

Wednesday, 9 February 2022

(9.59 am)

**Presentation by COUNSEL TO THE INQUIRY about the YORKSHIRE
REGIONAL BLOOD TRANSFUSION CENTRE**

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: Yes, good morning, sir. This morning

I'll be addressing matters around the Yorkshire

Regional Transfusion Centre.

The Inquiry has had the benefit of statements from Dr Flanagan, and prior to her death Dr Angela Robinson provided a personal statement and a statement as part of the response from the NHSBT.

Just for the purposes of the transcript, the relevant reference numbers for those statements are WITN6933001 in relation to Dr Flanagan, and WITN6926001 and WITN6926003 in relation to Dr Robinson.

The Yorkshire Regional Transfusion Centre was established in 1944 and was based in Leeds.

If we could have NY0R0000043, please. This is the Yorkshire Blood Transfusion Service annual report of 1988/89, and if we turn to page 3 we can see the geographical remit of the Centre. Unfortunately on this version it's not entirely clear but at the top left corner there's a list of regions, and if I just

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blood, platelet concentrates, cryoprecipitate, fresh frozen plasma, 5 litre plasma pools, SAG-M red cells, concentrated red cells, filtered red cells, dextran-sedimented red cells and saline-washed frozen red cells.

And if we can carry on down to the bottom of the page, we see this from the inspector:

"Visits were made to do donor sessions, a static session in the Centre and a mobile session in Cleckheaton. The procedures are basically the same for both and will change when the full computerisation programme is completed (scheduled for September 1988 ...)."

And if we go over the page:

"The donor centre in the RTC is equipped with six plasma beds (Haemonetics Ultralight portable machines) and two bleed beds."

If we carry on to page 7, under the heading of "Microbiology" we can see that testing for hepatitis B surface antigen was being carried out, as well as HIV antibody and syphilis, and then:

"Selected donations are also screened for tetanus antibody, CMV antibody, and [hepatitis B surface] antibody."

If we then look at the third paragraph in this

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read them out, it's: Airedale, Bradford, Calderdale, Dewsbury, East Yorkshire, Grimsby, Harrogate, Huddersfield, Hull, Leeds Eastern, Leeds Western, Northallerton, Pontefract, Scarborough, Scunthorpe, Wakefield and York. And that gives the indication of the coverage of the Centre.

In terms of the work of the Centre, again, if we can turn to NHBT0006233, please. And we pick up on page 3, what we have here is a Medicines Inspectorate report from June and July 1988, and we can see the introduction:

"The Yorkshire RTC in Leeds is located in the grounds of Seacroft Hospital. Part of the Centre is a new building opened in 1986 (Phase 1) and a new donor centre opened in June 1988. The Centre has not previously been formally inspected.

"The population served is 3.2 million, taking in 24 hospitals including two private hospitals. The Centre employs approximately 350 staff in total and collects around 150,000 donations annually."

At this time, if we go down to part 3, the senior staff list, we can see that Dr Tovey is the medical director, and Dr Angela Robinson is listed there as the assistant general manager.

And in terms of the products, we have: whole

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section, we can see an explanation of how the microbiology testing is completed, and there is also this reference.

"As each tube is sampled it is moved into a second rack."

It's been put into a microtitre plate.

"The microtitre plates are supposed to be labelled with the date and the number of the first sample on the plate as, after they have been sub-sampled, these plates are frozen and constitute the microbiology stored samples. (They are kept for two years.) In fact, several plates only carry the date."

So it would appear that some degree of stored sampling was being carried out at the Yorkshire Centre, albeit only being kept for two years in 1988.

In relation to -- sorry, sir.

If we can then turn on to page 9, under the heading "Future planned changes/developments", we can see that:

"The major imminent development is the complete computerisation of the system, right through from donor records to product issue. This system has been running successfully for some years at the Welsh Regional Transfusion Centre in Cardiff and the

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Yorkshire system has been installed in close collaboration with their Cardiff colleagues. It is planned to 'go live' in September 1988."

That's a whole series of points, sir, that we'll pick up through the presentation but since we were on this document in relation to the staffing and population coverage, it makes sense just to complete that document.

If we move on in time to 1991, 1992, we can see how things have progressed, particularly in relation to facilities.

Could we have NHBT0097056_002, please.

We can see that this is the business plan for 1991/1992. And if we turn the page, we see that by then the director/general manager is Dr Angela Robinson and the deputy director is Dr Flanagan.

Could we turn on to page 4, please. We have the "Overview", and then towards the middle of the page, the heading "Customers". And it's noted that:

"The Yorkshire [service] serves three ..."

I think it should say "distinct groups" rather than:

"... district groups of customers:

"161,000 Donors.

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plus a seventh team based from an office in Hull, operate six days per week visiting about 250 venues throughout Yorkshire. Additionally, three Plasma/whole blood donor suites are located in the HQ, Leeds, and Bradford town centres and a unique clinical therapeutic service is provided from a ward within Seacroft Hospital."

So we see there a growth in the number of plasma suites available within the Yorkshire region.

If we move on to February 1992, NHBT0017246, please, Sully.

We pick up a medical audit visit of the centre. And again, we see those involved: Dr Angela Robinson as the Medical Director and Dr Flanagan as the Deputy Medical Director.

First of all, if we go to 1.2, at the bottom of this page, we can see the work that the Centre was doing in relation to its relationships with the hospitals in its region.

"Two hospital transfusion committees have been established among the 14 hospitals served. These are the largest hospitals served by the Centre, accounting for approximately 30% of its services. They meet 3 monthly and the consultant haematologist from the Centre is invited to all meetings. Indeed it was

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"5.1% of the eligible members of the general public of Yorkshire who in voluntarily donating their Blood or Plasma are entitled to receive quality service, care and attention in all their contact with the BTS."

Of course, for our purposes, the information there about the numbers of donors is useful to note.

"Hospitals", by this time it's:

"27 NHS and private hospitals within the Yorkshire Health region are supplied with blood and approximately 23 products or constituents of blood valued at £7.1m ..."

Then under the heading "Bio Products Laboratory":

"Plasma to a value of £1.8m (1990/91) is supplied to BPL as the source material for processing."

If we turn the page, under the heading "Organisation":

"The Yorkshire BTS is headquartered in a recently extended and renovated facility within the grounds of Seacroft Hospital, Leeds. All Medical, Screening and Processing functions are carried out on this site together with Donor Services, Publicity, and Business Services. From this base six mobile teams,

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a feeling at the Centre that consultant RTC medical staff should play an enabling role in the establishment of such committees."

SIR BRIAN LANGSTAFF: Just pausing there, this is now 14 hospitals served, which compared with 27 and 24.

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: What area is this covering? What is it an audit of? Can we just go back up to the top?

MS FRASER BUTLIN: We can see at the top it's an audit of the Yorkshire RTC, so it's a little bit unclear why it's only 14 rather than the 27.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: The numbers aren't something we've been able to track through. It may be it's the early 90s, sir, so it may be it's the combination of hospitals becoming bigger trusts, but we would need to check exactly what was happening in Yorkshire to be able to say that was the situation.

SIR BRIAN LANGSTAFF: Yes. I mean, that seems the likeliest explanation but we simply don't know, really.

MS FRASER BUTLIN: We simply don't know, no.

The important point I wanted to highlight from this document, sir, was the interaction that we see in Yorkshire between the RTC and the hospitals that it

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1 was serving.

2 **SIR BRIAN LANGSTAFF:** Yes.

3 **MS FRASER BUTLIN:** If we just carry on where we were:

4 "The committee at one hospital is

5 multi-disciplinary and meetings were thought to be

6 helpful. The other committee is about to hold its

7 inaugural meeting along the same principles. The

8 agenda for the established committee has primarily

9 addressed terms of reference and ..."

10 Over the page. That's jumped a page.

11 "... and maximal order blood schedules for

12 surgical procedures. The audit of BTS activities has

13 been included in the terms of reference."

14 Then we read this about the regional transfusion

15 committee:

16 "The Regional Director of Public Health has been

17 approached about establishing a regional transfusion

18 committee, but he does not feel such a committee is

19 necessary and that audit of the Transfusion Service is

20 more appropriately undertaken at Hospital level

21 through their current audit committees or through

22 hospital transfusion committees.

23 "Two meetings a year are held with haemophilia

24 directors, haematologists in charge of blood banks and

25 scientists."

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1 They are the sort of overview documents that we

2 needed to pick up in relation to Yorkshire, if we can

3 then look at some of the more detailed points that

4 arise. As we've seen, the senior staff at the

5 Yorkshire Centre, the Regional Transfusion Director

6 was Dr Derrick Tovey, he was the director between 1966

7 and 1988.

8 Dr Tovey was succeeded by Dr Angela Robinson who

9 held the post until 1994. Dr Robinson was appointed

10 a senior registrar in clinical haematology and blood

11 transfusion at the Yorkshire Centre in 1971. She

12 became a consultant in clinical haematology and blood

13 transfusion in 1976, and this was a joint post with

14 the Seacroft Hospital in Leeds.

15 In the Inspectorate report we saw a moment ago

16 she was described as the assistant general manager of

17 the centre. In 1988 she was appointed -- sorry, she

18 took over from Dr Tovey in 1988 and was then appointed

19 chief executive and director of the Centre.

20 Between 1976 and 1992 she was also an honorary

21 consultant haematologist at the Seacroft Hospital and

22 between 1987 and 1994 she was an honorary senior

23 clinical lecturer at the department of medicine at

24 Leeds General Infirmary and St James's University

25 Hospital.

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1 That picks up the question of the interaction

2 with the hospitals and, if we carry on to page 4 of

3 this document, under the heading "Apheresis

4 activities" we can see, at this time in February 1992,

5 there were four apheresis clinics, one in Leeds, one

6 in Bradford.

7 In terms of the work of the staff, if we could

8 turn the page to page 5, please, we see the heading

9 "Donor counselling":

10 "One associate specialist has overall

11 responsibility for the counselling of donors positive

12 on HIV antibody testing. This is arranged at a local

13 hospital. Together with the consultant haematologist

14 she is also responsible for the counselling of donors

15 found positive for markers of Hepatitis C who are then

16 referred to a liver specialist. Donors positive for

17 [hepatitis B surface antigen] are counselled by the

18 Deputy Director who also arranges to counsel plasma

19 donors who have persistently elevated (above 100) ALT

20 values. Only consultant medical staff and the

21 associate specialists counsel donors.

22 "Look-back programmes would be carried out for

23 past HIV positive donations as necessary by the Deputy

24 Director via the consultant haematologist in charge of

25 the blood bank in the appropriate hospital."

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1 On 1 May 1994, Dr Robinson was appointed the

2 medical director of the NBA, succeeding Dr Gunson, and

3 that was a post she held until 2007.

4 Dr Robinson was a member of a wide number of

5 committees and working groups, including, whilst she

6 was a director at Yorkshire, she was chair of the

7 Northern Division meetings, and consequently from

8 14 August 1990 she was a co-opted member of the

9 Medical and Scientific Committee of the SNBTS. She

10 was a member of the ad hoc working Party on

11 hepatitis C look-back, the NBTS National Management

12 Committee from 1990 to 1992, and the NBTS/BPL liaison

13 committee between 1990 and 1992. She was obviously

14 involved in very many other committees and working

15 groups, particularly once she became medical director

16 of the NBA but they are the important groups whilst

17 she was at Yorkshire.

18 The third staff member to note is Dr Peter

19 Flanagan. He took up a post as consultant

20 haematologist at the Yorkshire Centre in October 1989

21 with half his time being spent as a laboratory

22 haematologist at Seacroft Hospital. He was then

23 promoted to deputy director in January 1992, which was

24 a full-time post, and he became clinical director in

25 April 1993.

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On the reorganisation of the Blood Service in two, three administrative zones, under the NBA, he was appointed clinical director of the Northern Zone in February 1995 based in the Leeds Blood Centre.

Turning now to the question of funding and the relationship of the Centre with the Health Authority, until 1995, the Yorkshire Centre was part of and funded by the Yorkshire Regional Health Authority. Dr Robinson's personal statement made clear that the Yorkshire Centre was initially funded by a lump-sum payment made by the Health Authority to cover all of its costs.

BPL didn't, during that period, make payments for the plasma provided to it but, as the Inquiry has heard previously, returned Factor VIII on a pro rata basis.

Dr Robinson's view of that was it worked well for the Yorkshire Centre as the volume of both recovered and apheresis plasma sent to BPL meant that the pro rata return of plasma products, for example Factor VIII and human albumin solution was sufficient to meet the regions requirements.

While initially all of the Centre's funding was received from the Regional Health Authority that changed to some extent when cross charging was

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apheresis service that the Yorkshire Centre provided but there were other specialist services like tissue typing and HLA typing that remained centrally funded. Cross-accounting is simply a mechanism whereby we were prohibited from making a profit from the service we provided.

"As far as donors and health service users are concerned, blood is free. There was some difficulty in us getting the message across but there was a cost element to the obtaining, testing, processing and distribution of blood."

The importance of the cross-charging question was that Dr Robinson noted in her statement at paragraph 34 that, in relation to BPL paying for plasma and BPL selling their fractionated products, the price for a unit of apheresis plasma, she says, proved to be insufficient to cover the cost of producing it at the Yorkshire Centre.

The question of costs is something that crops up in number of the documents that we will be looking at today.

In 1986, there is a series of letters and discussions between the Regional Health Authority and Dr Tovey, which may provide some insight into the relationship between the Centre and the Regional

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introduced in 1989 and BPL began to pay centres for the plasma they supplied.

Dr Flanagan has indicated in his statement that this changed further in 1990/1991 when the Yorkshire Regional Health Authority devolved funding for regional services to hospitals in the region.

Initially, that devolved funding only covered the purchase of blood and blood products from the Centre but it was subsequently expanded to all products and services.

In relation to cross-charging or cross-accounting, which was implemented in April 1991, Dr Robinson's statement has explained it in this way:

"The Yorkshire Regional Health Authority devolved the Transfusion Centre's total budget and apportioned it to the individual hospitals, who then had to buy blood and blood components back from the Centre. This meant that we had to come up with a unit price for whole blood, FFP, cryoprecipitate and platelets. The Regional Health Authority kept a central budget for specific services, particularly in relation to the management and treatment of rare disorders, because we would get sporadic requests throughout the region and couldn't expect one hospital to pay for these. One example would be the regional

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Health Authority.

If we could turn to NHBT0001079, please, and if we could pick it up at page 3, just to give a context to what we then look at. This is a letter from Dr Derrick Tovey to Dr Smithies at the DHSS, and he says this:

"My responsibilities as 'Director' have always been somewhat vague here in Leeds. My predecessor was labelled 'Regional Blood Transfusion Officer'. When I was invited to take over after his death, I consulted other Blood Transfusion Directors and the DHSS Adviser on Blood Transfusion and everyone advised me not to accept the post unless I was appointed Director. The Regional Health Authority somewhat reluctantly agreed. To be fair to them they have always been helpful to me and I cannot recall a time when they have not consulted me regarding any major decision necessary for the Regional Transfusion Centre. However, a couple of years ago I discovered that I was responsible to the Regional Medical Officer, the Administrator responsible to the Regional Administrator, and the Head Nurse responsible to the Regional Nursing Officer! Even the RHA realised this was ludicrous. We finally agreed on a compromise. We formed a Board of Management consisting of the Head

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Nurse, Administrator, Senior Chief Technician, with myself permanently in the Chair, and this has worked quite well.

"A year or so ago the RHA appointed Pricewaterhouse to study the administration of the RHA and as the BTS was under the direct supervision of the RHA we were included. Pricewaterhouse visited us for one half day and the final report accepted by the RHA contained one section on the BTC! As you will see, it suggested the appointment of a General Manager! No mention of the place of the Director. I immediately asked to see the newly appointed Regional General Manager and Regional Medical Officer. I was informed that the 'new' organisation would put the BTC under the care of the Regional Supplies Officer who was responsible to the Regional Personnel Officer who was responsible presumably to the Regional General Manager and the RHA!

"I immediately protested and enclose a copy of a letter I sent to the General Manager. Frankly he was astounded by the range of my duties and responsibilities! I then suggested that my job description and presumably by contract should reflect both my 'Director' role and my 'Managerial' role and the RHA after consultation with me has drawn up the

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remaining headings of functions as Dr Derrick Tovey saw them of the modern transfusion centre: "5. The investigation of blood transfusion problems in regional hospitals"; "Antenatal testing"; "Plasma exchange"; "Tissue typing"; and then "Other associations with clinical and GP services":

"Donors or antenatal patients with positive serological tests, eg Syphilis, Hepatitis B and HTLV III, need careful medical assessment and direct contact with the consultant or GP", and then a series of other functions.

Then at the bottom of this page, please, Dr Derrick Tovey says this:

"It is obvious therefore that what one may label the 'supplies aspect' of the Blood Transfusion Centre is only one segment of our activities and responsibilities. I maintain we have a major regional clinical role and therefore merit a much more direct access to the Regional Health Authority than is at present envisaged, namely BTS [to] 'Supplies' Manager [to] Personnel Manager [to] Regional Manager [to] Regional Health Authority."

Over the page:

"There is a continuing need to have access to both senior medical and administrative staff at

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enclosed proposed job description."

If we then turn on to page 10, please, Sully, we can see the letter referred to that Dr Derrick Tovey wrote to the Regional General Manager of the Yorkshire Health Authority. It's dated 13 February 1986. We see "A modern transfusion centre has many functions", and then a series of headings: "The collection of blood"; "Blood testing"; "Preparation of blood components"; "The issue of blood and blood products to hospitals in the region"; and this is worth picking up the detail:

"In order to ensure adequate stocks are available and that they are suitable and safe for transfusion, there is a need for direct clinical contact with hospital haematologists and other clinicians, eg cardiac surgeons. This necessitates a need for direct access to the clinical services. We cannot function efficiently if this clinical need is not carefully monitored, eg an additional cardiac surgeon say in Hull has major implications for. There is a growing demand in the hospital service for expertise in 'Transfusion Medicine', ie expert advice not only in the collection and preparation of blood and blood products, but also their administration."

If we turn over the page, we then see the

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Region. Decisions of major importance to patients and donors (eg AIDS) have to be taken quickly after consultation at a senior level, and the proposed structure would in my opinion prevent this.

"Up to the present I have had a necessary direct access to senior medical, nursing and administrative staff at the Regional Health Authority, and if this was replaced by a more circuitous consultative machine not only would the blood transfusion service suffer, but also patient and donor care."

So they were the concerns that Dr Derrick Tovey raised when the reorganisation was proposed and, if we turn now -- turn back now to page 6, we can see the job description after those discussions, and we see that his job title was to be "BTS Director/General Manager" and the managerial accountability was described in this way:

"The Director/General Manager is managerially accountable to the District Services Manager, but has a strong professional accountability to the Regional Medical Officer, who will be involved in professional issues relating to donor or patient medical care."

As far as the Inquiry has been able to establish, that is the position that was then followed thereafter, in terms of the interrelationship between

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the Centre and the Health Authority and, particularly, the director's role.

Moving on, then, sir, to the question of self-sufficiency. As a member of the working party to advise on plasma supplies for self-sufficiency in blood products, Dr Robinson was co-author of the preliminary report in June 1981, which set a national target of 100 million units of Factor VIII concentrates as a reasonable estimate of clinical requirements in England and Wales by the mid-1980s.

A supplement to that report was then presented to the advisory committee of the NBTS in a meeting on 28 September 1981. The report concluded that manual pheresis was the most economical way to meet the required plasma volumes but Dr Robinson was unhappy with that recommendation and we can see a letter that she then wrote to Dr Gunson. Could we have DHSC0002211_072, please.

In the middle of the page she sets out her main concern:

"My main concern is the emphasis on Manual Plasmapheresis as the most economical way of achieving the required volume for the following reasons.

"There is no code of practice regarding the running of 8 bedded plasmapheresis units ie staffing

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"Staffing levels

"Factor VIII yields [then over the page]

"Manual pheresis cannot safely be recommended as the most economic means of plasma collection."

Then the final two paragraphs of the letter:

"I have been given the go ahead for a 6 bedded automated plasmapheresis unit in Bradford, I shall liaise closely with Jim Smith to establish the Factor VIII yields achieved by this means of collection.

"It is important that a trial manual unit is set up as soon as possible so that direct comparisons can be made about the economic viability of such units."

We then have Dr Gunson's response at DHSC0002211_071, please. It's dated October 1981, and if we pick up the middle paragraph, please, he refers to the supplement:

"This was of course a supplement to the Preliminary Report and has to be taken in conjunction with the main report, where the point was made very forcibly that it was important to carry out a trial of manual pheresis. I agree it is essential that a code of practice will have to be established and staffing levels will have to be considered. I am pleased that you have got permission for your automated pheresis

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levels to ensure safety, the number of centrifuges required to ensure speed and safety.

"Such considerations could lead to higher equipment costs and staffing revenue.

"There has been no trial in this country of large manual plasmapheresis units and it is debatable if the donation time of one hour can be achieved safely with the staffing levels recommended in this document.

"The plasma volume may well be achieved but the only study so far done on Factor VIII yields from manually collected plasma is by Jim Smith at Oxford and the results were poor, ie one must not think in terms of kgm of plasma obtainable but of Factor VIII yields per kgm of plasma achieved.

"To date plasma collected by automated plasmapheresis has higher yields per kgm of plasma than plasma collected by any other method.

"ie a smaller volume of automated plasma is required compared to manual plasma.

"In conclusion I feel that until a properly conducted trial of manual plasmapheresis has been carried out in this country to establish --

"Equipment necessary

"Safety precautions [we can continue down]

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unit, since this will be the first one of its type in the country dealing with normal donors and the code of practice which has been set up for such units was based on much smaller numbers. There is a school of thought, to which I do not necessarily subscribe at the moment, that there ought to be one trained nurse per machine in such units, and it will be very interesting to see how you get on with your six-bedded unit."

So it appears that as at October 1981, the unit, automated pheresis unit in Bradford was the first of its type in the country.

SIR BRIAN LANGSTAFF: It says the first of its type dealing with "normal" donors.

MS FRASER BUTLIN: Dealing with normal donors, apologies.

SIR BRIAN LANGSTAFF: So there may be others dealing with a small cohort of dedicated plasma donors?

MS FRASER BUTLIN: Exactly. Apologies, sir, yes. The first of its type dealing with normal donors.

SIR BRIAN LANGSTAFF: So this is, I suppose, regular donors or people who come in off the street --

MS FRASER BUTLIN: It appears that way.

SIR BRIAN LANGSTAFF: -- and then offered plasmapheresis.

MS FRASER BUTLIN: And automated plasma plasmapheresis, yes, sir.

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1 **SIR BRIAN LANGSTAFF:** Yes.

2 **MS FRASER BUTLIN:** In terms of the setting of regional

3 targets, at the Yorkshire Centre, Dr Robinson set out

4 in her statement how the regional targets were set:

5 "The target was based on the Factor VIII

6 required nationally, and then apportioned between the

7 different regions, therefore our target didn't

8 necessarily equate to the demands of our local

9 population."

10 And Dr Flanagan in his statement describes the

11 process of the setting targets for supply of plasma to

12 BPL in this way:

13 "Essentially the price for plasma was set by the

14 CBLA and the national director of the NBTS and

15 approved by the NBTS steering committee. National

16 plasma volumes were developed by the CBLA and

17 individual RBTs then made a bid for the volume of

18 plasma they aimed to supply. Volumes were agreed."

19 If we can then pick up, in relation to targets,

20 DHSC0002267_039, please. We have here a letter from

21 Dr Derrick Tovey to the DHSS dated 19 April 1985.

22 Prior to this letter an administrator had

23 completed a form dealing with plasma procurement, and

24 the letter from Dr Derrick Tovey, here, accepts that

25 the administrator indicated that there was no detailed

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1 So if we can go back to that letter now,

2 DHSC0002267_039.

3 Middle paragraph of his letter, Dr Derrick Tovey

4 says this:

5 "... although we aim to achieve the target of

6 31,500 there is a gap. This gap can either be bridged

7 by increasing the SAG M collection, but until we have

8 had more experience of this we do not know if the

9 clinicians will accept a higher percentage. The

10 alternative is to open a third machine plasmapheresis

11 centre."

12 "The point I am making, is that we do intend to

13 reach the target, it is simply that we have not

14 decided at the present time, which of the alternatives

15 we will put into operation."

16 So we can see from the prior table that,

17 broadly, Yorkshire could meet their targets but in

18 that particular year that was a query over exactly how

19 they would meet that target.

20 In fact when we come to 1989 we have a letter

21 from Dr Robinson dated 22 March 1989 informing

22 Dr Gunson that the Yorkshire Centre had not met its

23 plasma target.

24 If we can go to that letter, please,

25 NHBT0027512.

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1 consideration about how a target in '87/88 would be

2 made. He says this:

3 "... although we aim to achieve the target of

4 31,500, there is a gap. This gap ..."

5 Apologies, sir, I should have taken you to

6 a document just prior to that. That's my fault.

7 I misread my notes. Could I just go back a document.

8 DHSC0002267_011. Apologies, I couldn't read my

9 handwriting, sir.

10 This will make much more sense.

11 This is a letter from an administrator for

12 Dr Derrick Tovey dated 9 April 1985. And if we turn

13 the page, we can see a table setting out the quantity

14 of fresh frozen plasma to be supplied to the BPL

15 from Leeds.

16 April 1985/March 1986, we have a total of

17 17,100, as against a target of 17,000.

18 April 1986/March 1987, we have a total 26,100,

19 with a target of 26,000.

20 Then April '87 to March '88, we have a total of

21 26,100, against a target of 31,500.

22 It's in relation to this gap between the total

23 that they will be able to supply and the target that

24 the region has been given that the letter from

25 Dr Tovey addresses.

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1 Dr Robinson indicates that she had -- they'd

2 finished planning their strategy for achieving their

3 plasma targets for the next few years and she provides

4 him with the overall plan.

5 If we can go down, please.

6 "1988/89 Volume achieved = 24,607L.

7 "Target was 26,000L."

8 And the shortfall is put down to:

9 "a) Industrial dispute over clinical grading

10 "b) Increased local use of Cryo and FFP

11 "c) Loss of 10,000 donations."

12 For 1989/1990, the target is 27,000 litres, and

13 the proposal is to increase SAG-M donations and to

14 extend Bradford by 18 and three quarter hours per

15 week.

16 "(Adequate number of donors already recruited.

17 Given the necessary staff recruitment, expansion can

18 take place immediately)."

19 If we turn the page we see a note on the targets

20 and the objectives, and then this action plan:

21 "Action plan necessary to achieve these targets:

22 "1) Extending the hours of the Bradford Centre

23 by 18 [and three quarter] hours by immediate staff

24 recruitment and training.

25 "2) Recruiting 4,500 more plasma donors for the

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1 St Paul's Street Centre and the New Donor Suite at
 2 Headquarters over a 3 year period (both at present are
 3 working under capacity because of the insufficient
 4 donor recruitment).
 5 "3) Increasing the number of SAG-M donations to
 6 provide an extra 4,000L/annum."
 7 And:
 8 "4) Improving ordinary whole blood donor
 9 recruitment and retention such that the 10,000
 10 donations lost in the last 2 years are regained and
 11 maintained."
 12 We'll pick up that issue of loss of donors
 13 shortly.
 14 Dr Gunson then visited the Regional Transfusion
 15 Centre in or around August 1989 and the -- it was
 16 agreed that the 1989/1990 target would be revised.
 17 We can see in a document relating to a CBLA-NBTS
 18 liaison meeting that costs were also an issue.
 19 Dr Robinson stated that the plasma supplied by the
 20 Yorkshire Centre was costing £15 per kilogram more
 21 than the income received from it.
 22 Just for the transcript, the reference is
 23 NHBT0000077_056.
 24 It's not entirely clear in that document whether
 25 Dr Robinson was referring to recovered or apheresis

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1 "I am back to my regional theme of linking
 2 plasma supply to BPL by RTCs, to the Regional uptake
 3 of BPL products, ie, if I am going to purchase 8M
 4 units of fVIII for regional distribution I would like
 5 the opportunity to supply the volume of source
 6 material required to produce 8M units of fVIII."
 7 So by 1991 there is a concern being raised by
 8 Dr Robinson that Yorkshire want to supply or have the
 9 opportunity to supply the volume of source material
 10 that is equivalent to what the region then distributes
 11 to the relevant centres.
 12 **SIR BRIAN LANGSTAFF:** Is she saying there that she'd like
 13 to supply more in order to get enough, or is she
 14 saying, "I'd like to supply just what is needed"?
 15 Because they're two different things. And is she
 16 complaining, perhaps, if the latter be so, that
 17 Yorkshire is being asked to do more than its weight?
 18 **MS FRASER BUTLIN:** That hadn't been my reading, sir, but
 19 it could certainly be a reading of the letter. The
 20 last paragraph of the letter might suggest otherwise:
 21 "If the target of 37,000 litres from the
 22 Yorkshire region is likely to be in excess of our
 23 allocated BPL quota please could you let me know ..."
 24 **SIR BRIAN LANGSTAFF:** Yes, but it is a question of who
 25 sets the target.

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1 plasma but Dr Flanagan comments on this in his
 2 statement and says that there was a significant
 3 concern to the Yorkshire Centre because the deficit in
 4 cost recovery for the plasma will have been added to
 5 the price charged for local components issued to
 6 hospitals in the region. And consequently, these
 7 charges will have appeared higher than those set by
 8 other RTCs, who were providing less plasma to BPL.
 9 So there was an impact across the board.
 10 We then pick up the situation in August 1991 in
 11 a letter dated 13 August. If we could turn to that,
 12 NHBT0016094, please. It's the second page.
 13 Having set out matters of the plasma being
 14 supplied, Dr Robinson said this to Dr Gunson:
 15 "What I can say is that the current uptake of
 16 BPL factor VIII products by the Yorkshire region
 17 indicates a likely annual usage of 8M units. Our
 18 1991/92 normal plasma input is targeted to be
 19 37,000 litres (24,000 litres recovered, 13,000 litres
 20 apheresed).
 21 "Assuming the fVIII yield is approximately
 22 190 iu/L the YBTS supply of source plasma to reach
 23 regional self-sufficiency in terms of the BPL fVIII
 24 uptake by the Yorkshire region is equivalent to
 25 42,000L.

30

1 **MS FRASER BUTLIN:** Indeed, yes.
 2 **SIR BRIAN LANGSTAFF:** And I thought the target was being
 3 set by BPL in the earlier documents.
 4 **MS FRASER BUTLIN:** Indeed.
 5 **SIR BRIAN LANGSTAFF:** And it was up to Yorkshire to see if
 6 they could achieve it.
 7 **MS FRASER BUTLIN:** Yes. Yes. So it could be read that
 8 way, sir.
 9 **SIR BRIAN LANGSTAFF:** So it's -- and the overall picture
 10 across the country that has been painted so far is
 11 this, is it: that regions are set targets by BPL
 12 looking at the region and saying, "You've got so many
 13 people in this region, this is your fair share of our
 14 needs."
 15 That may be all very well, but some of the
 16 regions have a much higher usage than others, and so
 17 if they get back pro rata, they don't get back enough.
 18 **MS FRASER BUTLIN:** Indeed.
 19 **SIR BRIAN LANGSTAFF:** Others are supplying more than they
 20 need, and that comes at a cost to them and
 21 they complain that the cost which is attributed to
 22 them by cost by cross-charging is actually less than
 23 the cost that they have, and so they have to charge
 24 more for other products supplied locally.
 25 **MS FRASER BUTLIN:** Indeed. And as you say, sir, that ties

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1 in much more clearly with the concerns about costs.
 2 And the concerns about cross-charging.
 3 **SIR BRIAN LANGSTAFF:** And it would fit in with the
 4 concerns which have been expressed elsewhere in the
 5 documents you have referred to where there's a concern
 6 that Yorkshire's supplies to its hospitals may be
 7 compared by clinicians in effect saying, "Well, you're
 8 charging us" --
 9 **MS FRASER BUTLIN:** Indeed.
 10 **SIR BRIAN LANGSTAFF:** -- I'm just picking figures at
 11 random for the point -- "£5 for this, but down in this
 12 other region they only charge £4."
 13 **MS FRASER BUTLIN:** Indeed, sir. That interpretation of
 14 this letter would certainly fit with those other
 15 documents. But it's not entirely clear.
 16 **SIR BRIAN LANGSTAFF:** It's not. Although the wording
 17 would suggest you're right in the first place, but the
 18 context is the opposite, perhaps.
 19 **MS FRASER BUTLIN:** Indeed. Indeed. Yes.
 20 I think perhaps -- let me just go back --
 21 apologies, sir. No.
 22 Either way, sir, it is clear from many of the
 23 documents that Dr Robinson was an advocate of
 24 plasmapheresis and indeed in her statement she said
 25 this:

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1 As a member of the UK Blood Transfusion Service
 2 Apheresis Working Party on behalf of the UK BTS NIBC
 3 Standing Committee for Blood Donors, Dr Robinson was
 4 also responsible for co-authoring the guidelines
 5 prepared by that working party, including guidelines
 6 for apheresis of volunteer donors within the UK Blood
 7 Transfusion Service.
 8 Moving on, then, to donors and selection of
 9 donors, Dr Robinson's personal statement made it clear
 10 that blood donation was not by appointment, so mobile
 11 teams had to make their presence known in an area in
 12 order to secure donors. The Yorkshire Centre produced
 13 a lot of its own publicity material and when the
 14 Centre was short of donors, Dr Robinson might put out
 15 a radio appeal for more to come forward.
 16 If we could turn on to NHBT0033679, please.
 17 We see a letter from Dr Robinson to Dr Gunson,
 18 addressing a campaign that the Yorkshire Centre
 19 mounted in January 1990 to reassure donors and
 20 non-donors that there was no risk of infection when
 21 giving blood. This had followed a sharp decline in
 22 donor attendance.
 23 What is useful to see is the bottom of the page,
 24 their plan of action, just to give a flavour of what
 25 the Centre was doing:

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1 "I became a national and internationally
 2 recognised expert in both donor and therapeutic
 3 apheresis and introduced the first voluntary donor
 4 automated plasmapheresis centre in the world in
 5 Bradford in 1982."
 6 Which is what we looked at earlier.
 7 Dr Robinson wrote up the pilot plasmapheresis
 8 programme in Yorkshire in an article she co-authored
 9 with others including Dr Tovey for Vox Sanguinis.
 10 It's DHSC0002263_064, please.
 11 If we just look at the abstract, we can see that
 12 there was a pilot study for large-scale automated
 13 plasmapheresis using a particular machine that:
 14 "... was undertaken in the Yorkshire Region of
 15 the [UK] to determine the viability of such
 16 a programme for national self-sufficiency in fresh
 17 plasma procurement for factor VIII concentrate
 18 production. The study was designed to resolve three
 19 areas of concern: donor safety and recruitment; a cost
 20 analysis, and the choice of anticoagulant for optimum
 21 factor VIII yields. The results show that large-scale
 22 automated plasmapheresis could safely and economically
 23 produce high-quality source plasma necessary for
 24 national self-sufficiency."
 25 And that was published, sir, in 1983.

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1 "Posters & Leaflets are being distributed for
 2 public display to the 7 district family practitioner
 3 committees within the Yorkshire region for display in
 4 all GP's surgeries.
 5 "All health centres
 6 "Community clinics
 7 "Libraries
 8 "Citizens Advice Bureaus etc."
 9 Then she enclosed a copy of the poster and
 10 leaflet.
 11 Then over the page:
 12 "Large simplified poster on similar lines as
 13 those enclosed to appear ... for a period of 3 months
 14 "on the backs of buses (100 in all) travelling
 15 within the Yorkshire Region.
 16 "At to all railway stations within the Yorkshire
 17 Region.
 18 "To follow up, informational Display Stands and
 19 a video are being prepared and will be coming online
 20 towards the end of March.
 21 "A press release by the Yorkshire region in
 22 association with the PRO agency [would] be prepared
 23 ..."
 24 So they were some of the measures that
 25 Dr Robinson took in order to increase donor numbers.

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1 Dr Robinson, in her statement, recalled
 2 attending a session at Wakefield Prison when she was
 3 a senior registrar, so that must have been prior to
 4 1976 when she became a consultant. She didn't recall
 5 any prison collections after 1976, once she was
 6 a consultant. She further recalled that:
 7 "When the plasmapheresis centre in Bradford was
 8 opened, the Yorkshire Centre didn't allow donors with
 9 a prison history to donate because of the association
 10 of institutionalisation increasing the incidence of
 11 hepatitis B and non-A, non-B hepatitis."
 12 So she in her statement thought that they
 13 were -- the Centre was not collecting blood from
 14 prisons by 1982. However, a separate document, sir,
 15 which the Inquiry has seen on a number of occasions,
 16 NHBT0008628_001, it's the Scottish Transfusion
 17 Directors' survey from 1983. If we just turn the page
 18 we see this in relation to Leeds:
 19 "Dr Derrick Tovey is different.
 20 "The Region has large prisons at Wakefield,
 21 Leeds, and Hull.
 22 "They tried to withdraw prison sessions, and got
 23 a very active response from the prisons, which asked
 24 that the sessions should continue.
 25 "The session staff get help from Prison staff to

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1 they'd find out.
 2 **MS FRASER BUTLIN:** Indeed, that might well be one
 3 interpretation of the situation.
 4 **SIR BRIAN LANGSTAFF:** Which might be thought to be part of
 5 the reason you didn't want to have collections in
 6 prison, but --
 7 **MS FRASER BUTLIN:** Indeed.
 8 **SIR BRIAN LANGSTAFF:** -- this is all comment and subject,
 9 of course, to being shown what it really means later.
 10 **MS FRASER BUTLIN:** Indeed.
 11 **SIR BRIAN LANGSTAFF:** Thank you.
 12 **MS FRASER BUTLIN:** In the documentation there are various
 13 examples of Dr Tovey's actions of letters to donors
 14 who'd tested positive for hepatitis. We can then pick
 15 it up more clearly in June 1990 when the Yorkshire
 16 Centre published a document entitled "Criteria for the
 17 Selection of Whole Blood and Apheresis Donors", at
 18 NHBT0033676. Third page, please, we see at points 4,
 19 5 and 6:
 20 "Only persons in good health should be accepted
 21 as donors of blood for therapeutic use.
 22 "The ultimate responsibility for the selection
 23 of donors rests with the RTD; the immediate
 24 responsibility is that of the medical officer or nurse
 25 in charge of the session who should evaluate the

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1 exclude volunteers who are medically unsuitable.
 2 Dr Tovey receive a letter from a prisoner, seeking
 3 reassurance that if an abnormal result was obtained on
 4 donation testing the prison donor would be informed.
 5 The prisoner considered this to be a valuable service
 6 performed by BTS."

7 So Dr Robinson's recollection was somewhat at
 8 odds with what we have here in 1983. In terms of the
 9 selection of donors, there are various examples in the
 10 documentation seen by the Inquiry of Dr Tovey
 11 responding with donors about whether or not they
 12 should be excluded, for example where they've tested
 13 positive for hepatitis.

14 **SIR BRIAN LANGSTAFF:** Just pausing for a moment, looking
 15 at the commentary there, which is written about Leeds,
 16 the last of the three paragraphs on the screen, the
 17 reassurance which the prisoner wished was that he be
 18 told if there was an abnormal result, and then there's
 19 this comment:

20 "The prisoner considered this to be a valuable
 21 service performed by BTS."

22 One implication of that might be that a prisoner
 23 or prisoners thought that it was useful to give blood
 24 because you could be tested. In other words, they
 25 thought they might be suffering from something and

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1 prospective donor's medical history.
 2 "If there is doubt about the suitability of
 3 a prospective donor, a donation should not be taken
 4 and details should be referred to the RTC for
 5 a decision."
 6 Then over the page, the second paragraph:
 7 "A significant part of the assessment procedure
 8 will usually rely on answers to questions relating to
 9 general health, past medical history and medication.
 10 This is combined with simple visual assessment of the
 11 donor and selected testing of samples collected at the
 12 time of donation."

13 There's then the reference to a set of
 14 questions -- standard set of questions that are to be
 15 asked, which we'll look at just in a moment. Then
 16 this, at the last paragraph, "Inspection of the
 17 Donor":

18 "The donor should appear to be in good health",
 19 and various other positions are noted.

20 "This procedure, used skillfully, will lead to
 21 rejection or suspension of most donors who are unfit
 22 to be bled and it should be carried out meticulously."

23 That's the suggestion of looking at a donor for
 24 poor physique, debilitation, undernutrition, or the
 25 suggestion of intoxication, either by alcohol or

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1 narcotic drugs.
 2 In terms of the questions to be asked, if we
 3 turn to page 7, we see the heading "Specific
 4 Questions":
 5 "All donors should be specifically questioned
 6 about the conditions listed on NBTS 110A and every
 7 donor should sign NBTS 110."
 8 They're documents that the Inquiry has looked at
 9 number of times:
 10 "Each prospective donor should be asked
 11 a standard set of questions prior to each donation by
 12 a donor attendant. Any condition declared should be
 13 discussed with the medical officer or nurse in charge
 14 ..."
 15 We can see those questions at page 33 of the
 16 document.
 17 We see a set of questions of feeling well,
 18 coughs and colds, and then at (x):
 19 "Have you read the AIDS leaflet?"
 20 So it might appear that the leaflet was given to
 21 donors and they were required to sign confirmation
 22 but, in terms of verbal questioning, it was limited to
 23 asking whether they had read the AIDS leaflet.
 24 Sir, I'm about to move on to a slightly
 25 different topic. I don't know whether it would be

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1 If we move forwards to 1990 in relation to the
 2 hepatitis B core testing, Dr Flanagan wrote to
 3 Dr Gunson on 25 June 1993 informing him that the
 4 Yorkshire Centre were in the process of developing
 5 a strategy for the introduction of hepatitis B core
 6 screening, and although he was keen for it to be
 7 introduced as soon as possible, he also felt it was
 8 very important that there was conformity on the
 9 principles underlying the core testing in different
 10 regions.
 11 Dr Robinson wrote around the same time to
 12 Dr Gunson stating she considered that core testing
 13 should be introduced as soon as feasible and that they
 14 would be in a position to do so by October '93.
 15 Of course as the Inquiry has heard, in
 16 October '93, Dr Gunson informed all RTDs that
 17 hepatitis B core testing wasn't to be introduced. But
 18 we can see from the documents that Yorkshire was keen
 19 to do so and ready to pursue that.
 20 If we can pick up, then, in relation to HIV
 21 Dr Robinson's statement addresses her awareness that
 22 HIV may not be confined to the gay community when she
 23 attended a symposium in Boston in 1982. And she
 24 stated in her statement that by 1983 more risk factors
 25 for HIV were becoming clear to her.

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1 appropriate to just take a ten-minute break before we
 2 continue.
 3 **SIR BRIAN LANGSTAFF:** Well, let's make it quarter of
 4 an hour, shall we --
 5 **MS FRASER BUTLIN:** Of course.
 6 **SIR BRIAN LANGSTAFF:** -- and come back at 20 past.
 7 So 11.20.

(11.06 am)

(A short break)

(11.20 am)

11 **MS FRASER BUTLIN:** Sir, I want to move on now to the
 12 question of screening of blood and blood products.
 13 And picking up first with hepatitis B.
 14 In May 1979 Dr Tovey raised concerns with
 15 Dr Lane that the hepatitis B testing was a little
 16 insensitive, and made -- using the HEPA test, and made
 17 enquiries whether alternatives might be available, and
 18 Dr Lane's response was that the RIA test would be
 19 discussed at the next Directors meeting in May 1979.
 20 At that meeting, in June 1979, Dr Lane offered
 21 to send reagents free of charge to anyone who wished
 22 to try out the RIA test, and Dr Tovey suggested there
 23 ought to be uniformity of practice in the use of the
 24 test, with a change by all RTCs to RIA if this were to
 25 be agreed policy.

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1 In terms of the practice in Yorkshire, we have
 2 a memo from Dr Tovey from September '83.
 3 NHBT0021385, please.
 4 Dr Tovey has written to medical officers as
 5 follows:
 6 "It has been agreed by Transfusion Directors and
 7 the DHSS that the enclosed AIDS leaflet should be made
 8 available on donor sessions, and I will arrange for
 9 these to be sent out in the next few days.
 10 "Obviously this is a very sensitive topic and we
 11 will therefore have to play this in a very low key.
 12 We wish to exclude donors who might be more likely to
 13 transmit AIDS but wish to avoid consternation to every
 14 homosexual donor. I would ask therefore, that you
 15 deal with any comments from donors after they have
 16 read this pamphlet, as tactfully as confidentially as
 17 possible. We certainly would not wish to exclude all
 18 homosexuals from donating blood, but obviously those
 19 who are promiscuous in this matter, should not
 20 donate."
 21 And then in the final paragraph:
 22 "I reiterate, this is a very delicate issue."
 23 Dr Robinson stated in her statement that she
 24 couldn't recall how the leaflet was distributed. She
 25 said this:

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1 "But I believe that with every call to a donor
2 centre, a leaflet was included, but there was no
3 specific means of ensuring that every donor read it."
4 Her recollection was that:
5 "We put the leaflet in every call-up letter and
6 also had the leaflet available at donor sessions."
7 On 21 November 1984, Dr Tovey issued some
8 modified instructions to the medical officers.
9 NHBT0096480_028, please.
10 If we go to the last page, page 4, he said this:
11 "As you will know there has been a lot of
12 activity in the field of AIDS of late and the DHSS are
13 requesting we take a stronger line re male
14 homosexuals. I have ensured the leaflet is available
15 at all sessions and prominently displayed. A new
16 leaflet will be available shortly and this refers to
17 'active male homosexuals'. In practice therefore,
18 they are really saying all male homosexuals should
19 refrain from donating. So this modifies somewhat my
20 instructions issued 1.9.83 [which we just looked at]
21 which were based on the current leaflet.
22 "If a donor has been registered and you have
23 therefore to put something on the card, put HRD (High
24 Risk Donor) and we will ensure he is not invited
25 again. If you wish to pass on any information to me,

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1 **SIR BRIAN LANGSTAFF:** Just before we leave this document,
2 it coincides with what Robinson says in her statement,
3 as you've just told me, that the leaflet was sent with
4 invitations, or at least to some extent was.
5 **MS FRASER BUTLIN:** Indeed.
6 **SIR BRIAN LANGSTAFF:** My question is how that fits with
7 what you showed me earlier this morning where it
8 was -- the mobile teams were described as having to
9 set up and advertise their presence locally because
10 there weren't invitations.
11 **MS FRASER BUTLIN:** Indeed. That's unclear, sir, how those
12 two things fit together and, unfortunately, this is as
13 much as we have. It may be that the mobile sessions,
14 there were two different streams operating, where some
15 were called up, and the mobile system where they
16 weren't called up, but I'm afraid we don't have any
17 further information on that.
18 **SIR BRIAN LANGSTAFF:** It may simply be that in parts of
19 Yorkshire there were -- both systems were operating --
20 **MS FRASER BUTLIN:** Indeed.
21 **SIR BRIAN LANGSTAFF:** -- which would -- it would seem odd
22 that there was no call-up system --
23 **MS FRASER BUTLIN:** It would.
24 **SIR BRIAN LANGSTAFF:** -- and yet they're able to say that
25 they've lost 10,000 donors, for instance, over

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1 write to me in confidence. I am commencing
2 a confidential record of these donors.
3 "If you are in doubt about any donor you might
4 record on the card 'HRD - letter to Dr Tovey'.
5 Further insight into the practice at Yorkshire
6 in relation to the AIDS leaflet can be identified in
7 a memorandum from 1989.
8 NHBT0021384.
9 It's from a Mr Frank to Dr Robinson and it says:
10 "All the old posters have either been used or
11 destroyed. From memory the sequence of events was:
12 "1. After any delays the grey AIDS leaflet
13 became available in late 1983. This was distributed
14 on session supported by a poster of our own production
15 inviting donors to read the leaflet.
16 "2. In late 1984 or early 1985 it was decided
17 that a leaflet should be sent with every invitation.
18 See attached sample letter and note dated 12.2.85.
19 This procedure was to last 6 months ...
20 "3. In September 1985 a revised leaflet was
21 produced and again every donor was required to have
22 one before donating.
23 "4. For something like [two and a half] years
24 we have used the 'data post' invitation which has
25 regularly been AIDS updated for public normal donors."

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1 a particular period.
2 **MS FRASER BUTLIN:** Precisely. So it may be that the
3 information saying that there were no call-ups is not
4 fully accurate. But we simply don't know.
5 **SIR BRIAN LANGSTAFF:** Yes.
6 **MS FRASER BUTLIN:** Before we leave the question of the
7 AIDS leaflet, just to pick up one issue that arose in
8 1991, we have a letter, we don't need to go to it but,
9 for the transcript, it's JPAC0000044_135, a letter
10 from Dr Robinson to Dr Wagstaff about the AIDS
11 leaflet, where she picks up an issue in Leeds and she
12 says this:
13 "I suppose what I'm saying is we shouldn't allow
14 pressure groups or people's sensibilities detract from
15 our main task, which is to keep our blood supply as
16 safe as possible and to retain public confidence in
17 the continual safety of our blood supply."
18 That appears to be picking up an issue in Leeds
19 which is noted in a letter from Leeds ACT UP in
20 June 1991. The Leeds ACT UP group wrote to the
21 National Directorate, expressing its opposition to the
22 policy of excluding high-risk groups from giving
23 blood, rather than those who indulge in high-risk
24 practices.
25 Dr Flanagan, in his statement, recalls sit-ins

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being orchestrated by that group in order to challenge the exclusion of men who have sex with men, the criteria of that. So there does appear to have been a localised or, in this context, an issue in relation to the Leeds ACT UP group.

In terms of HIV screening, HTLV-III screening, the Yorkshire Centre started screening on 14 October 1985, the nationally agreed date, and Dr Robinson's statement indicated that:

"On that date, all of the blood that we released but also all of the FFP and cryoprecipitate that was in storage was also tested. So anything released on or after that date would have been screened. That had involved the back testing of the all stocks as well in time for the start date."

In terms of donor counselling arising from that screening, HIV positive donors were always seen by Dr Townley, the associate specialist. That's a point we picked up earlier. Dr Townley had had the AIDS counselling training from St Mary's Hospital that the Inquiry has heard about before:

"Further arrangements were made for an assessment by an appropriate specialist to take place on the same day as the initial meeting with the Yorkshire doctor, to give early access to

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And she then picks up some concern about the position of donors if the testing was not specific enough, saying that:

"The actions of donors are entirely altruistic and not for their own benefit, and there is an aspect of collateral damage when something like screening is introduced, because it will have an impact on the donors to whom, as a service, we owe a duty of care. If we introduce something that is going to have an impact on them, we [I think she's referring to the Blood Service] are their only champions, and, for example, telling a donor that they're hepatitis or HIV positive when they're not because of a failure in the sensitivity and specificity of a test is highly damaging to that individual who is receiving no benefit whatsoever from donating their blood."

That's picking up concerns about the early screening tests.

The Yorkshire Centre began evaluating the second generation Ortho testing kits with a preliminary starting date for that trial in May 1991, and so in her statement, Dr Robinson stated that because they started testing in May 1991, by the time of the national screening that was introduced in September '91, there was no stockpile of unscreened

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psychological support services."

Dr Robinson's statement added that a donor was never given their results on the phone.

In terms of screening for hepatitis C, in a response to a request from Dr Gunson about when the Yorkshire Centre could start hepatitis C screening, the Yorkshire Centre said they could commence testing at the beginning of May 1991, with a universal release of hepatitis C tested product on 1 June 1991 provided satisfactory financial arrangements were in place.

The Inquiry has heard evidence already in relation to Dr Lloyd starting hepatitis C testing early, and Dr Robinson, in a statement she provided for the hepatitis C litigation, indicated that when she heard about this, she telephoned Dr Gunson to offer support. And she expressed her strong belief that patients throughout England were entitled to receive the same standard of product, and she believed it was necessary for all centres to commence screening at the same time.

Having said that, in relation to her statement for this Inquiry, she has said that she can:

"... see with hindsight that some infections would have been prevented with earlier screening and of course I would want to have prevented this."

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blood for release.

In relation to FFP and cryoprecipitate, although the shelf life of those products she said was two years, most of their stock would have been issued and used within three months. So she says this:

"I do not believe that we had any that was unscreened by the time of introduction of screening in September 1991 because we had been screening since May 1991."

SIR BRIAN LANGSTAFF: Can you help me with this: she says, as you've just told me, that there was screening from May 1991 onwards. You've said that she had earlier indicated she would be able to start screening in May 1991 and she supported Gunson's response to Lloyd, which was that Newcastle shouldn't go it alone, and recognised in retrospect that it would have saved a few infections had screening started earlier.

She can't have been talking about Leeds and Yorkshire when she said that, can she, if she was actually testing?

MS FRASER BUTLIN: Apologies, sir. What she says in her statement is that she didn't agree -- that she agreed with the need for a nationwide start date because they were part of a national organisation. What she picks up is whether screening prior to the second

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1 generation -- whether earlier screening tests would
 2 have been used.
 3 **SIR BRIAN LANGSTAFF:** Yes.
 4 **MS FRASER BUTLIN:** And that's where she says in hindsight
 5 some infections would have been prevented but there
 6 was the question of specificity.
 7 **SIR BRIAN LANGSTAFF:** So the question then arises when she
 8 would have been in a position to start the first
 9 generation tests which would have been, presumably,
 10 quite a lot earlier.
 11 **MS FRASER BUTLIN:** That's something we don't know.
 12 **SIR BRIAN LANGSTAFF:** Yes, thank you.
 13 **MS FRASER BUTLIN:** What we do have, sir, is the question
 14 of the funding of the tests and the costs involved for
 15 Yorkshire. We have a document, we don't particularly
 16 need to go to it but I'll read in the reference,
 17 NHBT0035120, where the cost to the Yorkshire Centre of
 18 HCV testing is estimated at £478,745.
 19 In a letter in December 1991, so subsequently,
 20 Dr Robinson informed Dr Gunson that the additional
 21 costs were allocated to purchasers -- in other words
 22 hospitals -- to meet, and that the Centre was
 23 recovering the costs of anti-HCV testing, subsequent
 24 confirmatory testing and counselling of donors by
 25 including these costs in its unit price for blood,

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1 identified as hepatitis C positive was addressed by
 2 the Centre.
 3 If we then to move look-back, first of all
 4 Australia antigen look-backs. There are number of
 5 documents that indicate that when the Yorkshire Centre
 6 was informed of either a patient developing jaundice
 7 after receiving a transfusion or a plasma batch being
 8 infected, a look-back exercise was undertaken with the
 9 retesting of the donor and testing samples that were
 10 held of previous donations.
 11 In relation to HTLV-III look-back, where a donor
 12 was identified as being HTLV-III positive and had
 13 donated into a pack of plasma, Dr Tovey informed BPL,
 14 and then carried out an exercise to identify patients
 15 who'd received that batch, and Dr Robinson was also
 16 involved in later exercises seeking to identify donors
 17 and recipients.
 18 In terms of hepatitis C look-back, if we could
 19 turn to NHBT0035171, please. This a memo from
 20 Dr Flanagan to Dr Robinson on 3 December 1990, and it
 21 relates to a discussion of the Scottish proposals for
 22 donor counselling on the introduction of hepatitis C
 23 testing, which the Inquiry has looked at with previous
 24 witnesses, particularly Dr Gillon. Dr Flanagan's memo
 25 is picking up on that document, which he says is:

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1 local products.
 2 In terms of that donor counselling, Dr Robinson
 3 confirmed that she recalled Dr Flanagan and herself
 4 doing a lot of work with hepatologists in the region
 5 to make sure that they'd accept hepatitis C positive
 6 donors and that we could refer them onwards.
 7 That's also reflected in the contemporaneous
 8 documentation. On 5 June 1991, Dr Flanagan wrote
 9 a letter to all directors of Public Health Districts
 10 served by the Centre informing them of the
 11 introduction of hepatitis C screening, informing them
 12 that the costs of hepatitis C testing would be
 13 recouped through an increase in unit costs of
 14 products, and asking for a steer as to who the most
 15 appropriate person to refer positive donors was.
 16 There are also letters from a consultant in
 17 communicable diseases at the Dewsbury Health
 18 Authority, confirming that small numbers of infected
 19 donors could be referred to him, but if there was
 20 rising numbers, alternative arrangements would be
 21 needed and from the Pontefract Health Authority,
 22 agreeing that all districts should do the same thing
 23 and refer all cases to a specialist unit, in their
 24 case Professor Lisowski's unit in Leeds.
 25 So the clinical care of donors who were

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1 "... a very informative and helpful document but
 2 ... one or two problems may arise if we were to
 3 attempt to adopt it in Yorkshire."
 4 It's the second point I want to go to. Sir, I'm
 5 sure you will recall that at this point in Dr Gillon
 6 counselling of donors document, there was a look-back
 7 provision in 1990 which was subsequently not pursued
 8 but the document that Dr Flanagan is looking at has
 9 the reference to look-back being carried out. His
 10 view at that time was that the:
 11 "The feasibility of any lookback programme will
 12 be determined by the number of HCV confirmed positive
 13 donors we find. If the number is large it would be
 14 a very large undertaking for RTCs within England &
 15 Wales, more so than for Scottish centres. This will
 16 obviously require a specific answer from the National
 17 Directorate."
 18 There's no explanation given to as why it would
 19 be more difficult for England and Wales centres than
 20 Scottish.
 21 As the Inquiry has heard, look-back wasn't, in
 22 fact, instituted nationally until 1995 and, on
 23 13 January, Dr Flanagan wrote to Dr Robinson who was,
 24 by then, of course, working at the NBA, confirming his
 25 agreement with the proposed procedures to be followed

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1 in that national hepatitis C look-back exercise. He
2 noted that he considered:

3 "... the main area of difficulty relating to
4 tracing within centres will be where computer records
5 are limited and that this would be more marked with
6 longstanding donors where the quality and ease of
7 accessibility of records would likely reduce with
8 time."

9 He indicated that the speed of the process would
10 depend on the number of the donors involved, and the
11 extent of resource thrown at it.

12 Dr Flanagan became involved in the small group
13 working to establish the protocols and documentation
14 for the look-back process. He produced, together with
15 Dr Hewitt, the draft *pro forma* that would be used by
16 the Regional Transfusion Centres to document the
17 component identified as requiring tracing -- by the
18 hospital to record the tracing, and the RTC to note
19 the outcome of that tracing. They're the *pro formas*
20 we have looked at in previous hearings.

21 Thereafter, the hepatitis C look-back at the
22 Yorkshire Centre followed the same methodology as was
23 required nationally.

24 To give a sense of the scale of the look-back
25 exercise in Yorkshire, could we turn to

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1 previous untested donations; 194 donations involved in
2 look-back; giving 345 components; 237 implicated
3 components for the hospital to trace; and 31
4 implicated components where the RTC was unable to
5 trace the ultimate destination.

6 Once again, it is a little unclear how these
7 figures add up. But they are what we have in relation
8 to the look-back work in Leeds.

9 Sir, there's one topic which I didn't address
10 earlier because I was conscious of time but, if I may,
11 I'd like to go back to it. It takes it somewhat out
12 of chronology but it is a point that I think will be
13 of relevance to many Core Participants. If I can just
14 have a moment I'll just find the point in my notes.
15 Apologies.

16 Yes. Thank you, sir.

17 And it's just to pick up this issue, which was
18 the provision of commercial blood products in the
19 region. So it's tracking back somewhat, but, as
20 I say, I think it's of importance to highlight orally
21 as well as in the presentation.

22 As at 1981, Dr Tovey wrote a letter making it
23 clear that the Yorkshire Centre neither purchased,
24 stored, nor distributed commercial Factor VIII.

25 The references for that are DHSC0002209_076

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1 BTHT0000001_035. This is a letter from Dr Parapia,
2 the consultant haematologist at Bradford, to his chief
3 executive. It says:

4 "Please find enclosed copy of letter I have
5 received from Peter Flanagan, Consultant Haematologist
6 at the Blood Transfusion Service, giving instructions
7 regarding hepatitis C Lookback. There are 21
8 transfusions which were given to patients at BRI and
9 SLH during the period 1980-1991."

10 He indicates what is required of them, and:

11 "The amount of work which will be required from
12 the Transfusion Department and myself is considerable
13 and I would hope that you or Brian Naylor are able to
14 make either staffing or money available to carry out
15 the task."

16 So in relation to the Bradford Royal Infirmary
17 and the SLH it was 21 transfusions that needed to be
18 traced.

19 Then if we turn to NHBT0036923_001, we can see
20 further details on the figures.

21 If we can just zoom in to the table, this is the
22 position as at 19 May 1995, and in the column relating
23 to Leeds we can see that: 89 donors had been
24 identified as hepatitis C antibody positive since
25 starting testing; 65 hepatitis C positive donors with

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1 and _077. We don't need to go to it.

2 However, by October 1983, the advisory committee
3 on the NBTS authored a report entitled the Regional
4 Purchase of Commercial Blood Products in which it was
5 noted that in Yorkshire there had been regional
6 purchase of all blood products since 1981 and Dr Tovey
7 reported that it was working well.

8 So as at July '81, there was no purchase, but at
9 some point after that it appears that the
10 Yorkshire Centre was purchasing commercial blood
11 products.

12 If we could now turn to BAYP0000011_058, please.

13 We can see a memo from Bayer, dated
14 13 April 1988, which addresses the Koate HT lot and
15 then the number:

16 "On receipt of your memo of 21.3.88, every
17 customer who used lot 50S021 was contacted and told of
18 the possible hepatitis B transmission and asked to
19 return any product that hadn't been used."

20 And then there's a table, and we can see towards
21 the bottom:

22 "Leeds BTS ... Dr Tovey ..."

23 And 264 vials had been returned.

24 Dr Robinson in her statement said that she
25 assumed that the Centre must have held and distributed

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1 the Factor VIII products received from BPL but she
2 couldn't remember. She thought that it would solely
3 be NHS products because she never had anything to do
4 with commercial products. That appears to be at odds
5 with the other documentation.

6 What is apparent from the documentation is that
7 Dr Robinson sought to encourage the use of
8 BPL products. And if we turn to NHBT0097035_069, we
9 can see a letter from Dr Robinson to Dr Gunson, and we
10 pick up -- dated 2 March 1990. We pick up the second
11 paragraph:

12 "Within Yorkshire I have developed and am
13 continuing to progress an effective relationship
14 between District General Managers and the Blood
15 Transfusion Service. This is demonstrated by the
16 identification of a representative for each District
17 General Manager, who will work with myself in
18 controlling the demand and source of supply of all
19 blood products so that overall the Region maximises
20 its usage of cost effective product through BPL."

21 She says:

22 "I would strongly recommend that all regions be
23 encouraged to look within their organisations so as to
24 achieve the same level of control and commitment to
25 BPL products as is evident within Yorkshire."

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1 reception we'll just have to try to live with it. But
2 we're ready to start again, and you are in the same
3 position, and it's just after or on 8 o'clock in the
4 morning for you.

5 A. 8 o'clock. Yes.

6 SIR BRIAN LANGSTAFF: So thank you once again for joining
7 us again then.

8 Ms Richards.

9 **Questioned by MS RICHARDS (continued)**

10 MS RICHARDS: Dr Lloyd, can you see and hear me?

11 A. Yes, I can, thank you.

12 Q. Now yesterday we had looked at your notes from
13 that April 1985 symposium on AIDS, where you outlined
14 some of the measures that might need to be considered
15 by the Transfusion Service. Before we look at those
16 measures, just one other matter relating to a response
17 to AIDS that I wanted to ask you about.

18 In 1983/84/85 you obviously weren't based at
19 the Centre. Do you know, either from discussions with
20 Dr Collins or discussions with Dr Peter Jones or
21 through any other route, whether Dr Collins was ever
22 asked to increase the production of cryoprecipitate at
23 that time?

24 A. Right. Production of cryoprecipitate was very much on
25 a -- it's a daily decision. Although it's a frozen

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1 That is echoed in Dr Flanagan's statement, where
2 he says:

3 "My recollection is that Angela Robinson clearly
4 tried to promote the use of BPL products as opposed to
5 commercial ones."

6 So that's everything I want to address orally.

7 Of course there is a much more substantial written
8 presentation available to those who wish to deal with
9 further detail.

10 SIR BRIAN LANGSTAFF: Well, thank you very much. We'll
11 take a break, then, until 1.00, when we are due, once
12 again, to hear from Dr Lloyd in Canada.

13 MS FRASER BUTLIN: Indeed.

14 SIR BRIAN LANGSTAFF: So 1.00. Thank you.

15 (11.54 am)

(The Luncheon Adjournment)

17 (12.59 pm)

DR HUW LAURENCE LLOYD (continued)

19 SIR BRIAN LANGSTAFF: Welcome back, Dr Lloyd. You can
20 hear me?

21 A. I can, thank you. Good afternoon.

22 SIR BRIAN LANGSTAFF: Good. And you can see me, I hope?

23 A. I can.

24 SIR BRIAN LANGSTAFF: Good. Well, that's a good start.

25 I hope we continue. If we have further patchy

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1 product, you can store it, so you look at how much you
2 have in your store, and you decide whether or not to
3 produce more. You don't necessarily produce it every
4 day. You would hopefully -- you would tend to do
5 a run, particularly in the old centre, where the
6 production was in a different building. But there was
7 no -- there's no problem in producing more
8 cryoprecipitate, it's not a difficult thing to do.
9 Once you're set up to produce it, you know, you can
10 turn the tap on. You can say: today, instead of
11 making just plain FFP for clinical use, fresh frozen
12 plasma for clinical use, we'll make cryoprecipitate.
13 And so you can do a run of another hundred that day if
14 you so wish.

15 So as far as I'm aware, we never -- we just
16 produced, the Centre -- in Anne Collins' day, the
17 Centre just produced enough cryoprecipitate to be sure
18 that there was product on the shelf for when it was
19 requested.

20 So if we were asked for more, then yes, we would
21 produce more. It wasn't a big issue.

22 Q. But as far as you know, and it may be you simply don't
23 know, was a request -- any particular request for more
24 as a response to the threat of AIDS in that early
25 period, do you know whether that was ever made to

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1 Dr Collins?

2 A. I don't recall her ever saying that she had received

3 a specific request. We've seen some of my data that

4 shows that the amount of cryoprecipitate going to

5 the RBI and therefore the Haemophilia Centre was

6 actually going down a little bit. But they could have

7 requested more. We obviously had the product.

8 Q. Thank you.

9 Now I want to move, then, to the donor leaflets

10 introduced in 1983. Again, I'm very conscious that

11 you were not in post at the Centre at that point in

12 time, but I'm going to ask you to look at a couple of

13 documents in any event.

14 If we start with NHBT0020668.

15 So, Dr Lloyd, this was a letter sent by

16 Dr Wagstaff from Sheffield, 6 July 1983, to his

17 Regional Transfusion Director colleagues, enclosing,

18 over the page, what was intended to be the final

19 version of the AIDS leaflet for national use.

20 A. Yes.

21 Q. Again, I'm not going to go through the detail of the

22 leaflet.

23 Now, that was early July 1983. The Inquiry

24 knows from other evidence that the Department of

25 Health became involved and the final leaflet was only

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1 Committee on the National Blood Transfusion Service,

2 "AIDS leaflet - First six months experience".

3 A. Yes.

4 Q. And we just need to look at the entry for Newcastle at

5 the top of the page:

6 "Distribution Method

7 "With call-up cards

8 "Displayed on industrial sessions. Issued to

9 Citizens Advice Bureaux STD Clinics

10 "No. used 110,000,

11 "Stock 3,000"

12 Then we have:

13 "Donor Response, Effect on Attendance

14 "Nil. 2 or 3 resigned because of homosexual

15 relationships"

16 Then:

17 "Other Comments

18 "One donor [I think that should be] [thought] he

19 could contract AIDS from donation. "Who is at Risk?"

20 (final ..."

21 That might be "paragraph" or "part".

22 A. Paragraph.

23 Q. "... may be read as 'if you get jaundice you may [get]

24 AIDS'. Majority don't know what Hepatitis B is."

25 So we can see there, I think -- please let me

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1 issued at the beginning of September.

2 And we'll just look briefly at that for the

3 benefit, really, of those watching. BPLL0007247.

4 There we have the national leaflet from

5 September 1983.

6 Do you know, either from your later involvement

7 or, again, from conversations with Dr Collins, whether

8 in Newcastle any earlier leaflet of Newcastle's own

9 devising was introduced, or whether Newcastle waited

10 for the national leaflet?

11 A. Sorry, I've lost you: "or whether Newcastle was ..."?

12 Q. Whether Newcastle introduced, as some centres did,

13 their own earlier leaflet or whether Newcastle waited

14 for this national leaflet to become available in

15 September?

16 A. I'm certainly not aware that we issued anything

17 earlier. I can't say we didn't, but I personally am

18 not aware of it.

19 Q. And then I'm again going to ask you to look at

20 a document you wouldn't have seen at the time but it

21 gives us some information about the method of

22 distribution of the leaflet deployed at Newcastle.

23 A. Mm-hm.

24 Q. CBLA 0001820, please.

25 This was a table compiled for the Advisory

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1 know if this is your understanding, Dr Lloyd, three

2 methods of distribution there described.

3 In terms of the general public it would appear

4 that the leaflet was being sent out with the call-up

5 cards, so donors could take a decision in advance

6 about not attending.

7 A. Mm-hm. Yes.

8 Q. And then in relation to the industrial sessions, where

9 presumably the Centre wouldn't know who individually

10 would be attending, it was on display.

11 And then Newcastle then took a further step,

12 which is to provide the leaflet to local Citizens

13 Advice Bureaux and STD clinics. Was that still --

14 A. Mm-hm.

15 Q. -- the system of distribution with later versions of

16 the leaflet when you came back to the Centre full

17 time?

18 A. Yes, we sent out AIDS leaflets when they were changed,

19 so they went out with the call-up cards. They were

20 more like little cards than letters in the earlier

21 days. But yes, we sent out a new -- new versions as

22 they became available, so we would do a new

23 distribution, but we still had the issue that at

24 industrial sessions, you -- we didn't individually

25 call up, the call-up was done within the factory or

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1 office complex. So then it was a matter of just
 2 displaying it at the clinic, which is not as good
 3 a situation as providing it in advance, I have to say.
 4 So yes, we continued to do this.

5 **Q.** Now, we've -- the Inquiry has heard evidence from
 6 the North London Regional Transfusion Centre about
 7 an additional measure which they introduced, which was
 8 the completion of a confidential exclusion
 9 questionnaire which enabled the donor to, as it were,
 10 save face, potentially, by ticking a box which meant
 11 that their donation might be used, for example, for
 12 research, rather than for transfusion. Do you know
 13 whether a system like that was ever in operation in
 14 the Northern Region?

15 **A.** Now, the confidential exclusion certainly rings a bell
 16 with me and I'm not sure now whether I'm just
 17 remembering what North London did or whether it was
 18 what we did. It is familiar but, again, I couldn't
 19 tell you definitively that that's what we had on the
 20 session, I'm sorry.

21 **Q.** If we then move forward to the point in time or
 22 a point in time at which you're at the Centre, if we
 23 go to NHBT0118280, please. So this is a memo from
 24 you, Dr Lloyd, dated 22 January 1987 to the sessional
 25 medical officers and the Regional Transfusion Centre

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1 detail, but every care must be taken not to offend
 2 donors. If the donor is suitable to donate, he or she
 3 should be shown back to the Clerk.

4 "Donors who are not suitable to donate should be
 5 offered further advice through an MO at the RTC."

6 Then if we just read paragraph (c):
 7 "Donors who are in any AIDS risk group must not
 8 be bled. Where there is any doubt about the risk they
 9 should not be bled, but in either case, the potential
 10 donor should be sympathetically dealt with and
 11 arrangements made for an MO from the Centre to contact
 12 them, especially where doubt exists. Some donors may
 13 not wish any further contact, and this should be
 14 respected. A note giving details MUST be sent to
 15 an MO at the Centre in a sealed envelope."

16 Now, obviously this memo has been prompted by
 17 the specific issue of questions about visits to Africa
 18 but if we can just go back and look at paragraph (b),
 19 please, Sully, thank you.

20 You're here emphasising that the medical officer
 21 must ensure that the donor has read and understood the
 22 AIDS leaflet or the AIDS poster; was that something --
 23 a new requirement that you were introducing at this is
 24 point in time or were you emphasising that which the
 25 MO should have been doing, in any event?

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1 medical officers?

2 **A.** Mm.

3 **Q.** The subject is "AIDS: Risk Groups in Africa and Donor
 4 Rejections", and then we can see the background from
 5 paragraph (a), because the leaflet now identifies
 6 certain risk groups in relation to Africa. I just
 7 wanted to ask you about (b), the arrangements at the
 8 sessions. It says here:
 9 "The arrangements at sessions should be as
 10 follows:
 11 "The Session Clerk will ask donors whether they
 12 have been in Africa and, if so, where in Africa and
 13 when. If the donor has been in the relevant area
 14 since 1978, then further questioning will be required.
 15 The Clerk will then take the donor to see the Session
 16 MO.
 17 "The Session MO will discuss the matter further,
 18 in confidence. It may be difficult to ask donors
 19 about their sexual activities in the rather public
 20 circumstances of a blood donor session. The MO must,
 21 however, ensure that the donor has read and understood
 22 the AIDS leaflet [and we can see the version there was
 23 September '86] or the AIDS poster."

24 **A.** Mm-hm.

25 **Q.** "It may be necessary to explain the risk group in more

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1 **A.** Goodness. Um ... trying to recall. Reading, you
 2 know, what I wrote, it doesn't look to me like I'm
 3 introducing something new. I'm just reinforcing
 4 an existing situation because of the -- particularly
 5 emphasising the change in risk areas, and I am not
 6 sure if they'd all been included in the new AIDS
 7 leaflet at that particular moment. I think there was
 8 some delay between recognising larger risk areas and
 9 actually getting that information into leaflets.

10 So, as far as I can see from the way I've
 11 written this, I'm just emphasising, you know, what
 12 we're already doing.

13 **Q.** We can take that down, thank you, Sully.

14 Can I then move and deal very briefly with the
 15 question of the introduction of screening or testing
 16 for HTLV-III or HIV, which was in October --

17 **A.** I'm sorry, I lost you then.

18 **Q.** Can you hear me again now?

19 **A.** I lost you again -- could you say -- yes, if you start
 20 that question again.

21 **Q.** Of course. I'm going to ask you very briefly about
 22 the introduction of HIV screening at the Centre. My
 23 understanding from the documents and from your
 24 statement is that you had no involvement, either in
 25 the decision making regarding HTLV-III screening or in

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1 its introduction at the Centre; is that right?
 2 **A.** Yes, that's correct.
 3 **MS RICHARDS:** Sir, I'm just going to show, for the sake of
 4 completeness, one document. It is not a document
 5 Dr Lloyd has seen and I'm not actually asking Dr Lloyd
 6 anything about it. It's just for the benefit of those
 7 watching and listening, DHSC0101735.
 8 Oh, you don't have it. In that case, I'll come
 9 back to it later.
 10 For the benefit of the transcript, it's a letter
 11 from Dr Collins to Dr Smithies in late 1985 and it
 12 sets out what arrangements had been made in terms of
 13 ensuring that hospitals did not use untested stocks.
 14 So the reference is on the transcript for the benefit
 15 of anyone who wants to consider that letter and, if
 16 I get a chance to display it later, I will.
 17 **Q.** Before I leave the issue of AIDS, Dr Lloyd, and come
 18 on to ask you about hepatitis C screening, I just
 19 wanted to ask you about investigation of cases of
 20 transfusion-transmitted or possible
 21 transfusion-transmitted HIV. I'll do that by
 22 reference to a document you've seen and talked about
 23 in your statement. It's at DHSC0020840_041.
 24 You can see, Dr Lloyd, this is a letter from you
 25 to Dr Rejman at the Department of Health --

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1 was HIV Positive. On the other hand there is no
 2 evidence to suggest that the individual is
 3 infectious."
 4 Then you refer to information relating to the
 5 individual's husband, who had been a donor, and the
 6 donation had been tested and was HIV negative.
 7 If we go over the page, we can see this was your
 8 report from, I think, 1986 where you set out the
 9 donation history of the individual and then, as
 10 I understand it, the investigations that were then
 11 made in relation to those two donors. If we look at
 12 the bottom of the page, we can see in relation to the
 13 second donor, who had donated at a time when no HIV
 14 testing was available, you record that:
 15 "The donor has left the factory at which the
 16 donations were made and has not replied to call-up
 17 requests made in 1984 and 1985. One further request
 18 to attend a donor session is being made ..."
 19 Then you go on to set out over the following
 20 pages -- I don't think we need to go through them --
 21 follow up of various other donations.
 22 **A.** Yes.
 23 **Q.** Do you recall whether this was the only such
 24 investigation which you carried out or were there
 25 others?

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1 **A.** Yes.
 2 **Q.** -- October 1992, and it concerned the Department of
 3 Health's scheme of payments for those infected with
 4 HIV through blood or tissue transfer. You refer to
 5 a file relating to the transfusion of a particular
 6 individual and, obviously, we're not going to mention
 7 that individual by name.
 8 **A.** Yes.
 9 **Q.** If I just read the first paragraph:
 10 "No new information has come to light since the
 11 original investigation. I enclose for your
 12 information a copy of the report I wrote in 1986 which
 13 identifies the donations originally transfused to
 14 [her] and the related investigations. One of the two
 15 units transfused to [her] came from a donor who
 16 subsequently donated and was found to be HIV Negative.
 17 The other donation came from a donor who left our area
 18 and to the best of our knowledge transferred into the
 19 West Midlands. At the time the Transfusion Centre
 20 based at Birmingham had no record of this donor
 21 donating and I have again checked with the Donor
 22 Service Department at the Birmingham Transfusion
 23 Centre and they still have no record of this
 24 individual donating. Therefore this leaves the
 25 possibility that this donation came from a donor who

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1 **A.** I don't recall any others. You know, the Northern
 2 Region didn't -- you know, had a very low incidence of
 3 HIV positivity amongst blood donors. I think we're
 4 talking perhaps about one in a year. So, on that
 5 basis, the chances of a donation which was infectious
 6 for HIV but was negative by test is presumably less
 7 than one per year. So it's not a common thing in the
 8 region and, therefore, I can understand that we, you
 9 know, you're not going to have had many investigations
 10 because there were very few infectious units at that
 11 time.
 12 So it doesn't surprise me that that's the only
 13 one I recall.
 14 **Q.** Would we be right to understand this case may
 15 illustrate the limitations of the investigations which
 16 you were able to undertake because, in relation to the
 17 second donor, whose donation may have been the
 18 infectious donation, you had no samples post the
 19 availability of testing and you were unable to track
 20 that donor once they'd left the area?
 21 **A.** Yes, we wouldn't have kept -- we didn't keep samples
 22 for later testing. And I think the donations, if
 23 I recall from what I just saw, were from 1982.
 24 **Q.** Yes.
 25 **A.** So, no, we certainly didn't keep samples. We weren't

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1 testing for HIV in 1982. And as you've said, we
2 had -- there were definite limitations on how we
3 further explored the possibility of that individual
4 being HIV positive.

5 Looking back on it, I'm not really sure that
6 they were. It would have been a very -- pretty
7 unusual for 1982 in the region. Not unknown,
8 certainly not, but we didn't -- as you saw, we only
9 followed up to the one transfusion centre in the West
10 Midlands that we thought the person might have
11 transferred to. We could, and perhaps should, have
12 circulated all the transfusion centres, both in the
13 UK -- in England and Wales and in Scotland. I don't
14 think there was -- there certainly wasn't a system for
15 doing it, but when you look back you say: well, yes,
16 maybe we -- (a) we should have done more, and (b), you
17 know, maybe there should have been a more formal
18 system that would have made it easier to do this.

19 **Q.** Then if I just ask you to look at a reply from
20 Dr Rejman to you.

21 DHSC0020840_031.

22 So this is a response to you, 4 November 1992,
23 and Dr Rejman sets out in the second paragraph:

24 "It would appear that the donor who failed to
25 re-attend may be the cause of the HIV infection."

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1 drive to understand -- to find people -- find out how
2 people had been infected through transfusion, that
3 information would have had to have come back in some
4 way, and I never had any -- I don't recall any further
5 follow-up on this.

6 **MS RICHARDS:** Sir, I should say we do have the Department
7 of Health files in relation to this application, and
8 it may be something we pick up in future hearings
9 relating to transfusion practice. There is nothing to
10 suggest any further information coming Dr Lloyd's way
11 from those files.

12 I'm going to move, then, to the question of
13 surrogate testing, first of all. So surrogate testing
14 for non-A, non-B hepatitis.

15 You told us yesterday you thought that probably
16 ALT testing should have been introduced. I'm just
17 going to ask you to look with me at a passage in your
18 statement and then just ask you a couple of further
19 questions in relation to that.

20 **A.** Mm-hm.

21 **Q.** So WITN6935001, please, Sully. Dr Lloyd's witness
22 statement's. And if we go to page 83.

23 So picking it up at the bottom of the page,
24 there's a heading "Surrogate testing for NANB", and
25 you say this in your final paragraph on that page:

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1 Then he goes on to set out a protocol agreed
2 with CDSC, and in the last paragraph he explains:

3 "We therefore agreed the following procedure, in
4 an effort to minimise the risk of any breach of
5 confidentiality concerning the donor."

6 And then we can see -- it essentially involves
7 contact being made with CDSC and then CDSC would
8 notify the Department but wouldn't notify the Regional
9 Transfusion Centre. We see that over the top of the
10 page.

11 **A.** Yes, yes.

12 **Q.** Do you know whether anything further was done in that
13 regard?

14 **A.** As far as I know, this donor did not come up on the
15 panel, on the CDSC. I think Dr Rejman would have let
16 us -- would have let me know, so I had no further
17 follow-up from this. I'm not quite sure how the
18 Department planned to deal with the information,
19 should it, you know, come to their attention. If CDSC
20 found that this person had been reported to them or
21 they had information that this person was HIV
22 positive, they were obviously prepared to send this
23 information in confidence to the Department, who
24 presumably would have some method of dealing with it.

25 And given that there was, you know, a definite

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1 "I did consider that surrogate testing might
2 have reduced risk, but the use of surrogate testing is
3 difficult in that there was no clear link between test
4 results and infectivity. I was not opposed to
5 additional testing but it was not being put forward
6 for use in the UK and I acquiesced in this decision
7 given the weight of expertise in the Transfusion
8 Service on the topic."

9 And then the top of the next page, you say:

10 "To decide not to introduce surrogate testing
11 given the information on the reduction in non-A, non-B
12 hepatitis in recipients was from my limited
13 perspective a decision not to apply a 'maximum safety'
14 ethos. I think that a substantive trial in the UK
15 would have provided a better basis on which to make
16 a decision. Data from other countries did not
17 necessarily apply in the UK and from what I have seen,
18 US data was also not current in terms of donor
19 screening and also due to the different blood
20 collection arrangements in the US.

21 "This was not a simple decision to make."

22 We have therefore that -- we have your evidence
23 yesterday, Dr Lloyd, that you think probably ALT
24 testing should have been introduced. The other form
25 of surrogate -- the surrogate marker potentially in

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1 relation to non-A, non-B hepatitis would be the
 2 anti-HBc testing. I'll come back to the later
 3 question of anti-HBc testing in relation to
 4 hepatitis B in the 1990s.

5 A. Yeah.

6 Q. But in relation to anti-HBc testing either on its own
 7 or combined with ALT testing as a surrogate marker for
 8 non-A, non-B hepatitis, do you have any views on
 9 whether that could or should have been introduced at
 10 some point in the 80s?

11 A. That, yeah, that's a difficult -- we know from studies
 12 that there was an overlap between those two tests,
 13 that they weren't defining the same range -- the same
 14 infectious nature of the donations. I didn't put that
 15 very well.

16 So you've got two tests, neither of which
 17 specifically identifies what became hepatitis C, but
 18 both do pick up some of it and they pick up different
 19 sort of spectrums of it. From what I read, ALT was
 20 probably more effective in doing that.

21 Oh dear, we've just lost -- I'm sorry, something
 22 has happened at this end.

23 Q. We can still see and hear you, Dr Lloyd. Can you see
 24 and hear --

25 A. You can?

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1 "Sheffield Medical School -- Thursday
 2 6th July 1989."

3 We don't need to go to the last page but your
 4 name is at the bottom of that document with that date
 5 of 6 July. So do we understand this is a lecture you
 6 attended and took notes of and this is your typed up
 7 copy of your notes?

8 A. Yes, yes. It's my writing in the top right-hand
 9 corner showing that I wanted to file it and, yes,
 10 these are the notes that I made.

11 Q. If we go over the page, we can see that there's
 12 a heading "Correlation with the Surrogate Markers for
 13 [non-A, non-B hepatitis]". I'm not proposing to go to
 14 that, but just note that that's there.

15 Then if we go to the third page, bottom of the
 16 page, there's a section on costs.

17 A. Mm-hm.

18 Q. You refer to the costs per sample for the kit and say:
 19 "It looks likely that this test will soon be
 20 required in the UK. The cost of testing will be in
 21 the order of £200,000 -- £230,000 [per annum]. We
 22 will lose about 600 donors from our present panel and
 23 will have to destroy at least 600 donations in the
 24 first year. The cost of this will be around
 25 £4,000-£5,000 to replace the lost donors and

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1 Q. Yes.

2 A. But I've lost my screen completely. Ah, we're back,
 3 I'm sorry. I think an auto switch-off occurred.

4 Q. Don't worry.

5 A. So, yes, we have this, sort of -- what I thought was
 6 that the ALT test was probably the more effective.
 7 Yes, you get a better coverage if you put the two
 8 together, but, you know, at the time, there seemed to
 9 be a fairly strong view that we shouldn't introduce
 10 it. I should have stood up and said we should.

11 Q. Well, we'll move next to the topic where you did stand
 12 up and say that you should, and that's the question of
 13 hepatitis C screening, Dr Lloyd.

14 Now, there's quite a number of documents I want
 15 to look at with you on this issue. We'll go through
 16 them in a largely chronological order. I'm going to
 17 ask you some questions about the various documents and
 18 your statement, and then some general questions woven
 19 in about this issue of screening for hepatitis C.

20 So I'm going to start with WITN6935032. So this
 21 is headed:

22 "The Chiron Corporation Test for Non-A, Non-B
 23 Hepatitis

24 "Lecture by Dr Michael Houghton of the Chiron
 25 Corporation

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1 £15,000-£20,000 for the destroyed donations, together
 2 with the additional clerical costs and medical costs
 3 of dealing with these 600 extremely anxious donors.
 4 An additional Medical Session may be required during
 5 the first year or two to deal with these donors.
 6 These donors will need to be referred to Specialists
 7 in the liver disease, which in turn will have
 8 considerable cost implications. The total cost to the
 9 BTS in the first year will be between £219,000 and
 10 £255,000 on a very crude costing."

11 Pausing there, that presumably is not part of
 12 the lecture. These are your own thoughts about what
 13 it's going to cost --

14 A. Yes, yes.

15 Q. -- and these are costs to the --

16 A. Yes, in Newcastle.

17 Q. -- northern Region --

18 A. Yes, this is -- this was me looking at what I'd seen
 19 and heard at the meeting and trying to translate it
 20 into what it was going to mean for our Centre.

21 Q. Were there other Regional Transfusion Directors at
 22 this lecture or meeting, as far as you can recall?
 23 You may have no memory at all of it.

24 A. I can't, no, I can't. I can't recall, no, I'm sorry.

25 Q. If we go over the page, we've got the "Summary":

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1 "A non-A, non-B Hepatitis ... has been
2 characterised and termed Hepatitis C virus."

3 Then I don't propose to read out the rest of
4 that paragraph.

5 If we go to the third paragraph, you say this:

6 "The impact on our donor base will be moderate
7 but not catastrophic, assuming that the 0.5%
8 positivity level is confirmed. We will lose and have
9 to replace 600 donors. There will be costs and
10 operational problems associated with identifying them
11 as HCV positive and they will have to be referred to
12 Consultants specialising in liver work."

13 Then the last sentence has your cost -- your
14 estimated cost to the Northern Region of the BTS --

15 A. Mm-hm.

16 Q. -- for the first year. So it looks from this as
17 though, as at July 1989, you were effectively planning
18 ahead, both in terms of what kind of funding might
19 need to be put in place, and what might need to be
20 done to ensure that there wasn't a significant loss of
21 donors without them being replaced; is that fair?

22 A. Yes, I think that's fair. I mean, I think the fact
23 that I could -- you know, it's going to be difficult
24 but it was certainly no way impossible, 600 donor
25 loss, and I think I mentioned it yesterday, that's not

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1 Then you go on, having introduced non-A, non-B
2 hepatitis to Mr Garland, to refer to the test. If we
3 look at the fourth paragraph, you say:

4 "Now that this test is available I suspect that
5 pressure will mount fairly rapidly for this test to be
6 introduced in this country. Previously, I had
7 expected that something as major as this which would
8 have to be introduced in all Transfusion Services in
9 the UK would be funded by the Department. However,
10 Dr Gunson has suggested to me that this will not be
11 the case and that Regions will be expected to fund
12 this new development themselves."

13 Now, that would indicate that you had had some
14 discussion with Dr Gunson on the issue of introducing
15 the tests and how they might be funded. Do you have
16 any further recollection of the discussions at that
17 point in time?

18 A. There is a letter that -- I think from a perhaps
19 a month later, in which Dr Gunson refers to the
20 Department not funding -- or that regions would have
21 to fund themselves. So there is some documentation,
22 it comes after this letter. So I don't recall the
23 exact discussions I had with Dr Gunson, whether that
24 was at a meeting or whether it was by phone.

25 Given the short interval between the meeting

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1 a lot of donors lost, compared to some of the problems
2 we had when a lot of our industry closed down.

3 Q. Then if we look at NHBT0000188_008. This is a letter
4 from you, 20 July 1989, so a couple of weeks after
5 you've attended --

6 A. Yes.

7 Q. -- that meeting, to the director of management
8 services at the Northern Regional Health Authority,
9 headed "Non-A Non-B Hepatitis". You say this in the
10 first paragraph:

11 "The problem of Non-A Non-B Hepatitis has been
12 with us for many years. This disease is transmissible
13 by blood but no test has been available to screen out
14 infected blood donors. Most people who have Non-A
15 Non-B Hepatitis, and continue to carry the virus, are
16 asymptomatic although a very small proportion of
17 people go on to get cirrhosis of the liver. The
18 effects of transfusion transmitted Non-A Non-B
19 Hepatitis vary from nil through a minor illness with
20 no jaundice to a moderately severe illness with
21 jaundice, with a small proportion of people going on
22 to become long-term carriers of the virus. It is
23 these people who get long-term carriage of the virus
24 who run the risk of getting cirrhosis of the liver,
25 and possibly even hepatic carcinoma."

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1 I attended in Sheffield and writing this, it was
2 probably something that was a phone call but, no,
3 I can't recall the details of it.

4 Q. Then if we go over the page, we can see you set out in
5 the first paragraph costs and some of the implications
6 in terms of loss of donors and loss of donations and
7 what would need to be done, and then the next
8 paragraph you give not a detailed estimate but
9 an estimate of the total figure in the first year and
10 then it would fall after the first year. Then you
11 say:

12 "At the moment there is nothing to be done about
13 this but I felt it was worth highlighting this
14 situation, as we do not know at what stage we might be
15 instructed to introduce this new test. At the present
16 time the virus detected by this test has been
17 designated as Hepatitis C virus."

18 A. Mm-hm.

19 Q. So what was it that prompted you to make this
20 relatively early contact with your Regional Health
21 Authority, and what then happened in terms of your
22 dialogue with the Health Authority?

23 A. Well, the fact that we -- this was quite a big, you
24 know, step to undertake. In the overall terms of the
25 NHS, you know, £250,000 seems nothing but, within our

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1 budget, it was significant. So I needed the RHA to be
 2 aware that -- you know, people don't like being
 3 surprised. You don't want someone to phone you up and
 4 say, "Oh, we're starting the test tomorrow, by the
 5 way, and we need £250,000". So you want to start the
 6 dialogue as early as possible and then they have time
 7 to ask questions and they have time to adjust their
 8 funding model for the next year.

9 So, you know, you asked me about my relationship
 10 with the RHA before. It was a reasonable
 11 relationship. And, you know, there was backwards and
 12 forwards and I didn't want to cause them a problem and
 13 this was just part of the process of getting this
 14 whole thing rolling so that they weren't blindsided by
 15 it.

16 Q. And we don't, I think, have the details of your
 17 further discussions with the Health Authority in
 18 documentary form, but you tell us in your statement
 19 you kept the Regional Health Authority informed as
 20 time went on, and the result, as I understand it, was
 21 that when we get to 1991, and we'll look at what
 22 happened in between in a moment but when you got to
 23 1991, you had the agreement of the Regional Health
 24 Authority for funds to be used to introduce testing;
 25 in broad terms, that's correct?

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1 Q. And of course --

2 A. And it wasn't transmitted by -- sorry, I was going to
 3 say, as far as I recall, Dr Gunson wasn't relaying the
 4 detail. And I think in a conversation with John Cash,
 5 I think, you know, he intimates that he can't actually
 6 pass some of this information on, it's not for
 7 publication and therefore presumably not for other
 8 distribution.

9 Q. And even though you wouldn't have seen it at the time,
 10 just to complete looking at this document,
 11 the discussion of the testing starts on page 4.

12 Yes, NHBT0005043. And if we go now to page 4.

13 I won't read it all out but we see paragraph 23
 14 is Dr Gunson talking about a paper that had been
 15 prepared and referring to a meeting that had taken
 16 place in Rome.

17 A. Yes.

18 Q. There's then, at paragraph 25, Dr Tedder giving the
 19 committee a summary of the history of the test.

20 26:

21 "Dr Metters explained that although the
 22 Department must bear in mind the possible litigation
 23 that could rise from a prolonged delay in the
 24 introduction of general screening, the NHS Management
 25 Executive would want to know more facts and figures

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1 A. Yes, that's correct. Yes.

2 Q. Now if we just then, however, go back to 1989, I just
 3 want to pick matters up in November 1989, with
 4 NHBT0005043.

5 Now, these are the minutes of a meeting of the
 6 Advisory Committee on the Virological Safety of Blood,
 7 6 November 1989. You weren't, of course, on this
 8 committee, and I think we see obviously that it was
 9 chaired by Dr Metters, who was Deputy Chief Medical
 10 Officer, and in terms of representing the Transfusion
 11 Service, it had Dr Gunson amongst its members.

12 We know from other material, Dr Lloyd, that
 13 the minutes of the Advisory Committee on the
 14 Virological Safety of Blood were intended to be
 15 confidential.

16 A. Yes.

17 Q. And as I understand it, your and your colleagues in
 18 the regional Transfusion Service did not at the time
 19 see these documents; is that correct?

20 A. Oh yes, absolutely. I think I said in my witness
 21 statement, if I had seen some of this or known some of
 22 this, I might have taken a somewhat stronger line.
 23 I didn't know that -- what was being discussed,
 24 particularly this early -- relatively early,
 25 November 1989.

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1 before backing such a move."

2 Dr Gunson then provides some more information
 3 based upon the North London Transfusion Centre's
 4 experience.

5 Then if we go to the next page, paragraph 28:

6 "The feeling of the Committee, as summed up by
 7 the Chairman, was that the test represented a major
 8 step forward, but that the Committee need to know
 9 a great deal more about it and acknowledge the need
 10 for a confirmatory test. It was agreed that while the
 11 UK would not want to go on in advance of an FDA
 12 decision, it could prove difficult if the FDA do not
 13 decide in favour of the test."

14 So that's the position as at November of 1989.

15 Now --

16 A. Yes.

17 Q. I don't know whether, from your subsequent involvement
 18 in this issue, you have any particular observations or
 19 comments upon the stance being taken by the ACVSB as
 20 at November 1989?

21 A. It's the sort of -- a little bit of the beginning
 22 of -- of the almost a dance around the issue of the
 23 test. There's no confirmatory test we hear -- we see
 24 in this -- being put forward. Well, the FDA, you
 25 know, are they, are they not going to approve it?

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1 It's -- at this stage, this particular document seems
 2 a little bit unclear. Although they're saying, "Yes,
 3 we should test", then they're saying, "Well, maybe
 4 there's issues, and maybe we don't want to do it just
 5 yet, or at all."
 6 **Q.** Now that's November 1989, and we'll be exploring,
 7 Dr Lloyd, with other witnesses or through other
 8 witnesses I hope some of the events, particularly from
 9 a Department perspective, through into 1990.
 10 I want to pick things up in the middle of 1990.
 11
 12 July of 1990 -- I don't, I'm afraid, have the
 13 document to display but I'll read the reference for
 14 the benefit of those listening, PRSE0000976 -- is
 15 a further meeting of the Advisory Committee on the
 16 Virological Safety of Blood, in which they recommend
 17 that there should be an evaluation of the two
 18 commercial kits that were then available, Ortho and
 19 Abbott, to be done in three centres: Glasgow, North
 20 London and Newcastle.
 21 So if we then pick things up with a letter
 22 copied to you in August 1990, NHBT0000061_180. We can
 23 see 30 August 1990, if we just look at the whole
 24 letter please, it's from Dr Gunson to Dr Rejman and we
 25 can see at the bottom it says, "Same letter to" and

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1 Dr Rejman. We've got the report itself at
 2 NHBT0000190_030, if we just look briefly at that.
 3 Yes, NHBT0000190_030. So "Comparison of
 4 Anti-HCV Tests using Abbott and Ortho Test Kits
 5 (A Multi-Centre Trial) Summary are Results of Phase I
 6 of the Trial", and this is authored by Dr Gunson,
 7 29 October.
 8 I'm not going to go through the detail of it.
 9 If we look over the page, however, we can see this is
 10 the study comparing the results of using the two
 11 different kits, the Abbott and the Ortho kits,
 12 involving Glasgow, yourself and north London.
 13 **A.** Yes.
 14 **Q.** We can see, if we go to page 3, paragraph 1.7:
 15 "All three RTCs reported that the tests were
 16 easy to perform and that the manufacturer's
 17 instructions were 'user-friendly'.
 18 There are then some specific comments made by
 19 yourself and the various -- and the other two centres
 20 but I'm not going to take up time looking at those
 21 specific comments.
 22 What did you understand the purpose of this
 23 comparative evaluation to be and for whose benefit it
 24 was being carried out?
 25 **A.** This seem to be to me to be a way of ensuring that

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1 then it's listed Dr Mitchell, Dr Lloyd (yourself),
 2 Dr Barbara and others.
 3 **A.** Yes.
 4 **Q.** Then we can see Dr Gunson says he hopes this is:
 5 "... the final draft of the proposals for the
 6 proposed study comparing anti-HCV testing using Ortho
 7 and Abbott test systems."
 8 Now, there had been some other studies and
 9 evaluations going on in the intervening period in
 10 which, I think, Newcastle was not involved, but can
 11 you recall how you came to be involved in this
 12 proposed comparison of the two tests?
 13 **A.** I'm not quite sure why we were. It may well have been
 14 that they wanted couple of centres or they wanted
 15 a centre that was comfortable using the Abbott test
 16 and the Abbott test equipment. We were certainly in
 17 a position to do it. And I think Ruthven Mitchell and
 18 I think the Glasgow Centre -- I'm not sure if they
 19 were using it as well, but certainly we were using the
 20 Abbott system, quite happy to participate. But
 21 I don't recall why we were approached, specifically.
 22 **Q.** If we look at NHBT0000042_045. So this is now
 23 a couple of months later, and Dr Gunson is sending
 24 a report on Phase I of this trial, which I think is
 25 how this particular evaluation was characterised, to

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1 both tests were suitable for use. It didn't -- we
 2 know that different centres in the UK used different
 3 test methods, different, you know, kits from different
 4 companies, and were used to using things in different
 5 ways. So you need to know that -- (a) that both tests
 6 are usable, that they're not completely terrible to
 7 use.
 8 I think we saw in some later tests that one of
 9 the test kits presented for comparison -- actually, it
 10 might have been for HIV -- you know, one of the test
 11 kits was actually quite difficult to use and difficult
 12 to get consistent results. So here we have a trial.
 13 It shows that both test kits are usable, within the
 14 transfusion centre setting, and they give comparable
 15 results. As one would expect, they're not perfectly
 16 the same but substantially the same.
 17 So it gave me quite a lot of confidence that,
 18 you know, we had something we could do, we could use
 19 this ...[frozen screen]...
 20 **Q.** Now, we know -- sorry, you froze for a moment then,
 21 Dr Lloyd, which is why I paused.
 22 **A.** Yeah.
 23 **Q.** We know that by this time -- this is August 1990, when
 24 the study protocol, as it were, is being drawn up, and
 25 then October 1990, when it's being concluded -- we

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1 know that there were a number of other countries which
2 had already introduced hepatitis C screening by this
3 point in time, I think Japan in November 1989 and then
4 a number of other countries throughout 1990.

5 A. Mm-hm.

6 Q. Do you recall whether you were aware of that at the
7 time or whether there was any discussion amongst
8 Regional Transfusion Directors about the fact that the
9 UK was arguably lagging behind other developed
10 nations?

11 A. I don't recall specific discussions. You know, one of
12 the problems we've seen and discussed with the
13 National Directorate splitting up the transfusion
14 centre directors into these divisional groups, we
15 didn't have a single forum where everyone could get
16 together. So whereas quite a lot of work on
17 virological matters was done from the North London
18 Centre, there wasn't that emphasis from the centres
19 that happen to be in the northern division. So we
20 were divorced from a lot of this discussion. So --
21 and of course we didn't have anyone from the
22 Department who might have brought perspective to bear.

23 So no, we didn't have a lot of discussion.
24 Certainly aware that this test is being used. I mean,
25 you know, I knew that at the time. There's no doubt

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1 supply."

2 Now, I think one of the observations you've made
3 in your witness statement, Dr Lloyd, as I understand
4 it, is that had you known this, that this was the view
5 of the committee at this point in time, it might have
6 made you want to start testing earlier than you did,
7 recognising that you were still earlier than everyone
8 else.

9 A. Absolutely.

10 Q. But this message was never conveyed to you --

11 A. -- absolutely.

12 Q. -- is that right?

13 A. I never saw this, never heard this.

14 And looking back now, I'm rather -- I'm somewhat
15 annoyed that this sort of information wasn't provided,
16 I'm left in the dark, and I'm sorry about that.

17 Q. Then if we go over the page, there's two further
18 paragraphs I want to read with you and then I want to
19 look at some of the observations you make on it in
20 your statement. So paragraph 18:

21 "The Chairman summed up the discussion by saying
22 there was agreement that the UK should introduce
23 hepatitis C testing as soon as practicable. RTCs
24 would decide individually whether to use Ortho or
25 Abbott test. The blood from any repeat positives

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1 about that. That: here's a test, it's being used,
2 we've done a test, shown it works. So, you know, next
3 step is to use it. It's sort of a logical
4 progression.

5 Q. If we then look at another meeting of the Advisory
6 Committee on the Virological Safety of Blood, from
7 November 1990.

8 NHBT0000073_018.

9 So we can see the date of the meeting,
10 21 November 1990. If we go over the page we've got
11 the heading "Hepatitis C testing":

12 "The Chairman recalled the summing up of the
13 last meeting and said that a note had gone to
14 Ministers telling them that the ACVSB was in favour of
15 introducing routine HCV testing in the UK. A further
16 submission was awaiting the decision of this meeting
17 as to which test would be the most suitable. The
18 Chairman reiterated the recommendation that all plasma
19 should be tested for HCV."

20 There's then a discussion of various papers and
21 studies which I'm not going to go through. If we go
22 to the top of the next page, paragraph 10 says:

23 "The Committee agreed that it was important to
24 start screening as soon as practicable as a measure
25 which would further enhance the safety of the blood

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1 would be set aside."

2 Then there's a discussion of the arrangements.

3 Then there's a reference in the penultimate
4 sentence there to the reference centres determining
5 a protocol for supplementary costing:

6 "A submission would go to Ministers regarding
7 this significant policy decision and the Management
8 Executive would consider the funding aspect."

9 Then if we go to the paragraph 21, further down
10 the page, last sentence:

11 "The Chairman stressed the importance of
12 a common date of introduction throughout the UK."

13 In fact I think I should read the sentences
14 above that.

15 "He reported [this is Dr Gunson] that some
16 centres had asked for a 6 month period in which to set
17 up testing. Dr Gunson himself thought this to be
18 excessive, but he said he would need to consult with
19 other Directors first. It was agreed that he would
20 hold off consultation until the submission had been
21 put to Ministers."

22 Then we had the sentence:

23 "The Chairman stressed the importance of
24 a common date of introduction throughout the UK."

25 What I wanted to do, Dr Lloyd, because you deal

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1 with this in your statement, is just look at a page
 2 from your statement where you comment upon these
 3 minutes.
 4 WITN6935001, please, Sully, page 86.
 5 You say this:
 6 "In the minutes of the November 1990 meeting of
 7 the ACVSB ... the statement:
 8 "The Chairman stressed the importance of
 9 a common date of introduction throughout the UK'
 10 [which is what we were just looking at]
 11 "is presented without any background
 12 information. There is nothing in the document that
 13 indicates why the Chairman ... came to this
 14 conclusion."
 15 Then you say this:
 16 "I note these statements in the document ..."
 17 Then paragraph 10 from the minutes:
 18 "The Committee agreed that it was important to
 19 start screening as soon as practicable ..."
 20 Paragraph 18:
 21 "The Chairman summed up the discussion by saying
 22 that there was agreement that the UK should introduce
 23 hepatitis C testing as soon as practicable."
 24 Then paragraph 21:
 25 "... some centres had asked for a 6 month period

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1 that that was an important issue.
 2 If I may go back to the minutes, paragraph 11.
 3 Q. Yes, so NHBT0000073_018, please, Sully, page 3.
 4 A. I hope I've got this right. I saw it briefly then and
 5 it reminded me.
 6 Q. So paragraph 11 should be on your screen, Dr Lloyd.
 7 A. Okay, yes. In that highlighted section in the middle,
 8 we see:
 9 "Both Dr Gunson and Dr Mitchell felt that if the
 10 results of the pilot study giving 6 true positives out
 11 of 10,000 donors were borne out in practice then
 12 counselling would be manageable."
 13 I think if you're saying that counselling would
 14 be manageable, you're obviously saying that the test,
 15 introducing the test would be manageable. So, you
 16 know, here we are with the first -- referring to the
 17 first generation test, saying that the number of
 18 positives is manageable. And I think that's important
 19 to remember as we go through this. Thank you.
 20 Q. Then going through this chronologically, I'm going to
 21 ask you to look next at a document from early
 22 January 1991, not a document you would have seen at
 23 the time. It's PRSE0002858, these are headed "JDC
 24 Notes of NBTS/SNBTS Management Meeting
 25 (7th January 1991)". So these are Dr Cash's own notes

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1 in which to set up testing."
 2 And your observation there is:
 3 "This suggests some disconnect in the thinking
 4 ... as soon as practicable ... but only if all
 5 together."
 6 A. Mm-hm.
 7 Q. Is there anything further you would wish to add on
 8 that issue and on the basis of what we see in those
 9 minutes, Dr Lloyd?
 10 A. No, I think that pretty much sums it up. You get the
 11 feeling through these minutes that, yes, we're going
 12 to do it but there always seems to be a little "if",
 13 a "but" behind it, instead of just getting on with it.
 14 I mean, they've already decided this is a test
 15 that needs to be done and yet we're flip flopping
 16 about. As to the "all together", I've seen that in
 17 documents that Dr Gunson produced before, so my
 18 feeling, and that's purely a personal thing, don't --
 19 can't say substantively, but it seems that it was
 20 Dr Gunson who had this view that "All together" was
 21 the necessary -- was the imperative. I'd seen it in
 22 other documents he'd prepared, so I feel that's where
 23 that came from.
 24 As is noted, there is no actual discussion
 25 recorded in the minutes as to how they came to decide

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1 of his meeting.
 2 A. Yes.
 3 Q. If we go to the second page and pick it up at
 4 paragraph 5, "HCV Donation Testing", Dr Cash has
 5 recorded here:
 6 "HG [that's Dr Gunson] conveyed his concern that
 7 DOH has still not decided on a start date. It now
 8 seemed probable that May/June 1991 would be the
 9 earliest possible.
 10 "2. HG advised that he believed that the major
 11 problem for DOH was mechanisms for finding the money
 12 for NBTS RTCs and for E/W [which I assume is
 13 'England/Wales'] confirmation testing."
 14 A. England/Wales, yes.
 15 Q. "The issue is one of DOH's disinclination to fund
 16 centrally and insist on cross charging -- ie
 17 increasing the unit cost of blood supplied to
 18 hospitals."
 19 Now, two questions arising out of that,
 20 Dr Lloyd. The first is, as I understand your
 21 evidence, you had not been working on any assumption
 22 that the Department of Health would be funding this.
 23 You'd been working since 1989 on the assumption that
 24 the region would be funding it; is that right?
 25 A. That's correct.

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1 Q. Secondly, did Dr Gunson ever communicate to you the
2 belief that is recorded here by Dr Cash that this was
3 an issue relating to the Department of Health trying
4 to find the mechanism for finding the money? Was that
5 something ever communicated to you at the time as
6 a potential cause of the hold-up?
7 A. No, no, I wasn't -- I don't recall ever being told
8 "We're on hold because they can't find the money".
9 That message never -- I can't recall it coming my way.
10 Q. Then, if we, still in --
11 A. I do note, if I may just interject there?
12 Q. Yes.
13 A. Under the same section 5, item 3:
14 "...[frozen screen]... requested a more
15 definitive operational description for a 'start date'
16 ..."
17 It gives the impression that John Cash and the
18 Scottish Transfusion Service are unhappy about this
19 vague issue of a start date, that they're not happy
20 with a May/June earliest possible. So again, that's
21 just an observation. Thank you.
22 Q. So if we then move a little further on in January 1991
23 to NHBT0000076_006, so this is a memo from Dr Gunson,
24 22 January '91 to the Regional Transfusion Directors
25 England and Wales so you would have received this,

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1 NHBT0000073_044.
2 This is you on 7 February writing to Dr Gunson,
3 saying:
4 "The Northern Region Blood Transfusion Service
5 would be able to start HCV testing from approximately
6 1st April 1991. The Company (Abbott Plc) would be
7 able to supply the first generation test by that date
8 without any problems. I understand that you have been
9 in touch with the Manufacturers with a view to
10 ascertaining when the second generation test would be
11 available."
12 Then there's a reference to a concern about the
13 relatively low incidence of positive confirmations and
14 saying it would be advantageous if there was a second
15 generation test with improved specificity.
16 As I read this letter, but please correct me if
17 I'm wrong, Dr Lloyd, you're saying it would be good to
18 have an improved second generation test but it's not
19 essential in order to get started, and you can start
20 with the first generation test; is that right?
21 A. Absolutely. Yes. We were ready to go with that first
22 generation test. We -- when we set things up, we
23 didn't know that a second generation test was sort of
24 just around the corner. You obviously know that
25 improved tests are going to come, that's the way it

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1 Dr Lloyd.
2 A. Yes.
3 Q. Paragraph 1:
4 "The Department of Health have agreed that
5 routine testing of all blood donations for anti-HCV
6 can be put into operation.
7 "2. I have been asked to try and ensure that
8 testing starts simultaneously in RTCs in England and
9 Wales and that it is co-ordinated with commencement of
10 testing in Scotland.
11 "3. Will you please advise me what you consider
12 to be the earliest date that you could commence
13 testing.
14 "4. Financial arrangements to cover routine
15 screening and supplementary tests have later still to
16 be concluded and I will advise of these at a later
17 date."
18 Then there's a reference to a protocol being
19 considered by the Advisory Committee on Transfusion
20 Transmitted Diseases, and 6, he says:
21 "[He] will inform Ortho and Abbott that routine
22 screening ... has been approved and ... will inform
23 them of the starting date in due course."
24 Now, you responded to the invitation in
25 paragraph 3 in a letter of 7 February.

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1 happens, but yes, we were ready to go with the first
2 generation test.
3 Q. And then we know that other Regional Transfusion
4 Directors also responded to Dr Gunson's request with
5 a range of different potential commencement dates.
6 The next, I think, global, communication from
7 Dr Gunson to RTDs is NHBT0000191_077.
8 Again, we can see this is a round-robin letter
9 from Dr Gunson, 15 February, to all RTDs.
10 If we go further down the page, he refers to
11 minutes of the management committee -- we know that's
12 the management committee of the National
13 Directorate -- and some papers.
14 If we go over the page, he refers there to
15 enclosing reports on the comparison of the Abbott and
16 Ortho tests, which of course was the work you'd been
17 involved with the previous autumn.
18 Then the second paragraph under paragraph 10:
19 "I have now been able to speak to all RTCs and
20 an agreed date for commencement for anti-HCV screening
21 of 1st July 1991 has emerged. This, of course, will
22 be dependent upon a reasonably normal blood collection
23 pattern at that time since if the later is still
24 disrupted by affairs in the Gulf [I think that should
25 be "latter"] we may have to reconsider the date."

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1 A. Yeah.
 2 Q. Do you ever any recollection of what your reaction or
 3 feelings were, bearing in mind you were ready to start
 4 at this point in time, on 1 April, being told it was
 5 going to be 1 July?
 6 A. I was upset. I thought this was unnecessary. And
 7 it's -- there's nothing there that tells you why
 8 it's 1 July. And it's this sort of this comment that
 9 an "agreed date ... has emerged". You know, where did
 10 it come from? Certainly not from me. And several
 11 other centres were ready and able to start earlier
 12 than this. So the agreed date is -- you know, I was
 13 unhappy with that. I was definitely unhappy with
 14 that. So that was setting me on the course for what
 15 happened afterwards.
 16 Q. Then if we go to PRSE0002280.
 17 You'll see when it comes up it's the further
 18 meeting of the Advisory Committee on the Virological
 19 Safety of Blood on 25 February 1991.
 20 If we go over the page there's a heading towards
 21 the bottom of the page "Hepatitis C: UKBTS pilot
 22 study".
 23 Then if we go over to the next page, please,
 24 Sully, and we just look at paragraph 6, it refers to
 25 a paper tabled by Dr Tedder. And we can see that the

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1 course. But in broad terms, what was -- what's your
 2 view of the suggestion that there should now be this
 3 further evaluation involving the second general
 4 election tests?
 5 A. Sorry, can you remind me the date, was this February
 6 1991?
 7 Q. This is 21 February 199 -- sorry --
 8 SIR BRIAN LANGSTAFF: 25th.
 9 MS RICHARDS: 25 February, thank you, sir, 1991.
 10 A. Right, thank you. Okay.
 11 If I read that paragraph again -- if you could
 12 perhaps enhance it for me?
 13 MS RICHARDS: Paragraph 6, please, Sully.
 14 A. If someone could bring --
 15 Q. We'll do that.
 16 A. Yeah. It's a confusing statement:
 17 "... likely availability of second generation
 18 tests ..."
 19 Saying we're not sure when, it's only the
 20 "likely availability". Then:
 21 "... Operational factors ... might influence
 22 decision [of] RTCs as to which screening test to
 23 choose."
 24 That's very strange. Why would you choose
 25 between a first generation test and a second

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1 question of second generation tests has now reared its
 2 head.
 3 "The Committee discussed the likely availability
 4 of the second generation tests and operational factors
 5 which might influence the decision by RTCs as to which
 6 screening test to choose. Licensing of the tests by
 7 FDA ..."
 8 That must be the second generation tests because
 9 we already know they'd already been licensed for the
 10 first generation.
 11 A. Yes.
 12 Q. "... had not yet been finalised. Members agreed it
 13 was important for proper evaluation of the Ortho and
 14 Abbott 1&2 tests to be carried out before RTCs decided
 15 which test they would adopt."
 16 So this is the decision or recommendation of
 17 the ACVSB that before testing is introduced, there
 18 should now be a further evaluation comparing the first
 19 and second generation tests, or looking at the second
 20 generation tests.
 21 Now you obviously didn't see this --
 22 A. Sorry --
 23 Q. -- but that information --
 24 A. -- no.
 25 Q. -- came to your attention. We'll look at how in due

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1 generation test? You might choose between two or
 2 three different manufacturers of a second generation
 3 test, but why would we be deciding whether to do
 4 a first or second generation test? That really does
 5 not make sense to me.
 6 "Members agreed it was important for proper
 7 evaluation of the Ortho and Abbott 1&2 tests to be
 8 carried out before RTCs decided which test they would
 9 adopt."
 10 So again, we're saying you might decide to go
 11 with some centres -- and this is interesting --
 12 evaluation -- centres decide which tests they would
 13 adopt. Would they adopt first generation or the
 14 second? So now we're suggesting that you might have
 15 a situation, once the second generation test
 16 eventually becomes available, that some centres will
 17 choose to use first generation tests ... [frozen
 18 screen]... doesn't make any sense.
 19 Q. Dr Lloyd, we lost you there for a --
 20 A. Either the minutes or -- okay. I was repeating
 21 myself.
 22 Q. No, no, we lost you for a couple of seconds, so I just
 23 wanted to check we didn't miss anything significant.
 24 A. Yes.
 25 Q. You said this:

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1 "So now we're suggesting that you might have
2 a situation, once the second generation test
3 eventually becomes available, that some centres will
4 choose to use first generation tests ..."
5 And then we missed possibly just a few seconds.

6 A. Okay.

7 Q. And then you said, "doesn't make any sense".

8 A. Okay.

9 Q. So could you just repeat that point?

10 A. Certainly.

11 This minute suggests that the situation might be
12 after this testing that some transfusion centres would
13 choose to use the first generation test, and some
14 centres would choose to use the second generation
15 test. And that makes no sense.

16 Either this minute is wrong and is -- does not
17 correctly reflect what was being said, or there was
18 a big problem over what they were talking about and
19 what they were suggesting. Very strange.

20 Q. And it may be that we will, with other witnesses, need
21 to explore the whole minutes, but I'll just flag up
22 that in paragraph 7 it says:

23 "The Chairman summed up the view of the
24 Committee following discussion ..."

25 And then if we go over the page, there's three

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1 **SIR BRIAN LANGSTAFF:** That's obviously assuming that there
2 is a substantial difference in quality, as you might
3 suggest from a second generation test. But it hadn't
4 yet been established?

5 A. Mm-hm.

6 **SIR BRIAN LANGSTAFF:** Well, if one makes that assumption,
7 that would follow, wouldn't it?

8 A. Yes. It would be extremely surprising if these
9 companies introduced a second generation test that was
10 no better than the first generation test, if I may say
11 so.

12 **SIR BRIAN LANGSTAFF:** Yes.

13 Ms Richards, the remit of the ACVSB was safety,
14 was it?

15 **MS RICHARDS:** One would hope so, given its name, yes.
16 I don't have the terms of reference memorised.

17 **SIR BRIAN LANGSTAFF:** I think we've looked at the terms of
18 reference --

19 **MS RICHARDS:** We have.

20 **SIR BRIAN LANGSTAFF:** -- and I think they do put a primacy
21 on safety.

22 **MS RICHARDS:** I think that's certainly right. I can
23 check.

24 **SIR BRIAN LANGSTAFF:** Well, we can check that.

25 **MS RICHARDS:** Yes.

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1 bullet points there, and then over the page, the top
2 of the page, the next point is:

3 "Ortho and Abbott 1 and 2 should in principle be
4 available among others from 1 July for RTCs to
5 choose ..."

6 So that is, I think, consistent with how you
7 were reading that earlier paragraph.

8 A. Mm-hm, right.

9 **SIR BRIAN LANGSTAFF:** Can you help me with this. The
10 principle, if it is a principle, that all regions
11 should act as one, together, at the same time, how
12 does that relate to whether they're allowed to choose
13 any one of four different tests?

14 A. I mean, this is strange. I can understand centres
15 going -- being told to do it together, and choose
16 between Ortho and Abbott, because they are giving you,
17 essentially, the same results. It is convenience to,
18 you know, what you're set up to use. But being told
19 here that it's okay to go with a first generation test
20 in one centre and a second generation test in another,
21 does not match with that decision to do all testing --
22 start all testing together, because you're saying we
23 can start the substantially different quality of
24 tests -- testing in different parts of the country in
25 different centres. It doesn't match.

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1 Dr Lloyd, just couple of other documents I want
2 to look at briefly with you and then perhaps we'll
3 take a break. The first is NHB0000191_110. So this
4 is a memo from you to colleagues within the Northern
5 Regional Centre or service, 14 March 1991.

6 A. Yes.

7 Q. "The start date for HCV testing set by the National
8 Directorate is currently 1st July. However two
9 Centres in particular are unhappy about this. One of
10 them is Cambridge."

11 Now, that would suggest you'd had some
12 discussions or communications with some other centres.
13 Do you recall what the unhappiness was?

14 A. No, I don't. I mean, when you read that, I would say
15 the only -- you know, if someone is unhappy about that
16 date, that -- I don't know whether they were unhappy
17 because it was too early or because it was too late.
18 But I think, if you look at some of the other
19 documentation, Cambridge was one of the centres that
20 was looking for a later date, but I -- that is purely
21 from my memory --

22 Q. No, you're absolutely right.

23 A. -- I don't have documentation about that.

24 Q. I think Cambridge had indicated it would be ready by
25 October so that might suggest the unhappiness --

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1 A. Yes.
 2 Q. -- from their perspective.
 3 You then refer to the Procurement Directorate
 4 "looking at FOUR potential suppliers of HCV kits".
 5 That, I think, is a reference not to a Northern Region
 6 Procurement Directorate but to the NHS Procurement
 7 Directorate or DoH Procurement Directorate.
 8 A. Yes. That's correct.
 9 Q. You say there:
 10 "... want ... several firms involved to enable
 11 them to obtain lower prices for the kits."
 12 Do you recall what the source of your
 13 information was in relation to that?
 14 A. No, I don't. I don't know how I came by that.
 15 I would imagine -- I mean, that's the sort of thing
 16 that ...[frozen screen]...
 17 Q. Sorry, we lost you again, Dr Lloyd.
 18 A. Okay. No, I'll wait for a moment. Okay.
 19 I don't know where I got that information from,
 20 I'm sorry. I think I was waffling a bit then.
 21 I don't know where it came from.
 22 Q. Then you say:
 23 "I suggest we proceed as intended, as soon as
 24 a second generation kit is available."
 25 So that's 14 March. If we then just still in

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1 was absolutely no reason why we couldn't have done it.
 2 And when I read this minute, I was really quite
 3 surprised, politely, that this point had been made.
 4 Certainly, there's no reason why we shouldn't
 5 have evaluated. I also note in the previous minutes
 6 of the ACVSB that you showed that original proposal
 7 for comparing the first and second generation tests
 8 was purely on the 10,000 samples. It wasn't a sort of
 9 a full-blown new study and maybe this letter alludes
 10 to a change in proposal from just testing stored
 11 samples to actually running, sort of, almost a live
 12 testing scenario, which would have been much more
 13 expensive and time consuming.
 14 Q. I'm not going to go to the next document, which is
 15 a letter from the Procurement Directorate, to
 16 Dr Gunson, on 21 March 1991, which sets out how it was
 17 proposed this second round comparative evaluation
 18 should be undertaken at Newcastle, North London and
 19 Glasgow, but the reference for the transcript is
 20 NHBT0000191_115.
 21 The document I want to display before we take
 22 a break, Dr Lloyd, is then Dr Gunson's letter of
 23 3 April to all RTDs, NHBT000073_065. This is the
 24 letter in which he communicates the delay from July to
 25 September for testing. So if we go to the bottom half

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1 March go to NHBT0000062_039. Now, this is an internal
 2 Department of Health memo, 8 March 1991, referring to
 3 the ACVSB decision to extend HCV screening evaluation.
 4 We can see paragraph 2 sets out what's said to be the
 5 additional costs, and so on, in relation to this
 6 further evaluation.
 7 Paragraph 3 then records:
 8 "I gather that Dr Gunson, who was not present at
 9 ACVSB on 25 February, has telephoned Mr Fuller to say
 10 that he doubts whether the Newcastle and Glasgow
 11 Centres have the laboratory capability to carry out
 12 the additional work now proposed. I understand also
 13 that Dr Rejman is unsympathetic to Dr Gunson's view on
 14 this. However, I think you should be aware that
 15 Dr Gunson has raised this point as it seems to
 16 underline the need to look very carefully at what
 17 ACVSB has advised to be sure that an evaluation on
 18 this scale is both necessary and practicable."
 19 A. Mm-hm.
 20 Q. Do you have any recollection of Dr Gunson exploring
 21 with you Newcastle's capability to carry out the
 22 additional work? Because, as I understand it, it was
 23 anticipated that Newcastle would be one of the centres
 24 evaluating the second generation kits.
 25 A. No, I don't recall him discussing it with us. There

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1 of the page --
 2 A. Yes.
 3 Q. -- you'll see:
 4 "You will recall that in my letter to you in
 5 15th February I suggested that 1st July 1991 might be
 6 an appropriate date to commence anti-HCV screening of
 7 blood donations."
 8 Then he refers to the availability of the second
 9 generation test kits, and also to the possibility of
 10 other companies supplying tests, which I think is what
 11 your internal memo, Dr Lloyd, had alluded to. It then
 12 says:
 13 "The Department of Health has agreed that there
 14 should be a 'second-round' comparative evaluation of
 15 anti-HCV test kits at the Newcastle, North London and
 16 Glasgow RTCs, together with appropriate confirmatory
 17 testing."
 18 Next paragraph:
 19 "It is undoubtedly in our interest that this
 20 evaluation takes place. However, to complete this
 21 study and become operational by 1st July 1991 is too
 22 tight a schedule. It is difficult to state precisely
 23 a revised date, but I think we should aim to commence
 24 routine screening for anti-HCV by 1st September 1991."
 25 Now, after the break I'll ask you about the

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1 decision that you then took. But can you just assist
 2 with this: Dr Gunson sets out in that fourth paragraph
 3 his view of "our interest", and then the proposal to
 4 move the date for testing back from July to
 5 September --
 6 **A.** Mm-hm.
 7 **Q.** -- or forward from July to September, however you want
 8 to characterise it. Had there been, as far as you're
 9 aware, any discussion between Dr Gunson or anyone else
 10 from the National Directorate and Regional Transfusion
 11 Directors, such as yourself, or did this come out of
 12 the blue?
 13 **A.** This came out of the blue. This came completely out
 14 of the blue. I had no idea this was being considered.
 15 July was already too late and, as perhaps we'll
 16 discuss later, this was, as they say, the straw that
 17 broke the camel's back, from my perspective.
 18 So it is -- it was -- yes, it was completely
 19 a surprise when this arrived.
 20 **MS RICHARDS:** Sir, I'm going to suggest we take our break
 21 now, I've run on slightly later than I normally would
 22 for this session, in any event, and then we can pick
 23 up Dr Lloyd's decision and the response to that
 24 decision in one go after the break.
 25 **SIR BRIAN LANGSTAFF:** Yes. Well, let's do that starting

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1 which you used, I believe?
 2 **A.** Mm-hm. Yes, that's correct.
 3 **Q.** In a nutshell, Dr Lloyd, what was your reasoning for
 4 going ahead in the way described here?
 5 **A.** Well, obviously I'd written it in my witness
 6 statement. We had the wherewithal to do the test. We
 7 had the -- funding was in place, we had the tests
 8 available. We had the equipment available. We had
 9 the staff who were more than competent to carry it
 10 out. Our own internal IT department had made sure
 11 that we could communicate the test results into our
 12 existing system, and so we were sitting on the start
 13 line ready to go. Then we're told to wait for -- if
 14 you look at the last letter from Dr Gunson, it didn't
 15 say, "We will start on 1 September" it was a "may
 16 start on 1 September".
 17 So we -- I felt that I could not delay testing.
 18 I mean, we had the wherewithal to remove infectious
 19 donations out of our system and therefore reduce the
 20 risk to patients receiving the blood. We really had
 21 no -- there was no alternative. I mean, there was --
 22 you can't not go ahead when everything is in place,
 23 just to meet some mythical common start date.
 24 **Q.** We can see you anticipated in that last sentence that
 25 there might be some problems with the

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1 at 2.50.
 2 **MS RICHARDS:** Thank you.
 3 **SIR BRIAN LANGSTAFF:** 2.50.
 4 **A.** Thank you.
 5 **SIR BRIAN LANGSTAFF:** Sorry, your equivalent.
 6 **A.** Yes.
 7 **(2.28 pm)**
 8 **(A short break)**
 9 **(2.50 pm)**
 10 **SIR BRIAN LANGSTAFF:** Yes.
 11 **MS RICHARDS:** Dr Lloyd, we had finished tantalisingly with
 12 Dr Gunson's letter of 3 April. We can pick up what
 13 you then did in response at NHBT0046745.
 14 We can see this is an internal meeting, medical
 15 staff committee meeting, 25 April 1991. And if we go
 16 to the top of page 3:
 17 "Hepatitis C testing began on April 24 testing
 18 for anti-HCV. This would be using the second
 19 generation test which had a low rate of false
 20 positivity. The timing of this introduction of
 21 testing may well cause some problems with the National
 22 Directorate."
 23 So we have there, I think, the state on which
 24 you introduced testing. And you tell us there it's
 25 the second generation test. It was the Abbott test

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1 National Directorate. Let's pick that up with
 2 a letter Dr Gunson wrote to you.
 3 NHBT0000062_054, please. And we go to page 3.
 4 So 29 April, Dr Gunson wrote to you. First
 5 paragraph refers to a telephone conversation. Second
 6 paragraph:
 7 "I was sorry to learn that you had taken this
 8 unilateral decision to proceed with testing without
 9 first discussing the issue, not only with me, but with
 10 other colleagues in RTCs given you must have been
 11 aware of the implications for them of your decision."
 12 Then he refers back to the ACVSB meeting and to
 13 a letter he wrote, which we've already looked at, in
 14 January --
 15 **A.** -- (overspeaking) -- problems.
 16 **Q.** And then over the page, we see, the top of the page,
 17 he refers to the 'second-round' evaluation. Then the
 18 next paragraph:
 19 "Unfortunately the timing stated in this letter
 20 slipped ..."
 21 And he explains that was the reason for his
 22 letter deferring the date to be aimed for as
 23 1 September 1991.
 24 Then the last paragraph he says:
 25 "I have written these details in some length to

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1 demonstrate that I had kept you fully informed of the
 2 national policy with respect to anti-HCV testing.
 3 There are still other matters which have not yet been
 4 concluded."
 5 Then he sets out what some of those are.
 6 Can you recall what your thoughts were on
 7 receiving this letter and do you have any particular
 8 comments on what we see set out in it?
 9 A. First of all, this letter follows the telephone
 10 conversation which was somewhat harder to listen to
 11 than this was to read. Dr Gunson was, how shall I put
 12 it, beside himself over what we had done, and I sort
 13 of realised that there would be issues.
 14 Then here we have a series of odds and ends as
 15 to why they can't do it. Certainly the second round
 16 evaluation is referred to, and this comes up
 17 elsewhere. We do now know from correspondence between
 18 Dr Gunson and, I think it was, Simon Pearl, the lawyer
 19 with the firm representing the NBA, probably, in
 20 litigation, in which Dr Gunson says the second-round
 21 evaluation was effectively a sham. It wasn't
 22 a serious thing. And that it was not actually
 23 necessary.
 24 So we now know that he thought it wasn't
 25 necessary, and yet here he is saying we've got to do

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1 Antibody. The comparative study of the Abbott and
 2 Ortho kits (first generation), was not going to
 3 influence my decision as to whether or not to start
 4 testing."
 5 "The next round of comparative trials which
 6 encompasses other manufacturers kits as well as second
 7 generation kits from Abbott and Ortho when started was
 8 not going to be completed in time to allow this Centre
 9 to meet the July deadline, even on the original
 10 schedule. The change in date based on a further delay
 11 in completion of the next round of evaluations would
 12 have delayed the introduction of testing (all
 13 transfused units negative) by several months, possibly
 14 taking us to November of this year.
 15 "If during that period anyone becomes infected
 16 and subsequently takes action, in my opinion, I would
 17 have had no defence. We that the wherewithal to test,
 18 including kits, equipment and staff and we had agreed
 19 to start previously. The delay is thus administrative
 20 and that not only forms no basis for a defence or
 21 a mitigation but also I think aggravates the
 22 situation.
 23 "I have therefore proceeded on the basis that
 24 all units available for transfusion from 1st July will
 25 have been tested."

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1 a second-round evaluation and we've got to, you
 2 know -- the procurement people have got to do this and
 3 that.
 4 None of it mattered. None of it mattered. Even
 5 if the second generation test had not been available
 6 for months, we would have gone ahead with the first
 7 generation test. So all of this is just some sort of
 8 way, to me, for Dr Gunson to sort of say, "I've got
 9 all these great reasons for delaying it, and you
 10 shouldn't have broken ranks". It was an unpleasant
 11 letter.

12 Q. We can see your response at NHBT0000074_010.

13 You say there:

14 "When a common date of 1st July was circulated
 15 sometime ago, I made a decision to start testing
 16 in April 1991 so that we could be assured that not
 17 only were all issues of blood and blood components
 18 negative for the antibody but that all units
 19 transfused from that date were negative.

20 "I set up the internal arrangements and made it
 21 clear that testing would start in the Region in the
 22 early part of the year. The decision to start testing
 23 was based on a test that was not perfect, but
 24 nevertheless, it was available and it did detect
 25 a group of people who appeared to be positive for the

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1 Just in terms of the mechanics of it, first of
 2 all, Dr Lloyd, is this right -- is it right to
 3 understand that the routine testing of donations
 4 started with effect from 24th April but then there
 5 was, as it were, a catch-up in terms of stored
 6 products --

7 A. I lost you then. Could you start again?

8 Q. Yes.

9 A. Is it right for me to?

10 Q. It's, in terms of the mechanics of putting screening
 11 into operation, is this correct: routine testing of
 12 donations began on 24 April but there'd also be
 13 a period of needing to test what was held in stock and
 14 so on, and is that what feeds, then, into this last
 15 sentence, all units will have been tested from 1 July?
 16 How do we understand the reference to 1 July?

17 A. I've re-read this letter. I think part of this
 18 letter, to be honest, was me trying to protect my own
 19 back, using this 1 July as a date when all units would
 20 be tested when, really, that wasn't the issue.
 21 I think I was trying to say: look, I thought we were
 22 going to have things all done by 1 July so I had to
 23 start in April. The dates don't really quite add up.

24 But we started on 24 April. There would be
 25 a period, and one can be criticised for this, but

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1 there would be a period when units of blood and
2 platelets and so on that were in stock were issued
3 untested. I don't think we went back and tried to
4 re-test samples, you know, from recently collected
5 blood. I don't think we did that, and I'm sorry for
6 that.

7 But we -- so 1 July really is -- it's a little
8 bit of a smokescreen. Not a big issue. The big thing
9 is we started on a certain date. Everything we
10 collected from that date was -- that we put into issue
11 was HCV negative. And it would take a little while
12 for things to clear through the system before
13 everything -- everything -- that was issued was HCV
14 negative.

15 Q. And then the way you've put it in your statement, and
16 I don't think I need display it, it's just two
17 sentences I wanted to read out:

18 "A delay until July displayed me, and a proposed
19 July until about 1st September was unacceptable. We
20 all knew that there were infectious donations in the
21 system that were being transfused to patients and we
22 had the means to stop that."

23 Again is that, in a nutshell, the essence of
24 your thinking?

25 A. Absolutely. Yes.

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1 hearings and then invite your comment.

2 So if we start with a letter from Dr Fraser,
3 NHBT0000074_018.

4 Do we have that, Sully? It's not come up on my
5 screen. NHBT0000074 -- thank you.

6 So 7 May '91, from Dr Fraser, picking it up in
7 the third line:

8 "I feel you are making an error of judgment here
9 and seem to be flouting the advice given by Dr Gunson,
10 who I thought had made it fairly clear, that
11 transfusion centres should not start testing until
12 September 1st at the earliest. Obviously, we need to
13 have some experience with regard to the newer
14 generation tests. The Transfusion Service normally
15 acts in unison when introducing new tests for
16 transfusion transmitted diseases. This certainly
17 happened for HIV I and HIV II. I think it would be
18 far better for you to wait to introduce this test
19 until a date has been agreed for all transfusion
20 centres to commence testing."

21 Is there anything in that letter that led you to
22 doubt your decision?

23 A. Oh, no, no. I mean, there was no -- there was nothing
24 in that letter that makes you think: oh my goodness,
25 we should have delayed. No, certainly not.

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1 Q. You also wrote to your Regional Health Authority and
2 you wrote a letter to your Regional Transfusion
3 Director colleagues. I'm not going to go through
4 those, I'll just read the references out so that
5 others have a record of them. The letter to the
6 Regional Health Authority, 30 April 1991, was
7 NHBT0000191_162, and your 2 May 1991 letter to RTDs is
8 NHBT0000074_014.

9 What I want to do, however, is now pick up some
10 of the letters that you got in response, or some of
11 what was being written about your decision, and then
12 ask you about that.

13 Dr Lloyd, we've already looked in earlier
14 hearings at Dr Cash's initial letter to you and your
15 reply to him; we've looked at the letters that
16 Dr Entwistle and Dr Martlew sent you; we've looked at
17 the letter that Dr Boulton sent you, and I don't know
18 if you've followed any of the Inquiry's evidence
19 Dr Lloyd, but he told the Inquiry last week this,
20 "I now feel quite strongly that Huw was right"; and
21 we've looked at the letter that Dr Contreras sent you,
22 and she said in her oral evidence to the Inquiry, "I'm
23 really sorry to have written this letter".

24 So what I'm now going to do is just show you
25 some of the letters that we haven't looked at in other

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1 Q. Then Dr Ala wrote to you on 8 May, NHBT0000074_020.
2 He says:

3 "I am afraid your decision to commence testing
4 before everyone else has come at a very inopportune
5 moment, for it will seriously undermine the whole
6 concept of establishing a National Service precisely
7 at the time when this proposal is being submitted for
8 reconsideration by the Department of Health. The
9 importance of supporting this concept goes far beyond
10 parochial interests, and the issue is an urgent one.

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

17 "If we cannot work together, we shall decline
18 separately."

19 You've commented on this letter in your
20 statement, Dr Lloyd --

21 A. I did, yes.

22 Q. -- WITN6935001, page 95. You described this, at the
23 top of the page, as:

24 "... a strange criticism to throw at Newcastle's
25 decision ... given that Dr Ala had stated in response

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1 to Dr Gunson's earlier request that they [in
2 Birmingham] would be able to start testing by April
3 ..."

4 Again, any further comment or observation on
5 Dr Ala's letter?

6 A. Yes. Fereydoun Ala's letter was very strange when he
7 talks about there being no scientific evidence
8 ...[frozen screen]... not being evidence of there
9 being sufficient infectivity in the supply, words to
10 that effect.

11 Q. Yes.

12 A. But those were things that had already been discussed
13 extensively that we knew that we had a problem, and
14 Dr Ala wasn't raising any complaints about starting
15 testing. So that argument -- I think, in the heat of
16 the moment, you know, people were throwing in
17 arguments just because they felt they had to say
18 something, they had to come up with something. So
19 I didn't take it seriously.

20 Q. Then the third letter I wanted to discuss briefly with
21 you was NHBT0000074_033. This was from Colonel Thomas
22 of the Army Blood Supply Depot, 17 May, third
23 paragraph:

24 "I must say that I was personally dismayed to
25 learn that you were going to break ranks over the

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1 Newcastle Saga: HCV Donation Testing".

2 A. Yes.

3 Q. I just want to --

4 A. May I?

5 Q. Yes.

6 A. May I just -- I'm sorry, I -- rather than come back to
7 this after this document, may I just say something
8 about the previous letters that I received?

9 Q. Of course.

10 A. Obviously, I was, you know, fairly upset by the tone
11 of the letters but I think there were two letters that
12 I received that and I'd like to point out were in
13 a much more reasonable tone, and I think it's fair
14 that I should say that the letters from Dr Martlew and
15 Dr Mitchell in Scotland were both, you know,
16 reasonable letters to send in the circumstances and
17 were not peppered with the sort of stuff that we saw
18 in some of the other letters. So I just would like to
19 make that point.

20 Q. Thank you, Dr Lloyd.

21 So I just really wanted to invite your attention
22 here and any observation you have on the last sentence
23 of the first paragraph, where Dr Cash puts it in these
24 terms:

25 "... we should make every effort to maximise

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1 agreed policy on the introduction of Hepatitis C
2 testing. As someone who might be considered an
3 outsider and therefore not bound by the collective
4 decision, I believe, and this is the policy of my
5 Director General, that it is vital that we maintain
6 a common front. Only in this manner are we going to
7 navigate the difficult waters ahead engendered by the
8 introduction of product liability and our requirement
9 to be licensed by the Medicines Control Agency".

10 Any observations, Dr Lloyd, on what Colonel
11 Thomas was saying there about maintaining a common
12 front and not breaking ranks?

13 A. Well, again, you see that at the end there, "going to
14 navigate difficult waters ahead engendered by the
15 production of product liability and our requirement to
16 be licensed": irrelevant, irrelevant stuff. I think,
17 again, as with Fereydoun Ala's letter, something
18 thrown in just to try to make the point: not relevant.
19 If you don't -- if you decide to delay testing, you're
20 deciding to issue infected units, and these sort of
21 arguments really don't -- didn't hold any sway with
22 me, that's for sure.

23 Q. Then I want to ask you now to look at your letter that
24 you wouldn't have seen at the time, it was from
25 Dr Cash to Dr Gunson, NHBT0000074_024, headed "The

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1 this disaster to our corporate advantage."

2 I wondered whether you have any observations,
3 either about the concept of characterising this as
4 a disaster, or the concept of maximising corporate
5 advantage?

6 A. Yes. When I saw this -- I mean, it doesn't surprise
7 me, in some ways, that, you know, Professor Cash wrote
8 something like this. But, yes, "corporate advantage"
9 is really pretty gross. But I don't know exactly what
10 corporate advantage he was trying to make. I don't
11 know.

12 Q. Then just in relation to a response of the Department
13 of Health -- or, sorry, I should say a response of
14 someone within the Department of Health, more
15 accurately, NHBT0000062_054.

16 This is a memo from Dr Rejman to Dr Metters,
17 30 April 1991. He says he encloses "a copy of
18 a letter sent by Dr Gunson ... to Mr Canavan".

19 I should just, if we go to the second page, we
20 can see what that is.

21 So Dr Gunson wrote to Mr Canavan enclosing
22 a copy of his letter to you, which we've already
23 looked at, Dr Lloyd, and referring to a call he'd had
24 from Ortho and then saying, "I fear the worst."

25 A. Mm-hm.

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1 Q. That's what Dr Rejman is referring to.
 2 If we go back to the first page, please, in
 3 Dr Rejman's memo.
 4 Point 2, he says:
 5 "This gives details of routine anti-HCV
 6 screening at Newcastle RTC which commenced last week.
 7 "3. This action was taken despite the agreed
 8 policy by the ACVSB that screening should start
 9 simultaneously in all the RTCs in the UK.
 10 "4. This had also been agreed by the RTC
 11 Directors with the National Director of the NBTS."
 12 Just pausing there, that appears to suggest that
 13 a policy of simultaneous screening was the consensus
 14 view agreed by RTC directors. Was that your
 15 understanding, that this had been agreed by
 16 RTC directors?
 17 A. ...[frozen screen]... correspondence I received and
 18 phone calls I received, it was quite clear that all
 19 the other directors believed that we were going to
 20 start on the same day. So yes, I have to say it was
 21 agreed. I do not recall actually being in a meeting
 22 where I said, "I agree to start on the same day".
 23 I might have done. Possible. Particularly when we
 24 thought the test was being introduced fairly promptly.
 25 So yes, it's -- I think it's fair to say RTC directors

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1 government decision or whatever. Of course they're
 2 going to come up and say that. They don't want to be
 3 left behind. They don't want to make less money. So
 4 I certainly feel no sympathy, if that's the right
 5 word. You know, tough. They're a big business.
 6 They're a multinational corporation and they can look
 7 after themselves.
 8 As for Scotland, I'm not quite sure what was
 9 being suggested here. Whether it means that Scottish
 10 NBTS was now put in the same position as some of
 11 the -- as the other transfusion centres in England,
 12 although somewhere along the line I have a feeling
 13 that the Scottish centres were also prepared to start
 14 earlier. I do note that with the exception of the
 15 letter from Dr Ruthven Mitchell, which as I said was
 16 a moderate, reasonable letter, none of the other
 17 Centre Directors from Scotland actually wrote and
 18 complained about my decision to start testing. So
 19 maybe the Scottish Blood Transfusion Services were not
 20 as comfortable with the delay, apart from, obviously,
 21 John Cash.
 22 Q. Were you surprised that the introduction by you of
 23 a measure designed to improve patient safety triggered
 24 such a response from others?
 25 A. When I decided to introduce the test, I knew there was

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1 agreed with the national director that it should start
 2 simultaneously, yes.
 3 Q. Then Dr Rejman's observation in paragraph 5, and
 4 obviously we can ask him about this, but it says:
 5 "This action has caused problems in that the
 6 other major competitor company feels disadvantaged,
 7 and has also caused problems in Scotland.
 8 "6. We are waiting for written reasons as to
 9 why this action was taken."
 10 Then he says he is:
 11 "... copying it to members of the Management
 12 Executive to determine whether action is required
 13 where an individual Region decides to oppose a
 14 universal agreement."
 15 Do you have any observations, Dr Lloyd, on
 16 paragraph 5, whether the problems it's said that had
 17 been caused are disadvantage to the other competitor
 18 company, and unspecified problems in Scotland?
 19 A. I have absolutely no sympathy for a large commercial
 20 company that happens to feel disadvantaged over
 21 something that happens. They're in the business of
 22 making money and I'm quite sure many companies, and
 23 you see it in the newspapers occasionally, companies
 24 come up and complain that they feel they've been
 25 disadvantaged by something that has happened, by some

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1 going to be a backlash. Or I was pretty sure. And
 2 what I -- when I re-read those letters, what I note is
 3 that nobody mentions the patients. The ...[frozen
 4 screen]... jolly good show, we're all -- no one is
 5 going to break ranks. And I sort of felt that was --
 6 there's something wrong with that. Wrong focus.
 7 Q. Just a handful of further questions about the
 8 correspondence and so on at this time.
 9 First of all, NHBT0000074_026.
 10 You wrote to Dr Gunson on 9 May 1991. You
 11 referred to Dr Contreras's letter and said your
 12 impression was "that there was a concerted attempt to
 13 obtain funding from the Department of Health", was
 14 this is an agreed strategy? And then you posed the
 15 question:
 16 "Would you be good enough to let me know whether
 17 there was in fact a strategy which involved delaying
 18 the introduction of the tests while awaiting central
 19 funding for this test. As far as I am aware, no
 20 previous communication has indicated that the start
 21 date for the test depended on funding direct from the
 22 Department of Health."
 23 Now do you recall if you had an answer from
 24 Dr Gunson to that question: was there a deliberate
 25 strategy here?

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1 A. I certainly don't recall any response. But obviously
 2 ...[frozen screen]... well, obviously -- but no,
 3 I don't ever recall receiving an answer to that.
 4 Q. Now, one of the things that happened next, and we can
 5 pick this up at NHBT0000192_024, was the suggestion
 6 that your action would be regarded as a trial and not
 7 the commencement of routine testing. So we can see
 8 this is a letter from Dr Gunson to all RTDs,
 9 9 May 1991. We can pick it up, I think, bottom of the
 10 page:
 11 "Dr Lloyd's premature introduction of the test,
 12 however, can be used to extend the scope of the
 13 evaluation if it is developed as part of a national
 14 policy. To this end DH have agreed that two other
 15 RTCs in England, namely Leeds and Liverpool, will take
 16 part in an extended trial using the Ortho 2nd
 17 generation kit. This will still be regarded as
 18 a trial and not the commencement of routine testing."
 19 There's further communication in relation to
 20 that suggestion. You've characterised it in your
 21 statement as a face-saving exercise and a charade, and
 22 I just wondered if you would care to elaborate upon
 23 that?
 24 A. Yeah, certainly. At the time when this came out, when
 25 Dr Gunson started talking about an extended trial, you

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1 is normally only a mild infection (not like AIDS)."
 2 Now, you have some observations from that in
 3 your statement, Dr Lloyd, but I just wondered if you
 4 could tell us orally what your response is to that.
 5 A. I mean, that's really a quite outrageous statement to
 6 be putting out and suggesting that people should pass
 7 it on to the general public. Dr Gunson knew that
 8 wasn't true. People who, unfortunately, you know,
 9 were HIV infected, developed AIDS and died, and there
 10 are people who contracted hepatitis C and developed
 11 severe disease cirrhosis and died: normally only
 12 a mild infection? No, sorry, that's wrong.
 13 Q. Then if I can just pick up a couple of other letters,
 14 NHBT0000076_009. This is a letter you wrote to
 15 Dr Gunson on 24 June 1991. You say in the second
 16 paragraph -- no, the first paragraph is what I wanted
 17 to pick up, second sentence:
 18 "The fact that many other countries have been
 19 testing for about a year now and in some cases longer,
 20 makes the UK position look increasingly unrealistic
 21 and very hard to defend."
 22 I'm not going to go through with you all the
 23 other dates for the other countries, we have those as
 24 a matter of record.
 25 SIR BRIAN LANGSTAFF: Are we actually looking on the same

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1 know, I -- my immediate reaction was that this was
 2 just Dr Gunson trying to save face. He'd told the
 3 Department, or the ACVSB, you know, "We're doing it
 4 all together, no problem here", and then this guy goes
 5 and does this differently, upsets everybody, and now,
 6 somehow, Dr Gunson has got to save face, either
 7 amongst his -- amongst the directors or the Department
 8 of Health.

9 So I saw this as nothing more than a face-saving
 10 exercise and I think you do have, again, some of that
 11 correspondence between Dr Gunson and Simon Pearl that
 12 that's exactly what this was, and I think there was
 13 also a letter that he wrote to Dr Contreras, in which
 14 he suggests that this was not a genuine trial that he
 15 was proposing.

16 Q. If we just go to the third page of this document,
 17 please, Sully. This a brief to answer press queries,
 18 "Line to Take" being set out by Dr Gunson.

19 I'm not going to go through all of it but if we
 20 can just go towards the bottom of the page, just above
 21 paragraph 6 "Legal Liability", there's a heading
 22 "Importance of Testing" and the suggested line to take
 23 is this:

24 "The new test will improve the safety of the
 25 blood supply but it should be noted that Hepatitis C

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1 page?
 2 MS RICHARDS: Sorry, first page, Sully, first paragraph.
 3 SIR BRIAN LANGSTAFF: Thank you.
 4 MS RICHARDS: Thank you. So it's the second sentence of
 5 that first paragraph.

6 "The fact that many other countries have been
 7 testing for about a year now and in some cases longer,
 8 makes the UK position look increasingly unrealistic
 9 and very hard to defend."

10 Do you recall any discussions taking place,
 11 whether they were at the division meetings that had
 12 replaced the RTD meetings, or with any others of your
 13 colleagues or with Dr Gunson around this time about
 14 this issue in relation to other countries? Did anyone
 15 ever come back to you with a response as to why this
 16 was not relevant?

17 A. No, I don't recall anyone coming back on this issue.
 18 No, I can't think of anybody coming back and saying,
 19 well, it doesn't -- you know, it's not relevant.
 20 I mean, you can make arguments about the United States
 21 had a much bigger problem therefore testing earlier
 22 might have made -- you know, might have been
 23 appropriate to them but not to us. But I don't recall
 24 anyone coming to me and saying, "Look, this is why
 25 this sort of position of us being late doesn't

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1 matter".

2 **Q.** Then if we look at the penultimate paragraph on this

3 page, beginning "The second of these valid

4 criticisms", so this is about not giving other centres

5 adequate warning, you say:

6 "The second of these valid criticisms resulted

7 from my view that had I informed everyone earlier,

8 pressure would have been brought to bear to stop me

9 instituting testing, a course that I believe was right

10 and am now even more convinced was right."

11 I think you say in your statement, Dr Lloyd,

12 that your real concern was that, somehow,

13 an instruction might be issued from the Department of

14 Health to instruct you not to go ahead; is that right?

15 **A.** Yes, that was my line of thinking. I didn't think

16 I was going to be stopped from doing it just by sort

17 of peer pressure. I thought if I was going to have be

18 stopped, it would have to come through the Department

19 of Health, because Dr Gunson had no -- I had no line

20 accountability to Dr Gunson. He couldn't stop me

21 directly ...[frozen screen]... he was the advisor on

22 the advisory ...[frozen screen]... to happen, and then

23 through the Department of Health, back through to

24 the Regional Health Authority, and then my boss would

25 have said, "Don't do it."

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1 If we look down at the --

2 **A.** I think it was on the -- 14 June, I think.

3 **Q.** Then if we look down the bottom of the page, just want

4 to look at the last paragraph. You say this:

5 "At the end of this meeting I felt confident

6 that as a Centre we had made the right decision to

7 proceed with Hepatitis C testing when we did. My only

8 regret is that we didn't introduce it earlier. The

9 coordinating activity of the National Directorate

10 appears to have provided us with a lowest common

11 denominator approach rather than a best possible

12 approach."

13 As I understand your statement, Dr Lloyd, this

14 remains your position. Your only regret now still is

15 that it wasn't -- that you didn't do it earlier than

16 you did?

17 **A.** Absolutely, yes. And I am sorry for that.

18 **Q.** Do you have a sense of how much earlier you could have

19 introduced it on a local basis in Newcastle, given the

20 other constraints about the way in which the ACVSB was

21 taking its decisions and so on?

22 **A.** There's a number of issues there. If you take the

23 purely logistical issue, we had the wherewithal to

24 introduce the first generation test earlier because we

25 had been the -- we had run the trial. So technically

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1 So that was what I was worried about happening.

2 **Q.** I think we lost a few seconds of your --

3 **A.** Fortunately the -- yes. Yes, that's what I thought

4 was would happen, would be that there would -- that

5 the route would be from the Department of Health

6 through to the Regional Health Authority, where the

7 person I reported to would then tell me not to start

8 testing.

9 But of course I was fortunate also in having

10 discussed this in advance with senior people at the

11 Regional Health Authority, and I have to thank,

12 I think it was, at the time, Professor Liam Donaldson

13 who supported me, and certainly understood the issues.

14 A very savvy individual.

15 **Q.** And then if we can look at a memo you wrote in

16 June of 1991 setting out your reflections.

17 NHBT0000192_092.

18 18 June 1991. It's not to anyone. It reads as

19 though this may be as it were a note to yourself,

20 almost, for the record.

21 **A.** It was, yes. It was a note to myself. I occasionally

22 did that. Helped me remember things.

23 **Q.** I'm not going to read through the detail of it. You

24 refer to a meeting held in York. I think that was the

25 Northern Region that had met.

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1 we could have continued to test when the trial ended.

2 So that's a sort of a technical issue.

3 The second issue is if, as we mentioned before,

4 the ACVSB had noted in November that we should test,

5 should start testing as soon as practicable, I think

6 the word was, we could then perhaps at that stage have

7 gone to the Regional Health Authority and said, "Do

8 you have some remaining sort of emergency funds which

9 you would be prepared to use so that we can purchase

10 this test kit for the first couple of months of 1991

11 before the new financial year starts?" You know, if

12 we'd gone to them in November, perhaps they could have

13 found funding for sort of January, February, March.

14 What I -- I say I didn't know, I probably --

15 perhaps I did know, but I hadn't thought about it in

16 that way, was that we couldn't start testing without

17 the Department of Health approval and the minister's

18 approval.

19 So there was a real -- there would have been

20 a real problem with starting testing before that

21 approval, which I think was given on 22 January 1991.

22 But even then, we could possibly have started

23 testing in January if the Regional Health Authority

24 had had some residual funding to fund the test.

25 **SIR BRIAN LANGSTAFF:** May I just ask about the funding.

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1 The position was, as I understand it, that, at
 2 this time, cross charging was in place. Am I right?
 3 **A.** Yes, yes, sir. But --
 4 **SIR BRIAN LANGSTAFF:** So the -- one way --
 5 **A.** We could change -- sorry.
 6 **SIR BRIAN LANGSTAFF:** -- one way of getting the money is
 7 to increase the price of the product supplied, that
 8 part of the budget?
 9 **A.** At that point -- that's a valid point, except
 10 that I thought that that sort of change I was --
 11 I would be one person going out to the whole series of
 12 health trusts and hospitals to try to renegotiate
 13 a contract, something I wouldn't do without the
 14 region, and if -- I don't know about all the regional
 15 funding issues, whether they would have had money that
 16 they could have, in turn, released to the hospital
 17 trusts, and so on, for them to bring it back.
 18 I might have been in a very strange position of
 19 having approval for an increase in funding or an
 20 agreement to increase funding by some hospitals, but
 21 not by others. That would have been difficult.
 22 **SIR BRIAN LANGSTAFF:** Yes, I see. Thank you very much.
 23 **MS RICHARDS:** Then a couple of other documents, picking up
 24 on something you've referred to about Dr Gunson's
 25 later communications.

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1 Then this:
 2 "However, I suppose we have to reinforce the
 3 arguments which were put forward in 1991 since we must
 4 have believed in them as proper ones to take at that
 5 time."
 6 There's then a comment, some comments on a paper
 7 from Dr Barbara that we don't, I'm afraid, have or
 8 haven't located, which sets out a number of matters.
 9 But if we go over the page, I just want to pick it up
 10 in the third paragraph, where Dr Gunson says:
 11 "The decision to carry out the comparative
 12 evaluation of the Ortho and Abbott second generation
 13 tests was made by ACVSB on 25 February 1991 on the
 14 grounds that the second generation tests had not been
 15 licensed by FDA. I think we must support this policy
 16 decision even though I think we may face some
 17 difficult questions on how the second generation tests
 18 introduced into other countries where screening had
 19 commenced with first generation tests."
 20 Then bottom of the page, he says:
 21 "I do not know how Huw resolved these problems
 22 since I did not discuss them with him. I did have
 23 'crie de coeur' [sic] from a Dr Codd at the Newcastle
 24 PHLS asking what he should do."
 25 Do you have any understanding of what that

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1 Could we start with NHBT0088807. So this is one
 2 of the documents, I think, you were referring to.
 3 This is now February 1999, and I anticipate is in the
 4 context of the litigation, which we know was brought
 5 against the National Blood Authority, and it's
 6 Dr Gunson writing to Dr Barbara and then we've got the
 7 reference in the first paragraph to Simon Pearl, who
 8 you correctly say was a solicitor in the firm
 9 representing the NBA.
 10 It would appear that there's a request from the
 11 solicitor to expand Dr Gunson's report to demonstrate
 12 that your decision, Dr Lloyd, was "maverick and
 13 premature". We see in this next paragraph Dr Gunson
 14 says:
 15 "With the benefit of hindsight I have indicated
 16 that we should have introduced routine testing without
 17 the second evaluation, or at least, tested the 10,000
 18 or so frozen donations whilst using the test
 19 routinely. I think we will be criticised severely for
 20 not doing this, since there were many countries
 21 throughout the world where the second generation tests
 22 had to directly supersede the use of first generation
 23 tests. By April 1991, only Denmark and some centres
 24 in the Netherlands and Italy were not screening
 25 routinely."

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1 references to, Dr Lloyd?
 2 **A.** Arthur Codd, who was a consultant with the Newcastle
 3 Public Health Laboratory Service, I suspect that we
 4 probably threw some request for confirmatory testing
 5 at him and he was a delightful gentleman, but I think
 6 probably got a little bit flustered and wasn't sure if
 7 he was going to get into difficulties for supporting
 8 what we did. So that was probably the sort of lines
 9 that this was taking.
 10 **Q.** Then we see Dr Gunson explains:
 11 "[He is] thinking of responding to Simon Pearl
 12 in terms roughly as set out above. I think it is
 13 important that our efforts [that's his and
 14 Dr Barbara's] correspond reasonably well."
 15 Then if we go to the report from Dr Gunson and
 16 Dr Barbara, or the statement, I should say, it's then
 17 produced at NHBT0088813_002. NHBT0088813_002.
 18 So we can see it's a joint statement by
 19 Dr Barbara and Dr Gunson, entitled "Unilateral
 20 Introduction of Anti-HCV Testing at Newcastle RTC in
 21 April 1991". I know you've had an opportunity to look
 22 at this, so there are only two passages I'm going to
 23 ask you about, Dr Lloyd, second page, bottom half of
 24 the page, it says:
 25 "Dr Lloyd ... did not raise any objections to

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1 the agreed starting date of 1 July ... However, we can
2 only conclude that he intended to begin testing in
3 April 1991, since he used the specious argument for
4 taking this premature action that he wished to ensure
5 that all products for issue had been tested by
6 1 July ..."

7 Then that refers, I think, to the letter that
8 we've already looked at, or one of them.

9 A. Yes, yes.

10 Q. Do you have any observations about what's set out
11 there?

12 A. Yes, as I said, the letter I sent to Dr Gunson
13 referring to 1 July, I think I, as I said before, I
14 was trying to protect my own back, a little bit, by
15 sort of making out that I wasn't quite as forthright
16 in starting this testing when I did. I was -- so
17 1 July, when we say here it's a specious argument,
18 there is some truth in that. It actually wasn't the
19 reason I started testing, but when Barbara and Gunson
20 saw that, they could use that information in this way,
21 so perhaps not unreasonable, given what I had written.

22 Q. Then the last part I wanted to ask you about in this
23 document is on the last page. Last paragraph:
24 "There is no doubt that Dr Lloyd's decision was
25 not in the interest of the Service as a whole and was

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1 statement is what about the patients, you know, it's
2 corporate speak, you know: "interests of the service",
3 never mind about the safety of the blood we're
4 issuing. I think that's it.

5 Q. Then can I ask you -- and this is now just really on
6 a point of detail, rather than the issues of principle
7 which we've been discussing, can I ask you to look at
8 WITN6935035. This is a letter from Dr Collins,
9 3 January 1991, and it says -- it's a letter for
10 donors who have been tested and whose test results
11 suggests hepatitis C positivity. I just wondered if
12 you can assist us in understanding the significance of
13 this in terms of the date. Was this a draft in
14 anticipation of the later introduction of testing, do
15 you know?

16 A. No, I think if you scroll up to the top of the
17 document, if you would, please, you'll see at the top
18 that, although it's under Dr Collins's name, the --
19 our reference shows that it was myself who drafted
20 this, and 3 January '91, this was after we had done
21 the first generation test.

22 So, yes, this must have been preparing ourselves
23 for the introduction of testing. I'm just looking at
24 the date ...[frozen screen]... Yes, it was written on
25 the 3 January, the reference number confirms that it

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1 taken in the knowledge that he was flaunting the
2 decisions of the Department of Health who had made it
3 clear through the ACVSB that they were the responsible
4 body to determine when routine anti-HCV testing should
5 start and the steps which should be taken prior to its
6 introduction."

7 Any observations, Dr Lloyd, on that and, in
8 particular, on the suggestion that this was not in the
9 interest of the Service as a whole?

10 A. Yes, yes, certainly some observations. I mean, first
11 of all, I'll come back to your question about in the
12 interests of the Service as a whole. "Flaunting the
13 decisions of the Department of Health", well, I wasn't
14 part to the minutes of the ACVSB and so I only had
15 limited knowledge of what their position was, as
16 provided through Dr Gunson.

17 Secondly, by the time I started testing, the
18 ACVSB, they had already said, "You will start
19 testing". So this argument that they were the
20 responsible body to determine when testing should
21 start doesn't hold water in this case. They'd already
22 said, "Go ahead". They had handed it over to
23 Dr Gunson to arrange starting.

24 So then we come back to "the interests of the
25 service as a whole". Well, what is missing in that

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1 was actually written -- typed up on 3 January. So it
2 was -- it has to have been in anticipation of
3 starting.

4 I can't think why else I would have prepared
5 that document at that stage ...[frozen screen]...

6 Q. An alternative explanation could be -- sorry, you're
7 frozen, Dr Lloyd, so I'll just wait until --

8 A. -- following on -- sorry.

9 Q. Carry on.

10 A. It is -- thank you. It is possible that I wrote this
11 letter as a follow-on to the first generation study
12 that we did and, as we got results back --
13 confirmatory testing results back, I drafted this so
14 that Dr Collins could contact those. There is
15 something in that letter, if I recall, that mentions
16 two tests; is that correct?

17 Q. Yes, the first paragraph says:

18 "When you donated blood recently, we included
19 two new tests for a form of Hepatitis or Jaundice
20 virus."

21 A. Okay. So this letter does refer to the comparative
22 first generation study we did.

23 Q. Thank you. That was what I --

24 A. So this is as the results of that study -- yeah.

25 That's where it came from, then, because it says two

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1 tests.

2 **Q.** Then, just in terms of once testing was fully
3 operational across for the Northern Region, I think
4 there came a point in the course of 1992 when it
5 appears that you learnt that Dr Collins had not been
6 communicating to donors who had tested positive the
7 fact of their positive test and what steps they should
8 take, for example, seeing a doctor, and so on.

9 **A.** Yes.

10 **Q.** The reference, just for the transcript, I don't
11 propose to go to it is NHBT0003991. How had that
12 happened and what steps were taken to rectify that
13 situation?

14 **A.** Steps to rectify: as soon as we found out, we sort of
15 piled resources then to get the letters out, dedicated
16 a secretary to help with it and we got on and got the
17 letters out.

18 How it came about, obviously, as a consultant,
19 I can't -- I couldn't sort of go to Dr Collins and
20 sort of look over her shoulder and say, "What are you
21 doing?" She had a degree of autonomy and
22 responsibility for doing the work, and it is
23 regrettable that I didn't realise that she wasn't
24 doing this work. I mean, it was a pretty
25 straightforward piece of business to, you know -- she

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1 **A.** It is.

2 **Q.** 18 May 1983. It refers to you having spoken to
3 Dr Gunson regarding hepatitis B core antibody testing.

4 "He says that the results of the trial have now
5 been completed and are being presented to the
6 appropriate Department of Health Committee on
7 Virological Safety."

8 Then the next paragraph discusses the test
9 results.

10 And then the third paragraph:
11 "With regard to the date of implementation of
12 the test in the [UK], Dr Gunson says he does not know
13 when this will be but thinks it will be in the autumn.

14 "As usual it looks as if the National
15 Directorate (now the NBA) and the Department of Health
16 are being incredibly slow in their deliberations and
17 of course should have introduced this test earlier
18 this year, given the information they had available
19 from the Liverpool study."

20 Is it right to understand from this, Dr Lloyd,
21 that your assumption and Dr Gunson's assumption was
22 that this test would be introduced, the only question,
23 really, was when rather than whether?

24 **A.** Oh, absolutely. I mean, once again, in this case --
25 referring to Sir Brian's comment -- we included

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1 received the results. I think we had probably helped
2 to draft -- you know, we'd got the drafts like this,
3 letters like this, so we knew what we were going to
4 do, but, for some reason, she was unable to carry it
5 out, and I don't really want to go into why she
6 couldn't carry it out, but she didn't.

7 **Q.** Dr Lloyd, I'm going to move in a moment to three
8 further short topics of questioning I have for you,
9 but before I do so, on the question of the
10 introduction of hepatitis C screening, is there
11 anything further that you would want to say or that we
12 haven't covered or haven't covered in your statement?

13 **A.** No, no, I don't -- nothing sort of springs to mind.
14 All I can say is it gave me some sleepless nights at
15 the time. It wasn't easy -- an easy decision. I was
16 certainly concerned for my position. But thankfully,
17 you know, we got through it. But I don't think
18 there's anything else.

19 **Q.** So I'm going to move now to an issue about the
20 introduction of hepatitis B core antibody testing.
21 Not as a surrogate measure for non-A, non-B hepatitis
22 but in relation to hepatitis B itself.

23 If we pick this up at WITN6935033.
24 This is a memo from you. I think it's an
25 internal memo from the names.

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1 the increased cost in the supply of blood, but of
2 course we were doing that before the year's contracts
3 were negotiated.

4 So we had informed hospitals that we were going
5 to introduce the test. Our haematologists in the
6 region knew we were going to introduce the test. We
7 were ready. I recall we had discussed it with our
8 supplier, Abbott, so that they were prepared to
9 deliver to us the suitable number of tests. So yes,
10 we were ready to go. And as you say in that comment,
11 I suggest that Dr Gunson also was expecting to start.

12 **Q.** And the reference to being "as usual ... incredibly
13 slow in their deliberations", is that harkening back
14 to the then not too distant past of the issue relating
15 to hepatitis C screening, do you think, or were there
16 other issues that you had in mind?

17 **A.** No, I think I was just referring to hepatitis C.

18 **Q.** Is this right: that the Newcastle Centre or the
19 Northern Region, had been involved in the trial of the
20 anti-HBc test kits?

21 **A.** Yes, I think we had. I think I've seen somewhere
22 a little -- a few sheets of paper sort of showing some
23 results, so yes, we did do some work on it. I can't
24 remember the results we got in terms of incidence.

25 **Q.** Just for the transcript --

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1 A. But I notice in that --
 2 Q. Carry on.
 3 A. Sorry.
 4 I notice at the bottom of this that we're
 5 talking about the information they had available from
 6 the Liverpool study. I haven't seen -- I may have
 7 seen it at the time, but obviously that was a study
 8 that I thought at the time was of note.
 9 Q. And I won't go to it but there's a letter from
 10 Dr Gunson to you in February of '93 which refers to
 11 your participation in the trial of test kits from
 12 Abbott and Pasteur, and the reference for the
 13 transcript is NHBT0018413.
 14 Can I then pick up this issue about anti-HBc
 15 testing with a meeting in July of '93,
 16 NHBT0016372_001.
 17 So we can see it's a meeting of RTDs/chief
 18 executives/general managers.
 19 If we go to page 4 --
 20 A. Sorry, I -- you said it was a meeting of RTDs, and
 21 I -- sorry, we lost the sound after that.
 22 Q. Yes, it was a meeting on 27 July '93 of
 23 RTDs/chief executives/general managers, and you were
 24 present along with a number of others who fell into
 25 that category.

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1 policy decisions from the DH to the NBA."
 2 So we can see what's set out there I think is
 3 self-evident. Do you have any recollection of the
 4 discussions at the meeting?
 5 A. No, I don't recall what else was said. I think that
 6 minute is fairly clear on where people were on this,
 7 with the Department of Health making the decisions
 8 and -- whereas it really should have been, by that
 9 stage, the NBA's responsibility.
 10 I may not have liked the NBA but, I mean, it was
 11 a clearly established, correctly established body, it
 12 had responsibility for the Transfusion Service in
 13 England and Wales, and therefore it should have had
 14 the authority to introduce the necessary tests as and
 15 when they saw appropriate.
 16 Q. Then if we pick matters up towards the end of 1993,
 17 at NHBT0005291_003.
 18 This is a letter from you dated
 19 8 November '93 to all consultant haematologists,
 20 finance managers and blood transfusion contract
 21 holders.
 22 This particular letter is addressed to
 23 Dr Hamilton.
 24 "As you know, we included provision for
 25 Hepatitis B Core Antibody testing in this year's [BTS]

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1 If we look at page 4, picking it up at
 2 paragraph 6.1, under the headed in "UK Advisory
 3 Committee on Transfusion Transmitted Diseases", you'll
 4 see there the reference to:
 5 "Considerable concern was expressed about the
 6 delay which had occurred by the Department of Health's
 7 insistence on deciding whether and when routine
 8 anti-HBc should be introduced."
 9 There's a reference to events during the past
 10 year in France.
 11 "Dr Gunson confirmed that he had written to
 12 Dr Metters ... stating that the UK Advisory Committee
 13 on Transfusion Transmitted Disease had decided that
 14 from a scientific point of view such routine screening
 15 is warranted and that the latest series of tests had
 16 shown that there are test kits which are satisfactory
 17 although all give false positive results.
 18 "It was recognised that the UK Advisory
 19 Committee on Transfusion Transmitted Diseases is not
 20 in a position to decide that the test can be
 21 introduced. However, it was agreed unanimously that
 22 the NBA should have the authority to make this
 23 decision. Dr Gunson and Mr Adey would ask the
 24 Chairman of the Authority if he would speak to the
 25 Minister of Health on this important transfer of

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1 Contracts. One Regional Transfusion Centre had
 2 started testing and there were clear indications that
 3 the UK would introduce this test ..."
 4 Then we see the purpose of it here described by
 5 you:
 6 "... to eliminate the small number of Hepatitis
 7 B transmissions by blood transfusion that occur due to
 8 a small group of individuals who are infectious but
 9 negative for Hepatitis B Surface Antigen, for which we
 10 currently test."
 11 Just pausing there, the purpose of this testing
 12 was to pick up this group who would not otherwise be
 13 picked up by the existing HBsAg testing, and meant
 14 that cases of hepatitis B transmission by blood
 15 transfusion did still occur. Is that right?
 16 A. Yes, yes. My understanding was that we were still --
 17 there was still some infectious units, that the
 18 surface antigen test was not picking them up. And
 19 I wish I could see the Liverpool study to sort of
 20 actually see the numbers, but obviously it was
 21 sufficient to make people such as Dr Gunson realise
 22 that this test should be introduced.
 23 Q. Then we can see next paragraph:
 24 "At the beginning of this year we were asked not
 25 to start this test and to wait until the whole country

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1 started testing. We have now been informed that this
2 test is not to be introduced, this instruction coming
3 from the Department of Health. I am told that the
4 decision was 'not taken lightly'."

5 Now, again, we'll obviously need to pick up
6 elsewhere the Department of Health's own
7 decision-making process. Do you recall any more about
8 how and when you learnt of the Department of Health's
9 decision?

10 **A.** No, no. As we know, the advisory committee at the
11 Department of Health minutes were not for circulation
12 so we wouldn't have seen anything about how they came
13 to this decision, and not taking it lightly. I find
14 that difficult. I'm putting it in context. The
15 Department of Health, for both HIV testing and for
16 hepatitis C testing, made decisions not to fund the
17 testing directly but to just offload it onto the
18 Health Authorities and the hospital services to just
19 take up the cost. So how they came to this decision
20 not to introduce a test that increased safety, when
21 they were almost certainly never going to have to deal
22 with the financial implications, I find difficult to
23 understand.

24 **Q.** It would appear that Dr Hamilton, to whom this was
25 addressed, was troubled by the decision. We can see

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1 "Dr Huw Lloyd, a former director of the Northern
2 Regional Transfusion Centre in Newcastle upon Tyne,
3 said he had been 'strongly in favour' of introducing
4 the hepatitis B test, known as anti-HBc screening.
5 'There was sufficient information to suggest that it
6 would improve the safety of blood transfusions' ..."

7 So we're now in the top right-hand column:

8 "His centre made all the arrangements for the
9 test to be introduced last year, but was then
10 instructed not to go ahead. 'I think that was not the
11 right decision to make', said Dr Lloyd, who has left
12 the service."

13 Then if we go to the bottom half of the page,
14 left-hand side. We can see there's reference to other
15 countries using anti-HBc testing, there's reference to
16 people in the service being angry and then, picking it
17 up, it says:

18 "Dr Lloyd said that the test could have been
19 introduced relatively inexpensively. 'But if you are
20 not very keen on it, you can make out that there are
21 a lot of additional costs'."

22 Then there's a reflection of the concern of
23 Dr Peter Hamilton and it would appear he wrote to the
24 BMJ in January 1994 about it.

25 Is that article an accurate reflection of your

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1 that from NHBT000 --

2 **A.** He would be.

3 **Q.** -- 5291_002.

4 So Dr Hamilton, who was Dr Peter Hamilton,
5 a haematologist at the Royal Victoria Infirmary, was
6 here three days later seeking advice from solicitors.
7 He referred to the letter he'd received from you, and
8 then said:

9 "As the Consultant in Administrative Charge of
10 Blood Bank at this hospital, I am charged with the
11 issue of 'safe blood' to patients. It would seem that
12 although there is a 'test' which could improve the
13 safety of the blood issued in my name it appears that
14 for financial reasons in this country it has been
15 decided not to use it."

16 Then he refers to the criminal prosecutions in
17 France, and asks for reassurance as to his position.

18 **A.** Mm-hm.

19 **Q.** Just one further document, I think then, on this
20 issue, which is at NHBT0097150_007, please. This is
21 a newspaper article in The Times, April 1995, so it's
22 a year and a half, or so, later. If we just pick it
23 up in the middle column, second paragraph down from
24 the top. I think we can leave the whole thing on the
25 screen, Sully, at the moment. It says:

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1 views as at 1995?

2 **A.** I've lost it. Sorry, is that article an accurate?

3 **Q.** An accurate reflection of your views, as at 1995?

4 **A.** Yes, it is. Apart from a comment in the second
5 section right-hand column, right at the end:

6 "Dr Lloyd, however, agrees with the Health
7 Department's decision in this case."

8 I don't know how that comment came about because
9 it does not match anything I had said earlier.

10 **Q.** I think that's a reference to testing for HTLV-I,
11 Dr Lloyd.

12 **A.** Is it? Oh, I see.

13 **Q.** Yes. That's how I read it.

14 **A.** Yes, thank you for that. Yes, you're quite right.

15 **Q.** As opposed to the anti-HBc.

16 **A.** Okay. But anti-HBc, yes, I -- that was my feeling at
17 the time. I think that's a fairly accurate reflection
18 of what I was thinking and we see some -- you know,
19 Dr Peter Hamilton was good at coming forward and
20 stating the point clearly, and I have to agree with
21 him.

22 **SIR BRIAN LANGSTAFF:** May I just ask, I suspect I know the
23 answer but I will ask you anyway and you can confirm
24 what I think may be the case. You did not, in this
25 case, go it alone in Newcastle?

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1 A. No.

2 **SIR BRIAN LANGSTAFF:** Could you have done so had you

3 wished?

4 A. I don't think so. We were -- I can't remember the

5 exact moment in which we were transferred to the NBA.

6 Once we were part of the NBA, that was certainly not

7 something I could have done on my own. You're in

8 a different situation. If it had been before, I think

9 there's some -- some of the documents we've just seen

10 make it much clearer that the Department of Health has

11 the authority and said no, and they said no before

12 I was trying to introduce it anyway. So, you know,

13 "Don't do the test" comes before the point at which we

14 had planned to introduce it. So there would have been

15 a difficulty going ahead, certainly.

16 **SIR BRIAN LANGSTAFF:** Yes, well, thank you very much.

17 **MS RICHARDS:** Sir, I've got about another 10 to 15 minutes

18 of questions for Dr Lloyd, and what I was going to

19 suggest, if it's okay with you and Dr Lloyd is I carry

20 on now, complete my questioning, and then we need only

21 have one perhaps slightly longer break to enable Core

22 Participants to suggest questions rather than the two

23 breaks, and that way we ought to be able to finish

24 Dr Lloyd's evidence today.

25 **SIR BRIAN LANGSTAFF:** Yes. Dr Lloyd you can have a break

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1 training or through those five years or so of house

2 officer work, whether there were ever discussions or

3 guidance or advice about minimising the use of blood

4 and blood products?

5 A. I did -- it sort of bought it back. One of the

6 documents presented by the Inquiry is *Notes on*

7 *Transfusion* dated, I think, 1977. Now, that was

8 a little after I was into my, sort of, general

9 clinical jobs. I certainly recall carrying that

10 notebook, that actual set of notes, with me. I think

11 that does refer to issues of using blood and that

12 there are safety issues.

13 In my training, there was very little said about

14 transfusion. We didn't have a lot of -- I can't

15 recall having a lot of information about the risks of

16 ...[frozen screen]... So, after that, in the first few

17 years, it was -- we just used it, and I was working,

18 particularly in my first job, in a relatively small

19 hospital. So I don't think there was a lot of general

20 knowledge of transfusion. I don't think we had

21 a haematologist -- I know we didn't have

22 a haematologist there.

23 Then we came to north -- when I moved to the

24 North Tees General Hospital in the second half of

25 1975, we did have a haematologist, Dr Roger Finney,

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1 now, should you wish. But you've heard what counsel

2 has had to say. It's a choice between having two

3 breaks, one now and one shortly afterwards, or just

4 the one.

5 The purpose of the break, of the slightly longer

6 break, is, as counsel has said, it's to allow those

7 who are participants in the Inquiry to suggest

8 questions to be put to you so that there is every

9 chance that every question that people significantly

10 wish to ask may be answered from your evidence.

11 We'll continue.

12 **MS RICHARDS:** Thank you.

13 **SIR BRIAN LANGSTAFF:** Unless you want to stop?

14 A. Yes, please continue. No, no, please continue.

15 **MS RICHARDS:** Dr Lloyd, the topic I'm going to ask you

16 about now is clinical transfusion practice. So the

17 extent to which transfusions were used in hospitals,

18 and whether they were used more than they needed to

19 be, and what measures, educational or persuasive

20 measures were or were not taken by the Regional

21 Transfusion Centre in that regard. Can I just start

22 by asking you to cast your mind back to the second

23 half of the 1970s, when you were working in your house

24 officer posts in a range of different disciplines.

25 Do you recall whether, either from your medical

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1 and, you know, I think sort of -- if I did, you know,

2 discuss issues of transfusion when there were things

3 I needed to know, I would discuss them with him. So

4 there was discussion and I don't think I was ever in

5 a position of wanting to or needing to do single unit

6 top-ups. Perhaps that's partly because of the type of

7 patients I was dealing with.

8 So yes, during those years, there was

9 discussion. Not massive, but things like *Notes on*

10 *Transfusion* did provide some backdrop to the fact

11 that, you know, there are safety issues. I don't

12 recall throwing this stuff around like confetti.

13 Q. Then, whether by reference to those SHO years or then

14 in the 1980s when you began to concentrate on

15 haematology and transfusion and you had some

16 experience with blood banking, and so on, do you

17 recall what the position was in terms of record

18 keeping? Were there -- how meticulous or rigorous an

19 approach were you instructed or advised to take from

20 the hospital's perspective about ensuring that there

21 were clear records of what was transfused and to whom,

22 both in the blood bank and in the patient's records?

23 A. Oh, in the patient's records, it was certainly drummed

24 into me that we always recorded the information on

25 transfusions, the donation number and what was

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1 transfused. So that went into the patient's record,
2 and, you know, that was -- that was very much
3 an imperative that we did that.

4 Hospital blood banking, the way in which records
5 were kept was varied. When I worked at the Freeman
6 Hospital, there was the consultant -- one of the two
7 consultant haematologists, initially one, Dr Mansoor
8 Qureshi, very, very interested and concerned about
9 record keeping, to the extent that he wrote computer
10 programmes to help the Department keep accurate
11 records of what was happening.

12 The other two hospitals were -- would have been
13 more manual. I can't remember exactly how they did
14 it. But yes, keeping records was certainly
15 an important issue, level of importance, you know, as
16 I say, Dr Qureshi was certainly up there amongst the
17 top, wanting to make sure we had everything correctly
18 recorded.

19 Q. Then if we could look at document you've exhibited to
20 your statement please WITN6935018. This is headed
21 "Transfusion -- Do We Have Any Choice?":

22 "The answer is Yes and No!

23 "In many instances there is no choice, but in
24 some cases there is a choice.

25 "The main choices can be summarised as follows:

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1 ...[frozen screen]... look at the clinical state of
2 the patient. Is this patient in distress or having
3 difficulties because the haemoglobin is low, or are
4 they actually coping with their current haemoglobin
5 level? Don't just top it up to a nominal value.

6 And of course, the next one, "Have a maximum
7 blood order schedule", which is sort of a more
8 organisational policy, particularly aimed at more
9 junior staff in a department. Junior staff are going
10 to be more cautious and therefore over-order blood
11 because they don't want to get caught out and screamed
12 at for not having enough blood ready for a procedure,
13 particularly in surgery. So if you provide them with
14 a maximum blood order schedule, you're not -- you're
15 allowing them to order less blood, and not put
16 themselves or perceive to put themselves in
17 a difficult position.

18 Q. And do you know when that process of having -- this
19 idea of the maximum blood order schedule, when that
20 was introduced in the region?

21 A. Oh, it wouldn't have been introduced across the region
22 as a single process but, you know, you have to
23 remember in the Northern Region most of the
24 haematologists -- well, all the haematologists,
25 possibly bar one, met on a fairly regular schedule --

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1 "Reduce your threshold for Transfusing ...

2 "Make judgements on clinical state not just on
3 the value.

4 "Have a maximum blood order schedule and do not
5 transfusion blood just because it has been
6 crossmatched.

7 "Use volume expanders.

8 "Use Autologous Techniques."

9 Then you refer to the possible use of blood
10 substitutes.

11 First of all, what was this document, was this
12 notes for a lecture or talk you were giving?

13 A. Yes, yes. This was notes for a talk I was giving.
14 I can't remember exactly who I was talking to but, you
15 know, one of the hospital -- perhaps, you know,
16 perhaps at one of the hospitals. So, you know, I did
17 do -- invited to talk here and there. And that's what
18 this is. Just personal notes, notes to me that I
19 could use for talking. It was probably supported by
20 some slides.

21 Q. I just wanted to ask you a little more about the
22 second and third of those choices. The "Make
23 judgments on clinical state not just on the value",
24 what did you mean by that?

25 A. Well, not just on the value of the haemoglobin. So

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1 it's not a schedule, but there was a regular meeting
2 every Friday at the Royal Victoria Infirmary and
3 haematologists would come in ...[frozen screen]... a
4 crossover of information between them, and
5 discussions. So things would tend to -- you know, to
6 permeate across the region perhaps faster than in an
7 area in a region that didn't have this very good
8 little meeting.

9 Q. And I think we can see a reference to --

10 A. I can't remember --

11 Q. We can see a reference to those meetings and to
12 hospital transfusion committees at NHBT0009710.

13 These are the notes of a November '91 visit to
14 the RTC by Dr Ala and Dr Hewitt. If we just go to
15 page 2, we pick it up at the bottom half of the
16 page first of all, paragraph 1.3, "Regional
17 Transfusion Committees", it says:

18 "There is no Regional Transfusion Committee.

19 The Northern Region Consultant Haematologists' Group
20 meets twice per year. There is also a weekly informal
21 meeting of the Regional Haematologists, which the RTD
22 attends."

23 Is that what you were referring to?

24 A. That was -- yes, correct. That's what I was referring
25 to.

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1 Q. Do you know when that weekly practice started? Was it
2 already ongoing when you came back to the Centre in
3 86/87?

4 A. It was -- that was going back -- that was operating
5 back in 1981. I recall going into it as a registrar
6 being in -- Dr Collins saying, "You know, you should
7 get across to that meeting". So that meeting had been
8 going for a long time. I suspect it was instituted by
9 Professor William Walker.

10 Q. Then the next paragraph refers to three-monthly
11 haematology audits. It says there:

12 "... topic-orientated and have included
13 transfusion matters."

14 Is there a system with which you were -- or
15 a process with which you were involved at the
16 Transfusion Service, was that done with the region and
17 the hospitals themselves?

18 A. I think that was a-- I think -- sorry. I think that
19 was the region and the hospital. It wasn't something
20 driven by us. We were perhaps not as intrusive into
21 the hospital blood banking as we might have been.

22 And you will perhaps note from other things I've
23 said that we -- when I moved from being -- well, I say
24 moved -- when I became chief executive, we
25 introduced -- we were able to appoint a consultant to

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1 I was still perhaps a senior registrar. But they
2 would have been one of the sort of -- one of the
3 hospitals that tended to be at the forefront of that
4 sort of issue.

5 Q. Looking back now, Dr Lloyd, do you think there is more
6 that could have been done, whether by the Regional
7 Transfusion Service or by the hospitals within the
8 region or, indeed, nationally perhaps, by the Chief
9 Medical Officer or the Department of Health, to
10 reinforce the message about using transfusion
11 appropriately and encouraging and educating doctors
12 and nurses about the better use of transfusion?

13 A. Certainly you can always do better. I -- you know,
14 I could have spent more time, and sort of recognised
15 that I wasn't spending as much time as I, you know,
16 perhaps should, in working at that level with the
17 hospitals. But we did have -- the Northern Region did
18 have a good group of consultant haematologists so --
19 you know, they understood these issues. Prior to
20 the -- prior to a hospital getting a consultant
21 haematologist, you were left with a pathologist
22 looking after the issues, and at that time that would
23 have, you know -- I'm sure there wouldn't have been
24 the same pressure on teaching people how to use
25 transfusion properly. But once you've got the

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1 become the head of our medical service, specifically
2 to sort of recognise -- you know, recognising that I
3 didn't have enough time to devote to some of these
4 issues such as hospital transfusion committees. And
5 of course, a bit like Anne Collins before me, for
6 a number of years I had very little in the way of
7 other sort of consultant-level support.

8 Q. And if we look at the top of the page we can just pick
9 up the reference to hospital transfusion committees.
10 It says:

11 "Twenty/twenty-one Hospital Transfusion
12 Departments are serviced by the RTC and of these,
13 three/four have set up Hospital Transfusion
14 Committees. These generally meet at three-monthly
15 intervals. The RTC is not actively involved, but two
16 of the RTCs invite an RTC Consultant as appropriate."

17 It sounds as though the establishment of the
18 hospital transfusion committees by the three or four
19 hospitals was relatively recent at that point in time.
20 Does that accord with your recollection?

21 A. I think so. I think so. You said this was 1991?

22 Q. November 1991, the date of this.

23 A. Dr Ala and Dr Hewitt, yes. When Dr Hewitt and Dr Ala
24 visited. So I think there was a hospital transfusion
25 committee at the Freeman Hospital before that, when

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1 haematologists there, you know, that was changing.

2 And you saw that when we had meetings with
3 the haematologists from around the regions, only twice
4 a year, we were able to work with them to change
5 transfusion practice. And, you know, the reduction in
6 the use of whole blood was also -- you know, we also
7 talked about single unit transfusions. So yes, could
8 have done more, but I don't think the Northern Region
9 at that time, by the end of the 1990s, was doing too
10 badly.

11 Q. Then last on this topic, NHBT0072687_001.

12 This is a letter from you to a consultant
13 cardiothoracic surgeon at the Freeman Hospital,
14 Dr Hilton, 11 June 1990. It says:

15 "Following the recent episode in which you
16 phoned myself requiring that we provide blood bags for
17 you to collect blood from staff in theatre for the
18 provision of immediate blood transfusion. I feel that
19 I need to reply to you and make my position clear."

20 Then you go on to describe these procedures as
21 highly dangerous, both because of the lack of proper
22 blood grouping, and the risks from that, and then, the
23 third paragraph, the fact that the blood would not
24 have been tested for hepatitis B or HIV antibodies.

25 Obviously this is before the introduction of the

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1 hepatitis C testing.
 2 And then you go on to talk about -- discuss
 3 the practice of using fresh whole blood in cardiac or
 4 cardiothoracic surgery.
 5 Do you recall how, if at all, this issue was
 6 resolved?
 7 **A.** Well, you'll also see in witness statements that one
 8 of the haematologists at the Freeman Hospital was
 9 saying something very similar to myself, that this
 10 wasn't a suitable procedure. I don't know -- I think
 11 that was probably a letter from Dr Patrick Kesteven
 12 to -- to Mr Colin Hilton.
 13 I would imagine that they worked it out between
 14 them but I don't recall any sort of long term
 15 follow-up. I did get a copy of -- it's a -- well,
 16 it's in the state -- one of the documents in the
 17 Inquiry -- another letter from Colin reminding me that
 18 they were not the only people wanting to use fresh
 19 whole blood in that clinical situation.
 20 I have no problem with them using fresh whole
 21 blood if that's -- was the best thing for the clinical
 22 care of the patient. I was concerned about it being
 23 done safely. And I wasn't going to participate in an
 24 unsafe procedure. But I don't know where it went
 25 after that.

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1 **Q.** Yes, so it says:
 2 "Transfusion Centres store a wide range of
 3 documents and records ..."
 4 Then if we skip down to the third paragraph:
 5 "Each group of documents or records can be
 6 viewed as having to be retained for certain minimum
 7 periods to satisfy specific legal requirements ..."
 8 Then you say:
 9 "The need to retain documents and records for
 10 use in future potential litigation is increasing as
 11 the level of litigation increases and it is imperative
 12 that major cases are not lost purely because the
 13 relevant documents are not available."
 14 Then if we -- I'll skip over the next paragraph
 15 and then it says:
 16 "To be of value, any records system needs to be
 17 simple, robust and reliable."
 18 Now, before I ask you a couple of questions
 19 about the recommendations in the report, this
 20 introduction seems to be very much focused upon the
 21 fear of litigation. Was that the context in which
 22 this report was commissioned, or -- how did it come
 23 about that you and your colleagues were producing
 24 this?
 25 **A.** I mean, obviously Dr Gunson asked for this report. He

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1 **Q.** Then my final topic, Dr Lloyd, is in relation to
 2 record keeping. We've covered already in your
 3 statement, and the documents we've got refers to the
 4 record-keeping systems at the Centre and your
 5 introduction of the various computerised systems, so
 6 I'm not proposing to ask you more about that, but you
 7 were involved in the production of a report about
 8 record storage, which is at NHBT0071590_001.
 9 So "Record Storage Report for the [NBTS] in
 10 England and Wales, Prepared on behalf of the National
 11 Directorate of the [NBTS] by Dr Lloyd, Dr Beal and
 12 Mr Martina, April 1992.
 13 Then if we go to page 4, we can just pick up the
 14 "Introduction". So the report explains:
 15 "Transfusion Centres store a wide range of
 16 documents and records ..."
 17 And then --
 18 **A.** Could we bring that up, could we bring that up on the
 19 screen, please?
 20 **Q.** Do you not have it on your screen?
 21 **A.** I don't, no. We've not moved on from Dr Hilton's
 22 letter yet.
 23 **Q.** Ah, let's try again. Could you reload it, Sully,
 24 because it was on my screen. Have you got it there?
 25 **A.** Yes, I have 1.1, "Introduction". Thank you.

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1 must have been concerned about retaining records.
 2 I know I've -- this little bit focuses on litigation
 3 but I think you'll see elsewhere in the document that
 4 it actually focuses on -- it actually includes a wide
 5 range of sort of legal requirements to retain records.
 6 Obviously a lot of the -- these records are
 7 retained because there is a potential to come back
 8 and -- for litigation. Whether that was Dr Gunson's
 9 focus, I can't remember how it -- I don't -- I haven't
 10 seen any letter from him sort of giving me and Dr Beal
 11 and Tony Martina a remit, a formal remit for doing
 12 this, for producing this. It's very much an
 13 organisational-wide process that you might apply to
 14 any sort of large organisation.
 15 **Q.** If we go to page 7, please, Sully, top half of the
 16 page. We can see outline recommendations and you
 17 identify there three categories: "Long Term", where
 18 the recommendation is to keep the records for
 19 30 years:
 20 "This covers Donor and Donation records and
 21 policy and management records as well as records
 22 directly linked to Donor and Donation records such as
 23 QA reports."
 24 Then you have "Intermediate Term" for
 25 a different category of documents, which was 10 years,

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and then a "Transient Term" storage period for 2 years.

There's more detail given about the categories and, in particular, the inclusion of donor and donation records, pages 10 to 11 of the report. I'm not going to go through that, but if we turn to page 14, we can pick up the recommendation at the bottom of the page, in terms of a basic system:

"Transfusion Centres should institute a records storage system which enables records of potential significance for litigation to be retained for 30 years."

Then the next paragraph says:

"A record of the destruction of records should be maintained, including the destruction of originals after transfer of records to other storage media.

"A scheme such as the Annual Policy statement records should be instituted."

Top of the next page:

"A formal written policy should be provided and followed. The system used should be audited ..."

Then the next paragraph says:

"The system proposed in this report can be adapted to each RTC's specific requirements ..."

Do you know when the recommendations in this

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a decision, we destroyed it. This is why we did it. It wasn't just a lackadaisical thing.

So in the centre, yes, we did start to follow this. Of course, we didn't have any years to do it. I believe, and this is very secondhand hearsay, through a colleague of mine after I'd left the service, who did say that the Transfusion Service were using this document, didn't go into details, but he sort of said that this document was still being used by the service after I'd left, and, you know, Tony and Dr Beal, you know, helped produce a -- what I think was a pretty sound document, and thanks to them.

Q. I think the Inquiry has heard some evidence or received some evidence that the Red Book guidelines around this time were 15 years, in relation to the kind of records you were here identifying should be kept for 30 years.

A. Yes.

Q. Was that your understanding and was the intention, therefore, to essentially depart from the Red Book guidance and create a longer term storage system?

A. Yes, definitely. I think the three of us recognised that you couldn't, sort of, rely on things, you know, just saying, oh, well, you know, it's a certain number of years. You actually had to look to the future, and

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report were implemented, either in the Northern Region or more generally across England and Wales?

A. I'll talk first about the Northern Region. Yes, we implemented a policy, basically what was outlined in this document. We took a large room in the building, moved out what was in it, and created a record storage facility. We appointed -- we gave someone the ...[frozen screen]... the documents, and so we started down this route. So the documents were in proper cabinets the sort of things you see sometimes in libraries, with big wheels that you move the cabinets up and down on tracks, allows you to have high density storage and, yet, you're able to access documents, find them very easily, and we certainly implemented the policy of keeping records of what we did.

It sounds silly: records of records. But,

I mean, if you're going to keep a record, you need to know that you've kept it, what it's about, where it is and if you decide to destroy it, you should -- you identify why you destroyed it and when you destroyed it, or when you destroyed it and why you destroyed it.

So then in the future, when someone comes along and says why haven't you kept such and such a record, you can go back to this long-term record that says, yes, this is where we looked at this, we made

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I do recall in this report I referred to litigation.

I can't remember the person's name but between an individual and English electric company, I think it is, in this report, someone who had pneumoconiosis. And there you see that the litigation was allowed to proceed long after what at the time were considered to be the sort of limits on bringing cases to court. So we recognised that we couldn't rely on some of these other documents.

And we also, I think, in this report, say, yes, we've said 30 years but when you start getting towards 30 years, you have documents that have been stored for 30 years, you need to stop and review your policy and decide whether you need to increase it again.

MS RICHARDS: Sir, those are the areas I'm proposing to cover with Dr Lloyd. I've obviously, inevitably, been longer than I said I was going to half an hour ago.

Can I suggest we take a long-ish break now, which will both give Dr Lloyd a break but will also enable me to consider questions and allow our legal representatives and Core Participants to formulate questions.

SIR BRIAN LANGSTAFF: How long do you think you need?

MS RICHARDS: There's been quite a lot of interest in Dr Lloyd's evidence, so I think if we took 40 minutes,

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1 that would give enough time, and then enable us to
2 conclude Dr Lloyd's evidence today safely and not have
3 to come back tomorrow.

4 **SIR BRIAN LANGSTAFF:** Very well. We shall come back not
5 before 5.15 for us, that's 12.15 for you, Dr Lloyd.

6 So not before 12.15.

7 **MS RICHARDS:** Thank you.

8 **THE WITNESS:** I will be here.

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

10 (4.35 pm)

11 (A short break)

12 (5.20 pm)

13 **SIR BRIAN LANGSTAFF:** Yes.

14 **MS RICHARDS:** Dr Lloyd, there are a relatively small
15 number of further questions.

16 The first is this: do you know how many donors
17 tested positive for hepatitis C in the period April to
18 September 1991?

19 **A.** No, unfortunately I don't. I did ask the Inquiry if
20 data on positive results could be obtained. So
21 unfortunately, no, I don't know. I'm sorry.

22 **Q.** Don't worry, if you don't know, you don't know.

23 The next question is about donor exclusion on
24 the basis of previous transfusions. You'll recall we
25 looked yesterday at both the national guidance and

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1 individual decision. It might start with a medical
2 officer -- in those days it was a medical officer at
3 the session and not a clinical nurse specialist, but
4 you would have -- they might recognise, particularly
5 being a general practitioner, they would recognise
6 that there was an issue that needed following up and
7 would do so.

8 And the second was, when that wonderful illness
9 book, duplicate book, information came back from the
10 session and the medical officer at the centre
11 looked at it, they might recognise that there was
12 a need to obtain additional information. Probably
13 more often, in that case, it was obtaining more
14 information rather than passing the -- asking the
15 donor to get further care and treatment. But I think
16 at the sessions the medical officer was probably the
17 one who was asking people to -- suggesting that they
18 get followed up.

19 There is of course the case of those who were
20 found to be positive for infectious and transmissible
21 disease.

22 **Q.** Yes.

23 **A.** Very different requirement to go and see somebody.

24 **Q.** Then if you had a donor who was being deferred or sent
25 away because they'd had a blood transfusion in the

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1 then the Northern Region zone guide or booklet on
2 donor selection, which looked at deferral of donors
3 who'd had a blood transfusion. What was your
4 understanding of the rationale for excluding donors or
5 deferring donors on the basis that they had had
6 a blood transfusion?

7 **A.** Right. I think the issue was that we know that
8 there's potential for infection, and if someone is
9 infected, there is a period between infection and --
10 the relevant tests becoming positive. So by
11 delaying -- by giving those months in between,
12 certainly if there was something transmitted then you
13 have a chance to pick it up on testing.

14 There's also a more general issue that people
15 who have been transfused presumably have had some
16 reasonably serious condition and therefore need time
17 to recuperate appropriately. So there's a little bit
18 of both. But I think the -- it was the first was
19 the -- sort of the issue there.

20 **Q.** Then when donors were either excluded or deferred --
21 and this next question is not limited to previous
22 blood transfusion -- what were the circumstances in
23 which a donor might be advised to go and see their GP
24 and have further testing?

25 **A.** I mean, that usually -- that was sort of a rather

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1 past -- I appreciate the period of time might vary
2 depending upon the particular set of guidance in
3 operation at that time, but if you were doing that,
4 was there any practice of telling donors why it was
5 a transfusion might mean they shouldn't give blood at
6 that stage? Would they be told, for example, "Well,
7 there is a risk of infection and you perhaps you might
8 yourself want to go and get tested"?

9 **A.** I don't recall that being certainly a written policy.
10 I'm pretty sure it wasn't a written policy. Did the
11 medical officer at the session do that? Certainly,
12 there was the option to discuss the issue. It depends
13 on the -- you know, it does depend on the individual
14 doctor, and patient -- sorry, the donor. But, no,
15 I don't think we had a proper policy on saying you
16 must tell the person who has received the transfusion
17 that they might be at risk.

18 **Q.** Cases of possible transfusion-associated hepatitis, is
19 it right to understand that you did not report such
20 cases to the CDSC?

21 **A.** Well, if a patient had a transfusion -- well, had
22 a transfusion and then developed hepatitis, that --
23 I don't think -- I don't think we were informing the
24 CDSC ourselves. Whether the hospitals did, because
25 the person -- the individual was still a patient of

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1 that hospital, becomes different once you start to get
 2 into look-back and find issues there. But no, I think
 3 the reporting in the case you referred -- in that
 4 situation you referred to, would have been more likely
 5 at the hospital and the transfusion centre level.

6 **Q.** Do you think it would have been helpful to have some
 7 kind of reporting obligation and a body, whether it
 8 was CDSC or another body, to whom all such cases of
 9 transfusion-associated hepatitis should be reported?

10 **A.** Oh yes, definitely it would have -- it is the sort of
 11 thing that, you know, you look at and think: well, we
 12 should have taken -- there should have been a broader
 13 sort of picture of this, and therefore information
 14 gathered -- should be gathered in one place, certainly
 15 something the National Directorate could have assisted
 16 with.

17 **Q.** Then next can I ask you to look at your statement,
 18 WITN6935001.

19 Page 108, please, Sully.

20 If we look at the bottom of the page,
 21 paragraph 171, there's the reference there to "Maximum
 22 benefit at minimal cost". And then I'm not asking you
 23 about the first sentence in the context of the
 24 question. I've just been asked to ask you more
 25 generally to talk about the concept and explain what

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1 about that, it's too expensive", to "We do need to
 2 care about the patients and our donors."

3 So it's a move that was occurring, and I think
 4 in some quarters of the Transfusion Service they were
 5 late in coming to that sort of conclusion.

6 **Q.** Next --

7 **A.** I hope that helps you.

8 **Q.** Thank you. The next question relates to the delays in
 9 the introduction of hepatitis C screening. One of the
 10 concerns expressed in documentation at the time is
 11 about false positives. What was your view on the
 12 issue of false positives and how to deal with donors
 13 or the possible situation of donors being given
 14 false-positive results?

15 **A.** Right. Well, if you go back to HIV screening, we'd
 16 already faced this issue. There were already cases of
 17 donors who were marked as positive, and they weren't
 18 because they were not infectious. So we've had to
 19 face that before. And so you try and -- you go down
 20 to your roots. One is get you positive on initial
 21 screening, you do repeat screening, you then do
 22 confirmatory tests, and you still end up with some
 23 where you're not quite sure.

24 So, in those cases, you are asking those people
 25 to be seen and I think in one of the letters from the

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1 it is when you talk about maximum benefit at minimum
 2 cost, and then the shift that you then talk about the
 3 move to whether risk of injury to patients becomes
 4 more important.

5 Can you just flesh that out for us?

6 **A.** Yes. Certainly if you read some of the documents that
 7 have been supplied and a couple of journal articles,
 8 there were groups, certain people who were saying we
 9 shouldn't move to maximum -- we shouldn't move to
 10 minimising risk, irrespective of cost. There was
 11 certainly this feeling that -- more than feeling --
 12 that, you know, you go for maximum benefit at minimum
 13 cost, which means that you leave a number of people at
 14 "risk of injury", as it's put here.

15 And certainly, you know, we've seen that that
 16 sort of almost paternalistic approach to care is not
 17 what we see today. And I think that move was
 18 occurring then. As I think I mentioned elsewhere in
 19 my statement, it wasn't a sort of a sudden change by
 20 the organisation, by the NBTS, but, you know, you
 21 could feel that change coming. We were prepared to
 22 introduce a test which was not going to, if you like,
 23 save a large number of lives -- it was going to save a
 24 lot of individual lives and distress, and so, you
 25 know, we're moving from, "Oh, we don't need to worry

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1 Centre, you know, we sort of expressed that. We don't
 2 think that you're infectious but you really need to
 3 see someone who can really take you through more
 4 detail, and get it sorted out. It's not going to be
 5 pleasant for the individual but that, I think, in my
 6 personal opinion, that's a more acceptable issue to
 7 handle than not testing at all.

8 So we're going to test, we're going to have
 9 positives, some of them will be false positives and
 10 we're going to do additional testing, we're going to
 11 pass them on for others and well try and, you know,
 12 support the individual during that initial phase when
 13 they're suddenly faced with "Oh my goodness, I might
 14 have something nasty".

15 The next question goes back to a completely
 16 different topic. This is about the actual process of
 17 donor screening.

18 **A.** Yes.

19 **Q.** In the Northern Region, could you just help us with
 20 understanding who was undertaking the screening. If
 21 we leave aside at the moment the Teesside office and
 22 talk about the rest of the sessions, whether they were
 23 general public sessions or industrial sessions in the
 24 Northern Region --

25 **A.** Okay.

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1 Q. -- was it a donor session clerk with, then, referral
2 to a medical officer in some instances?

3 A. Yes, the donor -- actually it was the same for both
4 the Teesside office and the new -- sessions out of
5 Newcastle. At both sites we employed people who were
6 specifically looking after donor issues. So they were
7 clerks, yes, but they were trained to carry out
8 certain tasks and they rotated between working within
9 the Centre, where they might be fielding some
10 questions from donors by phone, out to the sessions
11 where they would be asking donors the questions, and,
12 you know, recording information and making decisions.

13 And we did introduce training as ...[frozen
14 screen]... for the donor clerks to help them. And as
15 you said, then, if they couldn't resolve something,
16 they would pass it on.

17 And one thing we did try to do was to provide
18 them with better and more usable information. If you
19 look at some of those donor screening, donor care and
20 selection documents, one of which you presented to me,
21 from 1977 I think -- it was later, but anyway, those
22 documents are not that easy to use. You've got
23 different lists in different places, not easy -- it's
24 very well laid out. So we did try to improve what we
25 were giving to the donor services clerks to make those

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1 During the introduction -- the decision making
2 about the introduction of hepatitis C testing, or
3 indeed after you'd introduced it, did you get any
4 sense that litigation, in particular the fact that
5 there had been the HIV Haemophilia Litigation against
6 the Department of Health, and others, did you get any
7 sense that that was playing a role in the desire to
8 present a unified front?

9 A. I mean, that was my impression. I don't think I have
10 any documentary evidence to support it but my
11 impression was, you know, as long as we all start
12 together, no one can criticise us. And I think that
13 was probably the same with HIV, but certainly with
14 hepatitis C. As long as we all do it together, that's
15 a great defence because how could you -- how can you
16 go after one particular individual or one section of
17 the organisation when they all did it together?

18 I've said before, that completely forgets the
19 issue of the patients.

20 MS RICHARDS: Sir, those are the questions I'm proposing
21 to ask from those suggested by Core Participants. I'm
22 just going to check whether Dr Lloyd's representatives
23 have anything? No.

24 Do you have any questions for Dr Lloyd?

25 SIR BRIAN LANGSTAFF: No, I don't. I've asked the

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1 decisions.

2 Q. When in May/June of 1991 there was a backlash in
3 relation to your decision to introduce hepatitis C
4 screening ahead of the common start date, what was the
5 response, if any, of your Regional Health Authority?
6 Were they supportive of your position?

7 A. Yes. I had absolutely no problem. I had no adverse
8 comment from the Regional Health Authority, any of its
9 senior officers ...[frozen screen]... actually it was
10 probably the Regional General Manager at the time,
11 but, you know, no problem. There was -- I mean, they
12 didn't phone me up and slap me on the back and say,
13 "You're a jolly good fellow", but I had no complaints,
14 no one is saying, "You shouldn't have done this". No
15 one saying, "Oh, you've put us in a difficult
16 position". So I certainly have no complaints about
17 how they acted.

18 Q. And then the last question is this: did you get any
19 sense during the decision making in relation to
20 hepatitis C testing, whether from Dr Gunson and --

21 A. Sorry, could you --

22 Q. Yes, I'll start again.

23 A. I'm sorry, I'm going to have to ask you to start that
24 question again.

25 Q. No problem.

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1 questions I've had as we've gone along.

2 MS RICHARDS: Dr Lloyd, is there anything further you
3 would wish to add?

4 A. No, I don't think there's anything I wish to add in
5 terms of either answering the questions or discussing
6 the issues.

7 If I may, I'd just like to thank the staff --
8 pardon me -- the staff I worked with in the Centre.
9 They worked extremely hard. They were very dedicated,
10 and made a great change to that Centre. I know that
11 doesn't help people who are listening who have
12 suffered, but the Centre did get a lot better from
13 where it started to where it finished. That couldn't
14 have been done without the support of a lot of people.
15 Thank you.

16 MS RICHARDS: Sir.

17 SIR BRIAN LANGSTAFF: Can I thank you, for my part,
18 Dr Lloyd. We have trespassed on your time a little
19 bit today, and it has not been the most convenient of
20 times for you to give evidence, but you've been very
21 willing to do so and, indeed, had it not been for
22 Covid, you might even been here to give it in person,
23 and I would just like to acknowledge that.

24 A. Yes.

25 SIR BRIAN LANGSTAFF: I'd also like to thank you for

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1 plainly taking a very considerable effort to look at
 2 the documents which you've been sent by the Inquiry,
 3 so that you could refresh your memory. You are
 4 remarkable in your mastery of a lot of the detail of
 5 those documents, and it's been very helpful in dealing
 6 with your evidence as we have: evidence which has,
 7 throughout, been clear, to the point, and you've
 8 explained what you did very clearly to us in ways
 9 which will have given quite a number of people quite a
 10 lot of pause for thought. So thank you very much
 11 indeed for that, it has been most valuable.

12 **MS RICHARDS:** Sir, the Inquiry won't now sit --
 13 **A.** Thank you, Sir Brian, it's very kind of you.

14 **SIR BRIAN LANGSTAFF:** Not at all. You fully merit it,
 15 which is why I've said it.

16 **MS RICHARDS:** Sir, the Inquiry won't now sit tomorrow,
 17 because we've been able to conclude Dr Lloyd's
 18 evidence this afternoon. We resume on Friday with the
 19 evidence of Dr Dempsey, who was, as you know, based in
 20 Northern Ireland, providing haematology services in
 21 particular to people with haemophilia, children with
 22 haemophilia. So we'll be exploring issues relating to
 23 Northern Ireland haemophilia care on Friday.

24 **SIR BRIAN LANGSTAFF:** So 10.00 for Dr Dempsey on Friday --
 25 not tomorrow, we're not sitting tomorrow -- and I look

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1 forward to seeing you at 10.00 then.
 2 **MS RICHARDS:** Thank you, sir.
 3 (5.40 pm)
 4 (The hearing adjourned until 10.00 am on Friday,
 5 11 February 2022)
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(79) that's... - tough

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