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

read them out, it's: Airedale, Bradford, Calderdale, Dewsbury, East Yorkshire, Grimsby, Harrowgate, 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

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

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

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.

"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,

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

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

was serving.

SIR BRIAN LANGSTAFF: Yes.

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

"The committee at one hospital is multi-disciplinary and meetings were thought to be helpful. The other committee is about to hold its inaugural meeting along the same principles. The agenda for the established committee has primarily addressed terms of reference and ..."

Over the page. That's jumped a page.

"... and maximal order blood schedules for surgical procedures. The audit of BTS activities has been included in the terms of reference."

Then we read this about the regional transfusion committee:

"The Regional Director of Public Health has been approached about establishing a regional transfusion committee, but he does not feel such a committee is necessary and that audit of the Transfusion Service is more appropriately undertaken at Hospital level through their current audit committees or through hospital transfusion committees.

"Two meetings a year are held with haemophilia directors, haematologists in charge of blood banks and scientists."

That picks up the question of the interaction with the hospitals and, if we carry on to page 4 of this document, under the heading "Apheresis activities" we can see, at this time in February 1992, there were four apheresis clinics, one in Leeds, one in Bradford.

In terms of the work of the staff, if we could turn the page to page 5, please, we see the heading "Donor counselling":

"One associate specialist has overall responsibility for the counselling of donors positive on HIV antibody testing. This is arranged at a local hospital. Together with the consultant haematologist she is also responsible for the counselling of donors found positive for markers of Hepatitis C who are then referred to a liver specialist. Donors positive for [hepatitis B surface antigen] are counselled by the Deputy Director who also arranges to counsel plasma donors who have persistently elevated (above 100) ALT values. Only consultant medical staff and the associate specialists counsel donors.

"Look-back programmes would be carried out for past HIV positive donations as necessary by the Deputy Director via the consultant haematologist in charge of the blood bank in the appropriate hospital."

They are the sort of overview documents that we needed to pick up in relation to Yorkshire, if we can then look at some of the more detailed points that arise. As we've seen, the senior staff at the Yorkshire Centre, the Regional Transfusion Director was Dr Derrick Tovey, he was the director between 1966 and 1988.

Dr Tovey was succeeded by Dr Angela Robinson who held the post until 1994. Dr Robinson was appointed a senior registrar in clinical haematology and blood transfusion at the Yorkshire Centre in 1971. She became a consultant in clinical haematology and blood transfusion in 1976, and this was a joint post with the Seacroft Hospital in Leeds.

In the Inspectorate report we saw a moment ago she was described as the assistant general manager of the centre. In 1988 she was appointed -- sorry, she took over from Dr Tovey in 1988 and was then appointed chief executive and director of the Centre.

Between 1976 and 1992 she was also an honorary consultant haematologist at the Seacroft Hospital and between 1987 and 1994 she was an honorary senior clinical lecturer at the department of medicine at Leeds General Infirmary and St James's University Hospital.

On 1 May 1994, Dr Robinson was appointed the medical director of the NBA, succeeding Dr Gunson, and that was a post she held until 2007.

Dr Robinson was a member of a wide number of committees and working groups, including, whilst she was a director at Yorkshire, she was chair of the Northern Division meetings, and consequently from 14 August 1990 she was a co-opted member of the Medical and Scientific Committee of the SNBTS. She was a member of the ad hoc working Party on hepatitis C look-back, the NBTS National Management Committee from 1990 to 1992, and the NBTS/BPL liaison committee between 1990 and 1992. She was obviously involved in very many other committees and working groups, particularly once she became medical director of the NBA but they are the important groups whilst she was at Yorkshire.

The third staff member to note is Dr Peter Flanagan. He took up a post as consultant haematologist at the Yorkshire Centre in October 1989 with half his time being spent as a laboratory haematologist at Seacroft Hospital. He was then promoted to deputy director in January 1992, which was a full-time post, and he became clinical director in April 1993.

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

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

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

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

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

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 us. 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

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

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

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

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]

"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

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.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: In terms of the setting of regional targets, at the Yorkshire Centre, Dr Robinson set out in her statement how the regional targets were set:

"The target was based on the Factor VIII required nationally, and then apportioned between the different regions, therefore our target didn't necessarily equate to the demands of our local population."

And Dr Flanagan in his statement describes the process of the setting targets for supply of plasma to BPL in this way:

"Essentially the price for plasma was set by the CBLA and the national director of the NBTS and approved by the NBTS steering committee. National plasma volumes were developed by the CBLA and individual RBTSs then made a bid for the volume of plasma they aimed to supply. Volumes were agreed."

If we can then pick up, in relation to targets, DHSC0002267_039, please. We have here a letter from Dr Derrick Tovey to the DHSS dated 19 April 1985.

Prior to this letter an administrator had completed a form dealing with plasma procurement, and the letter from Dr Derrick Tovey, here, accepts that the administrator indicated that there was no detailed

consideration about how a target in '87/88 would be made. He says this:

"... although we aim to achieve the target of 31,500, there is a gap. This gap ..."

Apologies, sir, I should have taken you to a document just prior to that. That's my fault. I misread my notes. Could I just go back a document.

DHSC0002267_011. Apologies, I couldn't read my handwriting, sir.

This will make much more sense.

This is a letter from an administrator for Dr Derrick Tovey dated 9 April 1985. And if we turn the page, we can see a table setting out the quantity of fresh frozen plasma to be supplied to the BPL from Leeds.

April 1985/March 1986, we have a total of 17,100, as against a target of 17,000.

April 1986/March 1987, we have a total 26,100, with a target of 26,000.

Then April '87 to March '88, we have a total of 26,100, against a target of 31,500.

It's in relation to this gap between the total that they will be able to supply and the target that the region has been given that the letter from Dr Tovey addresses.

So if we can go back to that letter now, DHSC0002267_039.

Middle paragraph of his letter, Dr Derrick Tovey says this:

"... although we aim to achieve the target of 31,500 there is a gap. This gap can either be bridged by increasing the SAG M collection, but until we have had more experience of this we do not know if the clinicians will accept a higher percentage. The alternative is to open a third machine plasmapheresis centre."

"The point I am making, is that we do intend to reach the target, it is simply that we have not decided at the present time, which of the alternatives we will put into operation."

So we can see from the prior table that, broadly, Yorkshire could meet their targets but in that particular year that was a query over exactly how they would meet that target.

In fact when we come to 1989 we have a letter from Dr Robinson dated 22 March 1989 informing Dr Gunson that the Yorkshire Centre had not met its plasma target.

If we can go to that letter, please, NHBT0027512.

Dr Robinson indicates that she had -- they'd finished planning their strategy for achieving their plasma targets for the next few years and she provides him with the overall plan.

If we can go down, please.

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

"Target was 26,000L."

And the shortfall is put down to:

"a) Industrial dispute over clinical grading

"b) Increased local use of Cryo and FFP

"c) Loss of 10,000 donations."

For 1989/1990, the target is 27,000 litres, and the proposal is to increase SAG-M donations and to extend Bradford by 18 and three quarter hours per week.

"(Adequate number of donors already recruited. Given the necessary staff recruitment, expansion can take place immediately)."

If we turn the page we see a note on the targets and the objectives, and then this action plan:

"Action plan necessary to achieve these targets:

"1) Extending the hours of the Bradford Centre by 18 [and three quarter] hours by immediate staff recruitment and training.

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

St Paul's Street Centre and the New Donor Suite at Headquarters over a 3 year period (both at present are working under capacity because of the insufficient donor recruitment).

"3) Increasing the number of SAG-M donations to provide an extra 4,000L/annum."

And:

"4) Improving ordinary whole blood donor recruitment and retention such that the 10,000 donations lost in the last 2 years are regained and maintained."

We'll pick up that issue of loss of donors shortly.

Dr Gunson then visited the Regional Transfusion Centre in or around August 1989 and the -- it was agreed that the 1989/1990 target would be revised.

We can see in a document relating to a CBLA-NBTS liaison meeting that costs were also an issue. Dr Robinson stated that the plasma supplied by the Yorkshire Centre was costing £15 per kilogram more than the income received from it.

Just for the transcript, the reference is NHBT0000077_056.

It's not entirely clear in that document whether Dr Robinson was referring to recovered or apheresis

plasma but Dr Flanagan comments on this in his statement and says that there was a significant concern to the Yorkshire Centre because the deficit in cost recovery for the plasma will have been added to the price charged for local components issued to hospitals in the region. And consequently, these charges will have appeared higher than those set by other RTCs, who were providing less plasma to BPL.

So there was an impact across the board.

We then pick up the situation in August 1991 in a letter dated 13 August. If we could turn to that, NHBT0016094, please. It's the second page.

Having set out matters of the plasma being supplied, Dr Robinson said this to Dr Gunson:

"What I can say is that the current uptake of BPL factor VIII products by the Yorkshire region indicates a likely annual usage of 8M units. Our 1991/92 normal plasma input is targeted to be 37,000 litres (24,000 litres recovered, 13,000 litres apheresed).

"Assuming the fVIII yield is approximately 190 iu/L the YBTS supply of source plasma to reach regional self-sufficiency in terms of the BPL fVIII uptake by the Yorkshire region is equivalent to 42,000L.

"I am back to my regional theme of linking plasma supply to BPL by RTCs, to the Regional uptake of BPL products, ie, if I am going to purchase 8M units of fVIII for regional distribution I would like the opportunity to supply the volume of source material required to produce 8M units of fVIII."

So by 1991 there is a concern being raised by Dr Robinson that Yorkshire want to supply or have the opportunity to supply the volume of source material that is equivalent to what the region then distributes to the relevant centres.

SIR BRIAN LANGSTAFF: Is she saying there that she'd like to supply more in order to get enough, or is she saying, "I'd like to supply just what is needed"? Because they're two different things. And is she complaining, perhaps, if the latter be so, that Yorkshire is being asked to do more than its weight?

MS FRASER BUTLIN: That hadn't been my reading, sir, but it could certainly be a reading of the letter. The last paragraph of the letter might suggest otherwise:

"If the target of 37,000 litres from the Yorkshire region is likely to be in excess of our allocated BPL quota please could you let me know ..."

SIR BRIAN LANGSTAFF: Yes, but it is a question of who sets the target.

MS FRASER BUTLIN: Indeed, yes.

SIR BRIAN LANGSTAFF: And I thought the target was being set by BPL in the earlier documents.

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: And it was up to Yorkshire to see if they could achieve it.

MS FRASER BUTLIN: Yes. Yes. So it could be read that way, sir.

SIR BRIAN LANGSTAFF: So it's -- and the overall picture across the country that has been painted so far is this, is it: that regions are set targets by BPL looking at the region and saying, "You've got so many people in this region, this is your fair share of our needs."

That may be all very well, but some of the regions have a much higher usage than others, and so if they get back pro rata, they don't get back enough.

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: Others are supplying more than they need, and that comes at a cost to them and they complain that the cost which is attributed to them by cost by cross-charging is actually less than the cost that they have, and so they have to charge more for other products supplied locally.

MS FRASER BUTLIN: Indeed. And as you say, sir, that ties

in much more clearly with the concerns about costs. And the concerns about cross-charging.

SIR BRIAN LANGSTAFF: And it would fit in with the concerns which have been expressed elsewhere in the documents you have referred to where there's a concern that Yorkshire's supplies to its hospitals may be compared by clinicians in effect saying, "Well, you're charging us" --

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: -- I'm just picking figures at random for the point -- "£5 for this, but down in this other region they only charge £4."

MS FRASER BUTLIN: Indeed, sir. That interpretation of this letter would certainly fit with those other documents. But it's not entirely clear.

SIR BRIAN LANGSTAFF: It's not. Although the wording would suggest you're right in the first place, but the context is the opposite, perhaps.

MS FRASER BUTLIN: Indeed. Indeed. Yes.

I think perhaps -- let me just go back -- apologies, sir. No.

Either way, sir, it is clear from many of the documents that Dr Robinson was an advocate of plasmapheresis and indeed in her statement she said this:

"I became a national and internationally recognised expert in both donor and therapeutic apheresis and introduced the first voluntary donor automated plasmapheresis centre in the world in Bradford in 1982."

Which is what we looked at earlier.

Dr Robinson wrote up the pilot plasmapheresis programme in Yorkshire in an article she co-authored with others including Dr Tovey for Vox Sanguinis.

It's DHSC0002263_064, please.

If we just look at the abstract, we can see that there was a pilot study for large-scale automated plasmapheresis using a particular machine that:

"... was undertaken in the Yorkshire Region of the [UK] to determine the viability of such a programme for national self-sufficiency in fresh plasma procurement for factor VIII concentrate production. The study was designed to resolve three areas of concern: donor safety and recruitment; a cost analysis, and the choice of anticoagulant for optimum factor VIII yields. The results show that large-scale automated plasmapheresis could safely and economically produce high-quality source plasma necessary for national self-sufficiency."

And that was published, sir, in 1983.

As a member of the UK Blood Transfusion Service Apheresis Working Party on behalf of the UK BTS NIBC Standing Committee for Blood Donors, Dr Robinson was also responsible for co-authoring the guidelines prepared by that working party, including guidelines for apheresis of volunteer donors within the UK Blood Transfusion Service.

Moving on, then, to donors and selection of donors, Dr Robinson's personal statement made it clear that blood donation was not by appointment, so mobile teams had to make their presence known in an area in order to secure donors. The Yorkshire Centre produced a lot of its own publicity material and when the Centre was short of donors, Dr Robinson might put out a radio appeal for more to come forward.

If we could turn on to NHBT0033679, please.

We see a letter from Dr Robinson to Dr Gunson, addressing a campaign that the Yorkshire Centre mounted in January 1990 to reassure donors and non-donors that there was no risk of infection when giving blood. This had followed a sharp decline in donor attendance.

What is useful to see is the bottom of the page, their plan of action, just to give a flavour of what the Centre was doing:

"Posters & Leaflets are being distributed for public display to the 7 district family practitioner committees within the Yorkshire region for display in all GP's surgeries.

"All health centres

"Community clinics

"Libraries

"Citizens Advice Bureaus etc."

Then she enclosed a copy of the poster and leaflet.

Then over the page:

"Large simplified poster on similar lines as those enclosed to appear ... for a period of 3 months

"on the backs of buses (100 in all) travelling within the Yorkshire Region.

"At to all railway stations within the Yorkshire Region.

"To follow up, informational Display Stands and a video are being prepared and will be coming online towards the end of March.

"A press release by the Yorkshire region in association with the PRO agency [would] be prepared ..."

So they were some of the measures that Dr Robinson took in order to increase donor numbers.

Dr Robinson, in her statement, recalled attending a session at Wakefield Prison when she was a senior registrar, so that must have been prior to 1976 when she became a consultant. She didn't recall any prison collections after 1976, once she was a consultant. She further recalled that:

"When the plasmapheresis centre in Bradford was opened, the Yorkshire Centre didn't allow donors with a prison history to donate because of the association of institutionalisation increasing the incidence of hepatitis B and non-A, non-B hepatitis."

So she in her statement thought that they were -- the Centre was not collecting blood from prisons by 1982. However, a separate document, sir, which the Inquiry has seen on a number of occasions, NHBT0008628_001, it's the Scottish Transfusion Directors' survey from 1983. If we just turn the page we see this in relation to Leeds:

"Dr Derrick Tovey is different.

"The Region has large prisons at Wakefield, Leeds, and Hull.

"They tried to withdraw prison sessions, and got a very active response from the prisons, which asked that the sessions should continue.

"The session staff get help from Prison staff to

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

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

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

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

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

they'd find out.

MS FRASER BUTLIN: Indeed, that might well be one interpretation of the situation.

SIR BRIAN LANGSTAFF: Which might be thought to be part of the reason you didn't want to have collections in prison, but --

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: -- this is all comment and subject, of course, to being shown what it really means later.

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: Thank you.

MS FRASER BUTLIN: In the documentation there are various examples of Dr Tovey's actions of letters to donors who'd tested positive for hepatitis. We can then pick it up more clearly in June 1990 when the Yorkshire Centre published a document entitled "Criteria for the Selection of Whole Blood and Apheresis Donors", at NHBT0033676. Third page, please, we see at points 4, 5 and 6:

"Only persons in good health should be accepted as donors of blood for therapeutic use.

"The ultimate responsibility for the selection of donors rests with the RTD; the immediate responsibility is that of the medical officer or nurse in charge of the session who should evaluate the

prospective donor's medical history.

"If there is doubt about the suitability of a prospective donor, a donation should not be taken and details should be referred to the RTC for a decision."

Then over the page, the second paragraph:

"A significant part of the assessment procedure will usually rely on answers to questions relating to general health, past medical history and medication. This is combined with simple visual assessment of the donor and selected testing of samples collected at the time of donation."

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

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

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

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

narcotic drugs.

In terms of the questions to be asked, if we turn to page 7, we see the heading "Specific Questions":

"All donors should be specifically questioned about the conditions listed on NBTS 110A and every donor should sign NBTS 110."

They're documents that the Inquiry has looked at number of times:

"Each prospective donor should be asked a standard set of questions prior to each donation by a donor attendant. Any condition declared should be discussed with the medical officer or nurse in charge ..."

We can see those questions at page 33 of the document.

We see a set of questions of feeling well, coughs and colds, and then at (x):

"Have you read the AIDS leaflet?"

So it might appear that the leaflet was given to donors and they were required to sign confirmation but, in terms of verbal questioning, it was limited to asking whether they had read the AIDS leaflet.

Sir, I'm about to move on to a slightly different topic. I don't know whether it would be

appropriate to just take a ten-minute break before we continue.

SIR BRIAN LANGSTAFF: Well, let's make it quarter of an hour, shall we --

MS FRASER BUTLIN: Of course.

SIR BRIAN LANGSTAFF: -- and come back at 20 past.

So 11.20.

(11.06 am)

(A short break)

(11.20 am)

MS FRASER BUTLIN: Sir, I want to move on now to the question of screening of blood and blood products. And picking up first with hepatitis B.

In May 1979 Dr Tovey raised concerns with Dr Lane that the hepatitis B testing was a little insensitive, and made -- using the HEPA test, and made enquiries whether alternatives might be available, and Dr Lane's response was that the RIA test would be discussed at the next Directors meeting in May 1979.

At that meeting, in June 1979, Dr Lane offered to send reagents free of charge to anyone who wished to try out the RIA test, and Dr Tovey suggested there ought to be uniformity of practice in the use of the test, with a change by all RTCs to RIA if this were to be agreed policy.

If we move forwards to 1990 in relation to the hepatitis B core testing, Dr Flanagan wrote to Dr Gunson on 25 June 1993 informing him that the Yorkshire Centre were in the process of developing a strategy for the introduction of hepatitis B core screening, and although he was keen for it to be introduced as soon as possible, he also felt it was very important that there was conformity on the principles underlying the core testing in different regions.

Dr Robinson wrote around the same time to Dr Gunson stating she considered that core testing should be introduced as soon as feasible and that they would be in a position to do so by October '93.

Of course as the Inquiry has heard, in October '93, Dr Gunson informed all RTDs that hepatitis B core testing wasn't to be introduced. But we can see from the documents that Yorkshire was keen to do so and ready to pursue that.

If we can pick up, then, in relation to HIV Dr Robinson's statement addresses her awareness that HIV may not be confined to the gay community when she attended a symposium in Boston in 1982. And she stated in her statement that by 1983 more risk factors for HIV were becoming clear to her.

In terms of the practice in Yorkshire, we have a memo from Dr Tovey from September '83.

NHBT0021385, please.

Dr Tovey has written to medical officers as follows:

"It has been agreed by Transfusion Directors and the DHSS that the enclosed AIDS leaflet should be made available on donor sessions, and I will arrange for these to be sent out in the next few days.

"Obviously this is a very sensitive topic and we will therefore have to play this in a very low key. We wish to exclude donors who might be more likely to transmit AIDS but wish to avoid consternation to every homosexual donor. I would ask therefore, that you deal with any comments from donors after they have read this pamphlet, as tactfully as confidentially as possible. We certainly would not wish to exclude all homosexuals from donating blood, but obviously those who are promiscuous in this matter, should not donate."

And then in the final paragraph:

"I reiterate, this is a very delicate issue."

Dr Robinson stated in her statement that she couldn't recall how the leaflet was distributed. She said this:

"But I believe that with every call to a donor centre, a leaflet was included, but there was no specific means of ensuring that every donor read it."

Her recollection was that:

"We put the leaflet in every call-up letter and also had the leaflet available at donor sessions."

On 21 November 1984, Dr Tovey issued some modified instructions to the medical officers.

NHBT0096480_028, please.

If we go to the last page, page 4, he said this:

"As you will know there has been a lot of activity in the field of AIDS of late and the DHSS are requesting we take a stronger line re male homosexuals. I have ensured the leaflet is available at all sessions and prominently displayed. A new leaflet will be available shortly and this refers to 'active male homosexuals'. In practice therefore, they are really saying all male homosexuals should refrain from donating. So this modifies somewhat my instructions issued 1.9.83 [which we just looked at] which were based on the current leaflet.

"If a donor has been registered and you have therefore to put something on the card, put HRD (High Risk Donor) and we will ensure he is not invited again. If you wish to pass on any information to me, write to me in confidence. I am commencing a confidential record of these donors.

"If you are in doubt about any donor you might record on the card '?HRD - letter to Dr Tovey'."

Further insight into the practice at Yorkshire in relation to the AIDS leaflet can be identified in a memorandum from 1989.

NHBT0021384.

It's from a Mr Frank to Dr Robinson and it says:

"All the old posters have either been used or destroyed. From memory the sequence of events was:

"1. After any delays the grey AIDS leaflet became available in late 1983. This was distributed on session supported by a poster of our own production inviting donors to read the leaflet.

"2. In late 1984 or early 1985 it was decided that a leaflet should be sent with every invitation. See attached sample letter and note dated 12.2.85. This procedure was to last 6 months ...

"3. In September 1985 a revised leaflet was produced and again every donor was required to have one before donating.

"4. For something like [two and a half] years we have used the 'data post' invitation which has regularly been AIDS updated for public normal donors."

SIR BRIAN LANGSTAFF: Just before we leave this document, it coincides with what Robinson says in her statement, as you've just told me, that the leaflet was sent with invitations, or at least to some extent was.

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: My question is how that fits with what you showed me earlier this morning where it was -- the mobile teams were described as having to set up and advertise their presence locally because there weren't invitations.

MS FRASER BUTLIN: Indeed. That's unclear, sir, how those two things fit together and, unfortunately, this is as much as we have. It may be that the mobile sessions, there were two different streams operating, where some were called up, and the mobile system where they weren't called up, but I'm afraid we don't have any further information on that.

SIR BRIAN LANGSTAFF: It may simply be that in parts of Yorkshire there were -- both systems were operating --

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: -- which would -- it would seem odd that there was no call-up system --

MS FRASER BUTLIN: It would.

SIR BRIAN LANGSTAFF: -- and yet they're able to say that they've lost 10,000 donors, for instance, over a particular period.

MS FRASER BUTLIN: Precisely. So it may be that the information saying that there were no call-ups is not fully accurate. But we simply don't know.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: Before we leave the question of the AIDS leaflet, just to pick up one issue that arose in 1991, we have a letter, we don't need to go to it but, for the transcript, it's JPAC0000044_135, a letter from Dr Robinson to Dr Wagstaff about the AIDS leaflet, where she picks up an issue in Leeds and she says this:

"I suppose what I'm saying is we shouldn't allow pressure groups or people's sensibilities detract from our main task, which is to keep our blood supply as safe as possible and to retain public confidence in the continual safety of our blood supply."

That appears to be picking up an issue in Leeds which is noted in a letter from Leeds ACT UP in June 1991. The Leeds ACT UP group wrote to the National Directorate, expressing its opposition to the policy of excluding high-risk groups from giving blood, rather than those who indulge in high-risk practices.

Dr Flanagan, in his statement, recalls sit-ins

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

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."

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

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

generation -- whether earlier screening tests would have been used.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: And that's where she says in hindsight some infections would have been prevented but there was the question of specificity.

SIR BRIAN LANGSTAFF: So the question then arises when she would have been in a position to start the first generation tests which would have been, presumably, quite a lot earlier.

MS FRASER BUTLIN: That's something we don't know.

SIR BRIAN LANGSTAFF: Yes, thank you.

MS FRASER BUTLIN: What we do have, sir, is the question of the funding of the tests and the costs involved for Yorkshire. We have a document, we don't particularly need to go to it but I'll read in the reference, NHBT0035120, where the cost to the Yorkshire Centre of HCV testing is estimated at £478,745.

In a letter in December 1991, so subsequently, Dr Robinson informed Dr Gunson that the additional costs were allocated to purchasers -- in other words hospitals -- to meet, and that the Centre was recovering the costs of anti-HCV testing, subsequent confirmatory testing and counselling of donors by including these costs in its unit price for blood,

local products.

In terms of that donor counselling, Dr Robinson confirmed that she recalled Dr Flanagan and herself doing a lot of work with hepatologists in the region to make sure that they'd accept hepatitis C positive donors and that we could refer them onwards.

That's also reflected in the contemporaneous documentation. On 5 June 1991, Dr Flanagan wrote a letter to all directors of Public Health Districts served by the Centre informing them of the introduction of hepatitis C screening, informing them that the costs of hepatitis C testing would be recouped through an increase in unit costs of products, and asking for a steer as to who the most appropriate person to refer positive donors was.

There are also letters from a consultant in communicable diseases at the Dewsbury Health Authority, confirming that small numbers of infected donors could be referred to him, but if there was rising numbers, alternative arrangements would be needed and from the Pontefract Health Authority, agreeing that all districts should do the same thing and refer all cases to a specialist unit, in their case Professor Lisowski's unit in Leeds.

So the clinical care of donors who were

identified as hepatitis C positive was addressed by the Centre.

If we then to move look-back, first of all Australia antigen look-backs. There are number of documents that indicate that when the Yorkshire Centre was informed of either a patient developing jaundice after receiving a transfusion or a plasma batch being infected, a look-back exercise was undertaken with the retesting of the donor and testing samples that were held of previous donations.

In relation to HTLV-III look-back, where a donor was identified as being HTLV-III positive and had donated into a pack of plasma, Dr Tovey informed BPL, and then carried out an exercise to identify patients who'd received that batch, and Dr Robinson was also involved in later exercises seeking to identify donors and recipients.

In terms of hepatitis C look-back, if we could turn to NHBT0035171, please. This a memo from Dr Flanagan to Dr Robinson on 3 December 1990, and it relates to a discussion of the Scottish proposals for donor counselling on the introduction of hepatitis C testing, which the Inquiry has looked at with previous witnesses, particularly Dr Gillon. Dr Flanagan's memo is picking up on that document, which he says is:

"... a very informative and helpful document but ... one or two problems may arise if we were to attempt to adopt it in Yorkshire."

It's the second point I want to go to. Sir, I'm sure you will recall that at this point in Dr Gillon counselling of donors document, there was a look-back provision in 1990 which was subsequently not pursued but the document that Dr Flanagan is looking at has the reference to look-back being carried out. His view at that time was that the:

"The feasibility of any lookback programme will be determined by the number of HCV confirmed positive donors we find. If the number is large it would be a very large undertaking for RTCs within England & Wales, more so than for Scottish centres. This will obviously require a specific answer from the National Directorate."

There's no explanation given to as why it would be more difficult for England and Wales centres than Scottish.

As the Inquiry has heard, look-back wasn't, in fact, instituted nationally until 1995 and, on 13 January, Dr Flanagan wrote to Dr Robinson who was, by then, of course, working at the NBA, confirming his agreement with the proposed procedures to be followed

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

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

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

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

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

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

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

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

He indicates what is required of them, and:

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

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

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

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

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

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

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

Yes. Thank you, sir.

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

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

The references for that are DHSC0002209_076

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

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

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

If we could now turn to BAYP0000011_058, please.

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

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

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

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

And 264 vials had been returned.

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

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

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

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

She says:

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

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

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

So that's everything I want to address orally. Of course there is a much more substantial written presentation available to those who wish to deal with further detail.

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

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: So 1.00. Thank you.

(11.54 am)

(The Luncheon Adjournment)

(12.59 pm)

DR HUW LAURENCE LLOYD (continued)

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

A. I can, thank you. Good afternoon.

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

A. I can.

SIR BRIAN LANGSTAFF: Good. Well, that's a good start. I hope we continue. If we have further patchy

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

A. 8 o'clock. Yes.

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

Ms Richards.

Questioned by MS RICHARDS (continued)

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

A. Yes, I can, thank you.

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

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

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

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

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

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

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

Dr Collins?
A. I don't recall her ever saying that she had received a specific request. We've seen some of my data that shows that the amount of cryoprecipitate going to the RBI and therefore the Haemophilia Centre was actually going down a little bit. But they could have requested more. We obviously had the product.
Q. Thank you.
Now I want to move, then, to the donor leaflets introduced in 1983. Again, I'm very conscious that you were not in post at the Centre at that point in time, but I'm going to ask you to look at a couple of documents in any event.
If we start with NHBT0020668.
So, Dr Lloyd, this was a letter sent by Dr Wagstaff from Sheffield, 6 July 1983, to his Regional Transfusion Director colleagues, enclosing, over the page, what was intended to be the final version of the AIDS leaflet for national use.
A. Yes.
Q. Again, I'm not going to go through the detail of the leaflet.
Now, that was early July 1983. The Inquiry knows from other evidence that the Department of Health became involved and the final leaflet was only

issued at the beginning of September.
And we'll just look briefly at that for the benefit, really, of those watching. BPLL0007247.
There we have the national leaflet from September 1983.
Do you know, either from your later involvement or, again, from conversations with Dr Collins, whether in Newcastle any earlier leaflet of Newcastle's own devising was introduced, or whether Newcastle waited for the national leaflet?
A. Sorry, I've lost you: "or whether Newcastle was ..."?
Q. Whether Newcastle introduced, as some centres did, their own earlier leaflet or whether Newcastle waited for this national leaflet to become available in September?
A. I'm certainly not aware that we issued anything earlier. I can't say we didn't, but I personally am not aware of it.
Q. And then I'm again going to ask you to look at a document you wouldn't have seen at the time but it gives us some information about the method of distribution of the leaflet deployed at Newcastle.
A. Mm-hm.
Q. CBLA 0001820, please.
This was a table compiled for the Advisory

Committee on the National Blood Transfusion Service, "AIDS leaflet - First six months experience".
A. Yes.
Q. And we just need to look at the entry for Newcastle at the top of the page:
"Distribution Method
"With call-up cards
"Displayed on industrial sessions. Issued to Citizens Advice Bureaux STD Clinics
"No. used 110,000,
"Stock 3,000"
Then we have:
"Donor Response, Effect on Attendance
"Nil. 2 or 3 resigned because of homosexual relationships"
Then:
"Other Comments
"One donor [I think that should be] [thought] he could contract AIDS from donation. 'Who is at Risk?' (final ..."
That might be "paragraph" or "part".
A. Paragraph.
Q. "... may be read as 'if you get jaundice you may [get] AIDS'. Majority don't know what Hepatitis B is."
So we can see there, I think -- please let me

know if this is your understanding, Dr Lloyd, three methods of distribution there described.
In terms of the general public it would appear that the leaflet was being sent out with the call-up cards, so donors could take a decision in advance about not attending.
A. Mm-hm. Yes.
Q. And then in relation to the industrial sessions, where presumably the Centre wouldn't know who individually would be attending, it was on display.
And then Newcastle then took a further step, which is to provide the leaflet to local Citizens Advice Bureaux and STD clinics. Was that still --
A. Mm-hm.
Q. -- the system of distribution with later versions of the leaflet when you came back to the Centre full time?
A. Yes, we sent out AIDS leaflets when they were changed, so they went out with the call-up cards. They were more like little cards than letters in the earlier days. But yes, we sent out a new -- new versions as they became available, so we would do a new distribution, but we still had the issue that at industrial sessions, you -- we didn't individually call up, the call-up was done within the factory or

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

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

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

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

medical officers?

A. Mm.

Q. The subject is "AIDS: Risk Groups in Africa and Donor Rejections", and then we can see the background from paragraph (a), because the leaflet now identifies certain risk groups in relation to Africa. I just wanted to ask you about (b), the arrangements at the sessions. It says here:

"The arrangements at sessions should be as follows:

"The Session Clerk will ask donors whether they have been in Africa and, if so, where in Africa and when. If the donor has been in the relevant area since 1978, then further questioning will be required. The Clerk will then take the donor to see the Session MO.

"The Session MO will discuss the matter further, in confidence. It may be difficult to ask donors about their sexual activities in the rather public circumstances of a blood donor session. The MO must, however, ensure that the donor has read and understood the AIDS leaflet [and we can see the version there was September '86] or the AIDS poster."

A. Mm-hm.

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

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

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

Then if we just read paragraph (c):

"Donors who are in any AIDS risk group must not be bled. Where there is any doubt about the risk they should not be bled, but in either case, the potential donor should be sympathetically dealt with and arrangements made for an MO from the Centre to contact them, especially where doubt exists. Some donors may not wish any further contact, and this should be respected. A note giving details MUST be sent to an MO at the Centre in a sealed envelope."

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

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

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

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

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

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

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

Q. Can you hear me again now?

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

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

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

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

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

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

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

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

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

DHSC0020840_031.

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

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

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

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

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

A. Yes, yes.

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

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

And given that there was, you know, a definite

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

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

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

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

A. Mm-hm.

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

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

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

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

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

"This was not a simple decision to make."

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

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

A. Yeah.

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

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

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

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

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

A. You can?

Q. Yes.

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

Q. Don't worry.

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

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

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

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

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

"Lecture by Dr Michael Houghton of the Chiron Corporation

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

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

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

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

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

A. Mm-hm.

Q. You refer to the costs per sample for the kit and say:

"It looks likely that this test will soon be required in the UK. The cost of testing will be in the order of £200,000 -- £230,000 [per annum]. We will lose about 600 donors from our present panel and will have to destroy at least 600 donations in the first year. The cost of this will be around £4,000-£5,000 to replace the lost donors and

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

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

A. Yes, yes.

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

A. Yes, in Newcastle.

Q. -- northern Region --

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

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

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

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

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

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

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

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

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

A. Mm-hm.

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

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

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

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

A. Yes.

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

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

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

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

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

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

Given the short interval between the meeting

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

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

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

A. Mm-hm.

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

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

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

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

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

A. Yes, that's correct. Yes.

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

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

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

A. Yes.

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

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

Q. And of course --

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

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

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

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

A. Yes.

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

26:

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

before backing such a move."

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

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

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

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

A. Yes.

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

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

It's -- at this stage, this particular document seems a little bit unclear. Although they're saying, "Yes, we should test", then they're saying, "Well, maybe there's issues, and maybe we don't want to do it just yet, or at all."

Q. Now that's November 1989, and we'll be exploring, Dr Lloyd, with other witnesses or through other witnesses I hope some of the events, particularly from a Department perspective, through into 1990.

I want to pick things up in the middle of 1990.

July of 1990 -- I don't, I'm afraid, have the document to display but I'll read the reference for the benefit of those listening, PRSE0000976 -- is a further meeting of the Advisory Committee on the Virological Safety of Blood, in which they recommend that there should be an evaluation of the two commercial kits that were then available, Ortho and Abbott, to be done in three centres: Glasgow, North London and Newcastle.

So if we then pick things up with a letter copied to you in August 1990, NHBT0000061_180. We can see 30 August 1990, if we just look at the whole letter please, it's from Dr Gunson to Dr Rejman and we can see at the bottom it says, "Same letter to" and

then it's listed Dr Mitchell, Dr Lloyd (yourself), Dr Barbara and others.

A. Yes.

Q. Then we can see Dr Gunson says he hopes this is:

"... the final draft of the proposals for the proposed study comparing anti-HCV testing using Ortho and Abbott test systems."

Now, there had been some other studies and evaluations going on in the intervening period in which, I think, Newcastle was not involved, but can you recall how you came to be involved in this proposed comparison of the two tests?

A. I'm not quite sure why we were. It may well have been that they wanted couple of centres or they wanted a centre that was comfortable using the Abbott test and the Abbott test equipment. We were certainly in a position to do it. And I think Ruthven Mitchell and I think the Glasgow Centre -- I'm not sure if they were using it as well, but certainly we were using the Abbott system, quite happy to participate. But I don't recall why we were approached, specifically.

Q. If we look at NHBT0000042_045. So this is now a couple of months later, and Dr Gunson is sending a report on Phase I of this trial, which I think is how this particular evaluation was characterised, to

Dr Rejman. We've got the report itself at NHBT0000190_030, if we just look briefly at that.

Yes, NHBT0000190_030. So "Comparison of Anti-HCV Tests using Abbott and Ortho Test Kits (A Multi-Centre Trial) Summary are Results of Phase I of the Trial", and this is authored by Dr Gunson, 29 October.

I'm not going to go through the detail of it. If we look over the page, however, we can see this is the study comparing the results of using the two different kits, the Abbott and the Ortho kits, involving Glasgow, yourself and north London.

A. Yes.

Q. We can see, if we go to page 3, paragraph 1.7:

"All three RTCs reported that the tests were easy to perform and that the manufacturer's instructions were 'user-friendly'."

There are then some specific comments made by yourself and the various -- and the other two centres but I'm not going to take up time looking at those specific comments.

What did you understand the purpose of this comparative evaluation to be and for whose benefit it was being carried out?

A. This seem to be to me to be a way of ensuring that

both tests were suitable for use. It didn't -- we know that different centres in the UK used different test methods, different, you know, kits from different companies, and were used to using things in different ways. So you need to know that -- (a) that both tests are usable, that they're not completely terrible to use.

I think we saw in some later tests that one of the test kits presented for comparison -- actually, it might have been for HIV -- you know, one of the test kits was actually quite difficult to use and difficult to get consistent results. So here we have a trial. It shows that both test kits are usable, within the transfusion centre setting, and they give comparable results. As one would expect, they're not perfectly the same but substantially the same.

So it gave me quite a lot of confidence that, you know, we had something we could do, we could use this ...[frozen screen]...

Q. Now, we know -- sorry, you froze for a moment then, Dr Lloyd, which is why I paused.

A. Yeah.

Q. We know that by this time -- this is August 1990, when the study protocol, as it were, is being drawn up, and then October 1990, when it's being concluded -- we

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

A. Mm-hm.

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

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

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

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

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

NHBT0000073_018.

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

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

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

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

supply."

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

A. Absolutely.

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

A. -- absolutely.

Q. -- is that right?

A. I never saw this, never heard this.

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

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

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

would be set aside."

Then there's a discussion of the arrangements.

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

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

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

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

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

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

Then we had the sentence:

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

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

with this in your statement, is just look at a page from your statement where you comment upon these minutes.

WITN6935001, please, Sully, page 86.

You say this:

"In the minutes of the November 1990 meeting of the ACVSB ... the statement:

"'The Chairman stressed the importance of a common date of introduction throughout the UK' [which is what we were just looking at]

"is presented without any background information. There is nothing in the document that indicates why the Chairman ... came to this conclusion."

Then you say this:

"I note these statements in the document ..."

Then paragraph 10 from the minutes:

"The Committee agreed that it was important to start screening as soon as practicable ..."

Paragraph 18:

"The Chairman summed up the discussion by saying that there was agreement that the UK should introduce hepatitis C testing as soon as practicable."

Then paragraph 21:

"... some centres had asked for a 6 month period

in which to set up testing."

And your observation there is:

"This suggests some disconnect in the thinking ... as soon as practicable ... but only if all together."

A. Mm-hm.

Q. Is there anything further you would wish to add on that issue and on the basis of what we see in those minutes, Dr Lloyd?

A. No, I think that pretty much sums it up. You get the feeling through these minutes that, yes, we're going to do it but there always seems to be a little "if", a "but" behind it, instead of just getting on with it.

I mean, they've already decided this is a test that needs to be done and yet we're flip flopping about. As to the "all together", I've seen that in documents that Dr Gunson produced before, so my feeling, and that's purely a personal thing, don't -- can't say substantively, but it seems that it was Dr Gunson who had this view that "All together" was the necessary -- was the imperative. I'd seen it in other documents he'd prepared, so I feel that's where that came from.

As is noted, there is no actual discussion recorded in the minutes as to how they came to decide

that that was an important issue.

If I may go back to the minutes, paragraph 11.

Q. Yes, so NHBT0000073_018, please, Sully, page 3.

A. I hope I've got this right. I saw it briefly then and it reminded me.

Q. So paragraph 11 should be on your screen, Dr Lloyd.

A. Okay, yes. In that highlighted section in the middle, we see:

"Both Dr Gunson and Dr Mitchell felt that if the results of the pilot study giving 6 true positives out of 10,000 donors were borne out in practice then counselling would be manageable."

I think if you're saying that counselling would be manageable, you're obviously saying that the test, introducing the test would be manageable. So, you know, here we are with the first -- referring to the first generation test, saying that the number of positives is manageable. And I think that's important to remember as we go through this. Thank you.

Q. Then going through this chronologically, I'm going to ask you to look next at a document from early January 1991, not a document you would have seen at the time. It's PRSE0002858, these are headed "JDC Notes of NBTS/SNBTS Management Meeting (7th January 1991)". So these are Dr Cash's own notes

of his meeting.

A. Yes.

Q. If we go to the second page and pick it up at paragraph 5, "HCV Donation Testing", Dr Cash has recorded here:

"HG [that's Dr Gunson] conveyed his concern that DOH has still not decided on a start date. It now seemed probable that May/June 1991 would be the earliest possible.

"2. HG advised that he believed that the major problem for DOH was mechanisms for finding the money for NBTS RTCs and for E/W [which I assume is 'England/Wales'] confirmation testing."

A. England/Wales, yes.

Q. "The issue is one of DOH's disinclination to fund centrally and insist on cross charging -- ie increasing the unit cost of blood supplied to hospitals."

Now, two questions arising out of that, Dr Lloyd. The first is, as I understand your evidence, you had not been working on any assumption that the Department of Health would be funding this. You'd been working since 1989 on the assumption that the region would be funding it; is that right?

A. That's correct.

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

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

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

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

A. Yeah.
Q. Do you ever any recollection of what your reaction or feelings were, bearing in mind you were ready to start at this point in time, on 1 April, being told it was going to be 1 July?
A. I was upset. I thought this was unnecessary. And it's -- there's nothing there that tells you why it's 1 July. And it's this sort of this comment that an "agreed date ... has emerged". You know, where did it come from? Certainly not from me. And several other centres were ready and able to start earlier than this. So the agreed date is -- you know, I was unhappy with that. I was definitely unhappy with that. So that was setting me on the course for what happened afterwards.
Q. Then if we go to PRSE0002280.

You'll see when it comes up it's the further meeting of the Advisory Committee on the Virological Safety of Blood on 25 February 1991.

If we go over the page there's a heading towards the bottom of the page "Hepatitis C: UKBTS pilot study".

Then if we go over to the next page, please, Sully, and we just look at paragraph 6, it refers to a paper tabled by Dr Tedder. And we can see that the

question of second generation tests has now reared its head.

"The Committee discussed the likely availability of the second generation tests and operational factors which might influence the decision by RTCs as to which screening test to choose. Licensing of the tests by FDA ..."

That must be the second generation tests because we already know they'd already been licensed for the first generation.
A. Yes.
Q. "... had not yet been finalised. Members agreed it was important for proper evaluation of the Ortho and Abbott 1&2 tests to be carried out before RTCs decided which test they would adopt."

So this is the decision or recommendation of the ACVSB that before testing is introduced, there should now be a further evaluation comparing the first and second generation tests, or looking at the second generation tests.

Now you obviously didn't see this --
A. Sorry --
Q. -- but that information --
A. -- no.
Q. -- came to your attention. We'll look at how in due

course. But in broad terms, what was -- what's your view of the suggestion that there should now be this further evaluation involving the second general election tests?
A. Sorry, can you remind me the date, was this February 1991?
Q. This is 21 February 199 -- sorry --
SIR BRIAN LANGSTAFF: 25th.
MS RICHARDS: 25 February, thank you, sir, 1991.
A. Right, thank you. Okay.

If I read that paragraph again -- if you could perhaps enhance it for me?
MS RICHARDS: Paragraph 6, please, Sully.
A. If someone could bring --
Q. We'll do that.
A. Yeah. It's a confusing statement:

"... likely availability of second generation tests ..."

Saying we're not sure when, it's only the "likely availability". Then:

"... Operational factors ... might influence decision [of] RTCs as to which screening test to choose."

That's very strange. Why would you choose between a first generation test and a second

generation test? You might choose between two or three different manufacturers of a second generation test, but why would we be deciding whether to do a first or second generation test? That really does not make sense to me.

"Members agreed it was important for proper evaluation of the Ortho and Abbott 1&2 tests to be carried out before RTCs decided which test they would adopt."

So again, we're saying you might decide to go with some centres -- and this is interesting -- evaluation -- centres decide which tests they would adopt. Would they adopt first generation or the second? So now we're suggesting that you might have a situation, once the second generation test eventually becomes available, that some centres will choose to use first generation tests ...[frozen screen]... doesn't make any sense.
Q. Dr Lloyd, we lost you there for a --
A. Either the minutes or -- okay. I was repeating myself.
Q. No, no, we lost you for a couple of seconds, so I just wanted to check we didn't miss anything significant.
A. Yes.
Q. You said this:

"So now we're suggesting that you might have a situation, once the second generation test eventually becomes available, that some centres will choose to use first generation tests ..."

And then we missed possibly just a few seconds.

A. Okay.

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

A. Okay.

Q. So could you just repeat that point?

A. Certainly.

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

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

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

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

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

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

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

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

A. Mm-hm, right.

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

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

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

A. Mm-hm.

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

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

SIR BRIAN LANGSTAFF: Yes.

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

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

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

MS RICHARDS: We have.

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

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

SIR BRIAN LANGSTAFF: Well, we can check that.

MS RICHARDS: Yes.

Dr Lloyd, just couple of other documents I want to look at briefly with you and then perhaps we'll take a break. The first is NHBT0000191_110. So this is a memo from you to colleagues within the Northern Regional Centre or service, 14 March 1991.

A. Yes.

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

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

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

Q. No, you're absolutely right.

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

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

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

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

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

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

decision that you then took. But can you just assist with this: Dr Gunson sets out in that fourth paragraph his view of "our interest", and then the proposal to move the date for testing back from July to September --

A. Mm-hm.

Q. -- or forward from July to September, however you want to characterise it. Had there been, as far as you're aware, any discussion between Dr Gunson or anyone else from the National Directorate and Regional Transfusion Directors, such as yourself, or did this come out of the blue?

A. This came out of the blue. This came completely out of the blue. I had no idea this was being considered. July was already too late and, as perhaps we'll discuss later, this was, as they say, the straw that broke the camel's break, from my perspective.

So it is -- it was -- yes, it was completely a surprise when this arrived.

MS RICHARDS: Sir, I'm going to suggest we take our break now, I've run on slightly later than I normally would for this session, in any event, and then we can pick up Dr Lloyd's decision and the response to that decision in one go after the break.

SIR BRIAN LANGSTAFF: Yes. Well, let's do that starting

at 2.50.

MS RICHARDS: Thank you.

SIR BRIAN LANGSTAFF: 2.50.

A. Thank you.

SIR BRIAN LANGSTAFF: Sorry, your equivalent.

A. Yes.

(2.28 pm)

(A short break)

(2.50 pm)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Dr Lloyd, we had finished tantalisingly with Dr Gunson's letter of 3 April. We can pick up what you then did in response at NHBT0046745.

We can see this is an internal meeting, medical staff committee meeting, 25 April 1991. And if we go to the top of page 3:

"Hepatitis C testing began on April 24 testing for anti-HCV. This would be using the second generation test which had a low rate of false positivity. The timing of this introduction of testing may well cause some problems with the National Directorate."

So we have there, I think, the state on which you introduced testing. And you tell us there it's the second generation test. It was the Abbott test

which you used, I believe?

A. Mm-hm. Yes, that's correct.

Q. In a nutshell, Dr Lloyd, what was your reasoning for going ahead in the way described here?

A. Well, obviously I'd written it in my witness statement. We had the wherewithal to do the test. We had the -- funding was in place, we had the tests available. We had the equipment available. We had the staff who were more than competent to carry it out. Our own internal IT department had made sure that we could communicate the test results into our existing system, and so we were sitting on the start line ready to go. Then we're told to wait for -- if you look at the last letter from Dr Gunson, it didn't say, "We will start on 1 September" it was a "may start on 1 September".

So we -- I felt that I could not delay testing. I mean, we had the wherewithal to remove infectious donations out of our system and therefore reduce the risk to patients receiving the blood. We really had no -- there was no alternative. I mean, there was -- you can't not go ahead when everything is in place, just to meet some mythical common start date.

Q. We can see you anticipated in that last sentence that there might be some problems with the

National Directorate. Let's pick that up with a letter Dr Gunson wrote to you.

NHBT0000062_054, please. And we go to page 3.

So 29 April, Dr Gunson wrote to you. First paragraph refers to a telephone conversation. Second paragraph:

"I was sorry to learn that you had taken this unilateral decision to proceed with testing without first discussing the issue, not only with me, but with other colleagues in RTCs given you must have been aware of the implications for them of your decision."

Then he refers back to the ACVSB meeting and to a letter he wrote, which we've already looked at, in January --

A. -- (overspeaking) -- problems.

Q. And then over the page, we see, the top of the page, he refers to the 'second-round' evaluation. Then the next paragraph:

"Unfortunately the timing stated in this letter slipped ..."

And he explains that was the reason for his letter deferring the date to be aimed for as 1 September 1991.

Then the last paragraph he says:

"I have written these details in some length to

demonstrate that I had kept you fully informed of the national policy with respect to anti-HCV testing. There are still other matters which have not yet been concluded."

Then he sets out what some of those are.

Can you recall what your thoughts were on receiving this letter and do you have any particular comments on what we see set out in it?

A. First of all, this letter follows the telephone conversation which was somewhat harder to listen to than this was to read. Dr Gunson was, how shall I put it, beside himself over what we had done, and I sort of realised that there would be issues.

Then here we have a series of odds and ends as to why they can't do it. Certainly the second round evaluation is referred to, and this comes up elsewhere. We do now know from correspondence between Dr Gunson and, I think it was, Simon Pearl, the lawyer with the firm representing the NBA, probably, in litigation, in which Dr Gunson says the second-round evaluation was effectively a sham. It wasn't a serious thing. And that it was not actually necessary.

So we now know that he thought it wasn't necessary, and yet here he is saying we've got to do

a second-round evaluation and we've got to, you know -- the procurement people have got to do this and that.

None of it mattered. None of it mattered. Even if the second generation test had not been available for months, we would have gone ahead with the first generation test. So all of this is just some sort of way, to me, for Dr Gunson to sort of say, "I've got all these great reasons for delaying it, and you shouldn't have broken ranks". It was an unpleasant letter.

Q. We can see your response at NHBT0000074_010.

You say there:

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

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

Antibody. The comparative study of the Abbott and Ortho kits (first generation), was not going to influence my decision as to whether or not to start testing."

"The next round of comparative trials which encompasses other manufacturers kits as well as second generation kits from Abbott and Ortho when started was not going to be completed in time to allow this Centre to meet the July deadline, even on the original schedule. The change in date based on a further delay in completion of the next round of evaluations would have delayed the introduction of testing (all transfused units negative) by several months, possibly taking us to November of this year.

"If during that period anyone becomes infected and subsequently takes action, in my opinion, I would have had no defence. We that the wherewithal to test, including kits, equipment and staff and we had agreed to start previously. The delay is thus administrative and that not only forms no basis for a defence or a mitigation but also I think aggravates the situation.

"I have therefore proceeded on the basis that all units available for transfusion from 1st July will have been tested."

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

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

Q. Yes.

A. Is it right for me to?

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

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

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

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

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

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

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

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

A. Absolutely. Yes.

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

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

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

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

hearings and then invite your comment.

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

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

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

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

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

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

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

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

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

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

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

A. I did, yes.

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

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

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

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

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

Q. Yes.

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

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

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

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

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

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

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

Newcastle Saga: HCV Donation Testing".

A. Yes.

Q. I just want to --

A. May I?

Q. Yes.

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

Q. Of course.

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

Q. Thank you, Dr Lloyd.

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

"... we should make every effort to maximise

this disaster to our corporate advantage."

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

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

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

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

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

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

A. Mm-hm.

Q. That's what Dr Rejman is referring to.

If we go back to the first page, please, in Dr Rejman's memo.

Point 2, he says:

"This gives details of routine anti-HCV screening at Newcastle RTC which commenced last week.

"3. This action was taken despite the agreed policy by the ACVSB that screening should start simultaneously in all the RTCs in the UK.

"4. This had also been agreed by the RTC Directors with the National Director of the NBTS."

Just pausing there, that appears to suggest that a policy of simultaneous screening was the consensus view agreed by RTC directors. Was that your understanding, that this had been agreed by RTC directors?

A. ...[frozen screen]... correspondence I received and phone calls I received, it was quite clear that all the other directors believed that we were going to start on the same day. So yes, I have to say it was agreed. I do not recall actually being in a meeting where I said, "I agree to start on the same day". I might have done. Possible. Particularly when we thought the test was being introduced fairly promptly. So yes, it's -- I think it's fair to say RTC directors

agreed with the national director that it should start simultaneously, yes.

Q. Then Dr Rejman's observation in paragraph 5, and obviously we can ask him about this, but it says:

"This action has caused problems in that the other major competitor company feels disadvantaged, and has also caused problems in Scotland.

"6. We are waiting for written reasons as to why this action was taken."

Then he says he is:

"... copying it to members of the Management Executive to determine whether action is required where an individual Region decides to oppose a universal agreement."

Do you have any observations, Dr Lloyd, on paragraph 5, whether the problems it's said that had been caused are disadvantage to the other competitor company, and unspecified problems in Scotland?

A. I have absolutely no sympathy for a large commercial company that happens to feel disadvantaged over something that happens. They're in the business of making money and I'm quite sure many companies, and you see it in the newspapers occasionally, companies come up and complain that they feel they've been disadvantaged by something that has happened, by some

government decision or whatever. Of course they're going to come up and say that. They don't want to be left behind. They don't want to make less money. So I certainly feel no sympathy, if that's the right word. You know, tough. They're a big business. They're a multinational corporation and they can look after themselves.

As for Scotland, I'm not quite sure what was being suggested here. Whether it means that Scottish NBTS was now put in the same position as some of the -- as the other transfusion centres in England, although somewhere along the line I have a feeling that the Scottish centres were also prepared to start earlier. I do note that with the exception of the letter from Dr Ruthven Mitchell, which as I said was a moderate, reasonable letter, none of the other Centre Directors from Scotland actually wrote and complained about my decision to start testing. So maybe the Scottish Blood Transfusion Services were not as comfortable with the delay, apart from, obviously, John Cash.

Q. Were you surprised that the introduction by you of a measure designed to improve patient safety triggered such a response from others?

A. When I decided to introduce the test, I knew there was

going to be a backlash. Or I was pretty sure. And what I -- when I re-read those letters, what I note is that nobody mentions the patients. The ...[frozen screen]... jolly good show, we're all -- no one is going to break ranks. And I sort of felt that was -- there's something wrong with that. Wrong focus.

Q. Just a handful of further questions about the correspondence and so on at this time.

First of all, NHBT0000074_026.

You wrote to Dr Gunson on 9 May 1991. You referred to Dr Contreras's letter and said your impression was "that there was a concerted attempt to obtain funding from the Department of Health", was this is an agreed strategy? And then you posed the question:

"Would you be good enough to let me know whether there was in fact a strategy which involved delaying the introduction of the tests while awaiting central funding for this test. As far as I am aware, no previous communication has indicated that the start date for the test depended on funding direct from the Department of Health."

Now do you recall if you had an answer from Dr Gunson to that question: was there a deliberate strategy here?

A. I certainly don't recall any response. But obviously ...[frozen screen]... well, obviously -- but no, I don't ever recall receiving an answer to that.

Q. Now, one of the things that happened next, and we can pick this up at NHBT0000192_024, was the suggestion that your action would be regarded as a trial and not the commencement of routine testing. So we can see this is a letter from Dr Gunson to all RTDs, 9 May 1991. We can pick it up, I think, bottom of the page:

"Dr Lloyd's premature introduction of the test, however, can be used to extend the scope of the evaluation if it is developed as part of a national policy. To this end DH have agreed that two other RTCs in England, namely Leeds and Liverpool, will take part in an extended trial using the Ortho 2nd generation kit. This will still be regarded as a trial and not the commencement of routine testing."

There's further communication in relation to that suggestion. You've characterised it in your statement as a face-saving exercise and a charade, and I just wondered if you would care to elaborate upon that?

A. Yeah, certainly. At the time when this came out, when Dr Gunson started talking about an extended trial, you

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

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

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

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

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

is normally only a mild infection (not like AIDS)."

Now, you have some observations from that in your statement, Dr Lloyd, but I just wondered if you could tell us orally what your response is to that.

A. I mean, that's really a quite outrageous statement to be putting out and suggesting that people should pass it on to the general public. Dr Gunson knew that wasn't true. People who, unfortunately, you know, were HIV infected, developed AIDS and died, and there are people who contracted hepatitis C and developed severe disease cirrhosis and died: normally only a mild infection? No, sorry, that's wrong.

Q. Then if I can just pick up a couple of other letters, NHBT0000076_009. This is a letter you wrote to Dr Gunson on 24 June 1991. You say in the second paragraph -- no, the first paragraph is what I wanted to pick up, second sentence:

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

I'm not going to go through with you all the other dates for the other countries, we have those as a matter of record.

SIR BRIAN LANGSTAFF: Are we actually looking on the same

page?

MS RICHARDS: Sorry, first page, Sully, first paragraph.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Thank you. So it's the second sentence of that first paragraph.

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

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

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

matter".
Q. Then if we look at the penultimate paragraph on this page, beginning "The second of these valid criticisms", so this is about not giving other centres adequate warning, you say:
"The second of these valid criticisms resulted from my view that had I informed everyone earlier, pressure would have been brought to bear to stop me instituting testing, a course that I believe was right and am now even more convinced was right."
I think you say in your statement, Dr Lloyd, that your real concern was that, somehow, an instruction might be issued from the Department of Health to instruct you not to go ahead; is that right?
A. Yes, that was my line of thinking. I didn't think I was going to be stopped from doing it just by sort of peer pressure. I thought if I was going to have be stopped, it would have to come through the Department of Health, because Dr Gunson had no -- I had no line accountability to Dr Gunson. He couldn't stop me directly ...[frozen screen]... he was the advisor on the advisory ...[frozen screen]... to happen, and then through the Department of Health, back through to the Regional Health Authority, and then my boss would have said, "Don't do it."

So that was what I was worried about happening.
Q. I think we lost a few seconds of your --
A. Fortunately the -- yes. Yes, that's what I thought was would happen, would be that there would -- that the route would be from the Department of Health through to the Regional Health Authority, where the person I reported to would then tell me not to start testing.
But of course I was fortunate also in having discussed this in advance with senior people at the Regional Health Authority, and I have to thank, I think it was, at the time, Professor Liam Donaldson who supported me, and certainly understood the issues. A very savvy individual.
Q. And then if we can look at a memo you wrote in June of 1991 setting out your reflections.
NHBT0000192_092.
18 June 1991. It's not to anyone. It reads as though this may be as it were a note to yourself, almost, for the record.
A. It was, yes. It was a note to myself. I occasionally did that. Helped me remember things.
Q. I'm not going to read through the detail of it. You refer to a meeting held in York. I think that was the Northern Region that had met.

If we look down at the --
A. I think it was on the -- 14 June, I think.
Q. Then if we look down the bottom of the page, just want to look at the last paragraph. You say this:
"At the end of this meeting I felt confident that as a Centre we had made the right decision to proceed with Hepatitis C testing when we did. My only regret is that we didn't introduce it earlier. The coordinating activity of the National Directorate appears to have provided us with a lowest common denominator approach rather than a best possible approach."
As I understand your statement, Dr Lloyd, this remains your position. Your only regret now still is that it wasn't -- that you didn't do it earlier than you did?
A. Absolutely, yes. And I am sorry for that.
Q. Do you have a sense of how much earlier you could have introduced it on a local basis in Newcastle, given the other constraints about the way in which the ACVSB was taking its decisions and so on?
A. There's a number of issues there. If you take the purely logistical issue, we had the wherewithal to introduce the first generation test earlier because we had been the -- we had run the trial. So technically

we could have continued to test when the trial ended. So that's a sort of a technical issue.
The second issue is if, as we mentioned before, the ACVSB had noted in November that we should test, should start testing as soon as practicable, I think the word was, we could then perhaps at that stage have gone to the Regional Health Authority and said, "Do you have some remaining sort of emergency funds which you would be prepared to use so that we can purchase this test kit for the first couple of months of 1991 before the new financial year starts?" You know, if we'd gone to them in November, perhaps they could have found funding for sort of January, February, March.
What I -- I say I didn't know, I probably -- perhaps I did know, but I hadn't thought about it in that way, was that we couldn't start testing without the Department of Health approval and the minister's approval.
So there was a real -- there would have been a real problem with starting testing before that approval, which I think was given on 22 January 1991.
But even then, we could possibly have started testing in January if the Regional Health Authority had had some residual funding to fund the test.
SIR BRIAN LANGSTAFF: May I just ask about the funding.

The position was, as I understand it, that, at this time, cross charging was in place. Am I right?

A. Yes, yes, sir. But --

SIR BRIAN LANGSTAFF: So the -- one way --

A. We could change -- sorry.

SIR BRIAN LANGSTAFF: -- one way of getting the money is to increase the price of the product supplied, that part of the budget?

A. At that point -- that's a valid point, except that I thought that that sort of change I was -- I would be one person going out to the whole series of health trusts and hospitals to try to renegotiate a contract, something I wouldn't do without the region, and if -- I don't know about all the regional funding issues, whether they would have had money that they could have, in turn, released to the hospital trusts, and so on, for them to bring it back.

I might have been in a very strange position of having approval for an increase in funding or an agreement to increase funding by some hospitals, but not by others. That would have been difficult.

SIR BRIAN LANGSTAFF: Yes, I see. Thank you very much.

MS RICHARDS: Then a couple of other documents, picking up on something you've referred to about Dr Gunson's later communications.

Could we start with NHBT0088807. So this is one of the documents, I think, you were referring to. This is now February 1999, and I anticipate is in the context of the litigation, which we know was brought against the National Blood Authority, and it's Dr Gunson writing to Dr Barbara and then we've got the reference in the first paragraph to Simon Pearl, who you correctly say was a solicitor in the firm representing the NBA.

It would appear that there's a request from the solicitor to expand Dr Gunson's report to demonstrate that your decision, Dr Lloyd, was "maverick and premature". We see in this next paragraph Dr Gunson says:

"With the benefit of hindsight I have indicated that we should have introduced routine testing without the second evaluation, or at least, tested the 10,000 or so frozen donations whilst using the test routinely. I think we will be criticised severely for not doing this, since there were many countries throughout the world where the second generation tests had to directly supersede the use of first generation tests. By April 1991, only Denmark and some centres in the Netherlands and Italy were not screening routinely."

Then this:

"However, I suppose we have to reinforce the arguments which were put forward in 1991 since we must have believed in them as proper ones to take at that time."

There's then a comment, some comments on a paper from Dr Barbara that we don't, I'm afraid, have or haven't located, which sets out a number of matters. But if we go over the page, I just want to pick it up in the third paragraph, where Dr Gunson says:

"The decision to carry out the comparative evaluation of the Ortho and Abbott second generation tests was made by ACVSB on 25 February 1991 on the grounds that the second generation tests had not been licensed by FDA. I think we must support this policy decision even though I think we may face some difficult questions on how the second generation tests introduced into other countries where screening had commenced with first generation tests."

Then bottom of the page, he says:

"I do not know how Huw resolved these problems since I did not discuss them with him. I did have 'crie de coeur' [*sic*] from a Dr Codd at the Newcastle PHLS asking what he should do."

Do you have any understanding of what that

references to, Dr Lloyd?

A. Arthur Codd, who was a consultant with the Newcastle Public Health Laboratory Service, I suspect that we probably threw some request for confirmatory testing at him and he was a delightful gentleman, but I think probably got a little bit flustered and wasn't sure if he was going to get into difficulties for supporting what we did. So that was probably the sort of lines that this was taking.

Q. Then we see Dr Gunson explains:

"[He is] thinking of responding to Simon Pearl in terms roughly as set out above. I think it is important that our efforts [that's his and Dr Barbara's] correspond reasonably well."

Then if we go to the report from Dr Gunson and Dr Barbara, or the statement, I should say, it's then produced at NHBT0088813_002. NHBT0088813_002.

So we can see it's a joint statement by Dr Barbara and Dr Gunson, entitled "Unilateral Introduction of Anti-HCV Testing at Newcastle RTC in April 1991". I know you've had an opportunity to look at this, so there are only two passages I'm going to ask you about, Dr Lloyd, second page, bottom half of the page, it says:

"Dr Lloyd ... did not raise any objections to

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

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

A. Yes, yes.

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

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

Q. Then the last part I wanted to ask you about in this document is on the last page. Last paragraph:

"There is no doubt that Dr Lloyd's decision was not in the interest of the Service as a whole and was

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

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

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

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

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

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

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

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

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

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

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

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

A. -- following on -- sorry.

Q. Carry on.

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

Q. Yes, the first paragraph says:

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

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

Q. Thank you. That was what I --

A. So this is as the results of that study -- yeah. That's where it came from, then, because it says two

tests.
Q. Then, just in terms of once testing was fully operational across for the Northern Region, I think there came a point in the course of 1992 when it appears that you learnt that Dr Collins had not been communicating to donors who had tested positive the fact of their positive test and what steps they should take, for example, seeing a doctor, and so on.
A. Yes.
Q. The reference, just for the transcript, I don't propose to go to it is NHBT0003991. How had that happened and what steps were taken to rectify that situation?
A. Steps to rectify: as soon as we found out, we sort of piled resources then to get the letters out, dedicated a secretary to help with it and we got on and got the letters out.

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

received the results. I think we had probably helped to draft -- you know, we'd got the drafts like this, letters like this, so we knew what we were going to do, but, for some reason, she was unable to carry it out, and I don't really want to go into why she couldn't carry it out, but she didn't.
Q. Dr Lloyd, I'm going to move in a moment to three further short topics of questioning I have for you, but before I do so, on the question of the introduction of hepatitis C screening, is there anything further that you would want to say or that we haven't covered or haven't covered in your statement?
A. No, no, I don't -- nothing sort of springs to mind. All I can say is it gave me some sleepless nights at the time. It wasn't easy -- an easy decision. I was certainly concerned for my position. But thankfully, you know, we got through it. But I don't think there's anything else.
Q. So I'm going to move now to an issue about the introduction of hepatitis B core antibody testing. Not as a surrogate measure for non-A, non-B hepatitis but in relation to hepatitis B itself.

If we pick this up at WITN6935033.

This is a memo from you. I think it's an internal memo from the names.

A. It is.
Q. 18 May 1983. It refers to you having spoken to Dr Gunson regarding hepatitis B core antibody testing.

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

Then the next paragraph discusses the test results.

And then the third paragraph:

"With regard to the date of implementation of the test in the [UK], Dr Gunson says he does not know when this will be but thinks it will be in the autumn.

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

Is it right to understand from this, Dr Lloyd, that your assumption and Dr Gunson's assumption was that this test would be introduced, the only question, really, was when rather than whether?
A. Oh, absolutely. I mean, once again, in this case -- referring to Sir Brian's comment -- we included

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

So we had informed hospitals that we were going to introduce the test. Our haematologists in the region knew we were going to introduce the test. We were ready. I recall we had discussed it with our supplier, Abbott, so that they were prepared to deliver to us the suitable number of tests. So yes, we were ready to go. And as you say in that comment, I suggest that Dr Gunson also was expecting to start.
Q. And the reference to being "as usual ... incredibly slow in their deliberations", is that harkening back to the then not too distant past of the issue relating to hepatitis C screening, do you think, or were there other issues that you had in mind?
A. No, I think I was just referring to hepatitis C.
Q. Is this right: that the Newcastle Centre or the Northern Region, had been involved in the trial of the anti-HBc test kits?
A. Yes, I think we had. I think I've seen somewhere a little -- a few sheets of paper sort of showing some results, so yes, we did do some work on it. I can't remember the results we got in terms of incidence.
Q. Just for the transcript --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Is that article an accurate reflection of your

that from NHBT000 --

A. He would be.

Q. -- 5291_002.

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

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

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

A. Mm-hm.

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

views as at 1995?

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

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

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

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

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

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

A. Is it? Oh, I see.

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

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

Q. As opposed to the anti-HBc.

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

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

A. No.
SIR BRIAN LANGSTAFF: Could you have done so had you wished?
A. I don't think so. We were -- I can't remember the exact moment in which we were transferred to the NBA. Once we were part of the NBA, that was certainly not something I could have done on my own. You're in a different situation. If it had been before, I think there's some -- some of the documents we've just seen make it much clearer that the Department of Health has the authority and said no, and they said no before I was trying to introduce it anyway. So, you know, "Don't do the test" comes before the point at which we had planned to introduce it. So there would have been a difficulty going ahead, certainly.
SIR BRIAN LANGSTAFF: Yes, well, thank you very much.
MS RICHARDS: Sir, I've got about another 10 to 15 minutes of questions for Dr Lloyd, and what I was going to suggest, if it's okay with you and Dr Lloyd is I carry on now, complete my questioning, and then we need only have one perhaps slightly longer break to enable Core Participants to suggest questions rather than the two breaks, and that way we ought to be able to finish Dr Lloyd's evidence today.
SIR BRIAN LANGSTAFF: Yes. Dr Lloyd you can have a break

now, should you wish. But you've heard what counsel has had to say. It's a choice between having two breaks, one now and one shortly afterwards, or just the one.

The purpose of the break, of the slightly longer break, is, as council has said, it's to allow those who are participants in the Inquiry to suggest questions to be put to you so that there is every chance that every question that people significantly wish to ask may be answered from your evidence.

We'll continue.
MS RICHARDS: Thank you.
SIR BRIAN LANGSTAFF: Unless you want to stop?
A. Yes, please continue. No, no, please continue.
MS RICHARDS: Dr Lloyd, the topic I'm going to ask you about now is clinical transfusion practice. So the extent to which transfusions were used in hospitals, and whether they were used more than they needed to be, and what measures, educational or persuasive measures were or were not taken by the Regional Transfusion Centre in that regard. Can I just start by asking you to cast your mind back to the second half of the 1970s, when you were working in your house officer posts in a range of different disciplines.

Do you recall whether, either from your medical

training or through those five years or so of house officer work, whether there were ever discussions or guidance or advice about minimising the use of blood and blood products?
A. I did -- it sort of bought it back. One of the documents presented by the Inquiry is *Notes on Transfusion* dated, I think, 1977. Now, that was a little after I was into my, sort of, general clinical jobs. I certainly recall carrying that notebook, that actual set of notes, with me. I think that does refer to issues of using blood and that there are safety issues.

In my training, there was very little said about transfusion. We didn't have a lot of -- I can't recall having a lot of information about the risks of ...[frozen screen]... So, after that, in the first few years, it was -- we just used it, and I was working, particularly in my first job, in a relatively small hospital. So I don't think there was a lot of general knowledge of transfusion. I don't think we had a haematologist -- I know we didn't have a haematologist there.

Then we came to north -- when I moved to the North Tees General Hospital in the second half of 1975, we did have a haematologist, Dr Roger Finney,

and, you know, I think sort of -- if I did, you know, discuss issues of transfusion when there were things I needed to know, I would discuss them with him. So there was discussion and I don't think I was ever in a position of wanting to or needing to do single unit top-ups. Perhaps that's partly because of the type of patients I was dealing with.

So yes, during those years, there was discussion. Not massive, but things like *Notes on Transfusion* did provide some backdrop to the fact that, you know, there are safety issues. I don't recall throwing this stuff around like confetti.
Q. Then, whether by reference to those SHO years or then in the 1980s when you began to concentrate on haematology and transfusion and you had some experience with blood banking, and so on, do you recall what the position was in terms of record keeping? Were there -- how meticulous or rigorous an approach were you instructed or advised to take from the hospital's perspective about ensuring that there were clear records of what was transfused and to whom, both in the blood bank and in the patient's records?
A. Oh, in the patient's records, it was certainly drummed into me that we always recorded the information on transfusions, the donation number and what was

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

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

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

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

"The answer is Yes and No!

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

"The main choices can be summarised as follows:

"Reduce your threshold for Transfusing ...

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

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

"Use volume expanders.

"Use Autologous Techniques."

Then you refer to the possible use of blood substitutes.

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

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

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

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

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

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

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

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

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

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

A. I can't remember --

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

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

"There is no Regional Transfusion Committee. The Northern Region Consultant Haematologists' Group meets twice per year. There is also a weekly informal meeting of the Regional Haematologists, which the RTD attends."

Is that what you were referring to?

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

Q. Do you know when that weekly practice started? Was it already ongoing when you came back to the Centre in 86/87?
A. It was -- that was going back -- that was operating back in 1981. I recall going into it as a registrar being in -- Dr Collins saying, "You know, you should get across to that meeting". So that meeting had been going for a long time. I suspect it was instituted by Professor William Walker.
Q. Then the next paragraph refers to three-monthly haematology audits. It says there:
"... topic-orientated and have included transfusion matters."
Is there a system with which you were -- or a process with which you were involved at the Transfusion Service, was that done with the region and the hospitals themselves?
A. I think that was a-- I think -- sorry. I think that was the region and the hospital. It wasn't something driven by us. We were perhaps not as intrusive into the hospital blood banking as we might have been.
And you will perhaps note from other things I've said that we -- when I moved from being -- well, I say moved -- when I became chief executive, we introduced -- we were able to appoint a consultant to

become the head of our medical service, specifically to sort of recognise -- you know, recognising that I didn't have enough time to devote to some of these issues such as hospital transfusion committees. And of course, a bit like Anne Collins before me, for a number of years I had very little in the way of other sort of consultant-level support.
Q. And if we look at the top of the page we can just pick up the reference to hospital transfusion committees. It says:
"Twenty/twenty-one Hospital Transfusion Departments are serviced by the RTC and of these, three/four have set up Hospital Transfusion Committees. These generally meet at three-monthly intervals. The RTC is not actively involved, but two of the RTCs invite an RTC Consultant as appropriate."
It sounds as though the establishment of the hospital transfusion committees by the three or four hospitals was relatively recent at that point in time. Does that accord with your recollection?
A. I think so. I think so. You said this was 1991?
Q. November 1991, the date of this.
A. Dr Ala and Dr Hewitt, yes. When Dr Hewitt and Dr Ala visited. So I think there was a hospital transfusion committee at the Freeman Hospital before that, when

I was still perhaps a senior registrar. But they would have been one of the sort of -- one of the hospitals that tended to be at the forefront of that sort of issue.
Q. Looking back now, Dr Lloyd, do you think there is more that could have been done, whether by the Regional Transfusion Service or by the hospitals within the region or, indeed, nationally perhaps, by the Chief Medical Officer or the Department of Health, to reinforce the message about using transfusion appropriately and encouraging and educating doctors and nurses about the better use of transfusion?
A. Certainly you can always do better. I -- you know, I could have spent more time, and sort of recognised that I wasn't spending as much time as I, you know, perhaps should, in working at that level with the hospitals. But we did have -- the Northern Region did have a good group of consultant haematologists so -- you know, they understood these issues. Prior to the -- prior to a hospital getting a consultant haematologist, you were left with a pathologist looking after the issues, and at that time that would have, you know -- I'm sure there wouldn't have been the same pressure on teaching people how to use transfusion properly. But once you've got the

haematologists there, you know, that was changing.
And you saw that when we had meetings with the haematologists from around the regions, only twice a year, we were able to work with them to change transfusion practice. And, you know, the reduction in the use of whole blood was also -- you know, we also talked about single unit transfusions. So yes, could have done more, but I don't think the Northern Region at that time, by the end of the 1990s, was doing too badly.
Q. Then last on this topic, NHBT0072687_001.
This is a letter from you to a consultant cardiothoracic surgeon at the Freeman Hospital, Dr Hilton, 11 June 1990. It says:
"Following the recent episode in which you phoned myself requiring that we provide blood bags for you to collect blood from staff in theatre for the provision of immediate blood transfusion. I feel that I need to reply to you and make my position clear."
Then you go on to describe these procedures as highly dangerous, both because of the lack of proper blood grouping, and the risks from that, and then, the third paragraph, the fact that the blood would not have been tested for hepatitis B or HIV antibodies.
Obviously this is before the introduction of the

hepatitis C testing.

And then you go on to talk about -- discuss the practice of using fresh whole blood in cardiac or cardiothoracic surgery.

Do you recall how, if at all, this issue was resolved?

A. Well, you'll also see in witness statements that one of the haematologists at the Freeman Hospital was saying something very similar to myself, that this wasn't a suitable procedure. I don't know -- I think that was probably a letter from Dr Patrick Kesteven to -- to Mr Colin Hilton.

I would imagine that they worked it out between them but I don't recall any sort of long term follow-up. I did get a copy of -- it's a -- well, it's in the state -- one of the documents in the Inquiry -- another letter from Colin reminding me that they were not the only people wanting to use fresh whole blood in that clinical situation.

I have no problem with them using fresh whole blood if that's -- was the best thing for the clinical care of the patient. I was concerned about it being done safely. And I wasn't going to participate in an unsafe procedure. But I don't know where it went after that.

Q. Then my final topic, Dr Lloyd, is in relation to record keeping. We've covered already in your statement, and the documents we've got refers to the record-keeping systems at the Centre and your introduction of the various computerised systems, so I'm not proposing to ask you more about that, but you were involved in the production of a report about record storage, which is at NHBT0071590_001.

So "Record Storage Report for the [NBTS] in England and Wales, Prepared on behalf of the National Directorate of the [NBTS] by Dr Lloyd, Dr Beal and Mr Martina, April 1992.

Then if we go to page 4, we can just pick up the "Introduction". So the report explains:

"Transfusion Centres store a wide range of documents and records ..."

And then --

A. Could we bring that up, could we bring that up on the screen, please?

Q. Do you not have it on your screen?

A. I don't, no. We've not moved on from Dr Hilton's letter yet.

Q. Ah, let's try again. Could you reload it, Sully, because it was on my screen. Have you got it there?

A. Yes, I have 1.1, "Introduction". Thank you.

Q. Yes, so it says:

"Transfusion Centres store a wide range of documents and records ..."

Then if we skip down to the third paragraph:

"Each group of documents or records can be viewed as having to be retained for certain minimum periods to satisfy specific legal requirements ..."

Then you say:

"The need to retain documents and records for use in future potential litigation is increasing as the level of litigation increases and it is imperative that major cases are not lost purely because the relevant documents are not available."

Then if we -- I'll skip over the next paragraph and then it says:

"To be of value, any records system needs to be simple, robust and reliable."

Now, before I ask you a couple of questions about the recommendations in the report, this introduction seems to be very much focused upon the fear of litigation. Was that the context in which this report was commissioned, or -- how did it come about that you and your colleagues were producing this?

A. I mean, obviously Dr Gunson asked for this report. He

must have been concerned about retaining records. I know I've -- this little bit focuses on litigation but I think you'll see elsewhere in the document that it actually focuses on -- it actually includes a wide range of sort of legal requirements to retain records.

Obviously a lot of the -- these records are retained because there is a potential to come back and -- for litigation. Whether that was Dr Gunson's focus, I can't remember how it -- I don't -- I haven't seen any letter from him sort of giving me and Dr Beal and Tony Martina a remit, a formal remit for doing this, for producing this. It's very much an organisational-wide process that you might apply to any sort of large organisation.

Q. If we go to page 7, please, Sully, top half of the page. We can see outline recommendations and you identify there three categories: "Long Term", where the recommendation is to keep the records for 30 years:

"This covers Donor and Donation records and policy and management records as well as records directly linked to Donor and Donation records such as QA reports."

Then you have "Intermediate Term" for a different category of documents, which was 10 years,

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

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

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

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,

that would give enough time, and then enable us to conclude Dr Lloyd's evidence today safely and not have to come back tomorrow.

SIR BRIAN LANGSTAFF: Very well. We shall come back not before 5.15 for us, that's 12.15 for you, Dr Lloyd. So not before 12.15.

MS RICHARDS: Thank you.

THE WITNESS: I will be here.

SIR BRIAN LANGSTAFF: Thank you.

(4.35 pm)

(A short break)

(5.20 pm)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Dr Lloyd, there are a relatively small number of further questions.

The first is this: do you know how many donors tested positive for hepatitis C in the period April to September 1991?

A. No, unfortunately I don't. I did ask the Inquiry if data on positive results could be obtained. So unfortunately, no, I don't know. I'm sorry.

Q. Don't worry, if you don't know, you don't know.

The next question is about donor exclusion on the basis of previous transfusions. You'll recall we looked yesterday at both the national guidance and

then the Northern Region zone guide or booklet on donor selection, which looked at deferral of donors who'd had a blood transfusion. What was your understanding of the rationale for excluding donors or deferring donors on the basis that they had had a blood transfusion?

A. Right. I think the issue was that we know that there's potential for infection, and if someone is infected, there is a period between infection and -- the relevant tests becoming positive. So by delaying -- by giving those months in between, certainly if there was something transmitted then you have a chance to pick it up on testing.

There's also a more general issue that people who have been transfused presumably have had some reasonably serious condition and therefore need time to recuperate appropriately. So there's a little bit of both. But I think the -- it was the first was the -- sort of the issue there.

Q. Then when donors were either excluded or deferred -- and this next question is not limited to previous blood transfusion -- what were the circumstances in which a donor might be advised to go and see their GP and have further testing?

A. I mean, that usually -- that was sort of a rather

individual decision. It might start with a medical officer -- in those days it was a medical officer at the session and not a clinical nurse specialist, but you would have -- they might recognise, particularly being a general practitioner, they would recognise that there was an issue that needed following up and would do so.

And the second was, when that wonderful illness book, duplicate book, information came back from the session and the medical officer at the centre looked at it, they might recognise that there was a need to obtain additional information. Probably more often, in that case, it was obtaining more information rather than passing the -- asking the donor to get further care and treatment. But I think at the sessions the medical officer was probably the one who was asking people to -- suggesting that they get followed up.

There is of course the case of those who were found to be positive for infectious and transmissible disease.

Q. Yes.

A. Very different requirement to go and see somebody.

Q. Then if you had a donor who was being deferred or sent away because they'd had a blood transfusion in the

past -- I appreciate the period of time might vary depending upon the particular set of guidance in operation at that time, but if you were doing that, was there any practice of telling donors why it was a transfusion might mean they shouldn't give blood at that stage? Would they be told, for example, "Well, there is a risk of infection and you perhaps you might yourself want to go and get tested"?

A. I don't recall that being certainly a written policy. I'm pretty sure it wasn't a written policy. Did the medical officer at the session do that? Certainly, there was the option to discuss the issue. It depends on the -- you know, it does depend on the individual doctor, and patient -- sorry, the donor. But, no, I don't think we had a proper policy on saying you must tell the person who has received the transfusion that they might be at risk.

Q. Cases of possible transfusion-associated hepatitis, is it right to understand that you did not report such cases to the CDSC?

A. Well, if a patient had a transfusion -- well, had a transfusion and then developed hepatitis, that -- I don't think -- I don't think we were informing the CDSC ourselves. Whether the hospitals did, because the person -- the individual was still a patient of

that hospital, becomes different once you start to get into look-back and find issues there. But no, I think the reporting in the case you referred -- in that situation you referred to, would have been more likely at the hospital and the transfusion centre level.

Q. Do you think it would have been helpful to have some kind of reporting obligation and a body, whether it was CDSC or another body, to whom all such cases of transfusion-associated hepatitis should be reported?

A. Oh yes, definitely it would have -- it is the sort of thing that, you know, you look at and think: well, we should have taken -- there should have been a broader sort of picture of this, and therefore information gathered -- should be gathered in one place, certainly something the National Directorate could have assisted with.

Q. Then next can I ask you to look at your statement, WITN6935001.

Page 108, please, Sully.

If we look at the bottom of the page, paragraph 171, there's the reference there to "Maximum benefit at minimal cost". And then I'm not asking you about the first sentence in the context of the question. I've just been asked to ask you more generally to talk about the concept and explain what

it is when you talk about maximum benefit at minimum cost, and then the shift that you then talk about the move to whether risk of injury to patients becomes more important.

Can you just flesh that out for us?

A. Yes. Certainly if you read some of the documents that have been supplied and a couple of journal articles, there were groups, certain people who were saying we shouldn't move to maximum -- we shouldn't move to minimising risk, irrespective of cost. There was certainly this feeling that -- more than feeling -- that, you know, you go for maximum benefit at minimum cost, which means that you leave a number of people at "risk of injury", as it's put here.

And certainly, you know, we've seen that that sort of almost paternalistic approach to care is not what we see today. And I think that move was occurring then. As I think I mentioned elsewhere in my statement, it wasn't a sort of a sudden change by the organisation, by the NBTS, but, you know, you could feel that change coming. We were prepared to introduce a test which was not going to, if you like, save a large number of lives -- it was going to save a lot of individual lives and distress, and so, you know, we're moving from, "Oh, we don't need to worry

about that, it's too expensive", to "We do need to care about the patients and our donors."

So it's a move that was occurring, and I think in some quarters of the Transfusion Service they were late in coming to that sort of conclusion.

Q. Next --

A. I hope that helps you.

Q. Thank you. The next question relates to the delays in the introduction of hepatitis C screening. One of the concerns expressed in documentation at the time is about false positives. What was your view on the issue of false positives and how to deal with donors or the possible situation of donors being given false-positive results?

A. Right. Well, if you go back to HIV screening, we'd already faced this issue. There were already cases of donors who were marked as positive, and they weren't because they were not infectious. So we've had to face that before. And so you try and -- you go down to your roots. One is get you positive on initial screening, you do repeat screening, you then do confirmatory tests, and you still end up with some where you're not quite sure.

So, in those cases, you are asking those people to be seen and I think in one of the letters from the

Centre, you know, we sort of expressed that. We don't think that you're infectious but you really need to see someone who can really take you through more detail, and get it sorted out. It's not going to be pleasant for the individual but that, I think, in my personal opinion, that's a more acceptable issue to handle than not testing at all.

So we're going to test, we're going to have positives, some of them will be false positives and we're going to do additional testing, we're going to pass them on for others and well try and, you know, support the individual during that initial phase when they're suddenly faced with "Oh my goodness, I might have something nasty".

The next question goes back to a completely different topic. This is about the actual process of donor screening.

A. Yes.

Q. In the Northern Region, could you just help us with understanding who was undertaking the screening. If we leave aside at the moment the Teesside office and talk about the rest of the sessions, whether they were general public sessions or industrial sessions in the Northern Region --

A. Okay.

Q. -- was it a donor session clerk with, then, referral to a medical officer in some instances?

A. Yes, the donor -- actually it was the same for both the Teesside office and the new -- sessions out of Newcastle. At both sites we employed people who were specifically looking after donor issues. So they were clerks, yes, but they were trained to carry out certain tasks and they rotated between working within the Centre, where they might be fielding some questions from donors by phone, out to the sessions where they would be asking donors the questions, and, you know, recording information and making decisions.

And we did introduce training as ...[frozen screen]... for the donor clerks to help them. And as you said, then, if they couldn't resolve something, they would pass it on.

And one thing we did try to do was to provide them with better and more usable information. If you look at some of those donor screening, donor care and selection documents, one of which you presented to me, from 1977 I think -- it was later, but anyway, those documents are not that easy to use. You've got different lists in different places, not easy -- it's very well laid out. So we did try to improve what we were giving to the donor services clerks to make those

decisions.

Q. When in May/June of 1991 there was a backlash in relation to your decision to introduce hepatitis C screening ahead of the common start date, what was the response, if any, of your Regional Health Authority? Were they supportive of your position?

A. Yes. I had absolutely no problem. I had no adverse comment from the Regional Health Authority, any of its senior officers ...[frozen screen]... actually it was probably the Regional General Manager at the time, but, you know, no problem. There was -- I mean, they didn't phone me up and slap me on the back and say, "You're a jolly good fellow", but I had no complaints, no one is saying, "You shouldn't have done this". No one saying, "Oh, you've put us in a difficult position". So I certainly have no complaints about how they acted.

Q. And then the last question is this: did you get any sense during the decision making in relation to hepatitis C testing, whether from Dr Gunson and --

A. Sorry, could you --

Q. Yes, I'll start again.

A. I'm sorry, I'm going to have to ask you to start that question again.

Q. No problem.

During the introduction -- the decision making about the introduction of hepatitis C testing, or indeed after you'd introduced it, did you get any sense that litigation, in particular the fact that there had been the HIV Haemophilia Litigation against the Department of Health, and others, did you get any sense that that was playing a role in the desire to present a unified front?

A. I mean, that was my impression. I don't think I have any documentary evidence to support it but my impression was, you know, as long as we all start together, no one can criticise us. And I think that was probably the same with HIV, but certainly with hepatitis C. As long as we all do it together, that's a great defence because how could you -- how can you go after one particular individual or one section of the organisation when they all did it together?

I've said before, that completely forgets the issue of the patients.

MS RICHARDS: Sir, those are the questions I'm proposing to ask from those suggested by Core Participants. I'm just going to check whether Dr Lloyd's representatives have anything? No.

Do you have any questions for Dr Lloyd?

SIR BRIAN LANGSTAFF: No, I don't. I've asked the

questions I've had as we've gone along.

MS RICHARDS: Dr Lloyd, is there anything further you would wish to add?

A. No, I don't think there's anything I wish to add in terms of either answering the questions or discussing the issues.

If I may, I'd just like to thank the staff -- pardon me -- the staff I worked with in the Centre. They worked extremely hard. They were very dedicated, and made a great change to that Centre. I know that doesn't help people who are listening who have suffered, but the Centre did get a lot better from where it started to where it finished. That couldn't have been done without the support of a lot of people. Thank you.

MS RICHARDS: Sir.

SIR BRIAN LANGSTAFF: Can I thank you, for my part, Dr Lloyd. We have trespassed on your time a little bit today, and it has not been the most convenient of times for you to give evidence, but you've been very willing to do so and, indeed, had it not been for Covid, you might even been here to give it in person, and I would just like to acknowledge that.

A. Yes.

SIR BRIAN LANGSTAFF: I'd also like to thank you for

plainly taking a very considerable effort to look at the documents which you've been sent by the Inquiry, so that you could refresh your memory. You are remarkable in your mastery of a lot of the detail of those documents, and it's been very helpful in dealing with your evidence as we have: evidence which has, throughout, been clear, to the point, and you've explained what you did very clearly to us in ways which will have given quite a number of people quite a lot of pause for thought. So thank you very much indeed for that, it has been most valuable.

MS RICHARDS: Sir, the Inquiry won't now sit --

A. Thank you, Sir Brian, it's very kind of you.

SIR BRIAN LANGSTAFF: Not at all. You fully merit it, which is why I've said it.

MS RICHARDS: Sir, the Inquiry won't now sit tomorrow, because we've been able to conclude Dr Lloyd's evidence this afternoon. We resume on Friday with the evidence of Dr Dempsey, who was, as you know, based in Northern Ireland, providing haematology services in particular to people with haemophilia, children with haemophilia. So we'll be exploring issues relating to Northern Ireland haemophilia care on Friday.

SIR BRIAN LANGSTAFF: So 10.00 for Dr Dempsey on Friday -- not tomorrow, we're not sitting tomorrow -- and I look

forward to seeing you at 10.00 then.

MS RICHARDS: Thank you, sir.

(5.40 pm)

(The hearing adjourned until 10.00 am on Friday, 11 February 2022)

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