

1 Thursday, 5th November 2020
 2 (10.00 am)
 3 **SIR BRIAN LANGSTAFF:** Good morning, Professor.
 4 **A.** Good morning.
 5 **SIR BRIAN LANGSTAFF:** Let me just say a couple of things
 6 first, if I may, before Ms Richards starts questioning
 7 you again, because we're meeting under new conditions,
 8 as we all know, given the restrictions which were
 9 introduced as from today. Those who are watching
 10 remotely won't see, they never do see, the audience
 11 which is here. Nor do you. You just see the same
 12 faces. But for those who are watching out there and
 13 for your information, the only people who are present
 14 in the hearing room are the legal team supporting
 15 Ms Richards, your own counsel, some technicians, and
 16 a couple of members of Inquiry staff. There's no
 17 public here. But they are watching online.
 18 So this is the conditions under which we are
 19 currently meeting. I'll continue to wear a mask because
 20 that's what we ask people to do in these premises,
 21 though it does interfere with talking sometimes, which
 22 is why I take it down when I'm talking to you.
 23 Ms Richards.
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1 CHARLES RICHARD MORRIS HAY (continued)
 2 Examined by MS RICHARDS (continued)
 3 **MS RICHARDS:** Professor Hay I want to pick up the picture
 4 in relation to vCJD and the response to the risk of
 5 vCJD and the various notification exercises.
 6 We looked yesterday at your letter in
 7 November 1997, and the meeting you described following
 8 that. Your statement tells us that at some point
 9 after that, at Manchester you were able to switch
 10 products to those manufactured from US plasma fairly
 11 quickly; is that right?
 12 **A.** That's correct.
 13 **Q.** There is also evidence to suggest that that may not
 14 have been the position universally for all centres.
 15 Soumik, could we have on screen, please,
 16 HCDO0000133_188, please.
 17 This is a letter you wrote January 1998, it's
 18 addressed to Dr Ludlam, and it's "Implementation of
 19 our Recommendation on CJD". That is presumably
 20 a reference to the UKHCDO Committee's recommendation
 21 which you discussed yesterday afternoon?
 22 **A.** It is.
 23 **Q.** Then you talk about:
 24 "The commercial grapevine tells me that some
 25 centres, particularly Oxford, Birmingham Children's

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1 and Adults and the Royal Free Hospital are all still
 2 using large amounts of BPL products and continuing to
 3 order them. I suspect that these 3 centres all use
 4 significant amounts of 8Y, which may present them with
 5 a financial problem. I was able to implement our
 6 policy rapidly because there were essentially no
 7 attached revenue consequences. I hear that Frank Hill
 8 will be wanting to move straight to Recombinant but
 9 I worry that the other 2 centres were basically not
 10 fully sold on the policy. If they don't implement
 11 this policy it significantly undermines our position."
 12 Do you know whether the anxieties expressed in that
 13 letter, the concerns expressed in that letter,
 14 continued, or did other centres implement the UKHCDO
 15 recommendation?
 16 **A.** Well, I think that at some point BPL withdrew their
 17 products, and then there was a gap, substantial gap,
 18 until they started to manufacture the same products,
 19 using imported American plasma. I can't remember
 20 exactly how long that took.
 21 And the financial problem I'm alluding to is
 22 because those centres that continued to use a lot of
 23 8Y, 8Y was quite cheap, but it was also very popular,
 24 it had a good viral safety record. It was also
 25 reasonably all right on von Willebrand's disease. So

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1 some centres were genuinely quite attached to the
 2 product, it wasn't just because it was inexpensive.
 3 But the fact that it was inexpensive meant that for
 4 them to change to American products would have incurred
 5 a considerable cost.
 6 For me, that wasn't a problem because I had already
 7 switched all my patients to high-purity products so
 8 I was using more expensive products in any case.
 9 I can't honestly remember how long the situation went
 10 on.
 11 **Q.** Okay. We move, then, I think, to -- just before we
 12 get to the national notification exercise in 2004, you
 13 had an exchange of correspondence with BPL in 2003.
 14 Soumik, if we could have HCDO0000254_117, please.
 15 This is a letter that you wrote, in May of 2003, to
 16 BPL, and it says that you were recently notified by the
 17 Transfusion Transmitted Working Party that your centre,
 18 Manchester, had received batches manufactured from
 19 plasma pools contaminated with plasma from patients who
 20 subsequently developed vCJD, and you're expressing here
 21 displeasure at not having been informed of this directly
 22 by the manufacturer and having learnt of it through this
 23 route of the Transfusion Transmitted Disease Working
 24 Party rather than directly from BPL.
 25 What had actually happened that gave rise to this

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1 correspondence?
2 A. Well, it just struck me that there were various other
3 routes of communication that could have been used that
4 would have informed me much more quickly. It was
5 perfectly reasonable that they should inform the TTI
6 Working Party and they were coordinating the whole
7 thing. But had I been informed earlier I would have
8 acted earlier to identify the recipients of these
9 products.

10 And they had supplied these products to the
11 Manchester Centre through the Transfusion Service, and
12 either the Transfusion Service or the manufacturer
13 would have known that it had been supplied to me and
14 should and could have informed me earlier.

15 Q. The next I think key event in relation to vCJD and
16 Haemophilia Centres and haemophilia patients was the
17 2004 national notification exercise.

18 Now, as I understand it, this was triggered by
19 a case of vCJD reported in the recipient of a blood
20 donation in December 2003, and then a second possible
21 case in July 2004. Is that correct?

22 A. That's correct. I mean, this was obviously a game
23 changer because up until this point, the possibility
24 of a transmission through blood transfusion was a
25 theoretical possibility, and there was a lack of

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1 concrete proof that it could occur.
2 Q. And then if we go, please, Soumik, to WITN3289110,
3 we're going to look at some of the documents,
4 Professor, from the 2004 notification exercise.

5 So this is a letter of 7th September 2004 from the
6 CJD Incidents Panel, which your statement tells us had
7 been set up in 2000, and we can see from it, it's
8 setting out recommendations of the panel for tracing
9 and assessment of patients exposed to plasma products
10 using donations from individuals who subsequently
11 developed vCJD. We're told in the second paragraph it
12 was based upon a blood risk assessment carried out by
13 an external consulting firm or organisation which had
14 then been considered by the various committees who we
15 see described there, including the Committee on Safety
16 of Medicines. And then it reads:

17 "Batch specific manufacturing data from the
18 fractionators concerned has been used with the Risk
19 Assessment to estimate the potential vCJD infectivity in
20 each batch of implicated product. For each of the major
21 assumptions underlying the Risk Assessment, the most
22 precautionary option was chosen."

23 Then we can see the panel has identified what it
24 means by being "at-risk" for public health purposes.
25 And then there are three levels identified: high,

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1 medium, and (over the page) low.

2 We're told, in the third paragraph:
3 "The uncertainties underlying the assessment of
4 'risk' are great, and several precautionary assumptions
5 are involved. Therefore the 'at-risk' threshold for
6 public health purposes is not a precise guide for
7 advising individuals about their potential additional
8 risk of developing vCJD."

9 Then we can see in the bold print, there's
10 a recommendation of action to be taken. In relation to
11 those who fall within the high category:

12 "These batches should be traced and the individual
13 recipients considered 'at-risk' of vCJD for public
14 health purposes. The extent of individual exposure to
15 these batches should be documented.

16 "Medium: Efforts should be made to trace these
17 batches and assess the potential additional risk to
18 individual recipients to determine if special
19 precautions should be taken for public health purposes.
20 The extent of individual exposure to these batches
21 should be documented."

22 Then:

23 "Low: These batches do not need to be traced and
24 the individual recipients do not need to be informed."

25 We will look at some of the other documents in

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1 a moment but can you perhaps provide us with an overview
2 of what the response to this then was by UKHCDO and
3 individual Haemophilia Centre Directors.

4 A. Well, we were informed one way or the other, mostly by
5 the database and through the Transfusion Transmitted
6 Disease Working Party, of the batches that had been
7 implicated, and these changed with time, as further
8 patients presented with variant Jakob-Creutzfeldt
9 Disease, and we did our best to trace the ultimate
10 destination for all those products, who had received
11 them.

12 We -- obviously all the patients were written to,
13 including those who had not received British blood
14 products. The initial notification was to all patients
15 with bleeding disorders, not just those who had had
16 British products, because it was felt that they would
17 hear about this in the press and they might worry that
18 they would be affected in any case. So we felt we had
19 to write to everyone.

20 We had to speak to our surgical colleagues and the
21 hospital administration, because the measures included,
22 amongst those patients at high risk, certain types of
23 surgery had to be done with disposable instruments.
24 Endoscopes had to be quarantined if they were used in
25 high-risk individuals, so the notes had to be noted in

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1 that way. And if the patient required surgery, this
 2 became a consideration that had to be dealt with. And
 3 we had to report back to the database the risk level of
 4 each of our patients.

5 There are forms in the exhibits that show the
 6 returns to the database which show the amount of each
 7 batch that the patients had received, if they had
 8 received any. And if they had not received any
 9 implicated batch, that's also recorded. And the outcome
 10 of the discussion with the patient is also recorded,
 11 because this was a very unusual situation, and in the
 12 Advisory Committee we had lengthy discussions about how
 13 we should approach this, because this was a condition
 14 for which there was no test and there was no treatment.
 15 So we couldn't test the patients to discover whether
 16 they had been exposed or not. And even if we knew for
 17 sure that they had been exposed, there was no treatment
 18 and we were unsure of the likely natural history.
 19 Because, as things unfolded, recipients of implicated
 20 blood transfusions had developed variant
 21 Jakob-Creutzfeldt Disease as long as eight and a half
 22 years after exposure. And they were all homozygous. So
 23 there was the theoretical possibility that had been
 24 raised that heterozygotes might also develop variant
 25 Jakob-Creutzfeldt Disease but perhaps after a very

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1 prolonged period.

2 Now here we are 30 years down the line and that
 3 hasn't happened, but it was in those early days raised
 4 as a possibility. So far only homozygotes have
 5 developed a problem and no recipients of pooled blood
 6 products.

7 **Q.** This was a national exercise organised centrally by
 8 the CJD Incidents Panel with the notification, the
 9 information we see here, the assessment, the strong
 10 recommendation to recipients of this letter, which
 11 included UKHCDO, to take the steps there set out?

12 **A.** And the National Haemophilia Database collating the
 13 data and, amongst other things, reporting it on to the
 14 HPA, which continues on a six-monthly basis to this
 15 day.

16 **Q.** If we just look at some of the documents that were
 17 also provided by the CJD Incidents Panel at the time
 18 of publication of its recommendations on
 19 7th September.

20 We've got, please, Soumik, at WITN3289113.

21 We're not going to need to look at the detail of
 22 every document but just to see the broad nature of the
 23 accompanying documents.

24 So, again, dated 7th September, this was a table of
 25 the vCJD implicated batch numbers. So that information

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1 identified the source in terms of manufacture, PFC or
 2 BPL was identified. And then if we go over to the third
 3 page, we can see -- we don't need to go through the
 4 details of it -- the specific batches. That information
 5 had all been gathered and collated nationally, had it?

6 **A.** Yes.

7 **Q.** And then if we go, please, Soumik, to WITN3289114.

8 Again, we don't need to go to the detail of it, but
 9 this is a clinical information sheet produced by,
 10 amongst others, the Health Protection Agency. We can
 11 see the date from the bottom of the page,
 12 7 September 2004.

13 So this was, as it were, information for clinicians
 14 to accompany the recommendations.

15 **A.** Yes.

16 **Q.** And then if we go, please, to WITN3289115. We can see
 17 here there was also -- same date, 7 September 2004 at
 18 the bottom of the page -- again, a centrally prepared
 19 patient information sheet. We'll just look briefly at
 20 the various headings.

21 So 1, "What is variant CJD?" Then if we go over
 22 the page, "What's this about?" So it sets out what
 23 has led to the exercise, the first case reported: the
 24 death of a person from vCJD who had received a blood
 25 transfusion from a donor, so the first case of

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1 transfusion associated vCJD, and then a second
 2 probable case.

3 We can see the bottom half of that page talks about
 4 "Why am I being contacted?" So it explains to patients
 5 the purpose of communicating with them.

6 If we go to the next page, we can see a description
 7 of what measures are already being taken. And then
 8 point 5, "And in relation to blood?"

9 "Because it is uncertain whether vCJD can be
 10 transmitted by blood, the UK blood services have taken
 11 a number of precautionary measures."

12 Those are then set out from 1997 onwards.

13 We can see the bottom of the page the CJD Incidents
 14 Panel there referred to; it's established in 2000.

15 And then if we go over the page, we can then see
 16 under point 7 an explanation to patients of what has
 17 changed in terms of policy.

18 The next page, "Who is affected?" So it identifies
 19 the groups of those who may be affected by this.

20 And then "How does this affect me?" It talks about
 21 the practical implications for patients.

22 And then if we go over the page, we can see it
 23 continues by giving patients information about the
 24 extent to which they face a risk, that's point 11. "Does
 25 this mean I'm going to suffer from vCJD?"

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1 "Can I be tested? What happens if I develop strange
2 symptoms? Will this mean I won't be able to get life
3 insurance?" We can see from the top of the next page
4 that that's an issue that's already been addressed.
5 Insurers will not refuse insurance because someone is
6 categorised at risk for public health purposes. And
7 then it continues.

8 This was obviously a national leaflet prepared for
9 the benefit of patients.

10 **A.** Yes.

11 **Q.** Did Haemophilia Centres send this information sheet to
12 the patients whom they were notifying, as far as
13 you're aware?

14 **A.** As far as I'm aware, yes.

15 **Q.** Then if we go just to WITN3289118, please, Soumik.

16 This is described as the "Patient notification
17 exercise enquirer handling protocol."

18 If we go to the second page, at the bottom of the
19 page under the heading "timing", we can see a timed plan
20 of action: 9 September, information will be sent to
21 haemophilia doctors, immunologists medical directors of
22 trusts. Then the plan for haemophilia doctors and
23 consultant immunologists looking after patients with
24 primary immunodeficiency to send out patient letters on
25 20 September. And then a full press briefing by the

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1 Department of Health planned for 21 September.

2 Certainly, the letters we've seen, Professor Hay,
3 sent to patients, many of them are dated
4 20 September 2004. Again, as far as you're aware, was
5 the expectation of UKHCDO and the VCJD Incidents Panel
6 that all Haemophilia Centres would send those
7 communications to their patients at the same time?

8 **A.** Absolutely. Absolutely. I mean, the timing of this
9 was determined, as far as I remember, by launching of
10 a Parliamentary question which was going to alert the
11 press the following week, so the whole thing had to be
12 rushed along. And it was strongly emphasised to
13 centres that this matter had to be dealt with as a
14 matter of urgency.

15 **Q.** We can see that from the UKHCDO letter to directors at
16 WITN3289111. So this is 9 September. At this point
17 in time, you were Vice Chair, Professor Hill was
18 Chair, and this letter was sent by him. But we can
19 see it's to all Haemophilia Centre doctors. It's for
20 urgent and immediate attention. And then we can see
21 in the first main paragraph reference to the toolkit
22 which I think are the documents that we have just been
23 looking at.

24 **A.** Yes.

25 **Q.** And then the actions are:

14

1 "To brief Centre staff to ensure we can get
2 letters out to all patients so that they're given
3 comprehensive information at the same time. The
4 letter to patients needs some insertions, telephone
5 numbers, et cetera, and should go to all patients or
6 parents of children with haemophilia and other
7 bleeding disorders. If possible, use the letter as
8 sent. Some may wish to adapt because of local
9 reasons. Ensure you file copies in each patient's
10 notes."

11 Then this:

12 "It's felt that all patients need to be informed,
13 even those not affected so that they are informed about
14 the events and understand the implications."

15 Does it follow from that that UKHCDO, in relation to
16 this exercise, had decided to go further than the, as it
17 were, minimum requirements of the VCJD Incidents Panel
18 because your proposal was to communicate with every
19 patient, whether or not they'd ever received British
20 products within the relevant time frame?

21 **A.** That's an interesting question. I think -- I can't
22 remember whether the Incidents Panel wanted us to
23 write to everybody, or whether it was a UKHCDO
24 decision, to be perfectly honest. But I think,
25 whether it was or not, we certainly felt that we

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1 needed to inform all patients because the patients
2 would not necessarily know whether they'd had British
3 blood products or not, and they might think they were
4 involved. And so when we spoke to the patients, we
5 gave all of them a certain amount of core information,
6 whether they were affected or not, and then put it
7 into a personal context.

8 So if we, for example, knew that they had not been
9 exposed to UK products during that period, we could
10 tell them that and say, "Well, now you know all
11 about -- all that we know about variant
12 Jakob-Creutzfeldt Disease, but it shouldn't affect
13 you". And with the others who had had British blood
14 products at that point, we were still in the process
15 of working out which batches were affected and
16 assessing the level of risk. And so, you know, you
17 wouldn't be able to attribute a level of risk at that
18 point, but you would be able to tell them whether
19 they'd had British blood products and might be
20 involved. And so I don't really know the answer to
21 your question, but that was our thinking.

22 **Q.** And we can see the exposure assessment form that you
23 referred to at WITN3289116.

24 Again, we can see this is part of the
25 7 September 2004 production of documents, the date at

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1 the very bottom of the page.
 2 This is a form to be completed for all patients with
 3 bleeding disorders. And then a copy should be sent to
 4 the National Haemophilia Database. There's the start
 5 question:
 6 "Did the patient received any UK sourced pooled
 7 factor concentrates or anti-thrombin between 1980 and
 8 2001?"
 9 "Yes" or "no" gives the answer to whether the person
 10 is at risk of vCJD for public health purposes.
 11 There's then an exposure assessment, so that's an
 12 analysis undertaken by reference to each individual
 13 patient.
 14 Then over the page, we can see the last box asks the
 15 question:
 16 "Has the patient asked to know if they received the
 17 implicated batch? When was the patient informed if
 18 they'd received the implicated batch?"
 19 The purpose of that last box was presumably to
 20 ensure that patients received the information that they
 21 wanted to but were allowed to choose not to receive
 22 information if they didn't want to.
 23 **A.** That's right. I started to explain that earlier but
 24 didn't really finish. Because it was such an unusual
 25 situation in that there was no test that we could

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1 offer them and there was no treatment, we realised
 2 that some patients might prefer not to be told. So
 3 they were all provided with the background information
 4 about variant Jakob-Creutzfeldt Disease, transmission
 5 by blood transfusion, at the very least theoretical
 6 risk of transmission through pooled blood products,
 7 what we thought the risk was, the business about it
 8 having only affected homozygotes who made up about
 9 a third of the population and so on.
 10 But in relation to their own exposure, they were
 11 offered the choice of being told or not. But it was
 12 important to document that choice, both in the notes
 13 and centrally, so that you could continue to respect
 14 that choice or, at the very least, if there were
 15 overwhelming reasons to tell them, put the choice to
 16 them again.
 17 **Q.** Your statement tells us that not all patients could be
 18 traced.
 19 Do you know what steps were taken, first of all at
 20 Manchester in your capacity as Director of the Centre,
 21 to trace patients, or was that not a problem that
 22 affected Manchester?
 23 **A.** I don't remember it being a particular problem at
 24 Manchester. There are always some patients,
 25 particularly those with mild bleeding disorders, who

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1 are lost to follow-up and need a lot of chasing.
 2 I can't remember whether it was a particular problem
 3 in relation to this.
 4 There were also problems, of course, tracing who had
 5 received the implicated batches; I detail in my Section
 6 9 response.
 7 **Q.** Then if we move from 2004 to 2006. Could we, Soumik,
 8 have ABMU0000053, please. So if we just going
 9 a little closer.
 10 This is an email from you at 14 November 2006:
 11 "vCJD and plasma products: look back and patient
 12 notification."
 13 This is being sent by you now as Chair of UKHCDO to
 14 Centre Directors and you refer in the body of the email
 15 to:
 16 "... two further batches of concentrate which
 17 include donations from patients who subsequently
 18 developed vCJD, relating to products released in 1988
 19 through the Transfusion Service in Tooting, Wales,
 20 Colindale and Birmingham, not previously notified
 21 because it was not possible at that time to trace their
 22 distribution. If you received these products, you may
 23 have to notify your patients."
 24 Then if we go over the page, we don't need to go
 25 through the detail of it, but we can see this is

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1 a letter explaining that there have been these two
 2 further batches identified that weren't included in
 3 previous notifications.
 4 And is this right: essentially, what Centre
 5 Directors were being asked to do in 2006 was to check
 6 their records to see if they had received these batches,
 7 and if they had, to then go through the same exercise in
 8 relation to those batches as had been done in 2004.
 9 **A.** Yes, and we were also trying to stir up some centres
 10 that had not responded, in our view, adequately to the
 11 first request.
 12 **Q.** We then, I think, next see vCJD in 2007.
 13 Soumik, could we have HCDO0000131_006, please.
 14 So again, this is an email from you. This is
 15 January 2007. And then we see, if we go over the page,
 16 a draft press release. So this tells us that there's
 17 been a fourth and therefore presumably a third case,
 18 because we'd previously looked at cases 1 and 2 having
 19 triggered the 2004 notification -- a fourth case of vCJD
 20 associated with blood transfusion. So this is a draft
 21 press release from the Health Protection Agency.
 22 And then if we go, please, Soumik, to
 23 HCDO0000131_007. And zoom in on the top half of the
 24 page.
 25 This is an email from you in your capacity as Chair

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1 of UKHCDO, 16 January 2007. You were, I understand, in
2 this email, notifying all UKHCDO members about this
3 fourth case. The second paragraph explains that:

4 "The case contracted vCJD from the same donor as the
5 third case."

6 And then refers to the patient having been still
7 alive and manifesting clinical signs of suspected vCJD
8 eight and a half years after receiving the blood.

9 "This is the longest incubation period reported so
10 far in relation to this mode of transmission.

11 "It remains the case that vCJD has not been reported
12 in recipients of non-cellular pooled blood products.

13 This does not, therefore, change the advice that we
14 would offer our patients, and we were not planning
15 a mailing to patients."

16 Do I understand this to be you communicating news of
17 the fourth case to Directors, but because there were no
18 new implicated batches, there was no further
19 notification exercise to patients; is that right?

20 A. Yes. It strengthened the evidence that variant
21 Jakob-Creutzfeldt Disease could be transmitted by
22 a whole blood transfusion, but it didn't actually
23 change anything that we would have advised the
24 patients, or any of our actions. And so it was felt
25 that a further notification exercise would be

21

1 superfluous.

2 Q. Then there was then a further national notification
3 exercise in 2009. Soumik, could we have WITN3289130,
4 please.

5 We can see this is a letter from the Health
6 Protection Agency's CJD section, February 2009, to all
7 UK Haemophilia Centre doctors informing them of:

8 "A post-mortem finding of asymptomatic vCJD,
9 abnormal prion protein in a person with haemophilia."

10 Then the second paragraph explains that:

11 "This patient had been treated in the '90s with
12 several batches of UK sourced clotting factors,
13 including one batch of Factor VIII that was manufactured
14 using plasma from a donor who went on to develop vCJD."

15 Then it explains that:

16 "The haemophilia patient was in his 70s when he died
17 of a condition unrelated to vCJD, 11 years and 1 month
18 after receiving the batch of implicated Factor VIII."

19 Then the significance of this, we can probably pick
20 up from the last two lines of this page:

21 "This is the first time that vCJD abnormal prion
22 protein has been found in a patient with haemophilia or
23 any patient treated with plasma products."

24 Then if we go over the page, we're told that the
25 case doesn't change the public health vCJD "at risk"

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1 status of any patient, but then doctors, directors, are
2 asked to take these actions:

3 "Send the enclosed letter to all patients with
4 bleeding disorders (including those not at risk of
5 vCJD). Please do this as quickly as possible."

6 And then:

7 "Make arrangements for appointments with any
8 concerned patients."

9 Then we can see it encloses information leaflets for
10 both patients and for healthcare staff.

11 I don't think we need to go through the detail of
12 those leaflets -- you've exhibited them to your
13 statement -- but can you give us, again, an overview of
14 what triggered this 2009 exercise and how it was
15 implemented by UKHCDO and by you in Manchester?

16 A. Well, the significance of this particular case remains
17 uncertain, but it was certainly potentially evidence
18 of possible developing variant Jakob-Creutzfeldt
19 Disease in a patient with haemophilia, presumably
20 secondary to exposure to an implicated batch. The
21 patient did, in fact, die from carcinoma and had no
22 neurological signs or symptoms, and prion protein was
23 not found in any other parts of the autopsy. So
24 there's no evidence of abnormal prion protein in the
25 patient's brain, so it was just one little corner of

23

1 his spleen.

2 So the significance of this wasn't known, but there
3 was certainly the theoretical possibility that had the
4 patient not died of cancer and, say, lived another few
5 years, he might have developed variant Jakob-Creutzfeldt
6 Disease. We'll obviously never know.

7 I seem to remember that the patient was atypical
8 also in that I don't think he was a homozygote for
9 prion. I think he was heterozygous, which was also
10 a little odd. And, of course, it was 11 and a half
11 years after his exposure to the implicated batch.

12 So whatever the uncertainties surrounding the
13 interpretation of these findings, it was felt reasonable
14 to inform the patients that this was perhaps evidence of
15 transmission. So we wrote to all our patients again.

16 Q. And so, as with the 2004 notification, this was
17 a nationally organised and directed notification, to
18 the extent that there was actually a template letter
19 which we won't look at the leaflets but we'll look at
20 the letter. WITN3289132. This is the letter you were
21 being asked to send to patients.

22 We can see at the bottom it says it doesn't change
23 the way in which the patient will be treated. So the
24 purpose of this national notification presumably was to
25 ensure that patients had the maximum, up-to-date

24

1 information for them to understand the position and
 2 apply it to their own personal circumstances?
 3 **A.** That's right.
 4 **Q.** And then we can see the UKHCDO letter from you to your
 5 colleagues at WITN3289133, please, Soumik.
 6 This is a letter dated 16 February 2009 from you:
 7 "Dear colleagues ..."
 8 And it says:
 9 "Unfortunately, due to circumstances beyond our
 10 control, this notification exercise has to go live on
 11 Monday, February 16, 2009."
 12 And you go on to explain there that the timing has
 13 had to be accelerated because the matter's being picked
 14 up in the national press.
 15 **A.** Yes. We preferred them to hear from us.
 16 **Q.** Can you recall the kind of responses that your
 17 patients at Manchester showed in relation to this
 18 second notification exercise?
 19 **A.** Well, it varied. Some were distressed. Some were
 20 philosophical. Most of them thanked me for telling
 21 them. It did vary. Because apart from everything
 22 else, this was a little different from HIV and
 23 hepatitis C in that, you know, we had at this point
 24 been following it for a long, long time already. And,
 25 you know, we had been looking out for it, and frankly

25

1 when Jakob-Creutzfeldt Disease presents clinically,
 2 although it's very rare, it's a pretty easy diagnosis,
 3 and we hadn't spotted anything. So it seemed likely,
 4 at that point, that even if some patients did become
 5 affected, the numbers affected were likely to be quite
 6 small.
 7 And so I do not remember very much distress.
 8 I don't suppose the patients were very happy about it,
 9 but most of them seemed philosophical, and there wasn't
 10 much they could do about it, to be honest.
 11 **Q.** There's a follow-up letter, then, in April 2009 from
 12 you and Professor Hill to directors. WITN3289120,
 13 please.
 14 We can see it's a letter to update on the current
 15 position. Point 1:
 16 "The index patient investigation is continuing, and
 17 risk assessments are awaited on the four potential
 18 routes of acquisition of vCJD prion."
 19 What does that refer to, please, if you can
 20 remember?
 21 **A.** Err ... I'm not quite sure what that means.
 22 **Q.** Don't worry.
 23 **A.** Potential routes of acquisition of variant CJD prion.
 24 I mean, there is always the possibility, of course,
 25 that the patient had not acquired this from blood

26

1 products at all but from a beefburger, which you also
 2 can't exclude. And I think that they may be referring
 3 to that.
 4 Clearly, the patient had been in receipt of an
 5 implicated batch, and you would not be able to exclude
 6 that as the route, but there were other possibilities.
 7 **Q.** And then the second point in the letter is about the
 8 notification exercise. And you record here that:
 9 "Many centres wish to only contact patients in the
 10 'at risk for health purposes' group. Some Centre
 11 Directors, including some appointed since 2006, realise
 12 the 'at risk' status of their patients had not been
 13 determined, and patients who had received implicated
 14 batches had not had their notes identified as at risk
 15 for public health purposes. In some instances, there
 16 are contaminated instruments that need identification
 17 and public health follow-up to identify other patients
 18 who have been put at risk."
 19 So what is it that you, in your capacity as Chair of
 20 UKHCDO and/or in your capacity as director of the
 21 National Haemophilia Database by this time, what had you
 22 learnt about the notification exercise that gave rise to
 23 the need to write this letter?
 24 **A.** Well, a number of Centre Directors had retired and
 25 replacements had taken up post and, of course, were

27

1 not necessarily familiar with the previous
 2 notification exercise since they had been juniors when
 3 this took place. And the most recent notification had
 4 alerted them to all this and then they had gone away
 5 to find out which of their patients were implicated,
 6 and realised that the previous instructions had either
 7 not been followed or not followed adequately. And
 8 they had notified us, the Database UKHCDO, of this,
 9 and there was a catch-up necessary.
 10 They would also realise that if that was the case,
 11 then, since at-risk patients had not been identified,
 12 and had maybe had surgery, that they might have had
 13 the sort of surgery that was listed as a risk: gut
 14 surgery, that sort of thing, lymphoid surgery, with
 15 non-disposable instruments, which would have to be
 16 traced.
 17 **Q.** Then if we go over the page, we can see in the top
 18 paragraph, you set out that you're aware:
 19 "... there have been no notifications of at risk
 20 patients from some Centres to the [National Haemophilia
 21 Database] ... [or some] Centres have not accounted fully
 22 for the total units of implicated products they
 23 received."
 24 Without going through the detail of the rest of the
 25 letter, as I understand it, the proposal here was that

28

1 the National Haemophilia Database would tell each centre
 2 what information the database currently held in relation
 3 to patients at that centre insofar as relevant to this
 4 issue, so that centres could effectively work out what
 5 data was missing and what they needed to submit to the
 6 database. Is that an accurate summary?

7 **A.** Yes, that's accurate.

8 **Q.** There's a follow-up letter. I don't think we need to
 9 go to it, but there's a follow-up letter from this
 10 that you sent out in June 2009, that you've also
 11 exhibited to your statement.

12 There was then, in 2010, an issue with a mistaken
 13 or false notification. Can you outline what happened
 14 there, please.

15 **A.** What happened there was that some of -- when we
 16 originally worked out the period of risk, it was
 17 expressed in terms of years. And the problem with
 18 that is that towards the end of that period of risk,
 19 BPL were beginning to manufacture products using
 20 imported American plasma so that you had circulating
 21 at one and the same time BPL products that had been
 22 manufactured from British or American plasma. And as
 23 a result of that, some of the patients who had been
 24 notified that they were at risk, it turned out had
 25 been treated with US-sourced BPL products rather than

29

1 UK-sourced BPL products. So this applied to a very
 2 small number of people using specific products. So it
 3 applied almost exclusively to two centres: the
 4 Royal Free and Oxford.

5 The Royal Free in particular because it related to
 6 Factor XI concentrate, and the Royal Free looks after
 7 possibly the largest group of Factor XI deficient
 8 patients in the country, and they used concentrate to
 9 treat those patients rather than plasma. I've probably
 10 got the second largest group in the country, but my
 11 treatment practice is different, so it didn't affect us.

12 So we realised that some patients had been told that
 13 they were at risk but were not, so we had to identify
 14 those, and notify them.

15 **Q.** And we can see from WITN3289134, this is the letter
 16 that was then sent out by you on 7 April 2010 to all
 17 UKHCDO Centres and all haemophilia nurses. It reads:

18 "I have been told that a centre [that was in fact
 19 the Royal Free] has mistakenly identified and notified
 20 a number of patients that they were at an increased risk
 21 of vCJD for public health purposes. These patients had,
 22 in fact, only been treated with BPL products
 23 manufactured from American sourced plasma. I am writing
 24 to all Haemophilia Centres asking that all past vCJD
 25 risk notification are checked because I suspect that

30

1 this error may have been repeated in other centres."

2 So the matter having been raised with you, as
 3 I understand it, from other documents that you have
 4 exhibited to your statement, by the Royal Free, all
 5 centres were asked to do a check on their notifications.
 6 Do you know how many centres or how many patients turned
 7 out to have had the same problem as the Royal Free?

8 **A.** Well, the main other centres that are mentioned that
 9 were affected was Oxford. Most of the patients
 10 affected were at the Royal Free. I can't remember the
 11 precise number that were affected, but I think it was
 12 something like 20 patients.

13 **Q.** Then in 2013 there was what has been referred to in
 14 the materials as a "de-notification exercise".

15 So if we look, please, Soumik at WITN3289136.

16 We can see this is letter from the Health Protection
 17 Agency dated 24th January 2013 to Dr Dolan, who by now
 18 had taken over as chair of UKHCDO.

19 "Reassessment of vCJD risk from UK produced plasma
 20 products and de-notification of certain recipients."

21 We can see there's been a review by the Health
 22 Protection Agency of the risk assessment which has led
 23 to recommendations that:

24 "... individuals who received Factor VIII and
 25 Factor IX between 1990 and 2001 should remain notified

31

1 as 'at ... risk of vCJD for public health purposes' ...

2 But:

3 "(ii) Individuals who only received plasma products
 4 between 1980 and 1989 should now have their treatment
 5 history reassessed to confirm this fact and if it is
 6 confirmed, they should be de-notified."

7 Then if we go to the letter sent out by Dr Dolan to
 8 Directors, it's WITN3289137.

9 This Dr Dolan, enclosing the HPA letter, the
 10 recommendations. It says:

11 "Please do not take action immediately. What we
 12 have agreed is that NHD [the National Haemophilia
 13 Database] will review the records and generate lists for
 14 each Centre. These lists will then be sent to each
 15 Centre to be verified. There should be formal
 16 communication between each Centre and [the National
 17 Haemophilia Database] to confirm the risks and discuss
 18 any errors.

19 "In the meantime the UKHCDO Executive, NHD and
 20 Morbidity and Mortality Working Party will work on
 21 producing information which will be of help in
 22 discussions with patients who are to be 'de-notified'."

23 And without going through the detail of the
 24 remaining documents on this issue, can you set out what
 25 then happened in terms of the de-notification exercise,

32

1 from your perspective?

2 **A.** Well, we produced spreadsheets based on their previous

3 returns from each centre, which had lists of patients

4 that we considered could possibly be de-notified.

5 There was then a dialogue between each centre and the

6 database to fill out any missing data, and produce

7 a final corrected list of patients who should be told

8 that their risk had been reassessed and they were no

9 longer considered to be at public health risk.

10 This took a little time. I think it was quite a lot

11 of work for the database and for centres, but we wanted

12 to get it right, as you can imagine, given the history

13 of this exercise, and its complexity.

14 And then the patients were notified by the centre.

15 It was not clinically urgent. I think most centres

16 would have discussed it at the next patient appointment.

17 **Q.** And then in terms of the current position, does the --

18 **A.** I forgot one important thing. The other thing is that

19 they changed the policy in relation to endoscopes and

20 disposable instruments. And so we all had to take

21 these out of quarantine.

22 **Q.** I'm going to ask you about that in a moment, but just

23 in terms of this information, in this letter, does it

24 remain the case in terms of the current position, as

25 at 2020, that individuals who received Factor VIII and

33

1 Factor IX between 1990 and 2001 are regarded as at

2 risk of variant CJD for public health purposes?

3 **A.** Yes.

4 **Q.** Then in terms of the practical consequences of being

5 so regarded, could we have, please, BART0000924.

6 This is an annual general meeting of UKHCDO,

7 13th October 2005. If we could go, please, to the

8 fourth page. No, sorry, that's the wrong document.

9 I think on my note it's the wrong document.

10 Well, we can look at this and pick up the picture

11 from this, I think.

12 Could you just go back to the front page, please,

13 Soumik. and could we go on --

14 So this is a meeting on 16th May 2005. There's then

15 a second meeting in October that we'll look at.

16 If we could go on to the next page, please. And the

17 next page. Yes.

18 So under the heading "vCJD Issues", the second

19 paragraph reads:

20 "Endoscopies: Charles Hay reported the trouble

21 Manchester is having with endoscopies. From an ensuing

22 discussion it was clear that different policies are

23 being pursued in different centres."

24 Then there's a reference to updating information on

25 the website.

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1 What was the trouble that Manchester was having with

2 endoscopies and how was it resolved, if at all?

3 **A.** Well, the problem was that endoscopy, because there's

4 a lot of lymphoid tissue in the gut, was considered

5 a potential risk for transmission. So the worry was

6 that an endoscope could transmit variant

7 Jakob-Creutzfeldt Disease to the next patient that

8 used it, for example. I mean, endoscopes are

9 obviously cleaned in between use, but prion protein is

10 quite sticky, and we didn't have any evidence to know

11 whether the cleaning procedure for an endoscope would

12 get rid of prion protein were that instrument to be

13 contaminated with it.

14 There eventually emerged evidence suggesting, for

15 example, that metal instruments used during surgery,

16 if they were also cleaned several times, probably

17 would be safe, but that evidence wasn't around right

18 at the beginning.

19 So the instruction was that if you used an endoscope

20 in a patient that was considered at high risk, you

21 should quarantine that instrument and only use it for

22 that patient.

23 So we had a growing number of endoscopes with my

24 patients' names on them, that couldn't be used for

25 anybody else. And in fact, I had one patient with

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1 type 3 von Willebrand's disease who required repeat

2 endoscopy using a double-balloon endoscope, which is

3 a particularly expensive instrument, costing £50,000,

4 and we actually brought one just for him.

5 Eventually my hospital had something like

6 three-quarters of a million pounds' worth of endoscopes

7 in quarantine. And that was at least three-quarters of

8 all the endoscopes in the hospital and was threatening

9 the endoscopy service with collapse through lack of

10 instruments.

11 Now, the situation was eventually improved because

12 the Department of Health made money available for the

13 purchase of additional instruments.

14 I think some other centres were perhaps not

15 following this policy as assiduously, but my

16 understanding is that it was a problem in most really

17 large Haemophilia Centres, like the Royal Free, because

18 if you have a large number of patients, you're bound to

19 need to endoscope some of them on a fairly regular

20 basis.

21 **Q.** And you said, I think a few moments ago, when we were

22 talking about the 2013 de-notification exercise, that

23 there had been a change of policy in relation to

24 endoscopes.

25 **A.** Yes. Well, there was a change in policy overall,

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1 because that reassessment was more wide ranging than
2 merely reassessing the period of risk. It reassessed
3 the level of risk.

4 Now, if you remember right at the beginning, they
5 admitted that when they assessed the risk of
6 transmission through blood products, way back at the
7 beginning of this exercise, the vCJD Incidents Panel
8 always used their most pessimistic assumption. Now,
9 I remember at the time wondering how they could make
10 any assessment at all because so little was known.
11 There were so many variables. And I saw the
12 calculations and the assumptions themselves ran to
13 two pages of A4 single-spaced ten point type. So the
14 only way that they could make any sort of assessment
15 at all was by making educated assessments and lots and
16 lots of assumptions.

17 Now, it became clear by 2009, far less the later
18 period, that these assumptions had to be far too
19 pessimistic, because if they had been correct, we would
20 have seen tens of patients with variant
21 Jakob-Creutzfeldt Disease, and we had seen none. And so
22 when they made the reassessment, they had to take into
23 account what we observed in the previous decade, ie,
24 zero, so they changed their assumptions and they revised
25 their assessment of risk downwards in general.

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1 So we changed the period of risk and we also revised
2 downwards our assessment of the risk to those who
3 continued to be considered a public health risk.

4 So it was no longer felt necessary to quarantine
5 surgical instruments, to use disposable instruments,
6 and/or to quarantine endoscopes at all.

7 Q. You referred to "they" reassessing the risk in that
8 regard, was that the Health Protection Agency?

9 A. Yes, and the variant Jakob-Creutzfeldt Incidents
10 Panel. Yes. It wasn't our -- not our assessment.

11 Q. We have heard both from individual patients and
12 through the statements of some clinicians that there
13 were centres where the practical implications of the
14 policy over the years that it was in place was that
15 there were occasions where surgery was deferred or
16 cancelled, often at short notice, because of the
17 concern about instruments. Was that a problem in
18 Manchester?

19 A. I think it was a problem everywhere. It was a problem
20 that we tried to mitigate. Operations got cancelled
21 sometimes when people seemed to realise at the last
22 minute that the patient was at risk. You could
23 minimise cancellations by planning the whole thing, so
24 that you should identify who was and was not at risk
25 in advance of surgery, so that appropriate disposable

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1 instruments would be available, for example.

2 Q. Before we leave the topic of vCJD completely, there's
3 just one issue I wanted to ask you about arising out
4 of some of the exhibits to your statement and the vCJD
5 surveillance study. I'm not going to ask you about
6 the detail of that work because we have that covered
7 in documentation elsewhere, but if we have
8 WITN3289148, please.

9 This is a letter, it's from Professor Hill, dated
10 22nd June 2007, but you've exhibited it and it relates
11 in part to the database so I'm hoping you can help us
12 with it.

13 It refers to Professor Lee having obtained ethical
14 approval for a number of studies relating to vCJD,
15 haemophilia and implicated products.

16 And then below the two numbered paragraphs there's
17 a paragraph that says:

18 "With regard to the post-mortem studies, we have
19 obtained a list of patients with haemophilia whose Death
20 Certificates indicate that there may have been
21 a post-mortem or a post-mortem may occur. These names
22 are being linked on the Database and I will be writing
23 separately to enquire if you can check if a post-mortem
24 has taken place and whether or not material is
25 available. James Ironside has indicated he will be

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1 prepared, as in the original submission, to look at
2 relevant material."

3 So there appears to have been a proposal to study
4 material obtained either from post-mortems that have
5 already taken place or from post-mortems that may take
6 place prospectively.

7 I just want to show you two further documents and
8 then ask you questions about it.

9 If we have please, Soumik, WITN329150.

10 So this is a draft consent form for seeking consent
11 from the next of kin for results of post-mortem
12 examination. Reference is made in the bold print to the
13 concern about vCJD and the proposed prospective and
14 retrospective surveillance study that was being
15 undertaken.

16 It contains provisions for the relative to agree to
17 the post-mortem examination being performed. It
18 explains samples will be sent to the National CJD
19 Surveillance Centre in Edinburgh, where they will be
20 examined, that the results will be available to the
21 relative. And then it provides:

22 "It is ... your decision as to whether you wish to
23 be informed specifically of the results of the tests
24 for vCJD."

25 And then provisions made for the relative to sign.

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1 As I understand it, that addresses the question of
 2 obtaining consent from the next of kin for post-mortems
 3 postspectively, so any post-mortems that might be
 4 undertaken following the production of these documents.

5 If we go, please, Soumik, to WITN3289151. We can
 6 see this is a further document relating to the proposed
 7 vCJD surveillance study. We can see data is going to be
 8 collected through the National Haemophilia Database.

9 If we go to the third page, please, Soumik.

10 We can see, under the heading "Prospective study of
 11 postmortem material", provision is made for consent to
 12 be obtained from relatives, and we've just looked at
 13 a sample form.

14 In relation to the "Retrospective study of
 15 post-mortem and biopsy material", it says this:

16 "In the period 1985-1998, at least 88 postmortems
 17 were performed out of a total of 1,300 haemophilic
 18 deaths (as reported to the UKHCDO Database). Wherever
 19 possible, centres should establish the extent of their
 20 postmortem material and refer relevant sections to the
 21 CJD Unit following liaison with the study coordinator.
 22 Help with the tracking and retrieval of specimens may be
 23 available.

24 "No additional consent is required for this.

25 "In the case of biopsy material available in

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1 deceased patients, similar action should be taken.
 2 Where the patient is still alive [presumably in relation
 3 to biopsy material] consent would be required for such
 4 an examination using the retrospective analysis consent
 5 form".

6 It would appear that in relation to the
 7 retrospective study of post-mortem material and, indeed,
 8 biopsy material from deceased patients, there was no
 9 intention to notify relatives or seek their agreement.
 10 I'm seeking to establish this as a matter of fact. Is
 11 that your understanding from this material?

12 **A.** That's my understanding. I know that they took this
 13 question to the Ethical Committee, and it was
 14 discussed also with the CJD Unit in Edinburgh. And it
 15 was the Ethical Committee's opinion that we didn't
 16 need to. I wasn't involved in that, but I know that
 17 this issue was examined.

18 **Q.** Do you know whether in your capacity as director of
 19 the Manchester Centre or in your capacity as director
 20 of the National Haemophilia Database, the extent to
 21 which centres hold post-mortem material that would
 22 have been covered by this study?

23 **A.** Well, that's part of the problem because I don't think
 24 that they do. You know, after the Alder Hey scandal,
 25 retention of material was dramatically reduced. The

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1 Human Tissue Act has a lot to say about the retention
 2 of material. And so retrospectively there is little
 3 or nothing available.

4 And the sort of deposit, tiny deposit, of
 5 prion protein in the spleen of that patient that we
 6 reported in 2009 would not have been picked up by
 7 a standard autopsy. A standard autopsy would have
 8 completely missed it. It's not a microscopic
 9 appearance that we're talking about. It's carefully
 10 slicing up the spleen and using a very specific stain
 11 to see what you're looking for. So you have to be
 12 looking for that specifically.

13 So frankly, the chance that this would have picked
 14 anything up was relatively slight anyway. So I don't
 15 think there were large amounts of retained material.

16 **Q.** Do you know what the position is in relation to
 17 Manchester specifically when you became director in
 18 '94 --

19 **A.** I'm sure we had nothing. I know that I -- as
 20 a centre, we contributed nothing to this study.

21 **MS RICHARDS:** Sir, I note the time, and I'm about to move
 22 on to another topic, so would this be the right moment
 23 to take the break?

24 **SIR BRIAN LANGSTAFF:** Yes, it would. We'll take a break
 25 for half an hour as usual, allow you to get a cup of

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1 coffee, and we will be back at quarter to 12.

2 **MS RICHARDS:** Thank you, sir.

3 **SIR BRIAN LANGSTAFF:** Quarter to 12.

4 (11.16 am)

(A short break)

6 (11.46 am)

7 **SIR BRIAN LANGSTAFF:** Yes.

8 **MS RICHARDS:** Professor Hay, I'm going to ask you next
 9 a handful of questions about the functioning of
 10 UKHCDO, to your knowledge, in light of the roles
 11 you've held within UKHCDO, and about the National
 12 Haemophilia Database.

13 Could we please have on screen, Soumik, WITN3289082.

14 This is a constitution for the United Kingdom
 15 Haemophilia Centre Directors Organisation dated
 16 September 1991, and if we go over the page we see what
 17 was there being set out, it's:

18 "... non-profit making. It exists to promote the
 19 provision of the higher standards of care for patients
 20 with Haemophilia and other Inherited Bleeding Disorders.

21 "Its functions and purposes also include -

22 "a) the collection and analysis of statistics;

23 "b) the initiation of research;

24 "c) the provision of professional advice to other
 25 bodies;

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1 "d) the diagnosis and treatment of inherited
 2 thrombotic disorders within those Centres which elect to
 3 participate in this activity."
 4 Now you became a member of UKHCDO in 1987, so about
 5 four years before this. As far as you know, was this
 6 the first time there had been some form of written
 7 constitution?
 8 **A.** Yes, this corresponded with the organisation becoming
 9 a registered charity, and we took advice and decided
 10 we needed a constitution partly for that reason.
 11 We also reviewed the membership. When I became
 12 a member, it was a member of Haemophilia Centre
 13 Directors. So although the initials of the
 14 organisation have remained the same throughout this
 15 period, it's at this point that the membership was
 16 widened to include all doctors involved in haemophilia
 17 care. So it becomes the UK Haemophilia Doctors
 18 Organisation.
 19 **Q.** Prior to this, and if you don't know the answer to
 20 this, because it may predate '87, then please say so,
 21 were there any materials that set out the way in which
 22 UKHCDO was organised or would function in any written
 23 materials?
 24 **A.** Not as far as I'm aware.
 25 **Q.** Sorry, Professor, carry on.

45

1 **A.** Well, you know, I might have missed something but
 2 I have read a lot of the older minutes, recently.
 3 **Q.** Then if we go to page 6, we can see here there's
 4 a list of regional centres. Now previously we've --
 5 I've been referring to, and they were referred to in
 6 the minutes, as "Reference Centres". This seems to
 7 include what were the Reference Centres but add
 8 a handful of other centres such as Liverpool,
 9 Newcastle, Norwich, Truro, and Lord Mayor Treloar
 10 College. Was this the point at which the concept of
 11 Reference Centres changed to a concept of regional
 12 centres and became slightly broader?
 13 **A.** I think that had happened already, at an earlier
 14 stage. The Reference Centres were only ever about
 15 five centres. I think they included Sheffield,
 16 Manchester, Oxford, the Royal Free and St Thomas', and
 17 that was about it. Maybe Cardiff, I'm not sure.
 18 **Q.** Cardiff and Edinburgh --
 19 **A.** Yeah ... well, yeah. They were centres of reference
 20 and the Organisation of Haemophilia Care in the UK
 21 changed from time to time. There was a health service
 22 circular -- HSC197630, I think -- which described the
 23 Organisation of Haemophilia Care in the
 24 United Kingdom, and I think at that stage divided
 25 Haemophilia Centres into Reference Centres,

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1 Haemophilia Centres, and Associate Centres.
 2 And that was subsequently changed with HSG9330 --
 3 93, I can't remember the second name -- the second
 4 number -- which introduced the concept of
 5 Comprehensive Care Centres and Haemophilia Centres,
 6 depending on the level of service that they provided,
 7 and giving criteria for the designation. And that was
 8 subsequently audited, so that if you wanted to become
 9 a Comprehensive Care Centre you had to have an audit,
 10 and the level of service you were able to provide was
 11 audited anyway.
 12 **Q.** And in terms of the chair of UKHCDO, this constitution
 13 provided for an elected chairman with a three-year
 14 office that could be extended to six years.
 15 Do you know, prior to this, what the arrangements
 16 were for selecting the chair even?
 17 **A.** I think they were more informal. This formalised
 18 things. I think the chair -- I'm not entirely sure,
 19 to be honest, because I couldn't come across anything
 20 written.
 21 **Q.** That's all right. In terms of -- I'm sorry, carry on.
 22 **A.** I think the chair would be elected by affirmation in
 23 the past. It can still happen, because what happens
 24 is that the chair sends out an invitation and anybody
 25 can apply, and if there are more than -- if there is

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1 more than one applicant, and they have to have
 2 a proposer and seconder, then an election takes place,
 3 of the entire membership. So all the members vote.
 4 If there's only one applicant, and they are agreed,
 5 then they may be elected unopposed.
 6 What people frequently do is they canvas to discover
 7 what their support is and then they may or may not
 8 apply, depending on how much support they feel they've
 9 got. Similarly for the other post holders, the
 10 treasurer, the vice-chairman, the secretary.
 11 **Q.** Over the time of your involvement with UKHCDO, so
 12 either the period from '87, since you've been
 13 a member, or '92, since you've been an officeholder,
 14 how has UKHCDO been funded as an organisation?
 15 **A.** Well, it has very little funding. It's a registered
 16 charity. Charities are not allowed to trade. Before
 17 that, its only source of income was the annual general
 18 meeting, which generally generated a profit of
 19 something of the order of £20,000 to £30,000. When
 20 this new constitution became into being it was also
 21 decided that the members should pay an annual
 22 membership fee of £20. That brought in something of
 23 the order of £1,500 to £2,000. It was recently
 24 abandoned because it was considered that it was more
 25 trouble to collect than it was worth.

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1 **Q.** Again, over the time that you've been involved, to
2 what extent has the organisation received funding from
3 the Department of Health?

4 **A.** Well, the charity hasn't received very much funding.
5 After it became a charity, the organisation had to
6 form a trading arm. This is very common amongst
7 learned societies and so on, if they're registered as
8 a charity, because the source of the profit for the
9 annual general meeting would be industry and BPL
10 coming along with a stall and giving sponsorship for
11 the meeting.

12 And prior to being a charity, that was fine, but
13 once we were a charity, you couldn't continue in this
14 way. And so the UKHCDO limited company was formed,
15 initially to deal with the membership fees and to deal
16 with the annual general meeting, and, at a later date,
17 also took under its arm the National Haemophilia
18 Database.

19 Now, in the very early stages of the organisation,
20 shortly after being formed, the organisation did receive
21 some funding from the Medical Research Council,
22 predominantly to look at hepatitis, but I don't know
23 that it received very much direct funding from either
24 the NHS or the Department of Health.

25 Latterly, during my involvement, we did receive

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1 funding from the Department of Health, partly to support
2 our involvement with national procurement and various
3 other projects.

4 **Q.** So is this right, and please correct me if I'm wrong,
5 that the Department of Health does not provide
6 a regular ongoing amount of funding to UKHCDO, but has
7 funded UKHCDO to undertake or work on particular
8 projects? You mentioned national procurement; I think
9 I've seen some reference in the papers to UKHCDO's
10 work in relation to recombinant, there having been
11 possibly some funding in relation to that.

12 **A.** Yes, yes, that's correct. When I took over the
13 database, the big problem was it had previously run
14 with no funding per se but had effectively been
15 supported by the Oxford Health Authority in that they
16 had paid the salary of Rosemary Spooner and
17 a part-time secretary who helped Rosemary Spooner.
18 Those were the only paid staff running the database
19 back then.

20 Now, when I took it over, it appeared to me that the
21 database is withering on the vine and for it to be
22 sustainable it would have to be brought up to date and
23 to produce more interesting data, because we produced an
24 annual report at that point, but it wasn't producing
25 very much research, and the data wasn't timely enough to

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1 be of interest to the Department of Health.

2 As far as I could see, the data would be of use for
3 Department of Health planning purposes, which would
4 benefit the patient group as a whole. And so
5 I approached the Department of Health and had
6 conversations with, amongst others, Julia Stallibrass to
7 talk about the potential for getting funding from the
8 Department of Health, and she very reasonably said to me
9 what I've expected, and that was, "Well, you've got to
10 produce something of interest, and we would think about
11 it."

12 And so at that time we passed the hat around
13 industry and for a year or so we funded the database
14 through unrestricted grants from various suppliers.

15 Then there were these project grants that came
16 along, but funding was insecure, which is, to be honest,
17 the fate of disease databases, many of which fold after
18 a short period of time, through lack of funding, and we
19 clearly wanted a regular income stream so that the
20 database could develop and become more useful. And the
21 Department of Health did facilitate this. Apart from
22 providing us with project funding for various projects
23 that were obviously important, they facilitated
24 discussions with the commissioners so that the
25 commissioners now provide us with a lot of funding,

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1 which we charge them on a pro rata basis according to
2 the population served, so we get funding from
3 NHS England, the lead purchaser, which I think is the
4 London Consortium, NHS Scotland, and NHS Wales.

5 **Q.** You referred to there being, in the early stages of
6 the establishment of the new database, your words
7 I think were "unrestricted grants from various
8 suppliers".

9 **A.** Yes.

10 **Q.** First of all, by "suppliers" you mean pharmaceutical
11 companies?

12 **A.** Yes, that's exactly right. Yeah.

13 **Q.** What do you mean by "unrestricted grants"?

14 **A.** An unrestricted grant is an unconditional grant. I've
15 always felt it was -- they're always described as
16 "unrestricted grants". I've always felt that it was
17 probably the wrong word to use, but there you are.
18 These are grants that are given without conditions,
19 which would be an absolute prerequisite for the
20 organisation.

21 **Q.** And other than funding from pharmaceutical companies
22 towards costs of the National Haemophilia Database,
23 what other funding has UKHCDO received from
24 pharmaceutical companies, to your knowledge, over the
25 years you've been involved. There's the sponsorship

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1 of the AGM.
 2 **A.** Yes.
 3 **Q.** Has that continued to receive pharmaceutical company
 4 support?
 5 **A.** Yes.
 6 **Q.** And what other kind of matters are funded by
 7 pharmaceutical companies?
 8 **A.** Well, sometimes we get unrestricted grants from
 9 industry to fund non-commercial research, for example
 10 the -- several companies shared the cost to support
 11 research into risk factors for Factor VIII inhibitor
 12 development. Sometimes they come to us with a request
 13 for an analysis, for example of how their products are
 14 used, and we would provide them with an anonymised
 15 aggregate report focusing on the use of their product,
 16 which is useful market data, and we would charge them
 17 for that.
 18 Sometimes they need this to deal with an argument we
 19 had with NHS England, for example, in which case the
 20 data is provided to NHS England and to the
 21 pharmaceutical company, exactly the same data, but the
 22 pharmaceutical company will have to pay for it.
 23 An example of that is the recent discussion between
 24 Sobi and NHS England about the relative efficacy of
 25 their extended half life Factor VIII, and whether,

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1 because of its extended half life, you may need fewer
 2 units, and whether their product reduces the annualised
 3 bleed rate in the patients using it, for example.
 4 And that's the sort of question, to be honest, we
 5 welcome, because it's a question that's of interest to
 6 everybody. And it helps NHS England to make its own
 7 planning decisions.
 8 **Q.** Do you know whether there is any record of amounts
 9 received by UKHCDO, either from pharmaceutical
 10 companies or the Department of Health, prior to 1987?
 11 **A.** I don't know of any such record. The organisation was
 12 running on a far more amateurish basis compared with
 13 now. I mean now the database has a manager.
 14 Obviously since we've been operating as a company, we
 15 have had a board of directors. Their accounts are all
 16 audited and have to be submitted to Companies House,
 17 and we have detailed financial records from them.
 18 **Q.** I want to ask you a little more about the National
 19 Haemophilia Database itself. In what year was the
 20 database formally established and management
 21 transferred from Oxford to Manchester?
 22 **A.** Well, the database was established about the same time
 23 that Haemophilia Centres were established, way back in
 24 1968. And it started under the leadership of Rosemary
 25 Biggs, who was the then Centre Director in Oxford and

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1 an international authority on blood clotting in the
 2 UK. In fact, I think the first clotting textbook
 3 I bought was written by her. And Charlie Rizza worked
 4 with her. He took it over when she retired, and
 5 initially they were attempting to address simple basic
 6 questions that were not known. For example, how many
 7 patients with haemophilia are in the UK?
 8 And initially, it was very much focused on
 9 haemophilia A and B. And in the early years of the
 10 database, they didn't consider any other diseases, not
 11 even von Willebrand's disease, for several years. I'll
 12 give you a history of all of this in the final chapter
 13 of UKHCDO's rule 9 response.
 14 The database developed a little bit over subsequent
 15 years. And then in about 1999, I became more involved
 16 with the database because it needed to be upgraded
 17 technically, and I employed a software engineer who had
 18 written the Haemophilia Centre information system that I
 19 used in my centre, amongst other things. And we went
 20 down to Oxford to assess its technical requirements and,
 21 from that point on, liaised closely with Miss Spooner,
 22 who was running it.
 23 And then in 2001, she retired. It might have been
 24 2002. But her imminent retirement precipitated a bit of
 25 a crisis because, as was the case right across the UK,

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1 Oxford Health Authority reviewed all its posts as they
 2 felt they could and resisted attempts from outside
 3 organisations to get them to pay for what was a national
 4 function. So, you know, this is a little district
 5 Health Authority, and it's employing one and a half
 6 people for a national function, and it didn't want to
 7 continue to do that. So her post was threatened with
 8 not being refilled.
 9 So the organisation had to consider the future of
 10 the database, and so I was the chairman of the Data
 11 Management Working Party at that point. And we put up
 12 a proposal. The organisation summoned Oxford and
 13 Manchester to put rival proposals to the executive and
 14 the Advisory Committee, and then they decided that they
 15 preferred my proposal, and so the database was moved to
 16 Manchester.
 17 **Q.** Now, one of the issues that has arisen in relation to
 18 the database over the years in the various minutes
 19 that we have amongst the Inquiry's materials is the
 20 question of patients' consent to information about
 21 them being provided to the database or being held by
 22 the database.
 23 In some of the materials that you have produced
 24 over the years, what appears to be said is that prior
 25 to 2000, there was no consent process in relation to

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1 the collection of that material, and it was the Data
 2 Protection Act coming into force that then triggered
 3 a series of debates that play out through the minutes
 4 of various meetings about what form that consent
 5 should take. Is that an accurate summary?
 6 A. I think that is an accurate summary, but I think
 7 a little context might be helpful.
 8 Like many historic databases, the database started
 9 in a very different climate. And back in 1968, there
 10 was no data protection legislation, and since we were
 11 not conducting interventional research, I think it was
 12 felt perfectly reasonable to collect and hold this
 13 data.
 14 There was some data protection legislation prior to
 15 1998, but the 1998 Act harmonised this legislation
 16 across Europe and tightened things up considerably. And
 17 I was a member of the Information Technology Working
 18 Party and then chairman of the Data Management Working
 19 Party, both of which fulfilled the same role as a sort
 20 of oversight committee for the database.
 21 And the Information Technology Working Party,
 22 chaired by Brian Colvin in the late '90s, began to
 23 address this question. And I think we began to think,
 24 well, we weren't keeping the database a secret; the
 25 Haemophilia Society knew about it and so on, but we

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1 suspect that many of the patients did not.
 2 I think you've taken evidence from previous medical
 3 witnesses who have told you that they don't think that
 4 patients were being asked about the database back at
 5 that time, and I think that that is probably correct.
 6 So, you know, as with so many historic databases, it
 7 was a matter of catching up and taking advice on what
 8 was reasonable, and opinion on what was reasonable did
 9 change with time. So we established around 2000 -- our
 10 opinion was that the patients needed to be actively
 11 informed about the database, the data that was being
 12 held, the uses to which it was being put, and of course
 13 their rights under the Data Protection Act of 1998.
 14 Although the Act is dated 1998, there is always a gap
 15 before the conditions come into force. But we needed to
 16 inform the patients that they had rights under the 1998
 17 Act, and that these included the right to have their
 18 data withdrawn.
 19 Now, my personal starting point to take advice was
 20 to go to the Information Commissioner. Now, the
 21 Information Commissioner was based in Data Protection
 22 House, which is on the main street, or off the main
 23 street in Wilmslow, about three or four miles from where
 24 I am now. So it was particularly convenient to make an
 25 appointment to go and speak to a case worker to outline

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1 our situation with them, and to outline our proposals
 2 for addressing it. They were extremely helpful.
 3 They felt that the NHS purposes to which we were
 4 putting our data, any reporting to the NHS that took
 5 place -- of course, at that time, there was very
 6 little -- did not require any form of consent. Just as
 7 you don't give consent when you go along to a hospital
 8 or the GP, but it is assumed that they will handle your
 9 data and that they will handle your data securely. But
 10 any further purposes, for example research or sharing
 11 anonymised data with third parties, would require
 12 consent.
 13 There then followed a debate about what the nature
 14 of that consent should be. Should it be -- and of
 15 course a lot of this consent would have to be obtained
 16 retrospectively because we had held those patients' data
 17 for a considerable period of time anyway.
 18 Should that consent be written consent, or would
 19 implied consent be adequate? Now, implied consent is
 20 informed consent, as for written consent, but with an
 21 opt-out. And that was the pattern that was adopted by
 22 disease databases right across the UK. And the Data
 23 Protection Registrar considered that that was adequate,
 24 and so that was the form of consent that we had. But we
 25 had to have a process whereby we made sure that the

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1 patients were aware of the database and their right to
 2 an opt-out.
 3 So we produced a series of leaflets. I have
 4 included all of the leaflets as exhibits to my rule 9
 5 response. And you will see that they were reviewed at
 6 irregular intervals throughout that period and reissued,
 7 and each time we would print something like 30,000
 8 copies, distribute them to centres, centres could
 9 request further copies if they ran out, and we
 10 recommended that they should not be posted to patients
 11 because you don't know if they've been received or what
 12 response there should be, but should be given to them in
 13 an opportunist way. By that I mean when opportunity
 14 arises.
 15 This was another specific point that I discussed
 16 with the Information Commissioner and, indeed,
 17 subsequently with the NHS Research Authority and Ethics
 18 Committee because patients, particularly with mild
 19 bleeding disorders, are not seen very often. So getting
 20 this information to the patients could take quite a long
 21 time, and I had to know that that was acceptable.
 22 In general, both the NHS Research Authority and the
 23 Ethics Committee did not favour posting these things to
 24 the patients, and that's a position I entirely agree
 25 with because you don't know if it's been received, and

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1 perhaps most importantly, the recipient doesn't have the
2 immediate opportunity to have their questions answered,
3 because they may read this and then they may have
4 questions.

5 So when we sent the leaflets out, and you'll see
6 this also in my exhibits, it went out with a protocol,
7 "How to use this leaflet", basically. And they were
8 asked that either the nurses or the doctors give this
9 leaflet to the patient to read before they're seen so
10 that they can read it, digest it, take it away, and
11 they've got an immediate opportunity to ask either their
12 haemophilia doctor or their nurses anything more that
13 they might want to know about the database.

14 We also put this leaflet on our website, on the
15 website of the Haemophilia Society, and we have
16 a hyperlink between the Haemophilia Society website and
17 the UKHCDO website. And we have, for a number of years
18 now, included a complete list of all the data points
19 that we collect on our website so that everyone can look
20 at that. You can go on our website and explore it if
21 you wish. And you can see from the minutes that this
22 whole process was reviewed at regular intervals.

23 From 2013, we recognised that we had a problem in
24 that NHS Digital, who provided us with death
25 certification data, became more difficult to deal with

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1 in a number of different respects. They questioned
2 whether our consent process was adequate. That's one
3 thing. And we sought advice from them. Now, I know
4 from my conversations with other disease databases that
5 our experience with NHS Digital at that time was not
6 unique; it was par for the course. Our problem was that
7 you couldn't get consistent advice from them. We had
8 difficulty contacting the same person twice in a row.
9 We had difficulty contacting anybody, so we didn't know
10 which path to take. And they stopped sending us death
11 certification data, and they suggested to us eventually
12 that, rather than dealing with them, we should go to the
13 NHS Research Authority.

14 So I had a correspondence with the NHS Research
15 Authority Confidentiality Advisory Group, which are
16 based in Skipton House, Elephant & Castle, and this
17 culminated in a meeting that I went to with their
18 Confidentiality Advisory Group, in 2017, and we
19 discussed this for an hour-and-a-half.

20 Now the other thing that was happening in the
21 background was that GDPR was looming, and that would
22 also change the Data Protection Act in certain
23 fundamental ways, one of which was that an opt-out was
24 no longer considered adequate. Consent had to be
25 affirmative. And therefore you needed an opt-in. So

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1 that clearly would change our approach.

2 The meeting with the NHS Research Authority
3 Confidentiality Advisory Group was very constructive and
4 they confirmed that they didn't think that we needed to
5 have any form of consent for the NHS purposes to which
6 we put our data, ie, the increasing number of reports
7 that NHS England, for example, were requesting of us.

8 They asked whether I thought it would be possible to
9 get written informed consent from all our patients.

10 Now, there are 30,000 of them. I made it clear that we
11 clearly couldn't get consent from patients who had died,
12 and we didn't want to cull the database of patients who
13 had died, because their data was nevertheless very
14 useful, in all sorts of ways, not least for the
15 patients, many of whom have requested data on their
16 deceased relatives, as is their right. And we have sent
17 at least 500 reports out, and it would be unfortunate if
18 we'd had to cull that data.

19 I made it clear to them that some of the patients
20 were not seen frequently. They asked me over what
21 period I felt I could obtain written informed consent
22 from the whole group, and I told them, given the
23 frequency with which patients were seen and the fact
24 that some were lost to follow-up, it would be five years
25 and it would probably never be complete.

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1 Now, they accepted that, and the reason for them
2 questioning me so closely about the process and the
3 difficulty, actually, getting the patients face-to-face
4 to get consent was that they said at the time that if
5 I had told them that it was impossible to get consent,
6 as is sometimes the case with databases, then that would
7 form the basis of an application for exemption from our
8 common law duty of confidentiality and we could get
9 exemption under Section 251 of the NHS Act of I can't
10 remember which year. But we concluded that we could get
11 written consent, and we set up a process for doing that.

12 Now, entirely reasonably, the NHS RA CAG also wanted
13 an annual progress report of where we were up to, and we
14 felt at that point that the central record of who had
15 given consent and who had not would be useful, and of
16 course it would be absolutely required for us to give an
17 annual progress report.

18 So we wrote a series of age-appropriate information
19 sheets, which are included as exhibits in my Rule 9
20 response, age-appropriate consent forms, which you'll
21 notice have a QR code on them which is unique to the
22 patient. We wrote software on the database for centres
23 to access -- to get the appropriate paperwork for each
24 patient. So there's a button that they press and it
25 will produce a patient-specific consent form, and

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1 package of information, which is appropriate and
 2 personalised. That enables them to upload the whole
 3 thing, once it has been dealt with, to the database, so
 4 that we have an electronic record of each consent.
 5 We went to the Ethics Committee and they gave us
 6 ethics approval for the database as a research database,
 7 and that was the situation. And we were busily getting
 8 consent when Covid struck and that has obviously reduced
 9 the number of face-to-face interactions quite
 10 dramatically and slowed down obtaining consent.
 11 But the other thing that changed was we are still
 12 going through the process of sorting things out with NHS
 13 Digital to start sending us death certification data.
 14 Not least because clearly mortality data forms an
 15 important element of the UKHCDO response to their Rule 9
 16 request. There's a whole section on mortality.
 17 And we got to the point we wanted to make an annual
 18 report to NHS RA CAG, and at that point, they sort of
 19 indicated to us that their opinion had changed.
 20 So we organised a meeting with NHS RA CAG. It
 21 wasn't a meeting with the whole committee as it had been
 22 before. The whole committee is a very large room lined
 23 with people, it must be about 30 or 40 individuals,
 24 I never counted them. We met with, if you like, the
 25 executive of that committee earlier this year, and they

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1 indicated to us that they had revised their opinion.
 2 Not just in relation to UKHCDO, but in relation to other
 3 disease databases. And they felt that partly because of
 4 Covid but also because of the numbers involved, and
 5 because of several aspects that I had discussed with
 6 them at earlier meetings, including the fact that you
 7 can't take consent from people who have already died,
 8 you have a problem with people that are lost to
 9 follow-up and who refuse to come along. They had
 10 concluded that it was impractical to obtain written
 11 affirmative consent from all the participants in the
 12 database, and that we would be eligible for section 251
 13 exemption, which they strongly encouraged us to apply
 14 for.
 15 And they suggested two separate applications in
 16 relation to, firstly, the NHS purposes to which we put
 17 the data, and secondly, the research purposes to which
 18 we put the data.
 19 So we submitted two separate applications. I think
 20 they had also changed some of their procedures, both
 21 with NHS Digital and with the NHS RA CAG. Since we
 22 first dealt with them, they have realised that a lot of
 23 the difficulty that they have with applications is that
 24 we are trying to work out what they need and we don't
 25 necessarily know. So they have caseworkers who offer

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1 advice as you're developing your application to make
 2 sure that you're addressing the right questions --
 3 **Q.** So, what --
 4 **A.** -- in the right way.
 5 **Q.** What is then the current position if -- if -- for the
 6 period from 2000 until recently, the database operated
 7 on the basis of implied consent with an ability to opt
 8 out, and that information was disseminated to patients
 9 through the various situations of the leaflet that you
 10 produced?
 11 **A.** Yes.
 12 **Q.** You then, in the way you've described, started to move
 13 towards a written informed consent in relation to the
 14 holding and use of data, interrupted by the current
 15 pandemic. What is the UKHCDO's intention, then, from
 16 now onwards, in terms of whether it obtains some form
 17 of express consent?
 18 **A.** Well, the situation is that we submitted our two
 19 applications for Section 251 exemption. The Committee
 20 considered those on August 3 of this year, and
 21 subsequently -- and this has to be confirmed by the
 22 Secretary of State for Health or their representative,
 23 with the weird title of a "decision-maker", and they
 24 have confirmed that this has the approval of the
 25 Secretary of State for Health, and so we now no longer

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1 have to obtain written consent. I'll be describing
 2 this to the membership of UKHCDO at the AGM tomorrow.
 3 **Q.** Are there any purposes for which data held by the
 4 National Haemophilia Database is put for which you
 5 will be seeking express written consent, or express
 6 consent of any form, or is the position going to
 7 entirely revert to the 2000 to 2019 position of
 8 implied consent with opt-out?
 9 **A.** With this exemption, we do not need the patient's
 10 permission, though the patients still have the right
 11 to have their data removed, and we have removed one
 12 patient's data at his request only last week, despite
 13 this. So the patients can still opt to have their
 14 data removed, should they wish to do so. Although we
 15 don't have to ask for permission, we have always felt,
 16 at least since we started to think about this around
 17 2000, that the patients should know what we're doing,
 18 why we're doing it, and what we hold.
 19 So we will -- we're in the process of again revising
 20 our patient information, because although we revised it
 21 only last year, it has rapidly gone out of date. We
 22 don't anticipate that we will ever share named data, so
 23 I don't anticipate that there will be any exemptions.
 24 **Q.** There's one discrete issue arising out of the
 25 operation of the database I wanted to ask you about.

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1 Soumik, could we have, please, HCDO0000002_066,
 2 please.
 3 So this is a meeting in November 2003 of the
 4 UKHCDO's Data Management Group. If we go to the last
 5 page, please. This is in the context of patients'
 6 request to access information held about them.
 7 The minutes received read as follows:
 8 "Dr Hay continues to receive such requests.
 9 Patients do not really know what data is being held on
 10 the national database. Dr Hay has not prepared
 11 a leaflet to let them know what type of information they
 12 can expect, but he sends them a letter explaining this,
 13 together with an invoice for £10 instead. This often is
 14 sufficient for them to abandon their request."
 15 Now, that reads, Professor Hay, arguably, as seeing
 16 the abandonment of a request for data as an advantage to
 17 which the --
 18 A. I can see where you're coming from, and that is not
 19 the impression that I would wish to give, because
 20 I think early on, I think a lot of people thought that
 21 we held far more data than we did. So we would let
 22 them know what we did hold. In fact, although it may
 23 be a little scanty, particularly in the older -- in
 24 the earlier period, it is sometimes more useful than
 25 we think. And the £10 invoice was the fee that is set

1 out in the Data Protection Act of 1998. Since we've
 2 gone to GDPR, there is no fee at all. It's a nominal
 3 sum in any case.
 4 I deprecate the impression that is given here that
 5 we wanted to discourage anybody from making a request.
 6 We get a lot of phone calls from patients. We try to be
 7 as helpful and friendly as we can. It's clearly their
 8 right under the Act to get data. Sometimes, although
 9 the data from the early years is not extensive, it
 10 nevertheless tells them the brand of concentrate they
 11 were first exposed to and which year they were exposed
 12 to it. And for people that are trying to find out about
 13 the origin of their hepatitis C, that is a key piece of
 14 information which may have already been lost from their
 15 notes.
 16 I think a lot of the patients thought that we held
 17 as much information as the hospital might, and that we
 18 were an alternative source of really detailed data.
 19 And, of course, that was never the case.
 20 Q. A separate issue but still relating to records is the
 21 subject of my next question.
 22 Soumik, could we have NHB0091224_008, please.
 23 So this relates to the approach taken by the
 24 Skipton Fund to applications, and there are various
 25 communications between you and the Skipton Fund in the

1 materials that we have. I just wanted to ask you in
 2 particular about this one.
 3 You wrote on 5th July 2011 to Mr Stevens as chair of
 4 the Skipton Fund along with the chief executive or the
 5 then chief executive of the Haemophilia Society,
 6 Mr James.
 7 And you say:
 8 "We are writing to you jointly to express our
 9 concern and to question the approach currently being
 10 adopted by the Skipton Fund to a number of applications
 11 from the dependents of the deceased.
 12 "A number of cases have been rejected even though
 13 the deceased relative can show that they were treated
 14 with concentrate during the period of risk, because the
 15 notes have been destroyed or the patient died prior to
 16 the advent of HCV testing. We have heard of one case
 17 refused even though liver disease was mentioned on the
 18 death certificate. Some applications have been refused,
 19 even though evidence of chronically abnormal LFTs was
 20 also provided. In many cases, the notes have been
 21 destroyed because of the passage of time, but either the
 22 centre or UKHCDO can provide evidence of treatment with
 23 concentrate during the period of risk. Had this group
 24 been included from the inception of the Skipton Scheme,
 25 as both UKHCDO and the Haemophilia Society argued, it is

1 far more likely that the documentation would still have
 2 been available to support their application.
 3 "These refusals are causing considerable distress."
 4 Then you go on, on the second page, to set out in
 5 the first paragraph of that page your concern that
 6 Skipton, rather than applying a test on balance of
 7 probabilities, was applying a higher standard, of beyond
 8 reasonable doubt, in reaching decisions, and then you
 9 say:
 10 "On the balance of probabilities, all patients
 11 treated with clotting factor concentrate during the
 12 period of risk will have contracted hepatitis C, given
 13 the 100% infection rate documented in the literature.
 14 On the balance of probabilities they will also have
 15 developed chronic hepatitis C, given a 25% spontaneous
 16 remission-rate and should therefore be eligible for
 17 a part 1 payment, even if the documentary support for
 18 this has been destroyed and/or they died before the
 19 advent of HCV testing."
 20 Professor Hay, the Inquiry will be examining the
 21 operation of trusts and schemes for financial assistance
 22 in more detail in the early part of next year. What can
 23 you tell us about this particular issue, and the extent
 24 to which it was resolved or not following this
 25 communication?

1 A. Well, we never sent data directly to the Skipton Fund.
 2 I don't remember this. I think at some point the
 3 Secretary of State for Health stated that these cases
 4 should be settled on the balance of probabilities,
 5 which seemed the only reasonable basis on which it
 6 should be decided. And we wanted to do whatever we
 7 could to support the applications to the Skipton Fund.
 8 What happened in reality, was that patients who were
 9 scratching around for evidence would turn to us and ask
 10 for an extract of the data we held on their relative, or
 11 the patients themselves would. And we would provide
 12 that. And I think, after this, they did take that into
 13 account to some extent, because -- these were very often
 14 deceased patients whose notes had been destroyed after
 15 death, and they were left with very little
 16 documentation.
 17 But the data we held, scanty though it was, we felt
 18 should be adequate to support an application at least
 19 for a part 1 payment and, if they had a death
 20 certificate, perhaps part 2.
 21 Q. I want to move, then, to your involvement with -- or
 22 the involvement of the Haemophilia Database in an HCV
 23 look-back exercise.
 24 Henry, could we have, please, WITN3289157.
 25 So we can see this is a proposal submitted by you on

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1 behalf of UKHCDO and the database entitled "Hepatitis C
 2 Look-back Exercise in Patients with Bleeding
 3 Disorders: 2009/10".
 4 If we go to the third page, please, Soumik.
 5 You set out in this proposal the objectives. (1)
 6 was:
 7 "To document patients with bleeding disorders
 8 already tested."
 9 And to identify how many had hep C, whether they'd
 10 been offered treatment, what was the outcome, how many
 11 patients had died.
 12 Then (2) was to identify patients who had not been
 13 tested for hepatitis C, so that they could be offered
 14 advice, testing and, as necessary, treatment.
 15 Then if we turn on, please, Soumik, to page 6.
 16 Thank you.
 17 We can see here what you set out in the first main
 18 paragraph is that:
 19 "All patients with bleeding disorders treated with
 20 blood products during the period of risk (before 1987)
 21 should have been tested in 1992 or soon after. All
 22 should also have been tested for hepatitis B from the
 23 late 1970s or early eighties."
 24 Then you say, skipping over a sentence:
 25 "Those untested are most likely to have been mostly

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1 mild bleeders, reviewed annually or irregularly and then
 2 subsequently lost to follow-up."
 3 Then you go on to explain how it was arisen that
 4 patients were not tested, in the bottom half of the
 5 page, at (a), (b) and (c), you say:
 6 "(a) Many Haemophilia Centres did not follow up mild
 7 bleeders regularly at all once the diagnosis had been
 8 made ...
 9 "(b) Many such patients will have moved house ...
 10 and will thus have become lost to follow-up. In this
 11 way they may have fallen through the net and not have
 12 been screened.
 13 "(c) Some patients may have moved or registered with
 14 a new centre. The new centre may be unaware of their
 15 previous blood component or blood product treatment
 16 history and therefore may not have identified the
 17 patient at being at risk for hepatitis C."
 18 Then the top of the next page, at (d):
 19 "An unknown but significant number of mild bleeders
 20 may have been treated by non-specialist centres. These
 21 patients are often not followed systematically and are
 22 less likely also to be registered with the [National
 23 Haemophilia Database]."
 24 Then if we go on to page 9, you set out there
 25 a proposed approach using the database to generate

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1 lists, sending them to centres, asking the centres then
 2 to scrutinise those lists, effectively, and to work from
 3 there.
 4 So that was the proposal which was, as
 5 I understand it, then put into effect. Can you
 6 underline for us how the look-back exercise was then
 7 undertaken?
 8 A. Well, we provided centres with spreadsheets, giving
 9 them the information that we held and asked them to
 10 fill out the blanks, effectively. There were a number
 11 of objectives. We focused on the identification of
 12 patients who were untested, but the Department of
 13 Health added a lot to this, which was unfortunate in
 14 the end because it became overwhelming.
 15 They wanted information about treatment provided to
 16 patients and the outcomes, the number of patients with
 17 severe liver disease, and various other things for the
 18 purpose of healthcare planning and also to help them to
 19 work out how much funding they needed to put into the
 20 Skipton Fund. And that made this an extremely involved
 21 exercise.
 22 And so we asked centres for all this data. We asked
 23 all the centres that the patient had been registered
 24 with to provide us with data because we knew that the
 25 most recent centre might not know what the patient had

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1 been treated with, say, two, three, four decades before
2 in some other centre or maybe even district general
3 hospital.

4 So we approached this whole thing making no
5 assumptions about anything, other than if they had been
6 diagnosed outside the period of risk; ie, after 1991,
7 they would not have been exposed to an at-risk product.
8 So we were looking just at patients who had been
9 diagnosed before 1991 and making no assumptions about
10 the treatment that they might have had.

11 Unfortunately, that led to us asking for data on
12 something like 28,000 patients, some of whom -- about
13 a third whom had died because of the long timescale we
14 were looking at. And we were asking in some cases
15 multiple centres about the same patient to get the whole
16 picture because, you know, we have some patients
17 recorded on the database against seven different
18 Haemophilia Centres because they'd moved around the
19 country during their life.

20 And the centres were quite honestly completely
21 overwhelmed by this. They did try. We told them that
22 this data had been requested by the Department of
23 Health, but I don't think they were staffed to do it.
24 The patients who were lost to follow-up or who had died,
25 obtaining their records was sometimes difficult, and

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1 sometimes the records had been destroyed. And that sort
2 of collecting them together was quite difficult.

3 And this was primarily a problem for the non-severe
4 bleeders, because the severely affect patients are seen
5 very regularly; they're well documented, and pulling
6 their data together wasn't difficult. But they are
7 a small minority of all the patients who were
8 potentially at risk. So it rapidly became apparent that
9 we were not -- just not going to get all the data. The
10 testing data was just a small part of that.

11 So we had to go back to the Department of Health and
12 revise things, and we pointed out to them that we would
13 be able to extrapolate from, say, 10% of the data. And
14 they agreed a modification to the protocol whereby we
15 would still request the testing data on everybody, but
16 the more detailed data, such as the severity of their
17 liver disease, the treatment history and so on, would
18 only be requested from a randomly selected 10%. For
19 planning purposes, we could extrapolate from that.

20 Whilst it was entirely understandable that the
21 Department of Health might have wished to ask those
22 questions, this was the element that just completely
23 overwhelmed the centres and made it impossible for us to
24 pursue it. I have actually included as an exhibit to my
25 section 9 response a copy of the final report which

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1 gives you a flavour of how far we got. But after
2 a period of about three years, we had to abandon this
3 because we weren't getting any new data in.

4 Now, since that time, we have obviously launched
5 a less ambitious, deliberately less ambitious
6 hepatitis C look-back exercise which will be reported in
7 our UKHCDO section 9 response to the Inquiry, which
8 includes all the data that we got from this 2010
9 look-back but also any further information that we had
10 subsequently obtained.

11 I should add, incidentally, that prior to these
12 look-back exercises, UKHCDO issued and indeed published
13 several liver disease guidelines, including
14 recommendations on testing. So, you know, these
15 patients should all have been tested anyway. And
16 I anticipate that you're going to ask me, "Well, how
17 many untested patients did you identify?" And the
18 answer is: not very many. I think people continue to
19 come out of the woodwork in small numbers.

20 Q. We'll await with interest the UKHCDO response to the
21 Inquiry's request, but for the sake of completeness,
22 I'll just ask you to look briefly at the report of the
23 2010/11 exercise.

24 Soumik, it's WITN3289162.

25 We can see it's a report that's said to be up to

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1 31 March 2014. It's headed "Hepatitis C look-back
2 report".

3 "This report is comprised partly of data imputed
4 from the treatment records of NHD collected over many
5 years and partly from data collected specifically in an
6 HCV look-back exercise conducted from 2010. Centres
7 found the look-back exercise burdensome and in some
8 cases difficult, and the data is consequently
9 incomplete. Many patients were probably lost to
10 follow-up."

11 Then in terms of extrapolations, if we go down to
12 the bottom half of the page, you say:

13 "We strongly suspect there was under-reporting of
14 occasional treatment of mild bleeding disorders and so
15 suspect that far more of such patients were treated than
16 had been reported to NHD over the years."

17 So you:

18 "... felt obliged to consider all patients not
19 included above but registered with a bleeding disorder
20 during the period of risk ([approximately] 18,000 ...) to
21 be potentially at risk of HCV exposure unless the
22 centre could confirm that they had never been treated
23 with blood products or concentrates."

24 And then you report:

25 "Of the 9,090 patients whose previous treatment

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1 history was reported as 'unknown', HCV status was also
2 reported as 'unknown' in 7,567. Of the 1,523 patients
3 whose treatment history was reported to us as 'unknown'
4 but who had been HCV tested, 398 had evidence of active
5 HCV and 21 of past but cleared HCV. Thus 27.5 per cent
6 of those members of this group who were tested and had
7 a test result reported to us had evidence of previous
8 exposure to HCV."

9 Then you say this:

10 "Were this to be found in the whole of the 18,000
11 patients for whom we have no treatment reports, we would
12 expect about 5,000 additional patients whose exposure to
13 HCV has not been documented or who have not been tested.
14 It is likely that there is reporting bias, however, and
15 that those treated are less likely to be lost to
16 follow-up and that the true number of those exposed is
17 significantly ..."

18 Top of the next page:

19 "... lower than this statement. However, unless
20 this group are tested and reported we have no way of
21 making an accurate estimate."

22 Then you strongly recommend that:

23 "... all patients diagnosed with a bleeding disorder
24 before September 1992 should be tested for HCV because
25 Centres and the patients themselves will frequently not

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1 know what their treatment history is."

2 So Professor, subject to whatever is going to emerge
3 in the further material you provide to the Inquiry,
4 this, as I understand it, is the report that was
5 produced following the look-back exercise commissioned
6 by the Department of Health?

7 A. Yes.

8 Q. And --

9 A. This report is actually taken from one of our annual
10 reports. As a supplement to that.

11 Q. Do you know what steps have been taken, if any, by
12 centres in response to the recommendation that you set
13 out there in bold and italicised and underlined?

14 A. Well, I think I know that centres have attempted to
15 trace some of these patients. The database holds NHS
16 numbers. It doesn't hold NHS numbers for all the
17 patients, because we didn't collect NHS numbers for
18 the whole history of the database. So there are some
19 patients for whom we don't hold NHS numbers. Usually
20 these are very early registrants, so they may be dead.
21 But they are very difficult to trace, because some of
22 the early registrations we may not even have the whole
23 name. We mostly do, I hasten to add. This is a tiny
24 minority. Because these days we wouldn't accept
25 a registration of that quality. We would go back to

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1 the centre and chase them for the missing details.

2 Now the point about this is if you know the NHS
3 number, and the patient is registered with a GP, then
4 you should be able to trace the patient, or at least
5 the GP. And I know that in my centre, and we have asked
6 other centres to do the same, we need to trace all these
7 people.

8 You will hear, with our response to the Rule 9
9 request to UKHCDO, that that's not always been possible,
10 and in some cases when centres have asked the patient to
11 come up to the centre for review they have refused, but
12 we can at least write to the GP and ask if they've been
13 tested, and if not, ask the GP to arrange for them to be
14 tested and explain the situation in a letter.

15 UKHCDO has no direct patient responsibility but in
16 these exercises what we were trying to do is to
17 facilitate and make it easier for Haemophilia Centres,
18 whom we think do hold that responsibility, to follow
19 these patients up.

20 I know that in my own centre there have been some
21 patients who have refused to be tested, refused to come
22 up. Fortunately, very small numbers of those. Yes.

23 Sir, I note the time, and I'm going to be moving on
24 to a separate topic, so perhaps we could take lunch now.

25 SIR BRIAN LANGSTAFF: Yes. Let's take a break until

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1 2 o'clock, shall we.

2 MS RICHARDS: Before we cease the transmission and the
3 link with Professor Hay, just two matters, if I may,
4 sir.

5 The first directed to Professor Hay.

6 Professor Hay, you've been sent a document by the
7 Inquiry in the course of the morning which is a report
8 from Dr Biggs. It's essentially a precursor to the
9 report from Dr Rizza that you referred to yesterday, and
10 I may want to ask you some questions about it on the
11 issue of life expectancy, so I would invite you to check
12 your emails and perhaps read that over lunch. It's
13 a fairly short document.

14 And then, secondly, addressed to recognised legal
15 representatives who are not present in the room as they
16 normally are but are listening remotely, this hour is
17 the opportunity for the recognised legal
18 representatives, please, to communicate by email to me
19 and to Ms Scott any further questions in addition to
20 those they've already submitted that they would wish us
21 to consider asking Professor Hay this afternoon.

22 SIR BRIAN LANGSTAFF: Well, what I shall do, given that
23 we're asking you, Professor, to look at a report by
24 Dr Biggs, we'll extend the lunch break for
25 ten minutes.

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1 So it's ten past two, please, and I look forward
 2 to seeing you all then.
 3 **A.** Thank you.
 4 **(1.02 pm)**
 5 **(Luncheon Adjournment)**
 6 **(2.10 pm)**
 7 **SIR BRIAN LANGSTAFF:** Yes.
 8 **MS RICHARDS:** Professor Hay, a handful of questions next
 9 on the issue of consent, patient consent. And my
 10 questions are going to be essentially seeking to
 11 understand the factual basis for your understanding of
 12 current and previous practices.
 13 In relation to blood samples, you've said in your
 14 statement, paragraph 80.3:
 15 "One did not ask for consent to take blood samples.
 16 I think it is assumed that the patient has consented
 17 because they go along and allow the phlebotomist to take
 18 the sample. It is not normal to take verbal or written
 19 consent for blood sampling other than for the purpose of
 20 research."
 21 I understand your point, Professor, about the
 22 patient consenting by allowing the blood to be taken,
 23 but do you take that to mean, in terms of your own
 24 practice or your understanding of current practice, that
 25 the patient is consenting to any and every use of that

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1 sample, or is there some limit to the uses to which the
 2 sample can be put?
 3 **A.** Well, I think if the sample was to be stored, that
 4 would be a separate matter. Although the Human Tissue
 5 Act doesn't apply to plasma, as far as I'm aware. But
 6 the patient wouldn't necessarily know that, probably
 7 wouldn't.
 8 I mean, it isn't normal practice for ask for consent
 9 but you would -- and in a routine review appointment,
 10 you tend to take the same samples each time, and at some
 11 point you might -- well, the patient would often know
 12 what the samples were for, because the results would
 13 often be discussed. For example the HIV viral load, the
 14 CD4 count, the patients often want to know what those
 15 results are because they give them an index of their
 16 current status, so you discuss them.
 17 If you're taking a sample for something new,
 18 depending on what it was, you might describe it in
 19 general terms. I know, for example, if you refer
 20 a patient with abnormal liver function tests to be
 21 investigated by a hepatologist, they won't describe
 22 every single test that they're doing but they'll say,
 23 "Well, we're going to test for some hepatitis viruses
 24 and some antibody tests and liver function tests". They
 25 probably wouldn't say more than that unless the patient

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1 asked, and if the patient asks, then of course you'd
 2 tell them.
 3 But what I was trying to get across is that it is
 4 not normal practice to sit down and list every single
 5 test that's going to be done, every time, and say, "Is
 6 that all right?" Do you see what I mean?
 7 **Q.** Yes. In a sense you've anticipated, I think, two of
 8 my next questions.
 9 Where you have a patient who is a new patient or
 10 you're doing something which is not the standard array
 11 of tests you may have done many times before, and then
 12 explained the results, and you may assume that the
 13 patient has some, therefore, understanding of the
 14 purpose, but would you accept that, in principle,
 15 different considerations may arise, depending on the
 16 particular circumstances, with a patient who has not
 17 previously been tested or a patient where you're doing
 18 something new?
 19 **A.** Yes, absolutely. Because at the end of the
 20 consultation with a new patient, you would summarise
 21 where you think you're up to. They will probably want
 22 to know the range of possible diagnoses, and you will
 23 describe in general terms what the tests will be. You
 24 know, someone comes to me with easy bruising, I will
 25 give them an -- my personal evaluation of the bleeding

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1 history that I've just taken from them, and I will
 2 tell them, you know, "We're going to check a few
 3 clotting tests. We will probably have to get you back
 4 in on another occasion to check your platelet function
 5 tests", and you'll tell them they have to avoid
 6 aspirin and drugs like that for two weeks before the
 7 test, and so on.
 8 Similarly, if I saw a patient with a mild bleeding
 9 disorder that had been long since lost to follow-up, who
 10 was new to me and might have been treated with who knows
 11 what, in another hospital, I would explain to them that
 12 we had to test them for hepatitis C. I would give them
 13 an evaluation of the likelihood of that test being
 14 positive, and say, you know, "It may well be negative
 15 but we really need to know one way or the other."
 16 **Q.** And in relation to stored samples, could we look,
 17 please, Soumik, at WITN3289054.
 18 If we go to the second page. Now, this is
 19 a specific form at Manchester Royal Infirmary in
 20 relation to genetic testing, but if we go on to the next
 21 page we can see it's -- it seems to be an information
 22 sheet for patients. It asks the question "What is the
 23 purpose of obtaining a blood sample?"
 24 Then if we go over the page, it provides information
 25 about where the sample will be tested, how long the

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1 sample will be stored and then, if we go to the next
2 page, "What else might be done with my blood sample?"

3 Now I appreciate this is a leaflet specifically
4 concerned with the taking and storage of samples for
5 genetic testing. But would you consider that those
6 kinds of questions, where will it be stored, how long
7 will it be stored, what else might be done with it, are
8 the kind of questions which patients should be given
9 information about if samples are going to be stored?

10 **A.** Well, genetic testing was considered particularly
11 sensitive, and this is the form that we actually give
12 to them before we go through a formal consent
13 process -- and this leaflet was submitted to you as
14 one of the exhibits to my response -- as was the
15 consent form. And as the consent form says: it is our
16 plan to store your sample indefinitely, which is
17 unusual, actually, because that means even after the
18 patient has died, we may continue to store that. And
19 the patients are asked to consent to that in writing.

20 Now that's not for research purposes. That may be
21 to facilitate testing of relatives at some stage in the
22 future. And this leaflet and the accompanying consent
23 form were actually designed by the Genetics Working
24 Party of UKHCDO. And again, it's considered -- I don't
25 think this is really a very good example because the

1 status of genetic testing is in general a little bit
2 different.

3 I think if we were to store samples for potential
4 research in the future, some form like this would be
5 appropriate, but UKHCDO certainly don't do that, and
6 I don't have any research samples stored away either.
7 Research repositories have to be regulated and a form
8 like this would be appropriate for that sort of purpose.

9 **Q.** And what about -- it may be this is hypothetical if
10 you don't do it -- what about storing samples to keep,
11 essentially on the basis that there might come unknown
12 viruses in the future that one might want to -- or
13 other unknown issues in the future when one might want
14 to take the sample out and test at some future stage?
15 I mean, is that -- first of all is that something that
16 happens at Manchester, in your --

17 **A.** No -- well, all our virology departments, as far as
18 I'm aware, store samples for three years, and then
19 dispose of them, and that's in case they need to
20 investigate further. One of the other principles you
21 will have noticed, going through the consent process
22 in relation to genetic testing, is the principle that
23 if we want to re-test the sample for a different
24 condition, we would have to go back and ask the
25 patient for consent again. Because the consent is

1 extremely specific. And in the first -- the first
2 part of the consent form, you explain to the patient
3 that you are only going to test for the main
4 condition, which will be haemophilia A, B, or
5 von Willebrand's disease, or whatever, and that you
6 won't be testing for anything else.

7 So that they understand that you won't be digging it
8 out and using it as a research thing without their
9 permission. And we say quite explicitly to the
10 patients, "If we want to do that, we are obliged to come
11 back and ask you". Because, for example, once we have
12 a stored sample of DNA, we could in theory test that
13 sample for cancer genes, and -- just using that as an
14 example.

15 And the implications of testing for something that
16 might give you cancer are very different from the
17 implications of testing you for a hereditary bleeding
18 disorder. So the patient may be very happy, and has
19 often volunteered, to be tested for the familial gene,
20 but might prefer not to know if they have a gene that
21 predisposes them to cancer.

22 So it's an important principle that applies to
23 genetic testing.

24 Now, by the same token, I think if you stored
25 a sample and you wanted to do research on it, you'd have

1 to go back to the patient. I mean, I think that's the
2 current view. I don't think it has always been that,
3 but I think that, you know, even if you've got a sample
4 stored, you may have taken general consent that you have
5 a sample stored for research purposes, and in some cases
6 that consent includes consent to keep the result
7 anonymous. That would be one way of handling, for
8 example, testing for a new antibody test, where you may
9 not know what the implications of a positive test are,
10 or indeed how good the antibody test is. And then it's
11 helpful to test a group of patients anonymously on the
12 understanding, explained in advance, that the patients
13 will not be told the result.

14 **SIR BRIAN LANGSTAFF:** By "anonymous" you don't mean
15 without identifying the individual; you mean without
16 telling the individual?

17 **A.** Yes, that's right, and keeping the report anonymous as
18 well.

19 **SIR BRIAN LANGSTAFF:** Yes, well, I understand that last.
20 It was just the use of the word "anonymous", I just
21 wanted to clarify. Thank you very much.

22 **A.** Sure. All the reports would be anonymised but you
23 clearly need to identify the sample.

24 **MS RICHARDS:** Moving on, then, to the question of
25 hepatitis C testing, you say in your statement this:

1 "... it has never been customary, in any branch of
2 the health service, to provide pre-test counselling or
3 obtain specific consent for hepatitis C testing,
4 hepatitis A testing or hepatitis B testing."

5 Then you refer to information received from your
6 hepatology colleagues that in 2020 if they saw a patient
7 with abnormal liver function tests, they'd arrange
8 a battery of blood tests which would include viruses
9 such as HCV and would tell the patient words to the
10 effect of "I'm doing a few tests, including tests for
11 viruses."

12 Now I just wanted to explore with you what the
13 factual basis is for that, your belief that that is the
14 customary position.

15 Your own practice, as I understand it from your
16 evidence so far and your written evidence, is that
17 you -- I think you say almost invariably or invariably
18 did tell patients that you proposed to test them for
19 hepatitis C, thus affording them, presumably, an
20 opportunity to decline.

21 **A.** Well, I can't remember anyone declining, although they
22 have recently, when we've chased them up, the odd
23 patient. Well, I think this circles around what you
24 mean by "counselling", to be honest. Because my
25 understanding of the questions being put to me in my

1 Rule 9 request was that a comparison was being drawn
2 between the situation of formal counselling for
3 HIV testing and hepatitis C, and my answer was in
4 relation to that. Because whilst I would certainly
5 tell people I was testing them for hepatitis C, the
6 implications for that test are not the same as for
7 HIV.

8 And indeed, the process of counselling people
9 prior to HIV testing really only fully emerged a year
10 or two after we started to have a test, because to be
11 honest, back in 1984/85, when testing first became
12 available, the implications of the test were not fully
13 known.

14 So, you know, the conversation could be quite short
15 and would include assertions such as just having HIV
16 doesn't mean you've got AIDS. Because we didn't know
17 the natural history and so on. We didn't realise that
18 it would have major implications for getting a mortgage,
19 for getting life insurance, and all of those have to
20 take their place in the process of counselling to have
21 an HIV test once those things are known.

22 Now, with hepatitis C we knew that the natural
23 history was a prolonged one, that a significant
24 proportion of patients would have a very good prognosis,
25 whilst a significant minority would obviously get

1 serious liver disease.

2 So it would be a different conversation. I'm not
3 saying that you would -- I think in our practice we
4 probably talked more to our patients about hepatitis C
5 prior to testing even than the liver doctors do, because
6 the liver doctors see lots of people with abnormal liver
7 function tests. The commonest cause of abnormal liver
8 function tests in the general population is obesity.

9 Now, in my group of patients, that's sadly not the
10 case and, you know, if I see a bleeder, my concerns are
11 slightly different. If they've got abnormal liver
12 function tests, I would assume it was hepatitis C until
13 proven otherwise.

14 **Q.** So if you were, in 2020, seeing a patient, perhaps one
15 of the infrequently treated patients who'd been lost
16 to follow-up who has now come back to the centre, and
17 they either hadn't been tested for hepatitis C or you
18 don't know whether they'd been tested for hepatitis C
19 or not, and you thought it would be prudent for them
20 to be tested for hepatitis C, what information would
21 you typically now give that patient in advance of
22 undertaking the test?

23 **A.** Well, some of these patients are already concerned
24 because you've dragged them out of the woodwork, and
25 they're worried that you might be giving them bad

1 news. And they may have very little awareness of
2 hepatitis C because I think there is much less
3 awareness in the general public of hepatitis C than
4 there is, for example, of HIV. So you have to
5 introduce to them the possibility, having taken
6 whatever treatment history you can elicit, that there
7 is a possibility that they may have contracted
8 hepatitis C. And, you know, as I say, you would make
9 some sort of calculation based on what you'd been
10 told. You might not be able to assess the risk, but
11 you have to put that to them, and then you would say,
12 "I think we need to test you." And they will almost
13 invariably say yes.

14 **Q.** And so that would be your practice in 2020. Was your
15 practice in 1992, 1993, 1994, any different from that?

16 **A.** No, not really.

17 **Q.** And so the basis for -- if we leave aside pre-test
18 counselling in the way in which you've described it,
19 the basis for your -- the statement in your witness
20 statement that it's never been customary to obtain
21 specific consent for hepatitis C testing, are you
22 there talking about written consent, or are you there
23 talking about the practice that hepatologists,
24 colleagues tell you that they just say, "Well, we're
25 going to test for a range of viruses," without saying

1 any more?

2 **A.** Well, we certainly did get written consent. We do get

3 written consent for genetic testing, but not for any

4 other tests unless they're invasive, of course.

5 **Q.** In relation to HIV testing, and I just wanted to

6 understand your understanding of the current position,

7 you've said in -- again, I think it's the same

8 paragraph of your witness statement, you say that --

9 you're talking about HCV you say:

10 "Unlike HIV, which almost uniquely requires pre-test

11 counselling during the '80s, '90s and until fairly

12 recently," and then the impression your statement gives

13 is that the current practice in relation to HIV testing

14 would not necessarily involve the patient being told

15 they were being tested.

16 **A.** Well, that's my understanding. I mean, I personally

17 haven't tested any new patients for some time. If

18 someone came out of the blue and their last treatment

19 had been during the period of this, I would still go

20 through all of that business. But at the beginning,

21 I'm sure you appreciate, different clinicians had very

22 different approaches to imparting someone's HIV status

23 to them. I felt that Professor Preston's approach was

24 a very good one, and some of my colleagues not so

25 good. And then it became universal practice to

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1 carefully counsel people before they were tested.

2 And I only mention that because I think that the

3 implications have changed with time because the

4 treatment is very much better, and very few of our

5 patients have died from HIV since 1995. Life

6 insurance is also less of a problem.

7 I mean, at one time, if you had asked for a house

8 loan above a certain level, the insurance company would

9 insist you had an HIV test. I've been HIV tested twice

10 myself on that basis, and my GP told me that half the

11 residents in Lymm had had an HIV test for that reason.

12 And he counselled me, despite the fact that he knew

13 I was a consultant haematologist.

14 So I've seen both sides of this, shall we say. But

15 all pregnant women are tested, and -- you know, so

16 practice does change.

17 **Q.** I wanted to then ask you about some of your evidence

18 yesterday in relation to life expectancy. So this,

19 professor, was in the context of having asked you what

20 consideration was given at Sheffield in 1983, 1984, to

21 the possibility of reverting to cryoprecipitate more

22 extensively, at least for a period of time. And you

23 referred, when giving your evidence about increased

24 risk of death and from haemorrhage and decreased life

25 expectancy, to a paper by Dr Rizza, and I wanted to

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1 check first of all that I've got the correct one.

2 WITN3289047.

3 **A.** "Haemophilia treatment in the UK from 1969 to 1974."

4 British Journal of Haematology, 1977.

5 **Q.** That's the document we asked you to read over lunch

6 which I'll come on to.

7 But first of all, yesterday, your evidence was

8 that this was a potentially relevant piece of

9 material, and this is one of the exhibits to your

10 statement.

11 **A.** Yes.

12 **Q.** We can see it's by Dr Rizza and Ms Spooner.

13 "Treatment of haemophilia and related disorders in

14 Britain and Northern Ireland during 1976-80: report on

15 behalf of the directors of Haemophilia Centres in the

16 United Kingdom."

17 **A.** Yes.

18 **Q.** If we go to the second page, right-hand column,

19 please, Soumik, under the heading "Age at death and

20 causes of death". I wanted to check whether this was

21 the material that you were referring to,

22 Professor Hay, as relevant to the assessment being

23 made in Sheffield in 1983 and 1984. So we'll see

24 under the heading "Age at death and causes of death".

25 Can we scroll down? Thank you. That's perfect.

99

1 You'll see it says in that first paragraph, in the

2 last two sentences:

3 "The average ages of the patients who died were

4 46.7 years in the haemophilia A group, and 48.3 years in

5 the haemophilia B group. Comparable figures for 69 to

6 74 were 42.3 years and 33.6 years respectively."

7 Then if we go to the next paragraph, please. It

8 says:

9 "A more useful statistic was the median expectation

10 of life."

11 I think it's easier if we just go back to how it was

12 before. Thank you.

13 "This was calculated from life tables.

14 Surprisingly, the calculations yielded a median life

15 expectancy of 69.1 years for severely affected

16 haemophiliacs, as compared to 72.8 for normal males.

17 Those figures must clearly be viewed with caution since

18 the numbers in the calculations were relatively small

19 and also because of the possibility that deaths in

20 haemophiliacs may not all be reported to Haemophilia

21 Centre Directors."

22 Then there's reference to the number of deaths due

23 to cerebral haemorrhage in the following paragraph, at

24 26 of 89 deaths (29%).

25 Now, first of all, is that the report or study that

100

1 you were referring to in your evidence yesterday?

2 **A.** Yes.

3 **Q.** And what is it that you drew from this report when

4 this issue -- well, sorry. I'm going to start that

5 again.

6 Was this something that was expressly considered in

7 1983 and 1984 when the question of how to respond to the

8 AIDS crisis may have been being discussed in Sheffield?

9 **A.** Well, it was published in 1983, in March. And the

10 perception certainly was that the introduction of

11 concentrate had significantly improved life

12 expectancy.

13 Now, in the paragraphs you've just quoted me, they

14 compare the average age of death, which is not quite

15 the same thing as life expectancy, but they compare it

16 with the previous reports from Rosemary Biggs, which

17 you suggested I should read over lunch.

18 And -- now, Rosemary Biggs doesn't use actuarial

19 methods or life table, so the average age of death is

20 the only metric for comparison, and I'm sure you're

21 going to point out to me that it has gone up relatively

22 modestly.

23 **Q.** Yes.

24 **A.** I think, though, the headline figure that people took

25 away was the median life expectancy of 69.1, which has

101

1 been much quoted since.

2 Of course, Rosemary Biggs was not the only source

3 of data. There were other studies showing the average

4 life expectancy at that time was about 40, but -- you

5 know, back in the '60s and very early '70s, but it's

6 quite difficult comparing all these things because

7 people use different methods.

8 I've recently written a review which is about to be

9 published in the Journal of Thrombosis and Haemostasis

10 on mortality and haemophilia, and this is a difficulty

11 that besets the whole area. It's actually quite

12 difficult to compare.

13 Now, one other thing I'd say about the comparison

14 between these two is they report adjacent periods. And

15 the second report from Charlie Rizza is reporting

16 a period during which concentrate is being introduced

17 and patients established on home therapy. So you would

18 perhaps not expect a really dramatic difference because,

19 in terms of the therapeutic approach, the two periods

20 overlap somewhat.

21 What it's showing is a trend towards improved life

22 expectancy that would not flower fully until the period

23 after 1980, when most people were established on home

24 therapy.

25 **Q.** If we just look at the Biggs report because you've got

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1 the benefit of it and I have, but others watching

2 don't, so I'll just put it on screen.

3 It's PRSE0004645.

4 Soumik, it'll be in the knowledge of risk material,

5 so you may have it stored in a separate location.

6 **A.** It was part of my submission, as an exhibit, actually.

7 **Q.** We now have on screen and I know you have a copy,

8 Professor, the Biggs report. So we'll see that covers

9 period '69 to '74. And if we go to the fourth page of

10 that, please, Soumik.

11 **SIR BRIAN LANGSTAFF:** Can we just stop at the first page.

12 **MS RICHARDS:** Yes, back to the first page, please.

13 **SIR BRIAN LANGSTAFF:** And underneath the summary, just the

14 very first sentence, because before -- around

15 about 1960, as one understands it, the life expectancy

16 of a haemophiliac suffering from severe haemophilia

17 was probably in the region of 20 to 25 years. It

18 hadn't gone up very much since the 1930s. It had gone

19 up a bit but not much. That's probably about right,

20 is it?

21 **A.** Yes, it's about right. It's -- life expectancy was

22 about 29 years. And it improved a lot from the

23 no treatment era, when it would have been about ten or

24 15 years, and so from the 50s they would have had

25 blood transfusion and plasma, and cryoprecipitate was

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1 introduced in the mid to late 1960s.

2 **SIR BRIAN LANGSTAFF:** That's why I think Rosemary Biggs is

3 referring here, in the first sentence, is it, to 1967

4 because that's when cryoprecipitate would have been

5 introduced?

6 **A.** Yes, widely. I think it was described in '66.

7 **SIR BRIAN LANGSTAFF:** Yes.

8 So the first sentence she says -- is observational.

9 It expresses an opinion. Is that an opinion you would

10 agree with? That:

11 "Increasing amounts of cryoprecipitate and of

12 Factor VIII and Factor IX concentrate have greatly

13 improved the prospect for treatment of patients

14 suffering from A and B."

15 **A.** Yes.

16 **SIR BRIAN LANGSTAFF:** Thank you.

17 **A.** Unquestionably.

18 **SIR BRIAN LANGSTAFF:** So unquestionably the introduction

19 of cryoprecipitate, then, and later we know that

20 concentrates, the NHS concentrate, from probably about

21 1970 onwards, we're informed, formed an increasing

22 part of treatment, and then commercial concentrate,

23 when there wasn't enough NHS to go round, from about

24 1973 onwards. That, I think, is broadly the position,

25 isn't it?

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1 A. I agree.

2 **SIR BRIAN LANGSTAFF:** You weren't practising at the time

3 so this all done by report so I'm putting a very broad

4 picture to you. I'm not going to hold you to a point

5 answer, but I think that is broadly the

6 understanding --

7 A. No, no, I was a medical student at the time, but

8 obviously I've gone into the history.

9 **SIR BRIAN LANGSTAFF:** So you were going to go to the

10 fourth page --

11 **MS RICHARDS:** Yes.

12 **SIR BRIAN LANGSTAFF:** -- Ms Richards, I'm sorry.

13 **MS RICHARDS:** And to draw attention in particular for the

14 benefit of those listening -- Professor Hay has a hard

15 copy -- to the top of the page:

16 "In the early statistics the average age of death of

17 severely affected haemophilic patients was less than

18 20 years. Thus the age at death seems to have more than

19 doubled as a result of Factor VIII therapy."

20 And of course, I think we know broadly that in the

21 period she's here looking at, up until 1974, the

22 majority of Factor VIII therapy would have been

23 cryoprecipitate, although, as you've just observed, of

24 course, concentrates were starting to be used and were

25 then used much more increasingly in the years that

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1 followed.

2 A. Yes.

3 **SIR BRIAN LANGSTAFF:** Yes, I mean, the precise amounts of

4 cryoprecipitate compared to the precise proportion

5 is -- will be a matter for us to explore elsewhere,

6 but I think broadly what you've said must be right.

7 A. Yes, absolutely. And you should get those figures

8 that we have in the UKHCDO statistical response to

9 their Rule 9.

10 **SIR BRIAN LANGSTAFF:** Thank you.

11 **MS RICHARDS:** Then we can see reference in the table to

12 the age at death of patients having haemophilia A or

13 B, and for present purposes I'll just look at

14 haemophilia A. And we can see there the average age

15 at death: 42.3. And whilst we're looking at it, just

16 to observe, we also see the number of deaths from

17 intracranial bleeding, which -- the figures in both

18 reports are fairly small, but it's 16 out of 62, which

19 I think would have been approximately 25, 26 per cent

20 of deaths from that cause in that period.

21 This is looking at it very broadly, Professor Hay,

22 but is this right: before the availability of any form

23 of Factor VIII therapy, and so before the availability

24 of cryoprecipitate, the average age of death was around

25 25 years or so. But according to Dr Biggs in this, it

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1 almost doubled during the period '69 to '74, when most

2 of the Factor VIII therapy producing that result would

3 have been cryoprecipitate?

4 A. Well, I think my interpretation of what she is saying

5 is that it doubled from the period before

6 cryoprecipitate to the period that she is looking at.

7 **SIR BRIAN LANGSTAFF:** Yes.

8 A. Because the use of cryoprecipitate was already

9 well established in 1969, I think.

10 **MS RICHARDS:** Then when we look at the period covered by

11 Dr Rizza's report, we can see that the average age of

12 death increases again, but it's a much smaller margin,

13 around two and a half years.

14 A. Yes --

15 **SIR BRIAN LANGSTAFF:** It's about 10%, isn't it?

16 A. -- I'd agree with that, and to be honest, I think that

17 the actuarial calculation paints a much rosier picture

18 but you can't use that to compare with the earlier

19 period, because there isn't a similar calculation in

20 Rosemary Biggs' report. And I think that the period

21 that Charlie Rizza is reporting is a sort of

22 intermediate period, because it's a period during

23 which some centres are quite well advanced in

24 converting to concentrate, and others much less so.

25 But I know from the history of the Manchester Centre

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1 that there were still patients being treated with cryo

2 in the early eighties, and whilst I appreciate that

3 they were unusually conservative in their approach to

4 treatment in the Manchester Centre, it was a more

5 gradual process than I had realised.

6 Yes.

7 Q. And so would this be fair: that these two reports

8 don't provide any significant support for a conclusion

9 that reversion to cryoprecipitate in 1983,

10 particularly for a relatively short period of time,

11 maybe a couple of years, would have led to

12 a significant increase in deaths or a significant

13 decrease in life expectancy?

14 A. Well --

15 **SIR BRIAN LANGSTAFF:** You're asking in the absence of

16 HIV infection?

17 **MS RICHARDS:** Yes. Yes, we know, of course, as well

18 established in later reports, including those

19 co-authored by Professor Hay, that as a matter of

20 fact, the greatest impact upon mortality in the years

21 that followed was viral infection of HIV.

22 **SIR BRIAN LANGSTAFF:** Yes, but people would not have known

23 that --

24 **MS RICHARDS:** No.

25 **SIR BRIAN LANGSTAFF:** -- at the time for the purposes of

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1 this comparison?

2 **A.** Well, I think that I would agree that the increment in

3 life expectancy between these two reports is

4 relatively modest. It's not insignificant. And you

5 also have to recognise that the second report is an

6 intermediate period when there's still a lot of

7 patients being treated with cryoprecipitate, and not

8 everyone has been established on home therapy.

9 You will see that if you look at the report of the

10 Prophylaxis and the Home Therapy Working Parties from

11 the seventies and early eighties. I was unaware until

12 recently of the existence of this working party but

13 they did actually audit their roll-out of home

14 therapy, and it was slower than I had realised.

15 I think my view was rather coloured by my personal

16 experience in Sheffield, and I had assumed that all

17 other centres were as quick to do it as they were. But

18 that is actually not the case.

19 **MS RICHARDS:** Sir, I'm going to move on to a separate

20 topic. Before I do so, was there anything further

21 that you wished to ask --

22 **SIR BRIAN LANGSTAFF:** Only this, really: I just draw your

23 attention to the risk, I think, or the cause of death,

24 proportionately, which Dr Rizza in his paper

25 identified as being intracranial bleeding. I think it

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1 was about 29%, he said, of the cases that he was

2 looking at, died of that, if they didn't die of other

3 causes.

4 If one takes the 16 that we're looking at, it's

5 table III, the first item, "Intracranial bleeding",

6 then the total number of cases, 62, it's about -- just

7 over 25 per cent, it'd be 25% if it was 64. So it is

8 just over 25%. But there's not a great deal of

9 difference in those two figures, for what it's worth;

10 is there?

11 **A.** No, true, but -- I agree, and intracranial bleeding

12 was the commonest cause of death during that period.

13 But I would come back to the fact that, you know,

14 you wouldn't expect a dramatic difference looking at

15 two periods when, in one case, everyone is treated

16 with cryo and, in the second, you have a transitional

17 period, they're not all on home therapy during this

18 second period, or not for the whole of that period.

19 I can tell you that the number of patients dying

20 from intracranial haemorrhage now is less than 10%.

21 So treatment with concentrate, as currently practiced,

22 and with prophylaxis -- which may of course be very,

23 very important, because you will expect to prevent

24 a lot of the bleeds that might have occurred with

25 treatment on demand, but we have reduced that

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1 complication quite dramatically.

2 **SIR BRIAN LANGSTAFF:** I can full understand the

3 significance of prophylaxis, but just comparing these

4 two sets of data -- for what it's worth, as you've

5 indicated, they're not exactly comparable -- this --

6 well, what you're looking at on the screen at the

7 moment, the Biggs paper, is at a time when there was

8 some but very little home therapy, I think. Am

9 I right?

10 **A.** Yes, I think that's correct.

11 **SIR BRIAN LANGSTAFF:** So the two changes were -- it wasn't

12 just a change from a little Factor VIII concentrate to

13 a lot of Factor VIII concentrate, proportionately, but

14 also a change from a little home therapy to a lot of

15 home therapy proportionately. You still have a fairly

16 comparable death rate in these two studies over the

17 two periods so far as intracranial bleeding is

18 concerned. It doesn't allow for a very dramatic

19 distinction between the two, does it?

20 **A.** No.

21 **SIR BRIAN LANGSTAFF:** Thank you.

22 **MS RICHARDS:** Professor Hay, I've got a number of

23 questions now that I've been asked to ask by core

24 participants, and so we're going to dot about from

25 topic to topic, rather than follow a chronological or

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1 thematic order.

2 The first arises out of a passage in your statement

3 about research where you describe the difference between

4 an interventional study and observational research, and

5 your statement explains the different ethical

6 requirements that might attach to each.

7 Is the distinction between an interventional study

8 and observational research always clear-cut?

9 **A.** No, I don't think it is, actually. It may be a matter

10 of opinion.

11 We recently conducted a study internationally --

12 not UKHCDO, by the way, but investigator-led study --

13 which involved applying a number of quality of life

14 questionnaires to the patient at intervals. They had

15 to give consent to this anyway because -- you know,

16 written informed consent, but it wasn't regarded as an

17 interventional study in six out of the seven

18 countries. The seventh country was France, and in

19 France they said, well, if we'd asked fewer questions,

20 it would have been an observational study, but they

21 regarded it as an interventional study because it took

22 the patients more than an hour to fill out the forms.

23 And I think that illustrates a classical grey area,

24 and I can see their point, but that came down to a

25 matter of judgment.

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1 There are other studies where you may have -- you
 2 may record the results of interventions that are
 3 clinically indicated, and that should make it an
 4 observational study because the intervention would have
 5 occurred anyway -- for example, an operation or a blood
 6 sample or whatever -- and the intervention has not been
 7 done for the purpose of research. Because it's not been
 8 done for the purpose of research, that would be an
 9 observational study. But if you were to test a new
 10 agent such as a new Factor VIII concentrate, to
 11 establish safety and efficacy, that's unquestionably an
 12 interventional study because the patient wouldn't be
 13 given that agent if they weren't participating in the
 14 study. But once that same agent is fully licensed and
 15 we start to prescribe it in the normal way, when they
 16 participate in, of course, marketing surveillance study,
 17 that's an observational study, because they would be
 18 having that agent whether they were participating or
 19 not.

20 **Q.** Is there a risk --

21 **SIR BRIAN LANGSTAFF:** May I just ask a question?

22 **MS RICHARDS:** Yes.

23 **SIR BRIAN LANGSTAFF:** Just going back to the start of your
 24 answer there, you were describing where the
 25 intervention would have been done anyway, and you're

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1 simply observing the effect of it. That would be
 2 observational.

3 One of the situations I've come across on a number
 4 of occasions in cases which I've had to determine in
 5 the past have been cases where there were two possible
 6 forms of treatment: one conservative, the other
 7 interventionist. Both were entirely proper as a
 8 matter of practice, but the choice was left to the
 9 clinician. If the clinician chose the interventionist
 10 and had in the back of his mind that this might be
 11 a benefit to research which he was particularly
 12 interested in doing, would that make it
 13 interventionist or observational?

14 **A.** Well, that's an interesting question that speaks to
 15 the intent of the person in question. And that's
 16 a really grey one because if he was influenced by the
 17 fact that it was being studied and that introduced
 18 bias, that is -- that's actually a problem because it
 19 affects not only the ethics of the study but also its
 20 interpretation, because you want to avoid that sort of
 21 bias, you know? That is the advantage of a randomised
 22 comparison because then you have negated any biases
 23 from the operators. And randomised comparisons are
 24 always interventional by definition but can be
 25 difficult to conduct.

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1 I conducted a randomised trial comparing high dose
 2 with low dose immune intolerance, for example, in 17
 3 countries, and the biggest difficulty that we had there
 4 was that we were doing the study because so much was
 5 unknown, but nevertheless, clinicians around the world
 6 had very fixed views. They were all convinced that they
 7 were doing it the right way, and if they had, we
 8 wouldn't have needed to do a trial. So many refused to
 9 participate because they disagreed with our protocol.
 10 You know, what can you do? So ... yeah, it's difficult.

11 **MS RICHARDS:** And picking up from the Chair's point,
 12 professor --

13 **SIR BRIAN LANGSTAFF:** Well, it was a question, not
 14 a point.

15 **MS RICHARDS:** Sorry, question.

16 Is there a risk that observational research, the
 17 undertaking of observational research, the desire of
 18 a clinician to follow that through, might lead
 19 a clinician to keep a patient on the same treatment,
 20 rather than changing to what might have been a safer
 21 treatment?

22 **A.** I think that's unlikely. That would be really
 23 unethical.

24 **Q.** And in the early and mid-'80s, and I think you were
 25 engaged in research from roughly 1983 onwards at

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1 Sheffield, but in that period of time in the early and
 2 mid-'80s, what were the safeguards against clinicians
 3 undertaking something that was unethical, or
 4 a safeguard that might address some forms of
 5 subconscious or unconscious bias?

6 **A.** Well, subconscious or unconscious bias is a problem in
 7 research anyway throughout which is why the strongest
 8 evidence is always considered to be the results of
 9 a randomised controlled trial. Not that that trial
 10 design has -- doesn't have weaknesses, because it's
 11 often criticised because the subjects that participate
 12 in such a trial are selected, but it's the most
 13 reliable way of excluding bias.

14 Occasionally, you can also exclude bias by
 15 following natural experiments. And one example of
 16 that is a trial -- well, not a trial, an observational
 17 study that we conducted between Scotland and England,
 18 looking at the effect on the immune system of
 19 different types of concentrate.

20 Now, in those situations, the whole of Scotland used
 21 a Scottish high-purity product that had been prepared in
 22 one way because that was what was available to them, and
 23 the whole of England used different materials. So just
 24 through circumstance, you had two groups that were all
 25 treated in the same way, and that offered the

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1 opportunity to compare the two.
2 In a way, the next best thing would have been to
3 randomise them. And incidentally, the participants
4 were -- although it was an observational study, we had
5 to collect a lot more data than would have been normally
6 the case, so they were consented in the same way as they
7 would have been for an interventional study.

8 **Q.** Do you know --

9 **A.** The thing to do, to be honest, and this is what we try
10 to do currently, is to assess each case individually
11 and to make a judgment: is this an observational
12 thing? If you have to take additional samples, or are
13 you doing something burdensome, then it becomes
14 interventional, and you have to get consent for that.

15 **Q.** Do you know, in that period of '83 to '87 when you
16 were at Sheffield, and I appreciate you were the
17 junior to Professor Preston and Dr Greaves in terms of
18 your role at the time, but do you know what, if any,
19 ethical approval systems or other safeguards there
20 might have been in place at that time?

21 **A.** Well, the details have changed over the years, but the
22 basic principle has been the same throughout this
23 period. That is, if you want to do a clinical trial,
24 you have to take it to the Ethics Committee. They
25 have to approve everything, not least the patient

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1 information and the consent form. They have lay
2 members on every Ethical Committee, and they take
3 a particular interest in that area, as you might
4 expect. They also have statisticians on an Ethics
5 Committee.

6 So if, for example they consider that the trial
7 design is inadequate, then they could -- that is an
8 ethical issue. It's unethical to do a clinical trial
9 that is inadequate to answer the question because it
10 potentially puts -- in theory, it would possibly put
11 patients in harm's way without having any hope of
12 answering the question, and that would be considered
13 unethical.

14 So if you want -- if you participate in a clinical
15 trial of a new product, for example, the Alphanate trial
16 that was conducted in Sheffield in 1984, all the
17 participants would have been consented.

18 **Q.** That's, I think, the trial that you referred to
19 yesterday, is it, with the heat-treated products?

20 **A.** Yes.

21 **Q.** Did you have any involvement in that trial yourself,
22 in terms of selection of patients and what information
23 was or wasn't given to the patients?

24 **A.** Well, I don't remember much about it because it covers
25 a period when, for part of that time, I was at the

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1 Children's Hospital, partly because I was moving
2 about, they got the other senior registrar to get more
3 involved, and her name is actually one of the
4 co-authors. But my recollection is that patients were
5 given an information sheet and had to write consent.

6 **Q.** Moving to a different topic -- no, actually, sorry,
7 before leaving that. That trial -- would that trial
8 have gone before any kind of Ethics Committee for
9 approval?

10 **A.** Oh, yes, yes. At that time, they would have all been
11 hospital ethical committees. Much later, they
12 introduced a system for national approval, so you go
13 to an MREC, and they're arranged regionally for
14 multi-centre trials involving more than four centres.
15 But even when you get national approval, you still
16 have to take it to your local Ethics Committee and
17 your local R&D department and get approval from both
18 of them before you're allowed to start.

19 **Q.** And then moving to a completely different topic, in
20 your capacity as hospital haematologist responsible
21 for the blood bank, which I think was when you were at
22 Liverpool, did you ever become aware of any ongoing
23 issue about HBV infection and pools contaminated with
24 hepatitis B?

25 **A.** No, I can't remember.

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1 **Q.** This morning, I asked you about the notification
2 process in relation to variant CJD. Do you know
3 whether there was any, in earlier years, any
4 notification system to UKHCDO of suspected
5 contaminated batches -- contaminated with HIV or with
6 non-A, non-B hepatitis, hepatitis C? Was that
7 something that used to be drawn to the attention of
8 UKHCDO directly?

9 **A.** We had an adverse event working party and an adverse
10 event reporting system which I will be describing to
11 you in greater detail in the final chapter of our
12 UKHCDO Rule 9, and that collected adverse events,
13 including any new reports of hepatitis from the early
14 1980s onwards. I was a member of that committee.

15 The data was collated by the National Haemophilia
16 Database. We did -- we do report adverse events that
17 we think are specifically related to a product to the
18 manufacturer so that they can satisfy their regulatory
19 requirement to report it on to the regulators. That's
20 the European Medicines Agency and the Food and Drug
21 Administration.

22 This has result in the withdrawal of some batches,
23 which seemed to be giving lots of reactions, for
24 example. The investigation of new reports of hepatitis
25 after about 1988 all proved to be false reports, insofar

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1 as it was genuine hepatitis but not a new diagnosis.
2 You can imagine that we were particularly keen in
3 the years after 1985, when products had been introduced
4 that were marketed as only hepatitis-reduced, to
5 evaluate any further episodes of hepatitis sneaking
6 through.

7 And there were certainly reports with some products
8 in Canada as late as 1988 of some of the virally
9 attenuated products transmitting hepatitis C.
10 And hepatitis B seemed to be more difficult to eradicate
11 than hepatitis C, but then, on the other hand, all the
12 donors were tested for hepatitis B from probably the
13 early 1970s. So the only patients who would have got
14 through that testing net would have been those who were
15 in the window period at the time that they donated.
16 That is to say, the period when they were incubating
17 hepatitis B but had not yet become positive for the
18 tests. The window period, which we haven't discussed so
19 far, is a problem with the all viruses, and another one
20 of the reasons why we wanted to get away from
21 plasma-derived products.

22 If you go through this period, from the eighties
23 through to -- well, the present day, really, you will
24 see that donors have been subjected to more and more
25 tests, of increasing sensitivity, to progressively

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1 reduce that window period. And of course, donor
2 selection is also very important with all of that.

3 The other thing that's really important that we
4 haven't talked about before is repeat donation, because
5 the safest donor is a donor that repeatedly donates. If
6 you go back to the early 1980s, 50% of UK blood donors
7 were first time donors, and often the only time they
8 donated. They may only have donated once. And if you
9 test those for viruses, you'll find most of the
10 positives will be in first-time donors. So they are the
11 most risky donors. The safest donors are donors who
12 come repeatedly. And of course they're tested every
13 single time.

14 By the end of the eighties, at least 90% of blood
15 donors were repeat donors. And in the commercial
16 sector, people encouraged that too. So these days, most
17 plasma is actually derived from plasmapheresis donors,
18 who can donate far more frequently, because they're only
19 donating plasma, and they can donate as often as once
20 a month.

21 Anyway, I think I drifted off the subject a little.

22 **SIR BRIAN LANGSTAFF:** May I just ask a question.

23 **MS RICHARDS:** Yes.

24 **SIR BRIAN LANGSTAFF:** You were going to back to the early
25 1980s, and you said 50% of the blood donors then were

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1 first time donors, and most of the positives were in
2 that group. If you're talking in terms of positivity
3 for hepatitis C, or non-A non-B, as it was, how do you
4 know?

5 **A.** Well, that's a good question.

6 You'll see in my report, and in fact in some of
7 the exhibits -- the exhibit you showed me earlier
8 which has the proposal to the Department of Health of
9 the hepatitis C look-back -- who reviews this evidence
10 quite well, I thought, rereading it -- in the early
11 eighties there were a number of studies trying to
12 assess the frequency of non-A, non-B hepatitis.
13 Obviously without a specific test. And the way that
14 they approached it was they saw how many recipients of
15 multiple blood donations subsequently developed
16 hepatitis. Now, these would be patients undergoing,
17 say, open heart surgery, or some other surgical
18 intervention that required a large blood transfusion.

19 So they would be exposed to a number of donors as
20 a consequence of that. So you could evaluate how many
21 donations they'd been exposed to, and then you see what
22 percentage of them develop non-A, non-B hepatitis
23 thereafter. And from that you derive a figure for the
24 number of the donors that were infectious for non-A,
25 non-B hepatitis.

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1 Now, clearly, that methodology is relatively soft,
2 and you'll find somewhere in my exhibits there is
3 a table -- I know you're going to subject this to
4 independent statistical analysis -- which shows the risk
5 of contracting non-A, non-B hepatitis, based on the
6 number of donations that you're exposed to, and it gives
7 a range of percentage. The average is about 0.75% of
8 blood donors being infectious for non-A, non-B hepatitis
9 in the very early '80s, based on that methodology, but
10 it varied.

11 There are a number of papers that looked at this
12 from different countries, and of course, we do know that
13 the incidents of hepatitis C varied from country to
14 country. It was higher in America than in the UK, and
15 higher again in places like Italy and Japan, for some
16 reason, also had relatively high rates. So the rate
17 will genuinely vary from country to country. But based
18 on that soft methodology, in the early '80s we think it
19 would have been between about 0.5 and 1%.

20 Now, there are papers later on in that decade from
21 Contreras et al which I also quote. Once they had
22 a test, they were able to assess the prevalence in the
23 donor population accurately, bearing in mind also that
24 the donor population is not a cross-section of society.
25 You know, there are certain ethnic groups that donate

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1 less, which is actually a practical problem because
 2 there are ethnic differences in the frequency of blood
 3 groups as well. So that does give rise to practical
 4 problems.
 5 When I did my transfusion training, for example,
 6 blood donations from people from the Afro-Caribbean
 7 community were coded so you could identify them because
 8 they were particularly useful if you had a patient with
 9 sickle cell trait, for example, if they needed
 10 a transfusion.
 11 Anyway, I'm drifting again. Um -- (overspeaking) --
 12 **SIR BRIAN LANGSTAFF:** If I can --
 13 **A.** -- (overspeaking) -- this paper --
 14 **SIR BRIAN LANGSTAFF:** Sorry, you're going to talk to me
 15 about the Contreras paper. Sorry, I'm interrupting.
 16 My apologies. Please.
 17 **A.** The Contreras paper showed a tenfold reduction
 18 relative to those early soft indication -- early soft
 19 assessments. And this was attributed to the
 20 introduction of donor selection.
 21 Now, although donor selection -- you know, this is
 22 pre-donation exclusion. This is the process whereby
 23 all prospective donors have to read the leaflet, and
 24 if they fall into the following risk groups, not
 25 donate, please. Of course, although this was directed

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1 at the reduction in the risk of HIV, there is an
 2 overlap in the risk groups for HIV and hepatitis C,
 3 clearly. So donor selection dramatically reduced the
 4 risk of hepatitis C as well.
 5 **SIR BRIAN LANGSTAFF:** Just going back to the start of your
 6 answer, the question really arising out of your
 7 comment that about 50% of the donors would have been
 8 one-time donors, and they were the ones who created
 9 more of a problem than the regular donors back in the
 10 early '80s.
 11 Suppose that you had -- as your first example was
 12 surgery, involving quite number of transfusions,
 13 suppose, let's say, ten bags: five from first-time
 14 donors, five from other donors. How would you know
 15 which bag contained the infection if the person who was
 16 having the surgery actually later on developed and
 17 showed signs of hepatitis non-A, non-B? That was
 18 the point I was trying to understand.
 19 **A.** I see. Well, in the absence of a test, you wouldn't
 20 necessarily. You could go back to all those donors
 21 and test them for what you knew about, see if any of
 22 them had chronic liver disease and take a history.
 23 **SIR BRIAN LANGSTAFF:** Was that done, do you know?
 24 **A.** Well, there were latterly look-back exercises
 25 conducted by the Transfusion Service, but they did not

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1 occur until after hepatitis C testing became
 2 available, and they were really directed at people who
 3 were repeat donors who turned out to be positive for
 4 hepatitis C, then they went back and traced the
 5 recipients of previous donations.
 6 **SIR BRIAN LANGSTAFF:** I understand the repeat donors, it's
 7 the one-time donor and their infectivity which I was
 8 really trying to understand.
 9 **A.** The one-time donor, you couldn't do anything about.
 10 **SIR BRIAN LANGSTAFF:** Does it come down to the fact that's
 11 an estimate, really, which you have given us, which
 12 has, as far as you know, no basis in the literature?
 13 **A.** Sorry, I don't understand.
 14 **SIR BRIAN LANGSTAFF:** It's all right, it's probably more
 15 of a comment than a question.
 16 That's all I need to ask. Thank you very much.
 17 **MS RICHARDS:** Sir, I've got some questions still, but
 18 I note the time and I think it might be sensible to
 19 have a break and then I can complete the questions.
 20 **SIR BRIAN LANGSTAFF:** Yes, of course.
 21 Counsel will -- she needs to field questions from
 22 people who aren't here, to talk to her and give her
 23 further questions, because you will appreciate that
 24 counsel to the Inquiry ask the questions in an
 25 inquiry, and, in general, core participant counsel

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1 don't. That's a generality, but it's likely,
 2 I suspect, to be true in this case, particularly when
 3 they're not here in any event.
 4 So we shall take some time just to do that. How
 5 long do you think you need?
 6 **MS RICHARDS:** I've got most of the questions, sir, there's
 7 only a handful I haven't been able to consider, so
 8 half an hour will be ample. But that will give
 9 Professor Hay an opportunity to take a break and those
 10 watching to have an opportunity to take a break as
 11 well.
 12 **SIR BRIAN LANGSTAFF:** Yes, so we'll have a cup of tea and
 13 come back at -- will four o'clock be all right?
 14 **MS RICHARDS:** Yes.
 15 **SIR BRIAN LANGSTAFF:** Will four o'clock be okay?
 16 Four o'clock.
 17 **(3.25 pm)**
 18 **(A short break)**
 19 **(4.00 pm)**
 20 **SIR BRIAN LANGSTAFF:** Yes.
 21 **MS RICHARDS:** Professor Hay, you told us yesterday that in
 22 relation to Sheffield, there was no programme for
 23 prophylaxis and that that was formally introduced many
 24 years later. Were you aware of patients on home
 25 treatment administering treatment to themselves on

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1 a prophylactic basis?
 2 **A.** There were patients during the 1970s and in fact there
 3 was a Prophylaxis and Home Therapy Working Party
 4 chaired by Dr Peter Jones. I have been unable to
 5 source any of the minutes of their meetings but they
 6 did report on an annual basis to the annual general
 7 meeting of the UKHCDO and their findings are of some
 8 interest.

9 I think that the -- I wasn't aware of this working
 10 party at the time, you understand, but Peter Jones was
 11 quite well known. He wrote a chapter on comprehensive
 12 care in the first edition of Hemostasis and Thrombosis,
 13 which was one of the first textbooks of haemostasis
 14 I ever bought. And that chapter influenced me, and it
 15 did describe prophylaxis and prophylaxis was being
 16 practiced quite widely in his centre, and at Lord Mayor
 17 Treloar. And during that time, they published some
 18 papers on prophylaxis which you're probably aware of.
 19 So I was aware of prophylaxis, and it had been pioneered
 20 by Inga Marie Nilsson in Malmo in Sweden, and to some
 21 extent also in Holland.

22 So we knew about it, particularly in children, but
 23 it wasn't widely practiced for a number of reasons, not
 24 the least of which was the relatively inadequate supply
 25 of product, and then of course, when HIV came along,

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1 meetings of all sorts to have a commercial exhibition
 2 where manufacturers are allowed to set up a stall.
 3 That, again, is regulated in various ways, and the
 4 regulations will vary from country to country.
 5 **Q.** And what, if any steps, were taken within UKHCDO to
 6 try to ensure that this sponsorship didn't influence
 7 members' decision making about which products to
 8 purchase for treatment at their centres?
 9 **A.** I don't think UKHCDO felt that they had a part to play
 10 in that. Latterly, a lot of this is regulated because
 11 we purchased these products through a national
 12 contract, and that has been the case for a number of
 13 years. On an individual basis, though, I don't think
 14 UKHCDO felt that it had a role to play, or indeed
 15 could. You know, in individual conversations, people
 16 would recognise that being dependent on a single
 17 manufacturer was probably a bad idea anyway, because
 18 it made you very vulnerable to issues of supply should
 19 that manufacturer have a problem, and it would also
 20 open you up to an accusation of bias. So it was
 21 normal and general practice to have two or more
 22 suppliers, mostly more.
 23 **Q.** Would you have expected, in the 1980s, discussions
 24 about risks and the possible consequences of
 25 contracting non-A, non-B hepatitis or AIDS, if those

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1 treatment intensification did not seem like a very good
 2 idea.

3 **Q.** I know there was no programme of prophylaxis in
 4 Sheffield, but were patients informally, and of their
 5 own initiative, using their home treatment on
 6 a prophylactic basis, to your knowledge?

7 **A.** No, I don't think that they were. Not at that time.

8 **Q.** Then moving from that to funding from pharmaceutical
 9 companies to UKHCDO, during your time as a member of
 10 UKHCDO, how were decisions made about which
 11 pharmaceutical company would fund the annual general
 12 meeting?

13 **A.** Well, the manufacturers would approach UKHCDO and
 14 request to sponsor. It was very common, and still is,
 15 for pharmaceutical companies to offer sponsorship for
 16 meetings. That is all regulated. We would wish to
 17 have sponsorship from as many different sources as
 18 possible to avoid any accusation of bias.

19 **Q.** And what involvement, if any, in the annual general
 20 meeting would this sponsorship give the pharmaceutical
 21 company?

22 **A.** They would be allowed to attend certain parts of it.
 23 They would not be allowed to attend business meetings.
 24 And they would be allowed to set up a stall in an
 25 exhibition area. It's very common for scientific

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1 discussions took place, to be recorded in a patient's
 2 medical records?

3 **A.** Well, um ... how should I put this? Certainly in my
 4 own medical records you'll get more from reading the
 5 letters than what I've written. It may only be
 6 mentioned in passing. It was commonly advised that
 7 any critical discussions, for example, discussions of
 8 Jakob-Creutzfeldt Disease, hepatitis C or HIV, should
 9 be noted, even if it's only a short note.

10 **Q.** Is the answer to the question, then, they should be
 11 noted but they weren't always --

12 **A.** I think that's probably correct.

13 **Q.** -- in your experience?

14 **A.** I would say that the absence of a note doesn't mean
 15 that the conversation has not taken place, although
 16 I know that it would be a common legal judgment to the
 17 contrary.

18 **Q.** What role, if any, did lifestyle advice, with the aim
 19 of reducing bleeds, have on the treatment of patients
 20 under your care in the eighties, in particular mild
 21 and moderate haemophiliacs?

22 **A.** Well, it was well recognised early on that the
 23 patient's lifestyle affected their tendency to bleed,
 24 and the patients were certainly very well aware of it.
 25 They find out from experience the sort of activities

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1 that might cause them to bleed, and many of my
2 patients have talked to me about the way in which
3 haemophilia hangs over them like a cloud and they're
4 constantly worrying that they might do something that
5 might set something off. You know, something as
6 trivial as stepping awkwardly off a pavement might
7 cause an ankle bleed.

8 Not every patient is like that, of course, and,
9 you know, it was early observed that, for example, you
10 might have a pair of brothers, and one brother is
11 never out of hospital, and you hardly ever see the
12 other one, and the other one's probably got his nose
13 in a book, whilst brother number 1 is bouncing off the
14 walls. And so personality does come into it.

15 There are also other aspects of the clotting
16 mechanism that mean that some patients bleed much less.
17 About 10% of patients with severe haemophilia have
18 a relatively mild bleeding phenotype.

19 So early on, people would be advised to avoid
20 contact sports, to remain physically fit if they could,
21 because if they had good muscle bulk, they would be less
22 likely to bleed, but not to go looking for trouble,
23 essentially. So no rugby, no football, and no boxing,
24 that sort of thing. But running, cycling, swimming were
25 all good things to do and were encouraged, and we

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1 eventually started to encourage people to go to the gym
2 as well. So lifestyle was quite important.

3 **Q.** And then if we could have on screen HSOC -- this on
4 a completely different topic, professor -- 0005123,
5 please, Soumik.

6 So this is a letter from you to Mr Barker at the
7 Haemophilia Society in November 1994. If you could go
8 down to the bottom half of the page, please.

9 You say this:

10 "I would very much like to have a chat with you
11 about hepatitis C. I am obviously sympathetic towards
12 increasing patient awareness, but I do not feel that the
13 recent press coverage has been helpful in any way."

14 Then you talk about one specific patient, and I'm
15 not going to ask you about the specifics in relation to
16 that or any other individual.

17 Then you say:

18 "I'm rather worried that the whole thing is getting
19 out of hand. If the Society wants patients who have
20 contracted hepatitis C to obtain some compensation, I am
21 not sure that encouraging them in their mistaken belief
22 that they have a good case of negligence is the right
23 way to go about it. I get the strong impression that
24 although that's not the Society's official view, that
25 some members of the executive are certainly encouraging

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1 this point of view, and a lot of the lawyers ... are
2 doing so. I no longer have any very clear idea of the
3 Society's position on this, despite the recent rather
4 vague press releases, and I would like to talk to you
5 about it."

6 What was the purpose of writing to Mr Barker in
7 these terms and the purpose of asking to discuss this
8 issue with him?

9 **A.** Well, I wanted to know what the Haemophilia Society's
10 view about litigation was. Because a lot of cases
11 were being brought which had little chance of success,
12 because to succeed, they would have had to prove
13 individual negligence, and the patients in question
14 had not been managed in an unusual way. There were
15 patients who had severe haemophilia but were,
16 nevertheless, claiming that they should have been
17 treated with DDAVP, though they would not have
18 responded to that.

19 Now, I had every sympathy with their desire to be
20 compensated, because they had clearly been damaged by
21 their treatment. And my feeling at that time was that
22 surely this was a classical example of a situation where
23 there should be some form of no-fault compensation
24 scheme. But, in fact, I was told that whilst there was
25 all this litigation going on in the background, no such

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1 scheme would be put together.

2 So, you know, a lot of the litigation that was going
3 on at that point seemed unlikely to succeed. There was
4 more and more of it. We then had the campaign where
5 a whole series of patients from around the country
6 reported the Centre Directors to the General Medical
7 Council, claiming various acts of professional
8 misconduct, which were, as far as I knew, and certainly
9 in relation to the two complainants against me,
10 completely false.

11 And, you know, I was very sympathetic towards
12 a campaign for compensation, but that was hardly
13 calculated to get me on site. How would you feel if
14 someone made a complaint to the Bar Council about you,
15 for example?

16 So -- and I had gained the impression that elements
17 in the Haemophilia Society were encouraging this. It
18 was a slightly circular problem, though, because when
19 I was a little bit more senior, a little bit further on,
20 and was talking to the Department of Health, what they
21 told me was, so long as there was litigation going on in
22 the background, they couldn't put any scheme into place,
23 because it would influence the outcome of the
24 litigation.

25 And I think a lot of my colleagues and I felt as if

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1 we were slightly caught in the crossfire, because we
 2 were the closest target for the patients' ire, they
 3 blamed their medical attendants for their suffering, and
 4 we were not in any position to help with financial
 5 compensation. It was really the Department of Health
 6 that they needed to approach. But we were the only
 7 outlet, and they sought to increase the profile of their
 8 campaign by suing us all and reporting us to the
 9 General Medical Council.

10 **SIR BRIAN LANGSTAFF:** Excuse me, can you just help and
 11 tell me who it was that you spoke to at the Department
 12 of Health who suggested that having a form of
 13 compensation scheme would in some way influence the
 14 outcome of the -- of a court case? In other words,
 15 I think the suggestion is it might influence a judge
 16 in favour of or against the case.

17 **A.** I can't honestly remember. The various people
 18 that I dealt with at the Department of Health were
 19 Charles Lister, David Kutowski, and William Connon,
 20 over the years. It was probably one of the earlier
 21 ones, most likely Charles Lister.

22 **SIR BRIAN LANGSTAFF:** Thank you.

23 **A.** And of course there was the class action that I was
 24 involved in.

25 **SIR BRIAN LANGSTAFF:** Yes.

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1 **A.** Which was brought -- that was not claiming negligence,
 2 interestingly. That was brought under consumer
 3 protection legislation, which was a very interesting
 4 approach.

5 **MS RICHARDS:** Was this letter an attempt by you -- or, the
 6 meeting that you proposed follow it, an attempt by you
 7 to persuade the Haemophilia Society to dissuade
 8 patients from bringing legal claims?

9 **A.** No, it was an attempt to clarify what their position
 10 was.

11 **Q.** To what end?

12 **A.** I never did anything, either individually or
 13 collectively, to try to dissuade people from
 14 litigation. I did have an exchange with -- what's her
 15 name? Well, with one patient, you sent me a letter,
 16 in evidence, on -- that was in response to an enquiry
 17 from her in general terms.

18 **Q.** You referred to a campaign to bring cases to the
 19 General Medical Council. Obviously, Professor Hay,
 20 you're familiar with the complaints that were made
 21 against you. But what's the basis for your assertion,
 22 the factual basis for your assertion, that this was
 23 part of a campaign as opposed to individual cases?

24 **A.** Well, it was well recognised at the time that that was
 25 the case. I was not chairman at the time.

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1 Professor Hill was chairman at the time. He actually
 2 knows how many of these have -- were lodged. I don't.
 3 But there were a number. At one point I was told that
 4 there might be as many as 50. There were certainly
 5 two against me, both of which were entirely false, but
 6 they took a long time to resolve.

7 **Q.** I'm asking not specifically about the complaints
 8 against you, and you've explained what the outcome of
 9 those were, that they didn't go anywhere. But in
 10 terms of it being part of a campaign, you've said it
 11 was well recognised. By whom? Do you mean that was
 12 the view of the Haemophilia Centre Directors?

13 **A.** Well, it was well recognised by Haemophilia Centre
 14 Directors, and I refer to it in correspondence with
 15 one of the patients who'd actually raised it with me.
 16 It's my understanding that this was done to raise the
 17 profile of their campaign.

18 **Q.** But the factual basis for that understanding is
 19 discussions between Haemophilia Centre Directors?

20 **A.** Yes.

21 **Q.** Could we have on screen, please, HCDO0000266_004,
 22 please.

23 This is another letter from you. This is a few
 24 years later, to the Haemophilia Society, to
 25 Ms Pappenheim, December 2002. You're responding to

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1 a letter from her, and it's about what are said to be
 2 difficulties of accessing medical records.

3 Let me just pick it up at the bottom of the page
 4 because this may be of more general interest. You say
 5 in the last paragraph:

6 "Medical record-keeping 20 years ago was not as
 7 scrupulous even as it is now, and so patients should not
 8 be surprised or disappointed if they find that their
 9 records do not contain detailed records of batch
 10 numbers, et cetera, that may be medicolegally important
 11 with hindsight but had little apparent clinical
 12 relevance at the time."

13 Surely batch numbers would have had considerable
 14 clinical relevance at the time for two reasons? One is
 15 the single product batch dedication policy being
 16 followed at Sheffield and some other centres, and
 17 secondly, because that's the way in which you trace
 18 implicated batches.

19 **A.** Well, you'll remember yesterday we talked about
 20 ledgers. And every single unit of Factor VIII and
 21 Factor IX in the Manchester centre and, as you have
 22 already learned, in the Sheffield Centre is recorded,
 23 so we do record the batch numbers, but they are
 24 recorded in a ledger. Now, in Manchester, I think
 25 they may have had some other records as well before

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1 I came, but they are recorded in a ledger.
2 Now, the problem with showing the patient a ledger
3 is that it's full of information about treatment for
4 other people. You can't show that patient. You might
5 extract it if requested, but that would obviously be a
6 lot of work. But you can't show one patient's
7 information to another. So, yes, it is recorded, but
8 not invariably in the patient's notes.

9 Q. If a patient makes an application for information that
10 they believe is in their medical records wrongly, for
11 the reason you've given, but the centre nonetheless
12 holds it in another form, would the appropriate
13 response of the centre not be to tell the patient that
14 that information is held and provide it to the patient
15 in some form, photocopying the relevant page of the
16 ledger and just redacting out the irrelevant entries?

17 A. Well, if they make that request, but at that time,
18 they were just looking for evidence that they'd been
19 treated with one product or another, and the batch
20 numbers were not relevant, frankly. They really
21 wanted to know which supplier had supplied the product
22 they'd been treated with for specific episodes, and
23 that would be in the notes. Because, apart from
24 anything else, that's on the prescription chart.

25 Q. But the point I understand to be being made here is

1 that this information often won't be in the records.
2 A patient can't know to request a copy of the
3 information in another form such as a ledger unless
4 they're told by the centre that the information exists
5 in that form.

6 A. Yes, but the request that the patient asks for are
7 their clinical records, and those are provided. And
8 to be honest with you, my involvement with that would
9 be extremely peripheral. Because they make a request
10 for the patient records, that goes to the medical
11 records officer, they send me a form, which I have to
12 sign, or the consultant that is looking after them has
13 to sign, and we sign it, giving permission, and that
14 goes back to the medical records officer, and they
15 make the notes available. Or if the patient has
16 requested a copy, they will arrange to copy what they
17 have and present it to the patient.

18 Q. If we go over the page please, Soumik, to the second
19 paragraph, five lines down it says:

20 "Unfortunately there appears to be a feeding frenzy
21 amongst the patients at the moment."

22 Then you explain you don't have the time to go
23 through the records of patients individually, and
24 I understand the latter point. What do you mean by
25 there being a "feeding frenzy amongst the patients"?

1 A. Well, at that point in time, there was a legal
2 company, I can't remember which one it was, and they
3 were trying to mount a class action. And as far as
4 I can see, they were trying to do this relatively on
5 the cheap. And by that, I mean they weren't going
6 through the usual medical negligence process of
7 requesting the records and getting an expert to go
8 through the records and providing a report. They were
9 basically asking the patient to answer certain generic
10 questions, and the generic question that the patient
11 seemed to be interested in was: had they been treated
12 with a certain brand of American concentrate during
13 a certain period of time? Because the class action
14 was against that manufacturer.

15 So lots and lots of the patients came along and they
16 wanted to know that, and so they requested their notes.
17 Their notes were made available to them. But then
18 I think the problem often was that even though the
19 information they were looking for was actually in the
20 notes, they didn't know exactly how it was presented,
21 and they weren't quite sure what they were looking for,
22 and they might be presented with several thick volumes
23 of papers, because these patients had been patients of
24 the hospital often for many years, and so their notes
25 were really voluminous. And, to be honest, when I got

1 to Manchester, a lot of the notes were not in great
2 shape.

3 One of the reasons for that being that if you sent
4 them to the Medical Records Department to be re-bound,
5 they would hang on to them for a couple of months. And
6 these patients are presenting fairly regularly. You
7 didn't want their notes out of circulation for that
8 long. And at one point I actually employed somebody to
9 try to organise the notes and re-bind them. But we gave
10 up after a little while because it was all happening so
11 slowly. And he actually did that in the department.

12 So with some of these patients I actually went
13 through the notes with them to help them to find what
14 they were looking for. I can remember spending
15 three-quarters of an hour one time, in clinic, with
16 a patient who had been through his notes, had been
17 unable to find them, then -- we shuffled through them
18 all. It took me quite a long time. I showed him what
19 he wanted to find. I explained to him what it
20 signified. And then he came back to have another look
21 at his notes, and he couldn't find it again, and accused
22 us of taking this bit out. And -- you know, as if we
23 would have any motive to do that. You know, why should
24 we edit his notes when he's not even trying to sue us?

25 Anyway, there was a lot of that, and it was

1 generated by an attempt at a class action.
 2 **Q.** One final document -- sorry, two final documents. The
 3 penultimate one, HSOC0020017, please, Soumik.
 4 There is was a letter you wrote to the Department of
 5 Health in November 2005, and you've addressed it,
 6 I know, in your statement, and the context was the issue
 7 of funding for recombinant.
 8 If we go further down, please. Can we go to the
 9 next page. Yes.
 10 So you say that:
 11 "... any attempt to roll back the policy of
 12 recombinant ... would result in a considerable increase
 13 in such activity, with multiple judicial reviews, other
 14 legal activity and considerable patient protest.
 15 I suspect that it would cause complete chaos both for
 16 the [Department of Health] and for Haemophilia Centres."
 17 Then you say this:
 18 "Many centre directors are already fighting
 19 a low grade guerrilla war with patient activists who
 20 want a hepatitis C public enquiry and who are reporting
 21 their centre directors to the GMC and manipulating both
 22 newspapers and television."
 23 I've already asked you about the GMC, I don't need
 24 to ask you about that again.
 25 But why did you characterise attempts by campaigners

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1 to achieve a public inquiry as the fighting of a low
 2 grade guerilla war by directors against activists?
 3 **A.** Because of the way that they were conducting their
 4 campaign. Reporting your Centre Director to the
 5 General Medical Council on the grounds of -- well, for
 6 reasons that are entirely fictitious is a hostile act.
 7 And how they ever imagined that that would influence
 8 the Department of Health into giving a public Inquiry
 9 is entirely a mystery to me.
 10 What happens when you report somebody to the General
 11 Medical Council is that that individual gets no support
 12 whatsoever from their trust. Nobody wants to interfere
 13 with the action, and the doctor in question is isolated.
 14 If it's a serious complaint, they may be suspended from
 15 work. That certainly didn't happen to me. But, you
 16 know, it's a serious matter and it causes a lot of work
 17 and a lot of aggravation.
 18 And so I think to describe this, plus a degree of
 19 mischievous litigation, as "low grade guerilla warfare"
 20 is, if anything, a little bit of an understatement, and
 21 it goes back to what I said before about the medical
 22 profession feeling that they were caught in the
 23 crossfire. Because we had very little influence over
 24 whether there would be a public inquiry or not, and
 25 I think it's probably an uncontroversial thing to say

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1 that this inquiry might have been better held 20 or
 2 30 years ago, rather than now. You know, if there was
 3 going to be an inquiry, the earlier the better. So
 4 that's the background to that.
 5 **Q.** You -- I'm not going to put on screen, but you've
 6 dealt with it in your witness statement, but you also
 7 sent two emails to the Archer Inquiry which you've
 8 said in your witness statement the tone and wording of
 9 which you accept was intemperate and which you regret.
 10 **A.** Yes.
 11 **Q.** Do you understand why patients or some patients at
 12 least might want a public inquiry?
 13 **A.** Of course I do.
 14 **Q.** Do you --
 15 **A.** And, you know, the patients and their relatives have
 16 suffered greatly. And I perfectly understand on an
 17 emotional level how many of them have been very
 18 embittered by their experiences. I perfectly
 19 understand that.
 20 **Q.** And do you accept that patients have a right to, if
 21 they believe things have been done in a way that was
 22 wrong, or misguided, or incompetent, have a right to
 23 raise that through a range of different appropriate
 24 forums, in principle?
 25 **A.** In principle, I have no problem with that whatsoever.

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1 Similarly, if someone has behaved in a negligent way,
 2 it's entirely reasonable that they should take legal
 3 action.
 4 **Q.** One final document, HSOC0001265. It's the next page.
 5 Well, actually, we'll look at -- we'll go to the next
 6 page, first of all.
 7 This is a letter sent to the chief executive of the
 8 Haemophilia Society in September 2006. If we just go
 9 down to the bottom of the page. It's sent by you in
 10 your capacity as Chair of UKHCDO. And then if we just
 11 go up again, it says in the third paragraph:
 12 "The Committee asked me to emphasise to you [this is
 13 the Advisory Committee of UKHCDO] their collective view
 14 that a public enquiry [sic] into this matter is not in
 15 the patient's best interests and is likely to harm
 16 rather than enhance patient care."
 17 Why did you think that?
 18 **A.** Well, I was reporting back the discussion from the
 19 Advisory Committee.
 20 **Q.** Well, it's --
 21 **A.** And I think they felt -- patients were saying that
 22 there was some sort of conspiracy of silence which
 23 I don't think we recognised. I certainly, on
 24 a personal basis, have always tried to be as open and
 25 transparent as possible. So we did not feel that

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1 there was a conspiracy of silence, and when the
2 patients said, "We want to know the truth," we weren't
3 quite sure what truth they were after because, you
4 know, we felt that we had been quite open.

5 And when it comes to the suggestion that this
6 might harm them, well, I have to say to you that
7 I have seen many patients after the onset of this
8 inquiry who have been quite distressed by it. It has
9 not been universally welcomed by the body of patients.
10 I think it would be true to say that there is a lot of
11 ambivalence out there. Many patients who have come to
12 terms with what they've been through in the height of
13 the HIV era were upset that this raked it all up
14 again.

15 Now, I appreciate that that won't be the universal
16 view, and I'm sure that your witnesses very much welcome
17 the inquiry, but other patients don't. You will find
18 a wide range of opinions from the patient body, but I've
19 had to have many long conversations with some of my
20 patients, some of them in tears because this has brought
21 it all bubbling back up to the surface. And they have
22 clearly suffered greatly during the HIV era, losing
23 their children, for example, or their husbands, you
24 know, and I can think of nothing worse than to lose
25 one's child from an iatrogenic illness.

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1 You know, I don't dispute for one moment the degree
2 of suffering that the patient body went through as a
3 result of all of this. But many patients accept that
4 the treatment was given in good faith, and it couldn't
5 have been avoided. And so, you know, opinion in the
6 patient group is variable. And, you know ...

7 **MS RICHARDS:** Sir, those are my questions. I understand
8 you may have some for Professor Hay.

9 **Questions by SIR BRIAN LANGSTAFF**

10 **SIR BRIAN LANGSTAFF:** Yes. It's a bit of a ragbag arising
11 out of some of the things that counsel has been
12 through with you.

13 The first is this: you mentioned early on in your
14 evidence the issue of product re-calls.

15 **A.** Yes.

16 **SIR BRIAN LANGSTAFF:** And I just wonder if you can give me
17 some sense of how often products supplied to you by
18 a commercial supplier or, for that matter, by Elstree,
19 were re-called.

20 **A.** Not very frequently.

21 **SIR BRIAN LANGSTAFF:** So in terms of -- in any year, if
22 you could average it, how often might it happen?

23 **A.** Oh, much less frequently than that.

24 **SIR BRIAN LANGSTAFF:** I see. So the number of times that
25 you've had a product re-call would be less than the

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1 number of years you have been a Centre Director?

2 **A.** Yes, absolutely. And in the early years, there would
3 be odd batches rather than a whole product re-call.
4 It would be unusual to re-call a whole product, but
5 there may be a problem with an individual batch. You
6 might suddenly get a lot of reports of patients
7 getting reactions with a specific batch.

8 They would all be pyrogen tested to minimise the
9 risk of reactions, but sometimes, nevertheless, they
10 would give reactions. Reactions are much, much commoner
11 with plasma and cryoprecipitate and could be quite
12 severe.

13 **SIR BRIAN LANGSTAFF:** Thank you.

14 **A.** And as the product purity improves, there were fewer
15 and fewer of those reactions. Then there were
16 occasional product re-calls because of things like the
17 advent of heat treatment. Some unheated products were
18 re-called, and so on.

19 **SIR BRIAN LANGSTAFF:** Thank you. And how often did that
20 happen? The unheated product being re-called? Do you
21 remember?

22 **A.** Well, that only happened when they were being
23 introduced back in 1985. BPL re-called some of --
24 well, what was left of their unheated product, and
25 then they were going to heat it and re-issue it.

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1 **SIR BRIAN LANGSTAFF:** And that was the material that you
2 found unusable because it didn't dissolve very easily?

3 **A.** That's right.

4 **SIR BRIAN LANGSTAFF:** Thank you.

5 The second thing I wanted to ask you about was
6 this: when you were talking about relationships with
7 the pharmaceutical companies, you mentioned that
8 sometimes a pharmaceutical company would ask you, or
9 the haemophilia doctors, to conduct an analysis, and
10 you would charge them for it.

11 **A.** Yes.

12 **SIR BRIAN LANGSTAFF:** May I ask the basis upon which the
13 charge was worked out. Was it the cost to you, with
14 perhaps a small profit element, or was it the amount
15 that you thought the pharmaceutical company might be
16 willing to pay?

17 **A.** It's a compromise between those two, I would say. We
18 do not make a huge profit on it, but we need to cover
19 our costs. And that cost is currently calculated by
20 a manager.

21 **SIR BRIAN LANGSTAFF:** Did you ever have any, or much
22 push-back from the company to say, "Oh, we won't pay
23 that"?

24 **A.** Sometimes. Yes.

25 **SIR BRIAN LANGSTAFF:** But not usually?

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1 A. Well, we tried to avoid getting into that position by
2 not charging an outrageous amount.

3 **SIR BRIAN LANGSTAFF:** I see. Right.

4 The next question, when you were speaking about
5 talking to patients about the results of their HIV test,
6 you observed that you thought that Professor Preston's
7 approach in Sheffield was a good one. You said the
8 different clinicians had different practices, some good,
9 some not. Can you give me more detail about the some
10 that were good and the some that were not?

11 A. Well, I didn't feel that the practice in Liverpool was
12 very good, because as far as I could make out from my
13 conversations with my patients, they'd been informed
14 by post and offered very little support. So when
15 I arrived, I inherited a group of patients who were
16 understandably very angry, felt very let down. And
17 I agreed with them, frankly. And they needed a great
18 deal of psychological support, and many of them were,
19 quite understandably, very embittered about the way in
20 which they had originally been informed.

21 And, you know, I couldn't support that. Although it
22 was a long time ago, I don't think that that practice
23 was acceptable, even in 1985.

24 You know, we didn't know a great deal about HIV at
25 that time, but we did know that it was potentially

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1 fatal, because there'd been some cases of AIDS. We
2 didn't know how many of the patients would develop AIDS,
3 because in those early days, bearing in mind that it was
4 only an antibody test, what that test told us was that
5 the patient had been exposed to the AIDS virus, and
6 there was an expectation, soon to be dashed, that some
7 of those patients would actually be immune, in the way
8 that somebody who'd had hepatitis B but recovered from
9 acute attack would be immune. And, you know, with
10 hepatitis B, 95% of people turn out to be immune without
11 chronic viraemia.

12 Now we expected something similar to emerge
13 with HIV, and sadly it didn't. But, you know, that was
14 the level of knowledge in '85. But I think there was
15 a lot of uncertainty about it and patients should have
16 been told, apart from the fact that having a positive
17 test didn't mean they had AIDS, that they would be
18 monitored and supported.

19 **SIR BRIAN LANGSTAFF:** Thank you.

20 Were there --

21 A. And --

22 **SIR BRIAN LANGSTAFF:** Sorry.

23 So -- sorry.

24 A. And that we were looking for treatment and there was
25 a degree of uncertainty about the outlook.

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1 **SIR BRIAN LANGSTAFF:** Were there any other practices
2 elsewhere that you became aware of and thought were
3 poor? Or, for that matter, good?

4 A. Well, I heard that in some places patients were told
5 in groups. And I find that amazing, because there's
6 a confidentiality issue there, apart from anything
7 else. And I think it's always more sensitive to tell
8 people one at a time. I thought that the system
9 that I heard about at the Royal Free was particularly
10 good, where they were taken into a soundproof
11 counselling room, with a counsellor, and with someone
12 else, and they were -- they informed them. And
13 I think there is some video evidence of that, that I
14 understand the Royal Free have shared with ...

15 **SIR BRIAN LANGSTAFF:** Thank you.

16 The next question was this: it was in relation to
17 hepatitis-reduced products. Now, plainly,
18 hepatitis-reduced didn't mean to say that it had no
19 hepatitis virus in it.

20 A. Yes.

21 **SIR BRIAN LANGSTAFF:** But were those products, so far as
22 you were aware from your own experience at the time,
23 were they at all successful in producing a lower
24 incidence of the disease?

25 A. My understanding is that they were probably better

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1 than we initially thought, because -- to take Alpha
2 Profilate as an example, as I told you yesterday, 24
3 of the 27 patients in that study did not develop
4 non-A, non-B hepatitis, and three did. But once we
5 used it, commercially, I don't think any of the
6 patients developed hepatitis C from that particular
7 product. Other products were less successful. They
8 were all pretty good at eliminating hepatitis --
9 eliminating HIV, because fortunately it turned out
10 that HIV was more heat labile than the hepatitis
11 viruses.

12 And also -- they were generally a bit better. But
13 we continued to monitor the patient group, both for HIV
14 and hepatitis, for several years after that, because
15 there remained some residual doubt. And as time went
16 by, further viral steps were introduced and further
17 purification steps were introduced to progressively
18 increase the level of viral safety.

19 **SIR BRIAN LANGSTAFF:** So, in summing that up, I think what
20 you're saying is that some products, anyway, which
21 claimed to be virus-reduced, actually did work to some
22 extent?

23 A. Well, most of them worked very well.

24 The exception, about which I'm sure you're going
25 to come back, is to that early Armour product that

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1 transmitted HIV to a few patients, sadly. And that
 2 product is a good example of a product recall, where
 3 they recalled the whole of the product, because
 4 clearly the process as a whole was inadequate.
 5 **SIR BRIAN LANGSTAFF:** Yes. The last thing I want to ask
 6 you about is simply to get some information about how
 7 the national contract for a product works.
 8 Because of your policy, and your general policy
 9 that we've heard from others, of not all the eggs
 10 being in one basket, presumably whatever the national
 11 contract is, it's for a range of products.
 12 **A.** Yes.
 13 **SIR BRIAN LANGSTAFF:** Nationally negotiated.
 14 **A.** Yes.
 15 **SIR BRIAN LANGSTAFF:** And that shows cost advantage, does
 16 it, over negotiating per centre?
 17 **A.** Well, actually, the way to get the best price would be
 18 to go for a single product, but we don't want to do
 19 that for a variety of strategic reasons, which the
 20 Department of Health accept. And the Department of
 21 Health accept that there will be a financial price to
 22 pay for that strategy.
 23 And that sort of strategic approach is apparently
 24 accepted by the Department of Health in relation to
 25 a wide range of products and is not peculiar to our

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1 particular area.
 2 And the strategic reasons are: you don't want to
 3 be dependent on a single manufacturer, because if you
 4 become too dependent, apart from anything else, what's
 5 to stop them turning round and putting their price up
 6 at a later stage? You know, when the next contract
 7 comes round --
 8 **SIR BRIAN LANGSTAFF:** They're a monopoly supplier, and you
 9 might imagine they might do that. So I can understand
 10 that.
 11 **A.** Well --
 12 **SIR BRIAN LANGSTAFF:** Can I --
 13 **A.** They also --
 14 **SIR BRIAN LANGSTAFF:** Can I ask you just to -- if you know
 15 anything about, you may well not, because it's before
 16 you were centrally involved in much of this world, but
 17 in the 1970s, ending in about '79, I think it was,
 18 there was central contracting for commercial product.
 19 Then it ceased. And plainly, at some stage, national
 20 contracting, as you've described it, started up again.
 21 Roughly when was that? Do you remember?
 22 **A.** When did it really start or when --
 23 **SIR BRIAN LANGSTAFF:** When did national contracting start
 24 to replace the system of buying by centre.
 25 **A.** The first time we had a proper national contract was

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1 with recombinant for all.
 2 **SIR BRIAN LANGSTAFF:** I see.
 3 **A.** And we established a national contract, and that led
 4 to surprising discounts which had practical
 5 implications because it enabled us to start some
 6 patients earlier than we would otherwise have been
 7 able to. Obviously, we would have preferred to have
 8 started them all at once.
 9 But then there was this threat to the continued
 10 funding and one of the responses with the Department
 11 of Health to this funding threat was to introduce
 12 a system of central contracting for all products, for
 13 all the patients. So that was the first truly
 14 national contract for everybody. And so the
 15 Commercial Directorate became involved. Deloitte
 16 offered a device with the very first round, and our
 17 objective was to reduce the cost and, therefore, make
 18 the continued supply of recombinant Factor VIII for
 19 our patients more secure, and to maintain freedom of
 20 prescription to have as many suppliers as we could so
 21 that the market would not be vulnerable to
 22 interruptions of supply. Bearing in mind that, as
 23 recently as 2002, we'd had a major interruption in the
 24 supply of recombinant when Bayer stopped supplying.
 25 You know, so it's a very recent memory, a very real

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1 problem. And the Department of Health accepted that
 2 even though Deloitte said, well, you'll get the biggest
 3 saving if you just go for two suppliers, as group of
 4 clinicians, and with the department's support, we said
 5 no, we don't want to go down that route. And we
 6 organised it in such a way as to make the suppliers
 7 behave in a commercial, competitive way. And we told
 8 them that if they didn't offer us a good price, we
 9 wouldn't buy their product. Whether that was a real
 10 threat or not, it had the desired effect, and with each
 11 round, the price has reduced to an extent that, frankly,
 12 exceeded our expectations.
 13 Right at the outset of this, Deloitte told us that
 14 90% of the cost of a drug is usually profit. I was
 15 staggered by that. But when we did a survey, we
 16 discovered that the unit price for a given Factor VIII
 17 product varied by over 50% from one Haemophilia Centre
 18 to another. So even if we just paid the average price,
 19 we would have saved something like £15 million. So
 20 clearly, there was enormous scope. I mean, the
 21 manufacturers always said, "Oh this is an expensive
 22 product to manufacture. We're not making much money on
 23 it," and so on. And we had no way of knowing what
 24 profit they were making. But it has been very useful
 25 because during the period during which we've had this,

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1 we have wanted to improve the intensity of treatment and
2 the quality of treatment for the patients.

3 And when we started that contract, the average
4 amount that patients with severe haemophilia were using
5 was 120,000 units of Factor VIII a year. And it has
6 increased now to an average of about 300,000. But the
7 total cost of that has actually been reduced. We're now
8 paying the -- unit prices that are similar to those that
9 pertained in the 1970s.

10 **SIR BRIAN LANGSTAFF:** I see.

11 Now, just to give me a sense of how it is organised
12 as between yourself and the purchasing unit, is this
13 a question of the price being negotiated and you then
14 ask for supplies from the supplier, or is there
15 a central warehouse, as it were, either a notional
16 warehouse or an actual one, which has a store of the
17 product which you are, between you, obliged to take? Do
18 you ask the --

19 **A.** There's still some degree of prescribing freedom, and
20 different centres prescribe different products. The
21 price is set nationally by the national contract.
22 Each round is organised between UKHCDO and what was,
23 past, the Purchasing and Supplies Agency, but which is
24 now CMU, the Central Medicines Unit. It's actually
25 the same bunch of people. Coincidentally, they're

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1 just down the road from me.

2 And they organise the contract. We help them with
3 data, to facilitate that process. Their actual tenders
4 are assessed in a multi-disciplinary way by a group.
5 Very often the products are scored, partly by price,
6 partly by safety, ease of use, things like that.

7 We have even involved patients and haemophilia
8 nurses in some of those assessments.

9 **SIR BRIAN LANGSTAFF:** And when it comes to the question of
10 safety, what are the sort of considerations that would
11 make one product, nowadays, safer than another?

12 **A.** Well, the difficulty with safety -- and we haven't
13 always used it in every evaluation recently, because
14 we found that it didn't discriminate between the
15 products. In the past it most certainly would have
16 done, but it's difficult to demonstrate an increment
17 in safety between the various products, and some of it
18 comes down to opinion.

19 For example, some of the extended half life products
20 are pegylated, that is to say, a molecule of
21 polyethylene glycol is attached, and that's the method
22 that they used to extend its half life. Others have
23 bits of immunoglobulin attached, which is considered
24 more normal, and has less effect in the way in which the
25 product is dealt with.

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1 Now people are a little bit suspicious about
2 pegylated products because the polyethylene glycol is
3 excreted from the body more slowly, and although there
4 is no positive evidence, we would prefer it to disappear
5 more quickly. We don't know what the long-term
6 consequences of having polyethylene glycol in your body
7 might be.

8 There are many other pegylated drugs available, but
9 perhaps none given for an entire lifetime. And it's
10 that sort of consideration. So some clinicians have
11 said, "Well, I know there's not much evidence but
12 I would prefer not to take that risk", and they choose
13 to use other products. In my own centre, we have four
14 consultants with an interest in haemophilia and we reach
15 these decisions by consensus.

16 **SIR BRIAN LANGSTAFF:** Well, thank you very much. Those
17 are all the questions I have to ask.

18 Ms Richards?

19 **MS RICHARDS:** Professor Hay, do you have anything further
20 that you wish to say?

21 **THE WITNESS:** No, I don't.

22 **SIR BRIAN LANGSTAFF:** Well, it remains for me to say,
23 Professor, that we're very grateful to you for giving
24 up your time to be here virtually. I know that you
25 would have preferred, as we would have preferred, you

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1 to be here in person, but it's rather a long way for
2 you to come, I think. It would have been, anyway,
3 a long way for you to come. Those listening should
4 know that you were prepared to do that and, of course,
5 you have further evidence to give us in due course.
6 We'll have to decide whether we actually ask you to
7 give that orally or not at a later time.

8 But your willingness to engage is noted, and we
9 thank you very much for that. It's given us, this
10 evidence, at any rate, an insight into what we hadn't
11 had much evidence, as yet, orally given to us: the
12 period in which vCJD was a real threat and how it was
13 handled. It may still be a real threat, but at least we
14 know how it was handled in the 1990s, and what it was
15 like from your evidence to become a Haemophilia Centre
16 Director of a large centre at the end of the 1980s,
17 coming into the 1990s, with all the challenges and the
18 testing for hepatitis C that took place.

19 That's very valuable evidence for us to have. Thank
20 you very much indeed for coming, or being here, rather,
21 I should say, virtually to give it.

22 **THE WITNESS:** Thank you. I hope that it's been helpful.

23 **SIR BRIAN LANGSTAFF:** Well, I'm sure in many ways, it will
24 have been.

25 **MS RICHARDS:** Sir, that completes the evidence, obviously,

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1 for today and for this week. We're not sitting next
 2 week, and we resume remotely, so far as witnesses and
 3 core participants are concerned, the following week on
 4 the Tuesday, which I think is 17 November.
 5 **SIR BRIAN LANGSTAFF:** Yes, it is.
 6 **MS RICHARDS:** Yes, it is.
 7 **SIR BRIAN LANGSTAFF:** So those listening around the
 8 country should know that we will start on the 17th.
 9 We are then hearing evidence from?
 10 **MS RICHARDS:** We have evidence from three witnesses that
 11 week, Dr Al-Ismael, Dr Mitchell, and Dr Giangrande.
 12 **SIR BRIAN LANGSTAFF:** Thank you. So we start at
 13 ten o'clock on Tuesday, 17th November. Thank you very
 14 much.
 15 **(5.05 pm)**
 16 **(The hearing adjourned until Tuesday, 17th November at**
 17 **10.00 am)**
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1 **I N D E X**

2 CHARLES RICHARD MORRIS HAY 2

3 (continued)

4 Examined by MS RICHARDS (continued) 2

5 Questions by SIR BRIAN LANGSTAFF 148

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