

Thursday, 2 December 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Professor, I'm going to ask Kamila to ask you to take the oath.

PROFESSOR DAME CARMEN MARCELA CONTRERAS (affirmed)

Questions from MS RICHARDS

MS RICHARDS: Professor Contreras, I'm just going to ask you to tell us very briefly an overview of your career. You qualified as a doctor in Chile, I think, and then you came to the UK and you took up a post at the North London Blood Transfusion Centre in 1974 as a senior scientific officer?

Would you mind answering yes or no, rather than nodding because the transcript doesn't pick it up.

A. Yes.

Q. Briefly, what did that role entail?

A. After having been at the Medical Research Counsel and the Royal Postgraduate Medical School, I trained in red cell immunohaematology, so I was in charge of a small reference laboratory, and also of education in red -- in blood grouping, I would say, blood grouping and antibody screening for patients, advising the staff of the centre on those issues and doing research.

Q. You stayed in that role until May 1976. Then you

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A. Yes.

Q. You were in that post until February 1984, and then in February 1984 you became the medical director at the North London Regional Transfusion Centre?

A. Yes, I did.

Q. Had your predecessor, your immediate predecessor, been Dr Tom Davies?

A. Yes.

Q. You stayed in that post until November 1995, is that right?

A. No, as --

Q. As medical director of the Regional Transfusion Centre?

A. Yes, until 1995.

Q. Then you became executive director of the London and South East zone, which gave you a degree of responsibility not just for the North London Regional Transfusion Centre, which I think by then had moved to Colindale, but also for the Cambridge, Brentwood and Tooting centres; is that right?

A. Yes.

Q. You were working at that point then for the relatively newly established National Blood Authority?

A. Yes.

Q. You stayed in that post until August 1999, I think,

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became a medical assistant in blood transfusion, again at the in North London Transfusion Centre. What was the nature of that role?

A. It was very similar to the previous one but I had revalidated as a doctor in the UK and I had taken all my memberships and my exams, so I could be paid as a doctor. I had come as a British Council scholar and then I could enter the rat race, as you would say, and become a medical doctor.

Q. You were in that role until the middle of 1978 and then from July 1978 to February 1980 you were a senior registrar in haematology at St Mary's Hospital and at Northwick Park Hospital. Broadly, what did that role entail?

A. It was mostly to do with haematological patients, but I think I was appointed because of my interest in immunohaematology and haemolytic disease of the newborn, so I spent a large time of my time doing clinical and research work on what they call rhesus haemolytic disease of the newborn, Rh negative mothers who have Rh positive children and are incompatible, so doing exchange transfusions for babies, et cetera.

Q. Then in March 1980 you returned to the North London Regional Transfusion Centre as deputy director and consultant in blood transfusion, is that right?

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and then from August 1999 to February 2007 you were the national director of diagnostics, development and research at NHSBT?

A. Yes.

Q. You also took up a position as professor in transfusion of medicine at The Royal Free and UCH between 1988 and 2008?

A. Yes.

Q. We'll obviously come back to some of those positions of responsibility in more detail. You've sat on multiple committees and working groups during your career, I'm not going to ask you to go through them, you've listed them in your statement, and we'll look at some of those of most direct relevance to the Inquiry in due course, but at you're also the author of multiple papers and the co-author of the textbook *Blood Transfusion in Clinical Medicine*.

A. Yes.

Q. I understand from your statement, Professor Contreras, that you've not previously been asked to give evidence to any public inquiry looking into matters relating to infected blood?

A. Yes, that's right.

Q. You also say in your statement you haven't been involved in any litigation relating to transmission of

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1 infections through blood and blood products but you
2 did give evidence in criminal proceedings against the
3 Chief MLSO who was charged with offences relating to
4 the theft of plasma, alongside Dr Mark Patterson of
5 the National Heart Hospital in the 1980s?

6 **A.** Yes.

7 **Q.** So that's your only involvement in litigation?

8 **A.** Yes.

9 **Q.** I'm going to ask you now to tell us a bit about the
10 Regional Transfusion Centre itself, the North London
11 Centre. When you took up your post there in 1980, it
12 was located in Edgware; is that right?

13 **A.** Yes.

14 **Q.** You've said in your statement that it wasn't fit for
15 purpose. Ultimately, there was a move to a new centre
16 in Colindale but that wasn't until the end of the
17 1980s. In what sense was it not fit for purpose?

18 **A.** Well, it was -- it wasn't built for purpose so it was
19 really a collection of rooms, with not really clean
20 rooms, as are necessary in a blood centre. We were
21 very cramped, very crowded and, you know, it was
22 leaking, the pipes weren't working very well. It was
23 a real disaster zone.

24 **Q.** If we look at your witness statement, please, at
25 WITN5711001, and if we can go to page 18, please,

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1 "The structure [of the centre] comprised of
2 departments, as follows:

3 "a) Donor Services ..."

4 And if we go to the top of the next page, the
5 donor services department had responsibility for:

6 "- Donor records;

7 "- Donor organisation;

8 "- Donor recruitment and publicity;

9 "- Call-up and donor communications."

10 Again, we'll come on to a number of those areas
11 in the course of the morning.

12 "b) Mop teams: doctors, nurses, donor attendants
13 and drivers."

14 And you say that section had the majority of
15 staff members.

16 Is it right to understand those are the teams
17 that are going out to various different locations to
18 undertake the donor sessions?

19 **A.** Yes, and also at the static clinics.

20 **Q.** And then you refer to the:

21 "Static clinics for routine and apheresis
22 donations ..."

23 And again we'll come on to some of those issues.

24 They had:

25 "... doctors, nurses, donor attendants and

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1 Soumik, you describe here the staffing and structure
2 of the centre during your period as director, and I'm
3 going to just take this from your statement because
4 it's a useful summary.

5 So you tell us in paragraph 71 that, by the
6 mid-'90s, the staffing was around 350 people. That
7 comprised medical and scientific doctors, MLSOs -- can
8 you just tell us what the role of the MLSO was?

9 **A.** The Medical Laboratory Scientific Officers, who train
10 in the service, as compared with Scientific Officers
11 who have a university degree, but then they become
12 proper scientists. But they train from when they
13 leave school and they are trained mostly in the
14 National Health Service and, in our case, we trained
15 our -- and they have to pass exams from Junior MLSO to
16 proper MLSO, Chief MLSO and Senior MLSO, Medical
17 Laboratory Scientific Officer.

18 **Q.** Then going back to paragraph 71, you described:

19 "... scientific officers, nurses, technicians,
20 laboratory aides, admin and clerical staff, drivers,
21 team leaders, donor attendants, cleaners and porters."

22 I'll come back to some of the staffing issues in
23 relation to donor sessions at a later stage.

24 If we then go down to the bottom of the page and
25 we just see the departments, so you tell us there:

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1 receptionists."

2 Then we had the:

3 "d) Components Laboratory or Processing of
4 Blood."

5 So that's the laboratory where the mechanics of
6 the processing of the blood that has been collected at
7 the donor sessions is then processed into its various
8 components?

9 **A.** Yes.

10 **Q.** Then we have the biochemistry lab, and then the
11 microbiology lab. That's where, amongst other things,
12 the testing for screening for viral infections would
13 be undertaken; is that right?

14 **A.** Yes.

15 **Q.** Was that very much the responsibility of Dr John
16 Barbara at the North London centre?

17 **A.** Yes, it was -- well, Dr John Barbara's responsibility
18 and the consultant in charge of that microbiology, the
19 medical consultant. Dr John Barbara was a senior
20 scientific officer and there was also a medical
21 consultant. Usually -- most times was Dr Hewitt.

22 **Q.** And we anticipate hearing from both Dr Hewitt and
23 Dr Barbara over the coming hearings.

24 Then we have, bottom of the page, the:

25 "g) Blood Group Serology or Red Cell

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1 Immunohaematology ..."
 2 Department.
 3 Then if we go over the page, we can see a range
 4 of other departments set out there. (j) refers to
 5 the:
 6 "Teaching and Training Department, planned
 7 training for all grades of staff at the Centre as well
 8 as for Senior Registrars, nurses and MLSOs on
 9 rotation. The training and teaching were performed by
 10 consultants, scientists, nurses and MLSOs."
 11 "I'll come back to some aspects of training
 12 in due course.
 13 And then we can see the remaining departments
 14 there set out, including the quality department.
 15 So your statement gives the impression of
 16 a large centre. Was the North London Centre one of
 17 the largest Regional Transfusion Centres in the
 18 country?
 19 **A.** Physically we weren't, but in complexity we were,
 20 because our client hospitals -- because of the more
 21 graphics of -- and because we had the most demanding
 22 hospitals. So yes, insofar as the complexity of the
 23 work that we did, we were the most complex.
 24 **Q.** And yours was one of two transfusion centres in
 25 London, the other being the South London Centre in

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1 1980 until early 1984, when you took over from
 2 Dr Davies.
 3 What particular areas of the centre's work did
 4 you have responsibility for as deputy director?
 5 **A.** Mostly the scientific areas. Well, I was
 6 interested in red cell immunohaematology, blood
 7 grouping, and antibody screening, and transfusion
 8 reactions in hospitals. Teaching. I've always been
 9 passionate about teaching, so teaching not only of the
 10 centre staff but of the hospital staff, and HLA
 11 typing -- quality as well. And yes, and I started
 12 becoming interested in transfusion microbiology.
 13 **Q.** And then once you took over as director in
 14 February 1984, you were ultimately responsible for all
 15 aspects of functioning of the Centre; is that right?
 16 **A.** Yes. Ultimately, yes, but I had the Regional Health
 17 Authority managing me, but I was answerable to them.
 18 **Q.** Again, if we just go back to your statement, just to
 19 get an overview of the kinds of areas of
 20 responsibility you had.
 21 If we put the statement back on screen, please,
 22 Soumik. Thank you. And we go to page 14, bottom of
 23 the page.
 24 You tell us at paragraph 52 at the bottom of the
 25 page that:

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1 Tooting; is that right?
 2 **A.** Three. There was Brentwood as well.
 3 **Q.** Okay, so if we count Brentwood as part of London.
 4 And we'll look at some documents which give
 5 a flavour of the range of hospitals that were supplied
 6 by the centre in due course, but you were responsible,
 7 effectively, or the centre was responsible for
 8 supplies to the whole North Thames region; is that
 9 correct?
 10 **A.** Yes, North West Thames.
 11 **Q.** North West Thames region and that would encompass
 12 a number of the big teaching hospitals in London?
 13 **A.** Yes.
 14 **Q.** Was there any particular relationship or liaison
 15 between your centre and the South London Centre or the
 16 Brentwood centre other than through the divisional
 17 meetings?
 18 **A.** Well, at the Regional Transfusion Directors meetings
 19 as well, and the divisional meetings, and sometimes we
 20 might talk on issues -- on professional issues,
 21 but ...
 22 **Q.** Can I just ask you a little more, first of all, about
 23 your role and responsibilities in that period of time
 24 in the early eighties when you were the deputy
 25 director and consultant in blood transfusion. So from

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1 "[You were] responsible for budget control,
 2 collection, processing, testing, storage and
 3 distribution of blood, plasma and blood components."
 4 Over the next page:
 5 "[You were] responsible for the provision of
 6 reference services in Transfusion Medicine and for the
 7 provision of advice and training in transfusion
 8 medicine."
 9 I'm going to be asking you quite a lot about
 10 that later, Professor Contreras.
 11 "... responsible for regulatory compliance and
 12 research and development into blood transfusion."
 13 You were responsible for the design --
 14 ultimately responsible for the design and technical
 15 requirements of the new centre in the move from
 16 Edgware to Colindale.
 17 Then, paragraph 57, you talk about how, when you
 18 took over your directorship, you established firm
 19 relationships with the hospitals which the Centre
 20 served and, again, I'm going to come back to that.
 21 Paragraph 58 you refer to:
 22 "... training and research in [relation to]
 23 transfusion medicine and transfusion transmitted
 24 infections ..."
 25 So that's a broad overview, is it, of your

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1 responsibilities as director?
 2 **A.** Yes.
 3 **Q.** You mentioned a few minutes ago the Regional Health
 4 Authority. You were ultimately accountable to the
 5 Regional Health Authority and that was the North West
 6 Thames Regional Health Authority?
 7 **A.** Yes.
 8 **Q.** You told us in your statement that you would have
 9 monthly meetings with the regional medical officer.
 10 What was the purpose of having such regular contact?
 11 **A.** It was to update them on the progress or any
 12 problem -- progress of the Centre, any problems we
 13 might have, so that -- they were the holders of the
 14 purse, so -- and any advice I could have about any
 15 developments that might be happening in the hospitals
 16 we served. Because the regional medical officer
 17 always knew in advance if there was going to be more
 18 cardiac surgery in a hospital or if they were going to
 19 introduce bone marrow transplantation in a hospital.
 20 So it was a two-way communication, and -- yes.
 21 **Q.** And you described in your statement in terms of
 22 funding that, broadly speaking, the Centre was
 23 adequately funded. Is that right?
 24 **A.** Yes.
 25 **Q.** We can take the statement down, thank you, Soumik.

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1 interest of Regional Health Authorities to develop the
 2 services, and on having the adequate senior staff to
 3 relate to our hospitals.
 4 **Q.** And you have described in your statement -- can we go
 5 back to the statement, Soumik, page 56 and 57 --
 6 strengths and weaknesses of the National Blood
 7 Transfusion Service.
 8 We'll look just briefly first of all at what you
 9 say were the strengths, so voluntary, altruistic
 10 repeat donation, a truly public service. Public saw
 11 it as a national rather than regional service. Pride
 12 in staff.
 13 You talk about an improved information exchange
 14 between centres. Is that at the point in time at
 15 which it became a genuinely national service rather
 16 than the feudal system of the seventies and eighties?
 17 **A.** No, I think that we had some information, but of
 18 course the -- with the creation of the MBA -- well,
 19 there were no more centres or centre management teams,
 20 but gradually we became -- we became -- we exchanged
 21 more information with -- yeah, with the creation of
 22 divisions as well, you know, we tried to exchange more
 23 information between us.
 24 **Q.** Indeed I think that's probably the point picked up at
 25 subparagraph (h) at the bottom of the screen:

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1 Now I just want you to help us understand
 2 a little about the organisation of what was notionally
 3 called the National Blood Transfusion Service in the
 4 1970s and 1980s, but was something that you described
 5 in your statement as "a feudal system where we had
 6 autonomy over our own regions".
 7 In your own words, Professor Contreras, how did
 8 the National Blood Transfusion Service operate and the
 9 individual Regional Transfusion Centres operate?
 10 **A.** Well, as I said, we were quite autonomous in the way
 11 we dealt with our donors, in the way we dealt with
 12 with our hospitals and in the way we dealt with our
 13 regions. I was very lucky to have this constant
 14 contact with my Regional Health Authority. And the --
 15 we met at Regional Transfusion Directors meetings but
 16 it was in a very loose way and, yes, we agreed on some
 17 national policies like donor selection criteria, and
 18 later on with management information system, but we
 19 were really managing our own centres, and that could
 20 be seen by the collection rates of different centres
 21 per thousand population, you know, the number of
 22 collections, the -- I mean, the number of activities
 23 that we did. Not every centre had tissue typing
 24 developed, and not every centre had a tissue bank or a
 25 cord blood bank. So we were very dependent on the

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1 "There was increased exchange of information at
 2 the RTD meetings."
 3 You then refer to:
 4 "The creation of the management information
 5 system (MIS)."
 6 I'll come back to that at a later stage,
 7 Professor Contreras.
 8 If we go over the page to paragraph 227, you've
 9 then identified a number of weaknesses of the way in
 10 which the service was structured, prior to the
 11 creation of the National Blood Authority. So just so
 12 we understand it, when you say "It [in
 13 paragraph 227(a)] was a non-executive body with no
 14 real powers other than the power of persuasion", are
 15 you talking about there the period of time where there
 16 was the National Directorate --
 17 **A.** Yes.
 18 **Q.** -- and its relationship with all the individual --
 19 **A.** Yes.
 20 **Q.** -- Regional Transfusion Centres. Then you point out:
 21 "The regional transfusion centres had different
 22 levels of funding and involvement by their respective
 23 regional health authorities.
 24 "There were different IT systems in place,
 25 idiosyncratic to each centre ..."

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1 You then observe that, in terms of Dr Gunson's
 2 role as national director, once the National
 3 Directorate was established, he had no executive
 4 power, he could only advise and persuade.
 5 "Some [Regional Transfusion Centres] had severe
 6 structural deficits."
 7 What did you mean by that?
 8 **A.** That they were not adequately funded.
 9 **Q.** "RTCs were very different administratively and
 10 managerially.
 11 "There was duplication of research and
 12 development and little collaboration between centres.
 13 "Productivity was different at different
 14 centres.
 15 "Innovation was different at different centres.
 16 "Efficiency was different at different centres."
 17 You refer to the comparison of collections of
 18 blood and plasma per million of population, and:
 19 "Liaison with hospitals was different at
 20 different centres, as consultants and scientists at
 21 some centres had little or no relationship with
 22 clinicians at the hospitals they served."
 23 So that is a description of the downside, as it
 24 were, of having a system of a number of Regional
 25 Transfusion Centres, each autonomous, accountable only

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1 enough blood and collecting enough plasma for BPL, and
 2 issuing the different components. So I would say that
 3 some centres were so concentrated on the collection
 4 that they had very little contact with the hospitals.
 5 **Q.** Now we know that the last Regional Transfusion
 6 Directors meeting took place in January 1989. If we
 7 just look at the formal minutes, first of all, of that
 8 meeting.
 9 Soumik, it's NHB0018188, please. We can see
 10 the date there, 18 January 1989 and we can see,
 11 Professor Contreras, that you were in attendance. If
 12 we go to the second half of the second page, you'll
 13 see, Professor Contreras, there's a heading "National
 14 Director's Report", "Communications with the
 15 Directorate", and there's a report from Dr Gunson,
 16 I don't need to ask you to look at the detail of it,
 17 but if we look at the bottom paragraph, we can see
 18 Dr Gunson reporting that, since the last RTD meeting,
 19 a National Management Committee had been established
 20 and he proposed meetings between the Committee and
 21 Divisions. Then it says, towards the bottom of the
 22 page:
 23 "If this role for the National Management
 24 Committee and the Divisions was agreed he asked
 25 Directors to consider the future of the RTD Meeting

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1 to their Regional Health Authority; is that right?
 2 **A.** Yes.
 3 **Q.** In terms of the system of Regional Transfusion
 4 Director meetings, I think those took place roughly
 5 four times a year, you were a regular attendee at
 6 those meetings once you became director?
 7 **A.** Yes.
 8 **Q.** What did you see as the main purpose or benefit of
 9 those meetings?
 10 **A.** Exchange of information between centres and agreeing
 11 some national issues, like donor selection or
 12 introduction of testing or screening, progress in --
 13 mostly in production, and also exchanging information
 14 about plasma procurement, and all those issues. We
 15 hardly ever discussed what I call transfusion -- well,
 16 what's called transfusion medicine.
 17 **Q.** I'll want to come at a later stage to your own views
 18 about the importance of transfusion medicine and the
 19 attempts that were made by you and your colleagues at
 20 the centre to shape policy and practice in that
 21 regard, but what why do you think that wasn't
 22 a significant feature of the discussions amongst
 23 Regional Transfusion Directors?
 24 **A.** I think that -- I'm speculating for them -- it was
 25 because they were mostly concerned about collecting

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1 and suggested that the [go to the top of the next
 2 page] business part of the Meeting should be shorter
 3 ..."
 4 Then there's a discussion reported, I'm not
 5 going to go through all of it Professor Contreras.
 6 I think you've seen this document and were asked about
 7 it in your statement. That long paragraph talks about
 8 how contact would be maintained between Dr Gunson and
 9 Professor Cash.
 10 Then the second paragraph records:
 11 "Dr Wagstaff [summarising] the discussion which
 12 led him to ask if it was the wish of those present
 13 that the RTD Meetings should be discontinued and be
 14 replaced by an Annual Meeting open to all NBTS
 15 Consultants with a Scientific Agenda. This was agreed
 16 unanimously."
 17 Now, there's no record there to any particular
 18 contribution from you but I think you've seen very
 19 recently, and it was referred to in the course of
 20 Dr Napier's evidence, a different account of this
 21 meeting which suggests that the idea of ceasing to
 22 hold RTD meetings regularly was your idea. We'll just
 23 have a look at that and then I'll ask you about it.
 24 So that alternative record of the meeting is
 25 SBTS0000628_011. So you'll see at the top of the page

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1 it says "210th English Regional Transfusion Directors
2 Meeting, Wednesday 18 January 1989".

3 I'm afraid I don't know who the author of this
4 document is, Professor Contreras, but it's somebody's
5 account of attendance at the meeting. If we go to
6 page 3, we can see, halfway down the page,
7 a handwritten heading "Future of RTD meetings", and
8 what this says is:

9 "At this point, Dr Wagstaff and Dr Contreras
10 joined the meeting. Dr Wagstaff took the Chair and
11 Dr Contreras was invited to give her views on the
12 future of RTD meetings as this had been discussed in
13 her Division."

14 Then at the next sentence it says:

15 "She proposed that the RTD meetings be
16 abolished."

17 There's then various points set out, I'm not
18 going to go through the detail of them all. If we go
19 to the bottom of the page, thank you, the bottom of
20 the page, the last sentence asserts:

21 "There was no discussion of the advantages and
22 disadvantages of dissolving the RTD meetings."

23 Then, over the page, we have the author's
24 comment or reflection on this decision, with the last
25 paragraph under that heading, which has been

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1 We were very busy and transfusion directors
2 meetings took two days. We had to travel around the
3 world -- around the country, sorry, and stay overnight
4 because usually they took half an afternoon,
5 an afternoon and a morning. So it was to decide very
6 little, it could have been done by letter or by fax,
7 and we had the divisional meetings and the National
8 Management Committee meetings so I didn't see any
9 point of having this -- I called it sometimes a club,
10 continuing to meet.

11 **Q.** In terms of the divisional meetings, the North London
12 Regional Transfusion Centre fell within, I think, what
13 was called the Eastern Division, and your meetings
14 were, is this right, with your colleagues in
15 Brentwood, Tooting and Cambridge?

16 **A.** Yes.

17 **Q.** Is it right to understand that you would essentially
18 at least until the Regional Transfusion Directors
19 meetings were abolished, you would essentially pick up
20 at a divisional level the kind of topics that were
21 being discussed at the Regional Transfusion Director
22 meetings but approaching them from your divisional
23 perspective?

24 **A.** Yes.

25 **Q.** Now, obviously, as the 1990s moved on, the National

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1 underlined, saying:

2 "... none of this discussion took place, these
3 are my personal views and in the midst of a slightly
4 non-plussed silence, Dr Wagstaff concluded that the
5 210th was to be the last RTD meeting in its present
6 form."

7 So a slightly different account there of the
8 discussions that took place. Can you recall whether
9 this was something that was your idea, to stop holding
10 these regular RTD meetings?

11 **A.** Well, as it's stated in the RTD minutes in the
12 proper -- I think this was written by one of my
13 Scottish colleagues, because they had an interest, of
14 course, in the English and Wales Blood Transfusion
15 Service. If you look at the minute -- the original
16 meeting minutes, Dr Gunson, it was he who suggested,
17 this was a *fait accompli*.

18 Nobody consulted us about the existence of the
19 National Management Committee. This came -- Dr Gunson
20 came to the meeting to inform us that it had been
21 formed, and he was the one who suggested that this --
22 that we should continue meeting as divisions. So if
23 I said something, I must have agreed with him, there
24 was no point in having a National Management
25 Committee, divisional meetings and regional meetings.

22

1 Blood Authority was established and I just want to ask
2 you about the views you expressed about that at the
3 time, which you set out in a letter to Dr Gunson. So
4 that's NHBT0001875, please, Soumik?

5 So this is a letter, 19 July 1990, from you to
6 Dr Gunson, headed "Proposal to the Department of
7 Health for a Nationally Managed Blood Transfusion
8 Service in England and Wales", and you say this in the
9 second paragraph:

10 "Although in principle I am in favour of the
11 concept of a National Blood Transfusion Service that
12 should include Regional Transfusion Centres and the
13 CBLA, in the current NHS climate, I am against
14 a nationally managed Blood Transfusion Service. I
15 have discussed your paper with my colleagues at NLBTC
16 [that's the North London Blood Transfusion Centre] and
17 they all, except for Branko, agree with this reply."

18 Then you say, in the next paragraph, if I pick
19 it up in the fourth line:

20 "However, the paper [Dr Gunson's paper] does not
21 provide any concrete evidence that national management
22 would improve local management in the BTS. In some
23 Regions like our own, there would simply be another
24 tier of management -- since we effectively are
25 managing the centre ourselves and are not

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1 dictatorially 'managed' by the [Regional Health
2 Authority]. A National Management would increase
3 costs, reduce local accountability and be contrary to
4 the current climate of dispensing with large
5 'national' organisations."

6 You then talk about the co-ordination work
7 undertaken by the National Directorate since its
8 inception. Then, if we go over the page, you then set
9 out a number of numbered reasons for being against
10 a nationally managed Blood Transfusion Service. I'm
11 not going to go through all of them but I just wanted
12 to pick up a couple with you. The first is what you
13 say at paragraph 2. You say in the third line at
14 paragraph 2:

15 "National management would not 'supplement and
16 support' local management ... but would remove a level
17 of responsibility we currently hold and also, very
18 importantly, the local pride of staff ... It would no
19 longer be our Centre working for our hospitals. We
20 would be directed nationally and it is difficult to
21 maintain staff loyalty and pride ... We cannot see how
22 a centrally managed service would ... make this
23 service more efficient, and ... more accountable."

24 We've previously discussed, a few minutes ago,
25 Professor Contreras, some of the disadvantages of the

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1 Department of Health did not give him the funding.

2 And now, he didn't have any funding and wanted
3 to start this national management without -- he didn't
4 give us a good basis for it.

5 **Q.** If we just go to the next page, there was one other of
6 the numbered reasons I wanted to highlight, which is
7 paragraph 10. You expressed the concern that
8 uniformity would drag you down to the lowest common
9 denominator rather than raise standards generally. So
10 it would just be an extra tier of national management
11 rather than -- is this right, rather than
12 a fundamental reorganisation of the service?

13 **A.** Yes.

14 **Q.** Now, obviously, the National Blood Authority was, in
15 due course, established and, indeed, you took on
16 a role in the mid-'90s with the National Blood
17 Authority and subsequently with NHSBT. Looking back
18 now, do you consider the establishment of a national
19 service in the 1990s was the right course?

20 **A.** Yes, I do consider that, and I was really the
21 chairperson of the National Blood Service Committee
22 that, together with Bain & Company, the management
23 consultants, proposed the National Blood Authority but
24 that meant pain because we had to close some centres
25 or some activities at some centres. We had to abolish

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1 autonomous Regional Transfusion Centres so that people
2 were dependent on their relationships with their
3 Regional Health Authority, there were different
4 systems, different levels of funding and different
5 standards, and so on.

6 Given that you had those views about the
7 disadvantages of the feudal system, why was it that
8 you were concerned about the establishment now, in the
9 1990s, of a National Blood Transfusion Service?

10 **A.** I think that I believed that it hadn't gone far
11 enough. This was a middle-of-the-road solution with
12 no funding, with a large number of additional
13 management staff with high -- quite costly, but with
14 nothing -- not talking about reduction in the number
15 of centres, performance indicators, costing, and he
16 didn't say whether funding would come.

17 We were all short of cash to run the services.
18 So it was -- I have always been of the idea of a truly
19 national blood service and a truly well-managed
20 National Blood Service as was proven later on, but
21 this was a middle-of-the-road idea, very badly
22 conceived and with some staff that I don't know where
23 he would have got it from, because he had asked for
24 something similar a couple of years earlier after
25 I think it was an Ernst & Young report, and the

26

1 Regional Transfusion Directors, all those management
2 teams, so we had to be cost effective.

3 And I really believe that was the way to go.
4 I think that nowadays there are two or three testing
5 centres for the whole country; we had 15 before. And
6 so there wasn't a need for 15 -- to repeat 15 times
7 all the things we did.

8 **Q.** If we just look at your statement,
9 Professor Contreras.

10 Soumik, if we could have back WITN5711001 and go
11 to page 32. You'll see towards the bottom of the
12 page, in this part of your statement you were
13 commenting upon your letter to Dr Gunson, the letter
14 we've just looked at.

15 If we can just to the next page, please, and
16 look at paragraph 131. You said there that:

17 "[You] felt that there was a lot of inequality
18 between the different blood centres at the time with
19 respect to performance, how and to what extent they
20 were funded and managed and their relationship with
21 their hospitals and patients."

22 Then you observe that the proposal being put
23 forward by Dr Gunson didn't address properly, in your
24 view, how that inequality would be addressed.

25 Could I ask you just to elaborate upon the

28

1 particular respects in which you felt there was
 2 inequality between the different centres? How did
 3 that inequality manifest itself in the 1980s and early
 4 1990s?

5 **A.** In funding. Mostly it was, really, money. Some
 6 Regional Transfusion Centres never met with the
 7 Regional Health Authority. They were devolved to the
 8 district and the district had other priorities. So
 9 many were very short of cash. There is an example
 10 amongst the documents that I've been given, for
 11 example, of Dr Martlew asking for a plasmapheresis
 12 clinic. You know, we had three plasmapheresis
 13 clinics.

14 So I saw that there was inequality. We had more
 15 consultants, some of them had one or two consultants
 16 in the transfusion centres. We had more scientific
 17 officers. I could see that there was evidence of
 18 inequality. And there is a report that you provided
 19 me with from the Department of Health showing the
 20 inequalities amongst transfusion centres.

21 **Q.** Just to pick up on that issue of funding, can we just
 22 look at a letter that you wrote to your divisional
 23 colleagues in August 1991, it's DHSC0004369_014. I'm
 24 not going to go through it in particular detail and
 25 you're talking, amongst other things, about the

29

1 So I think it's right to understand that, at the
 2 time, you were expressing, I think on a number of
 3 occasions quite vociferously, your concerns about the
 4 underfunding of the service.

5 **A.** Yes.

6 **Q.** Did that change or improve once the National Blood
 7 Authority was established? Did it become a better
 8 funded service in your view?

9 **A.** Well, at least in my zone we broke even and were able
 10 to improve, for example we were able to establish two
 11 additional mobile teams in Ipswich -- and I can't
 12 remember the other place -- and we reduced -- we
 13 didn't have management team, Regional Transfusion
 14 Directors management -- we had only one management
 15 team. So we could -- yes, the service improved.

16 **Q.** Looking at it now, with the benefit of having worked
 17 both in the previous system for a number of years, as
 18 a Regional Transfusion Service Director, and then
 19 having worked for the National Blood Authority and for
 20 NHSBT, is it your view that there should have been
 21 an establishment of a properly funded National Blood
 22 Transfusion Service much earlier than there was?

23 **A.** Yes.

24 **Q.** Can I then just ask you broadly about relationships
 25 with the Department of Health. We'll come on to some

31

1 relationships with BPL and issues in relation to that
 2 but, if we just look at the last few lines on this
 3 page, you say:

4 "... in my opinion the problem of the NBTS was
 5 one of under-funding and of subsidy of BPL. I stated
 6 that if we wanted a properly organised National Blood
 7 Transfusion Service, the Department of Health would
 8 have to pay for it."

9 Then, if we go over the page, you say at the end
 10 of the first line:

11 "I insisted that many RTCs were under-funded and
 12 that a great deal of capital was needed for premises
 13 and equipment."

14 There's then a discussion about a number of
 15 specific points, I don't need to trouble you with.
 16 Then, if we look at the last paragraph of the letter,
 17 you say:

18 "My personal opinion is that the idea of an NBA
 19 was sold to the [Department of Health] on the basis of
 20 savings and cost-improvement. The present government
 21 and new NHS are not in favour of centralisation, hence
 22 the only incentive for advocating an NBA is cost
 23 savings. It is sad to see that the Department will
 24 allow such a short time for consultation about the
 25 future of the NBTS."

30

1 specific interactions with the Department of Health as
 2 we look at particular issues. But, as director in the
 3 1980s through into the mid-1990s, and the
 4 establishment of the NBA, to what extent did you have
 5 regular dealings with the Department of Health?

6 **A.** Well, there was always a representative of the
 7 Department of Health at our Regional Transfusion
 8 Directors meetings. And, you know, in some of the
 9 other committees that I took part in, they were all --
 10 many of them were established by the Department of
 11 Health, so there was always a deputy medical officer
 12 or a medic from the Department.

13 So those were the relationships that we had, but
 14 it was -- as regional centres, we had much closer
 15 relationship with our Regional Health Authority and
 16 the chairman, the medical officer, the treasurer.

17 **Q.** In terms of the individuals at the Department of
 18 Health with whom you had dealings, again, I'm thinking
 19 very much of the 1980s through to about around 1995,
 20 through attendance at Regional Transfusion Directors
 21 meetings and the like, who were the main individuals
 22 at the Department of Health who would attend meetings
 23 or with whom you might have dealings?

24 **A.** Well, for a time, we had dealings with Dr Diana
 25 Walford, Dr Hilary Pickles, Dr Alison Smithies. Very

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1 occasionally we would -- I had Ken Calman visiting the
 2 centre because he wanted to know what -- but it was
 3 mostly those, as far as I can remember, and also Roger
 4 Moore who then became Dr Gunson's deputy but, at the
 5 time, he was at the Department of Health, Tom Kelly,
 6 who did a study, the management study, and I can't
 7 remember who else.

8 **Q.** In terms of, then, of the Chief Medical Officer or
 9 Deputy Chief Medical Officers, you've referred to
 10 Ken Calman and he became Chief Medical Officer --
 11 I can't remember off the top of my head the date --

12 **A.** Yes.

13 **Q.** -- but in the 1990s, I think the early 1990s. Prior
 14 to that, do you recall having any interactions
 15 directly with his predecessor, who would have been
 16 Donald Acheson?

17 **A.** Very little.

18 **Q.** In terms of Deputy Chief Medical Officers, can you
 19 recall any particular dealings between Regional
 20 Transfusion Centres or the National Blood Transfusion
 21 Service and any Deputy Chief Medical Officers,
 22 Dr Harris or Dr Metters --

23 **A.** With Dr Harris, I remember writing to Dr Harris,
 24 I can't remember what about, but I remember writing --
 25 yes, with Dr Harris and Dr Jeremy Metters.

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1 London centre?

2 **A.** Yes.

3 **Q.** Then if we go over the page, the top of the page, we
 4 see three further functions:

5 "Collection of high-titre blood group antibody
 6 plasma for the preparation of blood grouping reagents
 7 at BGRL.

8 "Blood grouping, antibody testing and disease
 9 screening ... on collected blood.

10 "Storage under appropriate conditions and
 11 issuing of blood and blood products to District
 12 Hospitals within the region."

13 Again, are those all functions that the North
 14 London centre undertook?

15 **A.** Yes.

16 **Q.** Then if we look at Dr Gunson's description of
 17 functions performed to a greater or lesser degree in
 18 Regional Transfusion Centres and if we bear in mind
 19 this is as at 1984, and it's the point in time at
 20 which you became director, so if we think of 1984,
 21 antenatal blood group serology, was that done at North
 22 London?

23 **A.** Yes.

24 **Q.** "Quantitation of blood group antibodies by automated
 25 techniques"?

35

1 **Q.** If we then move on to some of the work of the North
 2 London Regional Transfusion Centre, I'm going to start
 3 by asking you to look at a document authored by
 4 Dr Gunson. It's at DHSC0001677. If we go to the
 5 second page, you'll see there's a letter from
 6 Dr Gunson to Dr Smithies at the Department of Health,
 7 July 1984, enclosing some documents for discussion.

8 If we go to page 5, one of the discussion
 9 documents is headed "Organisation of the Blood
 10 Transfusion Service". Then Dr Gunson describes the
 11 functions of Regional Transfusion Centres and he
 12 divided into functions performed by all RTCs and then
 13 functions performed to a greater or lesser degree.

14 I just want to get a sense of what functions were
 15 performed by the North London Regional Transfusion
 16 Centre?

17 So would it be right to understand that the
 18 North London Centre performed all the functions we see
 19 listed on this page: recruitment of blood donors,
 20 collection of units of whole blood; preparation of
 21 blood labile products; harvesting of plasma for
 22 fractionation at BPL; collection of hyperimmune
 23 specific antibody plasma for the preparation of
 24 specific immunoglobulins.

25 Those are all functions carried out by the North

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1 **A.** Yes.

2 **Q.** Cross-matching?

3 **A.** Yes.

4 **Q.** Acting as a regional reference centre for hospitals in
 5 case of transfusion problems?

6 **A.** Yes.

7 **Q.** "Preparation of blood grouping and antiglobulin
 8 reagents"?

9 **A.** Not antiglobulin reagents but blood grouping reagents,
 10 yes.

11 **Q.** Histocompatibility testing for the purposes there set
 12 out?

13 **A.** Yes.

14 **Q.** Next page, screening of donor blood for antibodies to
 15 specific diseases?

16 **A.** Yes.

17 **Q.** Provision of an immunology service for the diagnosis
 18 of conditions such as immunoglobulin abnormalities and
 19 complement abnormalities?

20 **A.** No.

21 **Q.** Therapeutic plasmapheresis?

22 **A.** Yes, but at hospitals.

23 **Q.** And then cytopheresis for platelets and granular
 24 sites?

25 **A.** Yes.

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- 1 Q. And screening of donor bloods for rare cell antigens?
 2 A. Yes.
 3 Q. So consistent with the impression you gave us in your
 4 evidence earlier, the North London Centre carried out
 5 a wide range of functions, more than some of the other
 6 centres might have done?
 7 A. Yes, and I must say that there is something missing
 8 here, and I forgot to say it when we were talking
 9 about my response to Dr Gunson -- I'm sorry to
 10 interfere -- but it is that never was transfusion
 11 medicine included in these documents. You know that,
 12 for me, the relationship with the blood centre and the
 13 physicians and surgeons and patients, is a great deal
 14 of the work of the blood centre, it should be.
 15 Q. We'll look at some of the documents and some of the
 16 evidence in that regard probably later on today.
 17 If we just go to the bottom of this page --
 18 well, actually no, if we just look at paragraph 3,
 19 first of all, I just want to ask for your observations
 20 on that.
 21 Dr Gunson said:
 22 "The regional organisation of the Service, and
 23 in particular, with regional financing, means that the
 24 primary aim is to provide a service for the region
 25 only. This means that difficulties can be experienced

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- 1 1993/1994 for the North London Blood Transfusion
 2 Centre. We don't, I think, appear to have any earlier
 3 reports. Would it be right to understand that the
 4 premises we see pictured here, these are the new
 5 premises, the purpose-built premises in Colindale?
 6 A. Yes, when I was appointed, they told me, "You have one
 7 wish, Dr Contreras", and I said, "I would like a new
 8 centre."
 9 Q. And that was 1989, I think, in which you -- (*unclear:*
 10 *overspeaking*)
 11 A. Yes.
 12 Q. -- new centre?
 13 A. Yes.
 14 Q. If we go to page 5 of this report, we can just get
 15 a sense of the objectives that were being set by the
 16 centre in its '93/'94 business plan, and the report
 17 describes eight objectives set for the year. I'm not
 18 going to go through all of them, but one is
 19 collection, so to collect 225,000 -- sorry, Soumik,
 20 can we go -- there, thanks.
 21 "To collect 225,000 whole blood donations."
 22 And it describes the centre having the highest
 23 collection rate in the country. And the second
 24 paragraph under that heading says:
 25 "A further increase in whole blood donations

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- 1 in one region because of the special conditions
 2 applying, eg platelet supplies to the London Teaching
 3 hospitals whilst other regional centres could, with
 4 planning, provide an excess over their regional needs.
 5 Whilst in emergencies RTCs will help each other out,
 6 there is little long-term co-operation in the
 7 rationalisation of blood collection and preparation of
 8 labile products between regions, although this occurs
 9 sporadically."
 10 Would you agree with his observations --
 11 A. Totally.
 12 Q. Then we can see at paragraph 4 he refers to some RTCs
 13 having assumed responsibilities for the major
 14 production of certain products, and an example for
 15 North West Thames is anti-tetanus specific plasma.
 16 Were there any other particular products that the
 17 North London Centre specialised in?
 18 A. Oh, yes. Eventually, we were involved in the
 19 collection of all specific plasmas, anti-hepatitis B,
 20 anti-tetanus, and we were one of the major producers
 21 of anti-D immunoglobulin, anti-herpes zoster, yeah.
 22 Q. I might come back to the issue about hepatitis B
 23 immunoglobulin later, Professor Contreras. Again,
 24 just sticking with an overview of the centre, if we go
 25 to NHBT0001997, please. This is an annual report for

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- 1 above the previously high level demanded a number of
 2 strategies. Basic to this was the recognition that
 3 the service must be more geared towards the needs of
 4 donors."
 5 I'll come back later, Professor Contreras, to
 6 some of the strategies that might have been deployed.
 7 But one of the main objectives, therefore, is to meet
 8 and identify target in terms of collection of
 9 donations and, although this is '93, '94, would it be
 10 right to understand that every year there would have
 11 been a target that you were aiming to reach?
 12 A. Yes, this was our own target, after discussion with
 13 the hospitals to see what advances or improvements
 14 they were making that would need more blood, like
 15 liver transplantation, for example.
 16 Q. I'm going to skip over objectives 2 and 3. If we can
 17 go to the right-hand column, objective 4:
 18 "Promote good transfusion practice at
 19 hospitals."
 20 And you've made reference there to "Hospital
 21 Transfusion Committees". Again, we'll come back to
 22 those in much more detail, but this is something
 23 you're identifying in '93, '94, the importance of
 24 promoting good transfusion practice in the hospitals.
 25 Had that been something that was a feature of

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1 work of the centre at an earlier stage?
 2 **A.** Since 1984.
 3 **Q.** Then fifth objective is improve cost effectiveness and
 4 efficiency. I don't think we probably need to look
 5 further at that.
 6 And then if we go to page 7, we've got a heading
 7 "Interactions with donors", and a number of
 8 subheadings. I just wanted to ask you about the
 9 heading "Donor Association", and it says under that
 10 heading:
 11 "The donor association continues to be a vital
 12 part of our recruitment strategy."
 13 And then further description of the work of the
 14 donor association is given. And then the next
 15 paragraph talks about telephone recruitment campaign
 16 and telephone retention of donors and telephoning
 17 lapsed donors and so on.
 18 What was -- sorry, how long had there been
 19 a donor association at the centre? Can you recall?
 20 **A.** Before my time. I think it was started by Dr Cleg --
 21 he encouraged donors to participate, and it was
 22 started with -- I believe it started with
 23 plasmapheresis donors.
 24 **Q.** And so one of the means of trying to meet your targets
 25 and ensure you had enough donations, was to have this

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1 good relationship with donors; is that right?
 2 **A.** Yes.
 3 **Q.** And to use donors to try to help you increase the
 4 number of donations?
 5 **A.** Yes. We had every year -- every six months, we had
 6 donor award ceremonies as well for donors who had
 7 given 50 or 100 donations. So there were many donors
 8 who have given 100 donations in their life.
 9 **Q.** If we go over to the next page we've got a heading:
 10 "Donor Recruitment - the personal touch!"
 11 Reference to call-up letters, posters, telephone
 12 calls, work of a public relations teams and so on. So
 13 would it be right to understand there might be
 14 a number of ways in which, as a centre, you could seek
 15 to try to increase the amount of blood that you
 16 collected?
 17 **A.** Yes. And I believe that the best one was giving good
 18 customer service to the donors, giving -- feeling
 19 them -- feel wanted and important, and that brought
 20 more donors in.
 21 **Q.** If we just go to page 19, please, we've got some
 22 statistics in terms of donation targets and number of
 23 donations.
 24 So this tells us about '89 onwards. I'm afraid
 25 we don't have similar statistics for the period prior

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1 to 1989. But we can see, can we, in that table or
 2 chart on the left, that for the year '89 to '90 you
 3 had a target of 210,000 donations. It wasn't met in
 4 that year, but you collected 194,423, and then we can
 5 see increases in the number of donations collected
 6 over the following years, so that in 1991/1992 you
 7 exceeded the target, and you continued to exceed the
 8 target over the following two years. Is that the
 9 right way to understand this?
 10 **A.** Yes.
 11 **Q.** Then if we can just go to page 24, this is to get
 12 a sense of the geographical area and the number of
 13 hospitals served by the North London Centre.
 14 Obviously, again, this is at 1993/94, so the position
 15 may have been a little different in earlier years.
 16 But we can see, I think, from this list that there are
 17 a large number of NHS hospitals to which the centre
 18 supplied blood and blood products, including a number
 19 of leading hospitals in London such as Charing Cross,
 20 Chelsea and Westminster, Great Ormond Street. We've
 21 got Harefield, Northwick Park, Royal Brompton,
 22 Royal Free, and so on. So a number of the leading
 23 teaching hospitals in London as well as a range of
 24 other hospitals.
 25 And then you also supplied private hospitals.

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1 **A.** Yes.
 2 **Q.** Had that always been a feature of the centre's
 3 responsibilities?
 4 **A.** Yes. Private hospitals are -- were always dependent
 5 on the blood service. And still are.
 6 **Q.** And then for the -- during the 1980s and first half of
 7 the 1990s, can you remember which haemophilia centres
 8 the centre supplied with factor concentrates?
 9 **A.** We never supplied factor concentrates, because it went
 10 directly to the haemophilia centres.
 11 **Q.** So let's start with commercial concentrates. Would it
 12 be right to understand then that the centre never held
 13 commercial concentrates?
 14 **A.** Never held commercial concentrates.
 15 **Q.** So if, for example, the haemophilia centre at the
 16 Royal Free Hospital, which fell within your area,
 17 wanted to purchase concentrates from Immuno, that
 18 would be a relationship directly between the
 19 Royal Free and the pharmaceutical company and it never
 20 had anything to do with the centre?
 21 **A.** Nothing to do with it.
 22 **Q.** And you didn't store the concentrates for any of the
 23 centres?
 24 **A.** No. Our allocation went directly to the hospitals
 25 that needed it, to the haemophilia centres.

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- 1 Q. I want to deal with commercial concentrates and then
2 BPL completely separately.
- 3 A. Yeah, yeah.
- 4 Q. So in terms of commercial concentrates, did you have
5 any allocation to was that absolutely nothing
6 whatsoever to do --
- 7 A. Nothing whatsoever.
- 8 Q. Then in relation to concentrates manufactured by BPL,
9 so BPL Factor VIII, Factor IX concentrates, you're
10 supplying the plasma to BPL over the years. Am
11 I right to understand, then, that the concentrates
12 that you are then allocated under the pro rata system
13 didn't physically come back to you but would go
14 directly from BPL to the individual Haemophilia
15 Centres?
- 16 A. Yes.
- 17 Q. So you had no role in distributing factor concentrates
18 at all?
- 19 A. No.
- 20 Q. And, do you recall, was there any system of regular
21 meetings or discussions with the Haemophilia Centre
22 Directors within the North West Thames area?
- 23 A. We -- Peter Kernoff was -- Peter Kernoff was the
24 director of the Royal Free Haemophilia Centre and he
25 was part of some of the meetings that we -- was it the

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- 1 National Management Committee or the liaison with
2 the -- with Elstree, with BPL. And of course, we --
3 since we all had hospitals allocated to us, for
4 example, I had the Royal Free. So the Haemophilia
5 Centre director would attend our hospital transfusion
6 committee. So, with every haemophilia centre that
7 there was in the region, there was a consultant and
8 they would attend our ...
- 9 Q. But of the hospital transfusion committees, I think,
10 were a creation of the early 1990s or thereabouts, or
11 do you --
- 12 A. No, we started them a little bit earlier. A little
13 bit earlier. But -- yeah.
- 14 Q. If we leave aside, then, haemophilia centres and
15 supply of factor concentrates, what was the system for
16 hospitals, hospital blood banks, to obtain products
17 from you? So if a hospital want to get a quantity of
18 whole bloods or red cell concentrates or some other
19 blood product or component that was processed at the
20 centre, how would that be done?
- 21 A. They -- according to the historical demand, we would
22 be providing -- we always believed that most of the
23 blood needed to be in the hospitals and not with us.
24 We didn't want to hold it. So we gave them what they
25 needed and we gave them the very -- the big users had

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- 1 deliveries once or twice or even three times a day,
2 and that was according to their plans, and they would
3 send us their demands on the week before or sometimes
4 the day before. So we supplied them with their needs,
5 whenever we could, but sometimes we couldn't meet all
6 the needs for their stocks.
- 7 Q. So were there hospitals where you would know that on
8 a daily basis they were bound to need a certain amount
9 of something --
- 10 A. **(Witness nodded).**
- 11 Q. -- so there would be a regular system?
- 12 A. Yes.
- 13 Q. Then the hospital blood banks would then also be
14 contacting the centre to say, "We need X, Y and Z
15 today, tomorrow, this week"?
- 16 A. Yes.
- 17 Q. Can I just come on to questions of regulation of the
18 work of Regional Transfusion Centres, and systems of
19 inspectional auditing.
- 20 If we go back to your witness statement,
21 Professor Contreras -- so, Soumik, WITN5711001 -- and
22 we go to page 29. Yes.
- 23 You say in paragraphs 113 and 114 of your
24 statement, that the centre was regularly inspected,
25 and you refer to inspections by the Medicines

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- 1 Inspectorate with power to close a centre for
2 non-compliance, and then a range of other forms of
3 regulation including external audits from other
4 Regional Transfusion Centres.
- 5 Then if we go to the bottom of the page,
6 paragraph 114, you say:
- 7 "Regulation of the blood services and BPL really
8 started formally after the removal of Crown Immunity
9 in April 1991 and the appointment of the MCA
10 (Medicines Control Agency) under the Medicines Act ...
11 as the licensing authority, ie blood centres needed
12 a licence from then on and inspections of Transfusion
13 Centres were mandatory every 2 years for holding
14 a manufacturer's licence."
- 15 Then over the page, you describe in
16 paragraph 115 the system prior to that, where you
17 could have inspections by the Medicines Inspectorate,
18 but these were "advisory, rather than enforceable".
- 19 And I think we saw with Dr Napier yesterday or
20 the day before some documents from the late seventies
21 which talked about informal inspections by the
22 Medicines Inspectorate.
- 23 Professor, is it right to understand that,
24 looking at the time you were so centre, so from 1980
25 through to 1991, where we had the formal system set

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1 up, you were inspected by the Medicines Inspectorate
2 but they didn't have any power to, for example, close
3 the centre or order or require you to take particular
4 steps?

5 **A.** Yes, well, they would require us to -- they made
6 a report, and then we had to reply to them -- we had
7 a time limit to respond to them, making all the
8 improvements that he was requiring or all -- or
9 complying with the Orange Guide, and we had to reply
10 to him.

11 And I even asked Mr Cavanagh, when we were at
12 Edgware, to try to close the centre so that we would
13 get a new centre quickly. But he said, "I don't have
14 the power to do that."

15 **Q.** And so in relation to these advisory inspections prior
16 to the system changing in 1991, would that involve,
17 for example, inspection of the centres' systems and
18 processes for record-keeping?

19 **A.** Yes.

20 **Q.** And the donor selection/donor screening systems, would
21 those be inspected?

22 **A.** Yes.

23 **Q.** And the processes of testing, so microbiological
24 testing, for example, would that also be part and
25 parcel of the inspection process?

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1 action.

2 "2. Follow-up inspection when clean room
3 facilities and procedures corrected.

4 "3. Full re-inspection within 2 years."

5 So although there wasn't the power to close the
6 centre, is it right to understand that the ways of
7 trying to ensure that centres complied with
8 recommendations would be: the Regional Health
9 Authority would be sent a copy, the inspectors could
10 come back --

11 **A.** Yes.

12 **Q.** -- to see what you'd been doing, and then the
13 inspectors would come back for a full reinspection on
14 a biannual basis?

15 **A.** Yes, and we would invite -- we usually would invite --
16 once we had corrected everything, we would invite them
17 to come and have evidence.

18 **Q.** Then if we just go back to your witness statement at
19 page 29. So WITN5711001, page 29. At paragraph 113.
20 The third bullet point refers to external audits from
21 other Regional Transfusion Centres.

22 So did that happen in the course of the 1980s,
23 that other centres would undertake audits of your
24 centre?

25 **A.** Yes. Yes. In the late eighties, I think it was.

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1 **A.** Yes.

2 **Q.** And recommendations might then be made?

3 **A.** Yes.

4 **Q.** And is it right to understand they couldn't be
5 enforced but the expectation was that you would comply
6 with the recommendations?

7 **A.** Yes.

8 **Q.** And I think we've got an example of an inspection
9 report at NHBT0006240.

10 So this is an inspection report of the North
11 London Centre, we can see it's now at Colindale, and
12 the date of the inspection is May 1989. So this is
13 prior to the new regime from 1991 onwards.

14 "Date of previous inspection:

15 "Purpose of visit ..."

16 This records this is the:

17 "First inspection of new centre."

18 So it's the first inspection at Colindale. But
19 there had been, had there, similar inspections carried
20 out at Edgware?

21 **A.** Edgware.

22 **Q.** Then we can see:

23 "Recommendations/Action:

24 "1. A copy of this report to be sent to the
25 Regional Health Authority for comment and proposed

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1 I can't remember very well, but --

2 **Q.** And likewise did you undertake audits of other
3 centres?

4 **A.** Yes.

5 **Q.** Can you recall which other centres you yourself
6 personally audited?

7 **A.** I really can't remember, but I remember going to
8 centres with a couple of members of my management
9 team, with my quality manager and another member of my
10 management team. But I can't remember which centres
11 they were.

12 **MS RICHARDS:** Sir, I note the time, I'm going to move on
13 to another topic so probably a good moment for having
14 a break.

15 **SIR BRIAN LANGSTAFF:** Yes.

16 Well, we'll take a break now until 11.45. It
17 allows all those who are watching at home -- that will
18 probably be about hundred people or so doing that --
19 to have a break, have a coffee, and the same for us
20 here.

21 Let me tell you what I say to all witnesses when
22 we come to any break, and it's this: you're giving
23 evidence. One of the rules which you must adhere to
24 is you may not discuss the evidence you have given, or
25 anything which you think you may yet be asked about in

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- 1 evidence with anyone, whoever that person is --
 2 a friend, family, lawyer, anyone -- but you can talk
 3 about anything else you like. So I look forward to
 4 seeing you at 11.45.
- 5 **A.** Thank you.
- 6 **(11.15 am)**
- 7 **(A short break)**
- 8 **(11.45 am)**
- 9 **MS RICHARDS:** Professor Contreras, I'm going to ask you in
 10 a moment about your understanding of the risks and
 11 seriousness of different forms of hepatitis but,
 12 before we look at hepatitis B and then non-A, non-B
 13 hepatitis, you've described in your witness statement
 14 how, as part of your teaching work, you would seek to
 15 educate students about the risks of blood by writing
 16 on the chalkboard the words "Blood can kill".
- 17 Now, obviously blood can kill not just because
 18 of transfusion-transmitted infections but for other
 19 reasons, but it can certainly kill because of
 20 transfusion-transmitted infections. Can you give us
 21 an idea of when you would be providing your students
 22 with such a stark warning? Is that a feature of your
 23 teaching in the 1980s?
- 24 **A.** Yes.
- 25 **Q.** What was it that you were trying to get your students

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- 1 to understand?
- 2 **A.** That you have to balance the risks between transfusion
 3 and no transfusion, and between transfusion and
 4 alternatives, and that there are several risks in
 5 transfusion and the worst one was errors. So I want
 6 them to understand that they have to think before
 7 transfusion.
- 8 **Q.** If we turn to hepatitis B, first of all, as
 9 a transfusion-transmitted infection, in your witness
 10 statement, if we have that back on screen, please,
 11 Soumik WITN57 -- thank you, you're ahead of me, and go
 12 to page 72, please. You've said, under the heading
 13 "Hepatitis B" that hepatitis B was something you were
 14 aware of both as a virus and in terms of its
 15 significance, its seriousness, from the 1960s onwards;
 16 is that right?
- 17 **A.** Yes.
- 18 **Q.** And it was something which you understood could
 19 potentially be fatal?
- 20 **A.** Yes.
- 21 **Q.** Now, we know that some form of screening of blood for
 22 hepatitis B was introduced in England and Wales in
 23 1972. So, by the time you started working at the
 24 North London Regional Transfusion Centre, there would
 25 have been testing for hepatitis B. Can you recall

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- 1 what your understanding was of the sensitivity of
 2 those tests in the 1970s and early 1980s?
- 3 **A.** Well, we later learned that they were not as
 4 sensitive, you know, the initial tests were not as
 5 sensitive as time evolved and we were getting better
 6 tests, so we realised that the sensitivity wasn't as
 7 good as it could have been, but that was a problem
 8 with the technology that we had, the techniques we had
 9 at the time.
- 10 **Q.** When you took over as deputy director in 1980, can you
 11 recall which type of test the centre was using at that
 12 point.
- 13 **A.** Not exactly, but I think that it was either the RIA,
 14 the radioimmunoassay that had some risks because it
 15 used a radioisotope, iodine-125, or we had already
 16 moved to reverse passive haemagglutination that was
 17 safer for staff and Dr Barbara made it more sensitive
 18 by diluting the -- and using the technology from --
 19 that was using haematology in microbiology and make
 20 it -- making it quite a sensitive technique.
- 21 **Q.** So in terms of the changes in the testing techniques
 22 used, Dr Barbara may be the person who may be able to
 23 assist in relation to that?
- 24 **A.** He is an expert in that.
- 25 **Q.** But would it be right to understand that there would

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- 1 have been an awareness in the centre amongst you and
 2 your colleagues that, notwithstanding the fact that
 3 testing had been in operation since the early 1970s,
 4 there could still be cases of hepatitis B being
 5 transmitted through transfusion?
- 6 **A.** Yes. We learnt that from Dr Dane, as well, that --
 7 and even now, perhaps, there are a few cases.
- 8 **Q.** Just so those following understand, Dr Dane was based
 9 where?
- 10 **A.** At the Middlesex Hospital.
- 11 **Q.** His area of expertise was?
- 12 **A.** Hepatitis and he was the discoverer of the surface
 13 antigen of the Dane particles, yeah.
- 14 **Q.** Now, if we then turn to non-A, non-B hepatitis, and if
 15 I ask you to go back in time, as it were, to say 1980,
 16 when you became deputy director at the centre, is it
 17 right to understand that you'd have been aware, by
 18 that point in time, that there was something that was
 19 termed, for want of a better description, non-A, non-B
 20 hepatitis?
- 21 **A.** Yes.
- 22 **Q.** It was, by then, understood that some, perhaps most,
 23 cases of post-transfusion hepatitis would be
 24 attributable to non-A, non-B hepatitis, whatever it
 25 was, rather than hepatitis B?

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1 A. Yes, but we had so few cases of post-transfusion
2 hepatitis in those days, that yeah, some of them were
3 still attributed to hepatitis B, and some to
4 non-A, non-B.

5 Q. Now, in terms of your understanding of the potential
6 seriousness of non-A, non-B hepatitis, you've
7 described in your witness statement how your
8 understanding changed over time, essentially through
9 the course of the 1980s. I'm not going to go through
10 everything you say in your statement but you've drawn
11 attention to -- and you're not the first witness to
12 have had done so -- to the publication of
13 Sheila Sherlock.

14 So if we could have, Soumik, WITN4032023.

15 Sir, this is a publication by Sheila Sherlock,
16 Professor of Medicine at the Royal Free, "Diseases of
17 the Liver and Biliary System". This is the sixth
18 edition which was published, I think, in 1981.

19 Then if we go to the next page -- sorry, keep
20 going. That just gives the date of publication.

21 Yeah, so we've got there page 257 of the
22 textbook, and again we've looked at this in earlier
23 hearings with other witnesses, Professor Contreras,
24 but we've got there the heading "Non-A, Non-B
25 Hepatitis". We can see Professor Sherlock saying:

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1 is also seen. The acute episode is usually mild and
2 often anicteric. Extra-hepatic manifestations do not
3 occur. Fulminant hepatitis is rare. The serum
4 bilirubin and transaminase levels tend to be lower
5 than with acute virus A or virus B infection. The
6 serum immunoglobulin M is normal. The course may be
7 prolonged, with serum transaminase levels waxing and
8 waning for many months. A mild, chronic hepatitis
9 develops in about a quarter, but this usually improves
10 with time. Circulating immune complexes may
11 contribute. Cirrhosis can develop."

12 Just ask you to bear that in mind.

13 And then if we carry on:

14 "In liver biopsies, in addition to the general
15 [go to the next page] features of acute virus
16 hepatitis, the picture is of one of marked sinusoidal
17 and portal zone cellular infiltration ..."

18 Then there's a description of other changes that
19 can sometimes be seen.

20 "Non-A, non-B hepatitis often progresses to a
21 mild chronic hepatitis. The prognosis of this is, at
22 the moment, uncertain but probably benign."

23 And you've drawn attention, I think, in your
24 statement, Professor Contreras, to those last two
25 sentences as representing in part your understanding

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1 "The elimination of hepatitis A and hepatitis B
2 from transfused blood did not eliminate
3 post-transfusion hepatitis. Some of the cases were
4 due to cytomegala infection but the majority were due
5 to another virus or viruses termed non-A, non-B. This
6 infection now accounts for about 75% of
7 post-transfusion hepatitis, possibly 15-20% of
8 sporadic hepatitis, depending on the geographic
9 location. Haemophiliacs receiving factor concentrates
10 obtained from commercial sources are particularly at
11 risk. Non-A, non-B hepatitis is largely blood spread.
12 It had also been reported with drug abuse, renal
13 transplant recipients, in dialysis centres and in
14 donors used for plasmapheresis."

15 So this is a textbook as I understand it you
16 were familiar with at the time, so you'd have read and
17 understood what was being set out here.

18 A. Yes.

19 Q. And you've explained you were -- you knew
20 Professor Sherlock in any event --

21 A. Yes.

22 Q. -- for a range of reasons. If we go over the page,
23 there's then a heading "Clinical course":

24 "The incubation period is about seven weeks,
25 although a short incubation type (one to four weeks)

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1 that non-A, non-B hepatitis was not necessarily as
2 serious as you later understood it to be. Is that
3 right?

4 A. Yeah, and -- yes, and we didn't see that much of
5 post-transfusion hepatitis -- because she was talking
6 about the general problem of non-A, non-B specific,
7 and she includes in that haemophilia patients. And
8 I was -- yeah, I was talking more of the transfusion
9 of labile blood components.

10 Q. Now those last two sentences:

11 "The prognosis of this is, at the moment,
12 uncertain and probably benign."

13 As I read it is talking about the mild chronic
14 hepatitis that might develop. So the mild chronic
15 hepatitis might be uncertain -- prognosis uncertain,
16 probably benign?

17 A. Yeah.

18 Q. But reading the passage as a whole, you would also
19 have understood that non-A, non-B hepatitis could lead
20 to cirrhosis and had been observed to lead to changes
21 in the liver. Is that fair?

22 A. Yes, but this is in the acute phase, and then -- then
23 he said that the majority of them improved. So the
24 changes in the liver were in the acute phase and in --
25 well, in the multiple -- multiply transfused. She

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1 didn't see. She was referred patients from all over
2 the world, Professor Sherlock. You know, you went to
3 her clinic and it was the United Nations there. So
4 she -- she saw a selected patient population. But,
5 yes, I interpreted that as the acute phase and then
6 they went to normal, as she said it.

7 **Q.** You've also in your statement explained that you would
8 have read a number of other publications at the time
9 because you read various medical journals. And you
10 tell us you believe you would have read -- there's an
11 article by Purcell and Alter that you've referenced,
12 and indeed the Inquiry has looked at on a number of
13 occasions in its hearings, an article by Dr Craske in
14 the mid-seventies, and Dr Preston's 1978 publication.
15 So you think you would have read those at the time?

16 **A.** Yes.

17 **Q.** If we look at your statement -- Soumik, can we have
18 that statement --

19 **SIR BRIAN LANGSTAFF:** May I just ask one question? Can we
20 just go back to that passage?

21 **MS RICHARDS:** WITN4032023, Soumik.

22 **SIR BRIAN LANGSTAFF:** The last paragraph. She isn't
23 saying that non-A, non-B hepatitis normally resolves
24 in its acute phase, is she, because she said it often
25 progresses to a chronic phase?

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1 previously examined.

2 Then paragraph 301 you say this:

3 "I have reflected back on these publications and
4 my interpretation today has not changed much from the
5 one I had when I first read these papers. They do not
6 point to serious chronic effects of [non-A, non-B]
7 hepatitis. The situation in the USA was different
8 from the UK, as the incidence of transfusion
9 transmitted infections has always been higher there."

10 Just pausing there, if we leave aside the
11 question of incidence, and the fact that there are
12 more cases reported in the States than in the UK,
13 which you may well be right about, that's -- why would
14 that be relevant to an understanding of the
15 seriousness of non-A, non-B hepatitis?

16 **A.** No, that wouldn't. The incidents would not.

17 **Q.** Then you go on to talk about interpreting Dr Preston's
18 findings, the biopsy findings, which he described in
19 that 1978 publication, as:

20 "... something particular to patients with
21 haemophilia, ie [if we go over the top of the page]
22 something related to repetitive immunological
23 assaults. The paper by John Craske also dealt with
24 patients with haemophilia."

25 Did you therefore, in your own thinking at the

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1 **A.** Yes.

2 **SIR BRIAN LANGSTAFF:** Is one to understand from the word
3 "mild" that, at the stage that it becomes chronic, it
4 may not show very much by way of symptoms?

5 **A.** Yes.

6 **SIR BRIAN LANGSTAFF:** But one doesn't know -- the next
7 sentence is one doesn't know what may happen after
8 that?

9 **A.** Yes, but she says "probably benign", as well.

10 **SIR BRIAN LANGSTAFF:** Yes, "at the moment, uncertain but
11 probably benign". I see, thank you.

12 **MS RICHARDS:** Yes. Sir, we've looked in earlier hearings
13 at some of the other passages in the book but they're
14 not passages that Professor Contreras has specifically
15 referred to, I'm not proposing to ask her about the
16 detail of them.

17 Sir, if we then go to your witness statement,
18 page 75, please. So you've described in the preceding
19 paragraphs in your statement the way in which
20 subsequent editions of Professor Sherlock's book
21 described non-A, non-B hepatitis in different terms.
22 Then at paragraph 300, you say you're aware of
23 publications which express contrary views, which you
24 would almost certainly have read at the time, and then
25 you give three examples that the Inquiry has

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1 time -- and I appreciate I'm asking you to go back to
2 a point in time at which your understanding was
3 different from how it is now, but did you therefore
4 read these papers, do you think, as saying that the
5 changes reported by Dr Craske, Dr Preston, were not
6 viral in origin? Was that your understanding when you
7 refer to "might be related to repetitive immunological
8 assaults"?

9 **A.** Yeah, that might not have been viral in origin, and if
10 they were, they were so repetitive that that viral
11 load was so high, that it was different to somebody
12 who was transfused with two or three units of blood.

13 **Q.** Do you recall whether that way of looking at these
14 publications, these studies, was something that was
15 discussed by you with colleagues, whether within the
16 centre or externally? Were there virologists or
17 indeed haemophilia clinicians with whom these issues
18 about non-A, non-B were discussed at the time?

19 **A.** Yes, I vaguely remember discussing -- I think it was
20 with Eric Preston -- that I said, "Well, couldn't" --
21 and in some of the papers that I read, there was this
22 view that it could be an autoimmune disorder, that it
23 was different and, yes, and I knew John Craske as
24 well, but I cannot remember discussing very well,
25 whether -- but there was some -- there was a view that

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1 it could -- that the haemophilia patients had more --
2 a greater immunological assault, regular immunological
3 assault.

4 **Q.** So what you described in your statement is you forming
5 your own views and understanding of the significance
6 of these different studies, your own understanding of
7 seriousness of non-A, non-B hepatitis. Would it have
8 been an issue upon which it would have been, at the
9 very least, useful to have some form of central advice
10 or steer or guidance from, whether from the Chief
11 Medical Officer or through the Regional Transfusion
12 Director meetings, or some other source? Rather than
13 you being left to reach your own interpretation of
14 what the medical literature was revealing?

15 **A.** Yes, perhaps it would have been useful to have some
16 central advice of experts or advice from the CMO. But
17 my problem is that we were not seeing the problem that
18 my haemophilia director colleagues were seeing.

19 **Q.** What you say, just picking up upon that, to some
20 extent, in paragraph 302 of your statement, you say:

21 "It is fair to say that my knowledge evolved
22 over time with respect to the seriousness of this
23 virus, because it takes a very long time for it to
24 show its severe chronic effects in a proportion of
25 infected subjects. Hence, I could not see at the time

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1 I couldn't know that there were going to be chronic
2 effects.

3 **Q.** My next question is a general one, rather than
4 necessarily specifically limited to non-A, non-B
5 hepatitis. Would you agree, as a general proposition,
6 that it may be in the nature of an infectious disease
7 that it can take a period of time for the full
8 implications of that condition to be clearly or
9 comprehensively or conclusively understood. Would you
10 agree with that?

11 **A.** I fully agree with that. Yeah, that's in the nature
12 of all diseases, yeah.

13 **Q.** Again, this is a very general question, it's not
14 related specifically to an issue about testing or
15 screening for non-A, non-B hepatitis. But, given
16 that, if one waits for the full implications to be
17 clearly or conclusively understood, it may be too late
18 by then to take preventative action as a general idea?

19 **A.** As a general, yes.

20 **Q.** Now, you told us that you had a greater understanding
21 about hepatitis B and, obviously, that had been
22 something that had been identified since the 1960s in
23 particular. Can we just look at one of the articles
24 that you referred to in your statement. It's
25 PRSE0000381. It's the Purcell, Alter, Dienstag

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1 an obvious health problem in the population, and did
2 not do so until the effects of the virus began to
3 manifest much later in time."

4 Now, this is going to be a very crude summary,
5 Professor Contreras, but there might be two reasons
6 why you're not seeing the effects of the virus
7 presenting itself. It might be because there aren't
8 any serious effects or it might be because it takes
9 a very long time for those effects to show themselves,
10 because this is a chronic condition where changes to
11 the liver or symptoms might only become apparent many
12 years after the event.

13 Do you recall whether you gave active
14 consideration at the time, either yourself or with
15 others, to the possibility that the reason you weren't
16 seeing this was because it was long term, rather than
17 because it wasn't a serious issue?

18 **A.** I can't remember, because I didn't know that there was
19 a long-term effect so I couldn't have thought that
20 there might be long-term effects, because we -- all we
21 could see was the reports from the hospitals that we
22 encouraged the hospitals to report to us, and we would
23 see a maximum of four cases of post-transfusion
24 hepatitis due to the transfusion of products that we
25 provided, that means labile blood components. But

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1 article, 1976, "Non-A, non-B hepatitis", and if we
2 could just go to page 4, it's a paragraph about
3 halfway down the page beginning:

4 "Although type non-A, non-B hepatitis is
5 associated with less severe acute illness than type B
6 disease, as judged by frequency of jaundice and
7 magnitude of SGPT elevations, the long-term prognosis
8 for the two diseases may be similar."

9 Then there are various observations set out and
10 there's reference to patients undergoing liver biopsy.
11 Then the last sentence of the paragraph reads:

12 "Thus, chronic non-A, non-B hepatitis is not
13 necessarily a benign infection and may be the cause of
14 a significant proportion of chronic hepatitis not
15 identifiable as type B disease."

16 Can you recall whether, late 1970s, first half
17 of the 1980s, the extent to which consideration was
18 given to the possibility that non-A, non-B hepatitis
19 might follow a similar pattern to hepatitis B, as
20 regards long-term effects of infection?

21 **A.** I just can't recall what I thought in the 1980s or
22 1990s. But what impressed me with this paper is that,
23 at the end, they state that the only means of
24 preventing -- perhaps that stuck in my mind -- of
25 preventing the transmission of this disease is to have

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1 all voluntary blood donors.

2 **Q.** You say, if we go back to your statement, then,
3 Soumik, please, WITN5711001, page 78, and it's just
4 the first sentence of paragraph 315, at the bottom of
5 the page, you say:

6 "With respect to non-A, non-B hepatitis, my
7 knowledge developed over time and in hindsight my
8 appreciation of the seriousness was perhaps later than
9 others in the medical community."

10 When you refer to being later than others in the
11 medical community, which others in the medical
12 community did you have in mind? I don't mean by name
13 but in terms of what kind of clinicians are you
14 identifying there who might have appreciated the
15 seriousness earlier than you did?

16 **A.** The liver disease specialists and the haemophilia
17 consultants or the doctors who dealt with haemophilia.

18 **Q.** Then if we look in your statement at page 86,
19 paragraph 339, you refer that your view did change
20 over time:

21 "... gradual appreciation that [non-A, non-B
22 hepatitis] infection could, in fact, lead to chronic
23 liver disease", and you talk about science and
24 medicine being evolving subjects.

25 Then when you say:

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1 We can take the statement down, thank you,
2 Soumik.

3 How would you decide roughly how much you needed
4 to collect in terms of blood; how many donor sessions
5 you might need to hold or how many donations you might
6 need to try to gather?

7 **A.** Well, with our team and our donor organiser, we based
8 it on historical data, as you saw with our business
9 plan, and also in consultation with the hospitals. We
10 had very strong links with the hospitals. So -- and
11 we had our predictions on how much we would need, but
12 I wouldn't do it on my own. I would do it with my
13 team of consultants and managers and donor organisers.

14 **Q.** Is it right to understand that, in terms of numbers of
15 donations you, by which I mean the centre, set its own
16 targets?

17 **A.** Yes, yes.

18 **Q.** How common was it to have shortages?

19 **A.** When I took office as a director, it was quite common.
20 We even had a contract with Oxford, with the Oxford
21 Transfusion Centre, and I remembered that last night,
22 I think, that to import blood on a regular basis, O
23 positives or -- group O positive or group O negative,
24 et cetera, and I don't remember having a contract with
25 Scotland, but -- and we had to get help from other

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1 "When the evidence was available, my view did
2 change, but this took some time."

3 I appreciate it's difficult, looking back,
4 Professor Contreras, but are you able to help us in
5 understanding what you think the point in time was,
6 the year was, when you would have realised that non-A,
7 non-B hepatitis could indeed lead to chronic serious
8 liver disease?

9 **A.** No, I cannot. I would be speculating.

10 **Q.** I appreciate it's a difficult question. If we just go
11 back to page 75 of your statement, paragraph 299, you
12 point there to the 8th edition of Professor Sherlock's
13 book, the 1989 edition, and you set out a summary of
14 what was said there, and you said there in the last
15 sentence of that paragraph:

16 "I think this is really when I began to
17 appreciate the true significance of [non-A, non-B]
18 Hepatitis."

19 So is that -- would that be your best estimate
20 that it's probably around 1989?

21 **A.** Yes.

22 **Q.** I want to come on to ask you now about the processes
23 for donors to give blood and the donor screening
24 processes at the North London Regional Transfusion
25 Centre.

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1 centres because although we collected more than
2 anybody else per thousand population, we still need --
3 our demand was greater than for any other centre.

4 **Q.** If you needed to try to increase the number of
5 donations relatively quickly -- you talked earlier
6 about some of the strategies, the importance of
7 treating your donors well, you had the donor
8 association, and so on, were there particular
9 strategies as, in fact, quick fix strategies, in terms
10 of publicity or advertising, that you might utilise?

11 **A.** Yeah, we could -- well, we didn't have much money for
12 publicity but we could telephone the donors, we had,
13 you know, this donor association also helped us to
14 telephone donors, and we went to local radio, and
15 local newspapers that were always extremely helpful,
16 in order to increase our supply if we were short.

17 **Q.** Now, in terms of the staffing arrangements at donor
18 sessions, we understand from looking at Regional
19 Transfusion Director minutes -- meeting minutes, that
20 in -- I think it was 1984, the Brentwood centre raised
21 a question about whether nurses could, as it were,
22 take the clinical lead at donor sessions, rather than
23 having a medical officer. What was the position in
24 relation to the North London Centre's donor sessions?
25 Was there always a medical officer in attendance?

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1 **A.** Yes, before Jean Harrison's brilliant idea to have
 2 nurses in teams, we had medical officers going to
 3 every mobile collection team and to every static
 4 clinic.
 5 **Q.** You referred to Dr Harrison's idea as a brilliant one.
 6 Did that therefore change --
 7 **A.** Yes.
 8 **Q.** -- did nurses become trained to lead the sessions?
 9 **A.** Yes, as it's happened in the Health Service. You had
 10 nurse -- consultant nurses, and yeah -- so yeah, it
 11 changed.
 12 **Q.** In terms of the kind of arrangements that were made
 13 for donor sessions, the inspection report that we
 14 looked at earlier, I might give you some specific
 15 details rather than asking you to call on your memory,
 16 NHBT0006240, please, Soumik.
 17 Sir, you'll recall we looked at the first page
 18 of this inspection report earlier.
 19 If we go to page 4, bearing in mind this is 1989
 20 and things may have changed, but we've got
 21 a description under the heading "Inspection, Blood
 22 Collection and Receipt" about the donor sessions. So
 23 it says:
 24 "Blood collection takes place at 28 mobile
 25 sessions per week, including 5 using the special

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1 but we can see from the second paragraph on the screen
 2 a reference to records. So:
 3 "Although the introduction of a computerised
 4 system of donor records is planned for later this
 5 year, the system currently in use is that of
 6 colour-coded cards. The record cards for all the
 7 donors on the appropriate panel are brought to each
 8 session; new donors are provided with buff-coloured
 9 cards."
 10 Then it goes on to describe how a donor
 11 completes the medical checklist and consent form and
 12 then a series of labels would be issued. The donor's
 13 name and blood group -- that presumably is -- is
 14 manually recorded and a barcoded donation number
 15 labels are attached. The donors is given their record
 16 card and the remaining barcode labels and then they
 17 proceed to go to another table where their haemoglobin
 18 is tested.
 19 Then if we go to the top of the next page, this
 20 obviously is the position as at 1989, so what's next
 21 described is not something that would have been in
 22 operation earlier in the 1980s. But it says:
 23 "At this stage, donors are given the opportunity
 24 of confidentially identifying themselves as members of
 25 high risk groups for AIDS. This system is unique to

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1 'Bloodmobile' truck, in addition to the static donor
 2 clinics at Deansbrook Road, Edgware, the West End
 3 Donor Centre in Margaret Street and then in Luton."
 4 Then it references to a mobile session taking
 5 place in a particular factory.
 6 So throughout the 1980s, is it right to
 7 understand that there were three static donor clinics.
 8 **A.** Yeah, the Luton clinic came into effect when I was
 9 a director.
 10 **Q.** So those were permanent clinics --
 11 **A.** Yes.
 12 **Q.** -- where members of the public would turn up to donate
 13 blood?
 14 **A.** Yeah.
 15 **Q.** Then, in terms of the mobile sessions, what kind of
 16 locations did they go to? Were they usually
 17 workplaces or would they also be community settings?
 18 **A.** Everywhere. Wherever we could find a hall that was
 19 large enough and the will of the managers, we went to
 20 churches, we went to universities, we went to
 21 hospitals, factories, and we had the bloodmobile that
 22 was stationed -- and at the three static clinics we
 23 dealt mainly with plasmapheresis and plateletpheresis.
 24 But we also had working donors and panel donors.
 25 **Q.** Then I'll be coming on to records in a little while,

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1 NLBTC and involves the donor ticking 'yes' or 'no' on
 2 a questionnaire asking them whether they belong to one
 3 (or more) of 7 defined risk groups. The questionnaire
 4 is ticked in a 'polling booth' type cubicle and is
 5 posted into a 'ballot box'. One of the many
 6 advantages of this procedure is that a donor in a risk
 7 group if he/she feels it is impossible not to donate,
 8 can identify the donation which can subsequently be
 9 removed and not used to treat patients."
 10 Now, we'll look at the leaflets and
 11 questionnaires, as I say, in a while. But can I just
 12 understand how this worked, at least by 1989. There's
 13 the questionnaire that's described here, which I think
 14 was introduced in '84 or '85, from recollection, and
 15 there was a degree of privacy, is this right, to the
 16 way in which the donor could complete that?
 17 **A.** Total privacy. If the premises had a little room,
 18 separate room, they would go into separate room. If
 19 not, we took screens so that they would be totally
 20 isolated, nobody could look at them, and then they
 21 could complete it and put it in a ballot box.
 22 **Q.** Would the expectation then be that that donor would
 23 simply quietly leave?
 24 **A.** Some of them would leave and some of them -- one of
 25 the papers that you provided to me states some of them

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1 would tick the box and, say, because they felt
2 pressurised by the workmates -- for example, if lots
3 of people from a building site came to donate and one
4 of them had a risk factor, they wouldn't not donate,
5 so they would say, "I don't want my blood to be used
6 for transfusion".

7 **Q.** I see. So they could still donate and therefore save
8 face, as it were?

9 **A.** Yeah, but the majority of them --

10 **Q.** But the questionnaire would have had one of the
11 barcode labels affixed to it --

12 **A.** Yeah.

13 **Q.** -- so you could identify that this was a donation
14 where the donor had ticked "yes" to being in
15 a high-risk group --

16 **A.** Yes.

17 **Q.** -- and so the donation would then subsequently be
18 removed?

19 **A.** Withdrawn, yeah.

20 **Q.** That's then, I think, the explanation for the last
21 sentence of that paragraph:

22 "One of the main advantages of this procedure is
23 that a donor in a risk group, if he/she feels it is
24 impossible not to donate, can identify the donation
25 which can subsequently be removed and not used to

77

1 or something extra, they would phone in --

2 **A.** Yes.

3 **Q.** -- the hospital blood bank, and then the arrangement
4 would be as described here?

5 **A.** Yes.

6 **Q.** Can we then look at some of the documentation relating
7 to donor screening.

8 **A.** Can I just say that this document, I've just glanced
9 at it, shows the difference that we had at different
10 centres because we decided, after having done some
11 trials, that we would not use lignocaine at donor
12 sessions, because an -- a local anaesthetic. Because
13 it was better to just go into the vein and donors
14 preferred it. So that showed how different
15 transfusion centres were.

16 **Q.** Soumik, could we then go to PRSE0004358, please. This
17 is a document, Professor Contreras, that we in the
18 Inquiry looked at with Dr Napier on Tuesday of this
19 week. So this is the 1977 Memorandum on the Selection
20 Medical Examination and Care of Blood Donors. So this
21 would, I think, be the guidance that was in force when
22 you became deputy director in 1980. There were then
23 various other versions of it in the course of the
24 1980s.

25 If we go to the page 3, bottom of page 3, we can

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1 treat patients."

2 **A.** Yes.

3 **Q.** Then the description that continues is the donors are
4 then led to a bleed bed by a donor attendant, and then
5 the donation is taken.

6 **A. (Witness nodded)**

7 **Q.** Just while we're in this document, if we just go to
8 page 12. This is about what subsequently happens and
9 the inspection report describes the various stages
10 that are undertaken. So this is about a later stage
11 when the products are ready for issue.

12 Just picking it up in the second paragraph,
13 under the heading "Blood Bank and Issue", I asked you
14 earlier about the arrangements for supply of products
15 to hospitals. This describes that:

16 "Orders for blood and blood products are either
17 standing, regular orders or telephone orders. When
18 hospitals 'phone in an order, a clerk notes the
19 request on a notepad and transcribes it onto
20 a duplicate order form. [A] copy is given to the
21 Issue department ..."

22 Does that reflect what you referred to earlier
23 where you'd have -- you'd known that there were orders
24 that were regularly being sent to Great Ormond Street
25 or the Royal Free, but if they needed something more

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1 see under the heading "Jaundice or Hepatitis", this
2 records that:

3 "Individuals who give a history of jaundice or
4 hepatitis or in whose blood anti-HBsAg is present may
5 be accepted as donors providing that they have not
6 suffered from jaundice or hepatitis in the previous
7 twelve months, have not been in house contact with
8 hepatitis or received a transfusion of blood or blood
9 products in the previous six months, and providing
10 their blood gives a negative reaction for the presence
11 of HBsAg when tested by a sensitive method ..."

12 We'll come back to this issue in a few minutes,
13 Professor Contreras, but was it your understanding,
14 when you became deputy director in 1980, that, at the
15 North London Centre, this was the practice --

16 **A.** Yes.

17 **Q.** -- that if you'd had hepatitis or jaundice in the last
18 12 months, you would be deferred, and you would be
19 asked to come back at a later stage, but if you'd had
20 hepatitis or jaundice two years ago, five years ago,
21 ten years ago, you could be accepted as a donor?

22 **A.** Yes.

23 **Q.** If we go over the page, please, there's a heading
24 "Examination of the donor". If we pick it up at
25 paragraph 2, it says:

80

1 (a) The medical history should be coupled with
2 a careful assessment of the donor's appearance. The
3 experienced doctor can detect at a glance the
4 potentially unsuitable donor."

5 Then there are some examples given: poor
6 physique, underweight, debilitated, undernourished,
7 mentally unstable, "those bearing the obvious stigmata
8 of disease should not be bled".

9 Would the arrangements at the North London
10 Centre's donor sessions have meant that there would be
11 a doctor who should be an experienced doctor at every
12 donor session?

13 **A.** Yes.

14 **Q.** How realistic was it to expect a doctor to be able to
15 detect at a glance the potentially unsuitable donor?

16 **A.** Well, we expected that the majority -- well, all
17 donors are voluntary donors, so they are in good
18 health. They feel okay to donate, you know? And the
19 majority of our donors are repeat donors as well. And
20 you could only see at a glance the physical appearance
21 of a donor, and some -- very occasionally donors were
22 rejected because they were -- well, underweight or if
23 somebody looked as if they were going to faint or
24 something like that, they would reject them as donors.
25 But that was all that could -- you cannot really

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1 Then the list includes:
2 "JAUNDICE or HEPATITIS (in the last year or
3 contact with a case within 6 months)."

4 Now would it be right to understand that,
5 therefore, the blood donor reading this would only
6 need to declare jaundice or hepatitis if it had been
7 in the last 12 months?

8 **A.** Yes.

9 **Q.** So this form wouldn't pick up any older cases of
10 jaundice or hepatitis?

11 **A.** No, it wouldn't.

12 **Q.** Then if we go to the next page, this is a slightly
13 more indistinct form, but this is the form, if we look
14 halfway down the -- sorry, Soumik, if we actually go
15 halfway down, if you keep it like that.

16 You've got NBTS 110 and, again, we'll see
17 a reference in various communications you had,
18 Professor Contreras, to form NBTS 110.

19 And then, as I understand it, if we look at the
20 writing below this, there's a session date -- sorry,
21 a session location is completed, a date, and then it
22 says:

23 "To [all] blood donors.

24 "Please sign below to show you have read the
25 accompanying notice NBTS 110A."

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1 predict that somebody has a hidden disease. Not a GP
2 could do it even after an examination.

3 **Q.** So for the most part, even the experienced doctor is
4 not going to be able to look at a donor and know, "You've
5 got hepatitis" or --

6 **A.** Oh, no.

7 **Q.** Or, "You've got HIV"?

8 **A.** Yeah.

9 **Q.** Now if we then just go to DHSC0003734_066.

10 This is a later version of the memorandum, but
11 can we go to page 11, please, because what it's got
12 here are the forms that I think were introduced with
13 the 1977 memorandum.

14 So this is form NBTS 110A and is it right to
15 understand that, at the North London Centre, this is
16 a form that would have been given to all donors?

17 **A.** Yes.

18 **Q.** And so it says -- it asks them to tell the clerk if
19 they've recently been in contact with a case of
20 infectious disease or had any inoculations or
21 vaccinations. It identifies certain illnesses which
22 mean that they cannot donate, and then it says:

23 "If you have had any of the following
24 conditions, please declare this and a decision will be
25 made in your individual case by the Doctor."

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1 So the donor was required to sign this to show
2 that they'd read the form that we've just looked at.

3 **A.** Yes.

4 **Q.** And that was -- again, I think, we'll come on to some
5 of the tweaks that were made by North London to the
6 form, but this was essentially a standard form across
7 all Regional Transfusion Centres.

8 Now -- we can take that down -- we know,
9 Professor Contreras, that the decision to readmit to
10 the donor panel donors who had had jaundice or
11 hepatitis longer ago than the last 12 months, was
12 a decision made by Regional Transfusion Directors
13 I think in 1977 or thereabouts, following the advice
14 of an advisory group on testing for hepatitis B
15 surface antigen and its antibodies. So it was before
16 you took up your role as deputy director.

17 Do you recall having any concerns about that
18 practice, that those with a history of jaundice or
19 hepatitis could freely donate and didn't have to
20 declare even that history?

21 **A.** No, I didn't have any concerns, because at the time
22 I thought, and there was evidence, that the majority
23 of cases of jaundice or hepatitis were due to
24 hepatitis A, as is the case presently.

25 **Q.** If we look at DHSC0002179_067, this is a 1976

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1 publication so, again, it pre-dates your appointment
 2 as deputy director in 1980, and it is from the
 3 International Society of Blood Transfusion. This part
 4 of the document is concerned with donor selection.
 5 If we go to page 7, if we just look at the top
 6 paragraph first of all:
 7 "The non-remunerated blood donor is the
 8 essential element around which every blood transfusion
 9 service is shaped. None may join the blood group
 10 whose blood may transmit disease to his fellows, or
 11 whose health may suffer as a result of his
 12 generosity."
 13 Would it be right to understand that those two
 14 principles set out in that second paragraph were two
 15 of the guiding principles in relation to donor
 16 selection for the Blood Transfusion Service: there
 17 shouldn't be harm to the donor and there shouldn't be
 18 harm to the recipient?
 19 We then have a heading "Examination of the
 20 donor", I'm not going to ask you to go through that,
 21 but there are some sample donor selection forms over
 22 the page.
 23 Now, these ask, if we look at point 5, for
 24 example:
 25 "Have you ever had hepatitis (yellow jaundice)?"

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1 of viral hepatitis at any time you should be excluded.
 2 Do you recall, first of all, whether you were
 3 ever aware of this particular advice?
 4 **A.** I must have been because I've joined the ISBT, but
 5 many -- many of the documents from the ISBT and the
 6 WHO are mostly directed to those countries that do not
 7 have guidelines and, while you don't know anything
 8 about the population or the donor population, most of
 9 the donations are replacement donors or paid donors.
 10 You know, I was a president of the ISBT so
 11 I remembered doing that, writing -- not myself, but
 12 signing to guidelines from all of the WHO.
 13 So it's very different. I'm Chilean, you know.
 14 It's very different when you have a history of
 15 hepatitis in a country where the majority of the
 16 donors are not voluntary donors and where, even if
 17 you -- a history of jaundice could have been
 18 hepatitis B, a carrier of hepatitis B, but the systems
 19 in place were not good enough, and -- lots of times in
 20 the developing world you just couldn't test properly
 21 or you didn't have kits. So you have to have
 22 a belt-and-braces approach.
 23 And this was international. So it had to be for
 24 African countries, South American countries,
 25 Asian countries as well. It wasn't really meant for

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1 Then if we go to the next page, another sample
 2 form asks -- the first question is:
 3 "Have you ever suffered from jaundice?"
 4 Then if we go to page 12, this is -- there's
 5 a heading "Viral Hepatitis", which reads:
 6 "In spite of recently developed tests for the
 7 detection of HBsAg, only a relatively small proportion
 8 of carriers can presently be detected. No routine
 9 screening test is presently available for the
 10 detection of hepatitis A virus, or of other viral
 11 agents that cause transfusion-associated hepatitis.
 12 It follows, therefore, that some general precautions
 13 should be taken in an attempt to reduce the risk of
 14 such viral agents being transmitted from donor to
 15 recipient.
 16 "Prospective donors should be excluded if it is
 17 known that they ..."
 18 Then there are number of exclusions set out here
 19 and on the next page, but it's the first one:
 20 "Give a history of viral hepatitis at any time,
 21 except during the first months of life. (This rule
 22 may not be acceptable in all countries and may have to
 23 be modified where viral hepatitis is endemic.)"
 24 So the advice of the International Society of
 25 Blood Transfusion in 1976 was: if you have a history

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1 countries like the UK.
 2 **Q.** It doesn't say that, does it?
 3 **A.** No, it doesn't say.
 4 **Q.** I mean -- and you refer to the World Health
 5 Organisation report (which I'm sure you were familiar
 6 with, but was provided to you I think in advance of
 7 your evidence) from 1952, which also records the same
 8 basic principle, that if you've a history of
 9 hepatitis, viral hepatitis, it should exclude you for
 10 all time.
 11 There's nothing in those documents which say
 12 this -- I mean, obviously it says not acceptable in
 13 all countries, but there's nothing in those documents
 14 which says this is advice or a principle limited to
 15 developing countries or countries where there isn't
 16 a voluntary system?
 17 **A.** No, it doesn't. But may I say that, first of all, the
 18 tests were not good enough. And we -- there was no
 19 evidence for that statement, either in ISBT or WHO.
 20 There was nothing to say that donors with a history of
 21 jaundice had -- were more -- were transmitting more
 22 hepatitis, by transfusion.
 23 **Q.** If we just then move from 1976 and the International
 24 Society of Blood Transfusion to the Council of
 25 Europe's Committee of Ministers in 1983. So that's

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1 NHBT0010651_004.
2 So this is concerned with Member States of the
3 Council of Europe. It's not concerned with the world
4 platform. And the specific recommendation here is
5 directed at AIDS.

6 If we go over the page, you'll see the
7 recommendation at the top of the page, point 1, is to
8 take steps which include -- and this is the fourth
9 paragraph down:

10 "- to provide all blood donors with information
11 on [AIDS] so that those in risk groups will refrain
12 from donating (an example of an information leaflet
13 for donors is appended)."

14 We'll look at the AIDS leaflets used in England
15 and Wales shortly.

16 But if we then go down the page, we can see the
17 sample information unit that -- the passage in italics
18 under the heading "Appendix" says:

19 "The present information leaflet for donors has
20 been prepared and is used by the American Red Cross;
21 it is given as an example for the convenience of
22 National Blood Transfusion Services wishing to draw up
23 their own information leaflet."

24 The rest of that page deals specifically with
25 the issue of AIDS.

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- 1 A. -- (overspeaking) --
2 Q. Can we then just, looking at later versions of the
3 guidance for the selection, medical examination and
4 care of blood donors, look at one that was adapted by
5 the North London Centre.
6 So this is NHBT0057118. It's headed:
7 "North London Blood Transfusion Centre Guidance
8 for the Selection, Medical Examination and Care of
9 Blood Donors
10 "Compiled 1985
11 "Revised April 1987."
12 I'm not going to go through it in any particular
13 detail, but it looks from this as though the North
14 London Centre took the national guidance that had been
15 agreed between Regional Transfusion Centres and then
16 made some of its own changes or amendments or
17 additions to it. Is that right, and if so, could you
18 recall --
19 A. Vaguely.
20 Q. And can you recall what it was that led the Centre to
21 want to reduce its own version?
22 A. I think that one of the issues was that the national
23 guidelines wanted the donors to sign that they were
24 not in a high-risk group of transmitting an infectious
25 agent. And, you know, nobody in this room could know

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1 But if we go to the top of the next page, this
2 American Red Cross leaflet appended to the Council of
3 Europe's recommendation under the heading "Hepatitis",
4 again envisages the permanent deferral of persons with
5 a past history of viral hepatitis.

6 Do you recall whether -- or first of all, do you
7 recall whether you ever saw this recommendation in or
8 around 1983?

- 9 A. I couldn't say whether I saw it or not.
10 Q. So I think it will probably follow from that that you
11 can recall whether this led to any discussion --
12 A. No.
13 Q. -- within the Blood Transfusion Service as to whether
14 the practice of allowing people with a history of
15 viral hepatitis to donate should be reviewed?
16 A. But what I knew -- what I remember is that we never
17 took -- that the Blood Service never took those
18 decisions on their own. It must have been on the
19 advice of specialists in hepatitis or in --
20 Q. It is certainly right to say that the -- as
21 I understand it, the decision of Regional Transfusion
22 Directors to allow those with a history of viral
23 hepatitis in 1977 to start donating reflected advice
24 given by the advisory group on testing for hepatitis B
25 surface antigen?

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- 1 whether we're in a risk group of transmitting some
2 infectious agent. So I think that that was the main
3 point. But I cannot remember very clearly.
4 Q. Just on that point you've made, Professor Contreras,
5 I think there's some correspondence between you and
6 Dr Gunson that may deal with that issue.
7 NHBT0009866.
8 This is a letter you wrote, 28 December 1989, to
9 Dr Gunson, and it refers to the form NBTS 110, so the
10 standard form that we looked at a few minutes ago.
11 You say in the second paragraph:
12 "At [the North London BTC] we hold
13 a considerable proportion of donor sessions in
14 industry, and we do not send any correspondence to
15 such donors. They are reminded by the local
16 organisers of our visits and are asked to attend. In
17 addition, 10% - 20% of our donors are first-time
18 donors and a significant number of known donors change
19 their donation venues without giving any notice
20 (people in London move house and work quite
21 regularly). These are the three main reasons for
22 donors arriving at a session without having had the
23 opportunity of reading the AIDS leaflet. We would
24 need to have a member of staff acting as
25 a receptionist at all donor sessions, ensuring that

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- 1 all donors read the leaflet before they are asked to
2 sign Form 110."
3 Then, if we go over the page:
4 "We have discussed NBTS 110 at length with the
5 consultants at this centre and we would all oppose
6 number 5 in your revised form."
7 I'm afraid we don't have the attachments to
8 match to that.
9 "We do not think that we can ask anybody to sign
10 confirming that 'they are not at risk'."
11 Just so I can understand what you were saying
12 here, Professor Contreras, properly, you did ask
13 donors to identify whether they were in specific risk
14 groups; is that right?
15 **A.** Yeah.
16 **Q.** So it might be, "Are you homosexual?" In the course
17 of the eighties, there were questions about whether
18 someone had been in certain parts of the world.
19 Indeed, I think that was a feature of forms at various
20 different stages?
21 **A.** Yes.
22 **Q.** Intravenous drug use, sexual contact with people who
23 were in such groups?
24 **A.** **(Witness nodded)**
25 **Q.** You'd ask those questions; is that right?

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- 1 **A.** Yes.
2 **Q.** So is it right to understand that the question you
3 were objecting to was a question which asked donors to
4 confirm that -- that they were not at risk of --
5 **A.** Of transmitting some -- an agent transmissible by
6 blood. You know, because those -- those were the main
7 re-examination group categories, the ones that we
8 said. But if you are the wife of a bisexual man, as
9 we saw -- as the evidence when we counselled our
10 donors, you have no idea that you are in a risk group.
11 So a number of donors who come very willingly to
12 donate do not know that their partner might have been
13 a drug addict or might have been at risk of HIV
14 transmission. So we could not ask donors to sign,
15 "I'm not at risk of transmitting anything".
16 **Q.** And I think, just to complete the correspondence,
17 Dr Gunson wrote to you in February 1990,
18 NHBT0000077_065, 26 February:
19 "Dear Marcela,
20 "Roger ..."
21 That would have been Roger Moore?
22 **A.** Yes.
23 **Q.** "... has shown me your letter advising him that you do
24 not propose to use the revised Form NBTS 110, and
25 instead you will be using your own version."

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- 1 And then third paragraph, Dr Gunson says:
2 "I do not have the authority to demand that you
3 use a particular form for your donors to sign, all
4 I ask is that you think very carefully about the
5 action you take in this regard."
6 And he makes the point that this is a form
7 that's been agreed by a majority of Regional
8 Transfusion Centres.
9 You wrote back in March at NHBT0000189_079, and
10 the second paragraph:
11 "I am most grateful for your concern regarding
12 my lack of full compliance regarding NBTS 110.
13 I understand your reasons for writing to me. However,
14 as I stated at the meeting of the Management
15 Committee, I agree with all the contents of the form
16 except for the sentence stating that donors confirm
17 they are not at risk of HIV infection. I know that
18 you and most of our colleagues see this 'confirmation'
19 within the context of the AIDS leaflet. I have
20 discussed the matter at length with my consultant
21 colleagues at the Centre and we all agree that we
22 cannot ask prospective donors to confirm that they are
23 not at risk. The proof for this lies in some of our
24 recently confirmed HIV seropositives who genuinely did
25 not think they were at risk."

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- 1 Is it right to understand, therefore, that you
2 used at the centre then a modified form NBTS 110, at
3 this point in time, which did not include the question
4 or the request to confirm that the person was not at
5 risk of HIV infection? Because you thought it would
6 be problematic for people to be able to answer that
7 question?
8 **A.** No, because people didn't know. There was
9 a proportion of the population who didn't know that
10 they were at risk of transmission.
11 And also, you can transmit other agents that we
12 were not testing for. We genuinely thought that if
13 a donor signed "I'm not at risk" and then they were
14 found to be positive for HIV, particularly for HIV,
15 but -- or hepatitis B, you know, that -- and they had
16 no idea that they were carrying those agents -- nobody
17 knows what they're carrying, really, in their blood.
18 **Q.** But so that there is no misunderstanding, your donors
19 were expected to identify if they were in specific
20 defined at-risk groups?
21 **A.** Oh yes, they signed themselves. We were the only ones
22 who had the self-exclusion questionnaire.
23 So, yeah, but -- if they were in at-risk groups,
24 they self-excluded themselves, but this was a general
25 statement.

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1 Q. Would I be right to understand from what you've
2 described and the correspondence that we've looked at,
3 that although there was an expectation that Regional
4 Transfusion Centres would use the same form across all
5 centres, as the correspondence indicates, if an
6 individual Regional Transfusion Centre wanted to do
7 their own thing, you could? Dr Gunson could ask you
8 not to, but he had no means of compelling you to do
9 something different; is that right?

10 A. Yes.

11 Q. Can we then go back to your statement, WITN5711001.
12 If we look at paragraph 173, page 45, please.
13 In fact 172 and 173.

14 So this was in the context of record-keeping,
15 which we'll look at after lunch, but you say there you
16 thought that the measures were adequate to prevent:

17 "... very adequate to prevent donors ...

18 suspected of carrying blood-borne infections from
19 continuing to give blood.

20 "173. Donors who were suspected of carrying
21 infections were personally approached and counselled
22 by a doctor", et cetera, et cetera.

23 Now, if we leave aside infections that are
24 identified through testing, how often was it that
25 a donor would be suspected, in the absence of a test,

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1 Q. So you were reliant upon donors not just truthfully
2 but also reliably --

3 A. Yeah.

4 Q. -- recalling that they ought to be answering in
5 a particular way.

6 Were questions about intravenous drug use asked
7 before AIDS and the AIDS leaflets in 1983? So was
8 that always a feature from the time you were there, in
9 1980, of the questioning?

10 A. I cannot remember.

11 Q. Military donors, if we can just come on to that as
12 a category, and in particular US military donors.

13 If we just start, first of all, with
14 NHBT0002981. This is a letter, 1990, to Roger Moore,
15 the national director. This is from Dr Hewitt. But
16 she records in the second sentence:

17 "We do ... collect a large number of donations
18 from MOD establishments!"

19 So that would be British military
20 establishments, presumably.

21 Again, had that always been a feature throughout
22 the time you were there of the donor sessions, that
23 you went to --

24 A. Yes.

25 Q. -- military bases?

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1 of carrying an infection and excluded from donation?
2 Whether on the basis of the doctor's assessment or
3 signs such as weight loss or other problems in
4 relation to health? Was it common for donors to be
5 excluded on that basis?

6 A. No, it was very uncommon. The majority -- as I said,
7 the majority of the people who come to donate are very
8 healthy and they're very well informed.

9 Q. Can I then ask you about specific categories of donors
10 who might be regarded as being at higher risk than
11 others.

12 We can take the statement down, thank you,
13 Soumik.

14 Intravenous drug users. What means were there
15 of trying to ensure that patients or donors with any
16 type of history of intravenous drug use did not give
17 blood?

18 A. The self-exclusion questionnaire, you know, and all
19 our leaflets that stated that. But still, we still
20 found that some -- some of our publications show that
21 they -- they had forgotten that they had used drugs
22 intravenously. So it was -- we were asking them to
23 state whether they had been -- they were intravenous
24 drug users but a number of them had -- would have
25 forgotten.

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1 A. Yes.

2 Q. Then if we look at NHBT0004776. This is a letter,
3 it's again from Dr Hewitt to Dr Gunson, it's
4 July 1992, headed "Donor Sessions in US Military
5 Establishments".

6 It says:

7 "For many years until 1986 we held regular blood
8 donor sessions at a US Military Establishment in
9 Bedfordshire. This was the only US Establishment
10 served by NLBTC but the donor session also served
11 a number of UK civilian personnel."

12 Just pausing there, do you recall whether there
13 was ever any thinking about whether military
14 personnel, British or American, whichever, should be
15 regarded as being at higher risk or should be regarded
16 as a high-risk group? Was that ever part of the
17 centre's thinking?

18 A. No.

19 Q. Was there ever any positive consideration given to it
20 at all? In other words did the centre satisfy itself
21 that military donors should not be regarded as high
22 risk?

23 A. Yeah, the only thing I remember -- I recall is that
24 what we discussed was that we did not want the
25 military personnel lined up by the boss or by the

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1 Captain or -- to give blood. We wanted it to be
 2 a fully voluntary act. So that was the only risk that
 3 could have been there, that their boss might have told
 4 them "You have to go and give blood", and we don't
 5 want any donors under pressure.

6 **Q.** There might, mightn't there, have been particular
 7 difficulties for a military donor in identifying
 8 themselves as ineligible because of being gay or
 9 because of intravenous drug use, and I think, as this
 10 and some other documents show, you couldn't be in a US
 11 military role and be gay; it was unlawful?

12 **A.** Yeah.

13 **Q.** Was consideration ever given to the fact that there
 14 might well be a pressure on donors not to answer
 15 truthfully because if they did they would be thrown
 16 out of the military?

17 **A.** Yes. But we learnt that, later on, when we had our
 18 first HIV positive, then we started thinking about it,
 19 that, you know, there were -- yeah, that they couldn't
 20 say that. But we had the self-exclusion questionnaire
 21 as well, and that -- even that was bypassed by some
 22 donors.

23 **Q.** I won't go to the remainder of the documents on this
 24 issue but I'll just give a couple of references for
 25 the transcript. So the second page of this letter

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1 "Certainly, the difference in rates was
 2 sufficiently obvious to prompt the cessation of blood
 3 collection from prisoners in North London in 1973 ..."

4 If we go over the page, this is one of the
 5 documents that Dr Barbara referred to, "HBsAg
 6 prevalence in Prisons, Borstals, [et cetera]". We can
 7 see the figures, first of all, for 1971: HBsAg rate in
 8 donors overall, 1 in 1,745; rate in prisons/borstals,
 9 1 in 92, ie 19 times higher; and then for the first
 10 half of 1972, the rate in the overall population, 1 in
 11 1,946; and then in prisons, borstals, 1 in 339, ie 5.7
 12 times higher.

13 Is it right to understand, Professor Contreras,
 14 that when you were arrived at the North London Centre
 15 in your post as deputy director, the Centre did not
 16 collect from prisons or borstals --

17 **A.** Yes. We did not.

18 **Q.** -- and that didn't change?

19 **A.** It did never -- it never changed.

20 **Q.** Just one last document, if we may. MDIA0000002. This
 21 is a press article, a Blood Transfusion Service --
 22 sorry, headline "'Hepatitis risk' in prisoners'
 23 blood":
 24 "A blood transfusion service is refusing to
 25 accept blood from prisons. Dr Thomas Cleghorn,

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1 actually appears under a different reference, we don't
 2 need to put these up, Soumik, which is NHBT0004777 and
 3 the letter discusses an issue raised in 1986 about
 4 whether HIV results would have to be reported to the
 5 US military authorities, and that was discussed at
 6 a Regional Transfusion Directors meeting in
 7 January 1986, the reference for which is NHBT0018200.

8 The third category I just wanted to ask you
 9 about before we break, because I note the time, was
 10 prison donations, if we just look at JPAC0000002_039.
 11 This is a letter from Dr Barbara to Dr Bird,
 12 a haematologist at the Churchill Hospital in Oxford,
 13 August 1994, and if we look at the third paragraph, it
 14 says this:

15 "Certainly, prior to the introduction of HBsAg
 16 screening of donors in 1971 the prison population
 17 represented an attractive source of donors -- a truly
 18 'captive' audience -- but in North London we noted
 19 HBsAg detection rates up to tenfold higher in donor
 20 sessions at prisons, compared with rates elsewhere.
 21 At the time we thought this might be due to increased
 22 levels of homosexuality: however, in the light of HCV
 23 epidemiology ... a considerable proportion of the HBV
 24 infections may have been drug associated."

25 Then skipping over a sentence:

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1 director of the North London Blood Transfusion Centre
 2 ..."

3 Was he the predecessor to Dr Davies?

4 **A.** Yes.

5 **Q.** "... said last night that the risk of hepatitis was
 6 considerably higher in the blood of prisoners than it
 7 was outside. He criticised the crowding and standards
 8 of sanitation in prisons.

9 "Dr Cleghorn said that in a closed community
 10 such as a prison there was a good chance of hepatitis
 11 being incubated and not being detected by tests. If
 12 infected blood was transfused the consequences could
 13 be serious, and could result in death for the patient.

14 "The centre used to take blood from prisoners in
 15 Wormwood Scrubs and Pentonville but stopped the
 16 practice about a year ago. Dr Cleghorn said last
 17 night that about 800 prisoners had been blood donors.
 18 He was concerned, he said, about the safety of the
 19 blood he was passing on and not about prisoners'
 20 rehabilitation."

21 We know from other evidence,
 22 Professor Contreras, that other centres continued to
 23 collect blood from prisons during the 1970s and into
 24 the 1980s, with some not stopping until late 1984,
 25 possibly 1985. Were you aware of that?

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- 1 **A.** Yes, in a way I was. Yes.
- 2 **Q.** Do you recall whether Regional Transfusion Directors
3 were troubled by that? Was any step taken to try to
4 persuade other centres to take a different course,
5 either by you or by others?
- 6 **A.** No, because I wasn't -- that was never discussed at an
7 RTD meeting that I remember, and because the decision
8 had been taken before my time, I didn't -- I perhaps
9 knew something that they were collecting blood from
10 prisons but, no, I can't remember.
- 11 **Q.** And it's right to say you only became a director in
12 February 1984 --
- 13 **A.** Yeah.
- 14 **Q.** -- so you wouldn't have been attending the RTD
15 meetings prior to that in any event.
- 16 **A.** Yeah.
- 17 **MS RICHARDS:** Sir, I've gone past one o'clock for which
18 I apologise. Perhaps we could take our lunch break
19 now.
- 20 **SIR BRIAN LANGSTAFF:** Yes. Well, we'll take a break.
21 We'll give everyone a full hour, shall we, and come
22 back at 2.05. So 2.05, if you please.

23 (1.05 pm)

24 (The Luncheon Adjournment)

25 (2.05 pm)

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- 1 **A.** Yes.
- 2 **Q.** Then (3), this would be the responsibility of the
3 hospital, presumably, where treatment was
4 administered?
- 5 **A.** Yes.
- 6 **Q.** So:
7 "Accurate recording in the patient's case-papers
8 of the batch number of the product used, with the date
9 of administration, and of the patient's name in the
10 hospital record of products received and issued."
11 So would you agree those are basic principles
12 but of fundamental importance?
- 13 **A.** Yes.
- 14 **Q.** Then we can see how that was, in particular in
15 relation to category (3) of records, was emphasised in
16 a 1973 document "Notes on Transfusion", HCDO0000861.
17 So we can see the title of the document there, this
18 the revised 1973 version, and if we go to page 3 --
19 and obviously this pre-dates your appointment as
20 Regional Transfusion Director -- but we can see:
21 "This edition of 'Notes on Transfusion', like
22 the four previous editions, has been prepared by the
23 Committee of Regional Transfusion Directors of the
24 Department of Health and Social Security and Welsh
25 Office."

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- 1 **MS RICHARDS:** Professor Contreras, the next issue I'm
2 going to ask you about is that of record-keeping. I'm
3 going to ask you first to look quickly with me at two
4 documents which we looked at earlier in the week with
5 Dr Napier but, for the benefit of those who may not be
6 familiar with them, the first is RLIT0000215. This is
7 a 1952 report of the World Health Organisation's
8 Expert Committee on Hepatitis. Soumik, if we can go
9 to page 20, please.

10 This one of number of preventative measures
11 which the Committee recommended in relation to the
12 response to transfusion-transmitted hepatitis,
13 "Maintenance of records":

14 "Subsidiary but important means of control are
15 afforded by the maintenance of accurate records of
16 origin, distribution, and administration of blood and
17 blood-products. Such records should include:

18 "(1) Record of the names, etc, of donors
19 contributing to each product;

20 "(2) Recording of batch numbers of products
21 issued to hospitals and systematic distribution of
22 products to hospitals."

23 Pausing there, (1) and (2), would be the
24 responsibility of the Blood Transfusion Service centre
25 to maintain?

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- 1 So your predecessors, as Regional Transfusion
2 Directors, would have contributed to this.
- 3 **A.** Yes.
- 4 **Q.** It's presumably a document you were familiar with?
- 5 **A.** I'm sure I am, yes.
- 6 **Q.** Then if we go just to page 18, we've got the heading
7 "Transfusion Records":
8 "A record of every transfusion should be made in
9 the patient's case notes in addition to the details
10 recorded in the transfusion laboratory. It is not
11 always appreciated that the main reason for accurate
12 recording is the protection of the patient."
13 Then I won't go through the details, but there
14 is then set out what should be recorded in the patient
15 records in the top half of the page, and then towards
16 the bottom of the page it sets out what should be
17 recorded in the laboratory records, and that
18 continues -- if we just go to the next page --
19 continues over the page.
20 So it would be right to understand that these
21 were the standards in terms of record-keeping that
22 hospitals using blood or blood products were expected
23 to maintain.
- 24 **A.** Yes.
- 25 **Q.** Now, I'm going to ask you to help us understand the

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1 record-keeping in relation, first of all, to
 2 categories (1) and (2) from the World Health
 3 Organisation, so record keeping in relation to donors
 4 and then record-keeping from the centre in relation to
 5 the products that were sent out to hospitals.
 6 In terms of donors, if we go to your witness
 7 statement, so if we could have back, Soumik,
 8 WITN5711001, and we go to page 43. You describe here
 9 the system at the North London Transfusion Centre in
 10 terms of records of donors. Something called 101
 11 cards; is that right?
 12 **A.** Yes.
 13 **Q.** You tell us in paragraph 162, towards the bottom of
 14 the page that this method of record-keeping was in
 15 place when you became director and you didn't make any
 16 changes to the system.
 17 If we just go back to look at paragraphs 160 and
 18 161, the 101 card would have details of the donor,
 19 name, address, date of birth, donor history, and
 20 they'd have different colours for various reasons.
 21 Then there'd be donor session details, which you
 22 describe in paragraph 161 as well, and there will be
 23 bleed sheets, specific to each donor session.
 24 So would it be right to understand that you
 25 would have -- for every session, you would have a list

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1 until it was labelled, you know, so you separated
 2 plasma or cryoprecipitate and platelets from the unit
 3 and they all had the same unique donation number.
 4 **Q.** So at the point in time at which a blood product or
 5 component left the centre to go to a hospital, you
 6 would know or you would be capable of ascertaining
 7 from whom the original donation or donations came?
 8 **A.** Yes. We could trace back to the donor.
 9 **Q.** What, then, of the position in relation to the records
 10 that the hospital was supposed to maintain in relation
 11 both to entries in the patient records and then
 12 entries in the hospital's laboratory or blood bank
 13 records? Did you ever have access to that data?
 14 **A.** No, I -- unless we were following up a unit or we
 15 followed up a report from a hospital of
 16 a transfusion-transmitted infection or an error or
 17 anything like that. Then we would have access to the
 18 records. Not routinely. But what we did was we had
 19 meetings with the medical laboratory scientific
 20 officers in charge of the blood banks and the
 21 consultant -- there was always a consultant
 22 haematologist in charge of a blood bank, and we had
 23 meetings to remind them of the importance of
 24 record-keeping.
 25 But we didn't -- and we also issued an issue

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1 of who had donated, is that right --
 2 **A.** Yes.
 3 **Q.** -- on the bleed sheets?
 4 **A.** Yes.
 5 **Q.** Then for every donor you'd have the 101 cards which
 6 set out their own personal history of donation?
 7 **A.** Yes, and for the new donors, we had a buff card,
 8 101 card, a new 101 card until they were grouped and
 9 they went to different colours.
 10 **Q.** That, I think, helps us understand how records were
 11 kept in relation to donors. Could you then just
 12 explain for us what the record-keeping was in relation
 13 to what then happened to the donation? So the unit of
 14 old blood or red cell concentrate or whatever else it
 15 was that was processed at the centre, what records
 16 were associated with the production of that unit?
 17 **A.** Every donation had a number attributed to it and, as
 18 I explained in one of the documents, we gave labels,
 19 additional labels with that unique donation number,
 20 and then later on we had a donation number and a donor
 21 number as well.
 22 So if a unit, a pack of blood, was split into
 23 fresh frozen plasma and platelets at the blood centre,
 24 their number of the donation would be on the
 25 additional packs, because that pack was not separated

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1 note for every hospital with the numbers of all the
 2 units given to them, and they had to sign -- it was an
 3 original and a copy, and I think they kept the
 4 original and sent the copy back to us, signed that
 5 they had received all those units.
 6 **Q.** Then if we can just look at a handful of documents
 7 about record-keeping, if we start at DHSC0101588,
 8 please, Soumik.
 9 This is a letter, 9 March 1982, from you -- oh,
 10 no, sorry, over the page, it's from Dr Davies, your
 11 predecessor. Just look at the next page. So it's
 12 from your predecessor to Dr Walford and if we go back
 13 now to page 1, heading "Record Keeping in the NBTS and
 14 Hospital Blood Banks", it refers to a letter to
 15 Dr Wagstaff. And there was a degree of investigation
 16 or enquiry ongoing in the Department of Health at this
 17 time about record-keeping?
 18 Then Dr Davies says in the second paragraph,
 19 second line:
 20 "Anyone investigating our records [the centre's
 21 records] would have seen that all issues of blood and
 22 blood components are fully recorded and Hospital staff
 23 sign issue slips on receipt of the blood."
 24 Was that the system that was in operation when
 25 you took over as director?

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- 1 A. Yes.
- 2 Q. And that continued to be the system?
- 3 A. Yes.
- 4 Q. And in due course it became computerised?
- 5 A. Yes.
- 6 Q. But that was the basic system.
- 7 And then -- and Dr Davies goes on to talk about
- 8 then the hospital records. He says, third paragraph,
- 9 fourth line:
- 10 "At Edgware, as I am sure at every other
- 11 Transfusion Centre, we have accurate records to
- 12 Hospitals and of returns from Hospitals but we have no
- 13 records of the 'final disposal', ie the recipients.
- 14 If it is assumed that 3 units are used per
- 15 transfusion, then last year approximately 53,000
- 16 patients received blood issued by Edgware. I foresee
- 17 problems in persuading the many hospitals we supply to
- 18 forward regular and accurate records of the recipients
- 19 for the RTC to match up with recorded issues to the
- 20 hospitals. I consider that once the hospital staff
- 21 have accepted the blood it is their responsibility to
- 22 keep records of the final disposal."
- 23 Was that your view as well?
- 24 A. Yes.
- 25 Q. And again, did that remain the position while you were

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- 1 permit the tracing of any unit of blood from
- 2 collection to transfusion or disposal'.
- 3 "Dr Contreras has informed me that, when trying
- 4 to investigate the ultimate fate of blood or blood
- 5 components involved in suspected cases of
- 6 transfusion-transmitted HIV or HBV infection, it has
- 7 been impossible in some cases for her or her staff to
- 8 know, with certainty, whether a specific unit of blood
- 9 was actually given to a particular patient, since no
- 10 entry was made in the patient's notes. On all
- 11 occasions, the records in the blood bank were adequate
- 12 but the fact that blood or blood derivatives were
- 13 issued for a named patient does not necessarily mean
- 14 that they were actually given to the specific
- 15 patient."
- 16 Then there's a reference to the new product
- 17 liability regime. The letter in some respects speaks
- 18 for itself.
- 19 Is it right to understand from this that this
- 20 issue about record-keeping came to your attention
- 21 because you'd been trying to trace what happened where
- 22 you had the possibility of a donor who may have
- 23 transmitted HIV or HBV?
- 24 A. It was before then. I always knew that a unit of
- 25 blood given, or the components given, given by

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- 1 director, the hospital was expected to maintain its
- 2 own records?
- 3 A. Yes. But it was much easier in my days because we
- 4 had -- they had computerised systems and so they
- 5 could -- like in a supermarket, they could run the
- 6 reader through the coder bars.
- 7 Q. Now it does seem as though there were problems about
- 8 the extent to which hospitals that you supplied were
- 9 maintaining accurate records. I want to look at
- 10 a couple of letters from 1988 in that regard.
- 11 If we start with NHBT0115386, please.
- 12 This is a letter from you to Dr Seymour at the
- 13 North West Thames Regional Health Authority,
- 14 3 May 1988, and it says this:
- 15 "You asked me to send you a draft for a letter
- 16 to District General Managers regarding record keeping
- 17 of units of blood transfused in hospitals. I propose
- 18 something along these lines ..."
- 19 And then this was your draft:
- 20 "The Director of North London Blood Transfusion
- 21 Centre [that's you] has informed me that some
- 22 clinicians, especially those in theatres and intensive
- 23 care units, are not complying with the DHSS Circular
- 24 on 'Record Keeping and Stock Control Arrangements
- 25 ...'. The circular states clearly that records 'must

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- 1 a donor, should -- we should always know the
- 2 ultimate -- somebody should know the ultimate fate of
- 3 that unit transfused.
- 4 And it was -- I think it was before that letter
- 5 when some units of plasma started disappearing, as
- 6 well, that it emphasised the need for adequate
- 7 record-keeping.
- 8 Q. And was it your experience that it was quite common to
- 9 find that hospitals were not adequately discharging
- 10 their record-keeping responsibilities?
- 11 A. Yes, it was quite common.
- 12 Q. This letter suggests that, at this point in time, the
- 13 problem was predominantly in terms of the patient
- 14 records, as opposed to the laboratory or blood bank
- 15 records?
- 16 A. Yes, the blood bank records were always quite -- very
- 17 good. And, you know, when they were issuing units,
- 18 particularly -- as I said, it was particularly in
- 19 theatre or ITU that units were not properly recorded.
- 20 Q. Then we can see there's a further letter in 1988 that
- 21 you wrote, NHBT0085222, 13 September 1988, this
- 22 particular letter is to a consultant haematologist at
- 23 the Queen Charlotte's Hospital, and the first
- 24 paragraph refers to you having made a visit to the
- 25 blood transfusion unit at the hospital. Then you say:

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1 "The purpose of this letter is to remind
2 clinicians of the DHSS Circular on Record Keeping and
3 Stock Control, which I enclose."

4 Then skipping over a few lines you say:

5 "We must ensure that the ultimate fate of a unit
6 of blood, a blood component or a blood product is
7 known beyond any doubt. I note that the system of
8 record keeping in your Blood Transfusion Laboratory is
9 very good. However, I am not quite sure whether
10 clinicians are fully aware that they are responsible
11 for ensuring that the donation numbers of the units
12 transfused are entered in the patient's notes. I know
13 that you supply self-adhesive forms for the donation
14 numbers of the units cross-matched by your laboratory.
15 However, clinicians must ensure that such forms are
16 stuck on the patient's notes and, in addition, the
17 person giving each unit of blood should enter the
18 number, date and time of administration with a legible
19 signature that will facilitate any further
20 investigations in case of adverse reactions to
21 transfusions. Accurate record keeping is vital and
22 traceability of every unit of blood must always be
23 maintained."

24 Then you go on to deal with another problem in
25 the next paragraph:

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1 the need to be able to trace every unit of blood but
2 would it also be right to understand that recording
3 the reason for transfusion would be important in terms
4 of wider issues about transfusion practice to ensure
5 that transfusions were only being given when they
6 needed to be given?

7 **A.** Yes.

8 **Q.** We can take that down, thank you.

9 **SIR BRIAN LANGSTAFF:** Can I just ask, the theft that took
10 place of plasma, was that about this time, 1980s?

11 **A.** Yes, sir. It was before I was -- when I was deputy
12 director, it was between 1980 and 1984 and, yes, it
13 occurred around that time.

14 **SIR BRIAN LANGSTAFF:** The plasma which was sent to the
15 hospital from where it was taken, that would have been
16 recorded in the way you've just described?

17 **A.** It should have been recorded.

18 **SIR BRIAN LANGSTAFF:** So if the hospital had been keeping
19 proper records, they should have known where each unit
20 of plasma had gone?

21 **A.** Yes, and that was what -- in effect, that was when the
22 Department became worried about transfusion records,
23 because the ultimate fate of many units of fresh
24 frozen plasma could not be known.

25 **SIR BRIAN LANGSTAFF:** It must follow that because

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1 "An essential part of record keeping involves
2 adequately completed transfusion request forms as well
3 as properly labelled tubes containing blood samples.
4 I have noted that a large number of transfusion
5 request forms at Queen Charlotte's are not completed
6 in a satisfactory way; information is often lacking
7 regarding previous pregnancies, transfusions,
8 diagnosis, etc."

9 What was the transfusion request form and why
10 was it important to have that completed
11 comprehensively?

12 **A.** The transfusion request form is the request form from
13 the clinician from the consultant treating the
14 patient. Usually it was filled in by a junior doctor
15 or senior registrar or registrar. It was the request
16 form with the name of the patient, the date of birth
17 of the patient, the hospital number -- it needed to
18 have all those -- the diagnosis, and the haemoglobin,
19 if red cells were needed, or the platelet count, if
20 platelets were needed, and the reason for the
21 transfusion. Every hospital had their own transfusion
22 request forms.

23 **Q.** Would it be right to understand that one of the
24 reasons why it was important to have such documents
25 completed accurately is the reason you've given here:

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1 presumably no one noticed for a while and because
2 presumably the consultant thought they could get away
3 with it, taking the plasma, that is some indication of
4 the poor state of recording keeping by the hospital at
5 the time?

6 **A.** Yes, sir.

7 **SIR BRIAN LANGSTAFF:** Yes, I see. Thank you.

8 **MS RICHARDS:** Professor Contreras gives, I think, an
9 outline of her own involvement in relation to
10 observing the then Chief Medical Laboratory Scientific
11 Officer at the Edgware Centre in her statement at
12 paragraph 44 for those who are interested in reading
13 it.

14 If we put your statement back on again,
15 WITN5711001, and we go to page 51, I'm going to come
16 back to the issue about jaundice enquiry reports, that
17 you deal with in paragraph 202.

18 Paragraph 203, you talk about the situation of
19 a donor who was found to have been excluded by another
20 Regional Transfusion Centre, and I think you explain
21 in paragraph 204 that there was no scheme prior to the
22 national information technology system which enabled
23 proper data sharing between different Regional
24 Transfusion Centres, which were, as you described,
25 these independent autonomous centres.

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1 So is it right to understand there was no system
2 for enabling centre A to tell centre B the details of
3 the donors they'd had excluded?
4 **A.** Yes, there was no system.
5 **Q.** And no way centre B could contact centre A and say,
6 "We've got a donor here, have you got any records of
7 that donor?" Was that possible?
8 **A.** Yes, if the donor told us that they'd been a donor at
9 another centre, then we would immediately contact the
10 other centre and say, "Could you please tell us
11 whether this donor is fit and send us the 101 card for
12 that donor".
13 **Q.** If we go over the page, please, Soumik, you, I think,
14 essentially make that observation in paragraph 208:
15 "There was no mechanism for a centralised
16 database shared with other RTCs about excluded donors.
17 It was only when donors told us they had moved, but
18 otherwise we did not really share information, until
19 the national IT system was created ..."
20 Then the bottom of the page, paragraph 210:
21 "With respect as to whether I believe the
22 measures in place between RTCs were adequate in
23 preventing donors who were suspected of carrying
24 blood-borne infections from continuing to give blood,
25 I have to say I do not think the systems were adequate

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1 Dr Barbara, you and Dr Briggs. Is this the case you
2 were thinking of?
3 **A.** I think it might be. It's a donor who came twice to
4 give and he was positive, yeah.
5 **Q.** Yes, exactly. We can see it's set out in the first
6 paragraph:
7 "In the absence of specific tests for non-A,
8 non-B hepatitis viruses, evidence for their
9 involvement in post-transfusion hepatitis ... can only
10 be circumstantial. This report describes an example
11 where two successive blood donations, spaced by 7
12 months from the same donor were both implicated in
13 cases of [post-transfusion hepatitis]."
14 Then you describe a donation given as whole
15 blood to a patient who became jaundiced six weeks
16 after transfusion.
17 Then if we go to the top of the next column it
18 talks about how the donor was:
19 "... asked to refrain from blood donation until
20 further notice and his records were withdrawn from our
21 routine donor file. Despite these recommendations, he
22 returned as a new donor 7 months later and his
23 donation was one of four units given as whole blood to
24 a patient."
25 And so, is that the occasion you were thinking

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1 because we did not really have a system that would
2 have prevented the risk of an infectious donor
3 donating somewhere else. All we could do was to
4 advise donors known or suspected of carrying
5 blood-borne infections that they should not continue
6 donating, giving them the reasons for this advice."
7 Then you say in paragraph 211 that the donations
8 by donors known to be carrying blood-borne infections
9 would only have taken place where a donor was
10 maliciously doing something, and you ever encountered
11 such an event.
12 But it might be the case, might it not,
13 Professor Contreras, that you could have a donor who
14 hasn't actually been adequately counselled or given
15 proper information, doesn't understand why they've
16 been excluded from another centre, who may perfectly
17 innocently, non-maliciously present themselves to
18 a further centre. So that could happen?
19 **A.** Oh yes, that could happen, but I must say that with
20 the papers I was sent, I was reminded of a donor that
21 we had at our centre --
22 **Q.** I'm going to ask you to look at the --
23 **A.** Yeah.
24 **Q.** So that is NHBT0000030_007. I'm hoping we're thinking
25 about the same thing. This is an article by

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1 of?
2 **A.** Yes.
3 **Q.** And can you help us in understanding how that
4 occurred?
5 **A.** Well, you know, as I said, the first donation went
6 into a patient who was -- one of the two units given
7 to that patient, and the hospital, I think weeks or
8 months after the transfusion, reported that the
9 patient had hepatitis, elevated transaminases,
10 I think.
11 So we went back to those donations and we had --
12 to those donors, and found that they were -- had
13 I think abnormal ALTs or something, and we told those
14 two donors not to -- to please not continue donating
15 because we thought that they had an infectious agent.
16 So we withdrew that 101 from -- or we marked
17 that 101 as non-suitable donor, and we counselled him
18 personally. We always -- we never referred donors to
19 the GP, but we -- Dr Hewitt was responsible to follow
20 up those donors and counsel them, and she had a team
21 of doctors to do this. So the donor was adequately
22 counselled to please not come and donate again and we
23 do not know why he came to donate again as a new
24 donor.
25 And that then -- as soon as we knew that it had

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1 been that donor -- and it was unfortunately after his
2 unit had been transfused -- that we realised that the
3 red cells had gone into a patient, so we informed the
4 hospital concerned, the consultant concerned, and they
5 followed up the patient and realised that that donor
6 had transmitted non-A, non-B hepatitis.

7 **Q.** And leaving aside whatever the motivation of the donor
8 was in coming back -- having been counselled not to --
9 coming back to donate, how was it that the centre's
10 records didn't identify this as a person who had, only
11 months previously, been advised not to donate?

12 **A.** Because if a donor comes as a new donor, and doesn't
13 tell us, and we had all this collection of 101 cards,
14 so there could be, you know, a hundred John Smiths in
15 our panel. So we couldn't go through all our record
16 system to identify that person as a previous donor --
17 until we were computerised.

18 **Q.** You anticipated my next question. So a computerised
19 system would be likely to pick that up?

20 **A.** Oh, yes.

21 **Q.** But it wouldn't be picked up on a manual system if the
22 donor told you they were a new donor?

23 **A.** Yes.

24 **Q.** Presumably if the donor said, "I've been here before",
25 even if they didn't give details about what they'd

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1 paragraphs 3 to 5:

2 "Dr Contreras drew attention of members to the
3 organisational difficulties of the recommendation
4 requiring that the records of donors who transfer to
5 give blood at a new Centre be checked to ensure that
6 previous donations had not been found antibody
7 positive. EAGA members agreed that this
8 recommendation should be considered further by the
9 Regional Transfusion Directors Committee."

10 "At the meeting of the Regional Transfusion
11 Directors Committee in July it was universally agreed
12 that it would not be practical or even possible at
13 some Centres to check previous records of donors in
14 this way."

15 And that essentially remained the situation and
16 remained a problem until there was a national
17 database, effectively, a national IT system sometime
18 after 1995?

19 **A.** Yes.

20 **Q.** If we then just go back to RLIT0000215, please. This
21 is the World Health Organisation report. If we go to
22 page 21 -- sorry, if we go to page 20, my apologies.

23 So we looked at the section on maintenance of
24 records, and then we have a section on reporting.

25 Second sentence:

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1 been told on the last occasion, would you then have --
2 rather than giving them the buff coloured new 101,
3 would there then have been, before that donor donated
4 or before their donation was used, a check on their
5 old records?

6 **A.** Oh yes, we would inform the centre. We would give him
7 or her a buff 101 card, because we didn't have the
8 records there, but if I've donated a unit before, then
9 we would immediately say, "This is not a new donor,
10 please check that there are records for this donor."

11 **Q.** Would you expect that check ordinarily to be done if
12 the system was working properly before any of the
13 donation was used?

14 **A.** Before any component was made.

15 **Q.** Okay. Then just on the issue of being able to check
16 records of donors from other centres, if we look at
17 JPAC0000035_159, please.

18 The issue under discussion here, as we can see
19 from the heading, is "Readmittance of blood donors who
20 have tested repeatedly positive but are not confirmed
21 HIV antibody positive". This is an undated document
22 but we can see that it must be at some point after
23 May 1987 because it refers to a meeting of the Expert
24 Advisory Group on AIDS in May 1987.

25 I just wanted to draw your attention to

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1 "... the committee feels that useful additional
2 information might be obtained by a simple follow-up
3 system to detect cases of serum hepatitis following
4 administration of blood and blood-products."

5 And then some further suggestions are made.

6 So is it fair to say that the importance of
7 reporting cases of post-transfusion hepatitis have
8 been recognised for decades?

9 **A.** Yes.

10 **Q.** Now in terms of the systems in place within England
11 and Wales, I just want to look at a couple of
12 documents that predate your time, just to see whether
13 the system described was the system in operation when
14 you took over.

15 So if we start with NHBT0016498, please.

16 You'll see, Professor Contreras, this is
17 a Regional Transfusion Directors meeting in
18 November 1973, so some years before you took up your
19 post as deputy director.

20 If we go to page 7 -- I should have said
21 Dr Davies, your predecessor, was at this meeting.

22 Page 7, second paragraph, describes:

23 "Dr Maycock [outlining] the present voluntary
24 system used by RTCs to gather information about
25 reactions and report them ..."

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1 Then he records at (i):
2 "Cases of Serum Hepatitis were reported to
3 Dr Maycock on a special form. This system had been in
4 use since 1946."

5 Then he goes on to then deal with transfusion
6 reactions and certain other reactions such as allergic
7 reactions.

8 Then if we look further down towards the bottom
9 of the page:

10 "It was recommended in Notes on Transfusion ...
11 that serum hepatitis, reactions to infected blood and
12 all severe reactions who'd be reported at once to
13 RTDs. The reason for this is because appropriate
14 action" --

15 Oh, the system has gone down.

16 Thank you.

17 At the bottom of the page:

18 "... appropriate action must be taken by the RTC
19 without delay regarding donors or procedures within
20 the centre."

21 Then if we -- sorry, I'll carry on:

22 "It was important for the same reasons that
23 reactions associated with plasma or plasma fractions
24 should be reported without delay to BPL."

25 Then if we go over the page, second sentence

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1 Transfusion Reaction'."

2 Then if we skip down a tiny bit, it says:

3 "It was further agreed that this subject should
4 be reviewed early next year."

5 Now, that's obviously 1973.

6 Come 1980, when you take up your post as deputy
7 director, was there still a system in place for
8 reporting -- for the Regional Transfusion Centre to
9 report cases of serum hepatitis, post-transfusion
10 hepatitis, and if so, to whom?

11 **A.** There was -- as far as I can remember, there was
12 a system of -- from North London Transfusion Centre,
13 Dr Barbara collated all those cases, and sent -- and
14 made a report, an annual report that was sent to the
15 CDSC at the Public Health Laboratory Service. I think
16 it was Dr Sheila Polakoff, who collated all -- it was
17 like mandatory; I don't know whether it was mandatory
18 but we sent all this -- were sent the -- the reporting
19 was centralised at CDSC.

20 **Q.** So obviously the reports to the Regional Transfusion
21 Centre and then the reports by the Regional
22 Transfusion Centre, would it be right to expect that
23 hospitals should report cases of hepatitis that might
24 have been associated with the use of blood or blood
25 product, you would expect hospitals to be reporting

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1 says:

2 "The numbers of cases of serum hepatitis and
3 other reactions reported varied widely between
4 regions.

5 "The method of reporting was then discussed.
6 Several Directors thought that reports to CSM
7 [presumably Committee on Safety of Medicines] should
8 be made by hospitals since the details of the yellow
9 report card issued by CSM could only be completed in
10 hospitals. After discussion it was agreed that if
11 reports of adverse reactions concerning blood and
12 blood products were to be made to CSM, such reports
13 were best made by RTDs because they almost always
14 heard of and investigated serious reaction associated
15 with blood and blood products. It was not essential
16 that the yellow card was used, providing the name of
17 the doctor in charge of the patient was reported.

18 "After discussion it was agreed.

19 "a. That cases of serum hepatitis should
20 continue to be reported to Dr Maycock on the usual
21 form, to which a space for the name of the doctor in
22 charge would be added.

23 "b. That any other serious reactions, eg to
24 infected blood, would be reported to Dr Maycock,
25 using, when appropriate the form 'Notification of

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1 that to you?

2 **A.** Yes.

3 **Q.** To what extent was that reliably done? It may be
4 impossible for you to answer because you only know
5 what's reported to you.

6 **A.** I think that, in my time -- because often the
7 haematologists in charge of the blood bank would not
8 know, but if there was -- if the -- if the
9 haematologists in charge of the blood bank knew or if
10 anybody knew that there might be an association
11 between the hepatitis or any transfusion event, and
12 the transfusion of a blood component, they would
13 report it to us.

14 **Q.** So there's reports to you and then your recollection
15 is, by the time you're there, the report is made by
16 the centre, you think, on an annual basis, to CDSC.

17 **A.** Yes, well, once the report was made, once we were
18 notified of a case of possible or probable
19 transfusion-transmitted infection, then we would go to
20 the hospital and we would contact the hospital, and
21 investigate whether this was a real case of
22 post-transfusion infection, and if it was a real case
23 of post-transfusion infection, we would then go to the
24 serum archive and investigate the units given to that
25 patient and, if necessary, call up the donors

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1 involved.

2 **Q.** Do you recall there being still in operation a yellow
3 card scheme, to use the phrase --

4 **A.** No.

5 **Q.** You don't. If we then look at your statement, so if
6 we have the witness statement back, please, Soumik,
7 WITN5711001, and go to page 51, we can pick up at
8 paragraph 202, I think, the system you were describing
9 operated by Dr Barbara and his team. You say in the
10 third line of paragraph 202:

11 "... Dr Barbara's team always prepared 'JE'
12 (jaundice enquiry) files for any reports of post
13 transfusion jaundice, or indeed of lab test positive
14 results for viral hepatitis in patients following
15 blood transfusion."

16 So that's the system in operation at North
17 London. Other than, you think, reporting that on
18 an annual basis to CDSC, was anything else done by way
19 of reporting by the centre of such cases --

20 **A.** Err --

21 **Q.** -- to the Department of Health or anywhere else?

22 **A.** No, because the CDSC was acting, I think, on behalf of
23 the Department of Health. So, you know, this report
24 went to Dr Polakoff and to region -- when we were
25 regional, to a regional medical officer.

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1 **Q.** Do you have any recollection of roughly how many
2 jaundice enquiry reports Dr Barbara's team might
3 gather in a year?

4 **A.** Not really, no. I remember that, you know, the real
5 cases of post-transfusion hepatitis were about for
6 a year or something like that.

7 **Q.** If we then -- if we assume a case has been reported to
8 you, and so Dr Barbara or his team are going to be
9 completing the jaundice enquiry report, what are the
10 steps that the centre would then be taking to
11 investigate that?

12 **A.** Well, we would be immediately in touch -- the doctor
13 concerned with that hospital and Dr Barbara would be
14 immediately in touch with the hospital, and see if we
15 could -- well, we would have access to the records.
16 We would go to the hospital and have access to the
17 records and investigate because, often, the cases that
18 were attributed to blood transfusion, the donor had
19 markers of a very longstanding hepatitis that was not
20 attributable to transfusion.

21 So the steps were: investigate where it was
22 a real case of post-transfusion hepatitis and then get
23 samples from the patient, and investigate the archive
24 samples because we always kept serum samples from all
25 the donations that we collected and so Dr Barbara's

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1 laboratory would go back to those archive samples and
2 investigate them, and anyone -- anybody found positive
3 or doubtful for positive, the donor would be contacted
4 and we would sample that donor again, and if found
5 positive, we would -- Dr Hewitt's team would advise
6 them not to continue donating and so complete the
7 jaundice enquiry.

8 **Q.** Having done all that, would you then, or the centre
9 then, be taking the next step of seeking to trace the
10 recipients, other recipients -- so not the one
11 reported by the hospital in the hospital report but
12 other recipients -- of donations over the years. Was
13 that step also done?

14 **A.** Yes, yes.

15 **Q.** So a form of look-back, I suppose, but on a local
16 basis, you would -- would you try to make contact?

17 **A.** Yeah, we would try to make contact and sometimes we
18 were successful and sometimes we couldn't find the
19 ultimate fate of those --

20 **Q.** And sorry, just thinking it through as I ask you the
21 question, you would presumably be dependent upon,
22 then, the reliability of hospital records?

23 **A. (Witness nodded)**

24 **Q.** Because you'd be able to see what had happened to
25 a donation three years ago from donor X, because your

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1 records ought to be capable, as I understand it, of
2 telling you that components made from that donation
3 had gone to Charing Cross Hospital, on such-and-such
4 a date; is that right?

5 **A.** Yes.

6 **Q.** But you wouldn't know what use had been made of them
7 by Charing Cross Hospital unless the hospital records
8 had been completed?

9 **A.** Mm. **(Witness nodded)**

10 **Q.** Would that then be handed over to the hospital to
11 follow up, to try to make contact with the patients
12 who'd been treated with the suspect donation
13 four years ago, or was that something the centre would
14 be doing?

15 **A.** No, we had no authority to go back to the patient, so
16 we -- if we knew -- if it was known that a recipient
17 had contracted -- was -- that had the possibility of
18 having been infected, then we would pass that
19 information on either to the haematologist or the
20 haematologist would pass it on to the relevant GP, or,
21 if there was a clinician in charge of that patient, to
22 the clinician in charge of the patient.

23 **Q.** If we just go to page 77 of your statement, you say in
24 paragraph 306, as you've just told us, that:

25 "Whenever a case of post transfusion Hepatitis

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1 was reported to our blood centre from hospitals in our
2 region, we conducted full investigations with further
3 testing of the patient samples and of the implicated
4 donors to identify possible source of infection."

5 Then you say this:

6 "307. At NLBTC we tested for markers of
7 Hepatitis B, including anti-HBc and LFTs."

8 Now can I just be clear what you're saying
9 there. You're not, as I read your statement, saying
10 that you screened all donations for anti-HBc.

11 A. That's right.

12 Q. You -- this was -- is this right: this was an
13 additional investigation that you undertook on
14 implicated donations?

15 A. Yes.

16 Q. And you'd be calling the donor back in?

17 A. Yes.

18 Q. Through Dr Hewitt's team or whoever it might have
19 been, and asking them to submit to further tests?

20 A. Yes.

21 Q. So there wasn't routine across-the-board anti-HBc
22 testing?

23 A. Sorry?

24 Q. There wasn't routine across-the-board anti-HBc
25 testing?

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1 Q. We know from other material that it was in 1981,
2 I think, that the pro rata system was introduced,
3 whereby an amount of plasma would be supplied by
4 a Regional Transfusion Centre to BPL and then there
5 would be a pro rata delivery back of concentrate from
6 BPL to the region.

7 Do you have any recollection, because this is
8 before obviously you took over, but do you have any
9 recollection of how well the pro rata system worked,
10 and whether it secured sufficient Elstree Factor VIII
11 concentrate?

12 A. There was never enough -- sufficient -- there was
13 never sufficient Factor VIII concentrate from Elstree.

14 Q. Can we go to CBLA0001800, please.

15 This a report from Dr Gunson to the Central
16 Blood Laboratories Authority, CBLA, headed "Plasma
17 supply for self-sufficiency". It's a report dated
18 January 1984. If we look at the second paragraph,
19 Dr Gunson says this:

20 "During the latter part of 1983 ... informal
21 comments from some RTDs gave cause for concern in that
22 the targets which had been agreed as a planned
23 programme were in jeopardy because of difficulties in
24 obtaining the necessary funds. Accordingly, in
25 December 1983, I wrote to each RTD asking for their

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1 A. Oh no, no, no. Only for our apheresis donors, but no,
2 it wasn't across the board.

3 Q. Did you ever get any impression as to whether
4 hospitals were either slow or reluctant to report
5 cases of post-transfusion hepatitis or possible cases
6 of post-transfusion hepatitis to you?

7 A. Not that I can remember.

8 Q. We can take the statement down. Actually, no, sorry,
9 we'll keep the statement up and go to page 24.

10 I'm going to ask you next about a different
11 topic, so self-sufficiency, supply of plasma to BPL.

12 If we start by looking -- sorry, Soumik, my
13 fault, paragraph 88 rather than page. Page 24.

14 So you have said in paragraph 88 that you can't
15 recall the exact plasma targets that were set before
16 the year 1989/1990. We looked earlier at the targets
17 that you had in relation to 1989 and 1990 onwards and
18 your recollection, as set out in your statement at 89,
19 was that:

20 "The targets ... must have been set by the
21 Department of Health in conjunction with BPL."

22 So these are not targets in terms of numbers of
23 donations which you set, this is the target of how
24 much plasma you supplied to BPL?

25 A. Yes.

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1 personal assessment of the situation with respect to
2 obtaining the necessary quantity of plasma by 1986 and
3 their views on their Region's attitude to the
4 subsidising of other Regions who could not attain
5 self-sufficiency. Their replies are summarised in the
6 Appendix to this report.

7 "It will be noted that only three RTDs are
8 confident that their RHA will support the programme
9 for increasing the plasma supply. The remaining
10 replies range between 'not hopeful of the necessary
11 finance' to 'an inability to predict the outcome of
12 discussions with the RHA'. Two factors in the replies
13 were of significance."

14 And then the first was that many RHAs weren't
15 willing to consider proposals on a more than
16 a year-by-year basis, and the second factor was about
17 demand for PPF.

18 If we could then turn to the next page, we've
19 got the results of Dr Gunson's survey set out centre
20 by centre, and if we go to page 3, we've got North
21 West Thames.

22 Now, this is a survey that would have almost
23 certainly, I think, have gone to Dr Davies rather than
24 you, because it's late 1983, but we can see what's set
25 out there:

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1 "Target 18,500 Kg. Budget for 1984/5 has not
2 yet been established but expects finances to be made
3 available to allow this target to be met."

4 And then for 1985:

5 "Increases in the 1984/5 levels could not be
6 made without additional space, and this has been
7 agreed by Regional Medical Officer and RHA Development
8 Department to be a priority. However, although RHA
9 are aware of expansion in plasma supply, no official
10 discussions have taken place and no finance
11 allocated."

12 Now, just pausing there, you then took over as
13 director in February '84. Can you recall the
14 substance of any conversations you held with your
15 regional medical officer about having sufficient
16 funding to be able to provide enough plasma to BPL to
17 meet your targets?

18 **A.** I remember having conversations with my regional
19 medical officer and the regional treasurer about
20 funding in general, because not only did we have to
21 supply plasma to BPL but we had a large demand for
22 fresh frozen plasma and platelets from hospitals. So
23 there was a general problem of funding. Yeah, that's
24 what I remember.

25 And I was passionate about self-sufficiency. So

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1 "Wedgwood Plates", which were I think something given
2 to donors who gave lots of donations?

3 **A.** 100 donations.

4 **Q.** But if we just look at the bottom of the page we can
5 pick up a discussion about plasmapheresis. It says:

6 "Dr Maycock suggested that, although Edgware was
7 the only centre at present at which many donors gave
8 100 or more donations by plasmapheresis, more regions
9 would eventually become involved in these awards."

10 So it would appear from this that, by 1973, at
11 the North London Centre, plasmapheresis was already
12 a well-established part of the system. I know you
13 weren't director for a number of years, but is that
14 your recollection, your understanding, that
15 plasmapheresis was a longstanding part of the
16 arrangements?

17 **A.** Yes, I remember -- because John Cleghorn, who was the
18 director at the time, was pioneering plasmapheresis
19 and he started with manual. I remember seeing manual
20 plasmapheresis when you had to collect a pint of blood
21 and then take it to the blood components, and then
22 separate the plasma and return the red cells to the
23 donor.

24 **Q.** If we go to NHBT0086659, this the draft of a letter to
25 The Economist from you and two of your colleagues,

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1 I must have made a case also for plasma, for BPL, but
2 we had the problem of, you know, supplying enough
3 plasma for the hospitals, teaching hospitals and
4 demanding hospitals, and supplying plasma to BPL.

5 **Q.** I think we probably see that point in the third
6 comment, on the right-hand side, this is in a column
7 headed "Confidence of RTD in ultimately achieving
8 target":

9 "Every effort will be made to achieve targets
10 but demands from teaching and specialised hospitals
11 reduce availability of plasma and doubtful whether the
12 region could become self-sufficient for Factor VIII."

13 In any event, I think it's right to understand
14 from one of your earlier answers that there was not,
15 at this point in time, enough BPL Factor VIII to meet
16 all the needs of the Haemophilia Centres in the region
17 that you supplied.

18 **A.** Yes.

19 **Q.** Now, in terms of plasmapheresis as a means of
20 increasing the amount of plasma that might be
21 available to provide, if we look at NHBT0016498,
22 please, this is a set of minutes we've already
23 looked at for a different purpose, November 1973, so
24 again before your time. If we go now to page 4, the
25 context of the discussion is something called

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1 October 1987, I just want to pick up what's said in
2 the second paragraph:

3 "... plasmapheresis is carried out at most of
4 the 14 Regional Transfusion Centres in England and
5 Wales, and plasmapheresis programmes are rapidly
6 expanding. At the North London Blood Transfusion
7 Service, Edgware, the first unpaid volunteers began
8 donating plasmapheresis in 1967. The number of
9 regular attenders now exceeds 2,500, and over 80% of
10 these donors attend for donation once a fortnight."

11 So is it right to understand that your centre's
12 experience was that plasmapheresis was a very good way
13 of -- provided you had the necessary facilities which
14 required funding, a very good way of increasing the
15 amount of plasma that you could obtain and therefore
16 supply?

17 **A.** Yes, the best way.

18 **Q.** You've told us in your statement that you -- there
19 were three, you describe, state-of-the-art aphaeresis
20 clinics as part of the centre's operations.

21 **A. (Witness nodded)**

22 **Q.** Is that right?

23 **A.** Yes, we had three, and they still exist. The Western
24 Donor Centre, Luton and -- oh God, it's gone out of my
25 mind, we had three plasmapheresis centres --

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- 1 Q. And then --
- 2 A. -- and Edware, of course!
- 3 Q. Then if we just go back to your statement, page 116,
- 4 paragraphs 467 through to 472 of your statement set
- 5 out your perception of the advantages and benefits of
- 6 plasmapheresis. If we go to the next page, Soumik,
- 7 and paragraph 472, you say:
- 8 "I therefore agree that plasmapheresis is
- 9 a crucial technique to increase plasma yields and
- 10 reduce wastage of red cells and in my view this has
- 11 not changed. Self-sufficiency in plasma products is
- 12 not achievable on the basis of recovered plasma
- 13 without a considerable wastage of red cells. Such
- 14 wastage would be immoral and unacceptable."
- 15 Now, the North London Centre, as you've
- 16 described, was obviously adequately funded or
- 17 reasonably well funded to undertake plasmapheresis,
- 18 perhaps because Dr Cleghorn had been a pioneer in this
- 19 field. Was it your understanding that other Regional
- 20 Transfusion Centres were not in such a good position,
- 21 at least at the beginning of the 1980s?
- 22 A. Yes, that's correct.
- 23 Q. Do you recall any discussions or any frustrations
- 24 being expressed to you or concerns about the inability
- 25 of other centres to do the kind of work that you would

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- 1 be able to undertake?
- 2 A. Yes, I remember at Regional Transfusion Directors
- 3 meetings frustration of some of our colleagues.
- 4 Q. More broadly in relation to self-sufficiency, can we
- 5 look at a letter you wrote to Dr Gunson in 1990.
- 6 NHBT0015646.
- 7 31 May 1990. And you say:
- 8 "I am writing on behalf of the Eastern Division
- 9 of Consultants in Blood Transfusion."
- 10 So this would effectively be you, Tooting,
- 11 Brentford and Cambridge, is that right?
- 12 A. Yes.
- 13 Q. "Members of the Division expressed their
- 14 dissatisfaction about the lack of interest of the
- 15 Department of Health in self-sufficiency. It was
- 16 stated that it is not enough to say that 'ministers
- 17 are committed to self-sufficiency' if this is not
- 18 backed by actions and financial support. We firmly
- 19 believe the time has come to reassess the situation
- 20 regarding self-sufficiency."
- 21 Then you go on to set out a number of other
- 22 concerns. You say:
- 23 "There are very good ethical and financial
- 24 reasons for the encouragement of self-sufficiency."
- 25 And then there are specific concerns about the

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- 1 relation to the position of BPL which I'm not going to
- 2 trouble you with.
- 3 On the broader issue of what you say, there is
- 4 a lack of interest in the Department of Health in
- 5 self-sufficiency, that was your position in 1990. To
- 6 what extent, if at all, was that your perception or
- 7 the perception, to your knowledge, of your colleagues
- 8 earlier in the decade?
- 9 A. I think it was always my perception.
- 10 Q. And if we then -- sorry to jump around, but if we go
- 11 back to your witness statement, page 105, you say at
- 12 paragraphs 420 and 421:
- 13 "With very few exceptions, the UK Blood Services
- 14 have always been self-sufficient in labile blood
- 15 components, ie red cells, FFP, cryoprecipitate and
- 16 platelets.
- 17 "421. All I can say is that my perception was
- 18 that the Department of Health decided not to
- 19 appropriately fund and subsidise self-sufficiency in
- 20 fractionated blood products."
- 21 Then if we go over to page 107, please -- sorry,
- 22 page 106 next. 425, you say:
- 23 "With the exception of when the Minister of
- 24 Health was Dr David Owen, I do not believe that the
- 25 Department of Health took a genuine interest in

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- 1 self-sufficiency in plasma derivatives from voluntary
- 2 donors."
- 3 Then you refer to an issue relating to prices
- 4 set for BPL and lack of incentive to collect plasma.
- 5 And then, if we go to the next page, please,
- 6 paragraph 432, you say this:
- 7 "There were two issues with regard to achieving
- 8 self-sufficiency in fractionated plasma products:
- 9 "(a) The funding was not available;
- 10 "(b) BPL did not have capacity or technology to
- 11 produce everything that was needed to achieve national
- 12 self-sufficiency."
- 13 Then:
- 14 "433. If every centre had been funded like
- 15 NLBTC we would have been flooded in plasma, with no
- 16 problem in achieving self-sufficiency."
- 17 And then top of the next page, you say:
- 18 "My view of historical events has not
- 19 changed ..."
- 20 And then if we can go to the bottom of this
- 21 page, you say at paragraph 437:
- 22 "As I have stated, the possibility of collecting
- 23 sufficient plasma from safe blood donors was always
- 24 there, given the willing donor population in the UK."
- 25 Top of the next page:

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1 "... but what was needed was the political will
2 and funding from the government and the Department of
3 Health to utilise the willing donor population to
4 donate regularly by plasmapheresis. Even if we had
5 collected all the required plasma for self-sufficiency
6 in blood products, BPL did not have the capacity or
7 state-of-the-art equipment to fractionate it all, nor
8 the sophisticated equipment to produce the high-purity
9 products available in the commercial market."

10 Does that continue to be your view of the
11 position in relation to the non-achievement of
12 self-sufficiency in blood products in the 1980s in the
13 UK?

14 **A.** Yes, it continues to be my view.

15 **Q.** Then can I just ask you about the production of
16 cryoprecipitate. That was presumably a blood
17 component produced at the North London Centre?

18 **A.** Yes, of course.

19 **Q.** To what extent, if Haemophilia Centre Directors or the
20 Department of Health had come to you in 1983, 1984,
21 and asked you to increase the production of
22 cryoprecipitate, as an interim measure in response to
23 the AIDS crisis, to what extent would you have been
24 able to do so?

25 **A.** To a large extent, but we were not asked to do it.

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1 So we're back in the 1973 Notes on Transfusion, and if
2 we go to page 4 for a useful summary, second and third
3 paragraphs in bold print:

4 "A transfusion should never be given without
5 a definite indication; not only is this in the
6 patient's interest, since an element of risk is
7 associated with every transfusion, but supplies of
8 blood are not unlimited and with the ever-growing
9 demand for blood it is imperative that it should not
10 be used unnecessarily.

11 "The use of transfusion to correct moderate or
12 slight degrees of anaemia that could be overcome as
13 effectively, if more slowly, by other means seems
14 unjustifiable unless some cogent reason for speed of
15 recovery exists. In some instances failure to
16 institute simpler and safer but equally effective
17 treatment earlier leads to the quite unnecessary use
18 of blood transfusion."

19 First of all, Professor, do you agree with what
20 is set out there?

21 **A.** Totally.

22 **Q.** Would you agree that what's set out there was nothing
23 new, even in 1973?

24 **A.** I think so.

25 **Q.** If we then move forward in time to an article you

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1 But we had the capability to do it.

2 **Q.** Was there ever any discussion with you by, first of
3 all, the Department of Health about that possibility?

4 **A.** No. Never.

5 **Q.** What about the Haemophilia Centre Directors or centres
6 that you supplied?

7 **A.** As far as I can recall, I cannot remember any
8 haemophilia director asking me for cryoprecipitate --
9 for more cryoprecipitate than the usual. We produced
10 a lot of cryoprecipitate, but that was usually for
11 foetal maternal -- for maternal haemorrhages and
12 massive transfusion.

13 **MS RICHARDS:** Sir, I'm going to move to another topic now,
14 so perhaps we could take the break now, and then I can
15 start with the next topic after the break.

16 **SIR BRIAN LANGSTAFF:** Yes. Well, we'll take a break until
17 3.40, in that case. 3.40.

18 (3.12 pm)

(A short break)

20 (3.42 pm)

21 **MS RICHARDS:** Professor Contreras, I'm going to ask you
22 next about the practice of transfusion and the use of
23 transfusions and steps taken by the centre in that
24 regard. Can we start by looking at a document we've
25 already looked at but a different page, HCDO0000861.

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1 wrote in 1989, NHBT0057960, please. This
2 a publication 1989, "New trends in Blood Transfusion,
3 authored by you. If we go, please, in the first page,
4 to the left-hand column, second paragraph, you say:

5 "Blood transfusion in clinical medicine has
6 experienced significant changes in recent years and
7 rapid developments continue to take place on many
8 fronts. Numerous factors will determine the future
9 use of blood and blood derivatives such as [and this
10 was your first paragraph:

11 "1) The tendency towards a more rational use of
12 blood and blood components for those patients who
13 really need them. Education of clinicians on the
14 proper use of blood is now becoming an accepted aspect
15 of medical training. Responsible clinicians are
16 re-examining the benefit-to-risk relationship of blood
17 transfusion. However, there is a great deal of ground
18 to be covered since many clinicians consider blood and
19 blood components on the same level as any drug that
20 they prescribe. In some countries, the establishment
21 of Hospital Transfusion Committees has helped a great
22 deal towards a more rational use of blood and it is
23 expected that such committees will be established in
24 more and more hospitals worldwide."

25 Then you set out a number of other factors, I'm

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1 not proposing to go to. But it's this issue about
 2 a more rational use of blood and blood components
 3 that I want to explore with you.
 4 Looking at really the period from 1980 onwards,
 5 when you became deputy director, in your experience,
 6 to what extent was the kind of guidance we saw in
 7 Notes on Transfusion cautioning against over-use of
 8 transfusion, to what extent was that faithfully
 9 adhered to by clinicians in your experience?
 10 **A.** No. No, not until later.
 11 **Q.** So is it right to understand that both unnecessary
 12 transfusion and over transfusion were problems?
 13 **A.** Yes.
 14 **Q.** That's why, as I understand your statement, you
 15 regarded it as an important part of the centre's
 16 responsibility to try to advise and educate treating
 17 clinicians on the principles and ethics of treating
 18 transfusion?
 19 **A.** Yes.
 20 **Q.** Do you have a sense of the extent to which that was
 21 done by other Regional Transfusion Centres outside of
 22 the North London Centre?
 23 **A.** Not really.
 24 **Q.** If we go back to your witness statement, page 92,
 25 you've set out from paragraph 367 onwards a number of

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1 measures which were taken by the centre, so 367:
 2 "An important initiative that the consultants
 3 and I were very committed to was liaison with the
 4 clinicians in the hospitals we served. We introduced
 5 the concept of Joint Transfusion Medicine consultant
 6 appointments ..."
 7 What was that?
 8 **A.** Region funded my centre for additional consultants,
 9 and so we offered joint appointments to some of our
 10 main user hospitals, some of the large teaching
 11 hospitals, and we were -- we initiated -- we were --
 12 we initiated -- that we started that initiative that
 13 was -- that we funded half of the consultant or
 14 sometimes a full consultant, but to be half of the
 15 time at the Transfusion Centre, and half of the time
 16 running a blood transfusion department in a hospital,
 17 the blood bank and all aspects of transfusion in that
 18 hospital.
 19 And that worked very well, and has continued,
 20 and that gave rise, I think, to the -- with other
 21 initiatives from our centre to the Better Blood
 22 Transfusion Initiative.
 23 **Q.** We'll come on to that. Then paragraph 367 continues:
 24 "... we educated clinicians in the '*appropriate*
 25 *use of blood*', meaning that blood components should

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1 only be used when strictly necessary and in the
 2 absence of alternatives."
 3 Then paragraph 368:
 4 "We started Hospital Transfusion Committees for
 5 education in transfusion medicine and to monitor blood
 6 component usage.
 7 "We performed audits of the usage of red cells,
 8 FFP and platelets and showed that there was a great
 9 deal of unnecessary transfusions."
 10 Bottom of the page:
 11 "We wrote a number of publications and gave
 12 numerous lectures regarding the risks of blood
 13 transfusion and measures to increase its safety ..."
 14 Go over the page:
 15 "We organised meetings on
 16 transfusion-transmitted infections, to educate and
 17 update the medical community ..."
 18 Then paragraph 373:
 19 "In essence, we were the precursors of the
 20 'Better Blood Transfusion Initiative' of the UK [Chief
 21 Medical Officers] which eventually managed to
 22 significantly reduce the usage of red cells and FFP in
 23 the country. The less blood components are used
 24 unnecessarily, the less possibility of
 25 transfusion-transmitted infections."

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1 Now, I'm going to ask you in a moment about some
 2 of the individual initiatives but, first of all, can
 3 you assist us with understanding what the Better Blood
 4 Transfusion Initiative of the Chief Medical Officers
 5 was and when roughly that took place?
 6 **A.** It was an initiative that came from the blood services
 7 to the Chief Medical Officers in -- the UK medical
 8 officer. So it came from -- also with the help of
 9 the -- our Scottish colleagues, who were also
 10 interested in appropriate use of blood, or what's now
 11 called patient blood management. And we went to the
 12 Department of Health and to the Chief Medical Officer
 13 and convinced him, with raw data, of our audits that
 14 we had done in blood transfusion, that now other
 15 consultants in other centres were doing, that there
 16 was inappropriate use of blood, of fresh frozen
 17 plasma, of red cells, of platelets. And that there
 18 was a great variation. For the same hip replacement
 19 you would have a hospital that on average used zero or
 20 one unit, and another hospital would use five or six
 21 units.
 22 And we showed this data to the clinicians and we
 23 showed this data to the Chief Medical Officer and this
 24 happened with fresh frozen plasma, with red cells,
 25 with platelets, et cetera.

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1 So the Chief Medical Officer was convinced that
2 something needed to be done, and wrote circulars,
3 aided by the Transfusion Service consultants, on the
4 appropriate use of blood and, you know, I think that
5 was the origin of the pre-admission clinics that many
6 of you might have seen in hospitals, where the --
7 before you have elective surgery you go a month before
8 that to have your haemoglobin done and your -- all
9 tests, so that everything is corrected before you go
10 to surgery, and not go to surgery with anaemia, for
11 example.

12 So that was the Better Blood Transfusion and
13 I think there were three circulars, and it's now
14 called Patient Blood Management. And they also
15 recommended that there should be a specialist in
16 transfusion that were -- not only consultants in
17 charge of blood transfusion but there were also nurses
18 or medical laboratory scientific officers that were
19 checking that blood was used appropriately and were
20 educating junior doctors on the appropriate use of
21 blood.

22 **Q.** And do you recall when that initiative was? If you
23 don't, don't worry, because we can find out easily by
24 other means.

25 **A.** I can't remember when the first one was.

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1 to meetings to the College of Surgeons, College of
2 Anaesthetists, so that we would -- and we involved
3 them in transfusion medicine. We also educated at the
4 hospital transfusion committee level, where there were
5 representatives of surgeons, and we also educated them
6 through audit, because we showed them the results of
7 the audits and that we had meetings with surgeons or
8 anaesthetists.

9 **Q.** Yes, you've said in your statement you performed
10 audits of usage of blood cells, FFP, platelets, which
11 showed a great deal of unnecessary transfusion. So
12 you would follow that up, would you --

13 **A.** Yeah.

14 **Q.** -- with the hospital or centre that was audited?

15 **A.** Yes, yeah. We went to the hospitals and said: Here
16 you are. You know, why, are you using so much --
17 what's the justification for you using five units for
18 this type of surgery when this -- or, when the mean is
19 so much and these hospitals are using so little?

20 So some clinicians did not know how much blood
21 they were using.

22 **Q.** Do you recall if the training and education that the
23 centre provided covered issues about patient consent
24 to transfusion and the kind of information about risks
25 that should be given to patients?

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1 **Q.** Dealing with a number of the initiatives you described
2 in your statement, in terms of the training and
3 education of clinicians, did that involve you, your
4 colleagues, going into hospitals in your area, and
5 lecturing or holding workshops or seminars?

6 **A.** Yes. We were very, very involved. You know, since
7 I started in this country, more or less. But we were
8 involved in going to hospitals and asking to -- more
9 or less to be invited and going to grand rounds and
10 going to hospitals and educating the consultant
11 haematologist and MLSOs, inviting clinicians to our
12 centre. We had regular meetings, annual meetings,
13 with consultants and MLSOs in charge of the blood
14 banks to educate them about transfusion, and we also
15 taught at all the medical schools that were in our
16 catchment area and we lectured nationally and
17 internationally.

18 **Q.** With the hospitals that you were going into, was your
19 audience predominantly haematologists and the MLSOs,
20 or would you seek to deliver training or education
21 information, say, to gynaecologists and obstetricians
22 or to surgeons?

23 **A.** Yes.

24 **Q.** Would it be across a range of different disciplines?

25 **A.** Yes, well, we -- we more or less asked to be invited

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1 **A.** Yes, we tried, yeah. We tried to get involved in the
2 consent form for hospitals and I think we managed it,
3 through the Better Blood Transfusion initiative, to
4 include transfusion as a risk in the patient consent
5 form.

6 **Q.** Do you have any sense of -- it may be an impossible
7 question but it's a question I particularly have been
8 asked by Core Participants to ask.

9 Do you have any sense of what difference it
10 might have made to overall infection levels if doctors
11 had been educated on patient blood management at
12 a much earlier stage?

13 **A.** I think it would certainly have made a difference,
14 because, you know, sometimes -- top-up transfusions,
15 for example, were not necessary, and -- well, as our
16 audit showed, yes, it would have made a difference
17 because much less blood was needed in a country. The
18 less blood you give, the less infections you transmit.

19 **Q.** Can I ask you to look at one letter you wrote to the
20 Department of Health in 1990, NHBT0000189_142, please.
21 This is a letter you wrote, 31 May 1990, to Dr Hilary
22 Pickles, she was a principal medical officer in the
23 Department of Health. In the second line you say:
24 "I am writing to give you some information on
25 what we have been doing at the North London Blood

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1 Transfusion Service to improve knowledge of blood
2 transfusion and promote sensible usage of blood and
3 blood derivatives."

4 Then if we go towards the bottom of the page,
5 you're dealing with a number of expects of the
6 proposals for cross-charging which I'm not going to
7 spend time on. The last two lines of the page:

8 "... an audit recently conducted by us in five
9 major hospitals ... revealed no justification for the
10 use of more than 50% of fresh frozen plasma ..."

11 Then if we go to the third paragraph on that
12 page:

13 "The consultants at this Centre firmly believe
14 that it is only through continuous contact with, and
15 education of our user hospitals that we will be able
16 to improve the practice of clinical blood transfusion
17 and make the best use of blood derivatives. NLBTC
18 supplies over 50 hospitals in the NHS, SHAs and in the
19 private sector. These hospitals have each been
20 allocated one consultant who pays regular visits and
21 is available for help and advice."

22 Just pausing there, that practice of the
23 allocation of a consultant, do you know when that
24 started?

25 **A.** As soon as I was appointed, more or less, director and

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1 hospitals supplied by NLBTC, looking at the practice
2 of transfusion of platelets and fresh frozen plasma.
3 It was necessary to search for a total of 600 case
4 notes in order to provide 200 cases for the audit.
5 Review included an assessment as to whether the
6 transfusions were indicated. Results of this analysis
7 were disappointing particularly for FFP, where only
8 21% of transfusions were indicated, and 60% were
9 definitely not indicated. With respect to platelets,
10 only 53% of transfusion were indicated while 19% were
11 definitely not indicated. From this retrospective
12 audit, we concluded that improvement in all aspects of
13 transfusion practice is necessary. Education
14 regarding the value of blood [top of the next page]
15 components and areas in which their use cannot be
16 justified is particularly needed. Hospital
17 transfusion committees are now being established in
18 the five audited hospitals and we intend to encourage
19 a further five hospitals to move in this direction in
20 the very near future. We view the audits as a means
21 of education and not as a reason for reprimanding
22 users."

23 I want to ask you two matters arising out of
24 this letter, professor. The first is, can you recall
25 what, if any, of the response of the Department of

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1 I asked for more consultants, and we distributed to
2 hospitals.

3 **Q.** Then it continues:

4 "During visits we discussed transfusion
5 practices within the hospital and give clinical and
6 technical advice when required. We monitor blood
7 transfusion laboratory stocks and returns on a monthly
8 basis and discuss the introduction of new forms of
9 therapy ... which might increase demands on the
10 transfusion service. We encourage blood donation in
11 hospitals by staff and patients' relatives and are now
12 starting to see much greater cooperation from hospital
13 authorities ..."

14 Then if we go to the last paragraph on this
15 page:

16 "We believe that the way forward in clinical
17 blood transfusion is the establishment of Hospital
18 Transfusion Committees with representatives from those
19 clinical specialities most concerned with blood usage,
20 including a nursing representative. Such committees
21 should meet on a quarterly basis and should deal with
22 matters such as transfusion practice within the
23 hospital, use and abuse of blood and blood components,
24 audit of the use of blood, etc. As a first step we
25 recently conducted a retrospective audit in five major

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1 Health was at that time to the kind of issues you were
2 raising here?

3 **A.** Well, the ultimate responsible laid with them, but
4 this was our local initiative. So, you know, I felt
5 it was my duty to inform them of what we were doing
6 and, you know, eventually it led to the CMO being
7 interested in this aspect.

8 **Q.** Well, no doubt we can ask the Department of Health
9 about that. Then the second matter I wanted to ask
10 you about is about the hospital transfusion
11 committees. So you describe here them being
12 established in the five hospitals that you'd audited.
13 Was that the first establishment of hospital
14 transfusion committees in your area that you're aware
15 of?

16 **A.** Yes. In my area, yes.

17 **Q.** Do you have any sense of how quick other regions were
18 to pick up upon the establishment of hospital
19 transfusion committees?

20 **A.** I think that some were quicker than others, but that's
21 all I can say.

22 **Q.** What, essentially, was the purpose and remit of the
23 hospital transfusion committee, in a nutshell?

24 **A.** It was to make clinicians aware of the usage of blood
25 and of the risks of transfusion and of their own

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1 practice of transfusion. Make clinicians aware of
2 transfusion medicine, because it was a nonentity
3 before, they took it like saline, you know. So it was
4 mostly educational and to share information at
5 hospital level on transfusion medicine.
6 **Q.** Would someone from your centre sit on the hospital
7 transfusion committees established in your region?
8 **A.** Yes, always a consultant, you know, including me.
9 **Q.** I'm going to move, then, from transfusion practice to
10 a new subject now -- the last, I think, topic for the
11 afternoon -- and that's specifically in relation to
12 AIDS and the response of the Blood Transfusion Service
13 and, in particular, the response of the North London
14 Regional Transfusion Centre.

15 First of all, in terms of your own knowledge
16 about AIDS, you've told us in your statement that one
17 of the publications to which the centre subscribed was
18 the MMWR, and you would read that -- it would come to
19 you, you'd read it and then you'd share it with
20 colleagues at the centre. So, as I understand your
21 statement, you were aware of the reports that emerged,
22 1981 and 1982, about this condition and you were aware
23 of the first reports in, I think, July 1982 in the
24 MMWRs in relation to patients with haemophilia, and
25 then aware in December 1982 about the San Francisco

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1 the multi-transfused child in California?
2 **A.** No, I cannot.
3 **Q.** So you recollect it was a pivotal moment in terms of
4 your own knowledge --
5 **A.** Yeah, yeah.
6 **Q.** -- but you don't know the extent to which that view
7 was shared by colleagues?
8 **A.** I must have shared it with Dr Barbara and Dr Hewitt
9 but I can't remember what we discussed, yes.
10 **Q.** Would you agree that that report should have been
11 a trigger for the National Blood Transfusion Service
12 generally to consider what action -- or to consider
13 whether action was required and, if so, what action,
14 and to do so urgently?

15 **A.** Yes.
16 **Q.** Now, I'm just going to ask you to look at some
17 documents from 1983, conscious as I do so that you
18 were, at that stage, the deputy director and not the
19 Regional Transfusion Director. So you weren't
20 attending RTD meetings in the course of 1983.

21 But if we start with NHBT0092845_008, please.
22 This is a meeting, 12 May 1983, of the Eastern
23 Division Consultants in the Blood Transfusion Service
24 and we can see that Dr Davies was present, but you
25 also were present.

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1 baby; is that right?
2 **A.** Yes.
3 **Q.** If we just go back to your statement, Soumik, if we
4 can have that up on the screen again, page 63,
5 paragraph 251 you say this:
6 "I believe a pivotal moment in my view
7 shifting" -- sorry, I should read the previous
8 paragraph to make sense of that.
9 So you say in paragraph 250:
10 "At first, I did not link this disease, which
11 was reported to be confined to homosexual men, with
12 blood transfusion."
13 Then 251:
14 "I believe a pivotal moment in my view shifting
15 was when I read a report by the CDC and MMWR of the
16 possible admission of AIDS to a multi-transfused
17 infant in San Francisco; the donor of the platelets
18 transfused to the infant was a homosexual male
19 subsequently found to have AIDS. I believe this
20 report was published at the end of 1982."
21 Your recollection in terms of the date there is
22 correct.
23 So can you recall what discussions were held,
24 either within the centre or with other colleagues,
25 following the report of the -- what had happened to

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1 And am I right in understanding the divisional
2 meetings weren't limited to the Regional Transfusion
3 Directors, other consultants at the centres would
4 attend these meetings?
5 **A.** Yeah.
6 **Q.** Now, if we just look down the page, over the page --
7 I'm trying to prove a negative here -- and to the next
8 page. There's nothing I can see in this document
9 which suggests any discussion about AIDS. Does that
10 surprise you, that at May 1983 the Eastern Division
11 has not got it high up on the agenda?
12 **A.** Now it surprises me. At the time I don't think it
13 did.
14 **Q.** And then, still in May 1983, if we go to NHBT0109173,
15 please.

16 If we just look at the bottom of the page, this
17 is dated 23 May 1973. I've read that as just a typo
18 and it should be 1983. It's dealing with AIDS so it
19 clearly can't be '73, and I've assumed the rest of the
20 date is probably correct.

21 It's from Dr Davies, your predecessor as
22 director and, if we go to the top of the page, we can
23 see it's -- this is directed to "All medical officers,
24 receptionists", and then to you and Dr Brozovic for
25 information.

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1 And then we can read what Dr Davies was
 2 saying -- headed "AIDS":
 3 "This subject has attracted considerable
 4 publicity and in view of the, not yet proven,
 5 possibility of transmission of blood and blood
 6 products, the Transfusion Service is involved. At the
 7 recent Transfusion Directors' Meeting [that's the
 8 regional directors meeting in May] it was agreed that
 9 donors should not be questioned about their private
 10 lives and until more information is known about AIDS,
 11 reasonable attempts should be made to advise
 12 homosexuals to refrain from giving blood. It is hoped
 13 that a pamphlet giving this advice will soon be
 14 available for distribution at donor clinics.
 15 "In the meantime, there must be no questioning
 16 of donors about their private lives, and should
 17 a donor volunteer the information that he is
 18 homosexual (gay), tell him that current advice is that
 19 he should postpone giving blood until more information
 20 becomes available or a screening test for AIDS is
 21 developed. If he insists on giving -- accept without
 22 argument and bleed into a single pack -- there is no
 23 need to make a note on the 101 or the pack."
 24 "Some reports suggest that the risk of AIDS
 25 increases with the level of promiscuity, and more so

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1 patient, that there was nothing wrong in asking donors
 2 about their sexual practices.
 3 **Q.** And then can you, in any event, help us understand
 4 what Dr Davies was proposing. In the event of a donor
 5 volunteering that they were gay, the suggestion is --
 6 the advice is postpone giving blood. That's perfectly
 7 understandable. But then it says:
 8 "If he insists on giving -- accept without
 9 argument and bleed into a single pack -- there is no
 10 need to make a note on the 101 or the pack."
 11 Does that mean that the blood would be used?
 12 **A.** No. No. It would go to the microbiology laboratory,
 13 to Dr Barbara, and it would -- I can't remember what
 14 it would -- what would be done, but we would not use
 15 that blood for transfusion.
 16 **Q.** Is that right, Professor Contreras? Because we can
 17 see that's clear in the last paragraph, where
 18 Dr Davies appears to be dealing with the category of
 19 donor who volunteers that they are promiscuous and/or
 20 use drugs. And there there's a clear steer the blood
 21 will be used for research or laboratory purposes only
 22 and not for transfusion, and there's a description
 23 that that will go on the label, "FOR DR BARBARA AIDS",
 24 with the word "HOLD", so Dr Barbara would, in those
 25 circumstances, presumably know that this was blood

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1 if associated with drug abuse. If a donor volunteers
 2 the information that he is in this category and
 3 insists that he misses to give blood, inform him that
 4 until the AIDS risk has been clarified, his blood will
 5 be used for research and laboratory purposes only and
 6 not for transfusion. If he agrees to this
 7 condition -- bleed on the 'B' sheet -- use a single
 8 pack, and label 'FOR DR BARBARA AIDS', and enter
 9 'HOLD' on the B bleed sheet."
 10 I want to ask you about a number of aspects of
 11 this. If we go back to the first paragraph -- in fact
 12 if we just look at the whole -- that's perfect,
 13 Soumik, thank you.
 14 So it appears to have been Dr Davies's firm view
 15 that there should be no questioning of donors about
 16 their private lives, which -- the inference I think
 17 might be drawn from this, that there would be no
 18 question to the donor, "Are you gay? Are you
 19 homosexual?" Was that your understanding of what was
 20 being suggested?
 21 **A.** Yes.
 22 **Q.** And did you agree with that, as far as you can recall?
 23 **A.** Not really, because we thought that there was
 24 nothing -- I started thinking that there was nothing
 25 wrong in asking -- you know, thinking about the

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1 that was not to be used for transfusion.
 2 **A.** Yeah.
 3 **Q.** But in relation to the category of donor described in
 4 the second paragraph, who simply volunteers that
 5 they're gay --
 6 **A.** Yeah.
 7 **Q.** -- but insists on giving, Dr Davies says there's no
 8 need to make a notice on the 101, so that's the donor
 9 form, donor card, or the pack. So Dr Barbara or the
 10 other microbiologist would have no way of knowing,
 11 would they, that that was a unit of blood from a donor
 12 who had volunteered that they were gay?
 13 **A.** Yeah, but then he says if he agrees to this condition,
 14 bleed on the B sheet. And the B sheet was not for
 15 transfusion, not for -- so I assume that it meant that
 16 it -- with the mechanism there, being bled on the
 17 B sheet, it meant that it was not for transfusion.
 18 **Q.** I'd read that as limited only to the category of donor
 19 who is promiscuous or drug use, but perhaps we can ask
 20 Dr Barbara what his recollection is.
 21 **SIR BRIAN LANGSTAFF:** Well, I think that my own
 22 interpretation of this would be if one looks at the
 23 last two paragraphs, the first of -- the second
 24 paragraph, the one beginning "In the meantime", that
 25 looks as though it's dealing with somebody who is gay

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1 but is not -- doesn't say, "I'm promiscuous", and
 2 doesn't say, "I have been taking drugs by injection".
 3 Then the next paragraph, by contrast, deals with
 4 someone who may say they're gay, but certainly says,
 5 "I'm promiscuous", and, in particular, if the
 6 promiscuity is in any way associated with drug abuse.
 7 So that's a different category.

8 And it says:

9 "If the donor volunteers the information that he
 10 is in this category and insists ..."

11 So you've got, second paragraph, somebody who is
 12 not admitting to promiscuity or drug use, insists on
 13 giving. Last paragraph, someone who does say, "I'm
 14 promiscuous" or "I have used drugs", or both, and
 15 insists.

16 And then the difference is, in the second
 17 paragraph: you bleed into a single pack and don't make
 18 a note. Last paragraph: you do bleed into a pack but
 19 you do make a note.

20 That's how I've read it.

21 So I was reading as counsel has read it and it
 22 may be -- it's not your document, so it may be you
 23 haven't had a chance to look at it and think about it.
 24 But do you see the point I'm making?

25 **A.** Yes, yes, and I think it's very confusing. Yeah.

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1 partners.

2 "2. Drug addicts, male and female, using
 3 injections.

4 "3. Sexual contacts of people suffering from
 5 AIDS.

6 Then the question:

7 "Can AIDS be transmitted by transfusion of blood
 8 and blood products?

9 "Almost certainly yes, but there is only the
 10 most remote chance of this happening with ordinary
 11 blood transfusions given in hospital."

12 We know the leaflet was then changed with later
 13 versions, so the reference to "homosexual men who have
 14 many different partners" became a reference to
 15 "practising homosexuals or bisexuals", and then in due
 16 course, just "homosexual". Do you have any thoughts
 17 on whether that took too long to make those changes
 18 and whether this first leaflet could or should have
 19 been in clearer and starker terms?

20 **A.** My personal view is that it could have been clearer,
 21 and we're talking to the male gay community. They
 22 didn't mind being asked these questions, but you have
 23 to remember that at that time, people didn't talk
 24 about their sexual activities or their sexual
 25 preferences. So it was very difficult for some of my

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1 **SIR BRIAN LANGSTAFF:** It's not clear, is it?

2 **A.** No.

3 **MS RICHARDS:** So that's May 1983. You tell us in your
 4 witness statement that your recollection is that the
 5 centre started a draft of its own leaflet through
 6 Dr Davies and Dr Barbara, and then eventually the
 7 national leaflet was produced. Just in terms of the
 8 timings, I'm not going to take you to all the
 9 documents because we know the dates, Dr Wagstaff
 10 circulated what was intended to be a final version of
 11 the leaflet to Regional Transfusion Directors on
 12 6 July. For the benefit of the transcript, but we
 13 don't need to go to it, that's NHBTO020668.

14 Then the first national leaflet was issued at
 15 the beginning of September, that's BPLL0007247, and
 16 I will ask you to look at that. Thank you.

17 This is the September 1983 leaflet:

18 "Will donors be questioned on sexual matters
 19 when they attend to give blood?

20 "Definitely not."

21 If we go to the next page, we've got the risk
 22 categories identified, "Who is at risk from AIDS?":

23 "Certain groups of people appear to be
 24 particularly susceptible; these are:

25 "1. Homosexual men who have many different

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1 older colleagues to think that you could be open with
 2 donors and ask them questions. So I think it took too
 3 long.

4 **Q.** Now, we can take that down, thank you, Soumik.

5 In terms of the method of distribution of the
 6 leaflet, we know from a meeting of Regional
 7 Transfusion Directors in September 1983 -- I don't
 8 think we've given you those minutes, professor,
 9 because it wasn't a meeting you were at -- but centres
 10 were encouraged to use different methods of
 11 distribution and there were three main methods
 12 identified: sending the leaflet out with the call-up
 13 to donors, so that they could read it in the privacy
 14 of their own home and decide not to attend, handing it
 15 to the donor on an individual basis at sessions; or
 16 leaving it available in the session for donors to pick
 17 up.

18 I want just to ask you to look at a document
 19 which indicates what the practice was at Edgware at
 20 the North London Centre, so it's CBLA0001820. This is
 21 a document for the "Advisory Committee on the National
 22 Blood Transfusion Service, AIDS leaflet -- First Six
 23 Months Experience". Then if we look down the list, we
 24 can see:

25 "EDGWARE -- Available at Sessions

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1 "[Number] used 4000, Stock 46,000."
 2 The effect on donor response or attendance is
 3 described as "nil". Then the comment is:
 4 "Donors say helpful and informative. High risk
 5 donors have asked will they ever be allowed to give
 6 blood again."
 7 So it would appear that the method chosen for
 8 distribution at Edgware was the third method, to make
 9 it available at sessions, rather than sending it out
 10 with the call-up invitations or handing it
 11 individually to each donor. Do you recall any
 12 discussions about why that particular method of
 13 distribution was going to be adopted?
 14 **A.** Yes, because it was -- well, we couldn't do it. We
 15 couldn't send it to the donors because we had
 16 postcards, so we couldn't enclose anything with
 17 a postcard, and we didn't have the staffing to give it
 18 individually to donors. So, at that time, it was
 19 available and some of the nurses or donor attendants
 20 said that we left it on top of the -- I think we left
 21 it on top of the chairs of each -- there were chairs
 22 in the waiting area, and the donor attendant said,
 23 well, some of them read it and some of them don't.
 24 **Q.** We can look, I think, at how the practice changed or
 25 was tightened up to some extent but, first, just

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1 **Q.** Then it says -- the second point is:
 2 "... that the leaflet should be revised to
 3 include reference to plasmapheresis donors ..."
 4 Do you know why that was being suggested?
 5 **A.** I can't remember. It must have been because
 6 plasmapheresis donors donate so often, so the risk of
 7 transmitting an infection is multiplied.
 8 **Q.** And then the third was:
 9 "... more positive publicity to discourage
 10 donation ... through dedicated journals."
 11 So using publications to try to get the message
 12 across about discouraging high-risk groups from
 13 donating.
 14 **A.** Yes.
 15 **Q.** Then in the middle of 1984, June/July 1984, as
 16 I understand it, you made a trip to the New York Blood
 17 Center.
 18 **A.** Yes.
 19 **Q.** What was the purpose of that trip and what did you
 20 learn that was of relevance or use to the way in which
 21 the centre operated back in Edgware?
 22 **A.** Well, we were concerned -- as a team, we were
 23 concerned, because more and more publications were
 24 coming forward about transfusion-transmitted AIDS at
 25 that time. So -- and I had a strong link with the

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1 taking it chronologically, if we could go to
 2 NHBT0092842. If we go to the second page, this now
 3 April 1984, so it's some months on from the leaflet
 4 first becoming available in September '83. This
 5 a meeting of the Eastern Division Consultants and we
 6 can see that you were in attendance. By this time,
 7 you are now the Regional Transfusion Director, having
 8 taken over in February 1984. Dr Hewitt, from North
 9 London is also there.
 10 If we go, please, to page 4, third paragraph
 11 down is a heading "AIDS". Dr Rogers, who was chairing
 12 this -- which centre was Dr Rogers, can you recall?
 13 **A.** Tooting.
 14 **Q.** "Dr Rogers expressed the view that DHSS policy on
 15 homosexual donors had been 'too laid back'. It was
 16 felt that the AIDS leaflet should be revised to
 17 include reference to plasmapheresis donors, and that
 18 more positive publicity to discourage donation should
 19 be channelled through dedicated journals."
 20 So three points made there. Policy being too
 21 laid back. Do you have any recollection of what
 22 that's referring to, whether it's the terms of the
 23 leaflet or something else?
 24 **A.** I think it refers to the leaflet and not us being
 25 proactive enough.

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1 New York Blood Center because my first tutor was
 2 working at the New York Blood Center,
 3 Professor Rubinstein. So, in conversation with him,
 4 he said, "Oh, we're -- we've got -- we're dealing with
 5 high-risk groups in a confidential manner", and so
 6 I said, "Well, we should go and see this", because
 7 there was -- everybody was so frightened of asking
 8 donors about their sexual practices, et cetera.
 9 So I got money -- I convinced my Regional Health
 10 Authority to pay for a trip to -- for Dr Barbara and
 11 myself to go and see, personally, how the New York
 12 Blood Center was dealing with this, donors in
 13 high-risk groups of transmitting HIV.
 14 And we went there, and we saw that the donors
 15 were quite happy. Especially because the demographics
 16 of New York is very similar to the London
 17 demographics, so ...
 18 And we went to the donor sessions, and we saw
 19 that the donors were quite happy to answer this --
 20 they had a self-exclusion questionnaire -- and to go
 21 into a cubicle and answer in confidence whether they
 22 were in a high-risk group and whether they wanted to
 23 exclude themselves or continue donations.
 24 So we learnt from them, from then -- them, and
 25 we, on the plane back, we wrote our self-exclusion

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1 questionnaire, and tested it in -- at the Western
 2 Donor Centre, at the plasmapheresis clinic -- the main
 3 plasmapheresis clinic at the time and then in the
 4 other plasmapheresis centres.
 5 **Q.** And my understanding, from reading various articles
 6 I think that were subsequently published by you or
 7 your colleagues at North London, is it was in around
 8 July 1984, so not long after you came back, that you
 9 did the trial of the questionnaire in one of the
 10 clinics.
 11 **A.** Yes.
 12 **Q.** Then I'm not sure of the precise date, it may be that
 13 the reports will tell us, it was then rolled out at
 14 a later stage across the other donor session
 15 locations?
 16 **A.** Yes.
 17 **Q.** Then perhaps just the last document for today, if we
 18 go to NHBT0017776. This is a memo from you,
 19 16 October 1984, to "All Medical Officers", "Re: AIDS
 20 Leaflet":
 21 "Because the revised AIDS leaflet is not yet
 22 available from the DHSS, we have had our present
 23 leaflet overprinted. In the section 'Who is at risk
 24 from AIDS?' -- No. 1 has been altered to 'Practising
 25 homosexuals'. These leaflets should now be available

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1 blood, but emphasising the AIDS risk.
 2 **MS RICHARDS:** Sir, given the time, I've still got a number
 3 of questions in relation to this topic, I'm not going
 4 to complete it within the next few minutes, so perhaps
 5 we could break until the morning.
 6 **SIR BRIAN LANGSTAFF:** Well, I think that's very sensible.
 7 Professor, we'll take a break now, until
 8 ten o'clock in the morning. Thank you very much so
 9 far and we look forward to seeing you then, at 10.00.
 10 Ten o'clock tomorrow.

11 (4.30 pm)

12 (Adjourned until 10.00 am the following day)

1 at all sessions -- the original leaflet is being
 2 withdrawn."
 3 Just before we look at the next paragraph, is it
 4 right to understand that you essentially had got fed
 5 up for waiting for the revised leaflet to be produced
 6 by the Department so you took this crude way of --

7 **A.** Yes.
 8 **Q.** Just printing over the existing one, changing the
 9 reference to "having had many sexual partners",
 10 whatever it was, to "practising homosexuals"?
 11 **A.** Yes.
 12 **Q.** Which was going to be the text of the new leaflet when
 13 it was eventually produced?
 14 **A.** Yes.
 15 **Q.** Then the second paragraph tells us:
 16 "A further leaflet 'Some Reasons Why You Should
 17 Not Give Blood' is also being distributed -- for
 18 donors to read before seeing the receptionist. We
 19 hope this will: (i) save some donors an unnecessary
 20 wait and (ii) focus attention on the AIDS leaflet."
 21 So this is an additional document that was being
 22 produced at the North London Centre; is that right?
 23 **A.** Yes.
 24 **Q.** Do you recall what the text of it was at all?
 25 **A.** It had the list of reasons why you should not give

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2	PROFESSOR DAME CARMEN MARCELA	1
3	CONTRERAS (affirmed)	
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