.  
 4 The issue of donors not necessarily responding  
 5 when they are followed up by the Regional Blood  
 6 Service is a theme that we see throughout the  
 7 time-frame.  
 8 **SIR BRIAN LANGSTAFF:** Just as a matter of interest, this  
 9 is 1950, is it?  
 10 **MS FRASER BUTLIN:** It is, sir, yes.  
 11 **SIR BRIAN LANGSTAFF:** If the Canadian -- just go back to  
 12 where we were please, Soumik. Thank you. The date  
 13 there is 28 February 1945. So, presumably, that was  
 14 the date when the plasma was first taken?  
 15 **MS FRASER BUTLIN:** It's very unclear at this point, sir,  
 16 and again it's something that we've highlighted that  
 17 we need to consider further.  
 18 **SIR BRIAN LANGSTAFF:** So it would suggest, as I think  
 19 there has been some reference in one of the other  
 20 documents you have just been showing me, that the  
 21 plasma might have been dried and reconstituted --  
 22 **MS FRASER BUTLIN:** Indeed.  
 23 **SIR BRIAN LANGSTAFF:** -- but it plainly had a long shelf  
 24 life.  
 25 **MS FRASER BUTLIN:** Indeed, yes. I think that's not

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1 something we've seen particularly before.  
 2 **SIR BRIAN LANGSTAFF:** This is -- we're told the plasma had  
 3 a much longer shelf life than red blood, it lasts for  
 4 two or three years. This is an example of it being  
 5 used five years after -- if this date is the date of  
 6 taking -- five years after it has been taken and,  
 7 presumably, if it's been dried, dried pretty  
 8 quickly --

9 **MS FRASER BUTLIN:** Indeed.

10 **SIR BRIAN LANGSTAFF:** -- and it would suggest that it was  
 11 wartime.

12 **MS FRASER BUTLIN:** Indeed, 1945. Yes, indeed. It's  
 13 something, sir, that we are aware we need to look  
 14 further at.

15 If we then continue into the 1960s we have  
 16 a number of examples where reverse look-back and  
 17 look-back had been mostly successful. One of those  
 18 examples is from Wales in December 1964. We have  
 19 a letter of December 1964, we don't need to put it up.  
 20 Dr Bevan informed Dr Maycock that there had been  
 21 a homologous serum jaundice case and the usual  
 22 follow-up of donors had been undertaken.

23 That was then followed up by a letter, which is  
 24 dated 4 January 1965, DHSC0100017\_002, please, Soumik.  
 25 So the letter refers to the earlier letter, which had

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1 simply said the usual follow up of donors had been  
 2 undertaken and it was addressing "three recent  
 3 donations from the implicated donor have been traced  
 4 back":

5 "One, as you know, went into post-vaccinal pool  
 6 no 50 which has now been destroyed. The second was  
 7 transfused in Orpington in 1962. A recent follow-up  
 8 of the recipient shows no evidence of any trouble  
 9 whatsoever and certainly no jaundice. The third was  
 10 transfused at Cuckfield Hospital in July, 1963.  
 11 A report has now been received to the effect that the  
 12 recipient was followed up for 12 months after  
 13 transfusion and there's no record of any jaundice  
 14 resulting.

15 "Although the donor involved has re-affirmed his  
 16 freedom from jaundice at any time, he has now been  
 17 [query] implicated on three occasions and he has,  
 18 therefore, been withdrawn from the panel."

19 So here we have an example of a donor being  
 20 identified as being problematic and the previous  
 21 donations being followed through.

22 A very similar example can be found in a report  
 23 from May 1965, DHSC0100017\_027, please.

24 This is a report, if we just look at the bottom  
 25 please, Soumik, we can see it's from the North East

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1 Metropolitan region and then we can see in section 7  
 2 a record of the bottle numbers that had been  
 3 transfused with the plasma batch number, which was not  
 4 recorded. So we have the bottle numbers of the whole  
 5 blood but no record of the plasma batch that was used.

6 We have the usual clinical notes, as well as  
 7 some liver function tests, and then, at the bottom of  
 8 the page, we have a note that's been added by the  
 9 Regional Transfusion Director, at the very bottom:

10 "Eight donors have been contacted deny a history  
 11 of jaundice or contact with a case."

12 There are eight different bottle numbers of  
 13 blood that were used so it appears that, at least in  
 14 relation to the blood, they had been able to contact  
 15 the eight donors in relation to the blood but, of  
 16 course, there was no record of the batch number of the  
 17 plasma. So it's simply another example of what was  
 18 being done during this period by way or both reporting  
 19 homologous serum jaundice and also the tracing work  
 20 that was being attempted.

21 The Inquiry -- we have also identified evidence  
 22 of ongoing difficulties in the 1960s with these  
 23 exercises. Firstly, there were issues around the  
 24 resource implications of following these processes.  
 25 If we could have DHSC0100015, please -- sorry \_241,

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1 apologies. This is a letter from Dr Drummond to  
 2 Dr Maycock, so from the Welsh region, dated  
 3 22 May 1962 and in that letter he says this:

4 "We discussed briefly at the recent MRC meeting  
 5 the matter of tracking down cases of HSJ [homologous  
 6 serum jaundice]. It is, I hope, a fair statement of  
 7 fact that our methods have produced, and are  
 8 producing, results in the way of cases of  
 9 post-transfusion serum hepatitis. More cases could be  
 10 traced, but the work has now become too great to be  
 11 adequately coped with, as I hinted in a previous  
 12 letter.

13 "It is worth considering what is involved in  
 14 a hypothetical case which has had, for example,  
 15 7 bottles of blood and 3 of SP Dried Plasma (of  
 16 different batches). Suppose the donors of the  
 17 7 bottles of blood have, between them, donated on  
 18 30 occasions. The fate of each donation has to be  
 19 accounted for -- that may mean going back 10 years, or  
 20 more, in some donors. For each donation transfused,  
 21 the recipients must be contacted. We have to  
 22 ascertain via the hospital, then GP, whether patient  
 23 still survives. If alive, we must ascertain from the  
 24 patient whether he, or she, had jaundice in the six  
 25 months following transfusion; several cases have come

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1 to light in this way. In the case of donations used  
 2 for plasma, the fate of the plasma must be ascertained  
 3 and recipients traced, as above. Finally, in case of  
 4 SP plasma, all the donors (if this region)  
 5 contributing to the pools must be accounted for and  
 6 all donations they have given back-traced as above.  
 7 "If this work is worthwhile, particularly as the  
 8 machinery for a continuing survey in one region, we  
 9 must have more hands for the job. As things are, this  
 10 work must be cut down rather than increased."  
 11 He goes on to ask for authorisation to use what  
 12 he describes as a bleeding session doctor for the work  
 13 one day a week.  
 14 Another issue that is raised in the  
 15 documentation about these processes and challenges of  
 16 them relates to the issue of reports of jaundice not  
 17 being made to the Regional Transfusion Services.  
 18 If we can have DHSC0100017\_034, please.  
 19 Again, this is a letter from Dr Drummond to  
 20 Dr Maycock, in July 1965, where he records:  
 21 "We have felt for some years that the Cardiff RI  
 22 does not notify us as many cases as it ought. I give  
 23 below figures on usage of blood and plasma and cases  
 24 of serum hepatitis notified to the BTS."  
 25 There's then data provided in letter whereby

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1 a number of cases of serum hepatitis are not being  
 2 detected at the Cardiff Royal Infirmary, although I am  
 3 not sure whether the figures are large enough to make  
 4 this difference significant."  
 5 **SIR BRIAN LANGSTAFF:** By "significant", he would be  
 6 meaning, presumably, "statistically significant", in  
 7 the sense that it is used in statistics.  
 8 **MS FRASER BUTLIN:** That would be my understanding of what  
 9 he saying, sir.  
 10 Dr Maycock then refers to a journal paper  
 11 relating to the incidence of jaundice in Philadelphia,  
 12 and that showed an incidence of 0.05 per cent. It's  
 13 just in the midst of the second paragraph:  
 14 "... i.e. slightly higher than that found in the  
 15 Welsh Region excluding the Cardiff Royal Infirmary.  
 16 However, he found an attack rate of anicteric  
 17 hepatitis equivalent to 870 per 10,000 units  
 18 transfused, i.e. an incidence of 8.7 per cent, and  
 19 concludes that in Philadelphia General Hospital there  
 20 may have been over 100 cases of anicteric hepatitis  
 21 for each icteric case diagnosed. His figures are  
 22 statistically significant."  
 23 Sir, the point of highlighting these two letters  
 24 is really the issue being raised by the Cardiff Centre  
 25 with Dr Maycock that perhaps reporting from the

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1 Dr Drummond compares the case incidence of serum  
 2 hepatitis at Cardiff RI with that of the rest of the  
 3 region or the apparent incidence in light of their  
 4 reports. He says at the end that using the case  
 5 incidence of the rest of the region:  
 6 "... the expected number of cases for the  
 7 Cardiff RI would be 13.6 cases (which is  
 8 0.034 per cent) and not 9 (which is 0.023 per cent) as  
 9 notified to the BTS."  
 10 So the case incidence that's reported appears to  
 11 be lower than that he would expect given the reporting  
 12 across the region.  
 13 He goes on, just over the page, please:  
 14 "I am not sufficient of a statistician to say  
 15 precisely what interpretation should be placed on  
 16 these figures, but it appears to me that 9 cases of  
 17 serum hepatitis is rather too few for Cardiff RI.  
 18 I would be interested to have the views of the  
 19 [Ministry statisticians] ..."  
 20 We then also have Dr Maycock's response.  
 21 DHSC0100017\_047, please.  
 22 Dr Maycock responds indicating that he hadn't  
 23 been able to show the letter to a statistician, but  
 24 halfway through the first paragraph he notes:  
 25 "It certainly looks on the face of it that

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1 hospital was too low and reporting was not happening  
 2 in the way they expected.  
 3 **SIR BRIAN LANGSTAFF:** So the difference is between  
 4 transfusions and units transfused?  
 5 **MS FRASER BUTLIN:** Yes.  
 6 **SIR BRIAN LANGSTAFF:** So -- otherwise it just looks, on  
 7 the face of it, which is why I was puzzling over the  
 8 wording, that exactly the same hospital, in exactly  
 9 the same study, has produced two completely different  
 10 results.  
 11 **MS FRASER BUTLIN:** Yes, indeed.  
 12 **SIR BRIAN LANGSTAFF:** The explanation appears to be to me  
 13 at the moment, but you can tell me if I'm right or  
 14 wrong as far as you can understand it -- or, so the  
 15 difference may be that the first, that's the incidence  
 16 of 0.05 per cent, is per transfusion, and the next is  
 17 per units transfused. But I don't quite understand  
 18 why that should produce the results that way round if  
 19 that's right. So I'm still a bit puzzled by this.  
 20 **MS FRASER BUTLIN:** I'm still somewhat puzzled by the  
 21 Philadelphia paper. But the point that is being  
 22 raised from my understanding is that, on the basis of  
 23 the number of units transfused, there is at that time  
 24 a broad understanding of the likely incidence of  
 25 jaundice, which is what Dr Drummond had raised in our

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1 previous letter as well, to say: that's what we would  
 2 expect across the region, but Cardiff's reporting  
 3 appears rather low. And my reading of Dr Maycock's  
 4 letter is that he is agreeing in light of also the  
 5 work done in Philadelphia. The precise figures from  
 6 the Philadelphia paper are not wholly clear.  
 7 **SIR BRIAN LANGSTAFF:** I'm just rowing back on what I said  
 8 a moment or two ago, it just doesn't make -- I'm not  
 9 very clear what sense it makes. I need to go to the  
 10 original article to see.  
 11 **MS FRASER BUTLIN:** I think we would. The point --  
 12 **SIR BRIAN LANGSTAFF:** It is not worth our while doing  
 13 that, it's not making that point.  
 14 **MS FRASER BUTLIN:** Exactly.  
 15 **SIR BRIAN LANGSTAFF:** It's a "Have you seen this article  
 16 by the way?" type of remark.  
 17 **MS FRASER BUTLIN:** That's exactly, sir, what I would say  
 18 that the Philadelphia paper is a little peripheral to  
 19 what we are drawing together for today and the point  
 20 of today is that Dr Maycock appears to be largely  
 21 agreeing with Dr Drummond that one would have expected  
 22 a greater reporting of homologous serum -- sorry serum  
 23 hepatitis from the Cardiff RI.  
 24 **SIR BRIAN LANGSTAFF:** Where he says "slightly higher than  
 25 the Welsh region", it is actually half as much again.

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1 the reverse look-back processes. There are some that  
 2 look at serum hepatitis and some that look at  
 3 jaundice, and others that are a mixture.  
 4 **SIR BRIAN LANGSTAFF:** They are creatures of their time.  
 5 **MS FRASER BUTLIN:** Precisely, sir.  
 6 Then if we can move on to just highlight  
 7 a couple of documents from the 1960s that deal with  
 8 problems arising because of record-keeping, if we  
 9 could have DHSC0100017\_044, please. This is a letter  
 10 from 1965 from the director of the -- sorry, the  
 11 director of the NBTs region 1, to Oxford's Regional  
 12 Transfusion Centre, noting that:  
 13 "Further to your letter of 9th June [and they  
 14 give the reference], we have now been able to contact  
 15 the above donor. The delay was due to her having  
 16 changed her name on marriage -- it is now Mrs [X] and  
 17 it was just by coincidence that we found this out.  
 18 This donor is a nurse and she has answered our  
 19 questions in the following way ..."  
 20 So there appears to have been a delay and  
 21 a difficulty in tracing a donor because they had  
 22 changed their name upon marriage, which one might  
 23 consider to be something which happens relatively  
 24 frequently.  
 25 Other difficulties of record-keeping are also

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1 **MS FRASER BUTLIN:** Indeed and one must then remember that  
 2 Cardiff is lower again than the Welsh region excluding  
 3 Cardiff.  
 4 **SIR BRIAN LANGSTAFF:** Yes.  
 5 **MS FRASER BUTLIN:** So there does appear to be  
 6 an understanding in 1965 that that reporting of  
 7 hepatitis from the hospital to the Regional  
 8 Transfusion Centre is not wholly accurate.  
 9 **SIR BRIAN LANGSTAFF:** This is in respect, is it, of  
 10 anicteric hepatitis reports or is it in respect of  
 11 jaundice?  
 12 **MS FRASER BUTLIN:** The letter from Dr Drummond -- if it is  
 13 helpful we can have it back up -- is in relation to  
 14 cases of serum hepatitis.  
 15 **SIR BRIAN LANGSTAFF:** So it's both icteric and anicteric,  
 16 because one of the documents which you were showing me  
 17 earlier was talking cases of jaundice and within six  
 18 months. So it was looking at acute cases and not at  
 19 the sort of slow-burn anicteric case, which may be  
 20 a more typical case of what we now know as  
 21 hepatitis C.  
 22 **MS FRASER BUTLIN:** Indeed. Unfortunately, this is  
 23 something of a generalisation, sir, but the documents  
 24 are not as cleanly defined as one might have wanted,  
 25 especially when one is looking at the look-back and

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1 present in the documentation we have. If we could  
 2 have DHSC0100113\_017, please. It is a letter from  
 3 June 1969 from the North East Metropolitan Regional  
 4 Blood Transfusion Centre to Dr Maycock. There is  
 5 a report enclosed of post transfusion jaundice but  
 6 I would just draw your attention to the last  
 7 paragraph:  
 8 "With reference to our other donor ... I am  
 9 afraid she has returned to her native Scotland --  
 10 address unknown -- the search continues!"  
 11 So an example -- and we've drawn out examples of  
 12 things that we've seen across a number of documents,  
 13 but an example of a donor having moved location and  
 14 therefore not being able to be traced.  
 15 If we move on into the 1970s, again we have  
 16 evidence of both look-back and reverse look-back being  
 17 carried out. One example is DHSC0100018\_172, please.  
 18 It's from the South London region, dated  
 19 21 March 1975, so a very similar form to what we were  
 20 looking at in the 1960s and here we have at  
 21 paragraph 8, point 8 on the form, the brief clinical  
 22 notes of what had happened to the patient and, above  
 23 it, we have a note of the bottle numbers for the blood  
 24 that had been transfused, at point 7.  
 25 Then at point 11, there's a space for remarks.

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1 We see there:  
 2 "All the donors have been re-sampled and tested  
 3 and one of them, whose donation was given to the  
 4 patient on 21st June, 1974, has been found to be very  
 5 weakly positive by radioimmunoassay by Dr Dane.  
 6 I think it is a fair assumption that this is indeed  
 7 a case of post transfusion jaundice."  
 8 So this is simply one example of many of the  
 9 process working and a report being provided, even in  
 10 1975, to the Department of Health.  
 11 A moment ago we noted the difficulties of  
 12 resourcing being raised by -- in one case, in Wales.  
 13 That issue reappears in 1978, February 1978. Although  
 14 the minutes don't deal specifically with look-back and  
 15 reverse look-back as being a difficulty for staffing,  
 16 it's perhaps worth just noting that there appear to  
 17 have been significant staffing issues. If we could go  
 18 to NHBT0018353, these are the minutes of the Regional  
 19 Transfusion Directors meeting of 22 February 1978 and  
 20 if we turn to internal page 7, there's a heading  
 21 "Medical Staffing":  
 22 "Directors discussed staff shortages in Regions  
 23 and the number of times they'd advertised without  
 24 result. Altogether they were 10 vacancies, including  
 25 one Deputy Directorship. There were 2 vacancies in

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1 goes to a point beyond the hepatitis C look-back, and  
 2 we'll see what I mean by that, but it's convenient to  
 3 deal with it now because it ties into the early  
 4 jaundice enquiries. But I expect it is something we  
 5 will come back to at a later point as well. It is  
 6 simply to set some of the basic position in place.  
 7 Once hepatitis B was identified then  
 8 investigations into post-transfusion hepatitis B was  
 9 taking place much as they did with post-transfusion  
 10 jaundice. It really merges in the documents to  
 11 exactly what was just being dealt with as  
 12 post-transfusion jaundice and then what was  
 13 specifically being dealt with as hepatitis B, in and  
 14 of itself. Very similar issues arose in relation to  
 15 those processes as we've already identified.  
 16 First of all, if I can pick up some of the  
 17 documents that deal with difficulties around batch  
 18 numbers, record-keeping and tracing of donors. If we  
 19 could have DHSC0100018\_056, please. Here we have  
 20 a report from Dr Maycock to a Dr Cuthbert dated  
 21 19 September 1974, attaching four reports of hepatitis  
 22 in patients associated with transfusion. In the first  
 23 example he notes:  
 24 "There seems little doubt that this is a case of  
 25 hepatitis B and a donor was found on retest to be

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1 Newcastle, Liverpool, South London and Bristol had one  
 2 vacancy. Brentwood and Cambridge each had a vacancy,  
 3 but had not received any applications. There was one  
 4 vacancy at Cardiff."  
 5 So although this is not specific to look-back,  
 6 it's an issue that has been raised in relation to  
 7 look-back and reverse look-back and we see a broader  
 8 context for that in 1978.  
 9 So drawing the threads together in relation to  
 10 early jaundice investigations, we've identified  
 11 a reporting system was in place but there are four  
 12 themes that arise from the documents that I wanted to  
 13 highlight today and I hope I've done so through the  
 14 documents. There were difficulties arising from  
 15 clinicians not reporting all cases of post-transfusion  
 16 jaundice, or serum hepatitis; there were difficulties  
 17 with record-keeping, in particular the noting of donor  
 18 numbers and batch numbers; there were problems  
 19 surrounding whether donors responded to the blood  
 20 services contact and with keeping up-to-date with the  
 21 contact details of donors; and there were resourcing  
 22 problems and staff shortages.  
 23 So that then takes us on to hepatitis B  
 24 look-back processes. Addressing that now, because it  
 25 straddles the early jaundice enquiries but it also

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1 positive for [hepatitis B antigen]."  
 2 So an example of a successful reverse look-back.  
 3 Then we have the fourth case:  
 4 "This patient clearly had hepatitis B for which  
 5 the fibrinogen may have been responsible.  
 6 Unfortunately no record of the batch number was kept."  
 7 We then come into 1985 at NHBT0115650\_303. We  
 8 have a letter from -- sorry, we have a letter from  
 9 Dr Hewitt to a Charing Cross Hospital senior lecturer  
 10 in haematology, dated 26 November 1985, which records  
 11 that:  
 12 "In May 1984 you reported to us a case of  
 13 probable post transfusion hepatitis B in this  
 14 patient."  
 15 She explains what had happened, and then says:  
 16 "In view of the high probability of post  
 17 transfusion hepatitis B in this case, we attempted to  
 18 contact and resample all the involved donors. A total  
 19 of 28 donors have given repeat samples and none has  
 20 any marker of past hepatitis B infection.  
 21 Unfortunately, we have been unable to contact the  
 22 remaining 4 donors, all of whom are young males and  
 23 who have not responded to letters or attended any  
 24 blood donor clinics in the interim, despite requests  
 25 to contact us. We are making one final effort to

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1 contact these four in an attempt to close this  
2 enquiry. I apologise for the long delay in sending  
3 this report to you, but unfortunately we have been  
4 unable to reach a definite conclusion."

5 So again, once it was a more specific matter of  
6 hepatitis B rather than the general jaundice  
7 enquiries, we see ongoing difficulties of contacting  
8 donors and difficulties around batch numbers.

9 We then come to a series of letters from 1990.  
10 In June 1989 a patient had died, and at that point  
11 the North London Regional Transfusion Centre were  
12 notified that the patient was suffering from  
13 hepatitis B. There was then a delay of a year before  
14 BPL were notified of the infectivity of the plasma  
15 that the patient had received.

16 For the purposes of today, we don't need to go  
17 into the detail of how that one-year delay arose, but  
18 out of that incident Dr Hewitt undertook a review of  
19 post-transfusion hepatitis B reports across the period  
20 of 1986 to 1989, and it's that report that I want to  
21 go to.

22 The document is NHBT0003770, please. It's  
23 a report she made to Dr Gunson, and if we pick up at  
24 the second paragraph, please:

25 "Between 1986-1989 there are a total of 14

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1 reports of hepatitis B to us which we felt were likely  
2 to be associated with blood transfusion. As you will  
3 see, we investigate 3-4 cases of possible/probable  
4 post-transfusion hepatitis B each year. Two of these  
5 ... were felt to be due to transfusion abroad and no  
6 recall of NLBTC donors followed. In a further two  
7 cases ... there was no donor follow-up because the  
8 reports involved an incidental finding of HBsAg  
9 positivity in a multi-transfused recipient, without  
10 any indication of date of seroconversion (or indeed,  
11 proof of a previous HBsAg negative status).

12 "In 8 of the remaining 10 cases, an attempt was  
13 made to contact all involved donors. The response  
14 rate was high, although not complete. In 3 cases, all  
15 resampled donors were negative for HBV markers ... and  
16 in other 3 one resampled donor was anti-HBc positive  
17 ... and withdrawn as 'possibly implicated'. One case  
18 ... was predicted by us, when a donor was detected  
19 HBsAg positive at the next donation, the previous  
20 donation was subsequently confirmed HBsAg negative.  
21 This donor was obviously in the early infectious stage  
22 of hepatitis B infection, but below the level of  
23 detection in [surface antigen] screening tests, at the  
24 time of the implicated donation. The final case ...  
25 has been fully documented.

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1 "This leaves 2 cases ... where the numbers of  
2 donors involved were huge, and recall of all donors  
3 thought to be logistically impossible. Examination of  
4 records revealed a common donor, found to be anti-HBc  
5 positive on recall."

6 Anti-HBc positive on recall.

7 "Thus out of 14 documented cases in 1986-1989;

8 "4 - not investigated for reasons given

9 "5 - 'implicated' donor anti-HBc positive, HBsAg  
10 negative

11 "3 - no HBV markers identified in resampled  
12 donors and no donor implicated

13 "1 - donor in early stage of HBV infection, but  
14 HBsAg negative.

15 "1 - donor had low level of HBsAg.

16 "This summary indicates that the checking of  
17 original HBsAg results on donors involved in PTHB  
18 enquiries is unlikely to be of help to BPL in deciding  
19 the fate of 'held' products. Our latest report to BPL  
20 involving 183 donors and 120 plasma donations  
21 forwarded to BPL required 15 hours of Senior  
22 Scientific Officer time to check original HBsAg  
23 results. If the checking of previous HBsAg test  
24 results is now to be part of BPL's requirements, we  
25 shall obviously require additional resources!"

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1 So again what we see in this report, which was  
2 the survey of a period of 1985 to 1989, are issues  
3 arising in relation to tracing donors and, at the end,  
4 concerns about resources and the work required to be  
5 able to do this sort of work.

6 There are other examples of investigations into  
7 hepatitis B being delayed.

8 If I can turn up NHBT0023823, please, Soumik.  
9 It is a letter from February 1995 which addresses in  
10 the first paragraph that:

11 "This [was] a jaundice enquiry that has been  
12 going on for almost three years now."

13 It's explained that in this case it related to  
14 bone marrow that was stored in a liquid nitrogen tank  
15 while infectious and it was then transmitted to other  
16 patients. So it is slightly different but the purpose  
17 of showing this document, sir, is paragraph 2:

18 "We thought we had solved the problem on two  
19 occasions, but both donors have proved to be negative  
20 of subsequent retesting. I am writing to you now  
21 because Richard Tedder asked me to go through with  
22 a fine-tooth comb all our non attending donors, and  
23 I am ashamed to see that I now see what I should have  
24 seen before - that four of those donors live in South  
25 London."

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1 And so contact was being made.  
 2 If we just go over the page -- sorry, one  
 3 further page -- we can see just an apology at the end:  
 4 "... I am really sorry that these donor  
 5 addresses hadn't 'clicked' with me earlier - my only  
 6 excuse is that we have closed (and reopened) this  
 7 enquiry on at least three occasions, as new evidence  
 8 has come to light - not to mention new lists of  
 9 donation numbers from UCH. However I have now written  
 10 it into my procedure that I must check the addresses  
 11 of lapsed donors in case they are attending you or  
 12 Colindale."  
 13 Sir, the point, really, of picking up this  
 14 document is simply the fact that some enquiries took  
 15 a number of years to complete and there were, again,  
 16 difficulties of identifying donors and donor addresses  
 17 in order to be able to complete those processes.  
 18 A further example of that, even into 1993,  
 19 NHBT0010671, it's a letter from a Dr Herborn,  
 20 a consultant haematologist, to Dr Gunson, about a  
 21 "Donor who has probably caused post-transfusion  
 22 Hepatitis B":  
 23 "Thank you for your advice concerning this  
 24 donor. As I mentioned on the telephone, he is now  
 25 linked with two cases of post-transfusion Hepatitis B.

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1 records. I just want to go through a few documents  
 2 dealing with this particular study.  
 3 If we could turn to NHBT0012414, please, and if  
 4 we can go to page 3 to start with, please. We have  
 5 a letter from August 1996 from a consultant  
 6 haematologist to Dr Hewitt about the hepatitis B  
 7 look-back study and it records this:  
 8 "A small start! These are the four unit number  
 9 proformas for those blood components sent to the  
 10 Atkinson Morley's Hospital. The blood bank at AMH was  
 11 closed down 2 [and a half] years ago. We can trace  
 12 three of the units, but one has sunk without trace; no  
 13 records exist of its fate either in AMH records or our  
 14 own at St George's (blood was transferred down here  
 15 after two weeks at AMH, and you resupplied AMH with  
 16 newer units).  
 17 "I am returning all four report forms. The  
 18 St George's reports will take some time to come  
 19 through. There are 82 of them, and all the old record  
 20 books have to be gone through to pick them up -- it's  
 21 laborious!"  
 22 To which Dr Hewitt replied, it's the second page  
 23 of this document, please:  
 24 "Thank you very much for the forms ...  
 25 "Please could you bear in mind that we can offer

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1 His tests for [hepatitis B surface antigen] have  
 2 always been negative but he has anti-HBc.  
 3 Unfortunately, we ran out of serum and could not test  
 4 him for anti-HBs.  
 5 "I wrote to him three times and the third letter  
 6 has been returned by the Post Office marked 'Not at  
 7 this Address'. He is not registered with a GP and  
 8 there does not seem to be any way we can contact him.  
 9 I wrote to a Doctor in each of the UK Transfusion  
 10 Centres."  
 11 So, again, a further example in 1993 of  
 12 difficulties of contacting donors and identifying  
 13 where they were.  
 14 In 1995, a study into the incidence of  
 15 hepatitis B in the donor population was undertaken.  
 16 The purpose of the study was said to be to assess the  
 17 transmissibility of hepatitis B in blood donations  
 18 negative for hepatitis B surface antigen but positive  
 19 for antibody to hepatitis B core. The study was  
 20 planned so that it took place after the hepatitis C  
 21 look-back. So we are a little further on in time.  
 22 The study went ahead after the hepatitis C  
 23 look-back but it's clear that the look-back exercise  
 24 that then followed wasn't straightforward, partly  
 25 because of difficulties with accessing medical

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1 help going through old record books, if your  
 2 laboratory staff would feel that an additional person  
 3 would indeed be a help and not a hindrance! The  
 4 majority of hospitals are able to complete this task  
 5 quite easily, because the records are on computer. If  
 6 this is not the case at St George's, then we would do  
 7 everything possible to lighten the load on your  
 8 staff", and they were expecting to employ a student  
 9 who might be used for it.  
 10 So, again, we see in 1996, in the hepatitis B  
 11 look-back study, difficulties being raised in relation  
 12 to medical records at the hospital level for exactly  
 13 what had happened to blood components.  
 14 We then continue to NHBT0030267\_002, please. We  
 15 have a report form around red cells that had been  
 16 issued to Lewisham, and we can see handwritten on this  
 17 very first page "untraceable". If we turn the page,  
 18 we can see at the top that there are records available  
 19 to identify receipt of the component and the fate of  
 20 the component, that it was transfused to a patient.  
 21 But if we go to point 5, we can see that, in relation  
 22 to the patient's surname and forename, it's simply  
 23 written "Unknown male" and then a note on the side,  
 24 "[Patient] transferred to another hospital from  
 25 [A&E]".

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1 So again another example of the limited  
2 information that was being identified in relation to  
3 some recipients and it's perhaps helpful to look at  
4 a draft report of the study from October 1996,  
5 NHBT0007899, please. It's an update that was given to  
6 the MSBT 10th meeting. So it's an update on the study  
7 as at 14 October 1996, and the key part of it, for our  
8 purposes today, is part 2, "Recipient tracing" where  
9 we can see the number of components, in relation --  
10 the first column is in relation to South Thames, the  
11 second column is in relation to East Anglia.  
12 We can work our way through identifying the  
13 number of components in South Thames was 1,122 and, at  
14 that stage, information was awaited on the fate of 576  
15 components. Information that was awaited on patients  
16 was 403 in South Thames, whereas in East Anglia there  
17 was just 204 components, of which 4 the fate of the  
18 component was awaited and nothing was awaited in  
19 relation to particular patients. But the other figure  
20 to note, of course, is also the "no notes available",  
21 there were three components in East Anglia where no  
22 notes were available, and it simply gives an indicator  
23 of some of the successes and difficulties of the  
24 recipient tracing.  
25 The final document in relation to hepatitis B

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1 4 blood donations listed in [the doctor's] email  
2 cannot therefore be implicated as a source of  
3 hepatitis B infection in patient [X].  
4 "I would stress that we have not received the  
5 minimum information necessary in order to document the  
6 details of this case. In particular, donation numbers  
7 have been provided in an email and not from a computer  
8 laboratory print-out. We therefore cannot vouch for  
9 the accuracy of the donation numbers provided to us.  
10 "If you could now provide the information  
11 requested, we can include it in the file and confirm  
12 that the correct donations have been investigated.  
13 Otherwise, I am now closing our investigation with the  
14 conclusion that patient [X's] hepatitis B infection  
15 was not due to the transfusion of the 4 units of  
16 'blood products' notified to us in [the doctor's]  
17 email. We have assumed that the blood products in  
18 question were red cells."  
19 As a final document in 2009, it's simply to note  
20 again the difficulties of that communication between  
21 the hospital and the blood services.  
22 Sir, I am about to move on to HTLV-III look-back  
23 but I note the time. I am happy to start and then  
24 break or whatever you would prefer.  
25 **SIR BRIAN LANGSTAFF:** Let's take a break now and have it

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1 that I want to go to today is NHBT0016619, please.  
2 It's a letter from 2009 from Dr Hewitt dealing with  
3 a notification that had been given about a patient  
4 with acute hepatitis B, diagnosed in December 2008.  
5 The second paragraph records that:  
6 "We forwarded to you a notification form on  
7 9th February 2009, requesting details about the  
8 infected patient, the test results, and a copy of the  
9 transfusion laboratory record for the patient in  
10 question. To date, I have not received any of this  
11 information."  
12 According to the email, the patient had  
13 undergone cardiac surgery and an orthopaedic  
14 procedure. They had received two units of blood  
15 products on each occasion and the donation numbers  
16 were quoted.  
17 "Whilst awaiting the further information, we  
18 identified the 4 donations listed in [the] email and  
19 established that all 4 donors had re-attended at least  
20 once since the donation transfused to patient [X] in  
21 the summer of 2008. The archived samples from all  
22 4 subsequent donations were retrieved and tested for  
23 the presence of anti-HBc. All 4 examples were  
24 anti-HBc negative. These results exclude any of the  
25 donors as having been infected with hepatitis B. The

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1 all in one go. So we'll come back, shall we, at 3.35.  
2 3.35.  
3 **(3.05 pm)**  
4 **(A short break)**  
5 **(3.36 pm)**  
6 **SIR BRIAN LANGSTAFF:** Yes.  
7 **MS FRASER BUTLIN:** Thank you. In this third and final  
8 part of the presentation, we're going to just be  
9 looking at the HTLV-III look-back. We are, of course,  
10 going back in time from where we were in relation to  
11 hepatitis B.  
12 Initially, we can see that HTLV-III look-back  
13 work was undertaken much the same way as for  
14 post-transfusion jaundice. If we can have  
15 DHSC0006923\_071, please, Soumik, we have a -- sorry,  
16 we have a letter from -- a draft letter from Dr Gunson  
17 to Dr Galbraith, dated 3 April 1984, which says:  
18 "The Regional Transfusion Centres already have  
19 systems available for the follow-up of donors who are  
20 implicated in patients who develop Transfusion  
21 Associated Hepatitis. I do not see that fundamentally  
22 the proposal to follow-up donors implicated in  
23 patients who develop AIDS or the follow-up of  
24 donations given by persons who subsequently develop  
25 AIDS is significantly different. From this point of

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1 view, therefore, I am sure that you would have full  
2 co-operation of the Regional Transfusion Directors in  
3 this matter."

4 The next day from that draft letter, there  
5 appears to have been a meeting between Dr Galbraith,  
6 Dr Gunson and Dr McEvoy. That's on 4 April 1984. If  
7 we could have CBLA0001833, please.

8 Here we have a note of the meeting setting out  
9 a process that was to be followed. Point 1:

10 "CDSC will inform the appropriate RTD when  
11 a patient is diagnosed with AIDS; if the patient  
12 admits to donating blood, contact will be by  
13 telephone.

14 "Investigation will be undertaken to find out  
15 whether the person is registered as a donor.

16 "If the answer is NO, CDSC will be informed.

17 "If the answer is YES, further action will be:

18 "Trace the fate of blood donations, with respect  
19 to all products, given during the previous FIVE years.

20 "If plasma has been sent to BPL for  
21 fractionation Dr RS Lane will be informed as soon as  
22 possible.

23 "The appropriate hospitals should be asked to  
24 identify the patients who received the blood products,  
25 provide any information they have on the subsequent

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1 be informed.  
2 "If the patient has received blood products  
3 which have been prepared and issued from the RTC the  
4 following action will be taken.

5 "Identification of the donors from whose blood  
6 the products were prepared.

7 "Again, after consideration of the  
8 practicalities of the situation with respect to the  
9 particular case in discussion with Dr McEvoy, it may  
10 be necessary to recall the donors for:

11 "(a) Interview and medical examination.

12 "(b) Collection of blood sample to carry out  
13 non-specific tests.

14 "Where this is done and by whom will be at the  
15 discretion of the RTD.

16 "If none of the donors involved fall into  
17 high-risk groups for AIDS, CDSC will be informed.

18 "If any donor is suspected of having AIDS then  
19 referral should be made for further medical  
20 examination and an investigation carried out with  
21 respect to previous donations as detailed in  
22 paragraph 1.3 above."

23 The point I flagged just a moment ago at 1.3.4,  
24 "Subsequent to consultation with the Defence  
25 Organisations a communication will be sent to the

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1 progress of the patients and the name of the patients'  
2 family doctors.

3 "Subsequent to consultation with the Defence  
4 Organisations a communication will be sent to the  
5 family doctor informing him of the circumstances and  
6 a copy of the letter sent to CDSC who will carry out  
7 any further follow-up."

8 We're going to pick up that point in a moment,  
9 sir. So if we just hold that in our minds, the  
10 process then continues:

11 "CDSC should be kept informed of progress."

12 Then a reverse look-back situation is addressed  
13 in part 2:

14 "CDSC will inform the appropriate RTD when  
15 a patient is diagnosed with AIDS who has stated that  
16 he/she has received a transfusion of blood and/or  
17 blood products.

18 "If the patient has received blood products  
19 derived from pooled plasma which may involve a large  
20 number of donors, Dr McEvoy will discuss with the RTD  
21 the practicalities of follow-up within the resources  
22 available. If the patient is a haemophiliac,  
23 Dr Craske, Consultant Virologist, PHLS, Manchester  
24 will also be involved. If the patient has received  
25 NHS products derived from pooled plasma, Dr Lane will

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1 family doctor", that issue was raised again at  
2 a meeting of the Regional Transfusion Directors on  
3 11 July --

4 **SIR BRIAN LANGSTAFF:** Just before we leave that last page,  
5 can we just go back to the second page. It's little  
6 (b) at the top of the page, 2.2(b), "Collection of  
7 blood samples", so this is from a suspected donor?

8 **MS FRASER BUTLIN:** Yes.

9 **SIR BRIAN LANGSTAFF:** The suggestion is there may be  
10 a collection of blood samples to carry out  
11 non-specific tests. So one wonders whether the  
12 implication of that might be that the donor isn't told  
13 what the tests are for.

14 **MS FRASER BUTLIN:** It's not something I can address.

15 **SIR BRIAN LANGSTAFF:** No, it's without there being  
16 specific evidence on it, it's -- if what people are  
17 looking for here is HTLV-III or indicators -- this  
18 being, what, April '84 -- indicators that there may be  
19 T cell abnormalities, difficult to know why it should  
20 be non-specific.

21 **MS FRASER BUTLIN:** Well, sir, it might be non-specific in  
22 the sense that the donor isn't told or it might be  
23 non-specific in that it is general tests that there  
24 isn't a specific test that they are recommending.

25 **SIR BRIAN LANGSTAFF:** It is not anyone speculating that

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1 that means that there was a recommendation to carry  
 2 out tests, pulling the wool over the eyes of the donor  
 3 is actually reading too much into it.  
 4 **MS FRASER BUTLIN:** One simply doesn't know, sir.  
 5 **SIR BRIAN LANGSTAFF:** Yes, thank you.  
 6 **MS FRASER BUTLIN:** In terms of the reference to the  
 7 defence organisations and a letter going to the family  
 8 doctor, we pick that up at the Regional Transfusion  
 9 Directors meeting of 11 July 1984, DHSC0002245\_002.  
 10 It's the second page of these minutes, under the  
 11 heading "AIDS":  
 12 "Dr Gunson had approached the Medical Defence  
 13 Union. Their reply was that an adequate precaution if  
 14 a patient had been given 'at risk' blood was that the  
 15 General Practitioner should be informed in confidence.  
 16 Previous experience with cases of venereal disease in  
 17 donors led some members to doubt this procedure.  
 18 "It is possible that a DHSS working group will  
 19 be set up and legal implications could be considered."  
 20 We can then turn to the first meeting of the  
 21 advisory committee of the NSBT working group on AIDS,  
 22 and we're going to look at a memo recording what  
 23 happened at that meeting. The memo is dated  
 24 27 November 1984.  
 25 It's DHSC0002251\_011, please.

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1 that testing will be carried out."  
 2 And there's discussion of a leaflet.  
 3 "Obviously HTLV-III positive donations would be  
 4 destroyed. The initial approach to such a donor would  
 5 be from the NBTS and afterwards counselling would be  
 6 essential. We look to the Expert Advisory Group for  
 7 guidelines but GPs should be involved, with the  
 8 donor's consent."  
 9 If we go over the page:  
 10 "It was agreed that follow up of previous  
 11 donations of plasma should be for 3-5 years.  
 12 "The Chairman requested the approval of the  
 13 Meeting to let the Group draft a flow diagram for AIDS  
 14 testing and following up of donations. The meeting  
 15 tomorrow will, if given approval, pass on  
 16 recommendations to the Expert Advisory Committee and  
 17 save considerable time."  
 18 So at this July 1985 meeting is the point at  
 19 which a much more structured discussion is starting in  
 20 relation to following up of donations.  
 21 And we see then the meeting of the working party  
 22 the next day, there was discussion about look-back.  
 23 DHSC0000406. It's internal page 4, please.  
 24 Under point 7, headed "Follow-up of recipients of  
 25 previous donations given by donors found to be

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1 The memo is written by an ME Abrams from Med SEB  
 2 to a Dr Harris, simply noting what the committee had  
 3 discussed, and under (vi) it was noted that:  
 4 "Donors should be told that HTLV-III testing  
 5 will be added to the other tests done."  
 6 We're now in November 1984:  
 7 "Donors with positive tests should be told the  
 8 answer -- although no unanimity on who should do it or  
 9 how. Follow up of such donors and patients, and  
 10 counselling, and contact tracing arrangements etc are  
 11 being considered by IMCD. There are very difficult  
 12 and complex issues to be taken on board: one  
 13 suggestion was a regional immunology service to deal  
 14 with all this at special centres."  
 15 We then see much more formalised processes  
 16 becoming a part of the discussions within the meetings  
 17 about screening of blood donations.  
 18 So if we go on to a meeting of the Regional  
 19 Transfusion Directors dated 10 July 1985, at  
 20 CBLA0002212, we can see at the top of the document the  
 21 date, and then if we go over to the third page, under  
 22 the heading of "AIDS" there was a report on a number  
 23 of meetings:  
 24 "It was felt not essential to have the GP's name  
 25 in all instances but that all donors must be informed

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1 HTLV-III positive":  
 2 "7.1. Efforts will be made to determine the  
 3 names of any patients who received blood and  
 4 components from the donations taken during the past  
 5 five years and the information regarding the known or  
 6 possible seropositivity of the donation given to the  
 7 Consultant in charge of the patient.  
 8 "7.2. If plasma from any of the donations was  
 9 sent for fractionation, full follow-up of all patients  
 10 receiving coagulation factor concentrates may be  
 11 difficult or impossible. Since patients suffering  
 12 from haemophilia A and B are being investigated for  
 13 anti-HTLV-III at present, it is recommended that no  
 14 additional follow-up be carried out."  
 15 That position was modified slightly by the  
 16 expert advisory group on AIDS on 30 July 1985.  
 17 PRSE0002628, please. It's internal page 5  
 18 please. I'm sorry, before we go there, we can see  
 19 that the meeting was 30 July 1985.  
 20 And then internal page 5, under the heading  
 21 7.4.3, "Follow up of blood donations previously given  
 22 by donors who are identified as positive for  
 23 HTLV-III":  
 24 "[X] said that the Screening Sub-Committee had  
 25 recommended that the haematologist in charge of the

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1 hospital blood bank should be informed if it was  
2 believed that an earlier donation could have  
3 transmitted HTLV-III infection. The haematologist  
4 would be asked to identify the recipient of the  
5 suspect donation and to inform the clinician in charge  
6 of the case when the blood had been transfused.  
7 The BTS was aware of the importance of good record  
8 keeping to enable the follow up of donations. It was  
9 suggested that these follow up investigations would  
10 provide a good opportunity to check on the  
11 transmission of the virus between spouses and from  
12 female to male, and a national registry would be  
13 useful. Members agreed with the Sub-Committee's  
14 recommendations and considered that it would be up to  
15 the clinician in charge of the patient to decide on  
16 what subsequent investigations should be made. It was  
17 also agreed that, although there might be practical  
18 difficulties, the follow up for donations, should go  
19 back a minimum of five years from the date of the  
20 donation."

21 From the evidence that was given to the  
22 Penrose Inquiry, it appears that the five-year rule  
23 was also used in Scotland, and we have seen nothing  
24 that suggests that that's not the position. We have  
25 had statements from the Northern Ireland Blood

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1 Transfusion Service, the Welsh Service and the  
2 Scottish Service. All of those indicate that the four  
3 nations operated the HTLV-III look-back procedure  
4 together, and it was a more centralise and structured  
5 process than the earlier hepatitis look-backs, and so  
6 it was a four nations process.  
7 **SIR BRIAN LANGSTAFF:** This is a five-year from the date of  
8 clinician.  
9 **MS FRASER BUTLIN:** Yes.  
10 **SIR BRIAN LANGSTAFF:** So if one is looking at a blood  
11 product, it may be as much as seven years ago?  
12 **MS FRASER BUTLIN:** It could be, indeed. Although you will  
13 note the difficulties highlighted in the earlier  
14 document in relation to blood products, and whether  
15 that was, in fact, feasible or not.  
16 **SIR BRIAN LANGSTAFF:** So probably this is related to  
17 transfusion as such?  
18 **MS FRASER BUTLIN:** I think that would be a fair reading of  
19 the document, sir. It's certainly a conclusion you  
20 could reach.

21 It is clear, however, that there was an issue  
22 about donors who self-excluded from donating and  
23 wouldn't then become known to the blood services  
24 subsequently. Dr Hewitt has raised this point in her  
25 witness statement and I'm sure we will explain that at

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1 a later point, but I raise it now simply so that I can  
2 take you, sir, to the minute of a meeting of the  
3 expert advisory group on AIDS of 26 November 1985.  
4 The document is DHSC0001736. So it's  
5 26 November 1985. And if we turn to the final page,  
6 page 12, under the "Agenda item 16 Any Other Business"  
7 we see:

8 "Dr Tedder, on behalf of Dr Contreras asked  
9 clinical members whether they would consider asking  
10 sero-positive patients as a matter of routine if they  
11 had donated blood since 1978 and where blood had been  
12 donated, if they would refer their patients to the  
13 Regional Transfusion Centre in order that recipients  
14 of donations could be followed up."

15 So we see him asking, and it appears at that  
16 stage unresolved, whether those who were identified as  
17 being HTLV-III positive should be asked about having  
18 given blood so that a look-back process could be  
19 followed in relation to them as well.

20 We have identified a number of examples of  
21 the notification process and the look-back process  
22 operating as expected from those meeting minutes, but  
23 I want to just look at one particular example now.

24 CBLA0000010\_209, please.

25 It's a letter from October '84 from the deputy

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1 medical director of the Wessex Regional Transfusion  
2 Centre to Dr Snape:

3 "To confirm Dr Smith's and my own telephone  
4 calls to you within the last day or two. We have been  
5 informed that one of our male donors has been admitted  
6 into a Bournemouth hospital; the clinical diagnosis  
7 is, almost certainly, AIDS."

8 Then he gives the details of his previous known  
9 donations, and we can see that the first one:

10 "Donation not used. Time expired plasma pooled  
11 and sent to BPL ..."

12 The second:

13 "Whole blood donation sent to one of our  
14 Portsmouth hospitals not returned ..."

15 Third:

16 "FFP sent to BPL [giving the batch and pack  
17 number]. Plasma reduced blood sent to one of our  
18 Portsmouth hospitals and not returned ..."

19 Then fourth:

20 "Plasma separated and frozen."

21 This was a very recent donation.

22 It indicates at the end of the letter:

23 "Regarding Donations 2 and 3. We are not  
24 getting in touch with the clinicians involved until  
25 the diagnosis is confirmed."

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1 But the indication is that they have -- or one  
 2 might read the letter as suggesting they have  
 3 identified who the clinicians for those patients are  
 4 and once -- if the diagnosis is confirmed, then they  
 5 would be getting in touch with the clinician.  
 6 This is then picked up in a further subsequent  
 7 report.  
 8 Apologies, sir, if I can just take a moment.  
 9 Yes, a fuller report of the incident was  
 10 prepared in October -- later, in October 1984.  
 11 DHSC0001111. If we can start at page 2, please.  
 12 Yes.  
 13 We see on this page a note of the "Donor  
 14 condition and products affected", but if we then go on  
 15 to the second page, the next page, the third page of  
 16 this document, we see under the heading "2. Actions  
 17 to secure/recall implicated products", and we see  
 18 that:  
 19 "Dr Smith (Wessex) was informed of [the]  
 20 implication of [the batch] ... and was asked to recall  
 21 all vials including any held by patients for home  
 22 therapy.  
 23 "Dr Napier ... was unavailable but Mr Booth ...  
 24 was informed ... and was asked to recall all vials ...  
 25 including home therapy issues.

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1 Centres within two years clearly underlines  
 2 a fundamental problem when carrying out follow-up of  
 3 donor incidents of this sort. Surely central  
 4 co-ordination of donor records is unavoidable."  
 5 That's the view of Dr Snape.  
 6 Before we leave that document, I just want to  
 7 highlight the second page, with the heading of the  
 8 report, so that the next document makes sense. It's  
 9 noted that it's a summary report on the recall of the  
 10 batch HL3186, and we see this picked up again in the  
 11 document CBLA0000010\_202.  
 12 This is a letter in 1988 from Dr Craske to  
 13 Dr Lane dealing with batch HL3186, and the second  
 14 paragraph:  
 15 "The follow-up we were doing eighteen months ago  
 16 of this incident was bedevilled at that time by the  
 17 reluctance of Haemophilia Centre Directors to cause,  
 18 what they considered to be, an unnecessary worry to  
 19 their patients, so that a follow-up of the recipients  
 20 who received this product has not been carried out in  
 21 the formal sense."  
 22 There then was reference to a paper that had  
 23 been published and Dr Lane's letter had prompted  
 24 Dr Craske to reopen the enquiry. Unfortunately, at  
 25 this point, we have not been able to trace that letter

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1 "Both telephone conversations were confirmed in  
 2 writing ..."  
 3 It goes on to explain that various batches were  
 4 then held pending investigation. Then on the next  
 5 page, we have a record of the results of the  
 6 Factor VIII recall and we can see that 400 vials were  
 7 despatched to Cardiff, broken down in that way:  
 8 150 were held at the RTC; in relation to Heath Park  
 9 101 out of 150 were recovered; Morriston 51 out of 60  
 10 were recovered; Carmarthen, 36 out of 40. So:  
 11 "A total of 338 vials was recovered; 9 patients  
 12 received the batch."  
 13 And we get similar information in relation to  
 14 Wessex.  
 15 We then have a note under "Follow-up actions":  
 16 "Dr Smith ... was asked to report any plasma  
 17 from this donor despatched to BPL (or PFL) within the  
 18 last 5 years. Dr Smith was also asked to determine  
 19 whether the donor had a history of attendance at local  
 20 special clinics more venereal disease."  
 21 Then, finally, there are, on the last page,  
 22 observations on the incident and there's just one  
 23 paragraph that I think is worth highlighting here, and  
 24 that's paragraph 5.3:  
 25 "The appearance of this donor at three different

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1 from Dr Lane. Efforts are ongoing but, in the fourth  
 2 paragraph of this letter, Dr Craske says:  
 3 "Your letter prompts me to re-open this enquiry,  
 4 as we [don't] know the outcome of patients who  
 5 received this and other batches which may have been  
 6 contaminated with HIV. I will consult my files and  
 7 let you have a report as to what is known at the  
 8 present time."  
 9 The point raised by Dr Craske in relation to the  
 10 Haemophilia Centre Directors is a point that's raised  
 11 also by Dr Rejman in 1992. He had prepared a memo to  
 12 Mr Canavan. It's a memo dated 6 February 1992,  
 13 DHSC0002585\_004.  
 14 We can see on the second page of the memo that  
 15 the context of it is about financial assistance and we  
 16 can see that in paragraph 7. But the paragraph I want  
 17 to draw your attention is paragraph 4 on the first  
 18 page, which notes that:  
 19 "... I think it is important to remember what  
 20 happened to the original 'look-back' pilot suggested  
 21 by EAGA. There was considerable resistance from some  
 22 Consultants to inform recipients who might be at risk  
 23 of HIV, and various reasons were put forward for this  
 24 including (i) not being of any benefit to a patient  
 25 who was likely to die from his primary disease in the

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1 near future and (ii) the distress that could be caused  
2 to a patient or his family of knowing that he was  
3 infected with HIV, when he was actually dying of  
4 another disease. There was also opposition from some  
5 local ethical committees on similar grounds. It is  
6 possible that the prospect of financial gain may make  
7 'look-back' easier on this occasion."

8 So it's noting, in this context in relation to  
9 blood transfusion in tissue recipients that  
10 Dr Rejman's understanding at that time was there had  
11 been resistance in relation to informing recipients of  
12 their risk of HIV.

13 The question of the reluctance of clinicians is  
14 also highlighted in two further documents, one of  
15 which is more contemporaneous. It's December 1985  
16 from a consultant -- between -- sorry, let me start  
17 again.

18 It's a document, a letter, from 1985 between two  
19 consultant haematologists, which gives us some  
20 indication of at least what one person's view was in  
21 addition to what we have already noted. It is  
22 NHBT0011051\_010, where it's noted that the screening  
23 process had started and it was agreed that if any  
24 positive donor was found their previous donations  
25 would be traced. One such donation had been

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1 been identified. Most of these will not belong to the  
2 high risk groups and will therefore provide  
3 an opportunity to study how this virus spreads, if at  
4 all, outside of the high risk groups. It can also be  
5 argued that these people and their close contacts  
6 should be identified and counselled for their own  
7 sakes. As you know it has been agreed that an attempt  
8 be made to identify and study these patients and their  
9 household contacts."

10 He then notes that:

11 "The project will be co-ordinated from Bristol  
12 but is totally dependent on considerable work on the  
13 part of each Regional Transfusion Service and other  
14 health service staff who will have to be contacted at  
15 the regional level."

16 He goes on towards the end of the letter to say:

17 "[He looks] forward to receiving details of both  
18 donors and patients whose permission we have to  
19 contact. Perhaps we could start with enquiries based  
20 on the donors picked up by screening since last  
21 October 14th, there are also instances in which  
22 patients infected by blood transfusion have brought  
23 the problem to light and a donor can be found by back  
24 tracing."

25 The focus of the study is set out rather more

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1 highlighted to them and, in the middle of the second  
2 paragraph, this haematologist indicates:

3 "I personally am not quite sure what the  
4 Transfusion Service hopes to achieve by this type of  
5 follow-up but I am told that it would be helpful if  
6 you could find out who received the donation and  
7 inform the Consultant in charge of the patient of this  
8 finding. I have to ask you to ensure that the  
9 recipient is not told because the worry inflicted on  
10 the poor recipient would be out of all proportion to  
11 the possible risk."

12 We then have an epidemiological study that was  
13 being run from 1986 from Bristol and there are  
14 a number of documents from that epidemiological study  
15 that I want to go to now.

16 The first is DHSC0002480\_047. This is a letter  
17 from Dr Wallington, who was running the study, to his  
18 colleague, setting out the nature of the study that  
19 was being proposed. It's a letter that went to the  
20 Regional Transfusion Centre Directors and it explained  
21 the need for further research. If we look at the end  
22 of the first page, we can see that he notes the  
23 following:

24 "Some patients will have been infected by  
25 transfusion in this country, but as yet they have not

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1 clearly in a letter to Dr Gunson in May 1987. The  
2 document is NHBT0004202. It is the first paragraph  
3 where you see him set out the point of the study:

4 "As you know it has been agreed within the NBTS  
5 that an attempt be made to identify, help and  
6 investigate patients who have received transfusions  
7 which might have infected them with HIV, also where  
8 necessary their household contacts."

9 If we turn the page, he sets out, in the second  
10 paragraph, what he terms "Task Two", the "Yellow  
11 sheets", which are the recipient tracing and study,  
12 and he says:

13 "... I have been questioned much more vigorously  
14 on the ethics of this part of the study than on Donor  
15 tracing, people have been very worried about the idea  
16 of approaching blood recipients a proportion of whom  
17 will be well and unsuspecting with such a dread  
18 diagnosis and even more in doubt about investigation  
19 of household contacts. Opinion has been changing  
20 rapidly and most people now believe that infected  
21 persons should be identified whenever possible for  
22 public health reasons. As this part of the study will  
23 undoubtedly prove controversial I think colleagues in  
24 Haematology should be fully informed before being  
25 presented with notification of a donation thought to

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1 be infectious."  
 2 So what I would suggest this document highlights  
 3 is that there clearly was an ongoing controversy about  
 4 whether recipients should be informed of the risks, as  
 5 we saw in earlier documents.  
 6 Then what we have -- sorry, sir. The next piece  
 7 of correspondence that we should go to is a response  
 8 from Dr Wallington to Dr Gunson in 1991.  
 9 What appears to have happened is that concerns  
 10 were raised in January 1991 by Dr Contreras that  
 11 nothing had been heard about the study despite her  
 12 sending a lot of data, and what we then have is the  
 13 response from Dr Wallington in relation to that.  
 14 The document is NHBT0004810.  
 15 What Dr Wallington says in the second paragraph  
 16 is:  
 17 "I think that Marcela's [Dr Contreras'] letter  
 18 expresses a reasonable concern. I have so far  
 19 received data on 84 donors on the comprehensive  
 20 questionnaire that she mentions. North London and one  
 21 or two other Regional Transfusion Centres including  
 22 the Manchester Centre have continued to send in  
 23 completed forms. Certain Transfusion Centres have  
 24 never sent them. Scotland has never participated  
 25 apart from a few forms from Edinburgh."

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1 AIDS conference in June 1988 in Stockholm. The  
 2 reference is NHBT0057880.  
 3 We see here the "Objective", which was:  
 4 "To trace past recipients who might have  
 5 received blood components infectious for HIV.  
 6 "... Donations were traced for 3 categories of  
 7 donors: (i) current donors found positive for  
 8 anti-HIV, (ii) ex-donors reported positive, (iii)  
 9 donors implicated in cases of transfusion-transmitted  
 10 HIV. Hospitals were notified of involved blood  
 11 components, traced their fate and blood samples were  
 12 obtained from living recipients wherever possible.  
 13 "Results. Previous donations had been given by  
 14 9 of 17 current donors, 4 ex-donors and 2 identified  
 15 as anti-HIV positive through infected recipients. Of  
 16 44 blood components made, 6 were unused, 9 not  
 17 traced by the hospital and 4 incorporated in plasma  
 18 pools for Factor VIII. Of recipients who could be  
 19 traced; 11 were deceased, 8 were not infected, 3 were  
 20 anti-HIV positive and 4 were not tested. Seven  
 21 recipients were notified as infected. In 2 cases  
 22 donors were implicated, 2 cases could not be solved  
 23 despite contact of all available donors, 1 could not  
 24 be pursued due to inadequate hospital records and  
 25 2 are incomplete.

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1 Then there is some discussion of other data  
 2 gathering exercises that had taken place, and towards  
 3 the end of the letter he says:  
 4 "I think at this stage we should abandon the  
 5 study as I do not think that we will learn more from  
 6 it that is not being learnt from other data gathering  
 7 efforts."  
 8 Then the final page:  
 9 "As you are well aware the look back element of  
 10 this study never got off the ground, people were  
 11 simply unwilling ..."  
 12 Exactly what they were unwilling to do, whether  
 13 it was the participation in the study or undertaking  
 14 some element of the look-back process is unclear from  
 15 the letters, and that is something we will need to  
 16 explore further.  
 17 But it perhaps suggests that there were  
 18 difficulties in the -- both -- there was controversy  
 19 in relation to informing recipients and there was  
 20 difficulties in obtaining data from transfusion  
 21 centres of exactly what was being done and who had  
 22 been traced.  
 23 The difficulties with look-back exercises are  
 24 also exemplified in a study by Dr Hewitt, Dr Moore and  
 25 Dr Barbara which was discussed at the IV International

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1 "Conclusions. These investigations are  
 2 time-consuming. Hospital records are often deficient.  
 3 The benefit produced by these enquiries has been  
 4 little, but 3 blood recipients have been identified as  
 5 seropositive and spread to their sexual partners  
 6 possibly averted."  
 7 That's obviously an extract of a conference  
 8 paper that was given, but it gives us some indication  
 9 of the conclusions of the work in relation to that  
 10 material.  
 11 We have a further report by Dr Hewitt from 1993,  
 12 DHSC0006351\_032 in tab 107.  
 13 At DHSC0006351\_32, if we start on page 1.  
 14 So we can see there the date it was received by  
 15 CDSC, in July 1993, and then if we go over the page we  
 16 have the "Abstract", which indicates the "Objective",  
 17 which was:  
 18 "To study the transmission of HIV by blood  
 19 donated from individuals subsequently identified to be  
 20 infected with HIV."  
 21 And the "Design" of the study, it was a:  
 22 "Retrospective study of previous donations from  
 23 individuals subsequently identified as infected with  
 24 HIV. Investigation of donations from individuals  
 25 believed to have transmitted HIV infection by

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transfusion. Investigation of donations transfused to recipients later found to be infected with HIV. In whom the only identified risk for infection was blood transfusion."

Then if we go down to the "Results":

"Five HIV infected recipients were identified, who had not previously been known to be infected. In addition, the RTC became aware of 2 recipients known to be anti-HIV positive but previously unreported. All infected in the recipients were transfused before 1985 with unscreened blood or components. Of the possible transfusion-transmitted HIV infections, one third were considered not due to transfusion, one third thought likely (without the identification of a culprit donor) and 5 donors were identified as likely to have been responsible for 6 reported cases. One case could not be investigated through lack of records and one is still under investigation."

What we note in the "Conclusions" are that:

"Investigations failed to reveal any infection arising after screening of blood donations commenced in 1985 [in this study]. Overall, 42% of identifiable recipients died within 6 months of transfusion. Eight of 32 ... living recipients were infected with HIV and 5 of these were newly detected through the

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not uncommon to find that a hospital laboratory has records of issuing a donation for a particular recipient, but the medical notes contain no information about the donations transfused. Such an omission obviously leaves room for doubt when investigating possible cases of transfusion transmitted infection. Hospital laboratory record keeping has generally much improved since the Health Circular relating to Record Keeping and Stock Control ... On the other hand, audits of blood transfusion practice continue to show gross deficits in the recording of information in medical notes.

"The majority of cases of transfusion transmitted HIV infection arise from blood transfusions given in 1982-1984. As record keeping was not satisfactory at that time, and usually related to non-computerised systems, it can often be difficult and time-consuming to retrieve information within the RTC, in the hospital laboratory and in the medical records department. Furthermore, recipients can be difficult to trace if no longer under hospital care. In many instances, recipients have moved home and are no longer registered with the General Practitioner caring for them at the time of transfusion. As

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investigation. Laboratory record keeping was generally deficient prior to 1985; accurate recording of transfusion details in patient medical records remains a conspicuous problem up to the date of the report. The investigation confirms the exceedingly small chance of transmission of HIV by transfusion of screened blood and blood components ..."

So, again, something that was highlighted in relation to early jaundice enquiries: the difficulties in relation to both laboratory record keeping and patient medical records and the challenges that that gives rise to in a look-back process.

It's perhaps instructive to go into the detail of this study in relation to one element and that's internal page 11.

Under the heading "Discussion":

"The investigation of possible transfusion-transmitted infection is extremely laborious and time-consuming. Investigation must be both thorough and methodical. This involves work for the RTC, hospitals, General Practitioners and FHSAs. Meticulous checking of the records at the RTC and hospital laboratory is necessary to ensure that the relevant donation is traced to the correct recipients and recorded in the patients' medical notes. It is

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contact is made first through a doctor a significant amount of time is spent in correspondence with FHSAs, to trace the appropriate GP. Sometimes the RTC has written to five or six doctors in an individual case (haematologist, surgeon, physician, referring physician GP) without any of them wishing to take responsibility for notifying the recipient. Not only does this cause extra work, but it considerably delays the investigation. On occasion several reminder letters have been necessary before the RTC has been supplied with relevant information. The period between initiation and completion of an investigation can be as long as one year. The more distant the transfusion, the longer the investigation will take."

If we go to the next paragraph and just pick it up halfway through:

"It is of continuing concern to the BTS that there is no mechanism for checking whether a lapsed donor has subsequently been reported as HIV positive through the confidential reporting system operated by the Communicable Disease Surveillance Centre. The failure of professionals to ask individuals diagnosed as infected with HIV about prior blood donation and then to notify the RTC also leads to missed opportunities to identify all recipients infected with

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1 HIV by transfusion."  
 2 So that was the discussion of Dr Hewitt in the  
 3 study -- sorry, Dr Hewitt in 1993.  
 4 The final point I want to picked up in relation  
 5 to the HTLV-III look-back is the issue of donors who  
 6 didn't subsequently return to give blood and the  
 7 difficulties that that appears to have raised and the  
 8 documents in relation to that that have been  
 9 identified.  
 10 If we could start with NHBT0099107, please it's  
 11 a letter from 9 August 1991 from Dr Hewitt to  
 12 a consultant paediatrician and if we pick up the third  
 13 paragraph:  
 14 "Our usual practice in reports of possible  
 15 transfusion transmitted HIV infection is to institute  
 16 a search for the records of the relevant donors. This  
 17 we have done. As you will know, routine screening of  
 18 blood donations for evidence of HIV infection did not  
 19 start until 1985. It was in September 1983 that the  
 20 Department of Health issued advice about the exclusion  
 21 of certain individuals from blood donation who might  
 22 be at risk of HIV infection. It is likely that once  
 23 we have traced the donors involved in [X]'s case, we  
 24 will find that a proportion have donated since 1985  
 25 and will therefore have been tested for anti-HIV. Our

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1 "Even if we decide to investigate no further, we  
 2 strongly believe that all cases of possible  
 3 transfusion transmitted infection should be notified  
 4 to the National Blood Transfusion Service so that we  
 5 may at least document the case."  
 6 Two final documents on this point, NHBT001 --  
 7 apologies, just give me one moment, sir.  
 8 Yes, only one further document, DHSC0014978\_092,  
 9 a letter from a clinical director of the South Thames  
 10 Blood Transfusion Service to Dr Rejman in relation to  
 11 a particular case:  
 12 "I fear that we're not going to satisfactorily  
 13 resolve this case. Of the 23 donors implicated, there  
 14 are 11 who are lost to follow-up. Attempts were made  
 15 to contact these donors in 1986, but they failed to  
 16 attend for further sampling when requested and have  
 17 not donated subsequently. As it happens,  
 18 a significant number were from a local college and had  
 19 moved on."  
 20 So a further example of the difficulty if donors  
 21 didn't re-attend.  
 22 Sir, will go to the final document,  
 23 NHBT0015135\_002, please. It's a letter from  
 24 August 1998 from Dr Gorman to Dr McGovern, dealing  
 25 with an application by a patient to the financial

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1 problem is what to do about the rest. It is possible  
 2 that one or more of the donors ceased donating before  
 3 1985 in response to requests from the Blood  
 4 Transfusion Service to self-exclude from blood  
 5 donation. In these cases, especially if we have no  
 6 recent record of an address, attempts at contact with  
 7 these ex-donors have been singularly successful. We  
 8 will, however, examine our records then determine what  
 9 action is necessary."  
 10 **SIR BRIAN LANGSTAFF:** Do you think it should be  
 11 "unsuccessful"?  
 12 **MS FRASER BUTLIN:** Yes, I read it twice, sir, and wondered  
 13 if what was being said was that it "singularly  
 14 successful", as in it was only successful on one  
 15 occasion or occasional moments. It doesn't quite  
 16 scan.  
 17 **SIR BRIAN LANGSTAFF:** I mean, that's the context, isn't  
 18 it?  
 19 **MS FRASER BUTLIN:** It is.  
 20 **SIR BRIAN LANGSTAFF:** Otherwise, the context it to put  
 21 "un" in front of "successful".  
 22 **MS FRASER BUTLIN:** Indeed.  
 23 **SIR BRIAN LANGSTAFF:** It's the use of the word  
 24 "singularly".  
 25 **MS FRASER BUTLIN:** The letter goes on:

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1 assistance schemes and trying to track whether they  
 2 traced the transfusions that they had received:  
 3 "Because (as you will appreciate) Ms [X] has  
 4 received a very large number of transfusions, we have  
 5 confined ourselves to identifying donors from two  
 6 groups of donations ..."  
 7 They are then set out, and then we go to the  
 8 last paragraph of the letter, where Dr Gorman says:  
 9 "However I feel that it is unlikely that all of  
 10 Mrs [X]'s donors will either be contactable now or  
 11 will have donated again since the index donation.  
 12 This is not for any sinister reasons, but simply  
 13 because a significant percentage of donors cease to  
 14 donate every year."  
 15 Therefore, she suggests it should be going to  
 16 the adjudication board in relation to the financial  
 17 assistance scheme. So, again, a recognition from  
 18 another consultant haematologist, Dr Gorman, that even  
 19 without the self-exclusion of donors, there's  
 20 a significant proportion of donors who simply don't  
 21 return on a regular basis.  
 22 So that brings me to an end of the presentation  
 23 on HTLV-III look-back, both in terms of its process  
 24 and some of the difficulties that were identified by  
 25 those undertaking it. There is, of course, a full

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1 written presentation with a large number of other  
2 references and other examples of the things I have  
3 highlighted today on Relativity for Core Participants,  
4 and I understand it will be on the website, the  
5 Inquiry website, at a later point.  
6 **SIR BRIAN LANGSTAFF:** Yes, well, thank you very much. So  
7 that's the end of your presentation today.  
8 **MS FRASER BUTLIN:** That's the end of the presentations for  
9 today, sir.  
10 **SIR BRIAN LANGSTAFF:** Tomorrow?  
11 **MS FRASER BUTLIN:** There will be a presentation tomorrow  
12 in relation to Professor Cash.  
13 **SIR BRIAN LANGSTAFF:** Yes. So that's a 10.00 start,  
14 Professor Cash, tomorrow.  
15 (4.30 pm)  
16 (Adjourned until 10.00 am the following day)  
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(45) all... - attendees: Dr Maycock

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(58) no... - organisational

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(65) tank - Tovey

F:

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(66) Tovey... - wasn't



<b>W</b>	150/19	52/15 53/24 54/7	22/1 22/2 22/22 23/1	<b>whom</b> [6] 76/20 89/6	83/15 84/12 85/21
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27/5 53/9 107/18	4/24 5/5 5/7 5/13 7/2	96/22 96/25 99/15	29/23 30/3 31/16 33/8	151/18	146/17 147/1 152/4
108/8 109/1 112/2	7/11 8/13 9/13 9/20	99/25 104/2 107/17	38/1 38/21 43/23 44/7	<b>why</b> [7] 17/24 56/14	157/23 159/19
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146/7	20/24 22/2 22/17	113/7 113/9 113/17	53/13 55/9 55/10 57/4	<b>wide</b> [1] 70/24	136/15 157/14 160/6
<b>ways</b> [2] 10/15 43/18	32/19 32/19 32/22	113/19 114/20 116/19	59/1 62/5 66/15 67/4	<b>wider</b> [1] 93/22	164/19
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F: