

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

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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?

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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

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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

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1 a matter of principle?

2 **A.** Yes, and I expressed my concern that that was not

3 being done.

4 **Q.** I ask you this not because you were involved in the

5 decision-making but as someone who was subsequently

6 involved in 1994/1995 when, as it were, it came back

7 onto the agenda. Do you have any understanding as to

8 why a look-back was not organised until 1995?

9 **A.** I always understood that that was a decision made by

10 the Department of Health and my understanding was that

11 part of the justification for that was that there was

12 no treatment available for hepatitis C, so one would

13 be seeking out individuals, establishing whether or

14 not they had been infected with hepatitis C but then

15 having nothing in the form of treatment to offer them.

16 I found that very strange because, of course,

17 the same could have been said for HIV in 1985. When

18 we started screening donations for HIV, there was no

19 treatment available for HIV infection, so I felt that

20 that didn't appear logical. I think having read

21 Dr Robinson's statement, because she knew far more

22 about the history of it, there seemed to have been

23 a lot of concern, even, I think, from virologists and

24 hepatologists, that seeking out individuals and

25 telling them they had had hepatitis C, when there was

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1 might be right for people to be traced and told.

2 One is the very one you have already alighted

3 on, so there are lifestyle adjustments that can be

4 made that can have a real beneficial impact upon

5 health if you are hepatitis C positive, is that right?

6 **A.** Yes, and I'm very sure we were telling our donors that

7 in 1991.

8 **Q.** Then a second might be -- the very idea that someone

9 ought to have the right to know key things about their

10 body, and we will see that as a theme that comes back,

11 as it were, to haunt you, I think, when we look at

12 issues relating to vCJD.

13 **A.** Yes.

14 **Q.** The third might be that although, as at 1991, the

15 treatments that became available for hepatitis C might

16 not then have been readily available, but those who,

17 for example, had already got liver damage, would

18 benefit, would they not, potentially, from knowing

19 that they had hepatitis C, having monitoring of the

20 state of their liver, potentially earlier

21 identification of something like hepatocellular cancer

22 than might otherwise have been the case?

23 **A.** Yes. And I think we go back to what I said yesterday

24 about HIV. When we identified HIV positive blood

25 donors, we said, "There is no treatment available at

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1 no treatment available, was putting an unnecessary

2 burden on them and, unlike HIV, there was no clear

3 evidence for easy spread to other people, in

4 particular sexual partners.

5 But I still struggle with that because I am sure

6 that in 1991, when we started screening blood

7 donations for hepatitis C, I mean we knew there was no

8 treatment available and we told our donors that, but

9 we did say to them that there is one thing you could

10 do which might be of help, because this could cause

11 you problems in the future and we would advise you to

12 limit your alcohol intake because that could be

13 a factor in making liver disease more likely or worse.

14 So there was something that could have been

15 offered. I know it is quite a burden to people to

16 tell them you have got this infection, there is no

17 treatment for it and, actually, you have to give up

18 alcohol, but there was something that could have been

19 done to try and minimise the effect, and I don't see

20 that in the discussions, and I see there were a lot of

21 discussions about the burden of seeking people out and

22 telling them they were infected.

23 **Q.** Can I explore with you for your comment, really, what

24 might be said to be three reasons, and I'm not

25 suggesting this is exhaustive, as to why people -- it

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1 the moment but unless you are known about at

2 a specialist centre, possibly" -- and in 1991 it might

3 have been very different with the arrangements for

4 liver disease -- "but when treatments do become

5 available, then you will be in a position to be

6 offered them."

7 **SIR BRIAN LANGSTAFF:** It goes wider than that too, doesn't

8 it, because from what we understand there is at least

9 a theoretical, something like 5%, chance of passing on

10 the hepatitis C infection to somebody else by sex?

11 **A.** Yes. And I think, certainly in 1991, it was very

12 uncertain what that risk was. I think it was

13 recognised that the risk was probably much less than

14 for HIV. And I think for HIV the risk of sexual

15 transmission was known to be much higher and that was

16 an added reason to seek people out, whereas for

17 hepatitis C I think the argument was made: well, there

18 probably isn't as big a risk, so we don't need to

19 worry about that.

20 **SIR BRIAN LANGSTAFF:** Well, that is equivalent to knowing

21 of a risk and choosing to ignore it.

22 **A.** And I would agree. And there was also -- it was

23 certainly not known at that stage the risk of a mother

24 passing it on to her baby. It just wasn't known.

25 I mean, later it became known that that was very low

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1 unless there was co-infection with HIV but at that
 2 time we didn't know.
 3 **SIR BRIAN LANGSTAFF:** You start off with the thesis it is
 4 blood-borne.
 5 **A.** Yes.
 6 **SIR BRIAN LANGSTAFF:** And so there is a risk of contact
 7 between the blood of infected person and an open wound
 8 or sore or, for that matter, the child in childbirth
 9 in the usual way that there can be --
 10 **A.** Yes.
 11 **SIR BRIAN LANGSTAFF:** -- of blood contact. So for all
 12 those reasons, those are all additional reasons why
 13 someone might be told, are they not?
 14 **A.** I agree. I think there was a lot of concern that
 15 because those risks were believed to be much less than
 16 HIV, it was a different situation.
 17 **SIR BRIAN LANGSTAFF:** Yes.
 18 **MS RICHARDS:** So one of the observations you have made in
 19 your witness statement, Dr Hewitt -- and perhaps we
 20 will put it on screen.
 21 It is WITN3101006, page 108.
 22 This is about the potential impact of losing
 23 those 3.5/4 years. You say this in paragraph 294:
 24 "Thus, when HCV look-back was eventually
 25 mandated in early 1995, a further 3.5 years had

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1 the mandate to undertake the look-back?
 2 **A.** Yes, it is.
 3 **Q.** If we just look at the top of the page. You say,
 4 picking it up in the fourth line:
 5 "... we ..."
 6 And I think by that you mean the Blood Services?
 7 **A.** Yes.
 8 **Q.** "... had no mandate to carry out HCV lookback.
 9 Without a central directive from the Department of
 10 Health there was little prospect of persuading
 11 Consultant Haematologists in charge of hospital blood
 12 transfusion laboratories to divert their already
 13 hard-pressed resources into an activity which was not
 14 mandated, and not supported with additional
 15 resources."
 16 Is this right, in principle the Regional
 17 Transfusion Centres, Blood Services, could have
 18 undertaken their own look-back, as it were, as
 19 an autonomous decision on their part, but the
 20 difficulty with that that you have identified here
 21 would have been securing the engagement of the
 22 hospitals in the absence of essential direction from
 23 the Department of Health or Chief Medical Officer?
 24 **A.** Yes. I mean, it was the size of the work that would
 25 be required. It was very different from HIV -- which

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

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

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1 was mandated -- because there were small numbers with
 2 the HIV look-back. With the hepatitis C look-back, it
 3 was much, much bigger.
 4 I mean, the two hospitals which North London
 5 supplied which had -- which used the most blood
 6 components from North London, they each had over
 7 100 blood components to trace in the look-back. And
 8 a busy laboratory can't just add that to their normal
 9 workload without making some additional resources
 10 available.
 11 **Q.** And do you know what the funding position was in
 12 relation to the look-back, how it was funded?
 13 **A.** We in the Blood Service did not have any additional
 14 resources. We just had to get on with it and do it.
 15 Within the hospitals there were real problems. Some
 16 of the hospitals did need extra resources and it was
 17 difficult for them to get those additional resources.
 18 I mean, they managed it, and sometimes it was helpful
 19 that we sent sort of a supporting letter saying,
 20 "Look" -- you know, re-emphasising, "This is
 21 a mandate, it needs to be done". And they would apply
 22 to their medical director and say, "Can we get
 23 somebody seconded to help us with this?"
 24 **Q.** Now, if we just then pick up the decision-making in
 25 1994 into 1995 in relation to the decision ultimately

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

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

9 "Objective:

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

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

25 Can you recall how it came about that this

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

5 A. I suspect it's Dr Ala.

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

7 A. Yes, I think it was Dr Ala.

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

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

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

20 A. I think we have probably heard that, during the late
21 1980s and early 1990s, views started changing
22 significantly from the "it's not a very serious thing"
23 to "it is a serious thing". I can't account for the
24 wording. I think it was possibly put there to
25 emphasise to those who were still doubters that it was

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1 meeting was held?

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

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

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

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

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

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

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

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

22 A. I think it is the latter, yes.

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

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

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

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1 for considering the implications of an 'HCV Look-Back'
 2 Policy in its operational detail, and wished to refer
 3 the topic to the MSBT [so the Advisory Committee for
 4 the Microbiological Safety of Blood and Tissue] with
 5 a recommendation that such a policy is implemented."
 6 As I understand it, that's what was done.
 7 I know you were not on the MSBT but a recommendation
 8 was made to the MSBT?
 9 **A.** Yes.
 10 **Q.** Was any consideration given, as far as you can recall,
 11 to the possibility at this time of conducting or
 12 inviting the Department of Health to conduct some form
 13 of broader public health campaign? Because what was
 14 being recommended here was limited in scope because,
 15 like the HTLV-III look-back, it would bite only on
 16 donors who had come back after September 1991?
 17 **A.** It was a targeted look-back. I don't know whether
 18 there were any discussions, either within the blood
 19 service or within MSBT, about a wider public campaign.
 20 **Q.** I won't go to the MSBT decision but, for the benefit
 21 of the transcript, it is PRSE0003635,
 22 15 December 1994.
 23 Can I pick matters up in January 1995, when you
 24 were involved in discussions and planning about in
 25 practice how the look-back might be undertaken?

19

1 **A.** No, sorry. I think it was that the Blood Service
 2 would merely provide the information to the hospitals
 3 and leave it to them to get on and do whatever was
 4 necessary together with clinicians and GPs looking
 5 after the patients, in contrast to the second
 6 paragraph.
 7 **Q.** We see that first option was described as:
 8 "It was felt that this policy would not be
 9 effective in practice ..."
 10 Then (ii):
 11 "Trace implicated recipients through hospitals
 12 and GPs, interview and counsel surviving recipients;
 13 obtain and test a sample of blood from them; refer
 14 infected patients for specialised counselling,
 15 investigation and possible treatment by Hepatology
 16 Centres."
 17 That was the option that was favoured by the
 18 meeting?
 19 **A.** Yes. It does note it was not clear how the added
 20 costs would be defrayed.
 21 **Q.** Then if we go over the page, there was an estimate in
 22 relation to what the overall case load might be. Then
 23 the decision of the meeting, we can see in the last
 24 four lines:
 25 "The Meeting felt that there is a serious case

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

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

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

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

14 Anyway.

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

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

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

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

21

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

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

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

14 Q. And so what happened in those cases?

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

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

23 A. Yes, we dealt with many recipients.

24 Q. Because the GPs were reluctant to do so?

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

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

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

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

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

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

25 What happened in relation to that issue? First

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

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

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

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

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

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

16 You say here:

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

24

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

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

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

16 A. Yes.

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

21 A. I'm not sure.

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

25 A. Yes.

25

1 actually have been an enormous exercise, because you
2 would have -- I just can't get my head round how we
3 would have done it. To identify all the donors who
4 had attended indeed that year, and then interrogate
5 the records to see if they'd attended again after
6 1991, and then drawn up a list for each year of those
7 donors, and then identified whether there were
8 donation samples stored. And if there were, identify
9 which of the many thousands of plates that sample was
10 in, removing the plate from storage, thawing it,
11 identifying which of the 96 wells on the plate
12 belonged to that donation, taking the tiny sample of
13 plasma out of the plate into a tube and then putting
14 it through a HCV test.

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

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

22 A. It would have needed very significant resources.

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

27

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

5 A. I've been trying to go over in my head what would have
6 been involved. First of all, I think it is important
7 to explain that a sample is retained from every blood
8 donation for a period of time. And that sample is
9 microlitres of plasma which are removed from the
10 sample tube at the time of testing and then
11 transferred into what's called a microtiter plate,
12 which is a plastic plate with a number of wells,
13 96 wells, and each donation sample would go into one
14 well. And it would be microlitres of the sample. And
15 then when the 96 wells were full, it was frozen in
16 long-term storage.

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

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

26

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

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

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

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

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1 Q. So it would have involved some form of interrogation
2 of records rather than a simple computer --
3 A. Yes. And many of the records were not on computer
4 because we are talking about the 1980s and they were
5 paper records.
6 Q. So, again, would it be right to understand that it
7 might have been possible to do something but it would
8 have required additional resourcing, significant
9 additional --
10 A. I would say very significant additional resources.
11 Q. Can we then just look at a later letter from you to
12 Dr Robinson in March of 1995.
13 NHBT0096456, please.
14 We can see that you say to Dr Robinson here:
15 "I visited our two largest users of blood/blood
16 components and have discussed with the Consultant
17 Haematologists and the chief MLSOs the procedure for
18 the HCV look-back.
19 "Look-back will create significant demand on
20 hard pressed resources at hospitals."
21 Then it would appear that those hospitals had
22 asked you to pass on two major concerns. One was the
23 problem in relation to records and the need for staff
24 to be involved manually in working through records.
25 Is that how we understand the paragraph beginning

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1 3 April 1995, from the Chief Medical Officer,
2 Dr Calman, sending this letter to doctors:
3 "... to inform [them] of the guidance and
4 procedures for the look back exercise announced by Tom
5 Sackville, Parliamentary Secretary for Health, on
6 11 January 1995 ..."
7 Then if we go to the third page, I'm not going
8 to go through it, but this is the guidance that was
9 issued nationally as to how it should be undertaken,
10 is that right?
11 A. Yes.
12 Q. If we go to page 5, I just want to pick up what's said
13 here and then ask you about it by reference to
14 a letter from you. So under the heading "General
15 Principles of the Look Back", it says:
16 "The presumption will be that each identified
17 recipient would be counselled and tested. However, in
18 exceptional situations such as severe psychiatric
19 illness or terminal physical illness, the consultant
20 or GM may feel is inappropriate to add to the
21 patient's distress."
22 That was the Chief Medical Officer identifying
23 as an exceptional situation a circumstance in which
24 the recipient might not be told --
25 A. Yes.

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1 "Firstly"?
2 A. Yes.
3 Q. Then, secondly, is the problem you have already
4 identified in relation to obtaining patient case
5 notes, and then you say:
6 "[You] sympathise fully with the situation in
7 which the hospitals find themselves. The transfusion
8 staff will do their best, but this exercise is
9 dependent upon factors outside their (and our)
10 control."
11 This is obviously you reporting back your local
12 experience to Dr Robinson?
13 A. Yes.
14 Q. Do you know whether others who were performing the
15 same exercise in other areas were getting the same
16 feedback and experiencing the same difficulties?
17 A. I don't know for certain but there would have been --
18 I mean, the two hospitals named here were our biggest
19 users and were probably some of the biggest users in
20 England. But there would have been other hospitals
21 which would have been significantly affected in the
22 same way.
23 Q. The Chief Medical Officer's announcement of the
24 look-back, I'll just go to it for the sake of
25 completeness, NHBT0002737. We can see it is a letter,

30

1 Q. -- that they had been transfused with an implicated
2 donation, is that right?
3 A. Yes.
4 Q. Then can I then ask you to look at NHBT0015661. This
5 is a letter from you, September 1995, and it is
6 addressed to solicitors who were advising you, or
7 advising the National Blood Authority, and you have
8 said in the second paragraph this:
9 "During the course of the HCV look-back, we
10 (Consultants at the transfusion centres) on occasions
11 receive a view from a general practitioner that, in
12 the GP's opinion, a patient is unsuitable for
13 notification and counselling on the possibility of HCV
14 transmission from blood transfusion. In some cases,
15 this is because of dementia, general medical
16 condition, (terminal malignancy) or that the patient
17 would be emotionally unable to cope with the
18 information."
19 Next paragraph:
20 "In these cases I generally discuss the matter
21 with the GP and note that we have agreed that the
22 patient should not be notified and counselled. The
23 question has now been asked, 'from a medico-legal
24 point of view should the patient's next of kin be
25 informed?'"

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

4 **A.** Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

10 **A.** Yes.

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

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

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

22 **A.** In being emotionally unable to --

23 **Q.** -- and that's obviously --

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

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1 if you see what I mean?

2 **SIR BRIAN LANGSTAFF:** Yes.

3 **MS RICHARDS:** Then if we can look at NHBT0096432_002.

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

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

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

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

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

25 Then you say you may need to recruit additional

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1 help and that will have a cost implication.
 2 In practice, how did it pan out? Did you have
 3 to recruit additional staff?
 4 **A.** We didn't recruit additional staff. I had a very good
 5 small team of people who worked very hard to make sure
 6 that we could carry out the work, and we did.
 7 I don't -- I'm pretty sure we didn't recruit any
 8 additional staff.
 9 **Q.** And over what period of time, roughly, was this
 10 look-back exercise undertaken?
 11 **A.** I can't -- I can't actually say. I would say the bulk
 12 was done within a few months. But as I think you will
 13 have seen from some documents, information did not
 14 come back from the hospitals all at once, and some
 15 hospitals were -- took more time than others to return
 16 information to us. So it was over a period of time.
 17 I would have said within months.
 18 **Q.** Just one discrete issue. If you had a donor who had
 19 donated in 1991 and you were now -- you might have
 20 counselled them in 1991 as part of the implementation
 21 of the screening exercise, to what extent would
 22 they -- either then or when you were undertaking this
 23 look-back exercise -- would there have been an attempt
 24 to join the dots between different Regional
 25 Transfusion Centres? Would you have tried to find out

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1 "1. Continue Look-Back using the present
 2 strategy, but with central exhortation to speed up the
 3 process.
 4 "2. Abandon the Look-Back entirely and offer
 5 hepatitis C tests to anyone who has been transfused.
 6 "3. Continue with the Look-Back but offer
 7 assistance to overcome the bottlenecks due to problems
 8 in tracing hospitals records and a shortage of
 9 suitably trained counsellors.
 10 "4. The Committee considered these options, but
 11 unanimously concluded it was important to continue
 12 with the present strategy. This had been carefully
 13 designed to identify and offer counselling and
 14 treatment to recipients of blood transfusion units
 15 implicated in the Look-Back in a structured way that
 16 would maximise benefits to them."
 17 Then 5 says:
 18 "The Committee also agreed that delay in the
 19 identification process that might be extended for the
 20 rest of 1996 would not disadvantage patients as the
 21 evidence was of a 20-30 year time frame for the liver
 22 damage to occur."
 23 Can I ask for your thoughts on the options that
 24 were there identified, recognising that you weren't,
 25 at the time, involved in this decision-making process

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1 about, at the look-back stage, other transfusion
 2 centres at which a donor might have donated, to pass
 3 that information on? Or should that already have
 4 been --
 5 **A.** That would have already been done at the initial stage
 6 in 1991.
 7 **Q.** Can we then pick matters up at the beginning of 1996.
 8 PRSE0001490.
 9 This is a letter dated 12 January 1996 from
 10 Dr Rejman, I think, at the Department of Health:
 11 "To all members of MSBT and Hepatitis C
 12 Look-Back Working Party."
 13 Is this a letter that you'd have received at the
 14 time?
 15 **A.** No, because I wasn't a member of MSBT and I was not
 16 a member of the Hepatitis C Look-Back Working Party.
 17 **Q.** If I can just invite you in any event to look at
 18 what's set out here. It says:
 19 "At the recent MSBT meeting it was noted that
 20 the Look-Back had been slower in achieving its
 21 objectives than had been predicted. A number of
 22 options on the way forward were considered and I would
 23 be grateful if you could say whether you agree with
 24 our understanding of what these were before we submit
 25 these options to the Minister:

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1 or a member of MSBT.
 2 Option 2, "offer hepatitis C tests who anyone
 3 who [had] been transfused". Now that could have been
 4 done to some extent, could it not, not by the Regional
 5 Transfusion Centres, because you are not giving
 6 transfusions but as a national NHS Department of
 7 Health led initiative, would that be right?
 8 **A.** That is correct. And I don't know whether
 9 considerations were made into how that would happen.
 10 In theory, blood transfusion laboratories could
 11 produce lists of everybody who had been transfused at
 12 their hospital in a certain year then there would have
 13 been a need to check records to see how many of these
 14 people were still alive and where they were and then
 15 they would be contacted. Or the alternative is to do
 16 what was done in other countries and say -- make
 17 public health announcements and say: anybody who has
 18 had a blood transfusion should come forward to have a
 19 hepatitis C test. And I have pointed out that not
 20 everybody knows they have had a blood transfusion.
 21 And conversely, many people think they have had
 22 a blood transfusion who haven't.
 23 So that would also be imperfect. It would
 24 obviously identify some individuals who wouldn't have
 25 been identified in the look-back but not all either.

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

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

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

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

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1 Q. Do you think it would have made a practical difference
2 if there had been some form of mandate or
3 encouragement or warning, however it might have been
4 expressed, from the Department of Health or the Chief
5 Medical Officer?

6 A. I personally think that, in some cases, the issue is
7 that the consultant haematologist was experiencing was
8 not supported by the -- I don't know, by the medical
9 director or the board, and so extra resources were
10 just not made available. And I think if something had
11 gone from the Department to chief executives it might
12 have moved the issue up the agenda.

13 Q. Understood. Can I then just ask you about a document
14 at NHBT0004632, May 1998. It is a letter from
15 Dr Flanagan in his capacity as chair of SACTTI to
16 National Medical Directors in relation to "HCV
17 Infections probably acquired by Transfusion", and it
18 says:

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

25 It records the issue having been brought to the

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1 case or was aware of that case and, if they were not,
2 then it was possibly a case which had not been
3 identified through look-back and, therefore, it would
4 be of relevance for that to be known to the blood
5 service.

6 Q. Then if we look at the third paragraph, it refers to
7 a paper that had been tabled at a SACTTI meeting and
8 it says:

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

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

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

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

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

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

9 Then various details are set out. Can you first
10 of all help us to understand what the issue was that
11 was being addressed here and then how it was tackled?

12 A. So the first thing I need to say is I really can't
13 remember very much about this but I can see from the
14 first paragraph that this related to hepatitis C was
15 a notifiable infection. So when a case of hepatitis C
16 was identified, it was reported to the Public Health
17 Laboratory Service. And very often the information
18 would include the possible source of infection,
19 because local public health teams would investigate
20 a case.

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

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1 be thought to be a particularly problematic period for
2 the National Blood Transfusion Service because of the
3 product liability issues that were under consideration
4 in the litigation?

5 A. Sorry, yes, because there will probably be people who
6 are not aware what -- of the significance of that.
7 The consumer product liability, Consumer Protection
8 Act, has a ten-year limitation so that a claim can be
9 brought under product liability. Sorry, I'm not --
10 I shouldn't be -- ten years, up to ten years after the
11 date that the product was put into circulation.

12 And the hepatitis C litigation was under the
13 Consumer Protection Act and it was evident that, the
14 precedent having been set, a person who had been
15 infected within that ten-year period could bring
16 a claim under the product liability legislation and
17 I think -- and, as I say, I have very little memory of
18 this, this was an attempt to make sure that
19 individuals who fell in that category were identified
20 and knew that there was a possibility that they could
21 bring a claim.

22 Q. It tells us it is going to be coordinated through
23 CDSC. Do you recall now what role the Regional
24 Transfusion Centres had or what, if any, role you had?

25 A. Well, from this letter it appears that the

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

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

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

15 **A.** Yes, Mike Busch was in San Francisco.

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

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

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

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

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

9 **A.** Yes.

10 **Q.** Better use of blood --

11 **A.** Yes.

12 **Q.** -- essentially.

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

21 **A.** Yes.

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

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

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

23 Is there anything there you disagree with?

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

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

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

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

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

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

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

52

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

6 **A.** Yes.

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

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

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

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

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1 "Do Patients Know They Have Been Transfused?"
 2 "Patients continue to express concern about
 3 receiving a blood transfusion, despite transfusion in
 4 the UK being safer now than ever before. However, not
 5 all patients who have been transfused are aware of
 6 this fact. We determined the proportion of patients
 7 who were aware of their transfusion and showed how
 8 awareness has changed with time."

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

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

22 Next paragraph:

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

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

55

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

9 **A.** I don't recall that.

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

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

16 (11.16 am)

17 (A short break)

18 (11.45 am)

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

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1 last few lines of the article:

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

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

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

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

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

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1 general principle?

2 **A.** Yes.

3 **Q.** Now, obviously, transfusions may be required

4 unexpectedly in emergency cases where a patient has

5 been in a road traffic accident and you can't seek

6 consent and you may need to use transfusion in order

7 to save life but, in those circumstances, would it be

8 good practice to ensure that the patient is informed

9 at an appropriate stage, assuming they recover, that

10 they have received a transfusion?

11 **A.** I agree that would be good practice.

12 **Q.** Then, can I ask you to look at one other document,

13 DHSC0006783_027. So this is a patient information

14 leaflet about receiving a blood transfusion. If we go

15 to the last page, it looks from this as though it

16 might have been produced by the Blood Service. Do you

17 know whether that's the case or not?

18 **A.** Yes, it was produced by the Blood Service to be used

19 in hospitals but it was felt that if the Blood Service

20 produced it there was somebody -- there was a central

21 organisation producing it and then providing it to all

22 the hospitals for use on patients, rather than having

23 hospitals design their own leaflets which, of course,

24 often happens within the Health Service.

25 **Q.** I'm not sure what the date is of this. If we look

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1 Then there is information about the safety of

2 transfusions. If we go on to the next page, we can

3 see there is reference to hepatitis B, C, HIV and, in

4 the second paragraph, a reference to vCJD?

5 **A.** Yes.

6 **Q.** So would it be again right to understand that this was

7 an attempt to try and ensure that patients were given

8 some of the basic information both about whether

9 a transfusion was required or not and about what the

10 risks were that were involved in it?

11 **A.** Yes, and I should point out this was an initiative by

12 the National Blood Transfusion Committee and the

13 National Blood Service, I think, then took on the task

14 of producing the leaflet.

15 **Q.** Do you recall whether this was a new initiative?

16 **A.** It was a new initiative.

17 **Q.** Is there any reason why it couldn't have been done

18 years earlier?

19 **A.** Probably not.

20 **Q.** I'm going to turn then to a different topic,

21 Dr Hewitt, and ask you about your involvement with the

22 Skipton Fund.

23 I think you are aware that Mark Mildred gave

24 evidence to the Inquiry --

25 **A.** Yes.

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1 down the bottom of the page, it says:

2 "This patient information leaflet was approved

3 by the Chief Medical Officer's National Blood

4 Transfusion Committee. Planned review date 2005."

5 Does that help understand roughly when --

6 **A.** It was clearly before 2005 but I don't know whether it

7 was 2004, 2003.

8 **Q.** But it's that kind of magnitude?

9 **SIR BRIAN LANGSTAFF:** It might look, from the very bottom,

10 the "/04" on the left-hand side and on the right-hand

11 side, that code seems to indicate 2004.

12 **MS RICHARDS:** Yes, it might well do.

13 **SIR BRIAN LANGSTAFF:** Probably the start of 2004, if it is

14 "1/04" or "2/04".

15 **MS RICHARDS:** If we then go to the second page. We can

16 see it explains in the first paragraph that blood

17 transfusion should only be used when really necessary.

18 It talks about asking the doctor to explain why you

19 need a transfusion. If we go to the next page, there

20 is a heading "Alternatives to ... transfusion":

21 "It is important that a blood transfusion is

22 given only when there is no alternative."

23 The last sentence of that paragraph:

24 "You may want to ask your doctor if these

25 [that's other methods] are possible in your case."

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1 **Q.** -- and you read or watched his evidence?

2 **A.** Yes.

3 **Q.** I'm not going to go through a lot of the details about

4 the mechanics or the documents, I just want to ask you

5 some broader issues about your involvement. So you

6 were appointed to the Skipton appeal panel in early

7 2007?

8 **A.** Yes.

9 **Q.** You had, by that time, provided to the Skipton Fund

10 administrator a letter of advice about anti-D

11 immunoglobulin?

12 **A.** Yes.

13 **Q.** I'm not going to put it up on screen, but for the

14 transcript, it is SKIP0000031_071. Then I think at

15 a later stage in 2010, you provided jointly with

16 Dr Dash(?), is it --

17 **A.** Dr Dash, yes.

18 **Q.** -- a further advice about intramuscular gamma globulin

19 including anti-D. Again, the reference for the

20 transcript is SKIP0000031_070.

21 I'm not going to be asking you about the

22 substantive content of that but just a question of

23 process really. Did you end up sitting on appeals

24 involving anti-D cases?

25 **A.** Some of the appeals that came to the appeal panel did

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1 involve anti-D cases, yes.

2 **Q.** Was there any consideration for the fact that you

3 might be thought to be marking your own homework, in

4 some respect?

5 **A.** The first occasion when I provided information to the

6 Skipton Fund was before I was appointed to the appeal

7 panel, and that was as an expert within NHSBT.

8 So you asked me about appeals involving anti-D.

9 I have always acted in my capacity in the appeals

10 panel without any influence about my employment with

11 NHSBT. They are two completely separate issues and

12 although I have information and knowledge from my role

13 within NHSBT, I did not let that influence my work on

14 the appeal panel.

15 **Q.** Do you know whether applicants would have been given

16 copies of those letters? We know the Skipton Fund

17 relied quite heavily on the advice that you produced

18 in their first stage decision-making, before any

19 question of it getting to an appeal panel. Do you

20 know whether your advices were routinely provided to

21 applicants?

22 **A.** I believe not. The second communication, which was

23 produced jointly with Dr Dash, who was the medical

24 director of BPL, was -- arose out of my concern that

25 women were being advised by -- generally by

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1 that information to be provided to individuals who had

2 made an application to the Skipton of the EIBSS on the

3 basis of intramuscular anti-D, but I can't confirm

4 whether that has always been the case.

5 **Q.** Then just on a point of detail. On those occasions,

6 and it might well be rare occasions, where there were

7 records which gave details of the batches that had

8 been used in an individual's treatment, would it be

9 possible for you to tell from those records, in

10 principle, if it was a BPL product or not, or was that

11 something you couldn't --

12 **A.** I could, and it is important to say that the routine

13 treatment provided in the UK is NHS-produced, either

14 BPL or from the Scottish equivalent. There were

15 a very small number of cases where intravenous anti-D

16 was used for women, generally not -- sometimes after

17 childbirth, where a large dose of anti-D was required

18 which couldn't conveniently be given by numerous

19 intramuscular injections. And that was provided using

20 an intravenous product that was imported from the

21 Irish Blood Transfusion Service, where intravenous

22 anti-D was the routine method of administering anti-D.

23 And because it did not have product licence in

24 the UK, it was imported for use on a named patient

25 basis. So there was a very small stock kept within

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1 hepatologists, women with hepatitis C were being

2 advised that intramuscular anti-D was the likely

3 source of their infection. And appeals were being

4 made on the basis that they had been advised that by

5 their hepatologists so it must be right. And I was

6 concerned that these women were being given incorrect

7 information and misled and given unrealistic

8 expectations about the source of their hepatitis C

9 infection.

10 And I think it arose because a professor of

11 hepatology had written to the Fund to say something to

12 the effect of: what is the situation with anti-D? And

13 that was passed to me and I asked Dr Dash to help me

14 to produce something which could be provided in

15 response to that enquiry as to why intramuscular

16 anti-D was not considered to be a risk for hepatitis C

17 transmission.

18 So, if you like, that was offered to the Fund to

19 say: look, this is how -- you have had this enquiry

20 from the hepatologist, here's the information.

21 And I hoped that that would then be disseminated

22 amongst hepatologists, to try to increase the

23 awareness about where the risk was, which was with

24 intravenous anti-D.

25 Subsequently I think that moves were made for

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1 England, and that was kept at the Colindale Blood

2 Centre. And when it was required for these very small

3 number of cases, which might be a woman after

4 childbirth where there had been a very large exposure

5 to Rh positive red cells or a woman who had been

6 inadvertently transfused inappropriately with

7 Rh positive blood when she was Rh negative, then that

8 product would be requested on a named patient basis,

9 and it would be issued from the Colindale centre with

10 the name and the hospital -- the name of the patient

11 and the hospital recorded in the central record.

12 When it became clear that the Irish product had

13 transmitted hepatitis C, the Irish Service carried out

14 a look-back, which included notifying all the

15 organisations which had received the batches of

16 intravenous anti-D. So a look-back exercise was

17 carried out within the English Service for those named

18 patients who had received the intravenous product.

19 **Q.** Then just more broadly in relation to the way in which

20 decisions were taken by the Skipton appeal panel,

21 there was no oral hearing -- and that wasn't by choice

22 of the panel, that was the way in which it was set up.

23 **A.** Yes.

24 **Q.** Do you recall whether that was a matter of concern to

25 you and your colleagues on the panel?

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

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

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

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

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

22 A. Yes.

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

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

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

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

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

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

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

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

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1 infection was a transfusion?

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

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

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

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1 transfusion. And then there will inevitably be cases
 2 that fall in the middle of that. And I have to say
 3 that I think that the balance -- the panel usually
 4 leans on -- sorry, the panel makes decisions by
 5 consensus and there's always -- I have to say, the
 6 medical experts nearly always agree. But in cases
 7 where the balance of probabilities is around 50% or
 8 there's a bit of dissension between the members, we
 9 would generally err on the side of the claimant.
 10 **Q.** And if you have -- and this is, I think, a scenario
 11 that was explored by Mr Mildred. If you have
 12 hypothetically a case in which you might be aware that
 13 the appellant underwent a procedure for which there
 14 might be a -- 1 in 5 people undergoing that procedure
 15 might have a transfusion, 4 out of 5 would not, no
 16 records, nothing else to assist you in determining
 17 whether there was, as a matter of fact, a transfusion
 18 in the individual case, my understanding of the
 19 evidence that Mr Mildred gave was that in such a case
 20 that wouldn't then be enough to satisfy the balance of
 21 probabilities, is that right?
 22 **A.** I think that is correct, yes.
 23 **Q.** Even though it would be -- if one in five people get
 24 a transfusion for that procedure, it is perfectly
 25 plausible that the individual could have had

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1 that would be taken into consideration in the
 2 decision.
 3 **SIR BRIAN LANGSTAFF:** I'm not sure I follow that exchange.
 4 I mean, either the absence of other cause is taken
 5 into account and does make a difference or it doesn't.
 6 And the example which counsel was putting to you, if
 7 I can put it this way, suppose that there is a 1 in 3
 8 chance that this particular operation -- let's say
 9 a 1 in 4 chance that this particular operation would
 10 require a transfusion. So it is quite plausible that
 11 it might have done. On the other hand, if that's all
 12 the information you have, it is three times more
 13 likely that there wasn't a transfusion. But then the
 14 claimant says, "I believe I had a transfusion", and
 15 sets out reasons for the belief. And adds, "And
 16 there's no other reason that I can think of why
 17 I might have had hepatitis C. I haven't had any
 18 injections, any needles, I haven't had my ears
 19 pierced, I haven't had any intravenous drugs", etc.
 20 If you had, let us suppose, a set of statistics
 21 which were able to show -- I don't know if there are
 22 such statistics -- that -- of the reasons that people
 23 give for having had hepatitis C -- this goes back to
 24 your donor example -- but suppose that you had more
 25 than -- say, 1 in 5 couldn't give you a proper reason

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1 a transfusion?
 2 **A.** Yes.
 3 **Q.** Therefore, in those kind of cases, the absence of
 4 records effectively is going to lead to the individual
 5 not receiving a payment from the Skipton Fund?
 6 **A.** Yes.
 7 **Q.** What role in the Skipton appeal panel's
 8 decision-making does the absence of other risk
 9 factors, the absence of other plausible explanations
 10 for hepatitis C transmission play? If you have
 11 someone in whom there is no evidence of intravenous
 12 drug use, they have no tattoos, there is no obvious
 13 other explanation, how does that weigh in the balance?
 14 **A.** Generally not. And I have talked to a lot of
 15 blood donors who are infected with hepatitis C, and in
 16 a large proportion there is no identified risk for the
 17 hepatitis C infection. It must have come from
 18 somewhere but we can't identify where it came from.
 19 In exactly the same way, individuals who have no
 20 identified risk other than a blood transfusion may
 21 have acquired it in another way that we don't know
 22 about. So the fact that they have no other identified
 23 risk doesn't mean there isn't any other risk. But, of
 24 course, if there is no other identified risk and there
 25 is a situation where transfusion is plausible, then

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1 why they had hepatitis C, they don't know where it
 2 came from. Most of them probably hadn't thought where
 3 it could have come from, any source. But there has to
 4 be a source somewhere?
 5 **A.** Yes, I think I said that.
 6 **SIR BRIAN LANGSTAFF:** So, in that case, are you going to
 7 say: well, this person -- it is not likely -- more
 8 likely than not that this person, who has no other
 9 source but a plausible transfusion, who could simply
 10 have got hepatitis C from somewhere unknown, but more
 11 likely got it from a source, and there is no source
 12 but the transfusion, do you say in the balance of
 13 probabilities that would be a case for -- what? What
 14 would be the result?
 15 **A.** I thought the question I was being asked was where
 16 there wasn't any evidence that there had been
 17 a transfusion.
 18 **SIR BRIAN LANGSTAFF:** I think it is, but the evidence is
 19 here that there is an operation or some procedure
 20 which normally could involve a transfusion but it is
 21 more likely not to.
 22 **A.** Yes.
 23 **SIR BRIAN LANGSTAFF:** That's the hypothesis.
 24 **A.** Yes. And in that case the panel would try to obtain
 25 more information about why -- what was the situation

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

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

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

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

21 **A.** Both.

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

25 **A.** Exactly.

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

7 **SIR BRIAN LANGSTAFF:** Thank you very much.

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

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

14 **A.** Exactly.

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

18 **A.** Exactly.

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

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

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

7 **A.** Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 A. Yes.

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

16 A. Yes.

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

20 A. Yes.

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

25 A. No.

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

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

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

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

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1 Q. So it operates effectively in the same way?

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

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

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

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

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

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

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

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

21 So vCJD is a prion disease?

22 A. Yes.

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

25 A. Yes.

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

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1 Blood and Tissues, SACTTI, they have all had some role
 2 to play at times. But there are some specific CJD
 3 bodies?
 4 A. Yes.
 5 Q. There is the National CJD Research and Surveillance
 6 Unit, that's, I think, its current title, based in
 7 Edinburgh?
 8 A. Yes.
 9 Q. Then there is a committee called SEAC?
 10 A. Yes.
 11 Q. So that is the Spongiform Encephalopathy Advisory
 12 Committee, have I got that right?
 13 A. Yes.
 14 Q. Then there is the CJD Incidents Panel --
 15 A. Yes.
 16 Q. -- and you were a member of the CJD Incidents Panel
 17 for a number of years?
 18 A. Yes, I was.
 19 Q. Now, I think your witness statement tells us that the
 20 presence of the variant with a different clinical and
 21 pathological picture from sporadic CJD was recognised
 22 in 1995?
 23 A. Yes.
 24 Q. You have referred to a description of the first cases
 25 of vCJD being written up and published in The Lancet

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

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

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1 meeting on 16 April 1996 at which you were present.
 2 So we will just pick that up, it is NHBT0000088_013,
 3 please, Paul.
 4 So we have got the date, 16 April 1996, we can
 5 see you were in attendance and the discussion about
 6 vCJD is on page 6:
 7 "Implications of a Possible [CJD] Variant for
 8 the UK Transfusion Services."
 9 Then it refers to the *ad hoc* meeting on 9 April:
 10 "This was in recognition of a change in
 11 perception of CJD as potentially infectious until
 12 otherwise proven. It was recognised that one
 13 difficulty is that there is limited information
 14 available from animal experiments in relation to the
 15 ability of prion transmission by transfusion. In
 16 particular the absence of information of transmission
 17 of BSE by blood between cattle was a cause for
 18 concern."
 19 Then there is a reference to concrete
 20 information being difficult to come by:
 21 "It was agreed that the first priority at this
 22 stage was to improve the level of knowledge so that
 23 appropriate decisions could then be made regarding
 24 donor selection, handling of blood components, etc.
 25 The following actions were agreed ..."

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1 "... and the minister are now keen to go down
 2 this route. Jeremy has been Peter Flanagan's notes of
 3 the Edinburgh meeting and is anxious for us to follow
 4 through with a proposal for a 'limited'
 5 CJD Lookback ... it was Jeremy's suggestion that any
 6 proposal (where the recipients will not be informed)
 7 needed to be submitted for Ethical Approval and legal
 8 advice."
 9 That is the issue we will come back on. That is
 10 the source of your understanding that it had
 11 essentially been a requirement of the Department of
 12 Health that ethical approval committee be sought?
 13 A. Absolutely, yes.
 14 Q. This then translated into the Transfusion Medicine
 15 Epidemiology Review, which I'm going to call TMER
 16 because it's less of a mouthful.
 17 A. Everybody calls it TMER, yes.
 18 Q. Am I right in understanding that is still ongoing in
 19 some form?
 20 A. Yes.
 21 Q. Is it now under the auspices of the Surveillance unit
 22 in Edinburgh, or don't you know?
 23 A. So when it was set up it covered all types of CJD.
 24 And, subsequently, when evidence arose that variant
 25 CJD had been transmitted through blood, that was

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1 Then we have a series of points of agreement of
 2 which the only one I'm really going to ask you about
 3 is the first:
 4 "Dr Robinson will ask MSBT for approval to do
 5 look-back on recipients of blood donations from donors
 6 who had subsequently developed CJD."
 7 That was a task which you then became involved
 8 with?
 9 A. Yes.
 10 Q. If we go to NHBT0008485, we will see that on
 11 22 April 1996, Dr Robinson wrote to you in relation to
 12 this issue and, if we pick it up in the second
 13 paragraph, it says:
 14 "... I am formally asking you if, together with
 15 Jack Gillon, you could start drafting a proposal for
 16 a CJD Lookback study prepared in a format that could
 17 be submitted to an ethical committee and also to
 18 obtain legal advice from Stephen Janisch with regard
 19 to not informing recipients, but only exchanging data
 20 with the CJD Surveillance Unit."
 21 I will come onto the ethical matters in a few
 22 minutes.
 23 There's then reference to looking as those the
 24 MSBT, Jeremy Metters, so that's the Deputy Chief
 25 Medical Officer:

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1 removed from doing the research study because it
 2 became a public health issue, but the TMER still
 3 exists for sporadic and familial CJD.
 4 Q. Then in relation to TMER, you have said in your
 5 statement, its main aim is to try and establish
 6 whether there was any link between vCJD and blood
 7 transfusion.
 8 A. That is correct.
 9 Q. It wasn't designed to investigate links with
 10 fractionated plasma products, why was that?
 11 A. Because that's not what we were asked to investigate.
 12 Q. It also included within it looking at sporadic CJD?
 13 A. And familial.
 14 Q. Then you have told us in your statement -- and again
 15 I'm going to try and summarise them with your
 16 assistance, try and get an understanding of what was
 17 being done in relatively lay person's terms -- you
 18 have told us in your statement that the first and most
 19 direct aim of the TMER was to establish whether
 20 individuals diagnosed with CJD had acted as blood
 21 donors and, if so, to trace the donations and identify
 22 the fate of the blood components through to their
 23 final destination, is that accurate?
 24 A. Yes.
 25 Q. So cases of vCJD, all cases of vCJD, would be reported

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1 to the TMER by the Surveillance Unit?

2 **A.** To the Blood Services by the Surveillance Unit, yes.

3 **Q.** In relation to sporadic CJD, it was a more limited

4 category of cases that were reported, I think, only

5 where relatives or next of kin knew that they had been

6 a blood donor?

7 **A.** Yes, because there are a larger number of cases of

8 sporadic CJD.

9 **Q.** Then, as I understand it, if blood components from the

10 donor were recorded as transfused, that would be

11 notified to the blood centre?

12 **A.** Through a look-back process with the hospital, yes.

13 **Q.** Then the identity of the recipient, where that could

14 be established, would be forwarded to the surveillance

15 unit for what you have described, or what the

16 documents describe, as "passive surveillance

17 purposes". We will obviously ask the Surveillance

18 Unit in due course. But what, again, in basic terms

19 does that mean?

20 **A.** That means that the names were checked against the

21 surveillance unit's register of cases of CJD and

22 continued to be checked at intervals in case a case

23 developed in the future. And, secondly, that if and

24 when the individual who had been identified died, but

25 a copy of the death certificate was passed to the

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1 components had been transfused and then to identify

2 the donors who had provided those. So this was

3 dependent on information about the person who

4 developed variant CJD and having received a blood

5 transfusion, information about which hospital the

6 transfusion had taken place, because there is no

7 database of people who have received a blood

8 transfusion.

9 The Blood Service would need to ask the hospital

10 concerned: is there a record of transfusion for this

11 person, can you give us the detail so we can now trace

12 the donors?

13 **Q.** You have described, I think, in your statement that it

14 effectively acted as a double check --

15 **A.** Yes.

16 **Q.** -- and, as a matter of fact, no cases were identified

17 through the R-TMER process that had not already been

18 identified in the look-back arm?

19 **A.** Exactly, which gave us confidence that it was working.

20 **Q.** Now, there were a number of ethical issues or

21 dimensions to this, hence the requirement for ethical

22 approval from a local ethical research committee.

23 One issue of concern was the question of

24 confidentiality and you have described in your

25 statement the use of control cases. Again, could you

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1 Surveillance Unit, so they could examine the

2 information on the death certificate, and use that.

3 But there was no active surveillance, no way of

4 saying -- no way of following what happened to the

5 patient this year, next year, the following year.

6 **Q.** So that was the first part of the study, the more

7 conventional look-back arm?

8 **A.** Yes.

9 **Q.** I will come onto the question of notification or

10 non-notification of recipients in a minute. Then your

11 statement tells us that the second part of the TMER

12 study was a reverse TMER, so it is known as the R-TMER

13 part of it.

14 Can you just again explain in fairly simple

15 terms, if you can, how that worked?

16 **A.** So, this was the opposite and this is exactly the same

17 thing when the Blood Service is informed, here is

18 a patient who has developed something which could have

19 been transmitted by blood transfusion, could you

20 investigate the donors? So it was work we did with

21 other infections.

22 So the starting point was a patient with CJD who

23 had a history of blood transfusion, and then it would

24 be a case for the Blood Service to identify -- to ask

25 the hospital concerned to identify what blood or blood

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1 just help us understand how that worked?

2 **A.** Yes. I had not appreciated, actually, before I had

3 reviewed all the papers, that there had been

4 a concern -- I knew there was a concern at the

5 Department of Health about it becoming widely known

6 that vCJD might be associated with blood transfusion

7 and I remember that we were asked not to include

8 anything about CJD in the title of the study, which is

9 why it has such a, you know, bland title.

10 And I understand from what I have seen since

11 that there were real concerns that if the Blood

12 Service informed a hospital about a blood component

13 that they wanted to trace, and the knowledge that this

14 was in relation to variant CJD, that that might cause

15 a lot of alarm and might lead to the individual who

16 had received that blood component being given that

17 information when the ethical advice was not to do

18 that.

19 And there were a variety of strategies, I think,

20 being considered and, in conjunction with the

21 Surveillance Unit, we agreed that the best way would

22 be to include in the study not just the cases we knew

23 of variant CJD but control cases who were patients

24 with other diagnosis who had been blood donors, whose

25 blood had been issued to hospitals, and when we issued

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

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

13 **A.** Yes.

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

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

24 **A.** Yes, that is correct.

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

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

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

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

12 Then page 7 sets out the proposal:
 13 "... no evidence that CJD, in either its
 14 classical or new variant forms, is transmitted by
 15 blood transfusion. Nevertheless, information in
 16 relation to the potential transmissibility of CJD by
 17 blood transfusion is very limited. The absence of
 18 information severely restricts ability of the
 19 transfusion services to provide definitive reassurance
 20 of the new variant form of CJD does not possess
 21 a threat to the blood supply. Furthermore, further
 22 definition of donors who might be at risk of
 23 developing CJD is required."

24 And so on.

25 And so the purpose was to try to establish

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1 I understand it?

2 **A.** Yes.

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

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

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

15 **A.** Yes.

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

19 **A.** Yes.

20 **Q.** If we just look at the documentation in relation to
 21 the proposal submitted to the Lothian Ethical Research
 22 Committee and the grant of ethical approval, it is
 23 NHBTO008903, please.

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

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

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

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

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

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

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

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

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

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1 "4. There is no intervention which can be
2 offered to individuals detected to be at risk of
3 developing disease, or to those who have already
4 developed symptomatic disease.
5 "For all the above reasons, it is considered
6 unethical to notify any individual who has received
7 blood from a donor who subsequently developed CJD."
8 Then if we go over the page. The second
9 paragraph says:
10 "It should be noted that should there be any
11 change in the capacity to diagnose the disease, or if
12 any intervention becomes available in the future, then
13 the transfusion services should have in place
14 a mechanism for contacting the identified recipients."
15 So the proposal when it started was
16 non-notification of recipients, but there was
17 a recognition that the situation might change?
18 A. Yes. And I think number 1 should have been: there is
19 no evidence that there is transmission through blood
20 transfusion. And that should have been included in
21 the -- a proviso: if information becomes available
22 which suggests that it has been transmitted through
23 blood transfusion, that would be a very significant
24 reason for changing from non-notification.
25 Q. And then if we can just look at the next page. Bottom

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1 witnesses as well. This is a reflection of the
2 precautionary principle, which I think really became
3 prominent after the Phillips Inquiry into BSE.
4 Q. Then if we go to page 15 of this document, this is, as
5 a matter of formality, the grant of ethical approval,
6 on 6 January 1997, by the Lothian Ethical Research
7 Committee.
8 Now, in 1999 you then sought further ethical
9 advice, first of all from Professor Kennedy and then
10 from Professor Len Doyal.
11 A. Yes.
12 Q. We will look at the correspondence in a moment but
13 what had changed that led you to want to get further
14 advice on the question of notification?
15 A. So there were over the years between 1996 and 1999
16 a variety of discussions, predominantly within the CJD
17 Incident Panel, about risk assessments which were
18 being carried out in relation to: what is the risk
19 that variant CJD could be transmitted through blood or
20 blood components?
21 And the early risk assessments did not really
22 lead to many believing that the risk was such that
23 individuals who we were identifying in the TMER should
24 be informed that they had been put at risk. I think
25 over that period the risk assessments changed, but

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1 paragraph. There is a heading:
2 "Exclusion of donors considered at refuse of
3 developing CJD.
4 "The transfusion services must exercise a high
5 level of suspicion about possible transmissibility of
6 CJD by blood and err on the side of caution in
7 deciding whether to accept donations from individuals
8 believed to be at refuse of developing CJD. To wait
9 until a causal connection is established on
10 a scientific basis may not be regarded as acting with
11 reasonable care. Thus, decisions about selection of
12 donors must not be delayed pending results of the
13 limited look-back but must be taken in the light of
14 current knowledge and guidelines."
15 Now, it could be said that's a very different
16 approach to the approach taken, for example, in
17 the 1980s in relation to HIV, where -- and I am sure
18 you are familiar from your knowledge of events, Dr
19 Hewitt -- issues about no conclusive proof, no causal
20 connection, no evidence, etc, feature large in the
21 story of what was -- decisions there.
22 This appears to propose a different approach,
23 which is essentially the opposite: to err on the side
24 of caution until the contrary is proved.
25 A. And I think this has been mentioned by earlier

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1 I think one of -- one of the main reasons was that we
2 in the Blood Services were trying to adopt the
3 precautionary principle. And we were saying: we are
4 identifying people who we know have developed -- who
5 have received blood components from individuals who
6 later developed variant CJD. We don't have the
7 evidence that it is transmitted through transfusion
8 but we would not want any of those individuals to
9 become blood donors themselves, because we would not
10 want that blood to go into the blood supply.
11 And it was -- that was the Blood Service's
12 stance on that. But no decision had been made about
13 notification of these recipients. So if they didn't
14 know, how could they not become blood donors? Now,
15 admittedly, many of them would not have been eligible
16 to be blood donors, but some of them would have been.
17 So the Blood Services said: a decision hasn't been
18 made but we are going to do something to make sure
19 that if any of those individuals donated blood, it
20 would not be used. And it was quite a complex thing
21 to do but that's what we did.
22 Q. This is the flagging -- (overspeaking) --
23 A. This is the flagging.
24 Q. -- is that right?
25 A. So this is, basically, even though they were not blood

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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?

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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

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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

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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."

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1 Then, if he is unable to, you ask if he can
2 suggest the name of another expert.
3 Now, I don't think we have anything that
4 suggests Professor Kennedy did give advice again on
5 this second occasion?
6 **A.** No. And I apologise for the fact that documentation
7 isn't there --
8 **Q.** Don't worry.
9 **A.** -- but you are probably going to go on to ...
10 **Q.** Yes.
11 So you -- whatever the response from
12 Professor Kennedy was, and it may have been
13 a telephone response and therefore not documented, you
14 then make contact with another professor of ethics?
15 **A.** Yes.
16 **Q.** Professor Doyal.
17 We have a letter from him at NHBT0004392_002.
18 So it is 20 December 1999, and it refers to
19 a meeting with you and Dr Knight. If you can tell us
20 who Dr Knight is?
21 **A.** Dr Knight is the consultant neurologist at the CJD
22 Research and Surveillance Unit.
23 **Q.** It refers to a meeting. The second paragraph says:
24 "As I understand it, the reasoning behind the
25 original decision not to inform recipients or donors

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1 wish to be informed of this fact -- if anything can be
2 said to practically turn on the provision of such
3 information."
4 Over the page he says:
5 "Therefore, the key moral issue is whether or
6 not there is a) evidence -- or the appearance of
7 evidence -- that there is a link between nvCJD and
8 blood and b) an effective diagnostic test."
9 Then he takes each in turn:
10 "If I understood you and Dr Knight, there is now
11 very little sound evidence that [new variant CJD] can
12 be transmitted by blood. The problem is that the
13 National Blood Authority has adopted a policy about
14 the non-use of the blood of the recipients of
15 potentially infected blood which entails that they
16 must be informed that they are ineligible to give it.
17 The Department has also insisted that as the medium of
18 potential transmission, white cells be removed from
19 blood for transfusion."
20 That is the process that Dr Williamson told us
21 about of leucodepletion:
22 "Both decisions suggest -- and will certainly do
23 so to the public -- that there is evidence of
24 transmissibility. Therefore, recipients or donors who
25 are told that their blood cannot be used must be

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1 in the circumstances described was based on the
2 premise that not doing so could in no way impinge on
3 their interests. This was because of the uncertainty
4 surrounding the mode of transmission and the lack of
5 a screening or diagnostic test to diagnose infection.
6 "The issue of the lack of any effective
7 intervention has also been mooted as a justification
8 for non-notification."
9 Then Professor Doyal's advice then is:
10 "I would discount this as relevant to any new
11 policy about notification. Many terminally ill people
12 both need and want to know confirmation about their
13 diagnosis and prognosis, despite the absence of
14 effective treatment. They require such information
15 because of decisions of their lives or deaths which
16 they may wish to make on its basis. It is impossible
17 with any certainty for clinicians effectively to judge
18 who these individuals are or what kind of information
19 they require, even when they are actively treating
20 them. Indeed, there are obvious difficulties in
21 assuming that when some patients reject information
22 which they may find distressing, they can be said to
23 be making an informed choice about their rejection.
24 It certainly cannot just be assumed that recipients or
25 donors who are linked to [new variant CJD] will not

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

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

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

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

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

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1 until 2 o'clock. 2 o'clock.

2 (1.02 pm)

3 (The short adjournment)

4 (2.00 pm)

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

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

17 **A.** Principal investigator, yes.

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

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

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

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

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

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

25 **A.** Agreed.

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

6 "As you have indicated, this course of action
7 appears to conflict with the stance adopted by the
8 NBA, as described in Dr Hewitt's letter dated
9 12 October 1999."

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

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

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

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

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

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1 Do you know, Dr Hewitt, what then happened in
2 relation to ethical approval and the Department of
3 Health stance?
4 **A.** I have been trying to remember and I should know but
5 I can't remember.
6 **Q.** Well, I asked the question because I don't currently
7 know the answer but I am sure we will be able to trace
8 it through with documents and/or with other witnesses.
9 What you say in your statement is that
10 ultimately, over the following I think it is three
11 years, there was a shift in view, leading to, as we
12 will come onto, notification then taking place to
13 recipients at the very end of December 2003?
14 **A.** Yes.
15 **Q.** But it was -- 2000, 2001, 2002, 2003, the position
16 remained that recipients were not, as a matter of
17 fact, being notified?
18 **A.** Yes, and there continued to be discussions at the CJD
19 incident panel and I think, over that time, opinions
20 changed, influenced by more up-to-date risk
21 assessments from the Department of Health analytical
22 team, whose correct title I think Dr Williamson gave
23 yesterday but I can't remember.
24 **Q.** We will just pick up, I think, probably three
25 documents that help understand what -- some of what

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1 Then the next paragraph records a discussion
2 about the position of flagging the donor databases,
3 which you have already told us about.
4 If you go over the page. The top of the page
5 records that:
6 "Given that these people could present as donors
7 in any of the UK countries we agreed that the
8 'flagging' information should be shared by all four
9 national blood services to ensure a coordinated
10 inclusive approach."
11 Is it right to understand that the system of
12 flagging was both agreed by the Department of Health
13 and it was agreed that it should be a system that was
14 shared between the four different blood services?
15 **A.** Yes, it is.
16 **Q.** And then the next paragraph deals with the position of
17 what should happen if a flagged person gave blood:
18 "In the event of a 'flagged' person giving
19 blood, it was agreed that the donation identified
20 through the flagging process should not be allowed to
21 enter the supply. It was also agreed that in the
22 spirit of openness and 'contracts' with donors, the
23 blood services would need to consider telling, or
24 offering to tell, the donor why their blood could not
25 be accepted. As, however, there is still little

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

10 It refers in the first paragraph to:

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

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

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

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

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

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

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

12 **A.** Yes.

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

15 And then the last paragraph reads as follows:

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

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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

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"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

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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.

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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."

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

7 **A.** Yes.

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

10 "The panel proposes four main courses of action:

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

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

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

22 Then over the page:

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

25 "The exception to this would be a small sub

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

8 Then 4 is about publicity, about the database.

9 So that is the way in which, at this stage, the panel
10 contemplated addressing the issue of notification; is
11 that right?

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

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

17 **A.** That was the intention.

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

20 **A.** That is correct.

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

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

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

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

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

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

24 Then 3:

25 "The exception to this would be a small sub

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

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

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

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

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

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

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1 incidents involving potential transmission through
 2 medical interventions."
 3 Then it refers to the consultation process and
 4 it says it included a public meeting held in 2002:
 5 "There was a wide range of views expressed."
 6 Then if we go to the next paragraph:
 7 "The Panel revised its proposals in the light of
 8 the consultation responses, recommending that patients
 9 considered 'at risk' should be notified and that
 10 necessary support mechanisms should be in place."
 11 So that, in due course, was the recommendation
 12 post-consultation of the CJD Incidents Panel to the
 13 Department of Health --
 14 **A.** That is right.
 15 **Q.** -- that notification for those categories of patients
 16 should now take place. Then it says:
 17 "The four Chief Medical Officers for England and
 18 the Devolved Administrations accepted this proposal in
 19 June 2003."
 20 It is right, as I understand it, Dr Hewitt, that
 21 although that proposal was accepted in June 2003 no
 22 steps were taken at that point to notify recipients?
 23 **A.** I'm not aware that any steps were taken. Could I just
 24 clarify the very first sentence in this letter --
 25 **Q.** Yes, of course.

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1 recognition of the first possible link occurred ... DH
 2 then instructed that notification should take place."
 3 That resulted in notifications being sent out
 4 essentially around the time of Christmas and New Year.
 5 As I am sure you are aware, Dr Hewitt, the evidence
 6 the Inquiry has heard in an individual case from Peter
 7 Buckland, who was the father of Mark Buckland, was
 8 a letter from the Health Protection Agency dated
 9 31 December 2003 arriving in early January 2004.
 10 From your perspective, could the notification
 11 process have taken place -- could and should the
 12 notification process have taken place earlier than the
 13 end of December 2003?
 14 **A.** Yes. I was quite clear about that and it was
 15 an example of how not to do a notification exercise.
 16 The time was awful. Individual GPs and local public
 17 health teams were put in the position of "This is
 18 something you must do now", without any plans really
 19 having been made in place. A lot of work was done,
 20 a lot of teleconferences with a lot of people working
 21 out it could be done well and quickly, and that really
 22 wasn't the situation we should have been in.
 23 **Q.** Is it the case that the agency that took the lead in
 24 the notification process was the Health Protection
 25 Agency?

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1 **A.** -- because it might be confusing for some individuals.
 2 The original letter wasn't to me it was to my
 3 alter ego. So it was written to the Minister,
 4 Secretary of State for Health.
 5 **Q.** You are absolutely right. So if we just go back to
 6 the second page.
 7 **A.** I think it was a source of frustration for the
 8 Incidents Panel that, following agreement with the
 9 recommendation in June 2003, there was no information
 10 that something was being set up.
 11 **Q.** The letter continues:
 12 "At this time, there was still no known cases of
 13 vCJD transmission via blood transfusion. However,
 14 while the necessary support mechanisms were being put
 15 in place, the first case of vCJD transmission via
 16 blood transfusion was confirmed in December 2003. The
 17 Department acted as quickly as possible to ensure that
 18 all similar recipients were contacted and given the
 19 information and support needed."
 20 Now, you observed in your witness statement --
 21 if we look at WITN3101009, please, Paul, page 140, it
 22 is paragraph 393, so bottom half of the page, last few
 23 lines of paragraph 393:
 24 "I understand that notification was advised ...
 25 action was not taken until December 2003, when the

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1 **A.** That is correct. I was involved in that, clearly, the
 2 Blood Service held the deals of the individuals who
 3 were to be informed and I did take part in the lot of
 4 the teleconferences, but the notification was handled
 5 by the public health teams.
 6 **Q.** Part of Mr Buckland's evidence was an expression of
 7 concern about the fact that his son's exposure had
 8 been known about for a number of years but had not
 9 been communicated to his son until the notification
 10 exercise that you have just described.
 11 **A.** Yes.
 12 **Q.** I'm not asking for comments on individual cases but
 13 I just wanted to invite your comment on one of the
 14 reasons Mr Buckland articulated as to why it would
 15 have mattered to his son to know. And he said it is
 16 because he could have made a choice to live his life
 17 to the full in a way he -- what remained of his life,
 18 of his young life, to the full in a way that he
 19 couldn't because he didn't know that he had possibly
 20 been exposed, as a matter of fact had indeed been
 21 exposed, to vCJD.
 22 Again, that perhaps picks up on some of the
 23 observations Professor Doyal was making. Would you
 24 agree with that as a matter of principle, that that's
 25 one of the considerations that would favour

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1 notification rather than non-notification?

2 **A.** I totally agree. And if I may be allowed to say, the

3 first case, which initiated this exercise, the case

4 where a recipient did develop variant CJD and hadn't

5 been informed, equally I did meet some of the family

6 and very rightly made the comment that if they had

7 known that their family member was at risk -- he died

8 without a diagnosis being made. If they had known

9 that he had been at risk, his last few months would

10 have been dealt with differently. And how they had

11 managed the situation would have been dealt

12 differently because they would have known what they

13 were dealing with, or what they were likely to be

14 dealing with.

15 **Q.** And there was an observation you made more generally

16 in your statement, Dr Hewitt.

17 If we can have the statement back, please.

18 WITN3101006, page 34.

19 This is paragraph 105, and you are here

20 reflecting on issues more broadly of notification.

21 You say this:

22 "With hindsight, I think the difficult issues

23 and strongly held views from both sides (those who

24 supported notification of the possibly affected,

25 despite the potential for psychological harm, and

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1 WITN3101018.

2 Now, you are setting out here more fully, as

3 I understand it, what you have learned from the TMER

4 by this stage?

5 **A.** This was a description of this first case.

6 **Q.** So if we look at the heading "Summary" and go to

7 "Methods". So that's describing, I think, the TMER?

8 **A.** Yes.

9 **Q.** Then "Findings":

10 "48 individuals were identified as having

11 received a labile blood component from a total of 15

12 donors who later became vCJD cases and appeared on the

13 surveillance unit's register."

14 So, as at the date of this article, TMER had

15 identified 48 people?

16 **A.** Yes.

17 **Q.** And then:

18 "One of these recipients was identified as

19 developing symptoms of vCJD 6.5 years after receiving

20 a transfusion of red cells donated by an individual

21 3.5 years before the donor developed symptoms of

22 vCJD."

23 So that's the case that you have described, the

24 individual?

25 **A.** Yes. And perhaps it would be helpful to say that,

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1 those who felt that such harm outweighed the benefits)

2 may have led to erring on the side of not acting soon

3 enough to impart potentially devastating news in terms

4 of possible exposure to HCV and vCJD ..."

5 Does that accurately reflect your views?

6 **A.** Yes.

7 **Q.** Can I then just pick up on a handful of other matters

8 relating to vCJD.

9 So we have learnt that the December 2003 was

10 when an individual died of vCJD who had received

11 a transfusion some years earlier, including a blood

12 component originating from a donor who later

13 developed vCJD.

14 **A.** Yes, that is correct.

15 **Q.** That was the confirmation, is that right, essentially?

16 **A.** It was the likely evidence, but one case ... I know

17 that the Department of Health were very anxious that

18 it couldn't be called "evidence", it was "suggestion

19 of a possibility", and it wasn't until subsequent

20 cases that gave definitive evidence that we could say

21 with confidence we do have the evidence that it is

22 transmitted through blood components.

23 **Q.** We can see this case being described in an article in

24 The Lancet in February 2004, co-authored by you,

25 Dr Knight and Professor Will and others.

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1 because of the time of this, it was non-leucodepleted

2 red cells.

3 **Q.** And then:

4 "Interpretation. Our findings raise the

5 possibility that this infection was transfusion

6 transmitted."

7 Then if we go to page 4., you set out various

8 further details about that individual case. But I'm

9 just going to draw attention to the last paragraph of

10 the article. So halfway down the right-hand column:

11 "Our report suggests that human prion diseases

12 may be transmissible through blood transfusion and

13 underlines the importance of epidemiological

14 surveillance systems. Although experimental studies

15 are important, only through the study of natural

16 disease can evidence of an actual iatrogenic risk can

17 be identified. The risk of vCJD is not restricted to

18 the UK, and the identification of cases of vCJD and

19 examination of history of blood donation may be

20 important in other European countries and elsewhere."

21 You go on in your witness statement to tell us

22 that two further cases were then identified linked to

23 a common donor, and that that essentially confirmed

24 the link --

25 **A.** Yes.

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1 Q. -- between vCJD and blood transmission.
 2 And I should just say, I don't think I need to
 3 go to it, but there was an *ad hoc* meeting held on
 4 15 December 2003 to discuss what should happen when
 5 the case came to light. I will give the reference for
 6 the transcript. DHSC0006827_006.
 7 Can we then look at RLIT0000777.
 8 So this is from the website of the CJD
 9 Surveillance Unit, and if we go to -- oh no, it's not
 10 got the page I wanted. I don't think it is printed
 11 out as we needed it. No, don't worry.
 12 My understanding, and this is what you say in
 13 your witness statement -- so we can take the document
 14 down -- is that TMER identified 67 people at risk of
 15 vCJD because they had received a blood component
 16 originating from a donor who later developed vCJD --
 17 A. Yes.
 18 Q. -- is that right?
 19 Then, in terms of the notification process,
 20 we've learnt how the initial notification process was
 21 handled by the Health Protection Agency but you have
 22 told us in your statement that there was then a 2005
 23 notification procedure until relation to donors
 24 identified through the reverse TMER, which was managed
 25 by you?

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1 all, were the Blood Services involved in that
 2 exercise?
 3 A. Indirectly. As part of the whole procedure the Blood
 4 Service had notified BPL or the Scottish equivalent of
 5 plasma donations which had originated from donors who
 6 had later developed variant CJD, and I had made myself
 7 a note to say that although plasma product recipients
 8 were not included in the TMER there was a separate
 9 exercise to identify what had happened to those
 10 implicated plasma products, which is now what we are
 11 talking about.
 12 So the Blood Services provided the information
 13 to the fractionators so they could identify which
 14 batches of product contained plasma from those
 15 original donations. And thereafter the only part that
 16 the Blood Service was involved in is where there were
 17 batches of albumin, which is a protein solution, which
 18 had been used within the Transfusion Service, because
 19 the Transfusion Service provides a therapeutic service
 20 for some patients who require plasma exchange. So we
 21 were the users of the products at that stage. But as
 22 far as I recall, that was the only involvement of the
 23 Blood Services.
 24 Q. You yourself might have had some knowledge of what was
 25 going on because of your involvement with

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1 A. Yes.
 2 Q. So why was this undertaken in a different way?
 3 A. So, just to be clear, this is the situation where
 4 a recipient has developed variant CJD and we have
 5 identified the donors whose blood had been transfused
 6 to those recipients. So those donors were considered
 7 to be at risk. And the decision was then taken that
 8 those donors should also be notified and told that
 9 they should not continue to give blood or donate other
 10 tissues or organs.
 11 And at the time we felt very strongly that these
 12 individuals whose risk for vCJD had been identified
 13 because they were blood donors, because they had
 14 volunteered to give blood, and we felt that it was our
 15 responsibility, as the Blood Service, to give them the
 16 information, and that outsourcing it to another
 17 organisation might seem very strange.
 18 I'm not sure whether that was correct or not.
 19 But that was what we felt very strongly at the time,
 20 that it was our responsibility to talk to our donors.
 21 Q. Notification of being at risk -- for those who had
 22 received fractionated product. So factor
 23 concentrates. We have heard evidence already in the
 24 Inquiry from Professor Hay and others about the
 25 notification exercise that were undertaken. First of

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1 CJD Incidents Panel?
 2 A. Yes.
 3 Q. But we can pick that up, I think, through the CJD
 4 Incidents Panel minutes as a matter of record. That
 5 notification exercise was then handled, as it were,
 6 through the CJD Incidents Panel and the Haemophilia
 7 Centre Directors Organisation, is that your
 8 understanding?
 9 A. It was actually handled by Public Health England,
 10 whatever its current title was at that time, who
 11 provided the risk calculations for the various batches
 12 and then informed users of which batches were at risk.
 13 Q. Then you referred a moment or two ago to there being
 14 an equivalent, as it were, of TMER but in relation to
 15 the fractionated products, so the same kind of
 16 exercise being undertaken. Who, as far as you know,
 17 undertook that?
 18 A. So that is what we were just talking about, yes. So
 19 Public Health England, it was their headquarters, with
 20 the haemophilia centres and with other users of other
 21 products.
 22 Q. So those -- no, there are a couple of further
 23 questions in relation to vCJD, sorry.
 24 So that was the system in relation to
 25 notification. In terms of other measures that the

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

7 **A.** Yes.

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

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

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

21 "Corneal transplant recipients

22 "Individuals with a family history of CJD

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

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

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

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

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

21 **MS RICHARDS:** I think 15 minutes would be fine.

22 **SIR BRIAN LANGSTAFF:** Very well, we will meet again at
23 3 o'clock, shall we? 3 o'clock.

24 **(2.45 pm)**

(A short break)

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

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

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

9 **A.** Yes.

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

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

17 Then below that, below the box:

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

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1 **(3.00 pm)**

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

5 **A.** Yes, I understand.

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

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

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

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

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

19 **A.** Yes.

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

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

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

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1 of any infection transmitted to a bleeding disorder
2 patient through treatment with fractionated products?
3 A. In general the Transfusion Centre would not be made
4 aware. We were not the manufacturer of the product.
5 Q. So would it be your understanding that that process
6 would be managed as between BPL, if it was
7 a BPL product, and the haemophilia centre directors?
8 A. Yes.
9 Q. I think it may be that you won't be able to answer the
10 next couple of questions but I just want to ascertain
11 if that's the case.
12 Does the national -- NHSBT or its predecessor
13 keep a record or hold a record, in terms of those
14 known to have potentially been exposed to vCJD, which
15 would identify how many of those were bleeding
16 disorder patients?
17 A. The records that are held within the Blood Service
18 would only relate to blood components.
19 Q. So you will only have the records essentially through
20 the TMER process?
21 A. Yes.
22 Q. Which would not include patients treated --
23 A. It did not include fractionated plasma products, yes.
24 Q. So would it be right then to understand that you would
25 not know how many of those with bleeding disorders

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

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

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1 doing that?

2 **A.** Yes.

3 **Q.** And was there any joined-up working between the Blood

4 Transfusion Service and Haemophilia Centres to ensure

5 that all those who might have been infected with

6 hepatitis C were identified?

7 **A.** No. I think for the reason I have just given.

8 **MS RICHARDS:** Sir, those are the questions I have been

9 proposing to ask by those put forward by Core

10 Participants.

11 **SIR BRIAN LANGSTAFF:** Yes. I have no questions of my own.

12 **MS RICHARDS:** Dr Hewitt, is there anything further that

13 you would wish to add?

14 **A.** Yes, I would like to, please. And I apologise if

15 I read it because there are some things I would like

16 to say.

17 **SIR BRIAN LANGSTAFF:** No, that's fine. Don't worry.

18 **A.** I know this has been a very long week of hearings,

19 unusually long because of a variety of matters. I was

20 originally due to give evidence next week and there

21 had to be some rejigging of the programme and I am

22 very grateful that the Inquiry team have accommodated

23 me before the break, as was originally intended. So

24 thank you very much.

25 I have in the past met some of the infected and

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1 cases and I am deeply sorry.

2 Thank you.

3 **SIR BRIAN LANGSTAFF:** Thank you for that. Thank you also

4 for the wealth of detail which you have provided in

5 your witness statements, all of them, more than most

6 witnesses, for the clarity with which you have

7 answered the questions, useful to us not only in

8 confirming much of what others have said but also in

9 giving us a really clear picture and further picture

10 of things such as look-back and vCJD in the 1990s and,

11 in particular, in the Blood Service's role.

12 It is going to be interesting to see, in due

13 course, what government witnesses say from their

14 perspective about some of the things that you have

15 described from yours.

16 But thank you very much indeed for the evidence

17 you have given.

18 **A.** Thank you.

19 **SIR BRIAN LANGSTAFF:** I'm going to have to ask you to bear

20 with me and just wait there for a bit longer because

21 I have something to say more generally to those people

22 who are here and those who are listening at home, and

23 it is this:

24 This is our last hearing of 2021, time to look

25 back on the past year and forward to the new. We

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1 affected, both on a one-to-one basis and when I have

2 met individuals who have been infected through a blood

3 transfusion, and I have met some people in a group

4 meeting for those with haemophilia. I have seen how

5 people in this room have listened very carefully and

6 attentively to those giving evidence. I have heard

7 and read evidence from the infected and affected, who

8 have recounted truly harrowing experiences and they

9 have done this with great courage and enormous

10 dignity.

11 I initially doubted what this Inquiry could

12 achieve given the number of years which have elapsed

13 since the events which it is examining. Many of the

14 infected and affected are no longer with us and nor

15 are some of those who could have filled in some of the

16 gaps in the documents -- the many, many documents that

17 the Inquiry has been dealing with. But I can see how

18 important it has been for the infected and the

19 affected to tell their stories and, more importantly,

20 for them to be listened to.

21 It's also important for everybody to understand

22 as completely as possible what happened and why and

23 this is long overdue. As I said in my statement, it

24 is a tragedy that treatment which was designed to save

25 and improve lives had the opposite effect in so many

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1 started under the shadow of Covid; it did not deter

2 us. We end under the uncertainties of its threat; it

3 will not deter us.

4 2021 has been a year when we have heard evidence

5 which has ranged from haemophilia centres, Treloar's

6 School, the Haemophilia Society to trusts and schemes,

7 government health ministers, from each of the four

8 nations, and then to former government ministers,

9 pharmaceuticals and the blood transfusion services.

10 It's certainly had its moments, some, as I said at the

11 time, unforgettable.

12 2022 promises to be a year when we keep up the

13 considerable pace at which we have been going. If it

14 isn't the year when our hearings end, as many of us --

15 I think most of us -- hope it will be, it will not be

16 for want of trying. But if we don't make it, it will

17 leave us very close to that goal.

18 The timetable to Easter includes more from

19 Regional Blood Transfusion Centres and will take us to

20 blood transfusion policy and practice,

21 self-sufficiency and production at BPL in Elstree, PFL

22 at Oxford and PFC in Edinburgh.

23 Amongst other matters, we will also take

24 evidence during from 2022 from Sir Robert Francis on

25 his Compensation Framework review, and we will hear

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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:

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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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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

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