

Tuesday, 27 October 2020

(10.00 am)

SIR BRIAN LANGSTAFF: This week is Birmingham and Bradford.

Presentation by MS RICHARDS

MS RICHARDS: Sir, yes. We start this morning with looking at some of the documents we referred to in the written note we've produced about Birmingham Haemophilia Centres, with particular focus upon the Birmingham Children's Hospital. That will be this morning.

This afternoon we will hear from Professor Franklin, who was the director of the Queen Elizabeth Hospital in Birmingham from 1983 to 1992, and his evidence will continue probably until tomorrow lunchtime. Then tomorrow afternoon we'll hear from Dr Wilde, who took over as director at the Queen Elizabeth Hospital in 1992, and then on Thursday we hear from Dr Parapia who was director at the Bradford Haemophilia Centre.

So starting with Birmingham, the documents I propose to refer to in the course of the morning will relate to the following issues: an overview of the centre and its facilities; supplies of blood products and treatment policies; knowledge of risk of

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491 patients registered, 103 attending for treatment, of which 80 haemophilia, 15 Christmas disease, 8 von Willebrand's.

We can see there the "Facilities", described as a 24-hour advisory service; specialist consultant service for surgical, dental, physiotherapy and social care; home therapy programme instituted, and I will come on to the home treatment arrangements; reference laboratory service; educational facilities, and then:

"Available factor concentrates: cryoprecipitate, freeze-dried Factor VIII and freeze-dried Factor IX."

Then in relation to the Children's Hospital we can see:

"Number of patients registered: 120.

"Number attending for treatment: 80 [sic]."

50, haemophilia; 10, Christmas disease.

SIR BRIAN LANGSTAFF: 60, in fact.

MS RICHARDS: Sorry, 60, yes.

50, haemophilia; 10, Christmas disease and then 7,900 units of cryo and 231 bottles of Oxford Factor IX administered.

Again, we will look back to that.

"Six children are receiving home care at the moment ... several more have applied" and then the same facilities.

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hepatitis and HIV; and testing for and treatment for HIV and hepatitis.

I won't be dealing with Professor Hill's time as chair of UKHCDO. We may well look at that in a hearing at a later stage, either when we look at vCJD, sir, or in the course, possibly, of a presentation on the work of UKHCDO over the years, but I won't be dealing with that today.

So haemophilia care in Birmingham, we know, was split between the Children's Hospital and the Queen Elizabeth Hospital. They were in fact designated jointly as a single haemophilia centre, although their patient population was different and they were obviously different hospitals.

The Children's Hospital director, until the middle of 1976, was Dr Jillian Mann, and she was then succeeded by Dr Frank Hill. The centre director at Queen Elizabeth Hospital was Professor Stuart until he was succeeded by Dr Franklin, now Professor Franklin, in 1983.

We can get a snapshot of numbers of patients if we go to SHIN0000045, please, Henry. If we could go to the last two pages, please. Thank you.

So we can see this is as at 1974. We have a summary in relation to the Queen Elizabeth Hospital,

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Sir, for your and, indeed, others' benefit, although I won't go to the details of the rest of the document now, similar figures are set out for other haemophilia centres within the West Midlands region, of which the most sizeable at the time were Coventry and North Staffordshire, as well as a number of rather smaller ones. We have similar data there.

Could we have up, please, Henry, SHOC -- sorry, I should say, although both hospitals were jointly designated as a single haemophilia centre, they were not designated as a reference centre, and it was, in fact, a number of years until the Children's Hospital was recognised as what was then called a comprehensive care centre. The reference centre for the West Midlands region remained the Oxford Haemophilia Centre during the 1970s and 1980s until 1989.

Henry, could we then have HSOC0019918_011, please. The screen has gone ominously blank ...

Thank you.

So this is a document from 1976. If we go -- it's a Haemophilia Society document. If we just go to the second page, we can see a theme which continues really over a number of years about what's said to be insufficient funding for a full range of facilities in Birmingham. So if we could go to the heading

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"Application for Grants" -- thank you -- the second paragraph refers to Dr Hill having been appointed as director at the Children's Hospital and having:

"... applied to the appropriate authorities for funds for new equipment to assist in the research projects ..."

We don't know what those are at this time, sir.

"... and diagnostic facilities that were planned both there and at the Queen Elizabeth Hospital. It had been made clear to him that equipment that he needed, to the cost of £4,000, could not be provided through the usual channels although he hoped to obtain the rest."

Then there's a welcoming of his appointment and it's reported that that could only help to improve the service in Birmingham, which had deteriorated and about which there had been several complaints. We don't have details, sir, of what those complaints were at that time.

We know also from documents -- I won't go to the individual documents -- that there had been concerns about a lack of a full-time nursing sister at both the BCH and QEH. There were also concerns expressed in contemporaneous documents in the 1970s about limited technical staff available to perform diagnostics, and

5

and haemostasis clinic.

SIR BRIAN LANGSTAFF: Pausing there for a moment, that says July 1976 appointed as full-time director. The document which is still on screen is a document which is dated April '76 and says he's now been appointed director. So it's probably, perhaps, I don't know, was it the time between his appointment and actually taking up the post formally or is the second date, that in July, simply wrong?

MS RICHARDS: I don't know, sir. We can check. He certainly took up his appointment as director in 1976 succeeding Dr Jillian Mann, but we can check the precise date and track down any discrepancy.

The division of responsibility between the Children's Hospital and Queen Elizabeth Hospital appears to have continued until 1992. At that point he ceased to have any involvement with the Queen Elizabeth Hospital, at least directly, and remained full time at the Children's Hospital until his retirement from clinical practice in 2008.

Sir, the first main topic I'm going to look at in the documents is issues relating to supplies of the various blood products for treatment in the West Midlands region and the treatment policies that were adopted in Birmingham in particular in the

7

issues over the adequacy of and funding for laboratory facilities in Birmingham continued really for a number of years, well into the 1980s.

If I turn then specifically to Dr, then

Professor, Hill, he was a registrar in pathology at the United Oxford Hospitals in the early 70s -- 1971 to 1973. He -- according to a statement he provided to the Inquiry in response to an individual witness statement from a patient, he says in relation to his career, he spent 11 months in laboratory and adult haematology in Oxford and six months in blood transfusion and immunopathology.

He then moved to the Great Ormond Street Hospital and was there between 1973 and 1976 and it's there, his statement says, he received training in paediatric, laboratory and clinical haematology.

He was then, in July 1976, appointed as full-time consultant and director of the centre at the Birmingham Children's Hospital. His statement suggested that he divided his time between the Children's Hospital, where he had primary responsibility and conducted eight sessions a week, and the Queen Elizabeth Hospital, so the adult hospital, where he provided two sessions a week, including, his statement says, running a haemophilia

6

second half of the 70s and first part of the 1980s.

Henry, could we go back to SHIN0000045. So 0000045.

We looked at the statistics in terms of numbers of patients at the end of this document but you will see this is a set of minutes of something called the "West Midlands Regional Health Authority Treatment of Haemophiliacs". It then became referred to subsequently as a working party. This meeting is 18 December 1975. We can see not yet in attendance, because Dr Hill's not arrived, but Dr Mann is there and Dr Stuart, representing the Queen Elizabeth Hospital.

If we go halfway down the page, to the bottom half of the page, we can see a heading:

"Availability of Cryoprecipitate and freeze-dried Factor VIII."

And there is a detailed discussion about supplies of cryoprecipitate and supplies of Factor VIII.

So we can see Dr Bird, who I think was from the regional transfusion centre at the time, explaining that there was an expectation of receipt of cryoprecipitate, and it's said:

"... at the present rate of demand it would be

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1 impossible to meet the West Midlands Region's
 2 need ..."
 3 That is, I think, for cryoprecipitate.
 4 "... and also supply to the Lister Institute
 5 with the amount of fresh plasma they require."
 6 There's a reference to financial allocations
 7 having been made by the DHSS but these not being
 8 sufficient and the Regional Health Authority having
 9 agreed to increase the blood donor teams and give high
 10 priority to necessary capital building work at the
 11 Blood Transfusion Centre.
 12 Then there's reference to a table which we don't
 13 have showing cryoprecipitate supplies to hospitals.
 14 At this stage it said over 60 per cent was supplied to
 15 the QEH and Children's Hospital. So that's the
 16 Birmingham hospitals. Dr Bird's reported to have said
 17 that:
 18 "... the requirement of the Queen Elizabeth
 19 Hospital was rising ... he stressed that if the
 20 present demand continued the supply of cryoprecipitate
 21 would soon be exhausted; there would not be enough for
 22 the Region, let alone the Lister Institute. He raised
 23 the question of centres buying commercially
 24 freeze-dried Factor VIII, and members then considered
 25 a paper by Dr Stuart on the availability

9

1 Sir, you will see from that, and we see it from
 2 a number of meetings over the following years, at that
 3 point in time cryoprecipitate was the main form of
 4 treatment used in Birmingham and, indeed, at the other
 5 centres in the West Midlands but there was an issue in
 6 relation to the supply of cryoprecipitate, it was
 7 said, and Directors' response was to say they were
 8 going *to have to make that up* by buying commercial
 9 products, and we will certainly see from the annual
 10 returns that commercial products then started to be
 11 used to a considerable extent in the second half of
 12 the 1970s.

13 If we just go to the bottom of this page,
 14 there's a discussion on home treatment:

15 "Members reported that the number of
 16 haemophiliacs on home treatment was steadily
 17 increasing. It was agreed that this was the
 18 preferable form of treatment but there was discussion
 19 concerning the possible increased requirement of
 20 cryoprecipitate/Factor VIII concentrate in order to
 21 offer this more widely."

22 If we go to the next page, second paragraph:

23 "The Working Party agreed that home treatment
 24 should be instituted in suitable patients where
 25 possible."

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1 of freeze-dried Factor VIII or concentrate from the
 2 Lister Institute ..."
 3 We don't, I'm afraid, have that paper.
 4 Then if we go to the top of the next page it
 5 records that:
 6 "Dr Stuart ..."
 7 So the then director at Queen Elizabeth:
 8 "... made the point that as the BTC was unable
 9 to meet all his requirements for cryoprecipitate it
 10 was necessary for him to purchase commercially
 11 manufactured concentrate."
 12 If we go to then a few lines down:
 13 "Following discussion, it was agreed:
 14 "(1) to draw the attention of the Regional
 15 Medical Officer to the possibility of an acute
 16 shortage of cryoprecipitate over the next few weeks.
 17 "(2) to draw the attention of the Regional
 18 Scientific Committee to the problem of the supply of
 19 cryoprecipitate and the cost consequences of buying
 20 commercial Factor VIII concentrate.
 21 "(3) to recommend to the Regional Scientific
 22 Committee that all Directors of Associated Haemophilia
 23 Centres be allowed to purchase commercially prepared
 24 concentrate should the necessity arise. The
 25 recommended Factor VIII was Kryobulin."

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1 We'll see in a little while some documents, sir,
 2 which show that home treatment was ongoing in
 3 Birmingham at this time and steadily increasing, and
 4 that the product used, at least to start with, was
 5 cryoprecipitate for home treatment.

6 That discussion about concerns in relation to
 7 supplies took place in 1975 against a background of
 8 national concerns about self-sufficiency, which we've
 9 obviously heard from other witnesses and in other
 10 documents, and also supra regional concerns. So there
 11 are a number of meetings that take place during this
 12 time of what's the snappily titled "Haemophilia Centre
 13 Directors, Regional Transfusion Directors and Regional
 14 Scientific Advisers from the Supra Regional Territory
 15 for which Oxford Haemophilia Reference Centre had
 16 responsibility". So this was a wider group than the
 17 West Midlands. I won't take time now going to the
 18 documents -- they are referenced in our written
 19 presentation -- but concerns about supplies, both
 20 nationally in terms of the failure to achieve
 21 self-sufficiency and within that broader region, were
 22 being voiced by Dr Rizza, Dr Biggs, Dr Maycock and
 23 others in the course of those meetings.

24 If we then move on to 1977, still now within the
 25 West Midlands region, could we have SHIN0000042,

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1 please. So here we have a meeting of the Working
2 Party on the Treatment of Haemophiliacs, as it's now
3 termed, the West Midlands Regional Health Authority.
4 This particular meeting is 23 May 1977 and we can see
5 that Dr Hill is there in attendance from the
6 Children's Hospital and Dr Stuart from the Queen
7 Elizabeth Hospital.

8 If we go to the second page, we can see in the
9 second paragraph, again, a discussion about supplies:

10 "Dr Bird said that the Blood Transfusion
11 Centre's stocks of Factor VIII concentrates had been
12 used up; the concentrate supplied by the
13 Lister Institute was not being used at the rate which
14 had been predicted, and the demand for cryoprecipitate
15 was going down. He pointed out that there was no
16 policy for the allocation of this material."

17 Then there are particular concerns expressed by
18 Dr Shinton, who was the director of the Haemophilia
19 Centre at Coventry, and there's a question as to why
20 he was having to pay for concentrate where Stoke and
21 Birmingham had a free allocation from Lister. This is
22 presumably NHS concentrate. We see from the last
23 sentence of this paragraph, it being pointed out that
24 much of the Factor VIII used by the Queen Elizabeth
25 Hospital was supplied direct by the Lister Institute.

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1 a long discussion -- I won't go through all of it --
2 about the availability of concentrate and freeze-dried
3 Factor VIII concentrate. There's a discussion about
4 the extent to which targets are being achieved. If we
5 look at the fifth paragraph down under that heading,
6 we'll see:

7 "Members then considered a paper by Dr Stuart,
8 showing 'Actual and Estimated Consumptions of
9 Factor VIII ...' Dr Stuart pointed out that it had
10 been estimated that in 1977, 2,022,500 units of
11 Factor VIII would be used ..."

12 The actual number was 2.197 million and then
13 an estimate in relation to cryoprecipitate showing
14 that the actual number of units of cryoprecipitate
15 used was significantly less. So there's a reduction
16 in the amount of cryoprecipitate from that which had
17 been expected, it would appear.

18 Then if we go to the next paragraph, please, we
19 see in the second sentence Dr Stuart explaining that
20 the amount of cryoprecipitate had dropped from just
21 over 2 million to just over 1.5 million between 1976
22 and 1977, while the amount of commercial Factor VIII
23 used had doubled and that produced by Lister had
24 remained the same. So the picture is of decreasing
25 use of cryoprecipitate but still being used in not

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1 So it appears that, at that time, the
2 Queen Elizabeth was receiving at least some supplies
3 of Lister Factor VIII directly from Elstree, not
4 simply reliant upon supplies from the Blood
5 Transfusion Centre.

6 If we just go to the next page, please, Henry.

7 This is in the context of a discussion about
8 funding for a haemophilia nursing centre but if we
9 just look at the third paragraph, we'll see again one
10 of many expressions of concern about inadequate
11 funding. Dr Shinton is recorded to have:

12 "... placed on record the fact that, in his
13 view, the first essential was to ensure adequate
14 central funding for the supply of commercial
15 Factor VIII concentrate for issue by the BTS in the
16 first instance ..."

17 It would appear he regarded that as more
18 important than funding for the appointment of
19 a haemophilia sister.

20 If we then move on a year to 1978, and go to
21 SHIN0000040, please, Henry, this is a meeting of the
22 same working party a year later, 15 May 1978, attended
23 again by Dr Hill and Dr Stuart representing the two
24 Birmingham hospitals.

25 If we go to the second page, please, there is

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1 insignificant quantities, significant increase in the
2 amount of commercial Factor VIII used and a steady
3 amount of Lister or NHS Factor VIII being used.

4 If we then, please, go to SHIN0000033, what we
5 see -- and I'm obviously not going to go to all the
6 minutes -- from the minutes throughout this period,
7 that there is a regular discussion in the
8 West Midlands region about supplies. I'll come on in
9 a few minutes to the fact that by 1979/1980 a regional
10 contract has been placed for the supply of commercial
11 concentrates and there is a decreasing amount of use
12 of cryoprecipitate. Concerns about shortfalls lead to
13 increased production of commercial supplies and this
14 is a meeting in which Professor Hill complained, for
15 example, about the cost consequences of having to
16 purchase commercial product. I'm afraid I haven't
17 noted the precise reference. I will come back to that
18 if necessary.

19 The idea of increasing the use of
20 cryoprecipitate wasn't apparently discussed again
21 until a meeting of the working party in June of 1982.
22 If we have SHIN0000032 -- Henry, that's the reference
23 I meant to give you -- and we go to the second page,
24 this is a meeting of June 1982, if we go to the bottom
25 of the second page to start with, "Supplies of

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1 cryoprecipitate and freeze-dried Factor VIII
2 Concentrate". So this is, again, a topic of regular
3 discussion at these meetings. There's reference to
4 an agreement having been reached between directors of
5 Transfusion Centres and BPL about the pro rata return
6 of BPL Factor VIII, and then if we go to the next
7 page, we can see it's recorded that, in the fourth
8 line down:

9 "In May 1982, the BPL had announced that due to
10 impending alterations, Factor VIII production would
11 diminish temporarily ..."

12 Then there's a discussion about solutions to
13 meet this reduced availability of NHS Factor VIII.
14 There's a recommendation that all centres should
15 endeavour to cut down on the use of Factor VIII as far
16 as possible, and increase their usage of
17 cryoprecipitate but then what the agreement is: any
18 shortfall would have to be met by increasing
19 purchasing of commercial Factor VIII.

20 So although there is a reference to a suggestion
21 or a recommendation that the way to deal with the
22 shortfall of NHS Factor VIII is to use less and use
23 more cryoprecipitate, in fact the solution that's
24 reached upon is purchase more commercial Factor VIII
25 concentrates.

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1 Hospital obtained its Commercial Factor VIII from two
2 firms only. These firms had been changed in ...
3 1977. ... Members gave details of the costs of
4 commercial Factor VIII from firms which they dealt
5 with and agreed that it was a good principle to buy
6 Factor VIII within the Region from at least two
7 commercial firms."

8 The view then expressed by Dr Stewart -- that's
9 a different Dr Stewart from the Stuart who is
10 a director at the Queen Elizabeth:

11 "... explained that there would be no saving
12 with a Regional Contract, as the amounts being
13 purchased would not increase the discount" and talks
14 about there being no financial gain, but then there is
15 a suggestion that further consideration will be given
16 to this at the next meeting.

17 If we then go to SHIN0000037, this is the
18 working parties meeting from December 1979. If we go
19 to the last page, please, we can see picking it up
20 four paragraphs down that, by this time there is
21 a regional contract in place. Other documentation
22 suggests that there was a one-year regional contract
23 for the West Midlands region that had been awarded to
24 Armour alone, which ran from around the middle of 1979
25 to the middle of 1980. We'll see Professor Stuart

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1 As I mentioned a few moments ago, sir, what we
2 see from the documents around this time is a move
3 towards a regional contract with commercial suppliers,
4 and if we pick that up in SHIN0000041, please, this is
5 a meeting in November 1977. If we go please to the
6 second page, we can see again the bottom half of the
7 page there is a discussion about cryoprecipitate and
8 freeze-dried Factor VIII concentrate supplies and
9 there's a reference towards the bottom of the page to
10 the possibility of central funding. If we go to the
11 next page, please, towards the bottom of the page
12 there, you'll see there's reference to DHSS central
13 contracts, and this is the point at which there is
14 discussed for the first time the possibility that the
15 region might save money on purchase of commercial
16 concentrates, with either central or regional
17 contracts.

18 If we then go to SHIN0000040, please, Henry, we
19 can see this is the meeting of May 1978, which we
20 looked at a few minutes ago. If we go to the third
21 page, we can see discussions about the contractual
22 arrangements for purchasing commercial Factor VIII.
23 So under the heading "DHSS Central Contracts" it said
24 that:

25 "Dr Stuart said that the Queen Elizabeth

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1 there raising a question of the rates for the purchase
2 of Commercial Factor VIII. The terms were no better
3 than if he'd purchased Factor VIII as an individual.
4 He didn't want to participate in a further regional
5 contract after the present two-year one expired. It
6 doesn't appear that it was two year from other
7 documents but it's not entirely clear.

8 Another regional contract then commenced, it
9 would appear, on 1 August 1980. The reference -- but
10 we don't need to go to it, Henry -- is SHIN0000035.
11 Again, it's a regional contract with Armour. That
12 appears to have been a two-year contract. The
13 arrangements according to the various discussions in
14 the minutes was that the commercial product would be
15 delivered directly to the Children's Hospital in
16 relation to Dr Hill's requirements for commercial
17 product but other product was delivered to the
18 transfusion centre and then called off by centres as
19 and when required. So there appears to have been
20 a difference in the practical arrangements for receipt
21 of the supplies as between the Children's Hospital,
22 where Dr Hill received what he requested directly from
23 Armour, and the other centres in the West Midlands
24 region including Queen Elizabeth, which appear to have
25 called off the supplies from the regional transfusion

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centre as and when they needed those supplies.

We don't have, I think, the contracts themselves, just the various references to them that we see in the minutes. We don't presently have the contracts themselves.

Those were the discussions and arrangements taking place in the second half of the 1970s, and we see there the increasing use of commercial concentrate. That emerges very starkly from the annual returns and we'll look at a handful of those returns over the second half of the 1970s and early part of the 1980s.

So if we start with the Children's Hospital annual return for 1975 that's at BWCT0000145_001, please, Henry. This is 1975. This is the Children's Hospital alone. The director is recorded as being Dr Jillian Mann. You will note there a reference to being "post vacant". I'm not sure what that's a reference to. We see the number of haemophiliac patients treated during the year, 48 plus 4 with Factor VIII antibodies and ten with Christmas disease. Then we can see from the return, if we go down to the table, the predominant usage is of cryoprecipitate, with a very small amount of NHS Factor VIII concentrate, no commercial concentrates being used in

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what is required. All patients who start home treatment are, of course, given extensive training beforehand at the hospital and home treatment is not started until we are quite sure that the patient has become an expert.

"We normally restrict home treatment to those patients who suffer many bleeds per month and/or live a considerable distance from a haemophilia centre. Most patients so far on home treatment use cryoprecipitate but freeze-dried concentrate is likely to become available for a few patients who, for example, travel a great deal in the course of their work and are away from home for long intervals."

So that's the letter. The instruction sheet that he referred to is at CWAL0000002 and, if we zoom in on the first half of the page please, Henry, we can see it's headed "Notes on home treatment using cryoprecipitate", so again reflective of the fact that the practice at that time was to use cryo for home treatment. "The following items are necessary for home treatment", and then we see a list of items, "a deep freeze", so that's a domestic freezer, portable refrigeration box for transport, cryogel packs to keep the cryoprecipitate cool during transport, a thermometer -- that's for the thawing

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1975, a small amount of NHS Factor IX concentrate for those with haemophilia B, and what looks like a tiny amount from the plasma fractionation laboratory in Oxford, but that last entry is not entirely clear.

That is 1975.

There are three documents that have been provided to the Inquiry by individual Core Participants that illuminate the use of cryoprecipitate at this time, both for surgery and for home treatment. We'll look at those documents, if we may.

Henry, could we please have, first of all, CWAL0000001. This is a circular letter from Dr Stuart, the director at the Queen Elizabeth Hospital, November 1975. We'll see it's a "Circular letter to all patients with a bleeding disorder who are registered at the Queen Elizabeth Hospital". He sets out the facilities at the QEH. If we go to the bottom of the page, he says that they are attempting to improve facilities along a number of lines and point 3 is:

"Provide home treatment facilities for severely affected patients who wish to have this. I have enclosed an instruction sheet which we issue to our own patients on home treatment to give you an idea of

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process -- packs of cryoprecipitate, tourniquet and then home treatment pack. So a pack of what was required in terms of supplemental equipment was available from the blood bank, we don't need to look at the detail of those.

If we go to the next page please, Henry, we see then if we zoom in on the section under the heading "Procedure for infusion of cryoprecipitate", we'll see there that there are then some detailed instructions for those on home treatment who, as Dr Stuart's letter had said, would have been trained in the process. They assess the severity of bleed, decide whether you can treat it satisfactorily at home, whether you need advice from the QEH, or whether you require to come to ward E4B.

"3. Complete a home treatment record sheet.

"4. Select six donor packs of cryo ...

"5. Fill a basin with water until the temperature is 37 degrees Centigrade ..."

Hence the need for the thermometer, and then various equipment has to be selected.

If we go over the page, we go to the top part of the page, please, Henry, we can see point 7:

"When all the cryoprecipitate has melted and is free flowing (this usually requires 5 minutes at

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37 degrees centigrade) ..."

So not a particularly long period of time, and then there are various practical instructions step-by-step. We don't need to go through all of it but it tells the patient exactly what to do, it identifies things that might go wrong and explains what the patient should do, and then essentially it explains that the patient will infuse the cryoprecipitate and then dispose of the equipment.

If we go to the next page, I should draw attention to paragraph -- sorry the next, please -- paragraph 15(c), which in the context of disposal of the equipment, refers to placing the needles in a brown bag and it says:

"Each brown bag should be kept in the orange-stripe 'hepatitis-risk' sack which must be kept in a safe place out of the reach of children."

There's also the practical advice of never allow children to have used syringes as a water pistol.

Then, bottom of the page:

"Telephone the Blood Bank at least 24 hours in advance ... before you call for a further supply of cryoprecipitate."

So there a really very revealing set of practical instructions which may help you, sir,

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haemophiliac.

If we return then to the annual returns and go to move on to the 1976 annual returns, if we could have, please, Henry, EWCT0000176. So this is the annual return for 1976 for the children's hospital. We've got the figures of patients treated that year, 46, three with inhibitors, five with Christmas disease, and we can see there, again, this is prior to the usage of commercial concentrate. The predominant treatment is with cryoprecipitate and then there is a smaller amount of NHS Factor VIII concentrate used and then, for those with Christmas disease, NHS Factor IX concentrate used.

If we then look at the Queen Elizabeth Hospital return for the same year, that's at HCDO0000028_002, please, Henry. If we go to page 8, we can see here the entry for 1976 Dr Stuart is director, 86 haemophiliac patients treated, 9 with antibodies, 7 with Christmas disease, and then if we go down the table we can see substantial amounts of cryoprecipitate used, reasonably substantial quantities of NHS Factor VIII concentrate but here at Queen Elizabeth Hospital we see that there are commercial concentrates that have been used, again in reasonably substantial quantities, in the course of

27

understand how, in practical terms, the patients on home treatment used cryoprecipitate for their bleeds. We heard, obviously, a lot of evidence last week about Dr Dormandy's use of cryoprecipitate at the Royal Free Hospital. It's clear from this that similar practices were in operation at the Queen Elizabeth Hospital in Birmingham in the mid-1970s.

The second document that I wanted to look at supplied by a Core Participant is JEVA0000012. This is a letter from Dr Jillian Mann, dated 19 June 1975. It's about a patient, Jonathan Evans, and you'll just see it's planning surgery but it's interesting to see how she describes how surgical cover will be provided. She says this:

"... we thought it wise to check Jonathan's blood for the presence of Factor VIII inhibitors before planning any surgical procedure, however minor. He does not have Factor VIII inhibitors, so it should be possible to carry out the procedure under cryoprecipitate cover in the usual way."

So you will see there a description of cryoprecipitate cover for surgery in the usual way. It appears, therefore, this wasn't a one-off but something that was something of a practice, and this is in the context of a patient who was a severe

26

1976, Factor VIII produced by Armour and Kryobulin produced by Immuno. There is also usage of either bovine or porcine Factor VIII concentrates and then NHS Factor IX concentrate for those with Christmas disease.

SIR BRIAN LANGSTAFF: So one could sum that up by saying that, broadly speaking, the usage of NHS concentrate is equal to the use of commercial concentrate, a little bit higher, cryoprecipitate is higher than either the NHS concentrate or the commercial, viewed in isolation, but there is less cryoprecipitate used overall than there is commercial concentrate by a ratio of 5 to 4?

MS RICHARDS: That sounds about right, sir.

SIR BRIAN LANGSTAFF: Broadly.

MS RICHARDS: Around this time, 1976, we know from other documents that the home treatment numbers are given as follows: 30 patients on home treatment at Queen Elizabeth and 7 patients on home treatment at the Children's Hospital. That's as at May 1976 in one of the meeting minutes.

If we then move on to 1977 for the Children's Hospital, we have BWCT0000190, please. So by now Dr Hill is the director. Number of patients treated during the year -- haemophilic patients treated during

28

the year, 54, 6 with antibodies, 9 Christmas disease patients, 1 with Factor IX antibodies. Then if we look at the treatment we'll see still substantial volume of cryoprecipitate being used, apparently no NHS Factor VIII concentrate at all, and then Armour Factor VIII concentrate being used and a small amount of the Immuno Kryobulin product. Then for those with Christmas disease it's still the NHS Factor IX concentrate that's being used.

We don't, I think, have the annual return for 1977 for the Queen Elizabeth Hospital but if we go to CBLA0000940 this is a report that was prepared for a West Midlands working party meeting in 1979. If we go to page 5, please, Henry, we've got figures there for 1977, for the Queen Elizabeth Hospital. We've got the number of patients there recorded, 79 haemophilia, 6 Christmas disease, 12 von Willebrand's. Then we can see there cryoprecipitate in usage, Lister in usage and then commercial Factor VIII concentrates, the product which is used most, and then Oxford Factor IX, no doubt for the Christmas disease patients.

So that's 1977 for the Queen Elizabeth Hospital. If we then go to 1978, we start to see a different picture emerging. The Children's Hospital if we have BWCT0000189, this is the annual return completed by

29

Lister NHS concentrate in use but, again, the largest product used is the commercial concentrate, and then Oxford Factor IX concentrate for those with haemophilia B.

SIR BRIAN LANGSTAFF: Could you just go back for a moment. Just remove the flash across the page if you can, Henry. Thank you.

On the children's, it's now talking in units; so can we go back to the slide before, which is 0000189, BWCT.

MS RICHARDS: BWCT0000189.

SIR BRIAN LANGSTAFF: Because, unhelpfully, the number of bottles of cryoprecipitate, or it would have been bags presumably, has not been translated there into units.

MS RICHARDS: It hasn't, no.

SIR BRIAN LANGSTAFF: 317,870 if the second one's about right.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So it gives the impression here, for the first year, there have been more units of commercial concentrate used than cryoprecipitate for treating children at the Children's Hospital.

MS RICHARDS: Yes.

If, in fact, we go back to -- sorry, Henry -- CBLA0000940, page 6, if we look at the

31

Dr Hill for the year 1978, total number of haemophiliac patients treated during the year, 62, 4 with antibodies, 6 Christmas disease patients, one with Factor IX antibodies. Then if we look down, we'll see it would appear that cryoprecipitate is still in use, a number has been crossed out and the number of bottles used looks like 4,541. There is usage in this year of NHS Factor Concentrate. There is then substantial usage, comparatively speaking, of commercial concentrate and it's solely the Armour concentrate which may, no doubt, reflect the fact that, as we've seen, there was by this time, or around this time, a contemplation of a regional contract with Armour as the sole commercial supplier. So we see there the volume of Factor VIII units for that year 287,198 Armour Factor VIII units and then again the normal picture in relation to Factor IX, the use of NHS Factor IX concentrate and not commercial.

If we go back to CBLA0000940, please, Henry, this is the document we looked at a few moments ago and we go to the sixth page, we need to pick the picture for 1978 in relation to QEHL from this document. So these are the statistics for 1978 and the Queen Elizabeth Hospital we see across the top line of the table, cryoprecipitate still in use,

30

Children's Hospital, the unit figures there are, as you said, sir, 317,870 for cryoprecipitate. The unit figure for commercial Factor VIII is less than that but the figure, if one adds together the Lister and commercial overall, shows that concentrates are being used significantly in excess of cryoprecipitate by that time.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: If we just go to SHIN0000036, please, Henry.

We're now at 1980, and these are minutes of the working party meeting on 19 May 1980. If we go to the bottom of page 2, please, this is describing the situation in the West Midlands region rather than simply looking at either the Children's Hospital in Birmingham or the Queen Elizabeth Hospital, but we'll see what's said there is the use of Factor VIII had been constant during the past four years.

"The use of commercial concentrate had increased from 21 per cent to 53 per cent during the same four-year period, and by a factor of 50 per cent between 1978-79. The use of cryoprecipitate had decreased ..."

And, you will see there, very substantially, sir: from just over 2 million units in 1976 to 443,400 units in 1979.

32

1 "... and this indicated that there had been
2 a move from using cryoprecipitate to using Commercial
3 Factor VIII which involved an increased cost to the
4 Region."

5 Then the observation is made:

6 "This seemed to be an apparent change of policy
7 to purchase commercial Factor VIII and was costing in
8 excess of £100,000 per year, yet no positive decision
9 to change to commercial supplies had actually been
10 made."

11 If we go to the top of the next page, we'll see
12 that:

13 "Dr O'Shea ..."

14 Who was, I think, the director at Shrewsbury.

15 "... said that he wished to continue to use
16 cryoprecipitate ... but he had been unable to obtain
17 the requested amounts ... from the BTS" and he asked
18 if that could be increased.

19 Then Dr Bird is recorded as saying it wasn't
20 possible to manufacture more cryo at the BTS because
21 the plasma was needed to send to BPL. Then this, in
22 the last sentence of that paragraph:

23 "The other members agreed that reversion to
24 using cryoprecipitate would be a retrograde step but
25 the financial implications were recognised."

33

1 This is the page in relation to haemophilia A
2 patients, haemophilia A carriers and von Willebrand's
3 disease patients. We can see 55 haemophilia A
4 patients, one carrier, 10 von Willebrand's disease
5 patients treated during the year.

6 Then we can see in the table, cryoprecipitate
7 still in usage. The volume now used in hospital
8 recorded as being 159,900 units, but nothing used for
9 home treatment for 1981.

10 There's NHS Factor VIII concentrate, but by far
11 and away the main treatment now used at the Children's
12 Hospital by 1981, as you'll see, is the Armour
13 Factor VIII concentrate. Hospital usage is 751,139
14 units. Home treatment usage is 413,680 units.

15 So by 1981 it's very clear from the returns that
16 the move to commercial products has effectively taken
17 place and that the sole commercial product being used,
18 at least at the Children's Hospital at that time, is
19 the Armour product.

20 For the sake of completeness we have also within
21 this the return in relation to patients with
22 haemophilia B. That continues to show the sole
23 treatment being with NHS Factor IX concentrate.

24 Then if we just complete the picture with 1982,
25 '83 and '84, just so that we can see how the usage

35

1 It's not said there why it was regarded as
2 a retrograde step.

3 **SIR BRIAN LANGSTAFF:** It may be the previous sentence.

4 **MS RICHARDS:** It may be, yes. Certainly the inconvenience
5 maybe; that's been referred to by other witnesses.

6 **SIR BRIAN LANGSTAFF:** And the comparative lack of
7 reactions.

8 **MS RICHARDS:** And there's reference then to there having
9 been no official policy statement on the production of
10 cryoprecipitate, but an encouragement to continue to
11 send supplies of plasma to BPL for the manufacture of
12 NHS Factor VIII.

13 So the plasma is being used essentially to
14 manufacture the NHS plasma VIII as a priority over the
15 manufacture of cryoprecipitate, appears to be the
16 picture.

17 If we then look at the 1981 return for the
18 Children's Hospital.

19 **SIR BRIAN LANGSTAFF:** It would follow, presumably, that
20 the cryoprecipitate which was made was made locally.

21 **MS RICHARDS:** Yes. Yes, absolutely, from the local
22 regional transfusion centre.

23 If we go then to the 1981 return for the
24 Children's Hospital, which is BWCT0000137, please,
25 Henry.

34

1 continued, if we go please, Henry, to BWCT0000141.

2 This is 1982 at the Children's Hospital. Again,
3 we've got the numbers of patients treated at the top.
4 We can see a modest amount of cryoprecipitate used,
5 some NHS factor concentrate used: 31,000-odd,
6 hospital; 191,000 for home treatment. But the bulk of
7 the treatment again is with the Armour product
8 Factor VIII: 752,512 units for hospital treatment,
9 465,082 units for home treatment.

10 So the pattern established at least by 1981
11 continues.

12 If we then look at 1983, BWCT0000140, please.

13 We can see, again, in the course of 1983, some
14 usage of cryoprecipitate in hospital only, some use of
15 NHS Factor VIII concentrate both in hospital and for
16 home treatment, but the bulk of the treatment, again,
17 is with the Armour Factor VIII concentrate, both for
18 hospital and home treatment, and the NHS Factor IX
19 concentrate remains the sole treatment for those with
20 haemophilia B.

21 That's 1983.

22 Then finally, for present purposes, 1984.

23 BWCT0000142 please, Henry.

24 This first page shows us treatment with
25 Factor IX. If we go to the second page, please, this

36

is 1984 usage by Dr Hill in relation to haemophilia A patients, carriers and von Willebrand's disease, we can see again there's a relatively small amount of cryoprecipitate used, including a small amount of home treatment, 13,000-odd units, some NHS factor concentrate used both in hospital and at home, but throughout 1984 the vast majority of the treatment is with Armour Factor VIII. You see there the figure, sir: at hospital, 843,729 units; home treatment, 825,537 units.

SIR BRIAN LANGSTAFF: If you look at those last three years and look at the relative proportions of commercial concentrate compared to NHS concentrate, it presents a picture where, in 1981 -- or, 1982, rather, it's roughly 25 times as much commercial as NHS, 1983 is about 15 times as much, and here it's about 8 times as much.

So it's a reducing proportion of the commercial compared to the NHS for some reason. It's tempting to think it might have been influenced by events elsewhere.

MS RICHARDS: I can only say, sir, there's no evidence in any minutes that there is a change of policy in response to, for example, the risk of AIDS and, of course, throughout 1983 and 1984, which are key years

37

former and 8 at the latter. This means that Birmingham have more patients than most of the reference centres ... Dr Hill treats all the patients with human Factor VIII in a similar way to Oxford. If that fails he uses [Factor IX] or FEIBA, but would use porcine [Factor VIII] if the cross-reactivity were favourable. He has FEIBA available in the pharmacy on a 'sale or return' basis and says he would be more inclined to use Hyate:C if that were similarly available."

Then this observation:

"He is extremely cost-conscious and would not use Hyate:C unless he thought there was a definite financial advantage in doing so."

So that's an observation from one of the pharmaceutical companies with whom he had dealings from time to time.

Sir, just perhaps to pick matters up in 1985, we know from documents that we'll look at with Professor Franklin this afternoon that in December 1984, following the Reference Centre Directors' meeting at BPL and the production of the UKHCDO AIDS advisory document, there was then a regional West Midlands meeting which looked at the move to heat-treated concentrates and, as I say,

39

when one is considering the state of knowledge about the risk of AIDS from blood products, by far and away the main treatment continues to be with commercial concentrates from Armour. Of course, the second feature through those years is that there is only one commercial supplier providing concentrates to the Children's Hospital.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Which may reflect the regional contract but is nonetheless a noticeable fact.

Just one other document I should look at from 1984. It's at IPSN000036_012, please, Henry. IPSN -- sorry -- 0000036_012.

This is a document we've looked at in relation to other centres. It's an internal I think Speywood report about approaches to the treatment of inhibitor patients in the UK, looking at it particularly as to what their attitude -- clinician's attitude is towards the use of Hyate:C, which was the porcine product.

If we go to page 8, please, Henry, we will just see what's said about Dr Hill's approach under the heading "Current attitudes towards Hyate:C":

"Dr Hill has responsibility for the patients at both the Children's Hospital and the Queen Elizabeth Hospital and has about 12 inhibitor patients at the

38

I will explore that with Professor Franklin in the course of his evidence. But if we just pick up matters up in 1985 at SHIN0000024, we'll see that in the course of 1985 the move is made regionally to heat-treated products. If we go to the bottom half of the page, Dr Ala (who was by this time the director of the Regional Transfusion Centre, I think) informed the committee that supplies of heat-treated Armour Factor VIII was steady and there was no cause for concern.

Pausing there, sir, you will see that the region appears to have remained with Armour as its supplier following the switch to heat-treated product. There's then a reference to NHS supplies and it's said that:

"The majority of the supplies were being used for children and patients at the Queen Elizabeth Centre. A new NHS Factor VIII wet-heated preparation was awaited."

Then if we go to the bottom of that page -- sorry, Henry -- last few lines, it will see that what is contemplated is that when there is more NHS Factor VIII, i.e. heated NHS Factor VIII, treatment policy should perhaps be changed so that children and young adults should take precedence. Then at the top of the next page we can see the position in relation

40

to Factor IX: the use of unheated Factor IX was continuing.

That takes one up to 1989. We don't have, in fact the -- sorry, 1985. We don't have the annual returns for 1985 but a later working party discussion in 1987 records Professor Hill saying there was a fall in the use of Factor VIII in 1985 and a number of operations had been postponed, and then a catch-up in the course of 1986.

We do have the returns for the Queen Elizabeth Hospital for 1986 but, again, I can pick that up with Professor Franklin. If we get to then 1988 just to complete, as it were, what the returns show us, BWCT0000143, sir, this is Dr Hill's return for the Children's Hospital in 1988. We can see there no longer usage of cryoprecipitate; various Factor VIII product concentrates used (no doubt all heat-treated) including NHS product; no longer Armour in 1988, it's Alpha's Profilate and Cutter's Koate being used. Then you will see at the bottom reference to "other materials", DDAVP.

That is, I think, the first reference in the returns that we have detected to DDAVP but we don't have all the returns, I should say, but from those that we have that appears to be the first reference to

41

to that.

If we look then at the contemporaneous documents, if we could have first of all, Henry, SHIN0000043, please.

These are the minutes of a meeting of the West Midlands working party, attended by Dr Hill and, indeed, Dr Stuart from the Queen Elizabeth Hospital.

If we go to the second page, we'll see, just over halfway down the page, a paragraph beginning "Dr Hill referred":

"Dr Hill referred to the hepatitis risk in respect of freeze-dried Factor VIII concentrate obtained from commercial sources, and with this in mind he asked whether it might not be advantageous to reserve the supplies of concentrate obtained from the Lister Institute for children, leaving the concentrate obtained from commercial sources, largely of foreign origin, for adults. Dr Stuart agreed with Dr Hill as to the hepatitis risk and said that in case of doubt he would prefer to use cryoprecipitate for children rather than commercially obtained freeze-dried Factor VIII concentrate."

Sir, bearing in mind, of course, that all of Professor Hill's patients were children, at the Children's Hospital. The evidence that we have from

43

DDAVP.

I am proposing to turn next to what the documents tell us about Professor Hill's knowledge of the risks of hepatitis and HIV. I note the time. Could I perhaps do that after the break?

SIR BRIAN LANGSTAFF: Yes. Let's take a break now, our usual morning break, for three-quarters of an hour, and come back at 11.50, if you please.

(11.05 am)

(A short break)

(11.51 am)

MS RICHARDS: Sir, I turn to consider what the documents tell us about Professor Hill's knowledge of and response to the risks of hepatitis and HIV.

In the statement that Professor Hill made to the Inquiry in response to an individual patient's statement, he said this about non-A, non-B hepatitis:

"At the time that I was seeing the patient, late 1970s, non-A, non-B hepatitis was thought to be a minor self-limiting condition with no serious long-term consequences. Unfortunately, this did not turn out to be the case later on."

So that's what Professor Hill says. Obviously, sir, we've looked at a wide range of materials from the 1970s and 1980s, and indeed earlier, in relation

42

returns and from the working party minutes does not suggest that what is outlined here was implemented, rather we see, as we've seen from the returns, an ever-increasing use of commercial material and a decreasing use of cryoprecipitate.

We know that Professor Hill, as a member of UKHCDO, attended a number of UKHCDO meetings. If we pick the picture up in November of 1979 -- Henry, could we have PRSE0000150 -- we can see these are minutes of a meeting on 20 and 21 November 1979, and Dr Hill's name appears as attending both days on that page. Professor Stuart from the Queen Elizabeth Hospital also attended.

Henry, if we could go on, please, to page 18 -- I think the paper numbers are out of order. Can you go to the preceding page. Thank you.

So we can see that there was reported at that meeting the report of the Hepatitis Working Party by Dr Craske. Picking it up about two thirds of the way down that paragraph:

"The Working Party felt that it was important for the incidence of chronic hepatitis in haemophilic patients to be assessed. There was much discussion regarding the incidence of chronic hepatitis in haemophilic patients, the possible value of liver

44

1 biopsies and the type of information which Directors
 2 would be willing to give to the Working Party."
 3 There was discussion about the completion of
 4 a form in which directors would submit information to
 5 Dr Craske in relation to signs of chronic hepatitis.
 6 If we go to the bottom of the page, there's
 7 discussion about the relevance of age, and then:
 8 "Dr Craske commented that most patients thought
 9 to have developed chronic liver disease had not
 10 previously had an overt attack of hepatitis."
 11 A recognition there of the potential risk of
 12 chronic liver disease.
 13 "There were various possible causes of
 14 hepatitis ..."
 15 Henry, can we then skip on three pages, please,
 16 because the document pages are out of order. Thank
 17 you:
 18 "... and one should keep an open mind [to] it."
 19 Then Dr Craske is reported as going on to say
 20 there were two types of non-A, non-B hepatitis, and
 21 the agreement is that there be a new form for
 22 directors to report cases of chronic hepatitis.
 23 The actual --
 24 **SIR BRIAN LANGSTAFF:** The inference there that when he
 25 talks about hepatitis, he is talking about --

45

1 That patient is recorded as having:
 2 "... died of a ... haemorrhage ... possible that
 3 his hepatitis indirectly contributed to his death.
 4 "A further patient at Oxford who died of causes
 5 unrelated to liver disease was found on post-mortem to
 6 have portal cirrhosis."
 7 That person was hepatitis B negative.
 8 The working party on hepatitis report their
 9 interest in further cases to collect further evidence
 10 of the prevalence of chronic liver disease. The
 11 preliminary results of the patients at Oxford so far
 12 studied for evidence of chronic liver disease are
 13 given in appendix 1. You will see there there's
 14 a summary:
 15 "70 out of 174 patients ... had persistent
 16 transaminitis but only 20 per cent [sic]" --
 17 **SIR BRIAN LANGSTAFF:** No, 20.
 18 **MS RICHARDS:** "... only 20 of these so far ..."
 19 So 20 out of 174, perhaps not an insignificant
 20 number.
 21 "... have been found to have clinical evidence
 22 suggestive of chronic liver disease."
 23 So that's part and parcel of the material that
 24 Dr Hill -- Professor Hill -- would have received, and
 25 was discussed at the annual UKHCDO meeting.

47

1 probably -- non-A, non-B?
 2 **MS RICHARDS:** Yes. Yes, there are a number of discrete
 3 discussions about hepatitis B. They are normally, in
 4 UKHCDO materials, by this time referred to -- it's
 5 referred to as hepatitis B. That's not invariably the
 6 case but that is generally the position.
 7 We can see the actual report that was being
 8 discussed at this meeting in November 1979 attended by
 9 Professor Hill at HCDO0000135_023.
 10 You will see there it is the "Report of the
 11 Haemophilia Centre Directors' Working Party 1979". If
 12 we go on to the second page, there's a discussion,
 13 "Hepatitis surveillance - (Non-A, Non-B ...)", and
 14 reference to there being an increase in the proportion
 15 of cases of non-A, non-B hepatitis reported in
 16 patients with mild coagulation defects receiving
 17 concentrate for the first time to cover operations.
 18 Then there is reference there to certain data in that
 19 respect.
 20 If we go over to page 5, please, Henry, you will
 21 see the heading "Mortality":
 22 "No further fatalities directly due to acute
 23 hepatitis have been reported. One patient had acute
 24 [non-A, non-B hepatitis] followed by persistent raised
 25 enzyme levels in 1978."

46

1 Professor Hill reported that back to the
 2 West Midlands region on 3 December.
 3 If we could have SHIN0000037, please, Henry.
 4 This is 3 December 1979. If we go to page 3,
 5 bottom half of the page:
 6 "[Professor] Hill said that at the Oxford
 7 meeting referred to in Minute 79/15 above, the
 8 Hepatitis Working Party had reported that Commercial
 9 Factor VIII carried the risk of hepatitis, and he was
 10 concerned that some children at the Children's
 11 Hospital had become hepatitis carriers."
 12 Then there's a reference to hepatitis B:
 13 "Members echoed Dr Hill's concern regarding the
 14 risk of hepatitis B."
 15 So it's unclear from what's reported by Dr Hill
 16 whether he is referring to just B, non-A non-B, or
 17 both.
 18 "And Dr Stewart undertook to discuss the whole
 19 question of the availability of cryoprecipitate and
 20 Factor VIII with the Regional Medical Officer."
 21 In between those two dates, so Professor Hill's
 22 attendance at the UKHCDO meeting and his reporting
 23 back to the West Midlands meeting, there's an
 24 interesting insight into Professor Hill's clinical
 25 practices from an individual witness. If we could

48

1 have up, please, Henry, WITN1103010, please.
 2 Thank you.
 3 You will see this is an extract from a patient's
 4 treatment record. This is a patient with mild
 5 haemophilia. You'll see the date of birth is 1979.
 6 We've obviously concealed the precise date of birth.
 7 But this was the treatment of a baby with mild
 8 haemophilia.
 9 If we look down to the bottom of the page, you
 10 will see there a number of dates from 28 November 1979
 11 through to 2 December 1979, treatment given:
 12 Factor VIII. So that's commercial Factor VIII
 13 material given to a baby with mild haemophilia to
 14 cover surgery at the end of November and beginning of
 15 December 1979.
 16 If we go to WITN1103011, please, this is
 17 a document relating to the same patient. If we zoom
 18 in on the bottom half of the page, please, Henry,
 19 you'll see there the first entry there:
 20 "Relatives at Glasgow with mild haemophilia ..."
 21 Is referred to. It's said in the second line:
 22 "... likely he has mild haemophilia."
 23 In fact, this particular patient, it turned out,
 24 the patient had been misdiagnosed and did not have
 25 mild haemophilia:

49

1 discussions at the UKHCDO meeting.
 2 There were, unsurprisingly, further discussions
 3 at the following year's meeting of UKHCDO, in
 4 September of 1980. I won't go to those documents but
 5 there was the routine update for the Hepatitis Working
 6 Party which Professor Hill also fed back to the
 7 regional working party in December of 1980.
 8 If we could then go please, Henry, to
 9 BAYP0000019_024, please.
 10 This is an internal Cutter document
 11 27 February 1981. It's a discussion or a report of
 12 a visit made by the Cutter sales representative to
 13 Birmingham Children's Hospital on 9 February. It
 14 says:
 15 "Most of the West Midlands Regional Health
 16 Authority have been firm Armour accounts for about
 17 four years. Dr Hill's attitude was therefore one of
 18 friendly hostility."
 19 There's then a discussion about usage. Then if
 20 we go down we can see:
 21 "Choice of product. Dictated by three
 22 parameters: price ..."
 23 There's a reference to the Regional Health
 24 Authority being contracted to Armour until
 25 October 1981. Then this:

51

1 "Patients [sic] told diagnosis. He will need
 2 twice daily cover with Cryoprecipitate for at least
 3 7 days to cover the operation."
 4 Then you will see the words "or
 5 Factor VIII concentrates" have been added above
 6 "Cryoprecipitate".
 7 Then if we look at the next entry, the 28th:
 8 "Operation arranged ...
 9 "Dr Hill has organised for Factor VIII
 10 infusion ..."
 11 **SIR BRIAN LANGSTAFF:** So it would be open to the inference
 12 that cryoprecipitate was perfectly acceptable as
 13 cover?
 14 **MS RICHARDS:** Yes, and for reasons that we do not know,
 15 Factor VIII concentrates were used instead, commercial
 16 Factor VIII concentrates, in this very young baby with
 17 mild haemophilia.
 18 **SIR BRIAN LANGSTAFF:** Who didn't actually have it, but
 19 they didn't know that at the time?
 20 **MS RICHARDS:** No. Who did contract hepatitis C, probably
 21 as a result of this infusion.
 22 **SIR BRIAN LANGSTAFF:** Yes.
 23 **MS RICHARDS:** You'll see how that -- you'll see the
 24 coincidence of timing, if I can put it that way, in
 25 terms of that treatment following on from the

50

1 "Hepatitis risk. He [Professor Hill] stated
 2 that some commercial products have a higher rate of
 3 infectivity than others. I questioned this closely --
 4 no names were given -- the inference was that Armour's
 5 product is the cleanest. Supposedly info from UK
 6 directors. I have no evidence of this at all (and
 7 frankly don't believe it!)
 8 "We discussed the general concern of altered
 9 liver architecture in haemophiliacs and the
 10 possibility that some of this could be caused by the
 11 high protein levels of some Factor VIII preparations.
 12 He thought that the Armour high potency product was
 13 a step in the right direction."
 14 Then you will just see the third factor that fed
 15 into choice of product was packaging and the
 16 availability of particular home treatment packs.
 17 I draw attention to it for the purposes of the
 18 discussion in relation to hepatitis and the risk of
 19 hepatitis from commercial concentrates.
 20 If we then go, please, to SHIN0000034, this is
 21 the West Midlands Working Party meeting that followed
 22 on a few months after the interaction with Cutter that
 23 we have looked at and if we go to the bottom of
 24 page 2, please, there's no reference to hepatitis at
 25 all. What we do see is the reasoning for the award of

52

1 the regional contract. So:

2 "Mr Edwards [who's from the regional supplies
3 department] laid on the table details of tenders
4 received for the Regional Contract for the supply of
5 Commercial Factor VIII ... tenders invited from
6 6 firms and 5 had replied ...

7 "Members considered the information before them
8 and recommended that the contract made by Armour
9 should be accepted. It was agreed that the home
10 treatment pack supplied by Armour was superior to that
11 of Cutter ... It was also felt that there were
12 advantages in remaining with the existing supplier and
13 thus avoiding the complexities of change over."

14 Then there was a discussion about the period of
15 the contract and a suggestion that a period of one
16 year was appropriate. So no discussion there of any
17 issue about relative risks of infectivity informing
18 the decision as to which firm's tender to accept.

19 We then, in terms of documents that refer to
20 hepatitis discussions, move on to January 1983. This
21 is the meeting at a London airport hotel with Immuno
22 we've looked at on a number of occasions. I'll come
23 back to it in a moment when we look at AIDS but
24 Professor Hill was one of the attendees at that
25 meeting and we know that there was a prolonged

53

1 until another product have been proved to be more
2 satisfactory."

3 So those are said to be the criteria or some of
4 the criteria for considering which tender to award.
5 I draw attention to (2) "Where firms have their donor
6 facilities in the US". The relevance of that is not
7 explained but an inference at least would be because
8 of the concerns about paid commercial donors and the
9 risk of hepatitis and/or transmission of AIDS.

10 Just to complete that picture, if we then look
11 at the following working party meeting, that's
12 SHIN000029 please, Henry, December 1983 if we look
13 towards the bottom half of that page under the heading
14 "Regional Contract", it just says:

15 "Dr Ala informed the committee that the lowest
16 tender was forwarded by the present supplier --
17 Armour, and no change was envisaged."

18 So there's no apparent consideration to that
19 issue about location of donor facilities or any other
20 factors going to infection risk. Price appears to be
21 the key factor there.

22 That's the material such as it is in relation to
23 how the risk of hepatitis was or was not being
24 considered at the Birmingham Children's Hospital in
25 the second half of the 1970s/beginning of the 1980s.

55

1 discussion about this possibility of hepatitis-reduced
2 factor commercial concentrates.

3 If we then look at SHIN0000030, this is
4 a meeting in June 1983, again attended by Dr Hill and
5 Professor Stuart from the Queen Elizabeth. If we go
6 to the second page, under the heading "Regional
7 Contract", there's a further discussion about the
8 tendering process:

9 "It was agreed Mr Stanton should invite tenders
10 on the basis of £3.5 million worth of units of
11 commercial Factor VIII. Dr Shinton, Dr Hill and
12 Mr Stanton would meet to adjudicate when the tenders
13 had been received."

14 So Dr Hill had a decision-making role in
15 relation to which tender to accept. Unfortunately
16 there are no minutes of those discussions:

17 "It was agreed that the following points should
18 be taken into consideration at the adjudication
19 meeting:

20 "The amount of effort involved in changing
21 supplier.

22 "Where firms have their donor facilities in the
23 US.

24 "Any public pressure for a change of products
25 (eg to heat-treated Factor VIII) should be resisted

54

1 Turn to consider the position in relation to
2 AIDS. We will just go briefly to that January 1983
3 meeting with Immuno at the London airport hotel,
4 PRSE0002647. If we go to the last page please, Henry,
5 we can see from the list of attendees that Dr Hill was
6 there is. Sir, whilst we've obviously looked at this
7 document on a number of occasions there maybe those
8 who have a particular interest in the children
9 Birmingham Children's Hospital who have not heard the
10 evidence in relation to this document, so I think it
11 is important to show, first of all, Dr Hill was there.
12 Then if we go to the previous page please, Henry, the
13 bottom half of the page under the heading "Acquired
14 Immunodeficiency Syndrome", we can see that in this
15 January 1983 meeting there was a detailed update
16 given, and possibly by Dr Craske, about the position
17 in relation to the developing knowledge of AIDS, but
18 reference is made to:

19 "Up to 10 December ... some 800 people had been
20 reported as suffering from AIDS ... 45 per cent
21 mortality."

22 Then up-to-date figures given in relation to the
23 haemophiliacs in the States affected -- 10 affected,
24 five died, youngest 7 -- and to the cases of blood
25 transfusion or platelets transfusion, including the

56

1 San Francisco baby case.

2 So that would all have come to Professor Hill's
3 attention on 24 January, if it wasn't already known to
4 him. If we just continue over the page, we see then
5 the discussion continuing in relation to the
6 incubation period appearing to be six months to two
7 years, and then the meeting's attention being
8 expressly drawn to the New England Journal of Medicine
9 Articles on 13 January. So, again, if Professor Hill
10 had not read those articles on 13 January in the New
11 England Journal of Medicine, he would have learnt
12 about them within the space of a couple of weeks
13 through this meeting.

14 We know that in June of 1983 Professor Bloom and
15 Dr Rizza on behalf of UKHCDO --

16 **SIR BRIAN LANGSTAFF:** Just before you leave that, the very
17 last paragraph beginning "Final comments", this is
18 looking to see what the infectious agent might be,
19 assuming there is one, and it might be not just one
20 but a mixture and the supposition there is that that
21 might include non-A, non-B.

22 **MS RICHARDS:** Yes.

23 **SIR BRIAN LANGSTAFF:** So if that is so, then non-A, non-B
24 would give rise not only to a risk of hepatitis but
25 also to a risk of giving rise to, in due course, the

57

1 large pool concentrates in such patients. Then
2 point 2, the idea that it would be circumspect to
3 continue a policy for the treatment of children and
4 mildly affected patients or previously unexposed
5 patients with NHS concentrates cryo or freeze-dried.

6 That wasn't, of course, as far as we can tell by
7 this stage, the policy at Birmingham Children's
8 Hospital. Most children were receiving commercial
9 concentrates, although some received NHS or
10 cryoprecipitate. So we don't know whether this led to
11 any change of approach on the part of Professor Hill,
12 these recommendations, such as they were. We've seen
13 no positive evidence of any change of approach in the
14 second half of 1983 following receipt of this letter.

15 **SIR BRIAN LANGSTAFF:** In terms of what it says, it says
16 continue doing what you are doing.

17 **MS RICHARDS:** Yes.

18 **SIR BRIAN LANGSTAFF:** It doesn't say change it.

19 **MS RICHARDS:** No. So perhaps not surprising that the
20 evidence doesn't establish a change of approach.

21 There is some discussion at around this time in
22 the West Midlands working party of the risks of AIDS
23 and if we could go then to SHIN0000030, this is
24 27 June 1983, West Midlands Working Party meeting. We
25 looked at it a few moments ago for a different

59

1 AIDS syndrome.

2 **MS RICHARDS:** Yes, and obviously whilst we know that not
3 to be the case, that was being advanced as one
4 possible matter to be considered.

5 **SIR BRIAN LANGSTAFF:** So it is regarded as a risk?

6 **MS RICHARDS:** Yes.

7 **SIR BRIAN LANGSTAFF:** Yes.

8 **MS RICHARDS:** We have not seen any document to show any
9 change of approach on the part of Professor Hill in
10 terms of treatment of his child patients in the months
11 that followed. If we go to HCDO000270_004, please,
12 this is the letter that we have seen before,
13 June 1983, sent out by Professor Bloom and Dr Rizza.
14 I think in our presentation we say this would have
15 been received by Professor Hill and Professor Franklin
16 in fact Professor Stuart was still the Queen Elizabeth
17 Hospital director, I think, at this point.

18 But, in any event, it would have been received
19 by Professor Hill. This made the treatment
20 recommendations that we see, if we just go down to the
21 paragraphs numbered 1 and 2. So the suggestion that
22 DDAVP should be considered for mildly affected
23 patients with haemophilia A or von Willebrand's and
24 minor lesions and reference there made to the
25 increased risk of transmitting hepatitis by means of

58

1 purpose. So it's three days after that letter. If we
2 turn on to the second page and go this time to the
3 bottom half of the page, the penultimate paragraph
4 says:

5 "Dr Shinton referred to a letter he had received
6 from Dr Ala, who made the point that cryoprecipitate
7 was probably a safer product than Factor VIII
8 concentrate in respect of transmission of Acquired
9 Immune Deficiency Syndrome (AIDS)."

10 Then Dr Ala asks the working party to advise on
11 the purchase of heat treated Factor VIII. So no
12 suggestion there that the cause of AIDS is something
13 other than, for haemophiliacs at least, use of blood
14 products. If we go to the next paragraph please,
15 Henry, we can see:

16 "After a lengthy discussion, it was agreed that
17 more information was required before a decision could
18 be made."

19 So apparently no positive decision made for any
20 change of approach. It's agreed instead two papers
21 should be produced during the next year, so not even
22 quickly. Top of the next page, the two papers are to
23 be:

24 "A discussion paper indicating the type of
25 product that would be delivered to each hospital and

60

the change in treatment policy that this would involve."

And:

"An economic appraisal of this development stating the amount of Factor VIII that would be saved per annum [et cetera, et cetera]. Would there be a substantial benefit to patients or considerable savings?"

We don't have, at least not at the moment, these discussion papers. We don't know if, I think, with any confidence, whether they were produced or not but that's the response to Dr Ala's observation that cryoprecipitate would be safer.

If we go over the page, the other reference to AIDS in this meeting is -- so next page, apologies, Henry -- top of the page under the heading "AIDS":

"Dr Shinton reported that the Regional Blood Transfusion Service was issuing a pamphlet to all donors in the hope they would voluntarily withdraw if they were likely to have AIDS."

Then there's a reference to interviewing as a way of screening donors:

"It was agreed that the situation should be reviewed constantly and treatment revised accordingly."

61

remained full time under his care.

SIR BRIAN LANGSTAFF: So it would follow that whatever was thought at the time of the risk that blood products might transmit the cause of AIDS, they were actually taking significant measures involving a fair bit of time and clinical investigation to discover if any person taking blood products had actually got any signs?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: Yes. So it appears they were taking at least the risk very seriously to that extent.

MS RICHARDS: Yes. In terms of examination of patients, the translation of that into any action in terms of changes of treatment policies is what one looks for but doesn't find.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: In relation to the Birmingham Children's Hospital, at least.

We know that Professor Hill attended the October 1983 UKHCDO annual meeting. I won't go to that but you'll recall, sir, that's the meeting at which Dr Chisholm raises the possibility of returning to the use of cryoprecipitate and Professor Bloom says there's no proof that commercial concentrates were the cause of AIDS.

63

There's no documentary evidence of any kind of constant review or revision of treatment policies.

Also, around this time, TREL0000335_020, please, Henry, this is a letter that Dr Hill dated 29 June 1983 from Treloar College from Dr Wassef at Treloar. We can see it is about a particular patient, bottom of the page:

"AIDS Related Investigations:

"Clinically he exhibits some of the stigmata of AIDS."

Those are then described. Then we go over the page:

"For your information, we have undertaken the enclosed AIDS-related tests. We are repeating these before the end of term and will let you have the results when they are available."

So, again, we've seen from earlier presentations the invitation sent out by UKHCDO in March 1983 to directors to monitor their patients for signs of AIDS and report back to UKHCDO. We can see here evidence of that being undertaken at Treloar and the results of that being fed back to Professor Hill. We don't know what, if any, observations Professor Hill was undertaking in that regard at the Birmingham Children's Hospital in relation to the patients who

62

If we then move on to the next West Midlands working party meeting, that's at SHIN0000029, this is December 1983, 5 December 1983. We've already looked at it in terms of the tender award. If we go over to the second page, this is the extent of the discussion in relation to AIDS:

"Dr Ala informed the committee that a blood transfusion handout was now available at donor sessions. It was agreed that if any case of AIDS was suspected, then the Regional Public Relations Office should be informed in case their help was required."

That is the only minuted reference to the risk of AIDS or any action in relation to it in this meeting in December 1983: contact the public relations office if required.

If we move to March of 1984, sir, if we could have, please, Henry BSHA0000119 we know that Professor Hill attended and presented a paper at the conference of the British Society for Haematology and Netherlands Society of Haematology joint meeting in late March of 1984, held in Exeter.

If we go to page 6, I think, Henry, we can see that there was a session on haemophilia chaired by Professor Bloom. We can see reference, if we go down the page, to there being a page presented by

64

Dr Kernoff and Professor Lee about the high risk of non-A, non-B hepatitis. We know, obviously, that translated into a paper that we heard about from Professor Lee last week.

Then there's reference to "Immune Function in Haemophiliacs", a paper presented by a number of representatives, including Professor Ludlam. Then we'll see two papers presented by Dr Hill, Professor Hill, one, referred to at the bottom of the page, about von Willebrand's, and, top of the next page, this was a paper about "Altered T-Cell Lymphocyte Populations in Haemophilic Boys", co-presented by Professor Hill. If we go on, please, to -- I think it's page 37, Henry. Yes.

So here's a summary of the paper presented by Professor Ludlam and others, and the second paragraph tells us that:

"Haemophiliacs are at risk of developing the acquired immunodeficiency syndrome possibly due to contamination of commercial Factor VIII concentrates by a causative virus."

Then if we go on two pages, please, we see a summary of the paper presented by Professor Hill and others relating to observations of haematological and immunological abnormalities, particularly in relation

65

That is I think a regional -- it looks like those would be regional statistics rather than just the Children's Hospital, but we don't have the appendix to the meeting.

Then over the next page we can see there's a discussion of the likely shortfall of 3.5 million units -- this is in terms of factor concentrate -- to be made up from commercial sources. Then there's going to be consideration of tenders and an adjudication by Dr Franklin, Dr Ibbotson and others, and I can no doubt ask Professor Franklin about that this afternoon or tomorrow.

We then get to December of 1984, and we see an emergency general meeting being held by -- or, an extraordinary general meeting being held by the West Midlands working party on 17 December 1984, and that is SHIN0000026_002.

It's not that. It's SHIN0000026_002.
Thank you.

So it's the West Midlands working party again, an extraordinary meeting held on 17 December -- this is 1984 -- to discuss the implication of AIDS on the provision of concentrate for the treatment of the haemophiliacs.

So this would appear to be the first detailed

67

to the T4:T8 ratios associated with high usage of Factor VIII products.

Still in March 1984, Professor Hill would no doubt, as a director, have received a further document from UKHCDO -- we don't need to go to it, we've looked at it a number of times -- which was concerned with hepatitis-reduced Factor VIII trials, clinical trials, but said in terms:

"All products except those derived from NHS Factor VIII are made from plasma imported from the USA and therefore they carry a putative risk of transmission of AIDS."

We then come to the working party meeting, the West Midlands working party meeting, 14 May 1984. That's SHIN0000028.

This is May 1984. If we look halfway down the page, under the heading "AIDS", Dr Ala refers to, when an appropriate screening test for HTLV was available, it would be essential for this to be introduced for blood donors.

Then bottom of the page refers to "Annual Statistics" compiled by Dr Hill:

"They showed an increase in usage of BPL Factor VIII supply with an appropriate decrease in Commercial Factor VIII purchase."

66

discussion that the working party has held on the implications of AIDS for treatment, and it follows that meeting of Reference Centre Directors on 10 December and the production by reference centres of their AIDS advisory document, although the latter may not have reached the working party by then.

We can see it refers to:

"A meeting was held to discuss the implication of the use of Factor VIII concentrate in the light of the death of two haemophiliacs from AIDS. Dr Hill informed the committee that following an outbreak of TB at the Children's Hospital, the incidence in haemophiliacs was similar to that in immunocompromised leukemic children."

There's a discussion in relation to that, and:

"A research product is now underway at the Children's to investigate immune states (T4 T8 sub-sets) antibodies to HTLV-III and other findings associated with the AIDS syndrome. The committee agreed with Dr Hill that seroconversion to HTLV-III antibody positivity was linked with Factor VIII concentrate which was more likely to be imported rather than NHS.

"The committee accepted that the use of Factor VIII concentrate was associated with the risk

68

of transfusing the AIDS virus."

Then if we go down a few lines:

"Dr Hill informed the committee that the statistics regarding the incidence of AIDS in HTLV-III positive patients had risen to 1 in 50. It was considered imperative that heat-treated Factor VIII should ... be made available to haemophiliacs as a matter of urgency. Unfortunately, the Chairman [that was Professor Shinton] informed the committee that this was unlikely to occur with NHS Factor VIII until 1 April, 1985, but that Armour heat-treated material would be available in January 1985. Following discussion, a treatment policy to cover the interim period was agreed upon ..."

Here we finally reach a change of treatment policy:

"1. Mildly affected patients - Haemophilia A, and von Willebrand's ... to be treated with DDAVP or cryoprecipitate.

"2. Newly diagnosed severe haemophiliacs to be managed wholly on cryoprecipitate."

So no suggestion that that was impossible to achieve, either clinically in terms of efficacy or in terms of supply:

"3. a) Patients with no previous exposure to

69

transmission of AIDS. Management as for Hepatitis B positive would be acceptable."

So that's the discussion that then took place in December of 1984, and obviously one issue for you, sir, will be whether those kind of discussions could or should have taken place earlier, and whether there should have been any changes in treatment, practice or approach at an earlier stage.

If we then just go to SHIN0000026_001, Henry. We can see this is the letter as sent to Professor Shinton, but it was sent to all members of the West Midlands working party, 19 December. It refers to the extraordinary meeting. Then says:

"Armour have agreed to heat all material which is returned to them at a cost of 4p per unit. I would be grateful if you could send any material back to the Regional Blood Transfusion Centre."

Sir, there are then further meetings in 1985 of the working party. I will just give the dates rather than go to the documents. On 15 February 1985 the West Midlands working party met again. On this occasion they noted that their interim guidance drawn up in the minutes we've just looked at was at odds, in some respects, with the UKHCDO's AIDS advisory document, and so there was an adjustment of treatment

71

commercial Factor VIII should continue on NHS Factor VIII."

Over the page:

"b) Patients with previous exposure to commercial Factor VIII should continue on NHS Factor VIII if available and heat-treated commercial Factor VIII when not.

"It was stressed that full discussion should take place with the recipients regarding use of therapeutic material, as the availability and speed of HTLV-III screening precluded its use for treatment guidance."

Then there's discussion about the financial implications and then, under the heading "General Advice":

"This was left to the discretion of the individual centre directors. The views of the meeting were that all haemophiliacs and parents of children affected, should be appraised of the action being taken locally. It was stressed that spouses of haemophiliacs should cease to be blood donors and that sexual activity should be regularised and a sheath used.

"Medical staff - that haemophiliacs should be treated as a high risk group from the point of view of

70

strategy to reflect the UKHCDO's AIDS advisory document.

There was a further revision of the treatment guidelines on 29 July 1985 following Professor Bloom's letter to the BMJ about the safety of unheated cryoprecipitate.

In the meantime, it would appear that efforts were made to obtain heat-treated Factor VIII supplies for patients at the Children's Hospital, and we can see two letters, CBLA0002092. This was from Dr Hill to Dr Snape, 18 March 1985. He says:

"I am anxious to receive sufficient Factor VIII concentrate of the heated type for the following patients with severe haemophilia."

And then lists nine patients. Then he says:

"I wish if possible to maintain all these patients on NHS concentrates either because they are allergic to other concentrates, or because they would be useful to include in a study of the use of heat-treated NHS Factor VIII concentrate and because this product is potentially safer. The other fifty severe haemophiliac boys under my care are all receiving Armour heat-treated Factor VIII."

So that seems to be the position as at March 1985: 50 boys with severe haemophilia receiving

72

1 Armour heat-treated product, a request for NHS product
2 on a named patient basis for these nine patients.

3 Then if we just go to BPLL0006105, please,
4 there's a slightly curious letter. This is a later
5 letter. It's from Dr Smith at BPL, dated
6 18 March 1991. It talks about 8Y transfer charges to
7 Children's Hospital, and says this:

8 "In 1985, BPL adopted (without publicising it)
9 the policy of ensuring that the limited supply of 8Y
10 would go first to HIV negative and previously
11 untreated patients. Many of these were children
12 attending Haemophilia Centres at Great Ormond Street
13 and Birmingham Children's Hospital. These children
14 were invaluable to BPL's clinical proof that 8Y does
15 not transmit HIV or hepatitis, but their value can be
16 extended further because they have never had anything
17 except 8Y. This may hold the key to other eg
18 immunological questions which cannot be answered any
19 other way.

20 "Supplies to these two hospitals, and to other
21 centres with patients in the first trial, were
22 guaranteed by delivery via PFL, which was given this
23 allocation 'for support of clinical trial'. When it
24 became clear that someone would have to pay for the
25 product, both centres (Dr Hann and Dr Hill) wished to

73

1 This is a document dated March 26, 1986. It's
2 an internal pharmaceutical rep memo. The author is
3 a Loftus S Lucas, and it's describing what is called
4 a "Satellite Meeting, Haemophiliac Centre Directors
5 Meeting, St Thomas's Hospital, London, 17 March 1986".

6 We can't be certain that this meeting was
7 attended by Professor Hill, but it looks likely as
8 though he did because he did attend the Haemophilia
9 Centre Directors' meeting at St Thomas' that day.

10 What is said by the author of this memo:

11 "I estimate that approximately 150 people
12 attended this meeting chaired by Dr Savidge. The
13 purpose of the meeting was to look at the viral safety
14 of AHF concentrates.

15 "There was little discussion about HTLV-III
16 inactivation, and most people assumed that all
17 heat-treating was sufficient."

18 Then there's some reference to some
19 presentations about hepatitis. Dr Preston did
20 a presentation on liver cirrhosis in which he
21 concluded that hepatitis leads to progressive liver
22 disease, and it records Dr Preston taking issue with
23 the published work of Professor Mannucci and reference
24 to biopsies taken by Professor Preston, with:

25 "Seven out of ten patients [progressing] from

75

1 continue the arrangement, on the understanding that
2 BPL would 'transfer charge' their RHA. That is what
3 my 'Transfer' stamp means."

4 So there appears to have been some debate in
5 1991 about a stamp that had appeared on some
6 documentation.

7 Then Dr Smith continues:

8 "When supplies of 8Y became adequate about 1990,
9 I asked again whether they wished to revert to assured
10 direct supplies from BPL, and they preferred that the
11 existing system should not be disturbed until they let
12 me know positively. If there is any difficulty in
13 Birmingham, Dr Lane should be invited to assess the
14 value of Dr Hill's several very productive clinical
15 trials before any abrupt decision is taken.

16 "As you will appreciate, these understandings
17 have not been documented but I will do my best to
18 recall distant events if controversy threatens."

19 So there appears to have been some arrangement
20 as between BPL and, amongst others, Birmingham
21 Children's Hospital and Dr Hill for receipt of 8Y, and
22 usage of 8Y in certain clinical trials.

23 Just picking up then events after 1985
24 relatively briefly, if we go, please, to ARMO0000519,
25 please.

74

1 chronic persistent hepatitis to either chronic active
2 hepatitis or full cirrhosis."

3 So I think probably reasonable to infer that
4 that material was known to Dr Hill.

5 Over the top of the next page we can see
6 a presentation by Dr Kernoff, described as "another of
7 our MONOCLATE investigators", saying:

8 "... from the platform that liver disease is
9 a very serious problem resulting from AHF concentrates
10 and acute [non-A, non-B] hepatitis."

11 Then there are various figures given by
12 Dr Kernoff including the following:

13 "... estimated attack rates from pooled plasma
14 produced AHF to be as follows:

15 "US Commercial: 100 per cent attack rate.

16 "UK Volunteer: 33 per cent [attack rate]."

17 **SIR BRIAN LANGSTAFF:** Now this is Dr Kernoff?

18 **MS RICHARDS:** This is.

19 **SIR BRIAN LANGSTAFF:** In 1986.

20 **MS RICHARDS:** Yes.

21 **SIR BRIAN LANGSTAFF:** In March, quoting from the published
22 work of prospective virgin patient studies which he
23 had been conducting himself, I think. Professor Lee
24 understood that the result of the study was that there
25 was essentially little difference between NHS

76

1 concentrate and commercial concentrate in terms of
2 causing hepatitis for those patients who had not been
3 treated with any form of concentrate previously.

4 This, from Dr Kernoff, suggests that there
5 is a huge difference. Both will cause it but it's
6 three times as likely in the US commercial as it is in
7 the NHS.

8 **MS RICHARDS:** Yes.

9 **SIR BRIAN LANGSTAFF:** That's what it seems to say.

10 **MS RICHARDS:** That's what it seems to say.

11 **SIR BRIAN LANGSTAFF:** And it is said by one of the authors
12 of a paper which has been taken at any rate to say the
13 opposite.

14 **MS RICHARDS:** Yes.

15 **SIR BRIAN LANGSTAFF:** That's the paper which you --
16 Professor Lee referred to published in the British
17 Journal of Haematology in 1985.

18 **MS RICHARDS:** That's right, sir, and clearly a matter that
19 will warrant further enquiry by the Inquiry.

20 **SIR BRIAN LANGSTAFF:** The question is really how one
21 reconciles those two.

22 **MS RICHARDS:** Yes.

23 **SIR BRIAN LANGSTAFF:** Yes, it might involve, I suppose, in
24 due course, seeing what the actual raw data said.

25 **MS RICHARDS:** If we are able to obtain it, then yes.

77

1 take you to any documents in relation to this -- that
2 in the autumn of 1986 Professor Hill discovered that
3 some of his patients had seroconverted following their
4 use of the Armour heat-treated Factor VIII product and
5 that was reported to, again, a working party
6 extraordinary meeting on 13 October 1986.

7 There are a number of documents that make
8 reference to that, and indeed, sir, I think you have
9 heard from at least one patient who was in that
10 unfortunate position.

11 Moving on then --

12 **SIR BRIAN LANGSTAFF:** I think in the paper which you have
13 prepared there's a reference to some correspondence
14 between himself and the pharmaceutical company
15 concerned.

16 **MS RICHARDS:** Yes.

17 Are you referring to paragraph 97, sir? No,
18 that's a different document.

19 **SIR BRIAN LANGSTAFF:** No, that's not what I had in mind.
20 I had in mind that there was a question of to whom the
21 outbreak was first reported.

22 **MS RICHARDS:** Yes. I will see if I can find the
23 references. They are later in the paper.

24 I am conscious of time, sir, so I am moving
25 relatively quickly through the documentary material,

79

1 **SIR BRIAN LANGSTAFF:** Plainly there is a difference of --
2 if it is the same data -- and there's a reference in
3 this to prospective study which he'd been conducting,
4 so he is talking about unheat-treated Factor VIII
5 product, as it would seem -- you would expect the raw
6 data at least to be open to interpretation and it's
7 been interpreted in two different ways by the same
8 author.

9 **MS RICHARDS:** Yes.

10 **SIR BRIAN LANGSTAFF:** It's curious.

11 **MS RICHARDS:** It curious, sir, and a matter that we will
12 need to investigate further.

13 Just still with this document, if we go to the
14 last page, we just see a reference to some research by
15 Dr Hill. Paragraph numbered 2 under the heading
16 "Conclusions":

17 "C Bishop is pursuing a study with Dr Hill
18 (Birmingham), who believes that the protein load is
19 perhaps as important as viral transmission. I believe
20 that we should support this study with Monoclate."

21 So we don't, I think, at the moment know more
22 about that particular study but it's one of a number
23 of studies that Dr Hill appears to have been involved
24 with around this time.

25 Sir, we know also -- I don't need, I think, to

78

1 but we will find that and come back to it if we can.

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

3 **MS RICHARDS:** The issue I was proposing to move on to is
4 what information was or may have been provided by
5 Professor Hill to his patients or their parents.

6 Dr Hill's statement to the Inquiry, if we just
7 have it up on screen, WITN3087001, please. Go to the
8 next page, next page.

9 He says in paragraph 5 this:

10 "... when a child was first diagnosed with
11 haemophilia I, or sometimes a member of my team, had
12 a discussion with the parents about treatment with
13 blood products and the risk of potential infection
14 with certain viruses."

15 So that's his evidence about the discussion that
16 might take place when a child was first diagnosed with
17 haemophilia. The evidence that the Inquiry has
18 received from patients paints a different picture.
19 I am not going to go to any of the underlying
20 documents but we have sought to summarise some of the
21 evidence that you have heard so far on this issue.

22 So we had evidence from Andrew Evans of his
23 parents being called to a meeting at the Children's
24 Hospital not long after February 1983 -- that was when
25 a New Scientist article was published, you may recall,

80

1 dealing with AIDS -- at which Professor Hill told
2 Mr Evans' parents, in response to a direct question as
3 to the chances of Mr Evans being infected with AIDS,
4 that he had more chance of getting arthritis through
5 a lack of treatment than getting AIDS through having
6 treatment.

7 We heard evidence from Mr O, an anonymous
8 witness, that his parents were not consulted when
9 there was a change of treatment from cryoprecipitate
10 to factor concentrate and that they were given no
11 warnings of the risks of infection from some products.

12 You heard from Mr AI, whose understanding was
13 that his parents had not been told there was any risk
14 of factor concentrates and then, when he moved on to
15 heat-treated factor concentrates, was told that the
16 products were safe and free from viruses so he
17 couldn't become infected and, in fact, was.

18 You heard from Elizabeth Hooper about her late
19 husband Paul, treated at the Children's Hospital, who
20 wasn't, as far as she was aware, ever warned of the
21 risks involved in receiving Factor VIII.

22 You heard the evidence of Stuart Gregg, that his
23 mother was never told of the risk of infection from
24 a Factor VIII concentrates, and the evidence of Mr AN
25 that neither he nor his parents were informed of any

81

1 course, have been some new patients by then.

2 In terms of the arrangements that were made for
3 testing children at the Children's Hospital for HIV,
4 Professor Hill's statement, that we had on screen
5 a moment ago, suggests that when HTLV-III testing came
6 in he tested his patients from stored samples. We
7 don't know precisely when testing was undertaken but
8 if we go, please, to ARMO0000375, this is, again,
9 an internal pharmaceutical sales rep document
10 reporting a visit to Dr Hill on 29 April 1985:

11 "The objective of the visit was to discuss
12 Dr Hill's research on AIDS and haemophiliacs and his
13 recent hepatitis B problem."

14 You will see there there's a reference to nine
15 children having been shown to be positive for
16 hepatitis B.

17 Then if we go over the page we will see under
18 the heading "AIDS Research":

19 "Dr Hill's original project involving the
20 children exposed to tuberculosis has been written up
21 for publication. He will send me a transcript.

22 "Dr Hill continues to screen haemophiliac
23 children for HTLV-III antibodies. Just over
24 50 per cent are positive."

25 Then it is recorded that:

83

1 risks from factor products and were told it was
2 a wonder product.

3 There is documentary evidence of Professor Hill
4 providing written information to parents in January of
5 1987. There's a letter informing them that the
6 Factor VIII supply was changing.

7 There is no documentary evidence that we've
8 found from any earlier date providing any equivalent
9 information.

10 So that's in terms of risks of treatment.

11 You can take that down, thanks, Henry.

12 In terms of the rates of HIV infection at the
13 Birmingham Children's Hospital, a report from
14 April of 1986 identified 60 per cent of the patients
15 at the Children's Hospital being positive to HIV.

16 In a report in March of 1987, Professor Hill
17 reported five haemophiliac AIDS deaths in the region,
18 four patients with AIDS symptoms, 140 haemophiliac HIV
19 carriers in the West Midlands region.

20 At a further working party meeting in
21 November 1987 it was reported that the number of
22 HIV patients was continuing to rise.

23 A 1990 UKHCDO return records that there were
24 23 patients at the Children's Hospital with HIV in
25 1989 and 38 negative patients. There would, of

82

1 "Dr Hill suspects that all children who have had
2 a long exposure to concentrate may well be infected!"

3 Further down the page it is recorded that
4 Dr Hill is now testing parents and siblings of
5 haemophilia patients.

6 Then if we go to ARNO0000391, there's again
7 an internal Armour update and it said:

8 "The situation now known to me at the present is
9 Birmingham Children's Hospital 32 patients,
10 52 per cent of those tested HTLV-III antibody
11 positive."

12 There is identification of specific batches said
13 to be involved. A very significant proportion of the
14 children treated at the Birmingham Children's Hospital
15 were infected with HIV.

16 If we go to DHSC0039636. This is a letter from
17 Dr Hill to the regional virus lab, 17 February 1986.

18 If we go to the text of the letter there's reference
19 to a particular haemophiliac and to there having been
20 samples sent to the lab in July and October 1984 and
21 it said:

22 "... I wonder if it's possible for you to get
23 them out and test them for HTLV-III antibody ..."

24 So there seems to be subsequent testing of
25 stored samples. The extent to which that was known to

84

the patients or their parents is unclear.

Well, Sir, then in terms of what information we have about how patients were told of their diagnosis of HIV, Professor Hill's statement says that on receipt of the test results he called in the parents of the children and asked them if they wanted to know the results and if they did he would explain them and discuss whether the child should be told. Again, Sir, you have heard a range of evidence from individuals which conflicts in a number of respects with that account.

So again Andrew Evans' recollection, or his mother's recollection, was Professor Hill informed her at a routine appointment with no further information being given. Mr O's evidence was that neither he nor his parents were informed that he was being tested for HTLV-III. His records show he was tested on a number of occasions. They suggest a delay, or his records and his evidence suggested a delay, between the date of his test and his parents being informed.

There was evidence from Mr Al that his mother was told he was HIV positive over the phone and then, Sir, you will recall, no doubt, the evidence we heard from Martin Beard and the correspondence we looked at -- I won't go into it again -- at least one

85

Inquiry has both from Children's Hospital patients and other centres which the Inquiry has read and analysed, and which will be disclosed in due course, but which I can't yet refer to by name for the purpose of the presentation.

One of the themes of the documents relating to the position in Birmingham, both at the Children's Hospital and the Queen Elizabeth Hospital in the latter part of the 1980s, are difficulties in terms of obtaining funding to ensure appropriate treatment and facilities for patients who were infected with HIV, but that is an issue I can explore with Professor Franklin in his evidence because that's information that he was privy to and part of attempts to obtain further funding.

On the issue of hepatitis C testing, there are, I think, just two documents that it would be worth looking at. These are general observations by Professor Hill after the event. DHSC0004003_038, please. This is Professor Hill, I think, having a conversation in his capacity as UKHCDO Chair with Mr Charles Lister at the Department of Health. So it doesn't necessarily follow that he's talking about his own practice within the Children's Hospital but it says this:

87

inference that you could draw from it is that there was a deliberate decision not to inform Martin of his infection.

SIR BRIAN LANGSTAFF: That is what the letter appears to say --

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: -- or at least to record the writer having been told by Professor Hill.

MS RICHARDS: Yes. Another witness, Mr Gregg, said that neither he nor his mother were ever told in terms of his diagnosis, it just became apparent over the years and another witness has told the Inquiry in her written statement that she found out her son was HIV positive by reading it in his medical records and when she raised that with her son she was informed that Professor Hill had already told him, at the age of about 12, of his diagnosis without his parents being present and she hadn't known.

So that's some of the information that the Inquiry's received. I should say that when I refer in the presentations to statements received or oral evidence received from the Inquiry, we are referring to only part of the evidence received by the Inquiry to those statements which have so far been disclosed. There are, of course, other statements that the

86

"I've been talking to Professor Frank Hill about allegations that the patients were tested for Hep C without their knowledge and that some found positive were not told until years later. He thinks that this is quite likely to be true."

Then there's a discussion of various possible explanations for that: some patients included without their knowledge in blind trials, there might have been a concern about telling people the bad news, especially if they already had HIV, concern that no-one knew exactly what a positive antibody test actually meant, some may have been children so that their parents were told but not them.

There's one further letter in which this is alluded to, HCDO0000254_644. This is a letter from Professor Hill, October 2004, to The Haemophilia Society, so again it's a number of years later. Bottom of the page, he says:

"It's difficult to comment further other than to say some clinicians may have considered they were acting in the best interest of their patients. When HCV antibody tests were introduced there were difficulties in interpretation. The test indicated past infection but until there was a PCR test, ongoing infection could not be excluded and then there was the

88

1 issue of treatment and how it would be funded. Many
2 of the patients with HCV were already coping with
3 advancing HIV and some clinicians may have been
4 concerned with presenting them with further
5 uncertainty."

6 Top of the next page:

7 "Since early 1990, medicine and its practice has
8 evolved from what could be described as
9 a paternalistic approach to a doctor patient
10 partnership."

11 So those are his reflections or contributions
12 after the event. We don't have any evidence from
13 Professor Hill directly in relation to what his
14 practice was in terms of either screening patients for
15 hepatitis C once the test was available or his
16 practice in terms of informing them but, there again,
17 you have a range of evidence from Professor Hill's
18 patients and we summarised some of the evidence
19 received so far in the note. So, again, Mr Evans, for
20 example, neither he nor his parents were informed by
21 Professor Hill that he had been infected with
22 hepatitis C. This only became apparent later, he
23 said, in a clinic appointment with Dr Wilde. Evidence
24 of Mr O that he wasn't told until 1995, again once he
25 transferred to the Queen Elizabeth Hospital, that he

89

1 disclose the details of his case to the Haemophilia
2 Centre Directors' meeting until (sic) it was
3 absolutely essential" --

4 **SIR BRIAN LANGSTAFF:** "Unless it was absolutely".

5 **MS RICHARDS:** Sorry:

6 "... unless it was absolutely essential to do
7 so. He had only discussed it with Dr Rizza and the
8 area supplies clinician apart from ourselves and the
9 DHSS. If this was the case then it might be possible
10 to hold the information from breaking into the public
11 domain for a little longer, although Dr Hill would
12 have to inform the parents of the children who had
13 seroconverted ..."

14 So it would appear from this, at this stage,
15 that the pharmaceutical company, the Department of
16 Health, Dr Rizza and the Area Supplies Commission had
17 been told this information by Dr Hill but not yet the
18 parents of the children who had seroconverted and it
19 wasn't information Dr Hill was planning to disclose to
20 his fellow directors at the next meeting.

21 **SIR BRIAN LANGSTAFF:** It was a document associated with
22 that but it was earlier in time, I think. It was
23 a report from the -- I think correspondence of some
24 sort between Armour, or considering it in Armour, the
25 response which they had had from the then Dr Hill

91

1 had hepatitis C. The evidence of Mr Gregg's mother
2 was that she was told that her son had non-A, non-B
3 hepatitis, but it was so poorly explained she thought
4 it meant he didn't have hepatitis A or hepatitis B and
5 so was free from viral hepatitis.

6 Sir, I am conscious of the time and there are
7 just two further documents I wanted to refer to. The
8 first may be the document you were referring to
9 earlier, Sir, ARMO0000510. This is the minutes of
10 a meeting between representatives of Rorer Health Care
11 and the Department of Health, and you will see from
12 the first paragraph it's a discussion about
13 seroconversion in response to Armour's heat-treated
14 Factor VIII, and reference to a case reported by
15 Dr Hill of the Birmingham Children's Hospital. If we
16 go to the next page, we'll see, second paragraph --
17 zoom in on the second paragraph, please -- Mr Jeffreys
18 is said to have asked how Rorer were proposing to
19 handle the current situation:

20 "It was inevitable that news of this additional
21 seroconversion and its circumstances would be in the
22 public domain fairly shortly, possibly by the end of
23 the next week, as there was a meeting of all
24 Haemophilia Centre directors in Edinburgh. Mr
25 Christie mentioned that Dr Hill did not intend to

90

1 about the seroconversion of people on heat-treated
2 Armour concentrate.

3 **MS RICHARDS:** Sir, there are a number of documents
4 associated with that issue, so we can find it at
5 a later stage if need be. There is just one further
6 document I wanted to refer to before we end the
7 presentation.

8 That is at -- I think it is ARMO0000370. Yes.
9 We have set out in our notes some documentary evidence
10 of interactions between pharmaceutical companies and
11 Professor Hill. This is one of the more striking
12 examples. It's from Armour dated March 27, 1985, to
13 Dr Hill:

14 "Dear Frank, you will note from the enclosed
15 copy letter that I have paid our first 1985 donation
16 to your research fund to the Finance Department of the
17 Central Birmingham Health Authority. We continue to
18 be very interested in the progress of this project,
19 and of course its extension into HTLV-III screening of
20 children who have been treated with non-treated and
21 latterly heat-treated Factor VIII."

22 It would appear that, as at 1985, Professor Hill
23 had a research fund to which Armour (who had, for many
24 years, been the sole commercial supplier to the
25 region) was making donations. At present, we don't

92

1 have any more information about this particular issue
 2 than as set out in that document.
 3 **SIR BRIAN LANGSTAFF:** The document which I had in mind was
 4 ARMO0000585.
 5 **MS RICHARDS:** Yes, if we zoom in on that, please. Ah yes.
 6 September 1986, again an internal memo:
 7 "Dr Hill rang me this morning to report two
 8 haemophilic children who had seroconverted to HIV
 9 antibody positive following a long course of Armour
 10 heat-treated Factorate."
 11 Then reference to the incident needing to be
 12 reported to the DHSS and he also believed that
 13 a publication describing his experience should be
 14 prepared.
 15 **SIR BRIAN LANGSTAFF:** So the course of events, according
 16 to this, if it's right, is that Dr Hill discovers that
 17 there are two children in his care who have now tested
 18 positive for HTLV-III. The first person he tells of
 19 this is the maker of the product before he tells the
 20 DHSS. He then has in mind telling who?
 21 **MS RICHARDS:** Well, the evidence suggests that it was
 22 reported to the DHSS, that earlier document we looked
 23 at; that it was reported to Dr Rizza, presumably in
 24 his capacity as someone effectively maintaining the
 25 database at Oxford at that stage; it was reported to

93

1 being any particular reference. The discussion in
 2 this meeting, perhaps understandably, is more general.
 3 **SIR BRIAN LANGSTAFF:** Thank you.
 4 **MS RICHARDS:** Obviously, there is more in the presentation
 5 I haven't covered, in particular in relation to the
 6 issue of vCJD but that's detailed in some considerable
 7 detail in our written presentation, which has already
 8 been provided to recognised legal representatives of
 9 Core Participants, and will be published on the
 10 Inquiry's website in due course, so I don't propose to
 11 say any more today about the Birmingham presentation.
 12 But we'll obviously continue our consideration of
 13 Birmingham with Professor Franklin this afternoon.
 14 **SIR BRIAN LANGSTAFF:** Yes. Well, we will do that at 2.00,
 15 shall we?
 16 (1.07 pm)
 17 (Luncheon Adjournment)
 18 (2.00 pm)
 19 **SIR BRIAN LANGSTAFF:** Professor Franklin, you don't need
 20 to wear a mask when you are giving evidence. It might
 21 help in fact if you don't. May you be sworn.
 22 **PROFESSOR IAN MAXWELL FRANKLIN (affirmed)**
 23 **Questioned by MS RICHARDS**
 24 **MS RICHARDS:** Professor Franklin, I'm going to ask you
 25 first for an overview of your career. You undertook,

95

1 the Area Regional Supplies Officer, that's presumably
 2 the West Midlands Area Regional Supplies Officer,
 3 responsible for the contracting, and then an
 4 inference, at least from the documents, that only then
 5 is it reported to the parents.
 6 **SIR BRIAN LANGSTAFF:** Is there any reason anywhere in the
 7 documentation why he should tell the producer of the
 8 product before he tells the DHSS?
 9 **MS RICHARDS:** No, I don't think so, sir.
 10 **SIR BRIAN LANGSTAFF:** Thank you.
 11 **MS RICHARDS:** There was then, as I think I mentioned,
 12 discussion of this at an extraordinary meeting of the
 13 working party on 13 October 1986 at SHIN0000019.
 14 If we go down the page, we'll see Dr Hill
 15 outlined the events culminating in the calling of the
 16 emergency meeting of the working party and reference
 17 to seroconversion. It's said:
 18 "He passed his findings to Armour
 19 Pharmaceuticals whose representatives met with members
 20 of the DHSS and jointly decided to withdraw all
 21 Armour Factor XIII."
 22 I'm not sure whether there's any reference in
 23 here to telling parents. If we can just look at the
 24 rest of the document, Henry -- if we keep on going.
 25 No. I'll double-check, sir, but I don't recall there

94

1 I think, various house officer and senior house
 2 officer roles in Leeds between 1974 and 1976?
 3 **A.** Yes, I did.
 4 **Q.** And then between I think 1977 and 1980 you were
 5 a research training fellow for the Medical Research
 6 Council?
 7 **A.** Yes.
 8 **Q.** Your work then, I think, was predominantly related to
 9 sickle cell anaemia?
 10 **A.** Yes, the research was, yes.
 11 **Q.** Did you undertake any clinical work during that
 12 period?
 13 **A.** I did nothing for the first year and then I used to
 14 attend a sickle cell anaemia clinic at The London
 15 School of Hygiene and at University College about
 16 a couple of times a month, and that carried on for
 17 those -- the last two years, and in the final year
 18 I used to go and help a general haematology clinic at
 19 the now defunct Royal Northern Hospital.
 20 **Q.** Then from 1980 to 1982, you were a senior registrar in
 21 haematology at University College Hospital?
 22 **A.** Yes, based there, yes.
 23 **Q.** That was your specialist haematology training to
 24 achieve membership of the Royal College of
 25 Pathologists?

96

1 A. Yes.

2 Q. Your statement and your CV tells us that between

3 October 1980 and February 1981, you worked for

4 approximately three months at Great Ormond Street

5 Hospital under Professor Hardisty?

6 A. That's right, yes.

7 Q. So you would, in the course of that period, have seen

8 children with bleeding disorders. You said you didn't

9 have a decision-making role in terms of what treatment

10 to provide to them?

11 A. No, I didn't. It was observational, I would say.

12 Q. Can you recall anything about what the treatment

13 policies were at Great Ormond Street at that stage?

14 A. I can't really. I remember they had Lister

15 Factor VIII. I think that was the first time I had

16 heard of Lister Factor VIII. I don't remember whether

17 they had commercial product and I don't remember

18 seeing cryoprecipitate used either.

19 Q. Then from March to September 1981 you were training in

20 blood transfusion medicine under Dr Barbara at the

21 North London Regional Transfusion Centre in Edgware?

22 A. Well, I didn't work with him. He taught me about

23 transfusion virology but also Dr Marcela, now Dame --

24 Professor Dame Marcela Contreras was the haematologist

25 who was actually leading my training.

97

1 out the programme there. He had been doing that for

2 a year or so. I was involved to a very small degree

3 while I was still a research fellow but then, yes,

4 I was quite involved with the early transplant

5 patients that were starting off what is now a very big

6 unit.

7 Q. You have said there was no involvement with the care

8 of those with bleeding disorders, save for the odd

9 patient?

10 A. Well, yes. I mean, I remember seeing the occasional

11 person with haemophilia on the wards but, really, it

12 was a haemophilia centre but couldn't have had many

13 patients, I think.

14 Q. Did you have any involvement in decisions as to how to

15 treat those occasional patients?

16 A. Don't remember having any such role, no.

17 Q. Do you have any recollection of what treatment was

18 routinely provided?

19 A. No, I'm afraid not, no.

20 Q. Then on completion of that specialist training you

21 gained membership of the Royal College of

22 Pathologists?

23 A. Yes.

24 Q. Then in September 1982, you took up your post as

25 a consultant at the Queen Elizabeth Hospital in

99

1 Q. You said in your statement that the focus in terms of

2 what you recall learning there was on hepatitis B. It

3 would seem likely that there must have been some

4 discussion of non-A, non-B hepatitis and its risks at

5 that time. Can you --

6 A. I think there was some. I mean, I have to say outside

7 the world of haemophilia, I would say even in general

8 haematology, there was probably a lack of appreciation

9 of the level to which blood transfusion red cells and

10 so on could transmit non-A, non-B hepatitis. I mean,

11 I think there was -- I'd heard of it. I think there

12 was -- generally there was a feeling that it was

13 something that largely happened in the United States

14 because of paid donors and that the volunteer donor

15 base in the UK was much safer.

16 So from that point of view there wasn't a lot of

17 exposure to knowledge of it.

18 Q. Then you moved to St Albans City Hospital, where you

19 spent, I think, around three months doing general

20 haematology work?

21 A. Yes, yes.

22 Q. Then January to August 1982 you were at UCH. You've

23 said in your statement you were mainly concerned with

24 the development of a bone marrow transplant programme?

25 A. Well, my boss, Professor Tony Goldstone, was setting

98

1 Birmingham?

2 A. Yes.

3 Q. You were around 33 years old at the time?

4 A. Just about, yes.

5 Q. Your statement suggests that your appointment was

6 principally to develop a bone marrow programme because

7 of your sickle cell experience; is that correct?

8 A. Yes. I mean, they had quite a large sickle cell

9 population, which I think made me attractive but they

10 particularly wanted to start doing -- we call them now

11 stem cell transplants, bone marrow transplants, yes.

12 Q. So in terms of haemophilia care, Professor Stuart was

13 still the director of the haemophilia centre at that

14 point?

15 A. He was.

16 Q. For that first 12 months, your statement describes you

17 only dealing with the care of patients with bleeding

18 disorders when you were on call?

19 A. Yes, so if we had haemophilia patients in the ward,

20 you would see them on the ward, the ward round, during

21 the day and then if there were any issues deal with

22 them at weekends or at night and, as you are fully

23 aware, the haemophilia care was a 24-hour service.

24 Men could come up for treatment to be seen on the

25 ward -- the treatment room was next to the ward --

100

1 pretty much any time of the day or night. So I'd get
 2 involved, to some extent, in those episodes.
 3 **Q.** I will ask you a little more about that in a few
 4 minutes.
 5 You then took over as the director of the
 6 haemophilia centre after approximately a year, so
 7 September 1983 or thereabouts?
 8 **A.** Yes.
 9 **Q.** Did Professor Stuart continue as a consultant or did
 10 he retire completely?
 11 **A.** No, he -- obviously, he was a professor. He had
 12 a research interest and he continued to provide
 13 out-of-hours cover on a one-in-three rota and at
 14 weekends, but he largely retained responsibility for
 15 the laboratory and the clinical -- the hospital
 16 laboratory and his research.
 17 **Q.** So is it fair to say that at the point at which you
 18 became a director of the Haemophilia Centre at the
 19 Queen Elizabeth Hospital your direct experience
 20 relating to the treatment of patients with bleeding
 21 disorders had been largely limited to those three
 22 months at Great Ormond Street and then the first
 23 12 months at QEH, working with --
 24 **A.** Yes, I was quite inexperienced really.
 25 **Q.** You remained consultant haematologist and director of

101

1 **Q.** I'm not going to be asking you about your work in
 2 Scotland, although that may be something that the
 3 Inquiry will need to ask you about at a later stage of
 4 its hearings.
 5 In terms of working parties or organisations you
 6 belonged to, you were, once you became director of the
 7 Queen Elizabeth Hospital Centre, a member of UKHCDO?
 8 **A.** Yes. I think that sort of went with the territory.
 9 **Q.** I think we've only got a record of you attending two
 10 meetings, one in 1983 and one in 1984. Does that
 11 sound about right?
 12 **A.** Yes, I don't remember -- well, it was a long time ago.
 13 I didn't actually remember many of the West Midlands
 14 working parties either, other than the early ones but
 15 I don't think I did go to them after that.
 16 **Q.** As you just alluded to, you were a member of the
 17 Working Party On the Treatment of Haemophiliacs for
 18 the West Midlands Regional Health Authority, and we'll
 19 look at some of the minutes of that in the course of
 20 your evidence.
 21 You gave evidence to the Archer Inquiry?
 22 **A.** I did.
 23 **Q.** You, I think, had some involvement in some litigation
 24 against the West Midlands Health Authority. You had
 25 to provide some schedules, I think you said, in

103

1 the Haemophilia Centre at the Queen Elizabeth Hospital
 2 until the end of July 1992 --
 3 **A.** Yes.
 4 **Q.** -- and then moved to Glasgow --
 5 **A.** Yes.
 6 **Q.** -- to take up a role as a consultant focusing on bone
 7 marrow transplantation?
 8 **A.** Yes.
 9 **Q.** You then worked for a number of years thereafter in
 10 the Blood Transfusion Service, initially locally and
 11 then as SNBTS's National Medical and Scientific
 12 Director?
 13 **A.** Yes, I started as National Medical and Scientific
 14 Director in early 1997.
 15 **Q.** I think you remained a professor of transfusion
 16 medicine throughout that period as well.
 17 **A.** Yes, and I continued to work on the transplant units
 18 as well.
 19 **Q.** Then 2011 to 2014, you had a similar role at the Irish
 20 Blood Transfusion Service?
 21 **A.** Yes, that was just solely the medical and scientific
 22 director, with no other hospital role.
 23 **Q.** As I think you know, the questions I ask you today are
 24 going to be focused upon your work at Birmingham.
 25 **A.** Yes.

102

1 relation to patients. Without, obviously, discussing
 2 any individual case, can you recall the nature of your
 3 involvement?
 4 **A.** There were four legal cases, I remember. Two of them
 5 related to areas of relevance to this Inquiry but none
 6 of those -- I don't think any of the cases got to
 7 court. I think those two were both -- well, they
 8 didn't proceed.
 9 The other two related to issues with care of
 10 haemophiliac -- people with haemophilia and I believe,
 11 but I'm not sure, that they were settled out of court.
 12 **Q.** Can I ask you just to give us an overview of what the
 13 facilities were at the Haemophilia Centre at QEH when
 14 you took up your post as director in 1983?
 15 **A.** Well, first of all, I had a co-director,
 16 Dr Frank Hill, who came to the hospital once a week to
 17 do the clinic, as I remember, in the morning, and then
 18 we would meet through the afternoon to discuss
 19 problems with particular patients and strategy,
 20 I suppose. We had a single room which was like
 21 a large office, which was a treatment room with
 22 a treatment couch, where patients could have their
 23 treatment administered, whether that was Factor VIII,
 24 those not on home treatment.
 25 I remember us giving FEIBA in there as well. It

104

1 was just one room. We had patient records in there.
2 Definitely patient records of home treatment, so that
3 would be sheets that the patients themselves had
4 filled in.

5 I don't remember whether we had all of the
6 patient records in there. I don't believe we could
7 have done. I think they must have been stored
8 somewhere else, in medical records, but we certainly
9 had quite a lot of filing cabinets with records.

10 We stored working stock of Factor VIII
11 concentrate. It was quite a busy room. I think cryo
12 was stored down in the blood bank, not in that room.

13 We only had facilities in there to treat one
14 patient at a time -- for reasons of confidentiality.
15 So that was a bit limiting. We had one nurse, of
16 sister grade, who was full time for haemophilia care,
17 and she would see patients who attended whether for
18 home therapy advice or supplies or people not on home
19 therapy with a bleed. She may be able to manage a lot
20 of those, otherwise she would then refer to doctors,
21 which would depend on who was around really on the
22 main team.

23 Medical support, in addition to myself and
24 Dr Hill were provided by a senior registrar, one
25 registrar and a couple of senior house officers, about

105

1 Children's -- Birmingham Children's Hospital,
2 General Hospital. So they all had junior doctors who
3 would then rotate, move round, to ensure that their
4 training was -- covered all the specialties.

5 Q. So Professor Hill would come and do clinics jointly
6 with you at the Queen Elizabeth. Did you have any
7 involvement in clinics at the Children's Hospital?

8 A. No, never.

9 Q. Can you recall when you started at Queen Elizabeth
10 Hospital? So first appointed as a consultant but
11 before you took over as director a year later, was
12 there any particular guidance or training that you
13 recall being given by Professor Stuart?

14 A. You know, I don't remember, to be honest.

15 Q. How did the relationship with Professor Hill, and the
16 fact that you were co-directors, how did that work in
17 practice?

18 A. I think it worked pretty well. I mean, I had a bit
19 more time to spend than him, but he was a trained and
20 experienced haemophilia -- well, I would say,
21 haemophilia expert. He'd trained at Great Ormond
22 Street, he'd trained in Oxford, and the systems,
23 although barely sufficient for the management of the
24 bleeds in the men with haemophilia, I thought it was
25 actually quite well organised in terms of managing the

107

1 four junior level doctors.

2 We had quite a good coagulation laboratory,
3 which was down in the hospital laboratory, but that
4 was about it really. There was no -- well, I suppose
5 we had a room -- two rooms and an out-patient clinic,
6 but that was part of the general out-patient
7 facilities. So really, in terms of special
8 facilities, there was really just this one room and
9 one person, one nurse.

10 Q. In terms of doctors -- we'll come back to your role
11 and Professor Hill's -- you've mentioned in your
12 statement already, and your evidence relating to
13 Professor Stuart, but there was a Dr Brian Borton ...?

14 A. Boughton.

15 Q. Boughton. Did he --

16 A. I do know he was a senior lecturer. He really only
17 was doing the same as I was doing in the first year,
18 which was one in three nights and one in three
19 weekends covering.

20 Q. Were there registrars, senior registrars, who
21 participated in the work of the clinic over the years
22 that followed?

23 A. Yes, yes, depending on -- they, a bit like me in my
24 training, would rotate through the department. There
25 were other hospitals in the area, Coventry, the

106

1 treatment.

2 Q. You said in your statement that you were, to some
3 extent, guided by Professor Hill because he was more
4 experienced. You also told the Archer Inquiry that
5 because you were -- I'm not directly quoting from you,
6 but you were relatively inexperienced --

7 A. Yes, I accept that.

8 Q. -- you needed guidance from more haemophilia experts
9 and tried to follow a consensus opinion. Is that
10 correct?

11 A. Yes.

12 Q. Let's have a look in terms of a rough idea of numbers
13 of patients, Professor Franklin.

14 Could we have UBFT0000252, please, Henry.

15 This is a report prepared jointly by you and
16 Professor Hill in April 1986. It was a request for
17 further resources, and we'll come on to that at
18 a later stage of your evidence, about funding problems
19 for the care of those with HIV.

20 But if we just look at the second paragraph on
21 this page, please, Henry, we can see it said:

22 "The haemophiliac population within the
23 West Midlands represents 11 per cent of all the
24 haemophiliacs in the [UK]. The majority
25 (about 75 per cent) are registered with the

108

1 Queen Elizabeth Hospital or Birmingham Children's
2 Hospital ... At the Queen Elizabeth there are
3 423 patients registered as having a bleeding disorder
4 ... of these approximately 90 attend regularly for
5 therapy or use Factor VIII concentrate at home."

6 So that's an accurate snapshot, is it, of the
7 numbers?

8 A. I think so, yes.

9 Q. I don't think we need to go to it but in a report the
10 following year you described Queen Elizabeth Hospital
11 as effectively the fifth largest haemophilia centre in
12 England and the largest not to receive any bespoke
13 funding as a reference centre?

14 A. Yes. I don't particularly remember that. In fact,
15 I only really realised how large we were until I was
16 preparing for this inquiry. But yes, it was clearly
17 quite a big centre.

18 Q. I think it's right that during the time you were
19 director, the QEH didn't have the status of
20 a reference centre?

21 A. No, I think they changed -- they seemed to be quite
22 obsessed with the rules around what a reference centre
23 was, the UK Haemophilia Centre Doctors' Organisation.
24 I think the Children's Hospital became a comprehensive
25 care centre.

109

1 Then we can see the products being used:
2 cryoprecipitate, 97,090 units, and that's just for
3 hospital treatment.

4 So no cryoprecipitate for home therapy by that
5 time. Does that accord with your recollection?

6 A. Yes, I don't remember any patients still -- if they
7 ever were, still being on cryoprecipitate at home.

8 Q. Then NHS factor concentrate we can see being used both
9 in hospital and for home treatment?

10 A. Yes.

11 Q. 338,000-odd in hospital, 569,000-odd for home
12 treatment. But then the predominant product is the
13 Armour Factor VIII, so the commercial product,
14 a smaller amount used in hospital but 1.2 million used
15 for home treatment?

16 A. Yes.

17 Q. We will look at some of the contracting arrangements
18 in a little while.

19 So that's haemophilia A patients.
20 Von Willebrand's we can see treated solely with
21 cryoprecipitate.

22 And then if we go to the document I had been
23 looking at -- sorry, Henry, HCDO0000206_004 -- we can
24 see there nine patients with haemophilia B, no
25 carriers, and the sole product used both in hospital

111

1 Q. Yes, in 1989.

2 A. Yes. So I think they changed the nomenclature, but
3 no, I think the adult centre remained the same status.

4 Q. Can we look at the annual return for 1983. Again,
5 just to get an idea of what treatments were being used
6 at that stage.

7 Henry, it is HCDO0000206_002.

8 So this is for the treatment of patients with
9 haemophilia B, and we can see it's a 1983 return.
10 Director: yourself and Dr Hill. Nine patients with
11 haemophilia B and the sole treatment there, NHS
12 Factor IX concentrate, and we can see both hospital
13 and home treatment.

14 A. I think I have a different one --

15 MS RICHARDS: I'm so sorry --

16 SIR BRIAN LANGSTAFF: We're looking at the wrong page.
17 We're looking at page 1 --

18 MS RICHARDS: I am looking at the wrong paper document.
19 I am so sorry.

20 Yes, sorry, this is the 1983 return for
21 haemophilia A patients, carriers and von Willebrand's
22 disease. So we can see 83 patients treated during the
23 year with haemophilia A, three carriers of
24 haemophilia A treated during the year, and 13 with
25 von Willebrand's disease treated during the year.

110

1 and for home treatment is the NHS Factor IX
2 concentrate?

3 A. Yes, I think we always -- as far as I remember, we
4 always had enough NHS Factor IX.

5 Q. You've said in your statement that the home treatment
6 programme was established before you took up your
7 post.

8 A. Yes.

9 Q. You didn't remember actually starting anyone on home
10 treatment yourself; is that correct?

11 A. No, I don't remember doing that, no.

12 Q. Was there any programme of prophylactic treatment at
13 the time?

14 A. No, I don't -- well, I don't remember that, and
15 certainly I don't think there was in the adults.
16 Prophylaxis was still -- was talked about and
17 considered to be beyond our ability to afford it,
18 I think, probably.

19 Q. One of the treatment policies in operation when you
20 joined was a policy of trying to keep patients on the
21 same product. Can you explain how that worked.

22 A. Yes. Well, as taught to me, and I think it does make
23 sense, the idea was that once you were exposed to one
24 batch of product, it would be best if you continued to
25 use that and not be given either different batches of

112

the same product or lots of different product.

And the idea there, I think, is to -- well, is to try to restrict the number of donors to which a particular person is exposed. You are still going to be exposed to a lot of donors but if you had -- say you had three treatments from the same batch of a US product, that might be a 20,000 donor exposure, which sounds a huge number, but if you have one treatment from one company, one from another and one from another company, that could be 60,000 donors. So the chances of becoming infected with something would have been much greater.

I think it did make a bit of a difference in terms of HIV but I don't think it made much difference for hepatitis.

Q. First of all, it was a policy you inherited?

A. Oh, yes. It wasn't my idea, no.

Q. The rationale was to reduce the risk of infection?

A. Reduce donor exposures and therefore, hopefully, reduce the risk of infection.

Q. How did that work in practice? How was a particular batch secured for a particular patient?

A. I can't actually remember exactly how. I mean, I think once a person was on a particular batch, that would be on their record in the treatment room. So if

113

commercial material. This was the sort of thing that had been happening at that time."

Then you refer to there having been a meeting of Haemophilia Centre Directors in which it was considered advisable that patients remain on the Factor VIII product they had been regularly using. So that's the approach you were just describing, Professor Franklin?

A. Yes.

Q. "Therefore it did not appear unreasonable at that time to propose that patients who had been using Armour for several years should continue to do so. There was never at any time sufficient NHS Factor VIII available to treat all patients and the decision of Dr Hill and myself was that patients should receive a regular supply of a one or other product and not a mixture of both."

So pausing there, the aim was if someone was receiving Armour they'd carry on receiving Armour. If someone was receiving NHS concentrate they would carry on receiving NHS concentrate, as much as you could?

A. Not only that they would stay on that same batch until that batch was exhausted, yes.

Q. You referred there to limited supplies of NHS material, and then times of glut, and having to

115

they were not on home treatment and were coming up for *ad hoc* treatment, the same batch would be given if available. And if they were on home treatment and coming up to replenish their home stock, they would be given the same batch if at all possible.

Q. We'll just look at a couple of documents about this. So could we have UBFT0000156, please.

This is a later letter, written in the context of HIV haemophilia litigation, but it's referring to an earlier letter from March 1984, and we don't have the earlier letter, Professor Franklin, which is why we are having to look at this as our best evidence of it. You refer to a letter you had sent to Dr Ala, the regional director of the transfusion centre, in March 1984, outlining reasons for seeking continuity in Factor VIII supply.

Then you talk about:

"... supplies of material NHS material had been very limited and both myself and my colleague ..."

Presumably that would have been Dr Hill?

A. Yes.

Q. "... were of the opinion that it was better to make a gradual change to NHS products that could be sustained rather than a sudden switch in times of glut and then a sudden transfer back of all patients to

114

transfer patients between different products. What, if anything, can you recall about that?

A. Well, I don't think we ever had a glut, actually, but we did -- there was -- there were times when the supply of NHS product increased, and so we -- I think there is some correspondence that you have between myself and the director of BPL, which made the NHS product. In light of that, I think we did transfer some people from commercial onto NHS, in the hope that that would be sustained. In the end, it turned out not to be sustained and, I presume, though I don't have any records, I presume we had to move them back. I wasn't very happy about that at the time.

Q. We might sense that from the tone of your letter to Dr Lane, Professor Franklin. If we have a look at it, BPLL0000853_002, please, Henry. So this is your letter, 24 May 1984, so a couple of months after the letter that we don't have but we have seen described in your letter to Dr Ala, and you are saying here:

"As co-director of the Haemophilia Centre at this hospital, I have been most disturbed at the sudden fall in supplies of NHS material for our patients. It is only a month or so ago that I was requested to change some patients to NHS from commercial material because of a glut of the former at

116

the Regional Transfusion Centre."

So it appears there had been at least temporary glut of NHS material?

A. Yes.

Q. "It appears that we will now be in the position of having to treat patients with commercial material who may never have been exposed to this in the past. This situation is particularly regrettable given the current interest amongst haemophiliacs in the acquired immune deficiency syndrome."

Obviously, we will come on to that later, Professor Franklin. You go on to say:

"Our efforts to reassure patients have included maintaining them on a single product so as to limit the pool of donors to which they are exposed as much as possible. Not only will this sudden and unexpected shortfall in NHS material mean that we will have to change this policy but it will also make epidemiological studies of hepatitis and AIDS meaningless."

What did you mean by the reference to epidemiological studies? Was that something you were involved with?

A. Not particularly as a study. I imagine that was just -- as we'll come on, you know, we knew -- we came

117

If we skip down to the fourth paragraph of the letter he says, in relation to the sudden and unexpected shortfall:

"Regional Transfusion Centres have monthly issue reports and six-monthly updates at the time of Pro-rata. Your RTC must have been aware of their Pro-rata issue of Factor VIII as far as back as December 1983 and known that this period would be affected by the yield and plasma supply ..."

I mean, whatever the precise cause of the fluctuation, was that a situation that persisted, as far as you can recall, in those first two or three years that you were there? Was this a perennial problem?

A. To be quite honest, until I saw these I had rather forgotten. I did know that I had some correspondence with Dr Lane. This change in treatment obviously came at a really critical period, sort of '84, and I think that was why I was concerned about it. I'm not sure. I think, thereafter -- after this, most of the major changes came about when the issue around requiring heat treatment came in and that sort of disrupted a lot of the regular supply issues. So I think after that, there was hardly any such thing as routine supplies for a couple of years.

119

to know how many people had -- were HTLV-III positive and I suppose it would have been perhaps helpful to know whether any of those had been from people who'd only ever had NHS material.

Q. Then if we just --

A. It wasn't a trial or formal --

Q. Not as far as your involvement's concerned?

A. No.

Q. Then if we look at the next paragraph:

"Could you perhaps let me know of the likely future supplies of NHS material so that I may plan the treatment strategy for my patients."

You go on to say that you find:

"... the sudden swings in supplies with no due notice to clinicians involved in the treatment of patients to be unacceptable."

I think it's fair to say that Dr Lane's response, which we have at BPLL0000853_001, suggests that this is an issue that you would need to take up with the Regional Transfusion Centre rather than BPL?

A. Yes, it was a fairly robust rebuttal, I suppose.

Q. We see that in his second paragraph:

"... Regional Transfusion Centres, and not the Blood Products Laboratory, determine the issuing policy within individual regions."

118

Q. Okay. It would seem that you received your supply of NHS Factor concentrate from the Regional Transfusion Centre?

A. Yes, I think we got all the supplies from there but I'm sure -- well, you were speaking this morning about the contracts, and so on but -- I think it was all stored over there, yes.

Q. So the cryoprecipitate was from the Regional Transfusion Centre?

A. Yes, that would have been made locally.

Q. The NHS Factor concentrate was made by BPL at Elstree but supplied to the Regional Transfusion Centre and then to you?

A. Yes.

Q. Then the commercial products, we'll look at the contracting arrangements in a few minutes, but your recollection is they were delivered to the RTC and then hospitals would call them off --

A. I think we called them off as we needed but it's a long time ago. I'm not 100 per cent sure.

Q. If it assists you, Professor Franklin, the documentation suggests that for Queen Elizabeth, although not the children's hospital, that that was probably the case.

A. Yes.

120

- 1 Q. Just generally, in terms of the treatment policies,
2 what use was there in this period 1982, 1983, 1984, of
3 cryoprecipitate?
- 4 A. Well, there was use. I remember doing it. I think
5 your previous chart suggested that we were using it
6 for von Willebrand's disease. I would have thought we
7 were using it for mild cases. It really depended on
8 the severity of the problem that was required but we
9 were definitely using it. In the absence of any more,
10 sort of, figures, I can't remember.
- 11 Q. What about DDAVP?
- 12 A. We certainly did use that. It was very useful, but it
13 was really good for things like dentistry in less
14 severe patients. As I'm sure you know -- I mean,
15 DDAVP works by releasing Factor VIII from the body
16 from the blood vessels. So if you are a very
17 severe -- a person with very severe haemophilia 0 to
18 1 per cent, you don't have Factor VIII to be released
19 from the blood vessels, but if your normal Factor VIII
20 level is between 5 and 10 per cent, say, you actually
21 have quite a bit and the DDAVP would release that and
22 then you would be able to give it, perhaps, for
23 a couple of days to tide you over. But it was very
24 short-lived. So it was something we used -- I mean,
25 I remember using it.

121

- 1 in relation to patients who were previously untreated
2 patients?
- 3 A. Well, I don't remember ever treating -- well, other
4 than possibly some with DDAVP, who were very mild,
5 I don't remember treating any totally new patients.
- 6 Q. The arrangements for obtaining the commercial product,
7 we know that there was a regional contract in place,
8 and it appears to have been with Armour at the time at
9 which we're talking when you arrived in 1982. As far
10 as you can recall, was all your commercial product at
11 QEH obtained pursuant to that contract or did you ever
12 make any separate arrangements yourself for the
13 procurement of commercial concentrates?
- 14 A. In normal times, it was always off that contract. The
15 period of time when the -- I think, maybe the BPL but
16 certainly the commercial unheated products were
17 recalled, we went through a period of having very
18 little and, although I have a vague memory of it, but
19 you have provided papers to show that I actually made
20 a personal plea to Armour for some extra supplies,
21 which they did provide us with, which was -- it was
22 commented by my colleagues was outside the spirit of
23 the agreement but it was a difficult time.
- 24 Q. The criteria for awarding the regional contract for
25 commercial product, before we look at any of the

123

- 1 Q. We saw reference this morning in the 1970s to
2 cryoprecipitate being used to provide cover for
3 surgery. Was that something which was still happening
4 when you joined QEH?
- 5 A. Yes, I think it was, yes.
- 6 Q. Then, in terms of NHS product, as opposed to
7 commercial, how were decisions taken as to which
8 patients would receive NHS product and which would
9 receive commercial; can you recall?
- 10 A. Yes, difficult. To be quite honest, I can't remember.
11 I'm sure that if we had a young man transferring from
12 the children's unit who had only been on NHS we would
13 have done everything possible we could to try and keep
14 them on that. But, at times, we had very little NHS
15 and so, apart from that sort of more general comment,
16 I don't remember specifics.
- 17 Q. Presumably your product and batch policy would mean
18 the converse as well: if you had a patient transferred
19 from the Children's Hospital who had been receiving
20 commercial concentrate, as we know many of the
21 children did, you would have been likely to keep them
22 on that?
- 23 A. Probably. It's unlikely it would have been the same
24 batch, perhaps, but yes.
- 25 Q. Was there any specific policy or approach or practice

122

- 1 documents, your statement refers to Professor Hill
2 suggesting that one might question suppliers of Factor
3 concentrates about their donor pools. If we just look
4 at your statement, I think it is your paragraph 11.
- 5 A. Yes, I remember him doing that.
- 6 Q. What you say is, you talk about -- in the early years
7 of your time working at QEH you recall there being a
8 committee of doctors in the region which determined
9 which clotting factors were to be bought, and we will
10 look at the documents in a moment.
- 11 What is it you can recall about Professor Hill
12 talking to you about donor pools and you asking for --
- 13 A. He would ask about whether they were collecting blood
14 from prisons, skid row locale -- I mean, this was
15 after the 1975 bad blood -- I can't remember the name
16 of the programme now, but the World in Action
17 programme and there was, you know, great concern about
18 the quality of product. I know he had certain views
19 about certain companies but -- and I think it was
20 really a combination, I think, of trying to reassure
21 himself and myself that we were hopefully getting the
22 best product, and also perhaps send a message back the
23 other way that this was an important issue that
24 companies should address.
- 25 Q. You say he had certain views about certain companies.

124

1 What can you recall about his views about particular
2 companies?
3 **A.** Well, there is a letter in the papers from a surgeon
4 in Stanford University to the then head of BPL,
5 Dr Maycock, being really quite damning about
6 one company's product, and that company was one that
7 Dr Hill was never very keen on.
8 **Q.** That's the letter from Dr Garrott Allen --
9 **A.** It is.
10 **Q.** -- to Dr Maycock, 1975?
11 **A.** Yes.
12 **Q.** Can you recall any other particular discussions you
13 had with Professor Hill about specific companies?
14 **A.** No. None beyond that, no.
15 **Q.** If we could just look at three meetings, one before
16 you arrived -- well, one whilst you were there but
17 before you took over as director, and then two after
18 you became director, just to get a sense of how
19 decisions were taken.
20 Could we please have? Henry, FHIN0000030.
21 This is a meeting of the West Midlands Regional
22 Health Authority's working party on the treatment of
23 haemophiliacs. We looked at it this morning during
24 the presentation, Professor Franklin.
25 It's dated 27 June 1983. We can see Dr Hill was

125

1 supplier."
2 What, if anything, can you tell us about why
3 that was regarded as important?
4 **A.** Not really. It seems a strange thing to say, really.
5 I would have thought you would want the best product,
6 but -- I think, I mean, to be -- there were
7 differences, which I've only been reminded about in
8 the last week by reading a lot of the correspondence
9 and meeting papers, that the different companies
10 prepared different packs. Some of these were
11 perceived to be easier to use by patients at home than
12 others. I can't see what other amount of effort was
13 relevant really.
14 **Q.** Then the second point:
15 "Where firms have their donor facilities in the
16 United States."
17 So that goes back to the issue that you were
18 discussing a few moments ago.
19 **A.** Well, I did think they all did. Maybe Immuno didn't.
20 I know possibly Bayer didn't, but Bayer I think never
21 made a lot of product, and it was very expensive. But
22 as far as I knew they were all American products.
23 **Q.** This appears to be looking at where in the
24 United States the donor facilities were.
25 **A.** I see, I'm sorry. Different meaning of "where", I beg

127

1 there, and then representing QEH would have been
2 Professor Stuart.
3 So this is the time that you were a consultant
4 at the hospital but not yet director?
5 **A.** Yes.
6 **Q.** If we go to the second page, we can see under the
7 heading "Regional Contract":
8 "It was agreed that Mr Stanton should invite
9 tenders ..."
10 And then:
11 "Mr Shinton, Dr Hill and Mr Stanton would meet
12 to adjudicate when the tenders had been received."
13 So the process appears to have been, and we see
14 it later involving you, that Mr Stanton, from the
15 regional supplies department, would -- was that
16 something from the Regional Health Authority?
17 **A.** I would have thought so, yes.
18 **Q.** Would invite the tenders from a range of commercial
19 companies, and then there would be involvement of two
20 of the Haemophilia Centre Directors here, Dr Shinton,
21 who was Coventry, Dr Hill, the Children's Hospital,
22 and Mr Stanton adjudicating.
23 Then we can see three criteria there set out, or
24 points to be taken into consideration:
25 "The amount of effort involved in changing

126

1 your pardon.
2 Yes, where in the United States they had their
3 collection facilities, yes, which would be away from
4 major conurbations and places where ...
5 **SIR BRIAN LANGSTAFF:** You may not remember this but was
6 there any appreciation that a number of the commercial
7 firms may have got their plasma supplies not from
8 their own donor facilities but from plasma brokers?
9 **A.** I certainly didn't have any awareness of that at the
10 time. I think I became aware when I was more involved
11 in plasma fractionation in Scotland but not -- not at
12 that time. No, I think it was an assumption they were
13 going -- we knew there were paid donors but I think
14 the assumption was that they were going out and
15 collecting their own plasma.
16 **SIR BRIAN LANGSTAFF:** Yes.
17 **MS RICHARDS:** Then we see the third point that's
18 identified to be taken into consideration is:
19 "Any public pressure for a change of products
20 (eg to heat-treated Factor VIII) should be resisted
21 until another product had been proved to be more
22 satisfactory."
23 Do you know what the reference to
24 "public pressure" refers to?
25 **A.** No.

128

1 Q. We can see that as at June 1983 there's a reference to
2 heat-treated Factor VIII. We'll come on to how and
3 when QEH moved to using heat-treated products, which
4 was either at the very end of 1984 or the beginning of
5 1985 as far as we can tell. Do you recall any
6 consideration being given in the course of '83 or '84
7 to starting to use heat-treated products earlier?

8 A. No. I think my only awareness of the heat-treated
9 product was the Bayer product, which was, as I say,
10 very expensive and beyond our budget. No.

11 Q. If we go to the next page, please, Henry -- sorry,
12 actually we'll go back to the previous page. My
13 apologies, Henry.

14 If we just look at the bottom part of the page,
15 Professor Franklin, under "Supplies of Cryoprecipitate
16 and Freeze-dried Factor VIII", we can see there
17 there's a discussion about the -- well, what is
18 described as "Receipts and Purchases", so presumably
19 who is using what in terms of Factor VIII.

20 There's a reference to a letter from Dr Shinton
21 about the risk of AIDS, and we'll come back on to the
22 question of AIDS. But then there's a reference to
23 asking the working party to advise on the purchase of
24 heat-dried Factor VIII. So that appears to be
25 something that at least Dr Ala was raising in June of

129

1 Government and -- probably in 1984 I would have been
2 able to work my way round this but I'm afraid I can't
3 anymore.

4 Q. Don't worry. We will move on then to the first of
5 these meetings that you did attend.

6 SHIN0000029, please, Henry.

7 So we can see this is a meeting on
8 5 December 1983. You had taken over as director by
9 this time, although Professor Stuart was there, you
10 were there, Dr Hill was there.

11 A. Yes.

12 Q. And a number of others. If we look down the page
13 towards the second half of the page, we can see under
14 the heading "Regional Contract" that:

15 "Dr Ala informed the committee that the lowest
16 tender was forwarded by the present supplier - Armour
17 Pharmaceutical Corporation, and no change was
18 envisaged."

19 So it doesn't appear that there's any
20 discussion, at least here, of those points that we saw
21 referred to in the previous document. It just seems
22 to be here the contract's been awarded on the basis of
23 price. Do you have any recollection or understanding
24 of that?

25 A. I don't, but I would perhaps suggest that that might

131

1 1983. Was that something that you recall becoming
2 involved with advising?

3 A. No. As you point out, I wasn't at this meeting. It
4 was quite prescient of him. But I don't remember any
5 particular fall-out or progression of that idea.

6 Q. Then the next page, please, Henry, if you go to the
7 heading "Funding of Commercial Factor VIII".

8 I don't know whether you can assist,
9 Professor Franklin, in understanding what's being
10 discussed here. In the second paragraph it's referred
11 to -- or, there's an issue about deducting from
12 districts with haemophilia centres in order to
13 "top-slice", and the possibility of applying for RCCD
14 funds. Do you know what any of that refers to?

15 A. RCCD is the revenue -- no, wait, revenue consequences
16 of ... I think it might mean revenue consequences of
17 some sort of development -- capital development. The
18 West Midlands Regional Health Authority had these sort
19 of arcane phrases, I don't know whether they were
20 common across the NHS, but -- so we were often
21 applying for money to support the haemophilia patients
22 from something called the regional consequences of
23 services capital development, RCDRS. So they had --
24 basically these are systems which the region divvied
25 up the money that they presumably had from central

130

1 still have been going on in the background.

2 Obviously, the tendering process was developed to
3 separate us as the users from the spending of the
4 money. I would have still thought that those
5 requirements, even if they were slightly strange, the
6 three requirements, would have still been informing
7 the decision as to which companies to ask to tender.
8 But obviously that's a very brief limit so it's not
9 explicit, is it?

10 Q. No. If we go to the next page, just two further
11 points to pick up, we can see that under "Any Other
12 Business", Professor Stuart informing the committee
13 that this would be his last attendance and in future
14 you would attend as sole representative. Just go down
15 the page. So we see that under "Any Other Business".

16 A. Yes.

17 Q. Then just going up from that, the paragraph headed
18 "AIDS" -- so this is now December 1983, there's
19 reference to there being a handout at donor sessions
20 at the blood transfusion centre, and then it says
21 this:

22 "It was agreed that if any case of AIDS was
23 suspected, then the Regional Public Relations Office
24 should be informed in case their help was required."

25 Are you able to cast any light on that because,

132

1 at first blush, it seems a bit odd to see the public
 2 relations office being involved?
 3 A. Well, tragically we did ultimately have men who
 4 developed AIDS, and I don't ever remember talking to
 5 the Regional Public Relations Office about it.
 6 Q. Then if we go on to the next meeting, which is
 7 SHIN0000028, so we're now in May of 1984, you weren't
 8 in fact at that meeting. You sent your apologies.
 9 But if we go over the page, we can see in the top
 10 section of the minutes it says:
 11 "From the annual statistics and supply of BPL
 12 expected, there could be a shortfall of 3.5 million
 13 units to be made up from Commercial sources. The
 14 Working Party agreed that Mr Stanton ... should, in
 15 due course, invite tenders and subsequently meet with
 16 Drs I Franklin and RM Ibbotson to adjudicate."
 17 Just pausing there, on this occasion it appears
 18 that the assessment of tenders is going to be by
 19 Mr Stanton, Dr Ibbotson -- where was Dr Ibbotson from?
 20 A. Stoke-on-Trent. I know him well.
 21 Q. And Dr Franklin, so yourself?
 22 A. Yes.
 23 Q. And then:
 24 "It was agreed that the following points should
 25 be taken into consideration ..."

133

1 can see that there is no express reference to any
 2 other aspect of safety or risk. Can you recall
 3 whether that factored into the decision-making process
 4 at all?
 5 A. Well, knowing what I know now, I suspect that it was
 6 accepted that all these products had non-A,
 7 non-B hepatitis in them, and that the issue of where
 8 the plasma came from was our only lever, if you like,
 9 of trying to manage that risk in any way?
 10 Q. In your witness statement at -- let me just find the
 11 paragraph -- yes, so two passages I wanted to ask you
 12 about. Paragraph 13. Do you have a copy of your
 13 statement?
 14 A. Yes, I do.
 15 Q. We can put it up on screen, Henry.
 16 It's WITN4032001, please.
 17 If we go to page 14. So paragraph 13, this is
 18 now talking about the particular products for treating
 19 patients. You say this:
 20 "The particular products used for treating
 21 patients at the Centre depended on availability -
 22 which changed over time ..."
 23 And we've touched on that.
 24 "... previous treatment history ..."
 25 Is that a reference to they have already been on

135

1 And then we see the same three points there
 2 articulated. So this is for the next round of the
 3 contract?
 4 A. Yes.
 5 Q. Can you recall anything about that subsequent
 6 adjudication process?
 7 A. I'm afraid I can't. I don't remember that at all.
 8 Q. So you don't know whether it would have been an
 9 informal or formal process or records kept of it?
 10 A. Well, ideally they would have been kept but I don't
 11 recollect any such meeting.
 12 Q. Do you know what, if any, steps were taken to get the
 13 information that would help you consider point 2, the
 14 point about donor facilities, what questions were
 15 asked or when enquiries were undertaken?
 16 A. Well, the only enquiries I remember were those that
 17 I think I also did ask in -- having been trained by
 18 Dr Hill as to what questions to ask, I probably asked
 19 myself, but I don't know whether the supplies
 20 department asked those questions in a formal way and
 21 required anything in writing. I don't know.
 22 Q. Okay. I think we can see some evidence, when we get
 23 to about 1986, of perhaps a more structured approach,
 24 but we don't have anything very clear in this stage.
 25 Apart from the reference to donor facilities, we

134

1 this product --
 2 A. Yes, whether they were always on NHS or commercial or
 3 vice versa.
 4 Q. Then you say:
 5 "... and also the specific reason for treatment
 6 being needed."
 7 What does that refer to?
 8 A. Well, I would think if you had someone who may have
 9 been a less severe haemophiliac who you might try to
 10 use DDAVP for tooth extraction or possibly cryo for,
 11 I don't know, a hernia operation, and if they had
 12 perhaps bowel cancer and needed a major resection, you
 13 might feel you had to use concentrate.
 14 Q. Then if we go, please, to page 22, paragraph 18, you
 15 say in the first sentence:
 16 "Decisions were taken on the basis of an
 17 assessment of risk and availability."
 18 We have covered availability. What did you mean
 19 by an assessment of risk?
 20 A. Sorry can you just run back up to the precise
 21 question?
 22 Q. Yes, of course.
 23 A. Right, there we are.
 24 Well, I think probably I've kind of explained
 25 that. If the risk was relatively low, tooth

136

1 extraction something like that, then you might -- you
2 definitely try to use DDAVP if you could, and then so
3 on down to some sort of major cancer operation.

4 I think I mentioned somewhere else in my
5 statement one patient had a large bladder tumour that
6 needed quite a big operation and that really had to be
7 done under concentrate cover.

8 I think they're the risks. That's the risk
9 strategy, isn't it, really?

10 **Q.** What role did patients have in decisions about what
11 treatment to have at this time '83, '84, '85?

12 **A.** Well, any patient is at liberty to refuse any
13 treatment at any time. I realise that might sound
14 a bit glib but it's true. Beyond that, probably not
15 a lot. I mean, we would have recommended what we
16 thought was appropriate for the particular procedure
17 they had.

18 **Q.** Can you recall whether patients were ever offered any
19 kind of choice of treatment? So you correctly
20 observed there's obviously an entitlement and
21 principle to refuse?

22 **A.** Yes.

23 **Q.** Were they ever given a choice between, for example,
24 NHS concentrate and commercial concentrate?

25 **A.** To be honest, I'm not sure I ever had that choice to

137

1 they are very unpleasant. But in the main they are
2 not life-threatening."

3 Do you see that? Because some of the evidence
4 the Inquiry's heard has posed this choice between
5 life-saving treatment to prevent, say, a cerebral
6 haemorrhage, on the one hand, and the risk of
7 treatments with concentrates. But, as I understand
8 the evidence you were giving there, you were making
9 the observation that most treatment for haemophiliacs
10 is of the life-enhancing, rather than life-saving,
11 nature.

12 **A.** Well, I did think that and I'm not sure I've changed
13 my view. I mean, I'd have to preface that by saying
14 I was not one of the long-standing haemophilia doctors
15 who had seen haemophilia care before decent treatment
16 was available and the long-term effect of even these
17 bleeds in some of the survivors that we did have was
18 pretty devastating in terms of arthritis, employment
19 prospects, personal relations, education. But I was
20 always slightly suspicious about the idea that if we
21 didn't carry on using concentrate -- and I did carry
22 on using concentrate -- that if that was stopped then
23 suddenly many, many, many, many people with
24 haemophilia would have died.

25 I mean, if you develop cerebral haemorrhage when

139

1 offer them. The supply of the NHS product was
2 insufficient, so I think possibly not, really.

3 **Q.** What about a choice between concentrates and
4 cryoprecipitate; was that a choice that was offered?

5 **A.** I don't remember offering that as a choice, no.

6 **Q.** You talked about assessment of risk and much might
7 depend upon the circumstances of the patient and the
8 risk of, for example, the bleed. Could we just look
9 at your evidence, your written evidence, to the
10 Archer Inquiry. There's just one point I wanted to
11 pick up with you. Henry, it's ARCH0000443. Could we
12 go, please, to page -- I'm sorry we've only got this
13 annotated version of your statement.

14 **A.** Yes, I couldn't find a clean version for you.

15 **Q.** Are these your annotations?

16 **A.** I don't think so. It's not my writing, no.

17 **Q.** We didn't think so either. If you could go to page 5,
18 please, it's the top paragraph. I'm going to come
19 back at a later stage in your evidence and ask you
20 about the precautionary principle, Professor Franklin,
21 but you say this about six lines down:

22 "... the regular use of Factor VIII as a home
23 therapy was a quality of life, rather than a life
24 saving, approach. Most home therapy was for incipient
25 joint or soft tissue bleeds. These are not trivial,

138

1 you are at home, you need an ambulance. You don't
2 need someone to put cryo -- to get cryo out of the
3 freezer, I think that was my feeling. So I was always
4 a bit sceptical about this but, I have to confess, you
5 know, I went with the -- I was at the meeting when
6 Professor Bloom said you should carry on with
7 concentrate and that's what I did, so --

8 **MS RICHARDS:** Yes, and we will come on to that.

9 Sir, I note the time. I think I'm about to move
10 on to a topic which will require looking at quite
11 a lot of documents, so would this be a convenient
12 point to take a half-hour break?

13 **SIR BRIAN LANGSTAFF:** Yes, let us take a break until
14 3.30 pm.

15 *(The witness was reminded not to discuss his evidence
16 during the break)*

17 (3.03 pm)

(A short break)

19 (3.30 pm)

20 **MS RICHARDS:** Professor Franklin, I'm going to ask you to
21 consider now your knowledge of the risks of hepatitis
22 and, in due course, AIDS.

23 Before we look at any specific documents, what,
24 if anything, can you recall being taught in your
25 general medical training and then your haematology

140

1 training about the risks of viral transmission from
 2 blood and blood products?
 3 A. Well, when I was in Leeds my main mentor, a chap
 4 called Brian Roberts, Dr Roberts, did say that, you
 5 know, blood transfusion was one of the more dangerous
 6 treatments in a way. It sounds a bit dramatic, and
 7 I think he was largely thinking of cross-match
 8 mistakes, blood group errors, but I think it did
 9 extend into concerns about hepatitis.
 10 He did, however, sort of temper that by saying
 11 it seemed to be mainly a problem in the USA rather
 12 than in the UK. I mean, I think relatively speaking
 13 that may be true but I think we now know that there
 14 was a lot of hepatitis risk in the UK. So that was
 15 there.
 16 As I say, when I was at the Blood Transfusion
 17 Centre, most of the experience or the training was in
 18 hepatitis B, and I think there was a sense of denial
 19 about non-A, non B in the UK. There was a meeting
 20 in -- Medical Research Council meeting about non-A,
 21 non-B hepatitis in 1979 when the then director of the
 22 Regional Transfusion Centre where I was training, in
 23 Edgware, Tom Cleghorn, said that he thought there was
 24 very little post-transfusion hepatitis in the UK at
 25 the time and quoted the fact that they were

141

1 journal. Various other journals over time. Online
 2 papers now, really, in the last 15 years. You're more
 3 likely to look for specific papers rather than open
 4 a magazine.
 5 Q. In your evidence to the Archer Inquiry -- which we'll
 6 look at, ARCH0000008.
 7 If we go to page 27, I think it should be --
 8 next page, please -- you say this about non-A, non-B
 9 hepatitis, picking it up four lines down:
 10 "Certainly to my mind it was not taken that
 11 seriously until a publication from the Sheffield group
 12 was published in 1985 with the lead author of Dr Hay,
 13 who showed quite clearly that quite a lot of patients
 14 with these liver abnormalities actually had
 15 significant liver damage."
 16 Then you refer to a 1983 publication from
 17 Manchester.
 18 So your recollection at the time you were giving
 19 your evidence to Archer was that it was this
 20 publication in 1985 which was significant in your own
 21 understanding of non-A, non-B; is that right?
 22 A. Well, yes. I think, though -- I don't know, you will
 23 be talking to both of the key workers on this paper,
 24 Charles Hay and Eric Preston, and I would be
 25 interested to hear what they say. I think when you

143

1 transplanting one and three quarters of a million
 2 units of red cells at that time, which is a huge
 3 amount.
 4 His colleague Dr Maycock, from BPL, agreed with
 5 that, that there wasn't much post-transfusion
 6 hepatitis, and even Dame Sheila Sherlock agreed,
 7 although she did caution about the use of commercial
 8 concentrates in that.
 9 So I think there is a sort of sense that the UK
 10 was protected by its non-remunerated volunteer donor
 11 population from this. So I didn't have a lot of
 12 awareness of understanding about it other than that --
 13 you know, what one got from textbooks or things like
 14 that.
 15 Q. Just before we look at some of the materials that you
 16 have referred to in your statement, what kind of
 17 journals, medical journals or other sources of
 18 information did you routinely have access to and would
 19 read?
 20 A. Well, it varied a little over time. I mean,
 21 throughout my career that would be the British Medical
 22 Journal, The Lancet and the New England Journal of
 23 Medicine. During my research it would have been
 24 papers about sickle cell disease, the journal Blood,
 25 which is probably the most prestigious haematology

142

1 look back now, I would say there's a high risk that
 2 a lot of this was damage due to a combination of
 3 hepatitis C and HIV.
 4 Professor Lee's evidence last week suggested
 5 that hepatitis C on its own, while certainly not being
 6 benign, was certainly consistent with long-term
 7 survival in most cases.
 8 Q. In your witness statement, if we go, please, to
 9 WITN4032001, and we go to page 26, picking it up in
 10 the last two paragraphs you talk about non-A, non-B
 11 hepatitis being considered "mild and relatively
 12 benign", and say that:
 13 "Unfortunately this reflected a lack of
 14 knowledge of the full long-term history of non-A,
 15 non-B..."
 16 Then you refer again to the Manchester paper and
 17 then the Sheffield paper.
 18 A. Yes.
 19 Q. We'll just look at those briefly, and then the
 20 textbook you refer to, as I think those are the
 21 particular documents you suggest that you were
 22 influenced by.
 23 Before we do that, you say you would have learnt
 24 more about non-A, non-B hepatitis from the reports by
 25 Dr Craske at the UKHCDO. Would you have seen those

144

1 before becoming a director?
 2 A. No.
 3 Q. So only from 1983 onwards?
 4 A. Yes.
 5 Q. Then we'll just look at the other documents that you
 6 refer to. So the Manchester paper is WITN4032009
 7 I hope, Henry. No.
 8 A. That's the Manchester paper.
 9 Q. It's certainly not the report I've got.
 10 Do you have PRSE0002564, Henry?
 11 So this is a full copy of the Manchester paper?
 12 A. Yes.
 13 Q. This I think is the paper you're referring to, "Liver
 14 disease in haemophiliacs: an overstated problem?"
 15 1983. We can see it refers to:
 16 "... biopsy ... on 12 multi-transfused
 17 haemophiliacs from the Manchester area with
 18 persistently abnormal liver function tests."
 19 If we go please, Henry, to -- it's page
 20 number 654 of the report, Henry. I think it's
 21 probably the sixth page of the electronic document.
 22 That's it.
 23 Go to the last paragraph on that page, we can
 24 see it says in this study:
 25 "Only one patient was found to have CAH ..."

145

1 cell disease, some of those were multi-transfused and
 2 yet it didn't seem to be something that was appearing
 3 in them, and for that reason it wasn't something that
 4 was foremost in my concern until I began to look after
 5 the haemophilia patients and it was obvious that all
 6 of them or virtually all of them had abnormal liver in
 7 function tests.
 8 So when this paper came along about that, about
 9 the time I began -- either just about the time
 10 I started or maybe it was a bit before but it was
 11 certainly around that time, it seemed to be -- it's
 12 not actually that reassuring when you read it again.
 13 Q. What I was going to ask you about, Professor Franklin,
 14 it's a study of 12 patients, I think.
 15 A. It is -- the only thing I would say, it's a very small
 16 study we're looking at.
 17 Q. As indeed many of them are.
 18 A. Yes.
 19 Q. Then if we look at the reference to Aledort, which was
 20 a slightly bigger study --
 21 A. Yes.
 22 Q. -- 16 per cent CAH and cirrhosis, it's not a small
 23 figure, it's still a significant figure?
 24 A. Yes.
 25 Q. Do you recall whether either you or Dr Hill at the

147

1 That's chronic active hepatitis?
 2 A. Yes.
 3 Q. "... with progression to micronodular cirrhosis. Four
 4 other patients had only mild chronic active hepatitis.
 5 We suggest that the true incidence of it severe
 6 histological liver abnormality in multi-transfused
 7 haemophiliacs may be less than previously reported but
 8 similar to the more recent results of 115 liver
 9 biopsies carried out worldwide (Aledort ... 1981)
 10 where the incidence of [chronic active hepatitis] and
 11 cirrhosis was 16 per cent."
 12 Then it goes on to say that liver biopsies may
 13 not be indicated, perhaps for self-evident reasons.
 14 Was this study which you recall reading at the
 15 time?
 16 A. Yes.
 17 Q. Do you recall any discussions with Professor Hill
 18 about non-A, non-B hepatitis or the risks of liver
 19 disease?
 20 A. Well, I think we did. I mean, can I remember
 21 a particular moment? I mean, no, I can't. I think my
 22 knowledge of non-A, non-B hepatitis was quite limited
 23 until I started looking after the men with
 24 haemophilia, and that's interesting because I was
 25 doing bone marrow transplants in patients with sickle

146

1 time had any opportunity to discuss this issue with
 2 liver specialists in Birmingham?
 3 A. Well, we did have liver specialists there. I don't
 4 remember discussing this -- discussing that, sorry.
 5 I do remember Frank Hill and myself talking
 6 about whether we should be doing liver biopsies, and
 7 we decided against. I think -- to be quite honest,
 8 I think by the time the Hay and Preston study came
 9 out, the issue was largely resolved, and I think we
 10 felt: what was the point? It's risky. You are well
 11 aware that there was a death at the Royal Free
 12 Hospital?
 13 Q. Yes.
 14 A. The -- not that money was the issue, but you need
 15 a lot of Factor VIII to safely do this. So we decided
 16 we wouldn't do that. 1983, the liver unit was only
 17 just starting at the Queen Elizabeth Hospital. There
 18 was a liver expert there, a guy called Elias, very
 19 good. He used to come and see my other haematology
 20 patients. There's no reason why we wouldn't have
 21 discussed these with him, but no, I don't think we had
 22 any systematic approach with the liver unit, no.
 23 Q. Then the 1985 Hay and Preston paper -- Henry, I'm
 24 hoping I've got the right reference here, PRSE0004229.
 25 Do you have that? Thank you.

148

1 So this is the 1985 study that you referred to
2 in The Lancet, and we can see there it refers to there
3 being:

4 "... an eight-year study of 79 unselected
5 patients with haemophilia ... [and] evidence of
6 chronic progressive liver disease in at least 17
7 (21 per cent). 8 patients had chronic active
8 hepatitis and 9 had cirrhosis ..."

9 What, if anything, can you recall your reaction
10 to this paper being?

11 A. Well, concern. It's quite, you know, serious, serious
12 data. I mean, I think as a pure study in hepatitis,
13 then I think the difficulty is that these were
14 probably taken from many patients who also had HIV; so
15 that affects its value as a pure study on non-A, non-B
16 hepatitis. But in terms of the seriousness to people
17 with haemophilia, it's obviously pretty bad news.

18 The only problem is and was -- certainly was --
19 was there wasn't really any treatment. So in terms of
20 what we discussed, it was -- what we discussed with
21 individual people was that this may not be good and we
22 probably reinforced avoiding alcohol, not a lot else
23 you can do. It also, of course, was published at the
24 height of the worry about HIV. So I think a lot of
25 the discussions in my clinic were dominated by worries

149

1 patients, a very significant number of patients,
2 proceeding to a chronic liver disease.

3 A. Well, it's probably actually an underestimate.

4 Q. Then, if we just look at the next page, which was the
5 second -- I'm sorry, Henry, it's a different
6 reference: WITN4032022.

7 Then we can see the clinical features set out:

8 "Chronic hepatitis can follow both the long and
9 short incubation types."

10 It says:

11 "Chronicity ... may develop insidiously and the
12 acute episode would not have been recognised if the
13 patient had not been under medical observation ...

14 "A characteristic feature is the marked
15 fluctuation in serum transaminase levels, extending
16 over many months."

17 Then:

18 "Liver histology shows the general features of
19 chronic hepatitis, usually of persistent or mild
20 chronic active type."

21 Then we see the next column "Prognosis and
22 course", it says:

23 "Clinical progress is toward improvement, but
24 cirrhosis has been reported."

25 Then "Treatment":

151

1 about HIV and AIDS.

2 Q. You've also referred in your statement to the
3 publication by Sheila Sherlock and, again, I think in
4 fairness to your evidence, we should probably look at
5 that because you say you did recall consulting this
6 textbook?

7 A. Yes. I mean, I did. That was my source of knowledge
8 about liver disease, really.

9 Q. You have referred in your statement to two passages.
10 Sorry, you referred in your statement to one passage
11 then more recently another?

12 A. I've since realised there are two passages relevant to
13 non-A, non-B in this book, yes.

14 Q. So we will look at the passage you refer to expressly
15 in your statement, first of all. Henry, it is
16 WITN4032021, please. So this is page 290 of the book.
17 We can pick it up at the bottom of the page, "Chronic
18 non-A, non-B hepatitis":

19 "Serial studies have shown that patients with
20 acute non-A, non-B hepatitis progress to chronic liver
21 disease. This applies to the blood
22 transfusion-related, the blood factor-related and the
23 sporadic disease. The incidence of chronicity seems
24 to be about 30 to 40 per cent."

25 That would suggest a significant number of

150

1 "Reassurance and regular supervision at
2 approximately three to six-month intervals."

3 So this is 1981, this publication?

4 A. Yes.

5 Q. So that was the part you refer to in your statement --

6 SIR BRIAN LANGSTAFF: Just one moment before you go
7 further, can you help me to understand the expression
8 "clinical progress is towards improvement", because
9 this is looking at a chronic disease, which is
10 measurable only by transaminase values but otherwise
11 one assumes is progressive in its natural way. We
12 know now, as a matter of fact or at least matter of
13 expert report to the Inquiry, it is progressive.

14 A. Yes.

15 SIR BRIAN LANGSTAFF: So "clinical progress", does that
16 mean that the transaminase values tend to not be as
17 bad later on or what does it mean?

18 A. Well, I can only speculate that it reflects
19 uncertainties at the time because there are parts of
20 this that seem to be suggesting one thing and parts
21 that seem to be suggesting something else.

22 SIR BRIAN LANGSTAFF: Yes.

23 A. So, on the one hand, they go on -- people go on to get
24 cirrhosis, on the other hand most people improve.
25 Also, we are supposed to be reassuring people. That

152

1 word crops up on quite a number of occasions.
 2 **SIR BRIAN LANGSTAFF:** But reassuring may mean telling
 3 people what isn't the case --
 4 **A.** Well, I would hope not but it could, yes.
 5 **SIR BRIAN LANGSTAFF:** Yes --
 6 **A.** That would be inappropriate reassurance, wouldn't it.
 7 I think -- I think it reflects the fact that even Dame
 8 Sheila Sherlock didn't really know what was going to
 9 be happening.
 10 **SIR BRIAN LANGSTAFF:** Do you happen to know if she
 11 actually wrote this chapter?
 12 **A.** I think this volume she wrote herself, solely, this
 13 whole book. I think later volumes she had co-authors.
 14 Maybe you --
 15 **MS RICHARDS:** I am just checking.
 16 **A.** Counsel has the volume but I think it is
 17 a single-author text -- only her name on the --
 18 **Q.** It's certainly only her name. I can look in more
 19 detail, sir, at the preface and acknowledgements but
 20 there isn't another author whose name is given on the
 21 text.
 22 You have also drawn the Inquiry's attention to
 23 an earlier passage in the book pages 257 to 259.
 24 Henry, those are at WITN4032023. Is there another
 25 page? Keep going.

153

1 The end of that paragraph says "Cirrhosis can
 2 develop."
 3 Then it talks about liver biopsies if you go to
 4 the next page. There's a description there of what
 5 might be seen in liver biopsies.
 6 Then it says:
 7 "Non-A, non-B hepatitis often progresses to
 8 a mild chronic hepatitis. The prognosis of this is,
 9 at the moment, uncertain but probably benign."
 10 Unfortunately, there is no reference that is one
 11 way or the other in relation to that last section.
 12 **A.** No. I mean, I think I wrote somewhere else in my
 13 statement that when it became clear that a lot of the
 14 men that I was looking after had got HIV, that
 15 I looked back at their notes from the period when
 16 I wasn't there and I was quite shocked to discover
 17 that virtually on the first injection of concentrate,
 18 regardless of type, they developed abnormal liver
 19 function tests. I like to think that, had I been
 20 there at that time, I might have been more concerned
 21 to not carry on but, I'm ashamed to say, I'm not sure
 22 I would have had that strength of character to go
 23 against the prevailing view.
 24 I think this is sort of showing that -- to be
 25 honest, I would interpret this as uncertainty from

155

1 **A.** I'm fairly sure it's only her that wrote the whole
 2 book from that plate.
 3 **Q.** Yes, certainly the plate only contains her name, you
 4 are right, Professor. So we see here, this is the
 5 other passage that you have drawn attention to,
 6 pages 257 onwards "Non-A, non-B hepatitis":
 7 "The elimination of hepatitis A and hepatitis B
 8 from transfused blood did not eliminate
 9 post-transfusion hepatitis. Some of the cases were
 10 due to cytomegala infection, but the majority were due
 11 to another virus or viruses termed non-A, non-B. This
 12 infection now accounts for about 75 per cent of
 13 post-transfusion hepatitis ..."
 14 It goes on to say:
 15 "Haemophiliacs receiving factor concentrates
 16 obtained from commercial sources are particularly at
 17 risk. Non-A, non-B hepatitis is largely blood
 18 spread."
 19 Then if we go over the page, I can see it says:
 20 "The agent has not been conclusively identified.
 21 It has been transmitted to chimpanzees."
 22 Then the clinical course is then described, an
 23 incubation period:
 24 "The acute episode is usually mild and often
 25 anicteric ... Fulminant hepatitis is rare."

154

1 someone who is the world expert not really knowing
 2 what's going to happen, to be honest, and I think also
 3 when we look back she hadn't -- even she hadn't got
 4 a long enough longitudinal experience of a disease
 5 that can take 15/20/30 years to destroy someone's
 6 liver.
 7 **Q.** In terms of the materials that you recall seeing at
 8 the time, bearing in mind that you were assuming
 9 responsibility for people with bleeding disorders in
 10 1982/1983, other documents that we have looked at, you
 11 recall looking at this book, you recall the Manchester
 12 report, you recall the Hay/Preston 1985 study?
 13 **A.** Yes.
 14 **Q.** The Inquiry sent you some earlier and other materials
 15 from the second half of the 1970s through to 1980.
 16 I am very happy to go through them with you if it
 17 would assist, Professor Franklin, but they include
 18 publications in The Lancet from Prince and then in
 19 1978 an earlier study from Professor Preston which, if
 20 I can put it this way, is not inconsistent with the
 21 1985 study; would you agree with that?
 22 **A.** Yes, it's quite small but absolutely, yes.
 23 **Q.** We have sent you also some material from Dr Craske
 24 from 1978 reporting some American information about
 25 liver biopsies with 50 per cent showing changes

156

compatible with cirrhosis. I think we sent you a letter, which we've looked at with a number of witnesses, from Dr Kernoff to Dr Colvin, describing non-A, non-B hepatitis as a serious disease with long-term consequences.

You wouldn't, I imagine, have seen that letter at the time. Do you recall whether, in the second half of the 1970s, you came across any of the materials that we've provided you with?

- A. Well, if I did they didn't impact that well. You showed a number of papers from Harvey Alter and colleagues. I don't remember those. It's quite likely I read the Prince paper but it didn't impact on me, I'm ashamed to say, no. I don't remember it.
- Q. As I say, I'm happy to go to each of those materials if it would assist Professor Franklin but, in an attempt to short-cut it, would you agree that, looking at that material, which you may not have seen at the time, that paints a rather different picture of non-A, non-B. It doesn't suggest it is necessarily going to be a mild or benign infection, it suggests it may be something rather more serious?
- A. It does. I'd still stick to my statement that I felt there was a bit of an atmosphere of denial in the UK over the risks of non-A, non-B hepatitis from UK blood

157

this is not me saying this -- by governmental regulatory advisory agencies responsible for the safety of blood and blood products, by the plasma fractionation industry and by the physicians looking after haemophiliacs. It also says, and I don't agree with this, by individuals with haemophilia. But I do think that hepatitis at that time does appear to have been viewed as an acceptable risk.

I mean, it was -- surely it must have gone to the Committee on Safety of Medicines, all these people getting hepatitis. I don't know.

- Q. Can I just see whether we're looking at the same document. Is that the "HIV in the blood supply and analysis of crisis decision-making"?
- A. Yes.
- Q. Sir, we've got that, I hope, at WITN4032024.
- Is that the right document, Professor Franklin?
- A. Yes, I think so. Yes, it is.
- Q. What was the page you were referring to?
- A. That's a good question. If you could run down. It's not far from the front. It should be four bullet points, I think. Two hypotheses. A bit further please, next page.
- Q. Ah, yes. I think it is your second point.
- A. Here we are.

159

transfusion and that was the area in which I had experience at that time. I did not have experience of treatment with concentrates, particularly not concentrates from America until through towards the end of '82 -- no, I started in '82. Towards the middle and end of '83 probably.

- Q. I think one of our witnesses used a term that there may have been a degree of wishful thinking on the part of haemophilia clinicians not wanting to think of non-A, non-B hepatitis as something serious, because of what was seen as the very great benefits that factor concentrates had brought. Do you feel able to comment on that from your own experience and perspective?
- A. I think there was definitely wishful thinking about HIV AIDS in some of the papers I've seen. I think there was in 1995, if you allow me to sort of -- there was an Institute of Medicine book from the United States that looked back at the disaster in relation to hepatitis and HIV, and it came up with a hypothesis that there wasn't enough effort made to introduce heat-treated safe products because there was a feeling that hepatitis was -- if you let me look at -- I scribbled this down.

Hepatitis was viewed as an acceptable risk --

158

- Q. "Hepatitis was viewed as an acceptable risk by the Government regulatory agencies responsible for the safety of blood and blood products, the plasma fractionation industry, the physicians who treated the individuals with haemophilia ..."

Pausing there. That, I think, is the bit you are associating yourself with --

- A. Well, I think it looks as if that was the case, yes. In terms of wishful thinking, I suppose the hope was it wasn't very serious.
- Q. In terms of the 1985 Hay/Preston research, would you accept that that wasn't something which showed something radically new or different, it was rather perhaps confirmatory of earlier fears; would that be a fair way of putting it?
- A. Yes. Well, I think it was the final -- yes, the final sort of straw that, as it turned out, maybe it wasn't all hepatitis C, but what it definitely meant was that we were going to see a lot of bad liver disease in that group of men who were having those concentrates before effective heat treatment, yes.
- Q. Move on to HIV/AIDS.
- I think I understand from your statement you think you would have seen the MMWR report in 1982?
- A. I started looking at them. They weren't easy to find

160

1 but yes, I did, because that was where -- I think
2 I mention in my report that the pre-internet era,
3 the -- actually knowledge was quite powerful, when
4 I think about it, because not everybody had it. Now
5 everybody has knowledge.

6 So we all knew that AIDS was happening in the
7 gay men in America. The journals were months out of
8 date, so you really relied on things like MMWR,
9 because it was a weekly report, and also word of mouth
10 by experts. Reading journals was -- you had to read
11 the journals but it was insufficient.

12 Q. So the July 1982 report we know is the report about
13 PCP being observed in some haemophiliacs in the
14 States?

15 A. Yes.

16 Q. You also, I think, read the New England Journal of
17 Medicine January 1983 Desforges article, and you noted
18 there the recommendation to switch back to
19 cryoprecipitate.

20 A. Yes, I wasn't responsible -- I was looking after
21 people with haemophilia, that was on my rota, but
22 I wasn't responsible for it at that time.

23 Yes, that was quite a prescient article.

24 Q. Then if we have up on screen, please, PRSE0002647.
25 This is the note of a meeting on

161

1 it?
2 Q. Yes.
3 A. No, I don't even remember being -- anyone talking
4 about this meeting. No.
5 Q. What about the issues that were raised? So the case
6 of the San Francisco baby which, as the Chair points
7 out, was reported in December of 1982 in the MMWRs and
8 the issues flagged up by Jane Desforges in her
9 article, do you recall any conversation about those
10 issues if not about the meeting?

11 A. I remember conversations about the doctors in
12 Birmingham, my colleagues being very concerned that
13 AIDS was going to be a problem in patients in the UK,
14 not necessarily only men with haemophilia but -- you
15 know, we transfused a lot of blood into people with
16 leukaemia. We were worried about them as well.

17 Yes, there was a big -- well, it was huge issue.

18 Q. Was it -- when was it reasonably clear to you that
19 AIDS was probably being transmitted by blood and blood
20 products? Was it from these January 1983 reports?

21 A. Yeah, difficult. Well, I suppose it was actually
22 from -- I mean, Chairman put me right on the MMWR.
23 I don't know whether I read that one. I read some of
24 them. But certainly by the time that -- the case of
25 the baby came out, then that was pretty clear. There

163

1 24 January 1983. It was with Immuno, to look at
2 hepatitis-reduced Factor VIII.

3 We know -- if we go to the last page please,
4 Henry -- from the list of attendees that
5 Professor Hill attended, Professor Stuart did not.
6 This is before you took over as director at
7 Queen Elizabeth. But there's what appears to be, from
8 the minutes, quite a lengthy discussion about AIDS.
9 There's a report about the San Francisco baby case
10 that had been reported in --

11 A. Yes, that must have been very shortly before this.

12 Q. Yes, that's absolutely --

13 A. And it wasn't yet published. But that goes to show
14 the importance of bush telegraph-type communications.

15 SIR BRIAN LANGSTAFF: I think it had actually been
16 published in the MMWR for the December, but it hadn't
17 yet got to The Lancet, which came later.

18 A. Yes.

19 MS RICHARDS: And there's a discussion about the
20 New England Journal of Medicine report.

21 Now, do you know whether this meeting, these
22 updates, were something that -- did Dr Hill come back
23 and discuss them with Professor Stuart, to your
24 knowledge, or with you?

25 A. I don't remember. This is Frank Boulton's note, isn't

162

1 was still other theories around but I think they began
2 to fall away.
3 Q. In your statement, you say that when HIV/AIDS became
4 a clinical issue, as co-directors we discussed our
5 approach and reached agreement. I'll try to find the
6 reference to that in your statement. But what
7 I wanted to ask you was what did you mean by that?
8 Co-directors is you and Dr Hill, so this is presumably
9 after you have taken over in September of 1983 as
10 director. What was the approach and the agreement
11 that was reached?

12 A. Sorry, that was from Archer or my current --

13 Q. That was from your current statement. Forgive me,
14 I'll find the reference.

15 A. Is that in relation to whether the men should be
16 looked after in the infectious diseases unit or --

17 Q. I don't think so but let me find it,
18 Professor Franklin, rather than asking you in the
19 abstract.

20 A. I think that would have been later, wouldn't it?

21 Q. There are a few references I haven't noted down.
22 I may have to come back to that tomorrow morning,
23 Professor Franklin, when I have found the reference to
24 the specific discussions you had with Dr Hill.

25 Can I ask you about the other materials which

164

your statement suggests or your Archer evidence suggests was influential on your approach and on your thinking.

You have referred in your statement to being guided by the advice of others, in particular UKHCDO and The Haemophilia Society, in terms of how to respond to the AIDS crisis.

A. I now know that wasn't The Haemophilia Society but, yes, I mean, absolutely. It was late '83, wasn't it, the meeting we went to when Morag Chisholm raised the issue of cryo? Yes.

Q. Yes, so 17 October 1983 was that meeting.

A. Yes. I mean, I think that was when I came away and thought, well, that's -- I can't remember -- I can't remember the discussion but I think that was -- we came away with a view to carry on. And then there was the next May, wasn't it, the letter from Professor Bloom to -- on The Haemophilia Society notepaper -- saying "carry on"?

So I think all the advice that I was getting from people who I would have looked up to and expected to give me definitive advice, that was where it came from.

Q. We'll take it in chronological stages. There's not too much we need to look at.

165

"... whilst it would be wrong to be complacent it would equally be counter-productive to alter our treatment programmes radically. We should avoid precipitate action and give those experts who are responsible a chance continually to assess the situation."

Was this, to some extent at least, influential on your thinking?

A. It sounds like wishful thinking now, doesn't it, but I think it was, yes. I mean, the advice of the experts -- I wasn't an expert. I wasn't an expert at bone marrow transplants and I would have taken advice from world experts in that as well. So yes, I mean I think that seemed to be the advice. Well, it was the advice -- clear, wasn't it?

Q. There's reference there to being "unaware of any proven case in our own haemophilic population". We know from other materials that there was in fact a case --

A. That seems an economy of the truth, I would have said.

Q. Do you recall when you first became aware of the Cardiff case?

A. Well, I think it was around about the same time as this. I think it was quite well known. Wasn't there a Bristol one?

167

The May '83 Haemophilia Society publication, that was actually in '83.

A. Oh, was it? Okay.

Q. That's WITN4032008.

A. I think I was aware of that at the time, even though I wasn't the co-director, because I think -- I mean, we had weekly meetings of everybody -- or maybe not -- maybe Frank wasn't there at every one of those because he was mainly at the Children's Hospital, but I do remember this.

Q. This, as we know, was authored by -- as it says, it was authored by Professor Bloom.

If we just go a little further down, please, Henry, if we pick it up about halfway down, it says:

"Bearing this in mind [that's the investment in BPL] it is important to consider the facts concerning AIDS and haemophilia. The cause of AIDS is quite unknown and it has not been proven to result from transmission of a specific infective agent in blood products."

Then it goes on to talk about the number of cases being small:

"... we are unaware of any proven case in our own haemophilia population."

And then towards the bottom of that paragraph:

166

Q. Yes.

A. Was that before or after? I don't -- I have to say I'm not sure.

Q. The Bristol case was certainly the first death, in the summer of 1983.

SIR BRIAN LANGSTAFF: Just on the same vein, I heard this morning from what counsel was saying that in June Frank Hill was told that one of the patients of his who was at Treloars had been reported to show the stigmata of AIDS.

A. Yes.

SIR BRIAN LANGSTAFF: Is that the sort of thing which you would have expected generally to have been mentioned in the UKHCDO discussions?

A. Well, I would have expected it to have been mentioned within the department, yes.

I mean, I did -- I think I may have put in my statement that I didn't recall any of the men in my clinic having stigmata of AIDS before we began testing. So if that had been the case with someone from the children's side, I would have -- well, I would have expected to know that.

SIR BRIAN LANGSTAFF: Yes. Thank you.

A. I mean, I think these are -- absolutely vital information to have.

168

1 **SIR BRIAN LANGSTAFF:** Yes.

2 **MS RICHARDS:** Then if we go from May 1983, this

3 publication, to the UKHCDO meeting that you've

4 referred to -- Henry, it's PRSE004440, please.

5 Let me check that. PRSE004440. I think

6 I omitted a zero.

7 We can see your name appearing. This is

8 17 October 1983. This would presumably have been your

9 first meeting that you attended as director?

10 **A.** Yes.

11 **Q.** If we go, please, to page 10, this is the discussion

12 that you've referred to already, Professor Franklin.

13 So Dr Morag Chisholm raising the question of reverting

14 to cryoprecipitate. Professor Bloom's response:

15 "... no need for patients to stop using the

16 commercial concentrates because at present there was

17 no proof that the commercial concentrates were the

18 cause of AIDS."

19 It might be said that's a somewhat surprising

20 statement. Do you recall whether there was any

21 challenge to that by anybody?

22 **A.** To be frank, I don't even know if I was in the room at

23 the time.

24 No, I don't have any recollection of this.

25 I mean, I've looked at it many times since. I think

169

1 vested in someone by their experience or knowledge,

2 I suppose, and I think, from reading the minute, it

3 just seemed to move effortlessly on to the -- the

4 senior figures in the UKHCDO decided that that wasn't

5 the right thing. And there was -- if Dr Chisholm

6 disagreed, there's no evidence in the minute that

7 anyone else sided with her. I think that's what

8 I mean.

9 **Q.** It may be difficult for you to answer this,

10 Professor Franklin, as I think you only attended this

11 and then the 1984 AGM, but I do not know whether from

12 your discussions with Dr Hill or any other colleagues

13 you have a view on the organisation of UKHCDO at the

14 time. Was it effectively being -- were policies and

15 recommendations being set by Professor Bloom and the

16 other older, more experienced figures? Was there too

17 much deference?

18 **A.** I think Mark Winter alluded to the fact that it would

19 have been good to have had some more direct -- well,

20 instruction or central advice rather than -- there's

21 a lot of discussion in all of these notes about, you

22 know, individual directors should decide. Well, I was

23 an individual director but I wasn't very experienced,

24 and actually neither was Mark at that time, and

25 I think we both would have benefited from something

171

1 you first showed it to Mark Winter. I remember going

2 to the meeting and I think I said in my statement that

3 I remembered going, because it was the first time

4 I had been to a meeting where people with the

5 condition that the meeting was about (i.e. people with

6 haemophilia) were actually present and I think that

7 was a good thing, but also it was a novel thing, and

8 I remember that. But no, I don't remember this.

9 **Q.** The observation you make about it in your witness

10 statement, if we just go back to that, it's

11 WITN4032001, and it's page 72 of your statement, it's

12 a sub-paragraph D in the first half of the page you

13 say:

14 "They recommended at the end of the 1983

15 meeting~...

16 That's the meeting we have just been looking at:

17 "... that patients did not switch from

18 concentrates to cryo."

19 Then you say this:

20 "I suspect that was taken not by vote but by the

21 sapiential authority of the senior figures and a lack

22 of organised alternative opinion."

23 Can I ask you to elaborate on what you meant by

24 that?

25 **A.** Well, sapiential authority is the authority that

170

1 a bit more forthright as to what to do. Even whether

2 it was right or wrong, that would have been helpful.

3 I think I've come to be not that happy about the

4 UKHCDO, to be blunt, as someone who was in a very

5 large haemophilia centre that was not a reference

6 centre and a lot of the minutes and the notes that you

7 and your colleagues have provided come from subgroups

8 of the reference centres' directors. They contained

9 far more useful information than the annual meeting of

10 the UKHCDO. I don't remember seeing those minutes.

11 I don't think those minutes were circulated to the

12 rank and file, if I can say. I think that was a shame

13 because they are far more useful than the two meetings

14 I went to.

15 I don't remember why I only went to the first

16 two. It's unlikely that I found them so unhelpful

17 that I didn't want to go, but the fact is I didn't go

18 and usually, if there was something really good and

19 valuable in meetings, I would have attended. The

20 meeting of the AIDS group for the HCDO was again

21 reference centres' doctors, very interesting minutes.

22 They would have been very helpful. So I'm sorry we

23 didn't get to see them or the hepatitis ones, we

24 didn't get to see those.

25 So I do feel a bit sad on behalf of the patients

172

1 at the Queen Elizabeth Hospital that we didn't get
2 enough advice. You know, there was more to be had,
3 I think, and I think it would have been -- it was
4 never going to be easy but it would have been better.
5 So definitely -- sorry, to cut things short. If
6 there'd have been more advice, Mark Winter mentioned
7 the CMO -- pretty silent in all this. I don't think
8 it necessarily had to be the CMO but something
9 definitive as to what we should do.

10 **MS RICHARDS:** Sir, I note the time. I am going to move on
11 to look at again some of the local West Midlands
12 meetings and the response to the HIV AIDS crisis. I'm
13 fairly confident we can finish Professor Franklin's
14 evident in the course of tomorrow morning by
15 lunchtime; so would that be a convenient point to stop
16 for today?

17 **SIR BRIAN LANGSTAFF:** Yes, it would. I'm sorry,
18 professor, I think, as you knew, but I'm sorry anyway,
19 that you have to come back and spread your evidence
20 over two days rather than one.

21 **A.** No, that's -- I'm here to help.

22 **SIR BRIAN LANGSTAFF:** Thank you very much for that.
23 There's just one thing I want to ask before you finish
24 for the day and it goes back to a question which
25 counsel asked you when she said in respect of the risk

173

1 of AIDS from blood products: when were you first clear
2 that the blood products carried AIDS?

3 Can I just alter the question a bit and say:
4 when were you first clear that there was a real risk
5 that they might?

6 **A.** Well, I suppose we were afraid they might, all
7 increasing through 1982.

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

9 **A.** I don't think I can give you even the baby date, but
10 I think that was always the worry, that that was going
11 to happen.

12 **SIR BRIAN LANGSTAFF:** Thank you very much.
13 We will take a break then until 10 o'clock
14 tomorrow. So 10 o'clock tomorrow.

15 (4.23 pm)
16 (Adjourned until 10.00 am the following day)
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24
25

174

INDEX

Presentation by MS RICHARDS	1
PROFESSOR IAN MAXWELL FRANKLIN (affirmed)	95
Questioned by MS RICHARDS	95

175

5 50 per cent [3] 32/20 83/24 156/25 52 per cent [1] 84/10 53 per cent [1] 32/19 54 [1] 29/1 55 [1] 35/3 569,000-odd [1] 111/11	abnormalities [2] 65/25 143/14 abnormality [1] 146/6 about [173] 1/8 4/23 5/17 5/22 5/24 8/18 12/6 12/8 12/19 13/9 14/7 14/10 15/2 15/3 16/8 16/12 16/15 17/5 17/12 18/7 18/21 19/14 26/3 26/11 28/14 31/16 37/16 37/16 38/1 38/16 38/21 38/25 42/3 42/13 42/17 44/19 45/3 45/7 45/25 45/25 46/3 51/16 51/19 53/14 53/17 54/1 54/7 55/8 55/19 56/16 57/12 62/6 65/1 65/3 65/10 65/11 67/11 70/13 72/5 73/6 74/5 74/8 75/15 75/19 78/4 78/22 80/12 80/15 81/18 85/3 86/17 87/23 88/1 88/9 90/12 92/1 93/1 95/11 96/15 97/12 97/22 100/4 101/3 103/1 103/3 103/11 105/25 106/4 108/18 108/25 112/16 114/6 114/17 116/2 116/13 119/19 119/21 120/5 121/11 124/3 124/6 124/11 124/12 124/13 124/17 124/19 124/25 125/1 125/1 125/5 125/13 127/2 127/7 129/17 129/21 130/11 133/5 134/5 134/14 134/23 135/12 135/18 137/10 138/3 138/6 138/20 138/21 139/20 140/4 140/9 141/1 141/9 141/19 141/20 142/7 142/12 142/24 143/8 144/10 144/24 146/18 147/8 147/8 147/9 147/13 148/6 149/24 150/1 150/8 150/24 154/12 155/3 156/24 158/15 161/4 161/12 162/8 162/9 162/19 163/4 163/5 163/9 163/10 163/11 163/16 164/25 166/14 166/21 167/23 170/5 170/9 171/21 172/3 about 75 per cent [1] 108/25 above [2] 48/7 50/5 abrupt [1] 74/15	absence [1] 121/9 absolutely [8] 34/21 91/3 91/4 91/6 156/22 162/12 165/9 168/24 abstract [1] 164/19 accept [4] 53/18 54/15 108/7 160/12 acceptable [5] 50/12 71/2 158/25 159/8 160/1 accepted [3] 53/9 68/24 135/6 access [1] 142/18 accord [1] 111/5 according [3] 6/7 20/13 93/15 accordingly [1] 61/25 account [1] 85/11 accounts [2] 51/16 154/12 accurate [1] 109/6 achieve [3] 12/20 69/23 96/24 achieved [1] 15/4 acknowledgements [1] 153/19 acquired [4] 56/13 60/8 65/19 117/9 across [4] 30/24 31/6 130/20 157/8 acting [1] 88/21 action [5] 63/13 64/13 70/19 124/16 167/4 active [6] 76/1 146/1 146/4 146/10 149/7 151/20 activity [1] 70/22 actual [5] 15/12 15/14 45/23 46/7 77/24 actually [25] 7/7 33/9 50/18 63/4 63/7 88/12 97/25 103/13 107/25 112/9 113/23 116/3 121/20 123/19 129/12 143/14 147/12 151/3 153/11 161/3 162/15 163/21 166/2 170/6 171/24 acute [7] 10/15 46/22 46/23 76/10 150/20 151/12 154/24 ad [1] 114/2 ad hoc [1] 114/2 added [1] 50/5 addition [1] 105/23 additional [1] 90/20 address [1] 124/24 adds [1] 32/4 adequacy [1] 6/1 adequate [2] 14/13 74/8 Adjourned [1] 174/16	Adjournment [1] 95/17 adjudicate [3] 54/12 126/12 133/16 adjudicating [1] 126/22 adjudication [3] 54/18 67/10 134/6 adjustment [1] 71/25 administered [2] 3/21 104/23 adopted [2] 7/25 73/8 adult [3] 6/10 6/23 110/3 adults [3] 40/24 43/18 112/15 advance [1] 25/22 advanced [1] 58/3 advancing [1] 89/3 advantage [1] 39/14 advantageous [1] 43/14 advantages [1] 53/12 advice [14] 24/14 25/18 70/15 105/18 165/5 165/20 165/22 167/10 167/12 167/14 167/15 171/20 173/2 173/6 advisable [1] 115/5 advise [2] 60/10 129/23 Advisers [1] 12/14 advising [1] 130/2 advisory [6] 3/5 39/23 68/5 71/24 72/1 159/2 affected [8] 22/23 56/23 56/23 58/22 59/4 69/17 70/19 119/9 affects [1] 149/15 affirmed [2] 95/22 175/3 afford [1] 112/17 afraid [6] 10/3 16/16 99/19 131/2 134/7 174/6 after [24] 20/5 42/5 52/22 60/1 60/16 74/23 80/24 87/19 89/12 101/6 103/15 116/17 119/20 119/23 124/15 125/17 146/23 147/4 155/14 159/5 161/20 164/9 164/16 168/2 afternoon [6] 1/12 1/16 39/20 67/12 95/13 104/18 again [42] 3/22 13/9 14/9 14/23 16/20 17/2 18/6 20/11 23/18 27/8	27/24 30/16 31/1 36/2 36/7 36/13 36/16 37/3 41/11 54/4 57/9 62/17 67/20 71/21 74/9 79/5 83/8 84/6 85/8 85/12 85/25 88/17 89/16 89/19 89/24 93/6 110/4 144/16 147/12 150/3 172/20 173/11 against [4] 12/7 103/24 148/7 155/23 age [2] 45/7 86/16 agencies [2] 159/2 160/2 agent [3] 57/18 154/20 166/19 AGM [1] 171/11 ago [9] 18/1 18/20 30/20 59/25 83/5 103/12 116/23 120/20 127/18 agree [3] 156/21 157/17 159/5 agreed [23] 9/9 10/13 11/17 11/23 19/5 33/23 43/18 53/9 54/9 54/17 60/16 60/20 61/23 64/9 68/20 69/14 71/14 126/8 132/22 133/14 133/24 142/4 142/6 agreement [6] 17/4 17/17 45/21 123/23 164/5 164/10 Ah [2] 93/5 159/24 AHF [3] 75/14 76/9 76/14 AI [2] 81/12 85/21 AIDS [68] 37/24 38/2 39/23 53/23 55/9 56/2 56/17 56/20 58/1 59/22 60/9 60/12 61/15 61/16 61/20 62/8 62/10 62/14 62/19 63/4 63/25 64/6 64/9 64/13 66/12 66/17 67/22 68/2 68/5 68/10 68/19 69/1 69/4 71/1 71/24 72/1 81/1 81/3 81/5 82/17 82/18 83/12 83/18 117/19 129/21 129/22 132/18 132/22 133/4 140/22 150/1 158/16 160/22 161/6 162/8 163/13 163/19 164/3 165/7 166/17 166/17 168/10 168/19 169/18 172/20 173/12 174/1 174/2 AIDS-related [1] 62/14 aim [1] 115/18	airport [2] 53/21 56/3 Ala [10] 40/6 55/15 60/6 60/10 64/7 66/17 114/13 116/19 129/25 131/15 Ala's [1] 61/12 Albans [1] 98/18 alcohol [1] 149/22 Aledort [2] 146/9 147/19 all [58] 10/9 10/22 15/1 16/5 17/14 22/12 22/16 23/1 24/24 25/4 29/5 39/3 41/17 41/24 43/3 43/23 52/6 52/25 56/11 57/2 61/18 66/9 70/18 71/11 71/14 72/16 72/22 75/16 84/1 90/23 94/20 104/15 105/5 107/2 107/4 108/23 113/16 114/5 114/25 115/14 120/4 120/6 123/10 127/19 127/22 134/7 135/4 135/6 147/5 147/6 150/15 159/10 160/18 161/6 165/20 171/21 173/7 174/6 allegations [1] 88/2 Allen [1] 125/8 allergic [1] 72/18 allocation [3] 13/16 13/21 73/23 allocations [1] 9/6 allow [2] 25/18 158/17 allowed [1] 10/23 alluded [3] 88/15 103/16 171/18 alone [3] 9/22 19/24 21/16 along [2] 22/20 147/8 Alpha's [1] 41/19 already [9] 57/3 64/3 86/16 88/10 89/2 95/7 106/12 135/25 169/12 also [31] 5/20 5/23 9/4 12/10 25/18 28/2 35/20 44/13 51/6 53/11 57/25 62/3 78/25 93/12 97/23 108/4 117/18 124/22 134/17 136/5 149/14 149/23 150/2 152/25 153/22 156/2 156/23 159/5 161/9 161/16 170/7 alter [3] 157/11 167/2 174/3 alterations [1] 17/10 altered [2] 52/8 65/11 alternative [1] 170/22 although [14] 2/13 4/2
--	--	---	---	---	---

(46) 50 per cent - although

A	21/10 21/14 27/2 27/3 27/5 29/10 29/25 41/4 47/25 63/20 66/21 110/4 133/11 172/9 annum [1] 61/6 anonymous [1] 81/7 another [12] 20/8 55/1 76/6 86/9 86/12 113/9 113/10 128/21 150/11 153/20 153/24 154/11 answer [1] 171/9 answered [1] 73/18 antibodies [8] 21/21 27/18 29/1 29/2 30/3 30/4 68/18 83/23 antibody [6] 68/21 84/10 84/23 88/11 88/22 93/9 anxious [1] 72/12 any [97] 7/13 7/17 17/17 26/17 37/23 53/16 54/24 55/19 58/8 58/8 58/18 59/11 59/13 60/19 61/11 62/1 62/23 63/6 63/7 63/13 64/9 64/13 71/7 71/16 73/18 74/12 74/15 77/3 77/12 79/1 80/19 81/13 81/25 82/8 82/8 89/12 93/1 94/6 94/22 95/1 95/11 96/11 99/14 99/16 99/17 100/21 101/1 104/2 104/6 107/6 107/12 109/12 111/6 112/12 115/13 116/12 118/3 119/24 121/9 122/25 123/5 123/12 123/25 125/12 128/6 128/9 128/19 129/5 130/4 130/14 131/19 131/23 132/11 132/15 132/22 132/25 134/11 134/12 135/1 135/9 137/12 137/12 137/13 137/18 140/23 146/17 148/1 148/22 149/19 157/8 163/9 166/23 167/16 168/18 169/20 169/24 171/12 anybody [1] 169/21 anymore [1] 131/3 anyone [3] 112/9 163/3 171/7 anything [9] 73/16 97/12 116/2 127/2 134/5 134/21 134/24 140/24 149/9 anyway [1] 173/18 anywhere [1] 94/6 apart [3] 91/8 122/15 134/25	apologies [3] 61/15 129/13 133/8 apparent [4] 33/6 55/18 86/11 89/22 apparently [3] 16/20 29/4 60/19 appear [13] 14/17 15/17 20/6 20/9 20/24 30/5 67/25 72/7 91/14 92/22 115/10 131/19 159/7 appeared [1] 74/5 appearing [3] 57/6 147/2 169/7 appears [23] 7/16 14/1 20/12 20/19 26/23 34/15 40/12 41/25 44/11 55/20 63/10 74/4 74/19 78/23 86/4 117/2 117/5 123/8 126/13 127/23 129/24 133/17 162/7 appendix [2] 47/13 67/4 appendix 1 [1] 47/13 Application [1] 5/1 applied [2] 3/24 5/4 applies [1] 150/21 applying [2] 130/13 130/21 appointed [5] 5/2 6/17 7/3 7/5 107/10 appointment [7] 5/14 7/7 7/11 14/18 85/14 89/23 100/5 appraisal [1] 61/4 appraised [1] 70/19 appreciate [1] 74/16 appreciation [2] 98/8 128/6 approach [16] 38/21 58/9 59/11 59/13 59/20 60/20 71/8 89/9 115/7 122/25 134/23 138/24 148/22 164/5 164/10 165/2 approaches [1] 38/16 appropriate [6] 5/4 53/16 66/18 66/24 87/10 137/16 approximately [5] 75/11 97/4 101/6 109/4 152/2 April [5] 7/5 69/11 82/14 83/10 108/16 April '76 [1] 7/5 April 1986 [1] 108/16 arcane [1] 130/19 ARCH0000008 [1] 143/6 ARCH0000443 [1]	138/11 Archer [7] 103/21 108/4 138/10 143/5 143/19 164/12 165/1 Archer Inquiry [4] 103/21 108/4 138/10 143/5 architecture [1] 52/9 are [91] 3/23 4/3 5/7 12/11 12/18 13/17 15/4 22/6 22/17 22/19 23/2 23/4 23/13 23/20 24/9 25/3 27/23 28/17 30/23 32/1 32/5 32/10 37/25 43/5 44/9 44/15 45/16 46/2 46/3 47/12 54/16 55/3 59/16 60/22 62/11 62/14 62/16 65/18 66/10 71/18 72/17 72/22 76/11 77/25 79/7 79/17 79/23 83/24 86/22 86/25 87/9 87/16 87/18 89/11 90/6 92/3 93/17 95/20 100/22 102/23 108/25 109/2 113/4 114/12 116/19 117/15 121/16 130/24 132/25 136/23 138/15 138/25 139/1 139/1 140/1 144/20 147/17 148/10 150/12 152/19 152/25 153/24 154/4 154/16 159/25 160/7 164/21 166/23 167/4 168/24 172/13 area [7] 91/8 91/16 94/1 94/2 106/25 145/17 158/1 areas [1] 104/5 arise [1] 10/24 ARMO0000370 [1] 92/8 ARMO0000375 [1] 83/8 ARMO0000510 [1] 90/9 ARMO0000519 [1] 74/24 ARMO0000585 [1] 93/4 Armour [44] 19/24 20/11 20/23 28/1 29/5 30/10 30/14 30/16 35/12 35/19 36/7 36/17 37/8 38/4 40/8 40/12 41/18 51/16 51/24 52/12 53/8 53/10 55/17 69/11 71/14 72/23 73/1 79/4 84/7 91/24 91/24 92/2 92/12 92/23 93/9	94/18 94/21 111/13 115/11 115/19 115/19 123/8 123/20 131/16 Armour Factor XIII [1] 94/21 Armour's [2] 52/4 90/13 ARNO0000391 [1] 84/6 around [15] 18/2 19/24 28/16 30/12 59/21 62/3 78/24 98/19 100/3 105/21 109/22 119/21 147/11 164/1 167/23 arranged [1] 50/8 arrangement [2] 74/1 74/19 arrangements [10] 3/8 18/22 20/13 20/20 21/6 83/2 111/17 120/16 123/6 123/12 arrived [3] 8/11 123/9 125/16 arthritis [2] 81/4 139/18 article [4] 80/25 161/17 161/23 163/9 articles [2] 57/9 57/10 articulated [1] 134/2 as [192] ashamed [2] 155/21 157/14 ask [18] 67/11 95/24 101/3 102/23 103/3 104/12 124/13 132/7 134/17 134/18 135/11 138/19 140/20 147/13 164/7 164/25 170/23 173/23 asked [9] 33/17 43/14 74/9 85/6 90/18 134/15 134/18 134/20 173/25 asking [4] 103/1 124/12 129/23 164/18 asks [1] 60/10 aspect [1] 135/2 assess [3] 24/12 74/13 167/5 assessed [1] 44/23 assessment [4] 133/18 136/17 136/19 138/6 assist [4] 5/5 130/8 156/17 157/16 assists [1] 120/21 associated [6] 10/22 66/1 68/19 68/25 91/21 92/4 associating [1] 160/7 assumed [1] 75/16	assumes [1] 152/11 assuming [2] 57/19 156/8 assumption [2] 128/12 128/14 assured [1] 74/9 atmosphere [1] 157/24 attack [4] 45/10 76/13 76/15 76/16 attempt [1] 157/17 attempting [1] 22/19 attempts [1] 87/14 attend [5] 75/8 96/14 109/4 131/5 132/14 attendance [4] 8/10 13/5 48/22 132/13 attended [15] 14/22 43/6 44/7 44/13 46/8 54/4 63/19 64/18 75/7 75/12 105/17 162/5 169/9 171/10 172/19 attendees [3] 53/24 56/5 162/4 attending [5] 3/1 3/15 44/11 73/12 103/9 attention [9] 10/14 10/17 25/11 52/17 55/5 57/3 57/7 153/22 154/5 attitude [3] 38/18 38/18 51/17 attitudes [1] 38/22 attractive [1] 100/9 August [2] 20/9 98/22 August 1982 [1] 98/22 author [6] 75/2 75/10 78/8 143/12 153/17 153/20 authored [2] 166/11 166/12 authorities [1] 5/4 authority [13] 8/7 9/8 13/3 51/16 51/24 92/17 103/18 103/24 126/16 130/18 170/21 170/25 170/25 Authority's [1] 125/22 authors [2] 77/11 153/13 autumn [1] 79/2 availability [10] 8/16 9/25 15/2 17/13 48/19 52/16 70/10 135/21 136/17 136/18 available [16] 3/10 5/25 23/11 24/4 39/7 39/10 62/16 64/8 66/18 69/7 69/12 70/6 89/15 114/3 115/13 139/16
----------	--	--	--	---	--

(47) although... - available

A	BCH [1] 5/23 be [200] Beard [1] 85/24 bearing [3] 43/23 156/8 166/15 became [13] 8/8 73/24 74/8 86/11 89/22 101/18 103/6 109/24 125/18 128/10 155/13 164/3 167/21 because [32] 8/11 31/12 33/20 45/16 55/7 72/17 72/18 72/20 73/16 75/8 87/13 98/14 100/6 108/3 108/5 116/25 132/25 139/3 146/24 150/5 152/8 152/19 158/10 158/22 161/1 161/4 161/9 166/6 166/8 169/16 170/3 172/13 become [4] 23/5 23/11 48/11 81/17 becoming [3] 113/11 130/1 145/1 been [134] 5/2 5/10 5/17 5/21 7/5 9/7 13/11 13/14 15/10 15/17 16/10 17/4 19/2 19/23 20/12 20/19 22/6 24/11 27/24 30/6 31/13 31/14 31/20 32/17 33/1 33/9 33/16 34/5 34/9 37/20 41/8 46/23 47/21 49/24 50/5 51/16 54/13 55/1 56/19 58/15 58/18 71/7 74/4 74/17 74/19 76/23 77/2 77/12 78/3 78/7 78/23 80/4 81/13 83/1 83/15 83/20 84/19 86/8 86/24 88/1 88/8 88/12 89/3 89/21 91/17 92/20 92/24 95/8 98/3 99/1 101/21 105/7 111/22 113/12 114/18 114/20 115/2 115/3 115/6 115/11 116/21 117/2 117/7 118/2 118/3 119/6 120/10 122/12 122/19 122/21 122/23 123/8 126/1 126/12 126/13 127/7 128/21 131/1 131/22 132/1 132/6 134/8 134/10 134/17 135/25 136/9 142/23 151/12 151/13 151/24 154/20 154/21 155/19 155/20 158/8 159/8 162/10 162/11 162/15	164/20 166/18 168/9 168/13 168/15 168/20 169/8 170/4 170/16 171/19 172/2 172/22 173/3 173/4 173/6 before [30] 25/22 26/17 31/9 53/7 57/16 58/12 60/17 62/15 74/15 92/6 93/19 94/8 107/11 112/6 123/25 125/15 125/17 139/15 140/23 142/15 144/23 145/1 147/10 152/6 160/21 162/6 162/11 168/2 168/19 173/23 beforehand [1] 23/3 beg [1] 127/25 began [4] 147/4 147/9 164/1 168/19 beginning [5] 43/9 49/14 55/25 57/17 129/4 behalf [2] 57/15 172/25 being [69] 9/7 12/22 13/13 13/23 15/4 15/25 16/3 19/12 19/14 21/16 21/18 21/25 29/4 29/6 29/9 32/5 34/13 35/8 35/17 35/23 40/15 41/19 46/7 46/14 51/24 55/23 57/7 58/3 62/21 62/22 64/25 67/14 67/15 70/19 80/23 81/3 82/15 85/15 85/16 85/20 86/17 95/1 107/13 110/5 111/1 111/7 111/8 122/2 124/7 125/5 129/6 130/9 132/19 133/2 136/6 140/24 144/5 144/11 149/3 149/10 161/13 163/3 163/12 163/19 165/4 166/22 167/16 171/14 171/15 believe [4] 52/7 78/19 104/10 105/6 believed [1] 93/12 believes [1] 78/18 belonged [1] 103/6 benefit [2] 4/1 61/7 benefited [1] 171/25 benefits [1] 158/11 benign [4] 144/6 144/12 155/9 157/21 bespoke [1] 109/12 best [6] 74/17 88/21 112/24 114/12 124/22 127/5 better [3] 20/2 114/22	173/4 between [26] 2/10 6/14 6/20 7/7 7/14 15/21 17/4 20/21 32/21 48/21 74/20 76/25 79/14 85/19 90/10 91/24 92/10 96/2 96/4 97/2 116/1 116/6 121/20 137/23 138/3 139/4 beyond [4] 112/17 125/14 129/10 137/14 big [4] 99/5 109/17 137/6 163/17 bigger [1] 147/20 Biggs [1] 12/22 biopsies [8] 45/1 75/24 146/9 146/12 148/6 155/3 155/5 156/25 biopsy [1] 145/16 Bird [3] 8/21 13/10 33/19 Bird's [1] 9/16 Birmingham [43] 1/3 1/8 1/10 1/14 1/21 2/9 4/25 5/16 6/2 6/19 7/25 9/16 11/4 12/3 13/21 14/24 26/7 32/15 39/2 51/13 55/24 56/9 59/7 62/24 63/17 73/13 74/13 74/20 78/18 82/13 84/9 84/14 87/7 90/15 92/17 95/11 95/13 100/1 102/24 107/1 109/1 148/2 163/12 birth [2] 49/5 49/6 Bishop [1] 78/17 bit [18] 28/9 63/5 105/15 106/23 107/18 113/13 121/21 133/1 137/14 140/4 141/6 147/10 157/24 159/22 160/6 172/1 172/25 174/3 bladder [1] 137/5 blank [1] 4/18 bleed [3] 24/12 105/19 138/8 bleeding [7] 22/16 97/8 99/8 100/17 101/20 109/3 156/9 bleeds [5] 23/7 26/2 107/24 138/25 139/17 blind [1] 88/8 blood [54] 1/24 6/11 7/23 9/9 9/11 13/10 14/4 24/4 25/21 26/16 38/2 56/24 60/13 61/17 63/3 63/7 64/7 66/20 70/21 71/17	80/13 97/20 98/9 102/10 102/20 105/12 118/24 121/16 121/19 124/13 124/15 132/20 141/2 141/2 141/5 141/8 141/16 142/24 150/21 150/22 154/8 154/17 157/25 159/3 159/3 159/13 160/3 160/3 163/15 163/19 163/19 166/19 174/1 174/2 Bloom [8] 57/14 58/13 63/23 64/24 140/6 165/18 166/12 171/15 Bloom's [2] 72/4 169/14 blunt [1] 172/4 blush [1] 133/1 BMJ [1] 72/5 body [1] 121/15 bone [6] 98/24 100/6 100/11 102/6 146/25 167/12 book [7] 150/13 150/16 153/13 153/23 154/2 156/11 158/18 Borton [1] 106/13 boss [1] 98/25 both [24] 4/9 5/9 5/22 12/19 22/9 36/15 36/17 37/6 38/24 44/11 48/17 73/25 77/5 87/1 87/7 104/7 110/12 111/8 111/25 114/19 115/17 143/23 151/8 171/25 bottles [3] 3/20 30/7 31/13 bottom [27] 8/14 11/13 16/24 18/6 18/9 18/11 22/19 25/20 32/12 40/5 40/19 41/20 45/6 48/5 49/9 49/18 52/23 55/13 56/13 60/3 62/7 65/9 66/21 88/18 129/14 150/17 166/25 bought [1] 124/9 Boughton [2] 106/14 106/15 Boulton's [1] 162/25 bovine [1] 28/3 bowel [1] 136/12 box [1] 23/23 boys [3] 65/12 72/22 72/25 BPL [20] 17/5 17/6 17/9 33/21 34/11 39/22 66/23 73/5 73/8 74/2 74/10 74/20 116/7 118/20 120/11	123/15 125/4 133/11 142/4 166/16 BPL's [1] 73/14 BPLL0000853 [2] 116/16 118/18 BPLL0006105 [1] 73/3 Bradford [2] 1/4 1/19 break [9] 42/5 42/6 42/7 42/10 140/12 140/13 140/16 140/18 174/13 breaking [1] 91/10 Brian [2] 106/13 141/4 brief [1] 132/8 briefly [3] 56/2 74/24 144/19 Bristol [2] 167/25 168/4 British [3] 64/19 77/16 142/21 broader [1] 12/21 broadly [2] 28/7 28/15 brokers [1] 128/8 brought [1] 158/12 brown [2] 25/14 25/15 BSHA0000119 [1] 64/17 BTC [1] 10/8 BTS [3] 14/15 33/17 33/20 budget [1] 129/10 building [1] 9/10 bulk [2] 36/6 36/16 bullet [1] 159/21 bush [1] 162/14 Business [2] 132/12 132/15 busy [1] 105/11 but [196] buy [1] 19/5 buying [3] 9/23 10/19 11/8 BWCT [1] 31/10 BWCT0000137 [1] 34/24 BWCT0000140 [1] 36/12 BWCT0000141 [1] 36/1 BWCT0000142 [1] 36/23 BWCT0000143 [1] 41/14 BWCT0000145 [1] 21/14 BWCT0000189 [2] 29/25 31/11 BWCT0000190 [1] 28/23 by [146] 1/5 2/17 2/19 9/7 9/25 11/8 12/22
----------	--	---	--	---	--

<p>B</p> <p>by... [139] 13/12 13/17 13/24 13/25 14/15 14/23 15/7 15/23 16/9 17/18 19/8 19/20 20/18 22/7 25/4 26/9 28/1 28/2 28/6 28/12 28/23 29/25 30/12 32/6 32/20 34/5 35/10 35/12 35/15 36/10 37/1 37/20 38/2 40/6 43/6 44/18 46/4 46/8 46/24 48/15 51/12 51/21 52/10 53/8 53/10 54/4 55/16 56/16 58/13 58/15 58/19 58/25 59/6 62/18 64/23 64/25 65/6 65/8 65/13 65/15 65/21 65/23 66/22 67/10 67/14 67/15 68/4 68/6 73/22 75/7 75/10 75/12 75/24 76/6 76/11 77/11 77/19 78/7 78/14 80/4 83/1 86/8 86/14 86/23 87/4 87/18 89/20 90/14 90/22 91/17 95/23 105/24 107/13 108/3 108/15 111/4 117/21 119/9 120/11 121/15 123/22 127/8 127/11 131/8 131/16 133/18 134/17 136/19 139/13 141/10 142/10 144/22 144/24 148/8 149/25 150/3 152/10 159/1 159/3 159/4 159/6 160/1 161/10 163/8 163/19 163/24 164/7 165/5 166/11 166/12 169/21 170/20 170/20 170/23 171/1 171/15 173/14 175/2 175/4</p>	<p>158/20 162/17 163/25 165/13 165/16 165/22 can [131] 2/21 2/24 3/4 3/13 4/22 7/10 7/12 8/10 8/15 8/21 13/4 13/8 17/7 18/6 18/19 18/21 19/19 21/22 23/16 24/13 24/23 27/8 27/16 27/20 29/17 31/6 31/9 35/3 35/6 35/25 36/4 36/13 37/3 37/22 40/25 41/11 41/15 44/9 44/15 44/17 45/15 46/7 50/24 51/20 56/5 56/14 59/6 60/15 62/6 62/20 64/22 64/24 67/5 67/11 68/7 71/10 72/9 73/15 76/5 79/22 80/1 82/11 87/12 92/4 94/23 97/12 98/5 104/2 104/12 107/9 108/21 110/4 110/9 110/12 110/22 111/1 111/8 111/20 111/23 112/21 116/2 119/12 122/9 123/10 124/11 125/1 125/12 125/25 126/6 126/23 127/2 129/1 129/5 129/16 130/8 131/7 131/13 132/11 133/9 134/5 134/22 135/1 135/2 135/15 136/20 137/18 140/24 145/15 145/23 146/20 149/2 149/9 149/23 150/17 151/7 151/8 152/7 152/18 153/18 154/19 155/1 156/5 156/20 159/12 164/25 169/7 170/23 172/12 173/13 174/3 174/9 can't [13] 75/6 87/4 97/14 113/23 121/10 122/10 124/15 127/12 131/2 134/7 146/21 165/14 165/14 cancer [2] 136/12 137/3 cannot [1] 73/18 capacity [2] 87/21 93/24 capital [3] 9/10 130/17 130/23 Cardiff [1] 167/22 care [17] 2/9 3/7 3/23 4/14 63/1 72/22 90/10 93/17 99/7 100/12 100/17 100/23 104/9 105/16 108/19 109/25</p>	<p>139/15 career [3] 6/10 95/25 142/21 carried [4] 48/9 96/16 146/9 174/2 carrier [1] 35/4 carriers [7] 35/2 37/2 48/11 82/19 110/21 110/23 111/25 carry [10] 26/19 66/11 115/19 115/20 139/21 139/21 140/6 155/21 165/16 165/19 case [25] 42/22 43/19 46/6 57/1 58/3 64/9 64/11 90/14 91/1 91/9 104/2 120/24 132/22 132/24 153/3 160/8 162/9 163/5 163/24 166/23 167/17 167/19 167/22 168/4 168/20 cases [10] 45/22 46/15 47/9 56/24 104/4 104/6 121/7 144/7 154/9 166/22 cast [1] 132/25 catch [1] 41/8 causative [1] 65/21 cause [8] 40/9 60/12 63/4 63/25 77/5 119/10 166/17 169/18 caused [1] 52/10 causes [2] 45/13 47/4 causing [1] 77/2 caution [1] 142/7 CBLA0000940 [3] 29/12 30/19 31/25 CBLA0002092 [1] 72/10 cease [1] 70/21 ceased [1] 7/17 cell [8] 65/11 96/9 96/14 100/7 100/8 100/11 142/24 147/1 cells [2] 98/9 142/2 cent [22] 9/14 32/19 32/19 32/20 47/16 56/20 76/15 76/16 82/14 83/24 84/10 108/23 108/25 120/20 121/18 121/20 146/11 147/22 149/7 150/24 154/12 156/25 centigrade [2] 24/19 25/1 central [8] 14/14 18/10 18/12 18/16 18/23 92/17 130/25 171/20 centre [63] 1/20 1/24 2/12 2/17 4/10 4/11 4/14 4/14 4/16 6/18</p>	<p>8/22 9/11 12/12 12/15 13/19 14/5 14/8 20/18 21/1 23/8 34/22 39/21 40/7 40/17 46/11 68/3 70/17 71/17 75/4 75/9 90/24 91/2 97/21 99/12 100/13 101/6 101/18 102/1 103/7 104/13 109/11 109/13 109/17 109/20 109/22 109/23 109/25 110/3 114/14 115/4 116/20 117/1 118/20 120/3 120/9 120/12 126/20 132/20 135/21 141/17 141/22 172/5 172/6 Centre's [1] 13/11 centres [19] 1/9 4/4 9/23 10/23 11/5 17/5 17/14 20/18 20/23 38/15 39/3 68/4 73/12 73/21 73/25 87/2 118/23 119/4 130/12 centres ... Dr Hill [1] 39/3 centres' [2] 172/8 172/21 cerebral [2] 139/5 139/25 certain [8] 46/18 74/22 75/6 80/14 124/18 124/19 124/25 124/25 certainly [18] 7/11 11/9 34/4 105/8 112/15 121/12 123/16 128/9 143/10 144/5 144/6 145/9 147/11 149/18 153/18 154/3 163/24 168/4 cetera [2] 61/6 61/6 chair [3] 2/4 87/21 163/6 chaired [2] 64/23 75/12 Chairman [2] 69/8 163/22 challenge [1] 169/21 chance [2] 81/4 167/5 chances [2] 81/3 113/11 change [21] 33/6 33/9 37/23 53/13 54/24 55/17 58/9 59/11 59/13 59/18 59/20 60/20 61/1 69/15 81/9 114/23 116/24 117/18 119/17 128/19 131/17 changed [6] 19/2 40/23 109/21 110/2 135/22 139/12 changes [4] 63/14</p>	<p>71/7 119/21 156/25 changing [3] 54/20 82/6 126/25 channels [1] 5/12 chap [1] 141/3 chapter [1] 153/11 character [1] 155/22 characteristic [1] 151/14 charge' [1] 74/2 charges [1] 73/6 Charles [2] 87/22 143/24 Charles Hay [1] 143/24 chart [1] 121/5 check [5] 7/10 7/12 26/15 94/25 169/5 checking [1] 153/15 child [4] 58/10 80/10 80/16 85/8 children [32] 3/23 25/17 25/19 31/22 40/16 40/23 43/16 43/20 43/24 48/10 56/8 59/3 59/8 68/14 70/18 73/11 73/13 83/3 83/15 83/20 83/23 84/1 84/14 85/6 88/12 91/12 91/18 92/20 93/8 93/17 97/8 122/21 children's [70] 1/10 2/10 2/15 3/12 4/12 5/3 6/19 6/21 7/15 7/19 9/15 13/6 20/15 20/21 21/13 21/15 27/5 28/20 28/22 29/24 31/8 31/22 32/1 32/14 34/18 34/24 35/11 35/18 36/2 38/7 38/24 41/15 43/25 48/10 51/13 55/24 56/9 59/7 62/25 63/17 67/3 68/12 68/17 72/9 73/7 73/13 74/21 80/23 81/19 82/13 82/15 82/24 83/3 84/9 84/14 87/1 87/7 87/24 90/15 107/1 107/1 107/7 109/1 109/24 120/23 122/12 122/19 126/21 166/9 168/21 Children's Hospital [1] 32/1 chimpanzees [1] 154/21 Chisholm [4] 63/22 165/10 169/13 171/5 choice [9] 51/21 52/15 137/19 137/23 137/25 138/3 138/4</p>	<p>138/5 139/4 Christie [1] 90/25 Christmas [13] 3/2 3/16 3/19 21/21 27/7 27/12 27/19 28/4 29/1 29/8 29/17 29/21 30/3 chronic [24] 44/22 44/24 45/5 45/9 45/12 45/22 47/10 47/12 47/22 76/1 76/1 146/1 146/4 146/10 149/6 149/7 150/17 150/20 151/2 151/8 151/19 151/20 152/9 155/8 chronicity [2] 150/23 151/11 chronological [1] 165/24 circular [2] 22/13 22/15 circulated [1] 172/11 circumspect [1] 59/2 circumstances [2] 90/21 138/7 cirrhosis [11] 47/6 75/20 76/2 146/3 146/11 147/22 149/8 151/24 152/24 155/1 157/1 City [1] 98/18 clean [1] 138/14 cleanest [1] 52/5 clear [13] 5/10 20/7 22/4 26/5 35/15 73/24 134/24 155/13 163/18 163/25 167/15 174/1 174/4 clearly [3] 77/18 109/16 143/13 Cleghorn [1] 141/23 clinic [9] 7/1 89/23 96/14 96/18 104/17 106/5 106/21 149/25 168/19 clinical [18] 6/16 7/20 47/21 48/24 63/6 66/7 73/14 73/23 74/14 74/22 96/11 101/15 151/7 151/23 152/8 152/15 154/22 164/4 clinically [2] 62/9 69/23 clinician [1] 91/8 clinician's [1] 38/18 clinicians [4] 88/20 89/3 118/15 158/9 clinics [2] 107/5 107/7 closely [1] 52/3 clotting [1] 124/9 CMO [2] 173/7 173/8 co [8] 65/13 104/15</p>
---	--	---	--	--	---

C					
co... [6] 107/16 116/20 153/13 164/4 164/8 166/6	44/4 48/8 49/12 50/15 52/2 52/19 53/5 54/2 54/11 55/8 59/8 63/24 65/20 66/25 67/8 70/1 70/5 70/7 76/15 77/1 77/6 92/24 97/17 111/13 115/1 116/9 116/25 117/6 120/15 122/7 122/9 122/20 123/6 123/10 123/13 123/16 123/25 126/18 128/6 130/7 133/13 136/2 137/24 142/7 154/16 169/16 169/17	17/2 18/8 21/9 21/25 22/1 23/10 27/9 27/11 27/13 27/22 28/4 28/7 28/8 28/10 28/12 29/5 29/6 29/9 30/8 30/10 30/11 30/18 31/1 31/2 31/3 31/21 32/18 35/10 35/13 35/23 36/5 36/15 36/17 36/19 37/6 37/13 37/13 43/12 43/15 43/16 43/22 46/17 60/8 67/7 67/23 68/9 68/22 68/25 72/13 72/20 77/1 77/1 77/3 81/10 84/2 92/2 105/11 109/5 110/12 111/8 112/2 115/20 115/21 120/2 120/11 122/20 136/13 137/7 137/24 137/24 139/21 139/22 140/7 155/17	confess [1] 140/4 confidence [1] 61/11 confident [1] 173/13 confidentiality [1] 105/14 confirmatory [1] 160/14 conflicts [1] 85/10 conscious [3] 39/12 79/24 90/6 consensus [1] 108/9 consequences [7] 10/19 16/15 42/21 130/15 130/16 130/22 157/5 consider [5] 42/12 56/1 134/13 140/21 166/16 considerable [4] 11/11 23/8 61/7 95/6 consideration [9] 19/15 54/18 55/18 67/9 95/12 126/24 128/18 129/6 133/25 considered [11] 9/24 15/7 53/7 55/24 58/4 58/22 69/6 88/20 112/17 115/5 144/11 considering [3] 38/1 55/4 91/24 consistent [1] 144/6 constant [2] 32/17 62/2 constantly [1] 61/24 consultant [8] 3/5 6/18 99/25 101/9 101/25 102/6 107/10 126/3 consulted [1] 81/8 consulting [1] 150/5 Consumptions [1] 15/8 contact [1] 64/14 contained [1] 172/8 contains [1] 154/3 contamination [1] 65/20 contemplated [1] 40/21 contemplation [1] 30/13 contemporaneous [2] 5/24 43/2 context [4] 14/7 25/12 26/25 114/8 continually [1] 167/5 continue [13] 1/15 33/15 34/10 57/4 59/3 59/16 70/1 70/5 74/1 92/17 95/12 101/9 115/12 continued [7] 6/2 7/16	9/20 36/1 101/12 102/17 112/24 continues [6] 4/22 35/22 36/11 38/3 74/7 83/22 continuing [3] 41/2 57/5 82/22 continuity [1] 114/15 contract [25] 16/10 18/3 19/12 19/21 19/22 20/5 20/8 20/11 20/12 30/13 38/9 50/20 53/1 53/4 53/8 53/15 54/7 55/14 123/7 123/11 123/14 123/24 126/7 131/14 134/3 contract's [1] 131/22 contracted [1] 51/24 contracting [3] 94/3 111/17 120/16 contracts [6] 18/13 18/17 18/23 21/2 21/5 120/6 contractual [1] 18/21 Contreras [1] 97/24 contributed [1] 47/3 contributions [1] 89/11 controversy [1] 74/18 conurbations [1] 128/4 convenient [2] 140/11 173/15 conversation [2] 87/21 163/9 conversations [1] 163/11 converse [1] 122/18 cool [1] 23/24 coping [1] 89/2 copy [3] 92/15 135/12 145/11 Core [3] 22/7 26/9 95/9 Corporation [1] 131/17 correct [3] 100/7 108/10 112/10 correctly [1] 137/19 correspondence [6] 79/13 85/24 91/23 116/6 119/16 127/8 cost [6] 5/11 10/19 16/15 33/3 39/12 71/15 cost-conscious [1] 39/12 costing [1] 33/7 costs [1] 19/3 couch [1] 104/22 could [49] 2/22 4/8	4/17 4/25 5/11 5/15 8/2 12/25 22/12 27/3 28/6 31/5 33/18 42/5 43/3 44/9 44/14 48/3 48/25 51/8 52/10 59/23 60/17 64/16 71/5 71/16 86/1 88/25 89/8 98/10 100/24 104/22 105/6 108/14 113/10 114/7 114/23 115/21 118/10 122/13 125/15 125/20 133/12 137/2 138/8 138/11 138/17 153/4 159/20 couldn't [3] 81/17 99/12 138/14 Council [2] 96/6 141/20 counsel [3] 153/16 168/7 173/25 counter [1] 167/2 counter-productive [1] 167/2 couple [7] 57/12 96/16 105/25 114/6 116/17 119/25 121/23 course [33] 1/22 2/6 12/23 23/2 23/12 27/25 36/13 37/25 38/4 40/2 40/4 41/9 43/23 57/25 59/6 77/24 83/1 86/25 87/3 92/19 93/9 93/15 95/10 97/7 103/19 129/6 133/15 136/22 140/22 149/23 151/22 154/22 173/14 court [2] 104/7 104/11 Coventry [4] 4/5 13/19 106/25 126/21 cover [12] 26/13 26/20 26/22 46/17 49/14 50/2 50/3 50/13 69/13 101/13 122/2 137/7 covered [3] 95/5 107/4 136/18 covering [1] 106/19 Craske [7] 44/19 45/5 45/8 45/19 56/16 144/25 156/23 crisis [3] 159/14 165/7 173/12 criteria [4] 55/3 55/4 123/24 126/23 critical [1] 119/18 crops [1] 153/1 cross [2] 39/6 141/7 cross-match [1] 141/7 cross-reactivity [1] 39/6

(50) co... - cross-reactivity

C	142/6 153/7 damning [1] 125/5 dangerous [1] 141/5 data [6] 4/7 46/18 77/24 78/2 78/6 149/12 database [1] 93/25 date [9] 7/8 7/13 49/5 49/6 56/22 82/8 85/19 161/8 174/9 dated [7] 7/5 26/10 62/4 73/5 75/1 92/12 125/25 dates [3] 48/21 49/10 71/19 day [5] 75/9 100/21 101/1 173/24 174/16 days [5] 44/11 50/3 60/1 121/23 173/20 DDAVP [11] 41/21 41/23 42/1 58/22 69/18 121/11 121/15 121/21 123/4 136/10 137/2 deal [3] 17/21 23/12 100/21 dealing [4] 2/3 2/8 81/1 100/17 dealings [1] 39/16 dealt [1] 19/4 Dear [1] 92/14 death [4] 47/3 68/10 148/11 168/4 deaths [1] 82/17 debate [1] 74/4 December [24] 8/10 19/18 39/21 48/2 48/4 49/11 49/15 51/7 55/12 56/19 64/3 64/3 64/14 67/13 67/16 67/21 68/4 71/4 71/12 119/8 131/8 132/18 162/16 163/7 December 1979 [2] 19/18 49/15 December 1983 [5] 55/12 64/3 64/14 119/8 132/18 December 1984 [1] 39/21 December of [1] 163/7 decent [1] 139/15 decide [2] 24/12 171/22 decided [4] 94/20 148/7 148/15 171/4 decision [12] 33/8 53/18 54/14 60/17 60/19 74/15 86/2 97/9 115/14 132/7 135/3 159/14	decision-making [2] 135/3 159/14 decisions [5] 99/14 122/7 125/19 136/16 137/10 decrease [1] 66/24 decreased [1] 32/22 decreasing [3] 15/24 16/11 44/5 deducting [1] 130/11 deep [1] 23/22 defects [1] 46/16 deference [1] 171/17 deficiency [2] 60/9 117/10 definite [1] 39/13 definitely [6] 105/2 121/9 137/2 158/15 160/18 173/5 definitive [2] 165/22 173/9 defunct [1] 96/19 degree [2] 99/2 158/8 degrees [2] 24/19 25/1 delay [2] 85/18 85/19 deliberate [1] 86/2 delivered [4] 20/15 20/17 60/25 120/17 delivery [1] 73/22 demand [3] 8/25 9/20 13/14 denial [2] 141/18 157/24 dental [1] 3/6 dentistry [1] 121/13 department [9] 53/3 87/22 90/11 91/15 92/16 106/24 126/15 134/20 168/16 depend [2] 105/21 138/7 depended [2] 121/7 135/21 depending [1] 106/23 derived [1] 66/9 described [8] 3/4 62/11 76/6 89/8 109/10 116/18 129/18 154/22 describes [2] 26/13 100/16 describing [5] 32/12 75/3 93/13 115/7 157/3 description [2] 26/21 155/4 Desforges [2] 161/17 163/8 designated [3] 2/12 4/10 4/11 destroy [1] 156/5	detail [3] 24/5 95/7 153/19 detailed [5] 8/18 24/9 56/15 67/25 95/6 details [5] 4/2 5/18 19/3 53/3 91/1 detected [1] 41/23 deteriorated [1] 5/16 determine [1] 118/24 determined [1] 124/8 devastating [1] 139/18 develop [4] 100/6 139/25 151/11 155/2 developed [4] 45/9 132/2 133/4 155/18 developing [2] 56/17 65/18 development [5] 61/4 98/24 130/17 130/17 130/23 DHSC0004003 [1] 87/19 DHSC0039636 [1] 84/16 DHSS [9] 9/7 18/12 18/23 91/9 93/12 93/20 93/22 94/8 94/20 diagnosed [3] 69/20 80/10 80/16 diagnosis [4] 50/1 85/3 86/11 86/17 diagnostic [1] 5/8 diagnostics [1] 5/25 Dictated [1] 51/21 did [60] 42/21 49/24 50/20 75/8 75/8 75/19 85/7 90/25 96/3 96/11 96/13 99/14 101/9 101/9 103/15 103/22 106/15 107/6 107/15 107/16 113/13 113/21 115/10 116/4 116/8 117/21 119/16 121/12 122/21 123/11 123/21 127/19 127/19 131/5 133/3 134/17 136/18 137/10 139/12 139/17 139/21 140/7 141/4 141/8 141/10 142/7 142/18 146/20 148/3 150/5 150/7 154/8 157/10 158/2 161/1 162/5 162/22 164/7 168/17 170/17 didn't [27] 20/4 50/18 50/19 90/4 97/8 97/11 97/22 103/13 104/8 109/19 112/9 127/19 127/20 128/9 138/17 139/21 142/11 147/2	153/8 157/10 157/13 168/18 172/17 172/17 172/23 172/24 173/1 died [4] 47/2 47/4 56/24 139/24 difference [6] 20/20 76/25 77/5 78/1 113/13 113/14 differences [1] 127/7 different [18] 2/13 2/14 19/9 29/23 59/25 78/7 79/18 80/18 110/14 112/25 113/1 116/1 127/9 127/10 127/25 151/5 157/19 160/13 difficult [5] 88/19 122/10 123/23 163/21 171/9 difficulties [2] 87/9 88/23 difficulty [2] 74/12 149/13 diminish [1] 17/11 direct [5] 13/25 74/10 81/2 101/19 171/19 direction [1] 52/13 directly [7] 7/18 14/3 20/15 20/22 46/22 89/13 108/5 director [48] 1/13 1/17 1/19 2/15 2/17 5/3 6/18 7/3 7/6 7/11 10/7 13/18 19/10 21/16 22/14 27/17 28/24 33/14 40/6 58/17 66/4 100/13 101/5 101/18 101/25 102/12 102/14 102/22 103/6 104/14 104/15 107/11 109/19 110/10 114/14 116/7 116/20 125/17 125/18 126/4 131/8 141/21 145/1 162/6 164/10 166/6 169/9 171/23 directors [21] 10/22 12/13 12/13 17/4 45/1 45/4 45/22 52/6 62/19 68/3 70/17 75/4 90/24 91/20 107/16 115/4 126/20 164/4 164/8 171/22 172/8 Directors' [5] 11/7 39/22 46/11 75/9 91/2 disagreed [1] 171/6 disaster [1] 158/19 disclose [2] 91/1 91/19 disclosed [2] 86/24 87/3 discount [1] 19/13	discover [2] 63/6 155/16 discovered [1] 79/2 discovers [1] 93/16 discrepancy [1] 7/13 discrete [1] 46/2 discretion [1] 70/16 discuss [9] 48/18 67/22 68/8 83/11 85/8 104/18 140/15 148/1 162/23 discussed [11] 16/20 18/14 46/8 47/25 52/8 91/7 130/10 148/21 149/20 149/20 164/4 discussing [4] 104/1 127/18 148/4 148/4 discussion [53] 8/18 10/13 11/14 11/18 12/6 13/9 14/7 15/1 15/3 16/7 17/3 17/12 18/7 41/5 44/23 45/3 45/7 46/12 51/11 51/19 52/18 53/14 53/16 54/1 54/7 57/5 59/21 60/16 60/24 61/10 64/5 67/6 68/1 68/15 69/13 70/8 70/13 71/3 75/15 80/12 80/15 88/6 90/12 94/12 95/1 98/4 129/17 131/20 162/8 162/19 165/15 169/11 171/21 discussions [15] 18/21 20/13 21/6 46/3 51/1 51/2 53/20 54/16 71/5 125/12 146/17 149/25 164/24 168/14 171/12 disease [40] 3/2 3/16 3/19 21/21 27/8 27/12 27/19 28/5 29/1 29/8 29/17 29/21 30/3 35/3 35/4 37/2 45/9 45/12 47/5 47/10 47/12 47/22 75/22 76/8 110/22 110/25 121/6 142/24 145/14 146/19 147/1 149/6 150/8 150/21 150/23 151/2 152/9 156/4 157/4 160/19 diseases [1] 164/16 disorder [2] 22/16 109/3 disorders [5] 97/8 99/8 100/18 101/21 156/9 disposal [1] 25/12 dispose [1] 25/9 disrupted [1] 119/22
----------	--	--	---	---	---

(51) crossed - disrupted

D	73/14 103/10 111/5 112/22 136/7 152/15 152/17 157/23 159/7 doesn't [8] 20/6 59/18 59/20 63/15 87/23 131/19 157/20 167/9 doing [13] 39/14 59/16 59/16 98/19 99/1 100/10 106/17 106/17 112/11 121/4 124/5 146/25 148/6 domain [2] 90/22 91/11 domestic [1] 23/22 dominated [1] 149/25 don't [93] 5/7 5/18 7/6 7/10 9/12 10/3 20/10 21/2 21/4 24/4 25/4 29/10 41/3 41/4 41/23 52/7 59/10 61/9 61/10 62/22 66/5 67/3 78/21 78/25 83/7 89/12 92/25 94/9 94/25 95/10 95/19 95/21 97/16 97/17 99/16 103/12 103/15 104/6 105/5 105/6 107/14 109/9 109/14 111/6 112/11 112/14 112/14 112/15 113/14 114/10 116/3 116/11 116/18 121/18 122/16 123/3 123/5 130/4 130/8 130/19 131/4 131/25 133/4 134/7 134/8 134/10 134/19 134/21 134/24 136/11 138/5 138/16 140/1 143/22 148/3 148/21 157/12 157/14 159/5 159/11 162/25 163/3 163/23 164/17 168/2 169/22 169/24 170/8 172/10 172/11 172/15 173/7 174/9 donation [1] 92/15 donations [1] 92/25 done [3] 105/7 122/13 137/7 donor [18] 9/9 24/17 54/22 55/5 55/19 64/8 98/14 113/7 113/19 124/3 124/12 127/15 127/24 128/8 132/19 134/14 134/25 142/10 donors [11] 55/8 61/19 61/22 66/20 70/21 98/14 113/3 113/5 113/10 117/15 128/13 Dormandy's [1] 26/4 double [1] 94/25	double-check [1] 94/25 doubled [1] 15/23 doubt [7] 29/21 30/11 41/17 43/19 66/4 67/11 85/23 down [35] 7/13 8/14 10/12 13/15 15/5 17/8 17/15 19/20 21/22 27/19 30/4 43/9 44/20 49/9 51/20 58/20 64/24 66/16 69/2 82/11 84/3 94/14 105/12 106/3 119/1 131/12 132/14 137/3 138/21 143/9 158/24 159/20 164/21 166/13 166/14 Dr [179] Dr Ala [9] 40/6 55/15 60/10 64/7 66/17 114/13 116/19 129/25 131/15 Dr Ala's [1] 61/12 Dr Barbara [1] 97/20 Dr Biggs [1] 12/22 Dr Bird [3] 8/21 13/10 33/19 Dr Bird's [1] 9/16 Dr Chisholm [2] 63/22 171/5 Dr Colvin [1] 157/3 Dr Craske [6] 44/19 45/5 45/8 45/19 56/16 156/23 Dr Dormandy's [1] 26/4 Dr Frank Hill [2] 2/17 104/16 Dr Franklin [3] 2/19 67/10 133/21 Dr Garrott Allen [1] 125/8 Dr Hann [1] 73/25 Dr Hay [1] 143/12 Dr Hill [60] 5/2 13/5 14/23 20/22 28/24 30/1 37/1 38/23 43/6 43/10 43/11 43/18 47/24 48/15 50/9 54/4 54/14 56/5 56/11 62/4 65/8 66/22 68/10 68/20 69/3 72/10 73/25 74/21 76/4 78/15 78/17 78/23 83/10 83/22 84/1 84/4 84/17 90/15 91/11 91/17 91/19 91/25 92/13 93/7 93/16 94/14 105/24 110/10 114/20 125/7 125/25 126/11 126/21 131/10	134/18 147/25 162/22 164/8 164/24 171/12 Dr Hill's [9] 8/11 20/16 38/21 41/14 44/11 51/17 74/14 83/12 83/19 Dr Ibbotson [3] 67/10 133/19 133/19 Dr Jillian [1] 2/16 Dr Jillian Mann [3] 7/12 21/17 26/10 Dr Kernoff [6] 65/1 76/6 76/12 76/17 77/4 157/3 Dr Lane [3] 74/13 116/15 119/17 Dr Lane's [1] 118/17 Dr Mann [1] 8/11 Dr Marcela [1] 97/23 Dr Maycock [4] 12/22 125/5 125/10 142/4 Dr Morag Chisholm [1] 169/13 Dr O'Shea [1] 33/13 Dr Parapia [1] 1/19 Dr Preston [1] 75/22 Dr Rizza [6] 12/22 57/15 58/13 91/7 91/16 93/23 Dr Roberts [1] 141/4 Dr Savidge [1] 75/12 Dr Shinton [6] 13/18 14/11 60/5 61/17 126/20 129/20 Dr Smith [2] 73/5 74/7 Dr Snape [1] 72/11 Dr Stewart [3] 19/8 19/9 48/18 Dr Stuart [13] 8/12 9/25 10/6 13/6 14/23 15/7 15/9 15/19 18/25 22/14 27/17 43/7 43/18 Dr Stuart's [1] 24/10 Dr Wassef [1] 62/5 Dr Wilde [2] 1/17 89/23 dramatic [1] 141/6 draw [6] 10/14 10/17 25/10 52/17 55/5 86/1 drawn [4] 57/8 71/22 153/22 154/5 dried [14] 3/11 3/11 8/17 9/24 10/1 15/2 17/1 18/8 23/10 43/12 43/21 59/5 129/16 129/24 dropped [1] 15/20 Drs [1] 133/16 Drs I Franklin [1] 133/16 due [13] 17/9 46/22	57/25 65/19 77/24 87/3 95/10 118/14 133/15 140/22 144/2 154/10 154/10 during [20] 4/16 12/11 21/20 23/24 28/25 28/25 30/2 32/17 32/19 35/5 60/21 96/11 100/20 109/18 110/22 110/24 110/25 125/23 140/16 142/23 E E4B [1] 24/15 each [3] 25/15 60/25 157/15 earlier [15] 42/25 62/17 71/6 71/8 82/8 90/9 91/22 93/22 114/10 114/11 129/7 153/23 156/14 156/19 160/14 early [7] 6/6 21/11 89/7 99/4 102/14 103/14 124/6 easier [1] 127/11 easy [2] 160/25 173/4 echoed [1] 48/13 economic [1] 61/4 economy [1] 167/20 Edgware [2] 97/21 141/23 Edinburgh [1] 90/24 education [1] 139/19 educational [1] 3/9 Edwards [1] 53/2 effect [1] 139/16 effective [1] 160/21 effectively [4] 35/16 93/24 109/11 171/14 efficacy [1] 69/23 effort [4] 54/20 126/25 127/12 158/21 effortlessly [1] 171/3 efforts [2] 72/7 117/13 eg [3] 54/25 73/17 128/20 eight [2] 6/22 149/4 eight-year [1] 149/4 either [16] 2/5 18/16 28/2 28/10 32/14 69/23 72/17 76/1 89/14 97/18 103/14 112/25 129/4 138/17 147/9 147/25 elaborate [1] 170/23 electronic [1] 145/21 Elias [1] 148/18 eliminate [1] 154/8 elimination [1] 154/7 Elizabeth [52] 1/14 1/18 2/11 2/18 2/25	5/9 6/23 7/15 7/18 8/12 9/18 10/7 13/7 13/24 14/2 18/25 19/10 20/24 22/14 22/17 26/6 27/14 27/23 28/19 29/11 29/15 29/22 30/24 32/15 38/24 40/16 41/10 43/7 44/12 54/5 58/16 81/18 87/8 89/25 99/25 101/19 102/1 103/7 107/6 107/9 109/1 109/2 109/10 120/22 148/17 162/7 173/1 Elizabeth Hooper [1] 81/18 else [6] 105/8 137/4 149/22 152/21 155/12 171/7 elsewhere [1] 37/21 Elstree [2] 14/3 120/11 emergency [2] 67/14 94/16 emerges [1] 21/9 emerging [1] 29/24 employment [1] 139/18 enclosed [3] 22/24 62/14 92/14 encouragement [1] 34/10 end [12] 8/5 49/14 62/15 90/22 92/6 102/2 116/10 129/4 155/1 158/5 158/6 170/14 endeavour [1] 17/15 England [6] 57/8 57/11 109/12 142/22 161/16 162/20 enhancing [1] 139/10 enough [5] 9/21 112/4 156/4 158/21 173/2 enquiries [2] 134/15 134/16 enquiry [1] 77/19 ensure [3] 14/13 87/10 107/3 ensuring [1] 73/9 entirely [2] 20/7 22/4 entitlement [1] 137/20 entry [4] 22/4 27/17 49/19 50/7 envisaged [2] 55/17 131/18 enzyme [1] 46/25 epidemiological [2] 117/19 117/22 episode [2] 151/12 154/24
----------	--	---	--	--	--

E	89/17 89/18 89/23 90/1 92/9 93/21 95/20 103/20 103/21 106/12 108/18 114/12 134/22 138/9 138/9 138/19 139/3 139/8 140/15 143/5 143/19 144/4 149/5 150/4 165/1 171/6 173/19 evident [2] 146/13 173/14 evolved [1] 89/8 EWCT0000176 [1] 27/4 exactly [3] 25/5 88/11 113/23 examination [1] 63/12 example [6] 16/15 23/12 37/24 89/20 137/23 138/8 examples [1] 92/12 except [2] 66/9 73/17 excess [2] 32/6 33/8 excluded [1] 88/25 Exeter [1] 64/21 exhausted [2] 9/21 115/23 exhibits [1] 62/9 existing [2] 53/12 74/11 expect [1] 78/5 expectation [1] 8/23 expected [6] 15/17 133/12 165/21 168/13 168/15 168/22 expensive [2] 127/21 129/10 experience [9] 93/13 100/7 101/19 141/17 156/4 158/2 158/2 158/13 171/1 experienced [4] 107/20 108/4 171/16 171/23 expert [7] 23/5 107/21 148/18 152/13 156/1 167/11 167/11 experts [5] 108/8 161/10 167/4 167/11 167/13 expired [1] 20/5 explain [2] 85/7 112/21 explained [4] 19/11 55/7 90/3 136/24 explaining [2] 8/22 15/19 explains [2] 25/6 25/8 explanations [1] 88/7 explicit [1] 132/9 explore [2] 40/1 87/12 exposed [6] 83/20	112/23 113/4 113/5 117/7 117/15 exposure [5] 69/25 70/4 84/2 98/17 113/7 exposures [1] 113/19 express [1] 135/1 expressed [3] 5/23 13/17 19/8 expression [1] 152/7 expressions [1] 14/10 expressly [2] 57/8 150/14 extend [1] 141/9 extended [1] 73/16 extending [1] 151/15 extension [1] 92/19 extensive [1] 23/2 extent [8] 11/11 15/4 63/11 64/5 84/25 101/2 108/3 167/7 extra [1] 123/20 extract [1] 49/3 extraction [2] 136/10 137/1 extraordinary [5] 67/15 67/21 71/13 79/6 94/12 extremely [1] 39/12	F facilities [24] 1/24 3/4 3/9 3/25 4/24 5/8 6/2 22/18 22/20 22/22 54/22 55/6 55/19 87/11 104/13 105/13 106/7 106/8 127/15 127/24 128/3 128/8 134/14 134/25 fact [24] 2/11 3/17 4/12 14/12 16/9 17/23 23/18 30/11 31/24 38/10 41/4 49/23 58/16 81/17 95/21 107/16 109/14 133/8 141/25 152/12 153/7 167/18 171/18 172/17 factor [173] 3/10 3/11 3/11 3/21 8/17 8/20 9/24 10/1 10/20 10/25 11/20 13/11 13/24 14/3 14/15 15/3 15/9 15/11 15/22 16/2 16/3 17/1 17/6 17/10 17/13 17/15 17/19 17/22 17/24 18/8 18/22 19/1 19/4 19/6 20/2 20/3 21/21 21/24 22/1 26/16 26/18 27/11 27/13 27/22 28/1 28/3 28/4 29/2 29/5 29/6 29/8 29/19 29/20 30/4 30/8 30/15 30/16	30/17 30/18 31/3 32/3 32/16 32/20 33/3 33/7 34/12 35/10 35/13 35/23 36/5 36/8 36/15 36/17 36/18 36/25 37/5 37/8 39/4 39/5 39/6 40/9 40/17 40/22 40/22 41/1 41/1 41/7 41/16 43/12 43/22 48/9 48/20 49/12 49/12 50/5 50/9 50/15 50/16 52/11 52/14 53/5 54/2 54/11 54/25 55/21 60/7 60/11 61/5 65/20 66/2 66/7 66/10 66/24 66/25 67/7 68/9 68/21 68/25 69/6 69/10 70/1 70/2 70/5 70/6 70/7 72/8 72/12 72/20 72/23 78/4 79/4 81/10 81/14 81/15 81/21 81/24 82/1 82/6 90/14 92/21 94/21 97/15 97/16 104/23 105/10 109/5 110/12 111/8 111/13 112/1 112/4 114/16 115/6 115/13 119/7 120/2 120/11 121/15 121/18 121/19 124/2 128/20 129/2 129/16 129/19 129/24 130/7 138/22 148/15 150/22 154/15 158/12 162/2 Factor IX [20] 3/11 3/21 22/1 27/13 28/4 29/2 29/8 29/20 30/4 30/17 30/18 31/3 35/23 36/18 36/25 41/1 41/1 110/12 112/1 112/4 Factor VIII [113] 3/11 8/17 8/20 10/20 10/25 13/11 13/24 14/3 14/15 15/3 15/11 15/22 16/2 16/3 17/1 17/6 17/13 17/15 17/19 17/22 17/24 18/8 18/22 19/4 19/6 20/2 21/21 21/24 26/16 26/18 27/11 27/22 28/1 28/3 29/5 29/6 29/19 30/15 30/16 32/3 32/16 33/3 33/7 35/10 35/13 36/8 36/17 37/8 39/4 39/6 40/9 40/22 40/22 41/7 41/16 43/12 43/22 48/9 48/20 49/12 49/12 50/9 50/15 50/16 53/5 54/11 54/25 60/7 60/11 61/5	65/20 66/2 66/7 66/24 66/25 68/9 68/21 68/25 69/6 69/10 70/1 70/5 70/7 72/8 72/12 72/20 72/23 78/4 79/4 81/21 82/6 90/14 97/15 104/23 105/10 109/5 111/13 114/16 115/6 115/13 119/7 121/15 121/18 121/19 128/20 129/2 129/16 129/19 129/24 130/7 138/22 148/15 162/2 Factor VIII ... [1] 15/9 Factor VIII concentrates [1] 50/5 factor-related [1] 150/22 Factorate [1] 93/10 factored [1] 135/3 factors [2] 55/20 124/9 facts [1] 166/16 fails [1] 39/5 failure [1] 12/20 fair [4] 63/5 101/17 118/17 160/15 fairly [4] 90/22 118/21 154/1 173/13 fairness [1] 150/4 fall [4] 41/6 116/22 130/5 164/2 fall-out [1] 130/5 far [21] 17/15 23/9 35/10 38/2 47/11 47/18 59/6 80/21 81/20 86/24 89/19 112/3 118/7 119/7 119/12 123/9 127/22 129/5 159/21 172/9 172/13 fatalities [1] 46/22 favourable [1] 39/7 fears [1] 160/14 feature [2] 38/5 151/14 features [2] 151/7 151/18 February [6] 51/11 51/13 71/20 80/24 84/17 97/3 February 1981 [1] 97/3 February 1983 [1] 80/24 fed [3] 51/6 52/14 62/22 feel [3] 136/13 158/12 172/25 feeling [3] 98/12 140/3 158/23	FEIBA [3] 39/5 39/7 104/25 fellow [3] 91/20 96/5 99/3 felt [4] 44/21 53/11 148/10 157/23 few [15] 10/12 10/16 16/9 18/1 18/20 23/11 30/20 40/20 52/22 59/25 69/2 101/3 120/16 127/18 164/21 FHIN0000030 [1] 125/20 fifth [2] 15/5 109/11 fifty [1] 72/21 figure [5] 32/3 32/4 37/8 147/23 147/23 figures [10] 4/3 27/6 29/14 32/1 56/22 76/11 121/10 170/21 171/4 171/16 file [1] 172/12 filing [1] 105/9 Fill [1] 24/18 filled [1] 105/4 final [4] 57/17 96/17 160/16 160/16 finally [2] 36/22 69/15 Finance [1] 92/16 financial [5] 9/6 19/14 33/25 39/14 70/13 find [11] 63/15 79/22 80/1 92/4 118/13 135/10 138/14 160/25 164/5 164/14 164/17 findings [2] 68/18 94/18 finish [2] 173/13 173/23 firm [1] 51/16 firm's [1] 53/18 firms [9] 19/2 19/2 19/4 19/7 53/6 54/22 55/5 127/15 128/7 first [49] 7/21 8/1 14/13 14/16 18/14 22/12 23/16 31/20 36/24 41/22 41/25 43/3 46/17 49/19 56/11 67/25 73/10 73/21 79/21 80/10 80/16 90/8 90/12 92/15 93/18 95/25 96/13 97/15 100/16 101/22 104/15 106/17 107/10 113/16 119/12 131/4 133/1 136/15 150/15 155/17 167/21 168/4 169/9 170/1 170/3 170/12 172/15 174/1 174/4 five [3] 27/7 56/24
----------	--	---	---	---	--	---

<p>F</p> <p>five... [1] 82/17</p> <p>flagged [1] 163/8</p> <p>flash [1] 31/6</p> <p>flowing [1] 24/25</p> <p>fluctuation [2] 119/11 151/15</p> <p>focus [2] 1/9 98/1</p> <p>focused [1] 102/24</p> <p>focusing [1] 102/6</p> <p>follow [5] 34/19 63/2 87/23 108/9 151/8</p> <p>followed [4] 46/24 52/21 58/11 106/22</p> <p>following [21] 1/23 10/13 11/2 23/20 39/21 40/13 50/25 51/3 54/17 55/11 59/14 68/11 69/13 72/4 72/13 76/12 79/3 93/9 109/10 133/24 174/16</p> <p>follows [3] 28/18 68/2 76/14</p> <p>foreign [1] 43/17</p> <p>foremost [1] 147/4</p> <p>Forgive [1] 164/13</p> <p>forgotten [1] 119/16</p> <p>form [5] 11/3 11/18 45/4 45/21 77/3</p> <p>formal [3] 118/6 134/9 134/20</p> <p>formally [1] 7/8</p> <p>former [2] 39/1 116/25</p> <p>forthright [1] 172/1</p> <p>forwarded [2] 55/16 131/16</p> <p>found [8] 47/5 47/21 82/8 86/13 88/3 145/25 164/23 172/16</p> <p>four [10] 19/20 32/17 32/20 51/17 82/18 104/4 106/1 143/9 146/3 159/21</p> <p>four-year [1] 32/20</p> <p>fourth [2] 17/7 119/1</p> <p>fractionation [4] 22/3 128/11 159/4 160/4</p> <p>Francisco [3] 57/1 162/9 163/6</p> <p>frank [9] 2/17 88/1 92/14 104/16 148/5 162/25 166/8 168/8 169/22</p> <p>Frank Boulton's [1] 162/25</p> <p>Frank Hill [2] 148/5 168/8</p> <p>Franklin [36] 1/13 2/19 2/19 39/20 40/1</p>	<p>41/12 58/15 67/10 67/11 87/13 95/13 95/19 95/22 95/24 108/13 114/11 115/8 116/15 117/12 120/21 125/24 129/15 130/9 133/16 133/21 138/20 140/20 147/13 156/17 157/16 159/17 164/18 164/23 169/12 171/10 175/3</p> <p>Franklin's [1] 173/13</p> <p>frankly [1] 52/7</p> <p>free [6] 13/21 24/25 26/4 81/16 90/5 148/11</p> <p>freeze [14] 3/11 3/11 8/17 9/24 10/1 15/2 17/1 18/8 23/10 23/22 43/12 43/21 59/5 129/16</p> <p>freeze-dried [12] 3/11 3/11 8/17 9/24 15/2 17/1 18/8 23/10 43/12 43/21 59/5 129/16</p> <p>freezer [2] 23/22 140/3</p> <p>fresh [1] 9/5</p> <p>friendly [1] 51/18</p> <p>from [228]</p> <p>from 1984 [1] 38/12</p> <p>from May 1983 [1] 169/2</p> <p>front [1] 159/21</p> <p>full [11] 4/24 5/22 6/18 7/3 7/19 63/1 70/8 76/2 105/16 144/14 145/11</p> <p>full-time [2] 6/18 7/3</p> <p>fully [1] 100/22</p> <p>Fulminant [1] 154/25</p> <p>function [4] 65/5 145/18 147/7 155/19</p> <p>fund [2] 92/16 92/23</p> <p>funded [1] 89/1</p> <p>funding [12] 4/24 6/1 14/8 14/11 14/14 14/18 18/10 87/10 87/15 108/18 109/13 130/7</p> <p>funds [2] 5/5 130/14</p> <p>further [29] 19/15 20/4 25/22 46/22 47/4 47/9 47/9 51/2 54/7 66/4 71/18 72/3 73/16 77/19 78/12 82/20 84/3 85/14 87/15 88/14 88/19 89/4 90/7 92/5 108/17 132/10 152/7 159/22 166/13</p> <p>future [2] 118/11 132/13</p>	<p>G</p> <p>gain [1] 19/14</p> <p>gained [1] 99/21</p> <p>Garrott [1] 125/8</p> <p>gave [2] 19/3 103/21</p> <p>gay [1] 161/7</p> <p>general [14] 52/8 67/14 67/15 70/14 87/18 95/2 96/18 98/7 98/19 106/6 107/2 122/15 140/25 151/18</p> <p>General Hospital [1] 107/2</p> <p>generally [4] 46/6 98/12 121/1 168/13</p> <p>get [14] 2/21 41/12 67/13 84/22 101/1 110/5 125/18 134/12 134/22 140/2 152/23 172/23 172/24 173/1</p> <p>getting [5] 81/4 81/5 124/21 159/11 165/20</p> <p>give [11] 9/9 16/23 22/25 45/2 57/24 71/19 104/12 121/22 165/22 167/4 174/9</p> <p>given [21] 19/15 23/2 28/17 47/13 49/11 49/13 52/4 56/16 56/22 73/22 76/11 81/10 85/15 107/13 112/25 114/2 114/5 117/8 129/6 137/23 153/20</p> <p>gives [1] 31/19</p> <p>giving [5] 57/25 95/20 104/25 139/8 143/18</p> <p>Glasgow [2] 49/20 102/4</p> <p>glib [1] 137/14</p> <p>glut [5] 114/24 115/25 116/3 116/25 117/3</p> <p>go [145] 2/22 2/22 4/2 4/20 4/21 4/25 5/20 8/2 8/14 10/4 10/12 11/13 11/22 13/8 14/6 14/20 14/25 15/1 15/18 16/4 16/5 16/23 16/24 17/6 18/5 18/10 18/18 18/20 19/17 19/18 20/10 21/22 22/18 24/6 24/22 24/22 25/4 25/6 25/10 27/2 27/16 27/19 29/11 29/14 29/23 30/19 30/21 31/5 31/9 31/24 32/9 32/11 33/11 34/23 36/1 36/25 38/20 40/5 40/19 43/8 44/14 44/16 45/6 46/12</p>	<p>46/20 48/4 49/16 51/4 51/8 51/20 52/20 52/23 54/5 56/2 56/4 56/12 58/11 58/20 59/23 60/2 60/14 61/14 62/11 63/20 64/4 64/22 64/24 65/13 65/22 66/5 69/2 71/9 71/20 73/3 73/10 74/24 78/13 80/7 80/19 83/8 83/17 84/6 84/16 84/18 85/25 90/16 94/14 96/18 103/15 109/9 111/22 117/12 118/13 126/6 129/11 129/12 130/6 132/10 132/14 133/6 133/9 135/17 136/14 138/12 138/17 143/7 144/8 144/9 145/19 145/23 152/6 152/23 152/23 154/19 155/3 155/22 156/16 157/15 162/3 166/13 169/2 169/11 170/10 172/17 172/17</p> <p>goes [6] 127/17 146/12 154/14 162/13 166/21 173/24</p> <p>going [33] 7/21 11/8 12/17 13/15 16/5 45/19 55/20 67/9 80/19 94/24 95/24 102/24 103/1 113/4 128/13 128/14 132/1 132/17 133/18 138/18 140/20 147/13 153/8 153/25 156/2 157/21 160/19 163/13 170/1 170/3 173/4 173/10 174/10</p> <p>Goldstone [1] 98/25</p> <p>gone [2] 4/18 159/9</p> <p>good [9] 19/5 106/2 121/13 148/19 149/21 159/20 170/7 171/19 172/18</p> <p>got [17] 27/6 29/14 29/15 36/3 63/7 103/9 104/6 120/4 128/7 138/12 142/13 145/9 148/24 155/14 156/3 159/16 162/17</p> <p>Government [2] 131/1 160/2</p> <p>governmental [1] 159/1</p> <p>grade [1] 105/16</p> <p>gradual [1] 114/23</p> <p>Grants [1] 5/1</p> <p>grateful [1] 71/16</p> <p>great [9] 6/13 23/12</p>	<p>73/12 97/4 97/13 101/22 107/21 124/17 158/11</p> <p>greater [1] 113/12</p> <p>Gregg [2] 81/22 86/9</p> <p>Gregg's [1] 90/1</p> <p>group [6] 12/16 70/25 141/8 143/11 160/20 172/20</p> <p>guaranteed [1] 73/22</p> <p>guidance [4] 70/12 71/22 107/12 108/8</p> <p>guided [2] 108/3 165/5</p> <p>guidelines [1] 72/4</p> <p>guy [1] 148/18</p>	<p>H</p> <p>had [161] 5/10 5/16 5/17 5/21 6/21 12/15 13/11 13/14 13/21 15/9 15/16 15/20 15/23 15/23 17/9 19/2 19/23 24/11 32/16 32/18 32/21 33/1 33/9 33/16 39/16 41/8 45/9 45/10 46/23 47/15 48/8 48/11 49/24 53/6 54/13 54/14 56/19 57/10 60/5 63/7 69/5 73/16 74/5 76/23 77/2 79/3 79/19 79/20 80/11 80/22 81/4 81/13 83/4 84/1 86/16 88/10 89/21 90/1 90/2 91/7 91/12 91/16 91/18 91/25 91/25 92/23 92/23 93/3 93/8 97/14 97/15 97/17 99/1 99/12 100/8 100/19 101/11 101/21 102/19 103/23 103/24 104/15 104/20 105/1 105/3 105/5 105/9 105/13 105/15 106/2 106/5 107/2 107/18 111/22 112/4 113/5 113/6 114/13 114/18 115/2 115/6 115/11 116/3 116/12 117/2 118/1 118/3 118/4 119/15 119/16 122/11 122/12 122/14 122/18 122/19 124/18 124/25 125/13 126/12 128/2 128/21 130/18 130/23 130/25 131/8 135/6 136/8 136/11 136/13 137/5 137/6 137/17 137/25 139/15 143/14 146/4 147/6 148/1 148/21 149/7 149/8</p> <p>149/14 151/13 153/13 155/14 155/19 155/22 158/1 158/12 161/4 161/10 162/10 162/15 164/24 166/7 168/9 168/20 170/4 171/19 173/2 173/8</p> <p>hadn't [4] 86/18 156/3 156/3 162/16</p> <p>haematological [1] 65/24</p> <p>haematologist [2] 97/24 101/25</p> <p>haematology [13] 6/11 6/16 64/19 64/20 77/17 96/18 96/21 96/23 98/8 98/20 140/25 142/25 148/19</p> <p>haemophilia [102] 1/9 1/20 2/9 2/12 3/2 3/16 3/19 4/4 4/10 4/15 4/21 6/25 10/22 12/12 12/15 13/18 14/8 14/19 22/2 23/8 29/16 31/4 35/1 35/2 35/3 35/22 36/20 37/1 46/11 49/5 49/8 49/13 49/20 49/22 49/25 50/17 58/23 64/23 69/17 72/14 72/25 73/12 75/8 80/11 80/17 84/5 88/16 90/24 91/1 98/7 99/11 99/12 100/12 100/13 100/19 100/23 101/6 101/18 102/1 104/10 104/13 105/16 107/20 107/21 107/24 108/8 109/11 109/23 110/9 110/11 110/21 110/23 110/24 111/19 111/24 114/9 115/4 116/20 121/17 126/20 130/12 130/21 139/14 139/15 139/24 146/24 147/5 149/5 149/17 158/9 159/6 160/5 161/21 163/14 165/6 165/8 165/18 166/1 166/17 166/24 170/6 172/5</p> <p>haemophilia A [10] 35/1 35/2 35/3 37/1 58/23 69/17 110/21 110/23 110/24 111/19</p> <p>haemophilia B [6] 31/4 35/22 36/20 110/9 110/11 111/24</p> <p>haemophiliac [16] 21/19 27/1 27/18 30/2 65/12 72/22 75/4 82/17 82/18 83/22 84/19 93/8 104/10</p>
--	--	--	---	--	--

(54) five... - haemophiliac

H	17/4 34/8 47/1 81/5 83/15 84/19 86/8 87/20 99/16 109/3 114/12 115/3 115/25 117/6 123/17 134/17 160/20 168/19 Hay [6] 143/12 143/24 148/8 148/23 156/12 160/11 Hay/Preston [2] 156/12 160/11 HCDO [1] 172/20 HCDO0000028 [1] 27/15 HCDO0000135 [1] 46/9 HCDO0000206 [2] 110/7 111/23 HCDO0000254 [1] 88/15 HCDO0000270 [1] 58/11 HCV [2] 88/22 89/2 he [112] 2/18 5/10 5/12 6/5 6/7 6/7 6/9 6/10 6/13 6/15 6/17 6/20 6/21 6/24 7/10 7/17 9/19 9/22 13/15 13/20 14/17 20/4 20/22 22/17 22/19 23/15 26/18 33/15 33/16 33/17 39/5 39/7 39/8 39/12 39/13 39/16 42/17 43/14 43/20 45/24 45/25 48/9 48/16 49/22 50/1 52/1 52/12 57/11 60/5 62/9 72/11 72/15 75/8 75/8 75/20 76/22 78/4 80/9 81/4 81/14 81/16 81/25 83/6 83/21 85/5 85/7 85/15 85/16 85/17 85/22 86/10 87/14 88/4 88/18 89/20 89/21 89/22 89/24 89/24 89/25 90/4 91/7 93/12 93/18 93/19 93/20 94/7 94/8 94/18 97/22 99/1 100/15 101/10 101/11 101/11 101/11 101/12 101/14 106/15 106/16 106/16 107/19 108/3 119/2 124/13 124/18 124/25 141/7 141/10 141/23 148/19 166/9 he'd [4] 20/3 78/3 107/21 107/22 he's [2] 7/5 87/23 head [1] 125/4 headed [2] 23/17 132/17	heading [18] 4/25 8/15 15/5 18/23 24/7 38/22 46/21 54/6 55/13 56/13 61/16 66/17 70/14 78/15 83/18 126/7 130/7 131/14 Health [15] 8/7 9/8 13/3 51/15 51/23 87/22 90/10 90/11 91/16 92/17 103/18 103/24 125/22 126/16 130/18 hear [4] 1/12 1/16 1/19 143/25 heard [16] 12/9 26/3 56/9 65/3 79/9 80/21 81/7 81/12 81/18 81/22 85/9 85/23 97/16 98/11 139/4 168/6 hearing [1] 2/5 hearings [1] 103/4 heat [31] 39/25 40/5 40/8 40/13 41/17 54/25 60/11 69/6 69/11 70/6 71/14 72/8 72/20 72/23 73/1 75/17 79/4 81/15 90/13 92/1 92/21 93/10 119/22 128/20 129/2 129/3 129/7 129/8 129/24 158/22 160/21 heat-dried [1] 129/24 heat-treated [25] 39/25 40/5 40/8 40/13 41/17 54/25 69/6 69/11 70/6 72/8 72/20 72/23 73/1 79/4 81/15 90/13 92/1 92/21 93/10 128/20 129/2 129/3 129/7 129/8 158/22 heat-treating [1] 75/17 heated [3] 40/17 40/22 72/13 height [1] 149/24 held [6] 64/21 67/14 67/15 67/21 68/1 68/8 help [9] 5/15 25/25 64/11 95/21 96/18 132/24 134/13 152/7 173/21 helpful [3] 118/2 172/2 172/22 Hence [1] 24/20 Henry [71] 2/22 4/8 4/17 8/2 14/6 14/21 16/22 18/18 20/10 21/15 22/12 23/16	24/6 24/23 27/4 27/16 29/14 30/19 31/7 31/24 32/9 34/25 36/1 36/23 38/12 38/20 40/20 43/3 44/8 44/14 45/15 46/20 48/3 49/1 49/18 51/8 55/12 56/4 56/12 60/15 61/16 62/4 64/17 64/22 65/14 71/9 82/11 94/24 108/14 108/21 110/7 111/23 116/16 125/20 129/11 129/13 130/6 131/6 135/15 138/11 145/7 145/10 145/19 145/20 148/23 150/15 151/5 153/24 162/4 166/14 169/4 Hep [1] 88/2 Hep C [1] 88/2 hepatitis [114] 2/1 2/2 42/4 42/14 42/17 42/19 43/11 43/19 44/18 44/22 44/24 45/5 45/10 45/14 45/20 45/22 45/25 46/3 46/5 46/13 46/15 46/23 46/24 47/3 47/7 47/8 48/8 48/9 48/11 48/12 48/14 50/20 51/5 52/1 52/18 52/19 52/24 53/20 54/1 55/9 55/23 57/24 58/25 65/2 66/7 71/1 73/15 75/19 75/21 76/1 76/2 76/10 77/2 83/13 83/16 87/16 89/15 89/22 90/1 90/3 90/4 90/4 90/5 98/2 98/4 98/10 113/15 117/19 135/7 140/21 141/9 141/14 141/18 141/21 141/24 142/6 143/9 144/3 144/5 144/11 144/24 146/1 146/4 146/10 146/18 146/22 149/8 149/12 149/16 150/18 150/20 151/8 151/19 154/6 154/7 154/7 154/9 154/13 154/17 154/25 155/7 155/8 157/4 157/25 158/10 158/20 158/23 158/25 159/7 159/11 160/1 160/18 162/2 172/23 hepatitis B [12] 46/3 46/5 47/7 48/12 48/14 71/1 83/13 83/16 90/4 98/2 141/18 154/7 hepatitis C [8] 50/20 87/16 89/15 89/22	90/1 144/3 144/5 160/18 hepatitis-reduced [3] 54/1 66/7 162/2 her [12] 81/18 85/13 86/12 86/13 86/15 90/2 153/17 153/18 154/1 154/3 163/8 171/7 here [18] 13/1 27/16 27/22 31/19 37/16 44/2 62/20 69/15 94/23 116/19 126/20 130/10 131/20 131/22 148/24 154/4 159/25 173/21 here's [1] 65/15 hernia [1] 136/11 herself [1] 153/12 high [7] 9/9 52/11 52/12 65/1 66/1 70/25 144/1 higher [3] 28/9 28/9 52/2 Hill [120] 2/17 5/2 6/5 13/5 14/23 16/14 20/22 28/24 30/1 37/1 38/23 39/3 41/6 42/15 42/23 43/6 43/10 43/11 43/18 44/6 46/9 47/24 47/24 48/1 48/6 48/15 50/9 51/6 52/1 53/24 54/4 54/11 54/14 56/5 56/11 57/9 58/9 58/15 58/19 59/11 62/4 62/22 62/23 63/19 64/18 65/8 65/9 65/13 65/23 66/3 66/22 68/10 68/20 69/3 72/10 73/25 74/21 75/7 76/4 78/15 78/17 78/23 79/2 80/5 81/1 82/3 82/16 83/10 83/22 84/1 84/4 84/17 85/13 86/8 86/16 87/19 87/20 88/1 88/16 89/13 89/21 90/15 90/25 91/11 91/17 91/19 91/25 92/11 92/13 92/22 93/7 93/16 94/14 104/16 105/24 107/5 107/15 108/3 108/16 110/10 114/20 115/14 124/1 124/11 125/7 125/13 125/25 126/11 126/21 131/10 134/18 146/17 147/25 148/5 162/5 162/22 164/8 164/24 168/8 171/12 Hill's [22] 2/3 8/11	20/16 38/21 41/14 42/3 42/13 43/24 44/11 48/13 48/21 48/24 51/17 57/2 74/14 80/6 83/4 83/12 83/19 85/4 89/17 106/11 him [10] 5/10 10/10 57/4 86/16 97/22 107/19 124/5 130/4 133/20 148/21 himself [3] 76/23 79/14 124/21 his [62] 1/15 5/14 6/9 6/15 6/19 6/20 6/25 7/7 7/11 7/20 10/9 14/12 40/2 47/3 47/3 48/22 58/10 63/1 79/3 80/5 80/15 80/22 81/8 81/13 81/22 81/25 83/6 83/12 85/12 85/16 85/17 85/18 85/19 85/20 85/20 85/21 86/2 86/10 86/11 86/14 86/17 86/17 87/13 87/21 87/23 89/11 89/13 89/15 89/20 91/1 91/20 93/13 93/17 93/24 94/18 101/16 118/22 125/1 132/13 140/15 142/4 168/8 histological [1] 146/6 histology [1] 151/18 history [2] 135/24 144/14 HIV [34] 2/1 2/2 42/4 42/14 73/10 73/15 82/12 82/15 82/18 82/22 82/24 83/3 84/15 85/4 85/22 86/13 87/11 88/10 89/3 93/8 108/19 113/14 114/9 144/3 149/14 149/24 150/1 155/14 158/16 158/20 159/13 160/22 164/3 173/12 HIV patients [1] 82/22 HIV/AIDS [2] 160/22 164/3 hoc [1] 114/2 hold [2] 73/17 91/10 home [59] 3/7 3/8 3/23 11/14 11/16 11/23 12/2 12/5 22/10 22/22 22/25 23/1 23/3 23/6 23/9 23/13 23/17 23/19 23/21 24/2 24/10 24/13 24/16 26/2 28/17 28/18 28/19 35/9 35/14 36/6
----------	---	---	--	--	--

(55) haemophiliac... - home

H	120/23 122/19 126/4 126/21 148/12 148/17 166/9 173/1 hospitals [9] 2/14 4/9 6/6 9/13 9/16 14/24 73/20 106/25 120/18 hostility [1] 51/18 hotel [2] 53/21 56/3 hour [4] 3/5 42/7 100/23 140/12 hours [2] 25/21 101/13 house [3] 96/1 96/1 105/25 how [23] 26/1 26/13 26/13 35/25 50/23 55/23 77/20 85/3 89/1 90/18 99/14 107/15 107/16 109/15 112/21 113/21 113/21 113/23 118/1 122/7 125/18 129/2 165/6 however [2] 26/17 141/10 HSOC0019918 [1] 4/17 HTLV [14] 66/18 68/18 68/20 69/4 70/11 75/15 83/5 83/23 84/10 84/23 85/17 92/19 93/18 118/1 HTLV-III [13] 68/18 68/20 69/4 70/11 75/15 83/5 83/23 84/10 84/23 85/17 92/19 93/18 118/1 huge [4] 77/5 113/8 142/2 163/17 human [1] 39/4 husband [1] 81/19 Hyate:C [4] 38/19 38/22 39/9 39/13 Hygiene [1] 96/15 hypotheses [1] 159/22 hypothesis [1] 158/21 I I actually [1] 123/19 I also [1] 134/17 I am [10] 42/2 79/24 79/24 80/19 90/6 110/18 110/19 153/15 156/16 173/10 I ask [1] 102/23 I became [1] 128/10 I been [1] 155/19 I beg [1] 127/25 I began [2] 147/4 147/9 I believe [2] 78/19	104/10 I came [1] 165/13 I can [12] 37/22 41/11 50/24 67/11 79/22 87/12 152/18 153/18 154/19 156/20 172/12 174/9 I can't [11] 87/4 97/14 113/23 121/10 122/10 124/15 127/12 131/2 134/7 146/21 165/14 I certainly [1] 128/9 I couldn't [1] 138/14 I did [11] 96/3 96/13 103/15 103/22 119/16 127/19 139/12 139/21 140/7 150/7 157/10 I didn't [6] 97/11 97/12 142/11 168/18 172/17 172/17 I do [5] 135/14 148/5 159/6 166/9 172/25 I don't [50] 7/6 7/10 78/25 94/9 94/25 95/10 97/17 103/12 103/15 104/6 105/5 107/14 109/9 109/14 112/11 112/14 112/14 112/15 113/14 116/3 116/11 122/16 123/3 123/5 130/4 130/8 130/19 131/25 133/4 134/10 134/19 134/21 136/11 138/5 138/16 143/22 157/12 157/14 159/5 159/11 162/25 163/23 164/17 168/2 169/22 172/10 172/11 172/15 173/7 174/9 I draw [2] 52/17 55/5 I estimate [1] 75/11 I ever [1] 137/25 I felt [1] 157/23 I found [1] 172/16 I had [11] 79/19 79/20 93/3 97/15 104/15 107/18 111/22 119/15 119/16 158/1 170/4 I have [9] 22/23 52/6 92/15 98/6 110/14 123/18 140/4 164/23 168/2 I haven't [3] 16/16 95/5 164/21 I heard [1] 168/6 I hope [2] 145/7 159/16 I imagine [1] 117/24 I knew [1] 127/22 I know [4] 124/18 127/20 133/20 135/5 I like [1] 155/19	I looked [1] 155/15 I may [2] 164/22 168/17 I mean [29] 98/6 98/10 99/10 100/8 107/18 113/23 119/10 121/14 121/24 127/6 137/15 139/13 139/25 141/12 142/20 146/20 146/21 149/12 150/7 155/12 159/9 163/22 165/9 165/13 166/6 168/17 168/24 169/25 171/8 I meant [1] 16/23 I mention [1] 161/2 I mentioned [3] 18/1 94/11 137/4 I might [1] 155/20 I note [3] 42/4 140/9 173/10 I now [1] 165/8 I omitted [1] 169/6 I only [2] 109/15 172/15 I perhaps [1] 42/5 I presume [2] 116/11 116/12 I probably [1] 134/18 I propose [1] 1/22 I read [3] 157/13 163/23 163/23 I realise [1] 137/13 I refer [1] 86/20 I remember [14] 97/14 99/10 104/4 104/17 104/25 112/3 121/4 121/25 124/5 134/16 146/20 163/11 170/1 170/8 I remembered [1] 170/3 I said [1] 170/2 I saw [1] 119/15 I say [4] 39/25 129/9 141/16 157/15 I scribbled [1] 158/24 I see [1] 127/25 I should [5] 4/9 25/10 38/11 41/24 86/20 I started [5] 102/13 146/23 147/10 158/5 160/25 I suppose [9] 77/23 104/20 106/4 118/2 118/21 160/9 163/21 171/2 174/6 I suspect [1] 135/5 I think [132] 8/21 9/3 21/2 33/14 38/15 40/7 41/22 44/15 56/10 58/14 61/10 67/1 76/3	76/23 78/25 79/8 87/17 87/20 91/22 92/8 94/11 96/1 96/4 96/8 97/15 98/6 98/11 98/11 99/13 100/9 102/23 103/8 103/23 103/25 104/7 105/7 105/11 109/21 109/24 110/3 112/18 112/22 113/2 113/24 116/5 116/8 118/17 119/18 119/20 119/23 120/6 120/19 121/4 123/15 124/4 124/19 124/20 127/20 128/10 128/13 129/8 134/17 134/22 136/24 137/4 137/8 138/2 140/3 140/9 141/7 141/8 141/12 141/13 141/18 142/9 143/7 143/22 144/20 145/13 145/20 146/20 146/21 147/14 148/7 148/8 148/9 149/12 149/13 149/24 150/3 153/7 153/13 153/16 155/12 155/24 156/2 157/1 158/16 159/22 159/24 160/6 160/8 160/16 160/23 161/1 161/4 161/16 164/1 165/13 165/15 165/20 166/6 167/10 167/14 167/23 167/24 168/17 168/24 169/5 169/25 170/2 170/6 171/2 171/7 171/10 171/25 172/3 172/12 173/3 173/3 173/18 174/10 I thought [1] 107/24 I turn [2] 6/4 42/12 I understand [1] 160/23 I used [2] 96/13 96/18 I want [1] 173/23 I wanted [5] 26/8 90/7 135/11 138/10 164/7 I was [26] 42/18 80/3 99/2 99/3 99/4 101/24 106/17 109/15 116/23 128/10 139/14 139/19 140/3 140/5 141/3 141/16 141/22 146/24 147/13 155/14 155/16 161/20 165/20 166/5 169/22 171/22 I wasn't [8] 116/13 130/3 155/16 161/22 166/6 167/11 167/11 171/23 I went [2] 140/5 172/14	I will [4] 3/7 40/1 71/19 101/3 I wish [1] 72/16 I won't [8] 2/3 2/8 4/2 5/20 15/1 51/4 63/20 85/25 I wonder [1] 84/22 I would [22] 71/15 97/11 98/7 107/20 121/6 126/17 127/5 131/1 131/25 132/4 143/24 147/15 153/4 155/22 155/25 165/21 167/12 167/20 168/15 168/21 168/22 172/19 I wrote [1] 155/12 I'd [4] 98/11 101/1 139/13 157/23 I'll [5] 16/8 53/22 94/25 164/5 164/14 I'm [39] 7/21 10/3 16/5 16/16 21/18 94/22 95/24 99/19 103/1 104/11 108/5 110/15 119/19 120/5 120/20 121/14 122/11 127/25 131/2 134/7 137/25 138/12 138/18 139/12 140/9 140/20 148/23 151/5 154/1 155/21 155/21 157/14 157/15 168/3 172/22 173/12 173/17 173/18 173/21 I've [10] 88/1 127/7 136/24 139/12 145/9 148/24 150/12 158/16 169/25 172/3 i.e [2] 40/22 170/5 IAN [2] 95/22 175/3 Ibbotson [4] 67/10 133/16 133/19 133/19 idea [10] 16/19 22/25 59/2 108/12 110/5 112/23 113/2 113/17 130/5 139/20 ideally [1] 134/10 identification [1] 84/12 identified [3] 82/14 128/18 154/20 identifies [1] 25/6 if [246] III [13] 68/18 68/20 69/4 70/11 75/15 83/5 83/23 84/10 84/23 85/17 92/19 93/18 118/1 illuminate [1] 22/8 imagine [2] 117/24 157/6 immune [4] 60/9 65/5 68/17 117/10
----------	--	--	---	---	--

(56) home... - immune

I	33/18 58/25 116/5	informing [5] 53/17	into [16] 6/3 31/14	30/10 31/8 34/1 35/15	Jonathan [1] 26/11
Immuno [6] 28/2 29/7	increasing [7] 11/17	82/5 89/16 132/6	48/24 52/15 54/18	37/15 37/16 37/18	Jonathan's [1] 26/15
53/21 56/3 127/19	12/3 16/19 17/18 21/8	132/12	63/13 65/3 85/25	37/19 38/12 38/15	journal [9] 57/8 57/11
162/1	44/4 174/7	infuse [1] 25/8	91/10 92/19 126/24	40/14 41/18 46/4	77/17 142/22 142/22
immunocompromised	incubation [3] 57/6	infusion [3] 24/8	128/18 133/25 135/3	48/15 49/21 51/11	142/24 143/1 161/16
[1] 68/13	151/9 154/23	50/10 50/21	141/9 163/15	60/1 60/20 65/14	162/20
immunodeficiency [2]	indeed [6] 4/1 11/4	inherited [1] 113/16	introduce [1] 158/22	67/18 67/18 67/20	journals [6] 142/17
56/14 65/19	42/25 43/7 79/8	inhibitor [2] 38/16	introduced [2] 66/19	73/5 75/1 75/3 77/5	142/17 143/1 161/7
immunological [2]	147/17	38/25	88/22	78/6 78/10 78/22	161/10 161/11
65/25 73/18	indicated [3] 33/1	inhibitors [3] 26/16	invaluable [1] 73/14	84/22 88/17 88/19	July [7] 6/17 7/3 7/9
immunopathology [1]	88/23 146/13	26/18 27/7	invariably [1] 46/5	90/12 92/12 93/16	72/4 84/20 102/2
6/12	indicating [1] 60/24	initially [1] 102/10	investigate [2] 68/17	94/17 109/18 110/9	161/12
impact [2] 157/10	indirectly [1] 47/3	injection [1] 155/17	78/12	114/9 118/17 120/19	July 1976 [2] 6/17 7/3
157/13	individual [12] 5/21	inquiry [20] 6/8 22/7	investigation [1] 63/6	122/23 125/25 130/10	July 1982 [1] 161/12
impending [1] 17/10	6/8 20/3 22/7 42/16	42/16 77/19 80/6	Investigations [1]	132/8 135/16 137/14	July 1992 [1] 102/2
imperative [1] 69/6	48/25 70/17 104/2	80/17 86/12 86/22	62/8	138/11 138/16 138/18	June [12] 16/21 16/24
implemented [1] 44/2	118/25 149/21 171/22	86/23 87/1 87/2 103/3	investigators [1] 76/7	145/9 145/19 145/20	26/10 54/4 57/14
implication [2] 67/22	171/23	103/21 104/5 108/4	investment [1] 166/15	147/11 147/14 147/15	58/13 59/24 62/5
68/8	individuals [3] 85/9	109/16 138/10 143/5	invitation [1] 62/18	147/22 147/23 148/10	125/25 129/1 129/25
implications [3] 33/25	159/6 160/5	152/13 156/14	invite [4] 54/9 126/8	149/11 149/17 151/3	168/7
68/2 70/14	industry [2] 159/4	Inquiry's [4] 86/20	126/18 133/15	151/5 153/18 154/1	June 1982 [1] 16/24
importance [1]	160/4	95/10 139/4 153/22	invited [2] 53/5 74/13	156/22 157/12 159/20	June 1983 [3] 54/4
162/14	inevitable [1] 90/20	insidiously [1] 151/11	involve [2] 61/2 77/23	169/4 170/10 170/11	58/13 129/1
important [7] 14/18	inexperienced [2]	insight [1] 48/24	involved [14] 33/3	170/11 172/16	junior [2] 106/1 107/2
44/21 56/11 78/19	101/24 108/6	insignificant [2] 16/1	54/20 78/23 81/21	items [2] 23/20 23/21	just [87] 4/21 11/13
124/23 127/3 166/16	infected [7] 81/3	47/19	84/13 99/2 99/4 101/2	its [13] 1/24 19/1	14/6 14/9 15/20 15/21
imported [2] 66/10	81/17 84/2 84/15	instance [1] 14/16	117/23 118/15 126/25	40/12 70/11 89/7	21/3 26/11 31/5 31/6
68/22	87/11 89/21 113/11	instead [2] 50/15	128/10 130/2 133/2	90/21 92/19 98/4	32/9 32/24 35/24
impossible [2] 9/1	infection [13] 55/20	60/20	involvement [7] 7/17	103/4 142/10 144/5	35/25 38/11 38/20
69/22	80/13 81/11 81/23	Institute [7] 9/4 9/22	99/7 99/14 103/23	149/15 152/11	39/18 40/2 41/12 43/8
impression [1] 31/19	82/12 86/3 88/24	10/2 13/13 13/25	104/3 107/7 126/19	IX [21] 3/11 3/21 22/1	48/16 52/14 55/10
improve [3] 5/15	88/25 113/18 113/20	43/16 158/18	involvement's [1]	27/13 28/4 29/2 29/8	55/14 56/2 57/4 57/16
22/20 152/24	154/10 154/12 157/21	instituted [2] 3/7	118/7	29/20 30/4 30/17	57/19 58/20 67/2 71/9
improvement [2]	infectious [2] 57/18	11/24	involving [3] 63/5	30/18 31/3 35/23	71/19 71/23 73/3
151/23 152/8	164/16	instruction [3] 22/24	83/19 126/14	36/18 36/25 39/5 41/1	74/23 78/13 78/14
inactivation [1] 75/16	infective [1] 166/19	23/14 171/20	IPSN [1] 38/13	41/1 110/12 112/1	80/6 83/23 86/11
inadequate [1] 14/10	infectivity [2] 52/3	instructions [3] 24/9	IPSN000036 [1] 38/12	112/4	87/17 90/7 92/5 94/23
inappropriate [1]	53/17	25/3 25/25	Irish [1] 102/19	J	100/4 102/21 103/16
153/6	infer [1] 76/3	insufficient [3] 4/24	isn't [4] 137/9 153/3	Jane [1] 163/8	104/12 105/1 106/8
incidence [7] 44/22	inference [6] 45/24	138/2 161/11	153/20 162/25	Jane Desforges [1]	108/20 110/5 111/2
44/24 68/12 69/4	50/11 52/4 55/7 86/1	intend [1] 90/25	isolation [1] 28/11	163/8	114/6 115/7 117/25
146/5 146/10 150/23	94/4	interaction [1] 52/22	issue [29] 11/5 14/15	January [12] 53/20	118/5 121/1 124/3
incident [1] 93/11	influenced [2] 37/20	interactions [1] 92/10	22/24 53/17 55/19	56/2 56/15 57/3 57/9	125/15 125/18 129/14
incipient [1] 138/24	144/22	interest [5] 47/9 56/8	71/4 75/22 80/3 80/21	57/10 69/12 82/4	131/21 132/10 132/14
inclined [1] 39/9	influential [2] 165/2	88/21 101/12 117/9	87/12 87/16 89/1 92/4	98/22 161/17 162/1	132/17 133/17 135/10
include [3] 57/21	167/7	interested [2] 92/18	93/1 95/6 118/19	163/20	136/20 138/8 138/10
72/19 156/17	info [1] 52/5	143/25	119/4 119/7 119/21	January 1983 [5]	142/15 144/19 145/5
included [2] 88/7	inform [2] 86/2 91/12	interesting [4] 26/12	124/23 127/17 130/11	53/20 56/2 56/15	147/9 148/17 151/4
117/13	informal [1] 134/9	48/24 146/24 172/21	135/7 148/1 148/9	161/17 163/20	152/6 153/15 159/12
including [7] 6/25	information [21] 45/1	interim [2] 69/14	148/14 163/17 164/4	January 1985 [1]	166/13 168/6 170/10
20/24 37/4 41/18	45/4 53/7 60/17 62/13	71/22	165/11	69/12	170/16 171/3 173/23
56/25 65/7 76/12	80/4 82/4 82/9 85/2	internal [6] 38/15	issues [9] 1/23 6/1	Jeffreys [1] 90/17	174/3
inconsistent [1]	85/14 86/19 87/14	51/10 75/2 83/9 84/7	7/22 100/21 104/9	JEVA0000012 [1]	K
156/20	91/10 91/17 91/19	93/6	119/23 163/5 163/8	26/9	keen [1] 125/7
inconvenience [1]	93/1 134/13 142/18	internet [1] 161/2	163/10	Jillian [4] 2/16 7/12	keep [7] 23/24 45/18
34/4	156/24 168/25 172/9	interpret [1] 155/25	issuing [2] 61/18	21/17 26/10	94/24 112/20 122/13
increase [6] 9/9 16/1	informed [15] 40/7	interpretation [2] 78/6	118/24	joined [2] 112/20	122/21 153/25
17/16 19/13 46/14	55/15 64/7 64/11	88/23	it's [89] 4/21 5/15 6/14	122/4	kept [4] 25/15 25/16
66/23	68/11 69/3 69/9 81/25	interpreted [1] 78/7	7/6 8/24 13/2 17/7	joint [2] 64/20 138/25	134/9 134/10
increased [7] 11/19	85/13 85/16 85/20	intervals [2] 23/13	20/7 20/11 22/15	jointly [5] 2/12 4/9	Kernoff [6] 65/1 76/6
16/13 32/18 33/3	86/15 89/20 131/15	152/2	23/17 26/5 26/11	94/20 107/5 108/15	76/12 76/17 77/4
	132/24	interviewing [1] 61/21	26/12 26/12 29/8		

K					
Kernoff... [1] 157/3	Lane's [1] 118/17	Let's [2] 42/6 108/12	10/2 13/13 13/25	143/6 144/1 144/19	major [4] 119/20
key [4] 37/25 55/21	large [6] 59/1 100/8	letter [36] 22/13 22/16	lists [1] 72/15	145/5 147/4 147/19	128/4 136/12 137/3
73/17 143/23	104/21 109/15 137/5	23/14 24/10 26/10	litigation [2] 103/23	150/4 150/14 151/4	majority [4] 37/7
kind [5] 62/1 71/5	172/5	58/12 59/14 60/1 60/5	114/9	153/18 156/3 158/23	40/15 108/24 154/10
136/24 137/19 142/16	largely [7] 43/17	62/4 71/10 72/5 73/4	little [12] 12/1 28/9	162/1 165/25 173/11	make [8] 11/8 79/7
knew [6] 88/11 117/25	98/13 101/14 101/21	73/5 82/5 84/16 84/18	75/15 76/25 91/11	looked [23] 8/4 18/20	112/22 113/13 114/22
127/22 128/13 161/6	141/7 148/9 154/17	86/4 88/14 88/15	101/3 111/18 122/14	30/20 38/14 39/24	117/18 123/12 170/9
173/18	largest [3] 31/1	92/15 114/8 114/10	123/18 141/24 142/20	42/24 52/23 53/22	maker [1] 93/19
know [72] 2/9 5/7 5/20	109/11 109/12	114/11 114/13 116/14	166/13	56/6 59/25 64/3 66/5	making [6] 54/14
7/6 7/10 28/16 39/19	last [21] 2/23 13/22	116/17 116/18 116/19	live [1] 23/7	71/23 85/24 93/22	92/25 97/9 135/3
44/6 50/14 50/19	19/19 22/4 26/3 33/22	119/2 125/3 125/8	lived [1] 121/24	125/23 155/15 156/10	139/8 159/14
53/25 57/14 58/2	37/11 40/20 56/4	129/20 157/2 157/6	liver [37] 44/25 45/9	157/2 158/19 164/16	man [1] 122/11
59/10 61/10 62/22	57/17 65/4 78/14	165/17	45/12 47/5 47/10	165/21 169/25	manage [2] 105/19
63/19 64/17 65/2	96/17 127/8 132/13	letters [1] 72/10	47/12 47/22 52/9	looking [22] 1/7 32/14	135/9
74/12 78/21 78/25	143/2 144/4 144/10	leukaemia [1] 163/16	75/20 75/21 76/8	38/17 57/18 87/18	managed [1] 69/21
83/7 85/6 102/23	145/23 155/11 162/3	leukemic [1] 68/14	143/14 143/15 145/13	110/16 110/17 110/18	management [2] 71/1
106/16 107/14 117/25	late [4] 42/19 64/21	level [3] 98/9 106/1	145/18 146/6 146/8	111/23 127/23 140/10	107/23
118/1 118/3 118/10	81/18 165/9	121/20	146/12 146/18 147/6	146/23 147/16 152/9	managing [1] 107/25
119/16 121/14 122/20	late 1970s [1] 42/19	levels [3] 46/25 52/11	148/2 148/3 148/6	155/14 156/11 157/18	Manchester [7]
123/7 124/17 124/18	later [21] 2/5 14/22	151/15	148/16 148/18 148/22	159/4 159/12 160/25	143/17 144/16 145/6
127/20 128/23 130/8	41/5 42/22 73/4 79/23	lever [1] 135/8	149/6 150/8 150/20	161/20 170/16	145/8 145/11 145/17
130/14 130/19 133/20	88/4 88/17 89/22 92/5	liberty [1] 137/12	151/2 151/18 155/3	looks [6] 22/2 30/7	156/11
134/8 134/12 134/19	103/3 107/11 108/18	life [6] 138/23 138/23	155/5 155/18 156/6	63/14 67/1 75/7 160/8	Mann [5] 2/16 7/12
134/21 135/5 136/11	114/8 117/11 126/14	139/2 139/5 139/10	156/25 160/19	lot [22] 26/3 98/16	8/11 21/17 26/10
140/5 141/5 141/13	138/19 152/17 153/13	139/10	load [1] 78/18	105/9 105/19 113/5	Mannucci [1] 75/23
142/13 143/22 149/11	162/17 164/20	life-enhancing [1]	local [2] 34/21 173/11	119/23 127/8 127/21	manufacture [4]
152/12 153/8 153/10	latter [3] 39/1 68/5	139/10	locale [1] 124/14	137/15 140/11 141/14	33/20 34/11 34/14
159/11 161/12 162/3	87/9	life-saving [2] 139/5	locally [4] 34/20	142/11 143/13 144/2	34/15
162/21 163/15 163/23	latterly [1] 92/21	139/10	70/20 102/10 120/10	148/15 149/22 149/24	manufactured [1]
165/8 166/11 167/18	lead [2] 16/12 143/12	life-threatening [1]	location [1] 55/19	155/13 160/19 163/15	10/11
168/22 169/22 171/11	leading [1] 97/25	139/2	Loftus [1] 75/3	171/21 172/6	many [17] 14/10 23/7
171/22 173/2	leads [1] 75/21	light [3] 68/9 116/8	London [5] 53/21 56/3	lots [1] 113/1	73/11 89/1 92/23
knowing [2] 135/5	learning [1] 98/2	132/25	75/5 96/14 97/21	low [1] 136/25	99/12 103/13 118/1
156/1	learnt [2] 57/11	like [12] 22/2 30/7	long [16] 15/1 23/13	lowest [2] 55/15	122/20 139/23 139/23
knowledge [16] 1/25	144/23	67/1 104/20 106/23	25/2 42/21 80/24 84/2	131/15	139/23 139/23 147/17
38/1 42/3 42/13 56/17	least [24] 7/18 12/4	121/13 135/8 137/1	93/9 103/12 120/20	Lucas [1] 75/3	149/14 151/16 169/25
88/3 88/8 98/17	14/2 19/6 25/21 35/18	142/13 155/19 161/8	139/14 139/16 144/6	Ludlam [2] 65/7 65/16	Marcela [2] 97/23
140/21 144/14 146/22	36/10 50/2 55/7 60/13	167/9	144/14 151/8 156/4	Luncheon [1] 95/17	97/24
150/7 161/3 161/5	61/9 63/11 63/18 78/6	likely [13] 23/10 49/22	157/5	lunchtime [2] 1/16	March [15] 62/18
162/24 171/1	79/9 85/25 86/7 94/4	61/20 67/6 68/22 75/7	long-standing [1]	173/15	64/16 64/21 66/3
known [7] 57/3 76/4	117/2 129/25 131/20	77/6 88/5 98/3 118/10	139/14	Lymphocyte [1] 65/12	72/11 72/25 73/6 75/1
84/8 84/25 86/18	149/6 152/12 167/7	122/21 143/3 157/13	long-term [5] 42/21		75/5 76/21 82/16
119/8 167/24	leave [1] 57/16	limit [2] 117/14 132/8	139/16 144/6 144/14	M	92/12 97/19 114/10
Koate [1] 41/19	leaving [1] 43/16	limited [6] 5/24 73/9	157/5	made [31] 5/10 9/7	114/15
Kryobulin [3] 10/25	lecturer [1] 106/16	101/21 114/19 115/24	longer [3] 41/16 41/18	10/8 33/5 33/10 34/20	March 1984 [3] 66/3
28/1 29/7	led [1] 59/10	146/22	91/11	34/20 40/4 42/15	114/10 114/15
L	Lee [4] 65/1 65/4	limiting [2] 42/20	longitudinal [1] 156/4	51/12 53/8 56/18	March 1985 [1] 72/25
lab [2] 84/17 84/20	76/23 77/16	105/15	look [65] 2/4 2/5 3/22	58/19 58/24 60/6	March 26 [1] 75/1
laboratory [10] 3/9	Lee's [1] 144/4	line [3] 17/8 30/25	7/21 14/9 15/5 21/10	60/18 60/19 66/10	March 27 [1] 92/12
6/1 6/10 6/16 22/3	Leeds [2] 96/2 141/3	49/21	22/10 24/4 26/8 27/14	67/8 69/7 72/8 83/2	Mark [4] 170/1 171/18
101/15 101/16 106/2	left [1] 70/16	lines [6] 10/12 22/20	29/3 30/4 31/25 34/17	100/9 113/14 116/7	171/24 173/6
106/3 118/24	legal [2] 95/8 104/4	40/20 69/2 138/21	36/12 37/11 37/12	120/10 120/11 123/19	Mark Winter [3] 170/1
lack [6] 5/22 34/6 81/5	lengthy [2] 60/16	143/9	38/11 39/19 43/2 49/9	127/21 133/13 158/21	171/18 173/6
98/8 144/13 170/21	162/8	linked [1] 68/21	50/7 53/23 54/3 55/10	magazine [1] 143/4	marked [1] 151/14
laid [1] 53/3	lesions [1] 58/24	list [3] 23/21 56/5	55/12 66/16 75/13	main [7] 7/21 11/3	marrow [6] 98/24
Lancet [4] 142/22	less [7] 15/15 17/22	162/4	94/23 103/19 108/12	35/11 38/3 105/22	100/6 100/11 102/7
149/2 156/18 162/17	28/11 32/3 121/13	Lister [16] 9/4 9/22	108/20 110/4 111/17	139/1 141/3	146/25 167/12
Lane [3] 74/13 116/15	136/9 146/7	10/2 13/13 13/21	114/6 114/12 116/15	mainly [3] 98/23	Martin [2] 85/24 86/2
119/17	let [9] 9/22 62/15	13/25 14/3 15/23 16/3	118/9 120/15 123/25	141/11 166/9	Martin Beard [1]
	74/11 118/10 135/10	29/18 31/1 32/4 43/16	124/3 124/10 125/15	maintain [1] 72/16	85/24
	140/13 158/23 164/17	87/22 97/14 97/16	129/14 131/12 138/8	maintaining [2] 93/24	mask [1] 95/20
	169/5	Lister Institute [4] 9/4	140/23 142/15 143/3	117/14	match [1] 141/7

M	165/9 165/13 166/6 167/10 167/13 168/17 168/24 169/25 171/8 meaning [1] 127/25 meaningless [1] 117/20 means [3] 39/1 58/25 74/3 meant [5] 16/23 88/12 90/4 160/18 170/23 meantime [1] 72/7 measurable [1] 152/10 measures [1] 63/5 medical [15] 10/15 48/20 70/24 86/14 96/5 102/11 102/13 102/21 105/8 105/23 140/25 141/20 142/17 142/21 151/13 medicine [9] 57/8 57/11 89/7 97/20 102/16 142/23 158/18 161/17 162/20 Medicines [1] 159/10 meet [7] 9/1 10/9 17/13 54/12 104/18 126/11 133/15 meeting [94] 8/9 13/1 13/4 14/21 16/14 16/21 16/24 18/5 18/19 19/16 19/18 28/21 29/13 32/11 39/22 39/24 43/5 44/10 44/18 46/8 47/25 48/7 48/22 48/23 51/1 51/3 52/21 53/21 53/25 54/4 54/19 55/11 56/3 56/15 57/13 59/24 61/15 63/20 63/21 64/2 64/14 64/20 66/13 66/14 67/4 67/14 67/15 67/21 68/3 68/8 70/17 71/13 75/4 75/5 75/6 75/9 75/12 75/13 79/6 80/23 82/20 90/10 90/23 91/2 91/20 94/12 94/16 95/2 115/3 125/21 127/9 130/3 131/7 133/6 133/8 134/11 140/5 141/19 141/20 161/25 162/21 163/4 163/10 165/10 165/12 169/3 169/9 170/2 170/4 170/5 170/15 170/16 172/9 172/20 meeting's [1] 57/7 meetings [13] 11/2 12/11 12/23 17/3 44/7	71/18 103/10 125/15 131/5 166/7 172/13 172/19 173/12 melted [1] 24/24 member [4] 44/6 80/11 103/7 103/16 members [9] 9/24 11/15 15/7 19/3 33/23 48/13 53/7 71/11 94/19 membership [2] 96/24 99/21 memo [3] 75/2 75/10 93/6 memory [1] 123/18 men [10] 100/24 107/24 133/3 146/23 155/14 160/20 161/7 163/14 164/15 168/18 mention [1] 161/2 mentioned [8] 18/1 90/25 94/11 106/11 137/4 168/13 168/15 173/6 mentor [1] 141/3 message [1] 124/22 met [3] 17/18 71/21 94/19 micronodular [1] 146/3 mid [1] 26/7 mid-1970s [1] 26/7 middle [4] 2/16 19/24 19/25 158/6 Midlands [37] 4/4 4/15 7/24 8/7 9/1 11/5 12/17 12/25 13/3 16/8 19/23 20/23 29/13 32/13 39/24 43/6 48/2 48/23 51/15 52/21 59/22 59/24 64/1 66/14 67/16 67/20 71/12 71/21 82/19 94/2 103/13 103/18 103/24 108/23 125/21 130/18 173/11 might [28] 18/15 25/6 37/20 43/14 57/18 57/19 57/21 63/4 77/23 80/16 88/8 91/9 95/20 113/7 116/14 124/2 130/16 131/25 136/9 136/13 137/1 137/13 138/6 155/5 155/20 169/19 174/5 174/6 mild [16] 46/16 49/4 49/7 49/13 49/20 49/22 49/25 50/17 121/7 123/4 144/11 146/4 151/19 154/24 155/8 157/21	mildly [3] 58/22 59/4 69/17 million [9] 15/12 15/21 15/21 32/24 54/10 67/6 111/14 133/12 142/1 mind [10] 43/14 43/23 45/18 79/19 79/20 93/3 93/20 143/10 156/8 166/15 minor [3] 26/17 42/20 58/24 minute [3] 48/7 171/2 171/6 minuted [1] 64/12 minutes [26] 8/6 16/6 16/6 16/9 18/20 20/14 21/4 24/25 28/21 32/10 37/23 43/5 44/1 44/10 54/16 71/23 90/9 101/4 103/19 120/16 133/10 162/8 172/6 172/10 172/11 172/21 misdiagnosed [1] 49/24 mistakes [1] 141/8 mixture [2] 57/20 115/16 MMWR [4] 160/24 161/8 162/16 163/22 MMWRs [1] 163/7 modest [1] 36/4 moment [11] 3/24 7/2 31/5 53/23 61/9 78/21 83/5 124/10 146/21 152/6 155/9 moments [4] 18/1 30/20 59/25 127/18 money [5] 18/15 130/21 130/25 132/4 148/14 monitor [1] 62/19 MONOCALATE [2] 76/7 78/20 month [4] 23/7 96/16 116/23 152/2 monthly [2] 119/4 119/5 months [13] 6/10 6/11 52/22 57/6 58/10 97/4 98/19 100/16 101/22 101/23 116/17 151/16 161/7 Morag [2] 165/10 169/13 Morag Chisholm [1] 165/10 more [44] 3/24 11/21 14/17 17/23 17/24 31/20 33/20 39/2 39/8 40/21 55/1 60/17	68/22 78/21 81/4 92/11 93/1 95/2 95/4 95/11 101/3 107/19 108/3 108/8 121/9 122/15 128/10 128/21 134/23 141/5 143/2 144/24 146/8 150/11 153/18 155/20 157/22 171/16 171/19 172/1 172/9 172/13 173/2 173/6 morning [12] 1/6 1/11 1/22 42/7 93/7 104/17 120/5 122/1 125/23 164/22 168/7 173/14 mortality [2] 46/21 56/21 mortem [1] 47/5 most [16] 4/5 23/9 29/20 39/2 45/8 51/15 59/8 75/16 116/21 119/20 138/24 139/9 141/17 142/25 144/7 152/24 mother [4] 81/23 85/21 86/10 90/1 mother's [1] 85/13 mouth [1] 161/9 move [20] 12/24 14/20 18/2 27/3 28/22 33/2 35/16 39/25 40/4 53/20 64/1 64/16 80/3 107/3 116/12 131/4 140/9 160/22 171/3 173/10 moved [5] 6/13 81/14 98/18 102/4 129/3 moving [2] 79/11 79/24 Mr [24] 53/2 54/9 54/12 81/2 81/3 81/7 81/12 81/24 85/15 85/21 86/9 87/22 89/19 89/24 90/1 90/17 90/24 126/8 126/11 126/11 126/14 126/22 133/14 133/19 Mr Al [2] 81/12 85/21 Mr AN [1] 81/24 Mr Charles [1] 87/22 Mr Edwards [1] 53/2 Mr Evans [2] 81/3 89/19 Mr Evans' [1] 81/2 Mr Gregg [1] 86/9 Mr Gregg's [1] 90/1 Mr Jeffreys [1] 90/17 Mr O [2] 81/7 89/24 Mr O's [1] 85/15 Mr Shinton [1] 126/11 Mr Stanton [7] 54/9 54/12 126/8 126/11	126/14 126/22 133/19 Mr Stanton ... should [1] 133/14 MS [4] 1/5 95/23 175/2 175/4 much [17] 13/24 37/15 37/16 37/17 44/23 98/15 101/1 113/12 113/14 115/21 117/15 138/6 142/5 165/25 171/17 173/22 174/12 multi [3] 145/16 146/6 147/1 multi-transfused [3] 145/16 146/6 147/1 must [6] 25/16 98/3 105/7 119/6 159/9 162/11 my [36] 72/22 74/3 74/17 80/11 97/25 98/25 106/23 113/17 114/19 118/12 123/22 129/8 129/12 131/2 137/4 138/16 139/13 140/3 141/3 142/21 142/23 143/10 146/21 147/4 148/19 149/25 150/7 155/12 157/23 161/2 161/21 163/12 164/12 168/17 168/18 170/2 myself [7] 105/23 114/19 115/15 116/7 124/21 134/19 148/5
				N	
				name [8] 44/11 87/4 124/15 153/17 153/18 153/20 154/3 169/7 named [1] 73/2 names [1] 52/4 national [3] 12/8 102/11 102/13 nationally [1] 12/20 natural [1] 152/11 nature [2] 104/2 139/11 necessarily [4] 87/23 157/20 163/14 173/8 necessary [4] 9/10 10/10 16/18 23/20 necessity [1] 10/24 need [21] 9/2 20/10 24/4 24/13 24/20 25/4 30/21 50/1 66/5 78/12 78/25 92/5 95/19 103/3 109/9 118/19 140/1 140/2 148/14 165/25 169/15 needed [8] 5/11 21/1 33/21 108/8 120/19	

N	137/24 138/1 NHS Factor VIII [5] 34/12 36/15 66/10 70/2 70/6 night [2] 100/22 101/1 nights [1] 106/18 nine [5] 72/15 73/2 83/14 110/10 111/24 no [96] 13/15 19/11 19/14 20/2 21/25 29/4 29/21 30/11 31/15 33/8 34/9 37/22 40/9 41/15 41/17 41/18 42/20 46/22 47/17 50/20 52/4 52/6 52/24 53/16 54/16 55/17 55/18 59/13 59/19 60/11 60/19 62/1 63/24 66/3 67/11 69/22 69/25 79/17 79/19 81/10 82/7 85/14 85/23 88/11 94/9 94/25 97/11 99/7 99/16 99/19 99/19 101/11 102/22 106/4 107/8 109/21 110/3 111/4 111/24 112/11 112/11 112/14 113/17 118/8 118/14 125/14 125/14 128/12 128/25 129/8 129/10 130/3 130/15 131/17 132/10 135/1 138/5 138/16 145/2 145/7 146/21 148/20 148/21 148/22 155/10 155/12 157/14 158/5 163/3 163/4 169/15 169/17 169/24 170/8 171/6 173/21 no-one [1] 88/11 nomenclature [1] 110/2 non [76] 42/17 42/17 42/19 42/19 45/20 45/20 46/1 46/1 46/13 46/13 46/15 46/15 46/24 46/24 48/16 48/16 57/21 57/21 57/23 57/23 65/2 65/2 76/10 76/10 90/2 90/2 92/20 98/4 98/4 98/10 98/10 135/6 135/7 141/19 141/19 141/20 141/21 142/10 143/8 143/8 143/21 143/21 144/10 144/10 144/14 144/15 144/24 144/24 146/18 146/18 146/22 146/22 149/15 149/15 150/13 150/13 150/18 150/18 150/20 150/20 154/6 154/6 154/11	154/11 154/17 154/17 155/7 155/7 157/4 157/4 157/20 157/20 157/25 157/25 158/10 158/10 non-A [37] 42/17 42/19 45/20 46/1 46/13 46/15 46/24 48/16 57/21 57/23 65/2 76/10 90/2 98/4 98/10 135/6 141/19 141/20 143/8 143/21 144/10 144/14 144/24 146/18 146/22 149/15 150/13 150/18 150/20 154/6 154/11 154/17 155/7 157/4 157/20 157/25 158/10 non-B [35] 42/17 42/19 45/20 46/1 46/13 46/15 46/24 48/16 57/21 57/23 65/2 76/10 90/2 98/4 98/10 141/21 143/8 143/21 144/10 144/15 144/24 146/18 146/22 149/15 150/13 150/18 150/20 154/6 154/11 154/17 155/7 157/4 157/20 157/25 158/10 non-B hepatitis [1] 135/7 non-remunerated [1] 142/10 non-treated [1] 92/20 none [2] 104/5 125/14 nonetheless [1] 38/10 nor [4] 81/25 85/15 86/10 89/20 normal [3] 30/17 121/19 123/14 normally [2] 23/6 46/3 North [2] 4/6 97/21 Northern [1] 96/19 not [135] 4/11 5/11 8/10 8/11 9/7 9/21 13/13 14/3 15/25 16/5 19/13 20/7 21/18 22/4 23/3 25/2 26/18 30/18 31/14 34/1 39/12 42/21 43/14 44/1 45/9 46/5 47/19 49/24 50/14 55/6 55/23 56/9 57/10 57/19 57/24 58/2 58/8 59/19 60/21 61/9 61/11 67/18 68/6 70/7 73/15 74/11 74/17 77/2 79/19 80/19 80/24 81/8 81/13 86/2 88/4 88/13 88/25 90/25 91/17 94/22 99/19 103/1	104/11 104/24 105/12 105/18 108/5 109/12 112/25 114/1 115/10 115/16 115/22 116/11 117/16 117/24 118/7 118/23 119/19 120/20 120/23 126/4 127/4 128/5 128/7 128/11 128/11 132/8 137/14 137/25 138/2 138/16 138/25 139/2 139/12 139/14 140/15 143/10 144/5 145/9 146/13 147/12 147/22 148/14 149/21 149/22 151/12 151/13 152/16 153/4 154/8 154/20 155/21 155/21 156/1 156/20 157/18 158/2 158/3 158/9 159/1 159/21 161/4 162/5 163/10 163/14 165/24 166/7 166/18 168/3 170/17 170/20 171/11 172/3 172/5 note [9] 1/8 21/17 42/4 89/19 92/14 140/9 161/25 162/25 173/10 noted [4] 16/17 71/22 161/17 164/21 notepaper [1] 165/19 notes [5] 23/17 92/9 155/15 171/21 172/6 nothing [2] 35/8 96/13 notice [1] 118/15 noticeable [1] 38/10 novel [1] 170/7 November [8] 18/5 22/15 44/8 44/10 46/8 49/10 49/14 82/21 November 1975 [1] 22/15 November 1977 [1] 18/5 November 1979 [1] 46/8 November 1987 [1] 82/21 now [38] 2/19 4/3 7/5 12/17 12/24 13/2 28/23 31/8 32/10 35/7 35/11 42/6 64/8 68/16 76/17 84/4 84/8 93/17 96/19 97/23 99/5 100/10 117/5 124/16 132/18 133/7 135/5 135/18 140/21 141/13 143/2 144/1 152/12 154/12 161/4 162/21 165/8 167/9 number [47] 3/14 3/15	4/6 4/12 4/23 6/2 11/2 11/15 12/11 15/12 15/14 21/19 22/20 28/24 29/16 30/1 30/6 30/7 31/12 41/7 44/7 46/2 47/20 49/10 53/22 56/7 65/6 66/6 78/22 79/7 82/21 85/10 85/17 88/17 92/3 102/9 113/3 113/8 128/6 131/12 145/20 150/25 151/1 153/1 157/2 157/11 166/21 number 654 [1] 145/20 numbered [2] 58/21 78/15 numbers [7] 2/21 8/4 28/17 36/3 44/15 108/12 109/7 nurse [2] 105/15 106/9 nursing [2] 5/22 14/8	occur [1] 69/10 October [10] 1/1 51/25 63/20 79/6 84/20 88/16 94/13 97/3 165/12 169/8 October 1980 [1] 97/3 October 1981 [1] 51/25 October 1983 [1] 63/20 October 1984 [1] 84/20 odd [6] 36/5 37/5 99/8 111/11 111/11 133/1 odds [1] 71/23 off [7] 20/18 20/25 26/23 99/5 120/18 120/19 123/14 offer [2] 11/21 138/1 offered [2] 137/18 138/4 offering [1] 138/5 office [6] 64/10 64/15 104/21 132/23 133/2 133/5 officer [6] 10/15 48/20 94/1 94/2 96/1 96/2 officers [1] 105/25 official [1] 34/9 often [3] 130/20 154/24 155/7 Oh [2] 113/17 166/3 Okay [3] 120/1 134/22 166/3 old [1] 100/3 older [1] 171/16 ominously [1] 4/18 omitted [1] 169/6 once [6] 89/15 89/24 103/6 104/16 112/23 113/24 one [81] 14/9 19/22 20/5 26/23 28/6 28/20 30/3 32/4 35/4 38/1 38/5 38/11 39/15 41/3 45/18 46/23 51/17 53/15 53/24 57/19 57/19 58/3 63/14 65/9 71/4 77/11 77/20 78/22 79/9 85/25 87/6 88/11 88/14 92/5 92/11 101/13 103/10 103/10 105/1 105/13 105/15 105/24 106/8 106/9 106/9 106/18 106/18 110/14 112/19 112/23 113/8 113/9 113/9 113/9 115/16 124/2 125/6 125/6 125/15 125/16 137/5 138/10 139/6 139/14 141/5 142/1 142/13
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(60) needed... - one

O one... [14] 145/25 150/10 152/6 152/11 152/20 152/23 155/10 158/7 163/23 166/8 167/25 168/8 173/20 173/23 one company's [1] 125/6 one's [1] 31/16 one-off [1] 26/23 ones [3] 4/7 103/14 172/23 ongoing [2] 12/2 88/24 Online [1] 143/1 only [43] 5/15 19/2 36/14 37/22 38/5 47/16 47/18 57/24 64/12 86/23 89/22 91/7 94/4 100/17 103/9 105/13 106/16 109/15 115/22 116/23 117/16 118/4 122/12 127/7 129/8 134/16 135/8 138/12 145/3 145/25 146/4 147/15 148/16 149/18 152/10 152/18 153/17 153/18 154/1 154/3 163/14 171/10 172/15 onto [1] 116/9 onwards [2] 145/3 154/6 open [4] 45/18 50/11 78/6 143/3 operation [7] 26/6 50/3 50/8 112/19 136/11 137/3 137/6 operations [2] 41/8 46/17 opinion [3] 108/9 114/22 170/22 opportunity [1] 148/1 opposed [1] 122/6 opposite [1] 77/13 or [111] 2/6 7/8 10/1 16/3 17/21 18/16 23/7 24/14 28/3 28/10 30/12 31/13 32/15 37/14 39/5 39/8 48/16 50/4 51/11 55/3 55/9 55/19 55/23 56/25 58/23 59/4 59/5 59/9 61/7 61/11 62/2 64/13 67/12 67/14 69/18 69/23 71/6 71/7 72/18 73/15 76/2 80/4 80/5 80/11 85/1 85/12 85/18 86/7 86/21 89/11 89/15 90/4	91/24 99/2 100/22 101/1 101/7 101/9 103/5 105/18 105/18 107/12 109/1 109/5 113/1 115/16 116/23 118/6 119/12 122/25 122/25 123/11 126/23 129/4 129/6 130/5 130/11 131/23 134/9 134/9 134/15 135/2 136/2 136/2 136/10 138/25 141/17 142/13 142/17 146/18 147/6 147/10 147/25 151/19 152/12 152/17 154/11 155/11 157/21 160/13 162/24 164/12 164/16 165/1 166/7 168/2 171/1 171/12 171/20 172/2 172/23 oral [1] 86/21 orange [1] 25/16 orange-stripe [1] 25/16 order [4] 11/20 44/15 45/16 130/12 organisation [2] 109/23 171/13 organisations [1] 103/5 organised [3] 50/9 107/25 170/22 origin [1] 43/18 original [1] 83/19 Ormond [6] 6/13 73/12 97/4 97/13 101/22 107/21 other [54] 4/3 11/4 12/9 12/9 19/21 20/6 20/17 20/23 28/16 33/23 34/5 38/11 38/15 41/20 55/19 60/13 61/14 68/18 72/18 72/21 73/17 73/19 73/20 86/25 87/2 88/19 102/22 103/14 104/9 106/25 115/16 123/3 124/23 125/12 127/12 132/11 132/15 135/2 142/12 142/17 143/1 145/5 146/4 148/19 152/24 154/5 155/11 156/10 156/14 164/1 164/25 167/18 171/12 171/16 others [9] 12/23 52/3 65/16 65/24 67/10 74/20 127/12 131/12 165/5 others' [1] 4/1 otherwise [2] 105/20 152/10	our [20] 12/18 22/24 42/6 58/14 76/7 92/9 92/15 95/7 95/12 112/17 114/12 116/22 117/13 129/10 135/8 158/7 164/4 166/23 167/2 167/17 ourselves [1] 91/8 out [39] 4/3 13/15 13/23 15/9 22/18 25/17 26/19 30/6 42/22 44/15 45/16 47/15 47/19 49/23 58/13 62/18 75/25 84/23 86/13 92/9 93/2 99/1 101/13 104/11 106/5 106/6 116/10 126/23 128/14 130/3 130/5 140/2 146/9 148/9 151/7 160/17 161/7 163/7 163/25 out-patient [2] 106/5 106/6 outbreak [2] 68/11 79/21 outlined [2] 44/2 94/15 outlining [1] 114/15 outside [2] 98/6 123/22 over [44] 1/17 2/7 4/23 6/1 9/14 10/16 11/2 15/21 15/21 21/11 24/22 32/24 34/14 43/9 46/20 53/13 57/4 61/14 62/11 64/4 67/5 70/3 76/5 83/17 83/23 85/22 86/11 101/5 106/21 107/11 120/7 121/23 125/17 131/8 133/9 135/22 142/20 143/1 151/16 154/19 157/25 162/6 164/9 173/20 overall [2] 28/12 32/5 overstated [1] 145/14 overt [1] 45/10 overview [3] 1/23 95/25 104/12 own [9] 22/25 87/24 128/8 128/15 143/20 144/5 158/13 166/24 167/17 Oxford [14] 3/20 4/15 6/6 6/11 12/15 22/4 29/20 31/3 39/4 47/4 47/11 48/6 93/25 107/22	53/10 packaging [1] 52/15 packs [5] 23/24 24/1 24/17 52/16 127/10 paediatric [1] 6/16 page [123] 4/22 8/14 8/15 10/4 11/13 11/22 13/8 14/6 14/25 16/23 16/25 17/7 18/6 18/7 18/9 18/11 18/11 18/21 19/19 22/19 23/16 24/6 24/22 24/23 25/10 25/20 27/16 29/14 30/21 31/6 31/25 32/12 33/11 35/1 36/24 36/25 38/20 40/6 40/19 40/25 43/8 43/9 44/12 44/14 44/16 45/6 46/12 46/20 48/4 48/5 49/9 49/18 52/24 54/6 55/13 56/4 56/12 56/13 57/4 60/2 60/3 60/22 61/14 61/15 61/16 62/7 62/12 64/5 64/22 64/25 64/25 65/10 65/11 65/14 66/17 66/21 67/5 70/3 76/5 78/14 80/8 80/8 83/17 84/3 88/18 89/6 90/16 94/14 108/21 110/16 110/17 126/6 129/11 129/12 129/14 130/6 131/12 131/13 132/10 132/15 133/9 135/17 136/14 138/12 138/17 143/7 143/8 144/9 145/19 145/21 145/23 150/16 150/17 151/4 153/25 154/19 155/4 159/19 159/23 162/3 169/11 170/11 170/12 page 1 [1] 110/17 page 10 [1] 169/11 page 14 [1] 135/17 page 18 [1] 44/14 page 2 [2] 32/12 52/24 page 22 [1] 136/14 page 26 [1] 144/9 page 27 [1] 143/7 page 290 [1] 150/16 page 3 [1] 48/4 page 37 [1] 65/14 page 5 [3] 29/14 46/20 138/17 page 6 [2] 31/25 64/22 page 72 [1] 170/11 page 8 [2] 27/16 38/20	pages [6] 2/23 45/15 45/16 65/22 153/23 154/6 pages 257 [2] 153/23 154/6 paid [4] 55/8 92/15 98/14 128/13 paints [2] 80/18 157/19 pamphlet [1] 61/18 paper [27] 9/25 10/3 15/7 44/15 60/24 64/18 65/3 65/6 65/11 65/15 65/23 77/12 77/15 79/12 79/23 110/18 143/23 144/16 144/17 145/6 145/8 145/11 145/13 147/8 148/23 149/10 157/13 papers [12] 60/20 60/22 61/10 65/8 123/19 125/3 127/9 142/24 143/2 143/3 157/11 158/16 paragraph [38] 5/2 11/22 13/9 13/23 14/9 15/5 15/18 25/11 25/12 33/22 43/9 44/20 57/17 60/3 60/14 65/16 78/15 79/17 80/9 90/12 90/16 90/17 108/20 118/9 118/22 119/1 124/4 130/10 132/17 135/11 135/12 135/17 136/14 138/18 145/23 155/1 166/25 170/12 paragraph 11 [1] 124/4 paragraph 13 [2] 135/12 135/17 paragraph 15 [1] 25/12 paragraph 18 [1] 136/14 paragraph 5 [1] 80/9 paragraph 97 [1] 79/17 paragraphs [3] 19/20 58/21 144/10 parameters [1] 51/22 Parapia [1] 1/19 parcel [1] 47/23 pardon [1] 128/1 parents [21] 70/18 80/5 80/12 80/23 81/2 81/8 81/13 81/25 82/4 84/4 85/1 85/5 85/16 85/20 86/17 88/13 89/20 91/12 91/18 94/5 94/23 part [13] 8/1 21/12	24/22 47/23 58/9 59/11 86/23 87/9 87/14 106/6 129/14 152/5 158/8 Participant [1] 26/9 Participants [2] 22/8 95/9 participate [1] 20/4 participated [1] 106/21 particular [28] 1/9 7/25 13/4 13/17 49/23 52/16 56/8 62/6 78/22 84/19 93/1 95/1 95/5 104/19 107/12 113/4 113/21 113/22 113/24 125/1 125/12 130/5 135/18 135/20 137/16 144/21 146/21 165/5 particularly [9] 25/2 38/17 65/25 100/10 109/14 117/8 117/24 154/16 158/3 parties [3] 19/18 103/5 103/14 partnership [1] 89/10 parts [2] 152/19 152/20 party [41] 8/9 11/23 13/2 14/22 16/21 29/13 32/11 41/5 43/6 44/1 44/18 44/21 45/2 46/11 47/8 48/8 51/6 51/7 52/21 55/11 59/22 59/24 60/10 64/2 66/13 66/14 67/16 67/20 68/1 68/6 71/12 71/19 71/21 79/5 82/20 94/13 94/16 103/17 125/22 129/23 133/14 passage [4] 150/10 150/14 153/23 154/5 passages [3] 135/11 150/9 150/12 passed [1] 94/18 past [3] 32/17 88/24 117/7 paternalistic [1] 89/9 Pathologists [2] 96/25 99/22 pathology [1] 6/5 patient [35] 2/13 6/9 23/4 25/5 25/7 25/8 26/11 26/25 42/18 46/23 47/1 47/4 49/4 49/17 49/23 49/24 62/6 73/2 76/22 79/9 89/9 99/9 105/1 105/2 105/6 105/14 106/5 106/6 113/22 122/18 137/5 137/12 138/7
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(61) one... - patient

P	75/11 75/16 88/9 92/1 104/10 105/18 116/9 118/1 118/3 139/23 149/16 149/21 152/23 152/24 152/25 153/3 156/9 159/10 161/21 163/15 165/21 170/4 170/5	picking [5] 19/19 44/19 74/23 143/9 144/9 picture [11] 15/24 29/24 30/17 30/22 34/16 35/24 37/14 44/8 55/10 80/18 157/19 pistol [1] 25/19 place [11] 12/7 12/11 19/21 21/7 25/17 35/17 70/9 71/3 71/6 80/16 123/7 placed [2] 14/12 16/10 places [1] 128/4 placing [1] 25/13 Plainly [1] 78/1 plan [1] 118/11 planned [1] 5/8 planning [3] 26/12 26/17 91/19 plasma [16] 9/5 22/3 33/21 34/11 34/13 34/14 66/10 76/13 119/9 128/7 128/8 128/11 128/15 135/8 159/3 160/3 plasma VIII [1] 34/14 plate [2] 154/2 154/3 platelets [1] 56/25 platform [1] 76/8 plea [1] 123/20 please [88] 2/22 2/23 4/8 4/18 13/1 14/6 14/21 14/25 15/18 16/4 18/4 18/5 18/11 18/18 19/19 21/15 22/12 23/16 24/6 24/23 25/11 27/4 27/16 28/23 29/14 30/19 32/9 32/12 34/24 36/1 36/12 36/23 36/25 38/12 38/20 42/8 43/4 44/14 45/15 46/20 48/3 49/1 49/1 49/16 49/18 51/8 51/9 52/20 52/24 55/12 56/4 56/12 58/11 60/14 62/3 64/17 65/13 65/22 73/3 74/24 74/25 80/7 83/8 87/20 90/17 93/5 108/14 108/21 114/7 116/16 125/20 129/11 130/6 131/6 135/16 136/14 138/12 138/18 143/8 144/8 145/19 150/16 159/23 161/24 162/3 166/13 169/4 169/11 plus [1] 21/20	pm [6] 95/16 95/18 140/14 140/17 140/19 174/15 point [23] 7/16 10/8 11/3 18/13 22/21 24/23 58/17 59/2 60/6 70/25 98/16 100/14 101/17 127/14 128/17 130/3 134/13 134/14 138/10 140/12 148/10 159/24 173/15 point 2 [2] 59/2 134/13 point 3 [1] 22/21 point 7 [1] 24/23 pointed [3] 13/15 13/23 15/9 points [8] 54/17 126/24 131/20 132/11 133/24 134/1 159/22 163/6 policies [8] 1/25 7/24 62/2 63/14 97/13 112/19 121/1 171/14 policy [17] 13/16 33/6 34/9 37/23 40/23 59/3 59/7 61/1 69/13 69/16 73/9 112/20 113/16 117/18 118/25 122/17 122/25 pool [2] 59/1 117/15 pooled [1] 76/13 pools [2] 124/3 124/12 poorly [1] 90/3 population [6] 2/13 100/9 108/22 142/11 166/24 167/17 Populations [1] 65/12 porcine [3] 28/3 38/19 39/6 portable [1] 23/23 portal [1] 47/6 posed [1] 139/4 position [8] 40/25 46/6 56/1 56/16 72/24 79/10 87/7 117/5 positive [16] 33/8 59/13 60/19 69/5 71/2 82/15 83/15 83/24 84/11 85/22 86/14 88/3 88/11 93/9 93/18 118/1 positively [1] 74/12 positivity [1] 68/21 possibility [7] 10/15 18/10 18/14 52/10 54/1 63/22 130/13 possible [16] 11/19 11/25 17/16 26/19 33/20 44/25 45/13 47/2 58/4 72/16 84/22	88/6 91/9 114/5 117/16 122/13 possibly [8] 2/6 56/16 65/19 90/22 123/4 127/20 136/10 138/2 post [10] 7/8 21/18 47/5 99/24 104/14 112/7 141/24 142/5 154/9 154/13 post-mortem [1] 47/5 post-transfusion [4] 141/24 142/5 154/9 154/13 postponed [1] 41/8 potency [1] 52/12 potential [2] 45/11 80/13 potentially [1] 72/21 powerful [1] 161/3 practical [5] 20/20 25/3 25/18 25/25 26/1 practice [11] 7/20 23/19 26/24 71/7 87/24 89/7 89/14 89/16 107/17 113/21 122/25 practices [2] 26/5 48/25 pre [1] 161/2 pre-internet [1] 161/2 precautionary [1] 138/20 precedence [1] 40/24 preceding [1] 44/16 precipitate [1] 167/4 precise [5] 7/13 16/17 49/6 119/10 136/20 precisely [1] 83/7 precluded [1] 70/11 predicted [1] 13/14 predominant [3] 21/23 27/9 111/12 predominantly [1] 96/8 preface [2] 139/13 153/19 prefer [1] 43/20 preferable [1] 11/18 preferred [1] 74/10 preliminary [1] 47/11 preparation [1] 40/17 preparations [1] 52/11 prepared [6] 10/23 29/12 79/13 93/14 108/15 127/10 preparing [1] 109/16 prescient [2] 130/4 161/23 presence [1] 26/16 present [11] 8/25 9/20 20/5 36/22 55/16 84/8	86/18 92/25 131/16 169/16 170/6 presentation [13] 1/5 2/7 12/19 58/14 75/20 76/6 87/5 92/7 95/4 95/7 95/11 125/24 175/2 presentations [3] 62/17 75/19 86/21 presented [7] 64/18 64/25 65/6 65/8 65/13 65/15 65/23 presenting [1] 89/4 presently [1] 21/4 presents [1] 37/14 pressure [3] 54/24 128/19 128/24 prestigious [1] 142/25 Preston [9] 75/19 75/22 75/24 143/24 148/8 148/23 156/12 156/19 160/11 presumably [11] 13/22 31/14 34/19 93/23 94/1 114/20 122/17 129/18 130/25 164/8 169/8 presume [2] 116/11 116/12 pretty [6] 101/1 107/18 139/18 149/17 163/25 173/7 prevailing [1] 155/23 prevalence [1] 47/10 prevent [1] 139/5 previous [8] 34/3 56/12 69/25 70/4 121/5 129/12 131/21 135/24 previously [6] 45/10 59/4 73/10 77/3 123/1 146/7 price [3] 51/22 55/20 131/23 primary [1] 6/21 Prince [2] 156/18 157/13 principally [1] 100/6 principle [3] 19/5 137/21 138/20 prior [1] 27/8 priority [2] 9/10 34/14 prisons [1] 124/14 privy [1] 87/14 pro [3] 17/5 119/6 119/7 Pro-rata [2] 119/6 119/7 probably [23] 1/15 7/6 46/1 50/20 60/7 76/3 98/8 112/18 120/24
----------	--	---	---	---	---

(62) patient... - probably

P	141/2 158/22 159/3 160/3 163/20 166/20 174/1 174/2 professor [139] 1/13 2/3 2/18 2/19 6/5 16/14 19/25 39/20 40/1 41/6 41/12 42/3 42/13 42/15 42/23 43/24 44/6 44/12 46/9 47/24 48/1 48/6 48/21 48/24 51/6 52/1 53/24 54/5 57/2 57/9 57/14 58/9 58/13 58/15 58/15 58/16 58/19 59/11 62/22 62/23 63/19 63/23 64/18 64/24 65/1 65/4 65/7 65/9 65/13 65/16 65/23 66/3 67/11 69/9 71/11 72/4 75/7 75/23 75/24 76/23 77/16 79/2 80/5 81/1 82/3 82/16 83/4 85/4 85/13 86/8 86/16 87/13 87/19 87/20 88/1 88/16 89/13 89/17 89/21 92/11 92/22 95/13 95/19 95/22 95/24 97/5 97/24 98/25 100/12 101/9 101/11 102/15 106/11 106/13 107/5 107/13 107/15 108/3 108/13 108/16 114/11 115/8 116/15 117/12 120/21 124/1 124/11 125/13 125/24 126/2 129/15 130/9 131/9 132/12 138/20 140/6 140/20 144/4 146/17 147/13 154/4 156/17 156/19 157/16 159/17 162/5 162/5 162/23 164/18 164/23 165/18 166/12 169/12 169/14 171/10 171/15 173/13 173/18 175/3 Professor Bloom [8] 57/14 58/13 63/23 64/24 140/6 165/18 166/12 171/15 Professor Bloom's [2] 72/4 169/14 Professor Dame [1] 97/24 Professor Frank [1] 88/1 Professor Franklin [29] 1/13 2/19 39/20 40/1 41/12 58/15 67/11 87/13 95/13 95/24 108/13 114/11	115/8 116/15 117/12 120/21 125/24 129/15 130/9 138/20 140/20 147/13 156/17 157/16 159/17 164/18 164/23 169/12 171/10 Professor Franklin's [1] 173/13 Professor Hardisty [1] 97/5 Professor Hill [48] 16/14 41/6 42/15 42/23 44/6 46/9 47/24 48/1 51/6 52/1 53/24 57/9 58/9 58/15 58/19 59/11 62/22 62/23 63/19 64/18 65/9 65/23 66/3 75/7 79/2 80/5 81/1 82/3 82/16 85/13 86/8 86/16 87/19 87/20 88/16 89/13 89/21 92/11 92/22 107/5 107/15 108/3 108/16 124/1 124/11 125/13 146/17 162/5 Professor Hill's [11] 2/3 42/3 42/13 43/24 48/21 48/24 57/2 83/4 85/4 89/17 106/11 Professor Lee [4] 65/1 65/4 76/23 77/16 Professor Lee's [1] 144/4 Professor Ludlam [2] 65/7 65/16 Professor Mannucci [1] 75/23 Professor Preston [2] 75/24 156/19 Professor Shinton [1] 71/11 Professor Stuart [13] 2/18 19/25 44/12 54/5 100/12 101/9 106/13 107/13 126/2 131/9 132/12 162/5 162/23 Profilate [1] 41/19 prognosis [2] 151/21 155/8 programme [8] 3/7 98/24 99/1 100/6 112/6 112/12 124/16 124/17 programmes [1] 167/3 progress [5] 92/18 150/20 151/23 152/8 152/15 progresses [1] 155/7 progressing [1] 75/25 progression [2] 130/5	146/3 progressive [4] 75/21 149/6 152/11 152/13 project [2] 83/19 92/18 projects [1] 5/6 prolonged [1] 53/25 proof [3] 63/24 73/14 169/17 prophylactic [1] 112/12 Prophylaxis [1] 112/16 proportion [3] 37/18 46/14 84/13 proportions [1] 37/12 propose [3] 1/22 95/10 115/11 proposing [3] 42/2 80/3 90/18 prospective [2] 76/22 78/3 prospects [1] 139/19 protected [1] 142/10 protein [2] 52/11 78/18 proved [2] 55/1 128/21 proven [3] 166/18 166/23 167/17 provide [6] 22/22 97/10 101/12 103/25 122/2 123/21 provided [12] 5/11 6/7 6/24 22/7 26/13 80/4 95/8 99/18 105/24 123/19 157/9 172/7 providing [3] 38/6 82/4 82/8 provision [1] 67/23 PRSE0000150 [1] 44/9 PRSE00002564 [1] 145/10 PRSE00002647 [2] 56/4 161/24 PRSE00004229 [1] 148/24 PRSE00004440 [1] 169/5 PRSE0004440 [1] 169/4 public [10] 54/24 64/10 64/14 90/22 91/10 128/19 128/24 132/23 133/1 133/5 public pressure [1] 128/24 publication [9] 83/21 93/13 143/11 143/16 143/20 150/3 152/3 166/1 169/3	publications [1] 156/18 publicising [1] 73/8 published [9] 75/23 76/21 77/16 80/25 95/9 143/12 149/23 162/13 162/16 purchase [10] 10/10 10/23 16/16 17/24 18/15 20/1 33/7 60/11 66/25 129/23 purchased [2] 19/13 20/3 Purchases [1] 129/18 purchasing [2] 17/19 18/22 pure [2] 149/12 149/15 purpose [3] 60/1 75/13 87/4 purposes [2] 36/22 52/17 pursuant [1] 123/11 pursuing [1] 78/17 put [6] 50/24 135/15 140/2 156/20 163/22 168/17 putative [1] 66/11 putting [1] 160/15	13/19 20/1 48/19 77/20 79/20 81/2 124/2 129/22 136/21 159/20 169/13 173/24 174/3 questioned [3] 52/3 95/23 175/4 questions [5] 73/18 102/23 134/14 134/18 134/20 quickly [2] 60/22 79/25 quite [32] 23/4 88/5 99/4 100/8 101/24 105/9 105/11 106/2 107/25 109/17 109/21 119/15 121/21 122/10 125/5 130/4 137/6 140/10 143/13 143/13 146/22 148/7 149/11 153/1 155/16 156/22 157/12 161/3 161/23 162/8 166/17 167/24 quoted [1] 141/25 quoting [2] 76/21 108/5
				R	
				radically [2] 160/13 167/3 raised [5] 9/22 46/24 86/15 163/5 165/10 raises [1] 63/22 raising [3] 20/1 129/25 169/13 ran [1] 19/24 rang [1] 93/7 range [5] 4/24 42/24 85/9 89/17 126/18 rank [1] 172/12 rare [1] 154/25 rata [3] 17/5 119/6 119/7 rate [6] 8/25 13/13 52/2 76/15 76/16 77/12 rates [3] 20/1 76/13 82/12 rather [21] 4/6 32/13 37/14 43/21 44/3 67/2 68/23 71/19 114/24 118/20 119/15 138/23 139/10 141/11 143/3 157/19 157/22 160/13 164/18 171/20 173/20 ratio [1] 28/13 rational [1] 113/18 ratios [1] 66/1 raw [2] 77/24 78/5 RCCD [2] 130/13 130/15 RCDRS [1] 130/23	

R	59/14 74/21 85/5	reference [73] 3/8	40/11 48/2 82/17	158/20 164/15	152/13 156/12 160/24
reach [2] 25/17 69/15	Receipts [1] 129/18	4/11 4/14 9/6 9/12	82/19 92/25 124/8	relations [6] 64/10	161/2 161/9 161/12
reached [5] 17/4	receive [5] 72/12	12/15 16/17 16/22	130/24	64/14 132/23 133/2	161/12 162/9 162/20
17/24 68/6 164/5	109/12 115/15 122/8	17/3 17/20 18/9 18/12	Region's [1] 9/1	133/5 139/19	reported [27] 5/15
164/11	122/9	20/9 21/17 21/19 34/8	regional [65] 8/7 8/22	relationship [1]	9/16 11/15 44/17
reaction [1] 149/9	received [18] 6/15	39/3 39/21 40/14	9/8 10/14 10/17 10/21	107/15	45/19 46/15 46/23
reactions [1] 34/7	20/22 47/24 53/4	41/20 41/22 41/25	12/10 12/13 12/13	relative [2] 37/12	48/1 48/8 48/15 56/20
reactivity [1] 39/6	54/13 58/15 58/18	46/14 46/18 48/12	12/14 13/3 16/9 18/3	53/17	61/17 79/5 79/21
read [9] 57/10 87/2	59/9 60/5 66/4 80/18	51/23 52/24 56/18	18/16 19/12 19/21	relatively [7] 37/3	82/17 82/21 90/14
142/19 147/12 157/13	86/20 86/21 86/22	58/24 61/14 61/21	19/22 20/4 20/8 20/11	74/24 79/25 108/6	93/12 93/22 93/23
161/10 161/16 163/23	86/23 89/19 120/1	64/12 64/24 65/5 68/3	20/25 30/13 34/22	136/25 141/12 144/11	93/25 94/5 146/7
163/23	126/12	68/4 75/18 75/23 78/2	38/9 39/24 40/7 48/20	Relatives [1] 49/20	151/24 162/10 163/7
reading [5] 86/14	receiving [13] 3/23	78/14 79/8 79/13	51/7 51/15 51/23 53/1	release [1] 121/21	168/9
127/8 146/14 161/10	14/2 46/16 59/8 72/23	83/14 84/18 90/14	53/2 53/4 54/6 55/14	released [1] 121/18	reporting [3] 48/22
171/2	72/25 81/21 115/19	93/11 94/16 94/22	61/17 64/10 67/1 67/2	releasing [1] 121/15	83/10 156/24
real [1] 174/4	115/19 115/20 115/21	95/1 109/13 109/20	71/17 84/17 94/1 94/2	relevance [3] 45/7	reports [3] 119/5
realise [1] 137/13	122/19 154/15	109/22 117/21 122/1	97/21 103/18 114/14	55/6 104/5	144/24 163/20
realised [2] 109/15	recent [2] 83/13 146/8	128/23 129/1 129/20	117/1 118/20 118/23	relevant [2] 127/13	representative [2]
150/12	recently [1] 150/11	129/22 132/19 134/25	119/4 120/2 120/8	150/12	51/12 132/14
really [31] 4/23 6/2	recipients [1] 70/9	135/1 135/25 147/19	120/12 123/7 123/24	reliant [1] 14/4	representatives [4]
25/24 77/20 97/14	recognised [4] 4/13	148/24 151/6 155/10	125/21 126/7 126/15	relied [1] 161/8	65/7 90/10 94/19 95/8
99/11 101/24 105/21	33/25 95/8 151/12	164/6 164/14 164/23	126/16 130/18 130/22	remain [1] 115/5	representing [3] 8/12
106/4 106/7 106/8	recognition [1] 45/11	167/16 172/5 172/8	131/14 132/23 133/5	remained [8] 4/15	14/23 126/1
106/16 109/15 119/18	recollect [1] 134/11	172/21	141/22	7/19 15/24 40/12 63/1	represents [1] 108/23
121/7 121/13 124/20	recollection [8] 85/12	referenced [1] 12/18	regionally [1] 40/4	101/25 102/15 110/3	request [2] 73/1
125/5 127/4 127/4	85/13 99/17 111/5	references [3] 21/3	regions [1] 118/25	remaining [1] 53/12	108/16
127/13 137/6 137/9	120/17 131/23 143/18	79/23 164/21	registered [5] 3/1	remains [1] 36/19	requested [3] 20/22
138/2 143/2 149/19	169/24	referred [24] 1/7 8/8	3/14 22/17 108/25	remember [50] 97/14	33/17 116/24
150/8 153/8 156/1	recommend [1] 10/21	23/15 34/5 43/10	109/3	97/16 97/17 99/10	require [3] 9/5 24/14
161/8 172/18	recommendation [3]	43/11 46/4 46/5 48/7	registrar [4] 6/5 96/20	99/16 103/12 103/13	140/10
reason [5] 37/19 94/6	17/14 17/21 161/18	49/21 60/5 65/9 77/16	105/24 105/25	104/4 104/17 104/25	required [9] 20/19
136/5 147/3 148/20	recommendations [3]	115/24 130/10 131/21	registrars [2] 106/20	105/5 107/14 109/14	23/1 24/3 60/17 64/11
reasonable [1] 76/3	58/20 59/12 171/15	142/16 149/1 150/2	106/20	111/6 112/3 112/9	64/15 121/8 132/24
reasonably [3] 27/21	recommended [4]	150/9 150/10 165/4	regrettable [1] 117/8	112/11 112/14 113/23	134/21
27/25 163/18	10/25 53/8 137/15	169/4 169/12	regular [6] 16/7 17/2	121/4 121/10 121/25	requirement [2] 9/18
reasoning [1] 52/25	170/14	referring [7] 48/16	115/15 119/23 138/22	122/10 122/16 123/3	11/19
reasons [4] 50/14	reconciles [1] 77/21	79/17 86/22 90/8	152/1	123/5 124/5 124/15	requirements [4] 10/9
105/14 114/15 146/13	record [6] 14/12 24/16	114/9 145/13 159/19	regularised [1] 70/22	128/5 130/4 133/4	20/16 132/5 132/6
reassurance [2] 152/1	49/4 86/7 103/9	refers [11] 5/2 25/13	regularly [2] 109/4	134/7 134/16 138/5	requires [1] 24/25
153/6	113/25	66/17 66/21 68/7	115/6	146/20 148/4 148/5	requiring [1] 119/21
reassure [2] 117/13	recorded [9] 14/11	71/13 124/1 128/24	regulatory [2] 159/2	157/12 157/14 162/25	research [16] 5/5
124/20	17/7 21/16 29/16	130/14 145/15 149/2	160/2	163/3 163/11 165/14	68/16 78/14 83/12
reassuring [3] 147/12	33/19 35/8 47/1 83/25	reflect [3] 30/11 38/9	reinforced [1] 149/22	165/15 166/10 170/1	83/18 92/16 92/23
152/25 153/2	84/3	72/1	relate [1] 1/23	170/8 170/8 172/10	96/5 96/5 96/10 99/3
rebuttal [1] 118/21	records [14] 10/5 41/6	reflected [1] 144/13	related [7] 62/8 62/14	172/15	101/12 101/16 141/20
recall [38] 63/21	75/22 82/23 85/17	reflections [1] 89/11	96/8 104/5 104/9	remembered [1]	142/23 160/11
74/18 80/25 85/23	85/18 86/14 105/1	reflective [1] 23/18	150/22 150/22	170/3	reservation [1] 136/12
94/25 97/12 98/2	105/2 105/6 105/8	reflects [2] 152/18	relating [6] 7/22 49/17	reminded [2] 127/7	reserve [1] 43/15
104/2 107/9 107/13	105/9 116/12 134/9	153/7	65/24 87/6 101/20	140/15	resisted [2] 54/25
116/2 119/12 122/9	red [2] 98/9 142/2	refrigeration [1] 23/23	106/12	remove [1] 31/6	128/20
123/10 124/7 124/11	reduce [3] 113/18	refuse [2] 137/12	relation [39] 2/25 3/12	remunerated [1]	resolved [1] 148/9
125/1 125/12 129/5	113/19 113/20	137/21	6/9 11/6 12/6 15/13	142/10	resources [1] 108/17
130/1 134/5 135/2	reduced [4] 17/13	regard [1] 62/24	20/16 30/17 30/22	rep [2] 75/2 83/9	respect [4] 43/12
137/18 140/24 146/14	54/1 66/7 162/2	regarded [4] 14/17	35/1 35/21 37/1 38/14	repeating [1] 62/14	46/19 60/8 173/25
146/17 147/25 149/9	reducing [1] 37/18	34/1 58/5 127/3	40/25 42/25 45/5	replenish [1] 114/4	respects [2] 71/24
150/5 156/7 156/11	reduction [1] 15/15	regarding [4] 44/24	52/18 54/15 55/22	replied [1] 53/6	85/10
156/11 156/12 157/7	refer [16] 1/22 53/19	48/13 69/4 70/9	56/1 56/10 56/17	report [26] 29/12	respond [1] 165/7
163/9 167/21 168/18	86/20 87/4 90/7 92/6	regardless [1] 155/18	56/22 57/5 62/25	38/16 44/18 45/22	response [12] 6/8
169/20	105/20 114/13 115/3	region [20] 4/4 4/15	63/17 64/6 64/13	46/7 46/10 47/8 51/11	11/7 37/24 42/14
recalled [1] 123/17	136/7 143/16 144/16	7/24 9/22 12/21 12/25	65/25 68/15 79/1	62/20 82/13 82/16	42/16 61/12 81/2
receipt [5] 8/23 20/20	144/20 145/6 150/14	16/8 18/15 19/6 19/23	89/13 95/5 104/1	91/23 93/7 108/15	90/13 91/25 118/18
	152/5	20/24 32/13 33/4	119/2 123/1 155/11	109/9 145/9 145/20	169/14 173/12

R	55/23 57/24 57/25 58/5 58/25 63/3 63/11 64/12 65/1 65/18 66/11 68/25 70/25 80/13 81/13 81/23 113/18 113/20 129/21 135/2 135/9 136/17 136/19 136/25 137/8 138/6 138/8 139/6 141/14 144/1 154/17 158/25 159/8 160/1 173/25 174/4 risk' [1] 25/16 risks [14] 42/4 42/14 53/17 59/22 81/11 81/21 82/1 82/10 98/4 137/8 140/21 141/1 146/18 157/25 risky [1] 148/10 Rizza [6] 12/22 57/15 58/13 91/7 91/16 93/23 RM [1] 133/16 RM Ibbotson [1] 133/16 Roberts [2] 141/4 141/4 robust [1] 118/21 role [8] 54/14 97/9 99/16 102/6 102/19 102/22 106/10 137/10 roles [1] 96/2 room [10] 100/25 104/20 104/21 105/1 105/11 105/12 106/5 106/8 113/25 169/22 rooms [1] 106/5 Rorer [2] 90/10 90/18 rota [2] 101/13 161/21 rotate [2] 106/24 107/3 rough [1] 108/12 roughly [1] 37/15 round [4] 100/20 107/3 131/2 134/2 routine [3] 51/5 85/14 119/24 routinely [2] 99/18 142/18 row [1] 124/14 Royal [5] 26/4 96/19 96/24 99/21 148/11 Royal Free [2] 26/4 148/11 RTC [2] 119/6 120/17 rules [1] 109/22 run [2] 136/20 159/20 running [1] 6/25	safe [3] 25/17 81/16 158/22 safely [1] 148/15 safer [4] 60/7 61/13 72/21 98/15 safety [6] 72/5 75/13 135/2 159/3 159/10 160/3 said [45] 4/23 8/24 9/14 9/16 11/7 13/10 18/23 18/25 24/11 32/2 32/16 33/15 34/1 38/21 40/14 42/17 43/19 48/6 49/21 55/3 66/8 75/10 77/11 77/24 84/7 84/12 84/21 86/9 89/23 90/18 94/17 97/8 98/1 98/23 99/7 103/25 108/2 108/21 112/5 140/6 141/23 167/20 169/19 170/2 173/25 sake [1] 35/20 sales [2] 51/12 83/9 same [21] 3/25 14/22 15/24 27/15 32/19 49/17 78/2 78/7 106/17 110/3 112/21 113/1 113/6 114/2 114/5 115/22 122/23 134/1 159/12 167/23 168/6 samples [3] 83/6 84/20 84/25 San [3] 57/1 162/9 163/6 San Francisco [3] 57/1 162/9 163/6 sapiential [2] 170/21 170/25 Satellite [1] 75/4 satisfactorily [1] 24/13 satisfactory [2] 55/2 128/22 save [2] 18/15 99/8 saved [1] 61/5 Savidge [1] 75/12 saving [4] 19/11 138/24 139/5 139/10 savings [1] 61/8 saw [3] 119/15 122/1 131/20 say [54] 4/9 11/7 37/22 39/25 41/24 45/19 58/14 59/18 77/9 77/10 77/12 86/5 86/20 88/20 95/11 97/11 98/6 98/7 101/17 107/20 113/5 117/12 118/13 118/17 121/20 124/6 124/25	127/4 129/9 135/19 136/4 136/15 138/21 139/5 141/4 141/16 143/8 143/25 144/1 144/12 144/23 146/12 147/15 150/5 154/14 155/21 157/14 157/15 164/3 168/2 170/13 170/19 172/12 174/3 saying [10] 28/6 33/19 41/6 76/7 116/19 139/13 141/10 159/1 165/19 168/7 says [36] 6/9 6/15 6/25 7/3 7/5 22/19 25/14 26/14 39/8 42/23 51/14 55/14 59/15 59/15 60/4 63/23 71/13 72/11 72/15 73/7 80/9 85/4 87/25 88/18 119/2 132/20 133/10 145/24 151/10 151/22 154/19 155/1 155/6 159/5 166/11 166/14 sceptical [1] 140/4 schedules [1] 103/25 School [1] 96/15 scientific [6] 10/18 10/21 12/14 102/11 102/13 102/21 Scientist [1] 80/25 Scotland [2] 103/2 128/11 screen [7] 4/18 7/4 80/7 83/4 83/22 135/15 161/24 screening [5] 61/22 66/18 70/11 89/14 92/19 scribbled [1] 158/24 second [40] 4/22 5/1 7/8 8/1 11/11 11/22 13/8 13/9 14/25 15/19 16/23 16/25 18/6 21/7 21/11 26/8 31/16 36/25 38/4 43/8 46/12 49/21 54/6 55/25 59/14 60/2 64/5 65/16 90/16 90/17 108/20 118/22 126/6 127/14 130/10 131/13 151/5 156/15 157/7 159/24 second half [1] 8/1 section [3] 24/7 133/10 155/11 secured [1] 113/22 see [154] 2/24 3/4 3/13 4/22 8/6 8/10 8/15 8/21 11/1 11/1 11/9 12/1 13/4 13/8 13/22 14/9 15/6 15/19	16/5 17/7 18/2 18/6 18/12 18/19 18/21 19/19 19/25 21/4 21/8 21/19 21/22 22/15 23/17 23/21 24/6 24/8 24/23 26/12 26/12 26/21 27/8 27/16 27/20 27/23 29/3 29/18 29/23 30/5 30/14 30/24 32/16 32/23 33/11 35/3 35/6 35/12 35/25 36/4 36/13 37/3 37/8 38/21 40/3 40/11 40/20 40/25 41/15 41/20 43/8 44/3 44/9 44/17 46/7 46/10 46/21 47/13 49/3 49/5 49/10 49/19 50/4 50/23 50/23 51/20 52/14 52/25 56/5 56/14 57/4 57/18 58/20 60/15 62/6 62/20 64/22 64/24 65/8 65/22 67/5 67/13 68/7 71/10 72/10 76/5 78/14 79/22 83/14 83/17 90/11 90/16 94/14 100/20 105/17 108/21 110/9 110/12 110/22 111/1 111/8 111/20 111/24 118/22 125/25 126/6 126/13 126/23 127/12 127/25 128/17 129/1 129/16 131/7 131/13 132/11 132/15 133/1 133/9 134/1 134/22 135/1 139/3 145/15 145/24 148/19 149/2 151/7 151/21 154/4 154/19 159/12 160/19 169/7 172/23 172/24 seeing [6] 42/18 77/24 97/18 99/10 156/7 172/10 seeking [1] 114/15 seem [6] 78/5 98/3 120/1 147/2 152/20 152/21 seemed [6] 33/6 109/21 141/11 147/11 167/14 171/3 seems [9] 72/24 77/9 77/10 84/24 127/4 131/21 133/1 150/23 167/20 seen [17] 30/12 44/3 58/8 58/12 59/12 62/17 97/7 100/24 116/18 139/15 144/25 155/5 157/6 157/18	158/11 158/16 160/24 Select [1] 24/17 selected [1] 24/21 self [4] 12/8 12/21 42/20 146/13 self-evident [1] 146/13 self-limiting [1] 42/20 self-sufficiency [2] 12/8 12/21 send [5] 33/21 34/11 71/16 83/21 124/22 senior [8] 96/1 96/20 105/24 105/25 106/16 106/20 170/21 171/4 sense [5] 112/23 116/14 125/18 141/18 142/9 sent [10] 58/13 62/18 71/10 71/11 84/20 114/13 133/8 156/14 156/23 157/1 sentence [5] 13/23 15/19 33/22 34/3 136/15 separate [2] 123/12 132/3 September [6] 51/4 93/6 97/19 99/24 101/7 164/9 September 1982 [1] 99/24 September 1983 [1] 101/7 September 1986 [1] 93/6 September of [1] 51/4 Serial [1] 150/19 serious [8] 42/20 76/9 149/11 149/11 157/4 157/22 158/10 160/10 seriously [2] 63/11 143/11 seriousness [1] 149/16 seroconversion [5] 68/20 90/13 90/21 92/1 94/17 seroconverted [4] 79/3 91/13 91/18 93/8 serum [1] 151/15 service [8] 3/5 3/6 3/9 5/16 61/18 100/23 102/10 102/20 services [1] 130/23 session [1] 64/23 sessions [4] 6/22 6/24 64/9 132/19 set [8] 4/3 8/6 25/24 92/9 93/2 126/23 151/7 171/15 sets [2] 22/18 68/18
----------	---	---	---	---	--

S	8/2	151/1	Society [8] 4/21 64/19	150/10 151/5 164/12	54/12 126/8 126/11
setting [1] 98/25	Shinton [10] 13/18	significantly [2] 15/15	64/20 88/17 165/6	172/22 173/5 173/17	126/14 126/22 133/14
settled [1] 104/11	14/11 54/11 60/5	32/6	165/8 165/18 166/1	173/18	133/19
Seven [1] 75/25	61/17 69/9 71/11	signs [3] 45/5 62/19	soft [1] 138/25	sort [16] 91/24 103/8	starkly [1] 21/9
several [4] 3/24 5/17	126/11 126/20 129/20	63/8	sole [8] 30/14 35/17	115/1 119/18 119/22	start [7] 1/6 12/4
74/14 115/12	SHOC [1] 4/8	silent [1] 173/7	35/22 36/19 92/24	121/10 122/15 130/17	16/25 21/13 23/1
severe [10] 26/25	shocked [1] 155/16	similar [7] 4/3 4/7	110/11 111/25 132/14	130/18 137/3 141/10	29/23 100/10
69/20 72/14 72/22	short [6] 42/10 121/24	26/5 39/4 68/13	solely [4] 30/10	142/9 155/24 158/17	started [8] 11/10 23/4
72/25 121/14 121/17	140/18 151/9 157/17	102/19 146/8	102/21 111/20 153/12	160/17 168/12	102/13 107/9 146/23
121/17 136/9 146/5	173/5	similarly [1] 39/9	solution [1] 17/23	sought [1] 80/20	147/10 158/5 160/25
severely [1] 22/22	short-cut [1] 157/17	simply [3] 7/9 14/4	solutions [1] 17/12	sound [2] 103/11	starting [5] 1/21 99/5
severity [2] 24/12	short-lived [1] 121/24	32/14	some [73] 1/7 12/1	137/13	112/9 129/7 148/17
121/8	shortage [1] 10/16	since [3] 89/7 150/12	14/2 24/9 36/5 36/13	sounds [4] 28/14	state [1] 38/1
sexual [1] 70/22	shortfall [6] 17/18	169/25	36/14 37/5 37/19	113/8 141/6 167/9	stated [1] 52/1
shall [1] 95/15	17/22 67/6 117/17	single [5] 2/12 4/10	48/10 52/2 52/10	source [1] 150/7	statement [46] 6/7 6/9
shame [1] 172/12	119/3 133/12	104/20 117/14 153/17	52/11 55/3 56/19 59/9	sources [6] 43/13	6/15 6/19 6/25 34/9
she [20] 2/16 26/13	shortfalls [1] 16/12	sir [45] 1/6 2/6 4/1 5/7	59/21 62/9 71/24 74/4	43/17 67/8 133/13	42/15 42/17 80/6 83/4
26/14 81/20 86/13	shortly [2] 90/22	5/18 7/10 7/21 11/1	74/5 74/19 75/18	142/17 154/16	85/4 86/13 97/2 98/1
86/15 86/15 86/18	162/11	12/1 18/1 25/25 28/14	75/18 78/14 79/3	space [1] 57/12	98/23 100/5 100/16
90/2 90/3 105/17	should [55] 4/9 10/24	32/2 32/24 37/9 37/22	79/13 80/20 81/11	speaking [4] 28/7	106/12 108/2 112/5
105/19 105/20 142/7	11/24 17/14 25/7	39/18 40/11 41/14	83/1 86/19 88/3 88/7	30/9 120/5 141/12	124/1 124/4 135/10
153/10 153/12 153/13	25/10 25/15 26/18	42/12 42/24 43/23	88/12 88/20 89/3	special [1] 106/7	135/13 137/5 138/13
156/3 156/3 173/25	38/11 40/23 40/24	56/6 63/21 64/16 71/5	89/18 91/23 92/9 95/6	specialist [3] 3/5	142/16 144/8 150/2
sheath [1] 70/22	41/24 45/18 53/9 54/9	71/18 77/18 78/11	98/3 98/6 101/2	96/23 99/20	150/9 150/10 150/15
sheet [3] 22/24 23/14	54/17 54/25 58/22	78/25 79/8 79/17	103/19 103/23 103/23	specialists [2] 148/2	152/5 155/13 157/23
24/16	60/21 61/23 64/11	79/24 85/2 85/8 85/23	103/25 108/2 111/17	148/3	160/23 164/3 164/6
sheets [1] 105/3	69/7 70/1 70/5 70/8	90/6 90/9 92/3 94/9	116/6 116/9 116/24	specialties [1] 107/4	164/13 165/1 165/4
Sheffield [2] 143/11	70/19 70/21 70/22	94/25 140/9 153/19	119/16 123/4 123/20	specific [8] 84/12	168/18 169/20 170/2
144/17	70/24 71/6 71/7 74/11	159/16 173/10	127/10 130/17 134/22	122/25 125/13 136/5	170/10 170/11
Sheila [3] 142/6 150/3	74/13 78/20 85/8	sister [3] 5/22 14/19	137/3 139/3 139/17	140/23 143/3 164/24	statements [3] 86/21
153/8	86/20 93/13 94/7	105/16	142/15 147/1 154/9	166/19	86/24 86/25
Sherlock [3] 142/6	115/12 115/15 124/24	situation [7] 32/13	156/14 156/23 156/24	specifically [1] 6/4	states [8] 56/23 68/17
150/3 153/8	126/8 128/20 132/24	61/23 84/8 90/19	158/16 161/13 163/23	specifics [1] 122/16	98/13 127/16 127/24
SHIN0000019 [1]	133/14 133/24 140/6	117/8 119/11 167/6	167/7 171/19 173/11	speculate [1] 152/18	128/2 158/19 161/14
94/13	143/7 148/6 150/4	six [7] 3/23 6/11 24/17	someone [10] 73/24	speed [1] 70/10	stating [1] 61/5
SHIN0000024 [1] 40/3	159/21 164/15 167/3	57/6 119/5 138/21	93/24 115/18 115/20	spend [1] 107/19	statistics [6] 8/4
SHIN0000026 [3]	171/22 173/9	152/2	136/8 140/2 156/1	spending [1] 132/3	30/23 66/22 67/2 69/4
67/17 67/18 71/9	show [9] 12/2 35/22	six months [1] 6/11	168/20 171/1 172/4	spent [2] 6/10 98/19	133/11
SHIN0000028 [2]	41/13 56/11 58/8	six-month [1] 152/2	someone's [1] 156/5	Speywood [1] 38/15	status [2] 109/19
66/15 133/7	85/17 123/19 162/13	six-monthly [1] 119/5	something [26] 8/6	spirit [1] 123/22	110/3
SHIN0000029 [3]	168/9	sixth [2] 30/21 145/21	26/24 26/24 60/12	split [1] 2/10	stay [1] 115/22
55/12 64/2 131/6	showed [5] 66/23	sizeable [1] 4/5	98/13 103/2 113/11	sporadic [1] 150/23	steadily [2] 11/16
SHIN0000030 [2] 54/3	143/13 157/11 160/12	skid [1] 124/14	117/22 121/24 122/3	spouses [1] 70/20	12/3
59/23	170/1	skip [2] 45/15 119/1	126/16 129/25 130/1	spread [2] 154/18	steady [2] 16/2 40/9
SHIN0000032 [1]	showing [5] 9/13 15/8	slice [1] 130/13	130/22 137/1 147/2	173/19	stem [1] 100/11
16/22	15/13 155/24 156/25	slide [1] 31/9	147/3 152/21 157/22	St [3] 75/5 75/9 98/18	step [5] 25/4 25/4
SHIN0000033 [1] 16/4	shown [2] 83/15	slightly [4] 73/4 132/5	158/10 160/12 160/13	St Thomas' [1] 75/9	33/24 34/2 52/13
SHIN0000034 [1]	150/19	139/20 147/20	162/22 171/25 172/18	St Thomas's [1] 75/5	step-by-step [1] 25/4
52/20	shows [3] 32/5 36/24	small [10] 21/24 22/1	173/8	staff [2] 5/25 70/24	steps [1] 134/12
SHIN0000035 [1]	151/18	29/6 37/3 37/4 99/2	sometimes [1] 80/11	Staffordshire [1] 4/6	Stewart [3] 19/8 19/9
20/10	Shrewsbury [1] 33/14	147/15 147/22 156/22	somewhat [1] 169/19	stage [13] 2/5 9/14	48/18
SHIN0000036 [1] 32/9	siblings [1] 84/4	166/22	somewhere [3] 105/8	59/7 71/8 91/14 92/5	stick [1] 157/23
SHIN0000037 [2]	sic [4] 3/15 47/16 50/1	smaller [3] 4/7 27/11	137/4 155/12	93/25 97/13 103/3	stigmata [3] 62/9
19/17 48/3	91/2	111/14	son [3] 86/13 86/15	108/18 110/6 134/24	168/10 168/19
SHIN0000040 [2]	sickle [6] 96/9 96/14	Smith [2] 73/5 74/7	90/2	138/19	still [24] 7/4 12/24
14/21 18/18	100/7 100/8 142/24	Snap [1] 72/11	soon [1] 9/21	stages [1] 165/24	15/25 29/3 29/8 30/6
SHIN0000041 [1] 18/4	146/25	snappily [1] 12/12	sorry [24] 3/18 4/8	stamp [2] 74/3 74/5	30/25 35/7 58/16 66/3
SHIN0000042 [1]	side [1] 168/21	snapshot [2] 2/21	25/11 31/24 38/13	standing [1] 139/14	78/13 99/3 100/13
12/25	sided [1] 171/7	109/6	40/20 41/4 91/5	Stanford [1] 125/4	111/6 111/7 112/16
SHIN0000043 [1] 43/4	significant [8] 16/1	SNBTS's [1] 102/11	110/15 110/19 110/20	Stanford University	113/4 122/3 132/1
SHIN0000045 [2] 2/22	63/5 84/13 143/15	so [224]	111/23 127/25 129/11	[1] 125/4	132/4 132/6 147/23
	143/20 147/23 150/25	social [1] 3/6	136/20 138/12 148/4	Stanton [8] 54/9	157/23 164/1

S	61/7 substantially [1] 32/23 succeeded [2] 2/17 2/19 succeeding [1] 7/12 such [6] 55/22 59/1 59/12 99/16 119/24 134/11 sudden [6] 114/24 114/25 116/22 117/16 118/14 119/2 suddenly [1] 139/23 suffer [1] 23/7 suffering [1] 56/20 sufficiency [2] 12/8 12/21 sufficient [5] 9/8 72/12 75/17 107/23 115/13 suggest [7] 44/2 85/18 131/25 144/21 146/5 150/25 157/20 suggested [4] 6/20 85/19 121/5 144/4 suggesting [3] 124/2 152/20 152/21 suggestion [6] 17/20 19/15 53/15 58/21 60/12 69/22 suggestive [1] 47/22 suggests [10] 19/22 77/4 83/5 93/21 100/5 118/18 120/22 157/21 165/1 165/2 suitable [1] 11/24 sum [1] 28/6 summarise [1] 80/20 summarised [1] 89/18 summary [4] 2/25 47/14 65/15 65/23 summer [1] 168/5 superior [1] 53/10 supervision [1] 152/1 supplemental [1] 24/3 supplied [6] 9/14 13/12 13/25 26/9 53/10 120/12 supplier [9] 30/14 38/6 40/12 53/12 54/21 55/16 92/24 127/1 131/16 suppliers [2] 18/3 124/2 supplies [45] 1/24 7/22 8/19 8/19 9/13 12/7 12/19 13/9 14/2 14/4 16/8 16/13 16/25 18/8 20/21 20/25 21/1 33/9 34/11 40/8 40/14 40/15 43/15 53/2 72/8 73/20 74/8 74/10 91/8	91/16 94/1 94/2 105/18 114/18 115/24 116/22 118/11 118/14 119/25 120/4 123/20 126/15 128/7 129/15 134/19 supply [21] 9/4 9/20 10/18 11/6 14/14 16/10 25/22 53/4 66/24 69/24 73/9 82/6 114/16 115/16 116/5 119/9 119/23 120/1 133/11 138/1 159/13 support [4] 73/23 78/20 105/23 130/21 suppose [9] 77/23 104/20 106/4 118/2 118/21 160/9 163/21 171/2 174/6 supposed [1] 152/25 Supposedly [1] 52/5 supposition [1] 57/20 supra [2] 12/10 12/14 sure [14] 21/18 23/4 94/22 104/11 119/19 120/5 120/20 121/14 122/11 137/25 139/12 154/1 155/21 168/3 surely [1] 159/9 surgeon [1] 125/3 surgery [5] 22/9 26/12 26/22 49/14 122/3 surgical [3] 3/6 26/13 26/17 surprising [2] 59/19 169/19 surveillance [1] 46/13 survival [1] 144/7 survivors [1] 139/17 suspect [2] 135/5 170/20 suspected [2] 64/10 132/23 suspects [1] 84/1 suspicious [1] 139/20 sustained [3] 114/24 116/10 116/11 swings [1] 118/14 switch [4] 40/13 114/24 161/18 170/17 sworn [1] 95/21 symptoms [1] 82/18 syndrome [6] 56/14 58/1 60/9 65/19 68/19 117/10 syringes [1] 25/19 system [1] 74/11 systematic [1] 148/22 systems [2] 107/22 130/24	T T-Cell [1] 65/11 T4 [1] 68/17 T4:T8 [1] 66/1 T8 [1] 68/17 table [6] 9/12 21/23 27/20 30/25 35/6 53/3 take [15] 12/11 12/17 40/24 42/6 70/9 79/1 80/16 82/11 102/6 118/19 140/12 140/13 156/5 165/24 174/13 taken [20] 35/16 54/18 70/20 71/6 74/15 75/24 77/12 122/7 125/19 126/24 128/18 131/8 133/25 134/12 136/16 143/10 149/14 164/9 167/12 170/20 takes [1] 41/3 taking [6] 7/8 21/7 63/5 63/7 63/10 75/22 talk [4] 114/17 124/6 144/10 166/21 talked [2] 112/16 138/6 talking [12] 31/8 45/25 78/4 87/23 88/1 123/9 124/12 133/4 135/18 143/23 148/5 163/3 talks [4] 19/13 45/25 73/6 155/3 targets [1] 15/4 taught [3] 97/22 112/22 140/24 TB [1] 68/12 team [2] 80/11 105/22 teams [1] 9/9 technical [1] 5/25 telegraph [1] 162/14 telegraph-type [1] 162/14 Telephone [1] 25/21 tell [6] 42/3 42/13 59/6 94/7 127/2 129/5 telling [4] 88/9 93/20 94/23 153/2 tells [6] 25/5 65/17 93/18 93/19 94/8 97/2 temper [1] 141/10 temperature [1] 24/19 temporarily [1] 17/11 temporary [1] 117/2 tempting [1] 37/19 ten [2] 21/21 75/25 tend [1] 152/16 tender [7] 53/18 54/15 55/4 55/16 64/4 131/16 132/7	tendering [2] 54/8 132/2 tenders [10] 53/3 53/5 54/9 54/12 67/9 126/9 126/12 126/18 133/15 133/18 term [7] 42/21 62/15 139/16 144/6 144/14 157/5 158/7 termed [2] 13/3 154/11 terms [44] 8/4 12/20 20/2 24/3 26/1 50/25 53/19 58/10 59/15 63/12 63/13 64/4 66/8 67/7 69/23 69/24 77/1 82/10 82/12 83/2 85/2 86/10 87/9 89/14 89/16 97/9 98/1 100/12 103/5 106/7 106/10 107/25 108/12 113/14 121/1 122/6 129/19 139/18 149/16 149/19 156/7 160/9 160/11 165/6 territory [2] 12/14 103/8 test [8] 66/18 84/23 85/5 85/20 88/11 88/23 88/24 89/15 tested [6] 83/6 84/10 85/16 85/17 88/2 93/17 testing [8] 2/1 83/3 83/5 83/7 84/4 84/24 87/16 168/20 tests [5] 62/14 88/22 145/18 147/7 155/19 text [3] 84/18 153/17 153/21 textbook [2] 144/20 150/6 textbooks [1] 142/13 than [36] 12/16 14/18 20/3 28/9 28/12 31/21 32/3 32/13 39/2 43/21 52/3 60/7 60/13 67/2 68/23 71/20 81/5 88/19 93/2 103/14 107/19 114/24 118/20 123/4 127/11 138/23 139/10 141/12 142/12 143/3 146/7 164/18 171/20 172/9 172/13 173/20 thank [16] 2/23 4/19 5/1 31/7 44/16 45/16 49/2 67/19 80/2 94/10 95/3 148/25 168/23 173/22 174/8 174/12 Thank you [2] 49/2 67/19	thanks [1] 82/11 that [761] that's [62] 9/15 16/22 17/23 19/8 21/14 21/18 23/14 23/22 23/25 27/15 28/20 29/9 29/22 34/5 36/21 39/15 42/23 46/5 47/23 49/12 55/11 55/22 61/12 63/21 64/2 66/15 71/3 77/9 77/10 77/15 77/18 79/18 79/19 80/15 82/10 86/19 87/13 94/1 95/6 97/6 109/6 111/2 111/19 115/7 125/8 128/17 132/8 137/8 140/7 145/8 145/22 146/1 146/24 159/20 162/12 165/14 166/4 166/15 169/19 170/16 171/7 173/21 that's -- I [1] 165/14 thawing [1] 23/25 their [36] 2/13 17/16 23/12 26/2 38/18 47/8 54/22 55/5 62/19 64/11 68/5 71/22 73/15 74/2 79/3 80/5 85/1 85/3 88/3 88/8 88/13 88/21 104/22 107/3 113/25 114/4 119/6 124/3 127/15 128/2 128/7 128/8 128/15 132/24 155/15 171/1 them [37] 21/3 53/7 57/12 71/15 82/5 84/23 84/23 85/6 85/7 88/13 89/4 89/16 97/10 100/10 100/20 100/22 103/15 104/4 116/12 117/14 120/18 120/19 122/14 122/21 135/7 138/1 147/3 147/6 147/6 147/17 156/16 160/25 162/23 163/16 163/24 172/16 172/23 theme [1] 4/22 themes [1] 87/6 themselves [3] 21/3 21/5 105/3 then [244] theories [1] 164/1 therapeutic [1] 70/10 therapy [7] 3/7 105/18 105/19 109/5 111/4 138/23 138/24 there [263] there'd [1] 173/6 there's [67] 5/14 9/6
----------	--	---	--	---	--

(67) stock - there's

T	127/19 127/22 128/2 128/12 128/14 130/19 130/23 130/25 132/5 134/10 135/25 136/2 136/11 137/17 137/23 139/1 139/1 141/25 143/25 152/23 155/18 156/17 157/10 160/25 164/1 170/14 172/8 172/13 172/22 174/5 174/6 they'd [1] 115/19 they're [1] 137/8 thing [10] 115/1 119/24 127/4 147/15 152/20 168/12 170/7 170/7 171/5 173/23 things [5] 25/6 121/13 142/13 161/8 173/5 think [186] thinking [7] 141/7 158/8 158/15 160/9 165/3 167/8 167/9 thinks [1] 88/4 third [4] 14/9 18/20 52/14 128/17 thirds [1] 44/19 this [283] Thomas' [1] 75/9 Thomas's [1] 75/5 those [64] 5/7 5/18 12/23 21/1 21/6 21/10 22/2 22/10 23/6 24/5 24/10 27/12 28/4 29/7 31/3 36/19 37/11 38/5 41/24 48/21 51/4 54/16 55/3 56/7 57/10 62/11 66/9 67/2 71/5 77/2 77/21 84/10 86/24 89/11 96/17 99/8 99/15 101/2 101/21 104/6 104/7 104/24 105/20 108/19 118/3 119/12 131/20 132/4 134/16 134/20 144/19 144/20 144/25 147/1 153/24 157/12 157/15 160/20 163/9 166/8 167/4 172/10 172/11 172/24 though [4] 75/8 116/11 143/22 166/5 thought [15] 26/15 39/13 42/19 45/8 52/12 63/3 90/3 107/24 121/6 126/17 127/5 132/4 137/16 141/23 165/14 threatening [1] 139/2 threatens [1] 74/18 three [23] 22/6 27/7 37/12 42/7 45/15	51/21 60/1 77/6 97/4 98/19 101/13 101/21 106/18 106/18 110/23 113/6 119/12 125/15 126/23 132/6 134/1 142/1 152/2 three years [1] 37/12 three-quarters [1] 42/7 through [16] 5/12 15/1 25/4 38/5 49/11 57/13 79/25 81/4 81/5 104/18 106/24 123/17 156/15 156/16 158/4 174/7 throughout [5] 16/6 37/7 37/25 102/16 142/21 Thursday [1] 1/18 thus [1] 53/13 tide [1] 121/23 time [101] 2/3 4/5 5/7 5/19 5/22 6/18 6/20 7/3 7/7 7/19 8/22 11/3 12/3 12/12 12/17 14/1 18/2 18/14 19/20 22/9 23/19 25/2 28/16 30/12 30/13 32/7 35/18 39/17 39/17 40/6 42/4 42/18 46/4 46/17 50/19 59/21 60/2 62/3 63/1 63/3 63/6 78/24 79/24 90/6 91/22 97/15 98/5 100/3 101/1 103/12 105/14 105/16 107/19 109/18 111/5 112/13 115/2 115/10 115/13 116/13 119/5 120/20 123/8 123/15 123/23 124/7 126/3 128/10 128/12 131/9 135/22 137/11 137/13 140/9 141/25 142/2 142/20 143/1 143/18 146/15 147/9 147/9 147/11 148/1 148/8 152/19 155/20 156/8 157/7 157/19 158/2 159/7 161/22 163/24 166/5 167/23 169/23 170/3 171/14 171/24 173/10 times [12] 37/15 37/16 37/17 66/6 77/6 96/16 114/24 115/25 116/4 122/14 123/14 169/25 timing [1] 50/24 tiny [1] 22/2 tissue [1] 138/25 titled [1] 12/12 to [1005]	today [4] 2/8 95/11 102/23 173/16 together [1] 32/4 told [20] 50/1 81/1 81/13 81/15 81/23 82/1 85/3 85/8 85/22 86/8 86/10 86/12 86/16 88/4 88/13 89/24 90/2 91/17 108/4 168/8 Tom [1] 141/23 Tom Cleghorn [1] 141/23 tomorrow [7] 1/15 1/16 67/12 164/22 173/14 174/14 174/14 tone [1] 116/14 Tony [1] 98/25 too [2] 165/25 171/16 took [11] 1/17 7/11 12/7 71/3 99/24 101/5 104/14 107/11 112/6 125/17 162/6 tooth [2] 136/10 136/25 top [14] 10/4 24/22 30/24 33/11 36/3 40/24 60/22 61/16 65/10 76/5 89/6 130/13 133/9 138/18 top-slice [1] 130/13 topic [3] 7/21 17/2 140/10 total [1] 30/1 totally [1] 123/5 touched [1] 135/23 tourniquet [1] 24/1 toward [1] 151/23 towards [11] 18/3 18/9 18/11 38/18 38/22 55/13 131/13 152/8 158/4 158/5 166/25 track [1] 7/13 tragically [1] 133/3 trained [5] 24/11 107/19 107/21 107/22 134/17 training [14] 6/15 23/2 96/5 96/23 97/19 97/25 99/20 106/24 107/4 107/12 140/25 141/1 141/17 141/22 transaminase [3] 151/15 152/10 152/16 transaminitis [1] 47/16 transcript [1] 83/21 transfer [4] 73/6 114/25 116/1 116/8 transferred [2] 89/25 122/18	transferring [1] 122/11 transfused [5] 145/16 146/6 147/1 154/8 163/15 transfusing [1] 69/1 transfusion [41] 6/12 8/22 9/11 12/13 13/10 14/5 17/5 20/18 20/25 34/22 40/7 56/25 56/25 61/18 64/8 71/17 97/20 97/21 97/23 98/9 102/10 102/15 102/20 114/14 117/1 118/20 118/23 119/4 120/2 120/9 120/12 132/20 141/5 141/16 141/22 141/24 142/5 150/22 154/9 154/13 158/1 transfusion-related [1] 150/22 translated [2] 31/14 65/3 translation [1] 63/13 transmission [7] 55/9 60/8 66/12 71/1 78/19 141/1 166/19 transmit [3] 63/4 73/15 98/10 transmitted [2] 154/21 163/19 transmitting [1] 58/25 transplant [3] 98/24 99/4 102/17 transplantation [1] 102/7 transplanting [1] 142/1 transplants [4] 100/11 100/11 146/25 167/12 transport [2] 23/23 23/25 travel [1] 23/12 treat [5] 24/13 99/15 105/13 115/14 117/6 treated [47] 21/20 27/6 27/18 28/24 28/25 30/2 35/5 36/3 39/25 40/5 40/8 40/13 41/17 54/25 60/11 69/6 69/11 69/18 70/6 70/25 72/8 72/20 72/23 73/1 77/3 78/4 79/4 81/15 81/19 84/14 90/13 92/1 92/20 92/20 92/21 93/10 110/22 110/24 110/25 111/20 128/20 129/2 129/3 129/7 129/8 158/22 160/4	treating [6] 31/22 75/17 123/3 123/5 135/18 135/20 treatment [131] 1/25 2/1 3/1 3/8 3/15 7/23 7/24 8/7 11/4 11/14 11/16 11/18 11/23 12/2 12/5 13/2 22/10 22/22 22/25 23/2 23/3 23/6 23/9 23/17 23/20 23/21 24/2 24/10 24/16 26/2 27/10 28/17 28/18 28/19 29/3 35/9 35/11 35/14 35/23 36/6 36/7 36/8 36/9 36/16 36/16 36/18 36/19 36/24 37/5 37/7 37/9 38/3 38/16 40/22 49/4 49/7 49/11 50/25 52/16 53/10 58/10 58/19 59/3 61/1 61/24 62/2 63/14 67/23 68/2 69/13 69/15 70/11 71/7 71/25 72/3 80/12 81/5 81/6 81/9 82/10 87/10 89/1 97/9 97/12 99/17 100/24 100/25 101/20 103/17 104/21 104/22 104/23 104/24 105/2 108/1 110/8 110/11 110/13 111/3 111/9 111/12 111/15 112/1 112/5 112/10 112/12 112/19 113/8 113/25 114/1 114/2 114/3 118/12 118/15 119/17 119/22 121/1 125/22 135/24 136/5 137/11 137/13 137/19 139/5 139/9 139/15 149/19 151/25 158/3 160/21 167/3 treatments [4] 110/5 113/6 139/7 141/6 treats [1] 39/3 TREL0000335 [1] 62/3 Treloar [3] 62/5 62/6 62/21 Treloars [1] 168/9 Trent [1] 133/20 trial [2] 73/21 118/6 trial' [1] 73/23 trials [5] 66/7 66/7 74/15 74/22 88/8 tried [1] 108/9 trivial [1] 138/25 true [4] 88/5 137/14 141/13 146/5 truth [1] 167/20 try [5] 113/3 122/13
----------	---	---	--	--	---

T	167/16 uncertain [1] 155/9 uncertainties [1] 152/19 uncertainty [2] 89/5 155/25 unclear [2] 48/15 85/1 under [24] 15/5 18/23 24/7 26/19 38/21 54/6 55/13 56/13 61/16 63/1 66/17 70/14 72/22 78/15 83/17 97/5 97/20 126/6 129/15 131/13 132/11 132/15 137/7 151/13 underestimate [1] 151/3 underlying [1] 80/19 understand [4] 26/1 139/7 152/7 160/23 understandably [1] 95/2 understanding [6] 74/1 81/12 130/9 131/23 142/12 143/21 understandings [1] 74/16 understood [1] 76/24 undertake [1] 96/11 undertaken [4] 62/13 62/21 83/7 134/15 undertaking [1] 62/24 undertook [2] 48/18 95/25 underway [1] 68/16 unexpected [2] 117/16 119/3 unexposed [1] 59/4 unfortunate [1] 79/10 Unfortunately [5] 42/21 54/15 69/8 144/13 155/10 unheat [1] 78/4 unheat-treated [1] 78/4 unheated [3] 41/1 72/5 123/16 unhelpful [1] 172/16 unhelpfully [1] 31/12 unit [8] 32/1 32/2 71/15 99/6 122/12 148/16 148/22 164/16 United [6] 6/6 98/13 127/16 127/24 128/2 158/19 United States [5] 98/13 127/16 127/24 128/2 158/19 units [24] 3/20 15/10 15/14 30/15 30/16 31/8 31/14 31/20 32/24 32/25 35/8	35/14 35/14 36/8 36/9 37/5 37/9 37/10 54/10 67/7 102/17 111/2 133/13 142/2 University [3] 96/15 96/21 125/4 unknown [1] 166/18 unless [3] 39/13 91/4 91/6 unlikely [3] 69/10 122/23 172/16 unpleasant [1] 139/1 unreasonable [1] 115/10 unrelated [1] 47/5 unselected [1] 149/4 unsurprisingly [1] 51/2 until [30] 1/15 2/15 2/18 4/12 4/16 7/16 7/19 16/21 23/4 24/18 51/24 55/1 69/11 74/11 88/4 88/24 89/24 91/2 102/2 109/15 115/22 119/15 128/21 140/13 143/11 146/23 147/4 158/4 174/13 174/16 untreated [2] 73/11 123/1 up [48] 4/8 7/8 7/11 11/8 13/12 18/4 19/19 28/6 39/18 40/2 40/3 41/3 41/8 41/11 44/8 44/19 49/1 56/19 56/22 67/8 71/23 74/23 80/7 83/20 99/24 100/24 102/6 104/14 112/6 114/1 114/4 118/19 130/25 132/11 132/17 133/13 135/15 136/20 138/11 143/9 144/9 150/17 153/1 158/20 161/24 163/8 165/21 166/14 up-to-date [1] 56/22 update [3] 51/5 56/15 84/7 updates [2] 119/5 162/22 upon [6] 1/9 14/4 17/24 69/14 102/24 138/7 urgency [1] 69/8 us [17] 36/24 41/13 42/3 42/13 54/23 55/6 65/17 76/15 77/6 97/2 104/12 104/25 113/6 123/21 127/2 132/3 140/13 USA [2] 66/11 141/11 usage [20] 17/16	21/23 27/9 28/2 28/7 29/18 29/18 30/8 30/9 35/7 35/13 35/14 35/25 36/14 37/1 41/16 51/19 66/1 66/23 74/22 use [50] 15/25 16/11 16/19 17/15 17/22 17/22 21/8 22/8 23/9 23/19 26/4 28/8 30/6 30/17 30/25 31/1 32/16 32/18 32/21 33/15 36/14 38/19 39/5 39/9 39/13 41/1 41/7 43/20 44/4 44/5 60/13 63/23 68/9 68/24 70/9 70/11 72/19 79/4 109/5 112/25 121/2 121/4 121/12 127/11 129/7 136/10 136/13 137/2 138/22 142/7 used [56] 11/4 11/11 12/4 13/12 13/13 13/24 15/11 15/15 15/23 15/25 16/2 16/3 21/25 25/19 26/2 27/11 27/13 27/21 27/24 28/11 29/4 29/6 29/9 29/20 30/7 31/2 31/21 32/6 34/13 35/7 35/8 35/11 35/17 36/4 36/5 37/4 37/6 40/15 41/17 41/19 50/15 70/23 96/13 96/18 97/18 110/5 111/1 111/8 111/14 111/14 111/25 121/24 122/2 135/20 148/19 158/7 useful [4] 72/19 121/12 172/9 172/13 users [1] 132/3 uses [1] 39/5 using [15] 23/17 33/2 33/2 33/24 115/6 115/11 121/5 121/7 121/9 121/25 129/3 129/19 139/21 139/22 169/15 usual [4] 5/12 26/20 26/22 42/7 usually [4] 24/25 151/19 154/24 172/18	varied [1] 142/20 various [11] 7/23 20/13 21/3 24/21 25/3 41/16 45/13 76/11 88/6 96/1 143/1 vast [1] 37/7 vCJD [2] 2/6 95/6 vein [1] 168/6 versa [1] 136/3 version [2] 138/13 138/14 very [45] 21/9 21/24 25/24 32/23 35/15 50/16 57/16 63/11 74/14 76/9 84/13 92/18 99/2 99/5 114/19 116/13 121/12 121/16 121/17 121/23 122/14 123/4 123/17 125/7 127/21 129/4 129/10 132/8 134/24 139/1 141/24 147/15 148/18 151/1 156/16 158/11 160/10 162/11 163/12 171/23 172/4 172/21 172/22 173/22 174/12 vessels [2] 121/16 121/19 vested [1] 171/1 via [1] 73/22 vice [1] 136/3 view [8] 14/13 19/8 70/25 98/16 139/13 155/23 165/16 171/13 viewed [4] 28/10 158/25 159/8 160/1 views [4] 70/17 124/18 124/25 125/1 VIII [132] 3/11 8/17 8/20 9/24 10/1 10/20 10/25 11/20 13/11 13/24 14/3 14/15 15/3 15/9 15/11 15/22 16/2 16/3 17/1 17/6 17/10 17/13 17/15 17/19 17/22 17/24 18/8 18/22 19/1 19/4 19/6 20/2 20/3 21/21 21/24 26/16 26/18 27/11 27/22 28/1 28/3 29/5 29/6 29/19 30/15 30/16 32/3 32/16 33/3 33/7 34/12 34/14 35/10 35/13 36/8 36/15 36/17 37/8 39/4 39/6 40/9 40/17 40/22 40/22 41/7 41/16 43/12 43/22 48/9 48/20 49/12 49/12 50/5 50/9 50/15 50/16 52/11 53/5 54/11	54/25 60/7 60/11 61/5 65/20 66/2 66/7 66/10 66/24 66/25 68/9 68/21 68/25 69/6 69/10 70/1 70/2 70/5 70/6 70/7 72/8 72/12 72/20 72/23 78/4 79/4 81/21 81/24 82/6 90/14 92/21 97/15 97/16 104/23 105/10 109/5 111/13 114/16 115/6 115/13 119/7 121/15 121/18 121/19 128/20 129/2 129/16 129/19 129/24 130/7 138/22 148/15 162/2 viral [4] 75/13 78/19 90/5 141/1 virgin [1] 76/22 virology [1] 97/23 virtually [2] 147/6 155/17 virus [4] 65/21 69/1 84/17 154/11 viruses [3] 80/14 81/16 154/11 visit [3] 51/12 83/10 83/11 vital [1] 168/24 voiced [1] 12/22 volume [5] 29/4 30/15 35/7 153/12 153/16 volumes [1] 153/13 voluntarily [1] 61/19 volunteer [3] 76/16 98/14 142/10 von [12] 3/3 29/17 35/2 35/4 37/2 58/23 65/10 69/18 110/21 110/25 111/20 121/6 von Willebrand's [7] 29/17 35/2 35/4 58/23 65/10 69/18 111/20 von Willebrand's disease [1] 110/25 vote [1] 170/20
U	UBFT0000156 [1] 114/7 UBFT0000252 [1] 108/14 UCH [1] 98/22 UK [14] 38/17 52/5 76/16 98/15 108/24 109/23 141/12 141/14 141/19 141/24 142/9 157/24 157/25 163/13 UKHCDO [26] 2/4 2/7 39/23 44/7 44/7 46/4 47/25 48/22 51/1 51/3 57/15 62/18 62/20 63/20 66/5 82/23 87/21 103/7 144/25 165/5 168/14 169/3 171/4 171/13 172/4 172/10 UKHCDO's [2] 71/24 72/1 ultimately [1] 133/3 unable [2] 10/8 33/16 unacceptable [1] 118/16 unaware [2] 166/23	underway [1] 68/16 unexpected [2] 117/16 119/3 unexposed [1] 59/4 unfortunate [1] 79/10 Unfortunately [5] 42/21 54/15 69/8 144/13 155/10 unheat [1] 78/4 unheat-treated [1] 78/4 unheated [3] 41/1 72/5 123/16 unhelpful [1] 172/16 unhelpfully [1] 31/12 unit [8] 32/1 32/2 71/15 99/6 122/12 148/16 148/22 164/16 United [6] 6/6 98/13 127/16 127/24 128/2 158/19 United States [5] 98/13 127/16 127/24 128/2 158/19 units [24] 3/20 15/10 15/14 30/15 30/16 31/8 31/14 31/20 32/24 32/25 35/8	updates [2] 119/5 162/22 upon [6] 1/9 14/4 17/24 69/14 102/24 138/7 urgency [1] 69/8 us [17] 36/24 41/13 42/3 42/13 54/23 55/6 65/17 76/15 77/6 97/2 104/12 104/25 113/6 123/21 127/2 132/3 140/13 USA [2] 66/11 141/11 usage [20] 17/16	V vacant [1] 21/18 vague [1] 123/18 valuable [1] 172/19 value [4] 44/25 73/15 74/14 149/15 values [2] 152/10 152/16	wait [1] 130/15 want [4] 20/4 127/5 172/17 173/23 wanted [8] 26/8 85/6 90/7 92/6 100/10 135/11 138/10 164/7 wanting [1] 158/9 ward [6] 24/15 100/19 100/20 100/20 100/25 100/25 wards [1] 99/11 warned [1] 81/20 warnings [1] 81/11 warrant [1] 77/19

W	102/16 102/18 103/12 104/7 104/15 104/25 106/4 107/18 107/20 107/25 112/14 112/22 113/2 116/3 120/5 121/4 122/18 123/3 123/3 125/3 125/16 127/19 129/17 133/3 133/20 134/10 134/16 135/5 136/8 136/24 137/12 139/12 141/3 142/20 143/22 146/20 148/3 148/10 149/11 151/3 152/18 153/4 157/10 157/10 160/8 160/16 163/16 163/17 163/21 165/14 167/13 167/14 167/23 167/24 168/15 168/21 170/25 171/19 171/22 174/6 went [6] 103/8 123/17 140/5 165/10 172/14 172/15 were [157] 2/11 2/14 4/5 4/9 4/10 5/8 5/18 5/23 7/25 11/7 12/21 20/2 21/6 26/6 33/25 39/6 39/9 40/15 41/13 43/24 45/13 45/20 50/15 51/2 52/4 53/11 59/8 59/12 61/11 61/20 63/4 63/10 63/24 70/18 72/8 73/11 73/14 73/21 81/8 81/10 81/16 81/25 82/1 82/23 83/2 84/15 85/3 85/16 86/10 87/11 88/2 88/4 88/13 88/20 88/22 88/22 89/2 89/20 90/8 90/18 96/4 96/20 97/13 97/19 98/22 98/23 99/5 100/3 100/18 100/21 103/6 103/16 104/4 104/7 104/11 104/13 105/24 106/20 106/25 107/16 108/2 108/5 108/6 109/15 109/18 110/5 111/7 112/23 114/1 114/1 114/3 114/22 115/7 116/4 117/22 118/1 119/13 120/5 120/17 121/5 121/7 121/9 122/7 123/1 123/4 123/16 124/9 124/13 124/21 125/16 125/19 126/3 127/6 127/10 127/17 127/22 127/24 128/12 128/13 128/14 130/19 130/20 131/10 132/5 134/12	134/14 134/15 134/16 136/2 136/16 137/18 137/23 139/8 139/8 141/25 143/18 144/21 147/1 149/13 149/25 154/9 154/10 156/8 159/19 160/19 160/20 161/7 162/22 163/5 163/16 169/17 170/6 171/14 172/11 174/1 174/4 174/6 weren't [2] 133/7 160/25 West [37] 4/4 4/15 7/24 8/7 9/1 11/5 12/17 12/25 13/3 16/8 19/23 20/23 29/13 32/13 39/24 43/6 48/2 48/23 51/15 52/21 59/22 59/24 64/1 66/14 67/16 67/20 71/12 71/21 82/19 94/2 103/13 103/18 103/24 108/23 125/21 130/18 173/11 West Midlands [34] 4/4 4/15 7/24 11/5 12/17 12/25 13/3 16/8 19/23 20/23 32/13 39/24 43/6 48/2 48/23 51/15 52/21 59/22 59/24 64/1 66/14 67/16 67/20 71/12 71/21 82/19 94/2 103/13 103/18 103/24 108/23 125/21 130/18 173/11 wet [1] 40/17 wet-heated [1] 40/17 what [97] 4/13 5/7 5/18 16/4 17/17 18/1 20/22 21/18 22/2 23/1 24/2 25/5 25/7 38/18 40/20 41/13 42/2 42/12 42/23 44/2 52/25 57/18 59/15 59/16 62/23 63/14 74/2 75/3 75/10 77/9 77/10 77/24 79/19 80/4 85/2 86/4 88/11 89/8 89/13 97/9 97/12 98/2 99/5 99/17 104/12 109/22 110/5 116/1 117/21 121/2 121/11 124/6 124/11 125/1 127/2 127/12 128/23 129/17 129/19 130/14 134/12 134/14 134/18 135/5 136/7 136/18 137/10 137/10 137/15 138/3 140/7 140/23 142/13 142/16	143/25 147/13 148/10 149/9 149/20 149/20 152/17 153/3 153/8 155/4 158/11 159/19 160/18 162/7 163/5 164/6 164/7 164/10 168/7 170/23 171/7 172/1 173/9 what's [7] 4/23 12/12 32/16 38/21 48/15 130/9 156/2 whatever [2] 63/2 119/10 when [60] 2/5 20/19 21/1 24/24 38/1 40/21 45/24 53/23 54/12 62/16 66/17 70/7 73/23 74/8 80/10 80/16 80/24 81/8 81/14 83/5 83/7 86/14 86/20 88/21 95/20 100/18 104/13 107/9 112/19 116/4 119/21 122/4 123/9 123/15 126/12 128/10 129/3 134/15 134/22 139/25 140/5 141/3 141/16 141/21 143/25 147/8 147/12 155/13 155/15 156/3 161/3 163/18 164/3 164/23 165/10 165/13 167/21 173/25 174/1 174/4 where [22] 6/21 6/24 11/24 13/20 20/22 37/14 54/22 55/5 98/18 104/22 127/15 127/23 127/25 128/2 128/4 133/19 135/7 141/22 146/10 161/1 165/22 170/4 whether [35] 24/12 24/13 24/14 43/14 48/16 59/10 61/11 71/5 71/6 74/9 85/8 94/22 97/16 104/23 105/5 105/17 118/3 124/13 130/8 130/19 134/8 134/19 135/3 136/2 137/18 147/25 148/6 157/7 159/12 162/21 163/23 164/15 169/20 171/11 172/1 which [114] 3/2 4/5 4/22 5/16 5/17 7/4 7/4 9/12 12/2 12/8 12/15 13/13 15/4 15/16 16/14 18/13 18/19 19/4 19/24 20/24 22/24 25/12 25/16 25/25 29/20 30/11 31/9 33/3 34/20 34/24	37/25 38/9 38/19 39/24 45/1 45/4 51/6 53/18 54/15 55/4 63/22 66/6 68/22 71/14 73/18 73/22 75/20 76/22 77/12 77/15 78/3 79/12 81/1 84/25 85/10 86/24 87/2 87/3 87/3 88/14 91/25 92/23 93/3 95/7 98/9 100/9 101/17 104/20 104/21 105/21 106/3 106/18 113/3 113/7 114/11 115/4 116/7 117/15 118/18 122/3 122/7 122/8 123/9 123/21 123/21 124/8 124/9 127/7 128/3 129/3 129/9 130/24 132/7 133/6 135/22 140/10 142/2 142/25 143/5 143/20 146/14 147/19 151/4 152/9 156/19 157/2 157/18 158/1 160/12 162/17 163/6 164/25 168/12 173/24 while [5] 12/1 15/22 99/3 111/18 144/5 whilst [4] 56/6 58/2 125/16 167/1 who [63] 1/13 1/17 1/19 8/21 13/18 19/9 22/16 22/23 23/1 23/7 23/11 24/10 26/25 33/14 40/6 47/4 50/18 50/20 56/8 56/9 60/6 62/25 77/2 78/18 79/9 81/19 84/1 87/11 91/12 91/18 92/20 92/23 93/8 93/17 93/20 97/25 104/16 105/16 105/17 105/21 106/20 107/2 115/11 117/6 122/12 122/19 123/1 123/4 126/21 129/19 133/3 136/8 136/9 139/15 143/13 149/14 156/1 160/4 160/20 165/21 167/4 168/9 172/4 who'd [1] 118/3 who's [1] 53/2 whole [3] 48/18 153/13 154/1 wholly [1] 69/21 whom [2] 39/16 79/20 whose [3] 81/12 94/19 153/20 why [8] 13/19 34/1 94/7 114/11 119/19 127/2 148/20 172/15	wide [1] 42/24 widely [1] 11/21 wider [1] 12/16 Wilde [2] 1/17 89/23 will [64] 1/10 1/12 1/15 1/23 3/7 3/22 8/5 11/1 11/9 16/17 19/15 21/17 25/8 26/13 26/21 32/23 38/20 40/1 40/11 40/20 41/20 46/10 46/20 47/13 49/3 49/10 50/1 50/4 52/14 56/2 62/15 71/5 71/19 74/16 74/17 77/5 77/19 78/11 79/22 80/1 83/14 83/17 83/21 85/23 87/3 90/11 92/14 95/9 95/14 101/3 103/3 111/17 117/5 117/11 117/16 117/17 117/18 124/9 131/4 140/8 140/10 143/22 150/14 174/13 Willebrand's [12] 3/3 29/17 35/2 35/4 37/2 58/23 65/10 69/18 110/21 110/25 111/20 121/6 willing [1] 45/2 Winter [3] 170/1 171/18 173/6 wise [1] 26/15 wish [2] 22/23 72/16 wished [3] 33/15 73/25 74/9 wishful [4] 158/8 158/15 160/9 167/9 with [216] withdraw [2] 61/19 94/20 within [10] 4/4 12/21 12/24 19/6 35/20 57/12 87/24 108/22 118/25 168/16 without [5] 73/8 86/17 88/3 88/7 104/1 WITN1103010 [1] 49/1 WITN1103011 [1] 49/16 WITN3087001 [1] 80/7 WITN4032001 [3] 135/16 144/9 170/11 WITN4032008 [1] 166/4 WITN4032009 [1] 145/6 WITN4032021 [1] 150/16 WITN4032022 [1] 151/6 WITN4032023 [1]
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<p>W</p> <p>WITN4032023... [1] 153/24</p> <p>WITN4032024 [1] 159/16</p> <p>witness [9] 6/8 48/25 81/8 86/9 86/12 135/10 140/15 144/8 170/9</p> <p>witnesses [4] 12/9 34/5 157/3 158/7</p> <p>won't [9] 2/3 2/8 4/2 5/20 12/17 15/1 51/4 63/20 85/25</p> <p>wonder [2] 82/2 84/22</p> <p>word [2] 153/1 161/9</p> <p>words [1] 50/4</p> <p>work [16] 2/7 9/10 23/13 75/23 76/22 96/8 96/11 97/22 98/20 102/17 102/24 103/1 106/21 107/16 113/21 131/2</p> <p>worked [4] 97/3 102/9 107/18 112/21</p> <p>workers [1] 143/23</p> <p>working [47] 8/9 11/23 13/1 14/22 16/21 19/18 29/13 32/11 41/5 43/6 44/1 44/18 44/21 45/2 46/11 47/8 48/8 51/5 51/7 52/21 55/11 59/22 59/24 60/10 64/2 66/13 66/14 67/16 67/20 68/1 68/6 71/12 71/19 71/21 79/5 82/20 94/13 94/16 101/23 103/5 103/14 103/17 105/10 124/7 125/22 129/23 133/14</p> <p>works [1] 121/15</p> <p>world [4] 98/7 124/16 156/1 167/13</p> <p>worldwide [1] 146/9</p> <p>worried [1] 163/16</p> <p>worries [1] 149/25</p> <p>worry [3] 131/4 149/24 174/10</p> <p>worth [2] 54/10 87/17</p> <p>would [164] 8/25 9/21 9/21 14/17 15/11 15/17 17/10 17/18 19/11 19/13 20/9 20/14 24/11 30/5 31/13 33/24 34/19 39/5 39/8 39/12 43/20 45/2 45/4 47/24 50/11 54/12 55/7 57/2 57/11 57/24 58/14 58/18</p>	<p>59/2 60/25 61/1 61/5 61/6 61/13 61/19 63/2 66/3 66/19 67/2 67/25 69/12 71/2 71/15 72/7 72/18 73/10 73/24 74/2 78/5 78/5 82/25 85/7 87/17 89/1 90/21 91/11 91/14 92/22 97/7 97/11 98/3 98/7 100/20 104/18 105/3 105/17 105/20 105/21 106/24 107/3 107/5 107/20 112/24 113/11 113/25 114/2 114/4 114/20 115/20 115/22 116/10 118/2 118/19 119/8 120/1 120/10 120/18 121/6 121/21 121/22 122/8 122/8 122/12 122/17 122/21 122/23 124/13 126/1 126/11 126/15 126/17 126/18 126/19 127/5 127/5 128/3 131/1 131/25 132/4 132/6 132/13 132/14 134/8 134/10 134/13 136/8 137/15 139/24 140/11 142/18 142/21 142/23 143/24 144/1 144/23 144/25 147/15 150/25 151/12 153/4 153/6 155/22 155/25 156/17 156/21 157/16 157/17 160/11 160/14 160/24 164/20 165/21 167/1 167/2 167/12 167/20 168/13 168/15 168/21 168/22 169/8 171/18 171/25 172/2 172/19 172/22 173/3 173/4 173/15 173/17</p> <p>wouldn't [5] 148/16 148/20 153/6 157/6 164/20</p> <p>writer [1] 86/7</p> <p>writing [2] 134/21 138/16</p> <p>written [8] 1/8 12/18 82/4 83/20 86/13 95/7 114/8 138/9</p> <p>wrong [6] 7/9 25/6 110/16 110/18 167/1 172/2</p> <p>wrote [4] 153/11 153/12 154/1 155/12</p> <p>X</p> <p>XIII [1] 94/21</p> <p>Y</p> <p>Yeah [1] 163/21</p>	<p>year [32] 14/20 14/22 19/22 20/5 20/6 20/12 21/20 27/6 27/15 28/25 29/1 30/1 30/2 30/8 30/15 31/20 32/20 33/8 35/5 53/16 60/21 96/13 96/17 99/2 101/6 106/17 107/11 109/10 110/23 110/24 110/25 149/4</p> <p>year's [1] 51/3</p> <p>years [25] 2/7 4/12 4/23 6/3 11/2 32/17 37/12 37/25 38/5 51/17 57/7 86/11 88/4 88/17 92/24 96/17 100/3 102/9 106/21 115/12 119/13 119/25 124/6 143/2 156/5</p> <p>yes [169] 1/6 3/18 31/18 31/23 32/8 34/4 34/21 34/21 38/8 42/6 46/2 46/2 50/14 50/22 57/22 58/2 58/6 58/7 59/17 63/9 63/10 63/12 63/16 65/14 76/20 77/8 77/14 77/22 77/23 77/25 78/9 79/16 79/22 86/6 86/9 92/8 93/5 93/5 95/14 96/3 96/7 96/10 96/10 96/22 96/22 97/1 97/6 98/21 98/21 99/3 99/10 99/23 100/2 100/4 100/8 100/11 100/19 101/8 101/24 102/3 102/5 102/8 102/13 102/17 102/21 102/25 103/8 103/12 106/23 106/23 108/7 108/11 109/8 109/14 109/16 110/1 110/2 110/20 111/6 111/10 111/16 112/3 112/8 112/22 113/17 114/21 115/9 115/23 117/4 118/21 120/4 120/7 120/10 120/14 120/25 122/5 122/5 122/10 122/24 124/5 125/11 126/5 126/17 128/2 128/3 128/16 131/11 132/16 133/22 134/4 135/11 135/14 136/2 136/22 137/22 138/14 140/8 140/13 143/22 144/18 145/4 145/12 146/2 146/16 147/18 147/21 147/24 148/13 150/7 150/13 152/4 152/14 152/22 153/4 153/5 154/3</p>	<p>156/13 156/22 156/22 159/15 159/18 159/18 159/24 160/8 160/16 160/16 160/21 161/1 161/15 161/20 161/23 162/11 162/12 162/18 163/2 163/17 165/9 165/11 165/12 165/13 167/10 167/13 168/1 168/11 168/16 168/23 169/1 169/10 173/17</p> <p>yet [8] 8/10 33/8 87/4 91/17 126/4 147/2 162/13 162/17</p> <p>yield [1] 119/9</p> <p>you [384]</p> <p>you'll [8] 18/12 26/11 35/12 49/5 49/19 50/23 50/23 63/21</p> <p>you're [2] 143/2 145/13</p> <p>you've [6] 98/22 106/11 112/5 150/2 169/3 169/12</p> <p>young [3] 40/24 50/16 122/11</p> <p>youngest [1] 56/24</p> <p>your [89] 4/1 62/13 92/16 95/25 96/8 96/23 97/2 97/2 98/1 98/23 99/24 100/5 100/5 100/7 100/16 101/19 102/24 103/1 103/20 104/2 104/14 106/10 106/11 106/12 108/2 108/18 111/5 112/5 112/6 116/14 116/16 116/19 118/7 119/6 120/1 120/16 121/5 121/19 122/17 123/10 124/1 124/4 124/4 124/7 128/1 133/8 135/10 135/12 138/9 138/9 138/13 138/15 138/19 140/21 140/24 140/25 142/16 143/5 143/18 143/19 143/20 144/8 149/9 150/2 150/4 150/9 150/10 150/15 152/5 158/13 159/24 160/23 162/23 164/3 164/6 164/13 165/1 165/1 165/2 165/2 165/4 167/8 169/7 169/8 170/9 170/11 171/12 172/7 173/19</p> <p>yourself [5] 110/10 112/10 123/12 133/21 160/7</p>	<p>Z</p> <p>zero [1] 169/6</p> <p>zoom [5] 23/15 24/7 49/17 90/17 93/5</p>	
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