

Thursday, 5 November 2020

(10.00 am)

SIR BRIAN LANGSTAFF: Good morning, professor.

A. Good morning.

SIR BRIAN LANGSTAFF: Let me just say a couple of things first, if I may, before Ms Richards starts questioning you again, because we're meeting under new conditions, as we all know, given the restrictions which were introduced as from today. Those who are watching remotely won't see, they never do see, the audience which is here. Nor do you. You just see the same faces. But for those who are watching out there and for your information, the only people who are present in the hearing room are the legal team supporting Ms Richards, your own counsel, some technicians, and a couple of members of Inquiry staff. There's no public here. But they are watching online.

So this is the conditions under which we are currently meeting. I'll continue to wear a mask because that's what we ask people to do in these premises, though it does interfere with talking sometimes, which is why I take it down when I'm talking to you.

Ms Richards.

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and Adults and the Royal Free Hospital are all still using large amounts of BPL products and continuing to order them. I suspect that these 3 centres all use significant amounts of 8Y, which may present them with a financial problem. I was able to implement our policy rapidly because there were essentially no attached revenue consequences. I hear that Frank Hill will be wanting to move straight to Recombinant but I worry that the other 2 centres were basically not fully sold on the policy. If they don't implement this policy it significantly undermines our position."

Do you know whether the anxieties expressed in that letter, the concerns expressed in that letter, continued, or did other centres implement the UKHCDO recommendation?

A. Well, I think that at some point BPL withdrew their products, and then there was a gap, substantial gap, until they started to manufacture the same products, using imported American plasma. I can't remember exactly how long that took.

And the financial problem I'm alluding to is because those centres that continued to use a lot of 8Y, 8Y was quite cheap, but it was also very popular, it had a good viral safety record. It was also reasonably all right on von Willebrand's disease. So

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CHARLES RICHARD MORRIS HAY (continued)

Questions by MS RICHARDS (continued)

MS RICHARDS: Professor Hay, I want to pick up the picture in relation to vCJD and the response to the risk of vCJD and the various notification exercises.

We looked yesterday at your letter in November 1997, and the meeting you described following that. Your statement tells us that at some point after that, at Manchester you were able to switch products to those manufactured from US plasma fairly quickly; is that right?

A. That's correct.

Q. There is also evidence to suggest that that may not have been the position universally for all centres.

Soumik, could we have on screen, please, HCDO0000133_188, please.

This is a letter you wrote January 1998, it's addressed to Dr Ludlam, and it's "Implementation of our Recommendation on CJD". That is presumably a reference to the UKHCDO Committee's recommendation which you discussed yesterday afternoon?

A. It is.

Q. Then you talk about:

"The commercial grapevine tells me that some centres, particularly Oxford, Birmingham Children's

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some centres were genuinely quite attached to the product, it wasn't just because it was inexpensive.

But the fact that it was inexpensive meant that for them to change to American products would have incurred a considerable cost.

For me, that wasn't a problem because I had already switched all my patients to high-purity products so I was using more expensive products in any case. I can't honestly remember how long the situation went on.

Q. Okay. We move, then, I think, to -- just before we get to the national notification exercise in 2004, you had an exchange of correspondence with BPL in 2003.

Soumik, if we could have HCDO0000254_117, please.

This is a letter that you wrote, in May of 2003, to BPL, and it says that you were recently notified by the Transfusion Transmitted Working Party that your centre, Manchester, had received batches manufactured from plasma pools contaminated with plasma from patients who subsequently developed vCJD, and you're expressing here displeasure at not having been informed of this directly by the manufacturer and having learnt of it through this route of the Transfusion Transmitted

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

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

17 Q. The next I think key event in relation to vCJD and
 18 Haemophilia Centres and haemophilia patients was the
 19 2004 national notification exercise.

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

24 A. That's correct. I mean, this was obviously a game
 25 changer because up until this point, the possibility

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1 it means by being "at-risk" for public health
 2 purposes. And then there are three levels identified:
 3 high, medium, and (over the page) low.

4 We're told, in the third paragraph:

5 "The uncertainties underlying the assessment of
 6 'risk' are great, and several precautionary
 7 assumptions are involved. Therefore the 'at-risk'
 8 threshold for public health purposes is not a precise
 9 guide for advising individuals about their potential
 10 additional risk of developing vCJD."

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

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

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

24 Then:

25 "Low: These batches do not need to be traced

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1 of a transmission through blood transfusion was a
 2 theoretical possibility, and there was a lack of
 3 concrete proof that it could occur.

4 Q. And then if we go, please, Soumik, to WITN3289110,
 5 we're going to look at some of the documents,
 6 professor, from the 2004 notification exercise.

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

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

25 Then we can see the panel has identified what

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1 and the individual recipients do not need to be
 2 informed."

3 We will look at some of the other documents in
 4 a moment but can you perhaps provide us with an
 5 overview of what the response to this then was by
 6 UKHCDO and individual Haemophilia Centre Directors.

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

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

23 We had to speak to our surgical colleagues and
 24 the hospital administration, because the measures
 25 included, amongst those patients at high risk, certain

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types of surgery had to be done with disposable instruments. Endoscopes had to be quarantined if they were used in high-risk individuals, so the notes had to be noted in that way. And if the patient required surgery, this became a consideration that had to be dealt with. And we had to report back to the database the risk level of each of our patients.

There are forms in the exhibits that show the returns to the database which show the amount of each batch that the patients had received, if they had received any. And if they had not received any implicated batch, that's also recorded. And the outcome of the discussion with the patient is also recorded, because this was a very unusual situation, and in the Advisory Committee we had lengthy discussions about how we should approach this, because this was a condition for which there was no test and there was no treatment. So we couldn't test the patients to discover whether they had been exposed or not. And even if we knew for sure that they had been exposed, there was no treatment and we were unsure of the likely natural history. Because, as things unfolded, recipients of implicated blood transfusions had developed variant Jakob-Creutzfeldt Disease as long as eight and a half years after exposure. And

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of every document but just to see the broad nature of the accompanying documents.

So, again, dated 7th September, this was a table of the vCJD implicated batch numbers. So that information identified the source in terms of manufacture, PFC or BPL was identified. And then if we go over to the third page, we can see -- we don't need to go through the details of it -- the specific batches. That information had all been gathered and collated nationally, had it?

A. Yes.

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

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

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

A. Yes.

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

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they were all homozygous. So there was the theoretical possibility that had been raised that heterozygotes might also develop variant Jakob-Creutzfeldt Disease but perhaps after a very prolonged period.

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

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

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

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

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

We're not going to need to look at the detail

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

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

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

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

Those are then set out from 1997 onwards.

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

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

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

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1 this.

2 And then "How does this affect me?" It talks

3 about the practical implications for patients.

4 And then if we go over the page, we can see it

5 continues by giving patients information about the

6 extent to which they face a risk, that's point 11.

7 "Does this mean I'm going to suffer from vCJD?"

8 "Can I be tested? What happens if I develop

9 strange symptoms? Will this mean I won't be able to

10 get life insurance?" We can see from the top of the

11 next page that that's an issue that's already been

12 addressed. Insurers will not refuse insurance because

13 someone is categorised at risk for public health

14 purposes. And then it continues.

15 This was obviously a national leaflet prepared

16 for the benefit of patients.

17 A. Yes.

18 Q. Did Haemophilia Centres send this information sheet to

19 the patients whom they were notifying, as far as

20 you're aware?

21 A. As far as I'm aware, yes.

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

23 This is described as the "Patient notification

24 exercise enquirer handling protocol."

25 If we go to the second page, at the bottom of

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1 in time, you were Vice Chair, Professor Hill was

2 Chair, and this letter was sent by him. But we can

3 see it's to all Haemophilia Centre doctors. It's for

4 urgent and immediate attention. And then we can see

5 in the first main paragraph reference to the toolkit

6 which I think are the documents that we have just been

7 looking at.

8 A. Yes.

9 Q. And then the actions are:

10 "To brief Centre staff to ensure we can get

11 letters out to all patients so that they're given

12 comprehensive information at the same time. The

13 letter to patients needs some insertions, telephone

14 numbers, et cetera, and should go to all patients or

15 parents of children with haemophilia and other

16 bleeding disorders. If possible, use the letter as

17 sent. Some may wish to adapt because of local

18 reasons. Ensure you file copies in each patient's

19 notes."

20 Then this:

21 "It's felt that all patients need to be

22 informed, even those not affected so that they are

23 informed about the events and understand the

24 implications."

25 Does it follow from that that UKHCDO, in

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1 the page under the heading "timing", we can see

2 a timed plan of action: 9 September, information will

3 be sent to haemophilia doctors, immunologists medical

4 directors of trusts. Then the plan for haemophilia

5 doctors and consultant immunologists looking after

6 patients with primary immunodeficiency to send out

7 patient letters on 20 September. And then a full

8 press briefing by the Department of Health planned for

9 21 September.

10 Certainly, the letters we've seen,

11 Professor Hay, sent to patients, many of them are

12 dated 20 September 2004. Again, as far as you're

13 aware, was the expectation of UKHCDO and the VCJD

14 Incidents Panel that all Haemophilia Centres would

15 send those communications to their patients at the

16 same time?

17 A. Absolutely. Absolutely. I mean, the timing of this

18 was determined, as far as I remember, by launching of

19 a Parliamentary question which was going to alert the

20 press the following week, so the whole thing had to be

21 rushed along. And it was strongly emphasised to

22 centres that this matter had to be dealt with as a

23 matter of urgency.

24 Q. We can see that from the UKHCDO letter to directors at

25 WITN3289111. So this is 9 September. At this point

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1 relation to this exercise, had decided to go further

2 than the, as it were, minimum requirements of the VCJD

3 Incidents Panel because your proposal was to

4 communicate with every patient, whether or not they'd

5 ever received British products within the relevant

6 time frame?

7 A. That's an interesting question. I think -- I can't

8 remember whether the Incidents Panel wanted us to

9 write to everybody, or whether it was a UKHCDO

10 decision, to be perfectly honest. But I think,

11 whether it was or not, we certainly felt that we

12 needed to inform all patients because the patients

13 would not necessarily know whether they'd had British

14 blood products or not, and they might think they were

15 involved. And so when we spoke to the patients, we

16 gave all of them a certain amount of core information,

17 whether they were affected or not, and then put it

18 into a personal context.

19 So if we, for example, knew that they had not

20 been exposed to UK products during that period, we

21 could tell them that and say, "Well, now you know all

22 about -- all that we know about variant

23 Jakob-Creutzfeldt Disease, but it shouldn't affect

24 you". And with the others who had had British blood

25 products at that point, we were still in the process

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1 of working out which batches were affected and
2 assessing the level of risk. And so, you know, you
3 wouldn't be able to attribute a level of risk at that
4 point, but you would be able to tell them whether
5 they'd had British blood products and might be
6 involved. And so I don't really know the answer to
7 your question, but that was our thinking.

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

10 Again, we can see this is part of the
11 7 September 2004 production of documents, the date at
12 the very bottom of the page.

13 This is a form to be completed for all patients
14 with bleeding disorders. And then a copy should be
15 sent to the National Haemophilia Database. There's
16 the start question:

17 "Did the patient received any UK sourced pooled
18 factor concentrates or anti-thrombin between 1980 and
19 2001?"

20 "Yes" or "no" gives the answer to whether the
21 person is at risk of vCJD for public health purposes.

22 There's then an exposure assessment, so that's
23 an analysis undertaken by reference to each individual
24 patient.

25 Then over the page, we can see the last box

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1 were overwhelming reasons to tell them, put the choice
2 to them again.

3 **Q.** Your statement tells us that not all patients could be
4 traced.

5 Do you know what steps were taken, first of all
6 at Manchester in your capacity as Director of the
7 Centre, to trace patients, or was that not a problem
8 that affected Manchester?

9 **A.** I don't remember it being a particular problem at
10 Manchester. There are always some patients,
11 particularly those with mild bleeding disorders, who
12 are lost to follow-up and need a lot of chasing.
13 I can't remember whether it was a particular problem
14 in relation to this.

15 There were also problems, of course, tracing
16 who had received the implicated batches; I detail in
17 my Section 9 response.

18 **Q.** Then if we move from 2004 to 2006. Could we, Soumik,
19 have ABMU0000053, please. So if we just going
20 a little closer.

21 This is an email from you at 14 November 2006:

22 "VCJD and plasma products: look back and
23 patient notification."

24 This is being sent by you now as Chair of
25 UKHCDO to Centre Directors and you refer in the body

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1 asks the question:

2 "Has the patient asked to know if they received
3 the implicated batch? When was the patient informed
4 if they'd received the implicated batch?"

5 The purpose of that last box was presumably to
6 ensure that patients received the information that
7 they wanted to but were allowed to choose not to
8 receive information if they didn't want to.

9 **A.** That's right. I started to explain that earlier but
10 didn't really finish. Because it was such an unusual
11 situation in that there was no test that we could
12 offer them and there was no treatment, we realised
13 that some patients might prefer not to be told. So
14 they were all provided with the background information
15 about variant Jakob-Creutzfeldt Disease, transmission
16 by blood transfusion, at the very least theoretical
17 risk of transmission through pooled blood products,
18 what we thought the risk was, the business about it
19 having only affected homozygotes who made up about
20 a third of the population and so on.

21 But in relation to their own exposure, they
22 were offered the choice of being told or not. But it
23 was important to document that choice, both in the
24 notes and centrally, so that you could continue to
25 respect that choice or, at the very least, if there

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1 of the email to:

2 "... two further batches of concentrate which
3 include donations from patients who subsequently
4 developed vCJD, relating to products released in 1988
5 through the Transfusion Service in Tooting, Wales,
6 Colindale and Birmingham, not previously notified
7 because it was not possible at that time to trace
8 their distribution. If you received these products,
9 you may have to notify your patients."

10 Then if we go over the page, we don't need to
11 go through the detail of it, but we can see this is
12 a letter explaining that there have been these two
13 further batches identified that weren't included in
14 previous notifications.

15 And is this right: essentially, what Centre
16 Directors were being asked to do in 2006 was to check
17 their records to see if they had received these
18 batches, and if they had, to then go through the same
19 exercise in relation to those batches as had been done
20 in 2004.

21 **A.** Yes, and we were also trying to stir up some centres
22 that had not responded, in our view, adequately to the
23 first request.

24 **Q.** We then, I think, next see vCJD in 2007.

25 Soumik, could we have HCDO0000131_006, please.

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1 So again, this is an email from you. This is
2 January 2007. And then we see, if we go over the
3 page, a draft press release. So this tells us that
4 there's been a fourth and therefore presumably a third
5 case, because we'd previously looked at cases 1 and 2
6 having triggered the 2004 notification -- a fourth
7 case of vCJD associated with blood transfusion. So
8 this is a draft press release from the Health
9 Protection Agency.

10 And then if we go, please, Soumik, to
11 HCDO0000131_007. And zoom in on the top half of the
12 page.

13 This is an email from you in your capacity as
14 Chair of UKHCDO, 16 January 2007. You were,
15 I understand, in this email, notifying all UKHCDO
16 members about this fourth case. The second paragraph
17 explains that:

18 "The case contracted vCJD from the same donor
19 as the third case."

20 And then refers to the patient having been
21 still alive and manifesting clinical signs of
22 suspected vCJD eight and a half years after receiving
23 the blood.

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

21

1 Then the second paragraph explains that:
2 "This patient had been treated in the '90s with
3 several batches of UK sourced clotting factors,
4 including one batch of Factor VIII that was
5 manufactured using plasma from a donor who went on to
6 develop vCJD."

7 Then it explains that:

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

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

14 "This is the first time that vCJD abnormal
15 prion protein has been found in a patient with
16 haemophilia or any patient treated with plasma
17 products."

18 Then if we go over the page, we're told that
19 the case doesn't change the public health vCJD "at
20 risk" status of any patient, but then doctors,
21 directors, are asked to take these actions:

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

25 And then:

23

1 "It remains the case that vCJD has not been
2 reported in recipients of non-cellular pooled blood
3 products. This does not, therefore, change the advice
4 that we would offer our patients, and we were not
5 planning a mailing to patients."

6 Do I understand this to be you communicating
7 news of the fourth case to Directors, but because
8 there were no new implicated batches, there was no
9 further notification exercise to patients; is that
10 right?

11 A. Yes. It strengthened the evidence that variant
12 Jakob-Creutzfeldt Disease could be transmitted by
13 a whole blood transfusion, but it didn't actually
14 change anything that we would have advised the
15 patients, or any of our actions. And so it was felt
16 that a further notification exercise would be
17 superfluous.

18 Q. Then there was then a further national notification
19 exercise in 2009. Soumik, could we have WITN3289130,
20 please.

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

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

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1 "Make arrangements for appointments with any
2 concerned patients."

3 Then we can see it encloses information
4 leaflets for both patients and for healthcare staff.

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

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

21 So the significance of this wasn't known, but
22 there was certainly the theoretical possibility that
23 had the patient not died of cancer and, say, lived
24 another few years, he might have developed variant
25 Jakob-Creutzfeldt Disease. We'll obviously never

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1 know.
 2 I seem to remember that the patient was
 3 atypical also in that I don't think he was
 4 a homozygote for prion. I think he was heterozygous,
 5 which was also a little odd. And, of course, it was
 6 11 and a half years after his exposure to the
 7 implicated batch.
 8 So whatever the uncertainties surrounding the
 9 interpretation of these findings, it was felt
 10 reasonable to inform the patients that this was
 11 perhaps evidence of transmission. So we wrote to all
 12 our patients again.
 13 **Q.** And so, as with the 2004 notification, this was
 14 a nationally organised and directed notification, to
 15 the extent that there was actually a template letter
 16 which we won't look at the leaflets but we'll look at
 17 the letter. WITN3289132. This is the letter you were
 18 being asked to send to patients.
 19 We can see at the bottom it says it doesn't
 20 change the way in which the patient will be treated.
 21 So the purpose of this national notification
 22 presumably was to ensure that patients had the
 23 maximum, up-to-date information for them to understand
 24 the position and apply it to their own personal
 25 circumstances?

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

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

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

28

notification exercise since they had been juniors when this took place. And the most recent notification had alerted them to all this and then they had gone away to find out which of their patients were implicated, and realised that the previous instructions had either not been followed or not followed adequately. And they had notified us, the Database UKHCDO, of this, and there was a catch-up necessary.

They would also realise that if that was the case, then, since at-risk patients had not been identified, and had maybe had surgery, that they might have had the sort of surgery that was listed as a risk: gut surgery, that sort of thing, lymphoid surgery, with non-disposable instruments, which would have to be traced.

Q. Then if we go over the page, we can see in the top paragraph, you set out that you're aware:

"... there have been no notifications of at risk patients from some Centres to the [National Haemophilia Database] ... [or some] Centres have not accounted fully for the total units of implicated products they received."

Without going through the detail of the rest of the letter, as I understand it, the proposal here was that the National Haemophilia Database would tell each

29

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

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

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

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

"I have been told that a centre [that was in fact the Royal Free] has mistakenly identified and notified a number of patients that they were at an increased risk of vCJD for public health purposes. These patients had, in fact, only been treated with BPL products manufactured from American sourced plasma. I am writing to all Haemophilia Centres

31

centre what information the database currently held in relation to patients at that centre insofar as relevant to this issue, so that centres could effectively work out what data was missing and what they needed to submit to the database. Is that an accurate summary?

A. Yes, that's accurate.

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

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

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

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asking that all past vCJD risk notification are checked because I suspect that this error may have been repeated in other centres."

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

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

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

So if we look, please, Soumik at WITN3289136.

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

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

We can see there's been a review by the Health

32

1 Protection Agency of the risk assessment which has led
 2 to recommendations that:
 3 "... individuals who received Factor VIII and
 4 Factor IX between 1990 and 2001 should remain notified
 5 as 'at ... risk of vCJD for public health purposes'
 6 ...
 7 But:
 8 "(ii) Individuals who only received plasma
 9 products between 1980 and 1989 should now have their
 10 treatment history reassessed to confirm this fact and
 11 if it is confirmed, they should be de-notified."
 12 Then if we go to the letter sent out by
 13 Dr Dolan to Directors, it's WITN3289137.
 14 This Dr Dolan, enclosing the HPA letter, the
 15 recommendations. It says:
 16 "Please do not take action immediately. What
 17 we have agreed is that NHD [the National Haemophilia
 18 Database] will review the records and generate lists
 19 for each Centre. These lists will then be sent to
 20 each Centre to be verified. There should be formal
 21 communication between each Centre and [the National
 22 Haemophilia Database] to confirm the risks and discuss
 23 any errors.
 24 "In the meantime the UKHCDO Executive, NHD and
 25 Morbidity and Mortality Working Party will work on

33

1 they changed the policy in relation to endoscopes and
 2 disposable instruments. And so we all had to take
 3 these out of quarantine.
 4 Q. I'm going to ask you about that in a moment, but just
 5 in terms of this information, in this letter, does it
 6 remain the case in terms of the current position, as
 7 at 2020, that individuals who received Factor VIII and
 8 Factor IX between 1990 and 2001 are regarded as at
 9 risk of variant CJD for public health purposes?
 10 A. Yes.
 11 Q. Then in terms of the practical consequences of being
 12 so regarded, could we have, please, BART0000924.
 13 This is an annual general meeting of UKHCDO,
 14 13th October 2005. If we could go, please, to the
 15 fourth page. No, sorry, that's the wrong document.
 16 I think on my note it's the wrong document.
 17 Well, we can look at this and pick up the
 18 picture from this, I think.
 19 Could you just go back to the front page,
 20 please, Soumik. and could we go on --
 21 So this is a meeting on 16th May 2005. There's
 22 then a second meeting in October that we'll look at.
 23 If we could go on to the next page, please.
 24 And the next page. Yes.
 25 So under the heading "vCJD Issues", the second

35

1 producing information which will be of help in
 2 discussions with patients who are to be
 3 'de-notified'.
 4 And without going through the detail of the
 5 remaining documents on this issue, can you set out
 6 what then happened in terms of the de-notification
 7 exercise, from your perspective?
 8 A. Well, we produced spreadsheets based on their previous
 9 returns from each centre, which had lists of patients
 10 that we considered could possibly be de-notified.
 11 There was then a dialogue between each centre and the
 12 database to fill out any missing data, and produce
 13 a final corrected list of patients who should be told
 14 that their risk had been reassessed and they were no
 15 longer considered to be at public health risk.
 16 This took a little time. I think it was quite
 17 a lot of work for the database and for centres, but we
 18 wanted to get it right, as you can imagine, given the
 19 history of this exercise, and its complexity.
 20 And then the patients were notified by the
 21 centre. It was not clinically urgent. I think most
 22 centres would have discussed it at the next patient
 23 appointment.
 24 Q. And then in terms of the current position, does the --
 25 A. I forgot one important thing. The other thing is that

34

1 paragraph reads:
 2 "Endoscopies: Charles Hay reported the trouble
 3 Manchester is having with endoscopies. From an
 4 ensuing discussion it was clear that different
 5 policies are being pursued in different centres."
 6 Then there's a reference to updating
 7 information on the website.
 8 What was the trouble that Manchester was having
 9 with endoscopies and how was it resolved, if at all?
 10 A. Well, the problem was that endoscopy, because there's
 11 a lot of lymphoid tissue in the gut, was considered
 12 a potential risk for transmission. So the worry was
 13 that an endoscope could transmit variant
 14 Jakob-Creutzfeldt Disease to the next patient that
 15 used it, for example. I mean, endoscopes are
 16 obviously cleaned in between use, but prion protein is
 17 quite sticky, and we didn't have any evidence to know
 18 whether the cleaning procedure for an endoscope would
 19 get rid of prion protein were that instrument to be
 20 contaminated with it.
 21 There eventually emerged evidence suggesting,
 22 for example, that metal instruments used during
 23 surgery, if they were also cleaned several times,
 24 probably would be safe, but that evidence wasn't
 25 around right at the beginning.

36

1 So the instruction was that if you used an
2 endoscope in a patient that was considered at high
3 risk, you should quarantine that instrument and only
4 use it for that patient.

5 So we had a growing number of endoscopes with
6 my patients' names on them, that couldn't be used for
7 anybody else. And in fact, I had one patient with
8 type 3 von Willebrand's disease who required repeat
9 endoscopy using a double-balloon endoscope, which is
10 a particularly expensive instrument, costing £50,000,
11 and we actually brought one just for him.

12 Eventually my hospital had something like
13 three-quarters of a million pounds' worth of
14 endoscopes in quarantine. And that was at least
15 three-quarters of all the endoscopes in the hospital
16 and was threatening the endoscopy service with
17 collapse through lack of instruments.

18 Now, the situation was eventually improved
19 because the Department of Health made money available
20 for the purchase of additional instruments.

21 I think some other centres were perhaps not
22 following this policy as assiduously, but my
23 understanding is that it was a problem in most really
24 large Haemophilia Centres, like the Royal Free,
25 because if you have a large number of patients, you're

37

1 pessimistic, because if they had been correct, we
2 would have seen tens of patients with variant
3 Jakob-Creutzfeldt Disease, and we had seen none. And
4 so when they made the reassessment, they had to take
5 into account what we observed in the previous decade,
6 ie, zero, so they changed their assumptions and they
7 revised their assessment of risk downwards in general.

8 So we changed the period of risk and we also
9 revised downwards our assessment of the risk to those
10 who continued to be considered a public health risk.

11 So it was no longer felt necessary to
12 quarantine surgical instruments, to use disposable
13 instruments, and/or to quarantine endoscopes at all.

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

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

18 Q. We have heard both from individual patients and
19 through the statements of some clinicians that there
20 were centres where the practical implications of the
21 policy over the years that it was in place was that
22 there were occasions where surgery was deferred or
23 cancelled, often at short notice, because of the
24 concern about instruments. Was that a problem in
25 Manchester?

39

1 bound to need to endoscope some of them on a fairly
2 regular basis.

3 Q. And you said, I think a few moments ago, when we were
4 talking about the 2013 de-notification exercise, that
5 there had been a change of policy in relation to
6 endoscopes.

7 A. Yes. Well, there was a change in policy overall,
8 because that reassessment was more wide ranging than
9 merely reassessing the period of risk. It reassessed
10 the level of risk.

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

24 Now, it became clear by 2009, far less the
25 later period, that these assumptions had to be far too

38

1 A. I think it was a problem everywhere. It was a problem
2 that we tried to mitigate. Operations got cancelled
3 sometimes when people seemed to realise at the last
4 minute that the patient was at risk. You could
5 minimise cancellations by planning the whole thing, so
6 that you should identify who was and was not at risk
7 in advance of surgery, so that appropriate disposable
8 instruments would be available, for example.

9 Q. Before we leave the topic of vCJD completely, there's
10 just one issue I wanted to ask you about arising out
11 of some of the exhibits to your statement and the vCJD
12 surveillance study. I'm not going to ask you about
13 the detail of that work because we have that covered
14 in documentation elsewhere, but if we have
15 WITN3289148, please.

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

20 It refers to Professor Lee having obtained
21 ethical approval for a number of studies relating to
22 vCJD, haemophilia and implicated products.

23 And then below the two numbered paragraphs
24 there's a paragraph that says:

25 "With regard to the post-mortem studies, we

40

1 have obtained a list of patients with haemophilia
2 whose Death Certificates indicate that there may have
3 been a post-mortem or a post-mortem may occur. These
4 names are being linked on the Database and I will be
5 writing separately to enquire if you can check if
6 a post-mortem has taken place and whether or not
7 material is available. James Ironside has indicated
8 he will be prepared, as in the original submission, to
9 look at relevant material."

10 So there appears to have been a proposal to
11 study material obtained either from post-mortems that
12 have already taken place or from post-mortems that may
13 take place prospectively.

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

16 If we have please, Soumik, WITN329150.

17 So this is a draft consent form for seeking
18 consent from the next of kin for results of
19 post-mortem examination. Reference is made in the
20 bold print to the concern about vCJD and the proposed
21 prospective and retrospective surveillance study that
22 was being undertaken.

23 It contains provisions for the relative to
24 agree to the post-mortem examination being performed.
25 It explains samples will be sent to the National CJD

41

1 "In the period 1985-1998, at least 88
2 postmortems were performed out of a total of 1,300
3 haemophilic deaths (as reported to the UKHCDO
4 Database). Wherever possible, centres should
5 establish the extent of their postmortem material and
6 refer relevant sections to the CJD Unit following
7 liaison with the study coordinator. Help with the
8 tracking and retrieval of specimens may be available.

9 "No additional consent is required for this.

10 "In the case of biopsy material available in
11 deceased patients, similar action should be taken.
12 Where the patient is still alive [presumably in
13 relation to biopsy material] consent would be required
14 for such an examination using the retrospective
15 analysis consent form".

16 It would appear that in relation to the
17 retrospective study of post-mortem material and,
18 indeed, biopsy material from deceased patients, there
19 was no intention to notify relatives or seek their
20 agreement. I'm seeking to establish this as a matter
21 of fact. Is that your understanding from this
22 material?

23 A. That's my understanding. I know that they took this
24 question to the Ethical Committee, and it was
25 discussed also with the CJD Unit in Edinburgh. And it

43

1 Surveillance Centre in Edinburgh, where they will be
2 examined, that the results will be available to the
3 relative. And then it provides:

4 "It is ... your decision as to whether you wish
5 to be informed specifically of the results of the
6 tests for vCJD."

7 And then provisions made for the relative to
8 sign.

9 As I understand it, that addresses the question
10 of obtaining consent from the next of kin for
11 post-mortems postspectively, so any post-mortems that
12 might be undertaken following the production of these
13 documents.

14 If we go, please, Soumik, to WITN3289151. We
15 can see this is a further document relating to the
16 proposed vCJD surveillance study. We can see data is
17 going to be collected through the National Haemophilia
18 Database.

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

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

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

42

1 was the Ethical Committee's opinion that we didn't
2 need to. I wasn't involved in that, but I know that
3 this issue was examined.

4 Q. Do you know whether in your capacity as director of
5 the Manchester Centre or in your capacity as director
6 of the National Haemophilia Database, the extent to
7 which centres hold post-mortem material that would
8 have been covered by this study?

9 A. Well, that's part of the problem because I don't think
10 that they do. You know, after the Alder Hey scandal,
11 retention of material was dramatically reduced. The
12 Human Tissue Act has a lot to say about the retention
13 of material. And so retrospectively there is little
14 or nothing available.

15 And the sort of deposit, tiny deposit, of
16 prion protein in the spleen of that patient that we
17 reported in 2009 would not have been picked up by
18 a standard autopsy. A standard autopsy would have
19 completely missed it. It's not a microscopic
20 appearance that we're talking about. It's carefully
21 slicing up the spleen and using a very specific stain
22 to see what you're looking for. So you have to be
23 looking for that specifically.

24 So frankly, the chance that this would have
25 picked anything up was relatively slight anyway. So

44

1 I don't think there were large amounts of retained
2 material.
3 **Q.** Do you know what the position is in relation to
4 Manchester specifically when you became director in
5 '94 --
6 **A.** I'm sure we had nothing. I know that I -- as
7 a centre, we contributed nothing to this study.
8 **MS RICHARDS:** Sir, I note the time, and I'm about to move
9 on to another topic, so would this be the right moment
10 to take the break?
11 **SIR BRIAN LANGSTAFF:** Yes, it would. We'll take a break
12 for half an hour as usual, allow you to get a cup of
13 coffee, and we will be back at quarter to 12.
14 **MS RICHARDS:** Thank you, sir.
15 **SIR BRIAN LANGSTAFF:** Quarter to 12.
16 (11.16 am)
17 (A short break)
18 (11.46 am)
19 **SIR BRIAN LANGSTAFF:** Yes.
20 **MS RICHARDS:** Professor Hay, I'm going to ask you next
21 a handful of questions about the functioning of
22 UKHCDO, to your knowledge, in light of the roles
23 you've held within UKHCDO, and about the National
24 Haemophilia Database.
25 Could we please have on screen, Soumik,

45

1 a member, it was a member of Haemophilia Centre
2 Directors. So although the initials of the
3 organisation have remained the same throughout this
4 period, it's at this point that the membership was
5 widened to include all doctors involved in haemophilia
6 care. So it becomes the UK Haemophilia Doctors
7 Organisation.
8 **Q.** Prior to this, and if you don't know the answer to
9 this, because it may predate '87, then please say so,
10 were there any materials that set out the way in which
11 UKHCDO was organised or would function in any written
12 materials?
13 **A.** Not as far as I'm aware.
14 **Q.** Sorry, professor, carry on.
15 **A.** Well, you know, I might have missed something but
16 I have read a lot of the older minutes, recently.
17 **Q.** Then if we go to page 6, we can see here there's
18 a list of regional centres. Now previously we've --
19 I've been referring to, and they were referred to in
20 the minutes, as "Reference Centres". This seems to
21 include what were the Reference Centres but add
22 a handful of other centres such as Liverpool,
23 Newcastle, Norwich, Truro, and Lord Mayor Treloar
24 College. Was this the point at which the concept of
25 Reference Centres changed to a concept of regional

47

1 WITN3289082.
2 This is a constitution for the United Kingdom
3 Haemophilia Centre Directors Organisation dated
4 September 1991, and if we go over the page we see what
5 was there being set out, it's:
6 "... non-profit making. It exists to promote
7 the provision of the higher standards of care for
8 patients with Haemophilia and other Inherited Bleeding
9 Disorders.
10 "Its functions and purposes also include -
11 "a) the collection and analysis of statistics;
12 "b) the initiation of research;
13 "c) the provision of professional advice to
14 other bodies;
15 "d) the diagnosis and treatment of inherited
16 thrombotic disorders within those Centres which elect
17 to participate in this activity."
18 Now you became a member of UKHCDO in 1987, so
19 about four years before this. As far as you know, was
20 this the first time there had been some form of
21 written constitution?
22 **A.** Yes, this corresponded with the organisation becoming
23 a registered charity, and we took advice and decided
24 we needed a constitution partly for that reason.
25 We also reviewed the membership. When I became

46

1 centres and became slightly broader?
2 **A.** I think that had happened already, at an earlier
3 stage. The Reference Centres were only ever about
4 five centres. I think they included Sheffield,
5 Manchester, Oxford, the Royal Free and St Thomas', and
6 that was about it. Maybe Cardiff, I'm not sure.
7 **Q.** Cardiff and Edinburgh --
8 **A.** Yeah ... well, yeah. They were centres of reference
9 and the Organisation of Haemophilia Care in the UK
10 changed from time to time. There was a health service
11 circular -- HSC197630, I think -- which described the
12 Organisation of Haemophilia Care in the
13 United Kingdom, and I think at that stage divided
14 Haemophilia Centres into Reference Centres,
15 Haemophilia Centres, and Associate Centres.
16 And that was subsequently changed with
17 HSG9330 -- 93, I can't remember the second name -- the
18 second number -- which introduced the concept of
19 Comprehensive Care Centres and Haemophilia Centres,
20 depending on the level of service that they provided,
21 and giving criteria for the designation. And that was
22 subsequently audited, so that if you wanted to become
23 a Comprehensive Care Centre you had to have an audit,
24 and the level of service you were able to provide was
25 audited anyway.

48

1 Q. And in terms of the chair of UKHCDO, this constitution
2 provided for an elected chairman with a three-year
3 office that could be extended to six years.
4 Do you know, prior to this, what the
5 arrangements were for selecting the chair even?
6 A. I think they were more informal. This formalised
7 things. I think the chair -- I'm not entirely sure,
8 to be honest, because I couldn't come across anything
9 written.
10 Q. That's all right. In terms of -- I'm sorry, carry on.
11 A. I think the chair would be elected by affirmation in
12 the past. It can still happen, because what happens
13 is that the chair sends out an invitation and anybody
14 can apply, and if there are more than -- if there is
15 more than one applicant, and they have to have
16 a proposer and seconder, then an election takes place,
17 of the entire membership. So all the members vote.
18 If there's only one applicant, and they are
19 agreed, then they may be elected unopposed.
20 What people frequently do is they canvas to
21 discover what their support is and then they may or
22 may not apply, depending on how much support they feel
23 they've got. Similarly for the other post holders,
24 the treasurer, the vice-chairman, the secretary.
25 Q. Over the time of your involvement with UKHCDO, so

49

1 And prior to being a charity, that was fine,
2 but once we were a charity, you couldn't continue in
3 this way. And so the UKHCDO limited company was
4 formed, initially to deal with the membership fees and
5 to deal with the annual general meeting, and, at
6 a later date, also took under its arm the National
7 Haemophilia Database.
8 Now, in the very early stages of the
9 organisation, shortly after being formed, the
10 organisation did receive some funding from the Medical
11 Research Council, predominantly to look at hepatitis,
12 but I don't know that it received very much direct
13 funding from either the NHS or the Department of
14 Health.
15 Latterly, during my involvement, we did receive
16 funding from the Department of Health, partly to
17 support our involvement with national procurement and
18 various other projects.
19 Q. So is this right, and please correct me if I'm wrong,
20 that the Department of Health does not provide
21 a regular ongoing amount of funding to UKHCDO, but has
22 funded UKHCDO to undertake or work on particular
23 projects? You mentioned national procurement; I think
24 I've seen some reference in the papers to UKHCDO's
25 work in relation to recombinant, there having been

51

1 either the period from '87, since you've been
2 a member, or '92, since you've been an officeholder,
3 how has UKHCDO been funded as an organisation?
4 A. Well, it has very little funding. It's a registered
5 charity. Charities are not allowed to trade. Before
6 that, its only source of income was the annual general
7 meeting, which generally generated a profit of
8 something of the order of £20,000 to £30,000. When
9 this new constitution became into being it was also
10 decided that the members should pay an annual
11 membership fee of £20. That brought in something of
12 the order of £1,500 to £2,000. It was recently
13 abandoned because it was considered that it was more
14 trouble to collect than it was worth.
15 Q. Again, over the time that you've been involved, to
16 what extent has the organisation received funding from
17 the Department of Health?
18 A. Well, the charity hasn't received very much funding.
19 After it became a charity, the organisation had to
20 form a trading arm. This is very common amongst
21 learned societies and so on, if they're registered as
22 a charity, because the source of the profit for the
23 annual general meeting would be industry and BPL
24 coming along with a stall and giving sponsorship for
25 the meeting.

50

1 possibly some funding in relation to that.
2 A. Yes, yes, that's correct. When I took over the
3 database, the big problem was it had previously run
4 with no funding per se but had effectively been
5 supported by the Oxford Health Authority in that they
6 had paid the salary of Rosemary Spooner and
7 a part-time secretary who helped Rosemary Spooner.
8 Those were the only paid staff running the database
9 back then.
10 Now, when I took it over, it appeared to me
11 that the database is withering on the vine and for it
12 to be sustainable it would have to be brought up to
13 date and to produce more interesting data, because we
14 produced an annual report at that point, but it wasn't
15 producing very much research, and the data wasn't
16 timely enough to be of interest to the Department of
17 Health.
18 As far as I could see, the data would be of use
19 for Department of Health planning purposes, which
20 would benefit the patient group as a whole. And so
21 I approached the Department of Health and had
22 conversations with, amongst others, Julia Stallibrass
23 to talk about the potential for getting funding from
24 the Department of Health, and she very reasonably said
25 to me what I've expected, and that was, "Well, you've

52

(13) Pages 49 - 52

1 got to produce something of interest, and we would
2 think about it."

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

6 Then there were these project grants that came
7 along, but funding was insecure, which is, to be
8 honest, the fate of disease databases, many of which
9 fold after a short period of time, through lack of
10 funding, and we clearly wanted a regular income stream
11 so that the database could develop and become more
12 useful. And the Department of Health did facilitate
13 this. Apart from providing us with project funding
14 for various projects that were obviously important,
15 they facilitated discussions with the commissioners so
16 that the commissioners now provide us with a lot of
17 funding, which we charge them on a pro rata basis
18 according to the population served, so we get funding
19 from NHS England, the lead purchaser, which I think is
20 the London Consortium, NHS Scotland, and NHS Wales.

21 Q. You referred to there being, in the early stages of
22 the establishment of the new database, your words
23 I think were "unrestricted grants from various
24 suppliers".

25 A. Yes.

53

1 the -- several companies shared the cost to support
2 research into risk factors for Factor VIII inhibitor
3 development. Sometimes they come to us with a request
4 for an analysis, for example of how their products are
5 used, and we would provide them with an anonymised
6 aggregate report focusing on the use of their product,
7 which is useful market data, and we would charge them
8 for that.

9 Sometimes they need this to deal with an
10 argument we had with NHS England, for example, in
11 which case the data is provided to NHS England and to
12 the pharmaceutical company, exactly the same data, but
13 the pharmaceutical company will have to pay for it.

14 An example of that is the recent discussion
15 between Sobi and NHS England about the relative
16 efficacy of their extended half life Factor VIII, and
17 whether, because of its extended half life, you may
18 need fewer units, and whether their product reduces
19 the annualised bleed rate in the patients using it,
20 for example.

21 And that's the sort of question, to be honest,
22 we welcome, because it's a question that's of interest
23 to everybody. And it helps NHS England to make its
24 own planning decisions.

25 Q. Do you know whether there is any record of amounts

55

1 Q. First of all, by "suppliers" you mean pharmaceutical
2 companies?

3 A. Yes, that's exactly right. Yeah.

4 Q. What do you mean by "unrestricted grants"?

5 A. An unrestricted grant is an unconditional grant. I've
6 always felt it was -- they're always described as
7 "unrestricted grants". I've always felt that it was
8 probably the wrong word to use, but there you are.
9 These are grants that are given without conditions,
10 which would be an absolute prerequisite for the
11 organisation.

12 Q. And other than funding from pharmaceutical companies
13 towards costs of the National Haemophilia Database,
14 what other funding has UKHCDO received from
15 pharmaceutical companies, to your knowledge, over the
16 years you've been involved. There's the sponsorship
17 of the AGM.

18 A. Yes.

19 Q. Has that continued to receive pharmaceutical company
20 support?

21 A. Yes.

22 Q. And what other kind of matters are funded by
23 pharmaceutical companies?

24 A. Well, sometimes we get unrestricted grants from
25 industry to fund non-commercial research, for example

54

1 received by UKHCDO, either from pharmaceutical
2 companies or the Department of Health, prior to 1987?

3 A. I don't know of any such record. The organisation was
4 running on a far more amateurish basis compared with
5 now. I mean now the database has a manager.
6 Obviously since we've been operating as a company, we
7 have had a board of directors. Their accounts are all
8 audited and have to be submitted to Companies House,
9 and we have detailed financial records from them.

10 Q. I want to ask you a little more about the National
11 Haemophilia Database itself. In what year was the
12 database formally established and management
13 transferred from Oxford to Manchester?

14 A. Well, the database was established about the same time
15 that Haemophilia Centres were established, way back in
16 1968. And it started under the leadership of Rosemary
17 Biggs, who was the then Centre Director in Oxford and
18 an international authority on blood clotting in the
19 UK. In fact, I think the first clotting textbook
20 I bought was written by her. And Charlie Rizza worked
21 with her. He took it over when she retired, and
22 initially they were attempting to address simple basic
23 questions that were not known. For example, how many
24 patients with haemophilia are in the UK?

25 And initially, it was very much focused on

56

1 haemophilia A and B. And in the early years of the
2 database, they didn't consider any other diseases, not
3 even von Willebrand's disease, for several years.
4 I'll give you a history of all of this in the final
5 chapter of UKHCDO's rule 9 response.

6 The database developed a little bit over
7 subsequent years. And then in about 1999, I became
8 more involved with the database because it needed to
9 be upgraded technically, and I employed a software
10 engineer who had written the Haemophilia Centre
11 information system that I used in my centre, amongst
12 other things. And we went down to Oxford to assess
13 its technical requirements and, from that point on,
14 liaised closely with Miss Spooner, who was running it.

15 And then in 2001, she retired. It might have
16 been 2002. But her imminent retirement precipitated
17 a bit of a crisis because, as was the case right
18 across the UK, Oxford Health Authority reviewed all
19 its posts as they felt they could and resisted
20 attempts from outside organisations to get them to pay
21 for what was a national function. So, you know, this
22 is a little district Health Authority, and it's
23 employing one and a half people for a national
24 function, and it didn't want to continue to do that.
25 So her post was threatened with not being refilled.

57

1 started in a very different climate. And back in
2 1968, there was no data protection legislation, and
3 since we were not conducting interventional research,
4 I think it was felt perfectly reasonable to collect
5 and hold this data.

6 There was some data protection legislation
7 prior to 1998, but the 1998 Act harmonised this
8 legislation across Europe and tightened things up
9 considerably. And I was a member of the Information
10 Technology Working Party and then chairman of the Data
11 Management Working Party, both of which fulfilled the
12 same role as a sort of oversight committee for the
13 database.

14 And the Information Technology Working Party,
15 chaired by Brian Colvin in the late '90s, began to
16 address this question. And I think we began to think,
17 well, we weren't keeping the database a secret; the
18 Haemophilia Society knew about it and so on, but we
19 suspect that many of the patients did not.

20 I think you've taken evidence from previous
21 medical witnesses who have told you that they don't
22 think that patients were being asked about the
23 database back at that time, and I think that that is
24 probably correct.

25 So, you know, as with so many historic

59

1 So the organisation had to consider the future
2 of the database, and so I was the chairman of the Data
3 Management Working Party at that point. And we put up
4 a proposal. The organisation summoned Oxford and
5 Manchester to put rival proposals to the executive and
6 the Advisory Committee, and then they decided that
7 they preferred my proposal, and so the database was
8 moved to Manchester.

9 **Q.** Now, one of the issues that has arisen in relation to
10 the database over the years in the various minutes
11 that we have amongst the Inquiry's materials is the
12 question of patients' consent to information about
13 them being provided to the database or being held by
14 the database.

15 In some of the materials that you have produced
16 over the years, what appears to be said is that prior
17 to 2000, there was no consent process in relation to
18 the collection of that material, and it was the Data
19 Protection Act coming into force that then triggered
20 a series of debates that play out through the minutes
21 of various meetings about what form that consent
22 should take. Is that an accurate summary?

23 **A.** I think that is an accurate summary, but I think
24 a little context might be helpful.

25 Like many historic databases, the database

58

1 databases, it was a matter of catching up and taking
2 advice on what was reasonable, and opinion on what was
3 reasonable did change with time. So we established
4 around 2000 -- our opinion was that the patients
5 needed to be actively informed about the database, the
6 data that was being held, the uses to which it was
7 being put, and of course their rights under the Data
8 Protection Act of 1998. Although the Act is dated
9 1998, there is always a gap before the conditions come
10 into force. But we needed to inform the patients that
11 they had rights under the 1998 Act, and that these
12 included the right to have their data withdrawn.

13 Now, my personal starting point to take advice
14 was to go to the Information Commissioner. Now, the
15 Information Commissioner was based in Data Protection
16 House, which is on the main street, or off the main
17 street in Wilmslow, about three or four miles from
18 where I am now. So it was particularly convenient to
19 make an appointment to go and speak to a case worker
20 to outline our situation with them, and to outline our
21 proposals for addressing it. They were extremely
22 helpful.

23 They felt that the NHS purposes to which we
24 were putting our data, any reporting to the NHS that
25 took place -- of course, at that time, there was very

60

(15) Pages 57 - 60

1 little -- did not require any form of consent. Just
2 as you don't give consent when you go along to a
3 hospital or the GP, but it is assumed that they will
4 handle your data and that they will handle your data
5 securely. But any further purposes, for example
6 research or sharing anonymised data with third
7 parties, would require consent.

8 There then followed a debate about what the
9 nature of that consent should be. Should it be -- and
10 of course a lot of this consent would have to be
11 obtained retrospectively because we had held those
12 patients' data for a considerable period of time
13 anyway.

14 Should that consent be written consent, or
15 would implied consent be adequate? Now, implied
16 consent is informed consent, as for written consent,
17 but with an opt-out. And that was the pattern that
18 was adopted by disease databases right across the UK.
19 And the Data Protection Registrar considered that that
20 was adequate, and so that was the form of consent that
21 we had. But we had to have a process whereby we made
22 sure that the patients were aware of the database and
23 their right to an opt-out.

24 So we produced a series of leaflets. I have
25 included all of the leaflets as exhibits to my rule 9

61

1 this and then they may have questions.

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

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

22 From 2013, we recognised that we had a problem
23 in that NHS Digital, who provided us with death
24 certification data, became more difficult to deal with
25 in a number of different respects. They questioned

63

1 response. And you will see that they were reviewed at
2 irregular intervals throughout that period and
3 reissued, and each time we would print something like
4 30,000 copies, distribute them to centres, centres
5 could request further copies if they ran out, and we
6 recommended that they should not be posted to patients
7 because you don't know if they've been received or
8 what response there should be, but should be given to
9 them in an opportunist way. By that I mean when
10 opportunity arises.

11 This was another specific point that I
12 discussed with the Information Commissioner and,
13 indeed, subsequently with the NHS Research Authority
14 and Ethics Committee because patients, particularly
15 with mild bleeding disorders, are not seen very often.
16 So getting this information to the patients could take
17 quite a long time, and I had to know that that was
18 acceptable.

19 In general, both the NHS Research Authority and
20 the Ethics Committee did not favour posting these
21 things to the patients, and that's a position
22 I entirely agree with because you don't know if it's
23 been received, and perhaps most importantly, the
24 recipient doesn't have the immediate opportunity to
25 have their questions answered, because they may read

62

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

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

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

64

(16) Pages 61 - 64

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

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

20 I made it clear to them that some of the
21 patients were not seen frequently. They asked me over
22 what period I felt I could obtain written informed
23 consent from the whole group, and I told them, given
24 the frequency with which patients were seen and the
25 fact that some were lost to follow-up, it would be

65

1 appropriate paperwork for each patient. So there's
2 a button that they press and it will produce
3 a patient-specific consent form, and package of
4 information, which is appropriate and personalised.
5 That enables them to upload the whole thing, once it
6 has been dealt with, to the database, so that we have
7 an electronic record of each consent.

8 We went to the Ethics Committee and they gave
9 us ethics approval for the database as a research
10 database, and that was the situation. And we were
11 busily getting consent when Covid struck and that has
12 obviously reduced the number of face-to-face
13 interactions quite dramatically and slowed down
14 obtaining consent.

15 But the other thing that changed was we are
16 still going through the process of sorting things out
17 with NHS Digital to start sending us death
18 certification data. Not least because clearly
19 mortality data forms an important element of the
20 UKHCDO response to their Rule 9 request. There's
21 a whole section on mortality.

22 And we got to the point we wanted to make an
23 annual report to NHS RA CAG, and at that point, they
24 sort of indicated to us that their opinion had
25 changed.

67

1 five years and it would probably never be complete.

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

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

20 So we wrote a series of age-appropriate
21 information sheets, which are included as exhibits in
22 my Rule 9 response, age-appropriate consent forms,
23 which you'll notice have a QR code on them which is
24 unique to the patient. We wrote software on the
25 database for centres to access -- to get the

66

1 So we organised a meeting with NHS RA CAG. It
2 wasn't a meeting with the whole committee as it had
3 been before. The whole committee is a very large room
4 lined with people, it must be about 30 or 40
5 individuals, I never counted them. We met with, if
6 you like, the executive of that committee earlier this
7 year, and they indicated to us that they had revised
8 their opinion. Not just in relation to UKHCDO, but in
9 relation to other disease databases. And they felt
10 that partly because of Covid but also because of the
11 numbers involved, and because of several aspects
12 that I had discussed with them at earlier meetings,
13 including the fact that you can't take consent from
14 people who have already died, you have a problem with
15 people that are lost to follow-up and who refuse to
16 come along. They had concluded that it was
17 impractical to obtain written affirmative consent from
18 all the participants in the database, and that we
19 would be eligible for section 251 exemption, which
20 they strongly encouraged us to apply for.

21 And they suggested two separate applications in
22 relation to, firstly, the NHS purposes to which we put
23 the data, and secondly, the research purposes to which
24 we put the data.

25 So we submitted two separate applications.

68

(17) Pages 65 - 68

1 I think they had also changed some of their
2 procedures, both with NHS Digital and with the
3 NHS RA CAG. Since we first dealt with them, they have
4 realised that a lot of the difficulty that they have
5 with applications is that we are trying to work out
6 what they need and we don't necessarily know. So they
7 have caseworkers who offer advice as you're developing
8 your application to make sure that you're addressing
9 the right questions --

10 Q. So, what --

11 A. -- in the right way.

12 Q. What is then the current position if -- if -- for the
13 period from 2000 until recently, the database operated
14 on the basis of implied consent with an ability to opt
15 out, and that information was disseminated to patients
16 through the various situations of the leaflet that you
17 produced?

18 A. Yes.

19 Q. You then, in the way you've described, started to move
20 towards a written informed consent in relation to the
21 holding and use of data, interrupted by the current
22 pandemic. What is the UKHCDO's intention, then, from
23 now onwards, in terms of whether it obtains some form
24 of express consent?

25 A. Well, the situation is that we submitted our two

69

1 So we will -- we're in the process of again
2 revising our patient information, because although we
3 revised it only last year, it has rapidly gone out of
4 date. We don't anticipate that we will ever share
5 named data, so I don't anticipate that there will be
6 any exemptions.

7 Q. There's one discrete issue arising out of the
8 operation of the database I wanted to ask you about.

9 Soumik, could we have, please, HCDO0000002_066,
10 please.

11 So this is a meeting in November 2003 of the
12 UKHCDO's Data Management Group. If we go to the last
13 page, please. This is in the context of patients'
14 request to access information held about them.

15 The minutes received read as follows:

16 "Dr Hay continues to receive such requests.
17 Patients do not really know what data is being held on
18 the national database. Dr Hay has not prepared
19 a leaflet to let them know what type of information
20 they can expect, but he sends them a letter explaining
21 this, together with an invoice for £10 instead. This
22 often is sufficient for them to abandon their
23 request."

24 Now, that reads, Professor Hay, arguably, as
25 seeing the abandonment of a request for data as

71

1 applications for Section 251 exemption. The Committee
2 considered those on August 3 of this year, and
3 subsequently -- and this has to be confirmed by the
4 Secretary of State for Health or their representative,
5 with the weird title of a "decision-maker", and they
6 have confirmed that this has the approval of the
7 Secretary of State for Health, and so we now no longer
8 have to obtain written consent. I'll be describing
9 this to the membership of UKHCDO at the AGM tomorrow.

10 Q. Are there any purposes for which data held by the
11 National Haemophilia Database is put for which you
12 will be seeking express written consent, or express
13 consent of any form, or is the position going to
14 entirely revert to the 2000 to 2019 position of
15 implied consent with opt-out?

16 A. With this exemption, we do not need the patient's
17 permission, though the patients still have the right
18 to have their data removed, and we have removed one
19 patient's data at his request only last week, despite
20 this. So the patients can still opt to have their
21 data removed, should they wish to do so. Although we
22 don't have to ask for permission, we have always felt,
23 at least since we started to think about this around
24 2000, that the patients should know what we're doing,
25 why we're doing it, and what we hold.

70

1 an advantage to which the --

2 A. I can see where you're coming from, and that is not
3 the impression that I would wish to give, because
4 I think early on, I think a lot of people thought that
5 we held far more data than we did. So we would let
6 them know what we did hold. In fact, although it may
7 be a little scanty, particularly in the older -- in
8 the earlier period, it is sometimes more useful than
9 we think. And the £10 invoice was the fee that is set
10 out in the Data Protection Act of 1998. Since we've
11 gone to GDPR, there is no fee at all. It's a nominal
12 sum in any case.

13 I deprecate the impression that is given here
14 that we wanted to discourage anybody from making
15 a request. We get a lot of phone calls from patients.
16 We try to be as helpful and friendly as we can. It's
17 clearly their right under the Act to get data.
18 Sometimes, although the data from the early years is
19 not extensive, it nevertheless tells them the brand of
20 concentrate they were first exposed to and which year
21 they were exposed to it. And for people that are
22 trying to find out about the origin of their
23 hepatitis C, that is a key piece of information which
24 may have already been lost from their notes.

25 I think a lot of the patients thought that we

72

1 held as much information as the hospital might, and
 2 that we were an alternative source of really detailed
 3 data. And, of course, that was never the case.
 4 **Q.** A separate issue but still relating to records is the
 5 subject of my next question.
 6 Soumik, could we have NHBT0091224_008, please.
 7 So this relates to the approach taken by the
 8 Skipton Fund to applications, and there are various
 9 communications between you and the Skipton Fund in the
 10 materials that we have. I just wanted to ask you in
 11 particular about this one.
 12 You wrote on 5th July 2011 to Mr Stevens as
 13 chair of the Skipton Fund along with the chief
 14 executive or the then chief executive of the
 15 Haemophilia Society, Mr James.
 16 And you say:
 17 "We are writing to you jointly to express our
 18 concern and to question the approach currently being
 19 adopted by the Skipton Fund to a number of
 20 applications from the dependents of the deceased.
 21 "A number of cases have been rejected even
 22 though the deceased relative can show that they were
 23 treated with concentrate during the period of risk,
 24 because the notes have been destroyed or the patient
 25 died prior to the advent of HCV testing. We have

73

1 developed chronic hepatitis C, given a 25% spontaneous
 2 remission-rate and should therefore be eligible for
 3 a part 1 payment, even if the documentary support for
 4 this has been destroyed and/or they died before the
 5 advent of HCV testing."
 6 Professor Hay, the Inquiry will be examining
 7 the operation of trusts and schemes for financial
 8 assistance in more detail in the early part of next
 9 year. What can you tell us about this particular
 10 issue, and the extent to which it was resolved or not
 11 following this communication?
 12 **A.** Well, we never sent data directly to the Skipton Fund.
 13 I don't remember this. I think at some point the
 14 Secretary of State for Health stated that these cases
 15 should be settled on the balance of probabilities,
 16 which seemed the only reasonable basis on which it
 17 should be decided. And we wanted to do whatever we
 18 could to support the applications to the Skipton Fund.
 19 What happened in reality, was that patients who
 20 were scratching around for evidence would turn to us
 21 and ask for an extract of the data we held on their
 22 relative, or the patients themselves would. And we
 23 would provide that. And I think, after this, they did
 24 take that into account to some extent, because --
 25 these were very often deceased patients whose notes

75

1 heard of one case refused even though liver disease
 2 was mentioned on the death certificate. Some
 3 applications have been refused, even though evidence
 4 of chronically abnormal LFTs was also provided. In
 5 many cases, the notes have been destroyed because of
 6 the passage of time, but either the centre or UKHCDO
 7 can provide evidence of treatment with concentrate
 8 during the period of risk. Had this group been
 9 included from the inception of the Skipton Scheme, as
 10 both UKHCDO and the Haemophilia Society argued, it is
 11 far more likely that the documentation would still
 12 have been available to support their application.
 13 "These refusals are causing considerable
 14 distress."
 15 Then you go on, on the second page, to set out
 16 in the first paragraph of that page your concern that
 17 Skipton, rather than applying a test on balance of
 18 probabilities, was applying a higher standard, of
 19 beyond reasonable doubt, in reaching decisions, and
 20 then you say:
 21 "On the balance of probabilities, all patients
 22 treated with clotting factor concentrate during the
 23 period of risk will have contracted hepatitis C, given
 24 the 100% infection rate documented in the literature.
 25 On the balance of probabilities they will also have

74

1 had been destroyed after death, and they were left
 2 with very little documentation.
 3 But the data we held, scanty though it was, we
 4 felt should be adequate to support an application at
 5 least for a part 1 payment and, if they had a death
 6 certificate, perhaps part 2.
 7 **Q.** I want to move, then, to your involvement with -- or
 8 the involvement of the Haemophilia Database in an HCV
 9 look-back exercise.
 10 Henry, could we have, please, WITN3289157.
 11 So we can see this is a proposal submitted by
 12 you on behalf of UKHCDO and the database entitled
 13 "Hepatitis C Look-back Exercise in Patients with
 14 Bleeding Disorders: 2009/10".
 15 If we go to the third page, please, Soumik.
 16 You set out in this proposal the objectives.
 17 (1) was:
 18 "To document patients with bleeding disorders
 19 already tested."
 20 And to identify how many had hep C, whether
 21 they'd been offered treatment, what was the outcome,
 22 how many patients had died.
 23 Then (2) was to identify patients who had not
 24 been tested for hepatitis C, so that they could be
 25 offered advice, testing and, as necessary, treatment.

76

1 Then if we turn on, please, Soumik, to page 6.
 2 Thank you.
 3 We can see here what you set out in the first
 4 main paragraph is that:
 5 "All patients with bleeding disorders treated
 6 with blood products during the period of risk (before
 7 1987) should have been tested in 1992 or soon after.
 8 All should also have been tested for hepatitis B from
 9 the late 1970s or early eighties."
 10 Then you say, skipping over a sentence:
 11 "Those untested are most likely to have been
 12 mostly mild bleeders, reviewed annually or irregularly
 13 and then subsequently lost to follow-up."
 14 Then you go on to explain how it was arisen
 15 that patients were not tested, in the bottom half of
 16 the page, at (a), (b) and (c), you say:
 17 "(a) Many Haemophilia Centres did not follow up
 18 mild bleeders regularly at all once the diagnosis had
 19 been made ...
 20 "(b) Many such patients will have moved house
 21 ... and will thus have become lost to follow-up. In
 22 this way they may have fallen through the net and not
 23 have been screened.
 24 "(c) Some patients may have moved or registered
 25 with a new centre. The new centre may be unaware of

77

1 the end because it became overwhelming.
 2 They wanted information about treatment
 3 provided to patients and the outcomes, the number of
 4 patients with severe liver disease, and various other
 5 things for the purpose of healthcare planning and also
 6 to help them to work out how much funding they needed
 7 to put into the Skipton Fund. And that made this an
 8 extremely involved exercise.
 9 And so we asked centres for all this data. We
 10 asked all the centres that the patient had been
 11 registered with to provide us with data because we
 12 knew that the most recent centre might not know what
 13 the patient had been treated with, say, two, three,
 14 four decades before in some other centre or maybe even
 15 district general hospital.
 16 So we approached this whole thing making no
 17 assumptions about anything, other than if they had
 18 been diagnosed outside the period of risk; ie, after
 19 1991, they would not have been exposed to an at-risk
 20 product. So we were looking just at patients who had
 21 been diagnosed before 1991 and making no assumptions
 22 about the treatment that they might have had.
 23 Unfortunately, that led to us asking for data
 24 on something like 28,000 patients, some of whom --
 25 about a third whom had died because of the long

79

1 their previous blood component or blood product
 2 treatment history and therefore may not have
 3 identified the patient at being at risk for
 4 hepatitis C."
 5 Then the top of the next page, at (d):
 6 "An unknown but significant number of mild
 7 bleeders may have been treated by non-specialist
 8 centres. These patients are often not followed
 9 systematically and are less likely also to be
 10 registered with the [National Haemophilia Database]."
 11 Then if we go on to page 9, you set out there
 12 a proposed approach using the database to generate
 13 lists, sending them to centres, asking the centres
 14 then to scrutinise those lists, effectively, and to
 15 work from there.
 16 So that was the proposal which was, as
 17 I understand it, then put into effect. Can you
 18 underline for us how the look-back exercise was then
 19 undertaken?
 20 A. Well, we provided centres with spreadsheets, giving
 21 them the information that we held and asked them to
 22 fill out the blanks, effectively. There were a number
 23 of objectives. We focused on the identification of
 24 patients who were untested, but the Department of
 25 Health added a lot to this, which was unfortunate in

78

1 timescale we were looking at. And we were asking in
 2 some cases multiple centres about the same patient to
 3 get the whole picture because, you know, we have some
 4 patients recorded on the database against seven
 5 different Haemophilia Centres because they'd moved
 6 around the country during their life.
 7 And the centres were quite honestly completely
 8 overwhelmed by this. They did try. We told them that
 9 this data had been requested by the Department of
 10 Health, but I don't think they were staffed to do it.
 11 The patients who were lost to follow-up or who had
 12 died, obtaining their records was sometimes difficult,
 13 and sometimes the records had been destroyed. And
 14 that sort of collecting them together was quite
 15 difficult.
 16 And this was primarily a problem for the
 17 non-severe bleeders, because the severely affect
 18 patients are seen very regularly; they're well
 19 documented, and pulling their data together wasn't
 20 difficult. But they are a small minority of all the
 21 patients who were potentially at risk. So it rapidly
 22 became apparent that we were not -- just not going to
 23 get all the data. The testing data was just a small
 24 part of that.
 25 So we had to go back to the Department of

80

Health and revise things, and we pointed out to them that we would be able to extrapolate from, say, 10% of the data. And they agreed a modification to the protocol whereby we would still request the testing data on everybody, but the more detailed data, such as the severity of their liver disease, the treatment history and so on, would only be requested from a randomly selected 10%. For planning purposes, we could extrapolate from that.

Whilst it was entirely understandable that the Department of Health might have wished to ask those questions, this was the element that just completely overwhelmed the centres and made it impossible for us to pursue it. I have actually included as an exhibit to my section 9 response a copy of the final report which gives you a flavour of how far we got. But after a period of about three years, we had to abandon this because we weren't getting any new data in.

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

81

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

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

So you:

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

And then you report:

"Of the 9,090 patients whose previous treatment history was reported as 'unknown', HCV status was also reported as 'unknown' in 7,567. Of the 1,523 patients whose treatment history was reported to us as 'unknown' but who had been HCV tested, 398 had evidence of active HCV and 21 of past but cleared HCV. Thus 27.5 per cent of those members of this group who were tested and had a test result reported to us had evidence of previous exposure to HCV."

Then you say this:

"Were this to be found in the whole of the

83

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

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

Soumik, it's WITN3289162.

We can see it's a report that's said to be up to 31 March 2014. It's headed "Hepatitis C look-back report".

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

82

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

Top of the next page:

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

Then you strongly recommend that:

"... all patients diagnosed with a bleeding disorder before September 1992 should be tested for HCV because Centres and the patients themselves will frequently not know what their treatment history is."

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

A. Yes.

Q. And --

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

84

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

4 A. Well, I think I know that centres have attempted to
5 trace some of these patients. The database holds NHS
6 numbers. It doesn't hold NHS numbers for all the
7 patients, because we didn't collect NHS numbers for
8 the whole history of the database. So there are some
9 patients for whom we don't hold NHS numbers. Usually
10 these are very early registrants, so they may be dead.
11 But they are very difficult to trace, because some of
12 the early registrations we may not even have the whole
13 name. We mostly do, I hasten to add. This is a tiny
14 minority. Because these days we wouldn't accept
15 a registration of that quality. We would go back to
16 the centre and chase them for the missing details.

17 Now the point about this is if you know the NHS
18 number, and the patient is registered with a GP, then
19 you should be able to trace the patient, or at least
20 the GP. And I know that in my centre, and we have
21 asked other centres to do the same, we need to trace
22 all these people.

23 You will hear, with our response to the Rule 9
24 request to UKHCDO, that that's not always been
25 possible, and in some cases when centres have asked

85

1 a report from Dr Biggs. It's essentially a precursor
2 to the report from Dr Rizza that you referred to
3 yesterday, and I may want to ask you some questions
4 about it on the issue of life expectancy, so I would
5 invite you to check your emails and perhaps read that
6 over lunch. It's a fairly short document.

7 And then, secondly, addressed to recognised
8 legal representatives who are not present in the room
9 as they normally are but are listening remotely, this
10 hour is the opportunity for the recognised legal
11 representatives, please, to communicate by email to me
12 and to Ms Scott any further questions in addition to
13 those they've already submitted that they would wish
14 us to consider asking Professor Hay this afternoon.

15 **SIR BRIAN LANGSTAFF:** Well, what I shall do, given that
16 we're asking you, professor, to look at a report by
17 Dr Biggs, we'll extend the lunch break for
18 ten minutes.

19 So it's ten past two, please, and I look
20 forward to seeing you all then.

21 A. Thank you.

22 (1.02 pm)

(Luncheon Adjournment)

24 (2.10 pm)

25 **SIR BRIAN LANGSTAFF:** Yes.

87

1 the patient to come up to the centre for review they
2 have refused, but we can at least write to the GP and
3 ask if they've been tested, and if not, ask the GP to
4 arrange for them to be tested and explain the
5 situation in a letter.

6 UKHCDO has no direct patient responsibility but
7 in these exercises what we were trying to do is to
8 facilitate and make it easier for Haemophilia Centres,
9 whom we think do hold that responsibility, to follow
10 these patients up.

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

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

18 **SIR BRIAN LANGSTAFF:** Yes. Let's take a break until
19 2 o'clock, shall we.

20 **MS RICHARDS:** Before we cease the transmission and the
21 link with Professor Hay, just two matters, if I may,
22 sir.

23 The first directed to Professor Hay.

24 Professor Hay, you've been sent a document by
25 the Inquiry in the course of the morning which is

86

1 **MS RICHARDS:** Professor Hay, a handful of questions next
2 on the issue of consent, patient consent. And my
3 questions are going to be essentially seeking to
4 understand the factual basis for your understanding of
5 current and previous practices.

6 In relation to blood samples, you've said in
7 your statement, paragraph 80.3:

8 "One did not ask for consent to take blood
9 samples. I think it is assumed that the patient has
10 consented because they go along and allow the
11 phlebotomist to take the sample. It is not normal to
12 take verbal or written consent for blood sampling
13 other than for the purpose of research."

14 I understand your point, professor, about the
15 patient consenting by allowing the blood to be taken,
16 but do you take that to mean, in terms of your own
17 practice or your understanding of current practice,
18 that the patient is consenting to any and every use of
19 that sample, or is there some limit to the uses to
20 which the sample can be put?

21 A. Well, I think if the sample was to be stored, that
22 would be a separate matter. Although the Human Tissue
23 Act doesn't apply to plasma, as far as I'm aware. But
24 the patient wouldn't necessarily know that, probably
25 wouldn't.

88

1 I mean, it isn't normal practice for ask for
2 consent but you would -- and in a routine review
3 appointment, you tend to take the same samples each
4 time, and at some point you might -- well, the patient
5 would often know what the samples were for, because
6 the results would often be discussed. For example the
7 HIV viral load, the CD4 count, the patients often want
8 to know what those results are because they give them
9 an index of their current status, so you discuss them.

10 If you're taking a sample for something new,
11 depending on what it was, you might describe it in
12 general terms. I know, for example, if you refer
13 a patient with abnormal liver function tests to be
14 investigated by a hepatologist, they won't describe
15 every single test that they're doing but they'll say,
16 "Well, we're going to test for some hepatitis viruses
17 and some antibody tests and liver function tests".
18 They probably wouldn't say more than that unless the
19 patient asked, and if the patient asks, then of course
20 you'd tell them.

21 But what I was trying to get across is that it
22 is not normal practice to sit down and list every
23 single test that's going to be done, every time, and
24 say, "Is that all right?" Do you see what I mean?

25 Q. Yes. In a sense you've anticipated, I think, two of

89

1 Similarly, if I saw a patient with a mild
2 bleeding disorder that had been long since lost to
3 follow-up, who was new to me and might have been
4 treated with who knows what, in another hospital,
5 I would explain to them that we had to test them for
6 hepatitis C. I would give them an evaluation of the
7 likelihood of that test being positive, and say, you
8 know, "It may well be negative but we really need to
9 know one way or the other."

10 Q. And in relation to stored samples, could we look,
11 please, Soumik, at WITN3289054.

12 If we go to the second page. Now, this is
13 a specific form at Manchester Royal Infirmary in
14 relation to genetic testing, but if we go on to the
15 next page we can see it's -- it seems to be an
16 information sheet for patients. It asks the question
17 "What is the purpose of obtaining a blood sample?"

18 Then if we go over the page, it provides
19 information about where the sample will be tested, how
20 long the sample will be stored and then, if we go to
21 the next page, "What else might be done with my blood
22 sample?"

23 Now I appreciate this is a leaflet specifically
24 concerned with the taking and storage of samples for
25 genetic testing. But would you consider that those

91

1 my next questions.

2 Where you have a patient who is a new patient
3 or you're doing something which is not the standard
4 array of tests you may have done many times before,
5 and then explained the results, and you may assume
6 that the patient has some, therefore, understanding of
7 the purpose, but would you accept that, in principle,
8 different considerations may arise, depending on the
9 particular circumstances, with a patient who has not
10 previously been tested or a patient where you're doing
11 something new?

12 A. Yes, absolutely. Because at the end of the
13 consultation with a new patient, you would summarise
14 where you think you're up to. They will probably want
15 to know the range of possible diagnoses, and you will
16 describe in general terms what the tests will be. You
17 know, someone comes to me with easy bruising, I will
18 give them an -- my personal evaluation of the bleeding
19 history that I've just taken from them, and I will
20 tell them, you know, "We're going to check a few
21 clotting tests. We will probably have to get you back
22 in on another occasion to check your platelet function
23 tests", and you'll tell them they have to avoid
24 aspirin and drugs like that for two weeks before the
25 test, and so on.

90

1 kinds of questions, where will it be stored, how long
2 will it be stored, what else might be done with it,
3 are the kind of questions which patients should be
4 given information about if samples are going to be
5 stored?

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

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

24 I think if we were to store samples for
25 potential research in the future, some form like this

92

1 would be appropriate, but UKHCDO certainly don't do
 2 that, and I don't have any research samples stored
 3 away either. Research repositories have to be
 4 regulated and a form like this would be appropriate
 5 for that sort of purpose.

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

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

93

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

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

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

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

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

22 **MS RICHARDS:** Moving on, then, to the question of
 23 hepatitis C testing, you say in your statement this:
 24 "... it has never been customary, in any branch
 25 of the health service, to provide pre-test counselling

95

1 condition, which will be haemophilia A, B, or
 2 von Willebrand's disease, or whatever, and that you
 3 won't be testing for anything else.

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

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

19 So it's an important principle that applies to
 20 genetic testing.

21 Now, by the same token, I think if you stored
 22 a sample and you wanted to do research on it, you'd
 23 have to go back to the patient. I mean, I think
 24 that's the current view. I don't think it has always
 25 been that, but I think that, you know, even if you've

94

1 or obtain specific consent for hepatitis C testing,
 2 hepatitis A testing or hepatitis B testing."

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

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

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

19 **A.** Well, I can't remember anyone declining, although they
 20 have recently, when we've chased them up, the odd
 21 patient. Well, I think this circles around what you
 22 mean by "counselling", to be honest. Because my
 23 understanding of the questions being put to me in my
 24 Rule 9 request was that a comparison was being drawn
 25 between the situation of formal counselling for

96

(24) Pages 93 - 96

HIV testing and hepatitis C, and my answer was in relation to that. Because whilst I would certainly tell people I was testing them for hepatitis C, the implications for that test are not the same as for HIV.

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

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

Now, with hepatitis C we knew that the natural history was a prolonged one, that a significant proportion of patients would have a very good prognosis, whilst a significant minority would obviously get serious liver disease.

97

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

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

A. No, not really.

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

99

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

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

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

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

98

any more?

A. Well, we certainly did get written consent. We do get written consent for genetic testing, but not for any other tests unless they're invasive, of course.

Q. In relation to HIV testing, and I just wanted to understand your understanding of the current position, you've said in -- again, I think it's the same paragraph of your witness statement, you say that -- you're talking about HCV you say:

"Unlike HIV, which almost uniquely requires pre-test counselling during the '80s, '90s and until fairly recently," and then the impression your statement gives is that the current practice in relation to HIV testing would not necessarily involve the patient being told they were being tested.

A. Well, that's my understanding. I mean, I personally haven't tested any new patients for some time. If someone came out of the blue and their last treatment had been during the period of this, I would still go through all of that business. But at the beginning, I'm sure you appreciate, different clinicians had very different approaches to imparting someone's HIV status to them. I felt that Professor Preston's approach was a very good one, and some of my colleagues not so good. And then it became universal practice to

100

(25) Pages 97 - 100

carefully counsel people before they were tested.

And I only mention that because I think that the implications have changed with time because the treatment is very much better, and very few of our patients have died from HIV since 1995. Life insurance is also less of a problem.

I mean, at one time, if you had asked for a house loan above a certain level, the insurance company would insist you had an HIV test. I've been HIV tested twice myself on that basis, and my GP told me that half the residents in Lymm had had an HIV test for that reason. And he counselled me, despite the fact that he knew I was a consultant haematologist.

So I've seen both sides of this, shall we say. But all pregnant women are tested, and -- you know, so practice does change.

Q. I wanted to then ask you about some of your evidence yesterday in relation to life expectancy. So this, professor, was in the context of having asked you what consideration was given at Sheffield in 1983, 1984, to the possibility of reverting to cryoprecipitate more extensively, at least for a period of time. And you referred, when giving your evidence about increased risk of death and from haemorrhage and decreased life expectancy, to a paper by Dr Rizza, and I wanted to

101

You'll see it says in that first paragraph, in the last two sentences:

"The average ages of the patients who died were 46.7 years in the haemophilia A group, and 48.3 years in the haemophilia B group. Comparable figures for 69 to 74 were 42.3 years and 33.6 years respectively."

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

"A more useful statistic was the median expectation of life."

I think it's easier if we just go back to how it was before. Thank you.

"This was calculated from life tables. Surprisingly, the calculations yielded a median life expectancy of 69.1 years for severely affected haemophiliacs, as compared to 72.8 for normal males. Those figures must clearly be viewed with caution since the numbers in the calculations were relatively small and also because of the possibility that deaths in haemophiliacs may not all be reported to Haemophilia Centre Directors."

Then there's reference to the number of deaths due to cerebral haemorrhage in the following paragraph, at 26 of 89 deaths (29%).

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

103

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

WITN3289047.

A. "Haemophilia treatment in the UK from 1969 to 1974." British Journal of Haematology, 1977.

Q. That's the document we asked you to read over lunch which I'll come on to.

But first of all, yesterday, your evidence was that this was a potentially relevant piece of material, and this is one of the exhibits to your statement.

A. Yes.

Q. We can see it's by Dr Rizza and Ms Spooner. "Treatment of haemophilia and related disorders in Britain and Northern Ireland during 1976-80: report on behalf of the directors of Haemophilia Centres in the United Kingdom."

A. Yes.

Q. If we go to the second page, right-hand column, please, Soumik, under the heading "Age at death and causes of death". I wanted to check whether this was the material that you were referring to, Professor Hay, as relevant to the assessment being made in Sheffield in 1983 and 1984. So we'll see under the heading "Age at death and causes of death". Can we scroll down? Thank you. That's perfect.

102

that you were referring to in your evidence yesterday?

A. Yes.

Q. And what is it that you drew from this report when this issue -- well, sorry. I'm going to start that again.

Was this something that was expressly considered in 1983 and 1984 when the question of how to respond to the AIDS crisis may have been being discussed in Sheffield?

A. Well, it was published in 1983, in March. And the perception certainly was that the introduction of concentrate had significantly improved life expectancy.

Now, in the paragraphs you've just quoted me, they compare the average age of death, which is not quite the same thing as life expectancy, but they compare it with the previous reports from Rosemary Biggs, which you suggested I should read over lunch.

And -- now, Rosemary Biggs doesn't use actuarial methods or life table, so the average age of death is the only metric for comparison, and I'm sure you're going to point out to me that it has gone up relatively modestly.

Q. Yes.

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

104

(26) Pages 101 - 104

1 away was the median life expectancy of 69.1, which has
2 been much quoted since.

3 Of course, Rosemary Biggs was not the only
4 source of data. There were other studies showing the
5 average life expectancy at that time was about 40,
6 but -- you know, back in the '60s and very early '70s,
7 but it's quite difficult comparing all these things
8 because people use different methods.

9 I've recently written a review which is about
10 to be published in the Journal of Thrombosis and
11 Haemostasis on mortality and haemophilia, and this is
12 a difficulty that besets the whole area. It's
13 actually quite difficult to compare.

14 Now, one other thing I'd say about the
15 comparison between these two is they report adjacent
16 periods. And the second report from Charlie Rizza is
17 reporting a period during which concentrate is being
18 introduced and patients established on home therapy.
19 So you would perhaps not expect a really dramatic
20 difference because, in terms of the therapeutic
21 approach, the two periods overlap somewhat.

22 What it's showing is a trend towards improved
23 life expectancy that would not flower fully until the
24 period after 1980, when most people were established
25 on home therapy.

105

1 15 years, and so from the 50s they would have had
2 blood transfusion and plasma, and cryoprecipitate was
3 introduced in the mid to late 1960s.

4 **SIR BRIAN LANGSTAFF:** That's why I think Rosemary Biggs is
5 referring here, in the first sentence, is it, to 1967
6 because that's when cryoprecipitate would have been
7 introduced?

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

9 **SIR BRIAN LANGSTAFF:** Yes.

10 So the first sentence she says -- is
11 observational. It expresses an opinion. Is that an
12 opinion you would agree with? That:

13 "Increasing amounts of cryoprecipitate and of
14 Factor VIII and Factor IX concentrate have greatly
15 improved the prospect for treatment of patients
16 suffering from A and B."

17 **A.** Yes.

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

19 **A.** Unquestionably.

20 **SIR BRIAN LANGSTAFF:** So unquestionably the introduction
21 of cryoprecipitate, then, and later we know that
22 concentrates, the NHS concentrate, from probably about
23 1970 onwards, we're informed, formed an increasing
24 part of treatment, and then commercial concentrate,
25 when there wasn't enough NHS to go round, from about

107

1 **Q.** If we just look at the Biggs report because you've got
2 the benefit of it and I have, but others watching
3 don't, so I'll just put it on screen.

4 It's PRSE0004645.

5 Soumik, it'll be in the knowledge of risk
6 material, so you may have it stored in a separate
7 location.

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

9 **Q.** We now have on screen and I know you have a copy,
10 professor, the Biggs report. So we'll see that covers
11 period '69 to '74. And if we go to the fourth page of
12 that, please, Soumik.

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

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

15 **SIR BRIAN LANGSTAFF:** And underneath the summary, just the
16 very first sentence, because before -- around
17 about 1960, as one understands it, the life expectancy
18 of a haemophiliac suffering from severe haemophilia
19 was probably in the region of 20 to 25 years. It
20 hadn't gone up very much since the 1930s. It had gone
21 up a bit but not much. That's probably about right,
22 is it?

23 **A.** Yes, it's about right. It's -- life expectancy was
24 about 29 years. And it improved a lot from the
25 no treatment era, when it would have been about ten or

106

1 1973 onwards. That, I think, is broadly the position,
2 isn't it?

3 **A.** I agree.

4 **SIR BRIAN LANGSTAFF:** You weren't practising at the time
5 so this all done by report so I'm putting a very broad
6 picture to you. I'm not going to hold you to a point
7 answer, but I think that is broadly the
8 understanding --

9 **A.** No, no, I was a medical student at the time, but
10 obviously I've gone into the history.

11 **SIR BRIAN LANGSTAFF:** So you were going to go to the
12 fourth page --

13 **MS RICHARDS:** Yes.

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

15 **MS RICHARDS:** And to draw attention in particular for the
16 benefit of those listening -- Professor Hay has a hard
17 copy -- to the top of the page:

18 "In the early statistics the average age of
19 death of severely affected haemophilic patients was
20 less than 20 years. Thus the age at death seems to
21 have more than doubled as a result of Factor VIII
22 therapy."

23 And of course, I think we know broadly that in
24 the period she's here looking at, up until 1974, the
25 majority of Factor VIII therapy would have been

108

(27) Pages 105 - 108

1 cryoprecipitate, although, as you've just observed, of
 2 course, concentrates were starting to be used and were
 3 then used much more increasingly in the years that
 4 followed.

5 **A.** Yes.

6 **SIR BRIAN LANGSTAFF:** Yes, I mean, the precise amounts of
 7 cryoprecipitate compared to the precise proportion
 8 is -- will be a matter for us to explore elsewhere,
 9 but I think broadly what you've said must be right.

10 **A.** Yes, absolutely. And you should get those figures
 11 that we have in the UKHCDO statistical response to
 12 their Rule 9.

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

14 **MS RICHARDS:** Then we can see reference in the table to
 15 the age at death of patients having haemophilia A or
 16 B, and for present purposes I'll just look at
 17 haemophilia A. And we can see there the average age
 18 at death: 42.3. And whilst we're looking at it, just
 19 to observe, we also see the number of deaths from
 20 intracranial bleeding, which -- the figures in both
 21 reports are fairly small, but it's 16 out of 62, which
 22 I think would have been approximately 25, 26 per cent
 23 of deaths from that cause in that period.

24 This is looking at it very broadly,
 25 Professor Hay, but is this right: before the

109

1 intermediate period, because it's a period during
 2 which some centres are quite well advanced in
 3 converting to concentrate, and others much less so.
 4 But I know from the history of the Manchester Centre
 5 that there were still patients being treated with cryo
 6 in the early eighties, and whilst I appreciate that
 7 they were unusually conservative in their approach to
 8 treatment in the Manchester Centre, it was a more
 9 gradual process than I had realised.

10 Yes.

11 **Q.** And so would this be fair: that these two reports
 12 don't provide any significant support for a conclusion
 13 that reversion to cryoprecipitate in 1983,
 14 particularly for a relatively short period of time,
 15 maybe a couple of years, would have led to
 16 a significant increase in deaths or a significant
 17 decrease in life expectancy?

18 **A.** Well --

19 **SIR BRIAN LANGSTAFF:** You're asking in the absence of
 20 HIV infection?

21 **MS RICHARDS:** Yes. Yes, we know, of course, as well
 22 established in later reports, including those
 23 co-authored by Professor Hay, that as a matter of
 24 fact, the greatest impact upon mortality in the years
 25 that followed was viral infection of HIV.

111

1 availability of any form of Factor VIII therapy, and
 2 so before the availability of cryoprecipitate, the
 3 average age of death was around 25 years or so. But
 4 according to Dr Biggs in this, it almost doubled
 5 during the period '69 to '74, when most of the
 6 Factor VIII therapy producing that result would have
 7 been cryoprecipitate?

8 **A.** Well, I think my interpretation of what she is saying
 9 is that it doubled from the period before
 10 cryoprecipitate to the period that she is looking at.

11 **SIR BRIAN LANGSTAFF:** Yes.

12 **A.** Because the use of cryoprecipitate was already
 13 well established in 1969, I think.

14 **MS RICHARDS:** Then when we look at the period covered by
 15 Dr Rizza's report, we can see that the average age of
 16 death increases again, but it's a much smaller margin,
 17 around two and a half years.

18 **A.** Yes --

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

20 **A.** -- I'd agree with that, and to be honest, I think that
 21 the actuarial calculation paints a much rosier picture
 22 but you can't use that to compare with the earlier
 23 period, because there isn't a similar calculation in
 24 Rosemary Biggs' report. And I think that the period
 25 that Charlie Rizza is reporting is a sort of

110

1 **SIR BRIAN LANGSTAFF:** Yes, but people would not have known
 2 that --

3 **MS RICHARDS:** No.

4 **SIR BRIAN LANGSTAFF:** -- at the time for the purposes of
 5 this comparison?

6 **A.** Well, I think that I would agree that the increment in
 7 life expectancy between these two reports is
 8 relatively modest. It's not insignificant. And you
 9 also have to recognise that the second report is an
 10 intermediate period when there's still a lot of
 11 patients being treated with cryoprecipitate, and not
 12 everyone has been established on home therapy.

13 You will see that if you look at the report of
 14 the Prophylaxis and the Home Therapy Working Parties
 15 from the seventies and early eighties. I was unaware
 16 until recently of the existence of this working party
 17 but they did actually audit their roll-out of home
 18 therapy, and it was slower than I had realised.

19 I think my view was rather coloured by my
 20 personal experience in Sheffield, and I had assumed
 21 that all other centres were as quick to do it as they
 22 were. But that is actually not the case.

23 **MS RICHARDS:** Sir, I'm going to move on to a separate
 24 topic. Before I do so, was there anything further
 25 that you wished to ask --

112

1 **SIR BRIAN LANGSTAFF:** Only this, really: I just draw your
2 attention to the risk, I think, or the cause of death,
3 proportionately, which Dr Rizza in his paper
4 identified as being intracranial bleeding. I think it
5 was about 29%, he said, of the cases that he was
6 looking at, died of that, if they didn't die of other
7 causes.

8 If one takes the 16 that we're looking at, it's
9 table III, the first item, "Intracranial bleeding",
10 then the total number of cases, 62, it's about -- just
11 over 25 per cent, it'd be 25% if it was 64. So it is
12 just over 25%. But there's not a great deal of
13 difference in those two figures, for what it's worth;
14 is there?

15 **A.** No, true, but -- I agree, and intracranial bleeding
16 was the commonest cause of death during that period.

17 But I would come back to the fact that, you
18 know, you wouldn't expect a dramatic difference
19 looking at two periods when, in one case, everyone is
20 treated with cryo and, in the second, you have
21 a transitional period, they're not all on home therapy
22 during this second period, or not for the whole of
23 that period.

24 I can tell you that the number of patients
25 dying from intracranial haemorrhage now is less than

113

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

2 **MS RICHARDS:** Professor Hay, I've got a number of
3 questions now that I've been asked to ask by core
4 participants, and so we're going to dot about from
5 topic to topic, rather than follow a chronological or
6 thematic order.

7 The first arises out of a passage in your
8 statement about research where you describe the
9 difference between an interventional study and
10 observational research, and your statement explains
11 the different ethical requirements that might attach
12 to each.

13 Is the distinction between an interventional
14 study and observational research always clear-cut?

15 **A.** No, I don't think it is, actually. It may be a matter
16 of opinion.

17 We recently conducted a study
18 internationally -- not UKHCDO, by the way, but
19 investigator-led study -- which involved applying
20 a number of quality of life questionnaires to the
21 patient at intervals. They had to give consent to
22 this anyway because -- you know, written informed
23 consent, but it wasn't regarded as an interventional
24 study in six out of the seven countries. The seventh
25 country was France, and in France they said, well, if

115

1 10%. So treatment with concentrate, as currently
2 practiced, and with prophylaxis -- which may of course
3 be very, very important, because you will expect to
4 prevent a lot of the bleeds that might have occurred
5 with treatment on demand, but we have reduced that
6 complication quite dramatically.

7 **SIR BRIAN LANGSTAFF:** I can full understand the
8 significance of prophylaxis, but just comparing these
9 two sets of data -- for what it's worth, as you've
10 indicated, they're not exactly comparable -- this --
11 well, what you're looking at on the screen at the
12 moment, the Biggs paper, is at a time when there was
13 some but very little home therapy, I think. Am
14 I right?

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

16 **SIR BRIAN LANGSTAFF:** So the two changes were -- it wasn't
17 just a change from a little Factor VIII concentrate to
18 a lot of Factor VIII concentrate, proportionately, but
19 also a change from a little home therapy to a lot of
20 home therapy proportionately. You still have a fairly
21 comparable death rate in these two studies over the
22 two periods so far as intracranial bleeding is
23 concerned. It doesn't allow for a very dramatic
24 distinction between the two, does it?

25 **A.** No.

114

1 we'd asked fewer questions, it would have been an
2 observational study, but they regarded it as an
3 interventional study because it took the patients more
4 than an hour to fill out the forms. And I think that
5 illustrates a classical grey area, and I can see their
6 point, but that came down to a matter of judgment.

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

116

1 Q. Is there a risk --

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

3 **MS RICHARDS:** Yes.

4 **SIR BRIAN LANGSTAFF:** Just going back to the start of your

5 answer there, you were describing where the

6 intervention would have been done anyway, and you're

7 simply observing the effect of it. That would be

8 observational.

9 One of the situations I've come across on a

10 number of occasions in cases which I've had to

11 determine in the past have been cases where there were

12 two possible forms of treatment: one conservative, the

13 other interventionist. Both were entirely proper as a

14 matter of practice, but the choice was left to the

15 clinician. If the clinician chose the interventionist

16 and had in the back of his mind that this might be

17 a benefit to research which he was particularly

18 interested in doing, would that make it

19 interventionist or observational?

20 **A.** Well, that's an interesting question that speaks to

21 the intent of the person in question. And that's

22 a really grey one because if he was influenced by the

23 fact that it was being studied and that introduced

24 bias, that is -- that's actually a problem because it

25 affects not only the ethics of the study but also its

117

1 a clinician to keep a patient on the same treatment,

2 rather than changing to what might have been a safer

3 treatment?

4 **A.** I think that's unlikely. That would be really

5 unethical.

6 **Q.** And in the early and mid-'80s, and I think you were

7 engaged in research from roughly 1983 onwards at

8 Sheffield, but in that period of time in the early and

9 mid-'80s, what were the safeguards against clinicians

10 undertaking something that was unethical, or

11 a safeguard that might address some forms of

12 subconscious or unconscious bias?

13 **A.** Well, subconscious or unconscious bias is a problem in

14 research anyway throughout which is why the strongest

15 evidence is always considered to be the results of

16 a randomised controlled trial. Not that that trial

17 design has -- doesn't have weaknesses, because it's

18 often criticised because the subjects that participate

19 in such a trial are selected, but it's the most

20 reliable way of excluding bias.

21 Occasionally, you can also exclude bias by

22 following natural experiments. And one example of

23 that is a trial -- well, not a trial, an observational

24 study that we conducted between Scotland and England,

25 looking at the effect on the immune system of

119

1 interpretation, because you want to avoid that sort of

2 bias, you know? That is the advantage of a randomised

3 comparison because then you have negated any biases

4 from the operators. And randomised comparisons are

5 always interventional by definition but can be

6 difficult to conduct.

7 I conducted a randomised trial comparing high

8 dose with low dose immune intolerance, for example, in

9 17 countries, and the biggest difficulty that we had

10 there was that we were doing the study because so much

11 was unknown, but nevertheless, clinicians around the

12 world had very fixed views. They were all convinced

13 that they were doing it the right way, and if they

14 had, we wouldn't have needed to do a trial. So many

15 refused to participate because they disagreed with our

16 protocol. You know, what can you do? So ... yeah,

17 it's difficult.

18 **MS RICHARDS:** And picking up from the Chair's point,

19 professor --

20 **SIR BRIAN LANGSTAFF:** Well, it was a question, not

21 a point.

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

23 Is there a risk that observational research,

24 the undertaking of observational research, the desire

25 of a clinician to follow that through, might lead

118

1 different types of concentrate.

2 Now, in those situations, the whole of Scotland

3 used a Scottish high-purity product that had been

4 prepared in one way because that was what was

5 available to them, and the whole of England used

6 different materials. So just through circumstance,

7 you had two groups that were all treated in the same

8 way, and that offered the opportunity to compare the

9 two.

10 In a way, the next best thing would have been

11 to randomise them. And incidentally, the participants

12 were -- although it was an observational study, we had

13 to collect a lot more data than would have been

14 normally the case, so they were consented in the same

15 way as they would have been for an interventional

16 study.

17 **Q.** Do you know --

18 **A.** The thing to do, to be honest, and this is what we try

19 to do currently, is to assess each case individually

20 and to make a judgment: is this an observational

21 thing? If you have to take additional samples, or are

22 you doing something burdensome, then it becomes

23 interventional, and you have to get consent for that.

24 **Q.** Do you know, in that period of '83 to '87 when you

25 were at Sheffield, and I appreciate you were the

120

(30) Pages 117 - 120

1 junior to Professor Preston and Dr Greaves in terms of
2 your role at the time, but do you know what, if any,
3 ethical approval systems or other safeguards there
4 might have been in place at that time?

5 **A.** Well, the details have changed over the years, but the
6 basic principle has been the same throughout this
7 period. That is, if you want to do a clinical trial,
8 you have to take it to the Ethics Committee. They
9 have to approve everything, not least the patient
10 information and the consent form. They have lay
11 members on every Ethical Committee, and they take
12 a particular interest in that area, as you might
13 expect. They also have statisticians on an Ethics
14 Committee.

15 So if, for example they consider that the trial
16 design is inadequate, then they could -- that is an
17 ethical issue. It's unethical to do a clinical trial
18 that is inadequate to answer the question because it
19 potentially puts -- in theory, it would possibly put
20 patients in harm's way without having any hope of
21 answering the question, and that would be considered
22 unethical.

23 So if you want -- if you participate in
24 a clinical trial of a new product, for example, the
25 Alphanate trial that was conducted in Sheffield in

121

1 your local R&D department and get approval from both
2 of them before you're allowed to start.

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

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

10 **Q.** This morning, I asked you about the notification
11 process in relation to variant CJD. Do you know
12 whether there was any, in earlier years, any
13 notification system to UKHCDO of suspected
14 contaminated batches -- contaminated with HIV or with
15 non-A, non-B hepatitis, hepatitis C? Was that
16 something that used to be drawn to the attention of
17 UKHCDO directly?

18 **A.** We had an adverse event working party and an adverse
19 event reporting system which I will be describing to
20 you in greater detail in the final chapter of our
21 UKHCDO Rule 9, and that collected adverse events,
22 including any new reports of hepatitis from the early
23 1980s onwards. I was a member of that committee.

24 The data was collated by the National
25 Haemophilia Database. We did -- we do report adverse

123

1 1984, all the participants would have been consented.

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

4 **A.** Yes.

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

8 **A.** Well, I don't remember much about it because it covers
9 a period when, for part of that time, I was at the
10 Children's Hospital, partly because I was moving
11 about, they got the other senior registrar to get more
12 involved, and her name is actually one of the
13 co-authors. But my recollection is that patients were
14 given an information sheet and had to write consent.

15 **Q.** Moving to a different topic -- no, actually, sorry,
16 before leaving that. That trial -- would that trial
17 have gone before any kind of Ethics Committee for
18 approval?

19 **A.** Oh, yes, yes. At that time, they would have all been
20 hospital ethical committees. Much later, they
21 introduced a system for national approval, so you go
22 to an MREC, and they're arranged regionally for
23 multi-centre trials involving more than four centres.
24 But even when you get national approval, you still
25 have to take it to your local Ethics Committee and

122

1 events that we think are specifically related to
2 a product to the manufacturer so that they can satisfy
3 their regulatory requirement to report it on to the
4 regulators. That's the European Medicines Agency and
5 the Food and Drug Administration.

6 This has result in the withdrawal of some
7 batches, which seemed to be giving lots of reactions,
8 for example. The investigation of new reports of
9 hepatitis after about 1988 all proved to be false
10 reports, insofar as it was genuine hepatitis but not
11 a new diagnosis.

12 You can imagine that we were particularly keen
13 in the years after 1985, when products had been
14 introduced that were marketed as only
15 hepatitis-reduced, to evaluate any further episodes of
16 hepatitis sneaking through.

17 And there were certainly reports with some
18 products in Canada as late as 1988 of some of the
19 virally attenuated products transmitting hepatitis C.
20 And hepatitis B seemed to be more difficult to
21 eradicate than hepatitis C, but then, on the other
22 hand, all the donors were tested for hepatitis B from
23 probably the early 1970s. So the only patients who
24 would have got through that testing net would have
25 been those who were in the window period at the time

124

1 that they donated. That is to say, the period when
2 they were incubating hepatitis B but had not yet
3 become positive for the tests. The window period,
4 which we haven't discussed so far, is a problem with
5 the all viruses, and another one of the reasons why we
6 wanted to get away from plasma-derived products.

7 If you go through this period, from the
8 eighties through to -- well, the present day, really,
9 you will see that donors have been subjected to more
10 and more tests, of increasing sensitivity, to
11 progressively reduce that window period. And of
12 course, donor selection is also very important with
13 all of that.

14 The other thing that's really important that we
15 haven't talked about before is repeat donation,
16 because the safest donor is a donor that repeatedly
17 donates. If you go back to the early 1980s, 50% of UK
18 blood donors were first time donors, and often the
19 only time they donated. They may only have donated
20 once. And if you test those for viruses, you'll find
21 most of the positives will be in first-time donors.
22 So they are the most risky donors. The safest donors
23 are donors who come repeatedly. And of course they're
24 tested every single time.

25 By the end of the eighties, at least 90% of

125

1 they approached it was they saw how many recipients of
2 multiple blood donations subsequently developed
3 hepatitis. Now, these would be patients undergoing,
4 say, open heart surgery, or some other surgical
5 intervention that required a large blood transfusion.

6 So they would be exposed to a number of donors
7 as a consequence of that. So you could evaluate how
8 many donations they'd been exposed to, and then you
9 see what percentage of them develop non-A, non-B
10 hepatitis thereafter. And from that you derive
11 a figure for the number of the donors that were
12 infectious for non-A, non-B hepatitis.

13 Now, clearly, that methodology is relatively
14 soft, and you'll find somewhere in my exhibits there
15 is a table -- I know you're going to subject this to
16 independent statistical analysis -- which shows the
17 risk of contracting non-A, non-B hepatitis, based on
18 the number of donations that you're exposed to, and it
19 gives a range of percentage. The average is about
20 0.75% of blood donors being infectious for non-A,
21 non-B hepatitis in the very early '80s, based on that
22 methodology, but it varied.

23 There are a number of papers that looked at
24 this from different countries, and of course, we do
25 know that the incidents of hepatitis C varied from

127

1 blood donors were repeat donors. And in the
2 commercial sector, people encouraged that too. So
3 these days, most plasma is actually derived from
4 plasmapheresis donors, who can donate far more
5 frequently, because they're only donating plasma, and
6 they can donate as often as once a month.

7 Anyway, I think I drifted off the subject
8 a little.

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

10 **MS RICHARDS:** Yes.

11 **SIR BRIAN LANGSTAFF:** You were going to back to the early
12 1980s, and you said 50% of the blood donors then were
13 first time donors, and most of the positives were in
14 that group. If you're talking in terms of positivity
15 for hepatitis C, or non-A non-B, as it was, how do you
16 know?

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

18 You'll see in my report, and in fact in some of
19 the exhibits -- the exhibit you showed me earlier
20 which has the proposal to the Department of Health of
21 the hepatitis C look-back -- who reviews this evidence
22 quite well, I thought, rereading it -- in the early
23 eighties there were a number of studies trying to
24 assess the frequency of non-A, non-B hepatitis.
25 Obviously without a specific test. And the way that

126

1 country to country. It was higher in America than in
2 the UK, and higher again in places like Italy and
3 Japan, for some reason, also had relatively high
4 rates. So the rate will genuinely vary from country
5 to country. But based on that soft methodology, in
6 the early '80s we think it would have been between
7 about 0.5 and 1%.

8 Now, there are papers later on in that decade
9 from Contreras et al which I also quote. Once they
10 had a test, they were able to assess the prevalence in
11 the donor population accurately, bearing in mind also
12 that the donor population is not a cross-section of
13 society. You know, there are certain ethnic groups
14 that donate less, which is actually a practical
15 problem because there are ethnic differences in the
16 frequency of blood groups as well. So that does give
17 rise to practical problems.

18 When I did my transfusion training, for
19 example, blood donations from people from the
20 Afro-Caribbean community were coded so you could
21 identify them because they were particularly useful if
22 you had a patient with sickle cell trait, for example,
23 if they needed a transfusion.

24 Anyway, I'm drifting again. Um --
25 (overspeaking) --

128

1 **SIR BRIAN LANGSTAFF:** If I can --
 2 **A.** -- (overspeaking) -- this paper --
 3 **SIR BRIAN LANGSTAFF:** Sorry, you're going to talk to me
 4 about the Contreras paper. Sorry, I'm interrupting.
 5 My apologies. Please.
 6 **A.** The Contreras paper showed a tenfold reduction
 7 relative to those early soft indication -- early soft
 8 assessments. And this was attributed to the
 9 introduction of donor selection.
 10 Now, although donor selection -- you know, this
 11 is pre-donation exclusion. This is the process
 12 whereby all prospective donors have to read the
 13 leaflet, and if they fall into the following risk
 14 groups, not donate, please. Of course, although this
 15 was directed at the reduction in the risk of HIV,
 16 there is an overlap in the risk groups for HIV and
 17 hepatitis C, clearly. So donor selection dramatically
 18 reduced the risk of hepatitis C as well.
 19 **SIR BRIAN LANGSTAFF:** Just going back to the start of your
 20 answer, the question really arising out of your
 21 comment that about 50% of the donors would have been
 22 one-time donors, and they were the ones who created
 23 more of a problem than the regular donors back in the
 24 early '80s.
 25 Suppose that you had -- as your first example

129

1 has, as far as you know, no basis in the literature?
 2 **A.** Sorry, I don't understand.
 3 **SIR BRIAN LANGSTAFF:** It's all right, it's probably more
 4 of a comment than a question.
 5 That's all I need to ask. Thank you very much.
 6 **MS RICHARDS:** Sir, I've got some questions still, but
 7 I note the time and I think it might be sensible to
 8 have a break and then I can complete the questions.
 9 **SIR BRIAN LANGSTAFF:** Yes, of course.
 10 Counsel will -- she needs to field questions
 11 from people who aren't here, to talk to her and give
 12 her further questions, because you will appreciate
 13 that counsel to the Inquiry ask the questions in an
 14 inquiry, and, in general, core participant counsel
 15 don't. That's a generality, but it's likely,
 16 I suspect, to be true in this case, particularly when
 17 they're not here in any event.
 18 So we shall take some time just to do that.
 19 How long do you think you need?
 20 **MS RICHARDS:** I've got most of the questions, sir, there's
 21 only a handful I haven't been able to consider, so
 22 half an hour will be ample. But that will give
 23 Professor Hay an opportunity to take a break and those
 24 watching to have an opportunity to take a break as
 25 well.

131

1 was surgery, involving quite number of transfusions,
 2 suppose, let's say, ten bags: five from first-time
 3 donors, five from other donors. How would you know
 4 which bag contained the infection if the person who
 5 was having the surgery actually later on developed and
 6 showed signs of hepatitis non-A, non-B? That was
 7 the point I was trying to understand.
 8 **A.** I see. Well, in the absence of a test, you wouldn't
 9 necessarily. You could go back to all those donors
 10 and test them for what you knew about, see if any of
 11 them had chronic liver disease and take a history.
 12 **SIR BRIAN LANGSTAFF:** Was that done, do you know?
 13 **A.** Well, there were latterly look-back exercises
 14 conducted by the Transfusion Service, but they did not
 15 occur until after hepatitis C testing became
 16 available, and they were really directed at people who
 17 were repeat donors who turned out to be positive for
 18 hepatitis C, then they went back and traced the
 19 recipients of previous donations.
 20 **SIR BRIAN LANGSTAFF:** I understand the repeat donors, it's
 21 the one-time donor and their infectivity which I was
 22 really trying to understand.
 23 **A.** The one-time donor, you couldn't do anything about.
 24 **SIR BRIAN LANGSTAFF:** Does it come down to the fact that's
 25 an estimate, really, which you have given us, which

130

1 **SIR BRIAN LANGSTAFF:** Yes, so we'll have a cup of tea and
 2 come back at -- will four o'clock be all right?
 3 **MS RICHARDS:** Yes.
 4 **SIR BRIAN LANGSTAFF:** Will four o'clock be okay?
 5 Four o'clock.
 6 (3.25 pm)
 7 (A short break)
 8 (4.00 pm)
 9 **SIR BRIAN LANGSTAFF:** Yes.
 10 **MS RICHARDS:** Professor Hay, you told us yesterday that in
 11 relation to Sheffield, there was no programme for
 12 prophylaxis and that that was formally introduced many
 13 years later. Were you aware of patients on home
 14 treatment administering treatment to themselves on
 15 a prophylactic basis?
 16 **A.** There were patients during the 1970s and in fact there
 17 was a Prophylaxis and Home Therapy Working Party
 18 chaired by Dr Peter Jones. I have been unable to
 19 source any of the minutes of their meetings but they
 20 did report on an annual basis to the annual general
 21 meeting of the UKHCDO and their findings are of some
 22 interest.
 23 I think that the -- I wasn't aware of this
 24 working party at the time, you understand, but
 25 Peter Jones was quite well known. He wrote a chapter

132

(33) Pages 129 - 132

1 on comprehensive care in the first edition of
 2 Hemostasis and Thrombosis, which was one of the first
 3 textbooks of haemostasis I ever bought. And that
 4 chapter influenced me, and it did describe prophylaxis
 5 and prophylaxis was being practiced quite widely in
 6 his centre, and at Lord Mayor Treloar. And during
 7 that time, they published some papers on prophylaxis
 8 which you're probably aware of. So I was aware of
 9 prophylaxis, and it had been pioneered by
 10 Inga Marie Nilsson in Malmo in Sweden, and to some
 11 extent also in Holland.

12 So we knew about it, particularly in children,
 13 but it wasn't widely practiced for a number of
 14 reasons, not the least of which was the relatively
 15 inadequate supply of product, and then of course, when
 16 HIV came along, treatment intensification did not seem
 17 like a very good idea.

18 Q. I know there was no programme of prophylaxis in
 19 Sheffield, but were patients informally, and of their
 20 own initiative, using their home treatment on
 21 a prophylactic basis, to your knowledge?

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

23 Q. Then moving from that to funding from pharmaceutical
 24 companies to UKHCDO, during your time as a member of
 25 UKHCDO, how were decisions made about which

133

1 we purchased these products through a national
 2 contract, and that has been the case for a number of
 3 years. On an individual basis, though, I don't think
 4 UKHCDO felt that it had a role to play, or indeed
 5 could. You know, in individual conversations, people
 6 would recognise that being dependent on a single
 7 manufacturer was probably a bad idea anyway, because
 8 it made you very vulnerable to issues of supply should
 9 that manufacturer have a problem, and it would also
 10 open you up to an accusation of bias. So it was
 11 normal and general practice to have two or more
 12 suppliers, mostly more.

13 Q. Would you have expected, in the 1980s, discussions
 14 about risks and the possible consequences of
 15 contracting non-A, non-B hepatitis or AIDS, if those
 16 discussions took place, to be recorded in a patient's
 17 medical records?

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

25 Q. Is the answer to the question, then, they should be

135

1 pharmaceutical company would fund the annual general
 2 meeting?

3 A. Well, the manufacturers would approach UKHCDO and
 4 request to sponsor. It was very common, and still is,
 5 for pharmaceutical companies to offer sponsorship for
 6 meetings. That is all regulated. We would wish to
 7 have sponsorship from as many different sources as
 8 possible to avoid any accusation of bias.

9 Q. And what involvement, if any, in the annual general
 10 meeting would this sponsorship give the pharmaceutical
 11 company?

12 A. They would be allowed to attend certain parts of it.
 13 They would not be allowed to attend business meetings.
 14 And they would be allowed to set up a stall in an
 15 exhibition area. It's very common for scientific
 16 meetings of all sorts to have a commercial exhibition
 17 where manufacturers are allowed to set up a stall.
 18 That, again, is regulated in various ways, and the
 19 regulations will vary from country to country.

20 Q. And what, if any steps, were taken within UKHCDO to
 21 try to ensure that this sponsorship didn't influence
 22 members' decision making about which products to
 23 purchase for treatment at their centres?

24 A. I don't think UKHCDO felt that they had a part to play
 25 in that. Latterly, a lot of this is regulated because

134

1 noted but they weren't always --

2 A. I think that's probably correct.

3 Q. -- in your experience?

4 A. I would say that the absence of a note doesn't mean
 5 that the conversation has not taken place, although
 6 I know that it would be a common legal judgment to the
 7 contrary.

8 Q. What role, if any, did lifestyle advice, with the aim
 9 of reducing bleeds, have on the treatment of patients
 10 under your care in the eighties, in particular mild
 11 and moderate haemophiliacs?

12 A. Well, it was well recognised early on that the
 13 patient's lifestyle affected their tendency to bleed,
 14 and the patients were certainly very well aware of it.
 15 They find out from experience the sort of activities
 16 that might cause them to bleed, and many of my
 17 patients have talked to me about the way in which
 18 haemophilia hangs over them like a cloud and they're
 19 constantly worrying that they might do something that
 20 might set something off. You know, something as
 21 trivial as stepping awkwardly off a pavement might
 22 cause an ankle bleed.

23 Not every patient is like that, of course, and,
 24 you know, it was early observed that, for example, you
 25 might have a pair of brothers, and one brother is

136

never out of hospital, and you hardly ever see the other one, and the other one's probably got his nose in a book, whilst brother number 1 is bouncing off the walls. And so personality does come into it.

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

So early on, people would be advised to avoid contact sports, to remain physically fit if they could, because if they had good muscle bulk, they would be less likely to bleed, but not to go looking for trouble, essentially. So no rugby, no football, and no boxing, that sort of thing. But running, cycling, swimming were all good things to do and were encouraged, and we eventually started to encourage people to go to the gym as well. So lifestyle was quite important.

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

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

You say this:

137

issue with him?

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

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

So, you know, a lot of the litigation that was going on at that point seemed unlikely to succeed. There was more and more of it. We then had the campaign where a whole series of patients from around the country reported the Centre Directors to the

139

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

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

Then you say:

"I'm rather worried that the whole thing is getting out of hand. If the Society wants patients who have contracted hepatitis C to obtain some compensation, I am not sure that encouraging them in their mistaken belief that they have a good case of negligence is the right way to go about it. I get the strong impression that although that's not the Society's official view, that some members of the executive are certainly encouraging this point of view, and a lot of the lawyers ... are doing so. I no longer have any very clear idea of the Society's position on this, despite the recent rather vague press releases, and I would like to talk to you about it."

What was the purpose of writing to Mr Barker in these terms and the purpose of asking to discuss this

138

General Medical Council, claiming various acts of professional misconduct, which were, as far as I knew, and certainly in relation to the two complainants against me, completely false.

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

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

And I think a lot of my colleagues and I felt as if we were slightly caught in the crossfire, because we were the closest target for the patients' ire, they blamed their medical attendants for their suffering, and we were not in any position to help with financial compensation. It was really the Department of Health that they needed to approach.

140

1 But we were the only outlet, and they sought to
 2 increase the profile of their campaign by suing us all
 3 and reporting us to the General Medical Council.
 4 **SIR BRIAN LANGSTAFF:** Excuse me, can you just help and
 5 tell me who it was that you spoke to at the Department
 6 of Health who suggested that having a form of
 7 compensation scheme would in some way influence the
 8 outcome of the -- of a court case? In other words,
 9 I think the suggestion is it might influence a judge
 10 in favour of or against the case.
 11 **A.** I can't honestly remember. The various people
 12 that I dealt with at the Department of Health were
 13 Charles Lister, David Kutowski, and William Connon,
 14 over the years. It was probably one of the earlier
 15 ones, most likely Charles Lister.
 16 **SIR BRIAN LANGSTAFF:** Thank you.
 17 **A.** And of course there was the class action that I was
 18 involved in.
 19 **SIR BRIAN LANGSTAFF:** Yes.
 20 **A.** Which was brought -- that was not claiming negligence,
 21 interestingly. That was brought under consumer
 22 protection legislation, which was a very interesting
 23 approach.
 24 **MS RICHARDS:** Was this letter an attempt by you -- or, the
 25 meeting that you proposed follow it, an attempt by you

141

1 **Q.** I'm asking not specifically about the complaints
 2 against you, and you've explained what the outcome of
 3 those were, that they didn't go anywhere. But in
 4 terms of it being part of a campaign, you've said it
 5 was well recognised. By whom? Do you mean that was
 6 the view of the Haemophilia Centre Directors?
 7 **A.** Well, it was well recognised by Haemophilia Centre
 8 Directors, and I refer to it in correspondence with
 9 one of the patients who'd actually raised it with me.
 10 It's my understanding that this was done to raise the
 11 profile of their campaign.
 12 **Q.** But the factual basis for that understanding is
 13 discussions between Haemophilia Centre Directors?
 14 **A.** Yes.
 15 **Q.** Could we have on screen, please, HCDO0000266_004,
 16 please.
 17 This is another letter from you. This is a few
 18 years later, to the Haemophilia Society, to
 19 Ms Pappenheim, December 2002. You're responding to
 20 a letter from her, and it's about what are said to be
 21 difficulties of accessing medical records.
 22 Let me just pick it up at the bottom of the
 23 page because this may be of more general interest.
 24 You say in the last paragraph:
 25 "Medical record-keeping 20 years ago was not as

143

1 to persuade the Haemophilia Society to dissuade
 2 patients from bringing legal claims?
 3 **A.** No, it was an attempt to clarify what their position
 4 was.
 5 **Q.** To what end?
 6 **A.** I never did anything, either individually or
 7 collectively, to try to dissuade people from
 8 litigation. I did have an exchange with -- what's her
 9 name? Well, with one patient, you sent me a letter,
 10 in evidence, on -- that was in response to an enquiry
 11 from her in general terms.
 12 **Q.** You referred to a campaign to bring cases to the
 13 General Medical Council. Obviously, Professor Hay,
 14 you're familiar with the complaints that were made
 15 against you. But what's the basis for your assertion,
 16 the factual basis for your assertion, that this was
 17 part of a campaign as opposed to individual cases?
 18 **A.** Well, it was well recognised at the time that that was
 19 the case. I was not chairman at the time.
 20 Professor Hill was chairman at the time. He actually
 21 knows how many of these have -- were lodged. I don't.
 22 But there were a number. At one point I was told that
 23 there might be as many as 50. There were certainly
 24 two against me, both of which were entirely false, but
 25 they took a long time to resolve.

142

1 scrupulous even as it is now, and so patients should
 2 not be surprised or disappointed if they find that
 3 their records do not contain detailed records of batch
 4 numbers, et cetera, that may be medicolegally
 5 important with hindsight but had little apparent
 6 clinical relevance at the time."
 7 Surely batch numbers would have had
 8 considerable clinical relevance at the time for two
 9 reasons? One is the single product batch dedication
 10 policy being followed at Sheffield and some other
 11 centres, and secondly, because that's the way in which
 12 you trace implicated batches.
 13 **A.** Well, you'll remember yesterday we talked about
 14 ledgers. And every single unit of Factor VIII and
 15 Factor IX in the Manchester centre and, as you have
 16 already learned, in the Sheffield Centre is recorded,
 17 so we do record the batch numbers, but they are
 18 recorded in a ledger. Now, in Manchester, I think
 19 they may have had some other records as well before
 20 I came, but they are recorded in a ledger.
 21 Now, the problem with showing the patient
 22 a ledger is that it's full of information about
 23 treatment for other people. You can't show that
 24 patient. You might extract it if requested, but that
 25 would obviously be a lot of work. But you can't show

144

(36) Pages 141 - 144

1 one patient's information to another. So, yes, it is
 2 recorded, but not invariably in the patient's notes.
 3 Q. If a patient makes an application for information that
 4 they believe is in their medical records wrongly, for
 5 the reason you've given, but the centre nonetheless
 6 holds it in another form, would the appropriate
 7 response of the centre not be to tell the patient that
 8 that information is held and provide it to the patient
 9 in some form, photocopying the relevant page of the
 10 ledger and just redacting out the irrelevant entries?
 11 A. Well, if they make that request, but at that time,
 12 they were just looking for evidence that they'd been
 13 treated with one product or another, and the batch
 14 numbers were not relevant, frankly. They really
 15 wanted to know which supplier had supplied the product
 16 they'd been treated with for specific episodes, and
 17 that would be in the notes. Because, apart from
 18 anything else, that's on the prescription chart.
 19 Q. But the point I understand to be being made here is
 20 that this information often won't be in the records.
 21 A patient can't know to request a copy of the
 22 information in another form such as a ledger unless
 23 they're told by the centre that the information exists
 24 in that form.
 25 A. Yes, but the request that the patient asks for are

145

1 requesting the records and getting an expert to go
 2 through the records and providing a report. They were
 3 basically asking the patient to answer certain generic
 4 questions, and the generic question that the patient
 5 seemed to be interested in was: had they been treated
 6 with a certain brand of American concentrate during
 7 a certain period of time? Because the class action
 8 was against that manufacturer.
 9 So lots and lots of the patients came along and
 10 they wanted to know that, and so they requested their
 11 notes. Their notes were made available to them. But
 12 then I think the problem often was that even though
 13 the information they were looking for was actually in
 14 the notes, they didn't know exactly how it was
 15 presented, and they weren't quite sure what they were
 16 looking for, and they might be presented with several
 17 thick volumes of papers, because these patients had
 18 been patients of the hospital often for many years,
 19 and so their notes were really voluminous. And, to be
 20 honest, when I got to Manchester, a lot of the notes
 21 were not in great shape.
 22 One of the reasons for that being that if you
 23 sent them to the Medical Records Department to be
 24 re-bound, they would hang on to them for a couple of
 25 months. And these patients are presenting fairly

147

1 their clinical records, and those are provided. And
 2 to be honest with you, my involvement with that would
 3 be extremely peripheral. Because they make a request
 4 for the patient records, that goes to the medical
 5 records officer, they send me a form, which I have to
 6 sign, or the consultant that is looking after them has
 7 to sign, and we sign it, giving permission, and that
 8 goes back to the medical records officer, and they
 9 make the notes available. Or if the patient has
 10 requested a copy, they will arrange to copy what they
 11 have and present it to the patient.
 12 Q. If we go over the page please, Soumik, to the second
 13 paragraph, five lines down it says:
 14 "Unfortunately there appears to be a feeding
 15 frenzy amongst the patients at the moment."
 16 Then you explain you don't have the time to go
 17 through the records of patients individually, and
 18 I understand the latter point. What do you mean by
 19 there being a "feeding frenzy amongst the patients"?
 20 A. Well, at that point in time, there was a legal
 21 company, I can't remember which one it was, and they
 22 were trying to mount a class action. And as far as
 23 I can see, they were trying to do this relatively on
 24 the cheap. And by that, I mean they weren't going
 25 through the usual medical negligence process of

146

1 regularly. You didn't want their notes out of
 2 circulation for that long. And at one point
 3 I actually employed somebody to try to organise the
 4 notes and re-bind them. But we gave up after a little
 5 while because it was all happening so slowly. And he
 6 actually did that in the department.
 7 So with some of these patients I actually went
 8 through the notes with them to help them to find what
 9 they were looking for. I can remember spending
 10 three-quarters of an hour one time, in clinic, with
 11 a patient who had been through his notes, had been
 12 unable to find them, then -- we shuffled through them
 13 all. It took me quite a long time. I showed him what
 14 he wanted to find. I explained to him what it
 15 signified. And then he came back to have another look
 16 at his notes, and he couldn't find it again, and
 17 accused us of taking this bit out. And -- you know,
 18 as if we would have any motive to do that. You know,
 19 why should we edit his notes when he's not even trying
 20 to sue us?
 21 Anyway, there was a lot of that, and it was
 22 generated by an attempt at a class action.
 23 Q. One final document -- sorry, two final documents. The
 24 penultimate one, HSOC0020017, please, Soumik.
 25 There is was a letter you wrote to the

148

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

149

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

151

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

150

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

152

(38) Pages 149 - 152

1 patients said, "We want to know the truth," we weren't
 2 quite sure what truth they were after because, you
 3 know, we felt that we had been quite open.
 4 And when it comes to the suggestion that this
 5 might harm them, well, I have to say to you that
 6 I have seen many patients after the onset of this
 7 inquiry who have been quite distressed by it. It has
 8 not been universally welcomed by the body of patients.
 9 I think it would be true to say that there is a lot of
 10 ambivalence out there. Many patients who have come to
 11 terms with what they've been through in the height of
 12 the HIV era were upset that this raked it all up
 13 again.

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

153

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
 9 the risk of reactions, but sometimes, nevertheless,
 10 they would give reactions. Reactions are much, much
 11 commoner with plasma and cryoprecipitate and could be
 12 quite 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.

155

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

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
 14 your 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

154

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?

156

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
 6 test, you observed that you thought that
 7 Professor Preston's approach in Sheffield was a good
 8 one. You said the different clinicians had different
 9 practices, some good, some not. Can you give me more
 10 detail about the some that were good and the some that
 11 were not?
 12 A. Well, I didn't feel that the practice in Liverpool was
 13 very good, because as far as I could make out from my
 14 conversations with my patients, they'd been informed
 15 by post and offered very little support. So when
 16 I arrived, I inherited a group of patients who were
 17 understandably very angry, felt very let down. And
 18 I agreed with them, frankly. And they needed a great
 19 deal of psychological support, and many of them were,
 20 quite understandably, very embittered about the way in
 21 which they had originally been informed.
 22 And, you know, I couldn't support that.
 23 Although it was a long time ago, I don't think that
 24 that practice was acceptable, even in 1985.
 25 You know, we didn't know a great deal about HIV

157

1 a degree of uncertainty about the outlook.
 2 **SIR BRIAN LANGSTAFF:** Were there any other practices
 3 elsewhere that you became aware of and thought were
 4 poor? Or, for that matter, good?
 5 A. Well, I heard that in some places patients were told
 6 in groups. And I find that amazing, because there's
 7 a confidentiality issue there, apart from anything
 8 else. And I think it's always more sensitive to tell
 9 people one at a time. I thought that the system
 10 that I heard about at the Royal Free was particularly
 11 good, where they were taken into a soundproof
 12 counselling room, with a counsellor, and with someone
 13 else, and they were -- they informed them. And
 14 I think there is some video evidence of that, that I
 15 understand the Royal Free have shared with ...
 16 **SIR BRIAN LANGSTAFF:** Thank you.
 17 The next question was this: it was in relation
 18 to hepatitis-reduced products. Now, plainly,
 19 hepatitis-reduced didn't mean to say that it had no
 20 hepatitis virus in it.
 21 A. Yes.
 22 **SIR BRIAN LANGSTAFF:** But were those products, so far as
 23 you were aware from your own experience at the time,
 24 were they at all successful in producing a lower
 25 incidence of the disease?

159

1 at that time, but we did know that it was potentially
 2 fatal, because there'd been some cases of AIDS. We
 3 didn't know how many of the patients would develop
 4 AIDS, because in those early days, bearing in mind
 5 that it was only an antibody test, what that test told
 6 us was that the patient had been exposed to the AIDS
 7 virus, and there was an expectation, soon to be
 8 dashed, that some of those patients would actually be
 9 immune, in the way that somebody who'd had hepatitis B
 10 but recovered from acute attack would be immune. And,
 11 you know, with hepatitis B, 95% of people turn out to
 12 be immune without chronic viraemia.
 13 Now we expected something similar to emerge
 14 with HIV, and sadly it didn't. But, you know, that
 15 was the level of knowledge in '85. But I think there
 16 was a lot of uncertainty about it and patients should
 17 have been told, apart from the fact that having
 18 a positive test didn't mean they had AIDS, that they
 19 would be monitored and supported.
 20 **SIR BRIAN LANGSTAFF:** Thank you.
 21 Were there --
 22 A. And --
 23 **SIR BRIAN LANGSTAFF:** Sorry.
 24 So -- sorry.
 25 A. And that we were looking for treatment and there was

158

1 A. My understanding is that they were probably better
 2 than we initially thought, because -- to take Alpha
 3 Profilate as an example, as I told you yesterday, 24
 4 of the 27 patients in that study did not develop
 5 non-A, non-B hepatitis, and three did. But once we
 6 used it, commercially, I don't think any of the
 7 patients developed hepatitis C from that particular
 8 product. Other products were less successful. They
 9 were all pretty good at eliminating hepatitis --
 10 eliminating HIV, because fortunately it turned out
 11 that HIV was more heat labile than the hepatitis
 12 viruses.
 13 And also -- they were generally a bit better.
 14 But we continued to monitor the patient group, both
 15 for HIV and hepatitis, for several years after that,
 16 because there remained some residual doubt. And as
 17 time went by, further viral steps were introduced and
 18 further purification steps were introduced to
 19 progressively increase the level of viral safety.
 20 **SIR BRIAN LANGSTAFF:** So, in summing that up, I think what
 21 you're saying is that some products, anyway, which
 22 claimed to be virus-reduced, actually did work to some
 23 extent?
 24 A. Well, most of them worked very well.
 25 The exception, about which I'm sure you're

160

1 going to come back, is to that early Armour product
2 that transmitted HIV to a few patients, sadly. And
3 that product is a good example of a product recall,
4 where they recalled the whole of the product, because
5 clearly the process as a whole was inadequate.

6 **SIR BRIAN LANGSTAFF:** Yes. The last thing I want to ask
7 you about is simply to get some information about how
8 the national contract for a product works.

9 Because of your policy, and your general policy
10 that we've heard from others, of not all the eggs
11 being in one basket, presumably whatever the national
12 contract is, it's for a range of products.

13 **A.** Yes.

14 **SIR BRIAN LANGSTAFF:** Nationally negotiated.

15 **A.** Yes.

16 **SIR BRIAN LANGSTAFF:** And that shows cost advantage, does
17 it, over negotiating per centre?

18 **A.** Well, actually, the way to get the best price would be
19 to go for a single product, but we don't want to do
20 that for a variety of strategic reasons, which the
21 Department of Health accept. And the Department of
22 Health accept that there will be a financial price to
23 pay for that strategy.

24 And that sort of strategic approach is
25 apparently accepted by the Department of Health in

161

1 **A.** The first time we had a proper national contract was
2 with recombinant for all.

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

4 **A.** And we established a national contract, and that led
5 to surprising discounts which had practical
6 implications because it enabled us to start some
7 patients earlier than we would otherwise have been
8 able to. Obviously, we would have preferred to have
9 started them all at once.

10 But then there was this threat to the continued
11 funding and one of the responses with the Department
12 of Health to this funding threat was to introduce
13 a system of central contracting for all products, for
14 all the patients. So that was the first truly
15 national contract for everybody. And so the
16 Commercial Directorate became involved. Deloitte
17 offered a device with the very first round, and our
18 objective was to reduce the cost and, therefore, make
19 the continued supply of recombinant Factor VIII for
20 our patients more secure, and to maintain freedom of
21 prescription to have as many suppliers as we could so
22 that the market would not be vulnerable to
23 interruptions of supply. Bearing in mind that, as
24 recently as 2002, we'd had a major interruption in the
25 supply of recombinant when Bayer stopped supplying.

163

1 relation to a wide range of products and is not
2 peculiar to our particular area.

3 And the strategic reasons are: you don't want
4 to be dependent on a single manufacturer, because if
5 you become too dependent, apart from anything else,
6 what's to stop them turning round and putting their
7 price up at a later stage? You know, when the next
8 contract comes round --

9 **SIR BRIAN LANGSTAFF:** They're a monopoly supplier, and you
10 might imagine they might do that. So I can understand
11 that.

12 **A.** Well --

13 **SIR BRIAN LANGSTAFF:** Can I --

14 **A.** They also --

15 **SIR BRIAN LANGSTAFF:** Can I ask you just to -- if you know
16 anything about, you may well not, because it's before
17 you were centrally involved in much of this world, but
18 in the 1970s, ending in about '79, I think it was,
19 there was central contracting for commercial product.
20 Then it ceased. And plainly, at some stage, national
21 contracting, as you've described it, started up again.
22 Roughly when was that? Do you remember?

23 **A.** When did it really start or when --

24 **SIR BRIAN LANGSTAFF:** When did national contracting start
25 to replace the system of buying by centre.

162

1 You know, so it's a very recent memory, a very
2 real problem. And the Department of Health accepted
3 that even though Deloitte said, well, you'll get the
4 biggest saving if you just go for two suppliers, as
5 group of clinicians, and with the department's
6 support, we said no, we don't want to go down that
7 route. And we organised it in such a way as to make
8 the suppliers behave in a commercial, competitive way.
9 And we told them that if they didn't offer us a good
10 price, we wouldn't buy their product. Whether that
11 was a real threat or not, it had the desired effect,
12 and with each round, the price has reduced to an
13 extent that, frankly, exceeded our expectations.

14 Right at the outset of this, Deloitte told us
15 that 90% of the cost of a drug is usually profit.
16 I was staggered by that. But when we did a survey, we
17 discovered that the unit price for a given Factor VIII
18 product varied by over 50% from one Haemophilia Centre
19 to another. So even if we just paid the average
20 price, we would have saved something like £15 million.
21 So clearly, there was enormous scope. I mean, the
22 manufacturers always said, "Oh this is an expensive
23 product to manufacture. We're not making much money
24 on it," and so on. And we had no way of knowing what
25 profit they were making. But it has been very useful

164

1 because during the period during which we've had this,
2 we have wanted to improve the intensity of treatment
3 and the quality of treatment for the patients.

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

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

12 Now, just to give me a sense of how it is
13 organised as between yourself and the purchasing unit,
14 is this a question of the price being negotiated and
15 you then ask for supplies from the supplier, or is
16 there a central warehouse, as it were, either
17 a notional warehouse or an actual one, which has
18 a store of the product which you are, between you,
19 obliged to take? Do you ask the --
20 **A.** There's still some degree of prescribing freedom, and
21 different centres prescribe different products. The
22 price is set nationally by the national contract.
23 Each round is organised between UKHCDO and what was,
24 past, the Purchasing and Supplies Agency, but which is
25 now CMU, the Central Medicines Unit. It's actually

165

1 more normal, and has less effect in the way in which
2 the product is dealt with.

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

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

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

20 Ms Richards?

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

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

24 **SIR BRIAN LANGSTAFF:** Well, it remains for me to say,
25 professor, that we're very grateful to you for giving

167

1 the same bunch of people. Coincidentally, they're
2 just down the road from me.

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

9 We have even involved patients and haemophilia
10 nurses in some of those assessments.

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

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

21 For example, some of the extended half life
22 products are pegylated, that is to say, a molecule of
23 polyethylene glycol is attached, and that's the method
24 that they used to extend its half life. Others have
25 bits of immunoglobulin attached, which is considered

166

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

10 But your willingness to engage is noted, and we
11 thank you very much for that. It's given us, this
12 evidence, at any rate, an insight into what we hadn't
13 had much evidence, as yet, orally given to us: the
14 period in which vCJD was a real threat and how it was
15 handled. It may still be a real threat, but at least
16 we know how it was handled in the 1990s, and what it
17 was like from your evidence to become a Haemophilia
18 Centre Director of a large centre at the end of the
19 1980s, coming into the 1990s, with all the challenges
20 and the testing for hepatitis C that took place.

21 That's very valuable evidence for us to have.

22 Thank you very much indeed for coming, or being here,
23 rather, I should say, virtually to give it.

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

25 **SIR BRIAN LANGSTAFF:** Well, I'm sure in many ways, it will

168

1 have been.
2 **MS RICHARDS:** Sir, that completes the evidence, obviously,
3 for today and for this week. We're not sitting next
4 week, and we resume remotely, so far as witnesses and
5 core participants are concerned, the following week on
6 the Tuesday, which I think is 17 November.
7 **SIR BRIAN LANGSTAFF:** Yes, it is.
8 **MS RICHARDS:** Yes, it is.
9 **SIR BRIAN LANGSTAFF:** So those listening around the
10 country should know that we will start on the 17th.
11 We are then hearing evidence from?
12 **MS RICHARDS:** We have evidence from three witnesses that
13 week, Dr Al-Ismail, Dr Mitchell, and Dr Giangrande.
14 **SIR BRIAN LANGSTAFF:** Thank you. So we start at
15 ten o'clock on Tuesday, 17th November. Thank you very
16 much.
17 **(5.05 pm)**
18 **(The hearing adjourned until Tuesday, 17th November at**
19 **10.00 am)**
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1	I N D E X	
2	CHARLES RICHARD MORRIS HAY	2
3	(continued)	
4	Questions by MS RICHARDS (continued)	2
5	Questions by SIR BRIAN LANGSTAFF	154
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

A	activity [3] 46/17 149/9 149/10 acts [1] 140/1 actual [2] 165/17 166/4 actually [34] 5/2 22/13 25/15 37/11 66/4 81/14 84/24 92/7 92/13 92/19 105/13 106/8 112/17 112/22 115/15 117/24 122/12 122/15 126/3 128/14 130/5 142/20 143/9 147/13 148/3 148/6 148/7 152/4 158/8 160/22 161/18 165/8 165/25 168/8 actuarial [2] 104/20 110/21 acute [1] 158/10 adapt [1] 15/17 add [3] 47/21 82/1 85/13 added [1] 78/25 addition [1] 87/12 additional [6] 7/10 7/19 37/20 43/9 84/2 120/21 address [3] 56/22 59/16 119/11 addressed [4] 2/18 13/12 87/7 149/2 addresses [1] 42/9 addressing [2] 60/21 69/8 adequate [5] 61/15 61/20 64/1 64/23 76/4 adequately [2] 20/22 29/6 adjacent [1] 105/15 adjourned [1] 169/18 Adjournment [1] 87/23 administering [1] 132/14 administration [2] 8/24 124/5 admitted [1] 38/12 adopted [2] 61/18 73/19 Adults [1] 3/1 advance [3] 40/7 95/10 98/21 advanced [1] 111/2 advantage [3] 72/1 118/2 161/16 advent [3] 73/25 75/5 155/17 adverse [4] 123/18 123/18 123/21 123/25 advice [10] 22/3 46/13 46/23 60/2	60/13 64/2 64/6 69/7 76/25 136/8 advised [3] 22/14 135/21 137/9 advising [1] 7/9 Advisory [7] 9/15 58/6 64/14 64/17 65/2 152/12 152/18 affect [4] 13/2 16/23 31/12 80/17 affected [16] 8/21 12/24 12/25 15/22 16/17 17/1 18/19 19/8 27/4 27/4 32/12 32/13 32/14 103/15 108/19 136/13 affects [1] 117/25 affirmation [1] 49/11 affirmative [2] 64/24 68/17 affording [1] 96/17 Afro [1] 128/20 Afro-Caribbean [1] 128/20 after [28] 2/9 9/25 10/4 14/5 21/22 23/10 25/6 31/7 44/10 50/19 51/9 53/9 75/23 76/1 77/7 79/18 81/17 92/13 97/8 105/24 124/9 124/13 130/15 146/6 148/4 153/2 153/6 160/15 afternoon [2] 2/21 87/14 again [25] 1/7 11/3 11/13 11/23 14/12 17/10 19/2 21/1 24/7 25/12 50/15 71/1 92/20 93/22 100/7 104/5 110/16 128/2 128/24 134/18 148/16 149/21 152/10 153/13 162/21 against [9] 80/4 119/9 140/4 141/10 142/15 142/24 143/2 147/8 149/25 age [12] 66/20 66/22 102/19 102/24 104/15 104/20 108/18 108/20 109/15 109/17 110/3 110/15 age-appropriate [2] 66/20 66/22 Agency [7] 11/15 21/9 32/20 33/1 39/15 124/4 165/24 Agency's [1] 22/22 agent [4] 116/16 116/19 116/20 116/24 ages [1] 103/3	aggravation [1] 150/16 aggregate [1] 55/6 AGM [2] 54/17 70/9 ago [4] 38/3 143/25 151/1 157/23 agree [7] 41/24 62/22 107/12 108/3 110/20 112/6 113/15 agreed [4] 33/17 49/19 81/3 157/18 agreement [1] 43/20 AIDS [7] 97/14 104/8 135/15 158/2 158/4 158/6 158/18 aim [1] 136/8 al [2] 128/9 169/13 Alder [1] 44/10 alert [1] 14/19 alerted [1] 29/3 alive [2] 21/21 43/12 all [118] 1/8 2/14 3/1 3/3 3/25 4/7 8/13 8/15 8/17 10/1 11/9 14/14 15/3 15/11 15/14 15/21 16/12 16/16 16/21 16/22 17/13 18/14 19/3 19/5 21/15 22/22 23/22 25/11 27/25 29/3 31/17 31/18 31/25 32/1 32/6 35/2 36/9 37/15 38/17 38/22 39/13 47/5 49/10 49/17 54/1 56/7 57/4 57/18 61/25 63/16 65/9 65/14 68/18 72/11 74/21 77/5 77/8 77/18 79/9 79/10 80/20 80/23 81/23 82/5 83/8 84/13 85/6 85/22 87/20 89/24 93/12 93/14 95/20 97/17 100/20 101/15 102/1 102/7 103/20 103/25 105/7 108/5 112/21 113/21 118/12 120/7 122/1 122/19 124/9 124/22 125/5 125/13 129/12 130/9 131/3 131/5 132/2 134/6 134/16 137/15 139/18 141/2 148/5 148/13 152/5 153/12 153/20 154/3 155/8 159/24 160/9 161/10 163/2 163/9 163/13 163/14 167/19 168/19 allow [3] 45/12 88/10 114/23 allowed [7] 18/7 50/5 123/2 134/12 134/13	134/14 134/17 allowing [1] 88/15 alluding [1] 3/21 almost [5] 31/3 96/15 99/12 100/10 110/4 along [9] 14/21 50/24 53/7 61/2 68/16 73/13 88/10 133/16 147/9 Alpha [1] 160/2 Alphanate [1] 121/25 already [15] 4/7 12/12 13/11 26/23 41/12 48/2 68/14 72/24 76/19 87/13 98/23 110/12 144/16 149/15 149/20 also [53] 2/13 3/23 3/24 9/12 9/13 10/3 10/21 11/22 19/15 20/21 25/3 25/5 27/25 29/9 30/10 36/23 39/8 43/25 46/10 46/25 50/9 51/6 63/3 63/12 64/21 66/14 68/10 69/1 74/4 74/25 77/8 78/9 79/5 81/24 83/16 101/6 103/19 109/19 112/9 114/19 117/25 119/21 121/13 125/12 128/3 128/9 128/11 133/11 135/9 137/5 151/5 160/13 162/14 alternative [1] 73/2 although [17] 27/1 47/2 60/8 70/21 71/2 72/6 72/18 88/22 96/19 109/1 120/12 129/10 129/14 136/5 138/16 157/23 167/5 always [18] 19/10 27/23 38/15 54/6 54/6 54/7 60/9 70/22 85/24 94/24 115/14 118/5 119/15 136/1 152/23 159/8 164/22 166/15 am [10] 1/2 12/9 31/25 45/16 45/18 60/18 114/13 138/2 138/13 169/19 amateurish [1] 56/4 amazing [1] 159/6 ambitious [2] 81/20 81/20 ambivalence [1] 153/10 America [1] 128/1 American [6] 3/19 4/4 30/20 30/22 31/24 147/6 amongst [9] 8/25 10/17 11/15 50/20 52/22 57/11 58/11	146/15 146/19 amount [6] 9/9 16/16 51/21 156/14 157/2 165/5 amounts [6] 3/2 3/4 45/1 55/25 107/13 109/6 ample [1] 131/22 an advantage [1] 72/1 analysis [6] 17/23 43/15 46/11 55/4 127/16 156/9 angry [1] 157/17 ankle [1] 136/22 annual [14] 35/13 50/6 50/10 50/23 51/5 52/14 66/15 66/19 67/23 84/24 132/20 132/20 134/1 134/9 annualised [1] 55/19 annually [1] 77/12 anonymised [3] 55/5 61/6 95/20 anonymous [4] 95/4 95/12 95/15 95/18 anonymously [1] 95/9 another [14] 24/24 45/9 62/11 90/22 91/4 125/5 143/17 145/1 145/6 145/13 145/22 148/15 164/19 166/13 answer [11] 17/6 17/20 47/8 82/8 97/1 108/7 117/5 121/18 129/20 135/25 147/3 answered [1] 62/25 answering [1] 121/21 anti [1] 17/18 anti-thrombin [1] 17/18 antibody [4] 89/17 95/6 95/8 158/5 anticipate [3] 71/4 71/5 82/6 anticipated [1] 89/25 anxieties [1] 3/12 any [72] 4/8 8/21 9/11 9/11 17/17 22/15 23/16 23/20 24/1 24/17 33/23 34/12 36/17 38/17 38/21 42/11 47/10 47/11 55/25 56/3 57/2 60/24 61/1 61/5 65/4 70/10 70/13 71/6 72/12 81/18 81/24 85/1 87/12 88/18 93/2 95/24 99/15 100/1 100/3 100/17 110/1 111/12 118/3 121/2 121/20 122/5 122/17 123/6 123/12 123/12
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(45) about... - any

A	111/7 134/3 140/25 141/23 157/7 161/24 approached [3] 52/21 79/16 127/1 approaches [1] 100/22 appropriate [9] 40/7 66/20 66/22 67/1 67/4 93/1 93/4 145/6 151/22 approval [8] 40/21 67/9 70/6 121/3 122/18 122/21 122/24 123/1 approve [1] 121/9 approximately [2] 83/10 109/22 April [2] 27/10 31/17 April 2009 [1] 27/10 April 2010 [1] 31/17 Archer [1] 151/6 are [123] 1/9 1/12 1/13 1/14 1/17 1/18 3/1 7/2 7/6 7/7 9/8 10/6 12/12 12/17 14/11 15/6 15/9 15/22 19/10 19/12 23/21 27/16 28/15 32/1 32/11 34/2 35/8 36/5 36/15 41/4 49/14 49/18 50/5 54/8 54/9 54/9 54/22 55/4 56/7 56/24 62/15 64/14 65/10 66/21 67/15 68/15 69/5 70/10 72/21 73/8 73/17 74/13 77/11 78/8 78/9 80/18 80/20 84/5 84/10 85/8 85/10 85/11 87/8 87/9 87/9 88/3 89/8 92/3 92/4 92/15 93/25 94/7 94/13 95/7 97/4 97/19 98/11 98/23 99/21 99/22 101/15 109/21 111/2 116/7 116/8 118/4 119/19 120/21 124/1 125/22 125/23 127/23 128/8 128/13 128/15 132/21 134/17 137/5 138/18 138/19 143/20 144/17 144/20 145/25 146/1 147/25 149/15 149/17 150/4 154/7 155/10 162/3 165/9 165/18 166/5 166/6 166/12 166/22 167/3 167/10 167/19 169/5 169/11 area [5] 105/12 116/5 121/12 134/15 162/2 aren't [1] 131/11	arguably [1] 71/24 argued [1] 74/10 argument [1] 55/10 arise [1] 90/8 arisen [2] 58/9 77/14 arises [2] 62/10 115/7 arising [4] 40/10 71/7 129/20 154/10 arm [2] 50/20 51/6 Armour [1] 161/1 around [13] 36/25 53/3 60/4 70/23 75/20 80/6 96/21 106/16 110/3 110/17 118/11 139/24 169/9 arrange [3] 86/4 96/6 146/10 arranged [1] 122/22 arrangements [2] 24/1 49/5 array [1] 90/4 arrived [1] 157/16 as [198] aside [1] 99/17 ask [40] 1/20 35/4 40/10 40/12 41/15 45/20 56/10 63/9 70/22 71/8 73/10 75/21 81/11 82/6 82/12 86/3 86/3 87/3 88/8 89/1 93/21 94/8 101/17 112/25 115/3 117/2 126/9 131/5 131/13 138/7 149/21 156/5 156/8 156/12 161/6 162/15 165/15 165/19 167/19 168/8 asked [14] 18/2 20/16 23/21 25/18 32/7 59/22 63/5 65/8 65/21 78/21 79/9 79/10 85/21 85/25 89/19 92/15 101/7 101/19 102/5 115/3 116/1 123/10 149/20 152/11 asking [10] 32/1 78/13 79/23 80/1 87/14 87/16 111/19 138/25 143/1 147/3 asks [4] 18/1 89/19 91/16 145/25 aspects [2] 68/11 137/5 aspirin [1] 90/24 assertion [2] 142/15 142/16 assertions [1] 97/13 assess [6] 71/9 57/12 99/10 120/19 126/24 128/10 assessed [2] 38/12 166/5	assessing [1] 17/2 assessment [15] 6/11 6/14 6/21 6/23 7/5 10/13 17/8 17/22 33/1 38/17 38/21 39/7 39/9 39/17 102/22 assessments [4] 27/16 38/22 129/8 166/10 assiduously [1] 37/22 assistance [1] 75/8 Associate [1] 48/15 associated [2] 12/6 21/7 assume [2] 90/5 98/12 assumed [3] 61/3 88/9 112/20 assumption [1] 38/15 assumptions [8] 6/23 7/7 38/19 38/23 38/25 39/6 79/17 79/21 asymptomatic [1] 22/24 attach [1] 115/11 attached [4] 3/7 4/1 166/23 166/25 attack [1] 158/10 attempt [5] 141/24 141/25 142/3 148/22 149/7 attempted [1] 85/4 attempting [1] 56/22 attempts [2] 57/20 149/22 attend [2] 134/12 134/13 attendants [1] 140/22 attention [4] 15/4 108/15 113/2 123/16 attenuated [1] 124/19 attribute [1] 17/3 attributed [1] 129/8 atypical [1] 25/3 audience [1] 1/10 audit [2] 48/23 112/17 audited [3] 48/22 48/25 56/8 August [1] 70/2 August 3 [1] 70/2 authored [1] 111/23 authority [9] 52/5 56/18 57/18 57/22 62/13 62/19 64/12 64/14 65/1 authors [1] 122/13 autopsy [3] 24/17 44/18 44/18 availability [2] 110/1 110/2 available [14] 37/19 40/8 41/7 42/2 43/8	43/10 44/14 74/12 97/10 120/5 130/16 146/9 147/11 167/10 average [13] 103/3 104/15 104/20 105/5 108/18 109/17 110/3 110/15 127/19 154/22 164/19 165/4 165/7 avoid [5] 90/23 118/1 134/8 137/9 157/1 avoided [1] 154/5 await [1] 82/10 awaited [1] 27/16 aware [16] 13/20 13/21 14/13 29/17 47/13 61/22 88/23 93/15 123/6 132/13 132/23 133/8 133/8 136/14 159/3 159/23 awareness [3] 99/1 99/3 138/3 away [5] 29/3 63/8 93/3 105/1 125/6 awkwardly [1] 136/21	basically [3] 3/9 63/4 147/3 basis [23] 10/18 38/2 53/17 56/4 66/8 69/14 75/16 88/4 93/8 96/11 99/17 99/19 101/10 131/1 132/15 132/20 133/21 135/3 142/15 142/16 143/12 152/23 156/12 basket [1] 161/11 batch [19] 6/19 6/22 9/10 9/12 11/4 18/3 18/4 23/4 23/10 24/14 25/7 28/4 144/3 144/7 144/9 144/17 145/13 155/5 155/7 batches [1] 4/20 7/14 7/17 7/19 7/23 7/25 8/9 11/9 17/1 19/16 20/2 20/13 20/18 20/19 22/8 23/3 28/13 123/14 124/7 144/12 155/3 battery [1] 96/6 Bayer [1] 163/25 be [265] bearing [3] 128/11 158/4 163/23 became [17] 9/5 38/24 45/4 46/18 46/25 48/1 50/9 50/19 57/7 63/24 79/1 80/22 97/9 100/25 130/15 159/3 163/16 because [157] 1/7 1/20 3/6 3/22 4/2 4/6 5/25 8/19 8/24 9/14 9/16 9/22 12/14 13/12 15/17 16/3 16/12 18/10 20/7 21/5 22/7 26/12 26/20 31/5 32/2 36/10 37/19 37/25 38/8 38/17 39/1 39/23 40/13 44/9 47/9 49/8 49/12 50/13 50/22 52/13 55/17 55/22 57/8 57/17 61/11 62/7 62/14 62/22 62/25 65/13 67/18 68/10 68/10 68/11 71/2 72/3 73/24 74/5 75/24 79/1 79/11 79/25 80/3 80/5 80/17 81/18 84/15 85/7 85/11 85/14 88/10 89/5 89/8 90/12 92/13 92/22 93/22 94/8 96/22 97/2 97/8 97/14 98/5 98/24 99/2 101/2 101/3 103/19 105/8 105/20 106/1 106/16 107/6 110/12
----------	---	--	---	---	--

(46) any... - because

<p>B</p> <p>because... [63] 110/23 111/1 114/3 115/22 116/3 116/10 116/13 116/18 116/24 117/22 117/24 118/1 118/3 118/10 118/15 119/17 119/18 120/4 121/18 122/8 122/10 125/16 126/5 128/15 128/21 131/12 134/25 135/7 137/11 139/3 139/5 139/13 140/13 140/17 140/21 143/23 144/11 145/17 146/3 147/7 147/17 148/5 150/1 150/22 153/2 153/20 155/16 156/2 157/13 158/2 158/4 159/6 160/2 160/10 160/16 161/4 161/9 162/4 162/16 163/6 165/1 166/15 167/4</p> <p>become [8] 27/3 48/22 53/11 77/21 123/6 125/3 162/5 168/17</p> <p>becomes [2] 47/6 120/22</p> <p>becoming [1] 46/22</p> <p>beefburger [1] 27/25</p> <p>been [175]</p> <p>before [31] 1/6 4/11 40/9 46/19 50/5 60/9 63/6 68/3 75/4 77/6 79/14 79/21 84/14 86/20 90/4 90/24 92/8 101/1 103/12 106/16 109/25 110/2 110/9 112/24 122/16 122/17 123/2 125/15 144/19 150/20 162/16</p> <p>began [2] 59/15 59/16</p> <p>beginning [5] 30/19 36/25 38/11 38/14 100/20</p> <p>behalf [2] 76/12 102/15</p> <p>behave [1] 164/8</p> <p>behaved [1] 151/25</p> <p>being [54] 7/1 12/9 12/12 18/22 19/9 19/24 20/16 25/18 26/12 35/11 36/5 41/4 41/22 41/24 46/5 50/9 51/1 51/9 53/21 57/25 58/13 58/13 59/22 60/6 60/7 71/17 73/18 78/3 91/7 96/23 96/24 100/15 100/15 102/22 104/8 105/17 111/5</p>	<p>112/11 113/4 117/23 127/20 133/5 135/6 139/4 143/4 144/10 145/19 146/19 147/22 155/20 155/22 161/11 165/14 168/22</p> <p>belief [2] 96/11 138/14</p> <p>believe [2] 145/4 151/20</p> <p>below [1] 40/23</p> <p>benefit [5] 13/16 52/20 106/2 108/16 117/17</p> <p>besets [1] 105/12</p> <p>best [4] 8/12 120/10 152/14 161/18</p> <p>better [5] 101/4 150/25 151/3 160/1 160/13</p> <p>between [25] 17/18 33/4 33/9 33/21 34/11 35/8 36/16 55/15 63/14 73/9 96/25 105/15 112/7 114/24 115/9 115/13 119/24 128/6 143/13 156/17 165/13 165/18 165/23 166/16 166/19</p> <p>beyond [2] 26/8 74/19</p> <p>bias [9] 84/5 117/24 118/2 119/12 119/13 119/20 119/21 134/8 135/10</p> <p>biases [1] 118/3</p> <p>big [1] 52/3</p> <p>biggest [2] 118/9 164/4</p> <p>Biggs [11] 56/17 87/1 87/17 104/18 104/19 105/3 106/1 106/10 107/4 110/4 114/12</p> <p>Biggs' [1] 110/24</p> <p>bind [1] 148/4</p> <p>biopsy [4] 42/25 43/10 43/13 43/18</p> <p>Birmingham [2] 2/25 20/6</p> <p>bit [11] 57/6 57/17 92/23 106/21 140/13 140/14 148/17 150/19 154/10 160/13 167/3</p> <p>bits [1] 166/25</p> <p>blamed [1] 140/22</p> <p>blanks [1] 78/22</p> <p>bleed [6] 55/19 136/13 136/16 136/22 137/6 137/12</p> <p>bleeder [1] 98/10</p> <p>bleeders [4] 77/12 77/18 78/7 80/17</p> <p>bleeding [22] 8/18</p>	<p>15/16 17/14 19/11 23/23 46/8 62/15 76/14 76/18 77/5 83/4 83/9 84/13 90/18 91/2 94/14 109/20 113/4 113/9 113/15 114/22 137/8</p> <p>bleeds [2] 114/4 136/9</p> <p>blood [44] 5/21 6/1 6/14 8/16 9/23 10/9 12/5 12/13 12/15 12/15 16/14 16/24 17/5 18/16 18/17 21/7 21/23 22/2 22/13 27/24 38/13 56/18 77/6 78/1 78/1 83/13 88/6 88/8 88/12 88/15 91/17 91/21 96/6 107/2 116/12 123/5 125/18 126/1 126/12 127/2 127/5 127/20 128/16 128/19</p> <p>blue [1] 100/18</p> <p>board [1] 56/7</p> <p>bodies [1] 46/14</p> <p>body [6] 19/25 153/8 153/18 154/2 167/5 167/9</p> <p>bold [3] 7/11 41/20 85/3</p> <p>book [1] 137/3</p> <p>both [15] 18/23 24/4 39/18 59/11 62/19 69/2 74/10 101/14 109/20 117/13 123/1 142/24 149/12 149/19 160/14</p> <p>bottom [12] 11/16 11/23 12/8 12/18 13/25 17/12 25/19 77/15 83/2 137/24 143/22 152/8</p> <p>bought [2] 56/20 133/3</p> <p>bouncing [1] 137/3</p> <p>bound [2] 38/1 147/24</p> <p>box [2] 17/25 18/5</p> <p>boxing [1] 137/14</p> <p>BPL [13] 3/2 3/16 4/13 4/17 5/1 11/6 30/19 30/21 30/25 31/1 31/24 50/23 155/23</p> <p>brain [1] 24/19</p> <p>branch [1] 95/24</p> <p>brand [2] 72/19 147/6</p> <p>break [9] 45/10 45/11 45/17 86/18 87/17 131/8 131/23 131/24 132/7</p> <p>Brian [3] 59/15 154/9 170/4</p>	<p>Brian Colvin [1] 59/15</p> <p>brief [1] 15/10</p> <p>briefing [1] 14/8</p> <p>briefly [2] 11/24 82/12</p> <p>bring [1] 142/12</p> <p>bringing [1] 142/2</p> <p>Britain [1] 102/14</p> <p>British [8] 8/16 8/19 16/5 16/13 16/24 17/5 30/22 102/4</p> <p>broad [2] 11/1 108/5</p> <p>broader [1] 48/1</p> <p>broadly [5] 108/1 108/7 108/23 109/9 109/24</p> <p>brother [2] 136/25 137/3</p> <p>brothers [1] 136/25</p> <p>brought [7] 37/11 50/11 52/12 139/4 141/20 141/21 153/20</p> <p>bruising [1] 90/17</p> <p>bubbling [1] 153/20</p> <p>bulk [1] 137/11</p> <p>bunch [1] 166/1</p> <p>burdensome [2] 82/23 120/22</p> <p>busily [1] 67/11</p> <p>business [3] 18/18 100/20 134/13</p> <p>but [214]</p> <p>button [1] 67/2</p> <p>buy [1] 164/10</p> <p>buying [1] 162/25</p> <p>by [117] 2/2 4/18 4/24 5/20 6/14 6/16 7/1 8/5 8/7 10/11 10/21 11/14 12/15 12/25 13/5 14/8 14/18 15/2 17/23 18/16 19/24 22/12 24/9 24/9 28/20 31/17 32/6 32/21 32/25 33/12 34/20 38/22 38/24 40/5 44/8 44/17 49/11 52/5 54/1 54/4 54/22 56/1 56/20 58/13 59/15 61/18 62/9 69/21 70/3 70/10 73/7 73/19 76/11 78/7 80/8 80/9 84/21 85/1 86/24 87/11 87/16 88/15 89/14 92/19 94/21 95/12 96/22 101/25 102/12 108/5 110/14 111/23 112/19 115/3 115/18 117/22 118/5 119/21 123/24 125/25 130/14 132/18 133/9 139/14 141/2 141/24 141/25 143/5 143/7 145/23 146/18 146/24 148/22 149/22</p>	<p>149/24 151/17 152/8 153/7 153/8 154/9 154/17 154/18 156/19 157/1 157/15 160/17 161/25 162/25 164/16 164/18 165/22 166/5 166/7 166/7 167/17 170/3 170/4</p> <p>C</p> <p>CAG [4] 66/14 67/23 68/1 69/3</p> <p>calculated [3] 103/13 140/7 156/19</p> <p>calculation [3] 99/9 110/21 110/23</p> <p>calculations [3] 38/19 103/14 103/18</p> <p>call [3] 154/25 155/3 155/4</p> <p>called [4] 154/19 155/18 155/20 155/23</p> <p>calls [3] 72/15 154/14 155/16</p> <p>came [7] 53/6 100/18 116/6 133/16 144/20 147/9 148/15</p> <p>campaign [8] 139/24 140/6 141/2 142/12 142/17 143/4 143/11 150/2</p> <p>campaigners [1] 149/23</p> <p>can [96] 6/9 6/25 7/11 8/4 11/7 11/15 11/21 12/8 12/11 12/14 12/18 12/21 13/4 13/8 13/10 14/1 14/24 15/2 15/4 15/10 17/8 17/10 17/25 20/11 22/21 23/12 24/3 24/7 25/19 26/2 26/15 27/13 27/18 29/16 30/13 31/16 32/19 32/25 34/5 34/18 35/17 40/18 41/5 42/15 42/16 42/20 47/17 49/12 49/14 63/7 63/18 63/18 63/19 70/20 71/20 72/2 72/16 73/22 74/7 75/9 76/11 77/3 78/17 82/15 86/2 88/20 91/15 99/6 102/12 102/25 106/13 109/14 109/17 110/15 113/24 114/7 116/5 118/5 118/16 119/21 124/2 124/12 126/4 126/6 129/1 131/8 141/4 146/23 148/9 149/4 153/23 154/16 157/9</p>	<p>162/10 162/13 162/15 can't [17] 3/19 4/9 16/7 19/13 28/1 32/13 48/17 66/11 68/13 96/19 110/22 123/9 141/11 144/23 144/25 145/21 146/21</p> <p>Canada [1] 124/18</p> <p>cancellations [1] 40/5 cancelled [2] 39/23 40/2</p> <p>cancer [4] 24/23 94/10 94/13 94/18</p> <p>canvas [1] 49/20</p> <p>capacity [8] 19/6 21/13 28/18 28/19 44/4 44/5 123/4 152/9</p> <p>carcinoma [1] 24/15</p> <p>Cardiff [2] 48/6 48/7</p> <p>care [9] 46/7 47/6 48/9 48/12 48/19 48/23 133/1 136/10 152/15</p> <p>carefully [2] 44/20 101/1</p> <p>Caribbean [1] 128/20</p> <p>carried [1] 6/14</p> <p>carry [2] 47/14 49/10</p> <p>case [38] 4/9 5/21 5/23 8/21 12/3 12/5 12/7 21/5 21/7 21/16 21/18 21/19 22/1 22/7 23/19 24/10 29/10 35/6 43/10 55/11 57/17 60/19 66/7 72/12 73/3 74/1 93/16 98/10 112/22 113/19 120/14 120/19 131/16 135/2 138/14 141/8 141/10 142/19</p> <p>cases [16] 21/5 73/21 74/5 75/14 80/2 82/23 85/25 95/3 113/5 113/10 117/10 117/11 139/3 142/12 142/17 158/2</p> <p>caseworkers [1] 69/7</p> <p>Castle [1] 64/15</p> <p>catch [1] 29/8</p> <p>catching [1] 60/1</p> <p>categorised [1] 13/13</p> <p>category [1] 7/13</p> <p>caught [2] 140/20 150/22</p> <p>cause [7] 98/7 109/23 113/2 113/16 136/16 136/22 149/11</p> <p>causes [4] 102/20 102/24 113/7 150/15</p> <p>causing [1] 74/13</p> <p>caution [1] 103/17</p> <p>CD4 [1] 89/7</p>
--	--	---	--	---	--

C					
cease [1] 86/20	certainly [17] 14/10	chased [1] 96/20	53/10 64/25 65/11	137/4 153/10 161/1	comparable [3] 103/5
ceased [1] 162/20	16/11 24/11 24/22	chasing [1] 19/12	67/18 72/17 95/21	168/4 168/5	114/10 114/21
cell [1] 128/22	93/1 97/2 100/2	chat [1] 138/1	103/17 127/13 129/17	comes [5] 90/17	compare [5] 104/15
cellular [1] 22/2	104/11 124/17 135/18	cheap [2] 3/23 146/24	139/13 153/21 161/5	153/4 162/8 166/11	104/17 105/13 110/22
cent [3] 83/21 109/22	136/14 138/18 140/3	check [8] 20/16 32/7	164/21	166/20	120/8
113/11	142/23 150/13 152/22	41/5 87/5 90/20 90/22	climate [1] 59/1	coming [5] 50/24	compared [3] 56/4
central [5] 66/16	166/17	102/1 102/20	clinic [1] 148/10	58/19 72/2 168/19	103/16 109/7
162/19 163/13 165/16	certificate [2] 74/2	checked [1] 32/2	clinical [8] 11/14	168/22	comparing [3] 105/7
165/25	76/6	chief [3] 73/13 73/14	21/21 121/7 121/17	comment [2] 129/21	114/8 118/7
centrally [4] 10/11	Certificates [1] 41/2	152/6	121/24 144/6 144/8	131/4	comparison [5] 96/24
11/23 18/24 162/17	certification [3] 63/24	child [1] 153/24	146/1	commercial [9] 2/24	104/21 105/15 112/5
centre [64] 4/19 5/13	64/10 67/18	children [3] 15/15	clinically [3] 26/25	54/25 107/24 126/2	118/3
8/6 15/3 15/10 19/7	cetera [2] 15/14 144/4	133/12 153/22	34/21 116/9	134/16 154/18 162/19	comparisons [1]
19/25 20/15 22/23	chair [13] 15/1 15/2	Children's [2] 2/25	clinician [4] 117/15	163/16 164/8	118/4
28/9 28/23 30/1 30/2	19/24 21/14 28/19	122/10	117/15 118/25 119/1	commercially [1]	compensated [1]
31/19 33/19 33/20	32/21 49/1 49/5 49/7	choice [5] 18/22	clinicians [8] 11/19	160/6	139/13
33/21 34/9 34/11	49/11 49/13 73/13	18/23 18/25 19/1	39/19 100/21 118/11	commissioned [1]	compensation [5]
34/21 42/1 44/5 45/7	152/9	117/14	119/9 157/8 164/5	84/21	138/13 139/17 140/6
46/3 47/1 48/23 56/17	Chair's [1] 118/18	choose [2] 18/7	167/12	Commissioner [3]	140/24 141/7
57/10 57/11 74/6	chaired [2] 59/15	167/14	closely [2] 57/14 66/3	60/14 60/15 62/12	competitive [1] 164/8
77/25 77/25 79/12	132/18	chose [1] 117/15	closer [1] 19/20	Commissioner was	complainants [1]
79/14 83/12 85/16	chairman [6] 49/2	chosen [1] 6/24	closest [1] 140/21	[1] 60/15	140/3
85/20 86/1 86/11	49/24 58/2 59/10	chronic [3] 75/1	clotting [6] 23/3 56/18	commissioners [2]	complaint [2] 140/8
98/16 103/21 111/4	142/19 142/20	130/11 158/12	56/19 74/22 90/21	53/15 53/16	150/12
111/8 122/23 133/6	challenges [1] 168/19	chronic viraemia [1]	137/5	committee [21] 6/17	complaints [2] 142/14
139/25 143/6 143/7	chance [2] 44/24	158/12	cloud [1] 136/18	9/15 43/24 58/6 59/12	143/1
143/13 144/15 144/16	139/4	chronically [1] 74/4	CMU [1] 165/25	62/14 62/20 67/8 68/2	complete [4] 63/16
145/5 145/7 145/23	change [13] 4/4 22/3	chronological [1]	co [2] 111/23 122/13	68/3 68/6 70/1 121/8	66/1 131/8 149/11
149/15 149/18 150/2	22/14 23/19 25/20	115/5	co-authored [1]	121/11 121/14 122/17	completed [1] 17/13
155/1 161/17 162/25	38/5 38/7 60/3 64/21	circles [1] 96/21	111/23	122/25 123/23 152/11	completely [7] 40/9
164/18 167/15 168/18	64/25 101/16 114/17	circular [2] 48/11	co-authors [1] 122/13	152/12 152/18	44/19 80/7 81/12
168/18	114/19	140/12	code [1] 66/23	Committee's [2] 2/20	123/3 137/20 140/4
centres [77] 2/14 2/25	changed [13] 8/10	circulating [1] 30/20	coded [1] 128/20	44/1	completeness [1]
3/3 3/9 3/14 3/22 4/1	12/23 35/1 39/6 39/8	circulation [1] 148/2	coffee [1] 45/13	committees [2] 6/16	82/11
5/18 13/18 14/14	47/25 48/10 48/16	circumstance [1]	Coincidentally [1]	122/20	completes [1] 169/2
14/22 20/21 28/8	67/15 67/25 69/1	120/6	166/1	common [5] 50/20	complexity [1] 34/19
29/19 29/20 30/3 31/3	101/3 121/5	circumstances [3]	Colindale [1] 20/6	66/9 134/4 134/15	complication [1]
31/18 31/25 32/3 32/7	changer [1] 5/25	25/25 26/8 90/9	collapse [1] 37/17	136/6	114/6
32/8 32/11 34/17	changes [1] 114/16	CJD [13] 2/19 6/8	collated [2] 11/10	commoner [1] 155/11	component [1] 78/1
34/22 36/5 37/21	changing [1] 119/2	10/12 10/21 12/1	123/24	commonest [2] 98/7	comprehensive [4]
37/24 39/20 43/4 44/7	chaos [1] 149/11	12/18 22/22 27/22	collating [1] 10/16	113/16	15/12 48/19 48/23
46/16 47/18 47/20	chapter [4] 57/5	35/9 41/25 43/6 43/25	colleagues [7] 8/23	commonly [1] 135/21	133/1
47/21 47/22 47/25	123/20 132/25 133/4	123/11	26/3 26/6 96/4 99/24	communicate [2] 16/4	comprised [1] 82/18
48/1 48/3 48/4 48/8	characterise [1]	CJD Unit [1] 43/25	100/24 140/19	87/11	compromise [1]
48/14 48/14 48/15	149/22	claimed [1] 160/22	collect [5] 50/14 59/4	communicating [2]	156/17
48/15 48/19 48/19	charge [4] 53/17 55/7	claiming [3] 139/9	63/17 85/7 120/13	12/10 22/6	concentrate [19] 20/2
56/15 62/4 62/4 66/25	156/10 156/13	140/1 141/20	collected [4] 42/17	communication [3]	31/6 31/9 72/20 73/23
77/17 78/8 78/13	charging [1] 157/2	claims [1] 142/2	82/19 82/20 123/21	5/5 33/21 75/11	74/7 74/22 104/12
78/13 78/20 79/9	Charities [1] 50/5	clarify [2] 95/19 142/3	collecting [1] 80/14	communications [2]	105/17 107/14 107/22
79/10 80/2 80/5 80/7	charity [7] 46/23 50/5	class [4] 141/17	collection [2] 46/11	14/15 73/9	107/24 111/3 114/1
81/13 82/22 84/15	50/18 50/19 50/22	146/22 147/7 148/22	58/18	community [1] 128/20	114/17 114/18 116/17
85/2 85/4 85/21 85/25	51/1 51/2	classical [2] 116/5	collective [1] 152/13	companies [10] 54/2	120/1 147/6
86/8 102/15 111/2	CHARLES [5] 1/25	139/15	collectively [1] 142/7	54/12 54/15 54/23	concentrates [4]
112/21 122/23 134/23	36/2 141/13 141/15	cleaned [2] 36/16	College [1] 47/24	55/1 56/2 56/8 133/24	17/18 83/13 107/22
144/11 149/13 165/21	170/2	36/23	coloured [1] 112/19	134/5 156/7	109/2
cerebral [1] 103/23	Charles Hay [1] 36/2	cleaning [1] 36/18	column [1] 102/18	Companies House [1]	concept [3] 47/24
certain [10] 8/25	Charlie [3] 56/20	clear [6] 36/4 38/24	Colvin [1] 59/15	56/8	47/25 48/18
16/16 32/23 64/21	105/16 110/25	65/11 65/20 115/14	come [21] 49/8 55/3	company [12] 51/3	concern [4] 39/24
101/8 128/13 134/12	Charlie Rizza [1]	138/20	60/9 68/16 82/9 86/1	54/19 55/12 55/13	41/20 73/18 74/16
147/3 147/6 147/7	56/20	clear-cut [1] 115/14	86/13 93/8 94/8 98/16	56/6 101/9 134/1	concerned [6] 6/20
	chart [1] 145/18	cleared [1] 83/20	102/6 113/17 117/9	134/11 146/21 156/8	24/2 91/24 98/23
	chase [1] 85/16	clearly [14] 28/3	125/23 130/24 132/2	156/15 156/22	114/23 169/5

C	111/7 117/12 consider [7] 57/2 58/1 83/8 87/14 91/25 121/15 131/21 considerable [6] 4/5 61/12 74/13 144/8 149/8 149/10 considerably [1] 59/9 consideration [3] 9/5 101/20 167/12 considerations [2] 90/8 166/12 considered [17] 6/16 7/15 34/10 34/15 36/11 37/2 39/10 50/13 61/19 64/23 70/2 92/6 92/21 104/7 119/15 121/21 166/25 consistent [1] 64/6 Consortium [1] 53/20 conspiracy [2] 152/21 152/25 constantly [1] 136/19 constitution [5] 46/2 46/21 46/24 49/1 50/9 constructive [1] 65/2 consultant [3] 14/5 101/13 146/6 consultants [1] 167/16 consultation [1] 90/13 consulting [1] 6/15 consumer [1] 141/21 contact [2] 28/8 137/10 contacted [1] 12/9 contacting [2] 64/7 64/8 contain [1] 144/3 contained [1] 130/4 contains [1] 41/23 contaminated [6] 4/21 28/15 36/20 123/7 123/14 123/14 context [5] 16/18 58/24 71/13 101/19 149/3 continue [6] 1/19 18/24 51/2 57/24 82/8 92/14 continued [11] 2/1 2/2 3/14 3/22 39/10 54/19 160/14 163/10 163/19 170/2 170/3 continues [4] 10/18 13/5 13/14 71/16 continuing [2] 3/2 27/15 contract [10] 135/2 161/8 161/12 162/8 163/1 163/4 163/15	165/4 165/22 166/3 contracted [4] 21/18 74/23 99/7 138/12 contracting [6] 127/17 135/15 162/19 162/21 162/24 163/13 contrary [1] 136/7 Contreras [3] 128/9 129/4 129/6 contributed [1] 45/7 control [1] 26/9 controlled [1] 119/16 convenient [1] 60/18 conversation [3] 97/12 98/1 136/5 conversations [5] 52/22 64/3 135/5 153/19 157/14 converting [1] 111/3 convinced [1] 118/12 coordinating [1] 5/8 coordinator [1] 43/7 copies [3] 15/18 62/4 62/5 copy [7] 17/14 81/15 106/9 108/17 145/21 146/10 146/10 core [4] 16/16 115/3 131/14 169/5 corner [1] 24/19 correct [10] 2/12 5/23 5/24 39/1 51/19 52/2 59/24 102/1 114/15 136/2 corrected [1] 34/13 corresponded [1] 46/22 correspondence [4] 4/13 5/3 64/13 143/8 cost [8] 4/5 55/1 156/13 156/19 161/16 163/18 164/15 165/8 costing [1] 37/10 costs [2] 54/13 156/19 could [59] 2/15 4/14 5/5 5/16 6/3 16/21 18/11 18/24 19/3 19/18 20/25 22/12 22/19 27/9 30/3 34/10 35/12 35/14 35/19 35/20 35/23 36/13 38/16 38/21 40/4 45/25 49/3 52/18 53/11 57/19 62/5 62/16 65/22 66/10 66/12 71/9 73/6 75/18 76/10 76/24 81/9 83/12 86/16 91/10 94/9 97/12 121/16 127/7 128/20 130/9 135/5 137/11 137/19	137/24 143/15 154/22 155/11 157/13 163/21 couldn't [11] 9/18 37/6 49/8 51/2 64/6 65/11 130/23 140/16 148/16 154/5 157/22 Council [7] 51/11 140/1 140/8 141/3 142/13 150/3 150/9 counsel [6] 1/15 101/1 131/10 131/13 131/14 154/11 counselled [1] 101/12 counselling [8] 95/25 96/22 96/25 97/6 97/19 99/18 100/11 159/12 counsellor [1] 159/12 count [1] 89/7 counted [1] 68/5 countries [3] 115/24 118/9 127/24 country [12] 31/8 31/11 80/6 115/25 128/1 128/1 128/4 128/5 134/19 134/19 139/25 169/10 couple [4] 1/5 1/16 111/15 147/24 course [30] 19/15 25/5 27/23 28/24 60/7 60/25 61/10 64/5 66/18 73/3 86/25 89/19 100/4 105/3 108/23 109/2 111/21 114/2 116/22 125/12 125/23 127/24 129/14 131/9 133/15 136/23 141/17 151/12 168/6 168/7 court [1] 141/8 cover [1] 156/18 coverage [1] 138/4 covered [3] 40/13 44/8 110/14 covers [2] 106/10 122/8 Covid [2] 67/11 68/10 created [1] 129/22 Creutzfeldt [13] 8/11 9/24 10/4 16/23 18/15 22/12 24/12 24/25 26/25 36/14 39/3 39/16 135/23 crisis [2] 57/17 104/8 criteria [1] 48/21 critical [1] 135/22 criticised [1] 119/18 cross [1] 128/12 crossfire [2] 140/20 150/22 cryo [2] 111/5 113/20	cryoprecipitate [14] 101/21 107/2 107/6 107/13 107/21 109/1 109/7 110/2 110/7 110/10 110/12 111/13 112/11 155/11 cull [2] 65/12 65/18 culminated [1] 64/16 cup [2] 45/12 132/1 current [11] 27/14 34/24 35/6 69/12 69/21 88/5 88/17 89/9 94/24 100/6 100/13 currently [6] 1/19 30/1 73/18 114/1 120/19 156/19 customary [3] 95/24 96/12 99/20 cut [1] 115/14 cycling [1] 137/15	61/22 63/11 65/13 66/25 67/6 67/9 67/10 68/18 69/13 70/11 71/8 71/18 76/8 76/12 78/10 78/12 80/4 85/5 85/8 123/25 databases [7] 53/8 58/25 60/1 61/18 64/3 66/7 68/9 date [7] 11/16 11/22 17/11 25/23 51/6 52/13 71/4 dated [7] 11/3 14/12 26/4 32/20 40/17 46/3 60/8 David [1] 141/13 day [2] 10/19 125/8 days [4] 10/7 85/14 126/3 158/4 DDAVP [1] 139/10 de [6] 32/17 32/23 33/11 34/6 34/10 38/4 de-notification [4] 32/17 32/23 34/6 38/4 de-notified [2] 33/11 34/10 dead [1] 85/10 deal [7] 51/4 51/5 55/9 63/24 113/12 157/19 157/25 dealing [1] 64/11 dealt [7] 9/6 14/22 67/6 69/3 141/12 151/5 167/2 Dear [1] 26/6 death [23] 12/4 41/2 63/23 64/10 67/17 74/2 76/1 76/5 101/24 102/19 102/20 102/24 102/24 104/15 104/21 108/19 108/20 109/15 110/3 110/16 113/2 113/16 114/21 death: [1] 109/18 death: 42.3 [1] 109/18 deaths [7] 43/3 103/19 103/22 103/24 109/19 109/23 111/16 debate [1] 61/8 debates [1] 58/20 decade [2] 39/5 128/8 decades [1] 79/14 deceased [6] 43/11 43/18 65/16 73/20 73/22 75/25 December [2] 5/22 143/19 December 2002 [1] 143/19 December 2003 [1] 5/22 decide [1] 168/8
----------	---	--	--	---	---

(49) concerns - decide

D	117/5 123/19	65/3 65/12 85/7 97/14	discounts [1] 163/5	do [82] 1/10 1/11 1/20	33/14
decided [5] 16/1	description [1] 12/12	97/15 113/6 134/21	discourage [1] 72/14	3/12 7/25 8/1 19/5	don't [56] 3/10 11/7
46/23 50/10 58/6	design [2] 119/17	143/3 147/14 148/1	discover [2] 9/19	20/16 22/6 23/24 27/6	11/13 17/6 19/9 20/10
75/17	121/16	150/14 156/2 157/12	49/21	27/9 32/7 32/8 33/16	24/5 25/3 27/7 27/21
decision [4] 16/10	designation [1] 48/21	157/25 158/3 158/14	discovered [1] 164/17	44/4 44/10 45/3 49/4	30/8 44/9 45/1 47/8
42/4 70/5 134/22	designed [1] 92/19	158/18 159/19 164/9	discrete [1] 71/7	49/20 54/4 55/25	51/12 56/3 59/21 61/2
decision-maker [1]	desire [2] 118/24	166/16	discriminate [1]	57/24 70/16 70/21	62/7 62/22 69/6 70/22
70/5	139/12	die [2] 24/15 113/6	166/16	71/17 75/17 80/10	71/4 71/5 75/13 80/10
decisions [4] 55/24	desired [1] 164/11	died [14] 23/9 24/23	discuss [3] 33/22	85/1 85/13 85/21 86/7	85/9 92/21 93/1 93/2
74/19 133/25 167/17	despite [3] 70/19	65/12 65/13 68/14	89/9 138/25	86/9 87/15 88/16	93/7 94/24 95/12
decline [1] 96/18	101/12 138/21	73/25 75/4 76/22	discussed [9] 2/21	89/24 93/1 93/7 94/7	98/18 106/3 111/12
declining [1] 96/19	destination [1] 8/13	79/25 80/12 92/14	34/22 43/25 62/12	94/22 98/5 100/2	115/15 122/8 131/2
decrease [1] 111/17	destroyed [5] 73/24	101/5 103/3 113/6	64/18 68/12 89/6	112/21 112/24 118/14	131/15 133/22 134/24
decreased [1] 101/24	74/5 75/4 76/1 80/13	difference [4] 105/20	104/9 125/4	118/16 120/17 120/18	135/3 142/21 146/16
dedication [1] 144/9	detail [11] 10/25	113/13 113/18 115/9	discussion [4] 9/13	120/19 120/24 121/2	149/20 152/22 153/16
deferred [1] 39/22	11/13 19/16 20/11	differences [1] 128/15	36/4 55/14 152/17	121/7 121/17 123/11	154/1 157/23 160/6
deficient [1] 31/8	24/5 29/23 34/4 40/13	different [30] 26/21	discussions [8] 9/16	123/25 126/15 127/24	161/19 162/3 164/6
definition [1] 118/5	75/8 123/20 157/10	31/11 36/4 36/5 59/1	34/2 53/15 135/13	130/12 130/23 131/18	167/7 167/23
degree [4] 150/17	detailed [4] 56/9 73/2	63/25 80/5 90/8 92/23	135/16 135/22 135/22	131/19 136/19 137/15	donate [4] 126/4
154/2 159/1 165/20	81/5 144/3	93/20 94/13 98/1	143/13	138/3 143/5 144/3	126/6 128/14 129/14
deliberately [1] 81/20	details [3] 11/8 85/16	98/11 99/15 100/21	disease [29] 3/25 5/1	144/17 146/18 146/23	donated [3] 125/1
Deloitte [3] 163/16	121/5	100/22 105/8 115/11	8/9 8/12 9/24 10/4	148/18 151/10 151/12	125/19 125/19
164/3 164/14	determine [2] 7/20	120/1 120/6 122/15	16/23 18/15 22/12	151/13 151/19 155/20	donates [1] 125/17
demand [1] 114/5	117/11	123/3 127/24 134/7	24/13 24/25 26/25	156/18 161/19 162/10	donating [1] 126/5
demonstrate [1]	determined [2] 14/18	137/20 151/22 157/8	36/14 37/8 39/3 53/8	162/22 165/19 167/21	donation [3] 5/22
166/18	28/12	157/8 165/21 165/21	57/3 61/18 64/3 68/9	168/6	125/15 129/11
department [33] 14/8	develop [7] 10/3 13/8	difficult [12] 63/24	74/1 79/4 81/6 82/3	doctor [2] 63/9 150/11	donations [7] 6/12
37/19 50/17 51/13	23/6 53/11 127/9	80/12 80/15 80/20	94/2 97/25 130/11	doctors [11] 14/3 14/5	20/3 127/2 127/8
51/16 51/20 52/16	158/3 160/4	82/23 85/11 105/7	135/23 159/25	15/3 22/23 23/20 47/5	127/18 128/19 130/19
52/19 52/21 52/24	developed [11] 4/22	105/13 118/6 118/17	diseases [1] 57/2	47/6 63/5 98/5 98/5	done [14] 9/1 20/19
53/12 56/2 78/24 80/9	6/13 9/24 10/9 20/4	124/20 166/18	disorder [4] 83/9	156/9	89/23 90/4 91/21 92/2
80/25 81/11 84/21	24/24 57/6 75/1 127/2	difficulties [1] 143/21	84/14 91/2 94/15	document [11] 11/1	108/5 116/13 116/14
123/1 126/20 140/14	130/5 160/7	difficulty [7] 64/7 64/8	disorders [12] 8/18	18/23 35/15 35/16	117/6 130/12 143/10
140/25 141/5 141/12	developing [3] 7/10	66/4 69/4 105/12	15/16 17/14 19/11	42/15 76/18 86/24	151/20 166/18
147/23 148/6 149/1	24/12 69/7	118/9 166/14	23/23 46/9 46/16	87/6 102/5 148/23	donor [13] 12/5 21/18
149/12 150/6 161/21	development [1] 55/3	digest [1] 63/7	62/15 76/18 77/5 83/4	152/3	23/5 125/12 125/16
161/21 161/25 163/11	device [1] 163/17	digging [1] 94/5	102/13	documentary [1] 75/3	125/16 128/11 128/12
164/2	diagnosed [3] 79/18	Digital [4] 63/23 64/4	Disorders: [1] 76/14	documentation [3]	129/9 129/10 129/17
department's [1]	79/21 84/13	67/17 69/2	Disorders: 2009/10 [1]	40/14 74/11 76/2	130/21 130/23
164/5	diagnoses [1] 90/15	direct [2] 51/12 86/6	76/14	documented [5] 7/17	donors [25] 124/22
departments [1]	diagnosis [4] 27/1	directed [4] 25/14	displeasure [1] 4/23	7/23 74/24 80/19 84/3	125/9 125/18 125/18
93/14	46/15 77/18 124/11	86/23 129/15 130/16	disposable [5] 9/1	documents [11] 6/5	125/21 125/22 125/22
dependent [3] 135/6	dialogue [1] 34/11	directly [4] 4/24 5/1	29/14 35/2 39/12 40/7	8/3 10/20 11/2 15/6	125/23 126/1 126/1
162/4 162/5	did [48] 3/14 8/12	75/12 123/17	dispose [1] 93/16	17/11 32/5 34/5 41/14	126/4 126/12 126/13
dependents [1] 73/20	13/18 17/17 24/15	director [9] 19/6	dispute [1] 154/1	42/13 148/23	127/6 127/11 127/20
depending [4] 48/20	26/20 27/3 51/10	28/19 44/4 44/5 45/4	disseminated [1]	does [15] 1/21 13/2	129/12 129/21 129/22
49/22 89/11 90/8	51/15 53/12 59/19	56/17 150/2 155/1	69/15	13/7 15/25 22/3 27/18	129/23 130/3 130/3
deposit [2] 44/15	60/3 61/1 62/20 72/5	168/18	dissolve [1] 156/2	34/24 35/5 51/20	130/9 130/17 130/20
44/15	72/6 75/23 77/17 80/8	Directorate [1] 163/16	dissuade [2] 142/1	101/16 114/24 128/16	dose [2] 118/8 118/8
deprecate [1] 72/13	82/7 88/8 96/16 100/2	directors [23] 8/6	142/7	130/24 137/4 161/16	dot [1] 115/4
derive [1] 127/10	112/17 122/5 123/6	14/4 14/24 19/25	distinction [2] 114/24	does it [4] 15/25 35/5	double [1] 37/9
derived [2] 125/6	123/25 128/18 130/14	20/16 22/7 23/21	115/13	114/24 130/24	doubled [3] 108/21
126/3	132/20 133/4 133/16	27/11 28/10 28/23	distress [2] 27/6	doesn't [10] 23/19	110/4 110/9
describe [6] 89/11	136/8 142/6 142/8	33/13 46/3 47/2 56/7	74/14	25/19 62/24 85/6	doubt [2] 74/19
89/14 90/16 115/8	148/6 149/22 152/16	102/15 103/21 139/25	distressed [2] 26/18	88/23 97/14 104/19	160/16
133/4 150/17	152/24 155/19 156/21	143/6 143/8 143/13	153/7	114/23 119/17 136/4	down [17] 1/22 10/6
described [9] 2/7 6/17	158/1 160/4 160/5	149/15 149/18 149/24	distribute [1] 62/4	doing [12] 66/13	57/12 67/13 83/1
13/23 48/11 54/6	160/22 162/23 162/24	disagreed [1] 118/15	distribution [1] 20/8	70/24 70/25 89/15	89/22 102/25 116/6
69/19 99/18 107/8	164/16	disappear [1] 167/7	district [2] 57/22	90/3 90/10 96/8	130/24 137/24 146/13
162/21	didn't [29] 18/8 18/10	disappointed [1]	79/15	117/18 118/10 118/13	149/4 152/8 157/17
describing [3] 70/8	22/13 31/12 36/17	144/2	divided [1] 48/13	120/22 138/19	164/6 166/2 166/20
	44/1 57/2 57/24 64/9	disciplinary [1] 166/5	DNA [1] 94/9	Dolan [3] 32/20 33/13	downwards [2] 39/7

(50) decided - downwards

D	33/21 34/9 34/11 62/3 67/1 67/7 89/3 115/12 120/19 164/12 165/23 earlier [14] 5/9 5/10 5/16 18/9 48/2 68/6 68/12 72/8 110/22 123/12 126/19 141/14 151/2 163/7 early [33] 10/7 51/8 53/21 57/1 72/4 72/18 75/8 77/9 85/10 85/12 105/6 108/18 111/6 112/15 119/6 119/8 123/22 124/23 125/17 126/11 126/22 127/21 128/6 129/7 129/7 129/24 136/12 136/24 137/9 154/13 155/2 158/4 161/1 early eighties [1] 111/6 ease [1] 166/7 easier [2] 86/8 103/11 easily [1] 156/2 easy [2] 27/1 90/17 Edinburgh [3] 42/1 43/25 48/7 edit [1] 148/19 edition [1] 133/1 educated [1] 38/22 effect [6] 78/17 96/8 117/7 119/25 164/11 167/1 effectively [4] 30/4 52/4 78/14 78/22 efficacy [2] 55/16 116/17 Efforts [1] 7/18 eggs [1] 161/10 eight [2] 9/25 21/22 eighties [7] 77/9 111/6 112/15 125/8 125/25 126/23 136/10 either [13] 5/14 29/5 41/11 50/1 51/13 56/1 63/5 63/9 74/6 93/3 98/17 142/6 165/16 elect [1] 46/16 elected [3] 49/2 49/11 49/19 election [1] 49/16 electronic [1] 67/7 element [3] 67/19 81/12 156/14 elements [1] 140/11 Elephant [1] 64/15 elicit [1] 99/6 eligible [2] 68/19 75/2 eliminating [2] 160/9 160/10 else [9] 26/21 37/7 91/21 92/2 94/3	145/18 159/8 159/13 162/5 elsewhere [3] 40/14 109/8 159/3 Elstree [1] 154/18 email [6] 19/21 20/1 21/1 21/13 21/15 87/11 emails [2] 87/5 151/6 embittered [2] 151/17 157/20 emerge [2] 84/18 158/13 emerged [2] 36/21 97/7 emotional [1] 151/16 emphasise [1] 152/11 emphasised [1] 14/21 employed [2] 57/9 148/3 employing [1] 57/23 enabled [1] 163/6 enables [1] 67/5 enclosed [1] 23/22 encloses [1] 24/3 enclosing [1] 33/14 encourage [1] 137/16 encouraged [3] 68/20 126/2 137/16 encouraging [3] 138/13 138/18 140/11 end [6] 30/18 79/1 90/12 125/25 142/5 168/18 ending [1] 162/18 endoscope [5] 36/13 36/18 37/2 37/9 38/1 endoscopes [8] 9/2 35/1 36/15 37/5 37/14 37/15 38/6 39/13 endoscopies [3] 36/2 36/3 36/9 endoscopy [3] 36/10 37/9 37/16 engage [1] 168/10 engaged [1] 119/7 engineer [1] 57/10 England [8] 53/19 55/10 55/11 55/15 55/23 65/6 119/24 120/5 enhance [1] 152/15 enormous [1] 164/21 enough [2] 52/16 107/25 enquire [1] 41/5 enquirer [1] 13/24 enquiry [3] 142/10 149/17 152/13 ensuing [1] 36/4 ensure [5] 15/10 15/18 18/6 25/22	134/21 entire [2] 49/17 167/11 entirely [10] 49/7 62/22 66/14 70/14 81/10 117/13 142/24 150/4 150/7 152/1 entitled [1] 76/12 entries [1] 145/10 episodes [2] 124/15 145/16 era [3] 106/25 153/12 153/22 eradicate [1] 124/21 Err [1] 27/20 error [1] 32/2 errors [1] 33/23 essentially [6] 3/6 20/15 87/1 88/3 93/8 137/13 establish [3] 43/5 43/20 116/17 established [11] 12/19 56/12 56/14 56/15 60/3 105/18 105/24 110/13 111/22 112/12 163/4 establishment [1] 53/22 estimate [3] 6/21 84/11 130/25 et [3] 15/14 128/9 144/4 ethical [8] 40/21 43/24 44/1 115/11 121/3 121/11 121/17 122/20 ethics [9] 62/14 62/20 67/8 67/9 117/25 121/8 121/13 122/17 122/25 ethnic [2] 128/13 128/15 Europe [1] 59/8 European [1] 124/4 evaluate [2] 124/15 127/7 evaluation [3] 90/18 91/6 166/15 even [23] 9/20 15/22 27/3 49/5 57/3 73/21 74/1 74/3 75/3 79/14 85/12 92/13 94/25 98/4 122/24 135/24 144/1 147/12 148/19 157/24 164/3 164/19 166/9 event [4] 5/17 123/18 123/19 131/17 events [3] 15/23 123/21 124/1 eventually [5] 36/21	37/12 37/18 64/11 137/16 ever [8] 16/5 48/3 71/4 123/6 133/3 137/1 150/5 156/21 every [12] 11/1 16/4 88/18 89/15 89/22 89/23 121/11 125/24 136/23 139/12 144/14 166/15 everybody [4] 16/9 55/23 81/5 163/15 everyone [4] 8/22 63/17 112/12 113/19 everything [2] 26/20 121/9 everywhere [1] 40/1 evidence [36] 2/13 22/11 24/11 24/18 25/11 36/17 36/21 36/24 59/20 74/3 74/7 75/20 83/20 83/23 96/14 96/14 101/17 101/23 102/7 104/1 119/15 126/21 142/10 145/12 154/14 159/14 167/6 167/13 168/7 168/12 168/13 168/17 168/21 169/2 169/11 169/12 exactly [5] 3/20 54/3 55/12 114/10 147/14 examination [3] 41/19 41/24 43/14 examined [2] 42/2 44/3 examining [1] 75/6 example [36] 16/19 36/15 36/22 40/8 54/25 55/4 55/10 55/14 55/20 56/23 61/5 65/6 89/6 89/12 92/22 94/9 94/11 95/5 99/4 116/11 118/8 119/22 121/15 121/24 124/8 128/19 128/22 129/25 135/22 136/24 139/15 140/9 153/23 160/3 161/3 166/21 exceeded [1] 164/13 exception [1] 160/25 exchange [2] 4/13 142/8 exclude [3] 28/1 28/4 119/21 excluding [1] 119/20 exclusion [1] 129/11 exclusively [1] 31/3 excreted [1] 167/5 Excuse [1] 141/4 executive [7] 33/24 58/5 68/6 73/14 73/14	138/18 152/6 exemption [5] 66/9 66/10 68/19 70/1 70/16 exemptions [1] 71/6 exercise [31] 4/12 5/19 6/6 10/11 12/3 13/24 16/1 20/19 22/9 22/16 22/19 24/8 26/9 26/17 28/7 28/21 29/1 32/17 34/7 34/19 38/4 38/14 76/9 76/13 78/18 79/8 81/21 82/13 82/21 82/22 84/20 exercises [4] 2/5 82/2 86/7 130/13 exhibit [3] 81/14 106/8 126/19 exhibited [4] 24/6 30/11 32/6 40/17 exhibition [2] 134/15 134/16 exhibits [9] 9/8 40/11 61/25 63/3 66/21 92/10 102/9 126/19 127/14 existence [1] 112/16 exists [2] 46/6 145/23 expect [6] 71/20 84/2 105/19 113/18 114/3 121/13 expectancy [13] 87/4 101/18 101/25 103/15 104/13 104/16 105/1 105/5 105/23 106/17 106/23 111/17 112/7 expectation [3] 14/13 103/10 158/7 expectations [1] 164/13 expected [3] 52/25 135/13 158/13 expensive [3] 4/8 37/10 164/22 experience [5] 64/4 112/20 136/3 136/15 159/23 experiences [1] 151/17 experiments [1] 119/22 expert [1] 147/1 explain [7] 18/9 26/11 77/14 86/4 91/5 93/24 146/16 explained [4] 90/5 95/10 143/2 148/14 explaining [2] 20/12 71/20 explains [6] 12/9 21/17 23/1 23/7 41/25
E	each [20] 6/22 6/22 9/7 9/9 15/18 17/23 29/25 33/19 33/20				

(51) downwards... - explains

E explains... [1] 115/10 explanation [1] 12/22 explicitly [1] 94/6 explore [3] 63/19 96/10 109/8 exposed [12] 6/11 9/19 9/21 16/20 72/20 72/21 79/19 84/7 127/6 127/8 127/18 158/6 exposure [11] 7/17 7/22 9/25 17/8 17/22 18/21 24/14 25/6 83/11 83/23 84/3 express [4] 69/24 70/12 70/12 73/17 expressed [3] 3/12 3/13 30/17 expresses [1] 107/11 expressing [1] 4/22 expressly [1] 104/6 extend [2] 87/17 166/24 extended [4] 49/3 55/16 55/17 166/21 extensive [1] 72/19 extensively [1] 101/22 extent [12] 7/16 7/22 13/6 25/15 43/5 44/6 50/16 75/10 75/24 133/11 160/23 164/13 external [1] 6/15 extract [2] 75/21 144/24 extrapolate [2] 81/2 81/9 extrapolations [1] 83/1 extremely [4] 60/21 79/8 93/23 146/3	33/4 35/7 35/8 55/2 55/16 74/22 107/14 107/14 108/21 108/25 110/1 110/6 114/17 114/18 116/16 144/14 144/15 163/19 164/17 165/6 Factor IX [4] 33/4 35/8 107/14 144/15 Factor VIII [18] 23/4 23/11 33/3 35/7 55/2 55/16 107/14 108/21 108/25 110/1 110/6 114/17 114/18 116/16 144/14 163/19 164/17 165/6 Factor XI [2] 31/6 31/7 factors [2] 23/3 55/2 factual [4] 88/4 96/11 142/16 143/12 fair [1] 111/11 fairly [7] 2/10 38/1 87/6 100/12 109/21 114/20 147/25 faith [1] 154/4 fall [2] 7/13 129/13 fallen [1] 77/22 false [4] 30/13 124/9 140/4 142/24 familial [1] 94/16 familiar [2] 28/25 142/14 far [28] 10/8 13/19 13/21 14/12 14/18 21/25 38/24 38/25 46/19 47/13 52/18 56/4 72/5 74/11 81/16 83/5 88/23 93/14 96/14 114/22 125/4 126/4 131/1 140/2 146/22 157/13 159/22 169/4 fatal [1] 158/2 fate [1] 53/8 fault [1] 139/17 favour [2] 62/20 141/10 February [3] 22/22 26/4 26/10 February 16 [1] 26/10 February 2009 [1] 22/22 fee [3] 50/11 72/9 72/11 feeding [2] 146/14 146/19 feel [5] 49/22 138/3 140/7 152/24 157/12 feeling [2] 139/14 150/21 fees [1] 51/4	felt [25] 8/19 8/22 15/21 16/11 22/15 25/9 39/11 54/6 54/7 57/19 59/4 60/23 65/22 66/16 68/9 70/22 76/4 83/8 100/23 134/24 135/4 140/19 152/20 153/3 157/17 few [7] 24/24 38/3 90/20 96/8 101/4 143/17 161/2 fewer [4] 55/18 116/1 155/14 155/15 fictitious [1] 150/4 field [1] 131/10 fighting [2] 149/15 149/24 figure [2] 104/25 127/11 figures [5] 103/5 103/17 109/10 109/20 113/13 file [1] 15/18 fill [3] 34/12 78/22 116/4 final [7] 34/13 57/4 81/15 123/20 148/23 148/23 152/3 financial [6] 3/5 3/21 56/9 75/7 140/24 161/22 find [12] 29/4 72/22 125/20 127/14 136/15 144/2 148/8 148/12 148/14 148/16 153/17 159/6 finding [1] 22/24 findings [2] 25/9 132/21 fine [1] 51/1 finish [1] 18/10 firm [1] 6/15 first [42] 1/6 12/3 12/5 15/5 19/5 20/23 23/14 46/20 54/1 56/19 69/3 72/20 74/16 77/3 86/23 93/12 93/23 93/23 97/9 102/1 102/7 103/1 103/25 106/13 106/14 106/16 107/5 107/10 113/9 115/7 125/18 125/21 126/13 129/25 130/2 133/1 133/2 152/5 154/13 163/1 163/14 163/17 first-time [2] 125/21 130/2 firstly [1] 68/22 fit [1] 137/10 five [5] 48/4 66/1	130/2 130/3 146/13 five years [1] 66/1 fixed [1] 118/12 flavour [1] 81/16 flower [1] 105/23 focused [2] 56/25 78/23 focusing [1] 55/6 fold [1] 53/9 follow [20] 15/25 19/12 27/10 28/16 30/8 30/9 65/25 68/15 77/13 77/17 77/21 80/11 82/25 84/6 86/9 91/3 98/16 115/5 118/25 141/25 follow-up [11] 19/12 28/16 65/25 68/15 77/13 77/21 80/11 82/25 84/6 91/3 98/16 followed [7] 29/6 29/6 61/8 78/8 109/4 111/25 144/10 following [12] 2/7 14/20 26/23 37/22 42/12 43/6 75/11 84/20 103/23 119/22 129/13 169/5 follows [1] 71/15 Food [1] 124/5 football [1] 137/13 force [2] 58/19 60/10 forgot [1] 34/25 form [32] 17/8 17/13 41/17 42/23 43/15 46/20 50/20 58/21 61/1 61/20 65/4 66/8 67/3 69/23 70/13 91/13 92/7 92/11 92/11 92/19 92/25 93/4 93/24 110/1 121/10 139/16 141/6 145/6 145/9 145/22 145/24 146/5 formal [3] 33/20 92/8 96/25 formalised [1] 49/6 formally [2] 56/12 132/12 formed [3] 51/4 51/9 107/23 forms [6] 9/8 66/22 67/19 116/4 117/12 119/11 fortunately [2] 86/13 160/10 forums [1] 151/23 forward [1] 87/20 found [6] 23/15 24/17 82/22 83/25 156/2 166/16 four [9] 27/16 46/19	60/17 79/14 122/23 132/2 132/4 132/5 167/15 four o'clock [3] 132/2 132/4 132/5 four years [1] 46/19 fourth [7] 21/4 21/6 21/16 22/7 35/15 106/11 108/12 fractionators [1] 6/20 frame [1] 16/6 France [2] 115/25 115/25 Frank [1] 3/7 frankly [5] 26/24 44/24 145/14 157/18 164/13 Free [12] 3/1 31/4 31/5 31/6 31/20 32/6 32/10 32/13 37/24 48/5 159/10 159/15 freedom [2] 163/20 165/20 frenzy [2] 146/15 146/19 frequency [3] 65/24 126/24 128/16 frequently [6] 49/20 65/21 84/16 126/5 154/20 154/23 friendly [1] 72/16 from [192] front [1] 35/19 fulfilled [1] 59/11 full [3] 14/7 114/7 144/22 fully [6] 3/10 29/21 97/7 97/10 105/23 116/21 function [10] 47/11 57/21 57/24 89/13 89/17 90/22 96/5 98/6 98/7 98/12 functioning [1] 45/21 functions [1] 46/10 fund [9] 54/25 73/8 73/9 73/13 73/19 75/12 75/18 79/7 134/1 fundamental [1] 64/22 funded [4] 50/3 51/22 53/4 54/22 funding [22] 50/4 50/16 50/18 51/10 51/13 51/16 51/21 52/1 52/4 52/23 53/7 53/10 53/13 53/17 53/18 54/12 54/14 79/6 133/23 149/3 163/11 163/12 further [24] 8/10 16/1	20/2 20/13 22/9 22/16 22/18 41/14 42/15 61/5 62/5 81/24 84/18 87/12 93/17 112/24 124/15 131/12 140/14 149/4 160/17 160/18 167/21 168/7 future [6] 58/1 92/18 92/25 93/9 93/10 93/11
F face [5] 13/6 66/5 66/5 67/12 67/12 face-to-face [2] 66/5 67/12 faces [1] 1/12 facilitate [4] 53/12 86/8 92/17 166/4 facilitated [1] 53/15 fact [20] 4/3 24/15 31/20 31/23 33/10 37/7 43/21 56/19 65/25 68/13 72/6 101/13 111/24 113/17 117/23 126/18 130/24 132/16 139/17 158/17 factor [26] 17/18 23/4 23/11 31/6 31/7 33/3	fatal [1] 158/2 fate [1] 53/8 fault [1] 139/17 favour [2] 62/20 141/10 February [3] 22/22 26/4 26/10 February 16 [1] 26/10 February 2009 [1] 22/22 fee [3] 50/11 72/9 72/11 feeding [2] 146/14 146/19 feel [5] 49/22 138/3 140/7 152/24 157/12 feeling [2] 139/14 150/21 fees [1] 51/4	felt [25] 8/19 8/22 15/21 16/11 22/15 25/9 39/11 54/6 54/7 57/19 59/4 60/23 65/22 66/16 68/9 70/22 76/4 83/8 100/23 134/24 135/4 140/19 152/20 153/3 157/17 few [7] 24/24 38/3 90/20 96/8 101/4 143/17 161/2 fewer [4] 55/18 116/1 155/14 155/15 fictitious [1] 150/4 field [1] 131/10 fighting [2] 149/15 149/24 figure [2] 104/25 127/11 figures [5] 103/5 103/17 109/10 109/20 113/13 file [1] 15/18 fill [3] 34/12 78/22 116/4 final [7] 34/13 57/4 81/15 123/20 148/23 148/23 152/3 financial [6] 3/5 3/21 56/9 75/7 140/24 161/22 find [12] 29/4 72/22 125/20 127/14 136/15 144/2 148/8 148/12 148/14 148/16 153/17 159/6 finding [1] 22/24 findings [2] 25/9 132/21 fine [1] 51/1 finish [1] 18/10 firm [1] 6/15 first [42] 1/6 12/3 12/5 15/5 19/5 20/23 23/14 46/20 54/1 56/19 69/3 72/20 74/16 77/3 86/23 93/12 93/23 93/23 97/9 102/1 102/7 103/1 103/25 106/13 106/14 106/16 107/5 107/10 113/9 115/7 125/18 125/21 126/13 129/25 130/2 133/1 133/2 152/5 154/13 163/1 163/14 163/17 first-time [2] 125/21 130/2 firstly [1] 68/22 fit [1] 137/10 five [5] 48/4 66/1	130/2 130/3 146/13 five years [1] 66/1 fixed [1] 118/12 flavour [1] 81/16 flower [1] 105/23 focused [2] 56/25 78/23 focusing [1] 55/6 fold [1] 53/9 follow [20] 15/25 19/12 27/10 28/16 30/8 30/9 65/25 68/15 77/13 77/17 77/21 80/11 82/25 84/6 86/9 91/3 98/16 115/5 118/25 141/25 follow-up [11] 19/12 28/16 65/25 68/15 77/13 77/21 80/11 82/25 84/6 91/3 98/16 followed [7] 29/6 29/6 61/8 78/8 109/4 111/25 144/10 following [12] 2/7 14/20 26/23 37/22 42/12 43/6 75/11 84/20 103/23 119/22 129/13 169/5 follows [1] 71/15 Food [1] 124/5 football [1] 137/13 force [2] 58/19 60/10 forgot [1] 34/25 form [32] 17/8 17/13 41/17 42/23 43/15 46/20 50/20 58/21 61/1 61/20 65/4 66/8 67/3 69/23 70/13 91/13 92/7 92/11 92/11 92/19 92/25 93/4 93/24 110/1 121/10 139/16 141/6 145/6 145/9 145/22 145/24 146/5 formal [3] 33/20 92/8 96/25 formalised [1] 49/6 formally [2] 56/12 132/12 formed [3] 51/4 51/9 107/23 forms [6] 9/8 66/22 67/19 116/4 117/12 119/11 fortunately [2] 86/13 160/10 forums [1] 151/23 forward [1] 87/20 found [6] 23/15 24/17 82/22 83/25 156/2 166/16 four [9] 27/16 46/19	60/17 79/14 122/23 132/2 132/4 132/5 167/15 four o'clock [3] 132/2 132/4 132/5 four years [1] 46/19 fourth [7] 21/4 21/6 21/16 22/7 35/15 106/11 108/12 fractionators [1] 6/20 frame [1] 16/6 France [2] 115/25 115/25 Frank [1] 3/7 frankly [5] 26/24 44/24 145/14 157/18 164/13 Free [12] 3/1 31/4 31/5 31/6 31/20 32/6 32/10 32/13 37/24 48/5 159/10 159/15 freedom [2] 163/20 165/20 frenzy [2] 146/15 146/19 frequency [3] 65/24 126/24 128/16 frequently [6] 49/20 65/21 84/16 126/5 154/20 154/23 friendly [1] 72/16 from [192] front [1] 35/19 fulfilled [1] 59/11 full [3] 14/7 114/7 144/22 fully [6] 3/10 29/21 97/7 97/10 105/23 116/21 function [10] 47/11 57/21 57/24 89/13 89/17 90/22 96/5 98/6 98/7 98/12 functioning [1] 45/21 functions [1] 46/10 fund [9] 54/25 73/8 73/9 73/13 73/19 75/12 75/18 79/7 134/1 fundamental [1] 64/22 funded [4] 50/3 51/22 53/4 54/22 funding [22] 50/4 50/16 50/18 51/10 51/13 51/16 51/21 52/1 52/4 52/23 53/7 53/10 53/13 53/17 53/18 54/12 54/14 79/6 133/23 149/3 163/11 163/12 further [24] 8/10 16/1	G gained [1] 140/10 game [1] 5/24 gap [3] 3/17 3/17 60/9 gathered [1] 11/9 gave [5] 5/2 16/16 28/22 67/8 148/4 GDPR [2] 64/20 72/11 gene [2] 94/16 94/17 general [26] 35/13 39/7 50/6 50/23 51/5 62/19 79/15 89/12 90/16 92/23 95/1 98/8 99/3 131/14 132/20 134/1 134/9 135/11 140/1 141/3 142/11 142/13 143/23 150/3 150/9 161/9 General Medical [2] 141/3 142/13 generality [1] 131/15 generally [2] 50/7 160/13 generate [2] 33/18 78/12 generated [2] 50/7 148/22 generic [2] 147/3 147/4 genes [1] 94/10 genetic [7] 91/14 91/25 92/6 92/22 93/19 94/20 100/3 Genetics [1] 92/19 genuine [1] 124/10 genuinely [2] 4/1 128/4 get [39] 4/12 13/10 15/10 34/18 36/19 45/12 53/18 54/24 57/20 64/6 65/9 65/11 66/5 66/7 66/10 66/12 66/25 72/15 72/17 80/3 80/23 89/21 90/21 97/25 100/2 100/2 109/10 120/23 122/11 122/24 123/1 125/6 135/19 138/15 140/7 155/6 161/7 161/18 164/3 gets [1] 150/9

G	goes [3] 146/4 146/8 150/20 going [45] 6/5 10/25 13/7 14/19 19/19 29/23 34/4 35/4 40/12 42/17 45/20 67/16 70/13 80/22 82/6 84/17 86/15 88/3 89/16 89/23 90/20 92/4 93/18 93/25 99/25 104/4 104/22 108/6 108/11 112/23 115/4 117/4 126/11 127/15 129/3 129/19 138/7 139/18 139/22 140/16 146/24 151/2 151/4 155/25 161/1 gone [8] 29/3 71/3 72/11 104/22 106/20 106/20 108/10 122/17 good [23] 1/3 1/4 3/24 92/21 95/8 97/23 100/24 100/25 126/17 133/17 137/11 137/15 138/14 154/4 157/7 157/9 157/10 157/13 159/4 159/11 160/9 161/3 164/9 got [21] 10/24 31/10 40/2 49/23 53/1 63/8 67/22 81/16 81/23 95/1 97/14 98/11 102/1 106/1 115/2 122/11 124/24 131/6 131/20 137/2 147/20 GP [6] 61/3 85/18 85/20 86/2 86/3 101/10 grade [3] 149/16 149/24 150/18 gradual [1] 111/9 grant [2] 54/5 54/5 grants [7] 53/5 53/6 53/23 54/4 54/7 54/9 54/24 grapevine [1] 2/24 grateful [1] 167/25 great [5] 7/6 113/12 147/21 157/18 157/25 greater [1] 123/20 greatest [1] 111/24 greatly [3] 107/14 151/15 153/22 Greaves [1] 121/1 grey [2] 116/5 117/22 grounds [1] 150/3 group [22] 28/9 31/7 31/10 52/20 64/14 64/17 65/2 65/23 71/12 74/8 83/21 84/10 95/9 98/9 103/4 103/5 126/14 154/6 157/16 160/14 164/5 166/6 groups [7] 12/25 120/7 128/13 128/16 129/14 129/16 159/6 growing [1] 37/5 guerilla [2] 149/24 150/18 guerrilla [1] 149/16 guide [1] 7/9 guidelines [1] 82/3 gut [2] 29/13 36/11 gym [1] 137/17	H had [220] hadn't [4] 27/2 98/17 106/20 168/12 haematologist [2] 101/13 123/4 Haematology [1] 102/4 haemophilia [89] 5/18 5/18 8/6 10/16 13/18 14/3 14/4 14/14 15/3 15/15 17/15 22/23 22/25 23/8 23/16 24/13 28/20 29/20 29/25 31/18 31/25 33/17 33/22 37/24 40/22 41/1 42/17 44/6 45/24 46/3 46/8 47/1 47/5 47/6 48/9 48/12 48/14 48/15 48/19 51/7 54/13 56/11 56/15 56/24 57/1 57/10 59/18 63/9 63/13 63/14 70/11 73/15 74/10 76/8 77/17 78/10 80/5 86/8 94/1 102/3 102/13 102/15 103/4 103/5 103/21 105/11 106/18 109/15 109/17 123/25 136/18 137/7 137/23 139/2 139/8 140/11 142/1 143/6 143/7 143/13 143/18 149/13 152/7 156/9 164/18 165/5 166/9 167/16 168/17 haemophilia A [5] 57/1 94/1 103/4 109/15 109/17 haemophilia B [1] 103/5 haemophiliac [1] 106/18 haemophiliacs [3] 103/16 103/20 136/11 haemophilic [2] 43/3 108/19	haemorrhage [3] 101/24 103/23 113/25 haemostasis [2] 105/11 133/3 half [18] 9/25 12/8 21/11 21/22 25/6 45/12 55/16 55/17 57/23 64/18 77/15 83/2 101/11 110/17 131/22 137/24 166/21 166/24 hand [3] 102/18 124/22 138/11 handful [4] 45/21 47/22 88/1 131/21 handle [2] 61/4 61/4 handled [2] 168/15 168/16 handling [2] 13/24 95/5 hang [1] 147/24 hangs [1] 136/18 happen [4] 49/12 150/14 154/22 155/20 happened [8] 5/2 10/7 30/14 30/15 34/6 48/2 75/19 155/22 happening [2] 64/19 148/5 happens [4] 13/8 49/12 93/13 150/8 happy [2] 27/7 94/15 hard [1] 108/16 hardly [2] 137/1 140/6 harm [2] 152/15 153/5 harm's [1] 121/20 harmonised [1] 59/7 has [65] 6/20 6/25 12/3 12/23 18/2 22/1 23/15 26/9 26/12 31/20 32/16 33/1 41/6 41/7 44/12 50/3 50/4 50/16 51/21 54/14 54/19 56/5 58/9 67/6 67/11 70/3 70/6 71/3 71/18 75/4 84/3 86/6 88/9 90/6 90/9 92/14 94/15 94/24 95/24 98/16 104/22 105/1 108/16 112/12 116/12 119/17 121/6 124/6 126/20 131/1 135/2 136/5 138/4 146/6 146/9 151/25 153/7 153/20 154/11 164/12 164/25 165/7 165/8 165/17 167/1 hasn't [2] 10/7 50/18 hasten [1] 85/13 hat [1] 53/3 have [285] haven't [5] 100/17	125/4 125/15 131/21 166/14 having [20] 4/23 4/24 18/19 21/6 21/20 32/4 36/3 36/8 40/20 51/25 97/13 99/5 101/19 109/15 116/24 121/20 130/5 141/6 158/17 167/8 HAY [25] 2/1 2/3 14/11 36/2 45/20 71/16 71/18 71/24 75/6 86/21 86/23 86/24 87/14 88/1 102/22 108/16 109/25 111/23 115/2 131/23 132/10 142/13 154/8 167/21 170/2 HBV [1] 123/7 HCDO0000002 [1] 71/9 HCDO0000131 [2] 20/25 21/11 HCDO0000133 [1] 2/16 HCDO0000254 [1] 4/14 HCDO0000266 [1] 143/15 HCV [14] 73/25 75/5 76/8 82/21 83/11 83/16 83/19 83/20 83/20 83/23 84/3 84/15 96/7 100/9 he [19] 23/8 24/24 25/3 25/4 41/8 56/21 71/20 101/12 101/13 113/5 113/5 117/17 117/22 132/25 142/20 148/5 148/14 148/15 148/16 he's [1] 148/19 headed [1] 82/16 heading [5] 14/1 35/25 42/20 102/19 102/24 headings [1] 11/25 headline [1] 104/25 health [59] 7/1 7/8 7/16 7/21 11/15 13/13 14/8 17/21 21/8 22/21 23/19 28/9 28/14 28/16 31/22 32/19 32/25 33/5 34/15 35/9 37/19 39/10 39/15 48/10 50/17 51/14 51/16 51/20 52/5 52/17 52/19 52/21 52/24 53/12 56/2 57/18 57/22 70/4 70/7 75/14 78/25 80/10 81/1 81/11 84/21	95/25 126/20 140/15 140/25 141/6 141/12 149/1 149/12 150/6 161/21 161/22 161/25 163/12 164/2 healthcare [2] 24/4 79/5 hear [4] 3/7 8/20 26/14 85/23 heard [5] 39/18 74/1 159/5 159/10 161/10 hearing [3] 1/14 169/11 169/18 heart [1] 127/4 heat [4] 122/3 155/17 155/25 160/11 heat labile [1] 160/11 heat-treated [1] 122/3 height [1] 153/11 held [15] 30/1 45/23 58/13 60/6 61/11 70/10 71/14 71/17 72/5 73/1 75/21 76/3 78/21 145/8 151/1 help [8] 34/1 40/19 43/7 79/6 140/23 141/4 148/8 166/3 helped [1] 52/7 helpful [6] 58/24 60/22 72/16 95/8 138/4 168/24 helps [1] 55/23 Hemostasis [1] 133/2 Henry [1] 76/10 hep [1] 76/20 hep C [1] 76/20 hepatitis [73] 26/22 51/11 72/23 74/23 75/1 76/13 76/24 77/8 78/4 81/21 82/16 89/16 91/6 95/23 96/1 96/2 96/2 96/17 97/1 97/3 97/21 98/4 98/13 98/17 98/18 98/20 99/2 99/3 99/8 99/21 123/8 123/15 123/15 123/22 124/9 124/10 124/15 124/16 124/19 124/20 124/21 124/22 125/2 126/15 126/21 126/24 127/3 127/10 127/12 127/17 127/21 127/25 129/17 129/18 130/6 130/15 130/18 135/15 135/23 138/2 138/12 149/17 158/9 158/11 159/18 159/19 159/20 160/5 160/7 160/9 160/11 160/15 168/20 hepatitis A [1] 96/2 hepatitis B [7] 77/8
----------	---	---	--	---	---

(53) getting - hepatitis B

H	history [17] 9/22 33/10 34/19 57/4 78/2 81/7 83/16 83/18 84/16 85/8 90/19 97/15 97/22 99/6 108/10 111/4 130/11 HIV [32] 26/21 89/7 97/1 97/5 97/7 97/14 97/19 99/4 100/5 100/10 100/14 100/22 101/5 101/9 101/10 101/11 111/20 111/25 123/14 129/15 129/16 133/16 135/23 153/12 153/22 157/5 157/25 158/14 160/10 160/11 160/15 161/2 HIV infection [1] 111/20 HIV testing [2] 97/1 97/7 hold [8] 44/7 59/5 70/25 72/6 85/6 85/9 86/9 108/6 holders [1] 49/23 holding [1] 69/21 holds [2] 85/5 145/6 Holland [1] 133/11 home [12] 105/18 105/25 112/12 112/14 112/17 113/21 114/13 114/19 114/20 132/13 132/17 133/20 homozygote [1] 25/4 homozygotes [2] 10/8 18/19 homozygous [1] 10/1 honest [11] 16/10 27/9 49/8 53/8 55/21 96/22 97/9 110/20 120/18 146/2 147/20 honestly [3] 4/9 80/7 141/11 hope [2] 121/20 168/24 hoping [1] 40/18 hospital [13] 3/1 8/24 37/12 37/15 61/3 73/1 79/15 91/4 122/10 122/20 123/4 137/1 147/18 hostile [1] 150/4 hour [6] 45/12 64/18 87/10 116/4 131/22 148/10 hour one [1] 148/10 house [5] 56/8 60/16 64/15 77/20 101/8 how [46] 3/20 4/9 9/16 13/2 24/8 32/8 32/8 36/9 38/16 49/22 50/3 55/4 56/23 63/4 76/20	76/22 77/14 78/18 79/6 81/16 82/6 91/19 92/1 95/7 103/11 104/7 126/15 127/1 127/7 130/3 131/19 133/25 135/18 140/7 142/21 147/14 150/5 151/16 154/17 154/22 155/19 158/3 161/7 165/12 168/14 168/16 however [2] 84/5 84/9 HPA [2] 10/18 33/14 HSC197630 [1] 48/11 HSG9330 [1] 48/17 HSOC [1] 137/19 HSOC0001265 [1] 152/3 HSOC0020017 [1] 148/24 huge [1] 156/18 Human [2] 44/12 88/22 husbands [1] 153/23 hyperlink [1] 63/14 hypothetical [1] 93/6 I I actually [2] 148/3 148/7 I agree [2] 108/3 113/15 I agreed [1] 157/18 I also [1] 128/9 I am [3] 60/18 138/2 138/13 I anticipate [1] 82/6 I appreciate [4] 91/23 111/6 120/25 153/14 I approached [1] 52/21 I arrived [1] 157/16 I ask [1] 156/12 I asked [1] 123/10 I be [1] 13/8 I became [2] 46/25 57/7 I been [1] 5/9 I being [1] 12/9 I bought [1] 56/20 I came [1] 144/20 I can [10] 72/2 113/24 114/7 116/5 129/1 131/8 146/23 148/9 153/23 162/10 I can't [10] 3/19 4/9 16/7 19/13 32/13 48/17 66/11 96/19 141/11 146/21 I certainly [1] 152/22 I conducted [1] 118/7 I could [2] 65/22 157/13	I couldn't [2] 49/8 157/22 I deprecate [1] 72/13 I detail [1] 19/16 I develop [1] 13/8 I did [2] 128/18 142/8 I didn't [1] 157/12 I do [4] 27/6 112/24 138/3 151/12 I don't [26] 17/6 19/9 24/5 27/7 30/8 44/9 45/1 51/12 56/3 71/5 80/10 92/21 93/2 94/24 122/8 131/2 133/22 134/24 135/3 142/21 149/20 152/22 154/1 157/23 160/6 167/23 I drifted [1] 126/7 I employed [1] 57/9 I entirely [1] 62/22 I ever [1] 133/3 I explained [1] 148/14 I felt [3] 65/22 100/23 140/19 I find [1] 159/6 I forgot [1] 34/25 I get [1] 138/15 I got [1] 147/20 I had [10] 4/6 37/7 62/17 64/13 66/6 111/9 112/18 112/20 139/12 140/10 I hasten [1] 85/13 I have [10] 47/16 61/24 81/14 106/2 132/18 146/5 151/24 153/5 153/6 167/19 I haven't [1] 131/21 I hear [1] 3/7 I heard [1] 159/5 I hope [1] 168/24 I inherited [1] 157/16 I just [8] 41/14 73/10 95/18 96/10 100/5 117/2 126/9 154/16 I knew [1] 140/2 I know [16] 43/23 44/2 45/6 64/2 85/4 85/20 86/11 89/12 106/9 111/4 127/15 133/18 136/6 149/2 167/13 168/1 I look [1] 87/19 I made [2] 65/10 65/20 I may [3] 1/6 86/21 87/3 I mean [11] 14/17 27/23 36/15 89/1 89/24 93/12 94/23 100/16 101/7 146/24	164/21 I might [1] 47/15 I need [1] 131/5 I never [2] 68/5 142/6 I no [1] 138/19 I note [3] 45/8 86/15 131/7 I only [1] 101/2 I perfectly [2] 151/15 151/17 I personally [1] 100/16 I put [1] 135/18 I refer [1] 143/8 I remember [2] 14/18 38/16 I right [1] 114/14 I said [1] 150/20 I saw [2] 38/18 91/1 I say [1] 99/8 I see [6] 98/10 130/8 154/24 157/3 163/3 165/11 I seem [1] 25/2 I shall [1] 87/15 I should [3] 82/1 104/18 168/23 I showed [1] 148/13 I started [1] 18/9 I suspect [4] 3/3 32/2 131/16 149/11 I take [1] 1/22 I think [98] 3/16 4/11 5/17 15/6 16/7 16/10 20/24 25/4 28/1 32/14 34/16 34/21 35/16 35/18 37/21 38/3 40/1 48/2 48/4 48/11 48/13 49/6 49/7 49/11 51/23 53/19 53/23 56/19 58/23 58/23 59/4 59/16 59/20 59/23 69/1 72/4 72/4 72/25 75/13 75/23 82/8 85/4 88/9 88/21 89/25 92/24 94/21 94/23 94/25 96/21 98/2 99/2 99/12 100/7 101/2 103/11 104/25 107/4 107/8 108/1 108/7 108/23 109/9 109/22 110/8 110/13 110/20 110/24 112/6 112/19 113/2 113/4 114/13 114/15 116/4 119/4 119/6 122/2 123/5 126/7 131/7 132/23 136/2 140/19 141/9 144/18 147/12 150/17 150/24 152/20 153/9 158/15 159/8 159/14 160/20 162/18 168/4	169/6 I thought [3] 65/8 126/22 159/9 I told [2] 65/23 160/3 I took [2] 52/2 52/10 I understand [10] 21/15 22/6 32/5 88/14 95/17 96/13 130/20 145/19 146/18 154/7 I understand it [3] 5/20 29/24 78/17 I want [4] 2/3 56/10 76/7 161/6 I wanted [6] 40/10 71/8 101/17 101/25 139/2 156/5 I was [20] 3/5 4/8 58/2 59/9 89/21 101/13 112/15 122/9 122/10 123/23 130/7 130/21 133/8 139/17 140/5 140/13 142/19 142/22 152/17 164/16 I wasn't [2] 44/2 132/23 I will [4] 41/4 90/17 90/19 123/19 I won't [1] 13/9 I worry [1] 3/9 I would [12] 5/9 87/4 91/5 91/6 97/2 98/12 100/19 113/17 138/1 138/22 156/17 167/14 I'd [2] 105/14 110/20 I'll [7] 1/19 57/4 70/8 82/12 102/6 106/3 109/16 I'm [38] 1/22 3/21 13/7 13/21 27/20 35/4 40/12 40/18 43/20 45/6 45/8 45/20 47/13 48/6 49/7 49/10 51/19 86/15 88/23 93/15 96/8 98/1 100/21 104/4 104/21 108/5 108/6 108/14 112/23 128/24 129/4 138/7 138/10 143/1 151/4 153/15 160/25 168/25 I've [21] 31/10 47/19 51/24 52/25 54/5 54/7 90/19 101/9 101/14 102/1 105/9 108/10 115/2 115/3 117/9 117/10 131/6 131/20 135/20 149/20 153/18 I've probably [1] 31/10 iatrogenic [1] 153/25 idea [3] 133/17 135/7 138/20 identification [2]
----------	--	---	---	---	---

(54) hepatitis B... - identification

I	impossible [2] 66/6 81/13 impractical [1] 68/17 impression [5] 72/3 72/13 100/12 138/16 140/10 improve [1] 165/2 improved [5] 37/18 104/12 105/22 106/24 107/15 improves [1] 155/14 imputed [1] 82/19 inadequate [4] 121/16 121/18 133/15 161/5 inception [1] 74/9 incidence [1] 159/25 incidentally [2] 82/1 120/11 incidents [10] 6/8 10/12 10/21 12/19 14/14 16/3 16/8 38/14 39/16 127/25 include [6] 20/3 46/10 47/5 47/21 96/6 97/13 included [11] 8/25 10/15 20/13 48/4 60/12 61/25 63/16 66/21 74/9 81/14 83/9 includes [2] 81/23 95/3 including [10] 6/17 8/16 23/4 23/23 28/10 68/13 82/3 96/8 111/22 123/22 income [2] 50/6 53/10 incompetent [1] 151/21 incomplete [1] 82/24 increase [4] 111/16 141/2 149/9 160/19 increased [3] 31/22 101/23 165/7 increases [1] 110/16 increasing [5] 65/5 107/13 107/23 125/10 138/3 increasingly [1] 109/3 increment [2] 112/6 166/18 incubating [1] 125/2 incubation [1] 21/24 incurred [1] 4/5 indeed [7] 43/18 62/13 82/2 95/7 97/6 135/4 168/22 indefinitely [1] 92/12 independent [1] 127/16 index [2] 27/15 89/9 indicate [1] 41/2 indicated [5] 41/7 67/24 68/7 114/10	116/9 indication [1] 129/7 individual [17] 7/15 7/16 7/20 7/22 8/1 8/6 17/23 39/18 95/13 95/14 135/3 135/5 138/8 139/6 142/17 150/9 155/5 individually [3] 120/19 142/6 146/17 individuals [7] 6/12 7/9 9/3 33/3 33/8 35/7 68/5 industry [3] 50/23 53/4 54/25 inexpensive [2] 4/2 4/3 infection [5] 74/24 111/20 111/25 123/7 130/4 infectious [2] 127/12 127/20 infectivity [2] 6/21 130/21 Infirmity [1] 91/13 influence [6] 134/21 140/17 141/7 141/9 150/5 150/23 influenced [2] 117/22 133/4 inform [4] 5/7 16/12 25/10 60/10 informal [1] 49/6 informally [1] 133/19 information [57] 1/13 10/13 11/5 11/9 11/14 11/18 11/24 13/5 13/18 14/2 15/12 16/16 18/6 18/8 18/14 24/3 25/23 30/1 34/1 35/5 36/7 57/11 58/12 59/9 59/14 60/14 60/15 62/12 62/16 66/21 67/4 69/15 71/2 71/14 71/19 72/23 73/1 78/21 79/2 81/24 91/16 91/19 92/4 96/3 98/20 121/10 122/6 122/14 144/22 145/1 145/3 145/8 145/20 145/22 145/23 147/13 161/7 informed [20] 4/23 5/6 5/9 5/16 8/2 8/7 15/22 15/23 18/3 42/5 60/5 61/16 65/9 65/22 69/20 107/23 115/22 157/14 157/21 159/13 informing [1] 22/23 infrequently [1] 98/15 Inga [1] 133/10 Inga Marie Nilsson [1] 133/10	inherited [3] 46/8 46/15 157/16 inhibitor [1] 55/2 initial [1] 8/17 initially [4] 51/4 56/22 56/25 160/2 initials [1] 47/2 initiation [1] 46/12 initiative [1] 133/20 inquiry [16] 1/16 75/6 81/22 84/19 86/25 131/13 131/14 149/23 150/6 150/23 150/25 151/2 151/6 151/11 153/7 153/16 Inquiry's [2] 58/11 82/11 insecure [1] 53/7 insertions [1] 15/13 insight [1] 168/12 insignificant [1] 112/8 insist [1] 101/9 insofar [2] 30/2 124/10 instances [1] 28/15 instead [1] 71/21 instruction [1] 37/1 instructions [1] 29/5 instrument [3] 36/19 37/3 37/10 instruments [11] 9/2 28/15 29/14 35/2 36/22 37/17 37/20 39/12 39/13 39/24 40/8 insurance [5] 13/10 13/12 97/17 101/6 101/8 Insurers [1] 13/12 intemperate [1] 151/8 intensification [1] 133/16 intensity [1] 165/2 intent [1] 117/21 intention [2] 43/19 69/22 interactions [1] 67/13 interest [8] 52/16 53/1 55/22 82/10 121/12 132/22 143/23 167/16 interested [2] 117/18 147/5 interested in [2] 117/18 147/5 interesting [4] 16/7 52/13 117/20 141/22 interestingly [1] 141/21 interests [1] 152/14 interfere [2] 1/21 150/11 intermediate [2]	111/1 112/10 international [1] 56/18 internationally [1] 115/18 interpretation [3] 25/9 110/8 118/1 interrupted [1] 69/21 interrupting [1] 129/4 interruption [1] 163/24 interruptions [1] 163/23 intervals [3] 62/2 63/21 115/21 intervention [4] 116/10 116/12 117/6 127/5 interventional [9] 59/3 115/9 115/13 115/23 116/3 116/18 118/5 120/15 120/23 interventionist [3] 117/13 117/15 117/19 interventions [1] 116/8 into [20] 16/18 39/5 48/14 50/9 55/2 58/19 60/10 75/24 78/17 79/7 108/10 129/13 137/4 140/17 150/6 152/13 157/1 159/11 168/12 168/19 intolerance [1] 118/8 intracranial [6] 109/20 113/4 113/9 113/15 113/25 114/22 introduce [2] 99/5 163/12 introduced [12] 1/9 48/18 105/18 107/3 107/7 117/23 122/21 124/14 132/12 155/23 160/17 160/18 introduction [3] 104/11 107/20 129/9 invariably [4] 96/15 96/15 99/13 145/2 invasive [1] 100/4 investigate [1] 93/17 investigated [1] 89/14 investigation [2] 27/15 124/8 investigator [1] 115/19 investigator-led [1] 115/19 invitation [1] 49/13 invite [1] 87/5 invoice [2] 71/21 72/9 involve [1] 100/14 involved [16] 7/7	16/15 17/6 44/2 47/5 50/15 54/16 57/8 68/11 79/8 115/19 122/12 141/18 162/17 163/16 166/9 involvement [8] 49/25 51/15 51/17 76/7 76/8 122/5 134/9 146/2 involving [2] 122/23 130/1 ire [1] 140/22 Ireland [1] 102/14 Ironside [1] 41/7 irregular [1] 62/2 irregularly [1] 77/12 irrelevant [1] 145/10 Ismail [1] 169/13 isn't [4] 89/1 108/2 110/19 110/23 isolated [1] 150/12 issue [19] 13/11 30/3 30/12 34/5 40/10 44/3 71/7 73/4 75/10 87/4 88/2 104/4 121/17 123/7 139/1 149/3 154/14 155/25 159/7 issued [1] 82/2 issues [4] 35/25 58/9 93/10 135/8 it'd [1] 113/11 it'll [1] 106/5 it's [85] 2/17 2/18 6/9 12/19 15/3 15/3 15/21 27/1 27/1 27/13 33/13 35/16 40/16 44/19 44/20 46/5 47/4 50/4 55/22 57/22 62/22 72/11 72/16 82/14 82/15 82/16 87/1 87/6 87/19 91/15 92/20 94/19 95/8 99/20 100/7 102/12 103/11 105/7 105/12 105/22 106/4 106/23 106/23 109/21 110/16 110/19 111/1 112/8 113/8 113/10 113/13 114/9 116/14 118/17 119/17 119/19 121/17 130/20 131/3 131/3 131/15 134/15 135/24 143/10 143/20 144/22 150/12 150/14 150/24 152/1 152/3 152/8 152/19 154/10 156/17 159/8 161/12 162/16 164/1 165/25 166/18 167/12 168/3 168/11 168/24 italicised [1] 85/3 Italy [1] 128/2 item [1] 113/9 its [11] 10/22 34/19
----------	--	--	--	--	---

I	114/8 114/17 117/2 117/4 120/6 126/9 129/19 131/18 141/4 143/22 145/10 145/12 152/7 152/10 154/16 162/15 164/4 164/19 165/12 166/2	162/7 162/15 164/1 167/7 167/13 168/1 168/6 168/16 169/10 knowing [1] 164/24 knowledge [5] 45/22 54/15 106/5 133/21 158/15 known [8] 5/15 24/21 38/17 56/23 97/11 97/20 112/1 132/25 knows [2] 91/4 142/21 Kutowski [1] 141/13	79/23 111/15 115/19 163/4 ledger [5] 144/18 144/20 144/22 145/10 145/22 ledgers [1] 144/14 Lee [1] 40/20 left [3] 76/1 117/14 155/24 legal [8] 1/14 87/8 87/10 136/6 142/2 146/20 149/10 152/1 legislation [4] 59/2 59/6 59/8 141/22 lengthy [1] 9/15 less [17] 38/24 78/9 81/20 81/20 84/5 99/2 101/6 108/20 111/3 113/25 128/14 137/7 137/12 154/23 154/25 160/8 167/1 let [5] 1/5 71/19 72/5 143/22 157/17 let's [2] 86/18 130/2 letter [41] 2/6 2/17 3/13 3/13 4/16 6/7 10/14 14/24 15/2 15/13 15/16 20/12 22/21 23/22 25/15 25/17 25/17 26/2 26/4 27/10 27/13 28/6 28/22 29/24 30/8 30/9 31/16 32/19 33/12 33/14 35/5 40/16 71/20 86/5 137/22 141/24 142/9 143/17 143/20 148/25 152/6 letters [4] 14/7 14/10 15/11 135/20 level [10] 9/7 17/2 17/3 38/10 48/20 48/24 101/8 151/16 158/15 160/19 levels [1] 7/2 LFTs [1] 74/4 liaised [1] 57/14 liaison [1] 43/7 licensed [1] 116/21 life [25] 13/10 55/16 55/17 80/6 87/4 97/17 101/5 101/18 101/24 103/10 103/13 103/14 104/12 104/16 104/20 105/1 105/5 105/23 106/17 106/23 111/17 112/7 115/20 166/21 166/24 lifestyle [3] 136/8 136/13 137/17 lifetime [1] 167/11 light [1] 45/22 like [20] 32/15 37/12	37/24 58/25 62/3 68/6 79/24 90/24 92/25 93/4 128/2 133/17 136/18 136/23 138/1 138/22 155/16 164/20 166/7 168/17 likelihood [1] 91/7 likely [12] 9/22 27/2 27/4 74/11 77/11 78/9 84/4 84/5 131/15 137/12 141/15 152/15 limit [1] 88/19 limited [1] 51/3 line [1] 10/6 lined [1] 68/4 lines [2] 23/13 146/13 link [1] 86/21 linked [1] 41/4 list [5] 34/13 41/1 47/18 63/16 89/22 listed [1] 29/12 listening [4] 87/9 108/16 168/5 169/9 Lister [2] 141/13 141/15 lists [5] 33/18 33/19 34/9 78/13 78/14 literature [2] 74/24 131/1 litigation [7] 139/3 139/18 139/21 140/16 140/18 142/8 150/18 little [30] 19/20 24/19 25/5 26/21 34/16 38/17 44/13 50/4 56/10 57/6 57/22 58/24 61/1 72/7 76/2 92/23 99/1 114/13 114/17 114/19 126/8 139/4 140/13 140/13 144/5 148/4 150/19 150/22 157/15 167/3 live [1] 26/9 lived [1] 24/23 liver [14] 74/1 79/4 81/6 82/3 89/13 89/17 96/5 97/25 98/4 98/5 98/6 98/7 98/12 130/11 Liverpool [3] 47/22 123/6 157/12 load [1] 89/7 loan [1] 101/8 local [3] 15/17 122/25 123/1 location [1] 106/7 lodged [1] 142/21 London [1] 53/20 long [20] 3/20 4/9 9/25 26/23 26/23 62/17 79/25 91/2 91/20 92/1 131/19	140/15 142/25 148/2 148/13 153/18 157/23 167/8 168/3 168/5 long-term [1] 167/8 longer [5] 34/15 39/11 64/23 70/7 138/20 longest [1] 21/24 look [36] 6/5 8/3 10/20 10/25 11/24 19/22 25/16 25/16 32/18 35/17 35/22 41/9 51/11 63/18 76/9 76/13 78/18 81/21 81/24 82/2 82/12 82/16 82/21 82/22 84/20 87/16 87/19 91/10 106/1 109/16 110/14 112/13 126/21 130/13 148/15 152/4 look-back [12] 76/9 76/13 78/18 81/21 81/24 82/2 82/16 82/21 82/22 84/20 126/21 130/13 looked [4] 2/6 21/5 42/23 127/23 looked at [3] 21/5 42/23 127/23 looking [23] 14/5 15/7 26/24 44/22 44/23 79/20 80/1 108/24 109/18 109/24 110/10 113/6 113/8 113/19 114/11 119/25 137/12 145/12 146/6 147/13 147/16 148/9 158/25 looks [1] 31/6 looming [1] 64/20 Lord [2] 47/23 133/6 lose [1] 153/24 losing [1] 153/22 lost [11] 19/12 65/25 68/15 72/24 77/13 77/21 80/11 82/25 84/6 91/2 98/15 lot [32] 3/22 19/12 34/17 36/11 44/12 47/16 53/16 61/10 69/4 72/4 72/15 72/25 78/25 106/24 112/10 114/4 114/18 114/19 120/13 134/25 138/19 139/3 139/21 140/19 144/25 147/20 148/21 150/15 150/15 153/9 155/6 158/16 lots [6] 38/22 38/23 98/5 124/7 147/9 147/9 low [6] 7/3 7/25 118/8 149/16 149/24 150/18 lower [2] 84/9 159/24
J	Jakob [13] 8/11 9/24 10/4 16/23 18/15 22/12 24/12 24/25 26/25 36/14 39/3 39/16 135/23 Jakob-Creutzfeldt [13] 8/11 9/24 10/4 16/23 18/15 22/12 24/12 24/25 26/25 36/14 39/3 39/16 135/23 James [2] 41/7 73/15 James Ironside [1] 41/7 January [4] 2/17 21/2 21/14 32/20 January 1998 [1] 2/17 January 2007 [1] 21/2 Japan [1] 128/3 jointly [1] 73/17 Jones [2] 132/18 132/25 Journal [2] 102/4 105/10 judge [1] 141/9 judgment [3] 116/6 120/20 136/6 judicial [1] 149/9 Julia [1] 52/22 Julia Stallibrass [1] 52/22 July [2] 5/23 73/12 July 2004 [1] 5/23 June [2] 30/10 40/17 June 2009 [1] 30/10 junior [1] 121/1 juniors [1] 29/1 just [68] 1/5 1/11 4/2 4/11 5/4 8/18 10/20 11/1 11/24 13/22 15/6 19/19 24/19 35/4 35/19 37/11 40/10 41/14 42/22 61/1 68/8 73/10 79/20 80/22 80/23 81/12 82/12 86/21 90/19 94/11 95/18 95/18 96/10 97/13 99/24 100/5 103/11 104/14 106/1 106/3 106/13 106/15 109/1 109/16 109/18 113/1 113/10 113/12	K keen [1] 124/12 keep [3] 93/7 95/4 119/1 keeping [3] 59/17 95/15 143/25 key [2] 5/17 72/23 kin [2] 41/18 42/10 kind [4] 26/15 54/22 92/3 122/17 kinds [1] 92/1 Kingdom [3] 46/2 48/13 102/16 knew [9] 9/20 16/19 59/18 79/12 97/21 101/13 130/10 133/12 140/2 know [129] 1/8 3/12 16/13 16/21 16/22 17/2 17/6 18/2 19/5 25/1 26/22 26/24 32/8 36/17 43/23 44/2 44/4 44/10 45/3 45/6 46/19 47/8 47/15 49/4 51/12 55/25 56/3 57/21 59/25 62/7 62/17 62/22 63/10 64/2 64/9 69/6 70/24 71/17 71/19 72/6 79/12 80/3 82/4 84/16 85/1 85/4 85/17 85/20 86/11 88/24 89/5 89/8 89/12 90/15 90/17 90/20 91/8 91/9 94/17 94/25 95/6 97/12 97/15 98/10 98/18 99/8 101/15 105/6 106/9 107/21 108/23 111/4 111/21 113/18 115/22 118/2 118/16 120/17 120/24 121/2 123/11 126/16 127/15 127/25 128/13 129/10 130/3 130/12 131/1 133/18 135/5 136/6 136/20 136/24 139/2 139/21 140/5 145/15 145/21 147/10 147/14 148/17 148/18 149/2 150/14 151/1 151/14 153/1 153/3 153/23 154/1 154/5 154/6 157/22 157/25 157/25 158/1 158/3 158/11 158/14	L labile [1] 160/11 lack [3] 6/2 37/17 53/9 LANGSTAFF [2] 154/9 170/4 large [7] 3/2 37/24 37/25 45/1 68/3 127/5 168/18 largest [2] 31/7 31/10 last [12] 17/25 18/5 23/13 40/3 70/19 71/3 71/12 95/17 100/18 103/2 143/24 161/6 late [4] 59/15 77/9 107/3 124/18 late 1960s [1] 107/3 later [11] 38/25 51/6 107/21 111/22 122/20 128/8 130/5 132/13 143/18 162/7 168/9 latter [1] 146/18 latterly [3] 51/15 130/13 134/25 launched [1] 81/20 launching [1] 14/18 law [1] 66/9 lawyers [1] 138/19 lay [1] 121/10 lead [2] 53/19 118/25 leadership [1] 56/16 leaflet [10] 13/15 63/4 63/6 63/12 69/16 71/19 91/23 92/9 92/18 129/13 leaflets [6] 24/4 24/6 25/16 61/24 61/25 63/2 learned [2] 50/21 144/16 learnt [2] 4/24 28/21 least [17] 18/16 18/25 37/14 43/1 65/15 65/17 67/18 70/23 76/5 85/19 86/2 101/22 121/9 125/25 133/14 151/11 168/15 leave [2] 40/9 99/17 leaving [1] 122/16 led [6] 12/3 33/1	legislation [4] 59/2 59/6 59/8 141/22 lengthy [1] 9/15 less [17] 38/24 78/9 81/20 81/20 84/5 99/2 101/6 108/20 111/3 113/25 128/14 137/7 137/12 154/23 154/25 160/8 167/1 let [5] 1/5 71/19 72/5 143/22 157/17 let's [2] 86/18 130/2 letter [41] 2/6 2/17 3/13 3/13 4/16 6/7 10/14 14/24 15/2 15/13 15/16 20/12 22/21 23/22 25/15 25/17 25/17 26/2 26/4 27/10 27/13 28/6 28/22 29/24 30/8 30/9 31/16 32/19 33/12 33/14 35/5 40/16 71/20 86/5 137/22 141/24 142/9 143/17 143/20 148/25 152/6 letters [4] 14/7 14/10 15/11 135/20 level [10] 9/7 17/2 17/3 38/10 48/20 48/24 101/8 151/16 158/15 160/19 levels [1] 7/2 LFTs [1] 74/4 liaised [1] 57/14 liaison [1] 43/7 licensed [1] 116/21 life [25] 13/10 55/16 55/17 80/6 87/4 97/17 101/5 101/18 101/24 103/10 103/13 103/14 104/12 104/16 104/20 105/1 105/5 105/23 106/17 106/23 111/17 112/7 115/20 166/21 166/24 lifestyle [3] 136/8 136/13 137/17 lifetime [1] 167/11 light [1] 45/22 like [20] 32/15 37/12	140/15 142/25 148/2 148/13 153/18 157/23 167/8 168/3 168/5 long-term [1] 167/8 longer [5] 34/15 39/11 64/23 70/7 138/20 longest [1] 21/24 look [36] 6/5 8/3 10/20 10/25 11/24 19/22 25/16 25/16 32/18 35/17 35/22 41/9 51/11 63/18 76/9 76/13 78/18 81/21 81/24 82/2 82/12 82/16 82/21 82/22 84/20 87/16 87/19 91/10 106/1 109/16 110/14 112/13 126/21 130/13 148/15 152/4 look-back [12] 76/9 76/13 78/18 81/21 81/24 82/2 82/16 82/21 82/22 84/20 126/21 130/13 looked [4] 2/6 21/5 42/23 127/23 looked at [3] 21/5 42/23 127/23 looking [23] 14/5 15/7 26/24 44/22 44/23 79/20 80/1 108/24 109/18 109/24 110/10 113/6 113/8 113/19 114/11 119/25 137/12 145/12 146/6 147/13 147/16 148/9 158/25 looks [1] 31/6 looming [1] 64/20 Lord [2] 47/23 133/6 lose [1] 153/24 losing [1] 153/22 lost [11] 19/12 65/25 68/15 72/24 77/13 77/21 80/11 82/25 84/6 91/2 98/15 lot [32] 3/22 19/12 34/17 36/11 44/12 47/16 53/16 61/10 69/4 72/4 72/15 72/25 78/25 106/24 112/10 114/4 114/18 114/19 120/13 134/25 138/19 139/3 139/21 140/19 144/25 147/20 148/21 150/15 150/15 153/9 155/6 158/16 lots [6] 38/22 38/23 98/5 124/7 147/9 147/9 low [6] 7/3 7/25 118/8 149/16 149/24 150/18 lower [2] 84/9 159/24

L	31/24	92/16 93/6 94/15 95/1	64/16 65/1 68/1 68/2	155/8	morning [4] 1/3 1/4
Ludlam [1] 2/18	manufacturer [7] 4/24	95/6 99/1 99/7 103/20	71/11 132/21 134/2	minimum [1] 16/2	86/25 123/10
lunch [5] 86/17 87/6	5/14 124/2 135/7	104/8 106/6 114/2	134/10 141/25	minority [3] 80/20	MORRIS [2] 2/1 170/2
87/17 102/5 104/18	135/9 147/8 162/4	115/15 116/7 116/8	meetings [6] 58/21	85/14 97/24	mortality [5] 33/25
Luncheon [1] 87/23	manufacturers [3]	117/2 125/19 126/9	68/12 132/19 134/6	minute [1] 40/4	67/19 67/21 105/11
Lymm [1] 101/11	134/3 134/17 164/22	135/20 143/23 144/4	134/13 134/16	minutes [8] 47/16	111/24
lymphoid [2] 29/13	manufacturing [1]	144/19 150/13 154/8	member [7] 46/18	47/20 58/10 58/20	mortem [10] 22/24
36/11	6/19	155/5 156/12 162/16	47/1 47/1 50/2 59/9	63/20 71/15 87/18	40/25 41/3 41/3 41/6
M	many [41] 14/11 28/8	168/15	123/23 133/24	132/19	41/19 41/24 42/25
made [20] 7/18 18/19	32/8 32/9 38/18 53/8	maybe [4] 29/11 48/6	members [7] 1/16	mischievous [1]	43/17 44/7
37/19 39/4 41/19 42/7	56/23 58/25 59/19	79/14 111/15	21/16 49/17 50/10	150/18	mortems [4] 41/11
42/21 61/21 65/10	59/25 65/15 74/5	Mayor [2] 47/23 133/6	83/21 121/11 138/17	misconduct [1] 140/2	41/12 42/11 42/11
65/20 77/19 79/7	76/20 76/22 77/17	me [46] 1/5 2/24 4/6	members' [1] 134/22	misguided [1] 151/21	mortgage [1] 97/17
81/13 102/23 133/25	77/20 82/7 82/8 82/20	5/4 5/6 5/15 5/16 13/2	membership [6]	Miss [1] 57/14	most [22] 6/24 26/19
135/8 140/8 142/14	82/24 90/4 118/14	26/19 51/19 52/10	46/25 47/4 49/17	Miss Spooner [1]	27/8 29/2 32/12 34/21
145/19 147/11	127/1 127/8 132/12	52/25 65/21 66/3 82/6	50/11 51/4 70/9	57/14	37/23 38/15 62/23
mailing [1] 22/5	134/7 136/16 142/21	87/11 90/17 91/3	memory [1] 164/1	missed [2] 44/19	77/11 79/12 105/24
main [6] 15/5 32/11	142/23 147/18 149/15	96/23 101/11 101/12	mention [1] 101/2	47/15	110/5 119/19 125/21
60/16 60/16 77/4	151/16 153/6 153/10	104/14 104/22 126/19	mentioned [6] 32/11	missing [3] 30/4	125/22 126/3 126/13
93/25	153/18 154/3 157/19	129/3 133/4 136/17	51/23 74/2 135/21	34/12 85/16	131/20 141/15 160/24
maintain [1] 163/20	158/3 163/21 167/10	140/4 140/7 140/15	154/13 156/7	mistaken [2] 30/13	166/17
major [3] 6/23 97/16	168/25	141/4 141/5 142/9	merely [1] 38/9	138/14	mostly [4] 8/7 77/12
163/24	March [2] 82/16	142/24 143/9 143/22	met [1] 68/5	mistakenly [1] 31/20	85/13 135/12
majority [1] 108/25	104/10	146/5 148/13 150/7	metal [1] 36/22	Mitchell [1] 169/13	motive [1] 148/18
make [20] 24/1 38/16	margin [1] 110/16	150/14 152/11 154/16	method [1] 166/23	mitigate [1] 40/2	mount [1] 146/22
38/21 55/23 60/19	Marie [1] 133/10	157/9 165/12 166/2	methodology [3]	mode [1] 21/25	move [7] 3/8 4/11
67/22 69/8 86/8 99/8	market [2] 55/7	167/24	127/13 127/22 128/5	moderate [1] 136/11	19/18 45/8 69/19 76/7
116/9 117/18 120/20	163/22	mean [30] 5/24 13/7	methods [2] 104/20	modest [1] 112/8	112/23
145/11 146/3 146/9	marketed [1] 124/14	13/9 14/17 27/23	105/8	modestly [1] 104/23	moved [4] 58/8 77/20
156/18 157/13 163/18	marketing [1] 116/23	36/15 54/1 54/4 56/5	metric [1] 104/21	modification [1] 81/3	77/24 80/5
164/7 166/13	mask [1] 1/19	62/9 88/16 89/1 89/24	microscopic [1] 44/19	molecule [1] 166/22	moving [6] 86/16
maker [1] 70/5	material [21] 41/7	93/12 94/23 95/12	mid [3] 107/3 119/6	moment [6] 8/4 35/4	95/22 122/10 122/15
makes [1] 145/3	41/9 41/11 42/21	95/13 96/22 97/14	119/9	45/9 114/12 146/15	123/3 133/23
making [9] 38/22 46/6	42/25 43/5 43/10	100/16 101/7 109/6	mid-'80s [2] 119/6	154/1	Mr [4] 73/12 73/15
72/14 79/16 79/21	43/13 43/17 43/18	136/4 137/6 143/5	119/9	moments [1] 38/3	137/22 138/24
84/11 134/22 164/23	43/22 44/7 44/11	146/18 146/24 158/18	might [55] 8/20 10/3	Monday [1] 26/10	Mr Barker [2] 137/22
164/25	44/13 45/2 58/18	159/19 164/21	16/14 17/5 18/13	money [2] 37/19	138/24
males [1] 103/16	84/18 102/9 102/21	means [3] 7/1 27/20	24/24 29/11 42/12	164/23	Mr James [1] 73/15
Malmo [1] 133/10	106/6 156/1	92/13	47/15 57/15 58/24	monitor [1] 160/14	Mr Stevens [1] 73/12
managed [1] 139/7	materials [7] 32/17	meant [1] 4/3	63/10 73/1 79/12	monitored [1] 158/19	MREC [1] 122/22
management [4]	47/10 47/12 58/11	meantime [1] 33/24	79/22 81/11 89/4	monopoly [1] 162/9	Ms [10] 1/6 1/15 1/24
56/12 58/3 59/11	58/15 73/10 120/6	measures [3] 8/24	89/11 91/3 91/21 92/2	month [2] 23/10 126/6	2/2 87/12 102/12
71/12	matter [15] 14/22	12/12 12/16	93/8 93/9 93/10 94/13	monthly [1] 10/18	108/14 143/19 167/20
manager [2] 56/5	14/23 32/4 43/20 60/1	mechanism [1] 137/6	94/17 98/25 99/10	months [1] 147/25	170/3
156/20	88/22 109/8 111/23	median [3] 103/9	114/4 115/11 117/16	Morbidity [1] 33/25	Ms Pappenheim [1]
Manchester [24] 2/9	115/15 116/6 117/14	103/14 105/1	118/25 119/2 119/11	more [52] 4/8 5/6 38/8	143/19
4/19 5/13 19/6 19/8	150/15 152/14 154/18	medical [20] 14/3	121/4 121/12 131/7	49/6 49/14 49/15	Ms Richards [6] 1/15
19/10 24/9 26/16 36/3	159/4	51/10 59/21 108/9	136/16 136/19 136/20	50/13 52/13 53/11	1/24 2/2 108/14
36/8 39/25 44/5 45/4	matter's [1] 26/12	135/17 135/19 140/1	136/21 136/25 141/9	56/4 56/10 57/8 63/10	167/20 170/3
48/5 56/13 58/5 58/8	matters [2] 54/22	140/22 141/3 142/13	142/23 144/24 147/16	63/24 72/5 72/8 74/11	Ms Scott [1] 87/12
91/13 93/13 111/4	86/21	143/21 143/25 145/4	150/25 151/11 153/5	75/8 81/5 83/5 89/18	Ms Spooner [1]
111/8 144/15 144/18	maximum [1] 25/23	146/4 146/8 146/25	154/22 155/6 156/15	98/3 100/1 101/21	102/12
147/20	may [64] 1/6 2/13 3/4	147/23 150/3 150/9	162/10 162/10 167/9	103/9 108/21 109/3	much [39] 5/6 27/6
manifesting [1] 21/21	4/17 12/25 15/17 20/9	150/21	mild [9] 19/11 62/15	111/8 116/3 120/13	27/9 49/22 50/18
manipulating [1]	28/1 32/2 35/21 41/2	Medicines [3] 6/18	77/12 77/18 78/6 83/4	122/11 122/23 124/20	51/12 52/15 56/25
149/19	41/3 41/12 43/8 47/9	124/4 165/25	91/1 136/10 137/8	125/9 125/10 126/4	73/1 79/6 95/19 99/2
manufacture [4] 3/18	49/19 49/21 49/22	medicolegally [1]	miles [1] 60/17	129/23 131/3 135/11	101/4 105/2 106/20
11/6 30/19 164/23	55/17 62/25 63/1 72/6	144/4	million [2] 37/13	135/12 135/19 139/23	106/21 109/3 110/16
manufactured [5]	72/24 77/22 77/24	medium [2] 7/3 7/18	164/20	139/23 140/13 143/23	110/21 111/3 118/10
2/10 4/20 23/5 30/22	77/25 78/2 78/7 85/10	meeting [19] 1/7 1/19	mind [4] 117/16	157/9 159/8 160/11	122/8 122/20 131/5
	85/12 86/21 87/3 90/4	2/7 35/13 35/21 35/22	128/11 158/4 163/23	163/20 167/1 167/5	137/6 138/1 153/16
	90/5 90/8 91/8 92/14	50/7 50/23 50/25 51/5	minimise [2] 40/5	167/7	154/23 155/10 155/10

(57) Ludlam - much

M	100/14 130/9 necessary [3] 29/8 39/11 76/25 need [27] 7/25 8/1 10/25 11/8 11/13 15/21 19/12 20/10 24/5 28/16 28/22 30/8 38/1 44/2 55/9 55/18 69/6 70/16 85/21 91/8 93/16 95/21 99/12 131/5 131/19 149/21 156/18 needed [13] 16/12 30/5 46/24 57/8 60/5 60/10 64/24 65/4 79/6 118/14 128/23 140/25 157/18 needs [2] 15/13 131/10 negated [1] 118/3 negative [1] 91/8 negligence [4] 138/15 139/6 141/20 146/25 negligent [1] 151/25 negotiated [2] 161/14 165/14 negotiating [1] 161/17 negotiating per [1] 161/17 net [2] 77/22 124/24 neurological [1] 24/16 never [11] 1/10 24/25 66/1 68/5 73/3 75/12 83/12 95/24 99/20 137/1 142/6 nevertheless [5] 65/14 72/19 118/11 139/9 155/9 new [20] 1/7 22/8 50/9 53/22 77/25 77/25 81/18 89/10 90/2 90/11 90/13 91/3 95/5 100/17 116/16 116/16 121/24 123/22 124/8 124/11 Newcastle [1] 47/23 news [2] 22/7 99/1 newspapers [1] 149/19 next [29] 5/17 12/11 12/24 13/11 20/24 34/22 35/23 35/24 36/14 41/18 42/10 45/20 73/5 75/8 78/5 84/8 88/1 90/1 91/15 91/21 103/7 120/10 149/5 152/3 152/4 157/4 159/17 162/7 169/3 NHBT0091224 [1]	73/6 NHD [4] 33/17 33/24 82/19 83/6 NHS [34] 51/13 53/19 53/20 53/20 55/10 55/11 55/15 55/23 60/23 60/24 62/13 62/19 63/23 64/4 64/12 64/13 65/1 65/4 65/6 66/11 66/14 67/17 67/23 68/1 68/22 69/2 69/3 85/5 85/6 85/7 85/9 85/17 107/22 107/25 NHS England [1] 53/19 NHS RA CAG [1] 69/3 NHS Scotland [1] 53/20 NHS Wales [1] 53/20 Nilsson [1] 133/10 no [59] 1/16 3/6 9/17 9/18 9/21 10/9 17/20 18/11 18/12 22/8 22/8 24/15 24/18 29/18 34/14 35/15 39/11 43/9 43/19 52/4 58/17 59/2 64/23 70/7 72/11 79/16 79/21 84/1 84/10 86/6 93/14 99/16 106/25 108/9 108/9 112/3 113/15 114/25 115/15 122/15 123/9 131/1 132/11 133/18 133/22 137/13 137/13 137/14 138/19 139/17 139/19 142/3 150/10 151/24 159/19 164/6 164/24 167/6 167/23 no treatment [1] 106/25 no-fault [1] 139/17 Nobody [1] 150/10 nominal [1] 72/11 non [26] 22/2 29/14 46/6 54/25 78/7 80/17 123/15 123/15 126/15 126/15 126/24 126/24 127/9 127/9 127/12 127/12 127/17 127/17 127/20 127/21 130/6 130/6 135/15 135/15 160/5 160/5 non-A [10] 123/15 126/15 126/24 127/9 127/12 127/17 127/20 130/6 135/15 160/5 non-B [9] 123/15 126/15 126/24 127/9 127/12 127/17 127/21 130/6 135/15	non-B hepatitis [1] 160/5 non-cellular [1] 22/2 non-commercial [1] 54/25 non-disposable [1] 29/14 non-profit [1] 46/6 non-severe [1] 80/17 non-specialist [1] 78/7 none [2] 39/3 167/11 nonetheless [1] 145/5 Nor [1] 1/11 normal [7] 88/11 89/1 89/22 103/16 116/22 135/11 167/1 normally [2] 87/9 120/14 Northern [1] 102/14 Norwich [1] 47/23 nose [1] 137/2 not [196] note [6] 35/16 45/8 86/15 131/7 135/24 136/4 noted [4] 9/4 135/24 136/1 168/10 notes [22] 9/3 15/19 18/24 28/13 72/24 73/24 74/5 75/25 145/2 145/17 146/9 147/11 147/11 147/14 147/19 147/20 148/1 148/4 148/8 148/11 148/16 148/19 nothing [4] 44/14 45/6 45/7 153/24 notice [2] 39/23 66/23 noticed [1] 93/18 notification [29] 2/5 4/12 5/19 6/6 8/17 10/12 13/23 19/23 21/6 22/9 22/16 22/18 25/13 25/14 25/21 26/9 26/17 28/7 28/21 29/1 29/2 30/13 32/1 32/17 32/23 34/6 38/4 123/10 123/13 notifications [3] 20/14 29/18 32/8 notified [9] 4/18 20/6 29/7 30/24 31/21 33/4 33/11 34/10 34/20 notified [1] 34/3 notify [3] 20/9 31/15 43/19 notifying [2] 13/19 21/15 notional [1] 165/17 November [9] 1/1 2/7 19/21 71/11 137/23	149/1 169/6 169/15 169/18 November 1994 [1] 137/23 November 1997 [1] 2/7 November 2003 [1] 71/11 November 2005 [1] 149/1 November 2020 [1] 1/1 now [68] 5/20 10/6 16/21 19/24 32/21 33/9 37/18 38/11 38/15 38/24 46/18 47/18 51/8 52/10 53/16 56/5 56/5 58/9 60/13 60/14 60/18 61/15 63/16 64/2 64/19 65/10 66/2 66/14 69/23 70/7 71/24 81/19 85/17 86/17 91/12 91/23 92/16 94/21 96/10 97/21 98/9 98/16 98/21 103/25 104/14 104/19 105/14 106/9 113/25 115/3 120/2 127/3 127/13 128/8 129/10 139/12 144/1 144/18 144/21 151/1 153/14 158/13 159/18 165/7 165/9 165/12 165/25 167/3 nowadays [1] 166/13 number [39] 12/16 28/23 31/2 31/21 32/14 37/5 37/25 40/21 48/18 63/15 63/25 65/6 67/12 73/19 73/21 78/6 78/22 79/3 84/6 85/18 103/22 109/19 113/10 113/24 115/2 115/20 117/10 126/23 127/6 127/11 127/18 127/23 130/1 133/13 135/2 137/3 142/22 154/24 155/1 number 1 [1] 137/3 numbered [1] 40/23 numbers [15] 11/4 15/14 27/4 68/11 82/9 85/6 85/6 85/7 85/9 86/13 103/18 144/4 144/7 144/17 145/14 nurses [4] 31/18 63/5 63/9 166/10 O o'clock [5] 86/19	132/2 132/4 132/5 169/15 obesity [1] 98/8 objective [1] 163/18 objectives [2] 76/16 78/23 obliged [3] 83/8 94/8 165/19 observational [14] 107/11 115/10 115/14 116/2 116/10 116/15 116/23 117/8 117/19 118/23 118/24 119/23 120/12 120/20 observe [1] 109/19 observed [4] 39/5 109/1 136/24 157/6 observing [1] 117/7 obtain [6] 65/22 68/17 70/8 96/1 99/20 138/12 obtained [6] 40/20 41/1 41/11 42/22 61/11 81/25 obtaining [4] 42/10 67/14 80/12 91/17 obtains [1] 69/23 obviously [17] 5/24 8/15 13/15 24/25 36/16 53/14 56/6 67/12 81/19 97/25 108/10 126/25 138/2 142/13 144/25 163/8 169/2 occasion [1] 90/22 occasional [2] 83/4 155/16 Occasionally [1] 119/21 occasions [2] 39/22 117/10 occur [3] 6/3 41/3 130/15 occurred [2] 114/4 116/11 October [2] 35/14 35/22 odd [3] 25/5 96/20 155/3 off [5] 60/16 126/7 136/20 136/21 137/3 offer [5] 18/12 22/4 69/7 134/5 164/9 offered [6] 18/22 76/21 76/25 120/8 157/15 163/17 office [1] 49/3 officeholder [1] 50/2 officer [2] 146/5 146/8 official [1] 138/17 often [19] 39/23 62/15 71/22 75/25 78/8 89/5
----------	--	--	--	---	--

(58) much... - often

O	119/7 123/23 open [4] 127/4 135/10 152/23 153/3 operated [1] 69/13 operating [1] 56/6 operation [3] 71/8 75/7 116/11 Operations [1] 40/2 operators [1] 118/4 opinion [10] 44/1 60/2 60/4 67/24 68/8 107/11 107/12 115/16 154/5 166/20 opinions [1] 153/17 opportunist [1] 62/9 opportunity [8] 62/10 62/24 63/8 87/10 96/18 120/8 131/23 131/24 opposed [1] 142/17 opt [7] 61/17 61/23 64/22 64/24 69/14 70/15 70/20 opt-in [1] 64/24 opt-out [4] 61/17 61/23 64/22 70/15 option [1] 6/24 or [139] 3/14 5/14 6/15 8/7 9/19 11/6 15/14 16/4 16/9 16/11 16/14 16/17 17/18 17/20 18/22 18/25 19/7 22/15 23/16 24/16 28/19 29/6 29/20 30/13 30/22 32/8 39/13 39/22 41/3 41/6 41/12 43/19 44/5 44/14 47/11 49/21 50/2 51/13 51/22 53/4 56/2 58/13 60/16 60/17 61/3 61/6 61/14 62/7 63/5 63/9 68/4 70/4 70/12 70/13 73/14 73/24 74/6 75/4 75/10 75/22 76/7 77/7 77/9 77/12 77/24 78/1 79/14 80/11 83/13 84/3 85/19 88/12 88/17 88/19 90/3 90/10 91/9 93/9 94/1 94/2 95/7 96/1 96/2 96/15 97/8 98/17 98/19 99/22 103/25 104/20 106/25 109/15 110/3 111/16 113/2 113/22 115/5 116/11 116/12 116/25 117/19 119/10 119/12 119/13 120/21 121/3 122/7 123/14 126/15 127/4 135/4 135/11 135/15 135/23 138/8 141/10 141/24 142/6 144/2 145/13 146/6 146/9 150/24 151/1 151/10 151/21 151/21 153/23 154/18 156/8 156/14 156/21 159/4 162/23 164/11 165/15 165/17 168/9 168/22 orally [2] 168/9 168/13 order [4] 3/3 50/8 50/12 115/6 organisation [16] 6/15 46/3 46/22 47/3 47/7 48/9 48/12 50/3 50/16 50/19 51/9 51/10 54/11 56/3 58/1 58/4 organisations [1] 57/20 organise [2] 148/3 166/3 organised [7] 10/11 25/14 47/11 68/1 164/7 165/13 165/23 origin [1] 72/22 original [1] 41/8 originally [2] 30/16 157/21 other [64] 3/9 3/14 5/4 8/3 8/7 10/17 15/15 24/17 28/5 28/17 32/3 32/5 32/11 34/25 37/21 46/8 46/14 47/22 49/23 51/18 54/12 54/14 54/22 57/2 57/12 64/3 64/19 67/15 68/9 79/4 79/14 79/17 85/21 88/13 91/9 93/10 93/17 100/4 105/4 105/14 112/21 113/6 116/7 117/13 121/3 122/11 124/21 125/14 127/4 130/3 137/2 137/2 137/5 138/8 141/8 144/10 144/19 144/23 149/10 153/16 159/2 160/8 167/10 167/15 others [7] 11/15 16/24 52/22 106/2 111/3 161/10 166/24 otherwise [2] 98/13 163/7 our [48] 2/19 3/5 3/11 8/12 8/23 9/7 17/7 20/22 22/4 22/15 25/12 26/8 39/9 39/17 39/17 51/17 60/4 60/20 60/20 60/24 63/12 63/17 63/18 64/1 64/4 64/5 64/25 65/5 65/9 66/9 69/25 71/2 73/17 81/22 84/24 85/23 92/11 93/14 98/2 98/3 101/4 118/15 123/20 156/19 162/2 163/17 163/20 164/13 out [76] 1/12 6/10 6/14 10/15 12/2 12/17 14/6 15/11 17/1 26/24 29/4 29/17 30/4 30/10 30/16 30/24 31/17 32/9 33/12 34/5 34/12 35/3 40/10 43/2 46/5 47/10 49/13 58/20 61/17 61/23 62/5 63/2 63/3 64/22 65/18 67/16 69/5 69/15 70/15 71/3 71/7 72/10 72/22 74/15 76/16 77/3 78/11 78/22 79/6 81/1 82/9 85/3 93/11 94/5 98/24 100/18 104/22 109/21 112/17 115/7 115/24 116/4 129/20 130/17 136/15 137/1 138/11 145/10 148/1 148/17 153/10 154/11 156/13 157/13 158/11 160/10 outcome [5] 9/13 76/21 140/18 141/8 143/2 outcomes [1] 79/3 outlet [1] 141/1 outline [3] 30/13 60/20 60/20 outlook [1] 159/1 outrageous [1] 157/2 outset [1] 164/14 outside [2] 57/20 79/18 over [40] 7/3 11/7 12/2 12/21 13/4 17/25 20/10 21/2 23/18 29/16 32/21 39/21 46/4 49/25 50/15 52/2 52/10 54/15 56/21 57/6 58/10 58/16 65/21 77/10 82/20 83/6 87/6 91/18 102/5 104/18 113/11 113/12 114/21 121/5 136/18 141/14 146/12 150/23 161/17 164/18 overall [1] 38/7 overlap [2] 105/21 129/16 oversight [1] 59/12 overspeaking [2] 128/25 129/2 overview [2] 8/5 24/7	overwhelmed [2] 80/8 81/13 overwhelming [2] 19/1 79/1 own [11] 1/15 18/21 25/24 55/24 86/11 88/16 96/13 133/20 135/19 159/23 167/15 Oxford [10] 2/25 31/4 32/12 48/5 52/5 56/13 56/17 57/12 57/18 58/4 P package [1] 67/3 page [57] 7/3 11/7 11/16 11/23 12/2 12/8 12/11 12/18 12/21 12/24 13/4 13/11 13/25 14/1 17/12 17/25 20/10 21/3 21/12 23/13 23/18 29/16 35/15 35/19 35/23 35/24 42/19 46/4 47/17 71/13 74/15 74/16 76/15 77/1 77/16 78/5 78/11 83/2 84/8 91/12 91/15 91/18 91/21 102/18 106/11 106/13 106/14 108/12 108/17 137/24 143/23 145/9 146/12 149/5 152/3 152/5 152/8 page 6 [2] 47/17 77/1 page 9 [1] 78/11 pages [1] 38/20 paid [3] 52/6 52/8 164/19 paints [1] 110/21 pair [1] 136/25 pandemic [1] 69/22 panel [11] 6/8 6/10 6/25 10/12 10/21 12/19 14/14 16/3 16/8 38/14 39/17 paper [6] 101/25 113/3 114/12 129/2 129/4 129/6 papers [5] 51/24 127/23 128/8 133/7 147/17 paperwork [1] 67/1 Pappenheim [1] 143/19 par [1] 64/5 paragraph [18] 6/13 7/4 15/5 21/16 23/1 29/17 36/1 40/24 74/16 77/4 88/7 100/8 103/1 103/7 103/24 143/24 146/13 152/10	paragraph 80.3 [1] 88/7 paragraphs [2] 40/23 104/14 parents [1] 15/15 Parliamentary [1] 14/19 part [16] 17/10 40/18 44/9 52/7 75/3 75/8 76/5 76/6 80/24 93/24 106/8 107/24 122/9 134/24 142/17 143/4 part 2 [1] 76/6 participant [1] 131/14 participants [5] 68/18 115/4 120/11 122/1 169/5 participate [5] 46/17 116/22 118/15 119/18 121/23 participate in [1] 116/22 participating [2] 116/20 116/25 particular [13] 19/9 19/13 24/10 31/5 51/22 73/11 75/9 90/9 108/15 121/12 136/10 160/7 162/2 particularly [14] 2/25 19/11 37/10 60/18 62/14 72/7 92/6 111/14 117/17 124/12 128/21 131/16 133/12 159/10 parties [2] 61/7 112/14 partly [8] 46/24 51/16 68/10 82/18 82/20 122/10 166/6 166/7 parts [2] 24/17 134/12 party [14] 4/19 5/1 5/8 8/9 33/25 58/3 59/10 59/11 59/14 92/20 112/16 123/18 132/17 132/24 passage [2] 74/6 115/7 passed [1] 53/3 passing [1] 135/21 past [7] 32/1 49/12 83/20 87/19 117/11 165/24 166/17 path [1] 64/9 patient [105] 9/4 9/13 11/24 13/23 14/7 16/4 17/17 17/24 18/2 18/3 19/23 21/20 23/2 23/8 23/15 23/16 23/20 24/13 24/15 24/23 25/2 25/20 27/15 27/24 28/3 34/22
----------	--	---	--

(59) often... - patient

P	percentage [2] 127/9 127/19 perception [1] 104/11 perfect [1] 102/25 perfectly [5] 5/7 16/10 59/4 151/15 151/17 performed [2] 41/24 43/2 perhaps [12] 8/4 10/4 25/11 37/21 62/23 76/6 86/16 87/5 98/14 105/19 156/14 167/11 period [57] 10/5 16/20 21/24 30/16 30/18 38/9 38/25 39/8 43/1 47/4 50/1 53/9 61/12 62/2 65/22 69/13 72/8 73/23 74/8 74/23 77/6 79/18 81/17 83/10 100/19 101/22 105/17 105/24 106/11 108/24 109/23 110/5 110/9 110/10 110/14 110/23 110/24 111/1 111/1 111/14 112/10 113/16 113/21 113/22 113/23 119/8 120/24 121/7 122/9 124/25 125/1 125/3 125/7 125/11 147/7 165/1 168/14 periods [4] 105/16 105/21 113/19 114/22 peripheral [1] 146/3 permission [4] 70/17 70/22 94/6 146/7 person [7] 12/4 17/21 22/25 64/7 117/21 130/4 168/3 personal [6] 16/18 25/24 60/13 90/18 112/20 152/23 personalised [1] 67/4 personality [1] 137/4 personally [1] 100/16 perspective [1] 34/7 persuade [1] 142/1 pertained [1] 165/10 pessimistic [2] 38/15 39/1 Peter [2] 132/18 132/25 Peter Jones [1] 132/25 PFC [1] 11/6 pharmaceutical [15] 54/1 54/12 54/15 54/19 54/23 55/12 55/13 56/1 133/23 134/1 134/5 134/10 156/7 156/8 156/15 phenotype [1] 137/8 philosophical [2]	26/19 27/8 phlebotomist [1] 88/11 phone [1] 72/15 photocopying [1] 145/9 physically [1] 137/10 pick [4] 2/3 23/13 35/17 143/22 picked [3] 26/13 44/17 44/25 picking [1] 118/18 picture [5] 2/3 35/18 80/3 108/6 110/21 piece [2] 72/23 102/8 pioneered [1] 133/9 place [13] 29/2 39/21 41/6 41/12 41/13 49/16 60/25 97/18 121/4 135/16 136/5 140/17 168/20 places [2] 128/2 159/5 plainly [2] 159/18 162/20 plan [3] 14/2 14/4 92/12 planned [1] 14/8 planning [6] 22/5 40/5 52/19 55/24 79/5 81/8 plasma [20] 2/10 3/19 4/20 4/21 6/11 19/22 23/5 23/16 30/20 30/22 31/10 31/25 32/23 33/8 88/23 107/2 125/6 126/3 126/5 155/11 plasma-derived [1] 125/6 plasmapheresis [1] 126/4 platelet [1] 90/22 play [3] 58/20 134/24 135/4 please [53] 2/15 2/16 4/15 6/4 10/24 11/12 11/21 13/22 19/19 20/25 21/10 22/20 23/24 26/3 27/12 27/18 30/14 32/18 33/16 35/12 35/14 35/20 35/23 40/15 41/16 42/14 42/19 45/25 47/9 51/19 71/9 71/10 71/13 73/6 76/10 76/15 77/1 87/11 87/19 91/11 102/19 103/7 106/12 106/14 129/5 129/14 137/21 137/24 143/15 143/16 146/12 148/24 149/4	plus [1] 150/17 pm [5] 87/22 87/24 132/6 132/8 169/17 point [41] 2/8 3/16 5/25 12/13 12/22 13/6 14/25 16/25 17/4 26/22 27/3 27/14 28/6 38/20 47/4 47/24 52/14 57/13 58/3 60/13 62/11 66/16 67/22 67/23 75/13 85/17 88/14 89/4 104/22 108/6 116/6 118/18 118/21 130/7 138/18 139/22 142/22 145/19 146/18 146/20 148/2 pointed [1] 81/1 points [1] 63/17 policies [1] 36/5 policy [13] 3/6 3/10 3/11 12/23 35/1 37/22 38/5 38/7 39/21 144/10 149/7 161/9 161/9 polyethylene [3] 166/23 167/4 167/8 pooled [4] 10/9 17/17 18/17 22/2 pools [2] 4/20 123/7 poor [1] 159/4 popular [1] 3/23 population [5] 18/20 53/18 98/8 128/11 128/12 position [18] 2/14 3/11 25/24 27/14 34/24 35/6 45/3 62/21 69/12 70/13 70/14 96/12 100/6 108/1 138/21 140/23 142/3 157/1 positive [6] 91/7 95/7 125/3 130/17 158/18 167/6 positives [2] 125/21 126/13 positivity [1] 126/14 possibilities [1] 28/5 possibility [10] 5/25 6/2 10/2 10/8 24/22 27/23 99/5 99/7 101/21 103/19 possible [13] 5/22 15/16 20/7 23/24 24/12 43/4 65/9 85/25 90/15 117/12 134/8 135/14 152/24 possibly [4] 31/7 34/10 52/1 121/19 post [18] 22/24 28/24 40/25 41/3 41/3 41/6	41/11 41/12 41/19 41/24 42/11 42/11 42/25 43/17 44/7 49/23 57/25 157/15 post-mortem [6] 40/25 41/19 41/24 42/25 43/17 44/7 post-mortems [4] 41/11 41/12 42/11 42/11 posted [1] 62/6 posting [1] 62/20 postmortem [2] 42/21 43/5 postmortems [1] 43/2 posts [1] 57/19 postspectively [1] 42/11 potential [8] 6/21 7/9 7/19 27/16 27/22 36/12 52/23 92/25 potentially [6] 24/11 80/21 83/11 102/8 121/19 158/1 pounds' [1] 37/13 practical [6] 13/3 35/11 39/20 128/14 128/17 163/5 practice [17] 31/11 88/17 88/17 89/1 89/22 96/13 98/2 99/14 99/15 99/23 100/13 100/25 101/16 117/14 135/11 157/12 157/24 practiced [3] 114/2 133/5 133/13 practices [3] 88/5 157/9 159/2 practising [1] 108/4 pre [4] 95/25 99/17 100/11 129/11 pre-donation [1] 129/11 pre-test [3] 95/25 99/17 100/11 precautionary [3] 6/24 7/6 12/16 precautions [1] 7/21 precipitated [1] 57/16 precise [4] 7/8 32/14 109/6 109/7 precursor [1] 87/1 predate [1] 47/9 predisposes [1] 94/18 predominantly [1] 51/11 prefer [4] 18/13 94/17 167/6 167/14 preferred [5] 26/14 58/7 163/8 168/2 168/2	pregnant [1] 101/15 premises [1] 1/21 prepared [6] 11/23 13/15 41/8 71/18 120/4 168/6 prerequisite [1] 54/10 prescribe [2] 116/21 165/21 prescribing [1] 165/20 prescription [2] 145/18 163/21 present [6] 1/13 3/4 87/8 109/16 125/8 146/11 presented [3] 8/11 147/15 147/16 presenting [1] 147/25 presents [1] 26/25 press [9] 8/20 14/8 14/20 21/3 21/8 26/13 67/2 138/4 138/22 Preston [1] 121/1 Preston's [2] 100/23 157/7 presumably [8] 2/19 18/5 21/4 24/13 25/22 43/12 96/17 161/11 pretty [2] 27/1 160/9 prevalence [1] 128/10 prevent [1] 114/4 previous [12] 20/14 28/25 29/5 34/8 39/5 59/20 78/1 83/15 83/23 88/5 104/17 130/19 previously [5] 20/6 21/5 47/18 52/3 90/10 price [10] 161/18 161/22 162/7 164/10 164/12 164/17 164/20 165/14 165/22 166/7 prices [1] 165/9 primarily [1] 80/16 primary [1] 14/6 principle [6] 90/7 93/19 94/19 121/6 151/23 151/24 principles [1] 93/17 print [3] 7/11 41/20 62/3 prion [10] 22/25 23/15 24/16 24/18 25/4 27/17 27/22 36/16 36/19 44/16 prion protein [1] 44/16 prior [10] 47/8 49/4 51/1 56/2 58/16 59/7 73/25 82/1 97/7 98/4 pro [1] 53/17 probabilities [4]
----------	--	--	---	---	--

(60) patient... - probabilities

<p>P</p> <p>probabilities... [4] 74/18 74/21 74/25 75/15</p> <p>probable [1] 12/7</p> <p>probably [24] 23/12 31/10 36/24 54/8 59/24 66/1 82/25 88/24 89/18 90/14 90/21 98/3 106/19 106/21 107/22 124/23 131/3 133/8 135/7 136/2 137/2 141/14 150/24 160/1</p> <p>problem [33] 3/5 3/21 4/6 10/9 19/7 19/9 19/13 30/17 32/9 36/10 37/23 39/24 40/1 40/1 44/9 52/3 63/22 64/5 68/14 80/16 101/6 117/24 119/13 125/4 128/15 129/23 135/9 140/12 144/21 147/12 151/24 155/5 164/2</p> <p>problems [2] 19/15 128/17</p> <p>procedure [1] 36/18</p> <p>procedures [1] 69/2</p> <p>process [19] 16/25 58/17 61/21 63/20 64/1 66/3 66/13 67/16 71/1 92/9 93/18 97/6 97/18 111/9 123/11 129/11 146/25 161/5 166/4</p> <p>procurement [2] 51/17 51/23</p> <p>produce [4] 34/12 52/13 53/1 67/2</p> <p>produced [8] 11/14 32/22 34/8 52/14 58/15 61/24 69/17 84/20</p> <p>producing [4] 34/1 52/15 110/6 159/24</p> <p>product [35] 4/2 6/22 55/6 55/18 78/1 79/20 120/3 121/24 124/2 133/15 144/9 145/13 145/15 154/14 154/25 155/3 155/4 155/14 155/16 155/20 155/24 160/8 161/1 161/3 161/3 161/4 161/8 161/19 162/19 164/10 164/18 164/23 165/18 166/13 167/2</p> <p>production [2] 17/11 42/12</p> <p>products [63] 2/10</p>	<p>3/2 3/17 3/18 4/4 4/8 4/8 5/11 5/12 6/11 8/13 8/17 8/19 10/10 16/5 16/14 16/20 16/25 17/5 18/17 19/22 20/4 20/8 22/3 23/17 27/25 29/22 30/19 30/21 30/25 31/1 31/2 31/24 32/23 33/9 38/13 40/22 55/4 77/6 83/13 122/3 124/13 124/18 124/19 125/6 134/22 135/1 154/17 155/17 159/18 159/22 160/8 160/21 161/12 162/1 163/13 165/21 166/6 166/17 166/19 166/22 167/4 167/15</p> <p>profession [1] 150/21</p> <p>professional [2] 46/13 140/2</p> <p>professor [39] 1/3 2/3 6/6 14/11 15/1 27/11 40/16 40/20 45/20 47/14 71/24 75/6 84/17 86/21 86/23 86/24 87/14 87/16 88/1 88/14 100/23 101/19 102/22 106/10 108/16 109/25 111/23 115/2 118/19 121/1 131/23 132/10 137/20 142/13 142/20 154/8 157/7 167/21 167/25</p> <p>Professor Hay [20] 2/3 14/11 45/20 71/24 75/6 86/21 86/23 86/24 87/14 88/1 102/22 108/16 109/25 111/23 115/2 131/23 132/10 142/13 154/8 167/21</p> <p>Professor Hill [4] 15/1 27/11 40/16 142/20</p> <p>Professor Lee [1] 40/20</p> <p>Professor Preston [1] 121/1</p> <p>Professor Preston's [2] 100/23 157/7</p> <p>Profilate [1] 160/3</p> <p>profile [2] 141/2 143/11</p> <p>profit [7] 46/6 50/7 50/22 156/14 156/18 164/15 164/25</p> <p>prognosis [1] 97/24</p> <p>programme [2] 132/11 133/18</p> <p>progress [2] 66/15</p>	<p>66/19</p> <p>progressively [2] 125/11 160/19</p> <p>project [2] 53/6 53/13</p> <p>projects [3] 51/18 51/23 53/14</p> <p>prolonged [2] 10/5 97/22</p> <p>promote [1] 46/6</p> <p>proof [1] 6/3</p> <p>proper [2] 117/13 163/1</p> <p>prophylactic [2] 132/15 133/21</p> <p>prophylaxis [10] 112/14 114/2 114/8 132/12 132/17 133/4 133/5 133/7 133/9 133/18</p> <p>proportion [2] 97/23 109/7</p> <p>proportionately [3] 113/3 114/18 114/20</p> <p>proposal [9] 16/3 29/24 41/10 58/4 58/7 76/11 76/16 78/16 126/20</p> <p>proposals [2] 58/5 60/21</p> <p>proposed [5] 41/20 42/16 78/12 96/16 141/25</p> <p>proposer [1] 49/16</p> <p>prospect [1] 107/15</p> <p>prospective [3] 41/21 42/20 129/12</p> <p>prospectively [1] 41/13</p> <p>protection [15] 11/15 21/9 22/22 32/20 33/1 39/15 58/19 59/2 59/6 60/8 60/15 61/19 64/21 72/10 141/22</p> <p>protein [7] 22/25 23/15 24/16 24/18 36/16 36/19 44/16</p> <p>protest [1] 149/11</p> <p>protocol [4] 13/24 63/4 81/4 118/16</p> <p>prove [1] 139/5</p> <p>proved [1] 124/9</p> <p>proven [1] 98/13</p> <p>provide [12] 8/4 48/24 51/20 53/16 55/5 74/7 75/23 79/11 84/18 95/25 111/12 145/8</p> <p>provided [11] 10/21 18/14 48/20 49/2 55/11 58/13 63/23 74/4 78/20 79/3 146/1</p> <p>provides [2] 42/3 91/18</p>	<p>providing [2] 53/13 147/2</p> <p>provision [3] 42/21 46/7 46/13</p> <p>provisions [2] 41/23 42/7</p> <p>PRSE0004645 [1] 106/4</p> <p>prudent [1] 98/19</p> <p>psychological [1] 157/19</p> <p>public [22] 1/17 7/1 7/8 7/16 7/21 13/13 17/21 23/19 28/14 28/16 31/22 33/5 34/15 35/9 39/10 99/3 149/17 149/23 150/6 150/23 151/11 152/13</p> <p>publication [1] 10/22</p> <p>published [4] 82/3 104/10 105/10 133/7</p> <p>pulling [1] 80/19</p> <p>purchase [2] 37/20 134/23</p> <p>purchased [1] 135/1</p> <p>purchaser [1] 53/19</p> <p>purchasing [2] 165/13 165/24</p> <p>purification [1] 160/18</p> <p>purity [3] 4/7 120/3 155/14</p> <p>purpose [12] 12/10 18/5 25/21 79/5 88/13 90/7 91/17 93/5 116/13 116/14 138/24 138/25</p> <p>purposes [22] 7/2 7/8 7/16 7/22 13/14 17/21 28/14 31/22 35/9 46/10 52/19 60/23 61/5 65/5 68/22 68/23 70/10 81/8 92/16 95/3 109/16 112/4</p> <p>purposes' [2] 28/9 33/5</p> <p>pursue [1] 81/14</p> <p>pursued [1] 36/5</p> <p>push [1] 156/22</p> <p>push-back [1] 156/22</p> <p>put [22] 16/17 19/1 28/17 58/3 58/5 60/7 63/12 65/5 68/22 68/24 70/11 78/17 79/7 88/20 96/23 99/11 106/3 121/19 135/18 139/19 140/17 151/4</p> <p>puts [1] 121/19</p> <p>putting [3] 60/24 108/5 162/6</p> <p>pyrogen [1] 155/8</p>	<p>Q</p> <p>QR [1] 66/23</p> <p>quality [3] 85/15 115/20 165/3</p> <p>quarantine [5] 35/3 37/3 37/14 39/12 39/13</p> <p>quarantined [1] 9/2</p> <p>quarter [2] 45/13 45/15</p> <p>quarters [3] 37/13 37/15 148/10</p> <p>question [35] 14/19 16/7 17/7 17/16 18/1 42/9 43/24 55/21 55/22 58/12 59/16 73/5 73/18 91/16 95/22 104/7 117/2 117/20 117/21 118/20 118/22 121/18 121/21 126/9 126/17 129/20 131/4 135/25 139/6 147/4 150/12 157/4 159/17 165/14 166/11</p> <p>questioned [1] 63/25</p> <p>questioning [2] 1/6 66/3</p> <p>questionnaires [1] 115/20</p> <p>questions [30] 2/2 41/15 45/21 56/23 62/25 63/1 69/9 81/12 87/3 87/12 88/1 88/3 90/1 92/1 92/3 96/23 115/3 116/1 131/6 131/8 131/10 131/12 131/13 131/20 147/4 154/7 154/9 167/19 170/3 170/4</p> <p>quick [1] 112/21</p> <p>quickly [4] 2/11 5/6 23/24 167/7</p> <p>quite [29] 3/23 4/1 27/4 27/20 34/16 36/17 62/17 67/13 80/7 80/14 94/6 97/12 104/16 105/7 105/13 111/2 114/6 126/22 130/1 132/25 133/5 137/18 147/15 148/13 153/2 153/3 153/7 155/12 157/20</p> <p>quote [1] 128/9</p> <p>quoted [2] 104/14 105/2</p> <p>R</p> <p>RA [4] 66/14 67/23 68/1 69/3</p> <p>ragbag [1] 154/10</p> <p>raise [2] 143/10</p>	<p>151/22</p> <p>raised [4] 10/2 10/7 32/4 143/9</p> <p>raked [1] 153/12</p> <p>ran [2] 38/19 62/5</p> <p>randomise [1] 120/11</p> <p>randomised [4] 118/2 118/4 118/7 119/16</p> <p>randomly [1] 81/8</p> <p>range [7] 90/15 99/25 127/19 151/22 153/17 161/12 162/1</p> <p>ranging [1] 38/8</p> <p>rapidly [3] 3/6 71/3 80/21</p> <p>rare [1] 27/1</p> <p>rata [1] 53/17</p> <p>rate [6] 55/19 74/24 75/2 114/21 128/4 168/12</p> <p>rates [1] 128/4</p> <p>rather [15] 5/1 30/25 31/9 64/11 74/17 112/19 115/5 119/2 138/10 138/21 151/1 152/15 155/3 168/3 168/23</p> <p>re [13] 93/20 147/24 148/4 154/14 154/19 154/25 155/3 155/4 155/16 155/18 155/20 155/23 155/25</p> <p>re-bind [1] 148/4</p> <p>re-bound [1] 147/24</p> <p>re-call [3] 154/25 155/3 155/4</p> <p>re-called [4] 154/19 155/18 155/20 155/23</p> <p>re-calls [2] 154/14 155/16</p> <p>re-issue [1] 155/25</p> <p>re-test [1] 93/20</p> <p>reach [1] 167/17</p> <p>reaching [1] 74/19</p> <p>reactions [6] 124/7 155/7 155/9 155/10 155/10 155/15</p> <p>read [9] 47/16 62/25 63/6 63/7 71/15 87/5 102/5 104/18 129/12</p> <p>reading [1] 135/19</p> <p>reads [4] 6/18 31/18 36/1 71/24</p> <p>real [4] 164/2 164/11 168/14 168/15</p> <p>realise [4] 28/11 29/9 40/3 97/15</p> <p>realised [6] 18/12 29/5 31/13 69/4 111/9 112/18</p> <p>reality [1] 75/19</p> <p>really [23] 17/6 18/10</p>
--	--	---	---	--	---

(61) probabilities... - really

R	152/22	refused [6] 74/1 74/3 86/2 86/12 86/12 118/15	release [2] 21/3 21/8 released [1] 20/4 releases [1] 138/22 relevance [2] 144/6 144/8 relevant [8] 16/5 30/3 41/9 43/6 102/8 102/22 145/9 145/14 reliable [1] 119/20 remain [3] 33/4 35/6 137/10 remained [2] 47/3 160/16 remaining [1] 34/5 remains [3] 22/1 24/10 167/24 remember [24] 3/19 4/9 14/18 16/8 19/9 19/13 25/2 27/6 27/19 32/13 38/11 38/16 48/17 66/11 75/13 96/19 122/8 123/9 141/11 144/13 146/21 148/9 155/21 162/22 remission [1] 75/2 remission-rate [1] 75/2 remotely [3] 1/10 87/9 169/4 removed [3] 70/18 70/18 70/21 repeat [5] 37/8 125/15 126/1 130/17 130/20 repeated [1] 32/3 repeatedly [2] 125/16 125/23 replace [1] 162/25 replacements [1] 28/24 report [36] 9/6 52/14 55/6 66/15 66/19 67/23 81/15 82/12 82/15 82/17 82/18 83/14 84/19 84/24 87/1 87/2 87/16 95/15 102/14 103/25 104/3 105/15 105/16 106/1 106/10 108/5 110/15 110/24 112/9 112/13 123/25 124/3 126/18 132/20 147/2 150/8 reported [16] 5/21 12/3 21/24 22/2 36/2 43/3 44/17 81/21 83/6 83/16 83/17 83/18 83/22 84/10 103/20 139/25 reporting [11] 10/17 60/24 83/3 84/4 105/17 110/25 123/19 141/3 149/18 150/2 152/17	reports [15] 65/6 65/17 84/1 84/25 95/20 104/17 109/21 111/11 111/22 112/7 123/22 124/8 124/10 124/17 155/6 repositories [1] 93/3 representative [1] 70/4 representatives [2] 87/8 87/11 request [18] 20/23 55/3 62/5 67/20 70/19 71/14 71/23 71/25 72/15 81/4 82/11 85/24 96/24 134/4 145/11 145/21 145/25 146/3 requested [6] 65/16 80/9 81/7 144/24 146/10 147/10 requesting [2] 65/7 147/1 requests [1] 71/16 require [2] 61/1 61/7 required [6] 9/4 37/8 43/9 43/13 66/18 127/5 requirement [1] 124/3 requirements [3] 16/2 57/13 115/11 requires [1] 100/10 rereading [1] 126/22 research [32] 46/12 51/11 52/15 54/25 55/2 59/3 61/6 62/13 62/19 64/12 64/13 65/1 67/9 68/23 88/13 92/16 92/25 93/2 93/3 94/5 94/22 95/2 115/8 115/10 115/14 116/13 116/14 117/17 118/23 118/24 119/7 119/14 residents [1] 101/11 residual [1] 160/16 resisted [1] 57/19 resolve [1] 142/25 resolved [2] 36/9 75/10 respect [1] 18/25 respectively [1] 103/6 respects [1] 63/25 respond [1] 104/8 responded [2] 20/22 139/11 responding [1] 143/19 response [17] 2/4 8/5 19/17 57/5 62/1 62/8 66/22 67/20 81/15 81/22 82/10 85/2 85/23 92/10 109/11	142/10 145/7 responses [2] 26/15 163/11 responsibility [2] 86/6 86/9 responsible [1] 123/4 rest [1] 29/23 restrictions [1] 1/8 result [9] 30/23 83/22 95/4 95/11 108/21 110/6 124/6 149/8 154/3 results [9] 41/18 42/2 42/5 89/6 89/8 90/5 116/8 119/15 157/5 resume [1] 169/4 retained [1] 45/1 retention [2] 44/11 44/12 retired [3] 28/23 56/21 57/15 retirement [1] 57/16 retrieval [1] 43/8 retrospective [4] 41/21 42/24 43/14 43/17 retrospectively [2] 44/13 61/11 returns [2] 9/9 34/9 revenue [1] 3/7 reversion [1] 111/13 revert [1] 70/14 reverting [1] 101/21 review [5] 32/25 33/18 86/1 89/2 105/9 reviewed [5] 46/25 57/18 62/1 63/20 77/12 reviews [2] 126/21 149/10 revise [1] 81/1 revised [4] 39/7 39/9 68/7 71/3 revising [1] 71/2 RICHARD [2] 2/1 170/2 Richards [7] 1/6 1/15 1/24 2/2 108/14 167/20 170/3 rid [1] 36/19 right [39] 2/11 3/25 18/9 20/15 22/10 26/1 34/18 36/25 38/11 45/9 49/10 51/19 54/3 57/17 60/12 61/18 61/23 65/17 69/9 69/11 70/17 72/17 89/24 95/15 102/18 106/21 106/23 109/9 109/25 114/14 118/13 131/3 132/2 138/15 151/19 151/21 156/3
----------	--------	--	--	--	--

(62) really... - right

R	164/7 routes [3] 5/5 27/17 27/22 routine [1] 89/2 row [1] 64/8 Royal [13] 3/1 31/4 31/5 31/6 31/20 32/6 32/10 32/13 37/24 48/5 91/13 159/10 159/15 Royal Free [11] 31/4 31/5 31/6 31/20 32/6 32/10 32/13 37/24 48/5 159/10 159/15 rugby [1] 137/13 rule [8] 57/5 61/25 66/22 67/20 85/23 96/24 109/12 123/21 rule 9 [7] 61/25 66/22 67/20 85/23 96/24 109/12 123/21 run [1] 52/3 running [4] 52/8 56/4 57/14 137/14 rushed [1] 14/21	S sadly [3] 98/9 158/14 161/2 safe [1] 36/24 safeguard [1] 119/11 safeguards [2] 119/9 121/3 safer [2] 119/2 166/13 safest [2] 125/16 125/22 safety [8] 3/24 6/17 116/17 160/19 166/7 166/12 166/14 166/19 said [21] 38/3 52/24 58/16 66/5 82/15 88/6 100/7 109/9 113/5 115/25 126/12 143/4 143/20 150/20 151/7 153/1 157/8 164/3 164/6 164/22 167/13 sake [1] 82/11 salary [1] 52/6 same [27] 1/11 3/18 11/22 14/16 15/12 20/18 21/18 30/21 32/9 47/3 55/12 56/14 59/12 64/7 80/2 85/21 89/3 94/21 97/4 100/7 104/16 116/20 119/1 120/7 120/14 121/6 166/1 sample [20] 42/23 88/11 88/19 88/20 88/21 89/10 91/17 91/19 91/20 91/22 92/12 93/11 93/20	94/9 94/10 94/22 95/1 95/2 95/21 116/12 samples [13] 41/25 88/6 88/9 89/3 89/5 91/10 91/24 92/4 92/24 93/2 93/7 93/15 120/21 sampling [1] 88/12 satisfy [1] 124/2 saved [1] 164/20 saving [1] 164/4 saw [4] 38/18 91/1 96/4 127/1 say [47] 1/5 16/21 24/23 44/12 47/9 73/16 74/20 77/10 77/16 79/13 81/2 83/2 83/24 89/15 89/18 89/24 91/7 94/6 95/23 96/15 99/8 99/11 99/13 99/24 100/8 100/9 101/14 105/14 125/1 127/4 130/2 136/4 137/25 138/9 143/24 149/6 149/14 150/25 153/5 153/9 156/17 156/22 159/19 166/22 167/22 167/24 168/23 saying [5] 98/2 99/25 110/8 152/20 160/21 says [12] 4/17 25/19 26/7 33/15 40/24 42/25 92/11 103/1 103/8 107/10 146/13 152/10 scandal [1] 44/10 scanty [2] 72/7 76/3 scheme [5] 74/9 139/17 139/19 140/17 141/7 schemes [1] 75/7 scientific [1] 134/15 scope [1] 164/21 scored [1] 166/6 Scotland [3] 53/20 119/24 120/2 Scott [1] 87/12 Scottish [1] 120/3 scratching [1] 75/20 screen [8] 2/15 45/25 106/3 106/9 114/11 137/19 143/15 151/4 screened [1] 77/23 scroll [1] 102/25 scrupulous [1] 144/1 scrutinise [1] 78/14 se [1] 52/4 second [22] 5/22 6/13 12/6 13/25 21/16 23/1 26/17 28/6 31/10 35/22 35/25 48/17	48/18 74/15 91/12 102/18 105/16 112/9 113/20 113/22 146/12 156/5 secondary [1] 24/14 seconder [1] 49/16 secondly [3] 68/23 87/7 144/11 secret [1] 59/17 secretary [5] 49/24 52/7 70/4 70/7 75/14 section [9] 19/17 22/22 66/10 67/21 68/19 70/1 81/15 81/22 128/12 section 251 [3] 66/10 68/19 70/1 sections [1] 43/6 sector [1] 126/2 secure [1] 163/20 securely [1] 61/5 see [77] 1/10 1/10 1/11 6/9 6/17 6/25 7/11 10/13 11/1 11/7 11/16 11/21 12/8 12/11 12/18 12/22 13/4 13/10 14/1 14/24 15/3 15/4 17/8 17/10 17/25 20/11 20/17 20/24 21/2 22/21 24/3 25/19 26/2 27/13 29/16 31/16 32/19 32/25 42/15 42/16 42/20 44/22 46/4 47/17 52/18 62/1 63/3 63/19 72/2 76/11 77/3 82/15 89/24 91/15 98/5 98/10 102/12 102/23 103/1 106/10 109/14 109/17 109/19 110/15 112/13 116/5 125/9 126/18 127/9 130/8 130/10 137/1 146/23 154/24 157/3 163/3 165/11 seeing [3] 71/25 87/20 98/14 seek [1] 43/19 seeking [4] 41/17 43/20 70/12 88/3 seem [2] 25/2 133/16 seemed [8] 27/2 27/8 40/3 75/16 124/7 124/20 139/22 147/5 seems [3] 47/20 91/15 108/20 seen [11] 14/10 39/2 39/3 51/24 62/15 63/7 65/21 65/24 80/18 101/14 153/6 selected [2] 81/8 119/19	selecting [1] 49/5 selection [5] 122/6 125/12 129/9 129/10 129/17 send [6] 13/18 14/6 14/15 23/22 25/18 146/5 sending [3] 64/10 67/17 78/13 sends [2] 49/13 71/20 senior [2] 122/11 140/13 sense [3] 89/25 154/17 165/12 sensible [1] 131/7 sensitive [2] 92/7 159/8 sensitivity [1] 125/10 sent [20] 14/3 14/11 15/2 15/17 17/15 19/24 30/10 31/17 33/12 33/19 41/25 63/2 65/17 75/12 86/24 142/9 147/23 151/6 152/6 152/8 sentence [4] 77/10 106/16 107/5 107/10 sentences [1] 103/2 separate [7] 68/21 68/25 73/4 86/16 88/22 106/6 112/23 separately [1] 41/5 September [14] 6/7 10/23 11/3 11/17 11/22 14/2 14/7 14/9 14/12 14/25 17/11 46/4 84/14 152/7 September 1991 [1] 46/4 September 1992 [1] 84/14 September 2006 [1] 152/7 series [4] 58/20 61/24 66/20 139/24 serious [3] 97/25 150/12 150/14 served [1] 53/18 service [9] 5/13 5/14 20/5 37/16 48/10 48/20 48/24 95/25 130/14 services [1] 12/15 set [18] 6/9 10/15 12/17 29/17 34/5 46/5 47/10 66/13 72/9 74/15 76/16 77/3 78/11 85/2 134/14 134/17 136/20 165/22 sets [2] 12/2 114/9 setting [1] 6/10 settled [1] 75/15	seven [2] 80/4 115/24 seventh [1] 115/24 seventies [1] 112/15 several [9] 7/6 23/3 36/23 55/1 57/3 68/11 82/3 147/16 160/15 severe [7] 79/4 80/17 106/18 137/7 139/8 155/12 165/5 severely [3] 80/17 103/15 108/19 severity [1] 81/6 shall [4] 86/19 87/15 101/14 131/18 shape [1] 147/21 share [1] 71/4 shared [2] 55/1 159/15 sharing [1] 61/6 she [7] 52/24 56/21 57/15 107/10 110/8 110/10 131/10 she's [1] 108/24 sheet [5] 11/14 11/24 13/18 91/16 122/14 sheets [1] 66/21 Sheffield [13] 48/4 101/20 102/23 104/9 112/20 119/8 120/25 121/25 132/11 133/19 144/10 144/16 157/7 short [8] 39/23 45/17 53/9 87/6 97/13 111/14 132/7 135/24 shortly [1] 51/9 should [57] 5/7 5/16 7/14 7/17 7/18 7/21 7/23 9/16 15/14 17/14 33/4 33/9 33/11 33/20 34/13 37/3 40/6 43/4 43/11 50/10 58/22 61/9 61/9 61/14 62/6 62/8 62/8 64/12 70/21 70/24 75/2 75/15 75/17 76/4 77/7 77/8 82/1 82/5 84/14 85/19 92/3 104/18 109/10 116/9 135/8 135/18 135/23 135/25 139/9 139/16 144/1 148/19 152/1 158/16 168/5 168/23 169/10 shouldn't [1] 16/23 show [6] 9/8 9/9 41/14 73/22 144/23 144/25 showed [5] 26/16 126/19 129/6 130/6 148/13 showing [3] 105/4 105/22 144/21 shows [2] 127/16 161/16
----------	--	--	--	---	---	---

(63) right... - shows

S	140/12 140/20 shuffled [1] 148/12 sic [1] 152/13 sickle [1] 128/22 sides [1] 101/14 sign [4] 42/8 146/6 146/7 146/7 significance [4] 23/12 24/10 24/21 114/8 significant [7] 3/4 78/6 97/22 97/24 111/12 111/16 111/16 significantly [3] 3/11 84/7 104/12 signified [1] 148/15 signs [3] 21/21 24/16 130/6 silence [2] 152/21 152/25 similar [4] 43/11 110/23 158/13 165/9 Similarly [3] 49/23 91/1 151/25 simple [1] 56/22 simply [2] 117/7 161/7 since [16] 28/10 29/1 29/10 50/1 50/2 56/6 59/3 69/3 70/23 72/10 81/19 91/2 101/5 103/18 105/2 106/20 single [9] 38/20 89/15 89/23 125/24 135/6 144/9 144/14 161/19 162/4 sir [11] 45/8 45/14 86/15 86/22 112/23 131/6 131/20 154/7 154/9 169/2 170/4 sit [1] 89/22 site [1] 140/7 sitting [1] 169/3 situation [10] 4/10 9/14 18/11 37/18 60/20 67/10 69/25 86/5 96/25 139/16 situations [3] 69/16 117/9 120/2 six [3] 10/18 49/3 115/24 six years [1] 49/3 skipping [1] 77/10 Skipton [10] 64/15 73/8 73/9 73/13 73/19 74/9 74/17 75/12 75/18 79/7 Skipton Fund [4] 73/8 73/9 75/12 75/18 slicing [1] 44/21 slight [1] 44/25 slightly [4] 48/1 98/11	140/12 140/20 slowed [1] 67/13 slower [1] 112/18 slowly [2] 148/5 167/5 small [9] 27/5 31/2 80/20 80/23 82/9 86/13 103/19 109/21 156/14 smaller [1] 110/16 sneaking [1] 124/16 so [253] Sobi [1] 55/15 societies [1] 50/21 society [12] 59/18 63/13 63/14 73/15 74/10 128/13 137/23 138/11 140/11 142/1 143/18 152/7 Society's [3] 138/17 138/20 139/2 soft [4] 127/14 128/5 129/7 129/7 software [2] 57/9 66/24 sold [1] 3/10 some [118] 1/15 2/8 2/24 3/16 4/1 6/5 8/3 10/20 15/13 15/17 18/13 19/10 20/21 26/18 26/18 27/3 28/9 28/10 28/14 29/19 29/20 30/15 30/23 31/13 37/21 38/1 39/19 40/11 46/20 51/10 51/24 52/1 58/15 59/6 65/20 65/25 69/1 69/23 74/2 75/13 75/24 77/24 79/14 79/24 80/2 80/3 82/23 85/5 85/8 85/11 85/25 86/12 87/3 88/19 89/4 89/16 89/17 90/6 92/17 92/25 93/11 95/3 98/23 99/9 100/17 100/24 101/17 111/2 114/13 119/11 124/6 124/17 124/18 126/18 127/4 128/3 131/6 131/18 132/21 133/7 133/10 137/6 138/12 138/17 139/16 141/7 144/10 144/19 145/9 148/7 151/10 152/21 153/19 153/19 154/8 154/11 154/17 155/17 155/23 157/9 157/9 157/10 157/10 158/2 158/8 159/5 159/14 160/16 160/21 160/22 161/7 162/20 163/6 165/20 166/10 166/19	166/21 167/12 somebody [3] 148/3 150/8 158/9 someone [6] 13/13 90/17 100/18 140/8 151/25 159/12 someone's [1] 100/22 something [22] 32/15 37/12 47/15 50/8 50/11 53/1 62/3 79/24 89/10 90/3 90/11 93/12 94/12 104/6 119/10 120/22 123/16 136/19 136/20 136/20 158/13 164/20 sometimes [13] 1/22 40/3 54/24 55/3 55/9 66/7 72/8 72/18 80/12 80/13 155/9 156/8 156/24 somewhat [1] 105/21 somewhere [1] 127/14 soon [2] 77/7 158/7 sorry [13] 35/15 47/14 49/10 104/4 108/14 118/22 122/15 129/3 129/4 131/2 148/23 158/23 158/24 sort [18] 29/12 29/13 38/21 44/15 55/21 59/12 67/24 80/14 93/5 99/9 110/25 118/1 136/15 137/14 152/21 161/24 166/12 167/12 sorting [1] 67/16 sorts [2] 65/14 134/16 sought [2] 64/2 141/1 Soumik [29] 2/15 4/14 6/4 10/24 11/12 13/22 19/18 20/25 21/10 22/19 26/3 32/18 35/20 41/16 42/14 42/19 45/25 71/9 73/6 76/15 77/1 82/14 91/11 102/19 106/5 106/12 137/21 146/12 148/24 soundproof [1] 159/11 source [6] 11/5 50/6 50/22 73/2 105/4 132/19 sourced [5] 17/17 23/3 30/25 31/1 31/24 sources [1] 134/7 spaced [1] 38/20 speak [2] 8/23 60/19 speaking [1] 157/4 speaks [1] 117/20 special [1] 7/20	specialist [1] 78/7 specific [14] 6/19 11/8 31/2 44/21 62/11 67/3 91/13 93/23 96/1 99/21 126/25 138/6 145/16 155/7 specifically [7] 42/5 44/23 45/4 82/21 91/23 124/1 143/1 specifics [1] 138/7 specimens [1] 43/8 spending [1] 148/9 spleen [3] 24/20 44/16 44/21 spoke [2] 16/15 141/5 sponsor [1] 134/4 sponsorship [6] 50/24 54/16 134/5 134/7 134/10 134/21 spontaneous [1] 75/1 Spooner [4] 52/6 52/7 57/14 102/12 sports [1] 137/10 spotted [1] 27/2 spreadsheets [2] 34/8 78/20 St [1] 48/5 staff [4] 1/16 15/10 24/4 52/8 staffed [1] 80/10 stage [6] 48/3 48/13 92/17 93/11 162/7 162/20 stages [2] 51/8 53/21 staggered [1] 164/16 stain [1] 44/21 stall [3] 50/24 134/14 134/17 Stallibrass [1] 52/22 standard [4] 44/18 44/18 74/18 90/3 standards [1] 46/7 start [12] 17/16 67/17 104/4 116/21 117/4 123/2 129/19 162/23 162/24 163/6 169/10 169/14 started [11] 3/18 18/9 56/16 59/1 69/19 70/23 97/8 137/16 162/21 163/9 165/4 starting [2] 60/13 109/2 starts [1] 1/6 State [3] 70/4 70/7 75/14 stated [1] 75/14 statement [20] 2/8 6/8 19/3 24/7 30/11 32/6 40/11 84/9 88/7 95/23 99/19 99/20 100/8 100/13 102/10 115/8	115/10 149/2 151/5 151/7 statements [1] 39/19 statistic [1] 103/9 statistical [2] 109/11 127/16 statisticians [1] 121/13 statistics [2] 46/11 108/18 status [6] 23/20 28/11 83/16 89/9 92/22 100/22 stepping [1] 136/21 steps [6] 10/15 19/5 85/1 134/20 160/17 160/18 Stevens [1] 73/12 sticky [1] 36/17 still [20] 3/1 16/25 21/21 43/12 49/12 67/16 70/17 70/20 73/4 74/11 81/4 100/19 111/5 112/10 114/20 122/24 131/6 134/4 165/20 168/15 stir [1] 20/21 stop [2] 106/13 162/6 stopped [2] 64/9 163/25 storage [1] 91/24 store [5] 92/12 92/14 92/24 93/15 165/18 stored [12] 88/21 91/10 91/20 92/1 92/2 92/5 93/2 94/9 94/21 95/1 95/2 106/6 storing [1] 93/7 straight [1] 3/8 strange [1] 13/9 strategic [3] 161/20 161/24 162/3 strategy [1] 161/23 stream [1] 53/10 street [2] 60/16 60/17 strengthened [1] 22/11 strong [2] 10/13 138/16 strongest [1] 119/14 strongly [4] 14/21 68/20 83/3 84/12 struck [2] 5/4 67/11 student [1] 108/9 studied [1] 117/23 studies [6] 40/21 40/25 105/4 114/21 116/7 126/23 study [30] 40/12 41/11 41/21 42/16 42/21 42/24 43/7 43/17 44/8 45/7	103/25 115/9 115/14 115/17 115/19 115/24 116/2 116/3 116/10 116/15 116/18 116/20 116/23 116/24 117/25 118/10 119/24 120/12 120/16 160/4 subconscious [2] 119/12 119/13 subject [4] 73/5 84/17 126/7 127/15 subjected [1] 125/9 subjects [1] 119/18 submission [2] 41/8 106/8 submit [1] 30/5 submitted [6] 56/8 68/25 69/25 76/11 87/13 92/9 subsequent [1] 57/7 subsequently [10] 4/22 6/12 20/3 48/16 48/22 62/13 70/3 77/13 81/25 127/2 substantial [1] 3/17 succeed [2] 139/5 139/22 success [1] 139/4 successful [2] 159/24 160/8 such [16] 18/10 43/14 47/22 56/3 71/16 77/20 81/5 83/5 96/7 97/13 116/16 119/19 139/19 145/22 149/9 164/7 suddenly [1] 155/6 sue [1] 148/20 suffer [1] 13/7 suffered [2] 151/15 153/21 suffering [4] 106/18 107/16 140/23 154/2 sufficient [1] 71/22 suggest [1] 2/13 suggested [4] 64/11 68/21 104/18 141/6 suggesting [1] 36/21 suggestion [2] 141/9 153/4 suing [1] 141/2 sum [1] 72/12 summarise [1] 90/13 summary [4] 30/6 58/22 58/23 106/15 summing [1] 160/20 summoned [1] 58/4 superfluous [1] 22/17 supplement [1] 84/25 supplied [4] 5/12 5/15 145/15 154/17 supplier [4] 145/15
----------	---	--	---	---	--	---

(64) shuffled - supplier

S	140/5 sympathy [1] 139/12 symptoms [2] 13/9 24/16 system [8] 57/11 119/25 122/21 123/13 123/19 159/9 162/25 163/13 systematically [1] 78/9 systems [1] 121/3	90/20 90/23 96/7 96/16 97/3 99/24 113/24 141/5 145/7 159/8 telling [2] 26/19 95/14 tells [6] 2/8 2/24 6/8 19/3 21/3 72/19 template [1] 25/15 ten [6] 38/20 87/18 87/19 106/25 130/2 169/15 ten minutes [1] 87/18 ten o'clock [1] 169/15 tend [1] 89/3 tendency [1] 136/13 tenders [1] 166/5 tenfold [1] 129/6 tens [1] 39/2 term [1] 167/8 terms [24] 11/5 12/23 30/17 34/6 34/24 35/5 35/6 35/11 49/1 49/10 69/23 83/1 88/16 89/12 90/16 105/20 121/1 122/6 126/14 138/25 142/11 143/4 153/11 154/21 test [42] 9/17 9/18 18/11 74/17 83/22 89/15 89/16 89/23 90/25 91/5 91/7 93/11 93/20 93/25 94/10 95/6 95/7 95/8 95/9 95/25 96/16 97/4 97/8 97/10 97/19 98/22 99/12 99/17 99/25 100/11 101/9 101/11 116/16 125/20 126/25 128/10 130/8 130/10 157/6 158/5 158/5 158/18 tested [29] 13/8 76/19 76/24 77/7 77/8 77/15 82/5 83/19 83/22 84/4 84/10 84/14 86/3 86/4 86/12 90/10 91/19 94/16 98/17 98/18 98/20 100/15 100/17 101/1 101/10 101/15 124/22 125/24 155/8 testing [33] 73/25 75/5 76/25 80/23 81/4 82/4 91/14 91/25 92/6 92/17 92/22 93/19 94/3 94/12 94/14 94/20 95/5 95/23 96/1 96/2 96/2 97/1 97/3 97/7 97/9 98/4 99/21 100/3 100/5 100/14 124/24 130/15 168/20 tests [18] 42/6 89/13 89/17 89/17 90/4	90/16 90/21 90/23 96/5 96/6 96/8 96/9 98/6 98/7 98/12 100/4 125/3 125/10 textbook [1] 56/19 textbooks [1] 133/3 than [45] 5/1 16/2 30/25 31/9 38/8 49/14 49/15 50/14 54/12 64/11 72/5 72/8 74/17 79/17 83/6 84/9 88/13 89/18 98/4 99/3 108/20 108/21 111/9 112/18 113/25 115/5 116/4 119/2 120/13 122/23 124/21 128/1 129/23 131/4 135/20 151/1 152/15 153/24 154/23 154/25 155/3 160/2 160/11 163/7 166/13 thank [22] 45/14 77/2 87/21 95/19 102/25 103/12 107/18 109/13 115/1 131/5 141/16 155/13 155/19 156/4 158/20 159/16 167/18 168/11 168/22 168/24 169/14 169/15 thanked [1] 26/19 that [881] that I [11] 25/3 45/6 57/11 62/11 64/16 68/12 72/3 112/6 141/17 159/10 159/14 that I dealt [1] 141/12 that is [18] 2/19 55/14 58/23 59/23 72/2 72/9 72/13 96/11 108/7 112/22 117/24 119/23 121/7 121/16 121/18 125/1 134/6 146/6 that it [1] 5/15 that's [58] 1/20 2/12 5/24 9/12 13/6 13/11 13/11 16/7 17/22 18/9 26/1 30/7 35/15 43/23 44/9 49/10 52/2 54/3 55/21 55/22 62/21 64/1 82/15 85/24 89/23 92/16 93/16 94/24 95/15 98/9 100/16 102/5 102/25 106/21 107/4 107/6 114/15 116/17 116/23 117/20 117/21 117/24 119/4 122/2 124/4 125/14 126/17 130/24 131/5 131/15 136/2 138/16 144/11 145/18 151/3 156/3 166/23 168/21	their [98] 3/16 7/9 14/15 18/21 20/8 20/17 25/24 28/11 28/13 29/4 32/7 33/9 34/8 34/14 38/15 39/6 39/7 43/5 43/19 49/21 55/4 55/6 55/16 55/18 56/7 60/7 60/12 61/23 62/25 63/9 63/9 64/16 65/13 65/16 65/17 67/20 67/24 68/8 69/1 70/4 70/18 70/20 71/22 72/17 72/22 72/24 74/12 75/21 78/1 80/6 80/12 80/19 81/6 84/16 89/9 94/6 97/18 100/18 109/12 111/7 112/17 116/5 124/3 130/21 132/19 132/21 133/19 133/20 134/23 136/13 138/14 139/12 139/14 140/22 140/22 141/2 142/3 143/11 144/3 145/4 146/1 147/10 147/11 147/19 148/1 149/18 150/1 150/10 151/14 151/17 152/12 153/22 153/23 155/24 157/5 162/6 164/10 166/4 them [114] 3/3 3/4 4/4 8/14 12/10 14/11 16/16 16/21 17/4 18/12 19/1 19/2 22/23 24/6 25/23 26/14 26/19 26/20 27/8 29/3 31/15 37/6 38/1 53/17 55/5 55/7 56/9 57/20 58/13 60/20 62/4 62/9 64/2 64/6 64/12 65/10 65/20 65/23 66/3 66/6 66/23 67/5 68/5 68/12 69/3 71/14 71/19 71/20 71/22 72/6 72/19 78/13 78/21 78/21 79/6 80/8 80/14 81/1 85/16 86/4 89/8 89/9 89/20 90/18 90/19 90/20 90/23 91/5 91/5 91/6 92/8 93/16 94/18 96/16 96/17 96/20 97/3 98/19 98/24 98/25 99/5 99/11 100/23 120/5 120/11 123/2 127/9 128/21 130/10 130/11 136/16 136/18 138/13 146/6 147/11 147/23 147/24 148/4 148/8 148/8 148/12 148/12 151/16 153/5 153/19 156/10 157/18	157/19 159/13 160/24 162/6 163/9 164/9 166/3 thematic [1] 115/6 themselves [4] 38/19 75/22 84/15 132/14 then [160] 2/23 3/17 4/11 5/22 6/4 6/16 6/18 6/25 7/2 7/11 7/24 8/5 11/6 11/12 11/21 12/1 12/6 12/13 12/17 12/21 12/21 13/2 13/4 13/14 13/22 14/4 14/7 15/4 15/9 15/20 16/17 17/14 17/22 17/25 19/18 20/10 20/18 20/24 21/2 21/10 21/20 22/18 22/18 23/1 23/7 23/12 23/18 23/20 23/25 24/3 26/2 27/10 28/6 29/3 29/10 29/16 30/12 31/17 32/16 33/12 33/19 34/6 34/11 34/20 34/24 35/11 35/22 36/6 40/23 41/15 42/3 42/7 47/9 47/17 49/16 49/19 49/21 52/9 53/6 56/17 57/7 57/15 58/6 58/19 59/10 61/8 63/1 66/8 69/12 69/19 69/22 73/14 74/15 74/20 76/7 76/23 77/1 77/10 77/13 77/14 78/5 78/11 78/14 78/17 78/18 83/1 83/14 83/24 84/12 85/18 87/7 87/20 89/19 90/5 91/18 91/20 93/15 95/8 95/22 96/3 99/11 100/12 100/25 101/17 103/7 103/22 107/21 107/24 109/3 109/14 110/14 113/10 118/3 120/22 121/16 123/3 124/21 126/12 127/8 130/18 131/8 133/15 133/23 135/25 137/19 138/6 138/9 139/23 146/16 147/12 148/12 148/15 149/14 152/9 155/15 155/25 162/20 163/10 165/15 169/11 theoretical [4] 6/2 10/2 18/16 24/22 theory [2] 94/10 121/19 therapeutic [1] 105/20 therapy [14] 105/18
----------	---	--	---	--	---

(65) supplier... - therapy

T	67/1 67/20 71/7 103/22 112/10 113/12 131/20 159/6 165/20 167/13 thereafter [1] 127/10 therefore [8] 7/7 21/4 22/3 64/24 75/2 78/2 90/6 163/18 these [53] 1/20 3/3 5/10 5/12 7/14 7/17 7/18 7/22 7/25 8/10 20/8 20/12 20/17 23/21 25/9 31/23 33/19 35/3 38/25 41/3 42/12 53/6 54/9 60/11 62/20 74/13 75/14 75/25 78/8 82/1 82/4 85/5 85/10 85/14 85/22 86/7 86/10 98/23 105/7 105/15 111/11 112/7 114/8 114/21 126/3 127/3 135/1 138/25 142/21 147/17 147/25 148/7 167/17 they [298] they'd [12] 16/4 16/13 17/5 18/4 76/21 80/5 96/5 98/18 127/8 145/12 145/16 157/14 they'll [1] 89/15 they're [18] 15/11 50/21 54/6 63/7 80/18 89/15 98/25 100/4 113/21 114/10 122/22 125/23 126/5 131/17 136/18 145/23 162/9 166/1 they've [7] 49/23 62/7 63/8 86/3 87/13 98/11 153/11 thick [1] 147/17 thing [23] 5/9 14/20 29/13 34/25 34/25 40/5 64/2 64/19 67/5 67/15 79/16 94/5 104/16 105/14 120/10 120/18 120/21 125/14 137/14 138/10 150/25 156/5 161/6 things [17] 1/5 9/22 10/17 49/7 57/12 59/8 62/21 67/16 79/5 81/1 97/19 105/7 137/15 151/20 154/11 155/16 166/7 think [128] 3/16 4/11 5/17 15/6 16/7 16/10 16/14 20/24 24/5 25/3 25/4 28/1 30/8 32/14 34/16 34/21 35/16 35/18 37/21 38/3 40/1	44/9 45/1 48/2 48/4 48/11 48/13 49/6 49/7 49/11 51/23 53/2 53/19 53/23 56/19 58/23 58/23 59/4 59/16 59/16 59/20 59/22 59/23 65/3 69/1 70/23 72/4 72/4 72/9 72/25 75/13 75/23 80/10 82/8 85/4 86/9 88/9 88/21 89/25 90/14 92/21 92/24 94/21 94/23 94/24 94/25 96/15 96/21 98/2 99/2 99/12 100/7 101/2 103/11 104/25 107/4 107/8 108/1 108/7 108/23 109/9 109/22 110/8 110/13 110/20 110/24 112/6 112/19 113/2 113/4 114/13 114/15 115/15 116/4 119/4 119/6 122/2 123/5 124/1 126/7 128/6 131/7 131/19 132/23 133/22 134/24 135/3 136/2 140/19 141/9 144/18 147/12 150/17 150/24 152/16 152/20 152/22 153/9 153/23 157/23 158/15 159/8 159/14 160/6 160/20 162/18 168/4 169/6 thinking [1] 17/7 third [10] 7/4 11/7 18/20 21/4 21/19 42/19 61/6 76/15 79/25 152/10 this [288] Thomas' [1] 48/5 those [62] 1/9 1/12 2/10 3/22 7/13 8/13 8/16 8/18 8/25 10/7 12/17 12/25 14/15 15/22 19/11 20/19 23/23 24/6 31/9 31/15 39/9 46/16 52/8 61/11 70/2 77/11 78/14 81/11 83/21 84/5 84/7 86/13 87/13 89/8 91/25 97/18 97/19 103/17 108/16 109/10 111/22 113/13 120/2 124/25 125/20 129/7 130/9 131/23 135/15 143/3 146/1 154/7 155/15 156/17 158/4 158/8 159/22 165/10 166/10 167/18 168/5 169/9 though [12] 1/21	70/17 73/22 74/1 74/3 76/3 104/25 135/3 139/10 140/12 147/12 164/3 thought [11] 18/18 65/8 72/4 72/25 98/19 126/22 156/15 157/6 159/3 159/9 160/2 threat [5] 163/10 163/12 164/11 168/14 168/15 threatened [1] 57/25 threatening [1] 37/16 three [11] 7/2 37/13 37/15 49/2 60/17 79/13 81/17 93/15 148/10 160/5 169/12 three years [2] 81/17 93/15 three-quarters [3] 37/13 37/15 148/10 threshold [1] 7/8 thrombin [1] 17/18 Thrombosis [2] 105/10 133/2 thrombotic [1] 46/16 through [42] 4/25 5/13 6/1 8/8 11/8 18/17 20/5 20/11 20/18 24/5 29/23 34/4 37/17 38/13 39/19 42/17 53/5 53/9 58/20 67/16 69/16 77/22 92/8 93/18 100/20 118/25 120/6 124/16 124/24 125/7 125/8 135/1 146/17 146/25 147/2 148/8 148/11 148/12 151/22 153/11 154/2 154/12 throughout [4] 47/3 62/2 119/14 121/6 Thursday [1] 1/1 thus [4] 77/21 83/21 96/17 108/20 tightened [1] 59/8 time [88] 8/10 10/21 14/16 15/1 15/12 16/6 20/7 23/14 26/23 28/20 30/21 34/16 38/16 45/8 46/20 48/10 48/10 49/25 50/15 52/7 53/3 53/9 56/14 59/23 60/3 60/25 61/12 62/3 62/17 64/4 66/6 74/6 81/19 86/15 89/4 89/23 100/17 101/3 101/7 101/22 105/5 108/4 108/9 111/14 112/4 114/12 119/8 121/2 121/4 122/9	122/19 124/25 125/18 125/19 125/21 125/24 126/13 129/22 130/2 130/21 130/23 131/7 131/18 132/24 133/7 133/22 133/24 139/14 142/18 142/19 142/20 142/25 144/6 144/8 145/11 146/16 146/20 147/7 148/10 148/13 157/23 158/1 159/9 159/23 160/17 163/1 168/1 168/9 timed [1] 14/2 timely [1] 52/16 times [3] 36/23 90/4 154/24 timescale [1] 80/1 timing [3] 14/1 14/17 26/11 tiny [2] 44/15 85/13 tissue [3] 36/11 44/12 88/22 title [1] 70/5 to [1143] today [2] 1/9 169/3 together [4] 71/21 80/14 80/19 139/20 token [1] 94/21 told [27] 6/13 7/4 18/13 18/22 23/18 31/13 31/19 34/13 59/21 65/23 66/6 80/8 95/11 99/10 100/15 101/10 132/10 139/18 140/15 142/22 145/23 158/5 158/17 159/5 160/3 164/9 164/14 tomorrow [1] 70/9 tone [1] 151/7 too [3] 38/25 126/2 162/5 took [16] 3/20 29/2 34/16 43/23 46/23 51/6 52/2 52/10 56/21 60/25 104/25 116/3 135/16 142/25 148/13 168/20 toolkit [1] 15/5 Tooting [1] 20/5 top [6] 13/10 21/11 29/16 78/5 84/8 108/17 topic [9] 40/9 45/9 86/16 112/24 115/5 115/5 122/15 123/3 137/20 total [4] 29/21 43/2 113/10 165/8 towards [6] 30/18 54/13 69/20 105/22 138/2 140/5	trace [9] 7/18 8/12 19/7 20/7 85/5 85/11 85/19 85/21 144/12 traced [5] 7/14 7/25 19/4 29/15 130/18 tracing [2] 6/10 19/15 tracking [1] 43/8 trade [1] 50/5 trading [1] 50/20 training [1] 128/18 trait [1] 128/22 transferred [1] 56/13 transfusion [17] 4/18 4/25 5/13 5/14 6/1 8/8 12/5 12/6 18/16 20/5 21/7 22/13 107/2 127/5 128/18 128/23 130/14 transfusions [2] 9/23 130/1 transitional [1] 113/21 transmission [8] 6/1 18/15 18/17 21/25 25/11 36/12 38/13 86/20 transmit [1] 36/13 transmitted [6] 4/18 4/25 8/8 12/15 22/12 161/2 transmitting [1] 124/19 transparent [1] 152/24 treasurer [1] 49/24 treat [1] 31/9 treated [24] 23/2 23/16 25/20 30/25 31/23 73/23 74/22 77/5 78/7 79/13 83/5 83/12 84/5 91/4 98/15 111/5 112/11 113/20 120/7 122/3 139/10 145/13 145/16 147/5 treatment [46] 9/18 9/21 18/12 31/11 33/10 46/15 74/7 76/21 76/25 78/2 79/2 79/22 81/6 82/19 83/4 83/15 83/18 84/1 84/16 99/6 100/18 101/4 102/3 102/13 106/25 107/15 107/24 111/8 114/1 114/5 117/12 119/1 119/3 132/14 132/14 133/16 133/20 134/23 136/9 139/14 144/23 154/4 155/17 158/25 165/2 165/3 Treloar [2] 47/23 133/6
----------	--	---	---	---	---

T	U				
trend [1] 105/22	UK [16] 12/15 16/20	106/15	Unlike [1] 100/10	130/25 132/10 141/2	21/22 22/1 22/24 23/6
trial [16] 118/7 118/14	17/17 22/23 23/3 31/1	understand [30] 5/20	unlikely [2] 119/4	141/3 148/17 148/20	23/9 23/14 23/19
119/16 119/16 119/19	32/22 47/6 48/9 56/19	15/23 21/15 22/6	139/22	158/6 163/6 164/9	23/24 27/17 31/22
119/23 119/23 121/7	56/24 57/18 61/18	25/23 29/24 32/5 42/9	unopposed [1] 49/19	164/14 168/7 168/11	32/1 32/22 33/5 35/25
121/15 121/17 121/24	102/3 125/17 128/2	78/17 84/19 88/4	unquestionably [3]	168/13 168/21	38/14 40/9 40/11
121/25 122/2 122/5	UK-sourced [1] 31/1	88/14 94/4 95/17	107/19 107/20 116/18	US-sourced [1] 30/25	40/22 41/20 42/6
122/16 122/16	UKHCDO [61] 2/20	96/13 100/6 114/7	unrelated [1] 23/9	use [19] 3/3 3/22	42/16 168/14
trials [1] 122/23	UKHCDO [61] 2/20	130/7 130/20 130/22	unrestricted [6] 53/5	15/16 36/16 37/4	verbal [1] 88/12
tried [3] 40/2 152/23	3/14 8/6 10/15 14/13	131/2 132/24 145/19	53/23 54/4 54/5 54/7	39/12 52/18 54/8 55/6	verified [1] 33/20
157/1	14/24 15/25 16/9	146/18 151/10 151/15	54/24	63/4 69/21 88/18	very [86] 3/23 9/14
triggered [4] 5/20	19/25 21/14 21/15	151/18 154/7 159/15	unsure [1] 9/21	95/18 104/19 105/8	10/4 17/12 18/16
21/6 24/8 58/19	24/9 26/2 28/19 29/7	162/10	untested [3] 77/11	110/12 110/22 166/7	18/25 27/1 27/6 27/7
trivial [1] 136/21	31/18 32/21 33/24	understandable [1]	78/24 82/7	167/15	31/1 44/21 50/4 50/18
trouble [4] 36/2 36/8	35/13 43/3 45/22	81/10	until [11] 3/18 5/25	used [19] 5/5 6/20 9/3	50/20 51/8 51/12
50/14 137/13	45/23 46/18 47/11	understandably [2]	69/13 86/18 98/13	31/8 36/15 36/22 37/1	52/15 52/24 56/25
true [4] 84/6 113/15	49/1 49/25 50/3 51/3	157/17 157/20	100/11 105/23 108/24	37/6 38/15 55/5 57/11	59/1 60/25 62/15 65/2
131/16 153/9	51/21 51/22 54/14	understanding [14]	112/16 130/15 169/18	109/2 109/3 120/3	65/14 68/3 75/25 76/2
truly [1] 163/14	56/1 63/15 67/20 68/8	37/23 43/21 43/23	unusable [1] 156/2	120/5 123/16 160/6	80/18 82/8 85/10
Truro [1] 47/23	70/9 74/6 74/10 76/12	88/4 88/17 90/6 95/10	unusual [5] 9/14	166/15 166/24	85/11 86/13 92/21
trust [1] 150/10	81/22 82/2 82/10	96/23 100/6 100/16	18/10 92/13 139/7	useful [8] 53/12 55/7	94/13 94/15 95/19
trusts [2] 14/4 75/7	85/24 86/6 92/20 93/1	108/8 143/10 143/12	155/4	65/14 66/18 72/8	97/23 99/1 100/21
truth [2] 153/1 153/2	109/11 115/18 123/13	160/1	unusually [1] 111/7	103/9 128/21 164/25	100/24 101/4 101/4
try [6] 72/16 80/8	123/17 123/21 132/21	understands [1]	up [58] 2/3 5/25 6/9	uses [2] 60/6 88/19	105/6 106/16 106/20
120/18 134/21 142/7	133/24 133/25 134/3	106/17	18/19 19/12 20/21	using [16] 3/2 3/19	108/5 109/24 114/3
148/3	134/20 134/24 135/4	understands it [1]	23/13 25/23 26/13	4/8 6/12 23/5 30/19	114/3 114/13 114/23
trying [11] 20/21 69/5	152/9 152/12 165/23	106/17	27/10 28/16 28/24	31/2 37/9 43/14 44/21	118/12 125/12 127/21
72/22 86/7 89/21	UKHCDO's [4] 51/24	understatement [1]	29/8 30/8 30/9 35/17	55/19 78/12 94/5	131/5 133/17 134/4
126/23 130/7 130/22	57/5 69/22 71/12	150/20	44/17 44/21 44/25	94/11 133/20 165/6	134/15 135/8 136/14
146/22 146/23 148/19	ultimate [1] 8/12	undertake [1] 51/22	52/12 58/3 59/8 60/1	usual [2] 45/12	138/1 138/20 140/5
TTI [1] 5/7	um [2] 128/24 135/18	undertaken [4] 17/23	65/25 66/13 66/15	146/25	141/22 150/22 151/16
Tuesday [3] 169/6	unable [2] 132/18	41/22 42/12 78/19	68/15 77/13 77/17	usually [3] 85/9	153/15 154/20 156/2
169/15 169/18	148/12	undertaking [3] 98/22	77/21 80/11 82/15	156/25 164/15	157/13 157/15 157/17
turn [3] 75/20 77/1	unaware [2] 77/25	118/24 119/10	82/25 84/6 86/1 86/10	V	157/17 157/20 160/24
158/11	112/15	unethical [4] 119/5	86/13 90/14 91/3	vague [1] 138/21	163/17 164/1 164/1
turned [4] 30/24 32/9	uncertain [2] 12/14	119/10 121/17 121/22	96/20 98/16 104/22	valuable [1] 168/21	164/25 166/6 167/18
130/17 160/10	24/11	unfolded [1] 9/23	106/20 106/21 108/24	valuable [1] 168/21	167/25 168/11 168/21
turning [1] 162/6	uncertainties [2] 7/5	unfortunate [2] 65/18	118/18 134/14 134/17	variable [1] 154/6	168/22 169/15
twice [2] 64/7 101/10	25/8	78/25	135/10 143/22 148/4	variables [1] 38/18	vice [2] 15/1 49/24
two [40] 20/2 20/12	uncertainty [2]	Unfortunately [3] 26/8	152/10 153/12 153/21	variant [15] 8/11 9/24	vice-chairman [1]
23/13 31/3 38/20	158/16 159/1	79/23 146/14	160/20 162/7 162/21	10/3 12/1 16/22 18/15	49/24
40/23 41/14 68/21	unconditional [1]	unheated [3] 155/17	168/1	22/11 24/12 24/24	video [1] 159/14
68/25 69/25 79/13	54/5	155/20 155/24	up-to-date [1] 25/23	27/22 35/9 36/13 39/2	view [9] 20/22 94/24
86/21 87/19 89/25	unconscious [2]	unique [2] 64/5 66/24	update [1] 27/13	39/16 123/11	112/19 138/17 138/19
90/24 97/8 103/2	119/12 119/13	uniquely [1] 100/10	updating [1] 36/6	variant CJD [4] 12/1	139/3 143/6 152/13
105/15 105/21 110/17	uncontroversial [1]	unit [7] 43/6 43/25	upgraded [1] 57/9	27/22 35/9 123/11	153/15
111/11 112/7 113/13	150/24	144/14 164/17 165/9	upload [1] 67/5	varied [4] 26/18	viewed [1] 103/17
113/19 114/9 114/16	under [17] 1/7 1/18	165/13 165/25	upon [3] 6/14 111/24	127/22 127/25 164/18	views [1] 118/12
114/21 114/22 114/24	12/22 14/1 35/25	United [3] 46/2 48/13	156/12	variety [1] 161/20	VIII [18] 23/4 23/11
117/12 120/7 120/9	42/20 51/6 56/16 60/7	102/16	upset [1] 153/12	various [17] 2/5 5/4	33/3 35/7 55/2 55/16
135/11 140/3 142/24	60/11 66/10 72/17	United Kingdom [3]	urgency [1] 14/23	6/16 11/25 51/18 53/5	107/14 108/21 108/25
144/8 148/23 151/6	83/3 102/19 102/24	46/2 48/13 102/16	urgent [2] 15/4 34/21	53/14 53/23 58/10	110/1 110/6 114/17
156/17 164/4	136/10 141/21	units [3] 29/21 55/18	us [50] 2/8 2/10 6/8	58/21 69/16 73/8 79/4	114/18 116/16 144/14
two pages [1] 38/20	under-reporting [1]	165/6	8/4 16/8 19/3 21/3	134/18 140/1 141/11	163/19 164/17 165/6
two weeks [1] 90/24	83/3	universal [2] 100/25	24/7 26/14 29/7 30/25	166/19	vine [1] 52/11
type [3] 37/8 38/20	undergoing [1] 127/3	153/15	31/12 40/19 53/13	vary [3] 26/20 128/4	viraemia [1] 158/12
71/19	underline [1] 78/18	universally [2] 2/14	53/16 55/3 63/23	134/19	viral [5] 3/24 89/7
type 3 [1] 37/8	underlined [1] 85/3	153/8	64/10 64/11 65/7	vCJD [44] 2/4 2/5 4/22	111/25 160/17 160/19
types [2] 9/1 120/1	underlying [2] 6/23	unknown [4] 78/6	66/19 67/9 67/17	5/17 5/21 6/13 6/21	virally [1] 124/19
typically [1] 98/21	7/5	93/8 93/10 118/11	67/24 68/7 68/20 75/9	7/10 7/15 11/4 12/4	virology [1] 93/14
	undermines [1] 3/11	unless [5] 83/11	75/20 78/18 79/11	12/6 12/14 13/7 14/13	virtually [2] 168/1
	underneath [1]	84/10 89/18 100/4	79/23 81/13 83/18	16/2 17/21 19/22 20/4	168/23
		145/22	83/22 87/14 109/8	20/24 21/7 21/18	virus [3] 158/7 159/20

V	91/9 95/5 99/18 115/18 116/22 118/13 119/20 120/4 120/8 120/10 120/15 121/20 126/25 136/17 138/5 138/15 139/7 141/7 144/11 150/1 151/20 151/25 157/20 158/9 161/18 164/7 164/8 164/24 166/5 167/1 168/3 168/5 ways [4] 64/22 65/14 134/18 168/25 we [461] we'd [4] 21/5 65/18 116/1 163/24 we'll [13] 11/24 24/25 25/16 35/22 45/11 82/10 87/17 102/23 106/10 132/1 152/4 152/4 168/8 we're [22] 1/7 6/5 6/13 7/4 10/25 23/18 44/20 70/24 70/25 71/1 87/16 89/16 90/20 99/24 107/23 109/18 113/8 115/4 164/23 165/9 167/25 169/3 we've [9] 10/24 14/10 42/22 47/18 56/6 72/10 96/20 161/10 165/1 weaknesses [1] 119/17 wear [1] 1/19 website [7] 36/7 63/12 63/13 63/14 63/15 63/17 63/18 week [6] 14/20 70/19 169/3 169/4 169/5 169/13 weeks [1] 90/24 weird [1] 70/5 welcome [2] 55/22 153/16 welcomed [1] 153/8 well [105] 3/16 5/4 8/7 16/21 24/10 26/18 28/23 32/11 34/8 35/17 36/10 38/7 44/9 47/15 48/8 50/4 50/18 52/25 54/24 56/14 59/17 69/25 75/12 78/20 80/18 82/6 85/4 87/15 88/21 89/4 89/16 91/8 92/6 93/14 95/16 95/17 96/19 96/21 98/23 99/24 100/2 100/16 104/4 104/10 110/8 110/13 111/2 111/18 111/21 112/6 114/11 115/25	117/20 118/20 119/13 119/23 121/5 122/8 125/8 126/17 126/22 128/16 129/18 130/8 130/13 131/25 132/25 134/3 135/18 136/12 136/12 136/14 137/17 139/2 142/9 142/18 142/18 143/5 143/7 143/7 144/13 144/19 145/11 146/20 150/3 152/4 152/17 152/19 153/5 155/22 155/24 157/1 157/12 159/5 160/24 160/24 161/18 162/12 162/16 164/3 166/14 167/13 167/18 167/24 168/25 well established [1] 110/13 went [10] 4/10 23/5 57/12 63/3 64/16 67/8 130/18 148/7 154/2 160/17 were [246] weren't [9] 20/13 59/17 81/18 108/4 116/19 136/1 146/24 147/15 153/1 what [131] 1/20 5/2 6/25 8/5 12/1 12/3 12/12 12/22 13/8 18/18 19/5 20/15 24/8 27/18 27/20 28/18 28/20 30/1 30/4 30/4 30/14 30/15 32/16 33/16 34/6 36/8 39/5 44/22 45/3 46/4 47/21 49/4 49/12 49/20 49/21 50/16 52/25 54/4 54/14 54/22 56/11 57/21 58/16 58/21 60/2 60/2 61/8 62/8 65/22 69/6 69/10 69/12 69/22 70/24 70/25 71/17 71/19 72/6 75/9 75/19 76/21 77/3 79/12 84/16 85/1 86/7 87/15 89/5 89/8 89/11 89/21 89/24 90/16 91/4 91/17 91/21 92/2 93/6 93/7 95/6 96/10 96/21 98/20 99/9 101/19 104/3 105/22 109/9 110/8 113/13 114/9 114/11 118/16 119/2 119/9 120/4 120/18 121/2 122/6 127/9 130/10 134/9 134/20 135/20 136/8 138/24 139/2 140/15 142/3	142/5 143/2 143/20 146/10 146/18 147/15 148/8 148/13 148/14 150/8 150/20 153/2 153/11 155/24 158/5 160/20 164/24 165/23 166/12 167/7 168/12 168/16 what's [4] 12/2 142/8 142/15 162/6 whatever [7] 25/8 75/17 84/17 94/2 99/6 116/12 161/11 whatsoever [2] 150/10 151/24 when [66] 1/22 16/15 18/3 23/8 26/25 29/1 30/15 38/3 38/12 39/4 40/3 45/4 46/25 50/8 52/2 52/10 56/21 61/2 62/9 63/2 67/11 85/25 93/10 96/20 97/9 101/23 104/3 104/7 105/24 106/25 107/6 107/25 110/5 110/14 112/10 113/19 114/12 116/22 120/24 122/9 122/24 123/5 124/13 125/1 128/18 131/16 133/15 140/13 147/20 148/19 150/8 152/25 153/4 155/22 156/6 157/4 157/15 162/7 162/22 162/23 162/23 162/24 163/25 164/16 165/4 166/11 where [22] 39/20 39/22 42/1 43/12 60/18 66/15 72/2 90/2 90/10 90/14 91/19 92/1 95/6 115/8 116/7 117/5 117/11 134/17 139/16 139/24 159/11 161/4 whereby [3] 61/21 81/4 129/12 Wherever [1] 43/4 whether [30] 3/12 9/19 12/14 16/4 16/8 16/9 16/11 16/13 16/17 17/4 17/20 19/13 36/18 41/6 42/4 44/4 55/17 55/18 55/25 64/1 65/8 69/23 76/20 98/18 102/20 116/24 123/12 150/23 164/10 168/8 which [141] 1/8 1/11 1/18 1/22 2/21 3/4 6/8 6/15 9/9 9/17 10/14 10/18 13/6 14/19 15/6 17/1 20/2 25/5 25/16	25/20 27/25 29/4 29/14 33/1 34/1 34/9 37/9 44/7 46/16 47/10 47/24 48/11 48/18 50/7 52/19 53/7 53/8 53/17 53/19 54/10 55/7 55/11 59/11 60/6 60/16 60/23 64/9 64/14 64/22 65/5 65/24 66/11 66/21 66/23 66/23 67/4 68/19 68/22 68/23 70/10 70/11 72/1 72/20 72/23 75/10 75/16 75/16 78/16 78/25 81/16 81/21 81/22 86/25 88/20 90/3 92/3 92/12 94/1 96/6 99/18 100/10 102/6 104/15 104/18 105/1 105/9 105/17 109/20 109/21 111/2 113/3 114/2 115/19 117/10 117/17 119/14 123/5 123/19 124/7 125/4 126/20 127/16 128/9 128/14 130/4 130/21 130/25 130/25 133/2 133/8 133/14 133/25 134/22 136/17 139/4 140/2 141/20 141/22 142/24 144/11 145/15 146/5 146/21 151/6 151/8 151/8 152/21 156/12 157/21 160/21 160/25 161/20 163/5 165/1 165/17 165/18 165/24 166/25 167/1 168/14 169/6 while [1] 148/5 whilst [7] 81/10 97/2 97/24 109/18 111/6 137/3 139/18 who [82] 1/9 1/12 1/13 4/21 6/12 6/16 7/13 8/13 8/16 8/18 12/4 12/24 12/25 16/24 18/19 19/11 19/16 20/3 23/5 28/12 28/17 30/23 32/21 33/3 33/8 34/2 34/13 35/7 37/8 39/10 40/6 52/7 56/17 57/10 57/14 59/21 63/23 65/12 65/13 66/17 66/17 68/14 68/15 69/7 75/19 76/23 78/24 79/20 80/11 80/11 80/21 83/19 83/21 84/3 86/12 87/8 90/2 90/9 91/3 91/4 98/16 103/3 124/23 124/25 125/23	126/4 126/21 129/22 130/4 130/16 130/17 131/11 138/12 139/8 141/5 141/6 148/11 149/16 149/17 153/7 153/10 157/16 who'd [3] 98/15 143/9 158/9 whole [26] 5/8 14/20 22/13 40/5 52/20 63/20 65/23 67/5 67/21 68/2 68/3 79/16 80/3 83/25 85/8 85/12 105/12 113/22 120/2 120/5 138/10 139/24 155/3 155/4 161/4 161/5 whom [8] 13/19 65/15 79/24 79/25 84/1 85/9 86/9 143/5 whose [5] 41/2 75/25 83/15 83/18 84/2 why [10] 1/22 12/9 70/25 107/4 119/14 125/5 148/19 149/22 151/10 152/16 wide [3] 38/8 153/17 162/1 widely [3] 107/8 133/5 133/13 widened [1] 47/5 will [66] 3/8 8/3 13/9 13/12 14/2 25/20 33/18 33/19 33/25 34/1 41/4 41/8 41/25 42/1 42/2 45/13 55/13 61/3 61/4 62/1 67/2 70/12 71/1 71/4 71/5 74/23 74/25 75/6 77/20 77/21 81/21 84/15 85/23 90/14 90/15 90/16 90/17 90/19 90/21 91/19 91/20 92/1 92/2 93/18 94/1 95/11 99/12 109/8 112/13 114/3 123/19 125/9 125/21 128/4 131/10 131/12 131/22 131/22 132/2 132/4 134/19 146/10 153/17 161/22 168/25 169/10 Willebrand's [4] 3/25 37/8 57/3 94/2 William [1] 141/13 William Connon [1] 141/13 willing [1] 156/16 willingness [1] 168/10 Wilmslow [1] 60/17 window [3] 124/25
----------	---	---	---	--	--

(68) virus... - window

<p>W</p> <p>window... [2] 125/3 125/11</p> <p>wish [9] 15/17 28/8 42/4 63/19 70/21 72/3 87/13 134/6 167/22</p> <p>wished [2] 81/11 112/25</p> <p>with [227]</p> <p>with HIV [1] 158/14</p> <p>with it [4] 36/20 40/19 92/2 151/5</p> <p>withdrawal [1] 124/6</p> <p>withdrawn [1] 60/12</p> <p>withdrew [1] 3/16</p> <p>withering [1] 52/11</p> <p>within [5] 7/13 16/5 45/23 46/16 134/20</p> <p>without [10] 29/23 34/4 54/9 94/6 95/13 95/13 99/25 121/20 126/25 158/12</p> <p>WITN3289047 [1] 102/2</p> <p>WITN3289054 [1] 91/11</p> <p>WITN3289082 [1] 46/1</p> <p>WITN3289110 [1] 6/4</p> <p>WITN3289111 [1] 14/25</p> <p>WITN3289113 [1] 10/24</p> <p>WITN3289114 [1] 11/12</p> <p>WITN3289115 [1] 11/21</p> <p>WITN3289116 [1] 17/9</p> <p>WITN3289118 [1] 13/22</p> <p>WITN3289120 [1] 27/11</p> <p>WITN3289130 [1] 22/19</p> <p>WITN3289132 [1] 25/17</p> <p>WITN3289133 [1] 26/3</p> <p>WITN3289134 [1] 31/16</p> <p>WITN3289136 [1] 32/18</p> <p>WITN3289137 [1] 33/13</p> <p>WITN3289148 [1] 40/15</p> <p>WITN3289151 [1] 42/14</p> <p>WITN3289157 [1] 76/10</p> <p>WITN3289162 [1] 82/14</p> <p>WITN329150 [1] 41/16</p>	<p>witness [4] 99/19 100/8 151/5 151/7</p> <p>witnesses [4] 59/21 153/15 169/4 169/12</p> <p>women [1] 101/15</p> <p>won't [9] 1/10 13/9 25/16 89/14 94/3 94/4 145/20 153/14 156/22</p> <p>wonder [1] 154/16</p> <p>wondering [1] 38/16</p> <p>woodwork [2] 82/9 98/24</p> <p>word [2] 54/8 95/18</p> <p>wording [1] 151/7</p> <p>words [3] 53/22 96/7 141/8</p> <p>work [13] 30/4 33/25 34/17 40/13 51/22 51/25 69/5 78/15 79/6 144/25 150/13 150/15 160/22</p> <p>worked [4] 30/16 56/20 156/13 160/24</p> <p>worker [1] 60/19</p> <p>working [16] 4/19 5/1 5/8 8/9 17/1 33/25 58/3 59/10 59/11 59/14 92/20 112/14 112/16 123/18 132/17 132/24</p> <p>works [1] 161/8</p> <p>world [2] 118/12 162/17</p> <p>worried [2] 98/25 138/10</p> <p>worry [4] 3/9 8/21 27/21 36/12</p> <p>worrying [1] 136/19</p> <p>worse [1] 153/24</p> <p>worth [4] 37/13 50/14 113/13 114/9</p> <p>would [194]</p> <p>wouldn't [10] 17/3 85/14 88/24 88/25 89/18 113/18 116/19 118/14 130/8 164/10</p> <p>write [5] 8/22 16/9 28/22 86/2 122/14</p> <p>writing [5] 31/25 41/5 73/17 92/15 138/24</p> <p>written [23] 8/15 46/21 47/11 49/9 56/20 57/10 61/14 61/16 65/9 65/22 66/12 68/17 69/20 70/8 70/12 88/12 96/14 99/22 100/2 100/3 105/9 115/22 135/20</p> <p>wrong [5] 35/15 35/16 51/19 54/8 151/21</p> <p>wrongly [1] 145/4</p>	<p>wrote [8] 2/17 4/16 25/11 66/20 66/24 73/12 132/25 148/25</p> <p>X</p> <p>XI [2] 31/6 31/7</p> <p>Y</p> <p>yeah [4] 48/8 48/8 54/3 118/16</p> <p>year [12] 49/2 53/4 56/11 66/11 68/7 70/2 71/3 72/20 75/9 97/7 154/21 165/6</p> <p>years [50] 9/25 10/6 21/22 23/9 24/24 25/6 30/17 39/21 46/19 49/3 54/16 57/1 57/3 57/7 58/10 58/16 63/16 66/1 72/18 81/17 82/20 83/6 93/15 103/4 103/4 103/6 103/6 103/15 106/19 106/24 107/1 108/20 109/3 110/3 110/17 111/15 111/24 121/5 123/12 124/13 132/13 135/3 141/14 143/18 143/25 147/18 151/1 155/1 155/2 160/15</p> <p>yes [80] 11/11 11/20 13/17 13/21 15/8 17/20 20/21 22/11 26/14 30/7 35/10 35/24 38/7 39/16 39/17 45/11 45/19 46/22 52/2 52/2 53/25 54/3 54/18 54/21 69/18 84/22 86/14 86/18 87/25 89/25 90/12 95/15 95/17 99/13 102/11 102/17 104/2 104/24 106/14 106/23 107/8 107/9 107/17 108/13 109/5 109/6 109/10 110/11 110/18 111/10 111/21 111/21 112/1 114/15 117/3 122/4 122/19 122/19 126/10 131/9 132/1 132/3 132/9 141/19 143/14 145/1 145/25 149/5 151/9 154/10 154/15 155/2 156/11 156/24 159/21 161/6 161/13 161/15 169/7 169/8</p> <p>yesterday [10] 2/6 2/21 87/3 101/18 102/7 104/1 122/3 132/10 144/13 160/3</p>	<p>yet [2] 125/2 168/13</p> <p>yielded [1] 103/14</p> <p>you [477]</p> <p>you'd [3] 89/20 94/22 99/9</p> <p>you'll [10] 63/2 66/23 90/23 103/1 125/20 126/18 127/14 135/19 144/13 164/3</p> <p>you're [29] 4/22 13/20 14/12 29/17 37/25 44/22 69/7 69/8 72/2 82/6 89/10 90/3 90/10 90/14 100/9 104/22 111/19 114/11 117/6 123/2 126/14 127/15 127/18 129/3 133/8 142/14 143/19 160/21 160/25</p> <p>you've [32] 24/6 30/10 40/17 45/23 50/1 50/2 50/15 52/25 54/16 59/20 69/19 86/24 88/6 89/25 94/25 97/14 98/24 99/18 100/7 104/14 106/1 109/1 109/9 114/9 143/2 143/4 145/5 149/1 151/4 151/6 154/25 162/21</p> <p>your [92] 1/13 1/15 2/6 2/8 4/19 6/8 16/3 17/7 19/3 19/6 20/9 21/13 24/6 26/2 26/15 28/18 28/19 30/11 32/6 34/7 40/11 42/4 43/21 44/4 44/5 45/22 49/25 53/22 54/15 61/4 61/4 69/8 74/16 76/7 87/5 88/4 88/7 88/14 88/16 88/17 90/22 92/12 93/13 95/23 96/4 96/11 96/13 96/13 96/14 99/14 99/14 99/19 99/19 100/6 100/8 100/12 101/17 101/23 102/7 102/9 104/1 113/1 115/7 115/10 117/4 121/2 122/25 123/1 123/4 129/19 129/20 129/25 133/21 133/24 136/3 136/10 142/15 142/16 149/2 150/2 151/5 151/7 152/9 153/15 154/14 159/23 161/9 161/9 167/9 168/1 168/10 168/17</p> <p>yourself [2] 122/5 165/13</p>	<p>Z</p> <p>zero [1] 39/6</p> <p>zoom [1] 21/11</p>	
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