Friday, 10 December 2021

(10.00 am)

DR PATRICIA ELIZABETH HEWITT (continued)

Questions by MS RICHARDS (continued)

MS RICHARDS: Dr Hewitt, before we turn to the HCV look-back, there is just one further question I have arising out of attempts to trace recipients of potentially HIV infected blood. Could we look at NHBT0010151_001, please.

If we go to the second page, this is a letter dated 12 December 1994 from you to Dr Rejman at the Department of Health. It is in the context, as I understand it, of an application to the Department of Health to be recognised as eligible for a payment from the Eileen Trust, and it is not the specific case that I'm going to be asking you about. If we look at the third paragraph you say this:

"My one problem with your proposal is that there will usually be other recipients who have been transfused from the same donor. In some cases, this will involve components from the same donation and in other cases there may be subsequent donations. I am most unhappy that the RTC is not provided with information which could facilitate the tracing and testing of other recipients who may have been at risk

of infection. I have expressed my concern on several occasions in the past. If the Department and the CDSC fail to disclose information which could enable the identification of other recipients who are infected, and therefore also eligible to submit a claim under the Department of Health Scheme, then some individuals will be denied access to the scheme."

What was the problem here, can you recall?

A. Yes, I can explain.

So the case in question related to an individual who had received blood transfusion before 1985. So the blood donors had not been tested for HIV and you can see that this letter was 1994. And I imagine that we had been asked to investigate the case and had been unable to contact those donors who had donated before 1985 and not since. So there were obviously more than one donor for whose HIV status was unknown, so we could not say whether this was a transfusion transmitted case or not.

The suggestion was made that for those donors whose HIV status we didn't know and with whom we couldn't make contact that we provided their details in what's called a Soundex code and that is a way of anonymising a name and there is a sort of way it is done, using the initial letters of the first name and

consonants from the surname, and that makes a Soundex code which is not unique but is fairly unique to a name, together with the date of birth, and that is how -- as I understand it, is how the Communicable Disease Surveillance Centre held their records for known HIV infected individuals.

So the suggestion was if we supplied the Soundex code of our unknown donors to CDSC, they could do a check to see whether any of the individuals who we do not know the HIV status of had been reported as HIV positive and then CDSC could report to the Department of Health and say, yes, there is a positive donor involved in this case, so payment can go ahead.

And that's fine and, as I said, I had no objection to that. What I objected to was that there was then no mechanism for the transfusion centre to be told, yes, one of those donors is HIV positive -- we know now is HIV positive. And, therefore, we could not trace any other recipients from that donor. So there would be other recipients who could be traced if that information was provided to the transfusion centre but who would not be traced because there was no feedback mechanism to say the transfusion centre must be informed.

Q. Was that resolved?

A. I don't know. I did not have a response.

Q. It may be we can pose that question to the Department of Health in that case.

Moving then to the hepatitis C look-back. You have observed in your look-back witness statement it was very different in some respects from the HIV look-back because it was a nationally coordinated exercise with, as it were, a direction or letter from the Chief Medical Officer?

A. Yes.

Q. That was the formal trigger, is that right --

A. Yes.

Q. -- although the Regional Transfusion Centres had been doing work in advance to be ready?

A. Yes, precisely.

Q. You managed the hepatitis C look-back for the North London Blood Transfusion Centre and, as you told us yesterday, ultimately also for the South London Regional Transfusion Centre?

A. Yes.

Q. Now, we know that began in 1995. It might be said that the obvious trigger for a formal national look-back exercise in relation to hepatitis C would have been the introduction of screening in the autumn of 1991, would you agree with that, first of all, as

a matter of principle?
A. Yes, and I expressed my concern that that was not being done.
Q. I ask you this not because you were involved in the decision-making but as someone who was subsequently involved in 1994/1995 when, as it were, it came back onto the agenda. Do you have any understanding as to why a look-back was not organised until 1995?
A. I always understood that that was a decision made by the Department of Health and my understanding was that part of the justification for that was that there was no treatment available for hepatitis C, so one would be seeking out individuals, establishing whether or not they had been infected with hepatitis C but then having nothing in the form of treatment to offer them.

I found that very strange because, of course, the same could have been said for HIV in 1985. When we started screening donations for HIV, there was no treatment available for HIV infection, so I felt that that didn't appear logical. I think having read Dr Robinson's statement, because she knew far more about the history of it, there seemed to have been a lot of concern, even, I think, from virologists and hepatologists, that seeking out individuals and telling them they had had hepatitis C, when there was

no treatment available, was putting an unnecessary burden on them and, unlike HIV, there was no clear evidence for easy spread to other people, in particular sexual partners.

But I still struggle with that because I am sure that in 1991, when we started screening blood donations for hepatitis C, I mean we knew there was no treatment available and we told our donors that, but we did say to them that there is one thing you could do which might be of help, because this could cause you problems in the future and we would advise you to limit your alcohol intake because that could be a factor in making liver disease more likely or worse.

So there was something that could have been offered. I know it is quite a burden to people to tell them you have got this infection, there is no treatment for it and, actually, you have to give up alcohol, but there was something that could have been done to try and minimise the effect, and I don't see that in the discussions, and I see there were a lot of discussions about the burden of seeking people out and telling them they were infected.
Q. Can I explore with you for your comment, really, what might be said to be three reasons, and I'm not suggesting this is exhaustive, as to why people -- it

might be right for people to be traced and told.

One is the very one you have already alighted on, so there are lifestyle adjustments that can be made that can have a real beneficial impact upon health if you are hepatitis C positive, is that right?
A. Yes, and I'm very sure we were telling our donors that in 1991.
Q. Then a second might be -- the very idea that someone ought to have the right to know key things about their body, and we will see that as a theme that comes back, as it were, to haunt you, I think, when we look at issues relating to vCJD.
A. Yes.
Q. The third might be that although, as at 1991, the treatments that became available for hepatitis C might not then have been readily available, but those who, for example, had already got liver damage, would benefit, would they not, potentially, from knowing that they had hepatitis C, having monitoring of the state of their liver, potentially earlier identification of something like hepatocellular cancer than might otherwise have been the case?
A. Yes. And I think we go back to what I said yesterday about HIV. When we identified HIV positive blood donors, we said, "There is no treatment available at

the moment but unless you are known about at a specialist centre, possibly" -- and in 1991 it might have been very different with the arrangements for liver disease -- "but when treatments do become available, then you will be in a position to be offered them."
SIR BRIAN LANGSTAFF: It goes wider than that too, doesn't it, because from what we understand there is at least a theoretical, something like 5%, chance of passing on the hepatitis C infection to somebody else by sex?
A. Yes. And I think, certainly in 1991, it was very uncertain what that risk was. I think it was recognised that the risk was probably much less than for HIV. And I think for HIV the risk of sexual transmission was known to be much higher and that was an added reason to seek people out, whereas for hepatitis C I think the argument was made: well, there probably isn't as big a risk, so we don't need to worry about that.
SIR BRIAN LANGSTAFF: Well, that is equivalent to knowing of a risk and choosing to ignore it.
A. And I would agree. And there was also -- it was certainly not known at that stage the risk of a mother passing it on to her baby. It just wasn't known. I mean, later it became known that that was very low

unless there was co-infection with HIV but at that time we didn't know.

SIR BRIAN LANGSTAFF: You start off with the thesis it is blood-borne.

A. Yes.

SIR BRIAN LANGSTAFF: And so there is a risk of contact between the blood of infected person and an open wound or sore or, for that matter, the child in childbirth in the usual way that there can be --

A. Yes.

SIR BRIAN LANGSTAFF: -- of blood contact. So for all those reasons, those are all additional reasons why someone might be told, are they not?

A. I agree. I think there was a lot of concern that because those risks were believed to be much less than HIV, it was a different situation.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: So one of the observations you have made in your witness statement, Dr Hewitt -- and perhaps we will put it on screen.

It is WITN3101006, page 108.

This is about the potential impact of losing those 3.5/4 years. You say this in paragraph 294:

"Thus, when HCV look-back was eventually mandated in early 1995, a further 3.5 years had

elapsed from the point when lookback could have started. As the majority of HCV infected donors were identified in the first 12 months of screening, we had lost vital time from first knowing of a donor whose previous donations would require investigation. The time delay was not so great a problem for blood centres, but produced serious difficulties in hospital laboratories, where records were generally kept for a finite number of years: often 10-12 years. By the time lookback started, 3 or 4 years of earlier hospital laboratory records would have been disposed of, preventing the tracing of recipients who had received potentially infectious blood components and who could have been traced if the lookback had started in 1991. Although approximately 50% of blood components are transfused to individuals who die of their underlying condition within 12 months of transfusion, and a further number of blood recipients will die in the following years, the opportunity was lost to identify and trace a small number of surviving recipients transfused in the early 1980s, because the hospital laboratory records had been destroyed in the years 1991 to 1995."

So that is a very real and direct consequence of the time lag between the beginning of screening and

the mandate to undertake the look-back?

A. Yes, it is.

Q. If we just look at the top of the page. You say, picking it up in the fourth line:

"... we ..."

And I think by that you mean the Blood Services?

A. Yes.

Q. "... had no mandate to carry out HCV lookback. Without a central directive from the Department of Health there was little prospect of persuading Consultant Haematologists in charge of hospital blood transfusion laboratories to divert their already hard-pressed resources into an activity which was not mandated, and not supported with additional resources."

Is this right, in principle the Regional Transfusion Centres, Blood Services, could have undertaken their own look-back, as it were, as an autonomous decision on their part, but the difficulty with that that you have identified here would have been securing the engagement of the hospitals in the absence of essential direction from the Department of Health or Chief Medical Officer?

A. Yes. I mean, it was the size of the work that would be required. It was very different from HIV -- which

was mandated -- because there were small numbers with the HIV look-back. With the hepatitis C look-back, it was much, much bigger.

I mean, the two hospitals which North London supplied which had -- which used the most blood components from North London, they each had over 100 blood components to trace in the look-back. And a busy laboratory can't just add that to their normal workload without making some additional resources available.

Q. And do you know what the funding position was in relation to the look-back, how it was funded?

A. We in the Blood Service did not have any additional resources. We just had to get on with it and do it. Within the hospitals there were real problems. Some of the hospitals did need extra resources and it was difficult for them to get those additional resources. I mean, they managed it, and sometimes it was helpful that we sent sort of a supporting letter saying, "Look" -- you know, re-emphasising, "This is a mandate, it needs to be done". And they would apply to their medical director and say, "Can we get somebody seconded to help us with this?"

Q. Now, if we just then pick up the decision-making in 1994 into 1995 in relation to the decision ultimately

to hold the look-back. There was a meeting, described as a *ad hoc* meeting, in, I think, Birmingham in August 1994. I just wanted to pick matters up there. NHBT0009383.

Now, this is headed "A Preliminary Position Paper, Meeting to Consider the Merits of an HCV 'Look-Back' Policy", 5 August 1994, West Midlands Blood Transfusion Service Centre:

"Objective:

"An *ad hoc* assembly of experts was convened on behalf of the Standing Advisory Committee on Transfusion-Transmitted Infection ... to discuss the desirability and feasibility of introducing a 'look back' policy to identify, test, counsel and, if necessary, refer surviving past recipients of blood components from donors later found to be anti-HCV seropositive after September 1991, when screening was introduced in the UK."

Then we can see a list of those attending and we can see you were present at that meeting, as indeed was Dr Barbara from North London and Dr Robinson, as national medical director of the NBA, and Dr Williamson, who was asked about this earlier in the week.

Can you recall how it came about that this

meeting was held?

A. Yes, I think I can. I was not a member of SACTTI at this point, Dr Williamson was, Dr Robinson was, professor Tedder was, and I'm fairly sure that Dr Ala was the chair of SACTTI at that point. And I think that there were sufficient of us within the blood services who were concerned that look-back had not taken place that we, in discussions, felt that we needed, we in the blood service needed to present a case to the Department of Health to say, look, this really needs to be done.

So Dr Ala convened a meeting with the people, I suppose, who were making most noise and representatives from SACTTI, and also, you will see, Dr Mutimer who was a hepatologist, his local hepatologist, and also invited was Dr Elias, who was another hepatologist, to get together a position paper to say this is why it needs to be done, we cannot tolerate a situation where it has not been done.

Q. We can see, and I won't go through the document in its entirety, there is reference at the bottom of the page to a paper by Ayob and others, I won't take you to that but just for the reference is PRSE0001046.

Then if we go over to page 3. Just before I ask you a question about it. This is described as

a preliminary position paper. So it is not a set of minutes, as such. Do you know who drafted this? It looks like actually, if anything, from the last page --

A. I suspect it's Dr Ala.

Q. -- I think it's probably Dr Ala, yes.

A. Yes, I think it was Dr Ala.

Q. In any event, if we see on page 3 "What is the efficacy of treatment in the long-term?" It says:

"There is growing evidence that this is not a trivial virus, and that a significant proportion of patients benefit from receiving therapy."

Leave aside the question of therapy, because that was obviously a developing picture in the course of the 1990s, describing it as "growing evidence that this is not a trivial virus" might be thought to be quite a curious way of putting it. It had surely been understood by 1991 that hepatitis C was a serious condition?

A. I think we have probably heard that, during the late 1980s and early 1990s, views started changing significantly from the "it's not a very serious thing" to "it is a serious thing". I can't account for the wording. I think it was possibly put there to emphasise to those who were still doubters that it was

the case that it was something serious and needed to be taken account of.

Q. If we go to page 4. I just want to pick up on what's said at paragraph 4, at the bottom of the page:

"It was generally acknowledged that we, in the Blood Transfusion Service, do have an ethical responsibility and 'duty of care' towards recipients of potentially infectious blood components such that they deserve to be identified, counselled, tested and offered treatment where that is appropriate. It was felt that, despite the current uncertainties regarding long-term efficacy of treatment, and its impact upon the natural history of hepatitis C, we have a moral obligation to inform and advise surviving potentially infected blood recipients."

Again, I don't know whether you can assist with this, but had that been a growing recognition of this moral or ethical responsibility? Was this something that had developed over the first half of the 1990s or is this just an articulation of something that the Blood Transfusion Service had long recognised?

A. I think it is the latter, yes.

Q. Just in relation to the meeting, do you have any independent recollection of the meeting now?

A. I can remember being in the room, I can remember the

corridor leading up to the room. I can't remember -- I don't know what you had in mind.
Q. Was it ultimately a consensus meeting. Was everyone very much of the same mind, as far as you can recall, or were there very much differences of view?
A. No, I think the people in the room had been selected -- well, invited, because they were the people who really felt very strongly this should be happening and we were trying to present the case to the Department of Health in as strong terms as possible.
Q. Then if we go to the next page. We can see in paragraph 5 there is a brief review of the policies of other countries, and then the heading is "The options for UKBTS are", and then two options:
"Confine itself to the role of an information 'clearing house', providing hospitals with the identity of implicated blood components, leaving it to them and General Practitioners, to follow-up potential recipients."
So that would have been the option, would it, of the National Blood Authority itself initiating its own look-back but then ultimately having no power to compel hospitals to do anything in particular in response?

A. No, sorry. I think it was that the Blood Service would merely provide the information to the hospitals and leave it to them to get on and do whatever was necessary together with clinicians and GPs looking after the patients, in contrast to the second paragraph.
Q. We see that first option was described as:
"It was felt that this policy would not be effective in practice ..."
Then (ii):
"Trace implicated recipients through hospitals and GPs, interview and counsel surviving recipients; obtain and test a sample of blood from them; refer infected patients for specialised counselling, investigation and possible treatment by Hepatology Centres."
That was the option that was favoured by the meeting?
A. Yes. It does note it was not clear how the added costs would be defrayed.
Q. Then if we go over the page, there was an estimate in relation to what the overall case load might be. Then the decision of the meeting, we can see in the last four lines:
"The Meeting felt that there is a serious case for considering the implications of an 'HCV Look-Back' Policy in its operational detail, and wished to refer the topic to the MSBT [so the Advisory Committee for the Microbiological Safety of Blood and Tissue] with a recommendation that such a policy is implemented."
As I understand it, that's what was done. I know you were not on the MSBT but a recommendation was made to the MSBT?

A. Yes.
Q. Was any consideration given, as far as you can recall, to the possibility at this time of conducting or inviting the Department of Health to conduct some form of broader public health campaign? Because what was being recommended here was limited in scope because, like the HTLV-III look-back, it would bite only on donors who had come back after September 1991?
A. It was a targeted look-back. I don't know whether there were any discussions, either within the blood service or within MSBT, about a wider public campaign.
Q. I won't go to the MSBT decision but, for the benefit of the transcript, it is PRSE0003635, 15 December 1994.
Can I pick matters up in January 1995, when you were involved in discussions and planning about in practice how the look-back might be undertaken?

A. Yes.
Q. So if we go to NHBT0002755, please.
This is a letter of 16 January 1995 from you to Dr Robinson, and you are commenting, I think, upon a proposal, you and Dr Barbara were commenting on a proposal or protocol that had been put together by others.
A. Yes.
Q. Then if we just pick it up towards the bottom of the page:
"Action by Haematologists at the hospital
"In our experience, haematologists are usually able to return information very quickly if there are computer records available in the blood transfusion laboratory. The further back the donation was transfused, the more likely there is to be a delay since computer records were not generally introduced until the late 1980s. The major reason for delay is likely to be difficulty in locating the medical records."
That's the patient's medical records, is that right?
A. That is correct, yes.
Q. "The haematologists have no control over the storage of medical records and this may well be a major

stumbling block. This may require input from sources other than the Transfusion Service."

Did your prediction prove to be correct, that this was a problem?

A. Yes. And if I can just explain. There was a step that the patient medical records should be inspected. First of all to establish if -- from the blood transfusion laboratory records it is only possible to identify the name and date of birth of the patient. There would then need to be a step to say: did this patient actually survive the episode? Are they still under hospital care? If not, who is the GP? There was something else ...

Anyway.

And that needed to be completed from the medical records. So the blood transfusion laboratory could do their piece but then the haematologist was expected to complete the rest from the patient medical records. And that was a major issue.

Q. Then if we go over the page, there is a heading:

"Action by Clinician in charge of the patient at the time of transfusion."

Your suggestion was that it would be unnecessarily complex to involve that clinician. Is it right to understand that's because they may have

not had any responsibility for dealings with the patient for many years by that point in time?

A. Absolutely. And if a patient was transfused during the course of, let's say, a hip replacement operation nine years ago, now writing to a consultant orthopaedic surgeon who was in charge at that time and saying, "We now know this, do you want to contact that patient and counsel that patient about possible hepatitis C infection?", well, you know, that was just completely ridiculous as far as we were concerned.

You know, as you say, we were commenting on a protocol which was basically drawn up by others.

Q. And then we have got a heading "Action by GP":

"The major issue here is who should perform the counselling. Many GPs will not feel themselves equipped to carry out this task as they have no in-depth knowledge of the issues relating to hepatitis C testing. The most obvious solution would be for the Transfusion Service to train appropriate staff (possibly nurses) to carry out this work but there will be resource implications. There is, however, no obvious alternative. Certainly, in our area, we would see the majority of GPs unable/unwilling to take on this task themselves."

What happened in relation to that issue? First

of all in terms of what was agreed as the national protocol and then in practice in your area.

A. So what was agreed was that the individual who currently had the care of the patient -- and that might have been a hospital clinician, in which case it was less of an issue, but usually a GP -- would be contacted and asked: is it appropriate for this person to be now notified? And if so, would you like to do this? And this was what was in the agreed protocol.

And as we predicted, many GPs did not feel they would be able to carry out that process and then referred it back to the transfusion centre, who did not have any additional staff to carry out that work.

Q. And so what happened in those cases?

A. So it was done without the additional resources. And as I said in my statement, other things that we might have been doing at the time were postponed until we had sufficient -- until this exercise had been carried out and we could go back to our day-to-day work that wasn't being done.

Q. So in relation to North London/South London, your team ended up directly dealing with recipients?

A. Yes, we dealt with many recipients.

Q. Because the GPs were reluctant to do so?

A. Yes. Yes. Not all. Some GPs were very happy to

carry out this work. And, as I said, many patients were under hospital care and it was done in that arena.

Q. And did you gain a sense of how widespread a problem that was? Were there other transfusion centres having to do likewise?

A. I'm quite sure there were, yes.

Q. Then can we go to the next page, please. Just the heading at the top of the page:

"Store donor samples prior to September 1991, where donor has not given blood since."

This is the cohort, the potentially huge cohort that was not covered by the HCV look-back because it was a targeted look-back in the way you have described.

You say here:

"the work involved in defining which samples relate to donors who have not been tested for anti-HCV is enormous. Furthermore, RTCs have different extents of archived samples, and the approach must be consistent across the country. There would be very enormous operational problems, on top of the ethical and legal considerations. Very often, it will be impossible to adequately confirm an ELISA reaction on a stored serum sample, which is likely to be of small

quantity.

"For these reasons, we would not advise any plans (at present) to test stored donor samples for donors who have not given blood since September 1991."

Can I just try to unpick that with you. The second paragraph gives a sense of: well, let's start with what we know we can do, and what we should have been doing since September 1991, which is trace -- look-back in relation to those donors who have returned to us since September 1991 and where we know the position in relation to their blood because it has been tested.

And, as it were, you are putting off the possibility, but not ruling it out, of a bigger exercise, is that right?

A. Yes.

Q. Now that bigger exercise wasn't then undertaken. But what were the ethical considerations, first of all, that might have made that difficult that you allude to here?

A. I'm not sure.

Q. The practical or operational difficulties, again, what were those? One can see it is a less straightforward exercise --

A. Yes.

Q. -- than the one that was undertaken. And it might not have been possible to do it perfectly or comprehensively. But some steps could have been taken, could they not?

A. I've been trying to go over in my head what would have been involved. First of all, I think it is important to explain that a sample is retained from every blood donation for a period of time. And that sample is microlitres of plasma which are removed from the sample tube at the time of testing and then transferred into what's called a microtiter plate, which is a plastic plate with a number of wells, 96 wells, and each donation sample would go into one well. And it would be microlitres of the sample. And then when the 96 wells were full, it was frozen in long-term storage.

And those were kept, as we have said, for a finite period of time. Usually because of space restrictions. You can imagine at North London we were taking 200,000 blood donations a year, so the numbers of trays that were needed to keep deep frozen mounted up.

There would have to have been an exercise to identify which donors, for example, attended in 1989 and hadn't attended after 1991 -- and that would

actually have been an enormous exercise, because you would have -- I just can't get my head round how we would have done it. To identify all the donors who had attended indeed that year, and then interrogate the records to see if they'd attended again after 1991, and then drawn up a list for each year of those donors, and then identified whether there were donation samples stored. And if there were, identify which of the many thousands of plates that sample was in, removing the plate from storage, thawing it, identifying which of the 96 wells on the plate belonged to that donation, taking the tiny sample of plasma out of the plate into a tube and then putting it through a HCV test.

And it was an enormous exercise. It couldn't have been done within the resources we had.

Q. So I can understand from the description that it is not a straightforward or easy exercise. It might not have been a perfect one. It might have been possible to do something, is this right, but with significant additional resources being provided?

A. It would have needed very significant resources.

Q. Would the logical way to have done it been to go back from September 1991 backwards, as it were, year-by-year?

A. Yes. And as we have said, by 1994 many transfusion centres would not have had any samples prior to 1991 because they were discarded on a rolling basis often after two to three years.

Q. I will come on in a little while to what other measures might have been put in place, not necessarily by the transfusion centres but by the Department of Health, for public health campaigns and so on.

Would another possibility have been, in principle at least, the blood transfusion centres contacting donors whose records you would have, who had not returned since September 1991, to invite them to come and -- for the purpose of a form of testing or screening, so that you could then know which previously implicated donations you had to follow through? Would that have been an option in principle?

A. In principle, yes. In practice, again, it is an enormous exercise, because we -- records were not kept in the way that we could easily identify which donors had donated and not donated since. If that makes sense. The records that the transfusion centre kept were -- enabled us to do lots of different things, but to say, "Let's identify all the donors who came in 1989 who didn't come after 1991", was not something you could do at the press of a button.

Q. So it would have involved some form of interrogation of records rather than a simple computer --
A. Yes. And many of the records were not on computer because we are talking about the 1980s and they were paper records.
Q. So, again, would it be right to understand that it might have been possible to do something but it would have required additional resourcing, significant additional --
A. I would say very significant additional resources.
Q. Can we then just look at a later letter from you to Dr Robinson in March of 1995.

NHBT0096456, please.

We can see that you say to Dr Robinson here:

"I visited our two largest users of blood/blood components and have discussed with the Consultant Haematologists and the chief MLSOs the procedure for the HCV look-back.

"Look-back will create significant demand on hard pressed resources at hospitals."

Then it would appear that those hospitals had asked you to pass on two major concerns. One was the problem in relation to records and the need for staff to be involved manually in working through records. Is that how we understand the paragraph beginning

"Firstly"?
A. Yes.
Q. Then, secondly, is the problem you have already identified in relation to obtaining patient case notes, and then you say:

"[You] sympathise fully with the situation in which the hospitals find themselves. The transfusion staff will do their best, but this exercise is dependent upon factors outside their (and our) control."

This is obviously you reporting back your local experience to Dr Robinson?
A. Yes.
Q. Do you know whether others who were performing the same exercise in other areas were getting the same feedback and experiencing the same difficulties?
A. I don't know for certain but there would have been -- I mean, the two hospitals named here were our biggest users and were probably some of the biggest users in England. But there would have been other hospitals which would have been significantly affected in the same way.
Q. The Chief Medical Officer's announcement of the look-back, I'll just go to it for the sake of completeness, NHBT0002737. We can see it is a letter,

3 April 1995, from the Chief Medical Officer, Dr Calman, sending this letter to doctors:

"... to inform [them] of the guidance and procedures for the look back exercise announced by Tom Sackville, Parliamentary Secretary for Health, on 11 January 1995 ..."

Then if we go to the third page, I'm not going to go through it, but this is the guidance that was issued nationally as to how it should be undertaken, is that right?
A. Yes.
Q. If we go to page 5, I just want to pick up what's said here and then ask you about it by reference to a letter from you. So under the heading "General Principles of the Look Back", it says:

"The presumption will be that each identified recipient would be counselled and tested. However, in exceptional situations such as severe psychiatric illness or terminal physical illness, the consultant or GM may feel is inappropriate to add to the patient's distress."

That was the Chief Medical Officer identifying as an exceptional situation a circumstance in which the recipient might not be told --
A. Yes.

Q. -- that they had been transfused with an implicated donation, is that right?
A. Yes.
Q. Then can I then ask you to look at NHBT0015661. This is a letter from you, September 1995, and it is addressed to solicitors who were advising you, or advising the National Blood Authority, and you have said in the second paragraph this:

"During the course of the HCV look-back, we (Consultants at the transfusion centres) on occasions receive a view from a general practitioner that, in the GP's opinion, a patient is unsuitable for notification and counselling on the possibility of HCV transmission from blood transfusion. In some cases, this is because of dementia, general medical condition, (terminal malignancy) or that the patient would be emotionally unable to cope with the information."

Next paragraph:

"In these cases I generally discuss the matter with the GP and note that we have agreed that the patient should not be notified and counselled. The question has now been asked, 'from a medico-legal point of view should the patient's next of kin be informed?'"

It was that specific issue upon which you were seeking legal advice, I think, about informing the next of kin?

A. Yes.

Q. What I want to ask you about is what's set out in the second paragraph, so not the next of kin issue.

I understand there might be cases in which the health of the patient is such that they, essentially, lack capacity to take decisions about their medical treatment and it would not be possible or practicable for them to be told or tested, an example is given there of dementia or terminal malignancy, so someone perhaps who is already in the last few weeks of their life.

It is really the third category given there that I just wanted to probe with you a little further Dr Hewitt:

"... or [because] the patient would be emotionally unable to cope with the information."

Now, that potentially sounds like it is involving a paternalistic judgement on the part of the GP, "I won't tell Mr or Mrs X because they will be upset", which doesn't seem right, in terms of the ethical or moral imperative to inform the patient?

A. I agree, and all I can add is that we are talking

about 25 years ago, and I do believe -- I know we have -- the issue of paternalism has been raised before. But things have changed significantly in the last 25 years and what was considered acceptable practice 25 years ago would not be considered acceptable practice in 2021.

Q. So this suggests that there may have been some cases and almost certainly, one would have thought, not limited to the London area --

A. Yes.

Q. -- in which individuals may not have been told, even though their GP knew, because the GP had made a judgment that they should not be told?

A. Indeed, and I know I have seen in some of the documents a case where one of my colleagues argued very strongly against the GP's opinion and that did come back to bite later.

Q. I'm not sure that this is a question you will be able to answer, Dr Hewitt. Do you have any sense of how many type cases there might have been, and you describe it here as being on occasions --

A. In being emotionally unable to --

Q. -- and that's obviously --

A. I think very few. I think, in my experience, the vast majority were individuals who were very elderly, at

the end of their life, or demented. I didn't personally have the experience of that and I did discuss most of these cases with GPs. So I can't recall it.

SIR BRIAN LANGSTAFF: May I just ask, in the case where you say it did later come back to bite, which party did it bite?

A. Well, the blood service later was contacted to enquire about whether a case could be investigated in somebody who had received a transfusion and was now known to be hepatitis C positive, and when the records were examined it was a case where my colleague had tried to convince the GP that the individual should be aware that the patient had been exposed through a blood transfusion. That hadn't happened, so the patient wasn't aware many years later, and it all went round in a big circle but I think -- I don't think it came back to bite the GP but it was a case where we had tried to say, "Look, this should happen", and it didn't.

SIR BRIAN LANGSTAFF: So it is still unclear to me really whether you were the bitten or the GP was?

A. Well, in the case -- we actually -- we, my colleague, had a great deal of additional work to untangle what had happened and why because we knew about this case,

if you see what I mean?

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Then if we can look at NHBT0096432_002.

This is an update from you as at October of 1995 about resourcing issues:

"I thought I should alert you to the fact that we are beginning to experience problems in accommodating the number of recipients who require counselling through the HCV look-back exercise.

"As you will be aware, the Department anticipated that the bulk of the counselling would be carried out by [GPs]. Unfortunately, especially at NLBTC, this is not the case."

And the next sentence describes the situation you have already told us about.

"We all recognise that we have a duty of care to the recipients and they should have benefit of expert counselling based on sound scientific knowledge. I am, nevertheless, concerned about the numbers of recipients requiring counselling at NLBTC and the additional workload this is creating. I have instituted a number of measures, which I hope will spread the load amongst the available counselling staff. The situation will be kept under review ..."

Then you say you may need to recruit additional

help and that will have a cost implication.

In practice, how did it pan out? Did you have to recruit additional staff?

A. We didn't recruit additional staff. I had a very good small team of people who worked very hard to make sure that we could carry out the work, and we did. I don't -- I'm pretty sure we didn't recruit any additional staff.

Q. And over what period of time, roughly, was this look-back exercise undertaken?

A. I can't -- I can't actually say. I would say the bulk was done within a few months. But as I think you will have seen from some documents, information did not come back from the hospitals all at once, and some hospitals were -- took more time than others to return information to us. So it was over a period of time. I would have said within months.

Q. Just one discrete issue. If you had a donor who had donated in 1991 and you were now -- you might have counselled them in 1991 as part of the implementation of the screening exercise, to what extent would they -- either then or when you were undertaking this look-back exercise -- would there have been an attempt to join the dots between different Regional Transfusion Centres? Would you have tried to find out

about, at the look-back stage, other transfusion centres at which a donor might have donated, to pass that information on? Or should that already have been --

A. That would have already been done at the initial stage in 1991.

Q. Can we then pick matters up at the beginning of 1996. PRSE0001490.

This is a letter dated 12 January 1996 from Dr Rejman, I think, at the Department of Health:

"To all members of MSBT and Hepatitis C Look-Back Working Party."

Is this a letter that you'd have received at the time?

A. No, because I wasn't a member of MSBT and I was not a member of the Hepatitis C Look-Back Working Party.

Q. If I can just invite you in any event to look at what's set out here. It says:

"At the recent MSBT meeting it was noted that the Look-Back had been slower in achieving its objectives than had been predicted. A number of options on the way forward were considered and I would be grateful if you could say whether you agree with our understanding of what these were before we submit these options to the Minister:

"1. Continue Look-Back using the present strategy, but with central exhortation to speed up the process.

"2. Abandon the Look-Back entirely and offer hepatitis C tests to anyone who has been transfused.

"3. Continue with the Look-Back but offer assistance to overcome the bottlenecks due to problems in tracing hospitals records and a shortage of suitably trained counsellors.

"4. The Committee considered these options, but unanimously concluded it was important to continue with the present strategy. This had been carefully designed to identify and offer counselling and treatment to recipients of blood transfusion units implicated in the Look-Back in a structured way that would maximise benefits to them."

Then 5 says:

"The Committee also agreed that delay in the identification process that might be extended for the rest of 1996 would not disadvantage patients as the evidence was of a 20-30 year time frame for the liver damage to occur."

Can I ask for your thoughts on the options that were there identified, recognising that you weren't, at the time, involved in this decision-making process

or a member of MSBT.

Option 2, "offer hepatitis C tests who anyone who [had] been transfused". Now that could have been done to some extent, could it not, not by the Regional Transfusion Centres, because you are not giving transfusions but as a national NHS Department of Health led initiative, would that be right?

A. That is correct. And I don't know whether considerations were made into how that would happen. In theory, blood transfusion laboratories could produce lists of everybody who had been transfused at their hospital in a certain year then there would have been a need to check records to see how many of these people were still alive and where they were and then they would be contacted. Or the alternative is to do what was done in other countries and say -- make public health announcements and say: anybody who has had a blood transfusion should come forward to have a hepatitis C test. And I have pointed out that not everybody knows they have had a blood transfusion. And conversely, many people think they have had a blood transfusion who haven't.

So that would also be imperfect. It would obviously identify some individuals who wouldn't have been identified in the look-back but not all either.

And I don't know whether those were considered.
Q. And so in any event, from your perspective, at the Regional Transfusion Centres, implementing this, what effectively happened, as I understand it, is that the look-back simply continued, with chasing letters having to be sent to hospitals, and we have some examples from you.
A. Yes, I wrote quite a lot of those.
I think the first option was one that the Blood Service was wanting to drive forward, a sort of -- a departmental message to hospital managers to say: look, you know, this needs to be dealt with. Rather than individual transfusion centres sending reminder after reminder letters to hospital consultant haematologists saying: we are still waiting for the information.
Q. And from your perspective, was there a central exhortation or a sufficient central exhortation?
A. No. No, I think that's what we were pressing for, but the Department held off that.
Q. And so you were left essentially to deal with it with your local hospitals?
A. Yes.
Q. I'm not going to go to the letters themselves but just for the transcript I will give a couple of references

to letters from you in the course of 1996 encouraging or chasing the hospitals you were dealing with.
NHBT0076980 and NHBT0022757, both of which you have exhibited to your look-back statement.
A. Could I add something there, just a very small point? I wrote a lot of reminder letters and I tried to make those helpful and encouraging and didn't always have responses to those but I did have one formal complaint from a hospital against me for writing the letters.
Q. Can we then just look at the observations you make about the look-back in your witness statement, so WITN3101006, picking it up at page 140. So, bottom part of paragraph 374 is the point you have already alluded to. You say in the last few lines:
"As matters progressed -- or in some cases didn't -- Dr Robinson suggested a further formal communication by the Department of Health to encourage particularly slow hospitals, but this suggestion was not thought appropriate. It was therefore left to the blood service to offer 'under-performing' hospital laboratories encouragement, advice, and reminders."
Then you deal, in the next paragraph, with the difficulties in terms of the delay and records not having been kept. If we go to the next page, paragraph 376, the last four lines, you say:

"Although it was not possible for them [that's the hospitals] to opt-out ... the speed and efficiency with which different hospital laboratories and individual clinicians engaged in the process was very variable."
Next paragraph:
"Not all hospitals or individual clinicians were enthusiastic. Some did not understand the process; many did not have any available resource for what could be a significant exercise and there were often gaps in the information they were able to provide."
Then paragraph 378 refers to the fact that, at least in terms of your area, the clinicians within the Blood Transfusion Centre had to take on the role of counselling/informing recipients.
A. Not all.
Q. In some cases.
A. In one of our hospitals they took on the whole task themselves.
Q. Then, if we go over the page. We can see paragraph 379 refers to a particular problem in relation to bottlenecks. So there were a whole load of responses that were essentially still awaited, is that right?
A. Yes.

Q. If we go to the bottom of the page, paragraph 380, it refers to a discussion in May 1996, in which it was minuted that:
"... the approach via the MSBT for a circular letter to be sent to all CEs of hospitals concerning the slow response of hospitals to requests for information to the HCV lookback exercise had not been approved. The MSBT wanted the specific 'poor performer' hospitals to be identified. Peter Flanagan asked how we should define 'a non-performing/poor performing' hospital and Dr Robinson responded that it was necessary to use personal knowledge of each hospital and ask if they had really tried their best, or whether their performance was due to a lack of resources. The recorded ACTION was for the three Zonal Directors to send a list of hospitals to Dr Robinson and she would then write to each hospital."
Again, it was left to the National Blood Authority and --
A. Yes.
Q. -- its directors --
A. Yes.
Q. -- essentially to try and encourage as much as possible hospitals to respond?
A. Yes.

Q. Do you think it would have made a practical difference if there had been some form of mandate or encouragement or warning, however it might have been expressed, from the Department of Health or the Chief Medical Officer?
A. I personally think that, in some cases, the issue is that the consultant haematologist was experiencing was not supported by the -- I don't know, by the medical director or the board, and so extra resources were just not made available. And I think if something had gone from the Department to chief executives it might have moved the issue up the agenda.
Q. Understood. Can I then just ask you about a document at NHBT0004632, May 1998. It is a letter from Dr Flanagan in his capacity as chair of SACTTI to National Medical Directors in relation to "HCV Infections probably acquired by Transfusion", and it says:

"My purpose in writing is to outline recommendations agreed at the meeting at SACTTI in March of this year in relation to the requirement to follow up reports of possible transfusion acquisition of hepatitis C infection identified within the PHLS or diagnostic laboratory network."

It records the issue having been brought to the

attention of SACTTI some time ago. Picking it up a few lines further down:

"In many instances the patients had not been identified through routine investigation of cases by local Blood Centres nor through the National HCV Lookback Programme. Dr Pat Hewitt in conjunction with staff at CPHL was asked to identify practical mechanisms whereby such cases might be investigated."

Then various details are set out. Can you first of all help us to understand what the issue was that was being addressed here and then how it was tackled?
A. So the first thing I need to say is I really can't remember very much about this but I can see from the first paragraph that this related to hepatitis C was a notifiable infection. So when a case of hepatitis C was identified, it was reported to the Public Health Laboratory Service. And very often the information would include the possible source of infection, because local public health teams would investigate a case.

And if the report that arrived at the central Public Health Laboratory Service indicated that transfusion was believed to be the source of the infection, there should be some mechanism to establish whether the blood service had been informed of that

case or was aware of that case and, if they were not, then it was possibly a case which had not been identified through look-back and, therefore, it would be of relevance for that to be known to the blood service.
Q. Then if we look at the third paragraph, it refers to a paper that had been tabled at a SACTTI meeting and it says:

"The paper assumes that all suspected transmission related to transfusion of anti-HCV tested blood, ie transfused after September 1991 are already being fully investigated. The proposed scheme will apply to transfusions taking place between 1988 and initiation of routine testing in September 1991. 1988 was selected on the basis of medico legal consideration arising through the current HCV litigation process."

Then it continues by saying that the coordination of the project would be through CDSC, and then it describes, at the bottom:

"[The] project aims to provide a pragmatic solution to a difficult problem."

So the three-year period that was selected, 1988 to 1991, appears from Dr Flanagan's letter to have been selected because of an awareness that that might

be thought to be a particularly problematic period for the National Blood Transfusion Service because of the product liability issues that were under consideration in the litigation?
A. Sorry, yes, because there will probably be people who are not aware what -- of the significance of that. The consumer product liability, Consumer Protection Act, has a ten-year limitation so that a claim can be brought under product liability. Sorry, I'm not -- I shouldn't be -- ten years, up to ten years after the date that the product was put into circulation.

And the hepatitis C litigation was under the Consumer Protection Act and it was evident that, the precedent having been set, a person who had been infected within that ten-year period could bring a claim under the product liability legislation and I think -- and, as I say, I have very little memory of this, this was an attempt to make sure that individuals who fell in that category were identified and knew that there was a possibility that they could bring a claim.
Q. It tells us it is going to be coordinated through CDSC. Do you recall now what role the Regional Transfusion Centres had or what, if any, role you had?
A. Well, from this letter it appears that the

Communicable Disease Surveillance Centre would be notifying the Transfusion Centre when they were aware of a case that fell within this thing but I have no recollections of that happening.

Q. Okay. Then could you look at PRSE0004329, please. This is an article, I think it is dated -- "Received for publication 1990", sorry, I'm just looking at the very bottom of the page, accepted April 1991.

It is an article in a journal called *Health Policy*, headed "Let's look at human immunodeficiency virus look-back before leaping into hepatitis C virus look-back". I don't want to go through the detail with you, it is an American article, as I understand it?

A. Yes, Mike Busch was in San Francisco.

Q. So what it details is a number of aspects of the US experience. There were just some general observations I wanted to invite your comment on. If we go to page 7., and we look, on the right-hand column, second paragraph, beginning:

"In light of the data showing the very limited efficacy of previous look-back efforts, we are warranted -- indeed, compelled -- to transcend these approaches. I am convinced that the appropriate response to this situation is an aggressive education

campaign for both physicians and the lay public about the risks and benefits, both in the past and the present, of transfusions. We need to disseminate information about the risks of all transfusion-transmitted diseases, both to previous and future transfusion recipients, in a well-orchestrated and long-term education campaign. This process should stress the importance of regular donations by low-risk individuals, as well as our commitment to and ongoing research on safer transfusion medicine policies and procedures. We should continue to accelerate our efforts to educate practising physicians about the indications for and risks of homologous (and autologous) transfusions. We should encourage all physicians to seek detailed transfusion histories from their patients and, on the basis of clinical findings and date(s) of transfusion(s), to test their patient for relevant viruses or diseases. The long-term gain from such a commitment of limited resources to transfusion medicine education will far outweigh the minimal short-term yield of any specific HCV look-back effort."

Is there anything there you disagree with?

A. There is nothing there I disagree with, no.

Q. To your knowledge, was the kind of well orchestrated

and long-term education campaign, with a number of different objectives here described, implemented in the United Kingdom?

A. I think we have heard about Better Blood Transfusion Initiative, the SHOT Initiative, the regional transfusion committees, hospital transfusion committees. Those were all part of that exercise.

Q. So those captured part of what he is talking about?

A. Yes.

Q. Better use of blood --

A. Yes.

Q. -- essentially.

But another part of what's being described here is ensuring that physicians proactively talk to their patients about whether they have had transfusions or might have had transfusions and, if so, arrange for them to be tested, which might identify a number of individuals who had been infected with, for example, hepatitis C who wouldn't be caught through the targeted look-back?

A. Yes.

Q. And that wasn't done, was it?

A. That wasn't. And I think I have probably mentioned it, and probably others have as well, GPs, for example, would not necessarily know that a patient had

been transfused because it was not information which was historically included in hospital discharge letters. It might be but it might not be. So unless one talks to the patients and asks them, that information may not be available.

Q. And another problem that the Inquiry has had reported, as well as a GP's lack of information -- about a lack of access to information about transfusion -- is a lack of information, lack of knowledge about infections such as hepatitis C. Do you, from your perspective in transfusion microbiology, have any information in relation to that?

A. I think we have seen that when the hepatitis C look-back programme started in 1995, many GPs felt they did not have sufficient knowledge about hepatitis C to adequately discuss the situation with individual patients. I think now awareness is very much greater, but GPs are asked to absorb an awful lot of information about an awful lot of things.

I used to say I'm very lucky because I have to know a lot about a very limited subject. GPs have to know an awful lot about numerous different subjects.

Q. And recognising that, is that one of the reasons perhaps why the suggestion -- sorry, could we just have that back -- of a long-term education campaign,

that's directed not just to doctors but also to the public, could be important, because that might help individuals understand that there might be causes for symptoms that they are experiencing that they hadn't otherwise appreciated?

A. Yes.

Q. And they might more likely to be proactive then to go to a doctor and say, "Could I be tested?" And so it is about educating the public as well as about educating doctors?

A. It is. Without then having a huge army of the worried well inundating GP surgeries with anxiety, which would be unwarranted. It is very a very difficult balance to make.

Q. Now, I'm not suggesting that the kind of public health campaign that's described here would be the responsibility of the Blood Service. It would have potentially a part to play. It would presumably have had to have been something much wider across the whole NHS, and therefore led by Department of Health or Departments of Health in the four nations of the United Kingdom. Chief Medical Officers perhaps.

Do you -- we have looked at decision-making in the first half of the 1990s and leading up to the implementation of the look-back programme in 1995. Do

you recall after that, once it was concluded and it would have been apparent -- indeed, would always have been known -- that there have been lots of people who haven't been identified, do you recall whether there were discussions within the Blood Transfusion Service about this kind of exercise being identified in this article? Or any recommendations made to the Department of Health?

A. I don't recall that.

MS RICHARDS: Sir, that brings me to the end of my look-back questions in relation to hepatitis C for Dr Hewitt, so it might be a good point at which to take our morning break.

SIR BRIAN LANGSTAFF: Yes, let's do that then, and come back at 11.45 am.

(11.16 am)

(A short break)

(11.45 am)

MS RICHARDS: Dr Hewitt, just a couple of points relating to transfusion practice, I wanted to pick up with you next. You have referred to the fact that patients -- there will be some patients who don't know they have been transfused and I wanted to look at an article which you co-authored in relation to that, WITN3101017, so this is a 1999 publication:

"Do Patients Know They Have Been Transfused?

"Patients continue to express concern about receiving a blood transfusion, despite transfusion in the UK being safer now than ever before. However, not all patients who have been transfused are aware of this fact. We determined the proportion of patients who were aware of their transfusion and showed how awareness has changed with time."

Then we pick it up halfway through the next paragraph. You describe the study:

"Between May 1995 and May 1996, 3,239 recruits to the study were asked, within 2 weeks of their transfusion, whether they were aware that they had received a blood transfusion. This question was asked in a standard way ... Patients who were not certain, but believe that they might have been transfused, were counted as being aware. We did not determine if any specific information or consent procedures relating to transfusion were being used at hospitals but simply identified what proportion of patients did not know that they had been transfused."

Next paragraph:

"In total, 537 of 3,239 (17%) patients were not aware that they had been transfused."

Then if we go over the page and just look at the

last few lines of the article:

"Despite increasing awareness during the year studied, and the exclusion of confused patients from the study, a significant proportion of patients were completely unaware that transfusion was involved in their surgical treatment.

"Where possible, information about the likely use of blood should be included in pre-operative information for patients. The issue of informed consent for transfusion might then be simplified."

As a matter of good medical practice, would it be right to understand that all patients who receive a transfusion should be informed of that, depending upon whether it is an emergency or not? It may be after the event, in some cases, rather than before but it shouldn't happen, should it, that the patients aren't told?

A. No, and I mean certainly now I would say it is included in the information that patients receive but back in 1995 that was not the case.

Q. Again, just as a matter of general practice, general medical practice, if you have a patient who is conscious and capacitous, then it should be part and parcel of what they are being asked to make a decision about, would you agree with that, as a matter of

general principle?
A. Yes.
Q. Now, obviously, transfusions may be required unexpectedly in emergency cases where a patient has been in a road traffic accident and you can't seek consent and you may need to use transfusion in order to save life but, in those circumstances, would it be good practice to ensure that the patient is informed at an appropriate stage, assuming they recover, that they have received a transfusion?
A. I agree that would be good practice.
Q. Then, can I ask you to look at one other document, DHSC0006783_027. So this is a patient information leaflet about receiving a blood transfusion. If we go to the last page, it looks from this as though it might have been produced by the Blood Service. Do you know whether that's the case or not?
A. Yes, it was produced by the Blood Service to be used in hospitals but it was felt that if the Blood Service produced it there was somebody -- there was a central organisation producing it and then providing it to all the hospitals for use on patients, rather than having hospitals design their own leaflets which, of course, often happens within the Health Service.
Q. I'm not sure what the date is of this. If we look

down the bottom of the page, it says:
"This patient information leaflet was approved by the Chief Medical Officer's National Blood Transfusion Committee. Planned review date 2005."
Does that help understand roughly when --
A. It was clearly before 2005 but I don't know whether it was 2004, 2003.
Q. But it's that kind of magnitude?
SIR BRIAN LANGSTAFF: It might look, from the very bottom, the "/04" on the left-hand side and on the right-hand side, that code seems to indicate 2004.
MS RICHARDS: Yes, it might well do.
SIR BRIAN LANGSTAFF: Probably the start of 2004, if it is "1/04" or "2/04".
MS RICHARDS: If we then go to the second page. We can see it explains in the first paragraph that blood transfusion should only be used when really necessary. It talks about asking the doctor to explain why you need a transfusion. If we go to the next page, there is a heading "Alternatives to ... transfusion":
"It is important that a blood transfusion is given only when there is no alternative."
The last sentence of that paragraph:
"You may want to ask your doctor if these [that's other methods] are possible in your case."

Then there is information about the safety of transfusions. If we go on to the next page, we can see there is reference to hepatitis B, C, HIV and, in the second paragraph, a reference to vCJD?
A. Yes.
Q. So would it be again right to understand that this was an attempt to try and ensure that patients were given some of the basic information both about whether a transfusion was required or not and about what the risks were that were involved in it?
A. Yes, and I should point out this was an initiative by the National Blood Transfusion Committee and the National Blood Service, I think, then took on the task of producing the leaflet.
Q. Do you recall whether this was a new initiative?
A. It was a new initiative.
Q. Is there any reason why it couldn't have been done years earlier?
A. Probably not.
Q. I'm going to turn then to a different topic, Dr Hewitt, and ask you about your involvement with the Skipton Fund.
I think you are aware that Mark Mildred gave evidence to the Inquiry --
A. Yes.

Q. -- and you read or watched his evidence?
A. Yes.
Q. I'm not going to go through a lot of the details about the mechanics or the documents, I just want to ask you some broader issues about your involvement. So you were appointed to the Skipton appeal panel in early 2007?
A. Yes.
Q. You had, by that time, provided to the Skipton Fund administrator a letter of advice about anti-D immunoglobulin?
A. Yes.
Q. I'm not going to put it up on screen, but for the transcript, it is SKIP0000031_071. Then I think at a later stage in 2010, you provided jointly with Dr Dash(?), is it --
A. Dr Dash, yes.
Q. -- a further advice about intramuscular gamma globulin including anti-D. Again, the reference for the transcript is SKIP0000031_070.
I'm not going to be asking you about the substantive content of that but just a question of process really. Did you end up sitting on appeals involving anti-D cases?
A. Some of the appeals that came to the appeal panel did

involve anti-D cases, yes.
Q. Was there any consideration for the fact that you might be thought to be marking your own homework, in some respect?
A. The first occasion when I provided information to the Skipton Fund was before I was appointed to the appeal panel, and that was as an expert within NHSBT.

So you asked me about appeals involving anti-D. I have always acted in my capacity in the appeals panel without any influence about my employment with NHSBT. They are two completely separate issues and although I have information and knowledge from my role within NHSBT, I did not let that influence my work on the appeal panel.
Q. Do you know whether applicants would have been given copies of those letters? We know the Skipton Fund relied quite heavily on the advice that you produced in their first stage decision-making, before any question of it getting to an appeal panel. Do you know whether your advices were routinely provided to applicants?
A. I believe not. The second communication, which was produced jointly with Dr Dash, who was the medical director of BPL, was -- arose out of my concern that women were being advised by -- generally by

hepatologists, women with hepatitis C were being advised that intramuscular anti-D was the likely source of their infection. And appeals were being made on the basis that they had been advised that by their hepatologists so it must be right. And I was concerned that these women were being given incorrect information and misled and given unrealistic expectations about the source of their hepatitis C infection.

And I think it arose because a professor of hepatology had written to the Fund to say something to the effect of: what is the situation with anti-D? And that was passed to me and I asked Dr Dash to help me to produce something which could be provided in response to that enquiry as to why intramuscular anti-D was not considered to be a risk for hepatitis C transmission.

So, if you like, that was offered to the Fund to say: look, this is how -- you have had this enquiry from the hepatologist, here's the information.

And I hoped that that would then be disseminated amongst hepatologists, to try to increase the awareness about where the risk was, which was with intravenous anti-D.

Subsequently I think that moves were made for

that information to be provided to individuals who had made an application to the Skipton of the EIBSS on the basis of intramuscular anti-D, but I can't confirm whether that has always been the case.
Q. Then just on a point of detail. On those occasions, and it might well be rare occasions, where there were records which gave details of the batches that had been used in an individual's treatment, would it be possible for you to tell from those records, in principle, if it was a BPL product or not, or was that something you couldn't --
A. I could, and it is important to say that the routine treatment provided in the UK is NHS-produced, either BPL or from the Scottish equivalent. There were a very small number of cases where intravenous anti-D was used for women, generally not -- sometimes after childbirth, where a large dose of anti-D was required which couldn't conveniently be given by numerous intramuscular injections. And that was provided using an intravenous product that was imported from the Irish Blood Transfusion Service, where intravenous anti-D was the routine method of administering anti-D.

And because it did not have product licence in the UK, it was imported for use on a named patient basis. So there was a very small stock kept within

England, and that was kept at the Colindale Blood Centre. And when it was required for these very small number of cases, which might be a woman after childbirth where there had been a very large exposure to Rh positive red cells or a woman who had been inadvertently transfused inappropriately with Rh positive blood when she was Rh negative, then that product would be requested on a named patient basis, and it would be issued from the Colindale centre with the name and the hospital -- the name of the patient and the hospital recorded in the central record.

When it became clear that the Irish product had transmitted hepatitis C, the Irish Service carried out a look-back, which included notifying all the organisations which had received the batches of intravenous anti-D. So a look-back exercise was carried out within the English Service for those named patients who had received the intravenous product.
Q. Then just more broadly in relation to the way in which decisions were taken by the Skipton appeal panel, there was no oral hearing -- and that wasn't by choice of the panel, that was the way in which it was set up.
A. Yes.
Q. Do you recall whether that was a matter of concern to you and your colleagues on the panel?

A. I'm not certain it was in the early days of the panel, but when the Skipton Fund ceased to exist, then there were different schemes in each of the four UK countries, and one of the appeal panel members is a member of the EIBSS appeal panel but also the equivalent in Scotland, where they do hold oral hearings, and that member of the appeal panel has said that that has been very helpful.

Q. And just to explore why it might be helpful, obviously, it might feel like a better process from the point of view of the appellant because they get a chance to present their case. It might feel a fairer process for them. But will also give a chance -- where there aren't records which establish the position clearly, it will give a chance, won't it, for the panel potentially to assess the plausibility, the credibility of the account that they are being given if it relies upon the perspective and recollections of the individual. Would you accept that?

A. Precisely. The appeal panel will often say: we need some more information, we cannot make a decision on the information that's been provided. And we will ask for additional information such as a description from the claimant about the circumstances.

And the appeal panel is very aware that some of these individuals are quite elderly. They may not -- they probably wouldn't be able to produce a written account providing the information that the appeal panel really needs to see. And being able to interview somebody or talk to somebody face to face, it might be easier to extract the information which is really needed to be -- to provide what the panel really wants to hear.

Q. So it would be fair to say -- because you now sit on the appeal panel for the EIBSS --

A. I'm still a member of the appeal panel, yes.

Q. You think it would be a good idea if there was an oral hearing process possible?

A. I think it would help in some cases, yes.

Q. Can I then just ask you to think about IDVU cases, intravenous drug use cases, where there was the possibility of some evidence of IVDU in the past. In practice, did any evidence of intravenous drug use effectively condemn an appeal to failure because it would be regarded as the more likely cause of hepatitis C?

A. It was regarded as the more likely source of hepatitis C, on the basis of expert reports from others, but there have been cases where information

has been provided on the application form, sometimes by a clinician or by somebody reading what has been input in the medical record, that there is a record somewhere of intravenous drug use, which is denied by the claimant. And sometimes there have been misunderstandings, clearly. And in those cases the appeal panel does consider what is the strength of the information that we have been provided for -- and the counter argument that the claimant is making, in order to make a decision on the balance of probabilities.

Q. That leads me on to the question of balance of probabilities. I just wanted to get a sense of how that works in practice in cases, of which there must have been many, when there are no records to show the transfusion, either because the records have been destroyed or lost or because there are some records but the transfusion is not recorded in the patient notes. Which we know, from everything you have told us in the context of the look-back, was not an uncommon occurrence?

A. Yes.

Q. So in those cases, how did the panel go about deciding whether it was satisfied, on the balance of probabilities, that the route of the hepatitis C

infection was a transfusion?

A. So, the panel would consider all the information provided, and it would be very important to understand the episode during which transfusion was suggested had happened. So a full description if it was an operation, an accident, what sort of injuries there were. And the panel -- this is where it is a positive advantage to have people who are older on the panel, because all the members of the panel are people who were practising in 1970s, 1980s, and were aware of what practice was then. Because we can't judge against what practice is now. We are talking about things that happened in the 1970s and 1980s.

So, using our knowledge of what the operation was or what the nature of the injuries were, how likely is it that transfusion would have been used, and in some cases it is absolutely clear that transfusion would more likely than not have been used. And, in that case, the panel would say: yes, on the balance of probabilities, transfusion would have occurred. Whether there was documentary evidence or not.

In other cases, it is very clear that the nature of the injuries or the nature of the intervention would be highly unlikely to have required a blood

transfusion. And then there will inevitably be cases that fall in the middle of that. And I have to say that I think that the balance -- the panel usually leans on -- sorry, the panel makes decisions by consensus and there's always -- I have to say, the medical experts nearly always agree. But in cases where the balance of probabilities is around 50% or there's a bit of dissension between the members, we would generally err on the side of the claimant.

Q. And if you have -- and this is, I think, a scenario that was explored by Mr Mildred. If you have hypothetically a case in which you might be aware that the appellant underwent a procedure for which there might be a -- 1 in 5 people undergoing that procedure might have a transfusion, 4 out of 5 would not, no records, nothing else to assist you in determining whether there was, as a matter of fact, a transfusion in the individual case, my understanding of the evidence that Mr Mildred gave was that in such a case that wouldn't then be enough to satisfy the balance of probabilities, is that right?

A. I think that is correct, yes.

Q. Even though it would be -- if one in five people get a transfusion for that procedure, it is perfectly plausible that the individual could have had

a transfusion?

A. Yes.

Q. Therefore, in those kind of cases, the absence of records effectively is going to lead to the individual not receiving a payment from the Skipton Fund?

A. Yes.

Q. What role in the Skipton appeal panel's decision-making does the absence of other risk factors, the absence of other plausible explanations for hepatitis C transmission play? If you have someone in whom there is no evidence of intravenous drug use, they have no tattoos, there is no obvious other explanation, how does that weigh in the balance?

A. Generally not. And I have talked to a lot of blood donors who are infected with hepatitis C, and in a large proportion there is no identified risk for the hepatitis C infection. It must have come from somewhere but we can't identify where it came from. In exactly the same way, individuals who have no identified risk other than a blood transfusion may have acquired it in another way that we don't know about. So the fact that they have no other identified risk doesn't mean there isn't any other risk. But, of course, if there is no other identified risk and there is a situation where transfusion is plausible, then

that would be taken into consideration in the decision.

SIR BRIAN LANGSTAFF: I'm not sure I follow that exchange. I mean, either the absence of other cause is taken into account and does make a difference or it doesn't. And the example which counsel was putting to you, if I can put it this way, suppose that there is a 1 in 3 chance that this particular operation -- let's say a 1 in 4 chance that this particular operation would require a transfusion. So it is quite plausible that it might have done. On the other hand, if that's all the information you have, it is three times more likely that there wasn't a transfusion. But then the claimant says, "I believe I had a transfusion", and sets out reasons for the belief. And adds, "And there's no other reason that I can think of why I might have had hepatitis C. I haven't had any injections, any needles, I haven't had my ears pierced, I haven't had any intravenous drugs", etc.

If you had, let us suppose, a set of statistics which were able to show -- I don't know if there are such statistics -- that -- of the reasons that people give for having had hepatitis C -- this goes back to your donor example -- but suppose that you had more than -- say, 1 in 5 couldn't give you a proper reason

why they had hepatitis C, they don't know where it came from. Most of them probably hadn't thought where it could have come from, any source. But there has to be a source somewhere?

A. Yes, I think I said that.

SIR BRIAN LANGSTAFF: So, in that case, are you going to say: well, this person -- it is not likely -- more likely than not that this person, who has no other source but a plausible transfusion, who could simply have got hepatitis C from somewhere unknown, but more likely got it from a source, and there is no source but the transfusion, do you say in the balance of probabilities that would be a case for -- what? What would be the result?

A. I thought the question I was being asked was where there wasn't any evidence that there had been a transfusion.

SIR BRIAN LANGSTAFF: I think it is, but the evidence is here that there is an operation or some procedure which normally could involve a transfusion but it is more likely not to.

A. Yes.

SIR BRIAN LANGSTAFF: That's the hypothesis.

A. Yes. And in that case the panel would try to obtain more information about why -- what was the situation

which makes the individual understand they may have received a blood transfusion.

So if an operation -- it doesn't often arise that an operation has a 1 in 4 chance of having a blood transfusion, but if it did why might we think that this particular operation required the blood transfusion? Were there particular complications? Was the patient so seriously ill that they had to be admitted to the intensive care unit afterwards, which might indicate that the operation had been unnecessarily complicated and therefore more likely to require a transfusion? It is very hard to give examples of that.

I mean I was asked was the -- I have forgotten what I was asked now -- oh, that -- the information that there was no identified risk. But that is taken into account but that information is only as good as the person who has taken the history.

SIR BRIAN LANGSTAFF: Well, actually it is only as good as the person who is giving the history.

A. Both.

SIR BRIAN LANGSTAFF: And you are not hearing from the person who is giving the history under the English system.

A. Exactly.

MS RICHARDS: What role, if any, in the appeal panels --

SIR BRIAN LANGSTAFF: Just one moment. You did say earlier, when we were talking about the question of look-backs, I think, that transfusions weren't historically included in discharge letter -- or they may be, they might not be, is what you said.

A. Yes.

SIR BRIAN LANGSTAFF: So unless you asked the patient, that information may not be available.

A. And it may still not be available, because the patient might not know either.

SIR BRIAN LANGSTAFF: So there you are saying, well, the patient's ability to give information is vital in deciding, effectively on the balance of probabilities, that there was a transfusion?

A. Because we asked the patient for more information about the particular episode, which will help understand what the situation was, why a blood transfusion may have been required.

SIR BRIAN LANGSTAFF: So it comes down to having some effective method of talking to the patient to discover why precisely they --

A. Yes. And some patients -- a large number of patients have been able to give a very good written description of the situation, which overwhelmingly would lead to

the appeal panel saying: yes, this sounds very likely that a blood transfusion was required; even though there's no information in the records, the GP hasn't got any records, we believe that a transfusion would have taken place given the description that the claimant has provided us with.

SIR BRIAN LANGSTAFF: Thank you very much.

A. And what I think I was trying to say was that some claimants may not have the ability to convey that information in writing, which might better come out on a face-to-face interview.

MS RICHARDS: Because they might not know what details could be important?

A. Exactly.

Q. Whereas if you have them in front of you, as your colleague in the Scottish scheme had, you can ask the right questions and tease out the right details.

A. Exactly.

Q. What consideration, if any, is given by the Skipton appeal panel, is given by the EIBSS, to the fact that -- as I think has become very clear in the evidence from you and your colleagues -- past transfusion practices weren't necessarily the best and transfusions have taken place that might be unnecessary, or more by way of blood/blood components

may have been used than could have been? How does that factor influence the decision-making process? Because you might have a case where you think, "Well, shouldn't need a transfusion", but shouldn't need doesn't mean it wasn't given?

A. Mm. And, you know, practice has changed a lot. So, again, that's important -- that emphasises the importance of a witness statement, either from the individual concerned or from somebody else who can give information of the situation and what they observed at the time.

Q. Mr Mildred had a recollection of you saying to the appeal panel that one would never ever give a transfusion to someone who had lost less than a unit of blood.

Now, you might have said you should never give a transfusion or it might be right to say you should never give a transfusion in those circumstances, but, as far as you can recall, is it your view that you have communicated that you would never give a transfusion to someone who had lost less than a unit of blood?

A. I don't recall saying that, and there is always the situation where it appears that there is a bleeding episode and a blood transfusion is started and then

the bleeding is successfully brought under control when less than a unit of blood has been given. That's always possible.

I mean, as you have said, it is good practice not to give a transfusion, but there might be situations where somebody is anticipating.

Q. Or indeed there might be occasions, particularly if one goes further back into the past, where there has been -- I think we heard some evidence to suggest, possibly particularly in the context of women who had given birth, this idea that you might just top them up a bit --

A. Yes.

Q. -- which would now potentially be regarded with horror as a practice?

A. Yes.

Q. Those kind of cases might be cases where there wasn't any real need for a transfusion but someone might, nonetheless, have been given a small amount of blood.

A. Yes.

Q. Just in relation to the EIBSS scheme. Is there any difference of approach between how the appeal panel considered matters under the Skipton scheme, as compared to the EIBSS scheme?

A. No.

Q. So it operates effectively in the same way?

A. Yes. The rules for the scheme, as far as I'm aware, haven't changed.

Q. Then can I just ask you about the role you have had in relation to advice to the Department of Health on eligibility for the Eileen Trust scheme.

We have seen in the documents some examples of you being asked by the Department of Health about whether it can be established that someone had received a transfusion that might have infected them with HIV. Did you have a formal role in that regard?

A. The HIV scheme has been very -- was very, very different. There was no formal scheme administrator. The hepatitis C -- the Skipton Fund was dealing with much larger numbers of claims, but the HIV scheme dealt with a very small number of claims and I -- with the hepatitis C scheme, the Skipton Fund, the rules set out that a documented history of blood transfusion, evidence of hepatitis C infection and no documented other risk would lead to an automatic payment. There was no requirement for the Blood Transfusion Service to confirm that this was known to be a case of transfusion-transmitted infection.

The HIV scheme worked very differently in that usually it was required for the -- because HIV

transmission was much less common than the hepatitis C transmission, it was required for the Blood Service to say: yes, we know about this case, we have investigated it and it is a case of transfusion-transmitted infection.

And those enquiries, "Do you know about this case?", tended to come to me from somewhere within the Department of Health and it would be different people at different times that there was no identified -- this is the scheme, this is the scheme administrator. It all seemed to me to be quite haphazard. So over the years I have communicated with different individuals within the Department of Health about individual claimants under the HIV scheme.

Q. So would it be right to understand it's *ad hoc* requests that come to you to look at what information or records the Blood Service might hold to be able to say "Well, this is what we have got documented in relation to possible implicated donation" or "This is what we don't have -- we don't have any records to draw a line between the two"; it is that kind of exercise, is it?

A. Yes, so if we had known about a case, we had investigated a case and agreed this was a case of HIV transmission through blood transfusion, then, as part

of that process, we should -- we, the Blood Service, would have informed whichever clinician who had made the enquiry this case would fall within the Eileen Trust. And I certainly did that with the very few cases that we dealt with, after the introduction of the screening of blood and I did it before, when the Fund -- the Trust was first established.

More often than not, the enquiries laterally came from the Department of Health relating to cases that were not known to the Blood Service and would then require an investigation because HIV transmission is very uncommon and, as I understood it, payments would not be made unless the transfusion service confirmed that this was likely to be the source.

Q. I want to come then to the final topic that I wanted to ask you about, which is vCJD. I just want to, if I may, first of all start by trying to get a simple as I can make it guide, with your assistance, to the background before then I ask about your direct involvement in the issue.

So vCJD is a prion disease?

A. Yes.

Q. It is an invariably fatal disease with potentially a long incubation period?

A. Yes.

Q. The agent responsible for the outbreak of BSE in cows is essentially the same agent responsible for the outbreak of vCJD in humans, is that right, in colloquial terms?
A. Yes.
Q. The likely cause of what I think I have seen described in some documents as the primary epidemic of vCJD is dietary exposure to food containing brain or spinal cord tissues from cattle infected with BSE?
A. That is correct.
Q. But a secondary cause, as we will come to look at, can then be onward transmission through blood or blood products and vCJD is a variant of what's sometimes called classic CJD?
A. Yes, I think you are going to hear from Professor Ironside who will give you excellent information, but what used to be called classic CJD is more correctly, I think, called sporadic CJD but, yes, when it was first described it was called new variant CJD and then stopped being new and was called variant CJD.
Q. There is also, I think, a kind of CJD which is familial, it can be inherited?
A. Exactly.
Q. Then there have been other forms of CJD or other forms

of transmission through -- leaving aside blood/blood components -- through medical treatments, so there is a growth hormone treatment that has been a cause of transmission and surgical instruments?
A. And that's sporadic CJD?
Q. That is sporadic CJD.
A. Yes.
Q. So the form of CJD that can be transmitted through blood/blood products is vCJD?
A. Until the description of vCJD -- and we only had sporadic and familial CJD -- there had been no evidence -- and there had been some studies to look at whether there was a risk through transfusion of blood, and there had been no evidence of that with sporadic and familial CJD.
Q. But it is now understood, and we will look at an overview of how that emerged, that vCJD is capable of being transmitted through that route?
A. That is correct.
Q. Now, there have been a number of different organisations, bodies, groups involved in looking at vCJD, looking more broadly at CJD, looking at the possible link in relation to blood safety. So Departments of Health and Chief Medical Officers, the Advisory Committee on the Microbiological Safety of

Blood and Tissues, SACTTI, they have all had some role to play at times. But there are some specific CJD bodies?
A. Yes.
Q. There is the National CJD Research and Surveillance Unit, that's, I think, its current title, based in Edinburgh?
A. Yes.
Q. Then there is a committee called SEAC?
A. Yes.
Q. So that is the Spongiform Encephalopathy Advisory Committee, have I got that right?
A. Yes.
Q. Then there is the CJD Incidents Panel --
A. Yes.
Q. -- and you were a member of the CJD Incidents Panel for a number of years?
A. Yes, I was.
Q. Now, I think your witness statement tells us that the presence of the variant with a different clinical and pathological picture from sporadic CJD was recognised in 1995?
A. Yes.
Q. You have referred to a description of the first cases of vCJD being written up and published in The Lancet

in the summer of 1996?
A. Yes. So the Department of Health had set up the National CJD Research and Surveillance Unit at some point, I think, following BSE.
Q. I think it was 1990 but, as you say, we will be able to hear directly --
A. Yes, and their remit was to look at all cases of CJD and, in doing so, they identified this new variant during 1995 and a description of those first 12 cases was published in 1996.
Q. You have said in your statement you first became aware of concerns about the possible risk of transmission of vCJD in early 1996?
A. Yes.
Q. You refer to and we have it described more fully from Dr Robinson, there was a meeting on 9 April 1996 of representatives of SACTTI and the CJD surveillance unit, which you didn't attend. I think you were away?
A. I was on holiday, yes.
Q. I'm not going to go to the document, but the reference for the transcript is DHSC0020783_088, and the notes described the meetings as having been organised by Dr Robinson and Professor Cash following reports of this new variant.
That was on 9 April. There was then a SACTTI

meeting on 16 April 1996 at which you were present. So we will just pick that up, it is NHBT0000088_013, please, Paul.

So we have got the date, 16 April 1996, we can see you were in attendance and the discussion about vCJD is on page 6:

"Implications of a Possible [CJD] Variant for the UK Transfusion Services."

Then it refers to the *ad hoc* meeting on 9 April:

"This was in recognition of a change in perception of CJD as potentially infectious until otherwise proven. It was recognised that one difficulty is that there is limited information available from animal experiments in relation to the ability of prion transmission by transfusion. In particular the absence of information of transmission of BSE by blood between cattle was a cause for concern."

Then there is a reference to concrete information being difficult to come by:

"It was agreed that the first priority at this stage was to improve the level of knowledge so that appropriate decisions could then be made regarding donor selection, handling of blood components, etc. The following actions were agreed ..."

Then we have a series of points of agreement of which the only one I'm really going to ask you about is the first:

"Dr Robinson will ask MSBT for approval to do look-back on recipients of blood donations from donors who had subsequently developed CJD."

That was a task which you then became involved with?

A. Yes.

Q. If we go to NHBT0008485, we will see that on 22 April 1996, Dr Robinson wrote to you in relation to this issue and, if we pick it up in the second paragraph, it says:

"... I am formally asking you if, together with Jack Gillon, you could start drafting a proposal for a CJD Lookback study prepared in a format that could be submitted to an ethical committee and also to obtain legal advice from Stephen Janisch with regard to not informing recipients, but only exchanging data with the CJD Surveillance Unit."

I will come onto the ethical matters in a few minutes.

There's then reference to looking as those the MSBT, Jeremy Metters, so that's the Deputy Chief Medical Officer:

"... and the minister are now keen to go down this route. Jeremy has been Peter Flanagan's notes of the Edinburgh meeting and is anxious for us to follow through with a proposal for a 'limited' CJD Lookback ... it was Jeremy's suggestion that any proposal (where the recipients will not be informed) needed to be submitted for Ethical Approval and legal advice."

That is the issue we will come back on. That is the source of your understanding that it had essentially been a requirement of the Department of Health that ethical approval committee be sought?

A. Absolutely, yes.

Q. This then translated into the Transfusion Medicine Epidemiology Review, which I'm going to call TMER because it's less of a mouthful.

A. Everybody calls it TMER, yes.

Q. Am I right in understanding that is still ongoing in some form?

A. Yes.

Q. Is it now under the auspices of the Surveillance unit in Edinburgh, or don't you know?

A. So when it was set up it covered all types of CJD. And, subsequently, when evidence arose that variant CJD had been transmitted through blood, that was

removed from doing the research study because it became a public health issue, but the TMER still exists for sporadic and familial CJD.

Q. Then in relation to TMER, you have said in your statement, its main aim is to try and establish whether there was any link between vCJD and blood transfusion.

A. That is correct.

Q. It wasn't designed to investigate links with fractionated plasma products, why was that?

A. Because that's not what we were asked to investigate.

Q. It also included within it looking at sporadic CJD?

A. And familial.

Q. Then you have told us in your statement -- and again I'm going to try and summarise them with your assistance, try and get an understanding of what was being done in relatively lay person's terms -- you have told us in your statement that the first and most direct aim of the TMER was to establish whether individuals diagnosed with CJD had acted as blood donors and, if so, to trace the donations and identify the fate of the blood components through to their final destination, is that accurate?

A. Yes.

Q. So cases of vCJD, all cases of vCJD, would be reported

to the TMER by the Surveillance Unit?
A. To the Blood Services by the Surveillance Unit, yes.
Q. In relation to sporadic CJD, it was a more limited category of cases that were reported, I think, only where relatives or next of kin knew that they had been a blood donor?
A. Yes, because there are a larger number of cases of sporadic CJD.
Q. Then, as I understand it, if blood components from the donor were recorded as transfused, that would be notified to the blood centre?
A. Through a look-back process with the hospital, yes.
Q. Then the identity of the recipient, where that could be established, would be forwarded to the surveillance unit for what you have described, or what the documents describe, as "passive surveillance purposes". We will obviously ask the Surveillance Unit in due course. But what, again, in basic terms does that mean?
A. That means that the names were checked against the surveillance unit's register of cases of CJD and continued to be checked at intervals in case a case developed in the future. And, secondly, that if and when the individual who had been identified died, but a copy of the death certificate was passed to the

Surveillance Unit, so they could examine the information on the death certificate, and use that. But there was no active surveillance, no way of saying -- no way of following what happened to the patient this year, next year, the following year.
Q. So that was the first part of the study, the more conventional look-back arm?
A. Yes.
Q. I will come onto the question of notification or non-notification of recipients in a minute. Then your statement tells us that the second part of the TMER study was a reverse TMER, so it is known as the R-TMER part of it.

Can you just again explain in fairly simple terms, if you can, how that worked?
A. So, this was the opposite and this is exactly the same thing when the Blood Service is informed, here is a patient who has developed something which could have been transmitted by blood transfusion, could you investigate the donors? So it was work we did with other infections.

So the starting point was a patient with CJD who had a history of blood transfusion, and then it would be a case for the Blood Service to identify -- to ask the hospital concerned to identify what blood or blood

components had been transfused and then to identify the donors who had provided those. So this was dependent on information about the person who developed variant CJD and having received a blood transfusion, information about which hospital the transfusion had taken place, because there is no database of people who have received a blood transfusion.

The Blood Service would need to ask the hospital concerned: is there a record of transfusion for this person, can you give us the detail so we can now trace the donors?
Q. You have described, I think, in your statement that it effectively acted as a double check --
A. Yes.
Q. -- and, as a matter of fact, no cases were identified through the R-TMER process that had not already been identified in the look-back arm?
A. Exactly, which gave us confidence that it was working.
Q. Now, there were a number of ethical issues or dimensions to this, hence the requirement for ethical approval from a local ethical research committee.

One issue of concern was the question of confidentiality and you have described in your statement the use of control cases. Again, could you

just help us understand how that worked?
A. Yes. I had not appreciated, actually, before I had reviewed all the papers, that there had been a concern -- I knew there was a concern at the Department of Health about it becoming widely known that vCJD might be associated with blood transfusion and I remember that we were asked not to include anything about CJD in the title of the study, which is why it has such a, you know, bland title.

And I understand from what I have seen since that there were real concerns that if the Blood Service informed a hospital about a blood component that they wanted to trace, and the knowledge that this was in relation to variant CJD, that that might cause a lot of alarm and might lead to the individual who had received that blood component being given that information when the ethical advice was not to do that.

And there were a variety of strategies, I think, being considered and, in conjunction with the Surveillance Unit, we agreed that the best way would be to include in the study not just the cases we knew of variant CJD but control cases who were patients with other diagnosis who had been blood donors, whose blood had been issued to hospitals, and when we issued

a request to a hospital to trace a blood component, it would be made clear that this might be from a case or from a control, and because that information was not known to the Blood Service, nor was it known to the hospital, and so it emphasised the importance of not giving any information that might suggest it was a variant CJD case.

Q. Now, two ethical components of the TMER was, first of all, that the surveillance unit would be passing on personal details of those diagnosed with CJD to the Blood Services, in the absence of patient consent because --

A. Yes.

Q. -- it wouldn't be possible to obtain patient consent. The patient would either be deceased or be beyond the stage at which they could give a capacitous consent, because of the stage at which vCJD would be diagnosed. So that was one concern.

The second was the way in which this was set up didn't lead to any contact being made with the recipient to tell them that they had been in receipt of blood or blood components from somebody who had then been subsequently diagnosed with vCJD?

A. Yes, that is correct.

Q. That was one of the main ethical concerns, as

I understand it?

A. Yes.

Q. So ethical approval was sought and obtained from the Lothian Ethical Research Committee and that's because that was the local research committee for the Surveillance Unit based in Edinburgh and they had some previous dealings with the Surveillance Unit, so they had a degree of familiarity with CJD issues, is that right?

A. Yes, but could I just add that we had asked for ethical advice before we made the submission to the ethics committee.

Q. My understanding is that it was in 1996 when you sought ethical advice from Professor Ian Kennedy?

A. Yes.

Q. We don't have, I think, a copy of that advice but it is referred to in some later correspondence in 1999 when the issue was looked at again.

A. Yes.

Q. If we just look at the documentation in relation to the proposal submitted to the Lothian Ethical Research Committee and the grant of ethical approval, it is NHBT0008903, please.

So this is the proposal for the look-back study. If we go over the page, you will see there is

a description and on the next page of the different types of CJD.

Then if we go to page 4, there is the heading "Transmission by blood transfusion", and setting out the position as at that date, which was that CJD had not been shown to be transmitted by transfusion of blood or plasma products.

Then if we go over to page 6, we have a reference under the heading "The UK position" to what had been discussed and agreed in the April 1996 meeting.

Then page 7 sets out the proposal:

"... no evidence that CJD, in either its classical or new variant forms, is transmitted by blood transfusion. Nevertheless, information in relation to the potential transmissibility of CJD by blood transfusion is very limited. The absence of information severely restricts ability of the transfusion services to provide definitive reassurance of the new variant form of CJD does not possess a threat to the blood supply. Furthermore, further definition of donors who might be at risk of developing CJD is required."

And so on.

And so the purpose was to try to establish

whether or not CJD was or could be transmitted by blood transfusion?

A. Yes, because there was a huge concern that variant CJD was so different from sporadic CJD there couldn't be reassurance that because sporadic CJD was not transmitted by blood the same would be the case for variant CJD.

Q. Then if we go over the page to page 8, the bottom half of the page describes the basic way in which the programme would operate.

Then if we go to page 9 we get to the issue of non-notification of the recipients. So, second paragraph:

"It is recommended that the limited look-back would take place without notification of the recipient. The reasons are as follows:

"1. There is no screening test available which can detect the possibility of an individual being susceptible to development to CJD in the future.

"2. There is no diagnostic test available to detect whether an individual has been infected with the agent which causes CJD.

"3. The diagnosis of CJD can only be made with certainty by examination of pathology specimens post-mortem.

"4. There is no intervention which can be offered to individuals detected to be at risk of developing disease, or to those who have already developed symptomatic disease.

"For all the above reasons, it is considered unethical to notify any individual who has received blood from a donor who subsequently developed CJD."

Then if we go over the page. The second paragraph says:

"It should be noted that should there be any change in the capacity to diagnose the disease, or if any intervention becomes available in the future, then the transfusion services should have in place a mechanism for contacting the identified recipients."

So the proposal when it started was non-notification of recipients, but there was a recognition that the situation might change?

A. Yes. And I think number 1 should have been: there is no evidence that there is transmission through blood transfusion. And that should have been included in the -- a proviso: if information becomes available which suggests that it has been transmitted through blood transfusion, that would be a very significant reason for changing from non-notification.

Q. And then if we can just look at the next page. Bottom

paragraph. There is a heading:

"Exclusion of donors considered at refuse of developing CJD.

"The transfusion services must exercise a high level of suspicion about possible transmissibility of CJD by blood and err on the side of caution in deciding whether to accept donations from individuals believed to be at refuse of developing CJD. To wait until a causal connection is established on a scientific basis may not be regarded as acting with reasonable care. Thus, decisions about selection of donors must not be delayed pending results of the limited look-back but must be taken in the light of current knowledge and guidelines."

Now, it could be said that's a very different approach to the approach taken, for example, in the 1980s in relation to HIV, where -- and I am sure you are familiar from your knowledge of events, Dr Hewitt -- issues about no conclusive proof, no causal connection, no evidence, etc, feature large in the story of what was -- decisions there.

This appears to propose a different approach, which is essentially the opposite: to err on the side of caution until the contrary is proved.

A. And I think this has been mentioned by earlier

witnesses as well. This is a reflection of the precautionary principle, which I think really became prominent after the Phillips Inquiry into BSE.

Q. Then if we go to page 15 of this document, this is, as a matter of formality, the grant of ethical approval, on 6 January 1997, by the Lothian Ethical Research Committee.

Now, in 1999 you then sought further ethical advice, first of all from Professor Kennedy and then from Professor Len Doyal.

A. Yes.

Q. We will look at the correspondence in a moment but what had changed that led you to want to get further advice on the question of notification?

A. So there were over the years between 1996 and 1999 a variety of discussions, predominantly within the CJD Incident Panel, about risk assessments which were being carried out in relation to: what is the risk that variant CJD could be transmitted through blood or blood components?

And the early risk assessments did not really lead to many believing that the risk was such that individuals who we were identifying in the TMER should be informed that they had been put at risk. I think over that period the risk assessments changed, but

I think one of -- one of the main reasons was that we in the Blood Services were trying to adopt the precautionary principle. And we were saying: we are identifying people who we know have developed -- who have received blood components from individuals who later developed variant CJD. We don't have the evidence that it is transmitted through transfusion but we would not want any of those individuals to become blood donors themselves, because we would not want that blood to go into the blood supply.

And it was -- that was the Blood Service's stance on that. But no decision had been made about notification of these recipients. So if they didn't know, how could they not become blood donors? Now, admittedly, many of them would not have been eligible to be blood donors, but some of them would have been. So the Blood Services said: a decision hasn't been made but we are going to do something to make sure that if any of those individuals donated blood, it would not be used. And it was quite a complex thing to do but that's what we did.

Q. This is the flagging -- (overspeaking) --

A. This is the flagging.

Q. -- is that right?

A. So this is, basically, even though they were not blood

donors, registering them as blood donors -- and that itself led to concerns -- and then ensuring that should any of those individuals who would be eligible to give blood, should any of those individuals attempt to donate blood, that blood would not be used.

And then, following that, if any of those individuals had attended to donate blood and become blood donors, the Blood Service would then have a duty to tell them: we cannot accept blood donations from you, for this reason.

So that was the dilemma we were in, and that was the dilemma we presented to the Incident Panel, and to say: look, we are going to take this action, we are going to ensure none of these individuals', if they donate blood, the blood would be used. And if they do come to donate, we would be duty bound to then tell them because we couldn't continue to let them donate blood in the knowledge that we couldn't be using it.

Q. And then you would have a situation in which some recipients with implicated donations would have found out that they had been recipients, and indeed that that had been known to the various agencies involved for some time, but they would have found out through the happenstance of coming to donate blood, and then others would remain in ignorance?

A. Exactly.

Q. Then I think if we look at NHBT0001259.

This is a letter from you to Dr Robinson dated 5 December 1997.

We can see -- if we just leave the whole page up, please, Paul.

We can see in the second paragraph you refer to the advice sought from Professor Kennedy, and you have set out the advice there. So even though we don't have in the direct form of a document from Professor Kennedy, this was your account of it not long after?

A. Yes.

Q. And four reasons there given: no evidence CJD was transmitted -- so you were putting it there as a reason?

A. Yes.

Q. "2. ... no screening tests ...

"3. The only diagnostic test is a brain biopsy.

"4. ... no therapeutic intervention ..."

But then if we look at the first paragraph, we can see something triggered you to write to Dr Robinson, which -- is this right, in understanding that those who had received implicated tissues, a different approach was being taken and they were

being notified, and you were concerned about the difference of approach. Is that correct?

A. Yes. These are specific tissues, eye tissues, which were and are considered to be high risk. So it was a different tissue, one was blood and one was eye. But still, there was a disparity.

Q. Over the page you, in the last paragraph, say:

"As different policies have been implemented with respect to these two groups of recipients, I think it is important to understand the reason for these differences."

You ask for it to be looked at again by MSBT and say you are uncomfortable that two different decisions have been taken.

Now, we can follow through MSBT decisions on paper with other witnesses, so I'm not going to ask you to look at those, but in 1999 you sought ethical advice again.

If we start with NHBT0017407, please.

This is your letter to Professor Ian Kennedy. You refer to a conversation in May 1996. You set out the previous history. And then if we look at the penultimate paragraph on the page, you say:

"You raised two important caveats at the time. Firstly, if there was any change in the capacity to

diagnose the disease and secondly, if any intervention became available, then the means to contact identified recipients must be in place."

Then, bottom paragraph, picking it up at the end of the second line:

"I have been asked to write to you again, to ask whether you consider that the ethical advice now needs reviewing. Two factors are relevant. Firstly, a test which might have application as a diagnostic test in the future has been developed by Professor Collinge at Imperial College School of Medicine."

You set out there it's still considered a research procedure at that stage.

Then:

"The second factor is more complex."

And you go on to describe what we've just been discussing, the fact that the Blood Transfusion Service was taking steps to flag individuals on their own records to ensure that blood donations from them weren't used.

Then we see the bottom paragraph, you say:

"... I have been asked to write to you and ask whether you could review the situation and the advice you have given in the past, in the light of new developments."

Then, if he is unable to, you ask if he can suggest the name of another expert.

Now, I don't think we have anything that suggests Professor Kennedy did give advice again on this second occasion?

A. No. And I apologise for the fact that documentation isn't there --

Q. Don't worry.

A. -- but you are probably going to go on to ...

Q. Yes.

So you -- whatever the response from Professor Kennedy was, and it may have been a telephone response and therefore not documented, you then make contact with another professor of ethics?

A. Yes.

Q. Professor Doyal.

We have a letter from him at NHBT0004392_002.

So it is 20 December 1999, and it refers to a meeting with you and Dr Knight. If you can tell us who Dr Knight is?

A. Dr Knight is the consultant neurologist at the CJD Research and Surveillance Unit.

Q. It refers to a meeting. The second paragraph says:

"As I understand it, the reasoning behind the original decision not to inform recipients or donors

in the circumstances described was based on the premise that not doing so could in no way impinge on their interests. This was because of the uncertainty surrounding the mode of transmission and the lack of a screening or diagnostic test to diagnose infection.

"The issue of the lack of any effective intervention has also been mooted as a justification for non-notification."

Then Professor Doyal's advice then is:

"I would discount this as relevant to any new policy about notification. Many terminally ill people both need and want to know confirmation about their diagnosis and prognosis, despite the absence of effective treatment. They require such information because of decisions of their lives or deaths which they may wish to make on its basis. It is impossible with any certainty for clinicians effectively to judge who these individuals are or what kind of information they require, even when they are actively treating them. Indeed, there are obvious difficulties in assuming that when some patients reject information which they may find distressing, they can be said to be making an informed choice about their rejection. It certainly cannot just be assumed that recipients or donors who are linked to [new variant CJD] will not

wish to be informed of this fact -- if anything can be said to practically turn on the provision of such information."

Over the page he says:

"Therefore, the key moral issue is whether or not there is a) evidence -- or the appearance of evidence -- that there is a link between nvCJD and blood and b) an effective diagnostic test."

Then he takes each in turn:

"If I understood you and Dr Knight, there is now very little sound evidence that [new variant CJD] can be transmitted by blood. The problem is that the National Blood Authority has adopted a policy about the non-use of the blood of the recipients of potentially infected blood which entails that they must be informed that they are ineligible to give it. The Department has also insisted that as the medium of potential transmission, white cells be removed from blood for transfusion."

That is the process that Dr Williamson told us about of leucodepletion:

"Both decisions suggest -- and will certainly do so to the public -- that there is evidence of transmissibility. Therefore, recipients or donors who are told that their blood cannot be used must be

informed of the circumstances surrounding this decision. On the hand, if they are given no explanation they will rightly demand it. On the other hand, if they are told nothing and allowed to give blood which is then simply destroyed, they would be doing so under false pretences. This is both immoral and illegal. If anything should now be clear in the practice of health care in Britain, is that deception is not an option for good clinical practice or public policy."

He then goes on to discuss the emergence of the screen or diagnostic test. I won't read that aloud but, in any event, his advice effectively was different from the advice that you had previously received and was to the effect that he believed recipients should be notified?

A. Yes, and I think I was -- I think it was quite an eye opener for me that there is no such thing as "this is ethical and this isn't". There are different opinions amongst ethicists. And Professor Doyal felt very differently from the previous ethical committee, both ethical committee and Professor Kennedy.

MS RICHARDS: Sir, I note the time. I probably have about another 20/25 minutes or so on CJD.

SIR BRIAN LANGSTAFF: Very well. Let's take a break now

until 2 o'clock. 2 o'clock.

(1.02 pm)

(The short adjournment)

(2.00 pm)

MS RICHARDS: Dr Hewitt, we looked before lunch at the advice you received from Professor Len Doyal. There is a letter then from Dr Knight commenting on that advice to you. I'm not going to go through the detail of that. For the transcript, it is NHBT0004320, and that was 25 January 2000.

What I want to do is, however, turn up NHBT0004364_004. This is a letter of 30 January 2000 from the chair of the Lothian Research Ethics Subcommittee or the relevant subcommittee addressed to Dr Will, who was conducting the TMER essentially with you, is that right? He was the Surveillance Unit --

A. Principal investigator, yes.

Q. And you were the principal investigator from the Blood Service's perspective?

We can see, picking it up in the second paragraph, it refers to the previous approval, the ethical approval, that had been given by the Committee and then it says:

"Crucially, you felt at that time that it would be inappropriate to contact either blood donors or

recipients, as it was felt unjustifiable to give these individuals information which might suggest that they are at risk of developing CJD. This decision was based on the fact that there is neither a test nor effective treatment for the disease.

"As you have indicated, this course of action appears to conflict with the stance adopted by the NBA, as described in Dr Hewitt's letter dated 12 October 1999."

This is the position in relation to blood donors. I'm not going to go back through all the various bits and pieces of correspondence:

"As you know, this followed a recommendation from MSBT that blood donations from individuals who had received blood from donors who later developed nvCJD should not enter the blood supply. It seems to have been agreed that such a donation would be disregarded and that the donor would be contacted and informed, at a face to face interview, that the blood could not be used and the reasons for the decision. Professor Doyal's letter to Dr Hewitt (dated 20 December 1999) [which is the letter we looked at before lunch] states that it would be 'immoral and illegal' to act otherwise. He also clearly argues that the lack of an effective intervention is not a

justification for non-notification, stating that 'many terminally ill people both need and want to know information about their diagnosis and prognosis despite the absence of effective treatment'. I would agree that it is usually reasonable to tell someone that they are definitely terminally ill so that they may, as the saying has it, 'put their affairs in order'. I know that we both feel that this is a far cry from being told that there is a possibility (which can be neither confirmed nor refuted) that one may have been 'donated' a virus, which may or may not be responsible for causing a lethal illness at some undetermined time in the future!

"Nevertheless, a National Policy, with which the Department of Health is in agreement must be adhered to. As a consequence I have no alternative to refuse your request for renewal of Ethical Approval for the above study."

So the ethical approval was, I think the phrase you have used in your statement was "withdrawn". It wasn't renewed, it doesn't matter which. So, as at the end of January 2000, the TMER no longer had the benefit of the ethical approval that had been granted previously for the policy of non-notification?

A. Agreed.

Q. Then we can see, at NHBT0004364_03, Professor Will wrote, copying you in, on 1 February 2000, to Dr Ailsa White at the Department of Health. In the first paragraph, he refers to having written to the local ethics committee. He refers then to the letter that we have just looked at, the refusal of the request to renew ethical approval. Then the next paragraph reads:

"As you may recall I was very uneasy about the ethical situation in relation to this national study when approval had only been given by local ethics committee. I contacted Dr Metters about this and I believe that a decision was made within the department of health that it was ethically appropriate for this study to continue under the original conditions.

"The situation is now very difficult. I believe that the lookback study in CJD addresses an issue of major public health importance and I personally feel it would be irresponsible to discontinue this study because of the absence of local ethical approval. I would therefore seek your advice on how to proceed with this issue and whether it would be possible for the department of health to provide ethical approval for this national study."

Do you know, Dr Hewitt, what then happened in relation to ethical approval and the Department of Health stance?

A. I have been trying to remember and I should know but I can't remember.

Q. Well, I asked the question because I don't currently know the answer but I am sure we will be able to trace it through with documents and/or with other witnesses.

What you say in your statement is that ultimately, over the following I think it is three years, there was a shift in view, leading to, as we will come onto, notification then taking place to recipients at the very end of December 2003?

A. Yes.

Q. But it was -- 2000, 2001, 2002, 2003, the position remained that recipients were not, as a matter of fact, being notified?

A. Yes, and there continued to be discussions at the CJD incident panel and I think, over that time, opinions changed, influenced by more up-to-date risk assessments from the Department of Health analytical team, whose correct title I think Dr Williamson gave yesterday but I can't remember.

Q. We will just pick up, I think, probably three documents that help understand what -- some of what

was happening during that time. First of all, if we go to NHBT0015384. This is a letter of 12 January 2000 from Dr Mike McGovern in the Department of Health to Dr Robinson. It was in response to a letter that Dr Robinson had written to Dr McGovern, which is at pages 3 and 4 of this document but I'm not going to go to that, but it gives us an understanding, as at the beginning of 2000, of the position of MSBT.

It refers in the first paragraph to:

"MSBT [discussing] the management of donors known to have received blood from people who subsequently developed variant CJD at the last meeting on 28th October 1999. This letter outlines that discussion and advice to the National Blood Authority ..."

Then he refers to his letter providing a full reply to Dr Robinson's letter of 22 December.

The next paragraph sets out TMER, a summary of the TMER study. Then the last sentence of that paragraph:

"The question is whether these people's blood, should they present as donors in the future, be prevented from entering the blood supply and if so how the situation should be managed."

Then the next paragraph records a discussion about the position of flagging the donor databases, which you have already told us about.

If you go over the page. The top of the page records that:

"Given that these people could present as donors in any of the UK countries we agreed that the 'flagging' information should be shared by all four national blood services to ensure a coordinated inclusive approach."

Is it right to understand that the system of flagging was both agreed by the Department of Health and it was agreed that it should be a system that was shared between the four different blood services?

A. Yes, it is.

Q. And then the next paragraph deals with the position of what should happen if a flagged person gave blood:

"In the event of a 'flagged' person giving blood, it was agreed that the donation identified through the flagging process should not be allowed to enter the supply. It was also agreed that in the spirit of openness and 'contracts' with donors, the blood services would need to consider telling, or offering to tell, the donor why their blood could not be accepted. As, however, there is still little

scientific knowledge to inform discussion with the donor, we agreed that the appropriate Health Department should be contacted in the first instance and every such incident discussed and managed on a case by case basis."

Then it refers to the NBA developing a protocol to deal with those cases.

The next paragraph refers to the proposed expert group on the management of CJD incidents. That, I think, is a reference to what became the CJD Incidents Panel?

A. Yes.

Q. And we will look at that shortly. That was due to meet for the first time.

And then the last paragraph reads as follows:

"It was clear from all the discussions that the decision to flag such potential donors was purely precautionary, not based on any new scientific information, and taken in the face of profound uncertainty. The most recent scientific opinion is that while 'blood may contain low levels of the infectious agent of CJD, blood components have never been identified as a cause of CJD in humans'. The information on vCJD however is in evolution and the position still is that there is no test for the agent,

even if there were the implications of a positive test would be difficult to ascertain, and there are no known treatments for the disease. In addition it is not known whether the agent can be transmitted by blood and cause disease in recipients. Because of this our current policy remains that people who may have been exposed to the vCJD agent through blood or blood products should not be informed as set out in the Executive Letter PL(CO) (98) I, issued 6 February 1998. However the policy will be kept under review in the light of developing science and lawyers will be seeking a Counsel's opinion on the extent of our obligations towards those who may have been affected by implicated products."

It would appear, Dr Hewitt, from this letter that as at January 2000, and leaving aside the position of flagged donors who then came to donate blood, the Department of Health's policy remained that there should be no notification?

A. Yes, that's what this letter says but I think earlier in the letter it said that the cases had to be decided -- discussed on a case-by-case basis.

Q. Yes. I'd read it -- and I may be wrong and it may be we will have to ask the Department of Health about this -- as the case-by-case basis would be how to deal

with donors who attended, and that leaving aside the presentation of donors, the policy then remained -- (overspeaking) --

A. Non-notification for the whole group, yes.

Q. In any event that's the position as at beginning of January?

A. Yes.

Q. We then have the establishment of the vCJD -- of the CJD Incidents Panel. And in due course, I think it was in October 2001, the panel initiated a consultation process, did they not?

A. Yes.

Q. And the question of notification was one of the issues on which consultees' views were sought.

A. Yes.

Q. We can look at that at NHBT0096710_001, please.

So we can see from this document, dated 10 October 2001, this covering notice is from the chair of the CJD Incidents Panel, Michael Banner:

"I am writing as the Chair of the CJD Incidents Panel to seek your views on the enclosed document entitled 'Management of public exposure to CJD through medical procedures". The CJD Incidents Panel was set up last year by the Chief Medical Officer to advise on these issues.

"The document has been drawn up in the knowledge that there is an unknown but possible risk that Creutzfeld-Jacob Disease (CJD) could be transmitted through surgical instruments, donated blood or other tissues or organs, from individuals who later develop CJD. These risks are very hard to evaluate but cannot be ruled out.

"The document sets out proposals for managing incidents of possible exposure to CJD. The Panel's proposals address such matters as informing people who have potentially been exposed, and how to deal with the surgical instruments that may have been used. It takes into account as best we can the current state of knowledge about the risks of transmission. It also attempts to chart a way forward, in handling the difficult ethical dilemmas which arise in dealing with a disease which is always fatal, for which there is no cure, which has an unknown incubation period and no diagnostic test."

If we go, first of all, in this document to page 61, we can see that the panel had a broad membership, and it included, amongst others, Professor Ironside from the National CJD Surveillance Unit. Professor Len Doyal, the ethicist from whom you had sought advice, and you, along with a list of other

names?

A. Yes.

Q. If we can then, please, go back to page 6. Just picking it up in the third paragraph. We see the description of risk there:

"The risk of transmitting CJD through medical interventions is not fully understood, and this document has been prepared in the face of great scientific uncertainty."

Then if we go to the next page we can see, in broad terms, the issues upon which views were being sought. Top of the page:

"It is possible that variant and sporadic CJD may be transmitted on surgical instruments used on patients incubating the disease, or in blood, other tissues or organs donated by individuals incubating the disease. These risks are unknown, but current procedures for decontaminating surgical instruments between uses cannot be guaranteed to eliminate the abnormal prion proteins that are thought to be responsible for the transmission of CJD. In addition, while there is evidence that sporadic CJD is not transmitted in blood, less is known about variant CJD. Therefore transmission of variant CJD in blood cannot be ruled out."

Would you see that, again, as a reflection of the precautionary principle, that rather than waiting until there is positive evidence of transmission by blood, here is the panel identifying measures that could be implemented at a stage where it is not known, still less proved that transmission takes place?

A. Yes.

Q. Then we can see, just above the first heading 1, it says:

"The panel proposes four main courses of action:

"1. Removing the instruments/blood products from use.

"This protects public health while the risks are being assessed. The Panel may advise that instruments are destroyed or that they are unlikely to pose a risk to the public and may be returned to use. The Panel will also advise on the removal from use of blood or plasma products donated by people who later develop CJD.

"2. Setting up a confidential database of all possibly exposed people."

Then over the page:

"3. Informing some individuals about their exposure to CJD.

"The exception to this would be a small sub

group of possibly exposed people who the Panel considers to be at sufficient risk to warrant public health action. It is proposed that these people are contacted and informed about their exposure so that they can be advised not to donate blood or organs, and to contact their doctor if they required surgery in the future."

Then 4 is about publicity, about the database. So that is the way in which, at this stage, the panel contemplated addressing the issue of notification; is that right?

A. That is right. It was essentially escalating actions for a small group of potentially exposed people and not the majority.

Q. But there would be a choice then, is this right, for the majority to be able find out?

A. That was the intention.

Q. That was the intention. That wasn't what was then put in place, is that right?

A. That is correct.

Q. So that's the position as at October 2001. The consultation then took place. We don't have all the documents available to display to you, Dr Hewitt, but, in any event, we can pick that up, I think, with other witnesses.

group of possibly exposed people who the Panel considers to be at sufficient risk to warrant public health action. It is proposed that these people are contacted ..."

Sorry, I should have read -- to make sense of it, I'm trying to go too quickly. If we go to the top of the page. We pick it up at the top of the page:

"It is proposed that most people would not be informed about their possible exposure."

Then the reasons are there set out. Then the next paragraph says:

"There is a strong argument that people should be able to choose whether or not they are told about their possible exposure. Therefore it is proposed that possibly exposed people are not asked for their informed consent before being recorded on this register. This is because such action would remove the choice of not being told about their exposure. Instead it is proposed that individuals who wish to know if they are on the database, and the details and significance of their exposure, should be able, after appropriate counselling, to obtain the information through their doctor."

Then 3:

"The exception to this would be a small sub

You tell us in your statement that, eventually, the decision was made that patients considered at risk should be notified. So there was a reversal of the original policy of non-notification of those recipients who had been identified through the TMER?

A. Yes, so it was the patients who had received transfusions from individuals who had later developed variant CJD.

Q. We can, I think, look at that, because it is set out in a later letter which just gives us some of the dates of the decisions, at PRIU0000015.

This is a letter from the Department of Health. It is from the then Minister of State, Caroline Flint, October 2006, to a coroner who had undertaken an investigation into the death of someone who had died following vCJD transmitted through blood.

The purpose for looking at it is just, if we go over to the second page, we can see the decision-making process set out. So if we pick it up in the third line -- sorry, second line, it says:

"... there has been a general shift in attitudes towards patient's rights to information. In the summer of 2000, the Department of Health established the CJD Incidents Panel. The Panel was asked to advise healthcare professionals on the management of

incidents involving potential transmission through medical interventions."

Then it refers to the consultation process and it says it included a public meeting held in 2002:

"There was a wide range of views expressed."

Then if we go to the next paragraph:

"The Panel revised its proposals in the light of the consultation responses, recommending that patients considered 'at risk' should be notified and that necessary support mechanisms should be in place."

So that, in due course, was the recommendation post-consultation of the CJD Incidents Panel to the Department of Health --

A. That is right.

Q. -- that notification for those categories of patients should now take place. Then it says:

"The four Chief Medical Officers for England and the Devolved Administrations accepted this proposal in June 2003."

It is right, as I understand it, Dr Hewitt, that although that proposal was accepted in June 2003 no steps were taken at that point to notify recipients?

A. I'm not aware that any steps were taken. Could I just clarify the very first sentence in this letter --

Q. Yes, of course.

A. -- because it might be confusing for some individuals. The original letter wasn't to me it was to my alter ego. So it was written to the Minister, Secretary of State for Health.

Q. You are absolutely right. So if we just go back to the second page.

A. I think it was a source of frustration for the Incidents Panel that, following agreement with the recommendation in June 2003, there was no information that something was being set up.

Q. The letter continues:

"At this time, there was still no known cases of vCJD transmission via blood transfusion. However, while the necessary support mechanisms were being put in place, the first case of vCJD transmission via blood transfusion was confirmed in December 2003. The Department acted as quickly as possible to ensure that all similar recipients were contacted and given the information and support needed."

Now, you observed in your witness statement -- if we look at WITN3101009, please, Paul, page 140, it is paragraph 393, so bottom half of the page, last few lines of paragraph 393:

"I understand that notification was advised ... action was not taken until December 2003, when the

recognition of the first possible link occurred ... DH then instructed that notification should take place."

That resulted in notifications being sent out essentially around the time of Christmas and New Year. As I am sure you are aware, Dr Hewitt, the evidence the Inquiry has heard in an individual case from Peter Buckland, who was the father of Mark Buckland, was a letter from the Health Protection Agency dated 31 December 2003 arriving in early January 2004.

From your perspective, could the notification process have taken place -- could and should the notification process have taken place earlier than the end of December 2003?

A. Yes. I was quite clear about that and it was an example of how not to do a notification exercise. The time was awful. Individual GPs and local public health teams were put in the position of "This is something you must do now", without any plans really having been made in place. A lot of work was done, a lot of teleconferences with a lot of people working out it could be done well and quickly, and that really wasn't the situation we should have been in.

Q. Is it the case that the agency that took the lead in the notification process was the Health Protection Agency?

A. That is correct. I was involved in that, clearly, the Blood Service held the deals of the individuals who were to be informed and I did take part in the lot of the teleconferences, but the notification was handled by the public health teams.

Q. Part of Mr Buckland's evidence was an expression of concern about the fact that his son's exposure had been known about for a number of years but had not been communicated to his son until the notification exercise that you have just described.

A. Yes.

Q. I'm not asking for comments on individual cases but I just wanted to invite your comment on one of the reasons Mr Buckland articulated as to why it would have mattered to his son to know. And he said it is because he could have made a choice to live his life to the full in a way he -- what remained of his life, of his young life, to the full in a way that he couldn't because he didn't know that he had possibly been exposed, as a matter of fact had indeed been exposed, to vCJD.

Again, that perhaps picks up on some of the observations Professor Doyal was making. Would you agree with that as a matter of principle, that that's one of the considerations that would favour

notification rather than non-notification?
A. I totally agree. And if I may be allowed to say, the first case, which initiated this exercise, the case where a recipient did develop variant CJD and hadn't been informed, equally I did meet some of the family and very rightly made the comment that if they had known that their family member was at risk -- he died without a diagnosis being made. If they had known that he had been at risk, his last few months would have been dealt with differently. And how they had managed the situation would have been dealt differently because they would have known what they were dealing with, or what they were likely to be dealing with.
Q. And there was an observation you made more generally in your statement, Dr Hewitt.
If we can have the statement back, please. WITN3101006, page 34.
This is paragraph 105, and you are here reflecting on issues more broadly of notification. You say this:
"With hindsight, I think the difficult issues and strongly held views from both sides (those who supported notification of the possibly affected, despite the potential for psychological harm, and

those who felt that such harm outweighed the benefits) may have led to erring on the side of not acting soon enough to impart potentially devastating news in terms of possible exposure to HCV and vCJD ..."
Does that accurately reflect your views?
A. Yes.
Q. Can I then just pick up on a handful of other matters relating to vCJD.
So we have learnt that the December 2003 was when an individual died of vCJD who had received a transfusion some years earlier, including a blood component originating from a donor who later developed vCJD.
A. Yes, that is correct.
Q. That was the confirmation, is that right, essentially?
A. It was the likely evidence, but one case ... I know that the Department of Health were very anxious that it couldn't be called "evidence", it was "suggestion of a possibility", and it wasn't until subsequent cases that gave definitive evidence that we could say with confidence we do have the evidence that it is transmitted through blood components.
Q. We can see this case being described in an article in The Lancet in February 2004, co-authored by you, Dr Knight and Professor Will and others.

WITN3101018.
Now, you are setting out here more fully, as I understand it, what you have learned from the TMER by this stage?
A. This was a description of this first case.
Q. So if we look at the heading "Summary" and go to "Methods". So that's describing, I think, the TMER?
A. Yes.
Q. Then "Findings":
"48 individuals were identified as having received a labile blood component from a total of 15 donors who later became vCJD cases and appeared on the surveillance unit's register."
So, as at the date of this article, TMER had identified 48 people?
A. Yes.
Q. And then:
"One of these recipients was identified as developing symptoms of vCJD 6.5 years after receiving a transfusion of red cells donated by an individual 3.5 years before the donor developed symptoms of vCJD."
So that's the case that you have described, the individual?
A. Yes. And perhaps it would be helpful to say that,

because of the time of this, it was non-leucodepleted red cells.
Q. And then:
"Interpretation. Our findings raise the possibility that this infection was transfusion transmitted."
Then if we go to page 4., you set out various further details about that individual case. But I'm just going to draw attention to the last paragraph of the article. So halfway down the right-hand column:
"Our report suggests that human prion diseases may be transmissible through blood transfusion and underlines the importance of epidemiological surveillance systems. Although experimental studies are important, only through the study of natural disease can evidence of an actual iatrogenic risk can be identified. The risk of vCJD is not restricted to the UK, and the identification of cases of vCJD and examination of history of blood donation may be important in other European countries and elsewhere."
You go on in your witness statement to tell us that two further cases were then identified linked to a common donor, and that that essentially confirmed the link --
A. Yes.

Q. -- between vCJD and blood transmission.

And I should just say, I don't think I need to go to it, but there was an *ad hoc* meeting held on 15 December 2003 to discuss what should happen when the case came to light. I will give the reference for the transcript. DHSC0006827_006.

Can we then look at RLIT0000777.

So this is from the website of the CJD Surveillance Unit, and if we go to -- oh no, it's not got the page I wanted. I don't think it is printed out as we needed it. No, don't worry.

My understanding, and this is what you say in your witness statement -- so we can take the document down -- is that TMER identified 67 people at risk of vCJD because they had received a blood component originating from a donor who later developed vCJD --

A. Yes.

Q. -- is that right?

Then, in terms of the notification process, we've learnt how the initial notification process was handled by the Health Protection Agency but you have told us in your statement that there was then a 2005 notification procedure until relation to donors identified through the reverse TMER, which was managed by you?

all, were the Blood Services involved in that exercise?

A. Indirectly. As part of the whole procedure the Blood Service had notified BPL or the Scottish equivalent of plasma donations which had originated from donors who had later developed variant CJD, and I had made myself a note to say that although plasma product recipients were not included in the TMER there was a separate exercise to identify what had happened to those implicated plasma products, which is now what we are talking about.

So the Blood Services provided the information to the fractionators so they could identify which batches of product contained plasma from those original donations. And thereafter the only part that the Blood Service was involved in is where there were batches of albumin, which is a protein solution, which had been used within the Transfusion Service, because the Transfusion Service provides a therapeutic service for some patients who require plasma exchange. So we were the users of the products at that stage. But as far as I recall, that was the only involvement of the Blood Services.

Q. You yourself might have had some knowledge of what was going on because of your involvement with

A. Yes.

Q. So why was this undertaken in a different way?

A. So, just to be clear, this is the situation where a recipient has developed variant CJD and we have identified the donors whose blood had been transfused to those recipients. So those donors were considered to be at risk. And the decision was then taken that those donors should also be notified and told that they should not continue to give blood or donate other tissues or organs.

And at the time we felt very strongly that these individuals whose risk for vCJD had been identified because they were blood donors, because they had volunteered to give blood, and we felt that it was our responsibility, as the Blood Service, to give them the information, and that outsourcing it to another organisation might seem very strange.

I'm not sure whether that was correct or not. But that was what we felt very strongly at the time, that it was our responsibility to talk to our donors.

Q. Notification of being at risk -- for those who had received fractionated product. So factor concentrates. We have heard evidence already in the Inquiry from Professor Hay and others about the notification exercise that were undertaken. First of

CJD Incidents Panel?

A. Yes.

Q. But we can pick that up, I think, through the CJD Incidents Panel minutes as a matter of record. That notification exercise was then handled, as it were, through the CJD Incidents Panel and the Haemophilia Centre Directors Organisation, is that your understanding?

A. It was actually handled by Public Health England, whatever its current title was at that time, who provided the risk calculations for the various batches and then informed users of which batches were at risk.

Q. Then you referred a moment or two ago to there being an equivalent, as it were, of TMER but in relation to the fractionated products, so the same kind of exercise being undertaken. Who, as far as you know, undertook that?

A. So that is what we were just talking about, yes. So Public Health England, it was their headquarters, with the haemophilia centres and with other users of other products.

Q. So those -- no, there are a couple of further questions in relation to vCJD, sorry.

So that was the system in relation to notification. In terms of other measures that the

blood services were involved in, the issue of leucodepletion Dr Williamson addressed, I don't propose to ask you about that. But the other measures taken in response to the possibility of transmission of vCJD primarily concerned donor exclusion policies, is that correct?

A. Yes.

Q. If we look at DHSC0038574_038, we can see this is a document -- it bears your name at the bottom and the date of 20 December 2000, "Ethical Position and Policy on Informing Donors and Recipients about Matters Relating to vCJD or CJD", and then -- I'm not going to go over again the ethical issues about notification but, in terms of donor exclusions, we can see the first paragraph explains that:

"A variety of individuals identified as being at risk of CJD, are excluded from blood donation in the UK. The categories of exclusion are as follows:

"Individuals who have been treated with pituitary hormones ... before 1985

"Corneal transplant recipients

"Individuals with a family history of CJD

"Individuals who have had brain surgery or an operation for tumour or cyst on the spine before August 1992 ..."

So those are four categories who by 2000 had been excluded?

A. And these all related to sporadic or familial CJD.

Q. Then, as we have seen from the documentation in relation to the notification decision-making, there was the flagging exercise to ensure that donors who had been identified through the TMER work did not have their donations used?

A. Yes.

Q. Then if we go to DHSC0004555_008, if you go to the next page. So if we look at that box at the top of the page, "A new rule for blood donors":

"From 5th April 2004 we can no longer accept blood donations from people who have received blood during the course of any medical treatment or procedure in the UK since 1st January 1980."

Then below that, below the box:

"We are sorry that we have had to ask you to stop giving blood for the time being. This new rule has been introduced as a purely precautionary measure in light of the latest scientific information. Our aim is to ensure that patients always receive blood and blood products that are as safe as we can make them. In this instance we are reducing the possible risk of vCJD ... being passed from donor to patient."

So was this the next step, as it were, in the development of donor exclusion policies to deal with the possible risk of vCJD?

A. Yes, and again it is a precautionary principle but it was to avoid the possibility of recycling of infection through blood, going from one person to another, and then to another. So it wouldn't have eliminated the initial risk and it would eliminate further risk of it being passed on again.

MS RICHARDS: Sir, those are the questions that I have for Dr Hewitt. Over lunch I have been sent a number of additional questions from Core Participants for me to consider but, rather than do that now, I wonder if we could take a shortish break, I can read the last of the questions I didn't have a chance to read and Core Participants can suggest any further questions arising out of the last 45 minutes, or so, of Dr Hewitt's evidence?

SIR BRIAN LANGSTAFF: Yes. How long do you think you might need?

MS RICHARDS: I think 15 minutes would be fine.

SIR BRIAN LANGSTAFF: Very well, we will meet again at 3 o'clock, shall we? 3 o'clock.

(2.45 pm)

(A short break)

(3.00 pm)

MS RICHARDS: Dr Hewitt, just a handful of questions and because they have come from different sources they will dot from topic to topic.

A. Yes, I understand.

Q. You referred in your evidence yesterday to the Blood Transfusion Centre being involved in advice and education on the appropriate use of blood and blood products to prevent the problem of over use. What did that advice and education entail, can you recall?

A. I think Professor Contreras actually covered that quite thoroughly in her evidence last week.

Q. Was that more Professor Contreras' role than yours?

A. Yes, it was not really -- all of us had some remit but it was not a major part of my remit.

Q. You have mentioned in your evidence today that there is no database of people who had received a blood transfusion?

A. Yes.

Q. Do you think that it would have been a good idea, would now be a good idea to have such a database?

A. Well, it clearly would make some things easier but I think it would be an enormous exercise. I believe Scandinavian countries do have that but they have a much smaller population.

Q. That anticipated the second question, which was did you know what the position is in other countries?
A. I know there is one in Scandinavia.
Q. Yesterday, your evidence touched on CMV testing --
A. Yes.
Q. -- in relation to blood that might be intended for immunosuppressed patients?
A. Yes.
Q. If that was tested and shown to show the presence of CMV would that be permitted to be used for non-immunosuppressed patients?
A. Absolutely, the majority of us have already been exposed to CMV.
Q. Would any warnings be given about the presence of CMV in blood and blood products to your knowledge?
A. No, because it would not present a risk to other groups of people.
Q. The next question is about the CUE questionnaire?
A. Yes.
Q. Do you know how many donors self-excluded under that process?
A. I can't give you absolute numbers, no.
Q. We looked yesterday at your letter to Dr McClelland in January 1985, in which you sent the questionnaire to him, following what looked like a conversation that

you had had. Do you know whether you sent the questionnaire to other centres?
A. I don't believe I did. I think Dr McClelland and I had had a conversation and he asked to be shown it -- he asked me to send him details.
Q. You also recalled, when giving evidence yesterday about donation sessions, that staff at collection clinics would on occasion refer concerns that they couldn't address with the donor at a clinic -- sorry, they do that by sending a note back to the clinical team?
A. Yes.
Q. What sort of matters were raised?
A. It might be situations where the medical officer didn't feel that they could make a definitive decision about the suitability for donation and had therefore informed the individual, "I won't take a donation today but I will send the details back and somebody will contact you". It is difficult to give specific examples, I'm afraid.
Q. The next question then is about the position of patients who had received fractionated products. So typically patients with bleeding disorders treated with factor concentrates. What role did the Regional Transfusion Centre play if notified or becoming aware

of any infection transmitted to a blooding disorder patient through treatment with fractionated products?
A. In general the Transfusion Centre would not be made aware. We were not the manufacturer of the product.
Q. So would it be your understanding that that process would be managed as between BPL, if it was a BPL product, and the haemophilia centre directors?
A. Yes.
Q. I think it may be that you won't be able to answer the next couple of questions but I just want to ascertain if that's the case.

Does the national -- NHSBT or its predecessor keep a record or hold a record, in terms of those known to have potentially been exposed to vCJD, which would identify how many of those were bleeding disorder patients?
A. The records that are held within the Blood Service would only relate to blood components.
Q. So you will only have the records essentially through the TMER process?
A. Yes.
Q. Which would not include patients treated --
A. It did not include fractionated plasma products, yes.
Q. So would it be right then to understand that you would not know how many of those with blooding disorders

created with concentrates or cryoprecipitate who might have been exposed to vCJD?
A. That is correct, we would not know.
Q. I suspect this next question, the same answer will follow. Do you know what, if any, guidelines have been given to that cohort regarding blood spillages and how to deal with them in terms of the risk of vCJD?
A. I don't know what guidelines would have been given.
Q. In relation to the 1995 hepatitis C look-back, is it correct that that look-back exercise did not include haemophiliacs, bleeding disorder -- (overspeaking) --
A. That is correct.
Q. And are you able to help us to understand why that was the case?
A. Because as I understood it, by that time haemophilia units which -- would have been or should have been offering hepatitis C testing to all their patients.
Q. So the assumption may have been made -- I do not mean necessarily directly by you because you weren't the architect of the look-back -- that it didn't need to include patients with haemophilia because, the assumption was --
A. They should already have been identified.
Q. -- the Haemophilia Centres should have already been

doing that?
A. Yes.
Q. And was there any joined-up working between the Blood Transfusion Service and Haemophilia Centres to ensure that all those who might have been infected with hepatitis C were identified?
A. No. I think for the reason I have just given.
MS RICHARDS: Sir, those are the questions I have been proposing to ask by those put forward by Core Participants.
SIR BRIAN LANGSTAFF: Yes. I have no questions of my own.
MS RICHARDS: Dr Hewitt, is there anything further that you would wish to add?
A. Yes, I would like to, please. And I apologise if I read it because there are some things I would like to say.
SIR BRIAN LANGSTAFF: No, that's fine. Don't worry.
A. I know this has been a very long week of hearings, unusually long because of a variety of matters. I was originally due to give evidence next week and there had to be some rejigging of the programme and I am very grateful that the Inquiry team have accommodated me before the break, as was originally intended. So thank you very much.

I have in the past met some of the infected and

affected, both on a one-to-one basis and when I have met individuals who have been infected through a blood transfusion, and I have met some people in a group meeting for those with haemophilia. I have seen how people in this room have listened very carefully and attentively to those giving evidence. I have heard and read evidence from the infected and affected, who have recounted truly harrowing experiences and they have done this with great courage and enormous dignity.

I initially doubted what this Inquiry could achieve given the number of years which have elapsed since the events which it is examining. Many of the infected and affected are no longer with us and nor are some of those who could have filled in some of the gaps in the documents -- the many, many documents that the Inquiry has been dealing with. But I can see how important it has been for the infected and the affected to tell their stories and, more importantly, for them to be listened to.

It's also important for everybody to understand as completely as possible what happened and why and this is long overdue. As I said in my statement, it is a tragedy that treatment which was designed to save and improve lives had the opposite effect in so many

cases and I am deeply sorry.

Thank you.

SIR BRIAN LANGSTAFF: Thank you for that. Thank you also for the wealth of detail which you have provided in your witness statements, all of them, more than most witnesses, for the clarity with which you have answered the questions, useful to us not only in confirming much of what others have said but also in giving us a really clear picture and further picture of things such as look-back and vCJD in the 1990s and, in particular, in the Blood Service's role.

It is going to be interesting to see, in due course, what government witnesses say from their perspective about some of the things that you have described from yours.

But thank you very much indeed for the evidence you have given.

A. Thank you.

SIR BRIAN LANGSTAFF: I'm going to have to ask you to bear with me and just wait there for a bit longer because I have something to say more generally to those people who are here and those who are listening at home, and it is this:

This is our last hearing of 2021, time to look back on the past year and forward to the new. We

started under the shadow of Covid; it did not deter us. We end under the uncertainties of its threat; it will not deter us.

2021 has been a year when we have heard evidence which has ranged from haemophilia centres, Treloar's School, the Haemophilia Society to trusts and schemes, government health ministers, from each of the four nations, and then to former government ministers, pharmaceuticals and the blood transfusion services. It's certainly had its moments, some, as I said at the time, unforgettable.

2022 promises to be a year when we keep up the considerable pace at which we have been going. If it isn't the year when our hearings end, as many of us -- I think most of us -- hope it will be, it will not be for want of trying. But if we don't make it, it will leave us very close to that goal.

The timetable to Easter includes more from Regional Blood Transfusion Centres and will take us to blood transfusion policy and practice, self-sufficiency and production at BPL in Elstree, PFL at Oxford and PFC in Edinburgh.

Amongst other matters, we will also take evidence during from 2022 from Sir Robert Francis on his Compensation Framework review, and we will hear

quite a bit more from government witnesses.

We will be listening to the Inquiry's expert groups on statistics and public health administration.

I promised at the outset that this Inquiry would put people at its heart first and last. I intend to honour that promise. So we will take evidence from panels of people infected and affected at the end of our evidence sessions before we turn to submissions.

Submissions. It was last Easter that I asked both recognised legal representatives and unrepresented Core Participants to start making preparations for final submissions or closing statements they may wish to make.

There is an early deadline, as you know, for you to tell me of the recommendations you suggest this Inquiry makes, to help ensure that the future fully learns from what happened in the past. The Inquiry needs your help to make it much more difficult for the errors of the past to be repeated in the future.

Why am I mentioning these submissions again now? It is so there will be no unnecessary delay when we reach that point in the hearing schedule.

So far I have spoken generally about the Inquiry and its timetable but I would like to add this message to each of you personally:

Thank you for your resilience, despite the challenges we have all faced. Thank you for your patience, especially for understanding that it takes time to find and then to search through vast swathes of evidence, to filter out, examine, consider and present the facts those volumes reveal, so that we may reach well justified conclusions and make soundly based recommendations.

It is not always easy to realise that we are doing what we can to avoid taking too long. Thank you to everyone who has supported the Inquiry's work this year in whatever way they have felt able. You are each and all of you an essential part of this Inquiry. I know that many of you who followed this Inquiry have contributed to Sir Robert Francis' Compensation Framework review. This can take a physical, mental and emotional toll in addition to what has been a tough year for many, as we continue to live with Covid.

Christmas gives us time to pause and reflect but it may also be a time when the strains you may have borne with fortitude so far well up and come to the fore, and if that should happen to you I would like you to know that the Inquiry's support line will remain open at the usual times over the festive

period. It is there for any of you who would like to have a confidential conversation. Please use it if it would help because that's what it is there for.

Finally, to all of you, do have a peaceful and restorative break. Until next year, thank you.

(3.17 pm)

(Adjourned until 10.00 am on Tuesday, 18 January 2022)

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