

Wednesday, 7 October 2020

(10.00 am)

DR BRIAN COLVIN, continued

MS RICHARDS: Dr Colvin, we were looking at documents around the middle of 1983, about the developing response to HIV and we'd looked at the letter from Professor Bloom and Dr Rizza, June 1983.

A. Yes.

Q. I'm just going to ask for that to go back on screen.

Henry, it is BART0000844. That might be the wrong reference. Apologies. It's the right one, good.

So we looked at the recommendations, I'm not going to go back to those, but if we just look at the first paragraph, we can see what's being said there about, I suppose -- relevant to an assessment of risk:

"So far one possible case has been reported ... This patient ... conforms to the definition published by the CDC in Atlanta ... but cannot be considered ... a definite case."

Then if we just go further down the page, please, Henry, below the paragraphs 1 and 2 that we looked at yesterday, Dr Colvin, we can see that it says:

"It was agreed there is as yet insufficient

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So we can see there already there is more information than we have in the UKHCDO letter. You know it's a haemophiliac in Cardiff from this, not mentioned by Professor Bloom and Rizza, and you know it's someone who's received American Factor VIII concentrate?

A. Sure.

Q. Then we can see it goes on to refer to three cases in haemophiliacs in Spain having been reported in The Lancet who have also received USA Factor VIII concentrate and then, in the same issue:

"... the tally of 11 reported cases in haemophiliacs in the USA is recorded and a paper describes a case in a multiply-transfused child in the USA."

So would you agree there's a lot more information relevant to an assessment of risk in Dr Galbraith's letter?

A. Dr Galbraith certainly has information which I wasn't aware of.

Q. Then if we then go to the second page, Henry, of the Galbraith letter, please -- sorry, before we do that I should perhaps just clarify, Dr Rizza and Professor Bloom obviously were providing a perspective as haemophilia clinicians. Dr Spence Galbraith was

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evidence to warrant restriction of the use of imported concentrates ..."

And reference is made to the FDA recommendations in March 1983.

Now, would you agree that there's really comparatively little information in here to enable clinicians such as yourself receiving this to make a reliable assessment of the risk?

A. Yes, I would. I agree.

Q. Henry, could we have up on screen next to this CBLA0000043_040. This is the Galbraith letter that you referred to yesterday, Dr Colvin.

A. Yes.

Q. I thought it might be instructive just to look at them side by side if we can.

In Dr Spence Galbraith's covering letter to the Department of Health and Social Security, and we can see it's a few weeks before Professor Bloom and Dr Rizza's letter, 9 May 1983, he says in the first paragraph:

"Last week whilst you were away in Geneva a case of [AIDS] in a haemophiliac in Cardiff who had received USA Factor VIII concentrate was reported. The case fits the recognised criteria for the diagnosis of AIDS."

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director of the CDSC, so he had an epidemiological and public health perspective to bring to bear?

A. Yes.

Q. We can see his recommendation at the top of the page. I'll come back to the recommendation in a moment, Dr Colvin, but we can see his recommendation is: "The temporary withdrawal of all blood products imported from the [USA] made from blood donated after 1978 ... until the risk of transmission of ... (AIDS) becomes clarified."

Then I want to go through his reasons with you and invite you to comment on them. His first reason is that the AIDS epidemic is probably due to a transmissible agent, and you would agree with that as a statement of knowledge at the time?

A. Yes.

Q. His second is that it's an agent probably transmitted by blood and blood products, and he sets out more details of a number of cases. Again, I think it is clear from your evidence yesterday you'd agree with that?

A. Yes, of course.

Q. His third reason -- go to paragraph 3, Henry -- is that:

"Although this number of cases of AIDS

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1 associated with the administration of factor VIII
 2 concentrate is very small in relation to the number of
 3 individuals receiving the product, this may NOT
 4 indicate that the risk is small ..."
 5 Again, you'd agree with that?
 6 A. I can understand that very well, yes.
 7 Q. Yes, and obviously from an epidemiological public
 8 health perspective that's where his advice might be
 9 key?
 10 A. Yes.
 11 Q. Point 4 then, please, Henry.
 12 "Factor VIII concentrate (and pooled products)
 13 would appear to have a high risk of being contaminated
 14 with AIDS ..."
 15 And that's because of the donor pool, and he
 16 goes on to say:
 17 "... possible that the AIDS agent may be present
 18 in blood of healthy persons for several months before
 19 onset of symptoms."
 20 Again, you would agree with those observations.
 21 A. Yes.
 22 Q. Then paragraph 5:
 23 "... apparently no ... means of ensuring that
 24 blood or blood products are free of the AIDS agent."
 25 That was also true at that time?

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1 action that was in the gift of an individual clinician
 2 such as yourself, but what, if any, observations do
 3 you have upon that proposal?
 4 A. It was very bold and decisive.
 5 Q. If it had been implemented for, as Dr Galbraith says,
 6 a temporary period whilst seeking to clarify the
 7 issues in relation to AIDS, the implications in terms
 8 of treatment would presumably have been, clinicians
 9 such as yourself would have had to adjust treatment
 10 programmes, greater use of cryoprecipitate would have
 11 probably been inevitable as a response?
 12 A. Not necessarily but I'm happy to talk to you about it.
 13 Q. Please do.
 14 A. So I think there would be two different sets of
 15 consequences. The first consequence would be: what do
 16 we do next? And I think you can see that from my own
 17 practice around that time, perhaps not quite half my
 18 practice was using commercial concentrate, but for
 19 some people I think, although you'll know better than
 20 I do, more than half and maybe almost the whole of
 21 their practice might have involved the use of
 22 commercial products. Because I've explained to you,
 23 and I think it's clear even from the correspondence
 24 you produced for me this morning, that I was
 25 committed, rightly or wrongly, to the National Health

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1 A. Yes.
 2 Q. Point 6 is: the mortality rate, again, whatever the
 3 precise figure, known to be very high.
 4 A. I understand.
 5 Q. So, in terms of the actual factual matters he there
 6 sets out, you would agree with all of those?
 7 A. It's a very carefully ordered and organised letter.
 8 Q. Now, I know you're aware of this letter now.
 9 A. Yes.
 10 Q. Was it a letter, as far as you know, that was ever
 11 shared with haemophilia clinicians at the time?
 12 A. The first time I knew about Dr Galbraith's work was
 13 when the document was shown to me when I was preparing
 14 to give an interview for the Panorama programme in
 15 2017.
 16 Q. So many, many years after the event?
 17 A. Yes.
 18 Q. Could we go back to the top of the page of this
 19 document, Henry. So above numbered paragraphs 1
 20 and 2. Next page.
 21 So we'll go back then to his recommendation, the
 22 temporary withdrawal of all blood products imported
 23 from the US made from blood donated after 1978, is
 24 proposed.
 25 Now, obviously, that kind of action is not an

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1 Service and what it was providing for our patients.
 2 So let us assume for a moment that half the
 3 concentrate in the country would have disappeared.
 4 That's not a bad calculation, and in fact if you look
 5 at the 1983 statistics, you'll find, I think, that
 6 half the product in the country is being NHS and half
 7 is commercial. So we're going to need to continue
 8 entirely on National Health Service product.
 9 I've already explained and we've discussed that
 10 if you have a patient having large quantities of
 11 cryoprecipitate, the chances are they will be at high
 12 risk of hepatitis C, and we know that the NHS at that
 13 time -- we thought that the NHS pool was not
 14 contaminated. Which of course we were wrong, it was
 15 contaminated. So I think that your options are to try
 16 to withdraw to cryoprecipitate as you were implying,
 17 which I think would have been exceptionally difficult
 18 because one would have had to somehow build up the
 19 supply of cryoprecipitate, which, though not
 20 impossible, would not have been possible within a few
 21 days or perhaps even a few weeks.
 22 So I think that the most likely response
 23 of UKHCDO would have been to use as much
 24 cryoprecipitate as we had, perhaps increase the supply
 25 of cryoprecipitate, as you implied, but I don't think

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1 we would have abandoned the use of NHS concentrate.
2 I just don't think that would have been in any way
3 practical, and it wouldn't necessarily -- particularly
4 if it was the case that the NHS pool was not
5 contaminated, it wouldn't have been harmful.

6 Now how would you manage a service that was
7 suddenly cut in half? I think the answer is probably
8 an abandonment of all surgery except absolutely
9 life-saving surgery, and I think the abandonment of
10 the home treatment programme and a reversion to
11 on-demand treatment only.

12 Even with that, you might want to scale down the
13 doses that you're using. Scaling down the doses
14 perhaps for -- and this could be controversial
15 ethically, I haven't really thought it through, but
16 maybe you keep the doses for little children the same
17 and maybe sort of reduce the doses for the adults.
18 I mean, I'm just purely speculating now in a very free
19 way and I'm not sure what I'm saying necessarily makes
20 sense but I'm trying to think what one could have
21 done.

22 Q. Yes.

23 A. If you look at the position in India, Dr Srivastava,
24 in Vellore, for many years has done work on how to
25 manage with a little bit of Factor VIII and I've

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1 patients that he was able to look at in I think the
2 end of '84, because that's when the testing became
3 possible, and they were all positive.

4 Now, I don't know whether you want to discuss
5 with me what he said, but I would like to say is that
6 he doesn't know, I don't think, because he said he
7 only took the blood when the testing became available
8 and there wasn't blood taken beforehand -- he doesn't
9 know whether all those tests were positive on the day
10 he tested them or whether they were all positive on
11 the day he started his unlicensed heat-treated
12 Factor VIII.

13 So what we do know is that probably by 1983
14 a very large number of those who had received large
15 amounts, or even perhaps, moderate amounts, of
16 commercial concentrate were already HIV positive and
17 that process had started in 1980. So that the
18 consequences of the temporary withdrawal of all blood
19 products in the way that Dr Galbraith perfectly
20 understandably recommended was a probable, I think,
21 significant reduction in anti-HIV positivity and
22 a significant, and probably very significant,
23 reduction in the quality of haemophilia care.

24 Q. We've looked, in these two documents, at the UKHCDO
25 perspective and Dr Galbraith's public health

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1 already explained to you or discussed with you the
2 fact that if you give a little bit of Factor VIII you
3 get a massive bang for your buck, if you like. So
4 immediately, from nothing to a little bit, you get
5 a fantastic benefit, and the benefit at the end is,
6 well, significant but, you know, it's what makes the
7 difference between somebody who is all right and
8 fantastic, which is not the same as having somebody
9 who's awful and surviving.

10 So I think that if you had abandoned all surgery
11 except for the most life-saving and if you had
12 abandoned the home treatment programme and if you had
13 cut back on dosage and accepted a few deaths and some
14 serious joint damage and some serious and very painful
15 illness, you might have got away with it.

16 Q. Yes. I'm not suggesting it would necessarily have
17 been without consequences, I just wanted to know
18 how -- (overspeaking) --

19 A. No, but I just wanted to try to share with you -- just
20 thinking about what you could conceivably do.

21 The next thing, before we move on, and the
22 second part of what I was going to say, was I wonder
23 what difference that would have actually made to the
24 final result. It's very interesting to hear
25 Mark Winter last week saying that he tested all his

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1 perspective. Could we then just look at
2 a communication from the Blood Transfusion Service at
3 this time.

4 Henry, it's NHBT -- you can take both those
5 documents down -- NHBT0020668.

6 Now this is an internal National Blood
7 Transfusion Service letter. I'm not suggesting you
8 would have seen this at the time. It's dated
9 6 July 1983 -- so within the same span of weeks of the
10 material we have been looking at -- and it's enclosing
11 a copy of a final form of an AIDS leaflet which is
12 going to be used in transfusion centres to try and
13 reduce the risk of donors who might be HIV positive
14 donating blood.

15 Can we just turn to the next page please, Henry.

16 We can just see what's set out there in terms of
17 question and answers. If we can go to the bottom of
18 the page, you will see there there's a question:

19 "Can AIDS be transmitted by transfusion of blood
20 and blood products?

21 "Almost certainly yes. There is only the most
22 remote chance of this happening with ordinary blood
23 transfusions given in hospitals. However, in the USA
24 about 10 patients suffering from haemophilia, an
25 illness in which the blood will not clot, have

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developed AIDS. Haemophiliacs are more susceptible to AIDS because they need regular injections of a product called Factor VIII. This is made from plasma obtained from many donors. Should just one of the donors be suffering from AIDS, then the Factor VIII could transmit the disease."

Would you agree with me that the answer that's being given there again is a very decisive, firm, unequivocal answer about risk, being communicated -- or the intention is within a few weeks to donors?

A. I understand.

Q. A much clearer statement of risk or association between blood products, blood and AIDS than we see in the letter that was produced by Dr Rizza and Professor Bloom?

A. Yes.

Q. Could we then go on to look at some documents that you would have seen at the time, Dr Colvin. Could we please have BART0002284. We've already looked at this document in part. It's the document co-authored by you and Dr Kernoff in 1983, "Haemophilia services in the North East Thames region, 1983". If we look to the next page under the heading "Summary", we see there's a reference to:

"Major advances in the management of

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particular complications of treatment and one is: "Plasma product-transmitted disease, particularly hepatitis, and possibly the acquired immune deficiency syndrome. An important function of haemophilia centres is one of regular patient health surveillance, which includes a commitment to public health. At present, this aspect of a haemophilia centre's work does not have an important impact on spending, although it does on workload."

Then there's a reference to the possibility of hepatitis-reduced concentrate. So there's a reference there to AIDS, but it's in fairly tentative terms; would you agree?

A. Yes, of course.

Q. Then I think that may be -- sorry. There is one further reference. If we go on, Henry. If you look at the pagination at the top of the page, Henry. It's page 7 in the internal pagination. It's probably page 8 of the document you have. Or page 9 possibly.

Then we can see a further reference to hepatitis and AIDS at the top of this page, paragraph 3.3:

"Impact of hepatitis and AIDS. There is likely to be an increased morbidity due to chronic liver disease (CLD) over the next decade. Whether this will result in significantly increased mortality will

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haemophilia."

And then reference to local regional arrangements and the role of the regional haemophilia centres, and then in paragraph 4, an issue there in relation to cost and the cost of commercial blood products and the importance of achieving national self-sufficiency.

Then if we go to the next page, please -- sorry, two pages further on. My apologies, Henry. That's the one. So if we look at the third paragraph down where it says:

"A fundamental problem in the UK is that the NHS is not self-sufficient in blood products."

We can see there reference being made in this paper:

"Not only is this expensive, but there are long-standing concerns regarding possible health risks. At present, the benefits of therapy outweigh potential disadvantages."

There's no specific reference to AIDS there. I am just going to show you what references there are to risks and then ask you a question.

A. Yes.

Q. Then if we go to the bottom of this page, please, we can see at paragraph 1.4 (b), reference is made to two

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probably not be known for several years. Clinical problems related to impaired immunity seem to be rare at present but conceivably could become a major clinical problem."

So that last sentence, I think, is the reference to AIDS?

A. Yes.

Q. Now, that is, I think, the only discussion in this paper of HIV and AIDS. Now, I'm conscious the paper was in part a paper looking at issues of funding for the future, but is there any reason you can think of why you and Dr Kernoff were not addressing more directly by August 1983 the AIDS risk?

A. Well, I think because we didn't appreciate what was going to happen next, and one can only read what we said and I believe that we've said it in good faith, but I can understand that you might think that more could have been said.

Q. Then if we move on to the autumn of 1983. It's PRSE0004440 please, Henry. So this is a meeting of the Haemophilia Centre Directors on 17 October 1983; the big group meeting, rather than the smaller meeting of Reference Centre Directors. We can see that you were in attendance at that meeting?

A. Sure, yes.

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1 Q. Could we go to page 10, please, Henry. We can see in
2 the second half of the page under the heading "Any
3 other business":

4 "Dr Chisholm raises the problem of patients
5 refusing to take up commercial Factor VIII because of
6 the AIDS care. She wondered, in view of the worry of
7 the patients, whether the directors could revert to
8 using cryoprecipitate for home therapy."

9 Then we see Professor Bloom's response:

10 He felt there was no need for patients to stop
11 using the commercial concentrates because, at present,
12 there was no proof that the commercial concentrates
13 were the cause of AIDS. Dr Chisholm pointed out that
14 there was a further problem in her region because of
15 problems in getting large amounts of concentrates,
16 whereas she could get unlimited supplies of
17 cryoprecipitate. Other directors reported they had
18 the same problems."

19 Then:

20 "After discussion, it was agreed that patients
21 should not be encouraged to go over to cryoprecipitate
22 for home therapy but should continue to receive the
23 NHS or commercial concentrates in their usual way."

24 Do you have any recollection of this discussion
25 or Dr Chisholm's intervention?

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1 unlimited supplies would be a logistic challenge for
2 any transfusion centre.

3 It's important to remember that the
4 cryoprecipitate is a transfusion centre product,
5 whereas concentrates are an Elstree or commercial
6 production facility.

7 Q. Yes. I mean, whatever one might precisely be meant by
8 terms such as "unlimited", the clear thrust of what
9 Dr Chisholm was saying was: I am in a position to use
10 cryoprecipitate rather than commercial concentrates;
11 what do others think of this suggestion?

12 A. Obviously, there's the issue of home treatment because
13 I think she's mentioning home treatment here and, as
14 we discussed yesterday, although I've done
15 cryoprecipitate on home treatment, I wouldn't
16 recommend it. I think it would have created huge
17 difficulties for patients for the reasons we discussed
18 yesterday and I think we also discussed yesterday the
19 fact that some of us, including myself -- and this
20 would have been around this time, I think -- were
21 trying to use cryoprecipitate where we thought it was
22 appropriate. But we also have to acknowledge, as we
23 discussed yesterday, that cryoprecipitate is also
24 capable of transmitting either hepatitis C or HIV,
25 although you only have one unit at a time -- although

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1 A. Well, I knew Dr Chisholm very well, and I think I can
2 just about remember her intervention in the sense that
3 I remember she was there and she said something, but
4 I don't remember any more about it than that.

5 Q. Do you recall whether you were in the category of
6 directors who were in a similar position to her: she
7 had problems getting commercial concentrates but could
8 get unlimited supplies of cryoprecipitate?

9 A. I find it quite difficult to believe that she truly
10 was able to get unlimited supplies of cryoprecipitate.
11 I can't believe that anybody would be able to get
12 unlimited supplies of cryoprecipitate. Getting large
13 amounts of commercial concentrates -- I mean, my
14 memory, if you were prepared to get the commercial
15 concentrates in, they were available to you. So
16 I don't quite understand that sentence really, any of
17 it, because I don't understand the difficulty getting
18 large amounts of commercial concentrate if she's
19 prepared to find it.

20 Q. That may be a funding issue, of course?

21 A. Of course, it could be a funding issue, and I don't
22 really understand the concept of unlimited supplies of
23 cryoprecipitate because you've got to collect the
24 blood for the cryoprecipitate and put it in the
25 freezer, and it has to go somewhere, and to provide

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1 you might be using ten units for a single dose.

2 Q. Was Professor Bloom right, in your view, to say that
3 at present there was no proof that commercial
4 concentrates were the cause of AIDS?

5 A. I think this is -- is it October '83?

6 Q. October '83.

7 A. So this seems to me to be more wishful thinking, if I
8 may say so.

9 Q. The agreement that's recorded at the bottom is
10 essentially: no action. Don't encourage your patients
11 to go over to cryoprecipitate. It's not even left as
12 clinical freedom for the individual clinician to
13 decide whether to encourage their patients to do that.
14 Patients should continue to receive the NHS or
15 commercial concentrates in their usual way.

16 Does that surprise you, that no slightly bolder
17 recommendation was being made by that time?

18 A. I think, at my personal level, it was always my choice
19 to use NHS concentrates where I was able to do, and
20 I only bought commercial concentrates when I had to.
21 I think that's in the papers that you have just handed
22 me this morning.

23 As I've said, there were others who didn't care
24 much for the NHS or its product, and I suspect there
25 may have been places where commercial concentrate was

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1 actually dominant and, therefore, I think that there
 2 may have been some concern that, were there to be
 3 a change in the recommendation, it would create
 4 enormous difficulties of the kind that we've just been
 5 discussing.

6 **Q.** But this is effectively just maintaining the status
 7 quo; no change whatsoever?

8 **A.** It is, isn't it? Yes.

9 **Q.** Which suggests to you is -- I'm conscious of your
 10 answering by reference to your own practice, and we'll
 11 come on to look at that, but as a general
 12 recommendation from UKHCDO, it is surprising to see no
 13 recommendation for change by October 1983. Would you
 14 agree?

15 **A.** Yes, and in fact, in retrospect, of course if it had
 16 been that Dr Galbraith's recommendation, whatever its
 17 difficulties had been implemented, there would have
 18 been a great deal of clarity, and we would have had
 19 a completely different problem to deal with.

20 **Q.** Yes.

21 **A.** We would have no doubt in some way dealt with it. But
 22 it would have created a whole range of new problems
 23 that we would have had to address.

24 **Q.** Then just looking again now at some documents local to
 25 you and the London hospital and your policies there,

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1 to give human Factor VIII to all the patients for all
 2 bleeds, and if that fails, to use porcine Factor VIII.
 3 He's treated two patients with Hyate:C to date: one
 4 congenital, one acquired."

5 The first question is: is that a correct
 6 statement of your policy at the time?

7 **A.** I think it must be, although I could comment on some
 8 unusual aspects of it, but I think it illustrates my
 9 commitment to NHS concentrate and to human concentrate
 10 rather, perhaps if I can avoid it, than FEIBA. But
 11 the difficulty with what I've said is that if you have
 12 a high-responding patient, the Factor VIII concentrate
 13 isn't going to work. So you can give as much human
 14 Factor VIII as you like to somebody who's got a high
 15 responding antibody, and it won't work. Because I
 16 said that I've got three low responders and two high
 17 responders, so for the low responders, it's possible
 18 that it actually will work. For the high responders,
 19 if the antibody against porcine Factor VIII is
 20 sufficiently weak, then I would certainly use porcine
 21 Factor VIII because I was able to get a measurable
 22 response in the laboratory. Because what happens is,
 23 if you have got an inhibitor that is a fairly moderate
 24 intensity, the intensity of the inhibitor will be
 25 lower against porcine because it's moderately high

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1 could we have, first of all, Henry, IPSN0000584_003.
 2 Can we go to the first page of that, please. Thank
 3 you.

4 We can see here this is a report. It looks like
 5 it's a UKHCDO-authored report. We don't have
 6 a precise date to it, but it's looking at data between
 7 1981 and 1983 and, if you take it from me, it's then
 8 got some incomplete data from 1984. So it looks most
 9 likely as though it was a document produced in 1984.

10 **A.** But it is about inhibitor patients.

11 **Q.** It is about inhibitor patients, absolutely.

12 **A.** Which is, in itself, extremely important. I haven't
 13 been sent this document, I think, but I think it is
 14 important to note that this is about inhibitor
 15 patients.

16 **Q.** Yes, absolutely. This is just one small part of it.
 17 I just wanted to ask you something about your
 18 treatment of inhibitor patients on the basis of this.

19 If we could go, please, to page 9, Henry, and
 20 the document looks at policies and approaches in
 21 different centres, and I just wanted to ask you about
 22 yours. So this is London Hospital:

23 "Dr Colvin has six inhibitor patients, three of
 24 whom are low responders, two are high responders, one
 25 has spontaneously acquired antibodies. His policy is

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1 against human. Then you give the porcine Factor VIII.
 2 You can measure the Factor VIII in the circulation,
 3 and you get a clinical response which is proportional
 4 to the laboratory response. So if you can use porcine
 5 Factor VIII, you've got a really measurable response
 6 which reflects clinical practice.

7 However, if you're going to use something like
 8 FEIBA or Autoplex, which I never used, this is an
 9 activated product which hasn't got any units
 10 associated with it that are actually meaningful. I
 11 mean, they gave quoted units, but those units were
 12 correctional units; they weren't real units. So you
 13 actually don't know what you are doing. So you give
 14 a very expensive and very potentially toxic product to
 15 somebody which you hope will stop the bleeding. Now,
 16 that's worth it if your patient's bleeding to death,
 17 but if you can get control with a product which does
 18 give you a measurable response which is proportional
 19 to the clinical effect, that's fantastic.

20 **Q.** Is there any particular reason why, by 1983, porcine
 21 Factor VIII would not have been the first port of call
 22 over human Factor VIII, in light of the AIDS risk?

23 **A.** Well, it was quite idiosyncratic as a treatment.
 24 Peter Kernoff was an expert in porcine Factor VIII, as
 25 was Christopher Ludlum, and it was particularly useful

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for acquired haemophilia. Maybe we don't need to discuss acquired haemophilia, but acquired haemophilia occurred in old normal people who got an antibody to Factor VIII and then started bleeding, and porcine Factor VIII was particularly good. Nothing to do with haemophilia itself. They got acquired haemophilia. It was an autoimmune response in a normal person. Nothing to do with congenital haemophilia.

But I think I was -- well, I was always influenced by Peter Kernoff, and the fact that Peter was an expert in this area meant that I was also very interested in it, and I would have used porcine Factor VIII for the reasons that I've suggested.

However, it was very allergenic. It caused a lot of allergic reactions. It was very likely to cause a fall in the platelet counts -- thrombocytopenia, which could be dangerous -- and it may well be that some people thought that this was an idiosyncratic treatment that didn't warrant use.

Q. Could we then go on to BART0000517. So this is a document I know you've only seen this morning, Dr Colvin. It's a letter dated 23 March 1984, and it's authored by you. It's to The London Hospital's district supplies officer, and it's really just to flesh out some of the evidence you gave yesterday

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than Cutter?

A. I really can't. What I think we did agree, and this may have come out elsewhere, was that it was always a good idea not to have one supplier only. I don't think there was any evidence that any particular product at that time was superior to another technically, so I think price would have been a feature. But you can see that, although I said I would like to have two suppliers, you can see in '81 I clearly had three, and in '83 I had four, although very small amounts of Hyland and Armour.

So I don't know the answer to that question. Of course, some of it might have been that there were people visiting the centre who were using a commercial product and sent in a return for a commercial product -- might even conceivably have been supplied elsewhere. I don't think it's very likely, but I'm a bit puzzled by these levels of 4,000, 3,500 and 5,500.

They are very small quantities. I mean, not much more than you'd use for a single bleed. So I really can't entirely explain that.

But if you ignore those -- although I am not suggesting you ignore all of them, but if you take them out of the equation, it does look as though, in those circumstances, I am using two suppliers, but

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about what products were being used when.

So we see there in paragraph 1, you are using NHS Factor IX. Paragraph 2, as you just said, not using Autoplex. You have referred to using FEIBA once, and then you say in paragraph 4:

"Our use of imported Factor VIII is entirely dependent on the supplies of NHS material. Our usage over the last few years has been ..."

Then we can see there the figures set out for 1981 and 1982 where we don't have the returns, and then 1983 we've already looked at because we had the 1983 return and the figures are consistent.

We can see that in '81 you were using small amount of Hyland, a larger amount of Armour, and a much larger amount of Immuno; in 1982, no Armour, again a large amount Immuno, and a reasonably large amount of Hyland (certainly an increase on the previous year); and then in 1983 there is a drop in the amount of commercial concentrates being used to the figures we looked at yesterday.

Can I just ask, first of all, can you recall what -- how you made the decision, or you and your colleagues at The London would have made the decision as to whether to purchase Factor VIII in a particular year from Immuno, rather than Armour, or Hyland rather

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I don't know why.

Q. The decision as to which commercial products to purchase, was that a decision taken largely by you and Dr Kernoff for the region, or was it done by others within the region?

A. I would have thought that it would have been Peter and myself, generally speaking, and I would have expected for me to be the person who chose what to buy for The London Hospital. But I can't explain these figures really.

Q. Then if we just go further down that page, we see that you refer there to the reduction in commercial concentrate purchased in 1983, and the explanation for that is it was almost entirely due to an increase in the supply of NHS material and the annual consumption of all forms of Factor VIII is fairly steady at about 1.5 million units a year.

A. Sure.

Q. So it would seem that, in the course of 1983, you have been able to use less concentrate because you've got more NHS available?

A. And that would fit in with my overall philosophy.

Q. Then could we have BART0002310, please.

Again, Dr Colvin, I know you've only seen this letter this morning. 22 February 1984. It's a letter

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from you to Dr Watters at The Haemophilia Society, and it's obviously part of a chain of correspondence with a document that you have been asked to comment on. I am not going to ask you about most of the detail of it, but there is just one comment I wanted to ask you about. If we go to the second page. You say at point 4 this:

"I agree [you are agreeing, I think, with what Mr Watters must have said or what The Haemophilia Society document must have said] that we know little about AIDS at present. In my opinion, there is no reason to spurn commercial concentrate, and we have to keep an open mind on the risk associated with NHS material."

Can I invite you to comment upon that because it seems to suggest that you don't think there's an increased risk from commercial material in relation to AIDS as at February '84?

- A. I don't think that follows. I think what I'm saying is that I believe we know little about AIDS at present, and that seems a statement. The question is whether we spurn commercial concentrate and the advice from UKHCDO and from our discussions is that it is not appropriate at the moment not to use commercial concentrate. I'm also pointing out that we're not

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distributed to donor sessions. It was noted that commercial suppliers also now are applying similar criteria in their donor selection. Heat treating concentrate has been tried but reported to cause loss of potency."

So that's, I think, an update from Dr Harrison. Then it says this:

"It was suggested that, until a positive test for AIDS and/or a vaccine is developed, it should be policy to avoid use of blood products except for essential treatments and to use cryoprecipitate or plasma instead of Factor VIII concentrate whenever possible."

Now, it's not entirely clear from the minutes whether that's a suggestion from Dr Harrison or someone else.

- A. I don't know.
Q. It's not clear whether that's a suggestion that is then agreed by others.
A. Sure.
Q. Did that become The London Hospital's -- your policy in May 1984?
A. I don't think it did specifically, no. I can't say that there was a specific policy in 1984 that that should be the case.

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entirely clear, and it's going to be very difficult to know, whether there's a risk associated with NHS material or not.

So I think it is what it is and the word "spurn" I suppose implies that I am not, on the evidence presented to me, recommending that we don't buy commercial concentrate at all. That's what it means.

- Q. Then if we can go on in the course of 1984 to another North East Thames region meeting. It's BART0000677. This is a document you had already seen, Dr Colvin. So these are the minutes of the Haemophilia Working Party of the North East Thames Region Association of Haematologists. This is 9 May 1984, and you're present, as is Dr Kernoff.

Could we just go down to the second page, please, Henry, and we can see halfway down the page is an update on AIDS, and it says this:

"Dr J Harrison ..."

That's Dr Jean Harrison --

- A. Jean Harrison, yes.
Q. -- who was the director of the Brentwood Regional Transfusion Centre?
A. Following Dr Jenkins' retirement.
Q. "... described the efforts made by the BTC Brentwood to exclude at-risk donors by information and leaflets

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- Q. Then the reference there to "essential treatments". Do you know what was being encompassed in that concept --

A. No, I don't, but obviously it doesn't have a specific meaning.

- Q. So it may be that was a suggestion rather a policy that was adopted?

A. It seems -- I mean, again, it is what it is. I understand what it says.

- Q. But you can't recall any particular change in your own practice at The London Hospital after May 1984?

A. No.

- Q. Then if we move on to late 1984, to December 1984.

Henry, could we have HCDO0000394_117.

This is a meeting, not one at which you attended, Dr Colvin, but this is a meeting that we know took place on 10 December 1984 at Elstree.

It's recorded here as being a note of Haemophilia Reference Centre Directors meeting but we can see there are a number of others who attend, including representatives of BPL and the PHLS, Dr Tedder and others. I'm just showing it to you to show that we can see Dr Kernoff in attendance.

A. Yes.

- Q. That's 10 December. Now that resulted in the

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production of a document that you would have seen, and we'll look at that next, HCDO0000270_007.

This is a document called Haemophilia Centre Directors Organisation AIDS Advisory Document. It was dated 14 December 1984 and our understanding is it was sent out -- we're not sure of the precise date -- to haemophilia clinicians.

A. Sure.

Q. Do you recall receiving this?

A. I don't recall this particular document being received but I recall December '84 very, very well, indeed.

Q. If we just look at the second page of the document, just so that we can see what was being recommended or suggested.

We can see that -- if we go towards the bottom of the page -- under the heading "Options in probably decreasing order of safety from AIDS for Haemophilia A", we've got heated UK concentrate as being the preferred option. It's noted that it's still a risk of non-A, non-B hepatitis. Second option:

"Single donor cryo or FFP."

Third option:

"Heated imported [concentrate] (... still [a non-A, non-B] hepatitis risk).

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Q. Yes, and we'll look at that in a moment. We will just go towards the bottom of the page and then the top of the next page.

So we can see then the recommendations:

"Concentrate is still needed; bleeding is the commonest cause of disability and death.

"2. Use DDAVP in mild Haemophilia A and [von Willebrand's disease] if possible."

Then we can then see the recommendations in relation to haemophilia A. It's:

"... cryo or [heat-treated] NHS Factor VIII (if available)."

And we will see the issue in relation to availability of that in a moment.

For children and virgin patients, those not previously exposed to concentrate.

And then:

"... [heated] NHS Factor VIII, if available or heat treated ... commercial."

For severe and moderate haemophiliacs who don't fall within the groups already identified.

Then haemophilia B, fresh frozen plasma or NHS Factor IX, essentially for mild, virgin, those not previously exposed. Then there's NHS Factor IX for those who had previously used it.

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"4. Unheated UK [concentrate].

"5. Unheated imported concentrate ..."

And the observation there is:

"... almost certain to be contaminated."

Would you agree with me that's -- I think it's clear from the heading, that's a set of options where safety is now the fundamental criterion that's informing that?

A. So obviously it says "probable decreasing order" so we don't know for certain.

Q. No.

A. And I mean, I can remember this really as if it was yesterday, in December '84, when I sit in my office with my head in my hands talking to Peter Kernoff saying, "What on earth do we do next?" because I think we'd reached, really, rock bottom, in December '84, of our understanding and our power to deal with this crisis, and I think really from January '85 onwards we began to address the problem and begin to get it right. But you're going to show me some documents which show that there was uncertainty on the relationship between 3 and 4, that is heated imported concentrate and unheated UK concentrate --

Q. Yes.

A. -- and that was a big dilemma.

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So those were the recommendations. But if we just look a moment further on, we can see it says:

"In individual patients there may need to be a choice. In general heated concentrate appears to be the recommendation of virologists consulted but individual Directors may wish to make up their own minds. This is particularly true of unheated NHS material."

So still being left to the judgment of individual clinicians exercising clinical freedom?

A. Well, I think one can put too much emphasis on the concept of clinical freedom.

My feeling here is that we are looking at a series of questions to which there are no answers. The success of heat treatment depends on: (1) the donor pool; (2) the size of the pool; (3) the method of viral activation. All of those are critical in what happens next.

Now, obviously it's possible later that the donor pool is affected by tests for HIV but at that time it would have just been the donor pool, with or without donor selection, and we know that the commercial people have been actually trying to improve their donor selection.

So those three issues will determine the safety

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of that product. You can't just talk about heat treatment. There are lots of different types of viral activation which were being tried out at the time. As you know, there was anxiety that the effect of the heat would actually damage the Factor VIII molecule and might reduce yield, which it did. It was also feared that this treatment would damage the molecule in a way which might result in inhibitor formation.

Most importantly, there was anxiety that the heat treatment wouldn't work. Now, why would we think the heat treatment wouldn't work? Well, all the work that had been done so far on hepatitis C -- which of course wasn't known by hepatitis C, it was just non A, non B -- suggested it didn't necessarily work and, although we now know that HIV is more heat-sensitive than HCV, we also know that in 1986 and 1987 a number of people in Canada and in Birmingham, UK, were infected with HIV from a heat-treated concentrate.

So I think we were in an impossible situation and this list, which is perfectly understandable and logical, is just a list of what is thought by one or more individuals to be the case.

Certainly in my own mind I was very concerned that if I use heat-treated commercial concentrate and it wasn't virally inactivated, I would infect a large

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of AIDS in treated Haemophiliacs is 1:300. It appears to be less than 1:800 in treated patients in the UK."

Now, I am not clear what the basis for those statements was. Do you know?

A. No, I don't know.

Q. Do you agree it doesn't necessarily appear to be correct in terms of an analysis of risk?

A. Well, I think it illustrates a level of ignorance that we all suffered from.

SIR BRIAN LANGSTAFF: Is it perhaps equating incidence with risk?

A. It might well be. But as I fear, we all know that the words "incidence" and "prevalence" sound the same but they are very different. Incidence is when things happen; prevalence is what's in the cooking pot.

MS RICHARDS: Then we can see that the next paragraph suggests that:

"A ... survey of 1,000 treated Haemophiliacs in England and Wales shows that 30 per cent are ..."

It says "HCTV", I think it must be "HTLV-III":

"... antibody positive. (The percentage may be higher in some centres - exposure to Commercial Factor VIII concentrate in the last 2 years may be a significant factor)."

Do you know what the source of that data was?

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number of my patients who were not yet infected. At some point I'd like to discuss what Dr Winter said in his evidence about the early heat-treated concentrates, because I know that many of my patients were not HIV positive, and if I had given them all a heated commercial concentrate which was actually transmitting HIV, I would have transmitted HIV to a very large number of my patients who were so far uninfected.

Q. Can we look then at what was locally with The London Hospital after this set of recommendations was produced.

So if we could have first, please, BART0000676.

So we can see this another meeting of the North East Thames Region Haemophilia Working Party. It's 13 December 1984. So it's three days after the meeting at which the recommendations have been agreed but it's before the document that we've just been looking at has actually been finally drawn up.

We see, again, you and Dr Kernoff are there, along with a number of others, including, on this occasion as well, from the Royal Free, Dr Tuddenham.

If we go to the second page, please, Henry, we see "Update on AIDS". The first paragraph there is:

"The American experience suggests that the risk

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A. No, I don't. I mean, the chances are -- which year are we in now? We're in --

Q. This is December '84.

A. -- December '84, aren't we? Well, of course, the testing has only really just started. This almost certainly comes from Richard Tedder and, interestingly enough, it might come mainly from his centre because the Middlesex has a number of people with haemophilia in it, it's not a big centre but it may well be that the -- and this is pure speculation now, but it might be that the people in the Middlesex centre might be tested quite quickly by Dr Tedder, because he is in that area and, if that was the case, then it wouldn't perhaps be surprising that not so many of them are anti-HTLV-III positive because they are not big treaters.

Q. It may be worth just looking at the previous page and see who was there, and perhaps you just tell us where some of them were from, because you may recall the names.

Do you know where Dr Bolton Maggs was based at that time?

A. I think Paula was at the Royal Free at that time. She was doing work -- I mean, she was a clinician, of course. She had been -- had a very distinguished

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1 career since, but I think she was doing work on
 2 Factor XI deficiency, which is particularly prevalent
 3 in the North London Royal Free community.
 4 Q. Dr Boots, I think was from --
 5 A. Colchester.
 6 Q. Dr Colvin is yourself. Dr Edwards?
 7 A. I don't know. Dr Edwards doesn't ring a bell.
 8 Q. Dr Harrison is Dr Jean Harrison from the Regional
 9 Transfusion Centre. Dr Mills?
 10 A. Southend.
 11 Q. Dr Oakey?
 12 A. That's Orsett.
 13 Q. So Essex?
 14 A. Yes.
 15 Q. Dr Oxley?
 16 A. Harlow.
 17 Q. And Dr Traub?
 18 A. Southend.
 19 Q. And then we've got Dr Tuddenham for the --
 20 A. And Sister Tubridy is my domiciliary nursing sister,
 21 who was the person who looks after haemophilia
 22 throughout the region.
 23 Q. If we go back to the second page -- thank you for
 24 that -- we can see it's said:
 25 "The clinical significance to those found to

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1 *pro tem* if treatment with cryoprecipitate or DDAVP is
 2 not possible."
 3 So just trying to unpick -- sorry, Henry, if we
 4 just keep the bottom of the previous page for the time
 5 being. So bottom of that page again. If we just try
 6 and unpick the recommendations there, the heat-treated
 7 as a matter of generality is the express preference
 8 "whenever possible". Is that a reference to supply?
 9 A. Well, not necessarily. I mean, I think you're
 10 probably going to ask me later about the way we used
 11 NHS unheated Factor VIII during the small transition
 12 period and I've already addressed my concerns about
 13 the risk of NHS unheated versus commercial heated. So
 14 I think I can -- I mean, I've already dealt with that
 15 part of the discussion.
 16 The small pool Factor VIII concentrate which is
 17 being described I think is the product that I used in
 18 the paper that I've submitted, which was
 19 Professor Machin was the first author and I looked
 20 after two patients. That shows that there were tiny
 21 amounts of an NHS small pool heat-treated concentrate
 22 available at around that time, probably the middle of
 23 '84, rather before this decision was made.
 24 Of course the new patients and the mild patients
 25 obviously had a certain priority. But I'm not aware

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1 have HTLV-III antibodies is not yet known."
 2 Then it is explained that:
 3 "BPL hope to have heat-treated Factor VIII
 4 concentrate available from April 1985 and that
 5 heat-treated Factor IX should be available later in
 6 the year."
 7 Then there's a reference to a particular concern
 8 about the effect of heat treatment on Factor IX
 9 concentrate and a further discussion in relation to
 10 Factor IX.
 11 Then we go to the next paragraph. We can see
 12 what's being agreed as at 13 December:
 13 "Emergency stocks of Factor VIII concentrate
 14 held by associate centres should be exchanged for
 15 a heat-treated product by the Royal Free."
 16 So that's the smaller centres in the local area,
 17 and then 2:
 18 "Heat-treated material should be used whenever
 19 possible with the exception of the NHS Factor IX
 20 concentrate."
 21 We will look at the whole thing. (iii) is:
 22 "All new patients, and mild haemophiliacs with
 23 injuries requiring maintenance of high levels of
 24 [Factor VIII] should be treated with Heat Treated NHS
 25 [Factor VIII] or small pool [Factor VIII] concentrate

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1 that by December '84 there was really any heat-treated
 2 NHS Factor VIII available, apart from my knowledge of
 3 the small pool, rather gently heated concentrate that
 4 I knew about and had obtained for my two patients.
 5 Q. So we can see there's a slight difference of emphasis
 6 between point 2 and point 3 here. New patients and
 7 mild haemophiliacs falling within the description
 8 there, it's cryoprecipitate or DDAVP and if cryo or
 9 DDAVP is not an option heat-treated NHS or the small
 10 pool factor concentrate. There's no "whenever
 11 possible" or aspiration or aim. It seems to be
 12 a clear statement that's what the policy should be for
 13 those categories; would you agree?
 14 A. That's really what it says. I mean, I think that when
 15 people are drafting their minutes or when they're
 16 making their statements they don't always know that
 17 40 years later every word they've used will be
 18 dissected.
 19 Q. No, no, understood. It's just this is the best guide
 20 we have --
 21 A. Yes, of course, and I'm not complaining, I'm just
 22 saying it's very difficult to interpret individual
 23 words at 40 years' distance.
 24 Q. The position of children is not expressly addressed
 25 there. Can you --

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1 A. Well, the chances are most of the new -- most of the
2 children will be new patients, if you like. But
3 I take your point that the children do have a very
4 high priority and that's, I think, a very fair point.

5 Q. Then if we just go to the top of the next page, to
6 complete the picture, there's a reference to family
7 members not volunteering as blood donors and then
8 elective surgery being delayed until the position is
9 clearer and the efficacy of heat treatment proven.

10 A. Which I think is the first time that's been mentioned.

11 Q. It is. So is it fair to infer that that course,
12 delaying elective surgery, for the reasons there
13 given, was a new measure being adopted around this
14 time?

15 A. I think it was and, in fact, I happen to have --
16 because of one of my rule 9 questions, I happened to
17 trip over correspondence with my surgeons in the very,
18 very late part of '84 where I postpone an operation
19 because that was the recommendation -- not then said
20 this recommendation, but clearly we've been talking
21 about it and so I contacted my surgeon and said,
22 "Let's wait".

23 The difficulty with that decision, by the way,
24 is that when would one be able safely to perform
25 a surgical procedure and I think the answer to that

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1 product was transmitting HIV, and that really caused
2 enormous alarm.

3 Q. It's slightly out of sequence but I might as well ask
4 you about it now. I know you gave evidence to one of
5 the other inquiries about it. As I understand it, you
6 were at the conference in Milan and received
7 information at the conference about the issue of
8 transmission from heat-treated concentrate?

9 A. Yes.

10 Q. What steps were then taken?

11 A. Well, I phoned home immediately and said, "Get this
12 product out of the fridges and out of the patients
13 immediately".

14 MS RICHARDS: Sir, I note the time. Is that a convenient
15 point at which to stop?

16 SIR BRIAN LANGSTAFF: Yes, it is. We'll meet again then
17 at 11.40.

18 (11.01 am)

19 (A short break)

20 (11.44 am)

21 MS RICHARDS: Dr Colvin, we were in December 1984. Just
22 a couple more documents or three more documents from
23 late '94/early '95 to look at.

24 BART0000519.

25 This is a document you've seen only this

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1 question, if you'd like me to give it to you, is
2 probably 1988. The reason I use that date is that
3 that's the date when the 8Y study is published. Even
4 that is not a proof that 8Y was safe. It's only
5 a probability but it's at the level of probability
6 around 90 per cent.

7 So I think that really from '88 onwards
8 published work that is safer or reasonably safe to
9 perform elective surgery.

10 Q. Then can I just ask for those who were on home
11 treatment at the time, what was the process that was
12 put into place at The London Hospital to try and get
13 back any stocks of what may have been untreated
14 commercial products?

15 A. I don't recall that, I'm afraid.

16 Q. Would you expect there to have been a process?

17 A. Well, it's likely. I think we saw yesterday that
18 I was using some commercial product in home treatment
19 but I don't know who it was for and why it was being
20 given; so, yes, you would have thought so.

21 By the way, if we're talking about recalling
22 product, I can remember the most dramatic event of
23 recalling product was at the time of the 1986 World
24 Federation of Haemophilia meeting in Milan when we got
25 the message that a particular commercial heat-treated

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1 morning, Dr Colvin, since you wrote it obviously many
2 years ago. 20 December 1984, you're writing to
3 Dr Harrison at the Regional Transfusion Centre, and it
4 says this:

5 "Dear Jean,
6 "At your request I am writing to confirm that
7 I am willing to continue to use non heat-treated NHS
8 concentrate for the time being. This decision is, of
9 course, in accordance with the discussions which took
10 place at the recent Regional Working Party In
11 Haemophilia."

12 Then you say you:
13 "... look forward to receiving heat-treated NHS
14 concentrate as soon as it is widely available."

15 We'll take it in stages as we go through the
16 correspondence, but can you recall, first of all, why
17 you were being asked by Dr Harrison to give this
18 confirmation?

19 A. No, I can't.

20 Q. You're setting out there a willingness to continue to
21 use non-heat-treated NHS concentrate in circumstances
22 where we know that the recommendation now from UKHCDO
23 is to use heat-treated concentrate in preference to
24 unheated concentrate. Why was that?

25 A. I've already explained, I think, that I was not

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confident that heat-treated concentrate would in fact prevent HIV infection, and that if it didn't, then all my patients who were HIV negative would become HIV positive. So, as I've explained, this was an absolutely impossible situation in which to -- to place ourselves. I believe that, from this letter, that the decisions that took place at the Regional Working Party allowed me to take that action, and I think Peter Kernoff and I worked together very closely to try to construct a rational policy.

I have also confirmed, as we know, that heat-treated commercial concentrate was still transmitting HIV in 1986/1987.

Q. Although you didn't know that, obviously, at the time?

A. No, of course I didn't, but I knew that HCV (or at least non-A, non-B) was not necessarily being eliminated by the heat treatment processes that were being used at the time. And I've also -- I'll confirm it again that the safety of a concentrate depends on the donor pool, the way it's been selected, the size of that donor pool, and the level of viral inactivation, and those changed quite a lot over the period of two years that led up to the final safety of products by 1988.

Q. Just on the issue of size of donor pool, do you recall

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A. No, I don't.

Q. Then we can see there the proposal now is you won't use NHS factor concentrate in the region after the current stocks are exhausted. So you will use up what you have of non-heat-treated NHS and then presumably move to heat-treated or others?

A. That's what it says.

Q. Then if we look at BART0000526, this is a letter from you to the district treasurer and the finance department at The London Hospital, 20 January 1985, and we can just look at the second paragraph. You said:

"As I indicated in a previous letter we have reasonable supplies of non heat treated National Health Service concentrate at the moment which should last us for another two or three months. As noted in Mr Knight's letter we will then have to buy commercial heat treated concentrate unless, by that time, heat treated [NHS] concentrate that begun to become available."

So it would look from this as though, in terms of the treatments you were using in the first few months of 1985, your proposal, your intention, was to use up the current stocks or supplies of NHS concentrate, not heat-treated concentrate, which might

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what you knew at the time about the relative difference in sizes between NHS and commercial concentrates?

A. No, I can't recall that detail.

Q. Then if we go, please, to BART0000524, we can see that this is not long after that last letter. It's a letter from Dr Harrison, "Dear Colleague", 2 January 85. It says:

"Following further discussions between myself and Drs Kernoff and Colvin, it has been decided that, in the light of recent findings reported in both the lay and medical press, non-heat treated NHS Factor VIII concentrate will not be used in the [North East] Thames region after current stocks are exhausted."

So is it right that there was further discussion after that last letter between you, Dr Kernoff and Dr Harrison?

A. Of course I have no recollection.

Q. That would seem a fair inference to draw from the correspondence?

A. It looks as though that's -- I mean, what is written is written.

Q. Do you know what the reference is to "findings reported in both the lay and medical press"?

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take you to approximately April of 1985?

A. That's the implication.

Q. At that point you would either have product from Elstree that's heat-treated or you would buy commercial products?

A. That's the implication.

Q. As far as you recall, is that what happened?

A. I have no recollection.

Q. What consideration did you give or do you think you would have given at this point in time to the fact that, notwithstanding the concerns you've expressed, the clear recommendation by this stage from UKHCDO was to prefer heat-treated over non-heat-treated?

A. I can only assume that Peter and I didn't agree with it.

Q. Then if we go on, please, to BART0000675.

This is a meeting now in May of 1985 of the Haemophilia Working Party of the North East Thames Region, and we can see again that you and Dr Kernoff are there.

If we go to the second page, we pick it up on the bottom half of the page, under the heading "Factor VIII Concentrate: Heat Treatment and Supply", we can see the position there set out as at May of 1985:

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"The requirement that all Factor VIII Concentrate should be heat treated means that more commercial product is being used than before with the attendant risk of Hepatitis B and Non A/Non B Hepatitis transmission."

Then there's reference to pilot samples of the NHS product being effective. There's a report, in the next paragraph, from trial users of the newer NHS dry heated product. Then it says this:

"When sufficient is available this product will be the first choice for all newly diagnosed patients, children and others not yet exposed to the HTLV-III virus and will replace cryoprecipitate as the preferred treatment in appropriate cases.

"The USA experience confirms that cryoprecipitate has caused less Hepatitis and HTLV-III antibody sero-conversion, related to the small pool donations and the fact that cryoprecipitate is prepared from the plasma of volunteer donors unlike the large pool Commercial Factor VIII concentrate which is chiefly from paid donations."

Then at the top of the next page it said:

"Dr Colvin proposes to replace the use of Cryoprecipitate by NHS [heat-treated Factor] VIII ... concentrate as soon as possible. In the meantime

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obviously touched on this to some extent but can I invite you to just summarise why you say cryoprecipitate for all patients in all circumstances was not a realistic choice.

A. Okay. So I've already indicated that I do use or did use cryoprecipitate for small children and also for the selected patients that I discussed in the paper we looked at yesterday.

I also explained that cryoprecipitate is allergenic and I also explained that cryoprecipitate is a single dose preparation whose actual dose is not known and that if you used ten bags of cryoprecipitate for one treatment, that would be ten patient exposures; that supply was not unlimited, contrary to what has been said elsewhere; and that the material was difficult to make up; and that certainly at night it would be extremely difficult to deliver eight-hourly treatment using cryoprecipitate in that way.

So I think all this is rehearsing material we've dealt with before and it is the case that I never believed that cryoprecipitate could be used in all circumstances for all patients.

Q. If one moves back from all patients, all circumstances, what about reversion to

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patients requiring infrequent treatments should continue on DDAVP and Cryoprecipitate."

So it would appear from this that by May of 1985 you're using DDAVP, you're using cryoprecipitate, and you're using commercial heat-treated products, or the region at least is using commercial heat-treated products.

A. Sure.

Q. The intention is to start using the NHS heat-treated product subject to availability?

A. I can't remember when the 8Y study starts. It must have been around '84 or '85 -- we will have to look to see when the 8Y study started -- but I was committed, as ever, to NHS activity, and I contributed, as we will probably discuss later, to the 8Y study.

Probably by the time we get to this paragraph I'm personally convinced of the safety of 8Y, although it hasn't been published and I can't be sure, and the proposal to replace the use of cryoprecipitate by 8Y seems appropriate, to me, at that point, I think.

Q. Now, in your statement, Dr Colvin, you said, in relation to the question of reverting to cryoprecipitate, that you didn't believe that reversion to cryoprecipitate for all patients in all circumstances was ever a realistic choice. We've

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cryoprecipitate -- in response to the AIDS crisis from January '83 onwards, say, what about reversion to cryoprecipitate for a much larger cohort of patients than you did?

A. Well, there's nothing I can say really.

Q. Would you accept that would have been possible?

A. I don't know.

Q. What are the factors that bring in uncertainty? Supply?

A. How much cryoprecipitate was available, how much we could arrange for material to be delivered to us, how much difficulty there would be in training people to do something that was extremely old fashioned, how to persuade people to use very large syringes to deliver treatment that had been delivered in small syringes. I mean, a whole host of logistic aspects.

But I don't think it ever actually occurred to me to do such a thing.

Q. So those logistical difficulties -- that's I think one of the phrases you use in your statement, in fact -- were not explored at the time. You didn't ask the questions that you have just posed, about whether you could get the supplies, how you could to the training, because, as you have just said, it didn't occur to you as an option at the time?

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1 A. I didn't think it was realistic.
 2 Q. But did you explore the practical realities with
 3 Dr Harrison or others?
 4 A. I don't recall.
 5 Q. What about the option of offering cryoprecipitate on
 6 an individual basis to your patients, explaining the
 7 pros and cons, as you have done to the Inquiry, and
 8 leaving the choice with the patient? Did that occur
 9 as an option?
 10 A. No.
 11 Q. Do you think it should have done?
 12 A. No.
 13 Q. Why?
 14 A. Because I don't think it was realistic. I really
 15 don't think that this was a realistic option. I don't
 16 think anybody that I knew ever thought that to go back
 17 to using cryoprecipitate for everybody in all
 18 circumstances in this position was realistic.
 19 Q. Forgive me, Dr Colvin, I understand your answer to all
 20 patients, all circumstances. What I'm inviting you to
 21 consider now is you could have sat down with
 22 individual patients, explained to them the risk of
 23 HIV, explained to them your view of the disadvantages
 24 of cryoprecipitate but the advantage in terms of viral
 25 safety, and the disadvantages of concentrate in terms

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1 A. Well, I think what happened was that there were
 2 a small number of patients with haemophilia or von
 3 Willebrand's disease that was not suitable for DDAVP
 4 who were likely to require quite significant amounts
 5 of product and had not been treated much in the past,
 6 where it seemed to me that cryoprecipitate was
 7 a realistic option to cover a particular procedure
 8 that would otherwise use a moderate but not very large
 9 amount of material.
 10 Q. So it was based upon the particular individual
 11 circumstances of a limited number of patients?
 12 A. Exactly.
 13 Q. If any patient had come to you -- and I'm thinking
 14 particularly here of the 1983/1984 period, the
 15 concerns about AIDS. If any particular patient had
 16 come to you and requested to change their treatment
 17 from concentrate to cryoprecipitate, would you have
 18 acceded to that request?
 19 A. I can't answer that question really. I would always
 20 try to meet my patients' requests if I was able to do
 21 so. I can see that if a patient wanted to have
 22 cryoprecipitate on a particular occasion, I would
 23 certainly have considered it. If they wanted to go
 24 back on to home treatment with cryoprecipitate, I'm
 25 not sure that would have been possible, and

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1 of viral safety but its advantages in the other
 2 respects you've identified, and given them a choice.
 3 That wouldn't necessarily have led to every patient
 4 taking you up upon that.
 5 A. Well, clearly, I did do that for some patients.
 6 I presented a paper (admittedly for only half a dozen
 7 patients) where that exactly happened. So it's
 8 a matter of what I could do at the time and what was
 9 realistic and what seemed sensible to me and, at this
 10 distance, I don't really think I can offer you any
 11 more detailed answer to the ones I've given.
 12 Q. Is it fair to say that it didn't occur to you to do
 13 this exercise of an individual conversation with every
 14 patient at the time?
 15 A. That's fair.
 16 Q. In terms of the categories of patients who you were
 17 during 1983 and 1984 treating with cryoprecipitate --
 18 leave aside the children who we've discussed -- you've
 19 referred to there being some other patients who were
 20 being treated with cryoprecipitate, and we can see
 21 that from a number of the documents and from the study
 22 you referred to.
 23 Can you recall what the characteristics of those
 24 patients were? Other than children, how did you
 25 decide which patients to offer cryoprecipitate to?

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1 I certainly wouldn't have recommended cryoprecipitate
 2 for major surgery.
 3 Q. Just dealing with home treatment, why would it not
 4 have been possible on an individual patient basis?
 5 A. Well, I said I think it might have been possible on an
 6 individual basis. Nobody ever suggested it to me, and
 7 I never suggested it to a patient.
 8 Q. Can we then consider the question of what information
 9 was provided to patients about risks of HIV.
 10 First of all, would you agree that, once we get
 11 to January 1983: the New England Journal of Medicine,
 12 we haven't looked, but there were reports in the
 13 national media in the early part of 1983, the meeting
 14 at London Airport with Immuno, once that was known,
 15 that there was at the very least a very real risk that
 16 blood products could transmit AIDS, would you agree
 17 that patients needed to be told that?
 18 A. I would expect that to be the case, yes.
 19 Q. The purpose of telling them, would you agree, would be
 20 so that they could exercise a degree of choice as to
 21 whether to continue with their treatment or not?
 22 A. Clearly, patient autonomy is important, so I accept
 23 what you say.
 24 Q. Because it would be their -- ultimately, it's their
 25 health if they don't have concentrates; potentially

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1 their life --

2 A. Sure. Yes, it's a matter of concern. I agree.

3 Q. Doing the best you can, Dr Colvin, when do you think

4 you began to tell patients about the risks of HIV?

5 A. Well, the answer is that I can't recall. Any comments

6 that were made by me about this would be in the

7 clinical notes of patients, and that's the only place

8 really one could look for a contemporaneous account of

9 what happened.

10 Q. I don't know whether you can answer this or not,

11 Dr Colvin: do you think it more likely than not that

12 you did tell your patients about the risks of HIV from

13 early 1983 onwards?

14 A. I know that I spoke to some patients because I have

15 recalled speaking to some patients, but I can't recall

16 obviously every patient. But there was -- certainly,

17 during '83/'84, I was talking to patients about the

18 risk of HIV, but I couldn't possibly tell you about

19 each individual patient or whether there was a general

20 policy of doing such a thing.

21 Q. The example or an example you give in your statement

22 is having conversations with patients who were

23 undergoing surgery or about to undergo surgery.

24 A. Sure.

25 Q. In terms of the routine clinic appointments that you

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1 in 1983/'84; this is before we get to the testing of

2 your patients for HIV -- any conversations with family

3 members, spouses about risks of HIV?

4 A. I have no particular recollection of such

5 conversation.

6 Q. Is this fair: if there had been -- as we've heard some

7 descriptions in some centres of group meetings being

8 organised. If there had been any kind of group

9 meeting that you'd organised, would you expect to

10 remember that?

11 A. The only group meeting I can remember was one that

12 took place much later when we did have such a group

13 meeting, but I don't remember any group meetings at

14 that time. Which is not to say there wasn't one, but

15 I don't remember such a group meeting.

16 Q. This is a hypothetical question, Dr Colvin, in some

17 respects, but I understand from your earlier answer

18 that the best guide to whether you did spell this out

19 to your patients at the time will be in your

20 handwritten notes.

21 A. Exactly.

22 Q. So if they are not in the notes, the inference -- the

23 correct inference to draw is in relation to that

24 patient you didn't spell it out?

25 A. I think that's an impossible conclusion to draw, but

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1 would have, as I understand it, at least with your

2 regularly treated patients, you'd have on a -- every

3 few months, you would expect to be seeing patients.

4 A. Yes.

5 Q. On those appointments, not for surgery but to

6 decide -- you know, to see how the patient is and plan

7 their treatment for the next few months, do you think

8 you would have told them then about the risks of HIV?

9 A. Well, it was in the press, and they would have had the

10 opportunity to see that information, and I would have

11 expected them to ask me and for me to speak to them

12 about it. But whether I did or exactly when I did, it

13 can only be a matter of record, and we're now looking

14 at 35 years ago and I can't make that kind of

15 recollection.

16 Q. Would you agree -- this is as a matter of principle,

17 as it were, rather than asking you to remember things

18 you have indicated you don't remember. Would you

19 agree that one reason why it would have been important

20 to share that information with patients is not only so

21 that they could take their own decisions about

22 treatment but so that they could think about the

23 safety of their close family?

24 A. Yes. I can see that point of view.

25 Q. Do you recall having any conversations with -- again,

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1 I did try to take clear notes.

2 Q. Well, can I press you a little on that because it's

3 really about what your note-keeping habits would have

4 been at the time, and I think you said yesterday you

5 regarded the keeping of accurate and comprehensive

6 notes as important.

7 A. Indeed.

8 Q. If you were telling your patients something as

9 significant as, you know, there is a risk that this

10 treatment could, if you continue with it or if you

11 start on it -- for a new patient -- could bring with

12 it a risk of what is understood to be, albeit

13 imperfectly, a fatal condition. That's the kind of

14 material that you would have included in your notes?

15 A. I would have expected to, yes.

16 Q. Can I come on then to the process of the testing of

17 your patients for HIV and then being informed of their

18 diagnosis.

19 We've seen reference and, indeed, you've made

20 reference to Dr Tedder and the tests that he performed

21 at the Middlesex. I understand from your statement

22 that you had access to testing facilities through Dr

23 or Professor Collier --

24 A. Yes, that's true.

25 Q. -- who was a colleague at The London Hospital?

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1 A. Yes.

2 Q. So what, as far as you can recall, were the

3 arrangements that you made for the testing of your

4 patients for HIV?

5 A. I think I must have looked to see who I thought was at

6 risk. And then we know that the virology department

7 had stored samples of serum, which I had not

8 control -- I mean, they did that anyway; it was

9 automatic. Professor Collier decided that we could

10 look at those samples and I think he had a test of his

11 own, actually. I think he then referred his results

12 to Dr Tedder, probably for confirmation of what the

13 results were, and then at that point I decided to --

14 once he was confident of the results, I decided to

15 communicate that to my patients.

16 Q. So, as I understand it from your statement and indeed

17 evidence you have given elsewhere, you did not tell

18 your patients in advance that you were testing their

19 sera for HIV?

20 A. That's correct.

21 Q. We will come on to why in a few minutes.

22 In terms of the stored sera, you referred to

23 communications with Professor Collier. Whose idea was

24 it, if I can put it that way, to use the stored sera

25 rather than asking for patients to come in and give

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1 potentially might have been infected, and that was

2 a problem that needed to be managed at that time.

3 Q. Just dealing, if I may, with the stored samples, so

4 a sample was taken at every clinic appointment?

5 A. Yes.

6 Q. A spare sample, as it were, that was stored?

7 A. Well, I wouldn't say it was spare. I think we -- the

8 virology department and the -- maybe the chemistry

9 department -- I'm not sure who stored the samples

10 where. But I think every time we did anything that

11 produced serum, it got stored.

12 Q. But as --

13 A. They're not spare exactly.

14 Q. You took -- you would take bloods on a routine clinic

15 appointment for a range of tests that were going to be

16 done there and then, as it were -- ALT tests, the

17 liver function tests. This is a sample that you were

18 keeping, not to test at that point in time but in case

19 it might need to be tested at some point in the

20 future?

21 A. I guess so. I mean, I don't think I was involved in

22 the process of keeping samples. I didn't say, "Please

23 keep this sample", particularly. I mean, my memory --

24 it's a very long time ago -- was that this is what

25 happened.

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1 fresh samples?

2 A. I imagine Professor Collier and I decided to do it

3 together, but I don't remember whose idea it was.

4 Q. Do you know or have any idea -- I don't expect you to

5 remember specifics of dates for individual patients --

6 but do you know when this stored sera would have been

7 stored? Because if you've got someone and it's sera

8 stored from two years ago, it's going to tell you if

9 they were HTLV-III positive two years ago but not

10 whether they have, subsequently, seroconverted?

11 A. Well, we did know. We did know that there were such

12 samples, yes.

13 Q. These were recent samples?

14 A. They were -- it's every three months or so that they

15 would be seen, and then they would automatically go

16 down into the store. So I think that the point you

17 are making, I think, is there may have been some

18 samples that went down at the time of testing. But

19 I think that the situation was different at this time

20 to the time later (when, of course, there were still

21 people who didn't know whether they were HIV positive

22 or not) at a later time, then they would have,

23 I think, been asked if they were happy for their

24 samples to be tested. We're talking now about the

25 crisis when there were probably 80 patients who

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1 Q. Just -- I know you have told us yesterday about how

2 when you first started out you could actually do quite

3 a lot of the testing yourself, you had, as it were,

4 the skills that you had learnt on the job in the 70s.

5 By the time we get to 1983/1984, where, physically,

6 did the blood get taken from the patient and who by?

7 A. Yes. Well, once we knew about the HIV risk and we had

8 reacted to it -- and I'm not sure exactly when that

9 was -- as you may come on later, there was

10 a discussion about high-risk labelling and once that

11 high-risk labelling came into play, then I arranged

12 that all my samples would be labelled by me before

13 I went down to the clinic, and then my nursing staff

14 took all the samples themselves so that patients

15 didn't have to go down to the phlebotomy department to

16 have their blood taken.

17 But exactly when that happened I don't recall,

18 but I do recall extremely clearly arranging all the

19 requests would be written out by me and that the

20 nursing staff would take the bloods.

21 Q. We'll come on to the question of what the applicable

22 standard might have been at the time, but why didn't

23 you tell patients that their blood was going to be

24 tested for HTLV-III?

25 A. I can't answer that question really because I think

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1 what we did was to recognise the need for the samples
2 to be tested, that there were 80 samples, probably,
3 that needed to be sorted out, which was a very large
4 number for a very small service, and that -- I must
5 have felt at the time that that was the only way to
6 proceed.

7 It's important to appreciate that the mindset of
8 a haematologist is, as Mark Winter was explaining,
9 that one is both a physician and a pathologist, and
10 that the purpose of being there at all is to address
11 a clinical problem and to solve it.

12 The advent of testing meant that finally we had
13 some kind of handle on what on earth was happening and
14 at the time, although of course things changed very
15 much in the later part of the 80s, it wouldn't
16 necessarily, and I don't think it particularly did,
17 occur to me that there was anything very special about
18 the anti-HTLV-III test that was different from any
19 other blood test.

20 Maybe that mindset was a wrong one but it was
21 a view that I think was very widely held in the
22 haemophilia treating community, and we felt that we
23 needed to get on to do this work.

24 Let's say for a moment, at the end of '84 or
25 early '85, I had brought up 80 patients one way or

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1 described to the Inquiry by some patients -- not
2 necessarily patients of yours, Dr Colvin, I can't
3 recall whose patients they might have been, but the
4 converse, some have described the sense of shock at
5 being told that they have HTLV-III in circumstances
6 where they didn't even know they were being tested
7 for it.

8 A. I can understand that. What I can say is that,
9 whichever way you look at it, there was going to be
10 a huge sense of shock. I mean, let's say we'd done
11 what I just said, bring 80 people up, testing them,
12 bringing the 80 people up again and then telling them.
13 They still have terrible shock, and it would be
14 extremely difficult to avoid giving information on the
15 telephone or by letter before they came to see me in
16 person.

17 The situation was terrible whichever way you
18 looked at it. I'd also say, and I know this isn't, in
19 a way, perhaps, evidence, but nobody ever said to me
20 in that period that they wished that I had asked their
21 consent before testing their blood and giving them the
22 information. I believe I gave every patient the
23 information personally and I don't believe that any
24 patient of mine ever complained at the time that they
25 hadn't been treated properly.

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1 another to discuss with them whether we were going to
2 test their blood. Because it needed to be done
3 quickly; it wasn't a question of waiting for the next
4 three-month appointment. They would then have been
5 brought up to see me and I would have said, "We have
6 this test which we think is now valid, but we're not
7 sure" -- because there were false positives and false
8 negatives -- "We can arrange for your blood to be
9 tested but it will take at least two or three weeks
10 for the results to come through and, when the results
11 do come through, we'll call you all up again to
12 deliver the message."

13 I wouldn't have wanted the patients to have
14 telephone me for the answer. I wouldn't have wanted
15 to write to them with the answer. What would have
16 happened would have been that, over quite a long
17 period of time, 80 patients would have had to come to
18 see me, had their blood tested, spent two weeks
19 worrying about what was going to happen next, and then
20 have to be brought all the way back again, often from
21 far away, in Essex, to be given the answer.

22 Now, maybe that was the right thing for us to
23 have done but I think it would have been extremely
24 difficult.

25 Q. Because the converse position is, as has been

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1 Q. In terms of the telling patients the test results, did
2 you only tell patients whose test was positive, and
3 leaving aside, I know, the uncertainties about exactly
4 what the positive test meant, but did you only tell
5 the patients who had tested positive or did you also
6 communicate the test results of those that were
7 negative to the patients?

8 A. I must have told the patients who were negative that
9 they were negative. Surely. I mean, I don't remember
10 but I must have done.

11 Q. Can we look at BART0000675, please. So this is the
12 document that we had been looking at for a different
13 purpose a moment ago, the meeting of 22 May 1985. If
14 we go to the second page we see at the top of the page
15 it says:

16 "Concern was expressed about the confidentiality
17 of personal details of HTLV-III [antibody] positive
18 patients. No lists are circulated to avoid the risk
19 of misuse by unauthorised people."

20 Then this:

21 "All patients will be informed of the result of
22 their HTLV-III antibody test on request ..."

23 Then it goes on to talk about being counselled
24 on the implications of a positive result.

25 This doesn't appear to suggest the intention

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1 within the region automatically to tell every patient.
 2 It was left to patients who didn't know they were
 3 being tested to request the result?
 4 **A.** To the best of my knowledge and belief, I went through
 5 all the positive tests and informed all of the
 6 patients in due course that their result was positive.
 7 Now, that's not an easy task and it would have taken
 8 a period of time and I think you have got another
 9 letter, which you may want to show me, which fleshes
 10 out the bones of this discussion to some extent.

11 But it was never my intention to withhold the
 12 results of anti-HTLV-III tests from my patients, and
 13 I don't believe any patient ever said to me that they
 14 thought that I had done so.

15 **Q.** Are you able to explain why these minutes, of
 16 a meeting which -- it was a regional meeting,
 17 obviously, not exclusive to The London Hospital but
 18 a meeting you attended -- records that patients will
 19 be informed of the result on request and then it goes
 20 on to say -- I didn't read this bit -- that:

21 "... doctors and dentists responsible for the
 22 care of 'positive' patients should be informed of
 23 positive tests ..."

24 So there appears, in this, to be automatic
 25 provision for telling treating doctors and dentists of

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1 "I now have anti-HTLV-III results from many of
 2 the home treatment patients ..."

3 So that may give us an idea of the timing. This
 4 is April 1985.

5 **A.** Yes.

6 **Q.** "... I am reluctant to give the list wide circulation
 7 because of doubts about the meaning of the test and
 8 the sensitive nature of the information."

9 Then you say this:

10 "By no means all the patients who are positive
 11 have been told the result of their test though I have
 12 not hidden the information from those who wish to
 13 know. If you need to talk to any of them about the
 14 AIDS problem perhaps you could give me a ring to
 15 discuss the latest position."

16 Can you explain that sentence, "By no means all
 17 the patients who are positive have been told the
 18 result"?

19 **A.** Well, if you go to the second paragraph:

20 "Secondly I have issued a set of guidelines for
 21 the management of haemophilia in general."

22 It goes on to say:

23 "This is also rather parochial but you will note
 24 that we are treating all samples from patients with
 25 haemophilia being 'High Risk' and are attempting to

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1 the result but patients will only be told on request.

2 **A.** Well, I'm puzzled by this note myself, because I find
 3 it hard to believe that there was a policy of telling
 4 people their results on request, in the sense they had
 5 to come and ask me to deliver those results. It
 6 doesn't make sense to me.

7 **Q.** Because that would be impossible if they didn't know
 8 they were being tested in any event?

9 **A.** I agree that's possible. When I look back on the
 10 40 or so patients who were positive under my care --
 11 which would not actually be the number who
 12 seroconverted under my care, because I saw a lot of
 13 patients who had seroconverted elsewhere. So I don't
 14 believe that I ever heard of or saw a patient who
 15 said, "Dr Colvin, you didn't tell me about my HTLV-III
 16 positivity", or HIV positivity. It just didn't -- to
 17 the best of my knowledge and belief, it never
 18 happened.

19 **Q.** Can we look at the letter that you may have just been
 20 alluding to, Dr Colvin. It's BART0000535_001.

21 So this is a letter from 16 April 1985. If we
 22 go down we can see -- go down to the bottom. We can
 23 see it's from you. It's "Dear [colleague]", and it's
 24 attaching a set, I think, of recommendations.

25 In the last paragraph you say this:

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1 deal with the difficult problem of providing adequate
 2 dental care for our patients."

3 Then the paragraph I think above -- sorry,
 4 I need -- can we go back to the main letter.

5 **Q.** Yes, of course.

6 **A.** Sorry I was choosing the wrong paragraph:

7 "Thirdly and perhaps most importantly ..."

8 Not "not importantly".

9 "... I have given all our home treatment
 10 programme patients a new set of home treatment rules
 11 together with some counselling on the AIDS problem and
 12 virtually all of them have now been spoken to."

13 So I think what this means is that I had
 14 a discussion with all the patients at risk, would have
 15 discussed whether they wanted to know about their
 16 situation and about the AIDS problem in general, and
 17 would have provided them with information.
 18 I clearly -- autonomy would also dictate that if
 19 a person didn't want to know the result of the test,
 20 then they could refuse to have it. But I don't
 21 remember anybody ever saying such a thing. So I think
 22 you need to take these two paragraphs together.

23 **Q.** Let me see if I've understood that, Dr Colvin.

24 So the paragraph you have just drawn attention
 25 to is to say you think you have spoken to all the home

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1 treatment patients or "virtually all of them", it says
 2 here, have been spoken to. It is clear from the next
 3 paragraph, the sentence I asked you about, that there
 4 must be some patients who have not been told the
 5 result of the positive test. Reading them together,
 6 it is your suggestion that that's because they may
 7 have not wanted to know?

8 A. I don't know. I mean, I've only seen this letter this
 9 morning.

10 Q. I know.

11 A. I am very surprised by it because my memory is, and
 12 I repeat it, that all the patients who were
 13 anti-HTLV-III positive as a result of the testing
 14 process were told of their results and were counselled
 15 and were involved in their care at a complete level,
 16 and I would never have dreamed of not telling patients
 17 about their results. It doesn't make sense to me.

18 Q. Okay. Can you recall if you communicated the results
 19 of the tests at specially arranged appointments? So
 20 for the 40 or so who were positive, did you bring
 21 forward their routine appointments to speak to them
 22 relatively urgently or was it at the next routine
 23 appointment?

24 A. I think there probably was a mixture, depending on
 25 whether -- perhaps when the appointment was coming up,

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1 Even my nursing staff -- there weren't that many
 2 nursing staff at that time, we were still very short
 3 of nursing staff. So, whilst I relied on my nursing
 4 staff, it was my job and I believe that I fulfilled my
 5 obligation by giving them the information and giving
 6 them the leaflet and then continuing to see them to
 7 the best of my ability with the counselling I had
 8 available to me.

9 Q. Did you advise them all as to the risk of sexual
 10 transmission?

11 A. Yes, of course.

12 Q. Were tests offered that stage or at a later stage to
 13 the partners of the patients?

14 A. Many, many partners were tested but exactly when
 15 I can't recall the detail, but there's no doubt that
 16 partner testing did take place at my centre.
 17 Although, as you know, I've said in my statement, that
 18 sadly one of my patient's partners was infected. But
 19 that wasn't -- mine was not the only centre where that
 20 happened, and only one -- I think one person was
 21 infected.

22 Q. One partner?

23 A. Yes.

24 Q. Then, in terms of the numbers who were infected with
 25 HIV, you have set those out in your statement. If we

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1 but I would have thought most of the communication
 2 would have been taking place outside the clinic.
 3 Because, I mean, the clinic itself is not a good place
 4 to have those sort of discussions.

5 So, I mean, I can recall one or two of the
 6 conversations but not many of them at a specific
 7 level. But I think that I would have -- I would have
 8 seen patients separately. But I can't confirm that
 9 and I again repeat that nobody under my care ever said
 10 to me, "You didn't do that properly."

11 Q. In terms of the counselling or information that was
 12 provided, what -- as far as you can recall at this
 13 stage, in 1985, what kind of information do you recall
 14 you were giving your patients who had tested positive?

15 A. That was obviously a long-term discussion. You can't
 16 just do the whole thing at once. And what I recall is
 17 that I assessed the situation, produced an information
 18 sheet on the subject and then gave them that
 19 information sheet, which -- it hasn't appeared in the
 20 papers, I don't have a copy myself, but there's no
 21 doubt there was such an information sheet and that was
 22 given to patients to explain to them their situation
 23 and the precautions they needed to take.

24 So there was no formal counselling at the time,
 25 it was down to me. But I did prepare a document.

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1 could just look at that, it's paragraph 63. I'll just
 2 put it up on screen as well for ease of reference.
 3 It's WITN3343007, Henry, and it's page 21 of that
 4 document. We can see it's paragraph 63, bottom half
 5 of the page:

6 "As of September 1987 (source personal
 7 educational lecture series).
 8 Severe haemophilia, 31; moderate/mild
 9 haemophilia A, 9; haemophilia B, 1; von Willebrand
 10 disease, 0."

11 Children is not there identified. How many --
 12 I don't know if you can recall an exact number, but
 13 approximately how many child patients were infected
 14 with HIV?

15 A. Okay. I had three patients who had been to Lord Mayor
 16 Treloar College, so they were shared care, and
 17 I didn't have really any influence on the treatment
 18 they had at the Lord Mayor Treloar. I know you will
 19 be discussing that at a later time. So those three
 20 patients were all anti-HIV positive.

21 There were three other children I can
 22 immediately remember who -- two of whom eventually
 23 died in adolescence of AIDS, and one of whom died of
 24 a head injury in early adolescence. Those are the
 25 patients that I can remember.

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1 Q. So six children, three of whom were Treloars children
2 who were infected with HIV?

3 A. I think that's the case, but of course, one of the
4 problems that I have identified for the Inquiry is
5 that, first of all, there's the definition of a child,
6 and then secondly, there's the definition of when the
7 childhood begins and when it ends and when the
8 infection takes place. So it's quite a complex
9 question which I find very difficult to answer.

10 But I believe, as far as I'm aware, that there
11 were six children under my care who were anti-HIV
12 positive.

13 Q. Is that number subsumed within the overall total here
14 which is 41?

15 A. Oh, yes. It's included within.

16 Q. And of those six children (and, again, without asking
17 you obviously to deal with any individual by name or
18 particular circumstances), do you recall whether those
19 six children or any of those six children, were they
20 all severe haemophiliacs or were some of them within
21 the moderate or mild group?

22 A. At least five were very severely affected, and one of
23 them -- the one who died of the head injury -- may
24 have been moderate rather than severe. By that
25 I would mean a level of, say, 1 or 2 per cent

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1 have been HCV positive as well.

2 So how to manage a patient who arrives on my
3 doorstep with no English who's got a terrible
4 haemophilia and is HIV positive is, if you like, for
5 you an example of how difficult our lives could be.

6 Q. Is it fair, however, to assume that the majority of
7 the numbers listed here were patients who were being
8 treated at The London Hospital and/or one of the
9 associate centres within the region at the relevant
10 time?

11 A. That's likely for the majority. The point I'm trying
12 to make is that the 41 patients were not all mine
13 exclusively by any means.

14 Q. If we just go over the page, please, to paragraph 64,
15 what you have said there, and this was in answer to
16 a question about what work was done to establish dates
17 of seroconversion, you said:

18 "The timing of infection was studied using
19 stored serum samples. The result was that it was
20 possible to determine the probable location and even
21 date of infection fairly accurately in a number of
22 patients."

23 Then you talk about the patients often wanting
24 to know the site and date infection, but given
25 significant movement between centres, many of them

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1 Factor VIII, as opposed to less than 1 per cent
2 Factor VIII.

3 So the answer is that all six were really
4 severely affected.

5 Q. Then you go on to say in the statement that some of
6 these were patients -- this is how I am reading it,
7 looking at your statement. Please correct me if I'm
8 wrong, Dr Colvin. Some of these were patients whose
9 treatment was shared between you and an associate
10 centre?

11 A. Yes, and some of them were patients who had come to me
12 already infected -- because this is 1987 now -- so
13 that some of them were patients who had, for some
14 reason, arrived in Whitechapel already infected. So
15 it might be that somebody came to Whitechapel for --
16 or at least to London for university. It might be
17 that we had another immigrant community.

18 There was one patient -- I am not sure if it was
19 '87 or not. But suddenly one day arrived in
20 Whitechapel an African refugee with no English who
21 turned out to have appalling haemophilia and was also
22 HIV positive. Although, curiously, he wasn't
23 hepatitis C positive. So his HIV positivity must have
24 been transmitted either sexually or by blood
25 transfusion because if he had concentrate, he would

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1 could have been infected at any centre they had
2 attended.

3 I'm not clear from that, Dr Colvin, whether work
4 was done at The London Hospital to -- at some point
5 after you got your initial results in 1985 or
6 thereabouts -- to do effectively what you've just told
7 us was done at the Royal Free and to look at the -- go
8 back and test?

9 A. Yes, we did. Yes, we did.

10 Q. Your statement doesn't tell us what the outcome of
11 that was.

12 A. The outcome was that some patients, particularly
13 perhaps the Lord Mayor Treloar patients, had been
14 seroconverted very early.

15 Q. What about the bulk of your patients?

16 A. I don't recall.

17 Q. In what form, if you can answer this, was that
18 information collated? In other words, if the Inquiry
19 wanted to try and find that information, where would
20 it have been?

21 A. Well, when these tests were done, I wrote out
22 a carding system, which I've described in my
23 statement, and I believe that in that carding system
24 are records of most, if not all, of that look-back, if
25 you would like to call it that, and when I retired

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1 I gave that carding system to John Pasi or Dan Hart
2 for safekeeping, and I believe they have kept it. But
3 it would be very difficult, I think, to go through
4 every single patient's notes to find out. I think
5 that would be the best source.

6 Q. Okay, thank you.

7 Then -- I've put your statement away. There was
8 something else I wanted to ask you about it.

9 You say, I think, somewhere in your statement
10 about two patients being infected at other hospitals.
11 So, as I understood, it was two patients under The
12 London Hospital's care but whose infection was
13 elsewhere.

14 A. I mean, there were a number of patients of mine who
15 could have been infected elsewhere, and sometimes I
16 knew they had been.

17 I think one of the points I wanted to make, and
18 it may be relevant, is that patients understandably
19 wanted to know where they'd been infected, and yet for
20 me, it wasn't -- what was much more important was to
21 look after them, having been infected, rather than
22 just spend a lot of time working out exactly when and
23 where they had been infected in a way that wasn't
24 necessarily going to help their care.

25 So, for me, it was much more important to look

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1 they wouldn't necessarily have received that treatment
2 at their haemophilia centre. Dr Winter gave us two
3 examples of that, and I'm just --

4 A. Do I have to reveal the centre at which they were
5 treated?

6 Q. The hospital but nothing else for present purposes.

7 A. Well, I mean, if I identify the centre at which the
8 person was treated, he can almost certainly be
9 identified fairly easily by the Inquiry or by other
10 people listening to this discussion.

11 Q. That would be possible to be identified simply from
12 naming a hospital?

13 A. Yes. I think it would.

14 Q. In that case, what I may ask -- we can perhaps ask you
15 to give that information in the form of a supplemental
16 written statement on that issue later.

17 Are you able to tell us anything about the
18 circumstances in which patients with bleeding
19 disorders became infected not at haemophilia centres
20 that doesn't identify anything?

21 A. Well, I think what I'm going to try to do is to, if
22 I may, not mention the centre itself for the moment.
23 I may mention it at a later time in private or in
24 a witness statement, but I can give you an example of
25 something that happened which is important.

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1 after my patients than to worry about exactly where
2 they had been infected. Because many of them, or some
3 of them, had been infected outside my care, but
4 I didn't care for them any less because they had been
5 infected away from my care.

6 Q. Were there any patients in respect of whom you were
7 able to establish that their infection had been not at
8 a haemophilia centre, yours or associate, but at
9 another hospital; for example, receiving emergency
10 treatment in an A&E department? Did you have any
11 patients that fell within that category?

12 A. Yes.

13 Q. What, if anything, without revealing any identifying
14 details about any individual patient -- what, if
15 anything, can you recall about that?

16 A. Well, this is very difficult because you've just said
17 that you don't want me to identify a patient, and of
18 course I can comply with that to the best of my
19 ability. But I will, if you wish, try to tell you
20 a story that is de-identified. Would you like me to
21 try to tell you a story that's de-identified?

22 Q. Yes. If it assists, Dr Colvin, what we are interested
23 in is examining if there were, as it were, systemic
24 failures or systemic problems which led to patients
25 with haemophilia being treated in circumstances where

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1 So a patient comes to London for educational and
2 professional purposes. He's a young man who's got
3 relatively mild haemophilia. He has had an injury,
4 a sports injury, and he's treated and develops HIV
5 infection. He is, understandably, deeply upset by
6 that, and I spend many, many, many hours with him and
7 with my nursing staff trying to manage his distress
8 and his clinical circumstances. Some years later, he
9 becomes mortally ill, and my haemophilia nurse and
10 I are told about this one morning, and we drive over
11 100 miles to try to reach him before his death, and
12 he's unfortunately passed away when we arrive there.

13 I tell this story really to illustrate the
14 terrible nature of what was happening and I tell it
15 particularly to describe his resentment at the fact
16 that he had been infected in a way which he thought
17 was completely unnecessary.

18 Now, I'm not in a position to judge whether his
19 infection was unnecessary or not, I wasn't there at
20 the time when he was treated and infected, but I do
21 know that he deeply resented what had happened and
22 I can understand that.

23 But the point that I was making before was that
24 I wasn't sure that that deep resentment necessarily
25 helped him to manage his situation, and that my job

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1 was to do my best to help somebody in a position which
2 was, of course, intolerable and terrible, and which
3 I and my nursing staff spent many, many hours trying
4 to resolve. It cut to the heart of what we were
5 trying to do.

6 **Q.** If we look at one further document, Dr Colvin, it's
7 BART0000509.

8 This is a document that you've seen:

9 "... enclosing a confidential list of patients
10 who were under our joint care whose anti-HTLV-III
11 results are known to me."

12 Then appended to this are, by reference to
13 different associate centres, lists of patients, dates
14 of testing and the result. Is this the means by which
15 you were communicating to the directors of the
16 associate centres which of their patients were
17 HTLV-III positive?

18 **A.** Obviously, I can't recall this letter. When I was
19 sent it, I was very surprised because I didn't
20 remember ever having seen it before. But when
21 I looked at it I was able to see that each of these
22 separate centres had been addressed and that, I think
23 you're right, this was the means by which
24 I communicated the anti-HTLV-III results to the
25 associate centres. It relates a bit, as I've pointed

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1 November 1985, 27 November 1985, and it's the
2 North East Thames Region Haemophilia Working Party
3 again.

4 You can see here what's being said:

5 "It was stressed that informed consent should be
6 obtained before patients are tested for HTLV-III
7 antibody and wherever possible counselling should be
8 offered prior to testing."

9 This is regional rather than simply limited to
10 The London Hospital, but this would seem to suggest
11 that there were still, at least regionally, patients
12 who had not yet been tested?

13 **A.** Of course it is possible. I can't be sure of this.

14 **Q.** Here it's being said that their informed consent
15 should be obtained before testing.

16 **A.** Yes, and -- indeed, I mean, there were one or two
17 patients who we realised, even in the late 80s, had
18 been at risk that we didn't realise had been at risk,
19 had been lost to follow-up, and somebody would come to
20 the hospital and my nurses and I would say, "Good
21 heavens, this patient is potentially anti-HTLV-III
22 positive" and then we would, of course, get their
23 consent before testing. Because the testing without
24 consent was really confined to that period, I think,
25 of crisis in the latter part of -- the very end

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1 out in my personal statement, to the letter which --
2 or the minutes that you have already referred to,
3 and I put that in my personal statement.

4 Now, my belief is that by this time all these
5 patients would have known of their status, and
6 I believe it was my duty to share with my associate
7 centre directors the information I had, for many
8 reasons, including the reason that at the time we were
9 regarding samples as hazardous, and therefore they
10 needed to know, partly for their own information about
11 how to treat these patients if they appeared in their
12 hospitals and also partly to know how to deal with
13 their samples.

14 **Q.** Just in terms of timing, is it right to infer from
15 this, 27 August 1985, by this time or around this time
16 you would have completed the process of the testing,
17 at least of the patients that you had identified as
18 being potentially at risk?

19 **A.** Obviously, I can't prove that but I believe so.

20 **Q.** Can we then just look at a couple of further documents
21 on the issue of providing information to patients.

22 BART0000674, please.

23 If we go to the third page, we can see under the
24 heading halfway down the page, "HTLV-III Antibody
25 Positivity" -- sorry, I should have said this is

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1 of '84/early '85.

2 **Q.** Can we just see the follow-up minutes to this. So
3 this is saying informed consent should be obtained
4 before patients are tested for HTLV-III antibody, and
5 then if we go to BART0000673 -- I hope this is the
6 right reference -- at the bottom -- so we can see the
7 date is 25 June 1986. So this is the middle of the
8 next year. Again, it's the same working party. You
9 are present, Dr Kernoff is present, and others.

10 If we go down towards the bottom of the page, we
11 can see it says:

12 "Amendments of Minutes of the last meeting -
13 27th November, 1985."

14 Then under "HTLV-III Antibody Positivity", it is
15 suggesting that the minutes should be amended to read
16 "informed consent should be obtained if it is possible
17 or reasonable to do so before patients are tested".

18 So the rather more absolute position that was
19 articulated in the minutes in November does not appear
20 to represent, in fact, the policy of the region, which
21 is you obtain informed consent if possible or
22 reasonable.

23 **A.** Well, minutes are, of course, the only record we have
24 of these discussions. They don't necessarily -- no
25 minute necessarily gives an absolutely accurate view

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1 what was decided. That is a sad fact of minutes in
2 general. But there is quite an interesting example of
3 where it's not quite clear what a minute perhaps
4 meant. Even a very definite minute may not have meant
5 exactly what it was said to mean in the minds of the
6 people who were present at the meeting.

7 Q. What we can see is in the middle of 1986, so away from
8 that crisis period that you've described, the position
9 that's being articulated -- presumably on mature
10 reflection, because you have taken the positive step
11 of amending a previous set of minutes -- is to say --
12 it's not "always obtain informed consent", it's
13 "obtain informed consent if possible or reasonable to
14 do", with no guidance as to the circumstances in which
15 it might be possible or reasonable to do that?

16 A. I can understand that. But, I mean, I think by the
17 middle of '86 -- I mean, we're now well into that
18 period -- I would expect that if I needed to consider
19 an anti-HIV test or anti-HTLV-III test, I would have
20 thought I would have obtained informed consent to get
21 it.

22 Q. In your witness statement, Dr Colvin, if I can find
23 the paragraph reference for you.
24 It's paragraph 56, Henry, it is WITN3343007.
25 If we go to page 19, we see, towards the bottom

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1 that British physicians and pathologists were indeed
2 searching very, very hard for the virological cause of
3 non-A, non-B. I think I accepted with
4 Professor Collier the idea that this particular acute
5 attack of non-A, non-B in a patient of mine might by
6 looked at by Arie Zuckerman.

7 Q. Would you have told the patient that?

8 A. I shouldn't think so, no.

9 Q. We go on to see you say -- you refer to:

10 "... an emerging discussion, which stimulated
11 a considerable divergence of medical and medico legal
12 opinion, as to whether further consent for anti-HIV
13 testing was needed."

14 Then you go on to say this "culminated in the
15 GMC guidance of 1988". I think you perhaps should
16 just look at that because we haven't looked at it in
17 the hearing so far.

18 Henry, it is NHBT0010410, please.

19 So the first page is a press notice, May 1988.
20 If we go over the page we see the GMC's paper that it
21 put out. There are a number of matters relating to
22 HIV and ethical considerations, which I don't need to
23 trouble you with, Dr Colvin.

24 If we could go to paragraph 12 please, Henry,
25 which should be the bottom of the next page.

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1 of the page, in paragraph 56, you are addressing the
2 issue that I've just been asking you about over the
3 last 20 minutes or so, Dr Colvin, about the process of
4 testing patients for HIV.

5 Then if we go to the next page, what you have
6 said there in the third -- actually, before we get to
7 that, in the first paragraph you refer to
8 Professor Zuckerman being particularly interested in
9 the search for the NANBH virus, which is not in itself
10 a controversial statement but you say that in the
11 context of a discussion about the retained samples.
12 Were the samples of sera that were retained at
13 The London made available to Professor Zuckerman?

14 A. Well, I think there was one particular occasion when
15 one of my patients had a nasty attack of clinical
16 non-A, non-B, when I must have discussed this with
17 Professor Collier probably, and he said, "Well,
18 Arie Zuckerman is particularly interested in looking
19 for the source of non-A, non-B hepatitis, may we share
20 this sample with Arie?"

21 And Arie wrote back to me initially saying that
22 he thought he had made a big advance in the search for
23 the virus, and in fact he later said that he hadn't.

24 Of course, it was during this time, and we just
25 heard from the Nobel Prize-winning material recently,

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1 If we pick it up in paragraph 12, under the
2 heading "Consent to investigation or treatment",
3 what's there said is:

4 "It has long been accepted, and is well
5 understood within the profession, that a doctor should
6 treat a patient only on the basis of the patient's
7 informed consent. Doctors are expected in all normal
8 circumstances to be sure that their patients consent
9 to the carrying out of investigative procedures
10 involving the removal of samples or invasive
11 techniques, whether those investigations are performed
12 for the purposes of routine screening, for example in
13 pregnancy or prior to surgery, or for the more
14 specific purpose of differential diagnosis.
15 A patient's consent may in certain circumstances be
16 given implicitly, for example by agreement to provide
17 a specimen of blood for multiple analysis. In other
18 circumstances it needs to be given explicitly, for
19 example before undergoing a specified operative
20 procedure or providing a specimen of blood to be
21 tested specifically for a named condition."

22 Then if we go over the page, at paragraph 13:

23 "Testing for HIV infection: the need to obtain
24 consent:

25 "The Council believes that the above principle

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should apply generally, but that it is particularly important in the case of testing for HIV infection, not because the condition is different in kind from other infections but because of the possible serious social and financial consequences which may ensue ..."

So, pausing there, Dr Colvin, you're right, I think, to point out at this is the first publication by the GMC on this specific issue, and it was in 1988. Would you accept that the GMC is not here saying anything new? It might be speaking for the first time on the issue but it's saying the long established principles of informed consent apply?

A. Of course the long established principles of consent apply, but I don't believe that it was ever the case that there was ever any other particular investigation which absolutely required specific patient consent. This was really the first time, in '88, that this had been suggested.

I referred earlier to the role of the haematologist. That is being both a physician and a pathologist. So if I was sent a patient for investigation, then I would decide which investigations to perform, and when I got the results of those investigations in my laboratory, I would then choose what further investigations were to be

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have been taken at the last appointment?

A. Yes.

Q. So for most of these patients they are likely to have been samples that would, in fact, have been taken in the course of 1984?

A. Possibly, yes.

Q. Possibly in 1983 but most likely 1984. At which time you may not have had, in June 1984, to pick a date, potentially, at random, you wouldn't that stage have been able to test for HIV but you would have known that testing for HIV was something that was being investigated.

A. Sure.

Q. How could it be said that a patient's giving informed consent to the use of their sample for testing for a virus that no-one's spoken to them about?

A. I mean, I understand what you're saying. I'm just telling you what I think was in our minds. What was in our minds wasn't necessarily appropriate. I mean, I personally don't regret what we did. Maybe I shouldn't say that but I really don't regret what happened.

But the position was that nobody explicitly said that HIV testing had to be done with informed consent until much later.

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performed to solve the problem.

Now, all that has a continual flow of information, of course, and it's my responsibility to choose the right tests in the right circumstances. However, there may be another instance where that chain of flow has been broken, and then it would be necessary to go back to the patient to ask for consent to continue a separate investigation that now became apparent.

But the reality was -- I think this was partly the mindset of haematologists -- that we felt that we were physicians who were also pathologists who had the task of solving problems and we believed, perhaps incorrectly, that we did have the kind of consent that we required to undertake these investigations to solve an urgent problem.

Now I can see there may be those who disagree with that view but that was the view I think that we had.

Q. These were samples, as I understand it from your evidence earlier, that they weren't samples that had been taken back in 1979 and stored since then, they were samples -- because you were using them for the purpose of finding out whether the patient was currently infected, they were the samples that would

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Q. You have previously made a number of observations at invitation about the lack of UKHCDO guidance on certain issues. Can you recall whether there was anything that emanated from UKHCDO at this time, either in the meetings or in any communications on the issue of how to go about the process of testing?

A. No, I can't. I mean, we had a look at something a while back, I think, which just said everybody ought to be tested for anti-HTLV. I mean, we had that discussion yesterday I think.

Q. Yes, but on the specific issue that you're talking about, about whether the patient's consent should be sought in advance --

A. I don't think, although I can't prove, but you are in a better position to judge than I am, I don't think that UKHCDO gave a view on that.

But I don't actually want to spend all my time blaming UKHCDO for the things that happened in our practice. I mean, I recognise that UKHCDO couldn't tell us exactly what to do about everything.

Q. Then just dealing with some issues of consent and information and testing more broadly, we looked yesterday at documents which showed the programmes of testing that would be undertaken at routine appointments in relation to liver function --

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- 1 A. Mmm.
- 2 Q. -- with some tests being undertaken more frequently,
- 3 depending upon the outcome of first sets of tests and
- 4 so on.
- 5 Can I just ask you to assist in relation to the
- 6 information provided to patients about that process.
- 7 Again, we're talking here typically late 1970s, early
- 8 1980s, so I'm asking you now about before HIV was on
- 9 the horizon in '82 and '83. What information do you
- 10 recall giving or thinking would have given to patients
- 11 about the reasons for taking samples of blood from
- 12 them?
- 13 A. Well, I think we would have told them that the liver
- 14 function tests that we had were not always normal,
- 15 that the outcome of those abnormalities was unclear,
- 16 and that we needed to continue to monitor their
- 17 progress or lack of it.
- 18 Q. Given that the practice, as I understand it, of taking
- 19 a sample that was then stored for potential future use
- 20 was a regular occurrence, it wasn't something that you
- 21 did new in 1984 --
- 22 A. No, sure.
- 23 Q. -- did you tell patients that you were doing that,
- 24 that you were taking a sample that was not going to be
- 25 specifically tested for liver function tests but would

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- 1 treated with, what their details were, and what was
- 2 happening to them.
- 3 Now, I've seen this -- obviously, you've given
- 4 it to me -- and it doesn't surprise me. That's the
- 5 way it was.
- 6 Q. I think we know, when we come on to it this afternoon,
- 7 it was an issue that then reared its head again in the
- 8 1990s at various UKHCDO minutes. I'll come onto that.
- 9 A. Of course. At this time, it looked completely routine
- 10 to us.
- 11 Q. Then just one further document before we break. BART
- 12 0000543_004.
- 13 So this is a letter, January 1986. This is you
- 14 sending data to Dr Craske. If we just go to the
- 15 second page, please. So we can see it's from you. If
- 16 we go back to the first page. We've obviously
- 17 concealed the names, but you are here sending
- 18 Dr Craske at the Public Health Laboratory in
- 19 Manchester information data about named individuals:
- 20 their HTLV-III result and the date of it.
- 21 Again, I understand why that data was being
- 22 collected by Dr Craske; we see it from the UKHCDO
- 23 minutes. But did your patients know that their test
- 24 results and names were being supplied to Dr Craske?
- 25 A. I don't believe so, no.

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- 1 actually be stored potentially for future use?
- 2 A. Not that I know of, no.
- 3 Q. Before we come to look at testing for HCV, which we
- 4 can do after lunch, there's just one small point which
- 5 will require us to look at two documents quickly that
- 6 I wanted to ask you about, and that's about providing
- 7 information about patients to third parties.
- 8 If we look at HCDO0000177_010. This is just an
- 9 example -- there are lots of other examples from lots
- 10 of centres about information that was provided to
- 11 Oxford. This happens to be January 1984. We can see
- 12 it's from you to Ms Spooner referring to the
- 13 registered details and making a number of comments
- 14 about specific named patients. We know that
- 15 information was regularly provided by centres --
- 16 A. Yes, sure.
- 17 Q. -- to Oxford for the purpose of inclusion on
- 18 a register. What did you tell patients about that
- 19 process, if anything?
- 20 A. Nothing. The policy was very clear that, from the
- 21 1960s, the UKHCDO record had been a named patient
- 22 basis, and the data that we had was transferred to
- 23 Oxford. The result, of course, was that we had the
- 24 best database, as I think I mentioned, in the world
- 25 for knowing who was where, what they were being

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- 1 MS RICHARDS: I think that probably is a convenient
- 2 moment, sir, to break for lunch.
- 3 SIR BRIAN LANGSTAFF: Yes. It looks like 2.00, then, that
- 4 we will meet again. So 2.00, if you please.
- 5 (1.02 pm)
- 6 (Luncheon Adjournment)
- 7 (2.00 pm)
- 8 MS RICHARDS: Dr Colvin, I'm going to ask you in a moment
- 9 about HCV testing. Before I do so, hepatitis B: your
- 10 statement says that you had a comparatively small
- 11 number of patients who had an ongoing hepatitis B
- 12 infection; is that right?
- 13 A. I think we all did. We all had a very small number of
- 14 hepatitis B infection -- patients who had ongoing
- 15 infections, yes.
- 16 Q. You had a larger cohort of patients who had shown some
- 17 signs of being infected in the past --
- 18 A. Yes, it was absolutely routine to test people for
- 19 evidence of previous hepatitis B infection. To begin
- 20 with that was just something that one thought of
- 21 because of the risk of hepatitis B infection from
- 22 blood products, but later of course, by '86, there was
- 23 a recombinant hepatitis B vaccine, so it became really
- 24 important to test people for hepatitis B or evidence
- 25 of previous infection so that one could offer

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1 vaccination to those who had not been infected,
 2 particularly, of course, small children, would then
 3 become routinely vaccinated against hepatitis B.
 4 **Q.** So in terms of the hepatitis B vaccine for your
 5 patients, your recollection is that was the mid-1980s?
 6 **A.** Yes. You see, the original hepatitis B vaccines were
 7 not recombinant so they would have been derived from
 8 human plasma. They were almost certainly non-infected
 9 because of the way they had been prepared and treated.
 10 But I think that by the 80s we had already become wary
 11 of blood products and the prospect in '86, I think it
 12 was, of a recombinant hepatitis B vaccine was very
 13 attractive.
 14 **Q.** Had you used the hepatitis B vaccine the
 15 non-recombinant --
 16 **A.** I'm not sure I had actually. I really can't be sure
 17 but I think as soon as the recombinant vaccine became
 18 available we all said: We've got to do this,
 19 particularly for children.
 20 **Q.** Were you aware of the possibility of sexual
 21 transmission of hepatitis B?
 22 **A.** Yes.
 23 **Q.** Were your patients counselled about that, those who
 24 did have infection?
 25 **A.** Yes, I mean, I had two or three patients that I --

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1 So the next question is: was it appropriate to
 2 test for hepatitis C without consent when that test
 3 became available? I want to quote very briefly from
 4 the Penrose Inquiry report, if I may. May I do that?
 5 **Q.** Yes.
 6 **A.** So in 32.40 of the Penrose Inquiry Report it states,
 7 it's a little extract:
 8 "Professor Nathanson ..."
 9 Who at that time I think was head of ethics at
 10 the BMA:
 11 "... recollected that in about 1986-87 the BMA
 12 had actually voted for a policy which allowed doctors
 13 to test without consent. As soon as the policy was
 14 agreed, the BMA took legal advice and they were
 15 advised that testing without consent was illegal. The
 16 policy was reversed the next year at the BMA's annual
 17 meeting of 600 representative doctors. In fact the
 18 BMA had received conflicting advice from two QCs on
 19 the topic. The rationale of the advice which was
 20 followed was that because the HIV test was not
 21 a standard test, the implied consent given was,
 22 therefore, required."
 23 So the position as far as hepatitis C was
 24 concerned was that we'd known about hepatitis C for,
 25 I suppose, 20 years and the patients had known as

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1 I don't recall whether -- it would have been back in
 2 the 70s probably that I would have -- I don't think we
 3 had any seroconversions from probably 1975 onwards.
 4 So yes, in principle, but I don't recall the detail.
 5 **Q.** Then can I move to the process for testing for
 6 hepatitis C. So this would have been 1990/1991,
 7 perhaps 1992, but the early 1990s.
 8 My understanding from your statement, Dr Colvin,
 9 was that was also done from stored sera without
 10 seeking patient consent in advance?
 11 **A.** Correct.
 12 **Q.** Bearing in mind that this is now the early 90s, and
 13 you weren't in what you described as the sort of acute
 14 phase, from late '84/early '85, of trying to deal with
 15 the HIV emergency, why was it that patients' consent
 16 was not sought for the testing?
 17 **A.** So you have already referred to hepatitis B, and
 18 nobody ever thought of -- I don't think -- requesting
 19 specific consent for hepatitis B testing in the past.
 20 Maybe people were requested -- maybe people did ask
 21 for permission but I don't remember that being done,
 22 and I think that hepatitis B testing in the past would
 23 have been done without consent largely. I think so.
 24 Hepatitis A testing, of course, also was done --
 25 anti-HAV testing also done without consent.

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1 well, and so I think that the testing was part of the
 2 routine work of looking at liver function and the
 3 healthcare of people with non-A, non-B infection. It
 4 wasn't HIV and the GMC guidance was about HIV testing.
 5 So it didn't really fall within the HIV testing
 6 regulations, if you like to call them that, of the
 7 GMC. There was obviously debate in the BMA, if not in
 8 the GMC, about what was appropriate, and it wouldn't
 9 be until, I think, 1999 that there was any advice that
 10 was clear from the GMC on communicable diseases in
 11 general.
 12 So I think in my mind whilst this was not what
 13 one might describe as a completely routine test,
 14 nevertheless it fell within the area of testing which
 15 was appropriate for the consent that had been given
 16 for the liver function test that had been performed
 17 over the previous 20 years.
 18 **Q.** Again, were the samples that you were using recent
 19 samples or were they --
 20 **A.** They would have been, I guess, contemporaneous
 21 samples, yes.
 22 **Q.** So they would have been taken over the months
 23 preceding the test. It would, presumably, have been
 24 perfectly straightforward to tell the patient that one
 25 reason why the sample was being taken was because

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1 there was, by that time, a realistic hope of having an
2 HCV test?
3 **A.** Well, that may indeed have been the case. We may well
4 have talked to patients about the possibility of
5 an anti-HCV test. Also, it's entirely possible that,
6 as the test became available, I may well have spoken
7 to patients and they may well have given me consent
8 for the test to be done. That's perfectly possible.
9 I can't be sure it was.

10 But, again, I point out the logistic
11 difficulties. We've got almost certainly over
12 100 patients now who might be anti-HCV positive, and
13 these patients will be coming up over a period of up
14 to a year. And clearly, you might say, "Well, get
15 them all up and invite them to be tested" and my
16 answer is that that would indeed itself have been
17 a major logistic problem, and the view I took was that
18 it wasn't essential and necessary for that to be done.
19 Once I had the results, we then the problem of how to
20 deliver them. You may want to talk to me about that.

21 But we're talking now about I'm sure over
22 100 tests because we have 80 positives.

23 **Q.** The Inquiry will be looking in some detail at the
24 different parts of ethical guidance issued by BMA and
25 to you, GMC, over the years in due course. Do you

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1 a need to decide whether it was necessary to go back
2 to the patients to ask for further consent and my view
3 at the time was, rightly or wrongly, that it wasn't
4 essential.

5 **Q.** Viewed with hindsight now, do you think that was the
6 right decision, not to tell patients in advance and
7 seek their consent to HCV testing?

8 **A.** I don't think it was essential.

9 **Q.** You don't think it was essential to seek their
10 consent?

11 **A.** Yes.

12 **Q.** Why is that?

13 **A.** I think I have already explained that I felt that it
14 was a natural progression from the liver function
15 tests into the solving of a problem that everybody
16 knew about, including the patients, that it would have
17 been extremely difficult in a very short space of time
18 to bring 100-plus patients to the hospital for
19 pre-test counselling. But I'm not aware that any
20 pre-test counselling went on -- it's possible it
21 did -- in this field in haemophilia care and, finally,
22 that, once again, nobody ever said to me that they
23 shouldn't have been tested after being told of their
24 results by me personally.

25 **Q.** Can you recall anything about how the testing was

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1 recall whether, on this issue of testing -- and
2 bearing in mind, as we've seen from the various
3 documents we looked at from the mid-80s, it had become
4 a topical issue in relation to HIV -- do you recall
5 whether you discussed it with colleagues or sought any
6 advice on the question of HCV testing?

7 **A.** No, I don't. I mean, I used to talk a lot to
8 Len Doyle, who was our professor of medical ethics at
9 Barts in London, but I don't recall discussing this
10 with him particularly myself, no.

11 **Q.** Whilst you are obviously right to say HCV is not HIV,
12 they're different viruses, perhaps with different
13 stigmas associated, perhaps not, but they were both
14 very serious conditions with potential for -- in terms
15 of mortality, HCV is a condition that you would have
16 known by the early 90s could, as with AIDS, lead to
17 serious illness and death --

18 **A.** All the more reason to get on with testing patients
19 and discussing it with them.

20 **Q.** I understand all the more reason to do the test and
21 tell the result, but does that not distinguish the HCV
22 testing process from a standard liver function test?

23 **A.** Well, it depends what you mean by "distinguish" and
24 "standard". It isn't a routine test. It couldn't be
25 because it had just come into action. But there was

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1 organised? Was it, again, done in-house at The London
2 Hospital or externally?

3 **A.** No, I don't know the answer to that question, but
4 I think Professor Collier would have certainly been
5 involved. He was a distinguished professor the
6 virology and he would have advised me and the advice
7 he gave me I think would have been taken.

8 **Q.** Then, in terms of the numbers who tested positive,
9 I just want to take that --

10 **A.** They're just over 80.

11 **Q.** -- from your statement.

12 Yes. So we've got, I think, the precise figures
13 in your statement. You said you believed
14 approximately 84 patients were found to be
15 anti-HCV positive at The London Hospital Haemophilia
16 Centre, and you've broken that down as: haemophilia A,
17 62; haemophilia B, 17; von Willebrand disease, 3; and
18 haemophilia carriers, 2?

19 **A.** Yes, that's the figure I had in my -- well, in my
20 collection of lectures.

21 **Q.** Do you have any recollection of approximately when
22 this was that this process of testing was undertaken,
23 as in which calendar year?

24 **A.** Oh, it would have been 1990.

25 **Q.** How then did you go about the process of communicating

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1 the test results to patients?
 2 A. This I can't recall precisely but I think I've said in
 3 my statement that I believe that I would have given
 4 the patients' personal information about the results.
 5 I couldn't absolutely swear that none of them received
 6 the information by post but I'm reasonably to very
 7 confident that they would have had a personal
 8 interview with me.

9 Q. Again, I appreciate I'm asking you to recall events
 10 from some time ago, but do you think they were called
 11 in for a special appointment to be informed of the
 12 result or was it a question of at their next routine
 13 appointment they would be told the result?

14 A. It might well have been a mixture actually.
 15 Obviously, people come in to the hospital from time to
 16 time for advice about other things, people come in for
 17 their routine appointments, people might be concerning
 18 and ask for an early consultation, or I might find
 19 myself in a position where I had a particular
 20 consultation that I needed to undertaken and would
 21 then tell the patient -- I'm really not sure. But
 22 I don't think you can assume that it was just a matter
 23 of telling people at their routine appointment. Even
 24 if it had been that, it wouldn't have made an enormous
 25 amount of difference, although obviously there were

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1 and the ability to test was relatively new, it was
 2 a condition which had been known about for a number of
 3 years?

4 A. Yes. If you remember, the Mannucci paper where
 5 I introduced the idea that some people thought that
 6 this was still a benign infection in 1982, which
 7 I know was perhaps against the run of play, as it
 8 were -- I mean, against the run of advice. The paper
 9 from Charles Hay in '85 gave a really definitive view
 10 that this was a serious problem which would have then
 11 been discussed with patients up to 1990. And then
 12 it's not very long before there's the issue of
 13 interferon therapy. Once you get to the point of
 14 interferon therapy being available, then not only is
 15 it important to know your anti-HCV status from a point
 16 of view of why your liver function tests aren't
 17 perfect, but it's also terribly and important to
 18 decide whether it's appropriate for you to consider
 19 some form of treatment for this condition.

20 Q. In terms of lifestyle advice, what kind of lifestyle
 21 advice would you expect -- do you think you would have
 22 given in the early '90s?

23 A. Well, the main thing is, as it would be for whether
 24 there was an anti-HCV positive test or not for
 25 somebody with abnormal liver function test, one would

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1 aspects of their known infection which needed to be
 2 dealt with and the communication needed to be done
 3 without delay.

4 Q. What information and advice in 1990/1991 do you think
 5 you were giving the patients when you told them their
 6 diagnosis and over the months that followed?

7 A. Well, obviously I can't recall that detail. But
 8 I think -- the Inquiry has provided me with
 9 a document, I think from 1996, which gives a list of
 10 things that I did for people with hepatitis C
 11 infection, just as I had a list of things that I asked
 12 people to know about HIV infection. So it's quite
 13 clear I did put together a list -- because an
 14 aide-memoire is very important for patients when you
 15 have been speaking to them, they don't necessarily
 16 remember exactly what you've said or might have
 17 interpreted what you said incorrectly. So an
 18 aide-memoire was important. The Inquiry asked me
 19 whether I remembered whether there was a previous
 20 aide-memoire and of course I don't know.

21 Q. In terms of the information that you think you would
 22 have been giving, whether with the assistance of an
 23 aide-memoire or not, at that initial stage of telling
 24 patients the diagnosis, you made the point that
 25 although it was relatively newly known as hepatitis C

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1 advise on limitation of alcohol consumption. That's
 2 probably the most important thing to consider.

3 Q. How had you gone about identifying the cohort of 100
 4 or so patients to be tested for hepatitis C?

5 A. Well, I don't remember exactly how I did that, but
 6 I would probably have looked through our register --
 7 we had a register -- and tried to remember who had or
 8 had not had blood products. I might have got that
 9 information from Oxford. I don't recall doing so.
 10 They had the power probably to tell me that.

11 But by the time we get to 1990, I have been
 12 director of the centre for up to, I don't know, 20 --
 13 up to 15 years. So in here, it's quite a lot of
 14 information about a very large number of patients. Of
 15 course, that's not reliable, and it needs to be
 16 checked against the register or against the Oxford
 17 register. But I think that in those days, before
 18 computers were that much used, because we're probably
 19 talking about '88 or something, perhaps the middle of
 20 the mid-'90s. I'm not sure when computers become
 21 really important, but it's probably in the '90s. I'm
 22 really relying on Oxford to have the data if I ask
 23 them for it -- I don't remember recall doing so, but
 24 I might well have done -- or my memory, or my own
 25 register at the hospital, or a combination of the

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1 three.

2 Q. So in terms of the criteria, would it have been every

3 patient who received a commercial concentrate or an

4 NHS concentrate prior to a certain date?

5 A. No. Anybody who had ever received blood products.

6 Q. So you would have been testing anyone who had received

7 cryoprecipitate, NHS Factor VIII in any incarnation,

8 and any form of commercial concentrate, and some

9 others --

10 A. And/or -- Yes. I mean, obviously things like FEIBA

11 or -- we didn't use Autoplex. But all the

12 human-derived blood products were a risk for

13 hepatitis C infection, and of course the blood

14 transfusion.

15 Q. Can I ask you a little about the arrangements that

16 were made at The London Hospital for the treatment of

17 those, first of all, who had been found to be HIV

18 positive, as you were a haematologist, not a physician

19 specialising in the care of those with HIV.

20 Can you just outline for us, please, what the

21 arrangements were in that second half of the '80s and

22 up until the middle '90s where I think you then had

23 some specialist assistance.

24 A. Well, I had always taken a view in the haemophilia

25 centre that patients who might be coming 60 miles from

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1 clinician?

2 A. I'm just coming on to that because to begin with, of

3 course, in 1985/'86, there's no treatment. All we can

4 do -- and it's a lot to do -- is to find out for

5 ourselves more about the natural history of the

6 condition, to discuss with our patients the natural

7 history of the condition, give them their list of

8 things they should and shouldn't do and the risks of

9 sexual transmission, all these things, with their

10 leaflet. And then a year or so has passed, everybody

11 I think has been informed, and I've completed my

12 initial counselling with Nigel's help, and then AZT

13 arrives -- so Zidovudine arrives.

14 At this point, I began to talk to my patients

15 about the possibility of zidovudine treatment and,

16 indeed, we treat patients who wished to be treated.

17 Because since Zidovudine is not that effective, and

18 since it's not entirely clear what the indications are

19 patients do, of course, have a significant role to

20 play in deciding whether they are going to be treated

21 or not and some patients, I know, decided they didn't

22 want to be treated.

23 But once we get slightly more effective

24 treatment, it becomes apparent that, as Mark

25 explained, there is a need for a specialist input. Of

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1 their home on the south-east coast to see me should

2 have what I might describe as a one-stop shop, so they

3 could come to the hospital, get everything dealt with

4 and go home. So what I did was to link my Wednesday

5 morning haemophilia clinic, which was also a general

6 clinic actually, to see the people with haemophilia at

7 the end of that clinic, and then a rheumatologist

8 would come to see the patients that I had selected who

9 needed a joint doctor on that day for their joints.

10 For the HIV clinic, to begin with, that was done

11 on a different day from the rheumatology clinic.

12 The Trust had appointed a counsellor, Nigel

13 Harvey, to assist me and what then happened was the

14 patients who were anti-HIV positive (although we

15 wouldn't advertise that fact; they happened to be

16 there, and we would make sure they were there when the

17 counsellor was available) would come and and their HIV

18 infection would be discussed with me in my routine

19 clinic with Nigel present. Then if there was a need

20 to do so, which there very well might be, then Nigel

21 would see them separately. Indeed, there's evidence

22 he went home to see patients. Some patients were

23 visited in their homes.

24 Q. So, in terms of the treatment of HIV-related

25 infections and/or AIDS, you were the prescribing

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1 course, in his case, it's him. But for me, I knew

2 that I now needed specialist advice about therapy

3 beyond just zidovudine. I think I could manage

4 zidovudine by myself.

5 So what I did was to go to the HIV specialist,

6 and then we made a decision which might be regarded as

7 controversial to see my HIV positive patients in the

8 Grahame Hayton Unit on a Wednesday afternoon. So what

9 I then did was do my clinic, and then instead of

10 having the HIV clinic at the end of my morning clinic,

11 I'd go off and have a sandwich, and then I'd go to the

12 Grahame Hayton Unit, which is the sexually transmitted

13 disease block, and separately from everything else we

14 would run an HIV-related haemophilia clinic.

15 Now, you might say, "What are you doing asking

16 your patients with haemophilia to go to the sexually

17 transmitted disease clinic?" and the answer to that

18 is, that's where the specialty is and that's where the

19 specialist knowledge is. I explained to my patients

20 what I recommend, and they all agreed because they

21 came to the clinic, and they were happy, as far as

22 I was aware, with the arrangements. The other

23 advantage of that, if you look at Mark's evidence, was

24 that, of course, they immediately got access to the

25 treatment without cost because, for all the

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authorities knew, they were part of the HIV process. I'd just like to emphasise that, in my mind, there wasn't any stigma for being HIV infected and, from my patients' point of view, although it's true they were attending the clinic which otherwise would deal with HIV for the other reasons it could be transmitted, they were in a separate clinic where they were looked after carefully by the HIV specialist, and I was always there.

Q. And that was, as I understand it from your statement, roughly the mid-'90s?

A. Yes.

Q. So the first decade --

A. Probably earlier than the mid-'90s because, I mean, '96, we get triple therapy. Now, we were certainly doing this HIV clinic in the Grahame Hayton Unit before '96 because I can recall -- I think I mentioned this in another context -- that some patients, by '96, were desperately ill and that the introduction of triple therapy changed everything. Mark referred to this in his evidence, that it was extremely difficult for patients who were actually dying in front of our eyes, who were prepared for death, who suddenly got better and, although you might think, well, it's wonderful to get better when you have been so ill,

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settled down to probably one or two hepatitis clinics a month, and one or two rheumatology clinics a month. So the emphasis was always on my trying to make sure that, for every clinic appearance for my patients, they saw me with the specialist, rather than going off to see a specialist separately. Partly because I wanted to know what was going on with them, and partly because I wanted to make sure they knew that I was there for them.

This can be extremely important in clinical practice in haemophilia care. For instance, for liver infection, it might well be that the hepatologist wants to do a liver biopsy. Well, it might be that I don't think a liver biopsy is a terribly good idea. I then need to discuss with him or her if we are going to do a liver biopsy, under what circumstances, and with what cover and when. So, for instance, doing a liver biopsy on a Friday afternoon wouldn't be something that I would be very keen on. Not that I was keen on doing liver biopsies anyway. But this relationship between a physician and a specialist I think is absolutely critical for haemophilia care.

Q. I think we've got a couple of documents that give a snapshot in relation to hepatitis C provision.

Henry, it's BART0000567_001, please. This is

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actually it's a very confusing time, and patients had great difficulty in coping with it.

Q. The counsellor to whom you have referred, that was someone from a social work background?

A. Yes, he was a social worker. I think he was a trained counsellor as well as a social worker.

Q. Was that a post that was filled at the centre for the rest of the time that you were there --

A. No.

Q. -- or was it something that was just for a few years?

A. I think for a few years. Nigel -- I can't remember where Nigel went, but he eventually went.

I think that the counselling aspects were, to some extent, taken on, apart from by me, by the nursing staff who were haemophilia-trained nursing staff. But I think during the critical period, when we were trying to sort of get used to what was happening to everybody, Nigel was there for the counselling service. But I can't remember the exact date that he left.

Q. In terms of care of liver disease, your statement says that you set up a joint clinic with a hepatologist.

A. This is another of my late Wednesday morning clinics. So I know there are only a certain number of Wednesday mornings in the week, in the month, but we eventually

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a document completed by you in October of 1991, and it's to send to Professor Preston in Sheffield. We can just see:

"Have you performed anti-HCV testing on your patients? Yes. First generation and second generation. What categories of patient do you test?"

We can see you have tested:

"Those who who've received inactivated or treated materials, those who'd received non-virally inactivated products, and those with abnormal ALTs."

You're asked if you measure ALT and AST levels in all patients. You answer: yes.

ALT and AST testing is four times a year.

Then you are asked about patients with clinical features of chronic liver disease. You identified there that you have two.

You're identifying, in 6, in terms of the stage of liver progression where you've got to.

"Are you treating any of your patients with chronic hepatitis C with interferon? No, but we're about to enter patients into a trial."

What, if anything, can you recall about the interferon trial?

A. Well, the position then was we had all these patients who were not actually themselves ill at this point.

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And, once again, I have a close relationship with the Royal Free and Paul Teifer (who is now a consultant at The London, actually, dealing with sickle cell disease) is at that time at the Royal Free working with Christine Lee, and he has a trial of interferon available. And it seemed to me that this would be a very good opportunity to attain knowledge about the success of interferon therapy at the same time as offering interferon therapy to some of my patients who were regarded as requiring it.

Now, I don't remember the exact details of the trial, but it was interferon alone, and it would have had entry criteria that meant you could know who was eligible and worth trying to treat with this drug. So probably through Christine Lee, or maybe I just knew Paul anyway, I said to him, or he said to me, "What about this possibility?" It seemed to be an ideal opportunity to offer my patients interferon therapy.

Q. What was your experience, as the clinician, of your patients' experiences on interferon, both under the trial and then latterly being treated?

A. It's horrible. The problem is that it gives you a flu-like illness. You feel absolutely dreadful. And certainly with interferon itself, you feel so ill while you are taking it that you almost wish you

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it could happen. But this raises the question of how much information is appropriate to give to people for a risk which is exceptionally low.

It's clear that I did discuss it with patients, but you'll also see, from the information sheet I provided, that there's quite a bit of reassurance in that sheet. But if a patient wanted to have a test, or their spouse wanted to have a test, I mean -- their personal contact wanted to have a test -- then, of course, they would be offered a test. But I'm not aware of any positives at all.

Q. Then:

"How many of your patients had died in the past five years? 14."

And then you have identified two in which liver disease was an important contributory factor.

"How many had developed hepatocellular carcinoma at that stage? Zero.

Autopsies: zero."

And that effectively completes the form.

There is a further snapshot from '94. I'll just look at it in terms of getting some statistics into the evidence. BART0002322_001.

A. Before you refer to that which is just coming up, I think it's important to note that I haven't filled

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hadn't started. It's extremely difficult. It was extremely challenging to complete a full course of interferon therapy, or indeed the later dual agent therapy, and I felt very sorry for my patients who had to go through this awful experience when it actually wasn't terribly successful.

Q. Then we can see, just continuing with the questionnaire, if we go to the next page, question 8 is not answered, but question 9:

"Are haemophiliacs with chronic liver disease seen jointly with your local gastroenterology or hepatology specialist? Routinely.

Do you discuss with your patients abnormal LFTs in hepatitis C?"

You have said yes.

"Are you testing contacts of patients with hepatitis C for antibody to hepatitis C?"

You said yes.

Can you recall what the outcome was in relation to the testing of spouses and sexual contacts --

A. I'm not aware of any transmission of hepatitis C in that way and, certainly, my review of the literature suggests that it is extremely unusual, if not -- I wouldn't say not impossible, but extremely unusual for that kind of transmission to take place; no doubt

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in this form correctly. I don't know whether you noticed this. If this is the one -- well, let's see what Henry produces, but I think what he is going to produce is evidence of my having mis-filled the form in.

Q. Perhaps you can assist us with how because what I was going to just to draw attention to was: we've got the numbers of patients here:

"How many anti-HCV positive patients do you have alive? 83. 17 of those are co-infected with HIV."

And then there are further questions which you answer. Which bit is filled in incorrectly?

A. If we can move on, Henry, I think there's a point where I've said:

"Do you routinely carry out additional investigations in patients with intermittently elevated liver enzymes?"

I've said "no". And then:

"Do you routinely carry out additional investigations in patients who are HCV antibody positive with persistently abnormal liver enzymes?"

And I've again said "no" which doesn't seem very logical and must be an error.

Q. In fact, you have gone on to answer in point 3 --

A. Yes, exactly.

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1 Q. -- "which of the investigations do you perform?" and
 2 you have identified them.
 3 A. Obviously, I didn't have the chance to tell the
 4 Inquiry this because I only saw the documents a couple
 5 of days ago. But you will see that I have left liver
 6 biopsy out as one of the things that we, in
 7 collaboration with the Royal Free, by and large didn't
 8 do.
 9 Q. Could we just have on screen, please, Henry,
 10 BART0000660, please. I'm not sure that's the right
 11 reference, Henry. BART0000666, my apologies.
 12 We can just see this is now October 1990. It's
 13 another meeting of the Haemophilia Working Party of
 14 the North East Thames Region Association, and you and
 15 Dr Kernoff and others are there. If we go to the
 16 second page, there's a discussion about treatments.
 17 We can see, I don't need to go through it in
 18 detail but we can see (i) and (ii) are talking and
 19 (iii) I think are talking about potential treatments
 20 for HIV, and then (iv) and (v) are talking about
 21 treatments and other matters relevant to hepatitis C.
 22 It looks as though, from the attendees on the
 23 first page, at this stage at least these are matters
 24 that are being considered without specialist
 25 hepatology or HIV physician advice, at least at this

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1 saying, by reference to the "District", I don't know
 2 whether he's talking there just Royal Free or the
 3 region, about the large number of patients and
 4 inadequacy of existing facilities and wanting to be
 5 able to use earmarked HIV/AIDS funding.
 6 What, if anything, can you recall about the
 7 issue at the time of trying to ensure sufficient
 8 funding for HIV care?
 9 A. I think that this is probably dealt with by my
 10 transferring all our HIV care to the sexually
 11 transmitted disease unit, the Grahame Hayton Unit,
 12 within the hospital, because I think the people with
 13 haemophilia just got lost, financially, in those
 14 arrangements.
 15 Now, when exactly when I transferred to the
 16 Grahame Hayton Unit I don't know, and I don't think
 17 I was necessarily thinking I was clever to bypass the
 18 financial arrangements, but I really don't recall any
 19 financial difficulty either with the haemophilia HIV
 20 practice in general or the drugs in particular.
 21 Now it would have been helpful, I guess, to have
 22 more counselling than was provided by the Trust on --
 23 I think on a secondment basis, but that's what we had.
 24 The other great advantage of the
 25 Grahame Hayton Unit was -- I've mentioned this in my

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1 meeting?
 2 A. Okay.
 3 Q. If you just look at the first page you can just assist
 4 me, do we have in that list of names anyone with a
 5 hepatology or HIV speciality?
 6 A. Oh, I see what you mean. Well, no -- Peter Kernoff
 7 who was the Chairman just before his death probably,
 8 or at least before his serious illness, but
 9 Christine Lee is a very important authority on
 10 haemophilia and hepatitis at the Royal Free. Of
 11 course she would have worked with the people at the
 12 Royal Free. But she's a pretty authoritative view on
 13 liver disease in haemophilia, and I would have thought
 14 that she was capable of giving very sound advice. But
 15 I guess you'll be asking her anyway.
 16 Q. I can indeed.
 17 Then if we could just please have -- again from
 18 the same time, 1990 -- BART0000573_004.
 19 We can see this is a letter being written by
 20 Dr Kernoff copied to you. It's to someone described
 21 as the "Regional HIV and AIDS Coordinator" in the
 22 North East Thames Regional Health Authority,
 23 8 October 1990. The concern is being raised by
 24 Dr Kernoff about funding for HIV care.
 25 If we look at the third paragraph, Dr Kernoff is

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1 submission -- that Colin Murray Parkes,
 2 a distinguished psychiatrist, internationally
 3 distinguished psychiatrist, was running a service, not
 4 related particularly to the patients but for the staff
 5 within the Grahame Hayton Unit, and our physicians and
 6 nurses joined in that counselling service for
 7 themselves. And I also was able to secure the
 8 services of Colin Murray Parkes to look after my own
 9 patients' psychiatric needs, which were considerable.
 10 Q. Can I then, on a slightly different topic, ask you to
 11 look at BART0000873_001.
 12 This is a letter from Professor Christine Lee to
 13 you, 14 December 1993. It's in the context of
 14 a particular piece of research funded by the Medical
 15 Research Council, and I don't need to ask you about
 16 that. We have documentation relating to that. But
 17 she says this:
 18 "I find it quite ridiculous that all this work
 19 and effort is being put into getting information from
 20 death certificates. I think the only valid
 21 information from death certificates is actually the
 22 date of death."
 23 Then she goes on to talk further about the
 24 authorship of a particular paper.
 25 What was the approach you took at The London

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1 Hospital on the issue of death certification and what
2 to record and what not to record and did your views
3 accord with Professor Lee's?
4 **A.** First of all, I haven't a very secure memory of what
5 I put on death certificates because I don't remember
6 signing very many. I'm not sure why I might not have
7 signed very many. But I do remember on one occasion,
8 I think, when a patient -- or a relative asked me not
9 to put HIV on the death certificate and my declining
10 their request. Because my view was that this was
11 a matter of fact which was my responsibility to put on
12 the death certificate. So, insofar as I have
13 a memory, I would have put "HIV infection" on the
14 death certificates.

15 As far as the research was concerned, I mean,
16 I think, as I recall, Sarah Darby was the leading
17 researcher in this area, which is mentioned in this
18 letter, and she was working with UKHCDO to look at the
19 pattern of deaths amongst the people with haemophilia
20 and HIV in the United Kingdom. As far as authorship
21 is concerned, I'm not sure that I would have had
22 a particular view on authorship.

23 **Q.** I don't need to ask you about that. There is quite
24 a lot of documentation about it and we have the final
25 study in any event.

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1 it's also a virus that's very difficult to virally
2 inactivate. And so I suspect that, with it being
3 a niche product and the need for some kind of
4 recognition that it was a risk, and knowing that viral
5 activation was either not possible or extremely
6 difficult, the view was that it was best to withdraw
7 it.

8 **Q.** Can I next ask you about the interactions you had with
9 pharmaceutical companies, and I'm really thinking here
10 of the 70s, 80s, 90s. You have given some information
11 in your statement about consultancy roles of the like
12 that you took up after your retirement with
13 pharmaceutical companies, but I'm talking about when
14 you were still a practising clinician.

15 First of all, in terms of the decision-making as
16 to which commercial products to use and to purchase,
17 you have told us, I think in answer to an earlier
18 question from me today, that that was ultimately your
19 call. Other than issues of cost, as we've seen teased
20 out in some of the correspondence, and leaving aside
21 your stated preference for NHS over commercial, did
22 anyone else seek to influence you in terms of which
23 particular commercial products you would purchase?

24 **A.** Well, I think that my stated preference for NHS factor
25 concentrate is actually extremely relevant. I was

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1 Just, again, on a variety of different topics,
2 porcine Factor VIII, you say in your statement that
3 that was withdrawn due to concern about the possible
4 transmission of porcine parvovirus. Do you know when
5 that was approximately?

6 **A.** I don't know the exact date, but I mean, Ipsen took
7 over from Speywood and there must be -- there must be
8 a date when the porcine Factor VIII was withdrawn.

9 It was always a rather sort of niche product, in
10 the sense that it only applied to a very small number
11 of patients. It's a pity it was withdrawn because it
12 was rather useful. Later it was possible to produce
13 recombinant porcine Factor VIII, although this was
14 after my retirement. I think it's mindbogglingly
15 expensive. I'm not quite sure what the rules are
16 these days on the use of porcine Factor VIII. But all
17 this was at the time when everybody was getting
18 extremely -- quite rightly -- nervous about any kind
19 of virus infection, and I think the manufacturers of
20 porcine Factor VIII, that's Speywood, must have
21 realised that there was a potential risk of parvovirus
22 infection. Whether porcine parvovirus is actually
23 capable of causing infection in humans I'm really not
24 sure, and of course parvovirus itself doesn't produce
25 a particularly worrying infection in most humans, but

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1 always an enthusiast and a true NHS supporter.

2 I, like many others, had commercial
3 representatives knocking on my door, speaking to me,
4 trying to persuade me to use their products. I did
5 see them and I hope they thought I was very difficult
6 to convince, because they had all sorts of arguments
7 for telling me that their products were better than
8 anybody else's.

9 Paradoxically, when we eventually got to 8Y,
10 I think that it was actually the best product
11 available, for a range of reasons that I can discuss
12 with you should you wish to discuss it, but by this
13 time the commercial manufacturers were making lots of
14 products which they believed, or liked to believe, had
15 advantages, and of course were more expensive. But as
16 it happened, I think that the NHS Factor VIII Y
17 Volkswagen got you from A to B as reliably and more
18 safely than some of the Commercial Department
19 Ferraris.

20 **Q.** So the purpose of pharmaceutical companies visiting
21 clinicians such as yourself is, as I think you've
22 recognised, to try to persuade the clinician to use
23 their product. That's why the pharmaceutical reps are
24 attending.

25 Do you have any recollection of what the

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1 pharmaceutical representatives may have said to you
 2 from time to time, particularly in the late 70s/early
 3 80s about the viral safety of their products?
 4 **A.** No. In fact, it was very interesting to hear that
 5 Mark Winter had access to a commercial heat-treated
 6 product in the spring of '84 when I was unaware that
 7 there was such a product available and, indeed, it
 8 wasn't available to me and it wasn't available to the
 9 Royal Free either.
 10 **Q.** Were there offers of funding, of training, products
 11 for patients? Were there financial incentives offered
 12 by pharmaceutical companies to you?
 13 **A.** I can't remember whether they invited me to take these
 14 kind of advantages, if you like to call them that, but
 15 if they did, I rejected them.
 16 **Q.** We've seen from the correspondence and returns that we
 17 looked at that you did change pharmaceutical product
 18 from time to time.
 19 **A.** Yes.
 20 **Q.** You already explained that your preference was to have
 21 more than one so that you weren't solely reliant upon
 22 one.
 23 **A.** Yes.
 24 **Q.** Again, thinking about the period really from '77, when
 25 you took over as consultant, through to 1984, what

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1 although the concentrate has already been used up.
 2 "There is, in fact, no evidence that new variant
 3 CJD can be passed on by factor concentrates and it is
 4 very unlikely that this will occur.
 5 "Nevertheless, I feel I must inform you that you
 6 were one of those who received one of the withdrawn
 7 batches of concentrate so that we can offer you
 8 a discussion about what this means. Please be assured
 9 that I do not believe that your health will be
 10 affected in any way."
 11 Was that -- we've seen various standard form
 12 documents in patient records, really, across the
 13 country.
 14 **A.** Yes.
 15 **Q.** This appears to be a document that you have drawn up
 16 yourself.
 17 **A.** Yes.
 18 **Q.** Did you send out the standard form notifications as
 19 well as far as you recall?
 20 **A.** I believe I did and I think this letter in itself
 21 I would regard as necessary but not sufficient.
 22 You'll see that I've included my bleep number,
 23 which is an important point, because if you tried to
 24 phone the hospital switchboard you could wait for
 25 quite a long time (not perhaps quite as long as

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1 factors, what reasons would lead you to change
 2 product?
 3 **A.** I really don't remember, and I think they were, in
 4 fact, equivalent -- all these products were
 5 effectively equivalent up to the time of the
 6 introduction of high purity concentrates, which we can
 7 discuss later if you like, but I'm not aware of any
 8 particular reason that I would use any particular
 9 commercial product that wasn't related to price,
 10 because I regarded them as, frankly, equivalent in
 11 both efficacy and safety.

12 **Q.** Let me move on to ask you about variant CJD --

13 **A.** Yes.

14 **Q.** -- and the information that was then provided by you
 15 to your patients.

16 There are two documents I'm going to ask you to
 17 look at. One is BART0002084_011.

18 So, this is a letter, November 1997. It looks
 19 like a standard form letter from you to patients:

20 "In recent weeks there has been growing concern
 21 about the remote possibility that new [VCJD] ... might
 22 be passed on by blood transfusion or even by the
 23 transfusion of blood products. Some batches of NHS
 24 factor concentrate which were issued a year or two ago
 25 have recently been withdrawn because of this concern,

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1 getting through to Virgin Media, but you did have to
 2 sometimes wait) and giving them the bleep number of me
 3 and the nursing staff was designed to make sure that
 4 patients could get me if they were worried.

5 In addition, I think that the number of patients
 6 we're talking about here was quite small, and I would
 7 hope and believe that we had a number of conversations
 8 with these patients that were personal, and that's why
 9 I say the letter was necessary but not sufficient.

10 **Q.** So this is one notification you would have sent out
 11 because of the particular withdrawn batches that are
 12 in issue here?

13 **A.** Yes.

14 **Q.** But as far as you can recall would you also have sent
 15 out the broader notifications?

16 **A.** Yes, I think so, yes, indeed.

17 **Q.** Then we can see a little later on -- this was '97 --
 18 a further notification.

19 HSOC0004260.

20 We can see again this is a letter from you.
 21 This is January 2001:

22 "We have been notified that another blood donor
 23 has developed variant CJD ...

24 "Our records show that this donor's plasma was
 25 used to make clotting factor concentrates and this

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1 material has now been used up so there is no immediate
2 action that can be taken."

3 Do you mean by that it can't be recalled?

4 A. Yes.

5 Q. "We know that on this occasion you/your son have/had
6 received plasma concentrate prepared from the affected
7 donor and this will be recorded ..." and then you
8 emphasise:
9 "... there is no evidence that [VCJD] is spread
10 by blood products and no one in the haemophilia
11 community has developed [it]. A fact sheet is
12 enclosed."

13 Again, you provided contact details.

14 What, if anything, can you recall about how
15 patients who received notifications such as this
16 responded?

17 A. Well, this was a perfectly beastly time, as you can
18 imagine, when we had been through all the hepatitis C
19 and HIV tragedy and then here we are with another
20 example of uncertainty and the likelihood or
21 possibility -- not the likelihood but the
22 possibility -- that might be a transmission of an
23 agent via a blood product.

24 So my recollection is that I had a number of
25 extremely difficult conversations with patients,

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1 adults, having to put patients back on plasma-derived
2 products that -- when they'd previously had some
3 recombinant products. Even some young children -- not
4 the very youngest children, I think some sort of
5 adolescents may have had to go back on to
6 plasma-derived products.

7 So this was a period of extreme difficulty and
8 distress not caused by a problem that became a major
9 clinical problem but caused by a problem which might
10 have become such a clinical problem. But it was
11 extremely uncomfortable and difficult to deal with.

12 Q. I'm not, I think, going to ask you any more about
13 recombinant, not least because you have dealt with it
14 in your witness statement and we have a lot of
15 documents from UKHCDO and the Department of Health
16 which tell the recombinant story that the Inquiry can
17 scrutinise in due course.

18 Ultimately, however, it was a question of
19 funding, was it not? Leaving aside the shortage that
20 you refer to because of the particular factory
21 problems, this came down to the Department of Health
22 not making available sufficient funding and
23 effectively saying it had to be sorted out on a local
24 basis?

25 A. Obviously, a little bit more complicated than that

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1 particularly parents of patients.

2 What's the date of this letter? Have you
3 got it?

4 Q. This is January 2001.

5 A. Okay. Well, this is a particularly difficult time,
6 because by this time, in 1997 -- I don't know if we're
7 going to talk about recombinants --

8 Q. We will, yes.

9 A. But by 1997, I have gone to my medical director and
10 said, "I can't do this anymore, I've got to have
11 recombinant product for my children" -- maybe I should
12 have said for these adults as well, but -- but, "I've
13 got to have it for the children."

14 The medical director accepted the situation, and
15 by 1998 Frank Dobson had said yes. But I couldn't
16 tolerate anymore the delivery of plasma-derived
17 concentrates, at least to my children, and then of
18 course the recombinant for all came in some time
19 later. I can't remember the exact date the
20 recombinant for all came in. But just at that time
21 one of the factories went down in the United States so
22 that we hadn't got enough recombinant to go round.

23 Now I can't remember whether this is exactly
24 contemporaneous or not but the result was that things
25 got extremely confused, and we found ourselves, for

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1 because the recombinant concentrates -- when
2 Factor VIII -- recombinant Factor VIII was first
3 introduced it contained human albumin. Now the human
4 albumin I think was safe but it was a biological
5 product, and therefore I think the Department of
6 Health perhaps took the view that it was still
7 biological and, therefore, what was the point of
8 paying all that money for the recombinant. There was
9 some credence for that view although I think it was in
10 many ways misguided.

11 The other problem was that it was, of course,
12 extremely expensive and it was thought not to be
13 affordable. But it soon became apparent that it was
14 necessary to purchase it.

15 Q. I wanted to ask you a couple of questions relating to
16 your testimony to the Lindsay Inquiry on the issue of
17 research. I'm not going to ask you about the specific
18 papers that you've referred to or that we have because
19 we have those in documentary form but if we could
20 have, please, Henry, LIND0000314, please.

21 Could we go to page 7. I just wanted to ask you
22 about some evidence you give in that top paragraph.
23 You set out there some studies that you had had some
24 involvement with, and then towards the last five lines
25 of that answer you say this:

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1 "... I guess I was doing some scientific work,
2 particularly early scientific work in '84, certainly;
3 I'm not sure about '83, but certainly in '84 we were
4 looking at previously untreated patients,
5 particularly -- perhaps mildly affected patients who
6 had not ever been treated before and then suddenly did
7 a treatment, partly for scientific reasons."

8 I wanted to ask you about what you meant there
9 by saying "partly for scientific reasons", because
10 treatment decisions for an individual should be
11 presumably only ever be driven by clinical
12 considerations?

13 A. I think these are the cryoprecipitate paper and the
14 8CRV paper. Now, the answer to that -- I've already
15 given the answer I think -- is that when a crisis
16 arose I -- with Professor Sam Machin, in that paper --
17 I gave two patients a heat -- an early heat-treated
18 low pool concentrate.

19 Now, this was not something that could be
20 planned for. As you are -- you are quite right in
21 saying, of course, that this had to be a specific
22 clinical indication, and in one case it was a young
23 woman who was truly a haemophiliac because her level
24 of Factor IX was very low, resulting -- because of her
25 genetic status (I can discuss it if you like in

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1 yesterday and the quite awful circumstances of this
2 young woman who, if she had been treated in any other
3 way, I think would have definitely been exposed to HCV
4 infection, quite possibly HIV. So my view was that
5 this was absolutely the best possible treatment for
6 her on the day.

7 Q. If we could just go to a further reference in your
8 evidence -- which is page 26, Henry, it's the top half
9 of the page -- the first part is you are answering
10 a question about not having a specific regime in place
11 for previously untreated patients. I have already
12 asked you about that so I don't need to ask you again,
13 but you then go on to say:
14 "What we were very aware of was that previously
15 untreated patients obviously must be given the best
16 available treatment; that goes without saying. That's
17 the whole basis of modern clinical ethics. But that
18 if we don't know what was the best treatment, then the
19 previously untreated patients were very suitable for
20 inclusion in scientific studies to establish what was
21 the best treatment."

22 You say that, of course, was an important part
23 of medical progress when you don't know the difference
24 between one treatment and another, and you believe
25 that both are potentially the best treatment, then

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1 detail) but she had a very low level of Factor VIII,
2 unlike most carriers, and had a major crisis during
3 pregnancy, and I was able to give her the 8CRV product
4 from Elstree, which was a low pool, early heat-treated
5 Factor VIII concentrate. I obtained consent --
6 I think from her husband -- to do that, and then we
7 followed her over a period of six months to a year to
8 make sure that she had not been infected.

9 The same thing applied to the paper we looked at
10 yesterday, which was to do with cryoprecipitate, and
11 for all those patients, fortunately, they avoided
12 hepatitis C and HIV infection.

13 Now, the only science involved was the
14 monitoring of a treatment that I decided, for clinical
15 reasons, with the patient's consent, to confirm the
16 lack of any infection as a result and that's what that
17 means.

18 Q. Would you accept, as a matter of general principle,
19 that in relation to previously untreated patients, or
20 indeed any patients, it would be wrong as a matter of
21 principle to give a treatment that is anything other
22 than the treatment you believe is the best treatment
23 that's clinically indicated for that patient?

24 A. Of course, and that was exactly the situation with the
25 use of cryoprecipitate in those patients we discussed

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1 it's permissible, with research ethics approval, to
2 study such a patient.

3 Can I just ask you to explain a little more what
4 you mean when you talk about not knowing the best
5 treatment, and then the particular suitability of
6 previously untreated patients for inclusion in
7 scientific studies.

8 A. Well, I think this must relate to the 8Y study. So we
9 get to the point where we're giving -- we're going to
10 be treating either previously untreated patients or
11 patients who had hardly any treatment in the past, and
12 the question is: when we get to 1984/'85 -- '85
13 really -- we have to decide what treatment to give
14 a new patient.

15 I think the answer is that we don't know what is
16 the safest treatment. We don't have any -- we know
17 that unheated product probably is capable of
18 transmitting a virus. We know that -- certainly by
19 1986, we know -- or before that we suspect that
20 heat-treated commercial products are capable of
21 transmitting HIV, and we believe and hope that we
22 believe that the new NHS superheated 80 degrees
23 Celsius 8Y will prove to be the best treatment for
24 previously untreated patients.

25 So in those circumstances, I think it was

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justifiable to mount the 8Y study and to contribute to it. Now, of course, it is true that I was the person who contributed more patients than anybody else to the 8Y study, but it was a fully -- I think -- ethical and well put together study from Oxford in which other centres participated. In many ways, in terms of any kind of investigational work that I ever did, I think it was the best thing that I ever did.

You'll be aware from my CV that I'm not an academic. I mean, it's true that I have an honorary professorship at Queen Mary for other reasons. It's true that I did some investigational work. But, generally speaking, I was working to help other people with their work I hope in an ethical way. But I wasn't an original researcher and I was doing my best for my patients, bearing in mind what I believed was the best available treatment. And this is a very good example of where my belief, as it happens correctly, was that the best treatment for my patient was to use 8Y as soon as possible and I relied on, admittedly, my hope that this was going to be the answer, which I think it was.

Q. Would you agree, as a matter of principle, that if you're in the situation you describe where you don't know which is the best available treatment, you want

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have been extremely difficult, we're trying to make the safest treatment possible, we believe this is the safest treatment, are you willing to go into this controlled trial with proper consent and to be able to contribute the necessary samples to get the answer?

So it's a little bit like the cryoprecipitate patients or the HCRV couple of patients, except that instead of being a response to -- a personal response to a critical situation where I'm doing my best for my patient then looking at them to make sure it's been all right, here we're doing a proper trial with informed consent, but it's obviously important that that consent is properly informed.

One of the things that I think was mentioned in a previous discussion was, you know, what is proper consent? It's quite clear that just signing a form isn't enough. I was involved, as I think I mentioned, with creating the patient consent form for operation at The London Hospital, and it was quite a long form. We tried to make it as short as possible, and I worked with the professor of medical ethics to make it as suitable as possible. When it came to having my own knee arthroscopy, when my knee went wrong, I signed the form without actually reading it. As I signed it, I thought, "Oh." Quite clearly, all my work on this

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to find out, you think that the treatment in the trial is a contender for that, that that is something that needs to be spelt out to the patients who are being invited to participate in the trial? They would need to be told: we don't know which is the best. We want, through this trial, to do it, and here are the pros and cons of different options.

A. Well, of course, ideally, you'd do what is known as a double-blind sort of trial where you take your best treatment, you take your hopeful treatment, and you compare the two using a randomised process. Well, I mean, this is unthinkable in terms of investigation of previously untreated patients because there are hardly any anyway, and to compare one of the available treatments that I just described with you with the 8Y I think would have been quite wrong because I suspected that any of the other treatments might transmit a virus, so I couldn't ethically do that. So the only thing I could do was to offer the 8Y in a clinical trial.

As far as the information sheet is concerned and the communication, I don't have a copy of the information sheet; maybe you do. But the information sheet and the communication to put such a patient into a study would have been along the lines that: things

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consent form hasn't been perhaps terribly useful since, as a receiver of the treatment, I'm not actually reading it properly. Bit of an eye-opener for me.

But, of course, in terms of this study, the 8Y study, essential for proper information and a proper information sheet and proper communication before entering a patient into the study. But I think it was ethical.

Q. Just perhaps one more question before the break. Picking up on the issue that you just mentioned about consent forms -- I'm not going to take you through all the various sets of UKHCDO minutes because we have them as a matter of record.

A. Yes.

Q. But is this right that, in the course of the 1990s and during part of the time when you were Chair of UKHCDO, there were two particular consent issues that were being considered by UKHCDO?

A. Yes.

Q. One was the issue of consent forms and whether there should be a written consent form for first treatment and changes of treatment, as to which my understanding from the documents is that it wasn't ever really resolved in that period.

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1 A. Not in my time. I think you know that I was in favour
 2 of a signed consent form for first use and for change
 3 of use. But as Chairman, I wasn't able to take the
 4 group with me, not least because I think there was
 5 also anxiety in the National Blood Transfusion Service
 6 because it had never been traditional to sign consent
 7 forms for blood transfusion, for reasons that we don't
 8 need to discuss but are self-evident.

9 Q. Being the potentially emergency nature of the
 10 transfusion?

11 A. Yes.

12 Q. The second issue in relation to consent that emerged
 13 during -- in UKHCDO discussions at around this time is
 14 the issue of the consent to data being held upon the
 15 UKHCDO database.

16 A. Which we've referred to earlier.

17 Q. And I can ask Professor Hay about that in due course.

18 A. Yes.

19 Q. But I think, as part of that, advice was sought by
 20 UKHCDO from Professor Doyle.

21 A. I'm not sure he ever really gave it. I was talking to
 22 Charlie a while back -- sorry, to Professor Hay
 23 a while back, and he couldn't -- there's reference in
 24 the Information Technology Working Party minutes that
 25 UKHCDO have that we arranged for Len to, for a fee,

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1 haemophilia, the fact they have now got two boys with
 2 severe haemophilia, probably need treatment, and have
 3 to have explained to them the whole sort of panoply of
 4 what it is to have haemophilia and how to manage it.

5 Now, I can't remember whether the boy needed
 6 treatment that night or not, but the task for
 7 a physician, even as experienced as I was at that
 8 point, of explaining to patients what on earth this is
 9 all about -- especially when it's quite likely they
 10 have already been accused of non-accidental injury by
 11 their local GP or Social Services -- this is
 12 a monumental task which can't be completed in a month,
 13 let alone an hour. And to get informed consent, valid
 14 consent, to treatment for that sort of situation's
 15 extremely difficult.

16 Now, fortunately, by then we were using
 17 recombinant, I think, so it was a bit easier. But it
 18 would have been a quite appalling task in any other
 19 circumstances and to get a signed consent form within
 20 an hour for an injection would have been quite
 21 impossible.

22 Q. I note the time, sir. Just before we break, would you
 23 agree, just picking up on your last answer then, that
 24 what lies at the heart of informed consent is the
 25 quality and extent of the information that's provided

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1 give us formal advice, but I don't think he
 2 necessarily ever did.

3 But the position was that when I very
 4 unexpectedly became Chairman of UKHCDO, my first duty
 5 I think was to sort out the Reference Centre Directors
 6 and really the constitution of UKHCDO, also to
 7 regulate the comprehensive care centres and to begin
 8 the process of national audit. And, of course, it was
 9 necessary for me to begin the process of putting right
 10 UKHCDO from Data Protection Act point of view, and
 11 also, as far as I could but I was unsuccessful, to
 12 look at the position of informed consent for
 13 treatment.

14 I'm not sure we have time for this, but just to
 15 give you an example of the difficulty of informed
 16 consent to treatment. In this period of perhaps
 17 around 2000, perhaps a little bit later actually, I'm
 18 called to the Emergency Department on a Friday evening
 19 at 7.00. And there, sitting in front of me, are
 20 a mother and father with identical twins with severe
 21 haemophilia, we find, at the age of 18 months maybe.
 22 They've both got severe haemophilia, and my job then
 23 is to look at the injuries or the bruises or the
 24 haemarthrosis the child has got and then to introduce
 25 to the family, who have got no family history of

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1 to the patient in circumstances which ensures that the
 2 patient understands that. Of course, there may be
 3 a huge variety of different situations but, as
 4 a matter of general principle, would you agree with
 5 that?

6 A. So I prefer the word "valid" consent to "written"
 7 consent or "informed" consent. Now, of course what is
 8 or is not valid consent depends very much on all the
 9 circumstances of the case and, of course, of the notes
 10 that are taken at the time. The answer to your
 11 question therefore is that signed consent is not
 12 necessarily enough. Informed consent implies
 13 a one-way traffic of information, whereas the concept
 14 of valid consent implies a two-way traffic.

15 MS RICHARDS: Thank you.

16 Sir, is that a convenient time at which to
 17 break? I've got a number of questions on a range of
 18 issues that have been requested by Core Participants
 19 to come on to.

20 SIR BRIAN LANGSTAFF: Well, I am sure there may yet be
 21 more, so we will take a break. Is half-an-hour long
 22 enough for you, do you think?

23 MS RICHARDS: Yes, it is.

24 SIR BRIAN LANGSTAFF: Very well. We will meet again at
 25 3.45.

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1 (3.15 pm)

(A short break)

3 (3.45 pm)

4 **MS RICHARDS:** Dr Colvin, I have a number of questions
5 suggested by others, and so they are going to be
6 somewhat miscellaneous in that they don't necessarily
7 follow a chronological sequence.

8 **A.** I understand.

9 **Q.** You gave evidence that there were clinicians who, in
10 contrast to your own preference, didn't care for NHS
11 products and preferred to use commercial concentrates.
12 Do you know which centres in particular that was true
13 of and why?

14 **A.** I think it might be unwise for me to comment, in the
15 sense that the work of the Inquiry is extremely
16 meticulous and I think you will find out for
17 yourselves if what I've said is true. I think it's
18 true but I think for me to make a specific allegation
19 might be unwise and I think it must come out, if it's
20 true, from your investigations.

21 Why, I think I can answer. Would that be
22 acceptable?

23 **Q.** Ultimately a matter for the chair --

24 **SIR BRIAN LANGSTAFF:** Yes.

25 **MS RICHARDS:** Certainly the why may be particularly

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1 than the Ferrari and maybe that's -- it shouldn't be
2 a joke because it's not a joke, it's a comparison to
3 try and produce colour to my speech. But I think
4 there were people who, understandably, felt -- and
5 I mentioned this before in my submission -- that there
6 was no limit to what we should do to promote the
7 healthcare of the haemophilia people, which I agreed
8 with, except that I wasn't always convinced that just
9 throwing more and more money at the problem would
10 solve the problem. It might even, sometimes, be
11 counter-productive.

12 Of course you have pointed out that, I think
13 repeatedly, that why didn't we go back to
14 cryoprecipitate, which was fundamentally a primitive
15 way of treating haemophilia.

16 So there were these positions. I think Mark
17 himself said that he believed there were factions
18 within UKHCDO. Now I don't know whether that was true
19 or not, because I wasn't the chairman of UKHCDO until
20 '93, and I wasn't even a member of the reference
21 committee, but you might reflect: why was Dr Colvin
22 invited to chair UKHCDO Reference Centres, or the
23 organisation, when he had never been a member? Now,
24 I'm not sure I know the answer to that question but
25 somebody must, and it does imply that there wasn't

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1 important.

2 **A.** I think that there were people, going back to the 70s,
3 who thought that the NHS response to the demand for
4 Factor VIII and IX was inadequate, both of volume and
5 of technical level.

6 David Owen mentioned this, in the sense that he
7 wanted to allocate -- well, he did allocate £500,000
8 to making things better, but Peter Jones, in his
9 statement on camera said he wanted 20 million and
10 Lord Owen said, "Well, you were never going to get
11 20 million", and I think that the -- it was felt by
12 some physicians that the response of the Department of
13 Health and the fractionation service was inadequate
14 not only in quantity but in quality, and that feeling
15 continued throughout the period that I was a physician
16 in this field.

17 Let's take the period after the introduction of
18 heat-treated concentrates, when people started to
19 fractionate at a much higher level using monoclonal
20 antibodies to produce much purer concentrates. The
21 word "purer" I think was used by Mark Winter.

22 One of the problems with the word "pure" is it
23 has quite a lot of emotional connotations, and
24 I mentioned this afternoon that there were those of us
25 who thought that the Volkswagen was good as or better

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1 always a consensus in UKHCDO.

2 Which, having been said, I do think that UKHCDO
3 made a magnificent contribution to the care of people
4 with haemophilia in the United Kingdom and the world
5 recognition of what haemophilia was and how it should
6 be treated. And if I had been critical in any way of
7 UKHCDO in the last two days, I do want to record that
8 I think that it was a world-leading organisation on
9 a voluntary basis.

10 I'm not sure whether you are going to ask me
11 about my time as -- further time as Chairman of
12 UKHCDO --

13 **Q.** I am not proposing to.

14 **A.** -- but the organisation was purely voluntary, and when
15 we got to '93/'96, it became apparent that it had to
16 be more professional.

17 This occurred with many organisations, I think
18 at this kind of time, where the old days of an amateur
19 effort had to be replaced by professionalism. I mean,
20 if I may make a further trivial comparison, I mean,
21 rugby football used to be entirely voluntary,
22 athletics used to be entirely voluntary, and then
23 after the Second World War, as we moved in towards the
24 millennium, everything became very professional and
25 everything got money associated with it.

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The whole, perhaps, emphasis of Thatcherism was about money and about business-like activity and I think it was the case by the time I became Chairman that the days of that kind of amateur approach were over and we needed to try and build something professional, which of course Professor Hay -- and you will be seeing him -- has done in the most amazing way, and it's now a significantly professional organisation.

So I think that, to come back to your earlier question, it may well have been that there were differences of opinion and you know that I tried to align myself to the Royal Free, with whom I had great relationships and much confidence, which included, therefore, Professor Pasi, who eventually came down to work at The London. But there were other centres, and I don't really want to name them, I think it will become apparent where that might not have been quite the same approach.

SIR BRIAN LANGSTAFF: I think you were asked why it was that some clinicians would have preferred not to have NHS concentrate.

I think that was the question, was it not?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: The answer you have given is for two

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value for promoting their particular product over another product.

Of course, if all these products are actually really equivalent, then things like chemical purity become important. And so I think that it may be that there were those who not only couldn't get the volume but thought that the chemical purity at, perhaps, almost any price was worth paying for.

Now, I'm not saying they were wrong. I cannot possibly say that. But it is, I think, the answer to your question, that there were those who saw the technological advances as really having precedence over any thought that a more modest approach, producing adequate volume and adequate quality, would compare.

Does that answer your question, sir?

SIR BRIAN LANGSTAFF: Well, it does and it doesn't, because I'm not sure I understand the reference to "chemical" purity. Let me -- I'll tell you why.

A. Yes.

SIR BRIAN LANGSTAFF: Would "biological" purity perhaps be a better word to use? Because my understanding so far -- and tell me if I'm wrong -- of purity is that you can, in the fractionation process, end up with quite a number of different proteins in the same

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reasons: (1) because you couldn't get hold of it, and second was because it was not as good.

A. Yes, sir, that's absolutely --

SIR BRIAN LANGSTAFF: In what respects wasn't it as good? Because I don't think you have answered that part.

A. I tried to answer but I am going to try and answer it again, in my discussion of the word "purity".

I think that there were those who thought that the only way forward was to have Factor VIII and only Factor VIII in the preparation, and that that was a very important part of the work and would lead to greater chemical purity, also mentioned by Mark. But whether that was better than something that was less sophisticated was not quite so clear.

It's important to remember that, as you were explaining earlier this afternoon, the pharmaceutical industry is there to make profits for their shareholders. Of course you know now, because I've told you, that I spent five or six years in the pharmaceutical industry after my retirement, and I am proud to have done that, but I became aware that they liked to think of themselves almost as part of the NHS, when they clearly were not. They were very heavily regulated by the time I became associated with them, but they always had to look for and find added

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fraction.

A. Yes.

SIR BRIAN LANGSTAFF: Factor VIII is one protein, so also is fibrinogen, and perhaps one or two other stray proteins as well.

A. Yes.

SIR BRIAN LANGSTAFF: In order to have a pure product, you wanted to have just the Factor VIII protein and not fibrinogen and not the others.

A. Yes.

SIR BRIAN LANGSTAFF: So that's what I mean by "biological purity".

A. Yes.

SIR BRIAN LANGSTAFF: That's the same thing as your "chemical" purity, is it, or not?

A. That's what I was driving at. I think I used the word "chemical" purity because Factor VIII is a huge molecule but there's very little of it in the blood, and so, as Professor Tuddenham discovered in 1984 when he tried to make Factor VIII from plasma, you start with a lot of plasma and you finish up with very little Factor VIII because there's hardly any of it. In that sense, by the time you've got down just to Factor VIII, you've almost got chemical purity without biological presence. Of course, when --

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1 **SIR BRIAN LANGSTAFF:** We are talking organic chemistry?
 2 **A.** Yes.
 3 **SIR BRIAN LANGSTAFF:** That's all that I wanted to clarify.
 4 Thanks.
 5 **A.** I think organic chemistry was never my strongest
 6 point.
 7 **MS RICHARDS:** Next, in a completely different topic, in
 8 relation to the transmission of hepatitis C, could we
 9 look at BART0002065, please. This should be the
 10 information sheet on hepatitis C.
 11 So this is the March 1995 information sheet that
 12 you referred to in your evidence earlier, Dr Colvin.
 13 If we go down to -- if you keep going down. Yes. So
 14 we can see there that you mentioned -- it says:
 15 "Dr Colvin will have mentioned the low risk of
 16 sexual transmission of the virus to any partner. He
 17 will have reassured you that ordinary, everyday
 18 household contact will not transmit the virus, so your
 19 family do not need to worry."
 20 Can you recall whether, other than what's set
 21 out here, any advice was given to patients about the
 22 particular risks of hepatitis C that may be associated
 23 with family members dealing with patients who bleed?
 24 **A.** I don't. I don't recall that, but I think that the
 25 evidence is that it's really quite difficult to

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1 **Q.** The next question, Dr Colvin, concerns the
 2 consideration that you gave second half of the 1970s,
 3 perhaps '77 onwards, really through into 1984/1985, to
 4 public health considerations.
 5 So we've talked in some considerable detail
 6 about the issue of risk to patients and what
 7 information should or shouldn't have been provided to
 8 patients in that regard.
 9 **A.** Yes.
 10 **Q.** What about wider public health implications? How did
 11 the consequences of potentially having people who may
 12 be infected with hepatitis or HIV, and how that might
 13 impact upon others and the risks they would pose of
 14 transmitting it to others, how did that factor into
 15 your general decision-making process about what
 16 information to give?
 17 **A.** I think during the '70s, for non-A, non-B, we had
 18 really no information that we could have imparted. We
 19 didn't know enough about it to give useful advice,
 20 I don't think.
 21 As far as HIV was concerned, I think that there
 22 was a desire to make sure that the known routes of
 23 infection were covered, but there was a lot of doubt
 24 about what level of protection there should be offered
 25 to hospital staff or to the isolation of patients

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1 transmit this disease sexually, as I've said.
 2 I think that if there were to be cuts with
 3 bleeding and there were to be cuts in a person who was
 4 also next to the blood of person with hepatitis C, of
 5 course I appreciate that that is a possible means of
 6 transmission. But the words "everyday household
 7 contact" doesn't, I think, imply the exchange of blood
 8 products in everyday life.
 9 **Q.** No. As I understand -- well, a reading of this might
 10 be that sharing plates, sharing cups, ordinary
 11 physical contact would not transmit the virus.
 12 **A.** I don't think there's really evidence that that
 13 happens.
 14 **Q.** No. So the question I have been asked to ask you,
 15 Dr Colvin, is: do you recall whether you gave any
 16 specific advice about what might be regarded as the
 17 additional risks that could arise if you are someone
 18 with a bleeding disorder and you bleed; the risk which
 19 isn't necessarily ordinary, everyday household contact
 20 that a family member might have hepatitis C
 21 transmitted through that route?
 22 **A.** I can't recall, but if I had a conversation with
 23 a patient, and if we handed out this form after that
 24 conversation, if they had a question to ask me about
 25 that issue, I would try to respond.

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1 within the hospital, or to advice on what might be
 2 described as public behaviour -- you know, the way to
 3 behave the public.
 4 I think that the contrast or the dilemma was
 5 between trying to reduce the risk of infection where
 6 there was a high risk and the desire to make sure that
 7 people who were HIV positive could lead as normal
 8 a life as possible within the limits of risk and
 9 I think that, in general, society tended to label
 10 people as being high risk when they weren't. And, of
 11 course, this was the great work of the Princess of
 12 Wales who actually made it quite clear that she was
 13 determined that people with HIV infection should be
 14 treated as people.
 15 I think that we in the hospital service tended
 16 to err on the side of safety with our high-risk
 17 policies (which I'm sure patients didn't like for very
 18 obvious reasons) and yet, at least to begin with, we
 19 felt obliged to invoke such procedures. But in public
 20 life, I think whether she knew it or not, the Princess
 21 of Wales was quite right.
 22 **Q.** I understand how the risks of infecting others was
 23 something that may have formed part of the information
 24 you gave to your patients once you were telling them
 25 that they were positive for HIV or hepatitis C. But

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when you were taking your decisions about what treatment to offer, in the period before patients were tested and diagnosed, did the risk that patients might unwittingly be infecting others, did the broader public health considerations come into play at all in your decision-making process about what treatments to use?

A. I'm not sure I still really fully understand the concept of a "broader public health implication".

Q. When you were deciding what treatments to provide to patients --

A. Yes.

Q. -- did you consider -- and indeed what information to provide to patients about risks before you knew that anyone had tested positive -- did you factor into your decision-making process the possibility that not only might your patient be infected or be at risk, but that others might be at risk?

A. I see what you mean. I think my answer to the question is: I don't know. Not least because I didn't know what on earth was going on, if that's any kind of satisfactory answer.

I think there was an enormous amount of ignorance of where we were and where we were going. And, of course, throughout this whole Inquiry, we

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experience of haemophilia care, we were trying to identify people with mild haemophilia, and I've already explained to you that many of them had no symptoms at all. I've also explained to you that a person with mild haemophilia is not, in some ways, a mild haemophiliac because if they're injured or get a bleed, they will go on bleeding until the bleeding is treated.

It's also the case that the person with mild haemophilia is different, depending on what activity they have. So if you have a young person who's a bit of a nerd and spends the whole of their life sitting in front of their computer screen, the chances of them having a bleed are quite small. So they can quite happily live a normal life in front of their computer screen, although they should get up from time to time to exercise.

If you have got a tearaway child, particularly somebody in difficult social circumstances who is hard to control, then, obviously you will give them advice about their activity. Whether it will be taken or not is another matter.

I recall another example where there was a child who was brought to my care who actually had extremely mild haemophilia, but generations of his family in the

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obviously -- I know this is implicit in any inquiry, is that one has to somehow try to separate what we now know from what we knew then. And I think in this period before we knew what was happening, it was perfectly obvious, from what you've shown me from UKHCDO, that we or my colleagues didn't -- and probably both of us didn't fully understand what was happening.

Q. The next question is about the structure of UKHCDO. You've told us how you were invited to become the chair.

A. Yes.

Q. Do you have any knowledge as to how in the years prior to that the Chairmanship of UKHCDO was determined?

A. No, I don't.

Q. If you could think for a moment about the position of mild haemophiliacs, Dr Colvin -- because that's the subject of the next question and, indeed, a number of later questions -- to what extent do you consider that lifestyle advice, advice about what activities to do or not to do in the management of haemophilia, in particular for mild haemophiliacs, could have been used as a means of avoiding bleeds of a severe nature and thus the need for treatment?

A. Yes. So I think that, during the early part of my

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past had been generals in the British Army. And the diagnosis of mild haemophilia in that particular case (where the mother was of course not a member of that family of generals but was a carrier of haemophilia) meant that the occupation of service in the British Army was not going to be possible. So the advice that one gave to patients determined, to some extent, their behaviour but didn't always determine what they did.

I had one patient, actually, who became a very distinguished person in one of the potentially combative -- not combative, but potentially high-risk services -- I had probably better not name which one it was. And he came to see me and said, "Dr Colvin, I want to join the Royal Marines" and I said, "Well, you know, you can't join the Royal Marines". He said, "Well, what about the police force?" So I said, "Well, I don't think the police force is going to take you". So he said, "But I want combat". So I said, "Well, it's very difficult".

He eventually went off and joined this other service without telling them that he had haemophilia. The first thing he did was fall off the back of a lorry and break his ankle and finished up in hospital under my care with a broken ankle and mild

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1 haemophilia. We put him right -- and this was after
2 the great HIV and hepatitis C crisis. He went back to
3 work and became a very distinguished person, but he
4 had decided not to reveal to his employers that he had
5 this condition.

6 Now, the only things that I would say always
7 I advised against were rugby, football and boxing.
8 But once we got on to prophylactic care later, one of
9 my severely affected patients became a world champion
10 cyclist. So I think -- and the reason he did that was
11 because I'd told his father it would be best for him
12 to go swimming. And he went swimming and then, when
13 he became a very fine swimmer, he got on a bike and
14 decided he was an even greater cyclist.

15 So, I'm sorry, the answer to your question,
16 I think, is that for people with mild haemophilia, one
17 would try to give them advice about what was the most
18 sensible thing to do, but what was sensible depended
19 on all the social circumstances that they were in, and
20 what would be suitable for one family might not be
21 suitable for another.

22 I also, finally, was invited many years ago --
23 I think I mentioned this earlier -- to give a paper to
24 The Haemophilia Society saying, "I can go skiing."
25 Now, whether it's really sensible for somebody with

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1 you were not yet the consultant and director at the
2 Royal Free. But what was your understanding of the
3 scope of self-sufficiency? In other words, was it
4 based upon hospital treatment, home treatment, or
5 prophylactic treatment as well?

6 A. Well, I think we'll never know. If I may -- and
7 perhaps this is unwise -- but I'd like to refer you to
8 Rudyard Kipling's Just So stories. The butterfly that
9 stamped is a story about a king who decides that he is
10 going to feed all the animals in the world for lunch,
11 and he gets lunch for all the animals of the world and
12 puts it on the quayside, and he invites all the
13 animals of the world to come for lunch, and just as
14 they are about to start their lunch, an enormous
15 animal comes out of the sea, eats everything, and
16 says, "What's for afters?"

17 Now, I don't mean this to be a trivial story,
18 it's a story that Rudyard Kipling wrote, but I think
19 that at a serious level there's an element of this in
20 the self-sufficiency argument. That Lord Owen for
21 very good reasons and with great sincerity said that
22 we will become self-sufficient, but did he really have
23 a clear idea, bearing in mind that Dr Jones
24 wanted 20 million and Lord Owen was
25 offering 500,000 -- did he have a really clear idea of

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1 haemophilia to go skiing or not is a matter for
2 debate. People might say, well, there's no point in a
3 person going -- with haemophilia going skiing because
4 they're going to get injured, and then it's going to
5 cost a lot of money to put them right. My argument
6 against that was that a lot of my patients with either
7 mild or severe haemophilia would go out on a Friday
8 night and get less than totally so sober and get
9 injured, and when they came to the hospital, I treated
10 them. I might say, "I really wish you hadn't spent
11 the evening getting drunk and getting into a fight,"
12 but of course you still get treated. It seemed
13 unreasonable to say to a patient, "I won't treat you
14 when you have got into a fight." That's obviously
15 unreasonable. Equally, therefore, it seemed
16 unreasonable to say: you mustn't go skiing.

17 Q. But lifestyle advice could be one part of the jigsaw
18 of trying to avoid bleeds.

19 A. Yes.

20 Q. We touched on -- self-sufficiency. You have dealt
21 with it in a number of parts during your evidence, so
22 I don't need to ask you in any detail about it.

23 Can I just ask this: in the mid-1970s when
24 Lord Owen made the pledge -- I think his term -- in
25 Parliament for self-sufficiency, and I'm aware that

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1 what the real demand would be?

2 I think the answer is that nobody could really
3 and it is not unfamiliar for desire to reach an
4 objective to fail to quite appreciate what the real
5 achievement of the objective might entail.

6 Q. As far as you are aware, however, did the haemophilia
7 clinician community in the second half of the 70s
8 understand that, according to Lord Owen in any event,
9 what was meant by self-sufficiency from the
10 Government's perspective was home treatment but not
11 prophylactic treatment? Was that understood by
12 clinicians?

13 A. I don't think -- despite Inga Marie Nilsson's work in
14 Sweden, I don't think that we had really appreciated
15 or got our heads round the idea that prophylaxis was
16 the answer, and I don't believe when David Owen
17 recommended and offered to create self-sufficiency for
18 the United Kingdom that he'd really thought of what it
19 would cost to offer prophylaxis because I don't think
20 the haemophilia treaters themselves had addressed that
21 idea either. Yet it was the correct answer to the
22 problem of haemophilia.

23 We now find ourselves in the United Kingdom with
24 patients who don't know what it's like to have severe
25 haemophilia because they don't suffer the same

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1 bleeding, and doctors who have got no idea what it's
 2 like to have haemophilia. At the end of my career,
 3 I was busy trying to train the doctors of the future
 4 with patients who weren't actually showing the signs
 5 of haemophilia, which is great, but it was the case
 6 that until we really grasped the reality or the
 7 possibility of prophylaxis and created the environment
 8 in which that could be achieved, haemophilia treatment
 9 was inadequate. And I don't think that in the 70s
 10 anybody, apart from possibly Inga Marie Nilsson, had
 11 really grasped the opportunity that was there to be
 12 taken if we had only had the resources available.

13 **Q.** You told us in your evidence earlier, and it's in your
 14 statement, that there was this small amount of
 15 heat-treated material available in 1985 which was then
 16 used for the patients that you described and the term
 17 you used was it was for certain special situations.

18 Other than the circumstances of those individual
 19 patients, what were the special situations for which
 20 this treatment was available?

21 **A.** Are we talking about the 8CRV material or the 8Y?

22 **Q.** It's the material that you talked about in 1985. We
 23 can look at your witness statement, perhaps for
 24 clarity.

25 **SIR BRIAN LANGSTAFF:** Wasn't it 1994 in the evidence you

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1 when I think the final study was published.
 2 Could we have CBLA0002224, please, Henry.
 3 We can see this is a document from July 1985
 4 from BPL.

5 **A.** Yes.

6 **Q.** And it's setting out some information as at July 1985
 7 about this product.

8 **A.** Yes.

9 **Q.** With some information about what was known about it at
 10 that stage. Is it right to understand that clinicians
 11 such as yourself wouldn't have been putting patients
 12 forward for this trial if it wasn't thought that
 13 likely that this was going to be a safe product?

14 **A.** But thinking and believing and knowing are very
 15 different things. The point that I was making was,
 16 and I'm no statistician, is that when you look at the
 17 number of patient who are treated in a previously
 18 untreated patients study -- because it needs to be
 19 previously untreated patients. If you look at the
 20 number of patients treated and the carefulness of
 21 their follow-up and the analysis of their results, if
 22 you're a statistician you can come up with confidence
 23 limits of how likely it is that this result is a true
 24 result which gives you certainty.

25 I think you'll find either in the 8Y study or in

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1 mentioned --

2 **A.** The 8CRV material was '84 and was an attempt by Oxford
 3 to create what I understand was an extremely small
 4 volume of material from what I seem to remember
 5 Charles Rizza described as "trustworthy donors", that is
 6 people who had, in some way, been regarded as being
 7 particularly suitable for giving blood, in very small
 8 pools, with early heat treatment.

9 Now why Oxford did that I'm not entirely clear.
 10 Perhaps they were just trying to think of the ways to
 11 improve the situation. But I became aware -- and
 12 I think this is recorded in Terry Snape's notes, that
 13 I became aware, with others, of the availability of
 14 this very small amount of concentrate, which I think
 15 they would only have given to me for people who hardly
 16 ever been treated before and for people who didn't
 17 need much treatment.

18 So I think it was a very niche product, if
 19 that's the right word for it.

20 **MS RICHARDS:** You have referred in your evidence to 1988
 21 being the year in which the safety of the 8Y product
 22 was established.

23 **A.** Mmm.

24 **Q.** I just wanted to ask you to look at a couple of
 25 documents to see what the position was prior to 1988,

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1 one of the commentaries on the 8Y study that it's
 2 pointed out that the confidence limits are not
 3 100 per cent. And I think you might also find there's
 4 a paper, quite a late paper, by Professor Mannucci
 5 again, where he looks at all the different ways in
 6 which plasma can be virally inactivated and tries to
 7 assess how safe they are.

8 One of the points that Duncan Thomas used to
 9 make, who was one of the leaders in the National
 10 External Quality Assurance Scheme (*sic*) and the NIBSC,
 11 the Biological Standards and Control organisation, one
 12 of the points he made many years ago was there is
 13 nothing -- there is no such thing as a safe blood
 14 product.

15 So you can do your study and you can measure
 16 your measurements and you can publish your results but
 17 those results still have confidence limits.

18 And the point that I was really making was that
 19 whilst we all hoped and believed and thought that this
 20 would work, and it did, I don't think that before 1988
 21 you could look a patient in the eyes and say,
 22 "I promise you that this is safe", because of the
 23 confidence limits statistical issue.

24 **Q.** I understand what you say about the ability to
 25 promise, the ability to say "conclusively established"

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or words to that effect. I think it's right, and we can look at the documentation if necessary, but it is material that you saw in advance of your evidence that there was, as one would expect, an interim reporting by Dr Smith in September of 1986 which suggested that, thus far, the indications were all very favourable?

A. Yes. Absolutely. I don't deny that at all. I think it's an extremely important point. But if you look back -- perhaps maybe I may go back to the issue in May '84, when it was decided in one or two, three, perhaps four centres to go to a heat-treated product that was commercial, there was, I think it's fair to say, zero evidence that that product was safe. Completely different scale of evidence to the evidence that later became apparent for 8Y.

I'm not criticising the decision, I'm just saying that if you're looking at real evidence and you want to say to a patient, "I promise you that this will work" or "I nearly promise you this will work", you need to have evidence which has been assessed by a statistician.

Q. This is now moving to a completely different topic, Dr Colvin.

Could you just very briefly outline in the 1970s what the approach would have been, from your

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patient had von Willebrand's disease.

However, that is not absolute, because there are people who are -- look as though they've got haemophilia but actually have a form of von Willebrand's disease.

So it's a very complicated issue and I think that, to begin with, we were struggling very much to classify von Willebrand's disease. And I mentioned I had some involvement in a project that was trying to classify von Willebrand's disease in my community. It didn't eventually come to anything.

But as time went by we got much, much better at diagnosing von Willebrand's disease and distinguishing it from haemophilia. But in the early days, before 1970 or so, it was -- well, it was difficult to make that diagnosis. The difference between haemophilia and von Willebrand's disease at a clinical level was people with von Willebrand's disease tended to get soft tissue nosebleeds and capillary bleeding, whereas people with haemophilia tended only to bleed after injury or surgery, or spontaneously if they had severe haemophilia. So you could tell some difference between the two conditions clinically but until the 70s you couldn't distinguish in the laboratory, and even then, even up to the late period, it wasn't

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perspective, to diagnosing haemophilia or von Willebrand's disease. Was there a standard model of diagnosis?

A. So this is a very complicated question.

The first thing to say is that people with haemophilia are usually male -- not always. In fact, Sir Frederick Treves had a patient under his care who was female and a true haemophiliac, and I looked after four of that family because the sons of that woman, or one of the other women who had true haemophilia, were all haemophiliacs, because both her X chromosomes were abnormal and, therefore, all her sons were bound to be haemophiliac. I looked after that family. So that family from the 19th century came down through to Whitechapel.

So, first of all, nearly all the patients with haemophilia are male.

Secondly, people with von Willebrand's disease do have low Factor VIII clotting activity, so they could be confused with haemophilia. But in the 70s, I think early 70s, the von Willebrand factor antigen and a material called von Willebrand factor were described, and once we had von Willebrand factor and von Willebrand factor antigen, if that was low as well as the Factor VIII level, it was likely that the

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always that straightforward.

Q. Next question is about records, record-keeping.

Do you agree that where you have a haemophiliac patient who has a life-long condition and may require a range of different blood products throughout their lives, it is very important that the details of those products should be recorded?

A. Yes.

Q. So one would expect -- and I'm talking generality here rather than The London Hospital. One would expect hospitals, haemophilia centres, in the 70s and 80s to be keeping very precise records of products used for patients?

A. I went to great lengths to keep records of all the products used at The London Hospital, and I also went to some lengths to try to make sure that people were treated with the same batch of material if it was available and those batches were recorded. So we took record-keeping very seriously and I believe the record-keeping should be taken very seriously.

Q. Then coming specifically to The London Hospital, my understanding is that in providing statements in response to some specific issues raised by individual patients, you have been told by St Barts that some of the -- the handwritten records that you would have

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1 kept at the time can no longer be located; is that
2 correct?
3 A. Well, I've been told by Barts NHS Health, who of
4 course have taken over the -- now the London -- the
5 hospital, I've been told that one patient's notes had
6 been destroyed in 2008. I was also -- managed to,
7 before lock-down, see the red envelope, the brown
8 envelope of another patient, and I also saw his
9 contemporary notes from 2009.

10 Oddly enough, I was the first person to write in
11 them because when I retired I saw him on one occasion
12 in my *ad hoc* presence in the clinic but the notes for
13 the period from 2009, I think it was, backwards were
14 not provided for me. So the only handwritten notes
15 I saw were those from 2009 onwards, in which
16 I happened to have written the first entry. But I had
17 to rely on the brown envelope and the contemporary
18 notes.

19 Otherwise, I have tried to get hold of notes and
20 haven't had a response other than the fact that the
21 notes were being sought, other than the brown envelope
22 systems for two of those patients. So for one patient
23 I have had no information of any kind.

24 So I can't say more than that. I've tried
25 repeatedly to get hold of the notes of rule 9 requests

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1 talking about the national experience.
2 Q. But would you accept, as a matter of generality, the
3 magnitude of the risk from the use of cryoprecipitate
4 is completely different from the risk of concentrates,
5 and indeed, that's the very reason why cryoprecipitate
6 was being recommended by UKHCDO for certain cohorts,
7 and indeed why you were using it for children and
8 others?

9 A. And why I wrote that paper for six patients being
10 treated under my care from '82 to '84 which we've
11 looked at. So yes, I agree.

12 Q. Then could we have up on screen, please, Henry,
13 JEBA0000008, please.

14 This is a document you saw this morning,
15 Dr Colvin. It's quite faint but if we could zoom in,
16 please, 4 July 1979. The name is redacted but it
17 seems likely it's from you as it's given the title of
18 senior lecturer of haematology in July 1979?

19 A. Yes.

20 Q. It's a description of an incident occurring when
21 a doctor, whose identity is not relevant for present
22 purposes, was on call in the department and the child
23 with mild haemophilia was given a bottle of commercial
24 concentrate, in that case Hemofil. If we can just
25 look at the second paragraph -- and you've said for

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1 and so far I have had that level of difficulty.

2 Q. Then moving on to the relative risks as between
3 cryoprecipitate and commercial concentrate, or indeed
4 NHS concentrate, you refer to the possibility that if
5 someone has lots and lots and lots and lots of
6 cryoprecipitate, there may be risks created. Would
7 you accept, however, that the risk from each bag of
8 cryoprecipitate was very, very small indeed?

9 A. Yes, of course. The point of Peter Kernoff's paper in
10 Gut or Christine Lee and Peter Kernoff I think, and
11 I think I mentioned this earlier, if you did get a bag
12 which was infected then you'd get a full dose. So if
13 you think that the level of exposure to the virus
14 makes a difference, then that might be important.

15 I mean, for instance, in Covid-19 there are
16 people who think that the load of virus you get at the
17 point that you're infected might have some relevance
18 to your short or long-term prognosis. Now, whether
19 that was the case, of course, I don't know.

20 But we know, I think, and you have the records,
21 that I think there may have been one or more
22 seroconversion to HIV from cryoprecipitate. I'm not
23 sure we have that evidence but --

24 Q. Not in your experience at The London?

25 A. Not in my experience at The London but, I mean, I'm

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1 reasons that are unclear that that concentrate was
2 given, and you have said this:

3 "I am rather unhappy about this incident for
4 a number of reasons. Firstly I understand that
5 through no fault of [their] own [the doctor] was
6 unaware of the arrangements for treating haemophilia
7 at The London ... did not even know where the
8 concentrate was kept. As you know there are
9 instructions for staff treating the disorders of
10 haemostasis of children and general instructions for
11 treating haemophilia available. Secondly I am anxious
12 that children with mild haemophilia should not receive
13 the commercial concentrate because of the substantial
14 hepatitis risk."

15 Then there is a reference to cost.

16 So it would seem clear from this that, as
17 at 1979, one of the factors influencing your
18 decision-making in relation to the treatment of
19 children with mild haemophilia was the risk of
20 hepatitis?

21 A. Yes. Of course I was wrong about the commercial
22 concentrate because the NHS would have been just as
23 good at transmitting the hepatitis.

24 Q. Concentrate *per se*, I think we can safely say,
25 substantial hepatitis risk?

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1 A. Yes.

2 Q. In relation to what went wrong on this occasion, was

3 this, as far as you can recall, a one-off or was there

4 a broader systemic problem that you became aware of?

5 A. I don't think there was a broader systemic problem in

6 '79 that I was aware of. I do think that I could and

7 should comment on the great difficulties that

8 haemophilia centres have in making sure that the right

9 people look after their patients.

10 So we had a regulation at The London that if

11 anybody came to the Emergency Department with

12 a bleeding disorder, they should immediately call the

13 registrar on call for haematology, and the reason for

14 this was that triage wouldn't help, because you had to

15 wait for however long, maybe even for triage, in the

16 Emergency Department, and when you had had your

17 triage, the triage person wouldn't necessarily fully

18 understand the importance of haemophilia or might not

19 even have heard of haemophilia really.

20 So the rule was that if somebody came to the

21 Emergency Department of The London Hospital, then

22 whatever the complaint, if they had a haemophilia card

23 with them or if they said, "I've got haemophilia", the

24 registrar would immediately be called, day or night.

25 Now did this always work? I can't necessarily

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1 hepatitis C in the community is 0.3 per cent, then

2 there's 100 per cent chance of being infected. There

3 is another argument which I think I address in my --

4 Q. Forgive me. On one treatment only?

5 A. Yes. There's another argument which I give in my

6 submission which is about the subtype of virus with

7 which a person is infected. And that's an issue which

8 I think you would have to ask Professor Hay or

9 Professor Preston because I know that

10 Professor Preston, in particular, was very interested

11 in any difference between the subtype of hepatitis C

12 that might be imported from other countries and the

13 type of hepatitis C that might be endemic in the

14 United Kingdom, or whether that made a difference.

15 Q. You will recall, Dr Colvin, I asked you earlier today

16 about your evidence in your statement that it wasn't

17 realistic to revert to cryoprecipitate for all

18 patients in all circumstances. I don't need to go

19 back over that.

20 One of your answers was about how realistic it

21 was to go down that route. If one thinks about

22 a patient who only rarely requires treatment -- so not

23 someone on home therapy, not a regularly treated

24 patient -- the question is: would it not be realistic

25 to at least discuss the reversion to cryoprecipitate

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1 convince you that it did always work because people

2 sometimes fail. But we had made every effort to make

3 sure that that happened and if you don't do that, then

4 you will get serious problems.

5 And equally, you can't have somebody on parade

6 24 hours a day, 7 days a week, with haemophilia

7 experience. It's a rare disease and we have to accept

8 that we do our best to make sure that people are

9 properly looked after with haemophilia. It's the

10 responsibility of the director to try to make sure

11 that this is never a systemic problem.

12 Q. I asked you a moment ago about the relative risks of

13 cryoprecipitate versus concentrate. Can I just ask

14 you to think further about the relative risks of NHS

15 concentrate and commercial concentrate.

16 Would you accept that, on a like-for-like basis

17 if only one treatment were required, for example, that

18 the risk of NHS factor was, in fact, lower than the

19 risk of commercial factor?

20 A. For hepatitis C?

21 Q. Yes.

22 A. No, I wouldn't.

23 Q. Why is that?

24 A. Well, if there are thousands of donations in a batch

25 of Factor VIII concentrate and the prevalence of

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1 with that category of patient?

2 A. Well, of course, if one is very rarely treated, one

3 perhaps very rarely sees the patient, and then you'd

4 have to address the issue when the patient came to see

5 you. If you had a very rarely treated patient who

6 required a small amount of treatment to treat

7 a particular bleed, then cryoprecipitate would be an

8 appropriate therapy.

9 Q. In terms of balancing risks, the decision to run

10 risks, you've set out your view in a number of parts

11 of the material about the benefits of treatment

12 outweighing the disadvantages or risks of treatment.

13 A. Yes.

14 Q. Would you accept that, as a matter of general

15 principle, a patient may view those risks very

16 differently from how a clinician may view them?

17 A. Oh, yes. Of course, I understand that entirely. And

18 when we were talking about consent earlier, we talked

19 about whether this consent was a one-way or a two-way

20 process.

21 Q. Because you might think, as, for example, you said in

22 your paper with Dr Kernoff in August 1983, that the

23 benefits of treatment outweighed the disadvantages.

24 But a patient faced with a possibility, for example,

25 of a premature death as against pain, discomfort,

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1 injury from a bleed may form a very different view,
2 and that's why it's so important for them to be at the
3 centre of the decision-making process.

4 **A.** Well, I mean, particularly in today's world, quite
5 properly the patient is at the centre of care. Now,
6 whether in the -- 30, 40, 50 years ago we fully
7 understood that the patient was at the centre of care
8 in the way we should have done I think is less clear.

9 I still interview patients for admission to
10 medical school, and one of the questions often asked
11 by my colleagues, and I may even ask it myself from
12 time to time, is: in a particular scenario, who is the
13 most important person in this scenario? And the
14 correct answer for the student who wants to be
15 a doctor is: it's the patient.

16 **Q.** Was that not the thinking in, say, the first half of
17 the 1980s, that the patient was the most important
18 person in the scenario?

19 **A.** I'm not saying it wasn't. I'm saying that attitudes,
20 I think, have developed over the last 50 years in
21 a way that patients are now more clearly at the centre
22 than perhaps they were in the earlier part of the
23 middle of the last century. I think this was
24 a process that continued over that period. The fact
25 that we correctly believe that the patient is the

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1 Now, obviously, he tried to give me a choice
2 between the things that he thought would be sensible,
3 but maybe orthopaedic surgeons are particularly
4 paternalistic. I hope I don't abuse orthopaedic
5 surgeons by making such a remark. But it is the
6 case that many of us, including myself, quite
7 appreciate that the doctor is the expert, and we want
8 to be told what the doctor thinks the best treatment
9 is.

10 But -- and I think this is terribly important --
11 we need to give patients the best information and the
12 choice of what we do next, and we don't always get
13 that right. Sometimes we don't. That, of course, is
14 sadly a fact of life. But my answer is that I do
15 believe in patient choice. I do believe that in the
16 past it was more paternalistic, but the process of
17 paternalism wasn't always completely disadvantageous
18 because it took the responsibility of what happened
19 next away from the unfortunate patient.

20 **Q.** Dr Colvin, I have asked you previously about UKHCDO
21 guidance or the absence of it. I'm not asking you to
22 go back to that.

23 Would it have assisted clinicians to make better
24 decisions in the latter part of the '70s and the early
25 part of the '80s in particular if there had been clear

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1 centre of the consultation may not have been as
2 appreciated as it should have been in the past.
3 I think it's hard for me to say anything other than
4 that.

5 **Q.** Others have used the term "paternalistic" to describe,
6 in some respects at least, the approach to clinical
7 decision-making in earlier decades.

8 Do you think that is a fair description of
9 clinical decision-making in this context in the '70s
10 and '80s for haemophilia clinicians?

11 **A.** I think it is, and I think it's also very interesting
12 to reflect on what it means because I think that the
13 correct putting of the patient first does create
14 a burden on the patient which can be difficult for the
15 patient to bear.

16 So if you take paternalism at one end and total
17 patient choice at the other end -- and of course
18 I completely agree with the idea of patient choice and
19 autonomy. When you're ill yourself, you may take
20 a different view in the sense that -- I was referring
21 to my arthroscopy a while back, and I wasn't, I think,
22 given a really clear choice between, shall we say,
23 physiotherapy, arthroscopy, and knee replacement. My
24 surgeon said, "You need an arthroscopy". And I said,
25 "Okay. You're the doctor. Let's get on with it".

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1 guidance from other sources, such as the Chief Medical
2 Officer, or the Department of Health and Social
3 Security?

4 **A.** Yes, I believe it would. I have written and helped to
5 write very many guidelines/documents in the field of
6 haemostasis and thrombosis in the period probably
7 dating from the early '90s when I became more
8 nationally active, if you like.

9 I thought that these guidelines/documents were
10 extremely valuable because they were based on expert
11 opinion. But many of these guidelines/documents were
12 challenged by people who quite rightly said, "These
13 are not statistically valid pieces of guidance. They
14 are just a group of self-styled experts who tell you
15 what to do because they think they know what they are
16 talking about."

17 I think I also mentioned in medico-legal work
18 that these documents tend to get relied on because
19 they are often the best bet about what is the correct
20 approach at the time. Now, of course, there has been
21 a tendency in medico-legal work, because of the burden
22 principle, for doctors to get away with, if you like,
23 anything that is regarded as being something that
24 a reasonable group of doctors would do. And I think
25 Montgomery has changed that view, in terms of consent,

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to the importance of warning and discussing material disadvantages as well as material benefits.

So I think that very clear guidelines/documents are actually a big responsibility for those expert groups because when you get down to looking at the medico-legal cases, the guidelines/documents give you a framework on which to provide your expert witness opinion. But, having said that, if the doctor whose practice is being criticised has written very clear reasons for what he or she has done and has not abided by the guidelines, I believe that is a defence in the sense that the guidelines are guidelines. They are not the law.

Does that answer your question? I am sorry. It's list --

Q. Yes, yes.

The last matter I wanted to ask you about, Dr Colvin, requires us to go back to a couple of documents. RFLT0000050, please, Henry. I want to go back to the January 1983 meeting that you attended at The London Airport hotel. We looked at one record of it. This is a second record.

So this is a note that was put together by the managing director of Immuno, Mr Norman Berry, and we can see from it that the location of the meeting in

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to go back over that because I read the key parts of it when I was asking you a question. But we can see, again, the first two and a half pages of this note deal with Dr Eibl talking about methods of chemical inactivation of viruses. Then if we go to the next page, we see, for example, considerable discussion about chimpanzee testing, observations and contributions from Professor Zuckerman. Then we see under the heading "Clinical trials design", considerable discussion over the nature of the design. Then we know from the rest of the note there's lunch, and then an after-lunch discussion about AIDS.

Then if we can go to the last page of this, please, Henry. Again, we see the list of attendees. It's predominantly but not exclusively Reference Centre Directors, but there are others present too, obviously, including yourself.

I just wanted to show you those again and press you as to whether you have any recollection of this meeting now because it does seem to have been a somewhat unusual meeting. Not common to meet at Heathrow Airport hotels, I would have thought?

A. No.

Q. Not common to have the great and the good of haemophilia and hepatitis care meeting with one

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January 1983 was the Excelsior Hotel, Heathrow Airport. We can see this is being sent to Dr Kernoff who you worked closely with.

If we go over the page, we can see Mr Berry's summary of discussions of the meeting. Professor Bloom is described as being in the chair. Then there is effectively a presentation by doctor -- I don't how you pronounce that -- Eibl of Immuno. The particular issue here was about the so-called hepatitis reduced concentrates, and we can see there's a detailed discussion. If we go to the second page of this, Henry, or the next page, we can see there's discussion then of -- in the numbered paragraphs of a range in particular of ethical issues being put forward, the use of children for the trials, who would benefit, difficulties in carrying out the trials, the practicability or otherwise of testing in chimpanzees.

Then if we go over the page, we can see in the second half of the page there's a summary from Professor Bloom at the end. Now, that's Mr Berry's note. I want to go back to the other note and then ask you a question. So if we go back to the other note, please, Henry, which is PRSE0002647. This is Dr Frank Boulton's note. We looked previously in some detail at the section of it on AIDS, and I'm not going

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particular pharmaceutical company?

A. Sure.

Q. And it's an important meeting, and there aren't many people I can ask about it.

A. I have no recollection of the meeting, I'm afraid.

Q. None at all?

A. I have no recollection of the meeting.

MS RICHARDS: Sir, those are my questions, subject to anything further from behind. Whilst I check that, I understand that you, sir, may have a handful of questions for Dr Colvin.

SIR BRIAN LANGSTAFF: Just one or two. I think you may be being asked one question here, Ms Richards.

(Pause)

MS RICHARDS: Before you ask your questions, I am asked just to go back to one particular issue, and I'll do so. We talked about -- I asked you about diagnosing haemophilia and von Willebrand's and you talked about some of the difficulties.

A. Yes.

Q. The particular question I am asked to put to you is: in the 1970s, so not earlier than that, was there a standard model of diagnosis for VWs and haemophilia, was there a standard set of tests or diagnostic approaches that would be undertaken by you?

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A. There was always difficulty in knowing who did or didn't have von Willebrand's disease, and one of the anxieties at UKHCDO was that many of those who had been diagnosed as having von Willebrand's disease might not actually have it, might even be normal persons.

The diagnosis of haemophilia itself can be very difficult if the level of haemophilia is very mild and the scientific advances that led to the effective diagnosis of von Willebrand's disease and its distinction from haemophilia continued throughout the time I was a haemophilia doctor.

I do not recall the exact date of the work that resulted in the discovery of the so-called von Willebrand factor and von Willebrand factor antigen. I think they were in the early 70s because I think they were beginning to establish this when I became *au fait* with haemophilia care.

But the results of haemophilia, normally low Factor VIII level, normal von Willebrand factor, and the results of von Willebrand's disease, low Factor VIII level, low von Willebrand factor, were relative rather than absolute. These were not helped by the fact that things like blood group could affect the level of Factor VIII and von Willebrand factor in

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So I fear I've repeated my answer.
Q. It may be it's a question I can take up with others, thank you, Dr Colvin.

Sir.

SIR BRIAN LANGSTAFF: I just want to go back, if I may, to your description of why it is that you don't entirely agree with or didn't agree at the time with Dr Winter's approach to heat-treated product.

A. Yes.

SIR BRIAN LANGSTAFF: What you said, I think, was you thought that you would not use commercial heat-treated product because of three things. The three things you identified was, first of all, the donor pool, the way that the donor pool was selected. The second was the size of the pool. The third, I think, was the possible effects or side effects of viral inactivation.

Considering the donor pool, the way selected, what was your impression of the donor pool from which the United States, certainly, commercial concentrates were drawn?

A. So the first thing I would say is that my view wasn't expressed in quite that way. What I said was that the safety of a product was dependent on the donor pool and the way it was selected and the size of the pool.

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the blood. They weren't helped by the fact that if you had an thyrotoxicosis, an overactive thyroid, your levels of factor and von Willebrand factor went much higher and might look normal. They weren't helped by the fact that if you were trying to look at a screaming child who you were trying to get a blood sample from, that in itself would lift the level of Factor VIII clotting activity in von Willebrand factor and therefore would tend to negate the results of your test.

Now, one of the criteria for diagnosing von Willebrand disease was that you had three levels, taken at separate times, that made you think that this was von Willebrand's disease rather than haemophilia and there is a form of von Willebrand's disease that looks exactly like haemophilia, unless you do some very sophisticated tests.

So, yes, there was a system for distinguishing between mild haemophilia and von Willebrand's disease in the 70s, but it became more and more sophisticated as the years went by and different sub-types of von Willebrand's disease became diagnosed.

Also it was the case that people who had very mild haemophilia were being diagnosed who would never have been diagnosed in the past.

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But it wasn't -- I didn't say "I wouldn't do this because that", but I think that's perhaps a nigger.

But the point that I was making was that if the donor pool, as it was, was very highly infected with HIV infection, then it might not be possible to inactivate the HIV by the heat treatment method that had been chosen. Because the viral inactivation acts on a principle of log kill. That is that you have logarithms of reduction. So if you have 10 to the 6th particles and your system of viral activation will deal with 10 to the third particles, you are still left with 10 to the third particles. So it means that if you have a very high level of contamination then a particular process of viral activation may not be effective because of the failure to address the number of logarithms of infection that are in that donor pool.

SIR BRIAN LANGSTAFF: So the first question mark over commercial concentrate was the nature of the donation input, if I can call it that way, the donor selection.

Now the Inquiry will hear, or will know, does know, that on 24 March 1983 the FDA in the United States made a recommendation to the pharmaceutical companies. But recommendation is something of a euphemism, perhaps, because it's a bit

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1 like meeting a policeman who says, "Well, I recommend,
2 sir, you had better move on"; you don't normally
3 disagree if you are prudent. So it was something --
4 a recommendation with potential teeth.

5 What it recommended was that there no longer
6 should factor concentrate be manufactured from donors
7 in the three particular groups: those who were men who
8 had sex with men, homosexuals; those who came from
9 Haiti; and those who used intravenous drugs.

10 Was that widely known in circles in which you
11 moved shortly afterwards?

12 **A.** I think I was aware, and certainly had been made aware
13 in this Inquiry, that those who were selecting donors
14 were encouraged to change their donor policies.

15 Whether they actually did so, I don't know, but my
16 impression was that they had promised to do so.

17 **Q.** So there would be a difference, it would follow,
18 between the post 24 March -- post March, if I can call
19 it that, plasma used for making product and the
20 pre-March?

21 **A.** That's possible.

22 **SIR BRIAN LANGSTAFF:** It's the Inquiry's understanding
23 that there was a degree of concern expressed, at least
24 in public circles, picked up I think by the press and
25 a statement made in Parliament, about the possibility

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1 the last paragraph:

2 "Regarding blood products from the USA ..."

3 Can we just highlight that, Henry.

4 "... in March this year the US Food and Drugs
5 Administration ... initiated new regulations for the
6 collection of plasma designed to exclude donors from
7 high-risk groups. Although future supplies of
8 [Factor VIII] both for export and for use in America
9 will of course be manufactured from plasma collected
10 in accordance with these regulations, there is still
11 a quantity of stock, some already in this country and
12 more in America awaiting shipment here, which has been
13 made from 'pre-March' plasma. The FDA has
14 recently ..."

15 This letter is, as I say, in August, 26 August
16 1983:

17 "The FDA has recently decided not to ban the use
18 of similar stocks intended for the USA market because
19 to do so would cause a crisis of supply. Obviously,
20 the same considerations apply here."

21 Now, just pausing there, this is talking about
22 supplying the UK with plasma which was thought to be
23 an unsafe basis for American concentrate of whatever
24 form. Was this ever discussed, to your recollection,
25 by the UKHCDO?

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1 that because commercial companies used plasma products
2 which had been manufactured and stored for a while,
3 a couple of years perhaps, back stock, that that might
4 no longer be able to be sold in the United States.

5 It was thought -- an actual implication of the
6 recommendation was that if you had old -- product made
7 from old plasma, you would simply not supply it or
8 withdraw the stuff that was already out there. That
9 would be, one would think, a logical interpretation?

10 **A.** Yes.

11 **SIR BRIAN LANGSTAFF:** Basically, the UK thought or some
12 people in the UK thought that the plasma companies
13 might try to dump --

14 **A.** I understand that --

15 **SIR BRIAN LANGSTAFF:** -- this product in the UK, and it
16 became, as I say, from the information the Inquiry
17 has, a matter of some concern. At least reflected in
18 a Parliamentary statement by Baroness Masham at one
19 stage, saying it wouldn't happen.

20 Shortly after that -- if we can just have,
21 Henry, if we may, the DHSC0002231_036.

22 I appreciate you haven't seen this. This is
23 a letter from, as you can see, the Joint Parliamentary
24 Under-Secretary of State at the DHSS has written to
25 the General Secretary of ASTMS, and if we go down to

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1 **A.** Not at all. But, of course, I wasn't in the --

2 I wasn't in the inner sanctum of the UKHCDO at the
3 time. I was a foot soldier.

4 **SIR BRIAN LANGSTAFF:** Did you ever hear any discussion of
5 this?

6 **A.** Not at all. No, no. Absolutely not. I mean, this is
7 the first I've seen such a letter. I was never aware
8 of this idea of dumping Factor VIII in the UK and
9 I wouldn't have been. I'm not making the excuse that
10 I was a foot soldier but I was just one of the UKHCDO
11 people. I wouldn't have had access to any kind of
12 reference centre data. Peter Kernoff would have done
13 but I wouldn't have done.

14 **SIR BRIAN LANGSTAFF:** I just imagined that you might have
15 listened to the press or the TV and picked up
16 something of this going on because of your particular
17 interest in.

18 **A.** Not to my knowledge, sir.

19 **SIR BRIAN LANGSTAFF:** But you didn't?

20 **A.** No.

21 **SIR BRIAN LANGSTAFF:** Well, if you had been, I imagine you
22 would have taken steps to ensure that none of that
23 stuff was used in your practice?

24 **A.** Indeed. And I mean, when we get back to 1986, when
25 I'm sitting in my room in Milan, I had this awful news

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1 that a heat-treated concentrate has transmitted HIV
 2 and, in that case, I did take immediate telephonic
 3 action.

4 **SIR BRIAN LANGSTAFF:** Now, there appears to have been
 5 general consensus by the end of 1984 that heat-treated
 6 product was probably safer. You had un-heat-treated
 7 product, and we saw the letter that counsel showed you
 8 earlier, where you said in effect that you were going
 9 to go on using up the existing stock. That's
 10 BART0000676. I think that's the right reference.
 11 No, it's not the one I --

12 **A.** I'm familiar with the other. I don't need to see
 13 the --

14 **SIR BRIAN LANGSTAFF:** So why exactly was it that you
 15 didn't do what you've accepted was perhaps the logical
 16 thing to do once it's been decided that a product is
 17 less safe than it might be, why did you go on using it
 18 up, rather than withdrawing it straight away?

19 **A.** So I think the argument is based on my discussions
 20 with Peter Kernoff at the time (and I think I have
 21 already answered the question, I am happy to answer it
 22 again) and that is that if it were to be the case that
 23 these commercial products which had been heat treated
 24 were not safe, from the HIV point of view, then all my
 25 HIV negative patients would become HIV positive, and

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1 **SIR BRIAN LANGSTAFF:** Well, it's quite interesting that
 2 you say that. Presumably, there wasn't much
 3 discussion then around this time, that you can recall,
 4 about the possibility of products becoming heat
 5 treated.

6 The reason I ask that is that it was in March
 7 '83 that Hyland were licensed by the FDA in the States
 8 to distribute heat-treated Factor VIII.

9 **A.** But they were --

10 **SIR BRIAN LANGSTAFF:** It had been around on that basis --

11 **A.** They were trying to produce a lower hepatitis risk
 12 product, and I wasn't available -- I'm sorry, I wasn't
 13 aware that such a treatment was available in the
 14 United Kingdom and, as I understand it, Mark's use of
 15 this product was based on his being provided with
 16 a supply which was enough for him and for Professor
 17 Savidge's -- Dr Savidge's use.

18 But it wasn't available to anybody, I think,
 19 as -- I mean, I wasn't aware it was available at all
 20 and I don't believe -- of course, sadly, Peter died
 21 some years ago. But, I mean, you could certainly ask
 22 Christine Lee, perhaps, if she was aware of the
 23 availability of this product. I don't believe that it
 24 was available to the nation as a whole in any way at
 25 all.

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1 I'd have an even bigger crisis on my hands.
 2 I've mentioned this in terms of the decision
 3 that Mark made (which I don't criticise because he
 4 said himself it was the most difficult decision he'd
 5 probably ever made) and that was that he said that he
 6 was personally convinced that this was the right thing
 7 to do but that conviction was based on zero evidence.

8 **SIR BRIAN LANGSTAFF:** Can I then go back to the period
 9 between May 1984 when Mark Winter and Jeff Savidge
 10 were going to use heat-treated commercial product and
 11 that period between then and December, you still had
 12 a certain amount of Factor VIII concentrate which came
 13 from America --

14 **A.** Yes.

15 **SIR BRIAN LANGSTAFF:** -- in use because you had to have.
 16 You didn't want it, but you had to have it to make
 17 sure there were supplies.

18 Did you think that perhaps changing that to use
 19 heat-treated commercial concentrate would involve no
 20 greater a risk to the patients and might involve less?

21 **A.** I didn't know it existed.

22 **SIR BRIAN LANGSTAFF:** But you didn't know about
 23 Mark Winter's decision at the time?

24 **A.** No, not at all. I don't think anybody else did
 25 either.

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1 **SIR BRIAN LANGSTAFF:** If anyone had wanted it, could they
 2 have obtained it on a named patient basis?

3 **A.** I've no idea what the level of supply was or what
 4 availability it was thought could be made.

5 **SIR BRIAN LANGSTAFF:** Subject to availability.

6 **A.** Sorry?

7 **SIR BRIAN LANGSTAFF:** Subject to availability.

8 **A.** Yes, but I've no idea about that, and of course, it is
 9 also the case -- and I made this very clear -- that my
 10 own particular interest was, where I could, to use the
 11 NHS.

12 **SIR BRIAN LANGSTAFF:** Yes.

13 **A.** I think that very much guided my thoughts because
 14 I wasn't keen to use commercial products. Of course,
 15 I used commercial products, and I used them in the
 16 period that you're talking about (and I recognise
 17 that) and, if that had serious consequences, which
 18 I think it did, then I'm very sad that that happened.
 19 But I wasn't aware of the availability of the
 20 concentrate that Dr Winter was describing, and I don't
 21 think there was any actual evidence that it was going
 22 to be effective.

23 **SIR BRIAN LANGSTAFF:** Yes, I see. Thank you very much.
 24 The next two or three questions are really --
 25 may seem to be quite random, but the first is this:

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1 you knew of the risk that factor concentrates might
2 give rise to HIV -- sorry, to causing AIDS before the
3 discovery of HIV --

4 A. Yes.

5 **SIR BRIAN LANGSTAFF:** -- or the identification of HIV.

6 Did you monitor at all any of your regular patients
7 for signs of the opportunistic infections which were
8 characteristic of that condition?

9 A. I didn't specifically monitor any patients, and
10 I don't think any of my patients showed any clinical
11 signs of the condition.

12 I mean, I think the characteristics of
13 infection, or the progression of infection such
14 pneumocystis pneumonia or throat infection with
15 Candida were the two big signs, I think, of AIDS in
16 that time. Because nobody, I think it's fair to say,
17 with haemophilia ever developed Kaposi's sarcoma. It
18 was actually a transmissible agent that was
19 transmitted by another route.

20 So I think that the characteristics of AIDS
21 which might have shown up were pneumocystis pneumonia,
22 that you couldn't possibly miss, and infection with
23 candidiasis in the throat, which I think you also
24 wouldn't miss.

25 However, it was the case -- and I know this --

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1 it would be extremely valuable because when you treat
2 somebody for the first time, about 20 per cent of
3 people will develop inhibitor to Factor VIII, and then
4 you are in serious trouble. Two things may happen:
5 either the inhibitor may go away, or it may get worse.
6 If it gets worse, then until the recent advances in
7 science, haemophilia became almost untreatable.

8 So to have a product which had a lower incidence
9 of inhibitor development in newly treated patients
10 would have been a big advance. The difficulty is that
11 it's quite difficult to prove that when you've got
12 quite limited numbers. But the people at the
13 Royal Free and I think in Manchester -- or, sorry,
14 Birmingham, and even our own sort of private
15 experience that wasn't published, was that people
16 treated with 8Y seemed to have an incidence of new
17 inhibitors when treated for the first time which was
18 lower than that which was associated with the
19 commercial products.

20 However, later, when very high purity products
21 became available, there were those who thought that
22 they had other advantages. For instance, there were
23 people who thought that the very pure products were
24 less likely to cause immunosuppression, in terms of
25 not immunosuppression caused by AIDS but

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1 that there were people who got pneumocystis pneumonia
2 not with haemophilia in my community because I'm sure
3 they didn't. But at that time before AIDS was really
4 well recognised, people were going down with
5 pneumonia, and it took a long while for it to be
6 appreciated that they had pneumocystis pneumonia
7 because they weren't known to be homosexual or drug
8 addicts or drug users.

9 So I am confident that nobody under my care
10 developed the characteristics of AIDS in that period.

11 **SIR BRIAN LANGSTAFF:** Thank you. The next thing -- you
12 said that 8Y, when it came into regular use, was
13 a really good product. Can you just help. What's so
14 good about it?

15 A. Well, it was effective. It did what it said on the
16 tin. When you gave it, you got a Factor VIII level.
17 Of course, you'd expect that. It was reasonably easy
18 to make up because some products were less soluble
19 than others, so it was reasonably easy to make up.
20 And it -- although intermediate purity, there were
21 people who thought, and this included the people at
22 the Royal Free and I think in Birmingham -- there were
23 people who thought that it had a very low incidence of
24 causing inhibitor development. Now, if this was the
25 case -- and it may have been but it's hard to prove --

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1 immunosuppression caused by concentrate exposure.

2 Then when recombinant factors became available,
3 there were different ways of making recombinant
4 factors, and one of the recombinant factors was
5 slightly altered in its structure of Factor VIII in
6 a way which some people thought increased the
7 likelihood of an inhibitor developing.

8 Now, we now go back to the concept of added
9 value in the commercial world, where all commercial
10 companies feel that it's their job to provide evidence
11 that their product is better than the opposition's
12 product, and everybody's, quite rightly, suspicious of
13 such claims unless they can be absolutely proven.

14 Generally speaking, the idea that one product
15 was more or less likely to produce inhibitors than
16 another was hard to confirm at a scientific level.
17 But those who used 8Y, particularly, I think,
18 Birmingham and the Royal Free, and maybe us to
19 a certain extent, got the impression that it was very
20 fit for purpose and that it was derived from
21 UK sources, which we generally thought was a good
22 idea, and that it might be less likely to cause
23 inhibitor development, despite the fact and even,
24 possibly, because of the fact that it wasn't totally
25 purified. Because it was possible that the presence

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1 of the proteins that you described, fibrinogen and
2 Factor XIII, a bit of immunoglobulin maybe,
3 conceivably could have protected the active agent from
4 the immune system.

5 Now, this is all speculation and I don't think
6 there's any hard scientific evidence, but I think
7 I could see how that might be true.

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

9 That's all I think that I have to ask you.

10 Ms Richards?

11 **MS RICHARDS:** Sir, I have no further questions but is
12 there anything that Dr Colvin would wish to add?

13 **A.** Well, I would like to make a very brief final
14 statement, and my brief final statement is that
15 I deeply regret that patients under my care were
16 infected with any viral agent and I also deeply regret
17 that there were patients who I looked after who were
18 infected by viral agents from other centres.

19 One of the things I tried to do was to provide
20 comprehensive care for my patients and their families
21 and of course I looked after many families across
22 a number of generations and that was a real challenge,
23 which I tried to meet.

24 I would like to thank the nursing staff at the
25 hospital for their dedication and the contribution to

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1 **A.** Thank you, sir.

2 **MS RICHARDS:** Then, sir, tomorrow the plan is that I will
3 conclude the presentation on Cardiff, and then we'll
4 move on to, and I expect to complete in the course of
5 tomorrow, the presentation in relation to St Thomas'
6 Hospital.

7 **SIR BRIAN LANGSTAFF:** So Cardiff we finish, St Thomas' we
8 complete.

9 **MS RICHARDS:** St Thomas' we start and I am anticipating we
10 will complete.

11 **SIR BRIAN LANGSTAFF:** You hope to complete.

12 **MS RICHARDS:** Yes.

13 **SIR BRIAN LANGSTAFF:** Very well. 10.00.

14 (5.17 pm)

15 (Adjourned until 10.00 am the following day)

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1 care they made in very difficult times. I have been
2 asked for the names of those nursing colleagues and
3 I'm happy to pay tribute to Sheila Hayden, Debra
4 Jones, Wanda Little and Cathy Woosey, who were the
5 main nurses who helped me to look after my patients.

6 The last thing I would like to say is that I had
7 an enormous admiration for my patients and their
8 families, who showed dignity, endurance and enormous
9 courage in the face of dreadful illness and personal
10 tragedy.

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

12 Can I finish by saying this, that you've been
13 particularly useful. Your evidence has been
14 particularly useful to the Inquiry because your
15 experience and recollection covers the mid-'70s to the
16 early 2000s, coming into it, dare I say it, as perhaps
17 one of the newer and younger doctors to practise in
18 that field at that time as a consultant. And can
19 I thank you for the lively and informative way you've
20 given us access to that perspective that you have and
21 to your thoughts.

22 I'm very grateful to you for having done so and
23 for having had the -- being prepared to come here to
24 give evidence, despite the challenges of Covid. So
25 thank you very much.

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2 DR BRIAN COLVIN, continued 1

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