

1 **Wednesday, 18 November 2020**

2 **(10.00 am)**

3 **SIR BRIAN LANGSTAFF:** Good morning, Dr Mitchell.

4 **THE WITNESS:** Good morning.

5 **SIR BRIAN LANGSTAFF:** Now, let me explain, before you are

6 given the oath to swear, what our setup is, so that

7 you understand, so that those who are present in the

8 hearing room understand, and those who are watching

9 remotely understand.

10 You are, as I understand it, at home?

11 **THE WITNESS:** Yes, I am.

12 **SIR BRIAN LANGSTAFF:** And your legal representative, your

13 solicitor, is watching remotely.

14 **THE WITNESS:** Yes.

15 **SIR BRIAN LANGSTAFF:** There are two members of the Inquiry

16 staff at your house but not in it.

17 **THE WITNESS:** That's true.

18 **SIR BRIAN LANGSTAFF:** I think your wife is in the house.

19 **THE WITNESS:** She's downstairs, yes.

20 **SIR BRIAN LANGSTAFF:** Now, that's your position. What you

21 need to know is that you are talking to a room in

22 which there are four members of the Inquiry legal

23 team, there are four members of the Inquiry staff, and

24 there is a technician whose job it is to make sure

25 that the right documents are displayed at the right

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1 time whenever they become relevant. That's the extent

2 of the number of people in a very large room. You

3 will understand immediately that we're all properly

4 socially distanced.

5 **THE WITNESS:** Yes.

6 **SIR BRIAN LANGSTAFF:** Although it would have been my

7 preference to have had you here so that you could see

8 us, we could see you, and there would be that sense of

9 immediacy and presence, those who would have been

10 here, had it not been for the virus, if I can call it

11 that, the coronavirus, they are watching remotely.

12 They have you visually available to them, and they

13 have a sound feed. They will at the end of the day

14 and during the day for most a transcript of what you

15 are saying so that there is a permanent record of it.

16 That will be checked at the end of the day so that we

17 know that it's accurate and corresponds to what you

18 actually said.

19 Those are the arrangements. We take a break

20 normally halfway through the morning for lunch and

21 halfway through the afternoon to enable you to get

22 a break and some refreshment if you want, and for

23 those who are watching to do exactly the same as well

24 as those here. So that's the setup. I'm going to ask

25 you now to take the oath. Mary, one of our members of

2

1 staff, will ask you.

2 **VIVIAN ERIC MITCHELL (affirmed)**

3 **Questioned by MS RICHARDS**

4 **MS RICHARDS:** Good morning, Dr Mitchell. Can you see and

5 hear me?

6 **A.** Yes, I can.

7 **Q.** I'm going to start just by asking you to help us with

8 an overview of your career. Your statement tells us

9 that you undertook your general medical rotation in

10 Sheffield hospitals from 1970 to 1973; is that right?

11 **A.** That's correct.

12 **Q.** Then between 1973 and 1975 you were working in Wales.

13 Could you just give us an overview of where you worked

14 and what kind of work and training you were

15 undertaking there?

16 **A.** I was a registrar for two years. Most of it was at

17 the University Hospital of Wales in Heath Park in the

18 north of Cardiff. Six months of it was the Llandough

19 Hospital which is on the western outskirts of Cardiff

20 in Penarth.

21 As I come from a medical background as opposed

22 to a pathology one, they put me through the various

23 laboratories, so I did a lot of laboratory

24 haematology; first of all in blood bank, then in

25 coagulation and in the general laboratory and, in

3

1 fact, that led to my being on call as an MLSO for six

2 months. They were quite keen on that.

3 I also did three or four months clinical work

4 with Jack Whittaker concerned with malignant and

5 non-malignant haematological disorders on the ward.

6 I spent about two to three months in coagulation with

7 Professor Bloom.

8 **Q.** Can you recall anything in relation to the two to

9 three months you spent with Professor Bloom? Can you

10 recall anything about the approach to treatment or the

11 policies in relation to treatment at that time?

12 **A.** Not really, no. I think we were using some

13 concentrate, but I believe we were using some

14 Factor IX concentrate. Even then, some of the --

15 a lot of the time was spent in the laboratory learning

16 coagulation techniques. It's an area they felt I was

17 lacking in because of my background.

18 **Q.** Did you have any involvement in decision-making

19 relating to choices of products or treatment plans for

20 patients?

21 **A.** Not at all.

22 **Q.** You then moved to the Sheffield Royal Infirmary where

23 you worked from 1975 to 1978 as a senior registrar in

24 haematology.

25 **A.** Yes.

4

1 **Q.** I think it was during this time that you undertook
 2 your MRCPATH exams?
 3 **A.** Yes. Towards the end of that time, yes.
 4 **Q.** You had six months at the Northern General Hospital.
 5 Briefly what did that entail?
 6 **A.** General malignant haematology. It's not a haemophilia
 7 centre. There are two consultants, and we had
 8 in-patients, out-patients, and, as I say, it was
 9 general malignant haematology and laboratory work.
 10 **Q.** Then you had a secondment during that time to the
 11 Blood Transfusion Centre in Sheffield. Was that under
 12 Dr Wagstaff?
 13 **A.** Yes, it was. Yes.
 14 **Q.** What did that entail?
 15 **A.** We rotated through the various departments in the
 16 Blood Transfusion Centre. We did -- there were a lot
 17 of exercises. There was a lot of technical work in
 18 the MRCPATH in those days. You were expected to be
 19 quite proficient in blood transfusion coagulation and
 20 other laboratory techniques. So one of the senior
 21 MLSOs would set up an exercise for me to do in the
 22 afternoon. I also did some sessions for them when
 23 they were short, going out on to the blood transfusion
 24 sessions, and, in those days, there was always
 25 a doctor present at those sessions. And I did --

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1 I fielded some of the telephone calls and so on from
 2 people asking for blood and blood products.
 3 **Q.** Do you recall during that secondment any discussions
 4 or any training in relation to pool sizes or risks of
 5 viral transmission?
 6 **A.** No. Obviously, we knew about testing for hepatitis B,
 7 which had been in place for some years. I don't
 8 remember discussion about pool sizes. Obviously, the
 9 only product -- I mean, they made fresh frozen plasma
 10 and cryoprecipitate there, but plasma for concentrates
 11 would be sent off to BPL.
 12 **Q.** Then the majority of this period, 1975 to 1978, is it
 13 right you were working with Professor Preston in
 14 Sheffield in the haematology -- in the haemophilia
 15 centre?
 16 **A.** Well, with Professor Preston and Professor Blackburn,
 17 of course. Professor Blackburn was actually head of
 18 department at that time, yes.
 19 **Q.** What, if anything, can you recall about the approach
 20 to treatment taken by Professor Blackburn and
 21 Dr Preston as he would then have been?
 22 **A.** Most of my time even then was involved with patients
 23 with malignant blood disorders. It's what the -- to
 24 a large extent what the senior registrars did.
 25 I don't think I even attended the haemophilia review

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1 clinics.
 2 The patients with haemophilia were treated on
 3 a ward -- well, in a room adjacent to one of the wards
 4 where we had adult patients. They were treated
 5 I think with -- largely with concentrate. I don't
 6 think it was a specific concentrate. I think there
 7 were several concentrates in use. I'm sure we used
 8 cryoprecipitate as well, but I can't remember how the
 9 patients were divided up.
 10 **Q.** You had some involvement in the Sheffield study which
 11 was reported in The Lancet in 1978. I'm just going to
 12 put that on screen.
 13 Soumik, it's PRSE0003622. If we zoom in on the
 14 right-hand column, please, top half of the page.
 15 We've looked at this already within the Inquiry,
 16 Dr Mitchell, on a number of occasions, but we can see
 17 it's The Lancet, 16 September, 1978. It's the article
 18 entitled "Percutaneous liver biopsy and chronic liver
 19 disease in haemophiliacs" and there are a number of
 20 names there recorded including Dr Triger,
 21 Professor Preston, Professor Blackburn, and we see
 22 your name there, VE Mitchell. Your capacity or your
 23 role at the time was senior registrar?
 24 **A.** Yes.
 25 **Q.** Can you recall what your involvement in the study was?

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1 **A.** Basically looking after the patients. So I admitted
 2 them on a Monday, clerked them in, worked out their
 3 dosage according to a protocol that Professor Preston
 4 had provided. Dr Triger came and talked to them on
 5 the Tuesday, did the liver biopsy -- and he was
 6 a considerable expert in hepatology -- and then they
 7 were treated for several days and then discharged on
 8 the Friday. So it's really looking after the patients
 9 whilst they were in hospital.
 10 **Q.** I'm not going to go through the detail of the article
 11 because we've looked at it on a number of occasions,
 12 but what you have said in your witness statement is
 13 that you understood from this work that, at least in
 14 some patients, liver disease was significant and
 15 progressive. Is that right?
 16 **A.** Yes, that's true. I mean, Professor Underwood -- we
 17 had meetings with Professor Underwood where he
 18 demonstrated the histopathology and some of the -- at
 19 that time, some of the pathology, quite persistent
 20 hepatitis, for example, was regarded as
 21 non-progressive, but there were some patients who
 22 showed progressive disease, including I believe two of
 23 the mild -- patients with mild haemophilia, yes.
 24 **Q.** You were also involved, your statement tells us, in an
 25 early study of the use of DDAVP in haemophilia. We

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1 don't, I'm afraid, have any specific documentation in
2 relation to that, although you have given us
3 a reference in your statement.

4 What, if anything, can you recall about that
5 DDAVP study?

6 **A.** I think the use of DDAVP in mild haemophilia had been
7 reported possibly the year before or the same year by
8 Professor Mannucci and I think Professor Preston
9 thought it was a good idea to actually establish our
10 own study, that it would work in our hands and to see
11 how successful it was. And, of course, it was
12 important to do -- because it doesn't work in every
13 patient as well as you would like it to, by doing it
14 once you would actually know whether it would work in
15 that patient at future times.

16 So I think it largely confirmed the findings of
17 Professor Mannucci. But it meant that
18 Professor Preston and Sheffield were using DDAVP at
19 a very early stage. I read a review by
20 Professor Mannucci, and he wrote a lot of those,
21 saying that he thought the take-up of DDAVP to treat
22 haemophilia in the rest of Europe had been very slow.
23 Well, that wasn't true of Sheffield.

24 **Q.** You then between 1978 and 1979 were a research fellow
25 at Sheffield university.

9

1 **A.** Yes, that's true.

2 **Q.** Then in November 1979, you took up a post as
3 consultant haematologist in Leicester and director of
4 the haemophilia centre.

5 **A.** I'm not sure they characterised me as director of the
6 haemophilia centre, but I was made responsible for
7 haemostasis, including haemophilia.

8 **Q.** You remained in that post until your retirement in
9 November 2003.

10 **A.** Well, I retired in March 2003, but then was asked back
11 for six months.

12 **Q.** I just wanted to ask you a little about the facilities
13 in Leicester before you arrived, which we can pick up
14 from an article that I understand you wrote in
15 The Bulletin.

16 Soumik, it's HCDO0000276_061. No, that's not
17 correct, I think, sorry. HCDO0000276_043. Then if we
18 could go, please, to page 4, I think.

19 This is an article which I understand to have
20 been written by you, and in the left-hand column you
21 describe the lack of services in Leicestershire in,
22 I think, the early part of the 1970s.

23 Then if we go down to where it says "no centre",
24 please, Soumik.

25 If we could see the bottom half of the page, you

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1 say this:

2 "There weren't haematologists. There was no
3 centre."

4 Then I think it says:

5 "The Blood Transfusion Service would not allow
6 even cryoprecipitate to be stored in Leicestershire."

7 Then you've described patients having to leave
8 Leicestershire to seek treatment elsewhere, or travel
9 long distances to obtain treatment and then how, in
10 1973, Dr Wood was appointed as the first consultant
11 haematologist. In 1975, he was joined by
12 Dr Hutchinson, and they were able with the support of
13 Professor Blackburn to establish Leicester as
14 a haemophilia centre.

15 Then you go on to describe how towards the end
16 of 1980, so a year or so into your appointment, a new
17 Haematology Department opened with a purpose-built
18 haemophilia centre. Is that an accurate summary?

19 **A.** Yes. That's fair enough, yes.

20 **Q.** So by the time you arrived, there were two consultants
21 in post but you, as I understand it, undertook a range
22 of haematology duties, but you took particular
23 responsibility for haemostasis and the care of
24 patients with bleeding disorders?

25 **A.** Yes. We were -- I mean, even by the standards of the

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1 day, we were very understaffed from a consultant point
2 of view. There were only three of us, and there were
3 three major hospitals. Most of my work, in fact, was
4 in malignant haematology, laboratory haematology and
5 I was made responsible -- as well as taking referrals
6 from the infirmary, I was made personally responsible
7 for one of these other hospitals, Glenfield Hospital,
8 which if it had been 20 miles away would have had two
9 consultant haematologists, but because it was only
10 four miles away, it was served, if you like, from
11 the LRI.

12 We're very large from a laboratory point of
13 view, with three departments, three blood banks and
14 over 70 MLSO staff. But we were very short on
15 consultants. So my colleagues had wanted somebody to
16 take over a section and, in fact, first of all, they
17 advertised for a paediatric haematologist, so it was
18 almost fortuitous that I came along to do haemostasis.

19 And it was ten years before we got a fourth
20 consultant, which I think then was expected --

21 **Q.** When you arrived, there was no haemophilia nurse but
22 a nurse was appointed in early 1981?

23 **A.** Yes.

24 **Q.** She was, I think your statement tells us, the first in
25 the Trent region and, your understanding is, one of

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1 the first in the UK to have a specialist nursing role?
 2 **A.** I don't think there were many in the UK at that time.
 3 I think -- I heard Charlie Hay say, I think, that he
 4 didn't know about haemophilia nurses until 1987, when
 5 he came across them at a haemophilia seminar. So it
 6 wasn't all that common then. She was a great boon.

7 **Q.** Your statement tells us I think she was involved in
 8 matters such as home and school visits, training
 9 patients and their parents for home therapy, liaising
 10 with the local Haemophilia Society, and then we'll
 11 come on at a later stage to her role in relation to
 12 HIV and HCV testing.

13 We're just going to look at an annual return
 14 from 1976, so before you arrived, but just to get an
 15 idea of numbers of patients being treated at that
 16 time. It's HCDO0000063_004, I think, or it might be
 17 83, sorry.

18 We can see here this is a return from 1976, and
 19 we get a sense of the number of patients. Total
 20 number of haemophilic patients treated during the
 21 year: 20. Total number of Christmas disease patients
 22 treated during the year: 4. And then we can see usage
 23 of cryoprecipitate. This form doesn't distinguish
 24 between hospital and home treatment. And then in
 25 terms of concentrates, Armour Factor VIII being used

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1 and Immuno, Kryobulin -- not, apparently, any NHS
 2 concentrates in 1976. And then NHS Factor IX
 3 concentrates being used for the care of patients with
 4 haemophilia B.

5 So that's 1976. When you arrived in late 1979,
 6 what, if anything, can you recall about the approach
 7 to treatment at that stage? What did you find?

8 **A.** If I could comment on this form a little, the thing
 9 that surprises me here, that with 20 patients with
 10 haemophilia A, they're only using about 180,000 units,
 11 which is a tiny, tiny amount of treatment, and would
 12 work out at about 9,000 units per patient per year.
 13 So it may be that this isn't a whole year or that the
 14 haemophilia -- the treatment of haemophilia had just
 15 started, if you like, just got underway.

16 When I arrived, there had been three intervening
 17 years, of course, and home treatment was already
 18 established, and I believe all the patients on home
 19 treatment were on commercial concentrate. There was
 20 NHS Factor VIII concentrate being used in the centre
 21 at that time but I don't think there was a great deal
 22 of it initially.

23 **Q.** You have said in your witness statement that the
 24 treatment policy which you adopted in Leicester was
 25 explicitly based on the reduction of risk and based on

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1 restricting the use of large donor pool concentrates
 2 whenever possible. Can you just elaborate a little
 3 upon your thinking, please.

4 **A.** I was convinced by the Sheffield work and the
 5 Sheffield report that there was a connection between
 6 the use of multi-donor factor concentrates and the
 7 development of liver disease, and I was further
 8 convinced that in some patients this could be
 9 progressive and, although there was doubt about the
 10 pathogenesis, the way in which the liver disease had
 11 occurred, it didn't really seem to matter. Whatever
 12 the pathogenesis was, the way to protect patients was
 13 to try to reduce, as far as possible, their exposure
 14 to multi-donor factor concentrates.

15 I came up with a policy which seemed to me,
 16 rightly or wrongly, to be a reasonable approach at
 17 that time.

18 **Q.** We'll go through the different elements of the policy
 19 in a moment. What you've said in your statement is
 20 that you essentially had to formulate your own policy.
 21 Was that because of an absence of any kind of national
 22 or regional guidance?

23 **A.** As far as I'm aware, yes. I wasn't aware of any.
 24 I must say, I was, to a large extent, professionally
 25 isolated from a haemostasis point of view. You know,

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1 I was a long way away from Sheffield, 70 miles from
 2 the reference centre. The reference centre didn't
 3 really play much of a role in guiding policy in
 4 Leicester, and there was nobody else other than myself
 5 and the sister who was really interested in
 6 haemostasis and haemophilia care. So I was
 7 professionally isolated, I suppose.

8 **Q.** Now the elements of your policy, first of all, in
 9 relation to patients with mild or moderate haemophilia
 10 and von Willebrand's disease, your approach was to use
 11 DDAVP and tranexamic acid wherever possible; is that
 12 right?

13 **A.** Yes. Although in moderate haemophilia it may well not
 14 be sufficient.

15 **Q.** Did you have any difficulty obtaining sufficient
 16 supplies of DDAVP or tranexamic acid?

17 **A.** No.

18 **Q.** And in relation to DDAVP, did you use it on its own
 19 without tranexamic acid or were they always used in
 20 combination?

21 **A.** I don't remember but I think certainly with a dental
 22 extraction or something like that, mucosal bleeding,
 23 they would have been used jointly. I'm not sure
 24 whether we always used them jointly but I think quite
 25 often we did.

16

1 Q. Do you recall whether there were any particular or
 2 frequent difficulties with the use of DDAVP or was it
 3 generally a successful mode of treatment for patients
 4 in those categories?
 5 A. I mean, there were precautions you had to take. It
 6 could result in fluid retention, for example. There's
 7 the tachyphylaxis, so that the response diminishes
 8 over time. You have to do a trial to make sure that
 9 the -- because the response varied from patient to
 10 patient, so if you were aiming at an operative
 11 procedure then you would need to do a trial first, to
 12 make sure that particular patient responded as hoped.
 13 But we used it -- well, we used it fairly often,
 14 I think.
 15 Q. Again, for these cohorts of patients, so patients with
 16 the mild or moderate haemophilia and von Willebrand's,
 17 if you weren't able to use DDAVP, with or without
 18 tranexamic acid, your policy was to use
 19 cryoprecipitate?
 20 A. Where possible, where feasible. Obviously, if someone
 21 was having a major operation with mild haemophilia --
 22 I mean, I think the Inquiry has mentioned the mild
 23 haemophiliac from outside of Leicester who required
 24 open heart surgery -- then DDAVP, we could use DDAVP
 25 to cover his catheterisation but we couldn't use DDAVP

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1 to cover his open heart surgery.
 2 Q. And in relation to that kind of surgery, could you use
 3 cryoprecipitate or were you then required to use
 4 concentrates?
 5 A. I'd use concentrate.
 6 Q. We will come on to that particular instance at a later
 7 stage.
 8 So DDAVP and cryo generally for mild to moderate
 9 patients and von Willebrand's and then, with children
 10 who had severe haemophilia, your policy was to treat
 11 them with cryoprecipitate until such time as they went
 12 on to home treatment; is that correct?
 13 A. That's correct.
 14 Q. Do you recall roughly typically at what age a child
 15 would start on home treatment or was there --
 16 A. I'm trying to think of that and honestly I can't.
 17 I think we may have been later than some other
 18 centres, so I think it may have been at round about 10
 19 or something like that.
 20 Q. I think you have said in your statement that the
 21 decision as to when to convert to home treatment would
 22 depend upon parents' wishes, frequency of bleeds and
 23 ease of venous access?
 24 A. Yes, and how well the people, the parents, got on with
 25 the training that the sister was giving them.

18

1 Q. Did you have any difficulty obtaining sufficient
 2 quantities of cryoprecipitate for use in the way in
 3 which you have described?
 4 A. No, I don't remember that we did.
 5 Q. Did you experience significant issues with allergic or
 6 other reactions to cryoprecipitate?
 7 A. Certainly it was known. I'm sure it may have
 8 happened. I don't remember it being a major problem
 9 but it's certainly an unwanted effect that is known.
 10 I've seen it more often with fresh frozen plasma in
 11 fact, but yes, it does happen.
 12 Q. Did the patients who were being treated with
 13 cryoprecipitate, whether they were adults with mild or
 14 moderate haemophilia or the parents of children being
 15 treated with cryoprecipitate, did they have any issues
 16 or protest about the fact that they would need to
 17 attend hospitals for bleeds to be treated with
 18 cryoprecipitate?
 19 A. Not often. I can remember one mother who was very
 20 keen for her child to go on to home treatment and who
 21 I believe wrote to The Haemophilia Society about it,
 22 who then forwarded her letter to me. But she was
 23 actually having -- she was a single mother and she was
 24 having considerable difficulty with the procedure,
 25 with the venapuncture, with her son, and we got her on

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1 to home treatment as quickly as we could.
 2 But by and large, no. I suppose we were lucky,
 3 in a way, that -- we're in Leicester, in the middle of
 4 the county. Most of our patients were actually from
 5 Leicestershire, so nobody was further away than 20
 6 miles and, in fact, most of them, because of the way
 7 the population is figured, I mean, you have Leicester
 8 with 300,000 and two-thirds of the rest of the
 9 population live in villages and towns surrounding
 10 Leicester. So most of our patients didn't have to
 11 travel far to get to the centre and that probably
 12 helped.
 13 Q. Do you recall whether you told your patients that the
 14 basis for your approach to their treatment was one of
 15 safety and reduction of risk?
 16 A. I'm sure we did. I don't specifically remember saying
 17 that to the people receiving cryoprecipitate.
 18 Q. Then, in relation to adults with severe haemophilia,
 19 and I'm talking here about haemophilia A for present
 20 purposes, your approach, as I understand it from your
 21 statement, was as much as possible to treat adult
 22 severely affected patients with NHS factor
 23 concentrates?
 24 A. Yes.
 25 Q. But as I understand your statement, there were

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1 insufficient supplies of NHS factor concentrates and
 2 therefore you also had to use, within the centre,
 3 commercial concentrates?
 4 **A.** Yes.
 5 **Q.** You obtained cryoprecipitate I think from the Regional
 6 Transfusion Centre. The NHS factor concentrates, were
 7 they supplied to you directly from BPL?
 8 **A.** No, I believe they also came from Longley Lane. Yes,
 9 from Sheffield.
 10 **Q.** Do you recall anything about how the system for
 11 allocating NHS concentrates worked within the Trent
 12 region?
 13 **A.** I think it was decided by the director,
 14 Dr Bill Wagstaff. I certainly spoke to him to try to
 15 get our allocation increased and I think he did do so.
 16 I mean, obviously there was a tradition that most of
 17 this went to Sheffield, but even for their purposes it
 18 was insufficient for them to treat the majority of
 19 their patients.
 20 **Q.** And your statement says that you would certainly have
 21 used more NHS product if it were available?
 22 **A.** Absolutely.
 23 **Q.** So the second element of your policy in relation to
 24 the treatment of adults with severe haemophilia A was,
 25 if you were using commercial concentrate, to adhere to

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1 one single concentrate as much as possible.
 2 **A.** As much as possible one batch of one commercial
 3 concentrate, yes. That was our policy.
 4 **Q.** When you arrived, I understand that Koate, which was
 5 produced by Cutter, was the commercial concentrate
 6 most often used in Leicester and you essentially
 7 continued its use; is that right?
 8 **A.** Well, that's what I remembered. The things you've
 9 sent me suggest that there were -- Humanate and
 10 possibly others were also in use at -- certainly two
 11 or three years before then. So I'm not sure. My
 12 memory was I would have continued with whatever
 13 intermediate purity product was in use then. But
 14 if -- I mean, there are documents which are missing,
 15 aren't there? And I don't really know what happened
 16 between '76 and '80.
 17 **Q.** You say in your statement that you would buy as much
 18 as possible of a batch from a single commercial
 19 supplier, and you say, in this way, patients had been
 20 treated for as long as 18 months using 100,000 units
 21 or more of the same batch.
 22 How did that reserving batches or batch
 23 dedication policy work in practice?
 24 **A.** Well, we would hope to only have one batch of one
 25 product in the hospital, except obviously at the times

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1 when we were changing over. And the sister made up
 2 the home treatment packs, which are kept, you know, in
 3 the cold room of the blood transfusion laboratory
 4 labelled for the patient so that when they arrived she
 5 would be able to hand this over to them, to sign it
 6 out to them. I suppose that was it, really. We would
 7 try just to have one batch of one product so that
 8 people couldn't make mistakes out-of-hours.
 9 **Q.** As far as you can recall, did you experience any
 10 difficulties in obtaining sufficient supplies of the
 11 one product that you seem to have predominantly used
 12 at least, the Koate?
 13 **A.** I would have said no but I know you have a document
 14 which suggests that we had to resort to BPL product at
 15 one stage with one patient.
 16 **Q.** Yes. We'll just look at that for the sake of
 17 completeness.
 18 WITN1167004, I think.
 19 So this is an extract from a patient's UKHCDO
 20 records and I appreciate you won't have had any access
 21 to any other records relating to this individual
 22 patient or others, but this shows predominant usage of
 23 Cutter's Factor VIII Koate but some usage, in 1980 and
 24 '81, of Humanate and, indeed, of Factor VIII in 1981,
 25 and also of the BPL, the NHS concentrate, in 1980 and

23

1 1984.
 2 So that would suggest, if these records are
 3 accurate, that you weren't always able to achieve
 4 compliance with your single concentrate policy?
 5 **A.** I don't think that's quite the case. I think what it
 6 means is that -- in my first year, for instance,
 7 I think it was fairly frantic and I was predominantly
 8 doing malignant haematology and other haematology
 9 work, so -- and there was no centre, there was no
 10 sister. I think it probably took us a year or so to
 11 (*unclear audio*). Although I had the policy, I think
 12 it took us a year or so to fully implement it. But
 13 from this it would look like it was implemented with
 14 this patient from 1981 onwards.
 15 The thing that more concerns me is the fact that
 16 the patient was given BPL Factor VIII in 1984, and I'm
 17 not clear of the -- for the reason that that happened.
 18 If it had been the end of '84 I would have thought
 19 that perhaps we were -- with increased access to
 20 NHS Factor VIII, we were using that before the patient
 21 switched on to heat-treated commercial concentrate.
 22 But unless these are out of order, it seems to be in
 23 the first half of 1984 that he was, for some reason,
 24 given BPL Factor VIII.
 25 I mean, I think that's the bit that's out of the

24

1 policy rather than the early treatments.

2 **Q.** Thank you.

3 To what extent was it part of the approach to

4 treatment at Leicester to give lifestyle advice to

5 patients, to try to avoid bleeds and thus avoid the

6 need for treatment?

7 **A.** I think it was standard that we would tell people. We

8 wanted, particularly the boys and young men, to live

9 as normal a life as possible. I mean, they are normal

10 people. But we would obviously have to advise them

11 against contact sports like rugby and so on and -- but

12 it was very important that they did exercise, that

13 they kept their muscles healthy, because that protects

14 the joints. I mean, swimming was the particular sport

15 that we would advocate, so we did try to get them to

16 avoid injury but we also wanted them to live a full

17 and happy life. So we had to be balanced about it.

18 **Q.** Then your policy in relation to the treatment of

19 patients with haemophilia B was, is this correct, to

20 use NHS Factor IX concentrates?

21 **A.** Yes.

22 **Q.** I know there are a couple of instances of usage of

23 commercial Factor IX concentrates but we will come on

24 to that at a later stage.

25 **A.** Just one I think.

25

1 **Q.** Generally speaking, it was NHS Factor IX.

2 **A.** Yes.

3 **Q.** We'll look at the 1983 returns.

4 So this is HCDO00001550_02, please, Soumik.

5 And if we go to the second page, please --

6 **A.** That page is interesting, because it says "registered

7 at Oxford", "registered at Oxford", I think there are

8 several other mentions of that, and that does show

9 that those patients were travelling to Oxford for

10 their treatment before treatment was available in

11 Leicester. I mean, it will be people at Oxford who

12 have written the "registered at Oxford" on the

13 returns.

14 **Q.** Then if we go to the second page so we can see here

15 this is the annual return for 1983. Total number of

16 haemophilia A patients treated during the year: 31.

17 And total number of von Willebrand's patients: 6.

18 Then we can see there is the usage of cryoprecipitate

19 in hospital for the treatment of haemophilia A

20 patients: 388 bags, 27,001 060 units, presumably, is

21 the calculation there. And then NHS factor

22 concentrates being used in hospital: 152,455. And

23 then at home: 57,850. And Cutter, Koate: 128,050 in

24 hospital, 423,870 for home treatment.

25 And then down the bottom of the page we've got

26

1 DDAVP, and then to the right-hand columns we've got

2 von Willebrand's disease, cryoprecipitate.

3 So this would suggest that certainly by 1983 you

4 were using a sole commercial product, Koate --

5 **A.** Yes.

6 **Q.** -- in particular for home treatment, with a much

7 smaller amount of NHS concentrates being used for home

8 treatment?

9 **A.** I think when I arrived, the majority of patients on

10 home treatment were on commercial concentrate, and

11 I didn't really have the ability to switch them over

12 to NHS with the amount of NHS we were receiving. So

13 that was continued.

14 **Q.** Then if we go on to page 4, I think it should be,

15 Soumik, this is the annual return in relation to

16 patients with haemophilia B.

17 We can see that you treated eight patients with

18 haemophilia B during that year and one carrier of

19 haemophilia B. And the treatment is NHS Factor IX

20 concentrate, used both in hospital and for home

21 treatment. And then "Other Materials ... FFP", fresh

22 frozen plasma, and that's been used for the carrier of

23 haemophilia B for in-patient treatment?

24 **A.** Yes.

25 **Q.** Then if we go to -- no, I think we will come on to

27

1 a later return at a later stage.

2 In terms of the home treatment programme, were

3 all the patients who were on home treatment patients

4 with either severe haemophilia A or patients with

5 haemophilia B?

6 **A.** They were always severe haemophilia A or B, yes.

7 **Q.** So no patients with the mild or moderate. And was

8 there any home treatment programme for

9 von Willebrand's patients?

10 **A.** No.

11 **Q.** How and when, as far as you can recall, did you become

12 aware of the association between the use of factor

13 concentrates and AIDS?

14 **A.** I'm not at all sure. 1983/84.

15 **Q.** In terms of information that you might have had, what

16 journals did you generally read at that time?

17 **A.** I received the BMJ as a member. I subscribed to

18 New England Journal of Medicine. I received the

19 British Journal of Haematology as a member. But

20 I must say that, of course, I had to keep abreast

21 of -- right across the field of haematology, so --

22 I heard someone, I think it was Mark, say the British

23 Journal of Haematology didn't have much haemophilia in

24 it but an awful lot of haematology. So I was not

25 concentrating on the haemophilia literature alone.

28

1 **Q.** We know that there were publications, for example, in
 2 January of 1983, in the New England Journal of
 3 Medicine, which talked about the occurrence of AIDS in
 4 haemophiliacs in the States. Is it likely that you
 5 would have read those at the time?
 6 **A.** Perfectly possible, yes.
 7 **Q.** We'll go to one document that you, I think, would have
 8 received at the time.
 9 Soumik, it's HCDO0000517_001.
 10 You'll see, Dr Mitchell, this is a letter dated
 11 22 March 1983.
 12 If we go to the second page for a moment,
 13 please, Soumik.
 14 We'll see that it's authored by Dr Craske,
 15 Dr Rizza and Professor Bloom, and it's been sent out
 16 on behalf of the UKHCDO. So if we go back to the
 17 first page, it's:
 18 "Dear Director ..."
 19 It's headed "(AIDS)", it refers to discussions
 20 in the Hepatitis Working Party and a recent meeting of
 21 Reference Centre Directors. And then it invites
 22 directors to essentially report any possible cases of
 23 AIDS to the authors of the letter.
 24 Do you recall, as a matter of fact, this letter
 25 at all?

29

1 **A.** Not as a matter of fact, no, but if it went to all
 2 haemophilia directors, I would have received it.
 3 **Q.** That's certainly our understanding, Dr Mitchell. That
 4 was its purpose.
 5 **A.** Yes.
 6 **Q.** Just looking at the first paragraph, which refers to
 7 discussions in the Hepatitis Working Party and
 8 a meeting of the Reference Centre Directors, did you
 9 at the time, as a director but not a Reference Centre
 10 Director and not a member of the Hepatitis Working
 11 Party, did you receive the reports or minutes of those
 12 working parties or Reference Centre Director meetings?
 13 **A.** No.
 14 **Q.** Then if we go, please, Soumik, to HCDO0000517_002.
 15 This is a report from Dr Craske dated
 16 1 March 1983 which we understand may have accompanied
 17 this letter. Again, I'm not sure whether -- have you
 18 got any actual recollection of seeing this report at
 19 the time?
 20 **A.** No, but I'd seen similar things, I think, about
 21 Kaposi's sarcoma and Pneumocystis carinii, yes, so
 22 I may well have had ...
 23 **Q.** Then if we go to page 3, we can see, at the bottom
 24 half of the page, under the heading "Aetiology",
 25 there's a discussion by Dr Craske of various theories.

30

1 He refers to the possibility of drugs such as
 2 amyl nitrate and then discounts that. He refers to
 3 cytomegalovirus and then discounts that as seeming
 4 unlikely.
 5 And then we go over the page to his point 3. He
 6 refers to the likelihood of an infectious agent with
 7 a similar epidemiology to that of hepatitis B. And
 8 then he goes on to say:
 9 "If (3) is the most likely cause, then it is
 10 possible that such an agent might be present in the
 11 plasma pools ..."
 12 If we go to the last page, please -- I'm sorry,
 13 the page before that, my apologies, Soumik -- we can
 14 see the last paragraph says:
 15 "It is thought likely that batches of
 16 factor VIII concentrate which might contain the AIDS
 17 agent came into use since January 1st 1980 in
 18 the USA."
 19 And then goes on to talk about the setting up of
 20 a reporting system reporting cases of AIDS.
 21 And then just to complete the picture, there's
 22 one further document.
 23 Soumik, its HCDO0000273_078.
 24 This is headed "Acquired Immune Sufficiency
 25 Syndrome Survey", "Spectrum of Disease Presentation in

31

1 the Acquired Immune Deficiency Syndrome (AIDS)", and
 2 it says:
 3 "Please complete and return to Miss RJD Spooner
 4 at Oxford Haemophilia Centre a report form AIDS/3 for
 5 all patients with blood coagulation defects seen by
 6 your Centre who fulfil any of the following criteria."
 7 Then on that page and over the page there's
 8 a list of symptoms and signs and abnormalities to look
 9 out for. I won't go through the detail of it with
 10 you, Dr Mitchell, but is it fair to assume that by
 11 March of 1983 you would have had at least the
 12 knowledge that's set out in these documents?
 13 **A.** Yes, I think so, although many of the clinical
 14 conditions there are very rare. As I understood it,
 15 the presentation was more likely to be candidiasis or
 16 pneumocystis pneumonia, but, yes, I presume I received
 17 these documents.
 18 **Q.** Now did you, as far as you can recall, provide your
 19 patients with any information at this time, spring of
 20 1983 onwards, about possible risks of AIDS from use of
 21 factor concentrates?
 22 **A.** I think both I and the sister will have talked to the
 23 patients about this. I think many of them were
 24 already aware because of reports in the media that
 25 there was this association.

32

1 Q. So you think you would have done. Can you remember,
 2 and I appreciate I'm asking you about matters of many
 3 years ago, but can you remember as a matter of fact
 4 whether it became your routine practice to do so or
 5 whether it was only if it was raised by a patient?
 6 A. No, I can't, no.
 7 Q. Now, as I understand your statement, your approach to
 8 treatment of patients didn't alter because the policy,
 9 you say in your statement, that you had in place to
 10 try to reduce the risk of liver disease was equally
 11 applicable to HIV and was, therefore, continued?
 12 A. I mean, both were my idea how to try and reduce
 13 transmission of an agent, whether that was a virus or
 14 not. I mean, the argument about pathogenesis is
 15 largely irrelevant, really. If the harm is being done
 16 by the concentrates, then you try to reduce exposure
 17 to concentrates. And I suppose I felt that it was
 18 very important to carry on treating patients but
 19 I would do all I could to try to reduce the exposure
 20 of the patient.
 21 Q. Can you recall whether you gave any active
 22 consideration at the time to the suspension of home
 23 treatment, for example, on a temporary basis?
 24 A. And substituting what?
 25 Q. And patients coming into the hospital to be treated

33

1 with cryoprecipitate.
 2 A. Yes. I don't think I gave it active consideration.
 3 I mean, one of the problems was that many of the
 4 patients in Leicester had received inadequate
 5 treatment. There was a more severe -- many of them
 6 had more severe joint problems than I was familiar
 7 with seeing in Sheffield. Some of them almost
 8 resembled a situation I saw in Karachi and Lahore many
 9 years later. So there were many patients who had very
 10 severe haemophilia arthropathy, and the idea of
 11 returning them to inadequate treatment, or what I felt
 12 was inadequate treatment, would not have appealed to
 13 me.
 14 You could compare that with the situation in the
 15 early 1990s when I had lads with severe haemophilia
 16 who were competing with local swimming clubs, and one
 17 of whom was working weekends as a lifeguard. I mean,
 18 these were muscled young men, you know, with -- who
 19 were fit and healthy and living normal lives. I think
 20 returning to inadequate treatment would have -- would
 21 not have been something I would seriously have
 22 considered.
 23 Q. Do you recall whether you gave any consideration to
 24 perhaps using porcine product, Hyate:C, for some
 25 patients or some bleeds other than for the use of

34

1 inhibitors?
 2 A. I did use it for inhibitors. I do not remember
 3 considering it for the treatment of people of --
 4 haemophilia A patients without that. It did have some
 5 disadvantages, and I understand that many patients
 6 became resistant to it with continued use.
 7 Q. We've heard some evidence from -- in relation to some
 8 centres that possibly in 1984 an approach was taken to
 9 defer non-urgent surgery because of the risk of AIDS.
 10 Do you recall whether that was something that was
 11 considered locally in Leicester?
 12 A. I don't think we did any surgery at that time.
 13 I think we were trying to do that, yes.
 14 Q. Now, there came a point in time, I understand from
 15 your statement, probably in early 1985 when patients
 16 were transferred to heat-treated product. And we'll
 17 just look at a couple of documents in relation to
 18 that.
 19 Soumik, could we have, first of all,
 20 CBLA0002067.
 21 We can see that this is a letter from you to
 22 Dr Snape at BPL. It's dated 25 February 1985, and it
 23 is in relation to obtaining supplies of heated
 24 Factor VIII concentrate for some patients who were
 25 regular users of NHS product. You then go on to say:

35

1 "We have several children who at present only
 2 receive cryoprecipitate but are in the severely
 3 affected category and might be expected to go on to
 4 home treatment in the next year or so."
 5 You then tell us:
 6 "There are 39 patients with mild to moderate
 7 severity haemophilia who might require treatment with
 8 Factor VIII concentrate in certain circumstances, and
 9 another patient with severe von Willebrand's who might
 10 be a potential user of NHS factor heat-treated
 11 concentrates."
 12 And then if we look at the handwritten PS, it
 13 says:
 14 "I have not included our severely affected
 15 adults at present receiving commercial heat-treated
 16 product."
 17 So it would appear that, certainly by
 18 25 February 1985, you were receiving commercial
 19 heat-treated product. I think you, again, were using
 20 the Koate heat-treated product --
 21 A. That's true, yes.
 22 Q. -- for severe haemophiliacs who were already being
 23 treated with commercial concentrates; is that right?
 24 A. Yes.
 25 Q. Then for the cohort described in the first paragraph

36

1 of this statement -- so patients who had been treated
2 with NHS product, and you were trying to get the
3 heat-treated NHS product -- at this point in time,
4 were they still receiving treatment with unheated NHS
5 product, as far as you recall?

6 **A.** Yes.

7 **Q.** Do you know how long it took for you to receive
8 sufficient supplies of heated NHS concentrate to be
9 able to treat this group of patients with it?

10 **A.** I can't remember exactly when we started to receive
11 NHS heat-treated concentrate. I should think it was
12 that summer.

13 **Q.** Then if we look at one further document. It's
14 CGRA0000559, please, Soumik. If we go to the second
15 page.

16 I should say, I don't think we have a date for
17 this, but it appears to be an internal Cutter
18 document, in any event. It's giving details about
19 Koate and Koate HT sales, so the heat-treated Koate.
20 If we just look at the bottom half of the page, "Koate
21 returned material". It says this:

22 "The December figures show returned Koate from
23 only the two centres, but the following centres have
24 subsequently returned or are in the process of
25 returning material."

37

1 your statement suggests that you had to get permission
2 to increase the centre's spending, but it was given,
3 and the delay was not major.

4 **A.** That's my understanding. It was ordered by
5 Mr Godfrey. He was the chief pharmacist. They called
6 him the unit pharmacist because the LRI was just one
7 unit in the Trust. He was always very helpful. But
8 in the case of a major and continuing expenditure like
9 this, he would have to pass it upwards, and sometimes
10 I got involved in discussions with the Medical
11 Director and the Chief Executive too.

12 This became an increasing problem later on, but
13 I don't think on this occasion we had a great delay.
14 It wasn't something the unit pharmacist could do on
15 his own.

16 **Q.** Then in relation to Factor IX concentrate for your
17 haemophilia B patients, your statement says that the
18 NHS Factor IX became available, I think you suggest,
19 from the autumn of 1985. Prior to that, you used
20 non-heat-treated NHS Factor IX in preference to
21 commercial products because you didn't consider the
22 commercial products to be safer. Is that correct?

23 **A.** I wasn't convinced of the safety of the first lot of
24 commercial heat-treated concentrate. I was a great
25 believer in the British voluntary donor system. And

39

1 And then we can see Leicester is there
2 identified. And then underneath that table, it says:

3 "All the centres which returned Koate in
4 December and those subsequently have replaced with
5 Koate HT."

6 So it looks from this as though, in early 1985,
7 you were seeking to return your unheated Koate to
8 Cutters and to receive heat-treated Koate in return.
9 Does that accord with your recollection?

10 **A.** I don't remember it specifically, but certainly it
11 looks as if that's what we and many other centres were
12 doing, and it makes sense, I think.

13 **Q.** Do you recall whether you took any steps in relation
14 to your patients who were on home treatment and who
15 might have supplies of Koate -- unheated Koate at
16 home?

17 Did you take any steps to ask them to bring that
18 in so that they could have it exchanged for
19 heat-treated product?

20 **A.** I don't remember whether the sister did that, but we
21 certainly seemed to be returning quite a large amount
22 of product compared with some of the other centres
23 there, so it may well be that we did take back
24 material from the home treaters.

25 **Q.** Then in relation to obtaining heat-treated products,

38

1 also the viricidal methods to be used by BPL were much
2 stronger; much more, I thought, likely to be
3 effective. And I also wasn't keen to change all my
4 patients on to intermediate purity heat-treated
5 products and then move them back on to NHS products
6 a few months later because I was always trying not to
7 expose people to large donor pools. So those were,
8 I think -- that was my thinking.

9 **Q.** Then could we have on screen, please, Soumik,
10 BAYP0000007_045, please.

11 This is an internal Cutter memo dated
12 4 July 1985. We'll just go to the second page,
13 please, Soumik.

14 Under the heading "Leicester", it says this:

15 "The problems we encountered at Leicester during
16 the last three months are almost over. These problems
17 were lack of stock and not being able to reserve
18 batches for them and pressure on Dr Mitchell to use
19 Profilate HT on six virgin haemophiliacs. Our
20 supplies to Leicester are back to normal. We are now
21 able to reserve small batches for their patients. And
22 despite all pressure from Barry Barber or Dr Mitchell,
23 four out of the six virgin haemophiliacs are now using
24 Koate HT. The other two patients continue to use
25 cryoprecipitate."

40

1 What, if anything, can you recall about the
2 events that seem to be described here?
3 **A.** I don't know whether this is correct. I'm not sure
4 that -- I'm not sure that we had six patients -- we
5 transferred six virgin haemophiliacs, as he calls
6 them. They won't have been virgin haemophiliacs at
7 all; they would have been patients who had been
8 treated for many years with cryoprecipitate, so they
9 weren't previously untreated patients. And I don't
10 know whether we transferred four of those to Koate HT.

11 It may have been that we discussed it with the
12 parents and said, "Do you want to wait until the BPL
13 product (which I would have preferred as a product if
14 it had been available), or do you want to transfer
15 over to commercial HT?" So I can't say whether this
16 is correct or not.

17 I don't think everything that's -- well,
18 certainly, as I've shown later, not everything in
19 these internal memos was correct.

20 **Q.** I think your statement, looking at this, suggests that
21 it might mean that you had six patients to transfer
22 from cryoprecipitate to heat-treated concentrate and
23 that you might have been keeping them on
24 cryoprecipitate longer to wait for the heat-treated
25 Koate to become available. Is that a possibility?

41

1 **A.** That is a possibility, yes. I think I did certainly
2 suggest that we did that, but whether we put them on
3 to Koate HT or NHS product, I'm not sure. Certainly,
4 our NHS usage increased considerably.

5 **Q.** Then we'll just look at the return for 1986, to
6 complete the picture in terms of product usage.
7 Soumik, it's HCDO0000333_002.

8 So we can see this is the annual return
9 for 1986. 38 haemophilia A patients treated in 1986;
10 7 von Willebrand's disease patients treated in 1986.
11 We can see there that for the haemophilia A patients
12 still using cryoprecipitate in hospital -- there is
13 then an increase in the amount of NHS concentrate
14 being used, so 271,000-odd in hospital; 240,000-odd
15 units for home treatment. And then there is only one
16 commercial concentrate identified, that's Koate;
17 174,570 hospital, and then 472,710 home treatment.
18 Then we can see towards the bottom of the page you are
19 using the porcine product. That would be, as you have
20 earlier referred, for a patient or patients with the
21 inhibitors?

22 **A.** Yes.

23 **Q.** Then DDAVP tranexamic acid. Then there's a reference
24 to topical thrombin, I think. What was that for?

25 **A.** Sometimes in babies and toddlers, toddlers

42

1 particularly, they fall. Their newly-emerging teeth
2 go into their lips, and they get a continuous ooze if
3 they have severe haemophilia. At that time, it was
4 sometimes -- people used to soak gauze swab in topical
5 thrombin and just gently compress that against the
6 lip, and it would mean that that mucosal bleed would
7 stop without the need for any intravenous treatment.
8 It's always good for small children to come to
9 hospital without having somebody stick a needle in
10 them. It made it less stressful and perhaps less
11 reluctant to come again on a different occasion.

12 We didn't use it very much, but it did have
13 a place. Later on, it was stopped.

14 **Q.** Then if we go to the fourth page, please, of this
15 document, we can see this is the 1986 return for
16 haemophilia B. Seven patients treated in 1986. And
17 we can see there the usage is predominantly NHS
18 Factor IX concentrate, both in hospital and at home.
19 There is the reference to the use of commercial
20 Factor IX, and we will come on to that later for the
21 patient to whom that related. And then tranexamic
22 acid is also referred to for haemophilia B patients.

23 By this time, 1986, is it correct to understand
24 that all the concentrates, whether it's NHS
25 Factor VIII, NHS Factor IX, or the commercial

43

1 concentrates would have been heat-treated
2 concentrates?

3 **A.** Yes, yes, indeed. Sorry, I think when you're looking
4 at cryoprecipitate and FFP, what this doesn't give you
5 is the number of patients who were treated with it.
6 In my BMJ letter, for example, I think I say that --
7 patients treated with cryoprecipitate, 28, or fresh
8 frozen plasma, 3. So although the number of bags is
9 few, because these are patients who required
10 infrequent treatment, the number of patients treated
11 with cryoprecipitate or FFP was actually -- well,
12 31 out of 76. So almost -- well, something like
13 40 per cent of the patients were receiving single
14 donor treatment.

15 **Q.** Dr Mitchell, we're going to come on to the BMJ article
16 next, in fact, but what I was going to suggest --
17 because we haven't looked at it in a hearing before,
18 what I was going to suggest is we take a break now.

19 Sir, if that's convenient to you. It is 11.10.

20 **SIR BRIAN LANGSTAFF:** Yes, it is.

21 **MS RICHARDS:** And then we will look at the BMJ letter in
22 full, as we have not previously looked at it.

23 **SIR BRIAN LANGSTAFF:** As I mentioned at the outset, we
24 take a break in the morning. It will be half-an-hour
25 long, so we will come back at 20 to 12.

44

1 **MS RICHARDS:** Sir, could you give Dr Mitchell the usual
 2 warning?
 3 **SIR BRIAN LANGSTAFF:** Yes, I will.
 4 There is only your wife to talk to at home but
 5 you mustn't talk to her or, for that matter, to anyone
 6 about the evidence you've given or you think you may
 7 yet be asked to give. You can talk about anything
 8 else you like but not about your evidence. That
 9 applies at any break.
 10 **A.** Yes.
 11 **SIR BRIAN LANGSTAFF:** Thank you very much. See you
 12 at 11.40.
 13 **(11.12 am)**
 14 **(A short break)**
 15 **(11.40 am)**
 16 **MS RICHARDS:** Dr Mitchell, we're going to look at the BMJ
 17 letter that you were referring to before the break.
 18 Soumik, it's PRSE0001555. If we could zoom in
 19 on it, it's the middle column.
 20 Dr Mitchell, I'm actually going to read it aloud
 21 because I think, for those who are following the
 22 Inquiry, it's not necessarily going to be easy to read
 23 the letter and, as I said, we haven't looked at it in
 24 hearings before.
 25 So it's a letter from you published in the

45

1 British Medical Journal, 20 July 1985, and it's in
 2 response to a letter from Professor Bloom, and it says
 3 this:
 4 "Professor Bloom and his co-authors state that
 5 cryoprecipitate should no longer be used. This
 6 recommendation by the Reference Centre Directors will
 7 have a major and, we believe, unfortunate effect on
 8 treatment policy in many haemophilia centres. One
 9 implication is that patients with von Willebrand's
 10 disease and haemophilia A of mild or moderate severity
 11 will have to be treated with large donor pool
 12 Factor VIII concentrates, albeit heat-treated, when
 13 desmopressin is not appropriate. Initially, because
 14 of concern about chronic liver disease in
 15 haemophiliacs and more recently with HTLV-III also in
 16 mind, we have for the past five years tried to
 17 restrict the exposure of our patients to large donor
 18 pool concentrates. Cryoprecipitate has played a major
 19 part in this policy, being used in the treatment of
 20 patients with von Willebrand's disease and those with
 21 mild to moderate haemophilia. Children with severe
 22 haemophilia are also treated with cryoprecipitate
 23 until they go on to home treatment.
 24 Even so, we used 1 million units of Factor VIII
 25 concentrate in 1984; 60 per cent in the form of

46

1 commercial concentrate. This exposure is limited by
 2 buying as much as possible of a batch from a single
 3 commercial supplier. In this way, patients have been
 4 treated for as long as 18 months using 100,000 units
 5 or more of the same batch."
 6 Then could we have the rest of that column,
 7 please, Soumik. Thank you.
 8 "This policy has resulted in a low prevalence of
 9 HTLV-III antibody in our patients. We recently tested
 10 76 patients, including 27 children, who have received
 11 blood products at the centre during the past five
 12 years. Seven of the 28 who had received commercial
 13 concentrate were HTLV-III antibody positive;
 14 25 per cent. There were no positive results from
 15 patients treated with NHS Factor VIII concentrate only
 16 (5), NHS Factor IX concentrate (12), cryoprecipitate
 17 (28) or fresh frozen plasma (3). The 7 positive
 18 patients all have severe haemophilia A and constitute
 19 37 per cent (7 of 19) of this most at risk group. All
 20 are adults aged 23 to 54 years. None have clinical
 21 features of HTLV-III infection.
 22 "All patients with mild or moderate
 23 haemophilia A, Christmas disease, von Willebrand's
 24 disease and factor X deficiency were HTLV-III antibody
 25 negative. Three severe adult haemophiliac patients

47

1 were positive for HTLV-III antibody on transfer to the
 2 centre in recent months, bringing the total number of
 3 our positive patients to 10.
 4 "Recurrent treatment with blood products is
 5 hazardous. Apart from the danger of HTLV-III
 6 infection, the severity and progressive nature of
 7 chronic liver disease in haemophilia has recently been
 8 re-emphasised. Cirrhosis of the liver has been
 9 reported in mildly affected, infrequently transfused
 10 haemophiliacs and in children. Although the
 11 pathogenesis of chronic liver disease in haemophilia
 12 is not completely understood, it is undoubtedly
 13 related to treatment with large donor pool
 14 concentrates, all of which contain non-A, non-B
 15 hepatitis viruses. We would agree that only
 16 heat-treated concentrate should be used, since this
 17 may protect the recipients from HTLV-III infection,
 18 but heat treatment has not so far been shown to
 19 eradicate hepatitis viruses.
 20 "The best approach seems to us to be a treatment
 21 policy which is designing to reduce as much as
 22 possible all the risks associated with blood products
 23 and which is tailored to the needs of each individual
 24 patient. HTLV-III antibody testing of all blood
 25 donations is expected to start in September 1985

48

1 (W Wagstaff, personal communication). During the
 2 intervening two to three months, we believe it is
 3 preferable to continue using cryoprecipitate, rather
 4 than treat patients with large donor pool concentrates
 5 which otherwise they might never need receive.
 6 "Adoption of the proposal by Shore et al that
 7 cryoprecipitate should be prepared only from the
 8 plasma of female donors would decrease the risks of
 9 HTLV-III infection during the interim. This policy
 10 could be extended to fresh frozen plasma and platelet
 11 rich plasma, and plasma from male donors could be used
 12 for preparing NHS heat-treated Factor VIII and IX
 13 concentrate. Desmopressin and antifibrinolytic
 14 therapy should be used when possible to avoid
 15 treatment with blood products."
 16 So that was the letter you sent, Dr Mitchell, to
 17 the BMJ in July 1985 and, obviously, it sets out the
 18 policy which you have been describing to us.
 19 Can we just look again at the figures. You
 20 explained in that letter that there were 7 patients
 21 who were infected with HIV. That was the information
 22 you had at the time. And those were 7 out of 28 who
 23 had received commercial products, and they were all
 24 patients with severe haemophilia A.
 25 **A.** Yes.

49

1 **Q.** None of the patients who had received any NHS
 2 Factor VIII seroconverted to HIV?
 3 **A.** No. Can I point out, perhaps, that the way we've
 4 divided it up there, it's the patients -- the 28 who
 5 received commercial concentrate are patients who
 6 received commercial concentrate at any time. So that
 7 may well include some patients with mild or moderate
 8 haemophilia who were treated before my policy came
 9 into effect.
 10 The patients with NHS Factor VIII concentrate,
 11 that small group, have only ever received Factor VIII
 12 concentrate. So the two groups are slightly different
 13 in that respect; one group is more all-embracing. So
 14 some of those 28, at the time of this letter, may
 15 actually have been transferred over on to NHS
 16 concentrate, but they had a history of having had
 17 commercial concentrate.
 18 **Q.** Your witness statement tells us that in fact there
 19 were eight patients at the centre who were infected
 20 with HIV in consequence of their treatment there. So
 21 there was an eighth patient who was not referred to in
 22 the BMJ letter because that test result came in at
 23 a later stage in 1985?
 24 **A.** Yes, that's true.
 25 **Q.** But all 8 were severe haemophiliacs. None mild or

50

1 moderate, none with von Willebrand, none with
 2 haemophilia B, and no children?
 3 **A.** Yes, that's right.
 4 **Q.** There is a reference in one of the internal Cutter
 5 documents that we've got which refers to a 17-year-old
 6 testing positive for HTLV-III in 1985. Do you know
 7 whether that's the eighth case or not? I don't want
 8 you to say anything that would identify any
 9 individual.
 10 **A.** He was actually 18, but yes.
 11 **Q.** Do you recall whether that eighth patient was
 12 a patient who had received only commercial
 13 concentrates?
 14 **A.** I don't recall that, no. He certainly had received
 15 commercial concentrate.
 16 **Q.** That figure of 8 does not, as I think your letter to
 17 the BMJ makes clear, include some adult patients who
 18 transferred to Leicester but were already infected
 19 with HIV and had already been tested and diagnosed
 20 with HIV?
 21 **A.** Yes. The letter's about the Leicester cohort, if you
 22 like. So I didn't include -- we were a growing
 23 centre. Having started off from nothing at all, we
 24 were a growing centre, and we were getting people
 25 joining us, some of whom lived nearby, in fact.

51

1 **Q.** Your statement explains that work was not undertaken
 2 to establish precisely when patients seroconverted.
 3 Do I correctly understand you did not have
 4 a bank of stored samples to test?
 5 **A.** We did not store samples, no.
 6 **Q.** Your statement also says that one partner of a patient
 7 tested positive for HIV.
 8 **A.** Yes.
 9 **Q.** Can I just ask you a little more about the process for
 10 testing patients for HTLV-III.
 11 Can you recall approximately when that process
 12 was undertaken and what the arrangements were?
 13 **A.** We had a letter from the UKHCDO saying that testing
 14 was available. I approached our consultant
 15 virologist, Dr Flower, who is on this letter, and she
 16 said, "I can do that for you." Only she chose to do
 17 it -- rather than do it through Dr Tedder, she sent it
 18 to the virus reference laboratory. She wanted to send
 19 it as a cohort and, therefore, the sister contacted
 20 the patients. They came up with a time convenient to
 21 them. She explained what was happening and what she
 22 was doing, took the sample, and they were sent off as
 23 a block.
 24 **Q.** Then do you have any recollection as to how long it
 25 took for the results to come back?

52

1 A. Longer than I would have liked, but I think it must
 2 have been two or three months, something like that,
 3 before Dr Flower approached me with the results.
 4 Q. What were then the arrangements for informing patients
 5 of their test results?
 6 A. They were all seen personally by me, often with the
 7 haemophilia sister present.
 8 Q. What information, as far as you can recall, did you
 9 provide to patients at that time. So in 1985 when you
 10 are telling them that they are HTLV-III positive, what
 11 else did you tell them?
 12 A. It's very difficult because it was very uncertain at
 13 the time. It wasn't even certain that the positive
 14 antibody test meant continuing infection, although
 15 I think most of us feared that it did. So I would
 16 have told them that they were positive, they'd been
 17 exposed to this virus, that it wasn't inevitable that
 18 they would develop AIDS, because that's what we
 19 understood at the time, and that we would carefully
 20 monitor their progress in the future. I don't know
 21 whether I gave general advice at that time because we
 22 didn't know an awful lot about the virus or its
 23 natural history.
 24 Q. Was advice given in relation to sexual transmission?
 25 A. It certainly was. I can't remember whether it was at

53

1 the same meeting or a subsequent meeting, but it
 2 certainly -- gave them advice generally about sexual
 3 transmission and also about making sure that they
 4 cleared up any blood with domestic bleach and covered
 5 grazes and so on. We gave them general advice on how
 6 to look after themselves and others.
 7 Q. What, if any, arrangements were made to offer tests
 8 for family members?
 9 A. I said in the statement that I didn't think we'd done
 10 this, but I've been thinking about it, and we must
 11 have done because I do remember meeting the person who
 12 was affected, and that can only have happened if, in
 13 fact, we did offer testing to relatives and sexual
 14 partners. So we must have done that, and my statement
 15 I think is in error.
 16 Q. One of the regrets you've expressed in the statement
 17 was the absence of any form of psychological support
 18 or formal counselling for patients.
 19 What, if anything, was available in terms of
 20 such support?
 21 A. Very little. The hospital itself didn't have
 22 a clinical psychologist at that time. We had a social
 23 worker for a time. She was a paediatric social
 24 worker, but she was willing to see adults, but she was
 25 then withdrawn. I can't remember if she was there at

54

1 the particular time we're talking about, '84/'85.
 2 Most of the counselling was done either by myself or,
 3 in large part, by the haemophilia sister.
 4 Q. What were the arrangements that were made for the
 5 ongoing monitoring of this cohort of patients who were
 6 HTLV-III positive and, in due course, for their
 7 treatment?
 8 A. We saw them regularly -- I think something like every
 9 three months. Although, of course, they could always
 10 come to us if they did become unwell. We were able to
 11 monitor their T4:T8 ratios. They were all in good
 12 health at that time.
 13 When treatment became available, I think that
 14 one or two of them may have received AZT from --
 15 whilst they were in the centre, but after that when
 16 treatment became more advanced and more complicated
 17 and really outside my level of expertise, we referred
 18 them to Professor Karl Nicholson and Dr Martin
 19 Wiselka, the infectious diseases consultants who were
 20 looking after HIV patients from other sources as well.
 21 Q. Was that an automatic referral, or did patients have
 22 to request it?
 23 A. No, they didn't request it. We offered it.
 24 Q. In terms of the arrangements for testing -- before
 25 I ask you about the arrangements for testing for HCV,

55

1 can I just ask you about information provided to
 2 patients about non-A, non-B hepatitis.
 3 I have asked you earlier about what information
 4 you thought you might have provided to patients about
 5 the risks of AIDS. What, if anything, can you recall
 6 telling patients in the 1980s, prior to any test for
 7 hepatitis C being available, about the risks of non-A,
 8 non-B hepatitis or the risks of liver disease?
 9 A. We would talk to patients about their liver function
 10 tests. They would know that they were having these
 11 blood tests, that they were being done on a regular
 12 basis. And we would talk to them, and we would say
 13 that -- talk to them that there is a possibility of
 14 viral transmission, and there is evidence that --
 15 I think rather than saying non-A, non-B, I've never
 16 found that patients really like to have their
 17 condition described to them in such -- it was the same
 18 with non-Hodgkins lymphoma which I was dealing with in
 19 my other role. It's not an easy thing for patients to
 20 have.
 21 So, I would say that there was evidence that
 22 there was inflammation of the liver, that we didn't
 23 know how severe that was, and that we were monitoring
 24 the situation. We had little to offer, and we would
 25 give them advice about alcohol and so on.

56

1 Q. I'm just going to ask you to look at a couple of
 2 documents.
 3 Soumik, could we have WITN1167005, please.
 4 So we can see here, this is -- again, it's an
 5 extract from some UKHCDO records, and it identifies
 6 chronic non-A, non-B hepatitis in 1982 and identifies,
 7 in fact, particular products and batches.
 8 Then if we could go please, Soumik,
 9 to WITN1167006.
 10 This is "Hepatitis Survey" -- this happens to be
 11 for the same patient as the document we've previously
 12 looked at, but I'm not asking you about the individual
 13 patient, Dr Mitchell.
 14 We can see "Hepatitis Survey". It's a form to
 15 be completed and sent to Miss Spooner at the Oxford
 16 Haemophilia Centre immediately a patient is suspected
 17 on clinical or laboratory grounds of having contracted
 18 hepatitis. Then we can see it identifies a type of
 19 therapeutic material received during the six months
 20 prior to development of hepatitis Koate or
 21 Factor VIII. Then there are details of the symptoms
 22 and signs there set out, which include jaundice,
 23 discoloured urine, et cetera and, if we just go to the
 24 bottom of the page, we can see the date, 1982.
 25 Were these forms forms that you were

57

1 routinely -- you or the sister routinely filling out
 2 in relation to patients and sending off to Oxford?
 3 A. I presume so. I presume so. Yes. I don't remember
 4 the forms particularly. They were obviously for
 5 patients who'd had clinical hepatitis. And clinical
 6 hepatitis was, in fact -- with non-A, non-B or with
 7 hepatitis C was, in fact, rare. Most patients were
 8 asymptomatic, but this patient obviously was not.
 9 Q. Do you recall whether you told your patients that you
 10 were proposing to send information about them on
 11 a named basis to Oxford as part of the Oxford return
 12 process?
 13 A. I think the patients were aware of the Oxford returns.
 14 I don't think we specifically asked individually for
 15 permission, for consent, but they were aware of them.
 16 And, in fact, I think in her article in the bulletin,
 17 Sister [redacted] actually refers to the Oxford
 18 returns, so I think it was widely known about.
 19 MS RICHARDS: Could we just stop the live transmission for
 20 a moment.
 21 SIR BRIAN LANGSTAFF: Yes, certainly.
 22 MS RICHARDS: We will remove from the transcript the name.
 23 SIR BRIAN LANGSTAFF: Yes.
 24 A. Sorry. (Pause)
 25 MS RICHARDS: So I've just been asking you more generally,

58

1 Dr Mitchell, about the process for submitting
 2 information to Oxford. We know from other centre
 3 records that, at least in early part of the 1980s,
 4 data was sent, including patient names, to Oxford, and
 5 I was simply asking you what knowledge you think your
 6 patients had of that process.
 7 A. Yes.
 8 Q. Your answer, I think, was you thought patients were
 9 aware of it, but you don't recall specifically raising
 10 it or asking for consent?
 11 A. No.
 12 Q. In terms of the process of testing for hepatitis C,
 13 can you recall what arrangements were made for the
 14 testing of patients with hepatitis C?
 15 A. I think they were very similar if not identical to
 16 those that we use in testing patients for
 17 HTLV-III antibody. The sister contacted them, invited
 18 them to attend for the blood test, saw them, told what
 19 the test was all about, sent the test off, and then
 20 I saw the patients individually to give them their
 21 results and to discuss the significance.
 22 Q. Can you recall -- this would have been, I think, the
 23 early 1990s --
 24 A. Yes.
 25 Q. -- what information were you able to provide to

59

1 patients, did you provide to patients, about
 2 hepatitis C at that time?
 3 A. It was somewhat similar in that, again, the complete
 4 significance of the antibody results was not known,
 5 and there were even suggestions that this just showed
 6 exposure rather than continuing infection. But on the
 7 assumption that there was continuing infection, we
 8 would give them general advice. They had already been
 9 advised, I think, to moderate alcohol. We might have
 10 reinforced that, and we would have talked about how
 11 they could keep others safe by -- and we would
 12 probably have mentioned the possibility of sexual
 13 transmission, although that was much less of
 14 a problem, as it turned out, than with HIV.
 15 And we would then say that we would review and
 16 keep an eye on them.
 17 Q. What were the arrangements for reviewing patients who
 18 had tested positive for hepatitis C?
 19 A. I think initially they were reviewed in the
 20 haemophilia centre, and of course they continued to
 21 attend haemophilia review clinics. But I think as
 22 treatment became available, I think one or two
 23 patients were treated in the centre by us. But then,
 24 again, as things became -- more expertise was
 25 obtained, we transferred -- or, we transferred that

60

1 part of their case to Professor Karl Nicholson and
 2 Dr Martin Wiselka. We did do a joint hepatitis
 3 clinic, so we saw the patients together.

4 **Q.** Your statement recalls some difficulty, at least in
 5 the early days I think, in obtaining funding for
 6 interferon and ribavirin?

7 **A.** Yes, that was particularly for the patient with
 8 hepatitis B. We had hoped that that might -- he might
 9 get rid of the virus but, in fact, it turned out that
 10 he became a carrier. And I wanted to give him
 11 interferon and ribavirin, and it took a bit of
 12 persuading to get the hospital to agree to fund that.

13 **Q.** You don't, I understand from your statement, have data
 14 as to precisely how many patients tested positive for
 15 hepatitis C?

16 **A.** Not nowadays, no. No longer.

17 **Q.** You have just mentioned there a patient with
 18 hepatitis B, and I wonder if we can look at an article
 19 in the British Journal of Haematology co-authored by
 20 you which considers two cases of hepatitis B.
 21 Soumik, it's IPSN0000156_089.
 22 So this is an article from 1988 in the British
 23 Journal of Haematology, "Transmission of hepatitis by
 24 dry heat-treated Factor VIII and IX concentrates" and
 25 then there are two cases that you describe here of

61

1 patients who were infected with hepatitis B following
 2 treatment with concentrates. Could you just briefly
 3 describe to us the circumstances of each case and the
 4 circumstances in which they were infected with
 5 hepatitis B?

6 **A.** One of them was a patient from elsewhere with mild
 7 haemophilia who required major open heart cardiac
 8 surgery. He had been treated in the past with
 9 cryoprecipitate and non-heat-treated Factor VIII
 10 commercial concentrate. He came along to us -- one of
 11 our problems was that operations were always carried
 12 out in the other hospitals, so the orthopaedic
 13 operations were usually at the Glenfield or the
 14 General, and the cardiac unit, the cardiothoracic
 15 unit, regional cardiothoracic unit, was at Glenfield,
 16 which stretched us a bit.

17 So we obviously gave him a trial of DDAVP and
 18 decided that was sufficient to take him through his
 19 cardiac catheterisation, but it wasn't sufficient to
 20 take him through his major cardiac surgery. I had to
 21 approach the virologist, consultant virologist, at
 22 that time to get access to hepatitis B vaccine, and he
 23 had to be tested to make sure that he wasn't immune
 24 because of previous infection. We gave him two doses
 25 of the Factor VIII -- sorry, the hepatitis B vaccine,

62

1 but the cardiac surgeons then said that they had to
 2 operate on him, they couldn't wait for the third
 3 injection, the vaccination. I should have said that
 4 we covered his catheterisation with DDAVP. Have
 5 I said that?

6 He had his operation, which was covered by
 7 heat-treated commercial Factor VIII concentrate. When
 8 we came to give him the third injection four months
 9 later, because it was -- second injection was one
 10 month after the first and then it was another four
 11 months after that, he was found actually to be
 12 hepatitis surface antigen positive, so -- and it was
 13 confirmed on repeat testing.

14 The Blood Transfusion Service tested the donors
 15 of the blood and platelet units he had received during
 16 the course of the operation and they were all
 17 negative, so there was circumstantial evidence and,
 18 I believed, fairly convincing evidence that he had
 19 been infected from his commercial concentrate,
 20 heat-treated commercial concentrate.

21 The other patient was a boy with severe
 22 Christmas disease. Because the parents were concerned
 23 about the risk of HIV, he was moved over on to
 24 commercial heat-treated Factor IX concentrate. They
 25 didn't want to wait until NHS heat-treated Factor IX

63

1 concentrate was available. After 11 months he was
 2 found to be positive for hepatitis B.

3 **Q.** We looked at the returns earlier for 1986 which showed
 4 some use of a commercial Factor IX concentrate, and
 5 that was in relation to this particular case?

6 **A.** Just this one.

7 **Q.** Because the rest of your patients were treated with
 8 NHS Factor IX concentrate, unheated and then heated?

9 **A.** Yes.

10 **Q.** Then, in relation to the response of the
 11 pharmaceutical companies to these two cases, I just
 12 want to look at a handful of documents with
 13 Dr Mitchell.

14 Could we have, please, Soumik, BAYP0000010_071.
 15 So we can see that this is a letter from you
 16 dated 3 April 1987 to Cutter. We don't, I think, need
 17 to go through the detail of it, but this was you
 18 reporting the first case, the case of the patient who
 19 had undergone cardiac surgery and developed
 20 hepatitis B, to Cutter.

21 Then if we look at the response, that's
 22 BAYP0000010_105, please, Soumik.

23 We can see -- this is a response dated
 24 14 May 1987 from GM Akin in Miles Pharmaceuticals, and
 25 the response is essentially yours in the last

64

1 paragraph, to say:
 2 "In view of the foregoing laboratory studies,
 3 with the lack of other hepatitis reports regarding
 4 this Lot, and considering the patient's having
 5 received blood and platelets, we do not believe
 6 Koate HT to be the probable source for his
 7 hepatitis B."
 8 So you reported this to the pharmaceutical
 9 company but their response was, as set out here, to
 10 reject the association with the heat-treated product?
 11 **A.** Yes.
 12 **Q.** As I understand your statement and the article that we
 13 just looked at, you remained of the view that it was
 14 the heat-treated product which transmitted hepatitis B
 15 in this case?
 16 **A.** Yes.
 17 **Q.** After you published your article, or after it was
 18 published, did you have any further response from the
 19 pharmaceutical company to the published article?
 20 **A.** No.
 21 **Q.** Then in relation to patient 2, if we have
 22 BAYP0000008_102, please, we can see here this is
 23 a letter from Cutter to you referring to a report of
 24 a development of hepatitis in a patient receiving
 25 Konyne and asking for further information, which you

65

1 submitted.
 2 We'll just look at BAYP0000008_259.
 3 We can see here that you were then requesting
 4 further information. You requested information on the
 5 follow-up carried out on the batch of Konyne which was
 6 reported to have caused hepatitis B positivity in one
 7 of the patients. It refers to the parents being keen
 8 to have further information.
 9 The outcome of that appears to have been, again,
 10 a rejection of there being any connection with the
 11 Cutter product. So if we look at BAYP0000008_288,
 12 please, we can see this is a letter from Cutter to
 13 you, July '86, it says:
 14 "Our representative ... has told [us] that you
 15 are still awaiting information on the batch ..."
 16 And there's an apology for the delay in
 17 responding, and then it says:
 18 "We can confirm that there have been no other
 19 reports of hepatitis related to administration of this
 20 batch ... the records confirm that the batch passed
 21 all tests ..."
 22 Then there's a reference to the patient having
 23 received National Health Service product shortly
 24 before the first injection of Konyne heat-treated.
 25 And so that's the response that you received.

66

1 Do you have any observations to make on the suggestion
 2 that the patient had received NHS product --
 3 **A.** It was 11 months before he was found to be hepatitis B
 4 positive, so I don't -- and he had been tested several
 5 times in the interval. So I don't believe for
 6 a moment it was due to his NHS product. And there
 7 were reports of intermediate purity heat-treated
 8 concentrates passing on or causing hepatitis B and
 9 hepatitis C. So, no, I remained convinced that it was
 10 due to his heat-treated Factor IX.
 11 I thought there was some -- one other thing when
 12 they referred to other people having had ... not on
 13 this one. One of the other things says something
 14 about six other patients, but they certainly weren't
 15 Leicester patients.
 16 **Q.** I'm not sure I've got the reference to that to hand,
 17 Dr Mitchell.
 18 **A.** No.
 19 **Q.** There is one other document I just wanted to ask you
 20 about. It's BAYP0000008_338. It's the bottom half of
 21 the page, so the first is reference to a different
 22 report in relation to Koate HT and hepatitis, and then
 23 this, under the heading, "Konyne HT":
 24 "Apparently Dr Mitchell was satisfied with the
 25 information provided as he has not raised the subject

67

1 again. I will let you know if there are any further
 2 developments but we are not actively following up this
 3 case at the moment."
 4 As I understand your statement, you have said
 5 that there wasn't a mechanism for resolving the
 6 dispute.
 7 **A.** Not that I'm aware -- with -- I would have raised it
 8 with any representative from Cutter I met, and I can't
 9 believe -- I don't know who Marie Tatt is but she
 10 knows this isn't correct because we published the
 11 letter. So she knows that we're not happy that it
 12 wasn't their product, otherwise we wouldn't have
 13 published the letter.
 14 **Q.** I wanted to ask you next about some observations in
 15 your statement, Dr Mitchell, and to offer you the
 16 opportunity to elaborate upon them.
 17 You say in your statement that you believe that
 18 heat-treated factor concentrates should have been made
 19 available sooner and that concerns about liver disease
 20 should have led to much greater efforts to make safer
 21 products from the late 1970s, and you express the view
 22 that it took the HIV epidemic to motivate governments
 23 and plasma fractionators into doing so.
 24 **A.** That is very much a personal view. I think you were
 25 asking me for my personal view and that was my

68

1 personal view, that there seemed to be, to a certain
2 degree, hurry and scurry after the realisation about
3 HIV, and a much more laid back view about liver
4 disease. There was controversy. I mean, there were
5 people like Professor Mannucci saying for some years
6 that this liver disease is non-progressive, and
7 I think there were some reports from Manchester and
8 elsewhere, but there are also people like the
9 Sheffield group and others who were emphasising the
10 serious nature of liver disease. And this -- as you
11 have demonstrated in this Inquiry, this wasn't a new
12 thing. This had been going on for years.

13 I don't think that governments, fractionators
14 and blood transfusion services really took the matter
15 seriously enough. But this is my personal view.

16 **Q.** There's one other no doubt personal view I wanted to
17 invite your comment on that you express in an article
18 in the Prescribers' Journal.

19 Soumik, it is WITN3174004.

20 This is an article you authored in 1992, it's
21 entitled "Coagulation factor concentrates", and
22 I understand the context for it is the debate over
23 higher purity products and their availability and the
24 possibility of recombinant. Is that correct?

25 **A.** It's actually an article that goes to primarily

69

1 non-haematologists. It's a Government publication
2 which was sent to everybody licensed to prescribe in
3 the United Kingdom, and the editorial board were
4 clinical pharmacologists and pharmacists. It was they
5 who insisted that there be clear identification of
6 costs, for example. But I was trying to give people
7 perhaps who were not aware of coagulation factor
8 concentrates a basic understanding. That was really
9 the purpose of it.

10 **Q.** So we can see, picking it up under the heading
11 "Cryoprecipitate", you refer to the discovery of
12 cryoprecipitate and how for a number of years -- or
13 how that was a major advance in haemophilia care, and:

14 "For a number of years cryoprecipitate provided
15 a safe and effective treatment for haemophilia A and
16 von Willebrand's disease."

17 You then go on, under the heading "Intermediate
18 purity products" to talk about the inevitability of
19 viral contamination. So you say:

20 "But producing batches of concentrate on this
21 scale, required the use of pooled plasma from thousands
22 of donations, so that viral contamination was
23 inevitable. By the late 1970s the dangers of
24 hepatitis and chronic liver disease were becoming
25 apparent. Most previously untreated patients who

70

1 received the concentrates showed evidence of non-A,
2 non-B hepatitis."

3 And then the point you just made, Dr Mitchell:
4 "Attempts to reduce the viral transmission
5 became more urgent after the realisation that HIV
6 could also be transmitted by blood products."

7 Then if we go over the page, you then talk --
8 and I am not going to go through the detail of it --
9 about high purity concentrates and recombinant.

10 Then I just wanted to go to the last page and
11 invite any further observations you have to make your
12 conclusion. You say this:

13 "The history of blood product use in haemophilia
14 should convince us that only the safest possible
15 treatment is permissible and that economic factors
16 cannot be the only, or even the most important,
17 consideration."

18 Then you go on to talk about high purity
19 concentrates and the demand for those products and the
20 demand for recombinant products.

21 Do you have any further observations to add to
22 the statement that you set out there, Dr Mitchell?

23 **A.** I think it's -- I believe it to be true, but also it
24 was perhaps a little bit of a response to the fact
25 that the editorial board had insisted that I talk

71

1 about the economic consequences in this article. So
2 although I did that, I wanted to point out that
3 although they are important they are not the most
4 important consideration. So it was, I suppose,
5 a little bit of a rebuff to their response. But,
6 I mean, it was written for non-haematologists.
7 I mean, obviously haematologists could read it but it
8 was meant for a much wider audience than that.

9 So it was something I believed. And the bit
10 about the relative impurity is really -- it's very
11 similar to what Ted Tuddenham was saying to you, when
12 you talked to him, about the impurity of concentrates.
13 And in cryoprecipitate, for instance, you are giving
14 Factor VIII, which is almost a trace contaminant of
15 the fibrinogen, fibronectin and other proteins that
16 are in that preparation.

17 There's something else that --

18 **Q.** Carry on, Dr Mitchell.

19 **A.** Sorry?

20 **Q.** I'm sorry, I didn't quite catch that last bit because
21 I spoke over you.

22 **A.** I'm sorry, I was just saying, is there anything else
23 you wanted me to elaborate on?

24 **Q.** No, not in that particular article, thank you.

25 **A.** Thank you.

72

1 Q. I wanted to just ask you more broadly about UKHCDO.
 2 You described to us already that certainly in
 3 the 1980s, early 1980s, when you arrived, you were
 4 very much on your own. Do I understand, first of all,
 5 in terms of regional influences, were there any
 6 regular meetings with the other Trent-based centres or
 7 with the Regional Transfusion Centre or the health
 8 authorities?
 9 A. No.
 10 Q. In terms of UKHCDO, did you generally attend the
 11 annual general meetings?
 12 A. Yes. Yes -- I don't know which was the first I went
 13 to. Whether it was 1980 or later than that, I don't
 14 know.
 15 Q. You have already told us that you didn't receive the
 16 Reference Centre Director minutes or the specific
 17 working party reports unless they were sent out
 18 specifically to directors. To what extent did the
 19 AGM, the annual AGM, or the setup of UKHCDO in the
 20 1980s allow the directors of smaller centres such as
 21 yourself to have a voice?
 22 A. Well, I imagine you could do if you were sufficiently
 23 determined but I don't think it was actually
 24 encouraged. It was very much a series of
 25 presentations by Dr Rizza and Dr Craske and others on

73

1 what they saw as the issue of the day or brief reports
 2 of what the various working parties -- had been done,
 3 and these obviously were summaries of -- because these
 4 working parties had met on a whole number of occasions
 5 through the year. So it was really just keeping the
 6 smaller centres up-to-date, I suppose, but in a brief
 7 way.
 8 Q. Then if we come forward into the 1990s, still on the
 9 topic of UKHCDO, if we could have, please,
 10 HCDO0000248_013, please.
 11 So this is now September 1992. It's the minutes
 12 of a meeting of centre directors.
 13 And if we go, please, Soumik, to page 5.
 14 We can see that under the heading 7 and the word
 15 "Re-Write", there was a discussion about the way in
 16 which haemophilia centres should be organised and
 17 funded. And if we pick it up in the long paragraph in
 18 the second half of the page, there's a reference to
 19 the aim of a document, this being a Department of
 20 Health produced document:
 21 "... to inform and remind purchasers that
 22 haemophilia care is both expensive and unpredictable."
 23 And then it goes on to talk, a few lines down,
 24 to definitions of a haemophilia centre and
 25 a comprehensive care centre:

74

1 "The designation of Centres would not come under
 2 the jurisdiction of the Department of Health but would
 3 emanate from the peer group."
 4 Then there's a reference to a lively discussion,
 5 and you're recorded as querying the figure of 40 plus
 6 patients for the designation of a comprehensive care
 7 centre. There's then reference to Dr Mayne saying it
 8 was:
 9 "... inadvisable to set a lower figure because
 10 the figure of 40 severely affected patients would
 11 indicate and guarantee that a Centre would have full
 12 experience of all the complications of haemophilia
 13 care. However she indicated that the figure was not
 14 rigid ..."
 15 Then you are recorded as expressing concern
 16 about the relationship between a haemophilia centre
 17 and a comprehensive care centre, feeling it could
 18 result in a loss of funds, and the conversation
 19 continues.
 20 Can you recall anything about this issue, this
 21 structural issue, and what your concerns were at the
 22 time?
 23 A. Yes. This reminds me. This was an initial attempt by
 24 the Reference Centre Directors to reorganise their
 25 structure and the structure of haemophilia care

75

1 generally. And I have no objection to their setting
 2 standards or enforcing those standards, but I had --
 3 this was sprung on us, effectively. I'm not accusing
 4 Dr Mayne of doing that but the -- many of the people
 5 in the audience whom this would affect, and their
 6 centres would be affected, were totally unaware of
 7 these proposals. I was certainly totally unaware.
 8 I wasn't sure whether Leicester would or would not
 9 qualify as a comprehensive care centre. In fact,
 10 three years later we did, and probably would have done
 11 at that time.
 12 But I was a bit concerned, if all the patients
 13 in Leicester were registered at Sheffield, as the only
 14 reference centre/comprehensive care centre, then that
 15 could have major repercussions on Leicester. It could
 16 even be that we would lose funding. There would have
 17 been some in the hospital authorities who would
 18 actually welcome such a move and say: oh, well, they
 19 are all Sheffield patients now, do we need another
 20 haemophilia sister? In fact, do we need a haemophilia
 21 sister at all? Do we need a new haemophilia centre
 22 that's been planned for the Osborn Building? Because
 23 these are now Sheffield patients.
 24 The other thing is that the representative of
 25 the Department of Health says that orthopaedic

76

1 operations, for example, would not be available. But
 2 we were not just doing orthopaedic operations, we were
 3 doing major cardiothoracic surgery on a number of
 4 occasions, including total correction of a Fallot's
 5 tetralogy in a small child, a baby effectively.

6 So I didn't feel that this was going to deliver
 7 the right result, not just for Leicester but for other
 8 places like Nottingham, et cetera. So I queried it.
 9 But, I mean, it did evolve. It didn't stay at this
 10 point. This was an intermediate stage.

11 **Q.** Then moving to a separate topic, Dr Mitchell, could we
 12 have NHBT0036651_002.

13 This is a letter dated July 1995 about the
 14 hepatitis C look-back, and it's a letter from you to
 15 the Trent Blood Transfusion Service in the Regional
 16 Transfusion Centre in Sheffield. It says you have
 17 finally been able to locate some funding which you
 18 hope will enable you to make progress:

19 "It will probably take us 2-3 months to trace
 20 all 100 patients who received infected donations."

21 What, if anything, can you recall about your
 22 involvement or Leicester's involvement in the
 23 hepatitis C look-back exercise?

24 **A.** Well, I think if you had asked me a few days ago
 25 I would have said I had no involvement in the Blood

77

1 Transfusion Service look-back, but my understanding
 2 from this letter is that the Blood Transfusion Service
 3 had approached us, I'm not sure why it came to me, but
 4 they probably spoke to our chief MLSO in blood
 5 transfusion and asked him to trace 100 donations which
 6 came from patients who had, subsequently, been found
 7 to be positive for hepatitis C antibody.

8 He was running three very busy blood banks in
 9 three different hospitals, and this would have
 10 involved a lot of work, looking at old ledgers and so
 11 on, which he couldn't spare the time or the staff to
 12 do. I think, therefore, it was suggested that some of
 13 his staff should be paid to do this, weekends or
 14 out-of-hours or something like that, and I imagine my
 15 job was to persuade the pathology business manager
 16 that he should provide this funding.

17 He would probably have said, "This is a Blood
 18 Transfusion Service look-back, why aren't they
 19 providing this?" So I was probably, if you like,
 20 a go-between. My last sentence I think is a little
 21 bit misleading. Although they may have informed us
 22 about 100 donations which came from people who
 23 subsequently -- came from donors who subsequently
 24 tested positive for hepatitis C antibody, that does
 25 not translate into 100 patients. So although there

78

1 would have been no difficulty at the time because the
 2 people reading this letter will only have been
 3 interested in the middle sentence, it might be
 4 misleading to people who are reading the letter now,
 5 analysing it at this stage.

6 If I looked up the report of the results of the
 7 look-back, which is published in Transfusion in
 8 September 2002, that shows that there were 9,222 blood
 9 components made from donors who were subsequently
 10 shown to have antibodies for hepatitis C virus. They
 11 were given to only half that number, 4,424 recipients,
 12 and of those only 1,351 were traced, and 50 per cent
 13 of those, so something like about 675, were found to
 14 be infected with hepatitis C virus.

15 So that's actually only -- if you do that in
 16 proportion, that would mean only seven of our -- seven
 17 patients in the Trent would be expected to become
 18 hepatitis C virus positive, antibody positive, as
 19 a result of receiving this 100 donations.

20 **Q.** Do you --

21 **A.** Many of the -- sorry?

22 **Q.** No, carry on.

23 **A.** Many of -- part of the reason for this is, of course,
 24 that because of the reasons that people get
 25 transfused, I think they found that about 50 per cent

79

1 of the patients were deceased by the time this
 2 look-back was done. And if you think of the
 3 reasons -- somebody with a ruptured aortic aneurysm,
 4 for example, may receive many, many units of blood,
 5 platelets, cryoprecipitate and so on. But, in fact,
 6 at that time, the outcome was quite poor, so many of
 7 these patients did die of the underlying condition,
 8 not of liver disease.

9 **Q.** Do you know --

10 **A.** I'm not an expert on this, and I'm sure you will be
 11 speaking to people who know far more about the blood
 12 transfusion look-back than I do.

13 **Q.** Do you recall anything more about what happened in
 14 Leicester, in terms of the completion of the look-back
 15 exercise?

16 **A.** My understanding is that anybody who was found to --
 17 who is traced and found to be -- have antibodies to
 18 hepatitis C were referred to the same doctors,
 19 Dr Karl Nicholson and Dr Martin Wiselka, who were part
 20 of a Trent-wide hepatitis C interest group.

21 **Q.** Then I wanted to ask you about a further publication
 22 of yours concerned now with parvovirus.

23 Could we please have, Soumik, BPLL0016110_039.
 24 If we look a little closer at the bottom left-hand
 25 column, go down to the bottom of the page, we can see

80

1 there's an article there or a letter, "Symptomatic
 2 parvovirus B19 infection and heat-treated Factor IX
 3 concentrate". And this is published in The Lancet
 4 of May of 1989. You're one of the authors. It says:
 5 "Dry heating of Factor VIII and IX concentrate
 6 at 80 degrees centigrade for 72 hours may prevent
 7 transmission of non-A, non-B hepatitis and HIV."
 8 But then you refer to a study showing:
 9 "A very low seroconversion rate for B19 virus
 10 after first treatment of haemophilic boys with NHS
 11 heat-treated Factor VIII concentrate."
 12 And then you say this:
 13 "We've seen 3 patients who had symptomatic B19
 14 infection after infusion of NHS heat-treated Factor IX
 15 concentrate. Patients had little previous exposure to
 16 blood products. Two had received only heat-treated
 17 factor concentrate."
 18 Then you go on to describe symptoms in those 3
 19 patients. And then if we go to the conclusion, so top
 20 of the next page -- sorry, top of the right-hand
 21 column, please, Soumik, we can see that the conclusion
 22 is -- well, penultimate paragraph:
 23 "Transmission of B19 virus by Factor IX
 24 concentrate is implicated in these patients by the
 25 development of clinical illness and serologically

81

1 confirmed B19 infection after infusion of Factor IX
 2 concentrate."
 3 And you go on at the end of that paragraph to
 4 suggest that:
 5 "B19 virus may be transmitted by heat-treated
 6 Factor IX concentrates."
 7 You set out what the B19 virus can cause there
 8 and refer to persistent B19 infection documented in
 9 children with leukaemia, et cetera:
 10 "Blood-borne viruses [this is the last sentence
 11 of the letter] may continue to present an infective
 12 hazard to haemophiliacs despite vigorous heat
 13 treatment of coagulation factor concentrates."
 14 Can you recall anything about what prompted the
 15 sending of this letter and the cases of B19 parvovirus
 16 that were observed in your patients?
 17 **A.** The publication actually was stimulated by the
 18 virologists who were very keen to publish this. As
 19 I understood it, the evidence was suggestive but not
 20 conclusive, because PCR investigations for viruses can
 21 remain positive even when the virus is not viable. So
 22 the parvovirus could have been in the blood
 23 transfusions, been degraded by the virucidal
 24 treatment, but you might still get a positive PCR.
 25 Nevertheless, the fact that we had three

82

1 patients presenting with clinical features of
 2 parvovirus -- I mean, it's a common infection. It
 3 commonly occurs in children where it's often called
 4 slapped cheek syndrome or fifth disease, and many of
 5 us will have had it in the past. But, nevertheless,
 6 three of these patients presented with clinical
 7 features suggestive -- well, showing this disease, and
 8 it was confirmed by doing antibody testing. And it
 9 seemed to us that this was highly suggestive that it
 10 had been passed on by the NHS Factor IX concentrate.
 11 **Q.** To what extent was it a wider problem? Were these the
 12 only three patients you recall --
 13 **A.** The only three we ever saw, and we were very alert to
 14 viral transmission. We didn't see any other patients.
 15 **Q.** Then can I ask you more generally about your
 16 interactions with pharmaceutical companies during your
 17 time as director, particularly in the 1980s,
 18 Dr Mitchell. We've seen reference to various Cutter
 19 documents in which we can see sales representatives
 20 paying you visits.
 21 Did you also receive visits routinely from
 22 representatives of other companies trying to persuade
 23 you to change products?
 24 **A.** Yes. Occasionally, yes.
 25 **Q.** Some evidence has been received by the Tribunal of

83

1 there being potentially offers of quite lavish
 2 hospitality by pharmaceutical companies. Do you
 3 recall anything of that kind being offered to you?
 4 **A.** Not lavish, no. I was given assistance to attend
 5 educational meetings. The first time, I think, was in
 6 1986. So I'd been a consultant for six years by then,
 7 and I was given assistance by Cutter to attend the
 8 World Federation of Haemophilia meeting in Milan.
 9 I mean, it was actually quite important for me
 10 to go to these meetings because I was, effectively,
 11 professionally isolated. It certainly wasn't on
 12 a lavish scale. I did hear people -- I did hear
 13 stories of people getting first-class flights and all
 14 that stuff. It never applied to me. I heard Leaky
 15 Parapia -- sorry, Professor Parapia, who I was quite
 16 friendly with, saying that he knew people had been
 17 lavishly treated. Well, I've often found myself in
 18 the same hotel as him, so I don't think we were in the
 19 lavish treatment group.
 20 **MS RICHARDS:** Sir, I've pretty much come to the end of my
 21 questions for Dr Mitchell, but we need to afford the
 22 opportunity for the recognised legal representatives
 23 to suggest any further questions. So I wonder whether
 24 we could take our lunch now, early, and it may be
 25 there are some further questions for you after lunch,

84

1 Dr Mitchell, or it may be there are very few.
 2 **SIR BRIAN LANGSTAFF:** Let me explain, Dr Mitchell. What
 3 happens is that those who have been watching remotely
 4 who are Core Participants, represented Core
 5 Participants, have a right to suggest further
 6 questions which they may have for you to Counsel for
 7 the Inquiry. And if they have any, or if she herself
 8 thinks of any further questions, she will ask those
 9 after the lunch break.

10 So you are nearly finished but not quite. So we
 11 will take a break, and we will take it until, shall we
 12 say, 1.45. Would that suit?

13 **A.** That's fine. Thank you very much.

14 **SIR BRIAN LANGSTAFF:** So 1.45. The same rules apply to
 15 this break as did last time. Thank you very much so
 16 far.

17 **A.** Thank you.

18 **SIR BRIAN LANGSTAFF:** 1.45.

19 (12.42 pm)

(Luncheon Adjournment)

20 (1.45 pm)

21 **MS RICHARDS:** Dr Mitchell, I have just a handful of
 22 further questions on a range of different topics.

23 First of all, you told us this morning that, in
 24 terms of the process for testing patients for HIV and
 25

85

1 HCV, the system at Leicester was to invite patients to
 2 come in, to inform them of the tests, and to seek
 3 their consent to the testing process. Is that
 4 a practice you would have expected to be standard at
 5 the time?

6 **A.** I don't see why not really.

7 **Q.** Thank you. Then you mentioned when I asked you
 8 shortly before the lunch break about funding from
 9 pharmaceutical companies that you'd had some funding
 10 from Cutter to attend educational conferences or an
 11 educational conference.

12 Were there any other sources of funding that
 13 were made available to you or those in your position
 14 to attend such conferences?

15 **A.** You had to apply for study leave, and the hospital
 16 might finance the trip. But they had a space on the
 17 form saying "Are you receiving funding from any other
 18 source?" So if you said there you were getting, you
 19 know, hotel and flight from Cutter, they would then
 20 just give you study leave only. Study leave without,
 21 you know, paying for it. That's what used to happen.

22 **Q.** So it was possible, in principle, to get funding from
 23 your health authority hospital employer, but if --

24 **A.** I think they welcomed funding from elsewhere, in fact.

25 **Q.** When you say "welcomed", is that because it would

86

1 release NHS funding, scarce NHS resources?

2 **A.** No. I think it's probably that the committee -- it
 3 was done by a committee. I think they probably had
 4 a very limited budget and, therefore, they didn't have
 5 to refuse lots of people if there was external
 6 funding, which was accepted then.

7 **Q.** Do you know whether there were any rules or policies
 8 or regulations at the time that limited or regulated
 9 the receipt of funding or hospitality or gifts that
 10 a clinician could receive from pharmaceutical
 11 companies?

12 **A.** I'm sure there were, but I don't know details. I'm
 13 sorry.

14 **Q.** Then going to back to your evidence about your
 15 treatment policy, Dr Mitchell, can you recall roughly
 16 how long it took you after you arrived at Leicester in
 17 late 1979 to develop and implement that policy?

18 **A.** I think it probably took a year or a bit more, because
 19 in the first year, there was no haemophilia centre,
 20 there was no base, there was no sister. We were all
 21 very, very busy. We didn't have all that many junior
 22 staff either, and it took me a while to find my way
 23 around. I wasn't presented with it when I -- I'd
 24 never seen those previous documents that you showed me
 25 of the returns from 1976. I wasn't given a folder,

87

1 and I had to find out who the patients were. So it
 2 did take a while, probably a year, 18 months, before
 3 it was fully implemented. But the policy of not
 4 giving concentrates to people with mild disease,
 5 I would have done that straight away.

6 **Q.** Once you had formulated for your own purposes that
 7 policy, is that something that you shared with any of
 8 your fellow directors at other centres?

9 **A.** Well, I was professionally isolated. I didn't even
 10 know -- Ted Blecher in Nottingham, for instance, was
 11 my nearest -- 30 miles away. I didn't even know him
 12 at that point.

13 When I went to my first UKHCDO annual meeting,
 14 the only people I knew there were Prof Bloom very,
 15 very slightly from having worked with him five years
 16 before, and Eric Preston who didn't need any advice
 17 from me about hepatitis really. He was the country's
 18 expert on hepatitis in haemophilia. So both I and the
 19 sister will have talked about it, perhaps with the
 20 people next to us or something like that at lunch, but
 21 I -- you know. Yes, we didn't keep quiet about it,
 22 no.

23 **Q.** And then I asked you this morning about the extent to
 24 which you were able to adhere to your policy, and we
 25 looked at those UKHCDO records that suggested in 1984

88

1 a patient receiving NHS Factor VIII.
 2 If you did for any reason change a patient's
 3 treatment programme or change product, is that
 4 something that you'd discussed with the patients and
 5 explained the reasons for the change?
 6 **A.** Absolutely. Yes, absolutely. We would always hope
 7 that we're changing to a better product than the one
 8 they'd been receiving, or a safer product.
 9 **Q.** I think you say in your statement if, with increasing
 10 availability, you transferred a patient from
 11 commercial to NHS concentrate, you would have
 12 explained why you believed it to be safer.
 13 **A.** Yes.
 14 **Q.** Then in terms of the shortfall of NHS factor
 15 concentrates, you've told us you'd raised that with
 16 Dr Wagstaff, the director of the Regional Transfusion
 17 Centre in Sheffield. Was there any other person or
 18 process with whom it could be raised or through which
 19 it could be raised?
 20 **A.** Not that I'm aware of. As I understand it, and
 21 I heard this several times at the annual general
 22 meetings of the UKHCDO, the amount of NHS factor
 23 concentrate which the Trent received was absolutely
 24 proportionate to the amount of plasma which Trent
 25 National Blood Transfusion Service sent down to the

89

1 fractionators.
 2 So Bill Wagstaff would then have this amount of
 3 whatever it was -- 8Y eventually, or before that, NHS
 4 Factor VIII concentrate -- to share amongst the five
 5 haemophilia centres in the Trent. It was a big
 6 region; a population of about 5 million, the same as
 7 Scotland, so he would have to decide. I presume
 8 traditionally most of it would have gone to Sheffield,
 9 although I think Charlie Hay said they only got
 10 40 per cent of what they needed. So it was rationed
 11 out. I think Bill Wagstaff was the person who made
 12 the decisions.
 13 **Q.** We may hear evidence in relation to another
 14 haemophilia centre of patients being provided with
 15 a document or statement which described what product
 16 they received so that if they required treatment at
 17 another centre, that other centre would know what
 18 treatment to give. Was there any such system in
 19 operation at Leicester, to your knowledge?
 20 **A.** No, there wasn't, but the patients knew what they were
 21 taking. It would be the first thing we would ask if
 22 there was a visiting haemophilia patient: what have
 23 you been receiving? And we would always write back to
 24 that centre saying what we'd given them and what
 25 batches it had come from. What batches of what

90

1 material, in other words.
 2 **Q.** In terms of cryoprecipitate supplies, you've told us
 3 already that there were not shortfalls in supply, but
 4 I think your statement queries whether it would have
 5 been possible for Trent to produce enough
 6 cryoprecipitate for everybody if there'd been a switch
 7 from concentrates to cryoprecipitate.
 8 Did you ever raise with Dr Wagstaff the
 9 possibility of obtaining more cryoprecipitate?
 10 **A.** No.
 11 **Q.** Then in terms of the discussions that you have told us
 12 you would have had, or that the nursing sister would
 13 have had, with patients to talk about risks of HIV or
 14 risks in relation to liver abnormalities, would you
 15 expect those kinds of discussions to have been
 16 recorded by you or by the sister in the patient's
 17 medical notes?
 18 **A.** I can't be certain. They may have been or, they may
 19 have been recorded in the letter to the GP. I can't
 20 be certain.
 21 **Q.** Would you --
 22 **A.** We did a lot more talking than writing.
 23 **Q.** Then in terms of the absence of counselling and any
 24 kind of formal psychological support, did you take any
 25 steps to try and obtain such specialist support, and

91

1 if so, what was the response to your efforts?
 2 **A.** I tried to get social worker support. I didn't try
 3 and get it -- it was beyond me to get a clinical
 4 psychologist for the Leicester Royal Infirmary.
 5 I did try and get social worker support. I was
 6 successful. And I then had a letter from the head of
 7 the Social Services Department saying they were being
 8 reorganised, and it was no longer -- I think they may
 9 actually have been moved out from the hospital to the
 10 community -- I'm not certain of that -- and it was no
 11 longer possible to assign specific social workers to
 12 specific tasks, but I was welcome to apply. But,
 13 I mean, that's not really what we needed. I think
 14 that happened other places as well.
 15 **Q.** Up until the point of your retirement in 2003, was
 16 there ever any psychological support available for
 17 patients?
 18 **A.** They still don't have a clinical psychologist attached
 19 to the haemophilia centre. I've looked at their
 20 quality report, which is what we would have called an
 21 audit report. And they have to -- there are clinical
 22 psychologists in the hospital now, obviously. That
 23 and counselling has increased enormously over this
 24 period of 40 years. But they have to -- even these
 25 days, they have to refer the patient to one of the

92

1 hospital clinical psychologists, and that can cause
 2 a delay of up to three months, apparently. So it's
 3 improved but not improved enormously. I know some
 4 centres do have their own clinical psychologist, which
 5 strikes me as ideal.

6 **Q.** Professor Parapia in his evidence provided the Inquiry
 7 with a document which was a record, or appeared to be
 8 a record of a meeting of something called the
 9 haemostasis club.

10 **A.** Yes.

11 **Q.** Do you have any knowledge of the haemostasis club and
 12 what it was?

13 **A.** It was -- the one I know about was run by Dr Savidge
 14 and was in St Thomas' and was largely very
 15 theoretical, not clinically based really at all.
 16 I went, I think, once or twice at the most. There was
 17 very little clinical stuff -- clinical discussion
 18 there at all. It was all about the intricacies of the
 19 clotting process. So it was people who were doing
 20 PhDs and things in clotting.

21 **Q.** And then last question. In relation to UKHCDO annual
 22 meetings, were you aware at those meetings or the
 23 scientific sessions which accompanied them of the
 24 presence of pharmaceutical companies and the
 25 sponsorship by pharmaceutical companies?

93

1 **A.** I think what they did is -- I don't think on the
 2 one-day meetings that happened. On the two-day
 3 meetings, which had a scientific meeting as well,
 4 I think there was a sort of display by pharmaceutical
 5 companies.

6 **Q.** Was there an opportunity for pharmaceutical companies
 7 to approach centre directors and try and influence
 8 them to purchase their products at the AGM or at the
 9 scientific sessions?

10 **A.** I suppose if in the lunchtime you went up to their
 11 stand, they would talk to you.

12 **MS RICHARDS:** Those are the questions I have for you,
 13 Dr Mitchell.

14 Sir, do you have any questions for Dr Mitchell?
Questioned by SIR BRIAN LANGSTAFF

15 **SIR BRIAN LANGSTAFF:** Yes, I do.
 16 Dr Mitchell, you said in an article in 1992 that
 17 only the safest possible treatment is permissible. As
 18 a statement of principle, do I take it you still think
 19 that's the right principle to have applied?

20 **A.** Yes.

21 **SIR BRIAN LANGSTAFF:** Now, can I just ask you one or two
 22 questions about how that pans out, in terms of
 23 practice?
 24 The risks -- because adopting that principle

94

1 must involve being alert to and safeguarding against
 2 what is a risk; am I right?

3 **A.** Yes.

4 **SIR BRIAN LANGSTAFF:** The risks theoretically posed by
 5 large pool factor concentrates would come from three
 6 main ways, I would suggest, and I want to know if you
 7 agree: first, the nature of the donors who make
 8 donations to the pool -- that's first -- secondly, the
 9 size of the pool and, thirdly, the frequency with
 10 which, or the amount with which that is given. The
 11 amount, I suppose, is a mixture of the treatment and
 12 its frequency during which the large pool concentrate
 13 is given. Is that broadly right?

14 **A.** I think it probably is, although I would have thought
 15 that also the number of batches one was exposed to
 16 would have a role as well, and that could vary
 17 enormously.

18 In the -- I noticed in the paper about liver
 19 biopsies in children that I've just been -- either
 20 I've been sent or read again, I was looking at that
 21 and the table, and I notice that the first patient,
 22 seven years old, had received 45 batches. Not 45
 23 treatments but 45 batches. Now, that must increase
 24 risk, I think, as well as the factors you've
 25 mentioned, and that is what I was trying not to do,

95

1 but it's all imperfect.

2 **SIR BRIAN LANGSTAFF:** Moving on from that, it would be
 3 wrong for me to comment on the degree to which it was
 4 or wasn't imperfect.

5 **A.** I mean, the treatment generally was imperfect. I'm
 6 not talking purely about one hospital. I mean, across
 7 the board our treatment was imperfect. We did not
 8 have the perfect treatment.

9 **SIR BRIAN LANGSTAFF:** I suppose that one thing which would
 10 contribute to reducing the risk would have been the
 11 factor which you also draw attention to in your
 12 statement, which is having taken steps earlier than
 13 were taken to secure the inactivation of virus by
 14 whatever means was available.

15 **A.** Yes.

16 **SIR BRIAN LANGSTAFF:** One way in which it was suggested,
 17 as I understand it, in the very early 1980s was the
 18 concept of giving patients small pool concentrates.
 19 Did that cross your radar?

20 **A.** No, it didn't, and I wasn't aware that this was
 21 available or that BPL were making small pool
 22 concentrates. It didn't -- well, I wasn't getting
 23 that information.

24 **SIR BRIAN LANGSTAFF:** So if there had been small pool
 25 concentrates available and if you had known about

96

1 them, is that something that you might have wanted to
 2 use, do you think?
 3 **A.** Absolutely, yes. Yes, particularly for people that
 4 you had to give concentrates to but who hadn't -- like
 5 the chap who had an open heart surgery, for example --
 6 **SIR BRIAN LANGSTAFF:** Well --
 7 **A.** -- might not need concentrate in the future because he
 8 was around 10 per cent or something.
 9 **SIR BRIAN LANGSTAFF:** One of the aspects of making sure
 10 a treatment is as safe as possible is, I suppose,
 11 auditing to see -- or "checking" might be a better
 12 word -- to see how successful it has been in practice
 13 or appears to have been in practice.
 14 You did that, I think, as reflected in your
 15 article where you talk about the comparative rate of
 16 infection with HTLV-III in Leicester as compared to
 17 the average or the mean across the country.
 18 Do you know whether you were broadly successful
 19 in reducing the incidence of hepatitis?
 20 **A.** No, I don't. No, I don't have that information now.
 21 I would hope that we had. And certainly one of the
 22 things that we will have done is to reduce the number
 23 of patients who were doubly infective, because that
 24 group seemed to do particularly badly.
 25 **Q.** So you would like to think, at any rate, that the --

97

1 if to the extent that those who were treated at
 2 Leicester developed hepatitis, that because they
 3 didn't also develop HIV/HTLV-III infection, their
 4 hepatitis was less severe and less progressive for
 5 them?
 6 **A.** I would hope so, and that's what I've understood.
 7 I mean, also the fact that so many of our patients --
 8 I think it must be about 40 per cent of them if you
 9 look at that letter -- were only receiving single
 10 donor products, that I would have hoped that the
 11 prevalence of hepatitis C in Leicester patients would
 12 have been less as well. But I don't have those
 13 figures.
 14 **SIR BRIAN LANGSTAFF:** Now, you are, I think, one of the
 15 clinicians who has particularly articulated the policy
 16 of the safest treatment permissible to us. Not many,
 17 perhaps, have set it out in such clear terms. You
 18 felt, I think, a little bit isolated in Leicester, in
 19 terms of having contact with fellow directors or
 20 fellow haematologists dealing with haemophilia. Did
 21 you ever have any reaction from others in the field,
 22 such as you had any reaction, to what you were doing
 23 and the policies you were applying in Leicester?
 24 **A.** Only after we published the letter, so, late in the
 25 day, and not a lot then either really.

98

1 Professor Bloom said it was a good letter and one or
 2 two other people expressed a view that it was
 3 a difficult policy to carry out because there would be
 4 mistakes made out-of-hours and so on.
 5 Perhaps it would have been more difficult for
 6 a large centre. On the other hand, large centres had
 7 many more staff and it was basically 25 per cent or
 8 20 per cent of me and a single-handed nurse and
 9 whatever we could grab of the junior staff. But
 10 I don't know the answer to that really.
 11 **SIR BRIAN LANGSTAFF:** One of the lessons which may --
 12 subject to what is submitted to me at the end of the
 13 Inquiry by those who are interested, may be that if
 14 other centres generally had adopted the policy which
 15 you adopted, there would have been a considerable
 16 reduction in the extent of infection, particularly
 17 with HIV.
 18 Assuming for the moment that that is so, because
 19 other centres may not have adopted the same policy so
 20 clearly, what do you think might be the main reasons
 21 why they didn't?
 22 **A.** I don't know. There were -- I mean, I've heard
 23 evidence from this Inquiry that many directors
 24 believed it was essential to have at least two or more
 25 types of concentrate in case there should be

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1 a shortfall in one of them. I think some people did
 2 try to be batch-specific but I don't know when they
 3 started doing that. I think you have to start doing
 4 it very early.
 5 I don't really know why people didn't. I think
 6 one -- just as important, or more important, in fact,
 7 was to be as careful as you could possibly be that you
 8 did not give concentrates unless you had to.
 9 So if you take the example of this mild
 10 haemophiliac from elsewhere who had open heart
 11 surgery, we could have done his cardiac
 12 catheterisation with concentrate, saying, "Well, this
 13 chap's going to have a whole pile of concentrate in
 14 a couple of months' time, so why not give it to him
 15 now?" But on the other hand, what if the cardiac
 16 surgeons found him to be unsuitable or he had in fact
 17 decided he didn't want the operation? We would then
 18 have given him commercial concentrate for no good
 19 reason.
 20 So you had to be -- all this, of course, was in
 21 another hospital as well, which is a problem for us.
 22 But, you know, so you had to be fairly obsessional
 23 about not giving concentrate unless you felt it was
 24 really necessary.
 25 **SIR BRIAN LANGSTAFF:** Yes. Well, thank you very much,

1 doctor.
 2 Ms Richards.
 3 **MS RICHARDS:** Dr Mitchell, is there anything further that
 4 you would like to say?
 5 **A.** Simply that the accounts I've read by people who have
 6 been affected by this have been harrowing and I'm very
 7 sorry for that. I do hope that this Inquiry -- well,
 8 this long and thorough Inquiry -- will help them and
 9 I do believe it will.
 10 **MS RICHARDS:** Thank you.
 11 Sir.
 12 **SIR BRIAN LANGSTAFF:** It's my turn to thank you, and it's
 13 thanks to you that are particularly due, for giving us
 14 such a straightforward account of what happened at
 15 Leicester in such a sensible, thorough, considered,
 16 clear and helpful way.
 17 It's always an intrusion to come into your home,
 18 to ask you questions and you have been prepared to
 19 allow us to do that. Can I thank you for that and
 20 apologise to your wife for any intrusion that she may
 21 feel from your being sequestered in front of a camera
 22 for so long during the day.
 23 But I simply wish you well in what remains of
 24 your retirement, if you have any retirement?
 25 **A.** Yes, I do. Thank you very much.

1 Thank you.
 2 **MS RICHARDS:** Sir, tomorrow we have Dr Giangrande at
 3 10 o'clock, and I anticipate that we should be able to
 4 complete Dr Giangrande's evidence by the end of the
 5 day. And we will not, therefore, need to sit on
 6 Friday.
 7 **SIR BRIAN LANGSTAFF:** Very well. Ten o'clock, then,
 8 tomorrow. Those of you who might have been expecting
 9 to hear the Inquiry on Friday -- it had been
 10 announced -- should know that the likelihood is,
 11 subject to anything unexpected tomorrow, that we will
 12 not be sitting to hear any further evidence on Friday.
 13 But it's Dr Giangrande tomorrow.
 14 **MS RICHARDS:** Yes, sir.
 15 **SIR BRIAN LANGSTAFF:** Thank you very much.
 16 **(2.09 pm)**
 17 **(Adjourned until 10.00 am the following day)**
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<p>MS RICHARDS: [14] 3/4 44/21 45/1 45/16 58/19 58/22 58/25 84/20 85/22 94/12 101/3 101/10 102/2 102/14</p> <p>SIR BRIAN LANGSTAFF: [31] 1/3 1/5 1/12 1/15 1/18 1/20 2/6 44/20 44/23 45/3 45/11 58/21 58/23 85/2 85/14 85/18 94/16 94/22 95/4 96/2 96/9 96/16 96/24 97/6 97/9 98/14 99/11 100/25 101/12 102/7 102/15</p> <p>THE WITNESS: [6] 1/4 1/11 1/14 1/17 1/19 2/5</p> <hr/> <p>'76 [1] 22/16 '80 [1] 22/16 '81 [1] 23/24 '84 [2] 24/18 55/1 '84/'85 [1] 55/1 '85 [1] 55/1 '86 [1] 66/13</p> <hr/> <p>... [2] 66/20 67/12</p> <hr/> <p>0</p> <p>001 [1] 29/9 002 [3] 30/14 42/7 77/12 004 [1] 13/16 013 [1] 74/10 02 [1] 26/4 039 [1] 80/23 043 [1] 10/17 045 [1] 40/10 060 [1] 26/20 061 [1] 10/16 071 [1] 64/14 078 [1] 31/23 089 [1] 61/21</p> <hr/> <p>1</p> <p>1 March 1983 [1] 30/16 1 million [1] 46/24 1,351 [1] 79/12 1.45 [3] 85/12 85/14 85/18 1.45 pm [1] 85/21 10 [2] 18/18 48/3 10 o'clock [1] 102/3 10 per cent [1] 97/8 10.00 [2] 1/2 102/17</p>	<p>100 [3] 77/20 78/5 78/22 100 donations [1] 79/19 100 patients [1] 78/25 100,000 [2] 22/20 47/4 102 [1] 65/22 105 [1] 64/22 11 months [2] 64/1 67/3 11.10 [1] 44/19 11.12 [1] 45/13 11.40 [2] 45/12 45/15 12 [2] 44/25 47/16 12.42 pm [1] 85/19 128,050 [1] 26/23 14 May 1987 [1] 64/24 152,455 [1] 26/22 16 September [1] 7/17 174,570 [1] 42/17 18 [1] 51/10 18 months [3] 22/20 47/4 88/2 18 November 2020 [1] 1/1 180,000 units [1] 14/10 19 [1] 47/19 1970 [1] 3/10 1970s [3] 10/22 68/21 70/23 1973 [3] 3/10 3/12 11/10 1975 [4] 3/12 4/23 6/12 11/11 1976 [5] 13/14 13/18 14/2 14/5 87/25 1978 [5] 4/23 6/12 7/11 7/17 9/24 1979 [4] 9/24 10/2 14/5 87/17 1980 [5] 11/16 23/23 23/25 31/17 73/13 1980s [7] 56/6 59/3 73/3 73/3 73/20 83/17 96/17 1981 [3] 12/22 23/24 24/14 1982 [2] 57/6 57/24 1983 [8] 26/3 26/15 27/3 29/2 29/11 30/16 32/11 32/20 1983/84 [1] 28/14 1984 [6] 24/1 24/16 24/23 35/8 46/25 88/25 1985 [12] 35/15 35/22 36/18 38/6 39/19 40/12 46/1 48/25 49/17 50/23 51/6 53/9 1986 [9] 42/5 42/9</p>	<p>42/9 42/10 43/15 43/16 43/23 64/3 84/6 1987 [3] 13/4 64/16 64/24 1988 [1] 61/22 1989 [1] 81/4 1990s [3] 34/15 59/23 74/8 1992 [3] 69/20 74/11 94/17 1995 [1] 77/13 1st [1] 31/17</p> <hr/> <p>2</p> <p>2-3 [1] 77/19 2.09 pm [1] 102/16 20 [3] 13/21 20/5 44/25 20 July 1985 [1] 46/1 20 miles [1] 12/8 20 patients [1] 14/9 20 per cent [1] 99/8 2002 [1] 79/8 2003 [3] 10/9 10/10 92/15 2020 [1] 1/1 22 March 1983 [1] 29/11 23 [1] 47/20 240,000-odd [1] 42/14 25 February 1985 [2] 35/22 36/18 25 per cent [2] 47/14 99/7 259 [1] 66/2 27 [1] 47/10 27,001 [1] 26/20 271,000-odd [1] 42/14 28 [6] 44/7 47/12 47/17 49/22 50/4 50/14 288 [1] 66/11</p> <hr/> <p>3</p> <p>3 April 1987 [1] 64/16 30 miles [1] 88/11 300,000 [1] 20/8 31 [1] 26/16 31 out [1] 44/12 338 [1] 67/20 37 per cent [1] 47/19 38 haemophilia A [1] 42/9 388 [1] 26/20 39 [1] 36/6</p> <hr/> <p>4</p> <p>4 July 1985 [1] 40/12 4,424 [1] 79/11 40 [2] 75/5 75/10 40 per cent [3] 44/13 90/10 98/8</p>	<p>40 years [1] 92/24 423,870 [1] 26/24 45 [3] 95/22 95/22 95/23 472,710 [1] 42/17</p> <hr/> <p>5</p> <p>5 million [1] 90/6 50 per cent [2] 79/12 79/25 54 years [1] 47/20 57,850 [1] 26/23</p> <hr/> <p>6</p> <p>60 per cent [1] 46/25 675 [1] 79/13</p> <hr/> <p>7</p> <p>70 [1] 12/14 70 miles [1] 16/1 72 hours [1] 81/6 76 [2] 44/12 47/10</p> <hr/> <p>8</p> <p>80 [1] 81/6 83 [1] 13/17 84 [1] 28/14 8Y [1] 90/3</p> <hr/> <p>9</p> <p>9,000 [1] 14/12 9,222 blood [1] 79/8</p> <hr/> <p>A</p> <p>ability [1] 27/11 able [12] 11/12 17/17 23/5 24/3 37/9 40/17 40/21 55/10 59/25 77/17 88/24 102/3 abnormalities [2] 32/8 91/14 about [97] 4/6 4/10 6/6 6/8 6/19 9/4 10/12 13/4 14/6 14/10 14/12 15/9 18/18 19/16 19/21 20/19 21/10 25/17 29/3 30/20 31/19 32/20 32/23 33/2 33/14 37/18 41/1 45/6 45/7 45/8 46/14 51/21 52/9 53/22 54/2 54/3 54/10 55/1 55/25 56/1 56/2 56/3 56/4 56/7 56/9 56/25 57/12 58/10 58/18 59/1 59/19 60/1 60/10 63/23 67/14 67/20 68/14 68/19 69/2 69/3 70/18 71/9 71/18 72/1 72/10 72/12 73/1 74/15 75/16 75/20 77/13 77/21 78/22</p>	<p>79/13 79/25 80/11 80/13 80/21 82/14 83/15 86/8 87/14 88/17 88/19 88/21 88/23 90/6 91/13 93/13 93/18 94/23 95/18 96/6 96/25 97/15 98/8 100/23 about 10 [1] 18/18 abreast [1] 28/20 absence [3] 15/21 54/17 91/23 absolutely [5] 21/22 89/6 89/6 89/23 97/3 accepted [1] 87/6 access [4] 18/23 23/20 24/19 62/22 accompanied [2] 30/16 93/23 accord [1] 38/9 according [1] 8/3 account [1] 101/14 accounts [1] 101/5 accurate [3] 2/17 11/18 24/3 accusing [1] 76/3 achieve [1] 24/3 acid [6] 16/11 16/16 16/19 17/18 42/23 43/22 Acquired [2] 31/24 32/1 across [4] 13/5 28/21 96/6 97/17 active [2] 33/21 34/2 actively [1] 68/2 actual [1] 30/18 actually [19] 2/18 6/17 9/9 9/14 19/23 20/4 44/11 45/20 50/15 51/10 58/17 63/11 69/25 73/23 76/18 79/15 82/17 84/9 92/9 add [1] 71/21 adhere [2] 21/25 88/24 adjacent [1] 7/3 Adjourned [1] 102/17 Adjournment [1] 85/20 administration [1] 66/19 admitted [1] 8/1 adopted [4] 14/24 99/14 99/15 99/19 adopting [1] 94/25 Adoption [1] 49/6 adult [4] 7/4 20/21 47/25 51/17 adults [6] 19/13 20/18 21/24 36/15 47/20</p>	<p>54/24 advance [1] 70/13 advanced [1] 55/16 advertised [1] 12/17 advice [8] 25/4 53/21 53/24 54/2 54/5 56/25 60/8 88/16 advise [1] 25/10 advised [1] 60/9 advocate [1] 25/15 Aetiology [1] 30/24 affect [1] 76/5 affected [8] 20/22 36/3 36/14 48/9 54/12 75/10 76/6 101/6 affirmed [1] 3/2 afford [1] 84/21 afraid [1] 9/1 after [19] 8/1 8/8 54/6 55/15 55/20 63/10 63/11 64/1 65/17 65/17 69/2 71/5 81/10 81/14 82/1 84/25 85/9 87/16 98/24 afternoon [2] 2/21 5/22 again [11] 17/15 30/17 36/19 43/11 49/19 57/4 60/3 60/24 66/9 68/1 95/20 against [3] 25/11 43/5 95/1 age [1] 18/14 aged [1] 47/20 agent [4] 31/6 31/10 31/17 33/13 AGM [3] 73/19 73/19 94/8 ago [2] 33/3 77/24 agree [3] 48/15 61/12 95/7 AIDS [12] 28/13 29/3 29/19 29/23 31/16 31/20 32/1 32/4 32/20 35/9 53/18 56/5 AIDS/3 [1] 32/4 aim [1] 74/19 aiming [1] 17/10 Akin [1] 64/24 al [1] 49/6 albeit [1] 46/12 alcohol [2] 56/25 60/9 alert [2] 83/13 95/1 all [49] 2/3 3/24 4/21 12/16 13/6 14/18 16/8 28/3 28/14 29/25 30/1 32/5 33/19 35/19 38/3 40/3 40/22 41/7 43/24 47/18 47/19 47/22 48/14 48/22 48/24 49/23 50/13 50/25 51/23 53/6 55/11</p>
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<p>A</p> <p>all... [18] 59/19 63/16 66/21 73/4 75/12 76/12 76/19 76/21 77/20 84/13 85/24 87/20 87/21 93/15 93/18 93/18 96/1 100/20</p> <p>all-embracing [1] 50/13</p> <p>allergic [1] 19/5</p> <p>allocating [1] 21/11</p> <p>allocation [1] 21/15</p> <p>allow [3] 11/5 73/20 101/19</p> <p>almost [5] 12/18 34/7 40/16 44/12 72/14</p> <p>alone [1] 28/25</p> <p>along [2] 12/18 62/10</p> <p>aloud [1] 45/20</p> <p>already [10] 7/15 14/17 32/24 36/22 51/18 51/19 60/8 73/2 73/15 91/3</p> <p>also [23] 4/3 5/22 8/24 21/2 21/8 22/10 23/25 25/16 40/1 40/3 43/22 46/15 46/22 52/6 54/3 69/8 71/6 71/23 83/21 95/15 96/11 98/3 98/7</p> <p>alter [1] 33/8</p> <p>although [17] 2/6 9/2 15/9 16/13 24/11 32/13 44/8 48/10 53/14 55/9 60/13 72/2 72/3 78/21 78/25 90/9 95/14</p> <p>always [13] 5/24 16/19 16/24 24/3 28/6 39/7 40/6 43/8 55/9 62/11 89/6 90/23 101/17</p> <p>am [7] 1/2 1/11 45/13 45/15 71/8 95/2 102/17</p> <p>amongst [1] 90/4</p> <p>amount [10] 14/11 27/7 27/12 38/21 42/13 89/22 89/24 90/2 95/10 95/11</p> <p>amyl [1] 31/2</p> <p>amyl nitrate [1] 31/2</p> <p>an initial [1] 75/23</p> <p>an intermediate [1] 77/10</p> <p>analysing [1] 79/5</p> <p>aneurysm [1] 80/3</p> <p>announced [1] 102/10</p> <p>annual [9] 13/13 26/15 27/15 42/8</p>	<p>73/11 73/19 88/13 89/21 93/21</p> <p>another [6] 36/9 63/10 76/19 90/13 90/17 100/21</p> <p>answer [2] 59/8 99/10</p> <p>antibodies [2] 79/10 80/17</p> <p>antibody [12] 47/9 47/13 47/24 48/1 48/24 53/14 59/17 60/4 78/7 78/24 79/18 83/8</p> <p>anticipate [1] 102/3</p> <p>antifibrinolytic [1] 49/13</p> <p>antigen [1] 63/12</p> <p>any [66] 4/18 6/3 6/4 9/1 14/1 15/21 15/23 16/15 17/1 19/1 19/15 23/9 23/20 23/21 28/8 29/22 30/18 32/6 32/19 33/21 34/23 35/12 37/18 38/13 38/17 43/7 45/9 50/1 50/6 51/8 52/24 54/4 54/7 54/17 56/6 65/18 66/10 67/1 68/1 68/8 71/11 71/21 73/5 83/14 84/23 85/7 85/8 86/12 86/17 87/7 88/7 88/16 89/2 89/17 90/18 91/23 91/24 92/16 93/11 94/14 97/25 98/21 98/22 101/20 101/24 102/12</p> <p>anybody [1] 80/16</p> <p>anyone [1] 45/5</p> <p>anything [19] 4/8 4/10 6/19 9/4 14/6 21/10 41/1 45/7 51/8 54/19 56/5 72/22 75/20 77/21 80/13 82/14 84/3 101/3 102/11</p> <p>aortic [1] 80/3</p> <p>Apart [1] 48/5</p> <p>apologies [1] 31/13</p> <p>apologise [1] 101/20</p> <p>apology [1] 66/16</p> <p>apparent [1] 70/25</p> <p>apparently [3] 14/1 67/24 93/2</p> <p>appealed [1] 34/12</p> <p>appear [1] 36/17</p> <p>appeared [1] 93/7</p> <p>appears [3] 37/17 66/9 97/13</p> <p>applicable [1] 33/11</p> <p>applied [2] 84/14 94/20</p> <p>applies [1] 45/9</p> <p>apply [3] 85/14 86/15</p>	<p>92/12</p> <p>applying [1] 98/23</p> <p>appointed [2] 11/10 12/22</p> <p>appointment [1] 11/16</p> <p>appreciate [2] 23/20 33/2</p> <p>approach [13] 4/10 6/19 14/6 15/16 16/10 20/14 20/20 25/3 33/7 35/8 48/20 62/21 94/7</p> <p>approached [3] 52/14 53/3 78/3</p> <p>appropriate [1] 46/13</p> <p>approximately [1] 52/11</p> <p>April [1] 64/16</p> <p>are [64] 1/5 1/7 1/8 1/10 1/15 1/21 1/22 1/23 1/25 2/11 2/15 2/19 2/23 5/7 7/19 22/14 22/14 23/2 24/2 24/22 25/9 25/22 26/7 32/14 36/2 36/6 37/24 40/16 40/20 40/20 40/23 42/18 44/9 45/21 46/22 47/20 50/5 50/12 53/10 53/10 57/21 61/25 66/15 68/1 68/2 69/8 72/3 72/3 72/13 72/16 75/15 76/19 76/23 79/4 84/25 85/1 85/4 85/10 86/17 92/21 94/12 98/14 99/13 101/13</p> <p>area [1] 4/16</p> <p>aren't [2] 22/15 78/18</p> <p>argument [1] 33/14</p> <p>Armour [1] 13/25</p> <p>around [2] 87/23 97/8</p> <p>arrangements [9] 2/19 52/12 53/4 54/7 55/4 55/24 55/25 59/13 60/17</p> <p>arrived [11] 10/13 11/20 12/21 13/14 14/5 14/16 22/4 23/4 27/9 73/3 87/16</p> <p>arthropathy [1] 34/10</p> <p>article [19] 7/17 8/10 10/14 10/19 44/15 58/16 61/18 61/22 65/12 65/17 65/19 69/17 69/20 69/25 72/1 72/24 81/1 94/17 97/15</p> <p>articulated [1] 98/15</p> <p>as [127]</p> <p>ask [17] 2/24 3/1 10/12 38/17 52/9</p>	<p>55/25 56/1 57/1 67/19 68/14 73/1 80/21 83/15 85/8 90/21 94/22 101/18</p> <p>asked [8] 10/10 45/7 56/3 58/14 77/24 78/5 86/7 88/23</p> <p>asking [9] 3/7 6/2 33/2 57/12 58/25 59/5 59/10 65/25 68/25</p> <p>aspects [1] 97/9</p> <p>assign [1] 92/11</p> <p>assistance [2] 84/4 84/7</p> <p>associated [1] 48/22</p> <p>association [3] 28/12 32/25 65/10</p> <p>assume [1] 32/10</p> <p>Assuming [1] 99/18</p> <p>assumption [1] 60/7</p> <p>asymptomatic [1] 58/8</p> <p>attached [1] 92/18</p> <p>attempt [1] 75/23</p> <p>Attempts [1] 71/4</p> <p>attend [8] 19/17 59/18 60/21 73/10 84/4 84/7 86/10 86/14</p> <p>attended [1] 6/25</p> <p>attention [1] 96/11</p> <p>audience [2] 72/8 76/5</p> <p>audio [1] 24/11</p> <p>audit [1] 92/21</p> <p>auditing [1] 97/11</p> <p>authored [3] 29/14 61/19 69/20</p> <p>authorities [2] 73/8 76/17</p> <p>authority [1] 86/23</p> <p>authors [3] 29/23 46/4 81/4</p> <p>automatic [1] 55/21</p> <p>autumn [1] 39/19</p> <p>availability [2] 69/23 89/10</p> <p>available [19] 2/12 21/21 26/10 39/18 41/14 41/25 52/14 54/19 55/13 56/7 60/22 64/1 68/19 77/1 86/13 92/16 96/14 96/21 96/25</p> <p>average [1] 97/17</p> <p>avoid [4] 25/5 25/5 25/16 49/14</p> <p>awaiting [1] 66/15</p> <p>aware [12] 15/23 15/23 28/12 32/24 58/13 58/15 59/9 68/7 70/7 89/20 93/22 96/20</p>	<p>away [6] 12/8 12/10 16/1 20/5 88/5 88/11</p> <p>awful [2] 28/24 53/22</p> <p>AZT [1] 55/14</p> <p>B</p> <p>B19 [9] 81/2 81/9 81/13 81/23 82/1 82/5 82/7 82/8 82/15</p> <p>babies [1] 42/25</p> <p>baby [1] 77/5</p> <p>back [18] 10/10 29/16 38/23 40/5 40/20 44/25 52/25 69/3 77/14 77/23 78/1 78/18 79/7 80/2 80/12 80/14 87/14 90/23</p> <p>background [2] 3/21 4/17</p> <p>badly [1] 97/24</p> <p>bags [2] 26/20 44/8</p> <p>balanced [1] 25/17</p> <p>bank [2] 3/24 52/4</p> <p>banks [2] 12/13 78/8</p> <p>Barber [1] 40/22</p> <p>Barry [1] 40/22</p> <p>Barry Barber [1] 40/22</p> <p>base [1] 87/20</p> <p>based [4] 14/25 14/25 73/6 93/15</p> <p>basic [1] 70/8</p> <p>basically [2] 8/1 99/7</p> <p>basis [4] 20/14 33/23 56/12 58/11</p> <p>batch [13] 22/2 22/18 22/21 22/22 22/24 23/7 47/2 47/5 66/5 66/15 66/20 66/20 100/2</p> <p>batch ... the [1] 66/20</p> <p>batch-specific [1] 100/2</p> <p>batches [11] 22/22 31/15 40/18 40/21 57/7 70/20 90/25 90/25 95/15 95/22 95/23</p> <p>BAYP000007 [1] 40/10</p> <p>BAYP000008 [4] 65/22 66/2 66/11 67/20</p> <p>BAYP000010 [2] 64/14 64/22</p> <p>be [90] 2/8 2/16 5/18 6/11 11/6 13/16 14/13 15/8 15/16 16/14 19/17 23/5 24/22 25/17 26/11 27/14 31/10 32/15 33/25 36/3 36/10 37/8 37/17</p>	<p>38/21 38/23 39/22 40/1 40/2 41/2 42/19 44/24 45/7 45/22 46/5 46/11 48/16 48/20 49/7 49/10 49/11 49/14 57/10 57/15 62/23 63/11 64/2 65/6 67/3 69/1 70/5 71/6 71/16 71/23 74/16 76/6 76/16 77/1 78/7 78/13 79/3 79/14 79/17 80/10 80/17 82/5 84/24 85/1 86/4 89/12 89/18 89/19 90/21 91/18 91/20 93/7 96/2 97/11 98/8 99/3 99/13 99/20 99/25 100/2 100/7 100/7 100/16 100/20 100/22 102/3 102/12</p> <p>became [10] 33/4 35/6 39/12 39/18 55/13 55/16 60/22 60/24 61/10 71/5</p> <p>because [45] 4/17 8/11 9/12 12/9 15/21 17/9 20/6 25/13 26/6 32/24 33/8 35/9 39/6 39/21 40/6 44/9 44/17 45/21 46/13 50/22 53/12 53/18 53/21 54/11 62/24 63/9 63/22 64/7 68/10 72/20 74/3 75/9 76/22 79/1 79/24 82/20 84/10 86/25 87/18 94/25 97/7 97/23 98/2 99/3 99/18</p> <p>become [5] 2/1 28/11 41/25 55/10 79/17</p> <p>becoming [1] 70/24</p> <p>been [82] 2/6 2/9 2/10 6/7 6/21 9/6 9/22 10/20 12/8 14/16 16/23 18/17 18/18 22/19 24/18 27/22 29/15 34/21 37/1 41/6 41/7 41/7 41/11 41/14 41/23 44/1 47/3 48/7 48/8 48/18 49/18 50/15 51/19 53/2 53/16 54/10 58/25 59/22 60/8 62/8 63/19 66/9 66/18 67/4 68/18 69/12 74/2 76/17 76/22 77/17 78/6 79/1 79/2 82/22 82/23 83/10 83/25 84/6 84/16 85/3 89/8 90/23 91/5 91/6 91/15 91/18 91/19 92/9 95/19 95/20 96/10 96/24</p>
--	--	---	--	---	--

<p>B</p> <p>been... [10] 97/12 97/13 98/12 99/5 99/15 101/6 101/6 101/18 102/8 102/9</p> <p>been small [1] 96/24</p> <p>before [21] 1/5 9/7 10/13 12/19 13/14 22/11 24/20 26/10 31/13 44/17 45/17 45/24 50/8 53/3 55/24 66/24 67/3 86/8 88/2 88/16 90/3</p> <p>behalf [1] 29/16</p> <p>being [26] 4/1 13/15 13/25 14/3 14/20 19/8 19/12 19/14 26/22 27/7 33/15 36/22 40/17 42/14 46/19 56/7 56/11 66/7 66/10 74/19 84/1 84/3 90/14 92/7 95/1 101/21</p> <p>believe [13] 4/13 8/22 14/18 19/21 21/8 46/7 49/2 65/5 67/5 68/9 68/17 71/23 101/9</p> <p>believed [4] 63/18 72/9 89/12 99/24</p> <p>believer [1] 39/25</p> <p>best [1] 48/20</p> <p>better [2] 89/7 97/11</p> <p>between [8] 3/12 9/24 13/24 15/5 22/16 28/12 75/16 78/20</p> <p>beyond [1] 92/3</p> <p>big [1] 90/5</p> <p>Bill [3] 21/14 90/2 90/11</p> <p>biopsies [1] 95/19</p> <p>biopsy [2] 7/18 8/5</p> <p>bit [11] 24/25 61/11 62/16 71/24 72/5 72/9 72/20 76/12 78/21 87/18 98/18</p> <p>Blackburn [5] 6/16 6/17 6/20 7/21 11/13</p> <p>bleach [1] 54/4</p> <p>Blecher [1] 88/10</p> <p>bleed [1] 43/6</p> <p>bleeding [2] 11/24 16/22</p> <p>bleeds [4] 18/22 19/17 25/5 34/25</p> <p>block [1] 52/23</p> <p>blood [39] 3/24 5/11 5/16 5/19 5/23 6/2 6/2 6/23 11/5 12/13 23/3 32/5 47/11 48/4 48/22 48/24 49/15 54/4 56/11 59/18 63/14 63/15 65/5 69/14 71/6</p>	<p>71/13 77/15 77/25 78/2 78/4 78/8 78/17 79/8 80/4 80/11 81/16 82/10 82/22 89/25</p> <p>Blood-borne [1] 82/10</p> <p>Bloom [7] 4/7 4/9 29/15 46/2 46/4 88/14 99/1</p> <p>BMJ [8] 28/17 44/6 44/15 44/21 45/16 49/17 50/22 51/17</p> <p>board [3] 70/3 71/25 96/7</p> <p>boon [1] 13/6</p> <p>borne [1] 82/10</p> <p>both [6] 27/20 32/22 33/12 43/18 74/22 88/18</p> <p>bottom [9] 10/25 26/25 30/23 37/20 42/18 57/24 67/20 80/24 80/25</p> <p>boy [1] 63/21</p> <p>boys [2] 25/8 81/10</p> <p>BPL [10] 6/11 21/7 23/14 23/25 24/16 24/24 35/22 40/1 41/12 96/21</p> <p>BPLL0016110 [1] 80/23</p> <p>break [11] 2/19 2/22 44/18 44/24 45/9 45/14 45/17 85/9 85/11 85/15 86/8</p> <p>BRIAN [1] 94/15</p> <p>brief [2] 74/1 74/6</p> <p>briefly [2] 5/5 62/2</p> <p>bring [1] 38/17</p> <p>bringing [1] 48/2</p> <p>British [6] 28/19 28/22 39/25 46/1 61/19 61/22</p> <p>broadly [3] 73/1 95/13 97/18</p> <p>budget [1] 87/4</p> <p>Building [1] 76/22</p> <p>built [1] 11/17</p> <p>bulletin [2] 10/15 58/16</p> <p>business [1] 78/15</p> <p>busy [2] 78/8 87/21</p> <p>but [131]</p> <p>buy [1] 22/17</p> <p>buying [1] 47/2</p> <p>by [65] 3/3 3/7 6/20 9/7 9/13 9/19 10/20 11/11 11/20 11/25 15/4 20/2 21/13 22/5 27/3 29/14 30/25 32/5 32/10 33/5 33/16 36/17 39/4 40/1 43/23 46/6 47/1 49/6 53/6</p>	<p>55/2 55/3 60/11 60/23 61/19 61/23 63/6 70/23 71/6 73/25 75/23 80/1 81/23 81/24 82/5 82/17 82/23 83/8 83/10 83/25 84/2 84/6 84/7 87/3 91/16 91/16 93/13 93/25 94/4 94/15 95/4 96/13 99/13 101/5 101/6 102/4</p> <p>C</p> <p>calculation [1] 26/21</p> <p>call [2] 2/10 4/1</p> <p>called [4] 39/5 83/3 92/20 93/8</p> <p>calls [2] 6/1 41/5</p> <p>came [16] 8/4 12/18 13/5 15/15 21/8 31/17 35/14 50/8 50/22 52/20 62/10 63/8 78/3 78/6 78/22 78/23</p> <p>camera [1] 101/21</p> <p>can [72] 2/10 3/4 3/6 4/8 4/9 6/19 7/16 7/25 9/4 10/13 13/18 13/22 14/6 15/2 19/19 23/9 26/14 26/18 27/17 28/11 30/23 31/13 32/18 33/1 33/3 33/21 35/21 38/1 41/1 42/8 42/11 42/18 43/15 43/17 45/7 49/19 50/3 52/9 52/11 52/16 53/8 54/12 56/1 56/5 57/4 57/14 57/18 57/24 59/13 59/22 61/18 64/15 64/23 65/22 66/3 66/12 66/18 70/10 74/14 75/20 77/21 80/25 81/21 82/7 82/14 82/20 83/15 83/19 87/15 93/1 94/22 101/19</p> <p>can't [10] 7/8 18/16 33/6 37/10 41/15 53/25 54/25 68/8 91/18 91/19</p> <p>candidiasis [1] 32/15</p> <p>cannot [1] 71/16</p> <p>capacity [1] 7/22</p> <p>cardiac [8] 62/7 62/14 62/19 62/20 63/1 64/19 100/11 100/15</p> <p>Cardiff [2] 3/18 3/19</p> <p>cardiothoracic [3] 62/14 62/15 77/3</p> <p>care [12] 11/23 14/3 16/6 70/13 74/22 74/25 75/6 75/13</p>	<p>75/17 75/25 76/9 76/14</p> <p>career [1] 3/8</p> <p>careful [1] 100/7</p> <p>carefully [1] 53/19</p> <p>carinii [1] 30/21</p> <p>carried [2] 62/11 66/5</p> <p>carrier [3] 27/18 27/22 61/10</p> <p>carry [4] 33/18 72/18 79/22 99/3</p> <p>case [11] 24/5 39/8 51/7 61/1 62/3 64/5 64/18 64/18 65/15 68/3 99/25</p> <p>cases [6] 29/22 31/20 61/20 61/25 64/11 82/15</p> <p>catch [1] 72/20</p> <p>categories [1] 17/4</p> <p>category [1] 36/3</p> <p>catheterisation [4] 17/25 62/19 63/4 100/12</p> <p>cause [3] 31/9 82/7 93/1</p> <p>caused [1] 66/6</p> <p>causing [1] 67/8</p> <p>CBLA0002067 [1] 35/20</p> <p>cent [11] 44/13 46/25 47/14 47/19 79/12 79/25 90/10 97/8 98/8 99/7 99/8</p> <p>centigrade [1] 81/6</p> <p>centre [58] 5/7 5/11 5/16 6/15 10/4 10/6 10/23 11/3 11/14 11/18 14/20 16/2 16/2 20/11 21/2 21/6 24/9 29/21 30/8 30/9 30/12 32/4 32/6 46/6 47/11 48/2 50/19 51/23 51/24 55/15 57/16 59/2 60/20 60/23 73/7 73/16 74/12 74/24 74/25 75/7 75/11 75/16 75/17 75/24 76/9 76/14 76/14 76/21 77/16 87/19 89/17 90/14 90/17 90/17 90/24 92/19 94/7 99/6</p> <p>centre's [1] 39/2</p> <p>centre/comprehensiv e [1] 76/14</p> <p>centres [20] 18/18 35/8 37/23 37/23 38/3 38/11 38/22 46/8 73/6 73/20 74/6 74/16 75/1 76/6 88/8 90/5 93/4 99/6 99/14 99/19</p>	<p>centres in [1] 90/5</p> <p>certain [6] 36/8 53/13 69/1 91/18 91/20 92/10</p> <p>certainly [23] 16/21 19/7 19/9 21/14 21/20 22/10 27/3 30/3 36/17 38/10 38/21 41/18 42/1 42/3 51/14 53/25 54/2 58/21 67/14 73/2 76/7 84/11 97/21</p> <p>cetera [3] 57/23 77/8 82/9</p> <p>CGRA0000559 [1] 37/14</p> <p>change [5] 40/3 83/23 89/2 89/3 89/5</p> <p>changing [2] 23/1 89/7</p> <p>chap [1] 97/5</p> <p>chap's [1] 100/13</p> <p>characterised [1] 10/5</p> <p>Charlie [2] 13/3 90/9</p> <p>Charlie Hay [1] 13/3</p> <p>checked [1] 2/16</p> <p>checking [1] 97/11</p> <p>cheek [1] 83/4</p> <p>chief [3] 39/5 39/11 78/4</p> <p>child [3] 18/14 19/20 77/5</p> <p>children [11] 18/9 19/14 36/1 43/8 46/21 47/10 48/10 51/2 82/9 83/3 95/19</p> <p>choices [1] 4/19</p> <p>chose [1] 52/16</p> <p>Christmas [3] 13/21 47/23 63/22</p> <p>chronic [6] 7/18 46/14 48/7 48/11 57/6 70/24</p> <p>circumstances [3] 36/8 62/3 62/4</p> <p>circumstantial [1] 63/17</p> <p>Cirrhosis [1] 48/8</p> <p>class [1] 84/13</p> <p>clear [5] 24/17 51/17 70/5 98/17 101/16</p> <p>cleared [1] 54/4</p> <p>clearly [1] 99/20</p> <p>clerked [1] 8/2</p> <p>clinic [1] 61/3</p> <p>clinical [18] 4/3 32/13 47/20 54/22 57/17 58/5 58/5 70/4 81/25 83/1 83/6 92/3 92/18 92/21 93/1 93/4 93/17 93/17</p> <p>clinically [1] 93/15</p> <p>clinician [1] 87/10</p>	<p>clinicians [1] 98/15</p> <p>clinics [2] 7/1 60/21</p> <p>closer [1] 80/24</p> <p>clotting [2] 93/19 93/20</p> <p>club [2] 93/9 93/11</p> <p>clubs [1] 34/16</p> <p>co [2] 46/4 61/19</p> <p>co-authored [1] 61/19</p> <p>co-authors [1] 46/4</p> <p>coagulation [8] 3/25 4/6 4/16 5/19 32/5 69/21 70/7 82/13</p> <p>cohort [4] 36/25 51/21 52/19 55/5</p> <p>cohorts [1] 17/15</p> <p>cold [1] 23/3</p> <p>colleagues [1] 12/15</p> <p>column [6] 7/14 10/20 45/19 47/6 80/25 81/21</p> <p>columns [1] 27/1</p> <p>combination [1] 16/20</p> <p>come [19] 3/21 13/11 18/6 25/23 27/25 43/8 43/11 43/20 44/15 44/25 52/25 55/10 74/8 75/1 84/20 86/2 90/25 95/5 101/17</p> <p>coming [1] 33/25</p> <p>comment [3] 14/8 69/17 96/3</p> <p>commercial [37] 14/19 21/3 21/25 22/2 22/5 22/18 24/21 25/23 27/4 27/10 36/15 36/18 36/23 39/21 39/22 39/24 41/15 42/16 43/19 43/25 47/1 47/3 47/12 49/23 50/5 50/6 50/17 51/12 51/15 62/10 63/7 63/19 63/20 63/24 64/4 89/11 100/18</p> <p>committee [2] 87/2 87/3</p> <p>common [2] 13/6 83/2</p> <p>commonly [1] 83/3</p> <p>communication [1] 49/1</p> <p>community [1] 92/10</p> <p>companies [10] 64/11 83/16 83/22 84/2 86/9 87/11 93/24 93/25 94/5 94/6</p> <p>company [2] 65/9 65/19</p> <p>comparative [1] 97/15</p> <p>compare [1] 34/14</p> <p>compared [2] 38/22</p>
--	--	---	--	---	---

<p>C</p> <p>compared... [1] 97/16</p> <p>competing [1] 34/16</p> <p>complete [5] 31/21 32/3 42/6 60/3 102/4</p> <p>completed [1] 57/15</p> <p>completely [1] 48/12</p> <p>completeness [1] 23/17</p> <p>completion [1] 80/14</p> <p>compliance [1] 24/4</p> <p>complicated [1] 55/16</p> <p>complications [1] 75/12</p> <p>components [1] 79/9</p> <p>comprehensive [5] 74/25 75/6 75/17 76/9 76/14</p> <p>compress [1] 43/5</p> <p>concentrate [68] 4/13 4/14 7/5 7/6 14/19 14/20 18/5 21/25 22/1 22/3 22/5 23/25 24/4 24/21 27/10 27/20 31/16 35/24 36/8 37/8 37/11 39/16 39/24 41/22 42/13 42/16 43/18 46/25 47/1 47/13 47/15 47/16 48/16 49/13 50/5 50/6 50/10 50/12 50/16 50/17 51/15 62/10 63/7 63/19 63/20 63/24 64/1 64/4 64/8 70/20 81/3 81/5 81/11 81/15 81/17 81/24 82/2 83/10 89/11 89/23 90/4 95/12 97/7 99/25 100/12 100/13 100/18 100/23</p> <p>concentrates [53] 6/10 7/7 13/25 14/2 14/3 15/1 15/6 15/14 18/4 20/23 21/1 21/3 21/6 21/11 25/20 25/23 26/22 27/7 28/13 32/21 33/16 33/17 36/11 36/23 43/24 44/1 44/2 46/12 46/18 48/14 49/4 51/13 61/24 62/2 67/8 68/18 69/21 70/8 71/1 71/9 71/19 72/12 82/6 82/13 88/4 89/15 91/7 95/5 96/18 96/22 96/25 97/4 100/8</p> <p>concentrating [1] 28/25</p> <p>concept [1] 96/18</p> <p>concern [2] 46/14 75/15</p>	<p>concerned [4] 4/4 63/22 76/12 80/22</p> <p>concerns [3] 24/15 68/19 75/21</p> <p>conclusion [3] 71/12 81/19 81/21</p> <p>conclusive [1] 82/20</p> <p>condition [2] 56/17 80/7</p> <p>conditions [1] 32/14</p> <p>conference [1] 86/11</p> <p>conferences [2] 86/10 86/14</p> <p>confirm [2] 66/18 66/20</p> <p>confirmed [4] 9/16 63/13 82/1 83/8</p> <p>connection [2] 15/5 66/10</p> <p>consent [3] 58/15 59/10 86/3</p> <p>consequence [1] 50/20</p> <p>consequences [1] 72/1</p> <p>consider [1] 39/21</p> <p>considerable [3] 8/6 19/24 99/15</p> <p>considerably [1] 42/4</p> <p>consideration [5] 33/22 34/2 34/23 71/17 72/4</p> <p>considered [3] 34/22 35/11 101/15</p> <p>considering [2] 35/3 65/4</p> <p>considers [1] 61/20</p> <p>constitute [1] 47/18</p> <p>consultant [8] 10/3 11/10 12/1 12/9 12/20 52/14 62/21 84/6</p> <p>consultants [4] 5/7 11/20 12/15 55/19</p> <p>contact [2] 25/11 98/19</p> <p>contacted [2] 52/19 59/17</p> <p>contain [2] 31/16 48/14</p> <p>contaminant [1] 72/14</p> <p>contamination [2] 70/19 70/22</p> <p>context [1] 69/22</p> <p>continue [3] 40/24 49/3 82/11</p> <p>continued [6] 22/7 22/12 27/13 33/11 35/6 60/20</p> <p>continues [1] 75/19</p> <p>continuing [4] 39/8 53/14 60/6 60/7</p>	<p>continuous [1] 43/2</p> <p>contracted [1] 57/17</p> <p>contribute [1] 96/10</p> <p>controversy [1] 69/4</p> <p>convenient [2] 44/19 52/20</p> <p>conversation [1] 75/18</p> <p>convert [1] 18/21</p> <p>convince [1] 71/14</p> <p>convinced [4] 15/4 15/8 39/23 67/9</p> <p>convincing [1] 63/18</p> <p>Core [2] 85/4 85/4</p> <p>coronavirus [1] 2/11</p> <p>correct [12] 3/11 10/17 18/12 18/13 25/19 39/22 41/3 41/16 41/19 43/23 68/10 69/24</p> <p>correction [1] 77/4</p> <p>correctly [1] 52/3</p> <p>corresponds [1] 2/17</p> <p>costs [1] 70/6</p> <p>could [47] 2/7 2/8 3/13 10/18 10/25 14/8 15/8 17/6 17/24 18/2 20/1 33/19 34/14 35/19 38/18 39/14 40/9 45/1 45/18 47/6 49/10 49/11 55/9 57/3 57/8 58/19 60/11 62/2 64/14 71/6 72/7 73/22 74/9 75/17 76/15 76/15 77/11 80/23 82/22 84/24 87/10 89/18 89/19 95/16 99/9 100/7 100/11</p> <p>couldn't [4] 17/25 23/8 63/2 78/11</p> <p>Counsel [1] 85/6</p> <p>counselling [4] 54/18 55/2 91/23 92/23</p> <p>country [1] 97/17</p> <p>country's [1] 88/17</p> <p>county [1] 20/4</p> <p>couple [4] 25/22 35/17 57/1 100/14</p> <p>course [10] 6/17 9/11 14/17 28/20 55/6 55/9 60/20 63/16 79/23 100/20</p> <p>cover [2] 17/25 18/1</p> <p>covered [3] 54/4 63/4 63/6</p> <p>Craske [4] 29/14 30/15 30/25 73/25</p> <p>criteria [1] 32/6</p> <p>cross [1] 96/19</p> <p>cryo [1] 18/8</p> <p>cryoprecipitate [42] 6/10 7/8 11/6 13/23</p>	<p>17/19 18/3 18/11 19/2 19/6 19/13 19/15 19/18 20/17 21/5 26/18 27/2 34/1 36/2 40/25 41/8 41/22 41/24 42/12 44/4 44/7 44/11 46/5 46/18 46/22 47/16 49/3 49/7 62/9 70/11 70/12 70/14 72/13 80/5 91/2 91/6 91/7 91/9</p> <p>Cutter [15] 22/5 26/23 37/17 40/11 51/4 64/16 64/20 65/23 66/11 66/12 68/8 83/18 84/7 86/10 86/19</p> <p>Cutter's [1] 23/23</p> <p>Cutters [1] 38/8</p> <p>cytomegalovirus [1] 31/3</p>	<p>defer [1] 35/9</p> <p>deficiency [2] 32/1 47/24</p> <p>definitions [1] 74/24</p> <p>degraded [1] 82/23</p> <p>degree [2] 69/2 96/3</p> <p>degrees [1] 81/6</p> <p>delay [4] 39/3 39/13 66/16 93/2</p> <p>deliver [1] 77/6</p> <p>demand [2] 71/19 71/20</p> <p>demonstrated [2] 8/18 69/11</p> <p>dental [1] 16/21</p> <p>department [6] 6/18 11/17 74/19 75/2 76/25 92/7</p> <p>departments [2] 5/15 12/13</p> <p>depend [1] 18/22</p> <p>describe [5] 10/21 11/15 61/25 62/3 81/18</p> <p>described [7] 11/7 19/3 36/25 41/2 56/17 73/2 90/15</p> <p>describing [1] 49/18</p> <p>designation [2] 75/1 75/6</p> <p>designing [1] 48/21</p> <p>desmopressin [2] 46/13 49/13</p> <p>despite [2] 40/22 82/12</p> <p>detail [4] 8/10 32/9 64/17 71/8</p> <p>details [3] 37/18 57/21 87/12</p> <p>determined [1] 73/23</p> <p>develop [3] 53/18 87/17 98/3</p> <p>developed [2] 64/19 98/2</p> <p>development [4] 15/7 57/20 65/24 81/25</p> <p>developments [1] 68/2</p> <p>diagnosed [1] 51/19</p> <p>did [73] 3/23 4/3 4/18 5/5 5/14 5/16 5/22 5/25 6/24 8/5 14/7 16/15 16/18 16/25 19/1 19/4 19/5 19/12 19/15 20/16 21/15 22/22 23/9 25/12 25/15 28/11 28/16 30/8 30/11 32/18 35/2 35/4 35/12 38/17 38/20 38/23 42/1 42/2 43/12 52/3 52/5 53/8 53/11 53/15 54/13</p>	<p>55/10 55/21 60/1 61/2 65/18 72/2 73/10 73/18 76/10 77/9 80/7 83/21 84/12 84/12 85/15 88/2 89/2 91/8 91/22 91/24 92/5 94/1 96/7 96/19 97/14 98/20 100/1 100/8 didn't [34] 13/4 15/11 16/2 20/10 27/11 28/23 33/8 39/21 43/12 51/22 53/22 54/9 54/21 55/23 56/22 63/25 72/20 73/15 77/6 77/9 83/14 87/4 87/21 88/9 88/11 88/16 88/21 92/2 96/20 96/22 98/3 99/21 100/5 100/17 die [1] 80/7</p> <p>different [6] 15/18 43/11 50/12 67/21 78/9 85/23</p> <p>difficult [3] 53/12 99/3 99/5</p> <p>difficulties [2] 17/2 23/10</p> <p>difficulty [5] 16/15 19/1 19/24 61/4 79/1</p> <p>diminishes [1] 17/7</p> <p>directly [1] 21/7</p> <p>director [11] 10/3 10/5 21/13 29/18 30/9 30/10 30/12 39/11 73/16 83/17 89/16</p> <p>directors [13] 29/21 29/22 30/2 30/8 46/6 73/18 73/20 74/12 75/24 88/8 94/7 98/19 99/23</p> <p>disadvantages [1] 35/5</p> <p>discharged [1] 8/7</p> <p>discoloured [1] 57/23</p> <p>discounts [2] 31/2 31/3</p> <p>discovery [1] 70/11</p> <p>discuss [1] 59/21</p> <p>discussed [2] 41/11 89/4</p> <p>discussion [5] 6/8 30/25 74/15 75/4 93/17</p> <p>discussions [6] 6/3 29/19 30/7 39/10 91/11 91/15</p> <p>disease [30] 7/19 8/14 8/22 13/21 15/7 15/10 16/10 27/2 31/25 33/10 42/10 46/10 46/14 46/20 47/23 47/24 48/7</p>
---	---	---	--	---	--

<p>D</p> <p>disease... [13] 48/11 56/8 63/22 68/19 69/4 69/6 69/10 70/16 70/24 80/8 83/4 83/7 88/4</p> <p>diseases [1] 55/19</p> <p>disorders [3] 4/5 6/23 11/24</p> <p>display [1] 94/4</p> <p>displayed [1] 1/25</p> <p>dispute [1] 68/6</p> <p>distanced [1] 2/4</p> <p>distances [1] 11/9</p> <p>distinguish [1] 13/23</p> <p>divided [2] 7/9 50/4</p> <p>do [65] 2/23 5/21 6/3 9/12 12/18 17/1 17/8 17/11 18/14 20/13 21/10 21/15 29/24 33/4 33/19 34/23 35/2 35/10 35/13 37/7 38/13 39/14 41/12 41/14 51/6 51/11 52/3 52/16 52/16 52/17 52/24 54/11 58/9 61/2 65/5 67/1 71/21 73/4 73/22 76/19 76/20 76/21 78/12 78/13 79/15 79/20 80/9 80/12 80/13 84/2 87/7 93/4 93/11 94/14 94/16 94/19 95/25 97/2 97/18 97/24 99/20 101/7 101/9 101/19 101/25</p> <p>doctor [2] 5/25 101/1</p> <p>doctors [1] 80/18</p> <p>document [12] 23/13 29/7 31/22 37/13 37/18 43/15 57/11 67/19 74/19 74/20 90/15 93/7</p> <p>documentation [1] 9/1</p> <p>documented [1] 82/8</p> <p>documents [10] 1/25 22/14 32/12 32/17 35/17 51/5 57/2 64/12 83/19 87/24</p> <p>does [5] 19/11 26/8 38/9 51/16 78/24</p> <p>doesn't [3] 9/12 13/23 44/4</p> <p>doing [13] 9/13 24/8 38/12 52/22 68/23 76/4 77/2 77/3 83/8 93/19 98/22 100/3 100/3</p> <p>domestic [1] 54/4</p> <p>don't [48] 6/7 6/25 7/5</p>	<p>9/1 13/2 14/21 16/21 19/4 19/8 20/16 22/15 24/5 34/2 35/12 37/16 38/10 38/20 39/13 41/3 41/9 41/17 51/7 51/14 53/20 58/3 58/14 59/9 61/13 64/16 67/4 67/5 68/9 69/13 73/12 73/13 73/23 84/18 86/6 87/12 92/18 94/1 97/20 97/20 98/12 99/10 99/22 100/2 100/5</p> <p>donations [7] 48/25 70/22 77/20 78/5 78/22 79/19 95/8</p> <p>done [14] 33/1 33/15 54/9 54/11 54/14 55/2 56/11 74/2 76/10 80/2 87/3 88/5 97/22 100/11</p> <p>donor [11] 15/1 15/6 15/14 39/25 40/7 44/14 46/11 46/17 48/13 49/4 98/10</p> <p>donors [6] 49/8 49/11 63/14 78/23 79/9 95/7</p> <p>dosage [1] 8/3</p> <p>doses [1] 62/24</p> <p>doubly [1] 97/23</p> <p>doubt [2] 15/9 69/16</p> <p>down [5] 10/23 26/25 74/23 80/25 89/25</p> <p>downstairs [1] 1/19</p> <p>Dr [62] 1/3 3/4 5/12 6/21 7/16 7/20 8/4 11/10 11/12 21/14 29/10 29/14 29/15 30/3 30/15 30/25 32/10 35/22 40/18 40/22 44/15 45/1 45/16 45/20 49/16 52/15 52/17 53/3 55/18 57/13 59/1 61/2 64/13 67/17 67/24 68/15 71/3 71/22 72/18 73/25 73/25 75/7 76/4 77/11 80/19 80/19 83/18 84/21 85/1 85/2 85/22 87/15 89/16 91/8 93/13 94/13 94/14 94/17 101/3 102/2 102/4 102/13</p> <p>Dr Bill Wagstaff [1] 21/14</p> <p>Dr Craske [4] 29/14 30/15 30/25 73/25</p> <p>Dr Flower [2] 52/15 53/3</p> <p>Dr Giangrande [2]</p>	<p>102/2 102/13</p> <p>Dr Giangrande's [1] 102/4</p> <p>Dr Hutchinson [1] 11/12</p> <p>Dr Karl Nicholson [1] 80/19</p> <p>Dr Martin [2] 55/18 80/19</p> <p>Dr Martin Wiselka [1] 61/2</p> <p>Dr Mayne [2] 75/7 76/4</p> <p>Dr Mitchell [30] 1/3 7/16 29/10 30/3 32/10 40/18 40/22 45/1 45/16 45/20 49/16 57/13 59/1 64/13 67/17 67/24 68/15 71/3 71/22 72/18 77/11 83/18 84/21 85/1 85/22 87/15 94/13 94/14 94/17 101/3</p> <p>Dr Preston [1] 6/21</p> <p>Dr Rizza [2] 29/15 73/25</p> <p>Dr Savidge [1] 93/13</p> <p>Dr Snape [1] 35/22</p> <p>Dr Tedder [1] 52/17</p> <p>Dr Trigger [2] 7/20 8/4</p> <p>Dr Wagstaff [3] 5/12 89/16 91/8</p> <p>Dr Wood [1] 11/10</p> <p>draw [1] 96/11</p> <p>drugs [1] 31/1</p> <p>dry [2] 61/24 81/5</p> <p>due [4] 55/6 67/6 67/10 101/13</p> <p>during [17] 2/14 5/1 5/10 6/3 13/20 13/22 26/16 27/18 40/15 47/11 49/1 49/9 57/19 63/15 83/16 95/12 101/22</p> <p>duties [1] 11/22</p> <p>E</p> <p>each [2] 48/23 62/3</p> <p>earlier [4] 42/20 56/3 64/3 96/12</p> <p>early [15] 8/25 9/19 10/22 12/22 25/1 34/15 35/15 38/6 59/3 59/23 61/5 73/3 84/24 96/17 100/4</p> <p>ease [1] 18/23</p> <p>easy [2] 45/22 56/19</p> <p>economic [2] 71/15 72/1</p> <p>editorial [2] 70/3 71/25</p>	<p>educational [3] 84/5 86/10 86/11</p> <p>effect [3] 19/9 46/7 50/9</p> <p>effective [2] 40/3 70/15</p> <p>effectively [3] 76/3 77/5 84/10</p> <p>efforts [2] 68/20 92/1</p> <p>eight [2] 27/17 50/19</p> <p>eighth [3] 50/21 51/7 51/11</p> <p>either [5] 28/4 55/2 87/22 95/19 98/25</p> <p>elaborate [3] 15/2 68/16 72/23</p> <p>element [1] 21/23</p> <p>elements [2] 15/18 16/8</p> <p>else [5] 16/4 45/8 53/11 72/17 72/22</p> <p>elsewhere [5] 11/8 62/6 69/8 86/24 100/10</p> <p>emanate [1] 75/3</p> <p>embracing [1] 50/13</p> <p>emerging [1] 43/1</p> <p>emphasised [1] 48/8</p> <p>emphasising [1] 69/9</p> <p>employer [1] 86/23</p> <p>enable [2] 2/21 77/18</p> <p>encountered [1] 40/15</p> <p>encouraged [1] 73/24</p> <p>end [9] 2/13 2/16 5/3 11/15 24/18 82/3 84/20 99/12 102/4</p> <p>enforcing [1] 76/2</p> <p>England [2] 28/18 29/2</p> <p>enormously [3] 92/23 93/3 95/17</p> <p>enough [3] 11/19 69/15 91/5</p> <p>entail [2] 5/5 5/14</p> <p>entitled [2] 7/18 69/21</p> <p>epidemic [1] 68/22</p> <p>epidemiology [1] 31/7</p> <p>equally [1] 33/10</p> <p>eradicate [1] 48/19</p> <p>ERIC [2] 3/2 88/16</p> <p>Eric Preston [1] 88/16</p> <p>error [1] 54/15</p> <p>essential [1] 99/24</p> <p>essentially [4] 15/20 22/6 29/22 64/25</p> <p>establish [3] 9/9 11/13 52/2</p> <p>established [1] 14/18</p> <p>et [4] 49/6 57/23 77/8 82/9</p> <p>et cetera [3] 57/23</p>	<p>77/8 82/9</p> <p>Europe [1] 9/22</p> <p>even [15] 4/14 6/22 6/25 11/6 11/25 21/17 46/24 53/13 60/5 71/16 76/16 82/21 88/9 88/11 92/24</p> <p>event [1] 37/18</p> <p>events [1] 41/2</p> <p>eventually [1] 90/3</p> <p>ever [5] 50/11 83/13 91/8 92/16 98/21</p> <p>every [2] 9/12 55/8</p> <p>everybody [2] 70/2 91/6</p> <p>everything [2] 41/17 41/18</p> <p>evidence [16] 35/7 45/6 45/8 56/14 56/21 63/17 63/18 71/1 82/19 83/25 87/14 90/13 93/6 99/23 102/4 102/12</p> <p>evolve [1] 77/9</p> <p>exactly [2] 2/23 37/10</p> <p>example [10] 8/20 17/6 29/1 33/23 44/6 70/6 77/1 80/4 97/5 100/9</p> <p>exams [1] 5/2</p> <p>except [1] 22/25</p> <p>exchanged [1] 38/18</p> <p>Executive [1] 39/11</p> <p>exercise [4] 5/21 25/12 77/23 80/15</p> <p>exercises [1] 5/17</p> <p>expect [1] 91/15</p> <p>expected [6] 5/18 12/20 36/3 48/25 79/17 86/4</p> <p>expecting [1] 102/8</p> <p>expenditure [1] 39/8</p> <p>expensive [1] 74/22</p> <p>experience [3] 19/5 23/9 75/12</p> <p>expert [3] 8/6 80/10 88/18</p> <p>expertise [2] 55/17 60/24</p> <p>explain [2] 1/5 85/2</p> <p>explained [4] 49/20 52/21 89/5 89/12</p> <p>explains [1] 52/1</p> <p>explicitly [1] 14/25</p> <p>expose [1] 40/7</p> <p>exposed [2] 53/17 95/15</p> <p>exposure [7] 15/13 33/16 33/19 46/17 47/1 60/6 81/15</p> <p>express [2] 68/21 69/17</p>	<p>expressed [2] 54/16 99/2</p> <p>expressing [1] 75/15</p> <p>extended [1] 49/10</p> <p>extent [9] 2/1 6/24 15/24 25/3 73/18 83/11 88/23 98/1 99/16</p> <p>external [1] 87/5</p> <p>extract [2] 23/19 57/5</p> <p>extraction [1] 16/22</p> <p>eye [1] 60/16</p> <p>F</p> <p>facilities [1] 10/12</p> <p>fact [28] 4/1 12/3 12/16 19/11 19/16 20/6 24/15 29/24 30/1 33/3 44/16 50/18 51/25 54/13 57/7 58/6 58/7 58/16 61/9 71/24 76/9 76/20 80/5 82/25 86/24 98/7 100/6 100/16</p> <p>factor [71] 4/14 13/25 14/2 14/20 15/6 15/14 20/22 21/1 21/6 23/23 23/24 24/16 24/20 24/24 25/20 25/23 26/1 26/21 27/19 28/12 31/16 32/21 35/24 36/8 36/10 39/16 39/18 39/20 43/18 43/20 43/25 43/25 46/12 46/24 47/15 47/16 47/24 49/12 50/2 50/10 50/11 57/21 61/24 62/9 62/25 63/7 63/24 63/25 64/4 64/8 67/10 68/18 69/21 70/7 72/14 81/2 81/5 81/11 81/14 81/17 81/23 82/1 82/6 82/13 83/10 89/1 89/14 89/22 90/4 95/5 96/11</p> <p>Factor IX [23] 4/14 14/2 25/20 25/23 26/1 39/16 39/18 39/20 43/18 43/20 43/25 47/16 63/24 63/25 64/4 64/8 67/10 81/2 81/14 81/23 82/1 82/6 83/10</p> <p>factor VIII [27] 13/25 14/20 23/23 23/24 24/16 24/24 31/16 35/24 36/8 43/25 46/12 46/24 47/15 49/12 50/2 50/10 50/11 57/21 61/24 62/9 62/25 63/7 72/14</p>
---	--	--	---	---	---

F	84/13 85/24 87/19 88/13 90/21 95/7 95/8 95/21 first-class [1] 84/13 fit [1] 34/19 five [4] 46/16 47/11 88/15 90/4 flight [1] 86/19 flights [1] 84/13 Flower [2] 52/15 53/3 fluid [1] 17/6 folder [1] 87/25 follow [1] 66/5 follow-up [1] 66/5 following [6] 32/6 37/23 45/21 62/1 68/2 102/17 foregoing [1] 65/2 form [7] 13/23 14/8 32/4 46/25 54/17 57/14 86/17 formal [2] 54/18 91/24 forms [3] 57/25 57/25 58/4 formulate [1] 15/20 formulated [1] 88/6 fortuitous [1] 12/18 forward [1] 74/8 forwarded [1] 19/22 found [11] 56/16 63/11 64/2 67/3 78/6 79/13 79/25 80/16 80/17 84/17 100/16 four [8] 1/22 1/23 4/3 12/10 40/23 41/10 63/8 63/10 fourth [2] 12/19 43/14 fractionators [3] 68/23 69/13 90/1 frantic [1] 24/7 frequency [3] 18/22 95/9 95/12 frequent [1] 17/2 fresh [6] 6/9 19/10 27/21 44/7 47/17 49/10 Friday [4] 8/8 102/6 102/9 102/12 friendly [1] 84/16 from [95] 3/10 3/21 4/23 6/1 8/13 10/14 12/1 12/6 12/10 12/12 13/14 13/18 15/25 16/1 16/1 17/9 17/23 20/4 20/20 21/5 21/7 21/8 21/9 22/18 23/19 24/13 24/14 30/15 32/20 35/7 35/14 35/21 37/22 38/6 38/24 39/19 40/22 41/22 45/25 46/2 47/2 47/14 48/5 48/17 49/7	49/11 51/23 52/13 55/14 55/20 57/5 58/22 59/2 61/13 61/22 62/6 63/19 64/15 64/24 65/18 65/23 66/12 68/8 68/21 69/7 70/21 75/3 77/14 78/2 78/6 78/22 78/23 79/9 83/21 86/8 86/10 86/17 86/19 86/22 86/24 87/10 87/25 88/15 88/17 89/10 90/25 91/7 92/6 92/9 95/5 96/2 98/21 99/23 100/10 101/21 front [1] 101/21 frozen [6] 6/9 19/10 27/22 44/8 47/17 49/10 fulfil [1] 32/6 full [3] 25/16 44/22 75/11 fully [2] 24/12 88/3 function [1] 56/9 fund [1] 61/12 funded [1] 74/17 funding [13] 61/5 76/16 77/17 78/16 86/8 86/9 86/12 86/17 86/22 86/24 87/1 87/6 87/9 funds [1] 75/18 further [19] 15/7 20/5 31/22 37/13 65/18 65/25 66/4 66/8 68/1 71/11 71/21 80/21 84/23 84/25 85/5 85/8 85/23 101/3 102/12 future [3] 9/15 53/20 97/7	G gauze [1] 43/4 gave [8] 33/21 34/2 34/23 53/21 54/2 54/5 62/17 62/24 general [11] 3/9 3/25 5/4 5/6 5/9 53/21 54/5 60/8 62/14 73/11 89/21 generally [11] 17/3 18/8 26/1 28/16 54/2 58/25 73/10 76/1 83/15 96/5 99/14 gently [1] 43/5 get [19] 2/21 13/14 13/19 20/11 21/15 25/15 37/2 39/1 43/2 61/9 61/12 62/22 79/24 82/24 86/22 92/2 92/3 92/3 92/5 getting [4] 51/24	84/13 86/18 96/22 Giangrande [2] 102/2 102/13 Giangrande's [1] 102/4 gifts [1] 87/9 give [16] 3/13 25/4 44/4 45/1 45/7 56/25 59/20 60/8 61/10 63/8 70/6 86/20 90/18 97/4 100/8 100/14 given [15] 1/6 9/2 24/16 24/24 39/2 45/6 53/24 79/11 84/4 84/7 87/25 90/24 95/10 95/13 100/18 giving [7] 18/25 37/18 72/13 88/4 96/18 100/23 101/13 Glenfield [3] 12/7 62/13 62/15 GM [1] 64/24 GM Akin [1] 64/24 go [40] 8/10 10/18 10/23 11/15 15/18 19/20 26/5 26/14 27/14 27/25 29/7 29/12 29/16 30/14 30/23 31/5 31/12 32/9 35/25 36/3 37/14 40/12 43/2 43/14 46/23 57/8 57/23 64/17 70/17 71/7 71/8 71/10 71/18 74/13 78/20 80/25 81/18 81/19 82/3 84/10 Godfrey [1] 39/5 goes [4] 31/8 31/19 69/25 74/23 going [18] 2/24 3/7 5/23 7/11 8/10 13/13 44/15 44/16 44/18 45/16 45/20 45/22 57/1 69/12 71/8 77/6 87/14 100/13 gone [1] 90/8 good [8] 1/3 1/4 3/4 9/9 43/8 55/11 99/1 100/18 got [11] 12/19 14/15 18/24 19/25 26/25 27/1 30/18 39/10 51/5 67/16 90/9 Government [1] 70/1 governments [2] 68/22 69/13 GP [1] 91/19 grab [1] 99/9 grazes [1] 54/5 great [4] 13/6 14/21 39/13 39/24 greater [1] 68/20	grounds [1] 57/17 group [9] 37/9 47/19 50/11 50/13 69/9 75/3 80/20 84/19 97/24 groups [1] 50/12 growing [2] 51/22 51/24 guarantee [1] 75/11 guidance [1] 15/22 guiding [1] 16/3	H had [114] had ... not [1] 67/12 hadn't [1] 97/4 haematological [1] 4/5 haematologist [3] 10/3 11/11 12/17 haematologists [6] 11/2 12/9 70/1 72/6 72/7 98/20 haematology [17] 3/24 4/24 5/6 5/9 6/14 11/17 11/22 12/4 12/4 24/8 24/8 28/19 28/21 28/23 28/24 61/19 61/23 haemophilia [93] 5/6 6/14 6/25 7/2 8/23 8/25 9/6 9/22 10/4 10/6 10/7 11/14 11/18 12/21 13/4 13/5 13/10 14/4 14/10 14/14 14/14 16/6 16/9 16/13 17/16 17/21 18/10 19/14 19/21 20/18 20/19 21/24 25/19 26/16 26/19 27/16 27/18 27/19 27/23 28/4 28/5 28/6 28/23 28/25 30/2 32/4 34/10 34/15 35/4 36/7 39/17 42/9 42/11 43/3 43/16 43/22 46/8 46/10 46/21 46/22 47/18 47/23 48/7 48/11 49/24 50/8 51/2 53/7 55/3 57/16 60/20 60/21 62/7 70/13 70/15 71/13 74/16 74/22 74/24 75/12 75/16 75/25 76/20 76/20 76/21 84/8 87/19 88/18 90/5 90/14 90/22 92/19 98/20 haemophilia A [14] 14/10 20/19 21/24 26/16 26/19 28/4 28/6 35/4 42/11 46/10 47/18 47/23 49/24	70/15 haemophilia B [11] 14/4 25/19 27/16 27/18 27/19 27/23 28/5 39/17 43/16 43/22 51/2 haemophilic [3] 17/23 47/25 100/10 haemophiliacs [11] 7/19 29/4 36/22 40/19 40/23 41/5 41/6 46/15 48/10 50/25 82/12 haemophilic [2] 13/20 81/10 haemostasis [7] 10/7 11/23 12/18 15/25 16/6 93/9 93/11 half [9] 7/14 10/25 24/23 30/24 37/20 44/24 67/20 74/18 79/11 half-an-hour [1] 44/24 halfway [2] 2/20 2/21 hand [9] 7/14 10/20 23/5 27/1 67/16 80/24 81/20 99/6 100/15 handed [1] 99/8 handful [2] 64/12 85/22 hands [1] 9/10 handwritten [1] 36/12 happen [2] 19/11 86/21 happened [8] 19/8 22/15 24/17 54/12 80/13 92/14 94/2 101/14 happening [1] 52/21 happens [2] 57/10 85/3 happy [2] 25/17 68/11 harm [1] 33/15 harrowing [1] 101/6 has [12] 17/22 46/18 47/8 48/7 48/8 48/18 66/14 67/25 83/25 92/23 97/12 98/15 have [206] haven't [2] 44/17 45/23 having [15] 11/7 17/21 19/23 19/24 43/9 50/16 51/23 56/10 57/17 65/4 66/22 67/12 88/15 96/12 98/19 Hay [2] 13/3 90/9 hazard [1] 82/12 hazardous [1] 48/5 HCDO000063 [1] 13/16 HCDO0001550 [1]
----------	--	---	---	--	---	---	--

H	82/5 82/12	higher [1] 69/23	hour [1] 44/24	I could [2] 14/8 33/19	22/8
HCDO00001550... [1] 26/4	heat-treated [36] 24/21 35/16 36/10	highly [1] 83/9	hours [4] 23/8 78/14	I did [6] 3/23 35/2	I retired [1] 10/10
HCDO0000248 [1] 74/10	36/15 36/19 36/20	him [17] 21/14 39/6	81/6 99/4	72/2 84/12 84/12 92/5	I right [1] 95/2
HCDO0000273 [1] 31/23	37/3 37/11 37/19 38/8	61/10 62/17 62/18	house [2] 1/16 1/18	I didn't [7] 27/11	I said [3] 45/23 54/9
HCDO0000276 [2] 10/16 10/17	38/19 38/25 39/24	62/20 62/24 63/2 63/8	how [20] 7/8 9/11 11/9	51/22 54/9 72/20 77/6	63/5
HCDO0000333 [1] 42/7	40/4 41/22 41/24 44/1	72/12 78/5 84/18	11/15 18/24 21/10	88/9 88/11	I saw [2] 34/8 59/20
HCDO0000517 [2] 29/9 30/14	46/12 48/16 49/12	88/11 88/15 100/14	22/22 28/11 33/12	I do [6] 35/2 54/11	I say [2] 5/8 44/6
HCV [3] 13/12 55/25	61/24 63/7 63/20	100/16 100/18	37/7 52/24 54/5 56/23	80/12 101/7 101/9	I should [3] 37/11
86/1	63/24 63/25 65/10	his [16] 17/25 18/1	60/10 61/14 70/12	101/25	37/16 63/3
he [45] 6/21 8/5 8/17	65/14 66/24 67/7	31/5 39/15 46/4 62/18	70/13 87/16 94/23	I don't [42] 6/7 6/25	I simply [1] 101/23
9/20 9/21 11/11 13/3	67/10 68/18 81/2	62/20 63/4 63/6 63/19	97/12	7/5 13/2 14/21 16/21	I spent [1] 4/6
13/5 21/15 24/23 31/1	81/11 81/14 81/16	65/6 67/6 67/10 78/13	However [1] 75/13	19/4 19/8 20/16 22/15	I spoke [1] 72/21
31/2 31/5 31/8 39/5	82/5	93/6 100/11	HT [10] 37/19 38/5	24/5 34/2 35/12 37/16	I subscribed [1] 28/17
39/7 39/9 41/5 51/10	heated [3] 35/23 37/8	histopathology [1]	40/19 40/24 41/10	38/10 38/20 39/13	I suppose [10] 16/7
51/14 61/8 61/10 62/8	64/8	8/18	41/15 42/3 65/6 67/22	41/3 41/9 41/17 51/7	20/2 23/6 33/17 72/4
62/10 62/22 62/23	Heath [1] 3/17	history [3] 50/16	67/23	51/14 53/20 58/3	74/6 94/10 95/11 96/9
63/6 63/11 63/15	heating [1] 81/5	53/23 71/13	HTLV [17] 46/15 47/9	58/14 67/4 67/5 68/9	97/10
63/18 63/23 64/1 67/3	help [2] 3/7 101/8	HIV [19] 13/12 33/11	47/13 47/21 47/24	69/13 73/12 73/13	I take [1] 94/19
67/4 67/25 78/8 78/11	helped [1] 20/12	49/21 50/2 50/20	48/1 48/5 48/17 48/24	73/23 84/18 86/6	I talk [1] 71/25
78/16 78/17 84/16	helpful [2] 39/7	51/19 51/20 52/7	49/9 51/6 52/10 53/10	87/12 94/1 97/20	I then [1] 92/6
88/17 90/7 97/7	101/16	55/20 60/14 63/23	55/6 59/17 97/16 98/3	98/12 99/10 99/22	I think [84] 4/12 7/5
100/16 100/17	hepatitis [64] 6/6 8/20	68/22 69/3 71/5 81/7	HTLV-III [15] 46/15	100/2 100/5	7/6 9/8 9/16 10/18
head [2] 6/17 92/6	29/20 30/7 30/10 31/7	85/25 91/13 98/3	47/9 47/13 47/21	I even [1] 6/25	10/22 11/4 12/20
headed [2] 29/19	48/15 48/19 56/2 56/7	99/17	47/24 48/1 48/5 48/17	I felt [2] 33/17 34/11	12/24 13/3 13/7 13/16
31/24	56/8 57/6 57/10 57/14	HIV/HTLV-III [1] 98/3	48/24 49/9 51/6 52/10	I fielded [1] 6/1	16/21 16/24 17/14
heading [6] 30/24	57/18 57/20 58/5 58/6	Hodgkins [1] 56/18	53/10 55/6 97/16	I gave [2] 34/2 53/21	17/22 18/17 18/18
40/14 67/23 70/10	58/7 59/12 59/14 60/2	home [31] 1/10 13/8	HTLV-III antibody [1]	I got [1] 39/10	21/5 21/15 23/18 24/5
70/17 74/14	60/18 61/2 61/8 61/15	13/9 13/24 14/17	59/17	I had [5] 24/11 34/15	24/7 24/10 24/11
health [7] 55/12 66/23	61/18 61/20 61/23	14/18 18/12 18/15	Humanate [2] 22/9	62/20 77/25 88/1	24/25 25/25 26/7
73/7 74/20 75/2 76/25	62/1 62/5 62/22 62/25	18/21 19/20 20/1 23/2	23/24	I have [5] 36/14 56/3	27/14 28/22 29/7
86/23	63/12 64/2 64/20 65/3	26/24 27/6 27/7 27/10	hurry [1] 69/2	76/1 85/22 94/12	30/20 32/23 34/19
healthy [2] 25/13	65/7 65/14 65/24 66/6	27/20 28/2 28/3 28/8	Hutchinson [1] 11/12	I heard [4] 13/3 28/22	35/13 36/19 38/12
34/19	66/19 67/3 67/8 67/9	33/22 36/4 38/14	Hyate:C [1] 34/24	84/14 89/21	39/18 40/8 41/20 42/1
hear [6] 3/5 84/12	67/22 70/24 71/2	38/16 38/24 42/15		I imagine [2] 73/22	42/24 44/3 44/6 45/21
84/12 90/13 102/9	77/14 77/23 78/7	42/17 43/18 45/4	I	78/14	51/16 53/1 53/15
102/12	78/24 79/10 79/14	46/23 101/17	I admitted [1] 8/1	I just [4] 10/12 64/11	54/15 55/8 55/13
heard [6] 13/3 28/22	79/18 80/18 80/20	home: [1] 26/23	I also [3] 4/3 5/22	67/19 71/10	56/15 58/16 58/18
35/7 84/14 89/21	81/7 88/17 88/18	home: 57,850 [1]	40/3	I knew [1] 88/14	59/8 59/22 60/9 60/21
99/22	97/19 98/2 98/4 98/11	26/23	I am [1] 71/8	I know [4] 23/13 25/22	60/22 61/5 64/16
hearing [2] 1/8 44/17	hepatitis B [16] 6/6	honestly [1] 18/16	I and [1] 32/22	93/3 93/13	68/24 69/7 78/12
hearings [1] 45/24	31/7 61/8 61/18 61/20	hope [6] 22/24 77/18	I anticipate [1] 102/3	I looked [1] 79/6	78/20 79/25 84/5
heart [5] 17/24 18/1	62/1 62/5 62/22 62/25	89/6 97/21 98/6 101/7	I appreciate [2] 23/20	I may [1] 30/22	86/24 87/2 87/3 90/9
62/7 97/5 100/10	64/2 64/20 65/7 65/14	hoped [3] 17/12 61/8	33/2	I mean [20] 8/16	90/11 91/4 92/8 93/16
heat [40] 24/21 35/16	66/6 67/3 67/8	98/10	I approached [1]	11/25 17/22 20/7	94/4 95/24 98/8 98/14
36/10 36/15 36/19	hepatitis C [18] 56/7	hospital [26] 3/17	52/14	21/16 22/14 25/9	98/18 100/1 100/3
36/20 37/3 37/11	58/7 59/12 59/14 60/2	3/19 5/4 8/9 12/7	I arrived [2] 14/16	33/14 34/3 34/17 69/4	100/5
37/19 38/8 38/19	60/18 61/15 67/9	13/24 22/25 26/19	27/9	72/6 72/7 77/9 83/2	I thought [2] 40/2
38/25 39/20 39/24	77/14 77/23 78/7	26/24 27/20 33/25	I ask [1] 55/25	84/9 92/13 96/5 98/7	67/11
40/4 41/22 41/24 44/1	78/24 79/10 79/14	42/12 42/14 42/17	I asked [2] 86/7 88/23	99/22	I tried [1] 92/2
46/12 48/16 48/18	79/18 80/18 80/20	43/9 43/18 54/21	I believe [1] 14/18	I mentioned [1] 44/23	I understand [13]
49/12 61/24 62/9 63/7	98/11	61/12 76/17 86/15	I believed [1] 63/18	I met [1] 68/8	10/14 10/19 11/21
63/20 63/24 63/25	hepatology [1] 8/6	86/23 92/9 92/22 93/1	I came [2] 12/18	I must [2] 15/24 28/20	20/25 22/4 33/7 35/5
65/10 65/14 66/24	her [7] 13/11 19/20	96/6 100/21	15/15	I notice [1] 95/21	35/14 65/12 68/4
67/7 67/10 68/18 81/2	19/22 19/25 19/25	hospital: [1] 26/22	I can [4] 2/10 3/6	I noticed [1] 95/18	69/22 73/4 89/20
81/11 81/14 81/16	45/5 58/16	hospital: 152,455 [1]	19/19 52/16	I presume [4] 32/16	I understood [2]
	here [13] 2/7 2/10	26/22	I can't [10] 7/8 18/16	58/3 58/3 90/7	32/14 82/19
	2/24 13/18 14/9 20/19	hospitality [2] 84/2	33/6 37/10 41/15	I queried [1] 77/8	I want [1] 95/6
	26/14 41/2 57/4 61/25	87/9	53/25 54/25 68/8	I read [1] 9/19	I wanted [6] 61/10
	65/9 65/22 66/3	hospitals [6] 3/10	91/18 91/19	I received [3] 28/17	68/14 69/16 72/2 73/1
	herself [1] 85/7	12/3 12/7 19/17 62/12	I certainly [1] 21/14	28/18 32/16	80/21
	high [2] 71/9 71/18	78/9	I come [1] 3/21	I remained [1] 67/9	I was [32] 3/16 4/16
		hotel [2] 84/18 86/19	I correctly [1] 52/3	I remembered [1]	10/6 12/5 12/6 15/4

<p>I</p> <p>I was... [26] 15/7 15/24 16/1 16/6 24/7 28/24 34/6 39/24 40/6 44/16 44/18 56/18 59/5 70/6 76/7 76/12 78/19 84/4 84/7 84/10 84/15 88/9 92/5 92/12 95/20 95/25</p> <p>I wasn't [7] 15/23 39/23 76/8 87/23 87/25 96/20 96/22</p> <p>I went [3] 73/12 88/13 93/16</p> <p>I won't [1] 32/9</p> <p>I wonder [2] 61/18 84/23</p> <p>I would [18] 22/12 23/13 24/18 30/2 33/19 34/21 41/13 53/1 53/15 56/21 68/7 77/25 88/5 95/6 95/14 97/21 98/6 98/10</p> <p>I'd [4] 18/5 30/20 84/6 87/23</p> <p>I'm [39] 2/24 3/7 7/7 7/11 8/10 9/1 10/5 15/23 16/23 18/16 19/7 20/16 20/19 22/11 24/16 28/14 30/17 31/12 33/2 41/3 41/4 42/3 45/20 57/1 57/12 67/16 68/7 72/20 72/22 76/3 78/3 80/10 80/10 87/12 87/12 89/20 92/10 96/5 101/6</p> <p>I've [14] 19/10 41/18 54/10 56/15 58/25 67/16 84/17 84/20 92/19 95/19 95/20 98/6 99/22 101/5</p> <p>idea [4] 9/9 13/15 33/12 34/10</p> <p>ideal [1] 93/5</p> <p>identical [1] 59/15</p> <p>identification [1] 70/5</p> <p>identified [2] 38/2 42/16</p> <p>identifies [3] 57/5 57/6 57/18</p> <p>identify [1] 51/8</p> <p>if [96] 2/10 2/22 6/19 7/13 9/4 10/17 10/23 10/25 12/8 12/10 14/6 14/8 14/15 17/10 17/17 17/20 21/21 21/25 22/14 24/2 24/18 26/5 26/14 27/14 27/25 29/12 29/16 30/1 30/14</p>	<p>30/23 31/9 31/12 33/5 33/15 36/12 37/13 37/14 37/20 38/11 41/1 41/13 43/2 43/14 44/19 45/18 51/21 54/7 54/12 54/19 54/25 55/10 56/5 57/8 57/23 59/15 61/18 64/21 65/21 66/11 68/1 71/7 73/22 74/8 74/9 74/13 74/17 76/12 77/21 77/24 78/19 79/6 79/15 80/2 80/24 81/19 85/7 85/7 86/18 86/23 87/5 89/2 89/9 90/16 90/21 91/6 92/1 94/10 95/6 96/24 96/25 98/1 98/8 99/13 100/9 100/15 101/24</p> <p>Ill [17] 46/15 47/9 47/13 47/21 47/24 48/1 48/5 48/17 48/24 49/9 51/6 52/10 53/10 55/6 59/17 97/16 98/3</p> <p>illness [1] 81/25</p> <p>imagine [2] 73/22 78/14</p> <p>immediacy [1] 2/9</p> <p>immediately [2] 2/3 57/16</p> <p>immune [3] 31/24 32/1 62/23</p> <p>Immuno [1] 14/1</p> <p>imperfect [4] 96/1 96/4 96/5 96/7</p> <p>implement [2] 24/12 87/17</p> <p>implemented [2] 24/13 88/3</p> <p>implicated [1] 81/24</p> <p>implication [1] 46/9</p> <p>important [9] 9/12 25/12 33/18 71/16 72/3 72/4 84/9 100/6 100/6</p> <p>improved [2] 93/3 93/3</p> <p>impurity [2] 72/10 72/12</p> <p>inactivation [1] 96/13</p> <p>inadequate [4] 34/4 34/11 34/12 34/20</p> <p>inadvisable [1] 75/9</p> <p>incidence [1] 97/19</p> <p>include [4] 50/7 51/17 51/22 57/22</p> <p>included [1] 36/14</p> <p>including [6] 7/20 8/22 10/7 47/10 59/4 77/4</p> <p>increase [3] 39/2 42/13 95/23</p>	<p>increased [4] 21/15 24/19 42/4 92/23</p> <p>increasing [2] 39/12 89/9</p> <p>indeed [2] 23/24 44/3</p> <p>indicate [1] 75/11</p> <p>indicated [1] 75/13</p> <p>individual [4] 23/21 48/23 51/9 57/12</p> <p>individually [2] 58/14 59/20</p> <p>inevitability [1] 70/18</p> <p>inevitable [2] 53/17 70/23</p> <p>infected [8] 49/21 50/19 51/18 62/1 62/4 63/19 77/20 79/14</p> <p>infection [16] 47/21 48/6 48/17 49/9 53/14 60/6 60/7 62/24 81/2 81/14 82/1 82/8 83/2 97/16 98/3 99/16</p> <p>infectious [2] 31/6 55/19</p> <p>infective [2] 82/11 97/23</p> <p>infirmary [3] 4/22 12/6 92/4</p> <p>inflammation [1] 56/22</p> <p>influence [1] 94/7</p> <p>influences [1] 73/5</p> <p>inform [2] 74/21 86/2</p> <p>information [17] 28/15 32/19 49/21 53/8 56/1 56/3 58/10 59/2 59/25 65/25 66/4 66/4 66/8 66/15 67/25 96/23 97/20</p> <p>informed [1] 78/21</p> <p>informing [1] 53/4</p> <p>infrequent [1] 44/10</p> <p>infrequently [1] 48/9</p> <p>infusion [2] 81/14 82/1</p> <p>inhibitors [3] 35/1 35/2 42/21</p> <p>initial [1] 75/23</p> <p>initially [3] 14/22 46/13 60/19</p> <p>injection [4] 63/3 63/8 63/9 66/24</p> <p>injury [1] 25/16</p> <p>Inquiry [14] 1/15 1/22 1/23 7/15 17/22 45/22 69/11 85/7 93/6 99/13 99/23 101/7 101/8 102/9</p> <p>insisted [2] 70/5 71/25</p> <p>instance [4] 18/6 24/6 72/13 88/10</p>	<p>instances [1] 25/22</p> <p>insufficient [2] 21/1 21/18</p> <p>interactions [1] 83/16</p> <p>interest [1] 80/20</p> <p>interested [3] 16/5 79/3 99/13</p> <p>interesting [1] 26/6</p> <p>interferon [2] 61/6 61/11</p> <p>interim [1] 49/9</p> <p>intermediate [5] 22/13 40/4 67/7 70/17 77/10</p> <p>internal [4] 37/17 40/11 41/19 51/4</p> <p>interval [1] 67/5</p> <p>intervening [2] 14/16 49/2</p> <p>into [9] 11/16 31/17 33/25 43/2 50/9 68/23 74/8 78/25 101/17</p> <p>intravenous [1] 43/7</p> <p>intricacies [1] 93/18</p> <p>intrusion [2] 101/17 101/20</p> <p>investigations [1] 82/20</p> <p>invite [3] 69/17 71/11 86/1</p> <p>invited [1] 59/17</p> <p>invites [1] 29/21</p> <p>involve [1] 95/1</p> <p>involved [5] 6/22 8/24 13/7 39/10 78/10</p> <p>involvement [6] 4/18 7/10 7/25 77/22 77/22 77/25</p> <p>IPSN0000156 [1] 61/21</p> <p>irrelevant [1] 33/15</p> <p>isn't [2] 14/13 68/10</p> <p>isolated [5] 15/25 16/7 84/11 88/9 98/18</p> <p>issue [3] 74/1 75/20 75/21</p> <p>issues [2] 19/5 19/15</p> <p>it's [51] 2/17 4/16 5/6 6/23 7/13 7/17 7/17 8/8 10/16 13/16 19/9 29/9 29/14 29/15 29/17 29/19 35/22 37/13 37/18 42/7 43/8 43/24 45/18 45/19 45/22 45/25 46/1 50/4 53/12 56/19 57/4 57/14 61/21 67/20 67/20 69/20 69/25 70/1 71/23 72/10 74/11 77/14 83/2 83/3 87/2 93/2 96/1 101/12 101/12 101/17 102/13</p>	<p>its [6] 16/18 22/7 30/4 31/23 53/22 95/12</p> <p>itself [1] 54/21</p> <p>IX [27] 4/14 14/2 25/20 25/23 26/1 27/19 39/16 39/18 39/20 43/18 43/20 43/25 47/16 49/12 61/24 63/24 63/25 64/4 64/8 67/10 81/2 81/5 81/14 81/23 82/1 82/6 83/10</p> <p>J</p> <p>Jack [1] 4/4</p> <p>Jack Whittaker [1] 4/4</p> <p>January [2] 29/2 31/17</p> <p>January 1st [1] 31/17</p> <p>jaundice [1] 57/22</p> <p>job [2] 1/24 78/15</p> <p>joined [1] 11/11</p> <p>joining [1] 51/25</p> <p>joint [2] 34/6 61/2</p> <p>jointly [2] 16/23 16/24</p> <p>joints [1] 25/14</p> <p>Journal [8] 28/18 28/19 28/23 29/2 46/1 61/19 61/23 69/18</p> <p>journals [1] 28/16</p> <p>July [5] 40/12 46/1 49/17 66/13 77/13</p> <p>July '86 [1] 66/13</p> <p>July 1985 [1] 49/17</p> <p>July 1995 [1] 77/13</p> <p>junior [2] 87/21 99/9</p> <p>jurisdiction [1] 75/2</p> <p>just [47] 3/7 3/13 7/11 10/12 13/13 13/14 14/14 14/15 15/2 23/7 23/16 25/25 30/6 31/21 35/17 37/20 39/6 40/12 42/5 43/5 49/19 52/9 56/1 57/1 57/23 58/19 58/25 60/5 61/17 62/2 64/6 64/11 65/13 66/2 67/19 71/3 71/10 72/22 73/1 74/5 77/2 77/7 85/22 86/20 94/22 95/19 100/6</p> <p>just saying [1] 72/22</p> <p>K</p> <p>Kaposi's [1] 30/21</p> <p>Karachi [1] 34/8</p> <p>Karl [3] 55/18 61/1 80/19</p> <p>Karl Nicholson [2] 55/18 61/1</p> <p>keen [5] 4/2 19/20</p>	<p>40/3 66/7 82/18</p> <p>keep [4] 28/20 60/11 60/16 88/21</p> <p>keeping [2] 41/23 74/5</p> <p>kept [2] 23/2 25/13</p> <p>kind [5] 3/14 15/21 18/2 84/3 91/24</p> <p>kinds [1] 91/15</p> <p>Kingdom [1] 70/3</p> <p>knew [4] 6/6 84/16 88/14 90/20</p> <p>know [44] 1/21 2/17 9/14 13/4 15/25 22/15 23/2 23/13 25/22 29/1 34/18 37/7 41/3 41/10 51/6 53/20 53/22 56/10 56/23 59/2 68/1 68/9 73/12 73/14 80/9 80/11 86/19 86/21 87/7 87/12 88/10 88/11 88/21 90/17 93/3 93/13 95/6 97/18 99/10 99/22 100/2 100/5 100/22 102/10</p> <p>knowledge [4] 32/12 59/5 90/19 93/11</p> <p>known [5] 19/7 19/9 58/18 60/4 96/25</p> <p>knows [2] 68/10 68/11</p> <p>Koate [24] 22/4 23/12 23/23 27/4 36/20 37/19 37/19 37/19 37/20 37/22 38/3 38/5 38/7 38/8 38/15 38/15 40/24 41/10 41/25 42/3 42/16 57/20 65/6 67/22</p> <p>Koate HT [7] 37/19 38/5 40/24 41/10 42/3 65/6 67/22</p> <p>Koate: [1] 26/23</p> <p>Koate: 128,050 [1] 26/23</p> <p>Konyne [4] 65/25 66/5 66/24 67/23</p> <p>Konyne HT [1] 67/23</p> <p>Kryobulin [1] 14/1</p> <p>L</p> <p>labelled [1] 23/4</p> <p>laboratories [1] 3/23</p> <p>laboratory [11] 3/23 3/25 4/15 5/9 5/20 12/4 12/12 23/3 52/18 57/17 65/2</p> <p>lack [3] 10/21 40/17 65/3</p> <p>lacking [1] 4/17</p> <p>lads [1] 34/15</p> <p>Lahore [1] 34/8</p> <p>laid [1] 69/3</p>
---	---	---	---	---	---

L	35/21 44/6 44/21 45/17 45/23 45/25 46/2 49/16 49/20 50/14 50/22 51/16 52/13 52/15 64/15 65/23 66/12 68/11 68/13 77/13 77/14 78/2 79/2 79/4 81/1 82/11 82/15 91/19 92/6 98/9 98/24 99/1 letter's [1] 51/21 leukaemia [1] 82/9 level [1] 55/17 liaising [1] 13/9 licensed [1] 70/2 life [2] 25/9 25/17 lifeguard [1] 34/17 lifestyle [1] 25/4 like [24] 9/13 12/10 14/15 16/22 18/19 24/13 25/11 39/8 44/12 45/8 51/22 53/2 55/8 56/16 69/5 69/8 77/8 78/14 78/19 79/13 88/20 97/4 97/25 101/4 liked [1] 53/1 likelihood [2] 31/6 102/10 likely [5] 29/4 31/9 31/15 32/15 40/2 limited [3] 47/1 87/4 87/8 lines [1] 74/23 lip [1] 43/6 lips [1] 43/2 list [1] 32/8 literature [1] 28/25 little [13] 10/12 14/8 15/2 52/9 54/21 56/24 71/24 72/5 78/20 80/24 81/15 93/17 98/18 live [4] 20/9 25/8 25/16 58/19 lived [1] 51/25 lively [1] 75/4 liver [22] 7/18 7/18 8/5 8/14 15/7 15/10 33/10 46/14 48/7 48/8 48/11 56/8 56/9 56/22 68/19 69/3 69/6 69/10 70/24 80/8 91/14 95/18 lives [1] 34/19 living [1] 34/19 Llandough [1] 3/18 local [2] 13/10 34/16 locally [1] 35/11 locate [1] 77/17 long [11] 11/9 16/1 22/20 37/7 44/25 47/4	52/24 74/17 87/16 101/8 101/22 longer [6] 41/24 46/5 53/1 61/16 92/8 92/11 Longley [1] 21/8 look [30] 13/13 23/16 24/13 26/3 32/8 35/17 36/12 37/13 37/20 42/5 44/21 45/16 49/19 54/6 57/1 61/18 64/12 64/21 66/2 66/11 77/14 77/23 78/1 78/18 79/7 80/2 80/12 80/14 80/24 98/9 look-back [8] 77/14 77/23 78/1 78/18 79/7 80/2 80/12 80/14 looked [11] 7/15 8/11 44/17 44/22 45/23 57/12 64/3 65/13 79/6 88/25 92/19 looking [8] 8/1 8/8 30/6 41/20 44/3 55/20 78/10 95/20 looks [2] 38/6 38/11 lose [1] 76/16 loss [1] 75/18 lot [12] 3/23 4/15 5/16 5/17 9/20 28/24 39/23 53/22 65/4 78/10 91/22 98/25 lots [1] 87/5 low [2] 47/8 81/9 lower [1] 75/9 LRI [2] 12/11 39/6 lucky [1] 20/2 lunch [6] 2/20 84/24 84/25 85/9 86/8 88/20 Luncheon [1] 85/20 lunchtime [1] 94/10 lymphoma [1] 56/18	making [4] 4/18 54/3 96/21 97/9 male [1] 49/11 malignant [7] 4/4 4/5 5/6 5/9 6/23 12/4 24/8 manager [1] 78/15 Manchester [1] 69/7 Mannucci [4] 9/8 9/17 9/20 69/5 many [25] 13/2 32/13 32/23 33/2 34/3 34/5 34/8 34/9 35/5 38/11 41/8 46/8 61/14 76/4 79/21 79/23 80/4 80/4 80/6 83/4 87/21 98/7 98/16 99/7 99/23 March [4] 10/10 29/11 30/16 32/11 March 2003 [1] 10/10 Marie [1] 68/9 Marie Tatt [1] 68/9 Mark [1] 28/22 Martin [3] 55/18 61/2 80/19 Mary [1] 2/25 material [5] 37/21 37/25 38/24 57/19 91/1 Materials [1] 27/21 matter [6] 15/11 29/24 30/1 33/3 45/5 69/14 matters [2] 13/8 33/2 may [32] 14/13 16/13 18/17 18/18 19/7 30/16 30/22 38/23 41/11 45/6 48/17 50/7 50/14 55/14 64/24 78/21 80/4 81/4 81/6 82/5 82/11 84/24 85/1 85/6 90/13 91/18 91/18 92/8 99/11 99/13 99/19 101/20 Mayne [2] 75/7 76/4 me [29] 1/5 3/5 3/22 5/21 10/5 14/9 15/15 19/22 22/9 24/15 34/13 43/3 53/6 68/25 72/23 75/23 77/24 78/3 84/9 84/14 85/2 87/22 87/24 88/17 92/3 93/5 96/3 99/8 99/12 mean [31] 6/9 8/16 11/25 17/5 17/22 20/7 21/16 22/14 24/25 25/9 25/14 26/11 33/12 33/14 34/3 34/17 41/21 43/6 69/4 72/6 72/7 77/9 79/16 83/2 84/9 92/13 96/5 96/6 97/17 98/7 99/22 means [2] 24/6 96/14	meant [3] 9/17 53/14 72/8 mechanism [1] 68/5 media [1] 32/24 medical [5] 3/9 3/21 39/10 46/1 91/17 Medicine [2] 28/18 29/3 meeting [10] 29/20 30/8 54/1 54/1 54/11 74/12 84/8 88/13 93/8 94/3 meetings [11] 8/17 30/12 73/6 73/11 84/5 84/10 89/22 93/22 93/22 94/2 94/3 member [3] 28/17 28/19 30/10 members [5] 1/15 1/22 1/23 2/25 54/8 memo [1] 40/11 memory [1] 22/12 memos [1] 41/19 men [2] 25/8 34/18 mentioned [6] 17/22 44/23 60/12 61/17 86/7 95/25 mentions [1] 26/8 met [2] 68/8 74/4 methods [1] 40/1 middle [3] 20/3 45/19 79/3 might [23] 13/16 28/15 31/10 31/16 36/3 36/7 36/9 38/15 41/21 41/23 49/5 56/4 60/9 61/8 61/8 79/3 82/24 86/16 97/1 97/7 97/11 99/20 102/8 Milan [1] 84/8 mild [19] 8/23 8/23 9/6 16/9 17/16 17/21 17/22 18/8 19/13 28/7 36/6 46/10 46/21 47/22 50/7 50/25 62/6 88/4 100/9 mildly [1] 48/9 miles [6] 12/8 12/10 16/1 20/6 64/24 88/11 million [2] 46/24 90/6 mind [1] 46/16 minutes [3] 30/11 73/16 74/11 misleading [2] 78/21 79/4 Miss [2] 32/3 57/15 Miss RJD Spooner [1] 32/3 Miss Spooner [1] 57/15 missing [1] 22/14 mistakes [2] 23/8	99/4 Mitchell [35] 1/3 3/2 3/4 7/16 7/22 29/10 30/3 32/10 40/18 40/22 44/15 45/1 45/16 45/20 49/16 57/13 59/1 64/13 67/17 67/24 68/15 71/3 71/22 72/18 77/11 83/18 84/21 85/1 85/2 85/22 87/15 94/13 94/14 94/17 101/3 mixture [1] 95/11 MLSO [3] 4/1 12/14 78/4 MLSOs [1] 5/21 mode [1] 17/3 moderate [13] 16/9 16/13 17/16 18/8 19/14 28/7 36/6 46/10 46/21 47/22 50/7 51/1 60/9 moment [6] 15/19 29/12 58/20 67/6 68/3 99/18 Monday [1] 8/2 monitor [2] 53/20 55/11 monitoring [2] 55/5 56/23 month [1] 63/10 months [23] 3/18 4/2 4/3 4/6 4/9 5/4 10/11 22/20 40/6 40/16 47/4 48/2 49/2 53/2 55/9 57/19 63/8 63/11 64/1 67/3 77/19 88/2 93/2 months' [1] 100/14 more [29] 19/10 21/21 22/21 24/15 32/15 34/5 34/6 40/2 46/15 47/5 50/13 52/9 55/16 55/16 58/25 60/24 69/3 71/5 73/1 80/11 80/13 83/15 87/18 91/9 91/22 99/5 99/7 99/24 100/6 morning [7] 1/3 1/4 2/20 3/4 44/24 85/24 88/23 most [19] 2/14 3/16 6/22 12/3 20/4 20/6 20/10 21/16 22/6 31/9 47/19 53/15 55/2 58/7 70/25 71/16 72/3 90/8 93/16 mother [2] 19/19 19/23 motivate [1] 68/22 move [2] 40/5 76/18 moved [3] 4/22 63/23
----------	--	--	--	---	---

<p>M</p> <p>moved... [1] 92/9</p> <p>moving [2] 77/11 96/2</p> <p>Mr [1] 39/5</p> <p>Mr Godfrey [1] 39/5</p> <p>MRCPath [2] 5/2 5/18</p> <p>MS [2] 3/3 10/1/2</p> <p>Ms Richards [1] 10/1/2</p> <p>much [26] 16/3 20/21 22/1 22/2 22/17 27/6 28/23 40/1 40/2 43/12 45/11 47/2 48/21 60/13 68/20 68/24 69/3 72/8 73/4 73/24 84/20 85/13 85/15 100/25 101/25 102/15</p> <p>mucosal [2] 16/22 43/6</p> <p>multi [2] 15/6 15/14</p> <p>multi-donor [2] 15/6 15/14</p> <p>muscled [1] 34/18</p> <p>muscles [1] 25/13</p> <p>must [8] 15/24 28/20 53/1 54/10 54/14 95/1 95/23 98/8</p> <p>mustn't [1] 45/5</p> <p>my [30] 2/6 4/1 4/17 6/22 12/3 12/15 22/11 24/6 31/13 33/12 39/4 40/3 40/8 44/6 50/8 54/14 55/17 56/19 68/25 68/25 69/15 78/1 78/14 78/20 80/16 84/20 87/22 88/11 88/13 101/12</p> <p>myself [3] 16/4 55/2 84/17</p>	<p>needle [1] 43/9</p> <p>needs [1] 48/23</p> <p>negative [2] 47/25 63/17</p> <p>never [4] 49/5 56/15 84/14 87/24</p> <p>nevertheless [2] 82/25 83/5</p> <p>new [5] 11/16 28/18 29/2 69/11 76/21</p> <p>New England [2] 28/18 29/2</p> <p>newly [1] 43/1</p> <p>newly-emerging [1] 43/1</p> <p>next [5] 36/4 44/16 68/14 81/20 88/20</p> <p>NHBT0036651 [1] 77/12</p> <p>NHS [53] 14/1 14/2 14/20 20/22 21/1 21/6 21/11 21/21 23/25 24/20 25/20 26/1 26/21 27/7 27/12 27/12 27/19 35/25 36/10 37/2 37/3 37/4 37/8 37/11 39/18 39/20 40/5 42/3 42/4 42/13 43/17 43/24 43/25 47/15 47/16 49/12 50/1 50/10 50/15 63/25 64/8 67/2 67/6 81/10 81/14 83/10 87/1 87/1 89/1 89/11 89/14 89/22 90/3</p> <p>NHS Factor IX [1] 27/19</p> <p>NHS Factor VIII [1] 24/20</p> <p>Nicholson [3] 55/18 61/1 80/19</p> <p>nitrate [1] 31/2</p> <p>no [56] 4/12 6/6 10/16 10/23 11/2 12/21 16/17 19/4 20/2 21/8 23/13 24/9 24/9 27/25 28/7 28/10 30/1 30/13 30/20 33/6 33/6 46/5 47/14 50/3 51/2 51/14 52/5 55/23 59/11 61/16 61/16 65/20 66/18 67/9 67/18 69/16 72/24 73/9 76/1 77/25 79/1 79/22 84/4 87/2 87/19 87/20 87/20 88/22 90/20 91/10 92/8 92/10 96/20 97/20 97/20 100/18</p> <p>nobody [2] 16/4 20/5</p> <p>non [25] 4/5 8/21 35/9</p>	<p>39/20 48/14 48/14 56/2 56/2 56/7 56/8 56/15 56/15 56/18 57/6 57/6 58/6 58/6 62/9 69/6 70/1 71/1 71/2 72/6 81/7 81/7</p> <p>non-A [8] 48/14 56/2 56/7 56/15 57/6 58/6 71/1 81/7</p> <p>non-B [8] 48/14 56/2 56/8 56/15 57/6 58/6 71/2 81/7</p> <p>non-haematologists [2] 70/1 72/6</p> <p>non-heat-treated [2] 39/20 62/9</p> <p>non-Hodgkins [1] 56/18</p> <p>non-malignant [1] 4/5</p> <p>non-progressive [2] 8/21 69/6</p> <p>non-urgent [1] 35/9</p> <p>none [5] 47/20 50/1 50/25 51/1 51/1</p> <p>normal [4] 25/9 25/9 34/19 40/20</p> <p>normally [1] 2/20</p> <p>north [1] 3/18</p> <p>Northern [1] 5/4</p> <p>not [99] 1/16 2/10 4/12 4/21 5/6 8/10 10/5 10/16 11/5 14/1 16/13 16/23 19/19 22/11 24/17 28/14 28/24 30/1 30/9 30/10 30/17 33/14 34/12 34/21 35/2 36/14 39/3 40/6 40/17 41/3 41/4 41/16 41/18 42/3 44/22 45/8 45/22 46/13 48/12 48/18 50/21 51/7 51/16 52/1 52/3 52/5 56/19 57/12 58/8 59/15 60/4 61/16 65/5 67/12 67/16 67/25 68/2 68/7 68/11 70/7 71/8 72/3 72/24 75/1 75/13 76/3 76/8 77/1 77/2 77/7 78/3 78/25 80/8 80/10 82/19 82/21 84/4 85/10 86/6 88/3 89/20 91/3 92/10 92/13 93/3 93/15 95/22 95/25 96/6 96/7 97/7 98/16 98/25 99/19 100/8 100/14 100/23 102/5 102/12</p> <p>notes [1] 91/17</p> <p>nothing [1] 51/23</p> <p>notice [1] 95/21</p> <p>noticed [1] 95/18</p>	<p>Nottingham [2] 77/8 88/10</p> <p>November [3] 1/1 10/2 10/9</p> <p>November 1979 [1] 10/2</p> <p>now [22] 1/5 1/20 2/25 16/8 32/18 33/7 35/14 40/20 40/23 44/18 74/11 76/19 76/23 79/4 80/22 84/24 92/22 94/22 95/23 97/20 98/14 100/15</p> <p>nowadays [1] 61/16</p> <p>number [20] 2/2 7/16 7/19 8/11 13/19 13/20 13/21 26/15 26/17 44/5 44/8 44/10 48/2 70/12 70/14 74/4 77/3 79/11 95/15 97/22</p> <p>numbers [1] 13/15</p> <p>nurse [3] 12/21 12/22 99/8</p> <p>nurses [1] 13/4</p> <p>nursing [2] 13/1 91/12</p> <p>O</p> <p>o'clock [2] 102/3 102/7</p> <p>oath [2] 1/6 2/25</p> <p>objection [1] 76/1</p> <p>observations [4] 67/1 68/14 71/11 71/21</p> <p>observed [1] 82/16</p> <p>obsessional [1] 100/22</p> <p>obtain [2] 11/9 91/25</p> <p>obtained [2] 21/5 60/25</p> <p>obtaining [7] 16/15 19/1 23/10 35/23 38/25 61/5 91/9</p> <p>obviously [13] 6/6 6/8 17/20 21/16 22/25 25/10 49/17 58/4 58/8 62/17 72/7 74/3 92/22</p> <p>occasion [2] 39/13 43/11</p> <p>Occasionally [1] 83/24</p> <p>occasions [4] 7/16 8/11 74/4 77/4</p> <p>occurred [1] 15/11</p> <p>occurrence [1] 29/3</p> <p>occurs [1] 83/3</p> <p>odd [2] 42/14 42/14</p> <p>off [5] 6/11 51/23 52/22 58/2 59/19</p> <p>offer [4] 54/7 54/13 56/24 68/15</p> <p>offered [2] 55/23 84/3</p> <p>offers [1] 84/1</p>	<p>often [8] 16/25 17/13 19/10 19/19 22/6 53/6 83/3 84/17</p> <p>oh [1] 76/18</p> <p>old [3] 51/5 78/10 95/22</p> <p>once [3] 9/14 88/6 93/16</p> <p>one [61] 2/25 3/22 5/20 7/3 12/7 12/25 19/19 20/14 22/1 22/2 22/2 22/24 22/24 23/7 23/11 23/15 23/15 25/25 27/18 29/7 31/22 34/3 34/16 37/13 39/6 42/15 46/8 50/13 51/4 52/6 54/16 55/14 60/22 62/6 62/10 63/9 64/6 66/6 67/11 67/13 67/13 67/19 69/16 81/4 89/7 92/25 93/13 94/2 94/22 95/15 96/6 96/9 96/16 97/9 97/21 98/14 99/1 99/11 100/1 100/6</p> <p>one-day [1] 94/2</p> <p>ongoing [1] 55/5</p> <p>only [34] 6/9 12/2 12/9 14/10 22/24 33/5 36/1 37/23 42/15 45/4 47/15 48/15 49/7 50/11 51/12 52/16 54/12 71/14 71/16 76/13 79/2 79/11 79/12 79/15 79/16 81/16 83/12 83/13 86/20 88/14 90/9 94/18 98/9 98/24</p> <p>onwards [2] 24/14 32/20</p> <p>ooze [1] 43/2</p> <p>open [5] 17/24 18/1 62/7 97/5 100/10</p> <p>opened [1] 11/17</p> <p>opened with [1] 11/17</p> <p>operate [1] 63/2</p> <p>operation [5] 17/21 63/6 63/16 90/19 100/17</p> <p>operations [4] 62/11 62/13 77/1 77/2</p> <p>operative [1] 17/10</p> <p>opportunity [3] 68/16 84/22 94/6</p> <p>opposed [1] 3/21</p> <p>or [137]</p> <p>order [1] 24/22</p> <p>ordered [1] 39/4</p> <p>organised [1] 74/16</p> <p>orthopaedic [3] 62/12 76/25 77/2</p>	<p>Osborn [1] 76/22</p> <p>other [44] 5/20 12/7 16/4 18/17 19/6 23/21 24/8 26/8 27/21 34/25 38/11 38/22 40/24 55/20 56/19 59/2 62/12 63/21 65/3 66/18 67/11 67/12 67/13 67/14 67/19 69/16 72/15 73/6 76/24 77/7 83/14 83/22 86/12 86/17 88/8 89/17 90/17 91/1 92/14 99/2 99/6 99/14 99/19 100/15</p> <p>others [7] 22/10 23/22 54/6 60/11 69/9 73/25 98/21</p> <p>otherwise [2] 49/5 68/12</p> <p>our [23] 1/6 2/25 9/9 9/10 20/4 20/10 21/15 22/3 30/3 36/14 40/19 42/4 46/17 47/9 48/3 52/14 62/11 66/14 78/4 79/16 84/24 96/7 98/7</p> <p>out [35] 5/8 5/23 8/2 14/12 23/6 23/8 24/22 24/25 29/15 32/9 32/12 40/23 44/12 49/17 49/22 50/3 57/22 58/1 60/14 61/9 62/12 65/9 66/5 71/22 72/2 73/17 78/14 82/7 88/1 90/11 92/9 94/23 98/17 99/3 99/4</p> <p>out-patients [1] 5/8</p> <p>outcome [2] 66/9 80/6</p> <p>outset [1] 44/23</p> <p>outside [2] 17/23 55/17</p> <p>outskirts [1] 3/19</p> <p>over [16] 12/14 12/16 17/8 23/1 23/5 27/11 31/5 32/7 40/16 41/15 50/15 63/23 69/22 71/7 72/21 92/23</p> <p>overview [2] 3/8 3/13</p> <p>own [7] 9/10 15/20 16/18 39/15 73/4 88/6 93/4</p> <p>Oxford [14] 26/7 26/7 26/9 26/11 26/12 32/4 57/15 58/2 58/11 58/11 58/13 58/17 59/2 59/4</p>
<p>P</p> <p>packs [1] 23/2</p> <p>paediatric [2] 12/17 54/23</p>					

<p>P</p> <p>page [30] 7/14 10/18 10/25 26/5 26/6 26/14 26/25 27/14 29/12 29/17 30/23 30/24 31/5 31/12 31/13 32/7 32/7 37/15 37/20 40/12 42/18 43/14 57/24 67/21 71/7 71/10 74/13 74/18 80/25 81/20</p> <p>page 3 [1] 30/23</p> <p>page 4 [2] 10/18 27/14</p> <p>page 5 [1] 74/13</p> <p>paid [1] 78/13</p> <p>pans [1] 94/23</p> <p>paper [1] 95/18</p> <p>paragraph [7] 30/6 31/14 36/25 65/1 74/17 81/22 82/3</p> <p>Parapia [3] 84/15 84/15 93/6</p> <p>parents [6] 13/9 18/24 19/14 41/12 63/22 66/7</p> <p>parents' [1] 18/22</p> <p>Park [1] 3/17</p> <p>part [9] 10/22 25/3 46/19 55/3 58/11 59/3 61/1 79/23 80/19</p> <p>Participants [2] 85/4 85/5</p> <p>particular [10] 11/22 17/1 17/12 18/6 25/14 27/6 55/1 57/7 64/5 72/24</p> <p>particularly [10] 25/8 43/1 58/4 61/7 83/17 97/3 97/24 98/15 99/16 101/13</p> <p>parties [3] 30/12 74/2 74/4</p> <p>partner [1] 52/6</p> <p>partners [1] 54/14</p> <p>party [4] 29/20 30/7 30/11 73/17</p> <p>parvovirus [5] 80/22 81/2 82/15 82/22 83/2</p> <p>pass [1] 39/9</p> <p>passed [2] 66/20 83/10</p> <p>passing [1] 67/8</p> <p>past [4] 46/16 47/11 62/8 83/5</p> <p>pathogenesis [4] 15/10 15/12 33/14 48/11</p> <p>pathology [3] 3/22 8/19 78/15</p> <p>patient [42] 9/13 9/15</p>	<p>14/12 17/9 17/10 17/12 23/4 23/15 23/22 24/14 24/16 24/20 27/23 33/5 33/20 36/9 42/20 43/21 48/24 50/21 51/11 51/12 52/6 57/11 57/13 57/16 58/8 59/4 61/7 61/17 62/6 63/21 64/18 65/21 65/24 66/22 67/2 89/1 89/10 90/22 92/25 95/21</p> <p>patient 2 [1] 65/21</p> <p>patient's [4] 23/19 65/4 89/2 91/16</p> <p>patients [174]</p> <p>patients: [2] 26/17 26/20</p> <p>patients: 388 [1] 26/20</p> <p>patients: 6 [1] 26/17</p> <p>Pause [1] 58/24</p> <p>paying [2] 83/20 86/21</p> <p>PCR [2] 82/20 82/24</p> <p>peer [1] 75/3</p> <p>Penarth [1] 3/20</p> <p>penultimate [1] 81/22</p> <p>people [35] 2/2 6/2 18/24 20/17 23/8 25/7 25/10 26/11 35/3 40/7 43/4 51/24 67/12 69/5 69/8 70/6 76/4 78/22 79/2 79/4 79/24 80/11 84/12 84/13 84/16 87/5 88/4 88/14 88/20 93/19 97/3 99/2 100/1 100/5 101/5</p> <p>per [13] 14/12 14/12 44/13 46/25 47/14 47/19 79/12 79/25 90/10 97/8 98/8 99/7 99/8</p> <p>Percutaneous [1] 7/18</p> <p>perfect [1] 96/8</p> <p>Perfectly [1] 29/6</p> <p>perhaps [9] 24/19 34/24 43/10 50/3 70/7 71/24 88/19 98/17 99/5</p> <p>period [2] 6/12 92/24</p> <p>permanent [1] 2/15</p> <p>permissible [3] 71/15 94/18 98/16</p> <p>permission [2] 39/1 58/15</p> <p>persistent [2] 8/19 82/8</p> <p>person [3] 54/11 89/17 90/11</p>	<p>personal [6] 49/1 68/24 68/25 69/1 69/15 69/16</p> <p>personally [2] 12/6 53/6</p> <p>persuade [2] 78/15 83/22</p> <p>persuading [1] 61/12</p> <p>pharmaceutical [11] 64/11 65/8 65/19 83/16 84/2 86/9 87/10 93/24 93/25 94/4 94/6</p> <p>Pharmaceuticals [1] 64/24</p> <p>pharmacist [3] 39/5 39/6 39/14</p> <p>pharmacists [1] 70/4</p> <p>pharmacologists [1] 70/4</p> <p>PhDs [1] 93/20</p> <p>pick [2] 10/13 74/17</p> <p>picking [1] 70/10</p> <p>picture [2] 31/21 42/6</p> <p>pile [1] 100/13</p> <p>place [3] 6/7 33/9 43/13</p> <p>places [2] 77/8 92/14</p> <p>planned [1] 76/22</p> <p>plans [1] 4/19</p> <p>plasma [14] 6/9 6/10 19/10 27/22 31/11 44/8 47/17 49/8 49/10 49/11 49/11 68/23 70/21 89/24</p> <p>platelet [2] 49/10 63/15</p> <p>platelets [2] 65/5 80/5</p> <p>play [1] 16/3</p> <p>played [1] 46/18</p> <p>please [27] 7/14 10/18 10/24 15/3 26/4 26/5 29/13 30/14 31/12 32/3 37/14 40/9 40/10 40/13 43/14 47/7 57/3 57/8 64/14 64/22 65/22 66/12 74/9 74/10 74/13 80/23 81/21</p> <p>plus [1] 75/5</p> <p>pm [3] 85/19 85/21 102/16</p> <p>pneumocystis [2] 30/21 32/16</p> <p>pneumonia [1] 32/16</p> <p>point [12] 12/1 12/12 15/25 31/5 35/14 37/3 50/3 71/3 72/2 77/10 88/12 92/15</p> <p>point 3 [1] 31/5</p> <p>policies [3] 4/11 87/7 98/23</p> <p>policy [32] 14/24</p>	<p>15/15 15/18 15/20 16/3 16/8 17/18 18/10 21/23 22/3 22/23 24/4 24/11 25/1 25/18 33/8 46/8 46/19 47/8 48/21 49/9 49/18 50/8 87/15 87/17 88/3 88/7 88/24 98/15 99/3 99/14 99/19</p> <p>pool [14] 6/4 6/8 15/1 46/11 46/18 48/13 49/4 95/5 95/8 95/9 95/12 96/18 96/21 96/24</p> <p>pooled [1] 70/21</p> <p>pools [2] 31/11 40/7</p> <p>poor [1] 80/6</p> <p>population [3] 20/7 20/9 90/6</p> <p>porcine [2] 34/24 42/19</p> <p>posed [1] 95/4</p> <p>position [2] 1/20 86/13</p> <p>positive [22] 47/13 47/14 47/17 48/1 48/3 51/6 52/7 53/10 53/13 53/16 55/6 60/18 61/14 63/12 64/2 67/4 78/7 78/24 79/18 79/18 82/21 82/24</p> <p>positivity [1] 66/6</p> <p>possibility [7] 31/1 41/25 42/1 56/13 60/12 69/24 91/9</p> <p>possible [22] 15/2 15/13 16/11 17/20 20/21 22/1 22/2 22/18 25/9 29/6 29/22 31/10 32/20 47/2 48/22 49/14 71/14 86/22 91/5 92/11 94/18 97/10</p> <p>possibly [4] 9/7 22/10 35/8 100/7</p> <p>post [3] 10/2 10/8 11/21</p> <p>potential [1] 36/10</p> <p>potentially [1] 84/1</p> <p>practice [6] 22/23 33/4 86/4 94/24 97/12 97/13</p> <p>precautions [1] 17/5</p> <p>precisely [2] 52/2 61/14</p> <p>predominant [1] 23/22</p> <p>predominantly [3] 23/11 24/7 43/17</p> <p>preferable [1] 49/3</p> <p>preference [2] 2/7 39/20</p>	<p>preferred [1] 41/13</p> <p>preparation [1] 72/16</p> <p>prepared [2] 49/7 101/18</p> <p>preparing [1] 49/12</p> <p>prescribe [1] 70/2</p> <p>Prescribers' [1] 69/18</p> <p>presence [2] 2/9 93/24</p> <p>present [8] 1/7 5/25 20/19 31/10 36/1 36/15 53/7 82/11</p> <p>presentation [2] 31/25 32/15</p> <p>presentations [1] 73/25</p> <p>presented [2] 83/6 87/23</p> <p>presenting [1] 83/1</p> <p>pressure [2] 40/18 40/22</p> <p>Preston [8] 6/13 6/16 6/21 7/21 8/3 9/8 9/18 88/16</p> <p>presumably [1] 26/20</p> <p>presume [4] 32/16 58/3 58/3 90/7</p> <p>pretty [1] 84/20</p> <p>prevalence [2] 47/8 98/11</p> <p>prevent [1] 81/6</p> <p>previous [3] 62/24 81/15 87/24</p> <p>previously [4] 41/9 44/22 57/11 70/25</p> <p>primarily [1] 69/25</p> <p>principle [4] 86/22 94/19 94/20 94/25</p> <p>prior [3] 39/19 56/6 57/20</p> <p>probable [1] 65/6</p> <p>probably [14] 20/11 24/10 35/15 60/12 76/10 77/19 78/4 78/17 78/19 87/2 87/3 87/18 88/2 95/14</p> <p>problem [5] 19/8 39/12 60/14 83/11 100/21</p> <p>problems [5] 34/3 34/6 40/15 40/16 62/11</p> <p>procedure [2] 17/11 19/24</p> <p>process [11] 37/24 52/9 52/11 58/12 59/1 59/6 59/12 85/25 86/3 89/18 93/19</p> <p>produce [1] 91/5</p> <p>produced [2] 22/5 74/20</p> <p>producing [1] 70/20</p>	<p>product [36] 6/9 21/21 22/13 22/25 23/7 23/11 23/14 27/4 34/24 35/16 35/25 36/16 36/19 36/20 37/2 37/3 37/5 38/19 38/22 41/13 41/13 42/3 42/6 42/19 65/10 65/14 66/11 66/23 67/2 67/6 68/12 71/13 89/3 89/7 89/8 90/15</p> <p>products [23] 4/19 6/2 38/25 39/21 39/22 40/5 40/5 47/11 48/4 48/22 49/15 49/23 57/7 68/21 69/23 70/18 71/6 71/19 71/20 81/16 83/23 94/8 98/10</p> <p>Prof [1] 88/14</p> <p>professionally [4] 15/24 16/7 84/11 88/9</p> <p>Professor [27] 4/7 4/9 6/13 6/16 6/16 6/17 6/20 7/21 7/21 8/3 8/16 8/17 9/8 9/8 9/17 9/18 9/20 11/13 29/15 46/2 46/4 55/18 61/1 69/5 84/15 93/6 99/1</p> <p>Professor Blackburn [5] 6/16 6/17 6/20 7/21 11/13</p> <p>Professor Bloom [6] 4/7 4/9 29/15 46/2 46/4 99/1</p> <p>Professor Mannucci [4] 9/8 9/17 9/20 69/5</p> <p>Professor Parapia [2] 84/15 93/6</p> <p>Professor Preston [6] 6/13 6/16 7/21 8/3 9/8 9/18</p> <p>Professor Underwood [2] 8/16 8/17</p> <p>proficient [1] 5/19</p> <p>Profilate [1] 40/19</p> <p>Profilate HT [1] 40/19</p> <p>programme [3] 28/2 28/8 89/3</p> <p>progress [2] 53/20 77/18</p> <p>progressive [7] 8/15 8/21 8/22 15/9 48/6 69/6 98/4</p> <p>prompted [1] 82/14</p> <p>properly [1] 2/3</p> <p>proportion [1] 79/16</p> <p>proportionate [1] 89/24</p> <p>proposal [1] 49/6</p> <p>proposals [1] 76/7</p> <p>proposing [1] 58/10</p>
---	--	---	--	---	--

<p>P</p> <p>protect [2] 15/12 48/17</p> <p>protects [1] 25/13</p> <p>proteins [1] 72/15</p> <p>protest [1] 19/16</p> <p>protocol [1] 8/3</p> <p>provide [5] 32/18 53/9 59/25 60/1 78/16</p> <p>provided [7] 8/4 56/1 56/4 67/25 70/14 90/14 93/6</p> <p>providing [1] 78/19</p> <p>PRSE0001555 [1] 45/18</p> <p>PRSE0003622 [1] 7/13</p> <p>PS [1] 36/12</p> <p>psychological [3] 54/17 91/24 92/16</p> <p>psychologist [4] 54/22 92/4 92/18 93/4</p> <p>psychologists [2] 92/22 93/1</p> <p>publication [3] 70/1 80/21 82/17</p> <p>publications [1] 29/1</p> <p>publish [1] 82/18</p> <p>published [9] 45/25 65/17 65/18 65/19 68/10 68/13 79/7 81/3 98/24</p> <p>purchase [1] 94/8</p> <p>purchasers [1] 74/21</p> <p>purely [1] 96/6</p> <p>purity [7] 22/13 40/4 67/7 69/23 70/18 71/9 71/18</p> <p>purpose [3] 11/17 30/4 70/9</p> <p>purposes [3] 20/20 21/17 88/6</p> <p>put [3] 3/22 7/12 42/2</p>	<p>8/19 16/24 24/5 38/21 72/20 80/6 84/1 84/9 84/15 85/10</p> <p>R</p> <p>radar [1] 96/19</p> <p>raise [1] 91/8</p> <p>raised [6] 33/5 67/25 68/7 89/15 89/18 89/19</p> <p>raising [1] 59/9</p> <p>range [2] 11/21 85/23</p> <p>rare [2] 32/14 58/7</p> <p>rate [3] 81/9 97/15 97/25</p> <p>rather [5] 25/1 49/3 52/17 56/15 60/6</p> <p>rational [1] 90/10</p> <p>ratios [1] 55/11</p> <p>re [2] 48/8 74/15</p> <p>re-emphasised [1] 48/8</p> <p>Re-Write [1] 74/15</p> <p>reaction [2] 98/21 98/22</p> <p>reactions [1] 19/6</p> <p>read [8] 9/19 28/16 29/5 45/20 45/22 72/7 95/20 101/5</p> <p>reading [2] 79/2 79/4</p> <p>realisation [2] 69/2 71/5</p> <p>really [23] 4/12 8/8 15/11 16/3 16/5 22/15 23/6 27/11 33/15 55/17 56/16 69/14 70/8 72/10 74/5 86/6 88/17 92/13 93/15 98/25 99/10 100/5 100/24</p> <p>reason [5] 24/17 24/23 79/23 89/2 100/19</p> <p>reasonable [1] 15/16</p> <p>reasons [4] 79/24 80/3 89/5 99/20</p> <p>rebuff [1] 72/5</p> <p>recall [37] 4/8 4/10 6/3 6/19 7/25 9/4 14/6 17/1 18/14 20/13 21/10 23/9 28/11 29/24 32/18 33/21 34/23 35/10 37/5 38/13 41/1 51/11 51/14 52/11 53/8 56/5 58/9 59/9 59/13 59/22 75/20 77/21 80/13 82/14 83/12 84/3 87/15</p> <p>recalls [1] 61/4</p> <p>receipt [1] 87/9</p> <p>receive [10] 30/11</p>	<p>36/2 37/7 37/10 38/8 49/5 73/15 80/4 83/21 87/10</p> <p>received [29] 28/17 28/18 29/8 30/2 32/16 34/4 47/10 47/12 49/23 50/1 50/5 50/6 50/11 51/12 51/14 55/14 57/19 63/15 65/5 66/23 66/25 67/2 71/1 77/20 81/16 83/25 89/23 90/16 95/22</p> <p>receiving [13] 20/17 27/12 36/15 36/18 37/4 44/13 65/24 79/19 86/17 89/1 89/8 90/23 98/9</p> <p>recent [2] 29/20 48/2</p> <p>recently [3] 46/15 47/9 48/7</p> <p>recipients [2] 48/17 79/11</p> <p>recognised [1] 84/22</p> <p>recollection [3] 30/18 38/9 52/24</p> <p>recombinant [3] 69/24 71/9 71/20</p> <p>recommendation [1] 46/6</p> <p>record [3] 2/15 93/7 93/8</p> <p>recorded [5] 7/20 75/5 75/15 91/16 91/19</p> <p>records [7] 23/20 23/21 24/2 57/5 59/3 66/20 88/25</p> <p>Recurrent [1] 48/4</p> <p>redacted [1] 58/17</p> <p>reduce [8] 15/13 33/10 33/12 33/16 33/19 48/21 71/4 97/22</p> <p>reducing [2] 96/10 97/19</p> <p>reduction [3] 14/25 20/15 99/16</p> <p>refer [4] 70/11 81/8 82/8 92/25</p> <p>reference [22] 9/3 16/2 16/2 29/21 30/8 30/9 30/12 42/23 43/19 46/6 51/4 52/18 66/22 67/16 67/21 73/16 74/18 75/4 75/7 75/24 76/14 83/18</p> <p>referral [1] 55/21</p> <p>referrals [1] 12/5</p> <p>referred [6] 42/20 43/22 50/21 55/17 67/12 80/18</p>	<p>referring [2] 45/17 65/23</p> <p>refers [8] 29/19 30/6 31/1 31/2 31/6 51/5 58/17 66/7</p> <p>reflected [1] 97/14</p> <p>refreshment [1] 2/22</p> <p>refuse [1] 87/5</p> <p>regarded [1] 8/20</p> <p>regarding [1] 65/3</p> <p>region [3] 12/25 21/12 90/6</p> <p>regional [7] 15/22 21/5 62/15 73/5 73/7 77/15 89/16</p> <p>registered [4] 26/6 26/7 26/12 76/13</p> <p>registrar [3] 3/16 4/23 7/23</p> <p>registrars [1] 6/24</p> <p>regrets [1] 54/16</p> <p>regular [3] 35/25 56/11 73/6</p> <p>regularly [1] 55/8</p> <p>regulated [1] 87/8</p> <p>regulations [1] 87/8</p> <p>reinforced [1] 60/10</p> <p>reject [1] 65/10</p> <p>rejection [1] 66/10</p> <p>related [3] 43/21 48/13 66/19</p> <p>relating [2] 4/19 23/21</p> <p>relation [27] 4/8 4/11 6/4 9/2 13/11 16/9 16/18 18/2 20/18 21/23 25/18 27/15 35/7 35/17 35/23 38/13 38/25 39/16 53/24 58/2 64/5 64/10 65/21 67/22 90/13 91/14 93/21</p> <p>relationship [1] 75/16</p> <p>relative [1] 72/10</p> <p>relatives [1] 54/13</p> <p>release [1] 87/1</p> <p>relevant [1] 2/1</p> <p>reluctant [1] 43/11</p> <p>remain [1] 82/21</p> <p>remained [3] 10/8 65/13 67/9</p> <p>remains [1] 101/23</p> <p>remember [17] 6/8 7/8 16/21 19/4 19/8 19/19 20/16 33/1 33/3 35/2 37/10 38/10 38/20 53/25 54/11 54/25 58/3</p> <p>remembered [1] 22/8</p> <p>remind [1] 74/21</p> <p>reminds [1] 75/23</p> <p>remotely [4] 1/9 1/13 2/11 85/3</p>	<p>remove [1] 58/22</p> <p>reorganise [1] 75/24</p> <p>reorganised [1] 92/8</p> <p>repeat [1] 63/13</p> <p>repercussions [1] 76/15</p> <p>replaced [1] 38/4</p> <p>report [10] 15/5 29/22 30/15 30/18 32/4 65/23 67/22 79/6 92/20 92/21</p> <p>reported [5] 7/11 9/7 48/9 65/8 66/6</p> <p>reporting [3] 31/20 31/20 64/18</p> <p>reports [8] 30/11 32/24 65/3 66/19 67/7 69/7 73/17 74/1</p> <p>representative [4] 1/12 66/14 68/8 76/24</p> <p>representatives [3] 83/19 83/22 84/22</p> <p>represented [1] 85/4</p> <p>request [2] 55/22 55/23</p> <p>requested [1] 66/4</p> <p>requesting [1] 66/3</p> <p>require [1] 36/7</p> <p>required [6] 17/23 18/3 44/9 62/7 70/21 90/16</p> <p>research [1] 9/24</p> <p>resembled [1] 34/8</p> <p>reserve [2] 40/17 40/21</p> <p>reserving [1] 22/22</p> <p>resistant [1] 35/6</p> <p>resolving [1] 68/5</p> <p>resort [1] 23/14</p> <p>resources [1] 87/1</p> <p>respect [1] 50/13</p> <p>responded [1] 17/12</p> <p>responding [1] 66/17</p> <p>response [13] 17/7 17/9 46/2 64/10 64/21 64/23 64/25 65/9 65/18 66/25 71/24 72/5 92/1</p> <p>responsibility [1] 11/23</p> <p>responsible [3] 10/6 12/5 12/6</p> <p>rest [4] 9/22 20/8 47/6 64/7</p> <p>restrict [1] 46/17</p> <p>restricting [1] 15/1</p> <p>result [5] 17/6 50/22 75/18 77/7 79/19</p> <p>resulted [1] 47/8</p> <p>results [7] 47/14 52/25 53/3 53/5 59/21 60/4 79/6</p>	<p>retention [1] 17/6</p> <p>retired [1] 10/10</p> <p>retirement [4] 10/8 92/15 101/24 101/24</p> <p>return [12] 13/13 13/18 26/15 27/15 28/1 32/3 38/7 38/8 42/5 42/8 43/15 58/11</p> <p>returned [4] 37/21 37/22 37/24 38/3</p> <p>returning [4] 34/11 34/20 37/25 38/21</p> <p>returns [6] 26/3 26/13 58/13 58/18 64/3 87/25</p> <p>review [4] 6/25 9/19 60/15 60/21</p> <p>reviewed [1] 60/19</p> <p>reviewing [1] 60/17</p> <p>ribavirin [2] 61/6 61/11</p> <p>rich [1] 49/11</p> <p>RICHARDS [2] 3/3 10/12</p> <p>rid [1] 61/9</p> <p>right [18] 1/25 1/25 3/10 6/13 7/14 8/15 16/12 22/7 27/1 28/21 36/23 51/3 77/7 81/20 85/5 94/20 95/2 95/13</p> <p>right-hand [3] 7/14 27/1 81/20</p> <p>rightly [1] 15/16</p> <p>rigid [1] 75/14</p> <p>risk [9] 14/25 20/15 33/10 35/9 47/19 63/23 95/2 95/24 96/10</p> <p>risks [11] 6/4 32/20 48/22 49/8 56/5 56/7 56/8 91/13 91/14 94/25 95/4</p> <p>Rizza [2] 29/15 73/25</p> <p>RJD [1] 32/3</p> <p>role [6] 7/23 13/1 13/11 16/3 56/19 95/16</p> <p>room [5] 1/8 1/21 2/2 7/3 23/3</p> <p>rotated [1] 5/15</p> <p>rotation [1] 3/9</p> <p>roughly [2] 18/14 87/15</p> <p>round [1] 18/18</p> <p>routine [1] 33/4</p> <p>routinely [3] 58/1 58/1 83/21</p> <p>Royal [2] 4/22 92/4</p> <p>rugby [1] 25/11</p> <p>rules [2] 85/14 87/7</p> <p>run [1] 93/13</p> <p>running [1] 78/8</p>
---	--	--	--	---	--

R	scurry [1] 69/2	101/21	Shore [1] 49/6	Snake [1] 35/22	91/25
ruptured [1] 80/3	second [8] 21/23 26/5 26/14 29/12 37/14 40/12 63/9 74/18	series [1] 73/24	short [3] 5/23 12/14 45/14	so [156]	specific [6] 7/6 9/1 73/16 92/11 92/12 100/2
S	secondly [1] 95/8	serious [1] 69/10	shortfall [2] 89/14 100/1	social [6] 54/22 54/23 92/2 92/5 92/7 92/11	specifically [5] 20/16 38/10 58/14 59/9 73/18
safe [3] 60/11 70/15 97/10	secondment [2] 5/10 6/3	seriously [2] 34/21 69/15	shortfalls [1] 91/3	socially [1] 2/4	Society [2] 13/10 19/21
safeguarding [1] 95/1	section [1] 12/16	seroconversion [1] 81/9	shortly [2] 66/23 86/8	sole [1] 27/4	Spectrum [1] 31/25
safer [4] 39/22 68/20 89/8 89/12	secure [1] 96/13	seroconverted [2] 50/2 52/2	should [17] 27/14 37/11 37/16 46/5 48/16 49/7 49/14 63/3 68/18 68/20 71/14 74/16 78/13 78/16 99/25 102/3 102/10	solicitor [1] 1/13	spending [1] 39/2
safest [3] 71/14 94/18 98/16	see [43] 2/7 2/8 3/4 7/16 7/21 9/10 10/25 13/18 13/22 26/14 26/18 27/17 29/10 29/14 30/23 31/14 35/21 38/1 42/8 42/11 42/18 43/15 43/17 45/11 54/24 57/4 57/14 57/18 57/24 64/15 64/23 65/22 66/3 66/12 70/10 74/14 80/25 81/21 83/14 83/19 86/6 97/11 97/12	serologically [1] 81/25	show [2] 26/8 37/22	some [43] 2/22 4/12 4/13 4/14 5/22 6/1 6/7 7/10 8/14 8/18 8/19 8/21 15/8 18/17 23/23 24/23 34/7 34/24 34/25 35/4 35/7 35/7 35/24 38/22 50/7 50/14 51/17 51/25 57/5 61/4 64/4 67/11 68/14 69/5 69/7 76/17 77/17 78/12 83/25 84/25 86/9 93/3 100/1	spent [3] 4/6 4/9 4/15
safety [2] 20/15 39/23	seeing [2] 30/18 34/7	Served [1] 12/10	showed [5] 8/22 60/5 64/3 71/1 87/24	somebody [3] 12/15 43/9 80/3	spoke [3] 21/14 72/21 78/4
said [20] 2/18 8/12 14/23 15/19 18/20 23/13 41/12 45/23 52/16 54/9 63/1 63/3 63/5 68/4 77/25 78/17 86/18 90/9 94/17 99/1	seek [2] 11/8 86/2	Service [8] 11/5 63/14 66/23 77/15 78/1 78/2 78/18 89/25	showing [2] 81/8 83/7	someone [2] 17/20 28/22	Sponsorship [1] 93/25
sample [1] 52/22	seeking [1] 38/7	services [3] 10/21 69/14 92/7	shown [3] 41/18 48/18 79/10	spoiler [2] 32/3 57/15	Spooner [2] 32/3 57/15
samples [2] 52/4 52/5	seem [3] 15/11 23/11 41/2	sessions [5] 5/22 5/24 5/25 93/23 94/9	shows [2] 23/22 79/8	sport [1] 25/14	sports [1] 25/11
sarcoma [1] 30/21	seemed [5] 15/15 38/21 69/1 83/9 97/24	set [8] 5/21 32/12 57/22 65/9 71/22 75/9 82/7 98/17	sign [1] 23/5	spring [1] 32/19	spring [1] 32/19
satisfied [1] 67/24	seeming [1] 31/3	sets [1] 49/17	significance [2] 59/21 60/4	sprung [1] 76/3	St [1] 93/14
Savidge [1] 93/13	seems [2] 24/22 48/20	setting [2] 31/19 76/1 73/19	significant [2] 8/14 19/5	St Thomas' [1] 93/14	staff [9] 1/16 1/23 3/1 12/14 78/11 78/13 87/22 99/7 99/9
saw [7] 34/8 55/8 59/18 59/20 61/3 74/1 83/13	seminar [1] 13/5	setup [3] 1/6 2/24 73/19	signs [2] 32/8 57/22	stage [10] 9/19 13/11 14/7 18/7 23/15 25/24 28/1 50/23 77/10 79/5	stand [1] 94/11
say [27] 5/8 11/1 13/3 15/24 22/17 22/19 28/20 28/22 31/8 33/9 35/25 37/16 41/15 44/6 51/8 56/12 56/21 60/15 65/1 68/17 70/19 71/12 81/12 85/12 86/25 89/9 101/4	send [2] 52/18 58/10	seven [5] 43/16 47/12 79/16 79/16 95/22	similar [5] 30/20 31/7 59/15 60/3 72/11	standard [2] 25/7 86/4 76/2 76/2	standards [3] 11/25 76/2 76/2
say [27] 5/8 11/1 13/3 15/24 22/17 22/19 28/20 28/22 31/8 33/9 35/25 37/16 41/15 44/6 51/8 56/12 56/21 60/15 65/1 68/17 70/19 71/12 81/12 85/12 86/25 89/9 101/4	sending [2] 58/2 82/15	several [6] 7/7 8/7 26/8 36/1 67/4 89/21	simply [3] 59/5 101/5 101/23	start [4] 3/7 18/15 48/25 100/3	started [4] 14/15 37/10 51/23 100/3
say [1] 76/18	severe [20] 18/10 20/18 21/24 28/4 28/6 34/5 34/6 34/10 34/15 36/9 36/22 43/3 46/21 47/18 47/25 49/24 50/25 56/23 63/21 98/4	severely [4] 20/22 36/2 36/14 75/10	since [2] 31/17 48/16	state [1] 46/4	statement [38] 3/8 8/12 8/24 9/3 12/24 13/7 14/23 15/19 18/20 20/21 20/25 21/20 22/17 33/7 33/9 35/15 37/1 39/1 39/17 41/20 50/18 52/1 52/6 54/9 54/14 54/16 61/4 61/13 65/12 68/4 68/15 68/17 71/22 89/9 90/15 91/4 94/19 96/12
say: oh [1] 76/18	severing [1] 31/3	severity [3] 36/7 46/10 48/6	single [8] 19/23 22/1 22/18 24/4 44/13 47/2 98/9 99/8	States [1] 29/4	stay [1] 77/9
saying [14] 2/15 9/21 20/16 52/13 56/15 69/5 72/11 72/22 75/7 84/16 86/17 90/24 92/7 100/12	seems [2] 24/22 48/20	sexual [4] 53/24 54/2 54/13 60/12	single [8] 19/23 22/1 22/18 24/4 44/13 47/2 98/9 99/8	steps [4] 38/13 38/17 91/25 96/12	stick [1] 43/9
says [19] 10/23 11/4 21/20 26/6 31/14 32/2 36/13 37/21 38/2 39/17 40/14 46/2 52/6 66/13 66/17 67/13 76/25 77/16 81/4	senior [4] 4/23 5/20 6/24 7/23	shall [1] 85/11	since [2] 31/17 48/16	still [7] 37/4 42/12 66/15 74/8 82/24 92/18 94/19	stimulated [1] 82/17
scale [2] 70/21 84/12	sense [3] 2/8 13/19 38/12	share [1] 90/4	signed [1] 102/12	stock [1] 40/17	stop [2] 43/7 58/19
scarce [1] 87/1	sensible [1] 101/15	shared [1] 88/7	situation [3] 34/8 34/14 56/24	stopped [1] 43/13	store [1] 52/5
school [1] 13/8	sent [13] 6/11 22/9 29/15 49/16 52/17 52/22 57/15 59/4 59/19 70/2 73/17 89/25 95/20	she [23] 12/24 13/6 13/7 19/22 19/23 19/23 23/4 52/15 52/16 52/17 52/18 52/21 52/21 54/23 54/24 54/24 54/25 68/9 68/11 75/13 85/7 85/8 101/20	six [12] 3/18 4/1 5/4 10/11 40/19 40/23 41/4 41/5 41/21 57/19 67/14 84/6	stoppage [1] 43/13	
scientific [3] 93/23 94/3 94/9	separate [1] 77/11	She's [1] 1/19	size [1] 95/9	stopped [1] 43/13	
Scotland [1] 90/7	September [4] 7/17 48/25 74/11 79/8	Sheffield [21] 3/10 4/22 5/11 6/14 7/10 9/18 9/23 9/25 15/4 15/5 16/1 21/9 21/17 34/7 69/9 76/13 76/19 76/23 77/16 89/17 90/8	sizes [2] 6/4 6/8	stoppage [1] 43/13	
screen [2] 7/12 40/9	September 1985 [1] 48/25		slapped [1] 83/4	stoppage [1] 43/13	
	September 1992 [1] 74/11		slightly [2] 50/12 88/15	stoppage [1] 43/13	
	September 2002 [1] 79/8		slow [1] 9/22	stoppage [1] 43/13	
	sequestered [1]		small [7] 40/21 43/8 50/11 77/5 96/18 96/21 96/24	stoppage [1] 43/13	
			smaller [3] 27/7 73/20 74/6	stoppage [1] 43/13	

<p>S</p> <p>stored [2] 11/6 52/4</p> <p>stories [1] 84/13</p> <p>straight [1] 88/5</p> <p>straightforward [1] 101/14</p> <p>stressful [1] 43/10</p> <p>stretched [1] 62/16</p> <p>strikes [1] 93/5</p> <p>stronger [1] 40/2</p> <p>structural [1] 75/21</p> <p>structure [2] 75/25 75/25</p> <p>studies [1] 65/2</p> <p>study [9] 7/10 7/25 8/25 9/5 9/10 81/8 86/15 86/20 86/20</p> <p>stuff [2] 84/14 93/17</p> <p>subject [3] 67/25 99/12 102/11</p> <p>submitted [2] 66/1 99/12</p> <p>submitting [1] 59/1</p> <p>subscribed [1] 28/17</p> <p>subsequent [1] 54/1</p> <p>subsequently [6] 37/24 38/4 78/6 78/23 78/23 79/9</p> <p>substituting [1] 33/24</p> <p>successful [5] 9/11 17/3 92/6 97/12 97/18</p> <p>such [15] 13/8 18/11 31/1 31/10 54/20 56/17 73/20 76/18 86/14 90/18 91/25 98/17 98/22 101/14 101/15</p> <p>Sufficiency [1] 31/24</p> <p>sufficient [7] 16/14 16/15 19/1 23/10 37/8 62/18 62/19</p> <p>sufficiently [1] 73/22</p> <p>suggest [11] 22/9 24/2 27/3 39/18 42/2 44/16 44/18 82/4 84/23 85/5 95/6</p> <p>suggested [3] 78/12 88/25 96/16</p> <p>suggestion [1] 67/1</p> <p>suggestions [1] 60/5</p> <p>suggestive [3] 82/19 83/7 83/9</p> <p>suggests [3] 23/14 39/1 41/20</p> <p>suit [1] 85/12</p> <p>summaries [1] 74/3</p> <p>summary [1] 11/18</p> <p>summer [1] 37/12</p> <p>supplied [1] 21/7</p> <p>supplier [2] 22/19 47/3</p>	<p>supplies [8] 16/16 21/1 23/10 35/23 37/8 38/15 40/20 91/2</p> <p>supply [1] 91/3</p> <p>support [8] 11/12 54/17 54/20 91/24 91/25 92/2 92/5 92/16</p> <p>suppose [10] 16/7 20/2 23/6 33/17 72/4 74/6 94/10 95/11 96/9 97/10</p> <p>sure [22] 1/24 7/7 10/5 16/23 17/8 17/12 19/7 20/16 22/11 28/14 30/17 41/3 41/4 42/3 54/3 62/23 67/16 76/8 78/3 80/10 87/12 97/9</p> <p>surface [1] 63/12</p> <p>surgeons [2] 63/1 100/16</p> <p>surgery [11] 17/24 18/1 18/2 35/9 35/12 62/8 62/20 64/19 77/3 97/5 100/11</p> <p>surprises [1] 14/9</p> <p>surrounding [1] 20/9</p> <p>Survey [3] 31/25 57/10 57/14</p> <p>suspected [1] 57/16</p> <p>suspension [1] 33/22</p> <p>swab [1] 43/4</p> <p>swear [1] 1/6</p> <p>swimming [2] 25/14 34/16</p> <p>switch [2] 27/11 91/6</p> <p>switched [1] 24/21</p> <p>symptomatic [2] 81/1 81/13</p> <p>symptoms [3] 32/8 57/21 81/18</p> <p>syndrome [3] 31/25 32/1 83/4</p> <p>system [5] 21/10 31/20 39/25 86/1 90/18</p> <p>T</p> <p>T4:T8 [1] 55/11</p> <p>table [2] 38/2 95/21</p> <p>tachyphylaxis [1] 17/7</p> <p>tailored [1] 48/23</p> <p>take [19] 2/19 2/25 9/21 12/16 17/5 38/17 38/23 44/18 44/24 62/18 62/20 77/19 84/24 85/11 85/11 88/2 91/24 94/19 100/9</p> <p>take-up [1] 9/21</p> <p>taken [4] 6/20 35/8</p>	<p>96/12 96/13</p> <p>taking [2] 12/5 90/21</p> <p>talk [15] 31/19 45/4 45/5 45/7 56/9 56/12 56/13 70/18 71/7 71/18 71/25 74/23 91/13 94/11 97/15</p> <p>talked [6] 8/4 29/3 32/22 60/10 72/12 88/19</p> <p>talking [5] 1/21 20/19 55/1 91/22 96/6</p> <p>tasks [1] 92/12</p> <p>Tatt [1] 68/9</p> <p>team [1] 1/23</p> <p>technical [1] 5/17</p> <p>technician [1] 1/24</p> <p>techniques [2] 4/16 5/20</p> <p>Ted [2] 72/11 88/10</p> <p>Ted Blecher [1] 88/10</p> <p>Ted Tuddenham [1] 72/11</p> <p>Tedder [1] 52/17</p> <p>teeth [1] 43/1</p> <p>telephone [1] 6/1</p> <p>tell [3] 25/7 36/5 53/11</p> <p>telling [2] 53/10 56/6</p> <p>tells [5] 3/8 8/24 12/24 13/7 50/18</p> <p>temporary [1] 33/23</p> <p>ten [2] 12/19 102/7</p> <p>Ten o'clock [1] 102/7</p> <p>ten years [1] 12/19</p> <p>terms [18] 13/25 28/2 28/15 42/6 54/19 55/24 59/12 73/5 73/10 80/14 85/25 89/14 91/2 91/11 91/23 94/23 98/17 98/19</p> <p>test [8] 50/22 52/4 53/5 53/14 56/6 59/18 59/19 59/19</p> <p>tested [9] 47/9 51/19 52/7 60/18 61/14 62/23 63/14 67/4 78/24</p> <p>testing [16] 6/6 13/12 48/24 51/6 52/10 52/13 54/13 55/24 55/25 59/12 59/14 59/16 63/13 83/8 85/25 86/3</p> <p>tests [5] 54/7 56/10 56/11 66/21 86/2</p> <p>tetralogy [1] 77/5</p> <p>than [18] 16/4 18/17 20/5 25/1 34/6 34/25 49/4 52/17 53/1 56/15 60/6 60/14 72/8 73/13</p>	<p>80/12 89/7 91/22 96/12</p> <p>thank [16] 25/2 45/11 47/7 72/24 72/25 85/13 85/15 85/17 86/7 100/25 101/10 101/12 101/19 101/25 102/1 102/15</p> <p>thanks [1] 101/13</p> <p>that [444]</p> <p>that's [38] 1/17 1/20 2/1 2/24 3/11 8/16 10/1 10/16 11/19 14/5 18/13 22/8 24/5 24/25 24/25 27/22 30/3 32/12 36/21 38/11 39/4 41/17 42/16 44/19 50/24 51/3 51/7 53/18 64/21 66/25 76/22 79/15 85/13 86/21 92/13 94/20 95/8 98/6</p> <p>their [33] 8/2 13/9 15/13 20/14 21/17 21/19 25/13 26/10 40/21 43/1 43/2 50/20 53/5 53/20 55/6 55/11 56/9 56/16 59/20 61/1 65/9 68/12 69/23 72/5 75/24 76/1 76/5 86/3 92/19 93/4 94/8 94/10 98/3</p> <p>them [60] 2/12 5/22 8/2 8/2 8/4 13/5 16/24 18/11 18/25 20/6 21/18 23/5 23/6 25/10 25/15 25/16 27/11 32/23 34/5 34/7 34/11 38/17 40/5 40/18 41/6 41/23 42/2 43/10 52/21 53/10 53/11 53/16 54/2 54/5 55/8 55/14 55/18 56/12 56/13 56/17 56/25 58/10 58/15 59/17 59/18 59/18 59/20 60/8 60/16 62/6 68/16 86/2 90/24 93/23 94/8 97/1 98/5 98/8 100/1 101/8</p> <p>themselves [1] 54/6</p> <p>then [131]</p> <p>theoretical [1] 93/15</p> <p>theoretically [1] 95/4</p> <p>theories [1] 30/25</p> <p>therapeutic [1] 57/19</p> <p>therapy [2] 13/9 49/14</p> <p>there [130]</p> <p>there'd [1] 91/6</p> <p>there's [13] 17/6 30/25 31/21 32/7 42/23 66/16 66/22</p>	<p>69/16 72/17 74/18 75/4 75/7 81/1</p> <p>therefore [6] 21/2 33/11 52/19 78/12 87/4 102/5</p> <p>these [23] 12/7 17/15 24/2 24/22 32/12 32/17 34/18 40/16 41/19 44/9 56/10 57/25 64/11 74/3 74/3 76/7 76/23 80/7 81/24 83/6 83/11 84/10 92/24</p> <p>they [107]</p> <p>they'd [2] 53/16 89/8</p> <p>they're [1] 14/10</p> <p>thing [8] 14/8 24/15 56/19 67/11 69/12 76/24 90/21 96/9</p> <p>things [6] 22/8 30/20 60/24 67/13 93/20 97/22</p> <p>think [133]</p> <p>thinking [3] 15/3 40/8 54/10</p> <p>thinks [1] 85/8</p> <p>third [2] 63/2 63/8</p> <p>thirdly [1] 95/9</p> <p>thirds [1] 20/8</p> <p>this [144]</p> <p>Thomas' [1] 93/14</p> <p>thorough [2] 101/8 101/15</p> <p>those [39] 1/7 1/8 2/9 2/19 2/23 2/24 5/18 5/24 5/25 9/20 17/4 26/9 29/5 30/11 38/4 40/7 41/10 45/21 46/20 49/22 50/14 59/16 71/19 76/2 79/12 79/13 81/18 85/3 85/8 86/13 87/24 88/25 91/15 93/22 94/12 98/1 98/12 99/13 102/8</p> <p>though [1] 38/6</p> <p>thought [9] 9/9 9/21 24/18 31/15 40/2 56/4 59/8 67/11 95/14</p> <p>thousands [1] 70/21</p> <p>three [23] 4/3 4/6 4/9 12/2 12/3 12/13 12/13 14/16 22/11 40/16 47/25 49/2 53/2 55/9 76/10 78/8 78/9 82/25 83/6 83/12 83/13 93/2 95/5</p> <p>three years [1] 76/10</p> <p>thrombin [2] 42/24 43/5</p> <p>through [14] 2/20 2/21 3/22 5/15 8/10</p>	<p>15/18 32/9 52/17 62/18 62/20 64/17 71/8 74/5 89/18</p> <p>thus [1] 25/5</p> <p>time [55] 2/1 4/11 4/15 5/1 5/3 5/10 6/18 6/22 7/23 8/19 11/20 13/2 13/16 14/21 15/17 17/8 18/11 28/16 29/5 29/8 30/9 30/19 32/19 33/22 35/12 35/14 37/3 43/3 43/23 49/22 50/6 50/14 52/20 53/9 53/13 53/19 53/21 54/22 54/23 55/1 55/12 60/2 62/22 75/22 76/11 78/11 79/1 80/1 80/6 83/17 84/5 85/15 86/5 87/8 100/14</p> <p>times [4] 9/15 22/25 67/5 89/21</p> <p>tiny [2] 14/11 14/11</p> <p>to [639]</p> <p>to WITN1167006 [1] 57/9</p> <p>toddlers [2] 42/25 42/25</p> <p>together [1] 61/3</p> <p>told [10] 20/13 53/16 58/9 59/18 66/14 73/15 85/24 89/15 91/2 91/11</p> <p>tomorrow [4] 102/2 102/8 102/11 102/13</p> <p>too [1] 39/11</p> <p>took [14] 10/2 11/22 24/10 24/12 37/7 38/13 52/22 52/25 61/11 68/22 69/14 87/16 87/18 87/22</p> <p>top [3] 7/14 81/19 81/20</p> <p>topic [2] 74/9 77/11</p> <p>topical [2] 42/24 43/4</p> <p>topics [1] 85/23</p> <p>total [6] 13/19 13/21 26/15 26/17 48/2 77/4</p> <p>totally [2] 76/6 76/7</p> <p>towards [3] 5/3 11/15 42/18</p> <p>towns [1] 20/9</p> <p>trace [3] 72/14 77/19 78/5</p> <p>traced [2] 79/12 80/17</p> <p>tradition [1] 21/16</p> <p>traditionally [1] 90/8</p> <p>training [4] 3/14 6/4 13/8 18/25</p> <p>tranexamic [6] 16/11 16/16 16/19 17/18</p>
--	---	--	--	--	--

<p>T</p> <p>tranexamic... [2] 42/23 43/21</p> <p>tranexamic acid [2] 16/19 17/18</p> <p>transcript [2] 2/14 58/22</p> <p>transfer [3] 41/14 41/21 48/1</p> <p>transferred [8] 35/16 41/5 41/10 50/15 51/18 60/25 60/25 89/10</p> <p>transfused [2] 48/9 79/25</p> <p>transfusion [20] 5/11 5/16 5/19 5/23 11/5 21/6 23/3 63/14 69/14 73/7 77/15 77/16 78/1 78/2 78/5 78/18 79/7 80/12 89/16 89/25</p> <p>transfusions [1] 82/23</p> <p>translate [1] 78/25</p> <p>transmission [12] 6/5 33/13 53/24 54/3 56/14 58/19 60/13 61/23 71/4 81/7 81/23 83/14</p> <p>transmitted [3] 65/14 71/6 82/5</p> <p>travel [2] 11/8 20/11</p> <p>travelling [1] 26/9</p> <p>treat [6] 9/21 18/10 20/21 21/18 37/9 49/4</p> <p>treated [70] 7/2 7/4 8/7 13/15 13/20 13/22 19/12 19/15 19/17 22/20 24/21 26/16 27/17 33/25 35/16 36/10 36/15 36/19 36/20 36/23 37/1 37/3 37/11 37/19 38/8 38/19 38/25 39/20 39/24 40/4 41/8 41/22 41/24 42/9 42/10 43/16 44/1 44/5 44/7 44/10 46/11 46/12 46/22 47/4 47/15 48/16 49/12 50/8 60/23 61/24 62/8 62/9 63/7 63/20 63/24 63/25 64/7 65/10 65/14 66/24 67/7 67/10 68/18 81/2 81/11 81/14 81/16 82/5 84/17 98/1</p> <p>treaters [1] 38/24</p> <p>treating [1] 33/18</p> <p>treatment [85] 4/10 4/11 4/19 6/20 11/8</p>	<p>11/9 13/24 14/7 14/11 14/14 14/17 14/19 14/24 17/3 18/12 18/15 18/21 19/20 20/1 20/14 21/24 23/2 25/4 25/6 25/18 26/10 26/10 26/19 26/24 27/6 27/8 27/10 27/19 27/21 27/23 28/2 28/3 28/8 33/8 33/23 34/5 34/11 34/12 34/20 35/3 36/4 36/7 37/4 38/14 42/15 42/17 43/7 44/10 44/14 46/8 46/19 46/23 48/4 48/13 48/18 48/20 49/15 50/20 55/7 55/13 55/16 60/22 62/2 70/15 71/15 81/10 82/13 82/24 84/19 87/15 89/3 90/16 90/18 94/18 95/11 96/5 96/7 96/8 97/10 98/16</p> <p>treatments [2] 25/1 95/23</p> <p>Trent [10] 12/25 21/11 73/6 77/15 79/17 80/20 89/23 89/24 90/5 91/5</p> <p>Trent-based [1] 73/6</p> <p>trial [3] 17/8 17/11 62/17</p> <p>Tribunal [1] 83/25</p> <p>tried [2] 46/16 92/2</p> <p>Triger [2] 7/20 8/4</p> <p>trip [1] 86/16</p> <p>true [7] 1/17 8/16 9/23 10/1 36/21 50/24 71/23</p> <p>Trust [1] 39/7</p> <p>try [14] 15/13 21/14 23/7 25/5 25/15 33/10 33/12 33/16 33/19 91/25 92/2 92/5 94/7 100/2</p> <p>trying [7] 18/16 35/13 37/2 40/6 70/6 83/22 95/25</p> <p>Tuddenham [1] 72/11</p> <p>Tuesday [1] 8/5</p> <p>turn [1] 101/12</p> <p>turned [2] 60/14 61/9</p> <p>twice [1] 93/16</p> <p>two [26] 1/15 3/16 4/6 4/8 5/7 8/22 11/20 12/8 20/8 22/10 37/23 40/24 49/2 50/12 53/2 55/14 60/22 61/20 61/25 62/24 64/11 81/16 94/2 94/22 99/2 99/24</p>	<p>two-day [1] 94/2</p> <p>two-thirds [1] 20/8</p> <p>type [1] 57/18</p> <p>types [1] 99/25</p> <p>typically [1] 18/14</p> <p>U</p> <p>UK [2] 13/1 13/2</p> <p>UKHCDO [12] 23/19 29/16 52/13 57/5 73/1 73/10 73/19 74/9 88/13 88/25 89/22 93/21</p> <p>unaware [2] 76/6 76/7</p> <p>uncertain [1] 53/12</p> <p>unclear [1] 24/11</p> <p>under [8] 5/11 30/24 40/14 67/23 70/10 70/17 74/14 75/1</p> <p>undergone [1] 64/19</p> <p>underlying [1] 80/7</p> <p>underneath [1] 38/2</p> <p>understaffed [1] 12/1</p> <p>understand [24] 1/7 1/8 1/9 1/10 2/3 10/14 10/19 11/21 20/20 20/25 22/4 30/16 33/7 35/5 35/14 43/23 52/3 61/13 65/12 68/4 69/22 73/4 89/20 96/17</p> <p>understanding [6] 12/25 30/3 39/4 70/8 78/1 80/16</p> <p>understood [6] 8/13 32/14 48/12 53/19 82/19 98/6</p> <p>undertaken [2] 52/1 52/12</p> <p>undertaking [1] 3/15</p> <p>undertook [3] 3/9 5/1 11/21</p> <p>underway [1] 14/15</p> <p>Underwood [2] 8/16 8/17</p> <p>undoubtedly [1] 48/12</p> <p>unexpected [1] 102/11</p> <p>unfortunate [1] 46/7</p> <p>unheated [4] 37/4 38/7 38/15 64/8</p> <p>unit [6] 39/6 39/7 39/14 62/14 62/15 62/15</p> <p>United [1] 70/3</p> <p>United Kingdom [1] 70/3</p> <p>units [9] 14/10 14/12 22/20 26/20 42/15 46/24 47/4 63/15 80/4</p> <p>university [2] 3/17</p>	<p>9/25</p> <p>unless [4] 24/22 73/17 100/8 100/23</p> <p>unlikely [1] 31/4</p> <p>unpredictable [1] 74/22</p> <p>unsuitable [1] 100/16</p> <p>until [9] 10/8 13/4 18/11 41/12 46/23 63/25 85/11 92/15 102/17</p> <p>untreated [2] 41/9 70/25</p> <p>unwanted [1] 19/9</p> <p>unwell [1] 55/10</p> <p>up [20] 5/21 7/9 9/21 10/2 10/13 15/15 23/1 31/19 50/4 52/20 54/4 66/5 68/2 70/10 74/6 74/17 79/6 92/15 93/2 94/10</p> <p>up-to-date [1] 74/6</p> <p>upon [3] 15/3 18/22 68/16</p> <p>upwards [1] 39/9</p> <p>urgent [2] 35/9 71/5</p> <p>urine [1] 57/23</p> <p>us [41] 2/8 3/7 3/8 3/13 8/24 9/2 12/2 12/24 13/7 24/10 24/12 36/5 48/20 49/18 50/18 51/25 53/15 55/10 60/23 62/3 62/10 62/16 66/14 71/14 73/2 73/15 76/3 77/19 78/3 78/21 83/5 83/9 85/24 88/20 89/15 91/2 91/11 98/16 100/21 101/13 101/19</p> <p>USA [1] 31/18</p> <p>usage [8] 13/22 23/22 23/23 25/22 26/18 42/4 42/6 43/17</p> <p>use [36] 7/7 8/25 9/6 15/1 15/6 16/10 16/18 17/2 17/17 17/18 17/24 17/25 18/2 18/3 18/5 19/2 21/2 22/7 22/10 22/13 25/20 28/12 31/17 32/20 34/25 35/2 35/6 40/18 40/24 43/12 43/19 59/16 64/4 70/21 71/13 97/2</p> <p>used [27] 7/7 13/25 14/3 14/20 16/19 16/23 16/24 17/13 17/13 21/21 22/6 23/11 26/22 27/7 27/20 27/22 39/19 40/1 42/14 43/4 46/5</p>	<p>46/19 46/24 48/16 49/11 49/14 86/21</p> <p>user [1] 36/10</p> <p>users [1] 35/25</p> <p>using [15] 4/12 4/13 9/18 14/10 21/25 22/20 24/20 27/4 34/24 36/19 40/23 42/12 42/19 47/4 49/3</p> <p>usual [1] 45/1</p> <p>usually [1] 62/13</p> <p>V</p> <p>vaccination [1] 63/3</p> <p>vaccine [2] 62/22 62/25</p> <p>varied [1] 17/9</p> <p>various [5] 3/22 5/15 30/25 74/2 83/18</p> <p>vary [1] 95/16</p> <p>VE [1] 7/22</p> <p>venapuncture [1] 19/25</p> <p>venous [1] 18/23</p> <p>very [43] 2/2 9/19 9/22 12/1 12/12 12/14 19/19 25/12 32/14 33/18 34/9 39/7 43/12 45/11 53/12 53/12 54/21 59/15 68/24 72/10 73/4 73/24 78/8 81/9 82/18 83/13 85/1 85/13 85/15 87/4 87/21 87/21 88/14 88/15 93/14 93/17 96/17 100/4 100/25 101/6 101/25 102/7 102/15</p> <p>viable [1] 82/21</p> <p>view [13] 12/2 12/13 15/25 65/2 65/13 68/21 68/24 68/25 69/1 69/3 69/15 69/16 99/2</p> <p>vigorous [1] 82/12</p> <p>VIII [28] 13/25 14/20 23/23 23/24 24/16 24/20 24/24 31/16 35/24 36/8 43/25 46/12 46/24 47/15 49/12 50/2 50/10 50/11 57/21 61/24 62/9 62/25 63/7 72/14 81/5 81/11 89/1 90/4</p> <p>villages [1] 20/9</p> <p>viral [6] 6/5 56/14 70/19 70/22 71/4 83/14</p> <p>virgin [4] 40/19 40/23 41/5 41/6</p> <p>viricidal [1] 40/1</p> <p>virologist [3] 52/15</p>	<p>62/21 62/21</p> <p>virologists [1] 82/18</p> <p>virucidal [1] 82/23</p> <p>virus [15] 2/10 33/13 52/18 53/17 53/22 61/9 79/10 79/14 79/18 81/9 81/23 82/5 82/7 82/21 96/13</p> <p>viruses [4] 48/15 48/19 82/10 82/20</p> <p>visiting [1] 90/22</p> <p>visits [3] 13/8 83/20 83/21</p> <p>visually [1] 2/12</p> <p>VIVIAN [1] 3/2</p> <p>voice [1] 73/21</p> <p>voluntary [1] 39/25</p> <p>von [13] 16/10 17/16 18/9 26/17 27/2 28/9 36/9 42/10 46/9 46/20 47/23 51/1 70/16</p> <p>von Willebrand [1] 51/1</p> <p>von Willebrand's [12] 16/10 17/16 18/9 26/17 27/2 28/9 36/9 42/10 46/9 46/20 47/23 70/16</p> <p>W</p> <p>W Wagstaff [1] 49/1</p> <p>Wagstaff [7] 5/12 21/14 49/1 89/16 90/2 90/11 91/8</p> <p>wait [4] 41/12 41/24 63/2 63/25</p> <p>Wales [2] 3/12 3/17</p> <p>want [8] 2/22 41/12 41/14 51/7 63/25 64/12 95/6 100/17</p> <p>wanted [15] 10/12 12/15 25/8 25/16 52/18 61/10 67/19 68/14 69/16 71/10 72/2 72/23 73/1 80/21 97/1</p> <p>ward [2] 4/5 7/3</p> <p>wards [1] 7/3</p> <p>warning [1] 45/2</p> <p>was [308]</p> <p>wasn't [21] 9/23 13/6 15/23 39/14 39/23 40/3 53/13 53/17 62/19 62/23 68/5 68/12 69/11 76/8 84/11 87/23 87/25 90/20 96/4 96/20 96/22</p> <p>watching [5] 1/8 1/13 2/11 2/23 85/3</p> <p>way [14] 15/10 15/12 16/1 19/2 20/3 20/6</p>
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(41) tranexamic... - way

<p>W</p> <p>way... [8] 22/19 47/3 50/3 74/7 74/15 87/22 96/16 101/16</p> <p>ways [1] 95/6</p> <p>we [244]</p> <p>we'd [2] 54/9 90/24</p> <p>we'll [10] 13/10 15/18 23/16 26/3 29/7 29/14 35/16 40/12 42/5 66/2</p> <p>we're [9] 2/3 12/12 13/13 20/3 44/15 45/16 55/1 68/11 89/7</p> <p>we've [10] 7/15 8/11 26/25 27/1 35/7 50/3 51/5 57/11 81/13 83/18</p> <p>Wednesday [1] 1/1</p> <p>weekends [2] 34/17 78/13</p> <p>welcome [2] 76/18 92/12</p> <p>welcomed [2] 86/24 86/25</p> <p>well [40] 2/23 6/16 7/3 7/8 9/13 9/23 10/10 12/5 16/13 17/13 18/24 22/8 22/24 30/22 38/23 41/17 44/11 44/12 50/7 55/20 73/22 76/18 77/24 81/22 83/7 84/17 88/9 92/14 94/3 95/16 95/24 96/22 97/6 98/12 100/12 100/21 100/25 101/7 101/23 102/7</p> <p>went [7] 18/11 21/17 30/1 73/12 88/13 93/16 94/10</p> <p>were [186]</p> <p>weren't [5] 11/2 17/17 24/3 41/9 67/14</p> <p>western [1] 3/19</p> <p>what [82] 1/6 1/20 2/14 2/17 3/14 5/5 5/14 6/19 6/23 6/24 7/25 8/12 9/4 14/6 14/7 15/19 18/14 22/8 22/15 24/5 25/3 28/15 33/24 34/11 38/11 41/1 42/24 44/4 44/16 44/18 52/12 52/21 52/21 53/4 53/8 53/10 53/18 54/7 54/19 55/4 56/3 56/5 59/5 59/13 59/18 59/25 60/17 72/11 73/18 74/1 74/2 75/21 77/21 80/13 82/7 82/14 83/11 85/2 86/21 90/10 90/15</p>	<p>90/17 90/20 90/22 90/24 90/24 90/25 90/25 92/1 92/13 92/20 93/12 94/1 95/2 95/25 98/6 98/22 99/12 99/20 100/15 101/14 101/23</p> <p>whatever [5] 15/11 22/12 90/3 96/14 99/9</p> <p>when [32] 5/22 12/21 13/4 14/5 14/16 18/21 22/4 23/1 23/4 27/9 28/11 34/15 35/15 37/10 44/3 46/12 49/14 52/2 52/11 53/9 55/13 55/15 63/7 67/11 72/11 73/3 82/21 86/7 86/25 87/23 88/13 100/2</p> <p>whenever [2] 2/1 15/2</p> <p>where [9] 3/13 4/22 7/4 8/17 10/23 17/20 17/20 83/3 97/15</p> <p>wherever [1] 16/11</p> <p>whether [30] 9/14 16/24 17/1 19/13 20/13 30/17 33/4 33/5 33/13 33/21 34/23 35/10 38/13 38/20 41/3 41/10 41/15 42/2 43/24 51/7 51/11 53/21 53/25 58/9 73/13 76/8 84/23 87/7 91/4 97/18</p> <p>which [72] 1/22 3/19 6/7 7/10 10/13 10/19 12/8 12/20 14/11 14/24 15/10 15/15 19/3 22/4 22/14 23/2 23/14 29/3 30/6 30/16 31/16 38/3 41/13 48/14 48/21 48/23 49/5 49/18 51/5 56/18 57/22 61/20 62/4 62/16 63/6 64/3 65/14 65/25 66/5 70/2 72/14 73/12 74/16 77/17 78/5 78/11 78/22 79/7 83/19 85/6 87/6 88/24 89/18 89/23 89/24 90/15 92/20 93/4 93/7 93/23 94/3 95/10 95/10 95/12 96/3 96/9 96/11 96/12 96/16 99/11 99/14 100/21</p> <p>while [2] 87/22 88/2</p> <p>whilst [2] 8/9 55/15</p> <p>Whittaker [1] 4/4</p> <p>who [85] 1/7 1/8 2/9 2/23 8/21 16/5 17/23 18/10 19/12 19/19 19/20 19/22 26/11</p>	<p>28/3 32/6 34/9 34/16 34/18 35/24 36/1 36/7 36/9 36/22 37/1 38/14 38/14 41/7 44/5 44/9 45/21 47/10 47/12 49/21 49/22 50/1 50/4 50/5 50/8 50/19 50/21 51/12 51/17 52/15 54/11 55/5 55/19 60/17 62/1 62/7 64/18 68/9 69/9 70/5 70/7 70/25 76/17 77/20 78/6 78/22 78/23 79/4 79/9 80/11 80/16 80/17 80/19 81/13 82/18 84/15 85/3 85/4 88/1 88/16 90/11 93/19 95/7 97/4 97/5 97/23 98/1 98/15 99/13 100/10 101/5 102/8</p> <p>who'd [1] 58/5</p> <p>whole [3] 14/13 74/4 100/13</p> <p>whom [5] 34/17 43/21 51/25 76/5 89/18</p> <p>whose [1] 1/24</p> <p>why [7] 78/3 78/18 86/6 89/12 99/21 100/5 100/14</p> <p>wide [1] 80/20</p> <p>widely [1] 58/18</p> <p>wider [2] 72/8 83/11</p> <p>wife [3] 1/18 45/4 101/20</p> <p>will [32] 2/3 2/13 2/16 3/1 18/6 25/23 26/11 27/25 32/22 43/20 44/21 44/24 44/25 45/3 46/6 46/11 58/22 68/1 77/18 77/19 79/2 80/10 83/5 85/8 85/11 85/11 88/19 97/22 101/8 101/9 102/5 102/11</p> <p>Willebrand [1] 51/1</p> <p>Willebrand's [12] 16/10 17/16 18/9 26/17 27/2 28/9 36/9 42/10 46/9 46/20 47/23 70/16</p> <p>willing [1] 54/24</p> <p>Wiselka [3] 55/19 61/2 80/19</p> <p>wish [1] 101/23</p> <p>wishes [1] 18/22</p> <p>with [167]</p> <p>withdrawn [1] 54/25</p> <p>within [3] 7/15 21/2 21/11</p> <p>without [6] 16/19 17/17 35/4 43/7 43/9</p>	<p>86/20</p> <p>WITN1167004 [1] 23/18</p> <p>WITN1167005 [1] 57/3</p> <p>WITN1167006 [1] 57/9</p> <p>WITN3174004 [1] 69/19</p> <p>witness [3] 8/12 14/23 50/18</p> <p>won't [3] 23/20 32/9 41/6</p> <p>wonder [2] 61/18 84/23</p> <p>Wood [1] 11/10</p> <p>word [2] 74/14 97/12</p> <p>words [1] 91/1</p> <p>work [15] 3/14 4/3 5/9 5/17 8/13 9/10 9/12 9/14 12/3 14/12 15/4 22/23 24/9 52/1 78/10</p> <p>worked [5] 3/13 4/23 8/2 21/11 88/15</p> <p>worker [4] 54/23 54/24 92/2 92/5</p> <p>workers [1] 92/11</p> <p>working [10] 3/12 6/13 29/20 30/7 30/10 30/12 34/17 73/17 74/2 74/4</p> <p>World [1] 84/8</p> <p>would [127]</p> <p>wouldn't [1] 68/12</p> <p>write [2] 74/15 90/23</p> <p>writing [1] 91/22</p> <p>written [3] 10/20 26/12 72/6</p> <p>wrong [1] 96/3</p> <p>wrongly [1] 15/16</p> <p>wrote [3] 9/20 10/14 19/21</p>	<p>7/24 8/16 8/23 10/1 11/19 11/19 11/25 12/23 15/23 16/13 18/24 19/11 20/24 21/4 21/8 22/3 23/16 25/21 26/2 27/5 27/24 28/6 29/6 30/5 30/21 32/13 32/16 34/2 35/13 36/21 36/24 37/6 42/1 42/22 44/3 44/3 44/20 45/3 45/10 49/25 50/24 51/3 51/10 51/21 52/8 58/3 58/21 58/23 59/7 59/24 61/7 64/9 65/11 65/16 73/12 73/12 75/23 83/24 83/24 88/21 89/6 89/13 93/10 94/16 94/21 95/3 96/15 97/3 97/3 100/25 101/25 102/14</p> <p>yet [1] 45/7</p> <p>you [396]</p> <p>you'd [3] 86/9 89/4 89/15</p> <p>You'll [1] 29/10</p> <p>you're [3] 44/3 75/5 81/4</p> <p>you've [8] 11/7 15/19 22/8 45/6 54/16 89/15 91/2 95/24</p> <p>young [2] 25/8 34/18</p> <p>your [98] 1/12 1/12 1/16 1/18 1/20 3/8 3/8 3/9 5/2 7/22 7/22 7/22 7/25 8/12 8/24 9/3 10/8 11/16 12/24 12/25 13/7 14/23 15/3 15/19 15/20 16/8 16/10 17/18 18/10 18/20 20/13 20/14 20/20 20/20 20/25 21/20 21/23 22/17 24/4 25/18 32/6 32/18 33/4 33/7 33/7 33/9 35/15 38/7 38/9 38/14 39/1 39/16 39/17 41/20 45/4 45/8 50/18 51/16 52/1 52/6 58/9 59/5 59/8 61/4 61/13 64/7 65/12 65/17 68/4 68/15 68/17 69/17 71/11 73/4 75/21 77/21 82/16 83/15 83/16 86/13 86/23 87/14 87/14 88/6 88/8 88/24 89/9 90/19 91/4 92/1 92/15 96/11 96/19 97/14 101/17 101/20 101/21 101/24</p> <p>yours [2] 64/25 80/22</p> <p>yourself [1] 73/21</p>	<p>Z</p> <p>zoom [2] 7/13 45/18</p>
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