

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

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.

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

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

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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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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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.

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

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

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?

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

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

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

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

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 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

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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

27

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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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

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 ..."

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:

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

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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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

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.

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

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

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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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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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.

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

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):

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

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 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 Miflin 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 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 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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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 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 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 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.

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.

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

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

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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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 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 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 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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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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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

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 ..."

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*

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

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

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

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

1 National Medical and Scientific Director.
 2 The SNBTS management board at that stage
 3 comprised (*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

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

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

16 On 1 October 2008, the National Health Service
17 Functions of the Common Services Agency Scotland Order
18 removed the production of blood fractions from the
19 functions of the CSA. The CSA remained responsible
20 for the provision of supplies of human blood for
21 transfusion and related services, and there was
22 a period of wider organisational structural change in
23 2012-2013 resulting in consolidation of a number of
24 CSA divisions, often called strategic business units,
25 and the centralisation of support services, but the

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1 SNBTS was considered of sufficient size and speciality
2 to retain its own identity.

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

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

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

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

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

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

14 **MS SCOTT:** Yes.

15 **SIR BRIAN LANGSTAFF:** Yes, thank you very much.
16 (12.59 pm)

(Luncheon Adjournment)

17 (2.00 pm)

18 **SIR BRIAN LANGSTAFF:** Yes.

19 **MS FRASER BUTLIN:** Thank you.

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

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

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

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

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

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

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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

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

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:

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

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 Panton 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

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,

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

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

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 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 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 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 **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 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 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 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 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 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 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 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 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.

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; Morryston 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

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

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

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."

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.

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

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

1 transfusion. Investigation of donations transfused to
 2 recipients later found to be infected with HIV. In
 3 whom the only identified risk for infection was blood
 4 transfusion."
 5 Then if we go down to the "Results":
 6 "Five HIV infected recipients were identified,
 7 who had not previously been known to be infected. In
 8 addition, the RTC became aware of 2 recipients known
 9 to be anti-HIV positive but previously unreported.
 10 All infected in the recipients were transfused before
 11 1985 with unscreened blood or components. Of the
 12 possible transfusion-transmitted HIV infections, one
 13 third were considered not due to transfusion, one
 14 third thought likely (without the identification of
 15 a culprit donor) and 5 donors were identified as
 16 likely to have been responsible for 6 reported cases.
 17 One case could not be investigated through lack of
 18 records and one is still under investigation."
 19 What we note in the "Conclusions" are that:
 20 "Investigations failed to reveal any infection
 21 arising after screening of blood donations commenced
 22 in 1985 [in this study]. Overall, 42% of identifiable
 23 recipients died within 6 months of transfusion. Eight
 24 of 32 ... living recipients were infected with HIV and
 25 5 of these were newly detected through the

1 investigation. Laboratory record keeping was
 2 generally deficient prior to 1985; accurate recording
 3 of transfusion details in patient medical records
 4 remains a conspicuous problem up to the date of the
 5 report. The investigation confirms the exceedingly
 6 small chance of transmission of HIV by transfusion of
 7 screened blood and blood components ..."
 8 So, again, something that was highlighted in
 9 relation to early jaundice enquiries: the difficulties
 10 in relation to both laboratory record keeping and
 11 patient medical records and the challenges that that
 12 gives rise to in a look-back process.
 13 It's perhaps instructive to go into the detail
 14 of this study in relation to one element and that's
 15 internal page 11.
 16 Under the heading "Discussion":
 17 "The investigation of possible
 18 transfusion-transmitted infection is extremely
 19 laborious and time-consuming. Investigation must be
 20 both thorough and methodical. This involves work for
 21 the RTC, hospitals, General Practitioners and FHSAs.
 22 Meticulous checking of the records at the RTC and
 23 hospital laboratory is necessary to ensure that the
 24 relevant donation is traced to the correct recipients
 25 and recorded in the patients' medical notes. It is

1 not uncommon to find that a hospital laboratory has
 2 records of issuing a donation for a particular
 3 recipient, but the medical notes contain no
 4 information about the donations transfused. Such an
 5 omission obviously leaves room for doubt when
 6 investigating possible cases of
 7 transfusion transmitted infection. Hospital
 8 laboratory record keeping has generally much improved
 9 since the Health Circular relating to Record Keeping
 10 and Stock Control ... On the other hand, audits of
 11 blood transfusion practice continue to show gross
 12 deficits in the recording of information in medical
 13 notes.
 14 "The majority of cases of transfusion
 15 transmitted HIV infection arise from blood
 16 transfusions given in 1982-1984. As record keeping
 17 was not satisfactory at that time, and usually related
 18 to non-computerised systems, it can often be difficult
 19 and time-consuming to retrieve information within the
 20 RTC, in the hospital laboratory and in the medical
 21 records department. Furthermore, recipients can be
 22 difficult to trace if no longer under hospital care.
 23 In many instances, recipients have moved home and are
 24 no longer registered with the General Practitioner
 25 caring for them at the time of transfusion. As

1 contact is made first through a doctor a significant
 2 amount of time is spent in correspondence with FHSAs,
 3 to trace the appropriate GP. Sometimes the RTC has
 4 written to five or six doctors in an individual case
 5 (haematologist, surgeon, physician, referring
 6 physician GP) without any of them wishing to take
 7 responsibility for notifying the recipient. Not only
 8 does this cause extra work, but it considerably delays
 9 the investigation. On occasion several reminder
 10 letters have been necessary before the RTC has been
 11 supplied with relevant information. The period
 12 between initiation and completion of an investigation
 13 can be as long as one year. The more distant the
 14 transfusion, the longer the investigation will take."
 15 If we go to the next paragraph and just pick it
 16 up halfway through:
 17 "It is of continuing concern to the BTS that
 18 there is no mechanism for checking whether a lapsed
 19 donor has subsequently been reported as HIV positive
 20 through the confidential reporting system operated by
 21 the Communicable Disease Surveillance Centre. The
 22 failure of professionals to ask individuals diagnosed
 23 as infected with HIV about prior blood donation and
 24 then to notify the RTC also leads to missed
 25 opportunities to identify all recipients infected with

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 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 "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 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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I N D E X

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MS FRASER BUTLIN: [44] 95/20 96/11 100/13 100/15 100/24 101/4 101/7 101/11 102/22 103/2 104/2 104/10 104/15 104/22 104/25 105/9 105/12 111/8 112/5 112/11 112/20 113/11 113/14 113/17 114/1 114/5 114/12 114/22 115/5 132/7 136/8 136/14 136/21 137/4 137/6 142/9 142/12 142/18 162/12 162/19 162/22 162/25 165/8 165/11 MS SCOTT: [56] 1/4 1/18 6/21 6/24 7/5 7/8 7/10 7/23 8/2 8/7 8/9 8/23 11/23 11/25 12/5 12/10 12/12 13/6 13/8 14/15 14/22 15/3 15/15 20/2 20/5 21/1 21/9 23/3 27/20 27/25 29/1 29/14 32/2 35/10 35/13 44/9 50/9 52/13 52/16 53/6 53/8 53/12 53/23 54/2 54/5 62/25 69/25 71/1 71/4 71/13 71/23 73/17 73/19 74/7 74/13 95/14 SIR BRIAN LANGSTAFF: [102] 1/3 6/17 6/23 7/1 7/6 7/9 7/21 7/24 8/4 8/8 8/22 11/20 11/24 12/1 12/6 12/11 13/4 13/7 14/10 14/16 14/23 15/13 19/23 20/3 20/22 21/8 22/25 27/18 27/21 28/23 29/12 32/1 35/8 35/11 44/7 50/4 52/11 52/14 53/4 53/7 53/9 53/20 53/24 54/3 62/24 69/23 70/24 71/2 71/9 71/21 73/12 73/18 74/4 74/10 95/9 95/15 95/19 96/8 100/9 100/14 100/16 101/2 101/5 101/10 102/18 103/1 103/24 104/8 104/11 104/18 104/23 105/2 105/10 111/5 112/3 112/6 112/12 113/7 113/12 113/15 113/24 114/4 114/9 114/15 115/4 131/25 132/6 136/4 136/9 136/15 136/25 137/5	142/7 142/10 142/16 162/10 162/17 162/20 162/23 165/6 165/10 165/13 . 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