

Friday, 25 June 2021

(10.00 am)

(Proceedings delayed)

(10.05 am)

Presentation by Counsel to the Inquiry re

Lord Mayor Treloar School and College (continued)

MS RICHARDS: Sir, before I come to some documentation relating to research undertaken at Treloar's, there are a handful of further materials and observations from the evidence about issues relevant to treatment, communication with pupils and parents, and issues of consent.

One document we haven't looked at yet is a book written by Dr Aronstam called Haemophilic Bleeding.

Soumik, it's RLIT0000666. We can see it's called:

"Haemophilic Bleeding; Early Management at Home."

If we go on I think about six pages, Soumik.

Sorry, the page before that, I think. Yeah.

We can see the date of publication, so it was published in 1985. I'm not entirely sure, sir, when precisely in 1985, or when precisely written, but clearly written by then.

If we could go then just to the preface. It's

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1977.

"From then on we began to collect data in depth on each bleeding episode. Constant review and analysis of these data have enabled us continually to update our practice and many of our innovations have been confirmed by controlled clinical studies.

"The information and recommendations in this book represent the Treloar Haemophilia Centre view of current best practice -- within a residential institution. I believe that extrapolation to everyday living is a valid one but recognise that the practicalities of our approach are not always appropriate. This reservation is stressed repeatedly in the text. I should also point out, however, that best treatment is best treatment however inconvenient. Our experience and our recommendations are on offer. It is for the haemophiliac or his adviser to balance the severity of his bleed against the urgency of his commitments and his assessment of the long term consequences of possible under-treatment."

Those are just some introductory observations that Dr Aronstam made. The particular passage I wanted to go to is in the chapter on prophylaxis. If we just pick it up at page 106, please. We can see there the heading "Prophylaxis", then Dr Aronstam

3

about another five pages on, please. That's it.

I just wanted to read what Dr Aronstam says in part here and then look at one particular passage in the main part of the book. He says:

"One hundred and fifty severely affected adolescent haemophiliacs have passed through the Lord Mayor Treloar College since 1973. They have been treated for bleeds at the Treloar Haemophilia Centre more than 15,000 times. Information on all bleeds has been recorded and many lessons have been learned. Mistakes were made, failures have been analysed and management regimes have been altered. This book is really the book of those haemophilic boys, for it is a distillate of the experience gained from the observation and treatment of all those bleeds over all those years.

"My own personal involvement began in 1977 when I was suddenly faced with the responsibility for the clinical care of 55 severe haemophiliacs boarding at the College, far from their homes and from the expertise of their own Haemophilia Centres. An immediate treatment strategy had to be devised and this was based initially on the results of an analysis of the crude data available from 5,500 bleeds which were seen and treated at the College between 1973 and

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talks about "Long-term prophylaxis", and says in the second paragraph:

"Some haemophilia doctors put young children on long-term prophylaxis in order to prevent haemophilic arthropathy. Rather higher doses and frequency may be needed since any joint bleed can initiate the process."

Then he talks about "Limited prophylaxis":

"... prophylaxis given for a fixed period of time, usually from one to eight weeks. Limited prophylaxis may be given for target joints ... It can also be prescribed for periods of stress such as examinations when bleeding may be more frequent in certain individuals. A 'bad patch' which many haemophiliacs undergo periodically can be another indication for limited prophylaxis".

Then if we go over the page he then talks about "Single dose prophylaxis":

"This is the giving of one dose of factor VIII to cover a 'one-off' situation. This may be a high-risk event such as a sporting occasion. Such an event may be high risk even when the haemophiliac is not playing. A major event such as the Cup Final could involve a long and heavy journey a lot of jostling, a large crowd and a lot of excitement.

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1 I would always advocate a dose before such an event.
 2 There are also occasions which are not in themselves
 3 high risk but are of such social significance that
 4 a bleed would be disastrous. Weddings and
 5 examinations are obvious instances. I am quite
 6 liberal in this matter and extend my list to include
 7 discotheques, important dates and Christmas shopping.
 8 My philosophy on the whole is that if it is important
 9 to a patient it warrants a prophylactic dose. I let
 10 him decide."

11 Of course, whether that is an accurate
 12 characterisation of the actual approach to treatment
 13 at Treloar's will be a matter ultimately for you to
 14 decide, sir.

15 **SIR BRIAN LANGSTAFF:** Well, it doesn't entirely fit with
 16 some of the evidence we've heard this week about those
 17 who didn't want to have it.

18 **MS RICHARDS:** Yes. Well, it doesn't fit in terms of the
 19 evidence in relation to prophylaxis. Perhaps more
 20 generally, it doesn't necessarily fit with any of the
 21 evidence we've heard about the provision of
 22 information in relation to the obtaining of informed
 23 consent.

24 "This category at our Centre gets the highest
 25 doses. Once we accept that a bleed must be avoided we

5

1 references to it.

2 **SIR BRIAN LANGSTAFF:** What this is indicating in 1985
 3 presumably a lot of the text prepared either earlier
 4 in '85 or late 1984, is a collaborative participative
 5 approach to treatment.

6 **MS RICHARDS:** Yes, absolutely, and one of the issues for
 7 you to consider is whether the reality lived up to
 8 what Dr Aronstam is here describing as being a proper
 9 approach.

10 **SIR BRIAN LANGSTAFF:** He obviously is recognising, at
 11 least at an intellectual level, that, at least so far
 12 as other doctors are concerned and other patients are
 13 concerned, they should talk about it with the doctor
 14 and reach a joint decision and the decision is the
 15 patient's.

16 **MS RICHARDS:** Yes.

17 We can take that down, thank you.

18 Then looking broadly at the question of
 19 communication with patients, we've heard, both in 2019
 20 and the oral evidence we heard then from witnesses who
 21 had attended Treloar's, and in the course of this
 22 week, evidence about what individual pupils were or
 23 were not told and what their parents were or were not
 24 told about risk at testing and so on.

25 In terms of hepatitis and information about

7

1 can't take choices. At least double our standard dose
 2 is indicated."

3 Then we have a paragraph, and the reason for
 4 going to this page, really, is because this is the
 5 only paragraph I can find in the book which refers to
 6 either hepatitis or AIDS. It's certainly the only
 7 page referenced in the index in relation to those
 8 subjects, and this is in 1985.

9 "No one could possibly argue that the infusion
 10 of a plasma product such as factor VIII for bleeding
 11 is unnecessary. The same can clearly not be said for
 12 prophylaxis. The risk of complications such as
 13 hepatitis and AIDS makes prophylaxis unacceptable to
 14 some doctors and some haemophiliacs. Extensive
 15 discussion on this subject is beyond the scope of this
 16 book. I feel very strongly, however, that this is
 17 a matter you should consider after discussion with
 18 your own doctors. Even if they feel prophylaxis is
 19 indicated, the ultimate decision is yours. It can,
 20 however, be very helpful to hear the objective views
 21 of someone who is not as emotionally involved as
 22 yourself."

23 That, as I say, is the only indexed reference to
 24 either AIDS or hepatitis, and certainly on a skim of
 25 the entire book I haven't identified any other

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1 hepatitis, you'll recall the evidence of Nick
 2 Sainsbury talking about being told there were two
 3 types of hepatitis, the fatal kind and non-fatal kind,
 4 and you'll recall his evidence about remembering in
 5 relation to that outbreak in the mid-1970s the red
 6 mark on the plate to identify which boys have
 7 hepatitis. There is another witness, the sister of
 8 a pupil at Treloar's, who also recalls her brother's
 9 cutlery and crockery being marked because he was
 10 infected with hepatitis so that recollection is not
 11 unique to Nick.

12 Then if we look at WITN3224001, please.

13 This is a statement from another pupil at
 14 Treloar's. If we go to the second page we can look at
 15 paragraph 9 towards the bottom of the page.

16 "While I was at the LMT, I was informed that
 17 I was infected with Hepatitis B. I was still a minor
 18 at the time, and I do not recall my mother ever being
 19 told about this diagnosis. She certainly never told
 20 me she had. A group of pupils were told collectively
 21 that we had been tested positive. We were also told
 22 that because we were Haemophiliacs we would get over
 23 it unlike other people."

24 Sir, again, that may be, in broad terms, again
 25 consistent with the kind of recollection Nick

8

1 described, of essentially being told, "It's not
2 something for you, as a haemophiliac, to worry about".
3 And that's the broad sense that emerges from the
4 evidence overall that the Inquiry has received.

5 In relation to communication about HTLV-III/HIV
6 and AIDS, there's a range of evidence the Inquiry has
7 received. Again, some we've heard orally in 2019 and
8 this week. Others are in the form of written
9 statements. One witness recalls a pupil, a roommate,
10 not returning to school after half term. People were
11 asking what had happened, and being told not to worry,
12 that people would be looked after.

13 Some witnesses have recalled some kind of
14 meeting with pupils at some stage regarding AIDS, in
15 which they were told, "Don't worry, only two people in
16 the UK with haemophilia have AIDS", so an attempt to
17 provide reassurance. And another witness, a mother,
18 recalls her sons being invited to a meeting at which
19 they were told that there was information about AIDS
20 and haemophiliacs in America but it was not something
21 for the pupils to worry about.

22 In relation to how individual pupils were
23 informed that they had tested positive for HTLV-III,
24 the evidence that the Inquiry has received and heard
25 suggests that there was not a single uniform approach

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1 I say for the most part. There is some limited
2 evidence of parents recalling being told themselves
3 but for the most part that's not the picture which
4 emerges from the evidence.

5 We know from the evidence we heard yesterday
6 that the headmaster was not involved in the process of
7 pupils being given this information, or involved in
8 the process of ensuring that parents were given that
9 information and the evidence that we have from
10 Mr Scott, the housemaster, or one of the housemasters,
11 indicates that he was not involved in that process.

12 So that which the vast majority of pupils
13 recall, in other words that they were told by the
14 staff at the Haemophilia Centre, it seems to be
15 consistent with all the evidence that we have. There
16 doesn't appear to have been any consideration given to
17 having someone there, whether parent or housemaster or
18 someone else *in loco parentis*, to provide emotional
19 and pastoral support at what must have been a horrific
20 time.

21 The evidence, then, about what support was
22 available to pupils given this information is at best
23 equivocal. Again, you'll recall Mr Macpherson's
24 evidence, his understanding that there was, in
25 principle at least, a psychiatrist, and a counsellor

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1 adopted. So, as you've heard, there are witnesses who
2 recall being told in a group with other pupils, being
3 told in a matter-of-fact way, or being told
4 essentially, "You have it, you don't, you have it, you
5 don't."

6 There are others who recall being told on their
7 own by Dr Aronstam, possibly with others.

8 You've heard, and we had evidence this week,
9 that there appears to have been the communication of
10 that information over quite a long period of time, in
11 the sense that there are some who, it appears, may
12 have been told in 1985, but others who may not have
13 been told until 1986. Which raises the question about
14 there being delays, given that we know that
15 Dr Aronstam certainly had a number of results by
16 March of 1985, and yet evidence of possibly as much as
17 a year or more before the individual is told.

18 And of course, we've heard evidence this week
19 which suggests that some pupils may not have been told
20 at all and you'll recall the extremely powerful
21 evidence of John Peach in that regard about his sons.

22 And, of course, evidence which paints a picture
23 that for the most part, parents do not appear to have
24 been told directly by Treloar's, by the Haemophilia
25 Centre, of their child's diagnosis.

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1 available, and there is evidence to suggest that that
2 was a facility that was available across the school as
3 a whole. So we have a statement from Ms Burton, who
4 was the headmaster's secretary for a period of time,
5 who recalls there being counsellors at the school, but
6 not a structured or organised arrangement in relation
7 to the haemophiliac students for them to be seen
8 specifically.

9 And if we go to the statement of Mr Scott, the
10 housemaster --

11 **SIR BRIAN LANGSTAFF:** Do we have any information as to
12 when the counsellors began their work? Were they
13 there for anyone at any time?

14 **MS RICHARDS:** So my reading of the evidence, sir, is that
15 there was no specific counselling facility that was
16 introduced into the school to address the HIV
17 diagnosis and the position of haemophiliac patients
18 being given this diagnosis and supporting them.

19 The evidence suggests that there was some form
20 of broader counselling service that might have been
21 available to all pupils as a matter of generality.

22 **SIR BRIAN LANGSTAFF:** Yes. Certainly the headmaster had
23 a number of relatively scathing things to say about
24 the way in which pupils were told, which he had not --
25 assuming that the evidence is accepted -- which he had

12

1 not understood.

2 **MS RICHARDS:** Yes.

3 **SIR BRIAN LANGSTAFF:** Before hearing it here.

4 **MS RICHARDS:** If we go to the statement of Mr Scott
5 at WITN5314001.

6 Mr Scott was a housemaster at Treloar from 1981
7 until his retirement in 2011 and, if we go to page 8,
8 he says in paragraph 41:

9 "In general terms I would consider the training
10 which I received to have been 'fit for purpose' in its
11 time, but with the benefit of hindsight, I feel that
12 it was perhaps lacking as regards supporting those
13 with HIV and/or AIDS."

14 The next paragraph:

15 "Clinical staff from the Treloar Haemophilia
16 Centre attended to explain medical information as
17 regards HIV/AIDS to staff, such issues as its means of
18 transmission, safe disposal of clinical waste and in
19 particular care that had to be taken around blood, so
20 we did receive some useful instruction, but there was
21 a lack of training which would have enabled staff to
22 offer psychological support to infected students."

23 Sorry, and the next paragraph:

24 "This particular requirement was beyond anything
25 which my past experience and training had prepared me

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1 Then if we go down the page, I referred
2 yesterday to the second paragraph under the heading
3 "AIDS/HIV", which referred to there being 43 patients
4 antibody positive.

5 If we go to the next paragraph, he says:

6 "Many of our patients are now showing clinical
7 evidence of HIV disease."

8 And further details are given in that regard.

9 Towards the bottom of that paragraph he says:

10 "We are likely therefore to have seven further
11 cases of AIDS within the next year or two and
12 I predict twenty to twenty-five cases in my
13 haemophiliac patients by 1990. There are gloomier
14 predictions about which suggest that up to 100% of the
15 infected haemophiliac population will eventually
16 succumb to the virus."

17 Again, sir, you may wish to contrast what
18 Dr Aronstam was saying there with what we've seen
19 referred to from time to time elsewhere about saying,
20 at least saying at some stages to others, we don't
21 know how many people will progress to AIDS, probably
22 a very small proportion of people will progress to
23 AIDS. At least by 1986 it appears that is no longer
24 Dr Aronstam's view.

25 Then he continues:

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1 for, and I found myself ill equipped to address
2 individual concerns when they were suddenly presented
3 with an HIV diagnosis and confronted with questions as
4 to what HIV/AIDS could mean for them."

5 So that was Mr Scott's recollection.

6 Then if we can go back to a document we've
7 looked at a couple of times before, it's Dr Aronstam's
8 1986 report to the region.

9 It's at HHFT0001073. So it gives us some
10 information about counselling and other matters.

11 If I pick it up at the beginning:

12 "The steady evolution of this Centre has been
13 shattered by the impact of AIDS HIV infection which
14 will exert a major influence on our policies for
15 several years to come. We have had to reassess our
16 priorities and this report will consider only those of
17 major relevance. The consumption of Factor VIII is
18 still clearly important and our patient population and
19 therapeutic policies are significant influences on
20 this. AIDS/HIV has added considerably to our workload
21 and there are other financial implications related to
22 therapy."

23 Then he refers to the Centre extending its
24 expertise from bleeding into offering a broader
25 service in relation to clotting.

14

1 "The bare facts do not reveal the cataclysmic
2 impact of the AIDS/HIV problem on our Haemophilia
3 Centre. The patients, their families, the Haemophilia
4 Centre staff and the community around us are all
5 profoundly affected and will continue to be so for
6 many years to come. We at the Centre have had to
7 devise a multi-faceted strategy for responding to many
8 different situations [if we go to the third page,
9 please, Soumik] which have arisen and others which
10 will arise in the future. Naturally, there are
11 implications for resources."

12 Then we see a heading "Counselling", in which
13 Dr Aronstam says this:

14 "All haemophiliac families, affected or not, are
15 encountering prejudice. They need support to deal
16 with this and the community around needs education.

17 "Adult haemophiliacs with the antibody live
18 a life haunted by fear. They need constant support,
19 and follow-up visits, which are now much more
20 frequent, require much more time at each visit.
21 Parents of children with HIV are devastated and need
22 even more support and time. They are plagued by
23 prejudice at school and in the neighbourhood and the
24 solution is to go out and educate but this requires
25 time.

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1 "Antibody positive haemophiliac children enter
2 adolescence with an increasing viral load. Nature has
3 programmed them for sexual experimentation at a time
4 of maximal infectiousness. The counselling involved
5 in this situation must be expert, intense, patient and
6 even more time consuming if breakout of the virus from
7 this group is to be averted.
8 "The advent of full-blown AIDS demands support
9 for the dying and for those who will be bereaved. It
10 is also important to realise that the advent of AIDS
11 is not just a matter of coming into hospital and
12 dying. It takes three to four years to die and in
13 between hospital admissions there are long periods
14 when the sufferer is at home, becoming weaker and
15 increasingly a drain on community resources. It is
16 during these times that the Haemophilia Centre must
17 remained involved. We cannot be seen to abandon those
18 who we have accepted as our lifelong responsibility."
19 Then he poses the question: "Who should
20 counsel?" And this may give us some insight into the
21 availability of counselling at the school. He says:
22 "In our Centre I and a nursing sister have done
23 it all up to now."
24 So there is no suggestion there of additional
25 counselling or extent of counselling available.

17

1 possibly of AZT.
2 That's the report that Dr Aronstam made to the
3 Wessex Region, the Regional Health Authority in, as
4 I say, we think 1986.
5 **SIR BRIAN LANGSTAFF:** Was any part of this report asking
6 for finance for a counsellor?
7 **MS RICHARDS:** No, it's a request for continued funding,
8 certainly. That, I think, is the purpose of it.
9 If we go to page 7 -- actually, I should have
10 referred to this. This provides some further
11 information about Dr Aronstam's involvement. He says:
12 "I am contracted to do five sessions a week
13 (mornings) at the Haemophilia Centre and five sessions
14 a week (afternoons) at the Department of Haematology,
15 Basingstoke District Hospital."
16 Then he refers to the difficulty of what he says
17 is maintaining his commitments to the Haemophilia
18 Centre, and he lists, amongst other things, the
19 increased counselling commitment as well as increase
20 in administration and paperwork consequent upon the
21 HIV situation, and he refers to his involvement in
22 various groups and working parties.
23 Point 7, he describes himself as a trained
24 AIDS/HIV counsellor. He says:
25 "... I have many patients referred to me for

19

1 "The specialised nature of the haemophiliac
2 condition makes it impossible to win the trust of the
3 patient unless you are seen to have a thorough
4 understanding of the primary illness. For this reason
5 I do not see a role for the injection of specialised
6 counsellors into our Unit. We have been allotted
7 a social worker from the local Department of Social
8 Work who will spend one morning a week at the Centre.
9 She will naturally be involved in social work with our
10 patients and I hope will be able to take on some of
11 the counselling load but obviously only a minor
12 component. I see myself as continuing to play the
13 major role in this area with the nursing sister. She
14 is young and in the nature of things likely to move on
15 in the next year or two. Continuity with the
16 haemophiliac families must be preserved."
17 Then there's a reference to the need for ongoing
18 medical surveillance, for immunological surveillance,
19 where he says:
20 "I believe it is essential to monitor the T-cell
21 markers, and we have had to develop the technique in
22 our own laboratories because of logistical
23 difficulties in getting fresh samples to Southampton.
24 This work is done by Haemophilia Centre staff."
25 Then there's a reference to treatment and the

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1 counselling who are not haemophiliacs."
2 He says in paragraph 8:
3 "I view the above as obligatory commitments.
4 There are, however, other commitments which it would
5 be irresponsible to ignore. Our experience at
6 Treloar's is almost unique and it is essential that it
7 is documented. Coordinating the necessary collection
8 of data and communicating the information must be done
9 and is time consuming."
10 Then he is essentially making out a case for
11 a further full time consultant, in what follows.
12 If we go to the next page he talks about
13 predictions and future requirements in relation to
14 funding. So he's asking for increased funding for the
15 laboratory, pay increases for staff, a third
16 consultant, funding to enable Centre staff to visit
17 patients in their home, funding for attendance at
18 education and conferences.
19 **SIR BRIAN LANGSTAFF:** Now, I think you're on a page
20 which is not on the screen.
21 **MS RICHARDS:** I'm so sorry, that's entirely my fault.
22 It's the page after that. I should have looked at the
23 screen. So you'll see here, sir, heading:
24 "Predictions and future requirements."
25 He is setting out here what he thinks the future

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1 requirements of the Centre are and what will need
2 enhanced funding, so he refers to "The Laboratory" and
3 then the heading "Medical Staff", underlined, in
4 relation to pay increases for medical staff. He
5 refers to the need to appoint a third consultant
6 haematologist, funding to enable Centre staff to visit
7 patients in their home, and then under the heading
8 "Education/Conferences", funding to enable staff to
9 keep abreast of current developments nationally and
10 internationally.

11 If we go over the page, what else is listed
12 there are all examples of the kind of conferences and
13 meetings he thinks staff should be funded to attend.
14 And then there's some reference in terms of spending
15 and revenue. So, no, there's no financial case there
16 put for the appointment of a counsellor to the Centre.

17 **SIR BRIAN LANGSTAFF:** No, but the -- I suppose the context
18 in which he is saying "I do all the counselling" is
19 saying that: AIDS is taking up a lot of his time. It
20 inevitably imposes demands. Those demands are real.
21 Please, therefore, appoint somebody else to share the
22 load.

23 **MS RICHARDS:** Yes, absolutely.

24 **SIR BRIAN LANGSTAFF:** Not the load of counselling but the
25 load of --

21

1 being provided to individual parents, Mr Macpherson
2 referred, I think, to a letter sent out by
3 Dr Tomlinson to try to reassure the parent cohort as
4 a whole about the risks of AIDS.

5 It may be he was referring to the document
6 at RLIT0000663.

7 Certainly the minutes of governing body meetings
8 that we have do refer to Dr Tomlinson writing to
9 parents.

10 This is a letter -- the date is not clear in the
11 top right-hand corner, as you'll see, and zooming in
12 doesn't help either, unfortunately. It's on
13 19 September 1980-something, but that's the best I've
14 been able to do. But it says:

15 "Dear Parents,

16 "You will no doubt have been concerned, as we
17 have, by the treatment of a haemophilic boy in
18 a Hampshire school and the interest in this that has
19 been aroused by the media."

20 You'll recall Mr Macpherson not having any
21 particular recollection about media problems.

22 "As you know, we've always had haemophilic boys
23 at this school, so that they have been able to have
24 immediate treatment and also continue their education.
25 They have always integrated well with the children

23

1 **MS RICHARDS:** Of the general haematology work.

2 **SIR BRIAN LANGSTAFF:** -- allowing me to do what I have to
3 do to fulfil my obligations to those who are my
4 patients who have suffered from HIV infection.

5 So there is a motive for his --

6 **MS RICHARDS:** Yes.

7 **SIR BRIAN LANGSTAFF:** -- for up-playing his own role and
8 downplaying the role of others, but it still doesn't
9 entirely explain, unless he is simply not mentioning
10 it deliberately, the absence of any reference to
11 counselling being available through the school.

12 **MS RICHARDS:** Yes, you're right. It doesn't mention it at
13 all and I don't think there's any evidence to suggest
14 that there was any kind of specialist counselling
15 available through the school in any event. And you've
16 seen what Mr Scott had to say. But you're right, it
17 doesn't refer to that.

18 **SIR BRIAN LANGSTAFF:** One way or the other I have to make
19 sense of what the headmaster told me yesterday as
20 against this contemporaneous account, albeit with
21 a motive, and Mr Scott's account.

22 **MS RICHARDS:** Yes.

23 And then in terms of information being provided
24 more broadly to parents of pupils at the school as
25 opposed to information about children's diagnosis

22

1 with other handicaps.

2 "We have been aware that the treatment the
3 haemophiliacs have had has now led to the risk of
4 infection with the virus which causes AIDS and we have
5 taken this very seriously. We have watched the
6 results of all the research being done, and have been
7 in touch with all the leading specialists in this
8 field. We are being extremely cautious and are
9 assuming that any haemophilic boy could be a carrier
10 of the virus. Even if this is so, the chance of any
11 of them eventually developing AIDS is very small."

12 And there is a contrast with what Dr Aronstam
13 was saying in his report to the region.

14 "The infection is extremely difficult to spread,
15 as the virus dies immediately it is outside the body.

16 "We are confident that the precautions we take
17 at the College make it impossible for the virus to be
18 passed on to any child or member of staff at the
19 school. The only risk we are left with is that of
20 close and intimate sexual contact with a possible
21 carrier of the virus, and this is of course against
22 the College rules and we trust the pupils will not put
23 themselves at risk in this way.

24 "We will continue to take every care, and we
25 assure you that the safety of the other children and

24

1 the school staff is our first concern. We also have
2 a responsibility to ensure that the haemophilic boys
3 should be treated in a humane way and not
4 unjustifiably ostracised.

5 "If you want any further information about this,
6 or details of the precautions being taken, please do
7 not hesitate to contact me or the Headmaster either by
8 telephone or by arranging to come and see us."

9 We can see the letter is from Dr Tomlinson, the
10 school medical officer. So that appears, on the face
11 of it, was a letter seemingly designed to reassure the
12 parents of all the pupils at the school that they
13 should not be concerned about HIV being passed on
14 amongst pupils at the school.

15 **SIR BRIAN LANGSTAFF:** Just as you've been talking, my mind
16 is still thinking about the counselling question.

17 Does any -- do any of the statements we have from
18 those who were actual pupils, or those who are the
19 parents of or family of those who were pupils who are
20 no longer with us, say anything about them being --
21 having any form of counselling which might meet the
22 description?

23 **MS RICHARDS:** I don't think so. There are entries in
24 medical records in the correspondence that refer to
25 the nursing sister, Jane Kershaw, the nursing sister

25

1 about the clinical aspects of their care, and then
2 what you might regard as counselling aspects are then
3 touched on in Jane Kershaw's letter.

4 So she says in paragraph 4, in relation to one
5 of the boys that:

6 "[He] is fully aware of his status and all its
7 implications, many discussions have taken place on the
8 subject of HIV and AIDS and also regarding
9 relationships and related emotional issues."

10 She refers to him harbouring "quite a lot of
11 anger about the situation aggravated by some negative
12 experiences". She also refers to having had some
13 contact with the parents of one of the boys and, in
14 relation to the other boy that she's discussing, there
15 is a discussion about whether that individual should
16 be told his HIV diagnosis.

17 So it's apparent from what is set out in this
18 letter and over the page -- and I'm not going to go to
19 it because there is quite a lot of detail about the
20 individual family even though it's redacted, so we
21 won't go to it, thanks, Soumik. We'll just go back to
22 the first page.

23 But there's a discussion which makes clear that
24 there's one particular pupil who hasn't been told
25 their HIV diagnosis, albeit it is described as being

27

1 at the Centre, having conversations with one
2 particular pupil about diagnosis and its implications.

3 In terms of any form of specialist counselling
4 or counselling other than through Dr Aronstam and the
5 nursing staff at the Centre, I can't recall anything.

6 I'm going to see if Ms Fraser Butlin has any
7 recollection -- no, hers is the same as mine -- from
8 the statements we've read, and I think we've read all
9 the statements the Inquiry has received which describe
10 attendance at Treloar's, either directly from a pupil
11 or from a family member. We've not detected anything
12 which refers to any form of external counselling
13 within the school or elsewhere.

14 **SIR BRIAN LANGSTAFF:** Yes, thank you.

15 **MS RICHARDS:** Just to get a sense of what the nursing
16 sister was talking about, if we go to TREL0000222_033.

17 This is a letter -- this is a number of years on
18 now in the Centre, September 1989, but it's a letter
19 from Jane Kershaw at the Haemophilia Centre to
20 a nursing sister at the Oxford Haemophilia Centre and
21 it's about a couple of specific pupils who have
22 recently left Lord Mayor Treloar College and will be
23 reverting to the care of the Oxford Haemophilia
24 Centre.

25 It refers to Dr Wassef writing to Dr Matthews

26

1 at the request of the parents.

2 So that's -- we've referred to that because it's
3 a relatively -- it's one of relatively few pieces of
4 documentation which show those kind of discussions,
5 the kind of discussions that you might think
6 counselling would encompass taking place, but it's
7 with the nursing sister and, as we see, it's rather
8 later on in the course of the 1980s rather than at
9 that particular point in time when boys were being
10 told their diagnoses and might have needed maximum
11 support.

12 **SIR BRIAN LANGSTAFF:** Yes, thank you very much.

13 **MS RICHARDS:** Then just a couple of further documents.

14 If we go to TREL0000365.

15 These are the extracts from minutes of
16 a governing body in February 1986.

17 Sir, you asked yesterday if we knew when the
18 first reference to AIDS was in the governing body
19 minutes, and the answer is we don't appear to have all
20 the governing body minutes so we're still checking to
21 try and find out what the position is in that regard.

22 But if we go to the second page, I looked at one
23 paragraph from this with Mr Macpherson yesterday but
24 if we perhaps just look at the rest of the discussion
25 under the heading "AIDS":

28

1 "The Headmaster commented that the correct
2 inference to draw from the Minute on this subject from
3 the last Meeting was that although 'very few' of the
4 haemophilic boys carrying the AIDS antibodies would
5 develop AIDS, this meant that at least one would do so
6 at some stage."

7 So, again, there appears to be something rather
8 different being said here to what we see in
9 Dr Aronstam's report to the region, which is a much
10 bleaker and, one might think, more realistic
11 assessment of the situation.

12 **SIR BRIAN LANGSTAFF:** Yes.

13 **MS RICHARDS:** Then there's a reference to advice from
14 Dr Aronstam about the risks of transmission, so:

15 "... a pupil actually suffering from AIDS posed
16 no greater danger to the other pupils and staff in the
17 College than any of the pupils carrying the AIDS
18 antibodies."

19 The advice being that it's the person with AIDS
20 who might in fact be at risk of being infected by
21 others with opportunistic infections and the like.

22 **SIR BRIAN LANGSTAFF:** So certainly at this stage he wasn't
23 taking the view that the AIDS antibody might be
24 protective?

25 **MS RICHARDS:** No. No, that's right.

29

1 So that's -- well, perhaps if we just look at
2 the bottom of the page. I think I referred
3 Mr Macpherson to the suggestion that the parents of
4 pupils were aware of their son's infection. Obviously
5 there's evidence to the contrary.

6 But then we can see a reference to the public
7 relations problems that might occur, and if we go to
8 the top of the next page, we see identified in the
9 second paragraph a further reference to public
10 relations. So we see Dr Whitfield emphasising his
11 view that "the College's policy and procedure" was
12 "exemplary", but suggesting:

13 "... it might be advisable to make contact with
14 the ... Health Authority for advice on how to handle
15 the public relations aspects of these matters."

16 The evidence in relation to pupils being told
17 about their hepatitis C diagnoses that the Inquiry has
18 received is much more limited, possibly because a lot
19 of those who have given statements to the Inquiry
20 received their diagnoses after they left Treloar's and
21 were receiving their diagnoses from their home
22 Haemophilia Centre. So the information is rather more
23 limited.

24 We've got a statement where a witness recalls
25 being informed by Dr Wassef about infection with

31

1 Then we can see at what's said to be a meeting
2 that had taken place between the headmaster and senior
3 staff to consider the action that should be taken once
4 it was determined a pupil was actually suffering from
5 AIDS, as opposed to merely carrying the antibodies.
6 And there's reference to a three-stage process:

7 "Stage 1: When a pupil had been identified as
8 actually suffering from AIDS, he would not be asked to
9 leave the College. Information on his condition
10 should be restricted to the parents and Headmaster,
11 and to Nurses and Senior staff who needed to know."

12 Again, that's not necessarily consistent with
13 what we saw yesterday about the school staff or the
14 headmaster not actually knowing which individuals were
15 infected, but in any event.

16 Stage 2 is described as:

17 "When a pupil is suffering from an
18 'opportunistic illness' exacerbated by AIDS he will be
19 nursed in the College Sick Bay, provided he is not too
20 severely ill."

21 Stage 3 was:

22 "When the pupil becomes so weak as to be unable
23 to benefit from further teaching (but not before)
24 he/she would be transferred to their home or hospital
25 for permanent nursing care."

30

1 hepatitis C, and his recollection that he was told it
2 would kill him but Dr Wassef wasn't sure how long that
3 process would take. So essentially told it was
4 something serious.

5 Another witness recalls their parents being told
6 at a meeting in Treloar's of the infection with
7 hepatitis C, but the gist of that was, "Well, your son
8 will be fine", and just to get on with life.

9 Again, another recalls just being told of
10 hepatitis C but not really being given any further
11 information at all.

12 There's one set of documents which does provide
13 an indication of a delay in a patient being told their
14 diagnosis. So we've got a test result from mid-1990
15 and evidence which suggests that the test result was
16 communicated in around mid-1991, so a delay there of
17 a year.

18 Then just a couple of documents more broadly on
19 treatment for hepatitis C.

20 If we go to TREL0000313_066.

21 This is a letter of 12 July 1991. I may have
22 referred to it yesterday, I'm not sure, in the context
23 of -- if we look further down the page -- in the last
24 paragraph there's a discussion there about non-A,
25 non-B hepatitis. So we can see there's a reference to

32

1 a liver examination and Dr Wassef says:
 2 "I explained to him that he has antibodies to
 3 HCV (non-A, non-B) ..."
 4 I'm not sure why in July 1991 the term
 5 "non-A, non-B" was being used rather than hepatitis C
 6 but in any event the letter continues:
 7 "... and that almost all haemophiliacs got that
 8 through Factor VIII transfusions in the past. I have
 9 explained the significance of this and the possible
 10 long term effect."
 11 And Dr Wassef describes passing that information
 12 on to the pupil's mother and providing a copy of
 13 a Haemophilia Society Bulletin article.
 14 Then at the bottom of the page Dr Wassef says:
 15 "We will be seeking advice regarding management
 16 of this condition following the recent publications on
 17 the value of Interferon in some cases of HCV
 18 infection."
 19 So a tentative reference there to the
 20 possibility of treatment with interferon.
 21 Then if we go to TREL0000137_046.
 22 This is a letter from 20 November 1995. It's
 23 from Dr Wassef to a Professor Arthur at Southampton
 24 General Hospital. It's not specifically in relation
 25 to a Treloar's pupil. It's in relation to a catchment

33

1 treatment and to testing. You obviously have heard
 2 the oral evidence both from 2019 and from this week,
 3 and we've referred in our written note to a number of
 4 other witness statements and documents in this regard,
 5 drawn from records, correspondence, and so on from the
 6 Treloar's material. It'll obviously be a matter for
 7 submissions in due course and for your judgment in due
 8 course, sir, but the evidence certainly that we have
 9 seen to date would tend to suggest, not by a slim
 10 margin but overwhelmingly, that parents were not told,
 11 or at least there was no system or process in general
 12 operation for telling parents of risks of viral
 13 infection, and the same true in relation to pupils.

14 Parents were not given details about or even
 15 core information about their children's treatment at
 16 Treloar's for haemophilia, and you'll recall again the
 17 evidence of Mr Peach, not aware that his sons were
 18 being switched from receipt of the NHS Lister
 19 concentrate to multiple American concentrates and
 20 there are similar examples in the material that we've
 21 referred to. Parents not being told that AIDS-related
 22 investigations or tests were being undertaken, or that
 23 pupils were being monitored for the stigmata of AIDS
 24 and, likewise, pupils not being told that.

25 And then, in relation to hepatitis, and with the

35

1 area pupil. But, again, it provides some indication
 2 of the broader picture in terms of availability of
 3 treatment:
 4 "Although I am aware of the ongoing dialogue
 5 between yourself and Dr Aronstam regarding
 6 arrangements to see all our Haemophilia patients with
 7 antibodies to HCV sometime in the near future, this is
 8 a 'one-off' patient whom I would be most grateful if
 9 you would kind enough to send an appointment direct to
 10 see you as soon as you possibly can."

11 Then there are details given about the specific
 12 patient, and their concern about consequences of
 13 hepatitis C.

14 So it tends to suggest that, in terms of
 15 referral for treatment and advice for the hepatitis
 16 and the liver care more generally, as at
 17 November 1995, that was still a matter in discussion
 18 as between Dr Aronstam and Southampton General
 19 Hospital, rather than there being by that point in
 20 time any specific arrangements to seek expert
 21 hepatology or care from a consultant physician
 22 (inaudible).

23 If I then just deal with an issue which has
 24 recurred throughout the oral evidence this week, and
 25 that's the question of consent or informed consent to

34

1 exception of some evidence of parents being given
 2 information in that 1974/75 outbreak, the evidence
 3 suggests parents were not systematically told if their
 4 sons were believed to have been infected with
 5 hepatitis.

6 There is no particular evidence to suggest,
 7 again, any systematic approach to informing parents
 8 about non-A, non-B hepatitis or the significance of
 9 abnormal liver function tests. Pupils appear to have
 10 been given limited information of the kind described.
 11 They might have been aware of friends going yellow,
 12 but hepatitis essentially portrayed as something that
 13 was not something that they needed to be concerned
 14 about.

15 Then, again, the evidence that we've seen tends
 16 to suggest that neither pupils nor parents were told
 17 that children were being tested for HTLV-III and, not
 18 having been told, were obviously not in a position to
 19 consent to that process of testing. Then of course,
 20 the evidence suggesting that parents for the most part
 21 were not told the outcomes of those tests.

22 Certainly, we've looked in the course of the
 23 week at some examples of medical records, and we've
 24 looked at where there have been in 1983 examinations
 25 being undertaken for immune system disturbance,

36

1 looking at lymph nodes, weight loss, etc, etc. So
2 we've seen examples of those kinds of examinations
3 being recorded in the notes. We've seen multiple
4 examples of letters being written to the home
5 clinician both in 1985 -- sorry, '83, '84, '85.

6 What we have not seen are any records which
7 record the communication of the diagnosis to the
8 patient. So we do not see for those witnesses whose
9 records we've looked at, either for the purposes of
10 their oral evidence or for the purpose of examining
11 the material more broadly, entries which say, "Saw X
12 today, informed X of their HTLV-III test result,
13 counselled X about their HTLV-III test result."

14 That kind of information simply does not appear
15 to have been recorded, at least in any of the records
16 that we have.

17 In terms of the impact of everything that I've
18 referred to, everything that we've heard in the course
19 of the week upon pupils, I'm not going to try to
20 summarise the powerful, emotional, eloquent evidence
21 that you've heard because I would not do it justice.
22 But everything that you have heard, sir, and read,
23 paints a very clear and powerful picture of the effect
24 that this has had on individuals' lives and, as I say,
25 I would do it an injustice if I tried to summarise it.

37

1 I can find out what the date was.

2 Sir, I'm then going to come to the question of
3 research. I use that as a very general heading. What
4 we'll see is there are references to research, to
5 trials, to studies, on multiple occasions in the
6 documents. It is not always easy to piece together,
7 for example, if one has something that looks like
8 a consent form or an entry in records referring to
9 a trial, what trial or study or piece of research, is
10 being referred to. But what is clear and what clearly
11 emerges from the documentation is that research was
12 regarded as a fundamental part of the work that was
13 undertaken in relation to Treloar's pupils, really
14 from the end of the 1960s onwards, and throughout the
15 1970s and 1980s.

16 I'm going to refer to a number of documents
17 which show pieces of research being undertaken, but it
18 won't necessarily be a comprehensive whole, because,
19 as I say, it's not always easy to work out whether
20 a document is referring to one particular trial or
21 several trials, and if so, which ones.

22 **SIR BRIAN LANGSTAFF:** Do we have an idea of the total
23 number of studies that might have been done, or the
24 range within which that might have fallen?

25 **MS RICHARDS:** We don't, really. I'm going to be referring

39

1 Sir, before then I turn to the question of
2 research, there's one short video clip to play, which
3 is just -- it's a brief interview of a kind with
4 Dr Aronstam.

5 So if we could play that, please, Soumik.
6 (Video of Interview with Dr Aronstam played)

7 **SIR BRIAN LANGSTAFF:** The date of that?

8 **MS RICHARDS:** We'll check. I don't know off the top of my
9 head. It's obviously presumably around the time of
10 the first --

11 **SIR BRIAN LANGSTAFF:** Oh, the setting up of the Macfarlane
12 Trust?

13 **MS RICHARDS:** Yes, exactly.

14 **SIR BRIAN LANGSTAFF:** So it would have been sometime in
15 1988, probably.

16 **MS RICHARDS:** Probably. It's late eighties, I would have
17 thought.

18 **SIR BRIAN LANGSTAFF:** Yes, or late '87. But it was the
19 end of '87 it was announced, Macfarlane and, given the
20 content, it sounds like before the first of the
21 Macfarlane special trusts.

22 **MS RICHARDS:** Yes.

23 **SIR BRIAN LANGSTAFF:** Special payments.

24 **MS RICHARDS:** Yes. We'll check. It's on, I think, the
25 Tainted Blood website, that video, so I'll see if

38

1 to a number of studies and references to a number of
2 projects, but it was an ongoing feature, if I can put
3 it that way, so they are studies that many of them
4 went on for a number of years. So whilst I can't give
5 a figure to the number of research products or
6 studies, what one can I think say is that there was
7 always research being undertaken. If you take any one
8 particular year, or even any one term, the picture
9 that emerges is that there were studies, trials, or
10 research, sometimes prospective, sometimes
11 retrospective, being undertaken.

12 **SIR BRIAN LANGSTAFF:** I mean, Dr Rainsford was
13 specifically appointed as a research fellow, was he
14 not?

15 **MS RICHARDS:** He was, yes.

16 **SIR BRIAN LANGSTAFF:** And Dr Kirk was also, I think,
17 a researcher?

18 **MS RICHARDS:** He was, yes. That was the basis for the
19 appointment of each of them, yes.

20 But Dr Arblaster and Dr Aronstam, although
21 appointed to undertake clinical roles, also very
22 closely involved, particularly Dr Aronstam, with
23 research undertaken at the college.

24 **SIR BRIAN LANGSTAFF:** Yes.

25 **MS RICHARDS:** So if we just look at a handful of general

40

1 documents before the break, just to give a flavour of
2 the role of research at the school.

3 If we go to AMRE000011_006.

4 **SIR BRIAN LANGSTAFF:** Now you're missing a --

5 **MS RICHARDS:** Oh, am I? Sorry. Five zeros.

6 AMRE000011_006.

7 **SIR BRIAN LANGSTAFF:** That's it.

8 **MS RICHARDS:** Sir, this is an undated document but it's
9 from, I think, probably the first half of the 1970s
10 because it's about obtaining funding for the
11 appointment of Dr Kirk. But it also gives some
12 background, some history in terms of the history of
13 research at the college, and also a flavour of the
14 importance of research.

15 So we can see the heading:

16 "Introduction

17 "Lord Mayor Treloar College is [a] unique
18 establishment since there are more than fifty boys
19 suffering from various coagulation defects (namely
20 Haemophilia, Christmas Diseases and von Willebrand's
21 Disease) in residence at the College for approximately
22 264 days each year. These boys usually come to
23 the College at the age of eleven and leave at the age
24 of sixteen to eighteen years of age. They are,
25 therefore, under continuous medical supervision for

41

1 also provided by the National Fund for Research into
2 Crippling Diseases) has set up an organisation at the
3 College and meticulous medical records are
4 maintained."

5 That's a reference I think to Dr Rainsford.

6 If we go over the page, it continues:

7 "Lord Mayor Treloar College has a large, modern
8 Sick Quarters built in [1958], which provides fourteen
9 beds for in-patient treatment. It is fully equipped
10 with a modern surgery, a physiotherapy department and
11 consulting rooms and is staffed by three State
12 Registered Nurses and two Medical Orderlies, all of
13 whom have been fully trained, by the present Research
14 Fellow Dr Rainsford, in the management and treatment
15 of haemophilia."

16 Then there's a reference to a physiotherapist
17 and the availability of hydrotherapy.

18 "Arrangements are such that any emergency can
19 now be dealt with at the College. The present
20 Research Fellow accomplished a great deal during his
21 stay at the college, and was responsible in part for
22 the research on which the foundation of the Alton
23 Centre was based. It is anticipated that Dr Rainsford
24 will stay in the locality of the School and continue
25 to work part-time at the Centre for the next two to

43

1 nine months of each year and often for many years.

2 "Day to day treatments afforded to these boys by
3 the Treloar Haemophilia Centre which is under the
4 direction of Dr PC Arblaster, Consultant Physician.

5 This Centre was established three years ago and is now
6 one of the best staffed and equipped Centres in the
7 country. There are adequate laboratory facilities
8 specialising in coagulation, under the direction of
9 Dr A Aronstam, Consultant Haematologist, who is also
10 Associate Director of the Centre. The boys are kept
11 under orthopaedic supervision by Mr Francis J
12 Moynihan, Consultant Orthopaedic Surgeon. The staff
13 at the Centre consists of a Medical Officer, who is
14 employed as full-time SHO in Haemophilia, a Medical
15 Officer of consultant status, who is employed for
16 [seven elevenths] of his time at the Haemophilia
17 Treatment Centre and [four elevenths] as Medical
18 Officer to Lord Mayor Treloar College and Florence
19 Treloar School. These medical officers have the
20 assistance of a team of Sisters and Nursing Staff."

21 Then we get to research.

22 "Since 1968, a Research Fellowship in
23 Haemophilia has been established at the College by the
24 National Fund for Research into Crippling Diseases.
25 The present Research Fellow (with secretarial help --

42

1 three years, and be paid by the Regional Health
2 Authority. During this extension of his work
3 Dr Rainsford will support the Centre, complete his
4 present research projects, and give assistance to the
5 new Research Fellow."

6 "The present arrangements at the College are
7 particularly suitable for a specific type of research
8 into haemophilia and other coagulation disorders,
9 namely the study of the relationship between
10 laboratory findings and close day-to-day clinical
11 observations. It is the only establishment in the
12 United Kingdom which can provide the opportunity and
13 the facilities for extensive clinical trials of
14 various kinds of treatment which cannot, at present,
15 be conducted anywhere else."

16 "A work of explanation is required about the
17 proposed association of the new Research Fellow and
18 Project with the Oxford Haemophilia Centre. There has
19 been close liaison between the Oxford Haemophilia
20 Centre and the care of haemophilic boys at the Treloar
21 College for the last ten years and more. In the last
22 year this type of association has been given
23 recognition by the DHSS by a plan to organise
24 Haemophilia Treatment and Research on a supra regional
25 basis. It is proposed that certain supra regional

44

1 centres, of which Oxford Centre is one, shall be
2 responsible for administrative duties such as ensuring
3 an adequate supply of Factor VIII, providing a
4 reference laboratory and teaching facilities,
5 providing holiday support, determining the number of
6 haemophiliac patients in their area of care and
7 organising research on a regional basis. Alton is
8 included in the region provisionally assigned to
9 Oxford. In this new organisational framework it's
10 hoped that exchange of NHS staff may be arranged
11 between the Oxford Centre and that at Alton and it is
12 proposed that the research facilities of the Oxford
13 Centre should be available to the Research Fellow at
14 the Treloar College. It is our opinion that the basic
15 NHS organisation at the Treloar College is now such
16 that a young Research Fellow could work for and obtain
17 a research degree by working both at the College and
18 at Oxford. The present application is for financial
19 support of such a fellow."

20 Then we see the heading:

21 "The Research Project."

22 "The Research Project is entitled 'The Promotion
23 of Haemostasis in Patients Suffering from Congenital
24 Deficiency of Blood Clotting Factor VIII or IX'. The
25 research will form the basis of a research degree to

45

1 fractions prepared from large donor pools in the
2 treatment of haemophilia. The consequences for the
3 patients of this increased treatment are improved
4 protection from crippling deformity and much extended
5 horizons of possible activities. But the danger of
6 contracting the blood-borne viruses causing hepatitis
7 is also increased. The residence of these boys in one
8 place provides an ideal opportunity to study this
9 complication of treatment.

10 "The Project will have two main aspects:

11 "1. Laboratory.

12 "2. Clinical planning and observation."

13 Then if we go to the next page, there's
14 a discussion under the heading "Laboratory
15 Observations". It says:

16 "In the laboratory observations will be made on
17 the levels of various important plasma constituents in
18 relationship to the clinical state of the boys at the
19 Treloar College and to observe the effects of
20 treatment on these constituents."

21 Then there are various particular aspects of
22 laboratory observation that are then recorded.

23 If we go just over halfway down the page we'll
24 see that paragraph (d) refers to:

25 "Liver function tests ... SGOT, SGPT [et cetera]

47

1 be submitted by the fellow to a [UK] University.

2 "Clinical and pathological observations made
3 during the last six years at Lord Mayor Treloar
4 College, on boys suffering from haemophilia, strongly
5 suggests that frequency and duration of spontaneous
6 bleeding is not solely due to a deficiency of the
7 known coagulation factors ... The most important
8 fundamental discovery concerning the diathesis of
9 haemophilia made over the past few years is probably
10 the recognition of Factor VIII related antigen. At
11 present the nature and function of this factor remains
12 to be determined. Investigations ..."

13 Sorry, this bit is rather faint -- and then
14 there's discussion about investigations on
15 von Willebrand's.

16 I'm not going to read all of this out but it
17 refers again to findings at Treloar College already
18 published in a 1971 publication.

19 "It is suggested, therefore, that we should
20 concentrate on this aspect of research in the near
21 future."

22 Then if we go to the next paragraph down it says
23 this:

24 "The existence of commercial concentrates of
25 human Factor VIII has led to much more liberal use of

46

1 will be carried out at regular intervals on blood
2 samples which are collected at the time of infusions
3 given to the boys. These samples will also be tested
4 for [I think that's probably hepatitis B antigen and
5 antibody]. An attempt will be made to trace the
6 source of infection in every instance of [the
7 patients] however mild clinically. Some of the tests
8 proposed may give abnormal results in response to
9 conditions other than viral hepatitis and such
10 associations will be recorded."

11 "(e) Observations will be made on blood samples
12 from boys having antibodies to Factor VIII in an
13 attempt to determine the natural history of such
14 antibodies in the patients."

15 Those are some of the laboratory studies
16 proposed. Then in terms of "Clinical Studies":

17 "Depending on the results of the current trial
18 of prophylactic therapy being completed by
19 Dr Rainsford [and I'll come on to the prophylaxis
20 studies] there may well be the need to hold a new
21 prophylactic trial [then this bit is very faint] with
22 increased ..."

23 Sorry, can we just look at the very first --

24 **SIR BRIAN LANGSTAFF:** "... increased and more frequent
25 dosage of Factor VIII."

48

1 **MS RICHARDS:** Thank you, sir.
 2 **SIR BRIAN LANGSTAFF:** I think it is probably better
 3 actually not highlighted.
 4 **MS RICHARDS:** I think it probably is, yes.
 5 **SIR BRIAN LANGSTAFF:** Because it's easier to read, I'm
 6 afraid, in the original.
 7 **MS RICHARDS:** Then it refers in the next paragraph to:
 8 "The careful studies of the records already
 9 carried out by Rainsford and ..."
 10 I'm not sure who the second name is but it's
 11 reference to a publication --
 12 **SIR BRIAN LANGSTAFF:** "Hall" it looks like, but it's
 13 difficult.
 14 **MS RICHARDS:** It looks like. Then there's a reference to
 15 a publication in the British Journal of Haematology:
 16 "... will form the basis for comparison in all
 17 clinical studies. These records will be [something]
 18 to ensure compatibility with previous observations and
 19 to provide the background against which to
 20 [something]" --
 21 **SIR BRIAN LANGSTAFF:** "Provide."
 22 "... provide the background against which to
 23 [ensure] the effects of treatment."
 24 **MS RICHARDS:** Yes, "to ensure" --
 25 **SIR BRIAN LANGSTAFF:** "... to measure the" --

49

1 Then the last page talks about the research
 2 fellow.
 3 "Should the application for research support be
 4 granted, Dr Peter John Kirk has expressed interest in
 5 undertaking the research project."
 6 Reference to appending his CV.
 7 "We consider Dr Kirk to be quite unusually well
 8 qualified to profit by the research opportunity and
 9 ..."
 10 And maybe you can read the next few words, sir,
 11 but I can't:
 12 "... [something] of the exceptional facilities
 13 at the College, and at the ..."
 14 **SIR BRIAN LANGSTAFF:** "... at the Oxford Centre."
 15 **MS RICHARDS:** "... the Oxford Centre."
 16 "It will be seen from Dr Kirk's [CV] that he has
 17 an excellent background for this research project. He
 18 has final qualifications in Laboratory Technology and
 19 is a qualified Medical Practitioner."
 20 Then there's reference to him graduating from
 21 the University of Aberdeen in 1972, now taking his
 22 MRCP examinations.
 23 "During his work as Senior House Officer at the
 24 Alton Haemophilia Centre Dr Kirk has shown great
 25 initiative, competence and responsibility and is

51

1 **MS RICHARDS:** "To measure", thank you, sir.
 2 "... to measure the effects of treatment."
 3 Then there's reference to some work on the role
 4 of tranexamic acid, and there's a suggestion that that
 5 work be extended by a controlled clinical trial and,
 6 again, there is some further documentation in relation
 7 to that.
 8 And there's a discussion halfway down that
 9 paragraph of dividing boys into two groups, one who
 10 would receive tranexamic acid for the first three days
 11 whenever they'd bled, plus Factor VIII replacement
 12 therapy, and the second group would merely be treated
 13 with replacement therapy alone.
 14 Then it says at the end of that paragraph:
 15 "This trial will need to be arranged so it does
 16 not interfere with any future trial of prophylactic
 17 therapy."
 18 Then:
 19 "In association with the laboratory study of
 20 therapy clinical observations will be made of the
 21 conditions of the boys with particular attention to
 22 the possibility of hepatitis. The work on hepatitis
 23 will be coordinated with that of Dr Craske of the
 24 Microbiology Laboratory at Bournemouth and with
 25 observations at Oxford."

50

1 already engaged in many of the research projects at
 2 present in progress. These include the study of
 3 antithrombin levels in patients and the study of
 4 hepatitis.
 5 "It is proposed that if Dr Kirk is appointed he
 6 should register as a student for the degree of Doctor
 7 of Medicine ... at the University of Aberdeen. We
 8 have every confidence he would obtain the degree in
 9 three years. Moreover we are sure that three years of
 10 research would be particularly beneficial to the
 11 future career of Dr Kirk who wishes to qualify as
 12 a Consultant Clinical Haematologist."
 13 Sir, as I say, undated but clearly in the first
 14 half of the 1970s, given --
 15 **SIR BRIAN LANGSTAFF:** Well, it looks though it is at
 16 a time when Dr Rainsford was bowing out to become
 17 part-time --
 18 **MS RICHARDS:** Yes.
 19 **SIR BRIAN LANGSTAFF:** -- Dr Kirk about to be appointed and
 20 is already working in the service at Alton. It also
 21 must be after '73 because there's reference to
 22 a '73 study in it. So it looks to be mid-seventies.
 23 Also it refers to viruses causing hepatitis, in the
 24 plural.
 25 **MS RICHARDS:** It does, which might suggest 1974 or

52

1 thereabouts.

2 **SIR BRIAN LANGSTAFF:** '74, '75, probably, but it's very
3 difficult to give an accurate date.

4 **MS RICHARDS:** Yes. I'm not sure we have a precise date
5 for Dr Kirk's involvement. Not least because he had
6 had some involvement in a house officer capacity
7 already, so there are some earlier references to him.
8 I'll check when we first see him referred to as
9 a research fellow or assistant research fellow, to see
10 whether we can give a more accurate date but it's
11 roughly '74, possibly '75.

12 **SIR BRIAN LANGSTAFF:** Yes.

13 **MS RICHARDS:** Sir, I'm going to be looking at a number of
14 documents in the course of the day, so perhaps now
15 would be a good time for a break before I start.

16 **SIR BRIAN LANGSTAFF:** Yes, probably 11.50?

17 **MS RICHARDS:** Certainly.

18 **SIR BRIAN LANGSTAFF:** 11.50.
19 (11.18 am)

20 (A short break)

21 (11.50 am)

22 **MS RICHARDS:** Sir, with thanks to all those who assisted
23 in relation to the date, the video that we looked at
24 before the break is November 1987.
25 **SIR BRIAN LANGSTAFF:** November '87?

53

1 **MS RICHARDS:** That's what I understand.

2 **SIR BRIAN LANGSTAFF:** Right.

3 **MS RICHARDS:** Yes, there are lots of nods from the
4 audience. Yes, November '87.

5 I've also been assisted over the break with the
6 likely date for the letter from Dr Tomlinson that we
7 looked at, September -- and then the year was unclear.
8 I'm very grateful to the member of The
9 Haemophilia Society who forwarded some information in
10 that regard and suggested, and this sounds right, that
11 it's probably September 1985 because it refers to
12 media interest in a school in Hampshire, and it was in
13 September 1985 in which there was some interest in
14 precisely that topic.

15 So it would seem to fit that that would be
16 September 1985.

17 **SIR BRIAN LANGSTAFF:** Yes. Thank you.

18 **MS RICHARDS:** Then to return then to some of the documents
19 about research at Treloar's.

20 If we go back in time from the document we were
21 looking at to 1970, AMRE000012_004, we see here
22 a letter from Dr Biggs in her capacity as director of
23 the Oxford Haemophilia Centre supporting the
24 continuation of funding for research at Treloar's. So
25 the letter is dated 14 December 1970 and she says, in

54

1 relation to application from the Lord Mayor Treloar
2 Trust, Alton, Hants:

3 "I feel this grant should be continued for
4 a number of reasons:

5 "1. The collection of 49 haemophilic patients
6 at the Alton School makes this a unique opportunity to
7 study the disease."

8 So again, that way of looking at the pupils
9 there which we've seen in really so many documents,
10 here articulated by Dr Biggs.

11 "The patients are particularly important since
12 crippling is still occurring and the question of
13 prevention is under study.

14 "2. The work which Dr Rainsford has already
15 done has defined the essential organisation required
16 to treat boys gathered into one school. This was in
17 itself a major research objective which has been
18 achieved. As a result of this work and the efforts of
19 local specialists and the Wessex Regional Hospital
20 Board, a basic service for the treatment of the boys
21 should soon be set up which will enable the Research
22 Fellow to concentrate on purely research projects.

23 "3. In addition to the basic organisational
24 research, Dr Rainsford has already initiated 7 other
25 research projects, all of which are important, and

55

1 will cease if support for research is not forthcoming.

2 "4. Good cooperation has already been
3 established between the work being carried out at
4 Alton and the work of other research centres,
5 particularly the one at Oxford, and we feel that it is
6 most desirable for this cooperative work to continue.

7 "5. Although not specifically stated in this
8 application, it is intended that Dr Rainsford should
9 continue to as Research Fellow. Dr Rainsford has
10 already shown himself to be an able organiser, to have
11 many original ideas of his own, and to have immense
12 energy and ability in obtaining cooperation from other
13 scientists."

14 There is a little more information about
15 Dr Rainsford's work at this time from AMRE000011_066.

16 This a letter from Dr Rainsford himself,
17 July 1970, and you'll see it was addressed, as was
18 Dr Biggs' letter, to Mr Guthrie (and Mr Guthrie was
19 the director of the National Fund for Research into
20 Crippling Diseases) and Dr Rainsford says this:

21 "I think I ought to bring you up-to-date with
22 regards to the research programme now being carried
23 out here.

24 "In the original suggested outline of research
25 six specific questions were posed ... about which,

56

1 with the exception of question three, conclusions had
2 been reached by the time I was appointed. With regard
3 to question three, epidemiological evidence here would
4 appear to show that no beneficial advantage would be
5 obtained from regular prophylactic injections, largely
6 because of the short half-life of Factor VIII in the
7 body.

8 "The present research program has been planned
9 so that there should be no overlapping with that being
10 carried out at Oxford. At present four separate
11 research projects are being undertaken".

12 Then he gives details of those four projects.

13 "Project I: Epidemiological evidence collected
14 here suggests that there is some seasonal variation in
15 the tendency to bleed in both haemophilia and
16 Christmas Disease."

17 So again, if we just skip down, we can see he
18 says:

19 "It is thought that more evidence on these
20 observations may be of fundamental importance and the
21 plasma-cortisol levels of the boys suffering from
22 these diseases is being routinely examined throughout
23 the year."

24 We're told that's an investigation being carried
25 out in cooperation with a Dr Shaw and Mrs Richardson,

57

1 undertaken in cooperation with Professor Martin and
2 Dr Sharrard at the St George's Medical School.

3 Then project 4:

4 "Investigations carried out in conjunction with
5 The Virus Reference Laboratory (Public Health
6 Laboratory Service) with Dr Yvonne Cossart has shown
7 that the incidence of Antibody to Australian Antigen
8 is extremely high in our cases of Christmas Disease
9 and Haemophilia. Dr Cossart has arranged to carry out
10 regular examination of our cases for this Antibody and
11 possibly to screen all the materials being
12 administered for Australian Antigen. It is probable
13 that much may be learned of the cause often serum
14 hepatitis and its prevention could well be the outcome
15 of these investigations. Furthermore, there is
16 a serious shortage of sera for the detection of
17 Australia Antigen in this country and the supply of
18 sera from these boys will, therefore, greatly augment
19 the present national bank of Australia Antibody sera,
20 which will permit more widespread research into the
21 relationship between the presence of Australia Antigen
22 and hepatitis.

23 "Dr Biggs has approved this programme and all
24 the projects are well under way."

25 That's an indication of some of the research

59

1 consultant pathologist and principal biochemist
2 respectively, at the Royal Hampshire County Hospital.

3 So that's project one. Project 2 involves --
4 and I'm picking this up from the third line of that
5 paragraph:

6 "Sera ... is being examined for the presence of
7 Rheumatoid Arthritis antibody ..."

8 And that is said to be:

9 "... a joint investigation, both clinical and
10 pathological ... being conducted by Mr Stanley Evans,
11 and myself. It is [described as] a fairly long term
12 project and the relationship between Rheumatoid
13 Arthritis antibody and the possible development of
14 Inhibitors for Factor VIII is being studied."

15 If we go over the page, project 3 refers to
16 a recent report about immunoglobulins in haemophilia,
17 and Dr Rainsford says:

18 "This was discussed with Professor Nicholas
19 Martin and Dr Rosemary Biggs and the serum of all our
20 boys with haemophilia and Christmas Disease is being
21 quantitatively examined for the immunoglobulins likely
22 to be involved. These investigations may indicate
23 those boys likely to develop inhibitors for Factor
24 VIII ..."

25 And it's explained that that's a project being

58

1 work being undertaken by Dr Rainsford in 1970, sir.

2 **SIR BRIAN LANGSTAFF:** Indeed, the Biggs letter from 1970,
3 her support for Dr Rainsford, the way she is
4 describing for those purposes how haemophilia -- boys
5 suffering from haemophilia came to be at Lord Mayor
6 Treloar's was because it was a research project.

7 **MS RICHARDS:** Yes. She refers to the organisational work
8 undertaken by Dr Rainsford and --

9 **SIR BRIAN LANGSTAFF:** And she's saying well, Rainsford
10 brought together a group of boys specifically to
11 research them.

12 **MS RICHARDS:** That appears to be what she's saying, sir,
13 yes.

14 **SIR BRIAN LANGSTAFF:** Yes.

15 **MS RICHARDS:** Then we can see, if we go to
16 AMRE0000007_002, an indication of some funding that
17 was made available by what was subsequently renamed
18 Action Research for the Crippled Child. I don't think
19 there's a date on this letter but, in any event, it
20 refers to an application having been received from
21 Mr Evans, FRCS of the Lord Mayor Treloar Trust, for
22 a grant of £24,815, but then we can see that
23 historically some of the grant is made available. So:

24 "In July 1967, £10,000 was made available to the
25 Lord Mayor Treloar Trust for a three-year

60

1 investigation at the Lord Mayor Treloar College and at
2 the Blood Coagulation Research Unit, Oxford,
3 of treatment of acute joint muscle haemorrhage in
4 haemophilia."

5 Then:

6 "In January 1971. £15,000 was made available to
7 the Lord Mayor Treloar Trust for continuation for
8 three years of the grant for research into
9 haemophilia.

10 I don't think this document tells us what
11 happens to the further application that's referred to
12 at the top of the page.

13 If we then go to AMRE000011_021, this is
14 a document entitled "Proposed Research Programme".
15 Again, it's undated. We can tell that it's sometime
16 earlier than August 1975 because there's a reference
17 in the last page to that. The text of it is quite
18 similar to the first document we looked at.

19 Sir, we see again, in the introduction,
20 reference to Treloar College being a unique
21 establishment because of the more than 50 boys
22 suffering from various coagulation defects in
23 residence there and under continuous medical
24 supervision. And then we can see set out in the
25 second paragraph, again, arrangements for the

61

1 its related antigen have any influence on the
2 frequency of bleeding in haemophilia."

3 2 is:

4 "To determine whether the post transfusion
5 levels of factor VIII and its related antigen has
6 a bearing on the frequency of bleeding ..."

7 3 is in relation to fibrinolysis, and there's
8 a discussion there again about the clinical trial and
9 tranexamic acid; 4, antithrombin.

10 Then if we go over the page, we can see
11 reference to "Completed Projects":

12 "1. A four-year study on the incidence of
13 jaundice and the presence of Australia antigen and
14 antibodies in boys being frequently transfused with
15 blood products has now been completed in cooperation
16 with the Virus Reference Laboratory, Public Health
17 Laboratory Service, Colindale. Two interim reports
18 concerning this project have already been circulated."

19 The second completed project is about plasma
20 cortisol levels. The third is in relation to
21 platelets, and then the fourth just refers to various
22 other papers which are said to be of worldwide
23 interest.

24 Then we have the heading:

25 "Current Projects.

63

1 treatment, which I think are largely a repetition of
2 what we've already seen.

3 The third paragraph refers again to the Research
4 Fellowship established in 1968, and it talks about it
5 being unfortunate if the organisation was allowed to
6 lapse for lack of financial support.

7 The next paragraph then says:

8 "It will be seen from the foregoing that the
9 College lends itself to a specific type of research
10 into haemophilia and other coagulation disorders,
11 namely to study the relationship between recognised
12 laboratory findings and clinical observations in these
13 somewhat uncommon conditions. It is also the only
14 establishment in the [UK] which can provide the
15 opportunity and the facilities for extensive clinical
16 trials of various kinds of treatment. This type of
17 research cannot, at present, be conducted anywhere
18 else."

19 Then there's a description under the heading
20 "Future Research". If we go over the page, at the end
21 of that long first paragraph, there's a reference to
22 a proposed research programme. 1 is:

23 "Measurement of platelet activity and its
24 relationship to factor VIII related protein and to
25 determine whether the basic levels of Factor VIII and

62

1 "1. A prophylactic trial, to determine whether
2 a prophylactic transfusion of Factor VIII administered
3 at weekly intervals would reduce the frequency of
4 bleeding in haemophilia, is now almost completed and
5 a report should shortly be available."

6 2 refers to the ongoing research project:

7 "... to determine whether there is
8 a relationship between immune arthritis and
9 factor VIII antibodies ..."

10 There's reference, towards the bottom of that
11 paragraph, to pre and post-transfusion samples of
12 blood being examined by Dr Holborow at Taplow.

13 Then if we go over the page, and we can see
14 that's to see whether there's some relationship to the
15 development of kidney disease in haemophilia, and then
16 we have the heading:

17 "Summary

18 "In proposing this future research it should be
19 mentioned that the Area Health Authority has agreed to
20 provide the Research Fellow with a full-time Research
21 Assistant on a permanent basis for as long as
22 a Fellowship exists. It must be fully realised that
23 there is a limit to what the Research Fellow can
24 accomplish with the help of one Research Assistant.
25 It is, however, envisaged that the Centre, which is

64

1 now fully operational, well staffed and well equipped,
2 will play a full part in assisting to carry out this
3 proposed programme. It is considered that a fully
4 trained and suitable candidate should be available in
5 August 1975 to replace the present Research Fellow.
6 This, of course, will depend on a three-year grant
7 being made available, which would secure his future
8 professional advancement to Consultant level".

9 This again appears to be looking at the
10 recruitment of Dr Kirk to supplement to the work of
11 Dr Rainsford.

12 Then:

13 "In addition, the Oxford Haemophilia Centre and
14 the MRC Research Unit at Oxford have in the past
15 assisted in all the research projects carried out at
16 the College and it is assumed that this close
17 collaboration with the proposed research work will
18 continue. It will, therefore, be necessary for this
19 Programme to be agreed, approved and sponsored by
20 Dr PG Arblaster, Consultant Physician and Director of
21 the Treloar Haemophilia Centre and Dr Rosemary Biggs,
22 Director of the Haemophilia Centre and MRC Research
23 Unit at Oxford."

24 Again, that's a broad update of the position as
25 at the mid-1970s and, again, there's a letter a little

65

1 tenure of the post. The work proposed is likely
2 greatly to improve our knowledge of the distressing
3 crippling caused by haemophilia".

4 Then there's a reference to the project in
5 relation to rheumatoid arthritis. Then she says:

6 "I have no hesitation in supporting the
7 application in full, particularly as I now believe
8 that truly satisfactory arrangements are likely to be
9 made for the day-to-day care of the boys at the
10 college. I approve both the plan to extend
11 Dr Rainsford's tenure until 1975 and the plan to seek
12 a new Research Fellow for 1976 and 1977."

13 Sir, I'm going to look now, then, at some of the
14 specific pieces of research and specific trials that
15 were undertaken, starting with prophylaxis. We can --
16 there are multiple documents in relation to this, sir,
17 I'm just going to just go to a handful.

18 We can start with DHSC0100026_146.

19 This is a letter dated 19 August 1972 from
20 Dr Arblaster to a Dr Wilson, a principal medical
21 officer in the Department of Health and Social
22 Security, and he says:

23 "I would be most grateful if the Department
24 would consider a research grant for a prophylactic
25 trial in haemophilia, to be conducted by the Treloar

67

1 earlier, November '73, from Dr Biggs --
2 AMRE000007_013 -- which makes clear the collaboration
3 between Treloar's and Oxford.

4 So we looked at her 1970 letter of support to
5 Mr Guthrie for funding for research. This is
6 November '73, where she says:

7 "In my opinion the research already carried out
8 at Alton has been of very great importance. The
9 careful records kept by Dr Rainsford about the boys at
10 Alton have been a great help in trying to estimate the
11 requirements for the haemophilic community for
12 Factor VIII, which is a very expensive therapeutic
13 material. The projects proposed by Dr Rainsford are
14 all in the first degree original and important.

15 I have a very high regard for Dr Rainsford's ability
16 in planning and carrying out his projects. In all the
17 research work, very close cooperation has occurred
18 between the Oxford Haemophilia Centre and those at
19 Alton, and in some projects, advice has been taken
20 from the Haemophilia Centre Directors Conference.

21 "In my opinion it is of the highest importance
22 for research to carry on at Alton. The close
23 cooperation between those working at the College and
24 the Research Centre at Oxford is important and
25 I believe certain to continue beyond Dr Rainsford's

66

1 Haemophilia Centre.

2 "I enclose a copy of the Protocol which has been
3 approved by Professor J Howell, Chairman of the
4 Research Committee of the Wessex Regional Hospital
5 Board.

6 "It has also been approved by a meeting of
7 several haemophilia treatment centre Directors, held
8 under the Chairmanship of Dr Rosemary Biggs, at Lord
9 Mayor Treloar College.

10 "Some points need clarification ..."

11 Then there is the reference to:

12 "1. The request for £20,000 is for drug bill
13 only. Current nursing, medical, and secretarial staff
14 should be able to service the trial."

15 Then there is reference to terminology as
16 between a "Switch Back Trial" and "Cross Over" trial
17 in paragraph 2. It says:

18 "... each boy would act as his own control and
19 where the trial duration is as planned, namely six
20 terms, three would be prophylaxis and three terms
21 placebo."

22 "3. The double blind method is suggested to
23 exclude observer boys, and perhaps even more
24 important, 'patient' boys. The haemophilia boys are
25 great adepts at taking the mickey out of doctors and

68

1 conducting their own treatment to suit scholastic and
2 social inconveniences!"

3 Then:

4 "4. The Ethical Committee of the North
5 Hampshire Hospital Management Committee have
6 considered the protocol in its earlier form, and I am
7 sending the latest draft again today."

8 We can see there the request for financial
9 support from the Department.

10 If we go to MRCO000065_013, and we zoom in on
11 the letter, we can see it's dated 10 January 1973, and
12 it's addressed to a Dr Stewart at the Medical Research
13 Council.

14 If we go to the bottom of the page we can see --
15 we'll see who it's from. From R Harwood in the
16 Research Division of the Department of Health and
17 Social Security. And then we can see it says in the
18 second paragraph -- if we just look at the heading,
19 first of all -- I'm sorry, Soumik -- under:

20 "Dear Mr Stewart,
21 "Trial of Factor VIII Concentrates at Lord Mayor
22 Treloar College."

23 Then the second paragraph:
24 "The purpose of this letter is to give you
25 formal notification that the Department will meet the

69

1 deal of trouble with it. She had sent it to number of
2 important persons to see what they thought of it and
3 they all objected to it for one reason or another.
4 She concluded that it would be very difficult to
5 organise a prophylactic trial from a Haemophilia
6 Centre and that perhaps the only place where it could
7 be done would be at Lord Mayor Treloar College. She
8 had sent the protocol to Drs Arblaster, Aronstam and
9 Rainsford (at their request) and they were now
10 planning to organise a trial along the lines similar
11 to those in the circulated protocol. Although there
12 were difficulties in organising a trial and in the
13 setting up of the control groups, Dr Biggs felt that
14 it was very important for a trial to be undertaken
15 because we really want to know whether the patients
16 are better having prophylactic therapy or just
17 receiving treatment 'on demand'. There were sharp
18 differences between these two modes of treatment.

19 "On Demand Treatment means giving treatment at
20 home or at hospital whenever a bleed occurred.
21 Prophylaxis involves treatment at regular intervals
22 regardless of whether or not bleeding occurs.
23 Dr Biggs suggested that the Directors should support
24 the conduct of this trial at the Lord Mayor Treloar
25 College."

71

1 costs of the drugs used in the haemophilia trial of
2 Factor VIII concentrates up to a maximum of £4,000 in
3 1973/74. I understand that no other research costs
4 are involved. It is anticipated that the Trial will
5 start in April.

6 "I note that the MRC [Medical Research Council]
7 intends to set up a small group, on which DHSS will be
8 represented to consider some revision of
9 Dr Arblaster's protocol and if appropriate, to monitor
10 the progress of the trial and assess its results.
11 I take it that you will be in touch with Dr Metters
12 about this. Time is short if the Trial is to begin at
13 the start of the school term in April, and I know
14 Dr Arblaster is anxious to begin."

15 Then we can see some further discussions about
16 this trial.

17 HCDO0001015, please.

18 So this was a meeting of the Haemophilia Centre
19 Directors in October of 1972. We can see Dr Aronstam
20 was present as was Dr Rainsford.

21 If we go to page 5, there's a discussion about
22 the protocol for a trial of prophylactic therapy in
23 haemophiliacs.

24 "Dr Biggs said she had been asked at the last
25 meeting to prepare a protocol. She had had a great

70

1 If we go over the page it appears that there was
2 a lengthy discussion at the Haemophilia Centre
3 Directors meeting about a prophylaxis trial, centering
4 around three topics in particular of the placebo
5 group, the material to be used, and details of the
6 trial organisation.

7 There's then a discussion about the placebo in
8 the following paragraph. It says in the fourth line:

9 "Some thought it very important that the placebo
10 be indistinguishable from the treatment material since
11 it was essential that the boys should not know to
12 which group they belonged. It was however pointed out
13 that the boys could be told that they were receiving
14 two different treatments."

15 There's then a discussion about choice of
16 material.

17 "It was decided that the trial material would
18 have to be provided in addition to the material
19 supplied for routine use at Lord Mayor Treloar
20 College. The conclusion was that a freeze-dried
21 concentrate should be used. Doctors Arblaster and
22 Aronstam decided to use the Immuno material from
23 Vienna if this was possible and had applied to the
24 Ministry of Health and Social Security for £15,000 to
25 buy enough material."

72

1 We have seen an exchange of correspondence in
2 relation to the application to the Department of
3 Health.

4 "It was pointed out that the Hyland concentrate
5 was also of good quality. Also, Doctors Maycock and
6 Bidwell thought that they could supply enough material
7 were they asked [and that obviously would be NHS
8 material]. Dr Biggs said she felt that any material
9 which could be made in England was too urgently needed
10 for treatment of serious bleeding for it to be
11 allocated to a clinical trial of prophylactic
12 therapy."

13 So it appears that the offer was made from
14 Maycock and Bidwell for a trial of NHS concentrate for
15 the prophylactic trial and the view expressed by
16 Dr Biggs is, "Don't use it for prophylaxis on the
17 children. Save that more generally for treatment on
18 demand".

19 Then there's a discussion:

20 "About the organisation of the trial, questions
21 were asked about the treatment of boys during holiday.
22 The trial treatment would have to lapse during
23 holidays and this was a pity. The frequency of dosage
24 was discussed. Dr Matthews said that previous workers
25 had advocated dosage varying in frequency from twice

73

1 proposed and agreed with one dissenting vote
2 (Professor Stewart, Middlesex) that the Chairman
3 should write to the Ministry of Health and Social
4 Security supporting the conduct of the trial of
5 prophylactic treatment at the Lord Mayor Treloar
6 College. It was also agreed that the Haemophilia
7 Society should be asked to make a contribution towards
8 the cost of the trial."

9 That's the background and the discussion that
10 took place amongst Haemophilia Centre Directors.

11 There are then a couple more documents I think
12 of interest in relation to this issue.

13 So if we go to AMRE0000007_019.

14 Again, it's not a brilliant copy. We can see
15 it's headed:

16 "Future Research.

17 "Observations made during the last four years at
18 Lord Mayor Treloar College of boys suffering from
19 haemophilia, strongly suggest that the frequency and
20 duration of spontaneous bleeding are not solely
21 a function of the presence of inadequate amounts of
22 factor VIII in the blood. These observations indicate
23 the following lines of investigation might be
24 pursued."

25 Then there are various lines of investigation

75

1 daily to once every three to four weeks. It was
2 decided that once weekly was the most frequently that
3 dosage could be given in practice and that trial
4 treatment must be allowed to lapse during holidays.

5 "It was stated that 10-15 boys could be included
6 in the trial at Lord Mayor Treloar College. Some
7 wondered if any significant results could be obtained
8 with so few boys. It was pointed out by Dr Aronstam
9 that each boy had many bleeds and that it was bleeding
10 frequency which was to be used as the criterion of
11 treatment effectiveness. Moreover, the boys would all
12 have periods in the treatment group and in the control
13 group. It was pointed out that since prophylactic
14 treatment might treble the usage of factor VIII, only
15 a highly significant result was of interest."

16 Then the last paragraph on this page:

17 "Co-operation of Haemophilia Centre Directors
18 would be required wherever possible to obtain parents'
19 consent for boys in the trial and to supervise boys in
20 the holiday".

21 Then over the page under the heading "Action":

22 "In conclusion it was pointed out that details
23 of this particular trial, including the choice of
24 therapeutic materials and questions of ethics, were
25 the responsibility of the Alton Centre and it was

74

1 discussed, a number of different research projects,
2 you'll see paragraph 6 refers to the serum hepatitis
3 project continuing at the request of the Public Health
4 Laboratory Service.

5 Then we can see paragraph 7 talks about
6 prophylaxis and this particular trial. It's not very
7 easy to read but it says:

8 "At a meeting attended by the Directors of the
9 various Haemophilia treatment Centres in the country
10 held at Oxford on 27 October 1972 [so those are the
11 minutes we've just looked at], it was unanimously
12 agreed that a Clinical Trial to evaluate prophylactic
13 therapy in the treatment of Haemophilia should be
14 carried out. It was decided that it should take the
15 form of a double-blind cross over trial and a protocol
16 for such a trial was drawn up by Dr Rosemary Biggs and
17 discussed. It became obvious after discussion that
18 such a trial could only be pursued at an establishment
19 like Lord Mayor Treloar College where boys are under
20 close daily observation for prolonged periods and
21 where meticulous day to day records on each boy are
22 maintained. Primarily this is due to the organisation
23 already set up by the Research Fellow and his
24 secretary, the cost of which is covered by the grant
25 from the National Fund for Research into Crippling

76

1 Diseases. Now that this organisation is established,
2 the Lord Mayor Treloar College is an ideal centre for
3 this type of research and in this respect it is unique
4 in this country. It would therefore be a pity if such
5 an organisation was allowed to lapse for lack of
6 financial support."

7 Then it refers to the Ministry of Health having
8 agreed to cover the cost of materials. It has the
9 formal approval of the Medical Research Council.

10 "Much time and trouble has been spent by the
11 Director of Lord Mayor Treloar Haemophilia Centre and
12 his Deputy in the detailed planning of this trial.
13 Boys to be included in this trial had to satisfy
14 certain strict criteria and were selected accordingly
15 by the Research Fellow. The trial commenced during
16 the Summer Term of 1973 and it is not likely to be
17 completed before the end of the Spring Term 1975.

18 "This trial is one of the most important
19 research studies now being carried out in this county
20 [I think it says, or 'country' might make more sense]
21 on the treatment of haemophilia and its implications
22 could be profound."

23 Then if we go to MRCO0000065_022.

24 This is an observation by I think someone in
25 either of the Department of Health or the Medical

77

1 ethically acceptable to conduct it at Lord Mayor
2 Treloar College on children.

3 "Several points concerning the designs of the
4 trial were discussed, and it became apparent that some
5 of the Directors present either had reservations about
6 it or disagreed with particular points. Dr Maycock
7 was asked whether the Plasma Fractionation Laboratory
8 or the Blood Products Laboratory would be able to make
9 the required amounts of Factor VIII concentrate, as
10 this might provide a considerable saving compared with
11 buying such concentrate from a commercial firm in
12 Austria at a cost of £15 - 20K. Dr Maycock replied
13 that he saw no difficulty in producing the material if
14 the appropriate financial assistance and sufficient
15 fresh frozen plasma was available. This statement
16 caused some lively discussion, and it was clear that
17 if more Factor VIII concentrate really did become
18 available from PFL or BPL, the Haemophilia Centre
19 Directors would want to use it for treatment rather
20 than in a clinical trial. Dr Maycock pointed out,
21 however, that it might be possible to increase
22 production, given the necessary raw materials and
23 funds, on a continuing basis rather than having to
24 spend the available finance on one single batch of
25 Factor VIII.

79

1 Research Council on the meeting and the discussion
2 that took place at the meeting in October '72, so it's
3 a note or a memo dated 8 November 1972.

4 "I attended the meeting of the Haemophilia
5 Centre Directors on October 27th. Several of the
6 agenda items were of interest, but one in particular
7 has special reference for us -- the proposed trial of
8 prophylactic therapy.

9 "Dr Biggs had been asked by the equivalent
10 meeting last year to produce a protocol, and it was
11 this that was debated. A subsequent (mark 2) version
12 of the protocol has been sent to DHSS and it is the
13 mark 2 version that we have received from the
14 Department of Health and Social Security."

15 That would suggest this a medical research
16 counsel note.

17 "Dr Biggs said it was clear that no individual
18 Haemophilia Centre could organise a trial of this
19 type -- for ethical reasons apart from anything
20 else -- but the Lord Mayor Treloar College at Alton
21 were able to undertake it, and any other centres who
22 could do so were welcome to join."

23 Just pausing there, it's not clear from any of
24 this material why it's thought that ethically it's
25 problematic to conduct this work elsewhere but it's

78

1 "In discussion with Dr Biggs, Dr Maycock,
2 Dr Arblaster, and Dr Aronstam I discovered that all
3 the objections raised by the Haemophilia Centre
4 Directors had already levelled at the protocol, and
5 the version which had been sent to the DHSS took
6 account of them so far as possible. The DHSS were
7 apparently sent the protocol many months ago, and the
8 people who hope to run the trial clearly now are
9 relying on the Council to speed up the process of
10 decision.

11 "There seemed to be two main issues -- first,
12 should a trial of the type described be carried out,
13 and second, should Factor VIII concentrate be provided
14 through Dr Maycock and Dr Bidwell or from commercial
15 sources. I think there is a case for the Department
16 deciding both these questions in general terms and
17 then the Council to play some part in perfecting the
18 design of the trial and becoming involved in an
19 advisory capacity."

20 And so there is quite an illuminating insight
21 from the attender from the Medical Research Council at
22 the Haemophilia Centre Directors meeting on the
23 discussions and the concerns that were being expressed
24 about the trial and the question of what product to
25 use.

80

1 There is also a discussion of the trial
2 at TREL0000521.

3 This is a meeting of the research sub committee
4 of the Wessex Regional Hospital Board,
5 8 February 1973. If we go to the bottom of the second
6 page, there is a discussion of the prophylactic trial
7 in haemophilia:

8 "The Committee received details of a proposed
9 trial to be carried out at the Lord Mayor Treloar
10 Hospital, Alton, under the direction and control of
11 Drs Arblaster and Aronstam, to establish whether or
12 not the use of Factor VIII material would reduce the
13 incidence of bleeding in haemophiliacs".

14 Top of the next page:

15 "Following discussions with the Chairman, this
16 proposal had been sent to the Department of Health and
17 Social Security, with the Board's support, and
18 a request made for funds to finance the research over
19 a period of three years.

20 "The Department of Health had now written to say
21 it was willing to make available £4,000 for the trial,
22 which would be carried out at Alton and a small
23 steering committee was being set up by the Department
24 of Health and the Medical Research Council to advise
25 on the protocol and suggest further revisions to the

81

1 MRC might prove to be simply to bring together those
2 people who could contribute to the design and conduct
3 of the proposed trial, and to ensure that adequate
4 arrangements had been made for its organisation and
5 the assessment of results. He suggested that
6 discussion might conveniently be directed to the
7 following four subjects:

8 "1. The trial protocol.

9 "2. Consideration of matters relating to
10 children involved in the trial.

11 "3. Consideration of matters relating to the
12 Lord Mayor Treloar College.

13 "4. Financial aspects."

14 Then if we go to the discussion of the trial
15 protocol, to the bottom half of the page, we can see
16 it records Dr Rainsford saying that the proportion of
17 clinically severely affected children at the college
18 was about 25%. Then there's a discussion of the
19 proportion in the population at large.

20 Then the next paragraph says:

21 "At the present time there were only 8 boys at
22 the college who fell into the 'severe' category.
23 Dr Aronstam pointed out that the significance of the
24 results would not be dependent upon only the number of
25 boys in the trial but also perhaps the total number of

83

1 trial plan where this could be done with advantage.

2 The funding of this project will be arranged by the
3 Department of Health direct with the North Hampshire
4 Group.

5 "The Committee noted this development with
6 satisfaction."

7 Sir, unfortunately, that doesn't cast any
8 further light on the question of consideration of
9 ethical implications.

10 If we go to MRCO0000065_011.

11 We zoom in again, it's not always easy to read
12 this. Sir, we can see:

13 "Trial of Factor VIII concentrates at Lord Mayor
14 Treloar College.

15 "Record of a meeting held at 20 Park Crescent
16 ... 9th March 1973 ...".

17 Sir, this appears to be a Medical Research
18 Council meeting, I think. We can see present
19 Dr Arblaster, Dr Aronstam, Dr Rainsford, as well as
20 Dr Bidwell, Dr Metters from the DHSS, Dr Stewart from
21 the MRC and Dr Bunje, chair, who I think one of the
22 earlier memos we looked at was addressed to. Then we
23 can see:

24 "[The chair] summarised the events that had led
25 up to the meeting and suggested that the role of the

82

1 'bleeds'. In order to answer criticisms of the
2 significance, the trial could be extended by a year
3 (or whatever time was appropriate) or the college
4 could accept more boys."

5 So there's a suggestion there potentially, or
6 one inference that one might be drawn of recruiting
7 boys to the college so that this could be a trial of
8 greater clinical and research significance.

9 "The limitation was not the number of boys who
10 would be accommodated but the availability of the
11 Factor VIII material."

12 Then we see the chair suggesting:

13 "... that the trial should be continued until at
14 least 15 boys had been included and the results should
15 then be examined with a view to assessing their
16 significance. It was agreed it would not be possible
17 to have 15 in the trial concurrently since the
18 resultant laboratory workload would be too heavy, but
19 that the trial could be lengthened as required.

20 Dr Bidwell confirmed that, as far as could be
21 foreseen, Factor VIII could be provided in sufficient
22 quantity over the period of the trial.

23 "It was agreed that the criteria of eligibility
24 for the trial could not be changed for combination of
25 ethical, statistical and practical reasons ..."

84

1 Again, it's not clear what the ethical reasons
2 are.
3 "... and it was agreed that the trial would be
4 continued, with continuous assessment of the
5 significance of the results, for as long as
6 necessary."
7 There's then a discussion about the number of
8 bleeds that one would need in order to be included in
9 the trial. The last sentence of that paragraph:
10 "If the trial was successful ..."
11 Sorry, can we just go up again, Soumik.
12 "... the use of Factor VIII might be extended to
13 those with lower frequency of bleeding."
14 Then there's a discussion about various aspects
15 of the arrangements. The penultimate paragraph on
16 that page says:
17 "Dr Arblaster reported that a letter for parents
18 had been prepared but that it would not be sent out
19 until all the other arrangements for the trial had
20 been confirmed."
21 Then there was a discussion about taking samples
22 on each boy, and to confirm Factor VIII levels, at the
23 bottom of the page. If we go over, we can see the
24 conclusion of the discussion:
25 "Costs. Dr Bidwell pointed out she could not

85

1 "Does the patient have ... classic haemophilia
2 with ... a compatible family history and ...
3 a factor VIII level of 1% or less?"
4 If no, then "stop", so they're not eligible.
5 "Is the age of the patient 7 years or greater?"
6 So that's the cut-off, 7-plus.
7 "Is the patient a male?"
8 "Has the patient a bleeding frequency of
9 7 episodes per 100 days during the past two school
10 terms?"
11 If yes, eligible for inclusion, if no, they're
12 not.
13 "Does the patient have Factor VIII inhibitors?"
14 If yes, they are not eligible for inclusion.
15 "Is an elective surgical, orthopaedic or other
16 procedure planned which would interfere with the
17 proper execution of the trial?"
18 If yes then, again, we see "stop", so not
19 included.
20 "Will the parent be participating in school
21 studies with requirements in conflict with those of
22 this trial?"
23 Again, if yes, it's stop.
24 "Have the patient and his parents (or guardian)
25 given their informed consent to participate in, and

87

1 readily assess the cost of producing Factor VIII in
2 financial terms."
3 She is said to be able to manufacture the
4 additional Factor VIII required:
5 "... provided the number of boys in the trial
6 was never more than 10 ...
7 "Dr Aronstam said that the extra time that the
8 technicians in his ... Department would require would
9 be organised locally."
10 So this meeting appears to be contemplating,
11 contrary to what we saw in the Haemophilia Centre
12 Directors discussion, that there would be a supply of
13 Factor VIII for the trial from Dr Bidwell.
14 We've got various documents associated with the
15 trial but it's not possible often to tell whether they
16 are early versions of documents or final versions.
17 I'll just look at one example, therefore.
18 MRCO0000065_021.
19 So this is -- it's headed:
20 "Study of Preventative Treatment in Haemophilia.
21 "A Controlled Trial.
22 "Data Forms.
23 "Determination of Patient Eligibility."
24 If we go to page 3, we can see the criteria for
25 a patient to be eligible:

86

1 fulfil the requirements of the trial?"
2 Again, that's seen as a requirement for
3 eligibility. The answer is, if the answer is no, then
4 they're not to be included.
5 "Is all the information on this data form
6 recorded fully?"
7 So that's the form.
8 As I say, there are other versions of this
9 document, but which chart a similar effect and it's
10 not clear which is the final version but there is no
11 marked difference between them for present purposes.
12 Then there's one -- again, one further document.
13 DHSC0100026_147.
14 I'm not going to go through all of this. Again,
15 it is not clear what the date is unfortunately. But
16 it's a discussion about the study, so prospective
17 study of preventative treatment in haemophilia.
18 We can see in the third paragraph it observes:
19 "The effects of prophylactic administration of
20 Factor VIII concentrates may be complex. For example,
21 a patient may gain sufficient assurance from such
22 treatment as to ignore symptoms which would ordinarily
23 cause him to consult his physician. Conversely, he
24 may be prompted to exert himself more strenuously than
25 he might otherwise, and thereby provoke a bleeding

88

1 episode. The effects of psychological influences on
2 bleeding in haemophilia have been stressed ... It
3 would be desirable to control these sources of
4 potential bias by designing a trial with two specific
5 requirements. First, the variation among patients
6 might be controlled by a 'switchback design', whereby
7 each patient serves as his own comparison. Secondly,
8 the individual variation of a single patient between
9 placebo and factor VIII might be controlled by
10 employment of a double-blind method."

11 Then we can see, over the page again, the
12 virtues of Lord Mayor Treloar College as "an ideal
13 location" for the treatment are extolled.

14 "An ideal location for carrying out a clinical
15 trial to evaluate prophylaxis would be a Centre where
16 a relatively large number of severely affected
17 haemophiliacs are closely observed daily; where the
18 'baseline' bleeding habits of the patients are known;
19 and where personnel and facilities exist for
20 separating clinical management from trial
21 administration. Such a location is the Lord Mayor
22 Treloar College."

23 Then we can see a discussion of eligibility
24 criteria. I don't propose to go through the details
25 of that, save to note that point 8, is:

89

1 Treloar's would not itself obtain consent but would
2 leave it to the home clinicians to do so.

3 If we go over the page, there's then
4 a discussion of the respective responsibilities of
5 Dr Rainsford and Dr Aronstam.

6 Dr Rainsford was going to be blind to the
7 treatment assignment. Dr Aronstam would be
8 responsible for trial administration.

9 There is, if we look at paragraph 4, reference
10 to Dr Tomlinson participating:

11 "The physician responsible (Dr Tomlinson and
12 Staff) for therapeutic infusions, will administer
13 concentrate or placebo to patients."

14 So that's an oddity, given what the evidence
15 elsewhere suggests about Dr Tomlinson. But in any
16 event, we then have the heading "Informed Consent":

17 "After tentative determination of a patient's
18 eligibility, the trial will be explained fully to the
19 patient and the patient's parents or guardian. The
20 following points will be made clear:

21 "1. During the entire trial, each patient will
22 receive an infusion once weekly of either concentrate
23 or placebo.

24 "2. The patient will not be told to which
25 treatment he is assigned.

91

1 "All patients must give their informed consent
2 as defined below, prior to the final determination of
3 eligibility."

4 If we go, then, to the next page, we can see
5 a heading:

6 "Trial Design.

7 "The trial for an individual patient will
8 consist of four school terms. During two of these
9 terms, the patient will receive once-weekly infusions
10 of freeze-dried Australia Antigen-screened factor VIII
11 concentrate, and during the other two terms,
12 once-weekly infusions of distinguishable placebo.

13 "The designation of these terms as treatment or
14 placebo periods will be made on a random basis."

15 Then it talks about it might be necessary to
16 delay treatment periods and the total trial period
17 shall in no instance exceed six school terms.

18 Then in terms of obtaining of consent, if we
19 look at the bottom, towards the bottom of the page,
20 "Division of Responsibility", point 1 says:

21 "It is hoped that the Medical Directors of
22 Haemophilia Units in the boy's home area will be
23 responsible for obtaining consent for inclusion in the
24 trial."

25 So it appears to have been contemplated that

90

1 "3. It must be understood that the only safe
2 assumption for the patient to make, is that he is
3 assigned to the placebo group. He should act
4 accordingly by not taking undue risks, and by promptly
5 reporting symptoms suggesting haemorrhage, as usual."

6 Top of the next page:

7 "4. All patients will receive best available
8 treatment, as usual, for bleeding episodes when they
9 occur."

10 And:

11 "5. Patients must agree an intention to
12 participate in the trial for a full four terms."

13 Then there's a further discussion about the
14 administration of the concentrate and so on.

15 So it appears to have been certainly built into
16 the protocol that informed consent along the lines
17 there discussed would be required.

18 You will note that in terms of the matters that
19 are said to be necessary to make clear to patients,
20 there is no discussion of possible risks of receiving
21 prophylactic concentrates, in other words, receiving
22 more concentrates than might otherwise be required for
23 treatment of bleeding on demand. So any possible
24 enhanced risks of viral infection with hepatitis, for
25 example, are not there identified.

92

1 **SIR BRIAN LANGSTAFF:** Well, if we go back a couple of
 2 pages, at the bottom of the page, what do we make of
 3 that?
 4 **MS RICHARDS:** We're told the placebo will be
 5 a hepatitis-free human plasma protein fraction, and is
 6 going to appear indistinguishable from the
 7 concentrate, but we're not told the concentrate is
 8 hepatitis free.
 9 **SIR BRIAN LANGSTAFF:** So we know that is hepatitis free at
 10 least, at least free of hepatitis B, presumably.
 11 **MS RICHARDS:** In terms of the placebo, yes. And we're
 12 told it's going to be, in terms of the actual
 13 concentrate, absolutely, we're told it would be
 14 Australia antigen screened. But of course, leaving
 15 aside any question over the adequacy of screening for
 16 hepatitis B, for Australia antigen, there is the
 17 broader question of other forms of viral hepatitis.
 18 **SIR BRIAN LANGSTAFF:** Yes.
 19 **MS RICHARDS:** So those are some of the background
 20 documents underpinning the prophylactic trial.
 21 Other evidence that we've got suggests that the
 22 trial did indeed commence in the summer of 1973. We
 23 have got one example, it may not be the only example,
 24 but it's one example we've got available for display,
 25 of a discussion by the home clinician with a parent.

93

1 directors of Haemophilia Centres and blood transfusion
 2 directors, 31 January 1974. Dr Arblaster,
 3 Dr Aronstam, and Dr Rainsford were all in attendance.
 4 There's a brief update at page 4 on the prophylaxis
 5 trial. So it's paragraph:
 6 "(c) Trial of prophylaxis at Alton - an Interim
 7 report:
 8 "Dr Arblaster described the aims of the trial
 9 and outlined some of the practical difficulties which
 10 they had come across early in the trial."
 11 Minutes don't reveal what they are.
 12 "Dr Aronstam then described the results of the
 13 first two terms of the trial. He stressed that the
 14 trial was still 'double blind'.
 15 Before leaving this document if we look at the
 16 previous page, and this is just so I don't have to
 17 come back to the document, there is reference in the
 18 bottom half of the page to a survey of Australia
 19 antigen in household contacts of haemophiliacs, and
 20 we've seen reference to that previously. But we can
 21 see that there is, following a report from Dr Ingram,
 22 it says:
 23 "Discussion about this paper included the
 24 following topics ...".
 25 And then paragraph (iii):

95

1 TREL0000318_012.
 2 Sir, this is a letter from a doctor based at the
 3 Warwick Hospital addressed to Dr Aronstam, April 1973,
 4 and it says in the second paragraph:
 5 "During these holidays I have had an opportunity
 6 to discuss the research project using Factor VIII
 7 concentrates with [the patient] and his mother and
 8 they have agreed to cooperate."
 9 There's then an update about the patient's
 10 condition, and then the last paragraph says:
 11 "[The patient] has not had an episode like this
 12 for some years and it is very much to be hoped that
 13 the new preventative treatment will bring his
 14 coagulation time under better control."
 15 That read with the earlier paragraph tends to
 16 suggest that this was a discussion about participation
 17 in the prophylactic trial.
 18 So it would indicate that there has been
 19 a discussion with parents, and pupil, but it doesn't
 20 tell us what the substance of that discussion was, or
 21 what information was provided.
 22 If we then look at a short update to the
 23 Haemophilia Centre Directors in early '74 on the
 24 trial, it is at CBLA0000187.
 25 Sir, this is the minutes of a joint meeting of

94

1 "A report was made of the tests made at the
 2 Alton Centre (Dr Rainsford)."
 3 So it appears that there was also participation
 4 by the Treloar's centre in this ongoing survey of
 5 Australia antigen in the household contacts of
 6 haemophiliacs that we know was being undertaken under
 7 the auspices of the Haemophilia Centre Directors at
 8 this time.
 9 If we then pick up the progress of this trial at
 10 NHBT0107241.
 11 This is one of the termly reports that we've
 12 previously looked at. This is authored by
 13 Dr Rainsford in January 1975, and it's reporting on
 14 the summer term 1974 and the autumn term 1974. We
 15 looked previously at what was said at the bottom of
 16 page 2 and 3 about the hepatitis outbreak. If we go
 17 to page 4, we see reference to the "Prophylactic
 18 Trial". So under the heading:
 19 "Research Programme
 20 "Prophylactic Trial - This trial is now complete
 21 and a report is being prepared.
 22 "A new research program to cover the next
 23 three years has been formulated and acceptance of this
 24 programme is awaited from the National Fund for
 25 Research ..."

96

1 Then we can see reference to preliminary work on
2 that and other projects, including the hepatitis
3 project.

4 So if we look further down we see the date,
5 January '75. We're told that prophylactic trial has
6 been completed.

7 Then if we pick matters up in the Haemophilia
8 Centre Directors meeting of September 1975.

9 OXUH0003735.

10 We see the date at the top of the page,
11 18 September 1975. Dr Aronstam, Dr Kirk and
12 Dr Rainsford are all present. If we go then to
13 page 8, we can see towards the bottom of the page an
14 update about the trial of prophylactic treatment.

15 "Dr Aronstam gave a report on the trial of
16 prophylaxis at the Lord Mayor Treloar College at
17 Alton. He presented the data which was being prepared
18 for publication. He said that there was evidence that
19 the boys in the treatment group were protected for
20 48 hours following a dose of factor VIII. Dr Aronstam
21 said that he had encountered difficulty in organising
22 the trial, and felt that an extension of the trial
23 should not include a placebo dose."

24 Then there's a discussion, following an
25 intervention from Dr Cash, that prophylaxis could

97

1 cryoprecipitate, 10 patients receiving Kryobulin and 5
2 patients receiving Elstree Factor VIII."

3 The bottom of the page says:

4 "Any Director who would like to contribute to
5 the Study should contact Dr Kirk at Lord Mayor Treloar
6 College ... A requirement for participation in this
7 trial is that a patient should receive only one type
8 of material for treatment and that samples for
9 virology testing be collected and sent to Dr Cossart
10 at the Virus Reference Laboratory.

11 "There was some discussion about the collection
12 of samples for LFT and virus testing and it was felt
13 that it was important to arrange for as many tests as
14 possible but it was also felt that frequent testing of
15 patients, particularly those on home therapy, could be
16 difficult. Therapeutic material should be saved for
17 virus testing in case new types of test were
18 developed."

19 You may wish to note, sir, that it appears to
20 have been regarded as something that could be achieved
21 for research purposes to keep a patient on one type of
22 concentrate for the purposes of research, but more
23 broadly for the purposes of treatment, we've seen that
24 wasn't the approach that was taken.

25 And if we go to page 4, there's a further

99

1 result in an annual dosage of more than 70,000 units
2 of Factor VIII per patient per year. Then someone
3 else points out that:

4 "... quite small doses were often effective for
5 'on demand' therapy and that even less might be
6 required for prophylaxis. Dr Stewart proposed that
7 the trial be continued on a regime of two doses a week
8 at 2 dose levels ...

9 "ACTION. It was agreed to recommend that the
10 trial be continued at 2 dose levels."

11 Then I will come back to this -- actually,
12 whilst we're here, we might as well pick it up here.
13 There's a discussion of two other aspects of research
14 being undertaken at Treloar's at this time. The
15 continuation on this page refers to a proposed pilot
16 study of hepatitis in haemophilic patients and I'll
17 come on to that this afternoon, but you'll see Dr Kirk
18 is referred to as introducing a paper on a proposal:

19 "... to study the incidence of hepatitis in
20 haemophilia patients who have received material of
21 known types. He was proposing, as a pilot study, to
22 keep detailed records on the following patients ..."

23 Then we see a reference to Treloar's, Newcastle,
24 and Oxford. I'll just concentrate on Treloar's:

25 "At Treloar College, 20 patients receiving

98

1 discussion about hepatitis and liver function tests in
2 the bottom half of this page. This is in the context
3 of the directors' study of jaundice and Factor VIII
4 antibodies. It says:

5 "There was a full discussion about the incidence
6 of hepatitis and the problem of anicteric cases."

7 Then -- sorry:

8 "Prof Stewart thought that the cases of
9 hepatitis should be more precisely defined according
10 to the criteria on which the diagnosis was made."

11 Then we can just see a slight difference of
12 approach between Dr Kirk and Dr Rainsford:

13 "It was felt that future statistics should
14 include [liver function test] results ..."

15 And that's said to be the view of Dr Craske and
16 Dr Kirk:

17 "... though others felt that [liver function
18 test] results were often said to be difficult to
19 interpret ..."

20 And that's said to be the views of Dr Maycock
21 and Dr Rainsford.

22 In any event, there we have an update on the
23 prophylaxis trial.

24 If we go to MRCO0000065_005.

25 **SIR BRIAN LANGSTAFF:** Just before you do, the last five

100

1 lines there.

2 **MS RICHARDS:** "Professor Ingram" -- sorry:

3 "The influence on the pool size of material used

4 for fractionation was discussed, Prof Ingram said that

5 NHS Factor VIII was derived from pools of 500-750

6 donations whereas the commercial factor VIII was often

7 derived from pools of 2,000 to 6,000 litres of plasma

8 and that the probability of including an infected

9 donation was greater ..."

10 Top of the next page -- sorry, do you need

11 the -- OXUH0003735. And if we go to the top of

12 page 5.

13 "... was greater with commercial factor VIII."

14 Then there's a discussion about not issuing for

15 use material that was hepatitis B antigen positive.

16 Is that the passage to which you were referring

17 to, sir?

18 **SIR BRIAN LANGSTAFF:** Yes, thank you.

19 **MS RICHARDS:** Sir, then if we just go to MRCO0000065_005.

20 And if we can zoom in, it's very difficult to read.

21 Sir, this is a letter from Dr Aronstam to the

22 Medical Research Council, 22 July 1975. We can see

23 it's headed "Prophylaxis in Haemophilia", and he says:

24 "You may remember Chairing a meeting at the

25 Medical Research Council three years ago when we

101

1 amount of time. But we can see:

2 "Summary: A double-blind controlled trial of

3 prophylactic factor VIII therapy has been carried out

4 on nine severe haemophiliacs at the Lord Mayor Treloar

5 College. Infusions were given once weekly and

6 calculated to give a post-infusion plasma

7 concentration of at least 0.25IU/ml of factor VIII."

8 Then it's said to have reduced the overall

9 bleeding frequency by 15%.

10 "The bleeding frequency in the first 3 days

11 post-infusion reduced by 66%. A moderate overall

12 reduction in morbidity was also achieved. It is

13 calculated that to reduce the incidence of bleeding in

14 severe haemophiliacs by 15% would require a 73%

15 increased usage of therapeutic materials. More than

16 twice this amount of material is likely to be needed

17 to reduce the bleeding frequency of the same group by

18 66%."

19 Sir, that's a summary of the findings. I've

20 just looked very briefly at a couple of pages, second

21 page, under the heading "Materials and Methods",

22 describes how the trial was conducted. We can see the

23 "Eligibility Criteria". The third paragraph asserts

24 that:

25 "The nature of the trial was fully explained to

103

1 discussed the protocol for a double-blind controlled

2 trial of prophylactic therapy in haemophilia.

3 Dr PG Arblaster, who is now in Arabia, and myself

4 together with Dr Rainsford attended for the Treloar

5 Haemophilia Centre where the trial has been carried

6 out.

7 "We have now gone as far as we can with this

8 trial in the face of, I may say, enormous difficulties

9 which I feel were a direct result of using a placebo

10 for this study.

11 "We have had to make some modifications to the

12 original protocol but nevertheless I believe our final

13 report, a copy of which I enclose, has done what we

14 set out to do - that is to establish that prophylactic

15 therapy actually works."

16 We can see a published paper on the trial at

17 NHBT0000091_036:

18 "Prophylaxis in Haemophilia: A Double-blind

19 Controlled Trial."

20 It's reported in the British Journal of

21 Haematology in 1976 and we can see it was received for

22 publication in July '75.

23 I'm not going to go through the detail of the

24 report because it's -- well, it's several pages long

25 and it would be -- I think take a disproportionate

102

1 the eligible boys and their parents or guardians were

2 asked to give their consent; if this was obtained the

3 boy was admitted to the trial."

4 As we've seen, the indications from the

5 documents are that that was a process, as it were,

6 delegated to the home clinicians, home treating

7 clinician, rather than directly undertaken by the

8 clinicians at Treloar's.

9 Then there is a description on the following

10 page of each of the nine boys. Then, if we go over to

11 the fourth page, we can see set out there the results

12 in both tabular and narrative form:

13 "Nine boys studied for a total of 27 boy-school

14 terms ... Ninety-seven infusions of high-dose and 95

15 of low-dose material given."

16 Then if we go to page 7, we can see "Development

17 of Inhibitors":

18 "No case of an inhibitor ... developed during

19 the trial ...

20 "No case of hepatitis associated antigen

21 developed during the trial, although one boy ...

22 developed antigen negative hepatitis 23 [days] after

23 entering the trial. He was withdrawn for the

24 remainder of that term."

25 Then the discussion is probably something that

104

1 merits reading in full by you, sir, rather than me
 2 simply reading out.
 3 **SIR BRIAN LANGSTAFF:** Yes.
 4 **MS RICHARDS:** But it talks about what might be required by
 5 way of dosage in order to achieve therapeutic benefit.
 6 If we go over the page, the last paragraph
 7 refers to problems in the trial, maybe what
 8 Dr Aronstam was referring to earlier when he described
 9 practical difficulties in the trial, or it may not.
 10 It said:
 11 "Some bleeds were bound to occur shortly after
 12 infusions of low-dose material and sooner or later
 13 a crop of bleeds will occur. On one occasion four
 14 boys were together in the sick bay within 24 [hours]
 15 of a low-dose infusion. They concluded that the
 16 material was the cause for their bleeding and it was
 17 difficult to persuade them to remain in the trial.
 18 Two, in fact, dropped out soon after this episode.
 19 The giving of a dose interferes with a boy's leisure
 20 and schooling and when inert material is given [so
 21 placebo] this may not be easily justified. In our
 22 view, future trials should compare only probably
 23 effective prophylactic regimens and should not include
 24 placebo doses."
 25 So that's the first trial of prophylaxis. I'm

105

1 not going to go through the same level of detail in
 2 relation to the other trials of prophylaxis because
 3 really we've seen the groundwork and the framework in
 4 the documents we've looked at, and the involvement of
 5 the Department of Health and Medical Research Council.
 6 But we can see, if we go to RLIT0000084, a later
 7 publication:
 8 "Twice weekly prophylactic therapy in
 9 haemophilia A", reported in 1977, so this is a later
 10 trial of prophylactic treatment, and the summary tells
 11 us that:
 12 "Factor VIII-containing materials were
 13 administered to four severely affected haemophiliacs
 14 twice weekly in doses calculated to raise the
 15 Factor VIII level to either 15% or 30% of average
 16 normal."
 17 Then it suggests that the results from the
 18 patients show the reduction in -- a significant
 19 reduction in bleeding frequency on both doses in the
 20 first 48 hours and so on.
 21 If we just go back to the text on this page, the
 22 first paragraph refers to the previous prophylactic
 23 trial, and then, if we pick it up at the bottom of the
 24 left-hand side of the page, please:
 25 "In view of the implications for the limited

106

1 financial and human resources available to service
 2 such a commitment, it is important to confirm these
 3 findings [so the findings of the earlier trial] and to
 4 establish the lowest dose which might be beneficial.
 5 The work reported here is a step along that path."
 6 So this was seen as building upon the
 7 prophylactic work previously undertaken.
 8 Details are given on the second page of the
 9 trial design. And if we look at the bottom of the
 10 page, we see the heading of the left-hand side
 11 "Prophylactic Materials." We can see that this was
 12 a trial that involved cryoprecipitate, apparently, but
 13 also involved Kryobulin.
 14 And then we'll just look at the last page under
 15 the heading -- oh, I'm so sorry, the page before that.
 16 So there's a heading, "Discussion". If we go to
 17 the right-hand side, I pick it up in -- sorry, the top
 18 half of the page, right-hand side. Second paragraph:
 19 "From the data presented it might reasonably be
 20 concluded that the 24-hourly prophylactic
 21 administration of a dose of factor VIII, calculated to
 22 raise the level to 30% would reduce the bleeding
 23 frequency by 90%. The application of a similar
 24 calculation to that explained above suggests that such
 25 a commitment would need nearly nine times the amount

107

1 of therapeutic material currently in use for
 2 haemophiliacs with comparable bleeding frequencies.
 3 "Clearly, this sort of commitment is not
 4 possible with known therapeutic materials, given the
 5 current limitations of human and financial resources,
 6 particularly in the UK."
 7 Then we can see that the authors then say that
 8 they think:
 9 "... further work in this field should be
 10 directed towards the possible benefits of limited
 11 periods of prophylaxis."
 12 So that's the next, as it were, step along the
 13 line of investigation of prophylaxis undertaken at
 14 Treloar's.
 15 Sir, I'll just mention, then, that there was
 16 then a third trial of prophylactic treatment. That
 17 did indeed, as anticipated here, look at short-term
 18 prophylaxis and whether that would reduce bleeding
 19 frequency, and we know -- and I won't go to the
 20 documents in relation to this third trial, but we know
 21 that the therapeutic material used for that trial
 22 included cryoprecipitate, NHS Factor VIII, and
 23 commercial Factor VIII. And it was conducted between
 24 1976 and 1977, with prophylaxis being administered
 25 twice weekly to five boys and three times weekly to 13

108

1 boys.
 2 If we could just go to the very final document
 3 of relevance, I think, on that third trial, it's
 4 Dr Kirk's update to the Haemophilia Centre Directors.
 5 PRSE0002268.
 6 So it's a meeting of Haemophilia Centre
 7 Directors January 1977. If we go to page 9, I think.
 8 Yeah, bottom of the page. We see reference to:
 9 "Trial of prophylactic treatment of haemophiliac
 10 patients at Alton ... Dr Kirk reported on the third
 11 trial of prophylactic treatment at Alton, the aim of
 12 which was to see if prophylactic treatment reduces the
 13 incidence of bleeds in severely affected haemophilic
 14 boys. All patients in the study already had bad
 15 joints."
 16 Now this records treatment with cryoprecipitate,
 17 Kryobulin and Hemofil, but there are other documents
 18 that suggest NHS concentrate used.
 19 Sir, I'll check the final published report to
 20 see if it clarifies that.
 21 Then we can see over the page there's then
 22 a discussion about the use of prophylaxis. About
 23 halfway down that long paragraph there's a reference
 24 to:
 25 "Dr Blecher [asking] which regime the boys

109

1 relation to the publications regarding the trials of
 2 prophylactic therapy, the third trial was written up
 3 in RLIT0000093:
 4 "Transfusion requirements of adolescents with
 5 severe haemophilia A."
 6 Aronstam, McLellan and Turk.
 7 I'm not going to it in any great detail but if
 8 we'd look at the bottom of the page, right-hand side,
 9 under the heading "Patients and methods", we can just
 10 see it says:
 11 "Seventy-five boys without inhibitors and with
 12 haemophilia A were studied during the years 1973-77."
 13 The next paragraph talks about third trial, so:
 14 "Prophylactic Factor VIII given to 15 of the
 15 boys for limited periods during 1976 and 1977.
 16 Prophylaxis was administered twice weekly to five boys
 17 during 1976 and three times weekly to 13 boys during
 18 1976 and 1977."
 19 Then the publication clarifies what products
 20 were used, so bottom of the page:
 21 "Each transfusion was of cryoprecipitate,
 22 [NHS] factor VIII concentrate, or commercial
 23 factor VIII concentrate, and was recorded as a single
 24 transfusion irrespective of dose."
 25 I don't think this document tells us which

111

1 preferred - on demand or prophylaxis. Dr Kirk replied
 2 that the 2 boys with the best results ... wanted to
 3 stop prophylactic treatment; the others wanted to go
 4 on. Possibly the 2 boys with good results had
 5 forgotten what a bad bleed was like. Prof Stewart
 6 felt that prophylactic treatment for haemophiliacs
 7 should not be entered into on a large scale until
 8 there was sufficient evidence that it was beneficial
 9 to the patients. Dr Rainsford said that the
 10 prophylactic trial was aimed to provide information
 11 for the future and not with the intention of immediate
 12 implementation."
 13 So you'll see there some reservation being
 14 expressed by some directors as to whether this --
 15 well, as to whether this was an appropriate way in
 16 which to treat patients.
 17 So that, I think, brings me to a convenient
 18 point at which to break for lunch.
 19 **SIR BRIAN LANGSTAFF:** Yes. We will take a break until
 20 two o'clock. Two o'clock.
 21 **MS RICHARDS:** Thank you, sir.
 22 **(1.03 pm)**
 23 **(The luncheon adjournment)**
 24 **(2.00 pm)**
 25 **MS RICHARDS:** Sir, just to complete the picture in

110

1 commercial concentrates were used, so we may need to
 2 fall back on what was said in the earlier documents in
 3 that regard.
 4 So that's the third trial of prophylactic
 5 treatment. There's one further document I'd like to
 6 refer to on that but we haven't yet got it available
 7 for screening, so I'll come back to that. I'm going
 8 to move then to one of the other major areas of study
 9 and research which was the hepatitis study. It was
 10 often referred to as such but, in fact, it is probably
 11 better regarded as a series of studies carried out
 12 over a number of years.
 13 If we go to HHFT0000053_001, we can see this is
 14 entitled:
 15 "The Incidence of Australia Antigen and Antibody
 16 in boys suffering from coagulation disorders.
 17 "Report of a Study at the Lord Mayor Treloar
 18 College."
 19 It is authored by Dr Rainsford and Dr Cossart
 20 and it tells us that:
 21 "Each year as many as 50 of the disabled boys
 22 attending the Lord Mayor Treloar School are suffering
 23 from haemophilia or other coagulation defects. This
 24 concentration in one residential of centre of patients
 25 needing repeated transfusions has provided a good

112

1 opportunity to study the incidence of Australia
2 antigen and antibody in a vulnerable group."
3 You'll note the words there used.
4 "The original plan was to follow the pattern of
5 antigen and antibody in the boys and to relate these
6 findings to clinical illness, frequency of transfusion
7 and the presence of Australia antigen in the blood and
8 blood products with which they were treated. It was
9 hoped to test the boys each term and to test an
10 aliquot of the blood, or pool of blood products, given
11 in each transfusion".
12 Then reference to various tests.
13 "The study has continued for 10 terms (Summer
14 1970 - Summer 1973).
15 "81 boys have come under observation,
16 71 haemophiliacs (11 with inhibitors) and 7 with
17 Christmas Disease, 2 with von Willebrand's, and 1 with
18 aplastic anaemia. 20 have been at the College
19 throughout the study, but it has not been possible to
20 examine the blood of every boy every term because of
21 hospital admissions. The collection of samples from
22 boys needing very frequent transfusion has been
23 difficult because it was thought undesirable to test
24 sera obtained less than a week after transfusion."
25 Then we can see reference in the top half of the

113

1 hepatitis, it probably also indicates immunity and it
2 is not surprising that clinical hepatitis is uncommon
3 in adult haemophiliacs.
4 "Although the amount of antigenic stimulus in
5 the transfusions given after screening began was less
6 than before, it is still significant."
7 Then we're told that:
8 "Only 12 of the 81 boys had suffered clinical
9 attacks of hepatitis, although most had frequently
10 been transfused since infancy. It would seem that
11 exposure to antigen positive blood in childhood is
12 likely to be followed by subclinical infection whereas
13 in adult life the clinical attack rate is about 50%.
14 "None of the 4 cases of clinical hepatitis
15 occurring during the study were antigen positive, and
16 this may be compared with the figure of 30-40% for
17 post-transfusion hepatitis generally during this
18 period."
19 It's undated but it's obviously written after
20 the conclusion of the ten terms, so at some point
21 after the summer of 1973. There's actually a more
22 detailed interim report, I am not going to go through
23 it in any detail, but it's at HHFT0000332.
24 We can see it's the same authors but it's headed
25 "Interim Report", and if we just go to the second

115

1 page to, in one particular period of time, examining
2 the transfusion samples, and then it's recorded in the
3 next paragraph that:
4 "Since the Spring term 1971 the Wessex Regional
5 Transfusion Centre has been screening all donors
6 supplying material for the treatment of these
7 boys ..."
8 Screening for Australia antigen.
9 There's then a reference to the results. In
10 terms of antigen, the position of three boys
11 described. In relation to antibody, again, there's
12 a description of the antibody results. If we go to
13 the next page, bottom half of the page. There's
14 a heading:
15 "Relation of Australia antigen and antibody to
16 hepatitis", and there's references to some attacks of
17 hepatitis and jaundice.
18 If we go over the page, we can just see the
19 "Summary and Conclusions":
20 "Three of the 81 boys with coagulation defects
21 were Australia antigen positive at some time during
22 the survey. One was a persistent carrier ...
23 "Thirty five to forty per cent of the boys were
24 antibody positive at all stages of the study. As
25 antibody is evidence of previous exposure to serum

114

1 page, we have a description of:
2 "The aim of the study ... to follow the pattern
3 of SH (Serum Hepatitis) Antibody and antigen in boys
4 suffering from Haemophilia and closely allied
5 disorders resident at the College, and to see how
6 these patterns correlated with clinical illness,
7 frequency of transfusion and with the presence of
8 [serum hepatitis] antigen in the blood and blood
9 products with which they were treated."
10 Then it was said:
11 "It was hoped that some of the boys might
12 provide serum which would be useful as a diagnostic
13 reagent."
14 Whether it was known that that was being done is
15 unclear. There's a description under the next heading
16 of the number of boys studied, so this is in the
17 interim stage from summer 1970 to autumn '71, at that
18 stage 54 boys had come under observation.
19 Then there are findings in relation to serum
20 hepatitis antigen and antibody.
21 If we go to the fifth page, there's a heading
22 "Hepatitis". Again, I'm not going through the detail
23 of the facts and figures but it records:
24 "Of the 53 boys concerned with these
25 investigations, only 6 have a definite history of

116

1 jaundice ..."
 2 Then reference to three of those cases
 3 contracted when at the college, the remaining three
 4 prior to entry.
 5 Then there are various tables if we go to the
 6 next page. So there are tables in terms of showing
 7 the incidence of serum hepatitis antibody.
 8 Next page is a table with the analysis of cases
 9 with antibody.
 10 If we go to the next page, a table showing serum
 11 hepatitis antibody in the sera of boys suffering from
 12 coagulation disorders at Lord Mayor Treloar, and then
 13 the remaining two tables deal with patients with
 14 inhibitors and Christmas Disease.
 15 So that's just really to give a flavour of the
 16 study. So that's one of the early hepatitis studies
 17 that was undertaken at the college.
 18 **SIR BRIAN LANGSTAFF:** Can you help at all with -- if you
 19 go back to the previous document, I think it is
 20 HHFT0000053_001, and go through it, please. Next
 21 page, next page, next page, and then the next page.
 22 What I'm looking for is there's a reference
 23 somewhere in there to there being a number of cases of
 24 post-transfusion hepatitis, not associated with the
 25 administration -- not necessarily the disease, and

117

1 "(a) That current methods of detecting
 2 [hepatitis B antigen] are still not sensitive enough."
 3 "(b) That other known viral agents are
 4 responsible, eg, hepatitis 'A', EB virus cytomegalo
 5 virus."
 6 "(c) That other, as yet unknown, viruses cause
 7 a significant amount of post transfusion hepatitis
 8 which is supported by the recent work of Feinstone
 9 et al."
 10 So there is a recognition there that there is
 11 something other than hepatitis B, essentially, causing
 12 post-transfusion hepatitis.
 13 Then if we look at the next paragraph it says:
 14 "The introduction of large pool factor VIII
 15 concentrates into the routines management of
 16 haemophiliacs has revolutionised their treatment."
 17 Then there are further observations made in that
 18 regard, including the introduction of home therapy.
 19 Then halfway down that paragraph a sentence
 20 beginning:
 21 "However, treatment with factor VIII
 22 concentrates does expose the patient to a much larger
 23 risk of contracting transfusion hepatitis since the
 24 fractionated product is processed from donor pools.
 25 Furthermore, commercial factor VIII concentrates are

119

1 I just wondered what justified it, but it's difficult
 2 to find it. But I can raise -- I'll raise it with you
 3 later.
 4 **MS RICHARDS:** Yes, I'll have a look at the document again
 5 and see if there's an answer to the question, sir.
 6 So, we see there, there's work being undertaken
 7 by Dr Rainsford in relation to studying for the
 8 incidence of hepatitis in the early part of the 1970s.
 9 There is then further work undertaken by Dr Kirk
 10 in the mid-seventies.
 11 If we look at CBLA0000312.
 12 This is a document produced by Dr Kirk in
 13 September of 1975, and it is a protocol for
 14 a prospective study of hepatitis and haemophilia
 15 associated with the use of Factor VIII concentrates.
 16 If we look at the introduction, it says:
 17 "The transfusion of blood or its derivatives has
 18 been linked with the transmission of viral hepatitis
 19 for many years."
 20 Then there's reference to hepatitis B, and at
 21 the end of that paragraph it says:
 22 "This failure to prevent post transfusion
 23 hepatitis may be explained by the following hypotheses
 24 ..."
 25 If we look at (a), (b) and (c):

118

1 made from very large pools of some 2,000-6,000 litres
 2 of plasma from paid donors. An outbreak of both
 3 non-'B' hepatitis and 'B' hepatitis associated with
 4 concentrates of this type has recently been reported
 5 by Craske et al."
 6 There is then a reference to Prince's
 7 publication with a suggestion that:
 8 "... recipients of all commercial blood have
 9 a ten-fold higher risk of developing non-'B' post
 10 transfusion hepatitis than recipients of all volunteer
 11 donor blood."
 12 Then Dr Kirk says this:
 13 "For these reasons it is proposed to conduct
 14 prospective study of hepatitis in order that the
 15 following question will be answered:
 16 "Does the administration of factor VIII
 17 concentrates to haemophiliacs on regular replacement
 18 therapy significantly increase the incidence of
 19 transfusion hepatitis?"
 20 So that's the purpose of the study, to look at
 21 the relationship between regular treatment with
 22 concentrates and transfusion hepatitis. Then Dr Kirk
 23 says:
 24 "It is hoped that some additional points will
 25 emerge ...

120

1 "(a) Any difference in the attack rates between
2 commercial factor VIII concentrates and home-produced
3 concentrates, [namely] Oxford and Elstree.

4 "(b) The assessment of the value of a positive
5 [hepatitis B antibody] test and the protection of the
6 patient from the development of hepatitis.

7 "(c) Further information on hepatitis due to
8 unknown viruses or agents other than hepatitis 'A',
9 'B', EB or cytomegalo virus."

10 Then (d) is about the role of radio immuno assay
11 testing for hepatitis B antigen.

12 So it is hoped that this will provide insight
13 into, and contribute to the knowledge of, the other
14 causes of post-transfusion hepatitis, essentially
15 non-A, non-B hepatitis.

16 We can then see reference to the method.
17 There's reference to three centres having agreed to
18 cooperate: Treloar's, Newcastle and Oxford Haemophilia
19 Centre, and we've got the numbers there. We'll see
20 what this currently envisages is 20 patients from
21 Alton, so from Treloar's, on cryo, ten on Kryobulin,
22 five on Elstree products. Then Newcastle will be
23 solely Hemofil, Oxford, a mix of Hemofil and Oxford
24 Factor VIII concentrate.

25 Then if we look at the text underneath that,

121

1 major surgical procedures are planned.

2 "(c) In the case of the Alton group, Lord Mayor
3 Treloar College boys must be able to complete three
4 academic terms ..."

5 (d) is a reference to preference for normal
6 liver function at the point of entry into the study,
7 and then (e) must be a minimum of 18 months. So:

8 "(e) Each patient must remain on the allotted
9 therapeutic material for a minimum time of
10 eighteen months. In the case of the College boys,
11 arrangements will be made with their home centres that
12 the allotted material is available for treatment
13 during the vacations."

14 So again, it appears to be practicable to
15 maintain a patient for the purposes of the study on
16 the same concentrate for 18 months, but as we've
17 observed throughout the course of the week, no attempt
18 to achieve that, it would appear, outside the scope of
19 the study.

20 **SIR BRIAN LANGSTAFF:** You could manage that with
21 concentrate. You couldn't manage it quite so easily
22 with cryoprecipitate, could you?

23 **MS RICHARDS:** In what sense, sir?

24 **SIR BRIAN LANGSTAFF:** Well, the idea of the concentrate is
25 to stick to the same brand and the same batch. That's

123

1 about halfway down that paragraph:

2 "Each patient will be treated with the same type
3 of material throughout the study and where possible,
4 batches should be arranged sequentially in order that
5 the patient may receive the same batch of his
6 particular brand over a period of three months. This
7 will be difficult to achieve and the co-operation of
8 the manufacturers has been sought in making large
9 batches available."

10 So again, just pausing there, it shows an
11 awareness of a policy of limiting exposure to
12 hepatitis, limiting exposure to multiple donors, by
13 adhering to one type of concentrate and, as far as
14 possible, limiting exposure to batches of that
15 concentrate, but this is only being contemplated for
16 the purposes of the study rather than putting into
17 effect as a broader approach of the treatment of all
18 pupils at Treloar's.

19 We'll see that expressly acknowledged to some
20 extent on the following page, but before we do that if
21 we look at the "Eligibility Criteria". So:

22 "(a) All patients with classic haemophilia on
23 regular replacement therapy are eligible for
24 inclusion."

25 Then there's an exclusion for patients for whom

122

1 possible. Because it's freeze-dried, transportable.

2 The cryoprecipitate is made on site, generally it's
3 not so transportable. It may simply be that
4 cryoprecipitate of its nature comes from a limited
5 number of donors anyway so you can never have the same
6 batch, in effect.

7 **MS RICHARDS:** I'd read it in the latter respect, sir.

8 **SIR BRIAN LANGSTAFF:** But you'd have a different
9 population giving rise to the plasma.

10 **MS RICHARDS:** As between the home centre and the -- and
11 Treloar's, yes, that's correct.

12 **SIR BRIAN LANGSTAFF:** So you'd have Manchester, Newcastle,
13 Leeds, London, cryoprecipitate finding its way through
14 to Treloar's.

15 **MS RICHARDS:** Yes.

16 **SIR BRIAN LANGSTAFF:** If anything, you'd think that would
17 increase the chances of there being some infection in
18 the supply.

19 **MS RICHARDS:** For those treated solely with
20 cryoprecipitate for that period of time, perhaps, yes.

21 Compared to treatment -- I mean, obviously not
22 necessarily compared to treatment with concentrates,
23 but compared to treatment with local
24 cryoprecipitate --

25 **SIR BRIAN LANGSTAFF:** Yes, absolutely.

124

1 **MS RICHARDS:** -- for an 18-month period, yes.
 2 **SIR BRIAN LANGSTAFF:** It's an internal -- one sort of cryo
 3 precipitated another?
 4 **MS RICHARDS:** Then the top of the next page talks about
 5 informed consent.
 6 "All patients or their parents/guardians must
 7 give their informed consent. The following points
 8 will be made clear:
 9 "(i) By limiting the transfused material to one
 10 type, the degree of donor exposure should be
 11 decreased."
 12 So an express recognition there of the
 13 advantages in safety terms of limiting transfused
 14 material to one type. Then it's said that patients or
 15 parents should also be told that it will be necessary
 16 for blood samples to be taken at fortnightly
 17 intervals.
 18 The next heading in this protocol is
 19 "Procedure". I don't need to go through the detail of
 20 that save to note that the second paragraph down
 21 refers to the taking of blood samples on a regular
 22 basis, and tested for bilirubin, SGOT, et cetera.
 23 If we go further down -- sorry, data recording
 24 refers to data being sent to Dr Cossart at Colindale
 25 and also shared with Dr Kirk.

125

1 Those boys on cryoprecipitate have been selected from
 2 treatment centres where only this material is
 3 available."
 4 Then if we go to the third paragraph on that
 5 page:
 6 "Commercial manufacturers, viz Travenol
 7 Laboratories and Serological Products have agreed to
 8 reserve large batches of concentrates for this study.
 9 The Directors, or their deputies, will be responsible
 10 for ensuring that a patient receives only his allotted
 11 material for a period of eighteen months after entry.
 12 Batches should be arranged so that an individual
 13 receives preferably only one batch over a three-month
 14 period."
 15 Then there are references to testing analysis,
 16 possible future extension of the study. It's said it
 17 is proposed to acquaint the UK Haemophilia Centre
 18 Directors with the pilot study at the meeting in
 19 September 1975 and those are the minutes of the
 20 meeting we looked at before lunch.
 21 Then bottom of the page:
 22 "Although this is, in principle, a simple study
 23 the operation and organisation of batches of material
 24 will present some problems. However, the actual units
 25 of factor VIII used will be no greater than in the

127

1 Then under the heading "Illness", if a patient
 2 develops symptoms suggestive of hepatitis, form C3
 3 should be completed. That's a procedure that "should
 4 [also] be followed if the liver function tests suggest
 5 hepatitis".

6 Then there's a reference to the outbreak of
 7 non-B hepatitis at Treloar's the previous year, so
 8 1974, where it's said:

9 "... it was found that the period of illness and
 10 abnormal liver function tests was relatively short."

11 Then it says:

12 "... should a patient become ill it will be
 13 necessary for serial blood samples to be taken for
 14 LFTs - perhaps twice weekly, depending on the clinical
 15 status of the patient."

16 Bottom of the page refers to arrangements during
 17 the holidays:

18 "Lord Mayor Treloar College boys require special
 19 arrangements for their treatment during the Christmas,
 20 Easter and Summer vacations to ensure continuity of
 21 therapy. College boys on concentrates have been
 22 selected from the following centres only - Oxford,
 23 The Royal Free and Newcastle. Arrangements are being
 24 made with these Centres that the boys receive only the
 25 therapeutic material to which they have been allotted.

126

1 normal day to day treatment and the study may indeed
 2 be viewed as a rationalisation of replacement therapy,
 3 since the probable donor exposure to each participant
 4 should be less than that experienced prior to his
 5 entry to this study."

6 So it's essentially being said that this -- I'm
 7 paraphrasing, clearly, but this is a benign thing for
 8 participants because their donor exposure is going to
 9 be reduced. What it doesn't explain is why, if that's
 10 the understanding, that's not the broad approach to
 11 therapy at Treloar's in any event.

12 So that's the protocol produced by Dr Kirk in
 13 September 1975. As I say, I won't go back to the
 14 discussion that was then held a few days later at the
 15 Haemophilia Centre Directors meeting about the study.
 16 There's a subsequent document which I'm going to go to
 17 later so I won't go to it now, but what it shows in
 18 fact in relation to Treloar's boys, 21 boys restricted
 19 to cryoprecipitate for the study, eight Kryobulin, six
 20 Hemofil, one Profilate, four given Elstree
 21 concentrate, and five Factor IX.

22 There is some evidence of consent being sought,
 23 interaction with the parents, and so, although it's
 24 not clear what information is then -- has been
 25 provided to elicit the consent, but we've just got

128

1 a handful of examples of documents.
 2 If we look first of all at TREL0000225_048, we
 3 can see a letter from Dr Kirk, December 1975. We
 4 looked I think at a very similar letter earlier in the
 5 week saying:
 6 "In view of the problems of hepatitis in
 7 haemophilia, I have been asked by Dr Rosemary Biggs,
 8 of the Oxford Haemophilia Centre, to conduct a survey
 9 on this subject."
 10 Whether that's -- assuming this relates to the
 11 same study, whether that's an entirely accurate way of
 12 describing a study set up and authored by Dr Kirk
 13 is -- it may be questionable.
 14 "Your son has been selected to receive only cryo
 15 when he requires transfusing. By limiting him to this
 16 type of factor VIII containing material it will be
 17 easier to trace the source should he contract
 18 hepatitis.
 19 "If you have any queries concerning this survey
 20 I would be happy to discuss the matter with you."
 21 So that appears to be the information that was
 22 provided, at least on this occasion, to a parent. It
 23 looks like it's a fairly standard form document, it's
 24 "Dear" and then blank.
 25 Then there is some correspondence which shows

129

1 that she's given him Kryobulin, and saying in the last
 2 paragraph:
 3 "I am sorry in this will interfere with your
 4 hepatitis trial."
 5 So again, obviously, knowledge from the home
 6 haemophilia clinician of the trial but doesn't tell us
 7 what was known by the patient or pupil.
 8 If we go to TREL0000103_018, we've got a letter
 9 here from April 1976 from Dr Kirk to a Dr Peard in
 10 Horsham, again referring to a particular pupil:
 11 "As you know, this boy is on the hepatitis study
 12 and I have just received the results of his liver
 13 function tests.
 14 "He would appear to be developing hepatitis
 15 which is probably associated with an infusion of
 16 Factor VIII concentrate (Hemofil B) on
 17 15 February 1976."
 18 Then reference is made to hepatitis B being
 19 negative, so it is possible that he's developing
 20 hepatitis maybe of the B or non-B type:
 21 "Please could you let me know if he becomes ill
 22 and should you see him I would appreciate further
 23 blood samples. If he requires admission I would be
 24 pleased to come to Horsham and see him."
 25 There doesn't appear to be any suggestion there

131

1 discussions between Dr Kirk and the home Haemophilia
 2 Centre in relation to this study, so we can again look
 3 at some examples.
 4 TREL0000280_074.
 5 This is Dr Mann at Birmingham Children's
 6 Hospital to Dr Kirk in September 1975, second
 7 paragraph:
 8 "We would be pleased to help in your study ...
 9 do in fact only use cryoprecipitate for our
 10 haemophiliacs, with one or two rare exceptions ..."
 11 And then refers to two patients and then says,
 12 last paragraph:
 13 "Please could you let me know when you wish to
 14 start this study? The quantities of blood which you
 15 will be removing will be quite large, and I wonder
 16 whether you had thought of giving iron therapy too?"
 17 Is the question posed.
 18 So there's an interaction with the home
 19 haemophilia clinician but doesn't tell us what, if
 20 anything, has been said to the patient or the
 21 patient's parents, in that regard.
 22 TREL0000211_022 is a little later on, April '77,
 23 but we can see from the last sentence it is concerned
 24 with the hepatitis trial. This is from Dr Swinburne
 25 to Dr Kirk in relation to a particular patient saying

130

1 of a change of course or a change of therapy, it's
 2 just an identification that through the concentrate
 3 being provided to this patient on the study, that they
 4 appear to be in the process of developing hepatitis.
 5 Then if we go to OXUH0003758_006.
 6 This is one of the reports produced by Dr Kirk.
 7 This is date 20 April 1976, and it's a report on the
 8 autumn term '75 and spring term '76 and there's
 9 a discussion of the hepatitis study on page 5. It
 10 says:
 11 "This started at the beginning of the Autumn
 12 term and the conditions for entry and other
 13 requirements are recorded elsewhere in the Protocol."
 14 So this appears to pre-date some of the other
 15 documents, this is suggesting that the start of the
 16 study may have predated, I think, some of the other
 17 documents we've looked at. But in any event:
 18 "The boys were restricted to a particular type
 19 of factor VIII replacement material. This is shown in
 20 Table VI.
 21 "Seventeen cases from Oxford ... were included
 22 from November 1975 whilst two Edinburgh patients
 23 joined in February 1976. It is apparent that in
 24 conducting a survey of this type it is difficult to
 25 ensure the collection of frequent blood samples unless

132

1 the patients are readily available. Furthermore,
 2 limiting patients to particular replacement materials
 3 also creates problems because of the overall shortage
 4 of factor VIII products. It is inevitable that some
 5 patients will receive, and have received, materials
 6 other than their specified product. The nursing and
 7 laboratory staff are to be congratulated on the
 8 careful and thorough way that specimens have been
 9 collected, separated and dispatched to the Virus
 10 Reference Laboratory. The work of Dr Hugh Platt and
 11 the Chemical Pathology Department of Basingstoke
 12 District Hospital has been invaluable in processing
 13 large numbers of liver function tests which has been
 14 accomplished quickly and efficiently".

15 Then if we go further down it says:

16 "So far no patients from Newcastle have
 17 registered on the study but it is hoped that 12
 18 patients restricted to Hemofil will be included in the
 19 near future."

20 Then this:

21 "Since the start, three of the College boys have
 22 contracted hepatitis."

23 Details are then given. The first is a boy who
 24 was restricted to Kryobulin. The last sentence of
 25 that paragraph says:

133

1 from chronic hepatitis and, if they are, whether this
 2 is benign or an aggressive process. Four boys have
 3 had liver scans which all show mild, but very
 4 definite, abnormalities. It is proposed to do further
 5 scans next term on other indicated boys. Regarding
 6 the problem with the acute hepatitis cases, it is
 7 important to exclude other causes of hepatitis apart
 8 from hepatitis B, namely: hepatitis A, cytomegalovirus
 9 and EB virus."

10 Then there's a reference to hepatitis A.

11 Sir, I think you asked earlier in the week about
 12 tests for hepatitis A. This tells us that a suitable
 13 test has not yet been devised which is uniformly
 14 satisfactory in relation --

15 **SIR BRIAN LANGSTAFF:** No, part of what lay behind the
 16 question was a sense that non-A, non-B has plainly
 17 been identified in some of the studies since 1974, if
 18 not before.

19 **MS RICHARDS:** Yes.

20 **SIR BRIAN LANGSTAFF:** And that suggests that A can be
 21 excluded, so there has to be some basis for excluding
 22 it.

23 **MS RICHARDS:** Yes.

24 **SIR BRIAN LANGSTAFF:** And I had assumed, without actually
 25 knowing it, that there was therefore a test. This

135

1 "Provisionally he has been labelled as a case of
 2 anicteric non-B hepatitis."

3 The second boy is described as showing clinical
 4 and laboratory evidence of hepatitis soon after being
 5 entered on the hepatitis study. It says at the bottom
 6 of the page:

7 "This case is interesting in that the probable
 8 source of the infective material can be
 9 identified ..."

10 And again the reference is to particular batches
 11 of Kryobulin:

12 "This was his first exposure to large pool
 13 concentrates ..."

14 Then the third is a patient described as a mild
 15 haemophiliac, which doesn't fit with what else we know
 16 about pupils at the college but, in any event, it
 17 refers to that patient receiving Hemofil. Said to be
 18 at risk of developing hepatitis B, and is going to be
 19 investigated further in the summer term.

20 Then the next paragraph:

21 "Apart from these three cases of acute
 22 hepatitis, a number of boys have permanently elevated
 23 liver function tests. At present work is directed at
 24 determining the significance of these findings for it
 25 is important to ascertain whether they are suffering

134

1 looks as though there is a test, although it is not
 2 a very good one.

3 **MS RICHARDS:** That seems to be Dr Kirk's view.

4 Then it continues with a discussion about the
 5 arrangements for the testing of samples.

6 And then -- sorry, that's the discussion, then,
 7 in this report about the hepatitis study, so we can
 8 see as at April 1976 it's identifying three boys with
 9 hepatitis and number of boys with permanently elevated
 10 liver function tests.

11 If we just finish by going to the next page,
 12 just below the heading "Home Treatment", so the next
 13 paragraph down, I just draw attention to this, it's
 14 not specifically relating to research as I understand
 15 it, but it says:

16 "Finally, acknowledgement must be made to the
 17 Army Blood Supply Depot at Aldershot, under the
 18 direction of Colonel John Winwick, for their continued
 19 help both in the supply of therapeutic materials in an
 20 emergency and the provision of normal plasma for use
 21 as standards in the variety of coagulation tests
 22 performed at this Centre."

23 So it would appear in some respect or another
 24 the Army Blood Supply Depot is providing materials to
 25 Treloar's.

136

1 If we can then go to page 11, I referred earlier
2 to who was getting what on the hepatitis study. You
3 can see here where the figures that I referred to were
4 drawn from, so cryoprecipitate, Kryobulin, Hemofil,
5 Profilate, Lister, Elstree concentrate and then
6 Factor IX.

7 There are, again, a handful of further documents
8 relating to information being provided to parents
9 and/or clinicians about participation in the study.

10 So TREL0000064_017 is a sheet of some kind about
11 a particular patient, saying:

12 "The above named patient is involved in
13 a national prospective hepatitis study. It is thus
14 very important that he receives only f.VIII containing
15 material of one type: in his case: CRYOPRECIPITATE."

16 So he's one of the category of boys receiving
17 cryoprecipitate, and that's signed by Dr Kirk.

18 Then TREL0000250_016 is a letter,
19 September 1975. So, again, it demonstrates that there
20 are communications ongoing between Dr Kirk in relation
21 to the hepatitis study and other clinicians, but less
22 clear as to the extent of parental or patient
23 involvement.

24 "Dear Dr Kirk,

25 "Thank you for your letter concerning your

137

1 differences between the cases restricted to Hemofil
2 and Kryobulin. In the next stage of the Study, I am
3 proposing to restrict patients to either commercial
4 concentrates as a group or Cryoprecipitate or Lister
5 Concentrate as I understand that all commercial
6 Factor VIII concentrates are being made from North
7 American plasma, including Kryobulin."

8 So that issue again about the source of
9 Kryobulin donations is there addressed.

10 "Would you have any objections to these
11 proposals or do you think it would still be worthwhile
12 to restrict patients to a particular brand of
13 commercial Factor VIII concentrate?"

14 There's an update of the position as of
15 April 1977.

16 Then in October 1977, there's a letter from
17 Dr Craske to Dr Aronstam at HHFT0000925_001,
18 7 October 1977.

19 First paragraph refers to:

20 "The arrangement which I had with Peter Kirk is
21 that we had been testing bloods taken from the boys at
22 intervals over the past two years as part of the
23 prospective study of the incidence of hepatitis, and
24 abnormal liver function tests associated with
25 different forms of Factor VIII therapy. Peter Kirk is

139

1 proposed study of patients with haemophilia.

2 "In answer to your queries:

3 "1. We will certainly find it easy to give [the
4 patient] cryoprecipitate only when he needs treatment.

5 "2. The blood samples that you require. We
6 will certainly collect clotted blood samples whenever
7 he has treatment."

8 Then the same question as Dr Mann had posed:

9 "Are you going to put the children on
10 prophylactic iron therapy?!"

11 Then 3:

12 "I would be pleased to notify you if [he] would
13 develop hepatitis."

14 Again, that doesn't tell us anything about what
15 the pupil or parents knew.

16 Then CBLA0000590. It's an update from Dr Kirk
17 on 1 April 1977 to Dr McGrath at the National
18 Institute for Biological Standards.

19 "Dear David,

20 "We have been conducting the Hepatitis Survey
21 for some 19 months and are almost in a position to
22 have a significant result. All the cases of clinical
23 hepatitis and almost all the cases of asymptomatic
24 hepatitis were confined to the patients restricted to
25 commercial concentrates. There were no significant

138

1 now writing up his results."

2 Just pausing there, there doesn't appear to be
3 any positive evidence of pupils or patients being
4 aware of bloods being tested in this way.

5 Then Dr Craske says:

6 "I [am] keen to continue our collaboration; this
7 is for two reasons:-

8 "1) We are interested in doing more work to try
9 and establish the aetiology of the non-B hepatitis we
10 have found associated particularly with commercial
11 freeze-dried Factor VIII [concentrates].

12 "2) I think it will be valuable to take serial
13 serum samples from these boys with the idea of trying
14 new tests, particularly those thought to give good
15 correlation with chronic liver damage."

16 Then picking that up in not the next paragraph
17 but the one below:

18 "We are particularly keen to obtain specimens as
19 early as possible from patients in whom hepatitis is
20 suspected ..."

21 Then the last sentence of that paragraph:

22 "In the absence of any symptoms of disease I
23 would suggest taking a blood specimen once a term from
24 each boy, this will give us pre-infection sera should
25 any hepatitis become evident at a later date."

140

1 So it would appear a bank to stored samples
2 essentially being built up there from Treloar's
3 pupils, with those samples being sent to the Public
4 Health Laboratory Service under Dr Craske.

5 Just actually on a separate point, but if we
6 look at the last paragraph, Dr Craske says:

7 "I shall be at the annual meeting of Haemophilia
8 Centre Directors at Oxford on the 24th October ... if
9 you wish, we can talk about this further on that
10 occasion."

11 Of course it is important to bear in mind that
12 whilst we have the minutes of the various Haemophilia
13 Centre Directors meetings, what they won't capture are
14 all the kinds of exchanges and discussions that might
15 have gone on outside a formal setting during the
16 Haemophilia Centre Directors meetings.

17 Then I think there's just two more documents in
18 relation to the hepatitis study.

19 The first is at HCDO0000544.

20 This is one set of minutes from the Hepatitis
21 Working Party. The date is 14 December 1977, and
22 Dr Kirk was a member of the Hepatitis Working Party.
23 Under the heading, "Investigation of Chronic
24 Hepatitis - Indication for Liver Biopsy", the minutes
25 record as follows:

141

1 an acute attack of Hemofil associated non-B hepatitis.
2 He still has abnormal liver function tests."

3 There is then recorded a discussion of problems
4 associated with the interpretation of abnormal liver
5 function tests and liver disease in haemophiliacs.

6 Then there's a further discussion over the page,
7 I won't go through the detail of it because it goes
8 wider now than the question of the hepatitis studies
9 at Treloar's, but there's a discussion about liver
10 biopsy, discussion about investigation of liver
11 disease, and three categories identified of patients
12 with abnormal liver function tests, and then
13 a proposal for investigations and recommendations to
14 the Haemophilia Centre Directors.

15 The last document then is an application for
16 a research grant from Dr Craske, so it's not directly
17 from Treloar's, but it does involve or include some
18 information about Treloar's.

19 CBLA0000756. It's a letter from a Mr or
20 Ms Buxton, principal medical officer to Dr Maycock, 19
21 April 1978, and you'll see it refers to an attached
22 application for a research grant from Dr Craske.

23 If we go to page 6 we can see Dr Craske is there
24 recording under the heading -- bottom of the page, I'm
25 sorry:

143

1 "Dr. Kirk opened the discussion by describing
2 the results of the prospective survey on hepatitis
3 carried out at Edinburgh and Alton. Forty-five boys
4 at Alton aged between 11 and 16 had been studied.
5 There was a higher proportion of patients treated with
6 freeze-dried products who had consistently abnormal
7 liver enzyme tests, compared with the boys treated
8 with cryoprecipitate. Fifteen of these boys had a
9 SGOT of at least two and a half times the upper limit
10 of normal for most of the period studied. They were
11 well and had no clinical evidence of chronic liver
12 disease."

13 Then there's reference to palpability of the
14 spleen and liver being enlarged in some cases:

15 "Five ... boys ... found to have abnormal BSP
16 tests ... no definite correlation with previous
17 Factor VII therapy, though this had yet to be fully
18 investigated."

19 In the next paragraph Dr Kirk continues:

20 "... two other boys with clinical symptoms and
21 signs consistent with chronic active hepatitis. One
22 had hepatitis B after a transfusion of Hemofil in
23 1974. He has evidence of chronic liver disease and is
24 still HB Ag positive three years after his acute
25 attack. The second patient had normal LFT's prior to

142

1 "Chronic sequelae

2 "A recent study carried by members of the
3 Haemophilia Directors' Hepatitis Working Party, in
4 which groups of haemophiliacs were confined to one
5 type of Factor VIII treatment, as far as possible, has
6 shown that 15/45 boys at the Lord Mayor Treloar
7 College, Alton, had consistently elevated serum enzyme
8 levels (two and a half times the upper limit of
9 normal) for periods of six months or more. There was
10 a due association with the use of freeze dried Factor
11 VIII concentrate", et cetera, et cetera, reference to
12 having evidence of chronic active hepatitis, one
13 hepatitis B.

14 Then the question Dr Craske poses in the next
15 paragraph is:

16 "... whether these changes are indicative of
17 early liver disease which, in a proportion of
18 patients, may be the forerunner of chronic active
19 hepatitis or cirrhosis."

20 Then a reference to non-A, non-B hepatitis.

21 Those are probably the most salient documents
22 relating to the hepatitis studies at Treloar's, but it
23 is clear that the incidence of hepatitis in boys at
24 Treloar's was studied over a prolonged period of time
25 in the 1970s, with then this particular focus under

144

1 Dr Kirk on limiting treatment to one type of product
2 add then examining the consequences, and we've seen
3 some of the results that were then reported.

4 I should say what we don't see is any indication
5 of any change in therapy or change in the approach to
6 treatment following the hepatitis studies.

7 Before I move on to look much more shortly at
8 a handful of the other types of research that are
9 undertaken at Treloar's, there's just one document
10 which takes me back to the prophylactic studies and
11 the question of what information was or wasn't made
12 available to parents or patients.

13 Soumik, could we have -- and this will have been
14 sent to you this afternoon, I think, CGRA0001060.

15 Thank you. You are ahead of me.

16 It's a letter from Dr Jones Newcastle, dated 12
17 April 1973.

18 "Dear Mr and Mrs Longstaff.

19 "I am sorry that you could not come to the last
20 clinic and I enclose another appointment. You will
21 have received a letter from Lord Mayor Treloar asking
22 for your permission for Peter to participate in the
23 special trial of regular factor VIII injections."

24 So that suggests there was a letter directly
25 from Treloar's to parents at least in this case.

145

1 receipt or use of placebo.

2 Just then going to, as I say, deal very much
3 more shortly with a handful of other types of research
4 that we know were undertaken at Treloar's.

5 So if we look at RLIT0000198, on the right-hand
6 side, and this a publication in the Lancet in 1980.

7 There's a heading:

8 "Double-blind controlled trial of three dosage
9 regimens in the treatment of haemarthroses in
10 haemophilia A."

11 And this was one of I think we've said in our
12 written note three studies but I think it is probably
13 in fact two studies, three reports referring to actual
14 studies, conduct at Treloar's to investigate the
15 optimum dosage of Factor VIII required to treat
16 a bleed. As I say, I won't go into the detail of it
17 but we can see here reference to the double-blind
18 controlled trial in terms of three dosage regime.
19 That's written up in 1980.

20 And then there's a further publication at
21 RLIT0000098.

22 This is probably about the same underlying
23 study, but there is a second double-blind controlled
24 trial at RLIT0000111.

25 And we can see this is "... a double-blind

147

1 Refers to someone else's parents also being accounts
2 for their permission. Then we can see Dr Jones saying
3 this:

4 "I saw the [reference to other set of parents]
5 last week and explained that I was in complete
6 agreement with the trial and that it could do nothing
7 but good for the boys and for other patients. It has
8 been most carefully worked out, was discussed at the
9 last meeting of the Haemophilia Directors in Oxford,
10 and has the support of the Medical Research Council of
11 the United Kingdom. I will of course be extremely
12 happy to discuss any points that concern you about the
13 trial when I see you, but I wonder if you would feel
14 able to sign the acceptance form for Lord Mayor
15 Treloar at this stage."

16 It refers to doctors trying to get things
17 organised for the next term.

18 Now this because of the date and because of the
19 reference to the involvement of the Medical Research
20 Council must be a reference to the first trial of
21 prophylaxis, which of course involved placebos. And
22 you'll see, sir, there's no reference at least in this
23 material, and indeed Dr Jones's approval of the trial
24 saying it could do nothing but good for the boys and
25 other patients, there's no reference there to the

146

1 controlled trial of two dose levels of factor VIII in
2 the treatment of high risk haemarthroses in
3 haemophilia A". Again, I'm not going to go through
4 the detail of them but it is a further evidence of
5 a different type of research being undertaken, and
6 trials being undertaken in relation to the pupils at
7 Treloar's. I just want to then look at a handful of
8 documents that show a degree of interaction with
9 parents, some in relation to this, the double blind
10 controlled trials of three or two doses, and some may
11 be in relation to other aspects of research or trials
12 at Treloar's.

13 But it gives us a flavour of some of the
14 interaction between Treloar's and parents.

15 TREL0000105_040.

16 So this is a letter from a parent May 1978 to
17 Dr Aronstam and Dr Painter.

18 "Thank you for your recent letter concerning the
19 higher dosage of Factor VIII. Whilst I agree to the
20 first part of your programme (the higher dosage) I do
21 not feel I can give my permission to your other
22 suggestion concerning the other substance you mention.
23 Before agreeing to anything like this I would like to
24 know a lot more about this 'other substance', and for
25 it to be tested at length so I would ask you not to

148

1 include [then the patient name redacted] in your
 2 programme."
 3 So there has clearly been a form of
 4 correspondence from Treloar's directly to a parent in
 5 relation to what appears to be the trial relating to
 6 higher dosages, but perhaps an indication of a lack of
 7 sufficient information to enable the parent to feel
 8 comfortable giving consent to all aspects of what had
 9 been required.
 10 Again, there is a letter expressing similar
 11 concerns from a different parent at TREL0000147_018.
 12 A letter in fact of the same date, this
 13 addressed to Dr Painter, suggesting agreement that the
 14 patient "should take part in your first project". So
 15 again, there's a letter referring to two projects.
 16 "If the second project only requires the
 17 monitoring of one bleed then this also has our
 18 consent. As a matter of interest we would be grateful
 19 if you would let us know the nature of the 'other
 20 substance' and the results you would hope to obtain."
 21 So again, some indication that whatever letter
 22 has gone out to parents from Treloar's, it's not
 23 giving information about what the actual substance is,
 24 that it's proposed the pupils should be treated with.
 25 Then again, the same month, TREL0000070_027,

149

1 the effects of a substance [again undefined what
 2 that is] which might improve the efficacy of the
 3 Factor VIII given, we would have no objection - in
 4 fact we are enthusiastic about him doing so."
 5 There a patient -- a parent expressing
 6 particular concerns. Again, it gives rise to the
 7 question and unfortunately we don't have copies of all
 8 the correspondence that went out from Treloar's,
 9 although we may still locate it. But it raises the
 10 question of whether the implications of receiving
 11 higher dosages, possible increased risks, had been
 12 spelt out to all parents. This is a parent who seems
 13 to be reaching that conclusion as it were on their own
 14 initiative or based on their own knowledge.
 15 There is then, at TREL0000147_019, a reply from
 16 Dr Painter to one of the letters which indicates what
 17 the other substance is, or provides some other
 18 information about the other substance. We're told
 19 that:
 20 "... it is in fact a hormone produced in the
 21 body and has the effect of concentrating the urine
 22 whenever the intake of blood is reduced ... has been
 23 found to raise the Factor VIII level in mild
 24 haemophiliacs ... As far as we can ascertain, no-one
 25 has tried the effects of using this substance in

151

1 there's a letter from another parent, which says:
 2 "We agree that if [some] definitive information
 3 can be obtained on the dosages of Factor VIII required
 4 that would be helpful. However, we are not happy
 5 about our son ... being included in an investigation
 6 conducted as you describe. We are anxious that the
 7 total amount of Factor VIII he receives should be kept
 8 to a minimum, particularly to lessen the risk of his
 9 developing antibodies to the material. Over recent
 10 holidays we have found that for most bleeds if they
 11 are treated promptly, and with sensible behaviour on
 12 [his] part, 3 240-unit bottles of Hemofil are
 13 sufficient to arrest the bleeding and avoid
 14 a recurrence. For a bleed in a 'difficult' place or
 15 if treatment is delayed a larger dose is necessary and
 16 the risk of a recurrence is considerable. From what
 17 we learn from [the pupil], it seems to me that the
 18 dose he normally receives at the Treloar Haemophilia
 19 Centre is quite high and we would not wish him to
 20 receive a higher dose except in [particular]
 21 circumstances."
 22 **SIR BRIAN LANGSTAFF:** "Peculiar circumstances".
 23 **MS RICHARDS:** "... except in peculiar circumstances."
 24 Sorry.
 25 "As regards [his] participation in a study of

150

1 conjunction with a transfusion of Factor VIII in
 2 a severe haemophiliac [and so] we intend to try this
 3 to see if it might either prolong the effective life
 4 of the injected material or perhaps enable a smaller
 5 dose to be as effective over a given period of time as
 6 the larger one."
 7 So we see the explanation there but it perhaps
 8 begs the question of why the explanation was not
 9 included in the information that was provided to
 10 parents in the first instance. The details of who
 11 this letter is addressed to is redacted, but what
 12 I can say, and it's interesting to note, is this is
 13 actually a letter addressed to a doctor who it appears
 14 may also have been a parent. And so an informed
 15 parent may have been able to raise questions and get
 16 an answer, and get information which should perhaps
 17 have been included in whatever is provided to parents
 18 in the first instance.
 19 There are then, I'm not going to go to them,
 20 I think but there are then again a handful of
 21 communications between Treloar's and doctors who are
 22 treating haemophilia clinicians about involvement in
 23 these studies.
 24 Perhaps one worth looking at TREL0000327_005.
 25 Here we have Dr Aronstam writing to

152

1 Dr Swinburne. The first paragraph refers to the trial
2 comparing a normal with a high dose for bleeds, and he
3 says:

4 "I enclose a copy of a paper based on the
5 identification of the high risk bleeds for your
6 information."

7 So again, we can see information being provided
8 to treating haemophilia clinicians but it's not
9 apparent that the same information is being provided
10 to parents.

11 Then a further type of research that was
12 undertaken at Treloar's is apparent from
13 HHFT0001201_004, and so this is an outline protocol
14 produced by Dr Jones and Dr Aronstam, and we can see
15 the aim describes the study as:

16 "... [forming] Stage I of a proposed
17 investigation into the potential benefits of High
18 Purity Factorate. The results obtained will form the
19 basis of the decision to proceed to Stage II - a trial
20 of Factorate in the prophylactic management of
21 Haemophilia."

22 Then:

23 "The objective ... is to compare the in-vivo
24 half-life and recovery of High Purity Factorate with
25 that of another commercially available factor VIII

153

1 of an Ethical Committee. There is no Regulatory
2 implication in this study."

3 Again, what we don't have is any kind of
4 understanding of the information being provided to
5 patients or parents to elicit informed consent.

6 If we go to TREL000012_113, we can see here
7 a document we've seen now on a number of occasions, so
8 the consent form which gives no information about what
9 trial is being consented to. It's just says "a trial
10 ... as explained by Dr Aronstam".

11 The reason for referring to it is if we go over
12 the page, we've got a very slightly different form,
13 where here the agreement is to:

14 "... taking part in the trial of a new
15 Factor VIII product as explained by Dr Aronstam."

16 It still doesn't say what the product is. But
17 somebody has written on the top, "HL [half life]
18 Trial", which would tend to suggest that it may be
19 related to the protocol that we just looked at.

20 And again, if we look at TREL000108_158, we've
21 got another example of a consent form in this format.

22 So again, someone has handwritten on it "HL [half
23 life] trial", and the consent is to taking part in
24 a new Factor VIII product as explained by Dr Aronstam.

25 There are some comments from the bottom of the

155

1 concentrate of Intermediate Purity (Hemofil No. 2)"

2 A little further down the page, under the
3 heading "Patient Numbers", it says there's a minimum
4 number of 12:

5 "Two centres will participate, with a minimum
6 number at each centre of 6."

7 The bottom of the page tells us that the
8 products to be used are Armour, Factorate High Purity
9 and Hemofil produced by Travenol.

10 If we go over the page, we can see the dose is
11 to be calculated so that the patient's Factor VIII
12 level will be raised to 50%.

13 There's then reference to investigations in
14 a range of blood samples. It says:

15 "The samples will be treated as fresh specimens
16 at each Centre."

17 But someone has then written "+ stored!"

18 Then the bottom of the page refers under the
19 heading "Ethics":

20 "Informed consent will be obtained from all
21 patients, who will have the right to refuse or to
22 withdraw consent without prejudice to their routine
23 treatment.

24 "The investigators undertake this pilot study on
25 their own responsibility and do not need the agreement

154

1 page from the parents saying:

2 "... very pleased to hear a new type of
3 Factor VIII has been manufactured and only hope it
4 proves successful."

5 Again, we can't ascertain from this what
6 information has actually been provided to the patient,
7 or their parents.

8 This work was written up at RLIT0000104.

9 I'm not proposing to go through the details
10 of it. We can see it was written up by a number of
11 authors and it refers to the involvement of both
12 Treloar's and the Royal Victoria Infirmary at
13 Newcastle upon Tyne. It may just be interesting to
14 note at page 6, under the heading "Acknowledgments":

15 "This work was supported by a grant from Armour
16 Pharmaceutical Company Ltd."

17 If we go to HHFT0001201_003, we can see a letter
18 from Armour to Dr Jones dated 23 December 1980, and it
19 would appear from this that Armour have had some
20 considerable involvement in the development of the
21 protocol and it refers to a discussion in Alton, so
22 presumably at Treloar's.

23 "Please find enclosed a copy of a Protocol,
24 revised according to our discussion in Alton on
25 1st December."

156

1 And then it refers then to discussion and
 2 agreement about various points:
 3 "The ... centres taking part will be Newcastle
 4 and Alton.
 5 "... each centre will recruit a minimum number
 6 of 6 cases ...
 7 "The study will start in January 1981."
 8 There's then an estimate of costs.
 9 If we go over the page, agreement that the costs
 10 will be met from research funds initially, and then
 11 Armour are going to reimburse on receipt of an
 12 invoice.
 13 "We agreed that the Hemofil 2 would be obtained
 14 and provided by us. We therefore need to know as a
 15 matter of urgency the quantities which you and
 16 Dr Aronstam calculate to be necessary."
 17 So a degree of close involvement it would appear
 18 from Armour in that trial which obviously was seeking
 19 to compare an Armour product with the Hemofil product.
 20 Then there are just, I think, just a few
 21 examples of other forms of treatment that I can refer
 22 to. I think probably in about 10 or 15 minutes so it
 23 may be worth completing it rather than having a break
 24 and coming back, if --
 25 **SIR BRIAN LANGSTAFF:** Yes, well, let's do that then, shall

157

1 page, we can see in paragraph 3:
 2 "Concern has been expressed as to whether AIDS
 3 might be introduced into U.K. haemophiliacs via the
 4 use of Hyland factor VIII or Autoplex. The Chairman
 5 of the Working Party has sought clarification from
 6 Travenol Laboratories as to whether any of their
 7 material is known to have produced this problem in the
 8 United States and it is hoped that an answer to this
 9 question will be available at the meeting."
 10 There is also, in relation to the UKHCDO study,
 11 some evidence of patient information, HHFT0001161.
 12 Sir, this not the solely Treloar's study, this is the
 13 UKHCDO's Inhibitor Working Party study, but we can see
 14 it's headed "Patient Consent Form", and this appears
 15 possibly to be a draft of some form of patient
 16 information leaflet.
 17 If we go to the third page you'll see that there
 18 is then a consent form, a blank standard consent form.
 19 But there is no evidence which indicates what
 20 form of consent, if any, was sought for the first
 21 Autoplex trial undertaken under the auspices of
 22 Treloar's alone in 1980 and 1981.
 23 We know there was also a study in relation to
 24 DDAVP. There is again some evidence of exchanges
 25 between Treloar's and parents in relation to that.

159

1 we. But if you begin to think that it's going to take
 2 too long --
 3 **MS RICHARDS:** Yes, I will --
 4 **SIR BRIAN LANGSTAFF:** Do remember people might appreciate
 5 a break.
 6 **MS RICHARDS:** Yes.
 7 So another area of study was trials of Autoplex.
 8 The report of that is at RLIT0000110. I think I can
 9 just refer to the heading here:
 10 "The use of an activated factor IX complex
 11 (Autoplex) and the management of haemarthroses in
 12 haemophiliacs with antibodies to factor VIII."
 13 We can see there again, it's origin is Treloar
 14 Haemophilia Centre.
 15 So that's a study resulting in this publication,
 16 a study I think carried out probably in 1980, 1981,
 17 published in 1982. There was a further study under
 18 the auspices of the UKHCDO's Inhibitor Working Party.
 19 It may be worth just looking at that.
 20 It's OXUH0000447_002.
 21 Sir, this is a report of the UK Factor VIII
 22 Inhibitor Working Party in October '83, so
 23 a subsequent study continuing the trial of Autoplex
 24 versus Factor VIII. Again, I am not proposing to go
 25 through the detail of it but if we go to the second

158

1 Although the information is relatively limited and
 2 there's no patient information leaflet or anything of
 3 that kind.
 4 If we look at HHFT0001430, we've got some
 5 handwritten notes about the involvement of seven
 6 Treloar's patients in a DDAVP trial in the summer
 7 of 1982.
 8 That was published at RLIT0000124, and I think
 9 also we can see:
 10 "The Influence of DDAVP on the Survival of
 11 Factor VIII in Severe Haemophiliacs."
 12 McLellan, Knight, McLellan, Wassef, Aronstam,
 13 Treloar Haemophilia Centre.
 14 Again, I'm not going to go to the detail, this
 15 is really just to try to give an understanding of the
 16 very wide range of research work and trials that were
 17 undertaken at Treloar's.
 18 There is also evidence of a number of students
 19 with inhibitors trialing the tolerance inducing
 20 protocol, and we saw reference to that with one of the
 21 witnesses earlier this week. We've got a number of
 22 examples of individual patients, individual pupils,
 23 being involved in that process. I won't go through
 24 the detail of them because they don't greatly add to
 25 the oral evidence you've already heard about that.

160

1 The one letter that may be worth looking at is
2 a rather later one in time, HHFT0000145_002. Just
3 before I look at this, the trials in relation to the
4 tolerance-inducing protocols for patients with
5 inhibitors in Treloar's appear to have been taking
6 place in the early part of the 1980s. It's perhaps
7 interesting to note in this letter in 1993 from
8 Dr Wassef to Dr Wallsley(?) at Poole, looking at the
9 paragraph beginning, "With regard to", the third
10 sentence reads:

11 "Inducing protocols [tolerance inducing] are now
12 coming to the fore again as treaters are encouraged by
13 the safety of materials."

14 So it tends to suggest that they, as it were,
15 perhaps unsurprisingly, fell out of popularity with
16 clinicians because of safety concerns and there is now
17 consideration being given to the reintroduction of
18 them.

19 There's one of the documents -- there is
20 a document in which Dr Wassef -- sorry, Dr Aronstam
21 expresses a concern about the use of the level of use
22 of Factor VIII exposure but I don't think I have
23 a reference to that it may be one of the documents we
24 looked at this morning.

25 **SIR BRIAN LANGSTAFF:** You give it -- I think it's in the
161

1 fact of a parent refusing to give their consent, and
2 indicating that at the bottom of the form.

3 Sir, there are just two further documents, then,
4 I want to look at today and they're just indications
5 of some of the interactions between Treloar's and
6 pharmaceutical representatives. So we've seen some
7 indication of that already.

8 IPSN0000331_001 is a letter from Speywood to
9 Dr Aronstam July 1980 and it's, I think, just one of
10 a range of communications from Speywood we've seen in
11 relation to different Haemophilia Centre Directors at
12 the time, but it's an approach to Dr Aronstam talking
13 about porcine product, in the second paragraph, and
14 making that available. Referring to difficulties in
15 terms of financing the research, and then offering
16 savings, towards the bottom of the page, on the price
17 of Humanate. Offering administration kits free of
18 charge, offering delivery within 24 hours, and so on.
19 Top of the next page, Mr Williams, the director says:

20 "I do hope you will be able to give us some
21 support and use Humanate for part of your treatment
22 programme."

23 We don't have any particular response from
24 Dr Aronstam to that letter so that might be thought to
25 be a fairly typical approach from what we've seen in

163

1 study, TREL0000173_070.

2 **MS RICHARDS:** I'm not sure that's the right reference, I'm
3 afraid, and I don't seem to have my hard copy. Yes,
4 I think we may have looked at this with one of the
5 witnesses in fact. If we look down the bottom of the
6 page -- yes, it is that paragraph. Thank you, sir.

7 It's the paragraph beginning:

8 "We have given him enough material to continue
9 his protocol through the summer ... We did try
10 increasing his exposure to antigen [et cetera, et
11 cetera]. It is possibly wrong to continue his
12 exposure to factor VIII at this level and I would be
13 interested in your own opinion."

14 The timing of this letter is July '83, so it's
15 not clear precisely what Dr Aronstam has in mind in
16 writing that, but in a letter from Aronstam to
17 Professor Bloom in July '83 might suggest that the
18 underlying concern to which Dr Aronstam was giving
19 limited voice is about the risk of AIDS.

20 Again, we've various examples of consent forms,
21 very much along the lines of the amongst we've already
22 looked at, they simply don't explain in the form what
23 it is the parent is consenting to so we've got
24 multiple other examples, all undated, along the lines
25 we've already looked at. We've got one example in

162

1 relation to other centres from a pharmaceutical
2 company to a Centre Director.

3 Then if we go to BAYP0000021_063, this is an
4 internal board meeting of Cutter Laboratories,
5 December 1980. The relevance for present purposes is
6 what's said at page 5, paragraph 8:

7 "It was agreed that full investigation should go
8 into the promises made by Carroll Jones and Sidney
9 Pugh to the Alton Centre where Doctor Aronstam had
10 been promised some form of financial support for
11 a research fellowship and had put in a great deal of
12 time and effort in putting forward a representation to
13 the Company. However, nothing materialised and it
14 seems that this was causing the Alton Centre to have
15 nothing to do with Cutter whatsoever. It was agreed
16 that this should now be looked into again with a view
17 to the Company being in a position to offer some form
18 of financial support for such a fellowship."

19 We don't presently have any more information
20 about this particular issue. But it does appear to
21 indicate perhaps a relationship between that which
22 a pharmaceutical company does or does not make
23 available to Dr Aronstam at Treloar's, and
24 Dr Aronstam's decisions about what products to
25 purchase for the Centre.

164

1 Sir, those are the documentary materials in
2 relation to research that I wanted to draw to the
3 attention of those listening and to you. There are
4 obviously other documents as well, but we hope that
5 gives some indication of the breadth and scope of
6 research that was being undertaken at Treloar's,
7 really from the late 60s, 1970 onwards. throughout the
8 1970s and well into the 1980s.

9 In terms of the question of the significance of
10 this research activity more generally, there may be
11 three issues which arise, and I'll identify them now
12 because I've no doubt that they are matters upon which
13 participants may wish to make submissions in due
14 course.

15 There's first of all the issue of patient
16 consent, and whether the ethical guidelines and
17 requirements in relation to obtaining informed patient
18 consent were adhered to and we've seen, obviously,
19 a range of material in that respect, and indeed, in
20 relation to a number of the studies, a dearth of
21 material.

22 The second broad issue, the ethical implications
23 of the particular study or trial or research and the
24 ethical implications of an individual pupil's
25 involvement in that research or trial, in other words,

165

1 to consider in due course, and that others may want to
2 make submissions on in due course. There may be
3 a multiplicity of other issues that arise out of the
4 examination of the research undertaken at Treloar's.

5 **SIR BRIAN LANGSTAFF:** Well, presumably your second
6 includes not only the ethical implications of
7 inclusion in a study, but of exclusion from it?

8 **MS RICHARDS:** Yes. Yes, so if we take the Hepatitis
9 Survey and limiting patients to one concentrate, which
10 might be thought to be a better thing than the
11 ordinary treatment regime, the patients who are not
12 being included on it are, by definition, continuing to
13 be exposed to multiple concentrates.

14 **SIR BRIAN LANGSTAFF:** Because I can see there may be an
15 argument that the rationale for doing the study would
16 suggest that that should be the norm, as opposed to
17 the exception. But that's a matter for submission in
18 due course.

19 **MS RICHARDS:** Indeed.

20 Sir, that completes the review of the
21 documentary material for the purposes of this week's
22 hearings.

23 **SIR BRIAN LANGSTAFF:** Yes. Well, that concludes this
24 presentation, does it?

25 **MS RICHARDS:** It does, sir.

167

1 were there aspects of that particular piece of
2 research, that particular study, which might have led
3 to the pupil being treated for their haemophilia in
4 a less than desirable or in an unsafe fashion, or in
5 a way that's increased the risk of exposure to viral
6 infection?

7 So that's looking at things essentially on
8 a trial-by-trial, piece-of-research by
9 piece-of-research basis.

10 Then the third issue is really to stand back and
11 look at the bigger picture of a pattern of research,
12 a pattern of studies, over many years in Treloar's,
13 and ask whether the focus on studying what is
14 repeatedly referred to as this unique group who offer
15 unique opportunities for clinical and laboratory
16 observation, whether that focus may have contributed
17 to a mindset on the part of the clinicians involved
18 with the care of pupils at Treloar's in which they may
19 have lost sight of questions about how properly to
20 treat individuals, how properly to communicate with
21 individuals as patients, and whether there was
22 a mindset of seeing pupils as objects for research and
23 study foremost, rather than as individual patients
24 first and foremost.

25 Sir, I raise those as issues that you may want

166

1 I should say that the written note which refers
2 to many -- not all of the documents, but most of the
3 documents that I've drawn attention to in the week,
4 will be published on the Inquiry's website, probably
5 next week, which will enable all those interested to
6 view it. It's already obviously been made available
7 to legal representatives and Core Participants, but it
8 will enable everyone who wishes to, to see what it
9 says.

10 **SIR BRIAN LANGSTAFF:** And looking ahead beyond next week?

11 **MS RICHARDS:** We have a break in hearings, not a break in
12 work, but a break in hearings for three weeks, and
13 then we resume on I think it's 19 July.

14 **SIR BRIAN LANGSTAFF:** I think it is too.

15 **MS RICHARDS:** Is that correct? For what will be a busy
16 two weeks. We are anticipating hearing three days of
17 evidence from Dr Diana Walford, medical officer within
18 the Department of Health, and then two days' of
19 evidence from Lord Simon Glenarthur, minister in key
20 parts in the 1980s.

21 **SIR BRIAN LANGSTAFF:** And that's the week beginning the
22 19th?

23 **MS RICHARDS:** That's the week beginning the 19th, so we're
24 anticipating sitting for five days that week.

25 Then in the following week, so the week

168

1 beginning the 26th, we're sitting, we hope, on the
2 27th, 28th and 29th to hear the evidence of
3 Lord Kenneth Clarke.
4 **SIR BRIAN LANGSTAFF:** Thank you. So 19 July, ten o'clock.
5 **MS RICHARDS:** Thank you, sir.
6 (3.25 pm)
7 (Adjourned until 19 July 2021 at 10.00 am)

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	I N D E X	
	Presentation by Counsel to the Inquiry re 1	1
	Lord Mayor Treloar School and College (continued)	
	(Video of Interview with Dr Aronstam 38	38
	played)	

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<p>MS RICHARDS: [79] 1/7 5/18 7/6 7/16 12/14 13/2 13/4 19/7 20/21 21/23 22/1 22/6 22/12 22/22 25/23 26/15 28/13 29/13 29/25 38/8 38/13 38/16 38/22 38/24 39/25 40/15 40/18 40/25 41/5 41/8 49/1 49/4 49/7 49/14 49/24 50/1 51/15 52/18 52/25 53/4 53/13 53/17 53/22 54/1 54/3 54/18 60/7 60/12 60/15 93/4 93/11 93/19 101/2 101/19 105/4 110/21 110/25 118/4 123/23 124/7 124/10 124/15 124/19 125/1 125/4 135/19 135/23 136/3 150/23 158/3 158/6 162/2 167/8 167/19 167/25 168/11 168/15 168/23 169/5</p> <p>SIR BRIAN LANGSTAFF: [77] 5/15 7/2 7/10 12/11 12/22 13/3 19/5 20/19 21/17 21/24 22/2 22/7 22/18 25/15 26/14 28/12 29/12 29/22 38/7 38/11 38/14 38/18 38/23 39/22 40/12 40/16 40/24 41/4 41/7 48/24 49/2 49/5 49/12 49/21 49/25 51/14 52/15 52/19 53/2 53/12 53/16 53/18 53/25 54/2 54/17 60/2 60/9 60/14 93/1 93/9 93/18 100/25 101/18 105/3 110/19 117/18 123/20 123/24 124/8 124/12 124/16 124/25 125/2 135/15 135/20 135/24 150/22 157/25 158/4 161/25 167/5 167/14 167/23 168/10 168/14 168/21 169/4</p> <p>'71 [1] 116/17 '72 [1] 78/2 '73 [4] 52/21 52/22 66/1 66/6 '73 because [1] 52/21 '74 [3] 53/2 53/11</p>	<p>94/23 '75 [5] 53/2 53/11 97/5 102/22 132/8 '76 [1] 132/8 '77 [1] 130/22 '83 [4] 37/5 158/22 162/14 162/17 '84 [1] 37/5 '85 [2] 7/4 37/5 '85 or [1] 7/4 '87 [4] 38/18 38/19 53/25 54/4 'A [2] 119/4 121/8 'B [4] 120/3 120/3 120/9 121/9 'bad [1] 4/14 'baseline' [1] 89/18 'bleeds' [1] 84/1 'country' [1] 77/20 'difficult' [1] 150/14 'double [1] 95/14 'fit [1] 13/10 'on [2] 71/17 98/5 'on demand' [1] 98/5 'one [2] 4/20 34/8 'opportunistic [1] 30/18 'other [2] 148/24 149/19 'patient' [1] 68/24 'severe' [1] 83/22 'switchback [1] 89/6 'The [1] 45/22 'very [1] 29/3</p> <p>-</p> <p>-- for [1] 125/1</p> <p>.</p> <p>... [9] 48/24 49/16 50/2 51/15 85/12 101/13 142/20 144/16 147/25 ... a [1] 147/25 ... increased [1] 48/24 ... the [2] 51/15 85/12 ... to [1] 50/2 ... two [1] 142/20 ... was [1] 101/13 ... whether [1] 144/16 ... will [1] 49/16</p> <p>0</p> <p>0.25IU/ml [1] 103/7 001 [4] 112/13 117/20 139/17 163/8 002 [3] 60/16 158/20 161/2 003 [1] 156/17 004 [2] 54/21 153/13 005 [3] 100/24 101/19 152/24 006 [3] 41/3 41/6</p>	<p>132/5 011 [1] 82/10 012 [1] 94/1 013 [2] 66/2 69/10 016 [1] 137/18 017 [1] 137/10 018 [2] 131/8 149/11 019 [2] 75/13 151/15 021 [2] 61/13 86/18 022 [2] 77/23 130/22 027 [1] 149/25 033 [1] 26/16 036 [1] 102/17 040 [1] 148/15 046 [1] 33/21 048 [1] 129/2 063 [1] 164/3 066 [2] 32/20 56/15 070 [1] 162/1 074 [1] 130/4</p> <p>1</p> <p>1 April 1977 [1] 138/17 1.03 [1] 110/22 10 [3] 86/6 113/13 157/22 10 January 1973 [1] 69/11 10 patients [1] 99/1 10,000 [1] 60/24 10-15 [1] 74/5 10.00 [2] 1/2 169/7 10.05 [1] 1/4 100 [1] 15/14 100 days [1] 87/9 106 [1] 3/24 11 [3] 113/16 137/1 142/4 11.18 [1] 53/19 11.50 [3] 53/16 53/18 53/21 113 [1] 155/6 12 [4] 115/8 133/17 145/16 154/4 12 July 1991 [1] 32/21 13 [2] 108/25 111/17 14 December 1970 [1] 54/25 14 December 1977 [1] 141/21 146 [1] 67/18 147 [1] 88/13 15 [8] 74/5 79/12 84/14 84/17 103/9 103/14 106/15 157/22 15 February 1976 [1] 131/17 15 of [1] 111/14 15,000 [2] 61/6 72/24 15,000 times [1] 2/9</p>	<p>15/45 [1] 144/6 158 [1] 155/20 16 [1] 142/4 18 [2] 123/7 123/16 18 September 1975 [1] 97/11 18-month [1] 125/1 19 [3] 143/20 168/13 169/4 19 August 1972 [1] 67/19 19 July 2021 [1] 169/7 19 months [1] 138/21 19 September 1980-something [1] 23/13 1958 [1] 43/8 1960s [1] 39/14 1967 [1] 60/24 1968 [2] 42/22 62/4 1970 [9] 54/21 54/25 56/17 60/1 60/2 66/4 113/14 116/17 165/7 1970s [8] 8/5 39/15 41/9 52/14 65/25 118/8 144/25 165/8 1971 [3] 46/18 61/6 114/4 1972 [5] 51/21 67/19 70/19 76/10 78/3 1973 [11] 2/7 2/25 69/11 77/16 81/5 82/16 93/22 94/3 113/14 115/21 145/17 1973-77 [1] 111/12 1973/74 [1] 70/3 1974 [7] 52/25 95/2 96/14 96/14 126/8 135/17 142/23 1974/75 [1] 36/2 1975 [15] 61/16 65/5 67/11 77/17 96/13 97/8 97/11 101/22 118/13 127/19 128/13 129/3 130/6 132/22 137/19 1976 [11] 67/12 102/21 108/24 111/15 111/17 111/18 131/9 131/17 132/7 132/23 136/8 1977 [13] 2/17 3/1 67/12 106/9 108/24 109/7 111/15 111/18 138/17 139/15 139/16 139/18 141/21 1978 [2] 143/21 148/16 1980 [7] 147/6 147/19 156/18 158/16 159/22 163/9 164/5</p>	<p>1980s [5] 28/8 39/15 161/6 165/8 168/20 1981 [4] 13/6 157/7 158/16 159/22 1982 [2] 158/17 160/7 1983 [1] 36/24 1984 [1] 7/4 1985 [10] 1/22 1/23 6/8 7/2 10/12 10/16 37/5 54/11 54/13 54/16 1986 [4] 10/13 15/23 19/4 28/16 1986 report [1] 14/8 1987 [1] 53/24 1988 [1] 38/15 1989 [1] 26/18 1990 [2] 15/13 32/14 1991 [3] 32/16 32/21 33/4 1993 [1] 161/7 1995 [2] 33/22 34/17 19th [2] 168/22 168/23 1st December [1] 156/25</p> <p>2</p> <p>2 dose [1] 98/8 2,000 [1] 101/7 2,000-6,000 litres [1] 120/1 2.00 [1] 110/24 20 [2] 98/25 113/18 20 April [1] 132/7 20 November 1995 [1] 33/22 20 Park Crescent [1] 82/15 20 patients [1] 121/20 20,000 [1] 68/12 2011 [1] 13/7 2019 [3] 7/19 9/7 35/2 2021 [2] 1/1 169/7 20K [1] 79/12 21 boys [1] 128/18 22 July 1975 [1] 101/22 23 [1] 104/22 23 December 1980 [1] 156/18 24 [1] 105/14 24 hours [1] 163/18 24,815 [1] 60/22 24-hourly [1] 107/20 240-unit [1] 150/12 24th October [1] 141/8 25 [1] 83/18 25 June 2021 [1] 1/1 264 days [1] 41/22 26th [1] 169/1</p>	<p>27 [1] 104/13 27 October 1972 [1] 76/10 27th [2] 78/5 169/2 28th [1] 169/2 29th [1] 169/2</p> <p>3</p> <p>3 days [1] 103/10 3.25 [1] 169/6 30 [2] 106/15 107/22 30-40 [1] 115/16 31 January 1974 [1] 95/2</p> <p>4</p> <p>4,000 [2] 70/2 81/21 40 [1] 115/16 41 [1] 13/8 43 patients [1] 15/3 45 [1] 144/6 48 hours [2] 97/20 106/20 49 [1] 55/5</p> <p>5</p> <p>5,500 [1] 2/24 50 [3] 112/21 115/13 154/12 50 boys [1] 61/21 500-750 [1] 101/5 53 [1] 116/24 54 [1] 116/18 55 [1] 2/19</p> <p>6</p> <p>6 cases [1] 157/6 6,000 litres [1] 101/7 60s [1] 165/7 66 [2] 103/11 103/18</p> <p>7</p> <p>7 episodes [1] 87/9 7 October 1977 [1] 139/18 7 years [1] 87/5 7-plus [1] 87/6 70,000 units [1] 98/1 113/16 73 [1] 103/14 74 [1] 70/3 75 [1] 36/2 750 [1] 101/5 77 [1] 111/12</p> <p>8</p> <p>8 February 1973 [1] 81/5 8 November 1972 [1] 78/3 81 [3] 113/15 114/20</p>
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8	152/22 155/8 157/2 157/22 160/5 160/25 161/21 162/19 163/13 164/20 164/24 166/19	152/13 156/6 acute [5] 61/3 134/21 135/6 142/24 143/1 add [2] 145/2 160/24	106/13 109/13 afforded [1] 42/2 afraid [2] 49/6 162/3 after [19] 6/17 9/10 9/12 20/22 31/20 52/21 76/17 91/17 104/22 105/11 105/18 113/24 115/5 115/19 115/21 127/11 134/4 142/22 142/24	AIDS [40] 6/6 6/13 6/24 9/6 9/14 9/16 9/19 13/13 13/17 14/4 14/13 14/20 15/3 15/11 15/21 15/23 16/2 17/8 17/10 19/24 21/19 23/4 24/4 24/11 27/8 28/18 28/25 29/4 29/5 29/15 29/17 29/19 29/23 30/5 30/8 30/18 35/21 35/23 159/2 162/19	56/10 62/2 63/18 66/7 76/23 80/4 109/14 160/25 162/21 162/25 163/7 168/6 also [44] 3/14 4/12 5/2 8/8 8/21 17/10 23/24 25/1 27/8 27/12 40/16 40/21 41/11 41/13 42/9 43/1 47/7 48/3 52/20 52/23 54/5 62/13 68/6 73/5 73/5 75/6 81/1 83/25 96/3 99/14 103/12 107/13 115/1 125/15 125/25 126/4 133/3 146/1 149/17 152/14 159/10 159/23 160/9 160/18
81... [1] 115/8	above [3] 20/3 107/24 137/12 abreast [1] 21/9 absence [2] 22/10 140/22 absolutely [4] 7/6 21/23 93/13 124/25 academic [1] 123/4 accept [2] 5/25 84/4 acceptable [1] 79/1 acceptance [2] 96/23 146/14 accepted [2] 12/25 17/18 accommodated [1] 84/10 accomplish [1] 64/24 accomplished [2] 43/20 133/14 according [2] 100/9 156/24 accordingly [2] 77/14 92/4 account [3] 22/20 22/21 80/6 accounts [1] 146/1 accurate [4] 5/11 53/3 53/10 129/11 achieve [3] 105/5 122/7 123/18 achieved [3] 55/18 99/20 103/12 acid [3] 50/4 50/10 63/9 acknowledged [1] 122/19 acknowledgement [1] 136/16 Acknowledgments [1] 156/14 acquaint [1] 127/17 across [2] 12/2 95/10 act [2] 68/18 92/3 action [4] 30/3 60/18 74/21 98/9 activated [1] 158/10 active [3] 142/21 144/12 144/18 activities [1] 47/5 activity [2] 62/23 165/10 actual [6] 5/12 25/18 93/12 127/24 147/13 149/23 actually [13] 19/9 29/15 30/4 30/8 30/14 49/3 98/11 102/15 115/21 135/24 141/5	added [1] 14/20 addition [3] 55/23 65/13 72/18 additional [3] 17/24 86/4 120/24 address [2] 12/16 14/1 addressed [8] 56/17 69/12 82/22 94/3 139/9 149/13 152/11 152/13 adepts [1] 68/25 adequacy [1] 93/15 adequate [3] 42/7 45/3 83/3 adhered [1] 165/18 adhering [1] 122/13 Adjourned [1] 169/7 adjournment [1] 110/23 administer [1] 91/12 administered [5] 59/12 64/2 106/13 108/24 111/16 administration [9] 19/20 88/19 89/21 91/8 92/14 107/21 117/25 120/16 163/17 administrative [1] 45/2 admission [1] 131/23 admissions [2] 17/13 113/21 admitted [1] 104/3 adolescence [1] 17/2 adolescent [1] 2/6 adolescents [1] 111/4 adopted [1] 10/1 adult [3] 16/17 115/3 115/13 advancement [1] 65/8 advantage [2] 57/4 82/1 advantages [1] 125/13 advent [2] 17/8 17/10 advice [6] 29/13 29/19 31/14 33/15 34/15 66/19 advisable [1] 31/13 advise [1] 81/24 adviser [1] 3/17 advisory [1] 80/19 advocate [1] 5/1 advocated [1] 73/25 aetiology [1] 140/9 affected [7] 2/5 16/5 16/14 83/17 89/16	afternoon [2] 98/17 145/14 afternoons [1] 19/14 Ag [1] 142/24 again [68] 8/24 8/24 9/7 11/23 15/17 29/7 30/12 32/9 34/1 35/16 36/7 36/15 46/17 50/6 55/8 57/17 61/15 61/19 61/25 62/3 63/8 65/9 65/24 65/25 69/7 75/14 82/11 85/1 85/11 87/18 87/23 88/2 88/12 88/14 89/11 114/11 116/22 118/4 122/10 123/14 130/2 131/5 131/10 134/10 137/7 137/19 138/14 139/8 148/3 149/10 149/15 149/21 149/25 151/1 151/6 152/20 153/7 155/3 155/20 155/22 156/5 158/13 158/24 159/24 160/14 161/12 162/20 164/16 against [5] 3/18 22/20 24/21 49/19 49/22 age [4] 41/23 41/23 41/24 87/5 aged [1] 142/4 agenda [1] 78/6 agents [2] 119/3 121/8 aggravated [1] 27/11 aggressive [1] 135/2 ago [3] 42/5 80/7 101/25 agree [3] 92/11 148/19 150/2 agreed [16] 64/19 65/19 75/1 75/6 76/12 77/8 84/16 84/23 85/3 94/8 98/9 121/17 127/7 157/13 164/7 164/15 agreeing [1] 148/23 agreement [6] 146/6 149/13 154/25 155/13 157/2 157/9 ahead [2] 145/15 168/10	AIDS-related [1] 35/21 AIDS/HIV [4] 14/20 15/3 16/2 19/24 aim [3] 109/11 116/2 153/15 aimed [1] 110/10 aims [1] 95/8 al [2] 119/9 120/5 albeit [2] 22/20 27/25 Aldershot [1] 136/17 aliquot [1] 113/10 all [66] 2/9 2/15 2/15 10/20 11/15 12/21 16/4 16/14 17/23 21/12 21/18 22/13 24/6 24/7 25/12 26/8 27/6 28/19 32/11 33/7 34/6 43/12 46/16 49/16 53/22 55/25 58/19 59/11 59/23 65/15 66/14 66/16 69/19 71/3 74/11 80/2 85/19 88/5 88/14 90/1 92/7 95/3 97/12 109/14 114/5 114/24 117/18 120/8 120/10 122/17 122/22 125/6 129/2 135/3 138/22 138/23 139/5 141/14 149/8 151/7 151/12 154/20 162/24 165/15 168/2 168/5 allied [1] 116/4 allocated [1] 73/11 allotted [5] 18/6 123/8 123/12 126/25 127/10 allowed [3] 62/5 74/4 77/5 allowing [1] 22/2 almost [5] 20/6 33/7 64/4 138/21 138/23 alone [2] 50/13 159/22 along [6] 71/10 92/16 107/5 108/12 162/21 162/24 already [20] 46/17 49/8 52/1 52/20 53/7 55/14 55/24 56/2	56/10 62/2 63/18 66/7 76/23 80/4 109/14 160/25 162/21 162/25 163/7 168/6 also [44] 3/14 4/12 5/2 8/8 8/21 17/10 23/24 25/1 27/8 27/12 40/16 40/21 41/11 41/13 42/9 43/1 47/7 48/3 52/20 52/23 54/5 62/13 68/6 73/5 73/5 75/6 81/1 83/25 96/3 99/14 103/12 107/13 115/1 125/15 125/25 126/4 133/3 146/1 149/17 152/14 159/10 159/23 160/9 160/18 altered [1] 2/12 although [13] 29/3 34/4 40/20 56/7 71/11 104/21 115/4 115/9 127/12 128/23 136/1 151/9 160/1 Alton [31] 43/22 45/7 45/11 51/24 52/20 55/2 55/6 56/4 66/8 66/10 66/19 66/22 74/25 78/20 81/10 81/22 95/6 96/2 97/17 109/10 109/11 121/21 123/2 142/3 142/4 144/7 156/21 156/24 157/4 164/9 164/14 always [8] 3/12 5/1 23/22 23/25 39/6 39/19 40/7 82/11 am [16] 1/2 1/4 5/5 19/12 34/4 41/5 53/19 53/21 69/6 115/22 131/3 139/2 140/6 145/19 158/24 169/7 America [1] 9/20 American [2] 35/19 139/7 among [1] 89/5 amongst [4] 19/18 25/14 75/10 162/21 amount [6] 103/1 103/16 107/25 115/4 119/7 150/7 amounts [2] 75/21 79/9 AMRE000007 [3] 60/16 66/2 75/13 AMRE0000011 [3] 41/6 56/15 61/13 AMRE0000012 [1] 54/21 AMRE000011 [1] 41/3 anaemia [1] 113/18 analysed [1] 2/11 analysis [4] 2/23 3/4

<p>A</p> <p>analysis... [2] 117/8 127/15</p> <p>anger [1] 27/11</p> <p>anicteric [2] 100/6 134/2</p> <p>announced [1] 38/19</p> <p>annual [2] 98/1 141/7</p> <p>another [15] 2/1 4/15 8/7 8/13 9/17 32/5 32/9 71/3 125/3 136/23 145/20 150/1 153/25 155/21 158/7</p> <p>answer [8] 28/19 84/1 88/3 88/3 118/5 138/2 152/16 159/8</p> <p>answered [1] 120/15</p> <p>antibodies [12] 29/4 29/18 30/5 33/2 34/7 48/12 48/14 63/14 64/9 100/4 150/9 158/12</p> <p>antibody [24] 15/4 16/17 17/1 29/23 48/5 58/7 58/13 59/7 59/10 59/19 112/15 113/2 113/5 114/11 114/12 114/15 114/24 114/25 116/3 116/20 117/7 117/9 117/11 121/5</p> <p>anticipated [3] 43/23 70/4 108/17</p> <p>anticipating [2] 168/16 168/24</p> <p>antigen [33] 46/10 48/4 59/7 59/12 59/17 59/21 63/1 63/5 63/13 90/10 93/14 93/16 95/19 96/5 101/15 104/20 104/22 112/15 113/2 113/5 113/7 114/8 114/10 114/15 114/21 115/11 115/15 116/3 116/8 116/20 119/2 121/11 162/10</p> <p>Antigen-screened [1] 90/10</p> <p>antigenic [1] 115/4</p> <p>antithrombin [2] 52/3 63/9</p> <p>anxious [2] 70/14 150/6</p> <p>any [66] 4/6 5/20 6/25 11/16 12/11 12/13 19/5 22/10 22/13 22/14 22/15 23/20 24/9 24/10 24/18 25/5 25/17 25/17 25/21 26/3 26/6 26/12 29/17 30/15 32/10 33/6 34/20 36/7 37/6 37/15</p>	<p>40/7 40/8 43/18 50/16 60/19 63/1 73/8 74/7 78/21 78/23 82/7 91/15 92/23 93/15 99/4 100/22 111/7 115/23 121/1 128/11 129/19 131/25 132/17 134/16 139/10 140/3 140/22 140/25 145/4 145/5 146/12 155/3 159/6 159/20 163/23 164/19</p> <p>anyone [1] 12/13</p> <p>anything [10] 13/24 25/20 26/5 26/11 78/19 124/16 130/20 138/14 148/23 160/2</p> <p>anyway [1] 124/5</p> <p>anywhere [2] 44/15 62/17</p> <p>apart [3] 78/19 134/21 135/7</p> <p>aplastic [1] 113/18</p> <p>apparent [5] 27/17 79/4 132/23 153/9 153/12</p> <p>apparently [2] 80/7 107/12</p> <p>appear [18] 10/23 11/16 28/19 36/9 37/14 57/4 93/6 123/18 131/14 131/25 132/4 136/23 140/2 141/1 156/19 157/17 161/5 164/20</p> <p>appears [21] 10/9 10/11 15/23 25/10 29/7 60/12 65/9 72/1 73/13 82/17 86/10 90/25 92/15 96/3 99/19 123/14 129/21 132/14 149/5 152/13 159/14</p> <p>appending [1] 51/6</p> <p>application [11] 45/18 51/3 55/1 56/8 60/20 61/11 67/7 73/2 107/23 143/15 143/22</p> <p>applied [1] 72/23</p> <p>appoint [2] 21/5 21/21</p> <p>appointed [5] 40/13 40/21 52/5 52/19 57/2</p> <p>appointment [5] 21/16 34/9 40/19 41/11 145/20</p> <p>appreciate [2] 131/22 158/4</p> <p>approach [13] 3/12 5/12 7/5 7/9 9/25 36/7 99/24 100/12 122/17 128/10 145/5 163/12 163/25</p>	<p>appropriate [5] 3/13 70/9 79/14 84/3 110/15</p> <p>approval [2] 77/9 146/23</p> <p>approve [1] 67/10</p> <p>approved [4] 59/23 65/19 68/3 68/6</p> <p>approximately [1] 41/21</p> <p>April [11] 70/5 70/13 94/3 130/22 131/9 132/7 136/8 138/17 139/15 143/21 145/17</p> <p>April 1973 [2] 94/3 145/17</p> <p>April 1976 [2] 131/9 136/8</p> <p>April 1977 [1] 139/15</p> <p>April 1978 [1] 143/21</p> <p>Arabia [1] 102/3</p> <p>Arblaster [14] 40/20 42/4 65/20 67/20 70/14 71/8 72/21 80/2 81/11 82/19 85/17 95/2 95/8 102/3</p> <p>Arblaster's [1] 70/9</p> <p>are [149] 1/9 3/12 3/16 3/21 5/2 5/2 5/3 5/5 7/12 7/12 9/8 10/1 10/6 10/11 14/19 14/21 15/6 15/8 15/10 15/13 16/4 16/10 16/14 16/19 16/21 16/22 17/13 18/3 20/1 20/4 21/1 21/12 21/20 22/3 24/8 24/8 24/16 24/19 25/18 25/19 25/23 27/2 28/15 34/11 35/20 37/6 39/4 40/3 41/18 41/24 42/7 42/10 43/3 43/18 44/6 47/3 47/21 47/22 48/2 48/15 52/9 53/7 54/3 55/11 55/25 57/11 59/24 62/1 63/22 66/13 67/8 67/16 68/24 70/4 71/16 75/11 75/20 75/25 76/10 76/19 76/21 80/8 85/2 86/16 87/14 88/8 89/13 89/17 89/18 92/19 92/25 93/19 95/11 97/12 104/5 107/8 109/17 112/22 116/19 117/5 117/6 119/2 119/3 119/17 119/25 122/23 123/1 126/23 127/15 127/19 132/13 133/1 133/7 133/23 134/25 135/1 137/7 137/20</p>	<p>138/9 138/21 139/6 140/8 140/18 141/13 144/16 144/21 145/8 145/15 150/4 150/6 150/11 150/12 151/4 152/19 152/20 152/21 154/8 155/25 157/11 157/20 161/11 161/12 163/3 165/1 165/3 165/12 167/11 167/12 168/16</p> <p>area [6] 18/13 34/1 45/6 64/19 90/22 158/7</p> <p>areas [1] 112/8</p> <p>argue [1] 6/9</p> <p>argument [1] 167/15</p> <p>arise [3] 16/10 165/11 167/3</p> <p>arisen [1] 16/9</p> <p>Armour [7] 154/8 156/15 156/18 156/19 157/11 157/18 157/19</p> <p>Army [2] 136/17 136/24</p> <p>Aronstam [59] 1/14 2/2 3/22 3/25 7/8 10/7 10/15 15/18 16/13 19/2 24/12 26/4 29/14 34/5 34/18 38/4 38/6 40/20 40/22 42/9 70/19 71/8 72/22 74/8 80/2 81/11 82/19 83/23 86/7 91/5 91/7 94/3 95/3 95/12 97/11 97/15 97/20 101/21 105/8 111/6 139/17 148/17 152/25 153/14 155/10 155/15 155/24 157/16 160/12 161/20 162/15 162/16 162/18 163/9 163/12 163/24 164/9 164/23 170/4</p> <p>Aronstam's [5] 14/7 15/24 19/11 29/9 164/24</p> <p>around [6] 13/19 16/4 16/16 32/16 38/9 72/4</p> <p>aroused [1] 23/19</p> <p>arrange [1] 99/13</p> <p>arranged [6] 45/10 50/15 59/9 82/2 122/4 127/12</p> <p>arrangement [2] 12/6 139/20</p> <p>arrangements [14] 34/6 34/20 43/18 44/6 61/25 67/8 83/4 85/15 85/19 123/11 126/16 126/19 126/23 136/5</p> <p>arranging [1] 25/8</p> <p>arrest [1] 150/13</p>	<p>arthritis [4] 58/7 58/13 64/8 67/5</p> <p>arthropathy [1] 4/5</p> <p>Arthur [1] 33/23</p> <p>article [1] 33/13</p> <p>articulated [1] 55/10</p> <p>as [170] 4/12 4/21 4/23 6/10 6/12 6/21 6/21 6/23 7/8 7/12 9/2 10/1 10/16 10/16 12/2 12/11 12/21 13/12 13/16 13/17 14/3 17/18 18/12 19/3 19/19 19/19 19/23 20/3 22/19 22/24 23/3 23/11 23/16 23/22 24/15 25/15 26/7 27/2 27/25 28/7 30/5 30/7 30/16 30/22 34/10 34/10 34/16 34/18 36/12 37/24 39/3 39/12 39/19 40/13 42/14 42/17 45/2 51/23 52/6 52/11 52/13 53/8 54/22 55/18 56/9 56/17 58/11 64/21 64/21 65/24 67/7 68/15 68/18 68/19 70/20 74/10 79/9 80/6 82/19 82/19 84/19 84/20 84/20 85/5 85/5 88/2 88/8 88/22 89/7 89/12 90/2 90/13 92/5 92/8 98/12 98/18 98/21 99/13 99/13 99/20 102/7 102/7 104/4 104/5 107/6 108/12 108/17 110/14 110/15 111/23 112/10 112/11 112/21 112/21 114/24 116/12 119/6 122/13 122/13 122/17 123/16 124/10 128/2 128/13 131/11 134/1 134/3 134/14 136/1 136/8 136/14 136/21 137/22 138/8 139/4 139/5 139/14 139/22 140/18 140/19 141/25 144/5 144/5 147/2 147/16 149/18 150/6 150/25 151/13 151/24 151/24 152/5 152/5 153/15 154/15 155/10 155/15 155/24 157/14 159/2 159/6 161/12 161/14 165/4 166/14 166/21 166/22 166/23 166/25 167/16</p> <p>as full-time [1] 42/14</p> <p>as Research [1] 56/9</p>	<p>ascertain [3] 134/25 151/24 156/5</p> <p>aside [1] 93/15</p> <p>ask [2] 148/25 166/13</p> <p>asked [11] 28/17 30/8 70/24 73/7 73/21 75/7 78/9 79/7 104/2 129/7 135/11</p> <p>asking [5] 9/11 19/5 20/14 109/25 145/21</p> <p>aspect [1] 46/20</p> <p>aspects [11] 27/1 27/2 31/15 47/10 47/21 83/13 85/14 98/13 148/11 149/8 166/1</p> <p>assay [1] 121/10</p> <p>asserts [1] 103/23</p> <p>assess [2] 70/10 86/1</p> <p>assessing [1] 84/15</p> <p>assessment [5] 3/19 29/11 83/5 85/4 121/4</p> <p>assigned [3] 45/8 91/25 92/3</p> <p>assignment [1] 91/7</p> <p>assistance [3] 42/20 44/4 79/14</p> <p>assistant [3] 53/9 64/21 64/24</p> <p>assisted [3] 53/22 54/5 65/15</p> <p>assisting [1] 65/2</p> <p>Associate [1] 42/10</p> <p>associated [10] 86/14 104/20 117/24 118/15 120/3 131/15 139/24 140/10 143/1 143/4</p> <p>association [4] 44/17 44/22 50/19 144/10</p> <p>associations [1] 48/10</p> <p>assumed [2] 65/16 135/24</p> <p>assuming [3] 12/25 24/9 129/10</p> <p>assumption [1] 92/2</p> <p>assurance [1] 88/21</p> <p>assure [1] 24/25</p> <p>asymptomatic [1] 138/23</p> <p>attached [1] 143/21</p> <p>attack [4] 115/13 121/1 142/25 143/1</p> <p>attacks [2] 114/16 115/9</p> <p>attempt [4] 9/16 48/5 48/13 123/17</p> <p>attend [1] 21/13</p> <p>attendance [3] 20/17 26/10 95/3</p> <p>attended [5] 7/21 13/16 76/8 78/4 102/4</p>
---	--	---	--	---	--

<p>A</p> <p>attender [1] 80/21</p> <p>attending [1] 112/22</p> <p>attention [4] 50/21 136/13 165/3 168/3</p> <p>audience [1] 54/4</p> <p>augment [1] 59/18</p> <p>August [3] 61/16 65/5 67/19</p> <p>August 1975 [2] 61/16 65/5</p> <p>auspices [3] 96/7 158/18 159/21</p> <p>Australia [15] 59/17 59/19 59/21 63/13 90/10 93/14 93/16 95/18 96/5 112/15 113/1 113/7 114/8 114/15 114/21</p> <p>Australian [2] 59/7 59/12</p> <p>Austria [1] 79/12</p> <p>authored [3] 96/12 112/19 129/12</p> <p>Authority [4] 19/3 31/14 44/2 64/19</p> <p>authors [3] 108/7 115/24 156/11</p> <p>Autoplex [5] 158/7 158/11 158/23 159/4 159/21</p> <p>autumn [4] 96/14 116/17 132/8 132/11</p> <p>availability [4] 17/21 34/2 43/17 84/10</p> <p>available [34] 2/24 11/22 12/1 12/2 12/21 17/25 22/11 22/15 45/13 60/17 60/23 60/24 61/6 64/5 65/4 65/7 79/15 79/18 79/24 81/21 92/7 93/24 107/1 112/6 122/9 123/12 127/3 133/1 145/12 153/25 159/9 163/14 164/23 168/6</p> <p>average [1] 106/15</p> <p>averted [1] 17/7</p> <p>avoid [1] 150/13</p> <p>avoided [1] 5/25</p> <p>awaited [1] 96/24</p> <p>aware [7] 24/2 27/6 31/4 34/4 35/17 36/11 140/4</p> <p>awareness [1] 122/11</p> <p>AZT [1] 19/1</p>	<p>95/17 98/11 106/21 112/2 112/7 117/19 128/13 145/10 157/24 166/10</p> <p>background [6] 41/12 49/19 49/22 51/17 75/9 93/19</p> <p>bad [2] 109/14 110/5</p> <p>balance [1] 3/17</p> <p>bank [2] 59/19 141/1 16/1</p> <p>bare [1] 16/1</p> <p>based [5] 2/23 43/23 94/2 151/14 153/4</p> <p>basic [4] 45/14 55/20 55/23 62/25</p> <p>Basingstoke [2] 19/15 133/11</p> <p>basis [12] 40/18 44/25 45/7 45/25 49/16 64/21 79/23 90/14 125/22 135/21 153/19 166/9</p> <p>batch [5] 79/24 122/5 123/25 124/6 127/13</p> <p>batches [7] 122/4 122/9 122/14 127/8 127/12 127/23 134/10</p> <p>bay [2] 30/19 105/14</p> <p>BAYP0000021 [1] 164/3</p> <p>be [318]</p> <p>bear [1] 141/11</p> <p>bearing [1] 63/6</p> <p>became [2] 76/17 79/4</p> <p>because [33] 6/4 8/9 8/22 18/22 27/19 28/2 31/18 37/21 39/18 41/10 49/5 52/21 53/5 54/11 57/6 60/6 61/16 61/21 71/15 102/24 106/2 113/20 113/23 124/1 128/8 133/3 143/7 146/18 146/18 160/24 161/16 165/12 167/14</p> <p>become [4] 52/16 79/17 126/12 140/25</p> <p>becomes [2] 30/22 131/21</p> <p>becoming [2] 17/14 80/18</p> <p>beds [1] 43/9</p> <p>been [110] 2/7 2/10 2/10 2/11 2/12 3/6 8/21 10/9 10/12 10/13 10/19 10/24 11/16 11/19 12/20 13/10 14/12 18/6 23/14 23/16 23/19 23/23 24/2 24/6 25/15 27/24 30/7 36/4 36/10 36/11</p>	<p>36/18 36/24 37/15 38/14 39/23 42/23 43/13 44/19 44/22 54/5 55/17 56/2 57/2 57/8 60/20 63/15 63/18 66/8 66/10 66/19 68/2 68/6 70/24 77/10 78/9 78/12 80/5 81/16 83/4 84/14 85/18 85/20 89/2 90/25 92/15 94/18 96/23 97/6 99/20 102/5 103/3 113/18 113/19 113/22 114/5 115/10 118/18 120/4 122/8 126/21 126/25 127/1 128/24 129/7 129/14 130/20 133/8 133/12 133/13 134/1 135/13 135/17 138/20 139/21 142/4 145/13 146/8 149/3 149/9 151/11 151/22 152/14 152/15 152/17 156/3 156/6 159/2 161/5 164/10 168/6</p> <p>before [23] 1/7 1/20 5/1 10/17 13/3 14/7 30/23 38/1 38/20 41/1 53/15 53/24 77/17 95/15 100/25 107/15 115/6 122/20 127/20 135/18 145/7 148/23 161/3</p> <p>began [4] 2/17 3/2 12/12 115/5</p> <p>begin [3] 70/12 70/14 158/1</p> <p>beginning [8] 14/11 119/20 132/11 161/9 162/7 168/21 168/23 169/1</p> <p>begs [1] 152/8</p> <p>behaviour [1] 150/11</p> <p>behind [1] 135/15</p> <p>being [113] 7/8 8/2 8/9 8/18 9/1 9/11 9/18 10/2 10/2 10/3 10/6 10/14 11/2 11/7 12/5 12/18 15/3 22/11 22/23 23/1 24/6 24/8 25/6 25/13 25/20 27/25 28/9 29/8 29/19 29/20 31/16 31/25 32/5 32/9 32/10 32/13 33/5 34/19 35/18 35/21 35/22 35/23 35/24 36/1 36/17 36/25 37/3 37/4 39/10 39/17 40/7 40/11 48/18 56/3 56/22 57/9 57/11 57/22 57/24</p>	<p>58/6 58/10 58/14 58/20 58/25 59/11 60/1 61/20 62/5 63/14 64/12 65/7 77/19 80/23 81/23 96/6 96/21 97/17 98/14 108/24 110/13 116/14 117/23 118/6 122/15 124/17 125/24 126/23 128/6 128/22 131/18 132/3 134/4 137/8 139/6 140/3 140/4 141/2 141/3 142/14 146/1 148/5 148/6 150/5 153/7 153/9 155/4 155/9 160/23 161/17 164/17 165/6 166/3 167/12</p> <p>believe [5] 3/10 18/20 66/25 67/7 102/12</p> <p>believed [1] 36/4</p> <p>belonged [1] 72/12</p> <p>below [3] 90/2 136/12 140/17</p> <p>beneficial [4] 52/10 57/4 107/4 110/8</p> <p>benefit [3] 13/11 30/23 105/5</p> <p>benefits [2] 108/10 153/17</p> <p>benign [2] 128/7 135/2</p> <p>bereaved [1] 17/9</p> <p>best [8] 3/9 3/15 3/15 11/22 23/13 42/6 92/7 110/2</p> <p>better [5] 49/2 71/16 94/14 112/11 167/10</p> <p>between [34] 2/25 17/13 30/2 34/5 34/18 44/9 44/19 45/11 56/3 58/12 59/21 62/11 64/8 66/3 66/18 66/23 68/16 71/18 88/11 89/8 100/12 108/23 120/21 121/1 124/10 130/1 137/20 139/1 142/4 148/14 152/21 159/25 163/5 164/21</p> <p>beyond [4] 6/15 13/24 66/25 168/10</p> <p>bias [1] 89/4</p> <p>Bidwell [7] 73/6 73/14 80/14 82/20 84/20 85/25 86/13</p> <p>bigger [1] 166/11</p> <p>Biggs [18] 54/22 55/10 58/19 59/23 60/2 65/21 66/1 68/8 70/24 71/13 71/23 73/8 73/16 76/16 78/9 78/17 80/1 129/7</p>	<p>Biggs' [1] 56/18</p> <p>bilirubin [1] 125/22</p> <p>bill [1] 68/12</p> <p>biochemist [1] 58/1</p> <p>Biological [1] 138/18</p> <p>biopsy [2] 141/24 143/10</p> <p>Birmingham [1] 130/5</p> <p>bit [2] 46/13 48/21</p> <p>blank [2] 129/24 159/18</p> <p>bleaker [1] 29/10</p> <p>Blecher [1] 109/25</p> <p>bled [1] 50/11</p> <p>bleed [10] 3/18 4/6 5/4 5/25 57/15 71/20 110/5 147/16 149/17 150/14</p> <p>bleeding [32] 1/14 1/17 3/3 4/13 6/10 14/24 46/6 63/2 63/6 64/4 71/22 73/10 74/9 75/20 81/13 85/13 87/8 88/25 89/2 89/18 92/8 92/23 103/9 103/10 103/13 103/17 105/16 106/19 107/22 108/2 108/18 150/13</p> <p>bleeds [12] 2/8 2/9 2/15 2/24 74/9 85/8 105/11 105/13 109/13 150/10 153/2 153/5</p> <p>blind [12] 68/22 76/15 89/10 91/6 102/1 102/18 103/2 147/8 147/17 147/23 147/25 148/9</p> <p>blind' [1] 95/14</p> <p>blood [36] 13/19 38/25 45/24 47/6 48/1 48/11 61/2 63/15 64/12 75/22 79/8 95/1 113/7 113/8 113/10 113/10 113/20 115/11 116/8 116/8 118/17 120/8 120/11 125/16 125/21 126/13 130/14 131/23 132/25 136/17 136/24 138/5 138/6 140/23 151/22 154/14</p> <p>blood-borne [1] 47/6</p> <p>bloods [2] 139/21 140/4</p> <p>Bloom [1] 162/17</p> <p>blown [1] 17/8</p> <p>board [4] 55/20 68/5 81/4 164/4</p> <p>Board's [1] 81/17</p> <p>boarding [1] 2/19</p> <p>body [7] 23/7 24/15 28/16 28/18 28/20 57/7 151/21</p>	<p>book [8] 1/13 2/4 2/12 2/13 3/8 6/5 6/16 6/25</p> <p>borne [1] 47/6</p> <p>both [13] 7/19 35/2 37/5 45/17 57/15 58/9 67/10 80/16 104/12 106/19 120/2 136/19 156/11</p> <p>bottles [1] 150/12</p> <p>bottom [33] 8/15 15/9 31/2 33/14 64/10 69/14 81/5 83/15 85/23 90/19 90/19 93/2 95/18 96/15 97/13 99/3 100/2 106/23 107/9 109/8 111/8 111/20 114/13 126/16 127/21 134/5 143/24 154/7 154/18 155/25 162/5 163/2 163/16</p> <p>bound [1] 105/11</p> <p>Bournemouth [1] 50/24</p> <p>bowing [1] 52/16</p> <p>boy [15] 23/17 24/9 27/14 68/18 74/9 76/21 85/22 104/3 104/13 104/21 113/20 131/11 133/23 134/3 140/24</p> <p>boy's [2] 90/22 105/19</p> <p>boy-school [1] 104/13</p> <p>boys [112] 2/13 8/6 23/22 25/2 27/5 27/13 28/9 29/4 41/18 41/22 42/2 42/10 44/20 46/4 47/7 47/18 48/3 48/12 50/9 50/21 55/16 55/20 57/21 58/20 58/23 59/18 60/4 60/10 61/21 63/14 66/9 67/9 68/23 68/24 68/24 72/11 72/13 73/21 74/5 74/8 74/11 74/19 74/19 75/18 76/19 77/13 83/21 83/25 84/4 84/7 84/9 84/14 86/5 97/19 104/1 104/10 104/13 105/14 108/25 109/1 109/14 109/25 110/2 110/4 111/11 111/15 111/16 111/17 112/16 112/21 113/5 113/9 113/15 113/22 114/7 114/10 114/20 114/23 115/8 116/3 116/11 116/16 116/18 116/24 117/11 123/3 123/10 126/18 126/21 126/24</p>
--	---	---	---	---	--

<p>B</p> <p>boys... [22] 127/1 128/18 128/18 132/18 133/21 134/22 135/2 135/5 136/8 136/9 137/16 139/21 140/13 142/3 142/7 142/8 142/15 142/20 144/6 144/23 146/7 146/24</p> <p>BPL [1] 79/18</p> <p>brand [3] 122/6 123/25 139/12</p> <p>breadth [1] 165/5</p> <p>break [12] 41/1 53/15 53/20 53/24 54/5 110/18 110/19 157/23 158/5 168/11 168/11 168/12</p> <p>breakout [1] 17/6</p> <p>brief [2] 38/3 95/4</p> <p>briefly [1] 103/20</p> <p>brilliant [1] 75/14</p> <p>bring [3] 56/21 83/1 94/13</p> <p>brings [1] 110/17</p> <p>British [2] 49/15 102/20</p> <p>broad [5] 8/24 9/3 65/24 128/10 165/22</p> <p>broader [5] 12/20 14/24 34/2 93/17 122/17</p> <p>broadly [5] 7/18 22/24 32/18 37/11 99/23</p> <p>brother's [1] 8/8</p> <p>brought [1] 60/10</p> <p>BSP [1] 142/15</p> <p>building [1] 107/6</p> <p>built [3] 43/8 92/15 141/2</p> <p>Bulletin [1] 33/13</p> <p>Bunje [1] 82/21</p> <p>Burton [1] 12/3</p> <p>busy [1] 168/15</p> <p>but [143] 1/23 3/11 5/3 9/20 10/12 11/3 12/5 13/11 13/20 16/24 18/11 21/17 21/24 22/8 22/16 23/13 23/14 26/18 27/23 28/6 28/22 28/23 30/15 30/23 31/6 31/12 32/2 32/7 32/10 33/6 34/1 35/8 35/10 36/12 37/22 38/18 39/10 39/17 40/2 40/20 41/8 41/11 46/16 47/5 49/10 49/12 51/11 52/13 53/2 53/10 60/19 60/22 76/7 78/6 78/20</p>	<p>78/25 83/25 84/10 84/18 85/18 86/15 88/9 88/10 88/15 91/1 91/15 93/7 93/14 93/24 94/19 95/20 98/17 99/14 99/22 102/12 103/1 105/4 106/6 107/12 108/20 109/17 111/7 112/6 112/10 113/19 115/19 115/23 115/24 116/23 118/1 118/2 122/15 122/20 123/16 124/8 124/23 128/7 128/17 128/25 130/19 130/23 131/6 132/17 133/17 134/16 135/3 136/15 137/21 140/17 141/5 143/9 143/17 144/22 146/7 146/13 146/24 147/12 147/17 147/23 148/4 148/13 149/6 151/9 152/7 152/11 152/20 153/8 154/17 155/16 158/1 158/25 159/13 159/19 161/22 162/16 163/12 164/20 165/4 167/7 167/17 168/2 168/7 168/12</p> <p>Butlin [1] 26/6</p> <p>Buxton [1] 143/20</p> <p>buy [1] 72/25</p> <p>buying [1] 79/11</p> <p>by [120] 1/5 1/14 1/24 3/6 10/7 10/15 10/24 10/24 11/13 14/13 15/13 15/23 16/18 16/22 18/24 23/2 23/17 23/19 25/7 25/8 27/11 29/20 30/18 31/25 34/19 35/9 42/2 42/11 42/23 43/1 43/11 43/13 44/1 44/23 44/23 45/17 46/1 48/18 49/9 50/5 51/8 55/10 57/2 58/10 60/1 60/8 60/17 64/12 65/19 66/9 66/13 67/3 67/25 68/3 68/6 73/15 74/8 76/8 76/16 76/23 76/24 77/10 77/15 77/24 78/9 80/3 81/23 82/2 84/2 89/4 89/6 89/9 92/4 92/4 93/25 96/4 96/12 103/9 103/11 103/14 103/17 104/7 105/1 105/4 107/23 110/14 112/19 115/12 118/7 118/9 118/12 118/23 119/8 120/5 122/12 125/9 128/12 129/7 129/12</p>	<p>129/15 131/7 132/6 136/11 137/17 142/1 144/2 153/14 154/9 155/10 155/15 155/24 156/10 156/15 157/14 161/12 164/8 166/8 166/8 167/12 170/2</p> <p>C</p> <p>C3 [1] 126/2</p> <p>calculate [1] 157/16</p> <p>calculated [5] 103/6 103/13 106/14 107/21 154/11</p> <p>calculation [1] 107/24</p> <p>called [2] 1/14 1/16</p> <p>came [1] 60/5</p> <p>can [112] 1/15 1/21 3/24 4/6 4/11 4/15 6/5 6/11 6/19 7/17 8/14 14/6 25/9 30/1 31/6 32/25 34/10 39/1 40/2 40/6 41/15 43/18 44/12 48/23 51/10 53/10 57/17 60/15 60/22 61/15 61/24 62/14 63/10 64/13 64/23 67/15 67/18 69/8 69/11 69/14 69/17 70/15 70/19 75/14 76/5 82/12 82/18 82/23 83/15 85/11 85/23 86/24 88/18 89/11 89/23 90/4 95/20 97/1 97/13 100/11 101/20 101/22 102/7 102/16 102/21 103/1 103/22 104/11 104/16 106/6 107/11 108/7 109/21 111/9 112/13 113/25 114/18 115/24 117/18 118/2 121/16 124/5 129/3 130/2 130/23 134/8 135/20 136/7 137/1 137/3 141/9 143/23 146/2 147/17 147/25 148/21 150/3 151/24 152/12 153/7 153/14 154/10 155/6 156/10 156/17 157/21 158/8 158/13 159/1 159/13 160/9 167/14</p> <p>can't [5] 6/1 26/5 40/4 51/11 156/5</p> <p>candidate [1] 65/4</p> <p>cannot [3] 17/17 44/14 62/17</p> <p>capacity [3] 53/6 54/22 80/19</p> <p>capture [1] 141/13</p> <p>care [12] 2/19 13/19</p>	<p>24/24 26/23 27/1 30/25 34/16 34/21 44/20 45/6 67/9 166/18</p> <p>career [1] 52/11</p> <p>careful [3] 49/8 66/9 133/8</p> <p>carefully [1] 146/8</p> <p>carried [20] 48/1 49/9 56/3 56/22 57/10 57/24 59/4 65/15 66/7 76/14 77/19 80/12 81/9 81/22 102/5 103/3 112/11 142/3 144/2 158/16</p> <p>carrier [3] 24/9 24/21 114/22</p> <p>Carroll [1] 164/8</p> <p>carry [3] 59/9 65/2 66/22</p> <p>carrying [5] 29/4 29/17 30/5 66/16 89/14</p> <p>case [11] 20/10 21/15 80/15 99/17 104/18 104/20 123/2 123/10 134/1 134/7 145/25</p> <p>case: [1] 137/15</p> <p>case: CRYOPRECIPITATE [1] 137/15</p> <p>cases [19] 15/11 15/12 33/17 59/8 59/10 100/6 100/8 115/14 117/2 117/8 117/23 132/21 134/21 135/6 138/22 138/23 139/1 142/14 157/6</p> <p>Cash [1] 97/25</p> <p>cast [1] 82/7</p> <p>cataclysmic [1] 16/1</p> <p>catchment [1] 33/25</p> <p>categories [1] 143/11</p> <p>category [3] 5/24 83/22 137/16</p> <p>cause [4] 59/13 88/23 105/16 119/6</p> <p>caused [2] 67/3 79/16</p> <p>causes [3] 24/4 121/14 135/7</p> <p>causing [4] 47/6 52/23 119/11 164/14</p> <p>cautious [1] 24/8</p> <p>CBLA0000187 [1] 94/24</p> <p>CBLA0000312 [1] 118/11</p> <p>CBLA0000590 [1] 138/16</p> <p>CBLA0000756 [1] 143/19</p> <p>cease [1] 56/1</p>	<p>cell [1] 18/20</p> <p>cent [1] 114/23</p> <p>centering [1] 72/3</p> <p>centre [101] 2/8 3/8 5/24 10/25 11/14 13/16 14/12 14/23 16/3 16/4 16/6 17/16 17/22 18/8 18/24 19/13 19/18 20/16 21/1 21/6 21/16 26/1 26/5 26/18 26/19 26/20 26/24 31/22 42/3 42/5 42/10 42/13 42/17 43/23 43/25 44/3 44/18 44/20 45/1 45/11 45/13 51/14 51/15 51/24 54/23 64/25 65/13 65/21 65/22 66/18 66/20 66/24 68/1 68/7 70/18 71/6 72/2 74/17 74/25 75/10 77/2 77/11 78/5 78/18 79/18 80/3 80/22 86/11 89/15 94/23 96/2 96/4 96/7 97/8 102/5 109/4 109/6 112/24 114/5 121/19 124/10 127/17 128/15 129/8 130/2 136/22 141/8 141/13 141/16 143/14 150/19 154/6 154/16 157/5 158/14 160/13 163/11 164/2 164/9 164/14 164/25</p> <p>centres [15] 2/21 42/6 45/1 56/4 76/9 78/21 95/1 121/17 123/11 126/22 126/24 127/2 154/5 157/3 164/1</p> <p>certain [4] 4/14 44/25 66/25 77/14</p> <p>certainly [14] 6/6 6/24 8/19 10/15 12/22 19/8 23/7 29/22 35/8 36/22 53/17 92/15 138/3 138/6</p> <p>cetera [6] 47/25 125/22 144/11 144/11 162/10 162/11</p> <p>CGRA0001060 [1] 145/14</p> <p>chair [3] 82/21 82/24 84/12</p> <p>Chairing [1] 101/24</p> <p>Chairman [4] 68/3 75/2 81/15 159/4</p> <p>Chairmanship [1] 68/8</p> <p>chance [1] 24/10</p> <p>chances [1] 124/17</p> <p>change [4] 132/1</p>	<p>132/1 145/5 145/5</p> <p>changed [1] 84/24</p> <p>changes [1] 144/16</p> <p>chapter [1] 3/23</p> <p>characterisation [1] 5/12</p> <p>charge [1] 163/18</p> <p>chart [1] 88/9</p> <p>check [4] 38/8 38/24 53/8 109/19</p> <p>checking [1] 28/20</p> <p>Chemical [1] 133/11</p> <p>child [2] 24/18 60/18</p> <p>child's [1] 10/25</p> <p>childhood [1] 115/11</p> <p>children [11] 4/3 16/21 17/1 23/25 24/25 36/17 73/17 79/2 83/10 83/17 138/9</p> <p>children's [3] 22/25 35/15 130/5</p> <p>choice [2] 72/15 74/23</p> <p>choices [1] 6/1</p> <p>Christmas [8] 5/7 41/20 57/16 58/20 59/8 113/17 117/14 126/19</p> <p>chronic [9] 135/1 140/15 141/23 142/11 142/21 142/23 144/1 144/12 144/18</p> <p>circulated [2] 63/18 71/11</p> <p>circumstances [3] 150/21 150/22 150/23</p> <p>cirrhosis [1] 144/19</p> <p>clarification [2] 68/10 159/5</p> <p>clarifies [2] 109/20 111/19</p> <p>Clarke [1] 169/3</p> <p>classic [2] 87/1 122/22</p> <p>clear [18] 23/10 27/23 37/23 39/10 66/2 78/17 78/23 79/16 85/1 88/10 88/15 91/20 92/19 125/8 128/24 137/22 144/23 162/15</p> <p>clearly [9] 1/24 6/11 14/18 39/10 52/13 80/8 108/3 128/7 149/3</p> <p>clinic [1] 145/20</p> <p>clinical [39] 2/19 3/6 13/15 13/18 15/6 27/1 40/21 44/10 44/13 46/2 47/12 47/18 48/16 49/17 50/5</p>
---	---	---	---	---	--

<p>C</p> <p>clinical... [24] 50/20 52/12 58/9 62/12 62/15 63/8 73/11 76/12 79/20 84/8 89/14 89/20 113/6 115/2 115/8 115/13 115/14 116/6 126/14 134/3 138/22 142/11 142/20 166/15</p> <p>clinically [2] 48/7 83/17</p> <p>clinician [5] 37/5 93/25 104/7 130/19 131/6</p> <p>clinicians [9] 91/2 104/6 104/8 137/9 137/21 152/22 153/8 161/16 166/17</p> <p>clip [1] 38/2</p> <p>close [8] 24/20 44/10 44/19 65/16 66/17 66/22 76/20 157/17</p> <p>closely [3] 40/22 89/17 116/4</p> <p>clotted [1] 138/6</p> <p>clotting [2] 14/25 45/24</p> <p>co [2] 74/17 122/7</p> <p>co-operation [2] 74/17 122/7</p> <p>coagulation [13] 41/19 42/8 44/8 46/7 61/2 61/22 62/10 94/14 112/16 112/23 114/20 117/12 136/21</p> <p>cohort [1] 23/3</p> <p>Colindale [2] 63/17 125/24</p> <p>collaboration [3] 65/17 66/2 140/6</p> <p>collaborative [1] 7/4</p> <p>collect [2] 3/2 138/6</p> <p>collected [4] 48/2 57/13 99/9 133/9</p> <p>collection [5] 20/7 55/5 99/11 113/21 132/25</p> <p>collectively [1] 8/20</p> <p>college [73] 1/6 2/7 2/20 2/25 24/17 24/22 26/22 29/17 30/9 30/19 40/23 41/13 41/17 41/21 41/23 42/18 42/23 43/3 43/7 43/19 43/21 44/6 44/21 45/14 45/15 45/17 46/4 46/17 47/19 51/13 61/1 61/20 62/9 65/16 66/23 67/10 68/9</p>	<p>69/22 71/7 71/25 72/20 74/6 75/6 75/18 76/19 77/2 78/20 79/2 82/14 83/12 83/17 83/22 84/3 84/7 89/12 89/22 97/16 98/25 99/6 103/5 112/18 113/18 116/5 117/3 117/17 123/3 123/10 126/18 126/21 133/21 134/16 144/7 170/2</p> <p>Colleague's [1] 31/11</p> <p>Colonel [1] 136/18</p> <p>combination [1] 84/24</p> <p>come [16] 1/7 14/15 16/6 25/8 39/2 41/22 48/19 95/10 95/17 98/11 98/17 112/7 113/15 116/18 131/24 145/19</p> <p>comes [1] 124/4</p> <p>comfortable [1] 149/8</p> <p>coming [3] 17/11 157/24 161/12</p> <p>commence [1] 93/22</p> <p>commenced [1] 77/15</p> <p>commented [1] 29/1</p> <p>comments [1] 155/25</p> <p>commercial [17] 46/24 79/11 80/14 101/6 101/13 108/23 111/22 112/1 119/25 120/8 121/2 127/6 138/25 139/3 139/5 139/13 140/10</p> <p>commercially [1] 153/25</p> <p>commitment [4] 19/19 107/2 107/25 108/3</p> <p>commitments [4] 3/19 19/17 20/3 20/4</p> <p>committee [8] 68/4 69/4 69/5 81/3 81/8 81/23 82/5 155/1</p> <p>communicate [1] 166/20</p> <p>communicated [1] 32/16</p> <p>communicating [1] 20/8</p> <p>communication [5] 1/11 7/19 9/5 10/9 37/7</p> <p>communications [3] 137/20 152/21 163/10</p> <p>community [4] 16/4 16/16 17/15 66/11</p> <p>company [5] 156/16 164/2 164/13 164/17 164/22</p>	<p>comparable [1] 108/2</p> <p>compare [3] 105/22 153/23 157/19</p> <p>compared [6] 79/10 115/16 124/21 124/22 124/23 142/7</p> <p>comparing [1] 153/2</p> <p>comparison [2] 49/16 89/7</p> <p>compatibility [1] 49/18</p> <p>compatible [1] 87/2</p> <p>competence [1] 51/25</p> <p>complete [5] 44/3 96/20 110/25 123/3 146/5</p> <p>completed [8] 48/18 63/11 63/15 63/19 64/4 77/17 97/6 126/3</p> <p>completes [1] 167/20</p> <p>completing [1] 157/23</p> <p>complex [2] 88/20 158/10</p> <p>complication [1] 47/9</p> <p>complications [1] 6/12</p> <p>component [1] 18/12</p> <p>comprehensive [1] 39/18</p> <p>concentrate [37] 35/19 46/20 55/22 72/21 73/4 73/14 79/9 79/11 79/17 80/13 90/11 91/13 91/22 92/14 93/7 93/7 93/13 98/24 99/22 109/18 111/22 111/23 121/24 122/13 122/15 123/16 123/21 123/24 128/21 131/16 132/2 137/5 139/5 139/13 144/11 154/1 167/9</p> <p>concentrates [28] 35/19 46/24 69/21 70/2 82/13 88/20 92/21 92/22 94/7 112/1 118/15 119/15 119/22 119/25 120/4 120/17 120/22 121/2 121/3 124/22 126/21 127/8 134/13 138/25 139/4 139/6 140/11 167/13</p> <p>concentrating [1] 151/21</p> <p>concentration [2] 103/7 112/24</p> <p>concern [6] 25/1 34/12 146/12 159/2 161/21 162/18</p> <p>concerned [7] 7/12 7/13 23/16 25/13</p>	<p>36/13 116/24 130/23</p> <p>concerning [7] 46/8 63/18 79/3 129/19 137/25 148/18 148/22</p> <p>concerns [5] 14/2 80/23 149/11 151/6 161/16</p> <p>concluded [3] 71/4 105/15 107/20</p> <p>concludes [1] 167/23</p> <p>conclusion [5] 72/20 74/22 85/24 115/20 151/13</p> <p>conclusions [2] 57/1 114/19</p> <p>concurrently [1] 84/17</p> <p>condition [4] 18/2 30/9 33/16 94/10</p> <p>conditions [4] 48/9 50/21 62/13 132/12</p> <p>conduct [8] 71/24 75/4 78/25 79/1 83/2 120/13 129/8 147/14</p> <p>conducted [7] 44/15 58/10 62/17 67/25 103/22 108/23 150/6</p> <p>conducting [3] 69/1 132/24 138/20</p> <p>Conference [1] 66/20</p> <p>conferences [3] 20/18 21/8 21/12</p> <p>confidence [1] 52/8</p> <p>confident [1] 24/16</p> <p>confined [2] 138/24 144/4</p> <p>confirm [2] 85/22 107/2</p> <p>confirmed [3] 3/6 84/20 85/20</p> <p>conflict [1] 87/21</p> <p>confronted [1] 14/3</p> <p>Congenital [1] 45/23</p> <p>congratulated [1] 133/7</p> <p>conjunction [2] 59/4 152/1</p> <p>consent [35] 1/12 5/23 34/25 34/25 36/19 39/8 74/19 87/25 90/1 90/18 90/23 91/1 91/16 92/16 104/2 125/5 125/7 128/22 128/25 149/8 149/18 154/20 154/22 155/5 155/8 155/21 155/23 159/14 159/18 159/18 159/20 162/20 163/1 165/16 165/18</p> <p>consented [1] 155/9</p> <p>consenting [1] 162/23</p>	<p>consequences [4] 3/20 34/12 47/2 145/2</p> <p>consequent [1] 19/20</p> <p>consider [9] 6/17 7/7 13/9 14/16 30/3 51/7 67/24 70/8 167/1</p> <p>considerable [3] 79/10 150/16 156/20</p> <p>considerably [1] 14/20</p> <p>consideration [5] 11/16 82/8 83/9 83/11 161/17</p> <p>considered [2] 65/3 69/6</p> <p>consist [1] 90/8</p> <p>consistent [4] 8/25 11/15 30/12 142/21</p> <p>consistently [2] 142/6 144/7</p> <p>consists [1] 42/13</p> <p>constant [2] 3/3 16/18</p> <p>constituents [2] 47/17 47/20</p> <p>consult [1] 88/23</p> <p>consultant [12] 20/11 20/16 21/5 34/21 42/4 42/9 42/12 42/15 52/12 58/1 65/8 65/20</p> <p>consulting [1] 43/11</p> <p>consuming [2] 17/6 20/9</p> <p>consumption [1] 14/17</p> <p>contact [5] 24/20 25/7 27/13 31/13 99/5</p> <p>contacts [2] 95/19 96/5</p> <p>containing [3] 106/12 129/16 137/14</p> <p>contemplated [2] 90/25 122/15</p> <p>contemplating [1] 86/10</p> <p>contemporaneous [1] 22/20</p> <p>content [1] 38/20</p> <p>context [3] 21/17 32/22 100/2</p> <p>continually [1] 3/4</p> <p>continuation [3] 54/24 61/7 98/15</p> <p>continue [11] 16/5 23/24 24/24 43/24 56/6 56/9 65/18 66/25 140/6 162/8 162/11</p> <p>continued [10] 1/6 19/7 55/3 84/13 85/4 98/7 98/10 113/13 136/18 170/3</p> <p>continues [5] 15/25 33/6 43/6 136/4</p>	<p>142/19</p> <p>continuing [5] 18/12 76/3 79/23 158/23 167/12</p> <p>continuity [2] 18/15 126/20</p> <p>continuous [3] 41/25 61/23 85/4</p> <p>contract [1] 129/17</p> <p>contracted [3] 19/12 117/3 133/22</p> <p>contracting [2] 47/6 119/23</p> <p>contrary [2] 31/5 86/11</p> <p>contrast [2] 15/17 24/12</p> <p>contribute [3] 83/2 99/4 121/13</p> <p>contributed [1] 166/16</p> <p>contribution [1] 75/7</p> <p>control [6] 68/18 71/13 74/12 81/10 89/3 94/14</p> <p>controlled [13] 3/6 50/5 86/21 89/6 89/9 102/1 102/19 103/2 147/8 147/18 147/23 148/1 148/10</p> <p>convenient [1] 110/17</p> <p>conveniently [1] 83/6</p> <p>conversations [1] 26/1</p> <p>Conversely [1] 88/23</p> <p>cooperate [2] 94/8 121/18</p> <p>cooperation [7] 56/2 56/12 57/25 59/1 63/15 66/17 66/23</p> <p>cooperative [1] 56/6</p> <p>coordinated [1] 50/23</p> <p>Coordinating [1] 20/7</p> <p>copies [1] 151/7</p> <p>copy [7] 33/12 68/2 75/14 102/13 153/4 156/23 162/3</p> <p>core [2] 35/15 168/7</p> <p>core information [1] 35/15</p> <p>corner [1] 23/11</p> <p>correct [3] 29/1 124/11 168/15</p> <p>correlated [1] 116/6</p> <p>correlation [2] 140/15 142/16</p> <p>correspondence [6] 25/24 35/5 73/1 129/25 149/4 151/8</p> <p>cortisol [2] 57/21 63/20</p> <p>Cossart [5] 59/6 59/9</p>
--	---	---	--	--	---

<p>C</p> <p>Cossart... [3] 99/9 112/19 125/24</p> <p>cost [5] 75/8 76/24 77/8 79/12 86/1</p> <p>costs [5] 70/1 70/3 85/25 157/8 157/9</p> <p>could [41] 1/25 4/24 6/9 14/4 24/9 38/5 45/16 59/14 71/6 72/13 73/6 73/9 74/3 74/5 74/7 76/18 77/22 78/18 78/22 82/1 83/2 84/2 84/4 84/7 84/19 84/20 84/21 84/24 85/25 97/25 99/15 99/20 109/2 123/20 123/22 130/13 131/21 145/13 145/19 146/6 146/24</p> <p>couldn't [1] 123/21</p> <p>Council [14] 69/13 70/6 77/9 78/1 80/9 80/17 80/21 81/24 82/18 101/22 101/25 106/5 146/10 146/20</p> <p>counsel [4] 1/5 17/20 78/16 170/2</p> <p>counselled [1] 37/13</p> <p>counselling [22] 12/15 12/20 14/10 16/12 17/4 17/21 17/25 17/25 18/11 19/19 20/1 21/18 21/24 22/11 22/14 25/16 25/21 26/3 26/4 26/12 27/2 28/6</p> <p>counsellor [4] 11/25 19/6 19/24 21/16</p> <p>counsellors [3] 12/5 12/12 18/6</p> <p>country [4] 42/7 59/17 76/9 77/4</p> <p>county [2] 58/2 77/19</p> <p>couple [7] 14/7 26/21 28/13 32/18 75/11 93/1 103/20</p> <p>course [23] 5/11 7/21 10/18 10/22 24/21 28/8 35/7 35/8 36/19 36/22 37/18 53/14 65/6 93/14 123/17 132/1 141/11 146/11 146/21 165/14 167/1 167/2 167/18</p> <p>cover [3] 4/20 77/8 96/22</p> <p>covered [1] 76/24</p> <p>Craske [11] 50/23 100/15 120/5 139/17 140/5 141/4 141/6</p>	<p>143/16 143/22 143/23 144/14</p> <p>creates [1] 133/3</p> <p>Crescent [1] 82/15</p> <p>Crippled [1] 60/18</p> <p>crippling [7] 42/24 43/2 47/4 55/12 56/20 67/3 76/25</p> <p>criteria [7] 77/14 84/23 86/24 89/24 100/10 103/23 122/21</p> <p>criterion [1] 74/10</p> <p>criticisms [1] 84/1</p> <p>crockery [1] 8/9</p> <p>crop [1] 105/13</p> <p>cross [2] 68/16 76/15</p> <p>crowd [1] 4/25</p> <p>crude [1] 2/24</p> <p>cryo [3] 121/21 125/2 129/14</p> <p>cryoprecipitate [20] 99/1 107/12 108/22 109/16 111/21 123/22 124/2 124/4 124/13 124/20 124/24 127/1 128/19 130/9 137/4 137/15 137/17 138/4 139/4 142/8</p> <p>Cup [1] 4/23</p> <p>current [7] 3/9 21/9 48/17 63/25 68/13 108/5 119/1</p> <p>currently [2] 108/1 121/20</p> <p>cut [1] 87/6</p> <p>cut-off [1] 87/6</p> <p>cutlery [1] 8/9</p> <p>Cutter [2] 164/4 164/15</p> <p>CV [2] 51/6 51/16</p> <p>cytomegalo [2] 119/4 121/9</p> <p>cytomegalo virus [1] 121/9</p> <p>cytomegalovirus [1] 135/8</p>	<p>dated [6] 54/25 67/19 69/11 78/3 145/16 156/18</p> <p>dates [1] 5/7</p> <p>David [1] 138/19</p> <p>day [11] 42/2 42/2 44/10 44/10 53/14 67/9 67/9 76/21 76/21 128/1 128/1</p> <p>day-to-day [2] 44/10 67/9</p> <p>days [8] 41/22 50/10 87/9 103/10 104/22 128/14 168/16 168/24</p> <p>days' [1] 168/18</p> <p>DDAVP [3] 159/24 160/6 160/10</p> <p>deal [7] 16/15 34/23 43/20 71/1 117/13 147/2 164/11</p> <p>dealt [1] 43/19</p> <p>Dear [6] 23/15 69/20 129/24 137/24 138/19 145/18</p> <p>dearth [1] 165/20</p> <p>debated [1] 78/11</p> <p>December [6] 54/25 129/3 141/21 156/18 156/25 164/5</p> <p>December 1975 [1] 129/3</p> <p>December 1980 [1] 164/5</p> <p>decide [2] 5/10 5/14</p> <p>decided [4] 72/17 72/22 74/2 76/14</p> <p>deciding [1] 80/16</p> <p>decision [5] 6/19 71/4 71/4 80/10 153/19</p> <p>decisions [1] 164/24</p> <p>decreased [1] 125/11</p> <p>defects [4] 41/19 61/22 112/23 114/20</p> <p>deficiency [2] 45/24 46/6</p> <p>defined [3] 55/15 90/2 100/9</p> <p>definite [3] 116/25 135/4 142/16</p> <p>definition [1] 167/12</p> <p>definitive [1] 150/2</p> <p>deformity [1] 47/4</p> <p>degree [8] 45/17 45/25 52/6 52/8 66/14 125/10 148/8 157/17</p> <p>delay [3] 32/13 32/16 90/16</p> <p>delayed [2] 1/3 150/15</p> <p>delays [1] 10/14</p> <p>delegated [1] 104/6</p> <p>deliberately [1] 22/10</p>	<p>delivery [1] 163/18</p> <p>demand [4] 71/19 73/18 92/23 110/1</p> <p>demand' [2] 71/17 98/5</p> <p>demands [3] 17/8 21/20 21/20</p> <p>demonstrates [1] 137/19</p> <p>department [20] 18/7 19/14 43/10 67/21 67/23 69/9 69/16 69/25 73/2 77/25 78/14 80/15 81/16 81/20 81/23 82/3 86/8 106/5 133/11 168/18</p> <p>depend [1] 65/6</p> <p>dependent [1] 83/24</p> <p>depending [2] 48/17 126/14</p> <p>Depot [2] 136/17 136/24</p> <p>depth [1] 3/2</p> <p>deputies [1] 127/9</p> <p>Deputy [1] 77/12</p> <p>derivatives [1] 118/17</p> <p>derived [2] 101/5 101/7</p> <p>describe [2] 26/9 150/6</p> <p>described [12] 9/1 27/25 30/16 36/10 58/11 80/12 95/8 95/12 105/8 114/11 134/3 134/14</p> <p>describes [4] 19/23 33/11 103/22 153/15</p> <p>describing [4] 7/8 60/4 129/12 142/1</p> <p>description [6] 25/22 62/19 104/9 114/12 116/1 116/15</p> <p>design [4] 80/18 83/2 90/6 107/9</p> <p>design' [1] 89/6</p> <p>designation [1] 90/13</p> <p>designed [1] 25/11</p> <p>designing [1] 89/4</p> <p>designs [1] 79/3</p> <p>desirable [3] 56/6 89/3 166/4</p> <p>detail [13] 27/19 102/23 106/1 111/7 115/23 116/22 125/19 143/7 147/16 148/4 158/25 160/14 160/24</p> <p>detailed [3] 77/12 98/22 115/22</p> <p>details [13] 15/8 25/6 34/11 35/14 57/12 72/5 74/22 81/8 89/24 107/8 133/23 152/10</p>	<p>156/9</p> <p>detected [1] 26/11</p> <p>detecting [1] 119/1</p> <p>detection [1] 59/16</p> <p>determination [3] 86/23 90/2 91/17</p> <p>determine [5] 48/13 62/25 63/4 64/1 64/7</p> <p>determined [2] 30/4 46/12</p> <p>determining [2] 45/5 134/24</p> <p>devastated [1] 16/21</p> <p>develop [4] 18/21 29/5 58/23 138/13</p> <p>developed [4] 99/18 104/18 104/21 104/22</p> <p>developing [7] 24/11 120/9 131/14 131/19 132/4 134/18 150/9</p> <p>development [6] 58/13 64/15 82/5 104/16 121/6 156/20</p> <p>developments [1] 21/9</p> <p>develops [1] 126/2</p> <p>devise [1] 16/7</p> <p>devised [2] 2/22 135/13</p> <p>DHSC0100026 [2] 67/18 88/13</p> <p>DHSS [6] 44/23 70/7 78/12 80/5 80/6 82/20</p> <p>diagnoses [4] 28/10 31/17 31/20 31/21</p> <p>diagnosis [12] 8/19 10/25 12/17 12/18 14/3 22/25 26/2 27/16 27/25 32/14 37/7 100/10</p> <p>diagnostic [1] 116/12</p> <p>dialogue [1] 34/4</p> <p>Diana [1] 168/17</p> <p>diathesis [1] 46/8</p> <p>did [5] 13/20 79/17 93/22 108/17 162/9</p> <p>didn't [1] 5/17</p> <p>die [1] 17/12</p> <p>dies [1] 24/15</p> <p>difference [3] 88/11 100/11 121/1</p> <p>differences [2] 71/18 139/1</p> <p>different [10] 16/8 29/8 72/14 76/1 124/8 139/25 148/5 149/11 155/12 163/11</p> <p>difficult [12] 24/14 49/13 53/3 71/4 99/16 100/18 101/20 105/17 113/23 118/1 122/7 132/24</p>	<p>difficulties [6] 18/23 71/12 95/9 102/8 105/9 163/14</p> <p>difficulty [3] 19/16 79/13 97/21</p> <p>direct [3] 34/9 82/3 102/9</p> <p>directed [3] 83/6 108/10 134/23</p> <p>direction [4] 42/4 42/8 81/10 136/18</p> <p>directly [6] 10/24 26/10 104/7 143/16 145/24 149/4</p> <p>director [9] 42/10 54/22 56/19 65/20 65/22 77/11 99/4 163/19 164/2</p> <p>directors [32] 66/20 68/7 70/19 71/23 72/3 74/17 75/10 76/8 78/5 79/5 79/19 80/4 80/22 86/12 90/21 94/23 95/1 95/2 96/7 97/8 109/4 109/7 110/14 127/9 127/18 128/15 141/8 141/13 141/16 143/14 146/9 163/11</p> <p>directors' [2] 100/3 144/3</p> <p>disabled [1] 112/21</p> <p>disagreed [1] 79/6</p> <p>disastrous [1] 5/4</p> <p>discotheques [1] 5/7</p> <p>discovered [1] 80/2</p> <p>discovery [1] 46/8</p> <p>discuss [3] 94/6 129/20 146/12</p> <p>discussed [9] 58/18 73/24 76/1 76/17 79/4 92/17 101/4 102/1 146/8</p> <p>discussing [1] 27/14</p> <p>discussion [62] 6/15 6/17 27/15 27/23 28/24 32/24 34/17 46/14 47/14 50/8 63/8 70/21 72/2 72/7 72/15 73/19 75/9 76/17 78/1 79/16 80/1 81/1 81/6 83/6 83/14 83/18 85/7 85/14 85/21 85/24 86/12 88/16 89/23 91/4 92/13 92/20 93/25 94/16 94/19 94/20 95/23 97/24 98/13 99/11 100/1 100/5 101/14 104/25 107/16 109/22 128/14 132/9 136/4 136/6 142/1 143/3 143/6 143/9 143/10 156/21</p>
---	---	---	--	---	---

<p>D</p> <p>discussion... [2] 156/24 157/1</p> <p>discussions [8] 27/7 28/4 28/5 70/15 80/23 81/15 130/1 141/14</p> <p>disease [16] 15/7 41/21 55/7 57/16 58/20 59/8 64/15 113/17 117/14 117/25 140/22 142/12 142/23 143/5 143/11 144/17</p> <p>diseases [6] 41/20 42/24 43/2 56/20 57/22 77/1</p> <p>disorders [5] 44/8 62/10 112/16 116/5 117/12</p> <p>dispatched [1] 133/9</p> <p>display [1] 93/24</p> <p>disposal [1] 13/18</p> <p>disproportionate [1] 102/25</p> <p>dissenting [1] 75/1</p> <p>distillate [1] 2/14</p> <p>distinguishable [1] 90/12</p> <p>distressing [1] 67/2</p> <p>District [2] 19/15 133/12</p> <p>disturbance [1] 36/25</p> <p>dividing [1] 50/9</p> <p>Division [2] 69/16 90/20</p> <p>do [36] 8/18 10/23 12/11 16/1 18/5 19/12 21/18 22/2 22/3 23/8 23/14 25/6 25/17 29/5 37/8 37/21 37/25 39/22 78/22 91/2 93/2 100/25 101/10 102/14 122/20 130/9 135/4 139/11 146/6 146/24 148/20 154/25 157/25 158/4 163/20 164/15</p> <p>doctor [5] 7/13 52/6 94/2 152/13 164/9</p> <p>Doctor Aronstam [1] 164/9</p> <p>doctors [9] 4/3 6/14 6/18 7/12 68/25 72/21 73/5 146/16 152/21</p> <p>document [25] 1/13 14/6 23/5 39/20 41/8 54/20 61/10 61/14 61/18 88/9 88/12 95/15 95/17 109/2 111/25 112/5 117/19 118/4 118/12 128/16 129/23 143/15 145/9 155/7 161/20</p> <p>documentary [2] 165/1 167/21</p> <p>documentation [4] 1/7 28/4 39/11 50/6</p> <p>documented [1] 20/7</p> <p>documents [33] 28/13 32/12 32/18 35/4 39/6 39/16 41/1 53/14 54/18 55/9 67/16 75/11 86/14 86/16 93/20 104/5 106/4 108/20 109/17 112/2 129/1 132/15 132/17 137/7 141/17 144/21 148/8 161/19 161/23 163/3 165/4 168/2 168/3</p> <p>does [15] 25/17 32/12 37/14 50/15 52/25 87/1 87/13 119/22 120/16 143/17 164/20 164/22 164/22 167/24 167/25</p> <p>does it [1] 167/24</p> <p>doesn't [18] 5/15 5/18 5/20 11/16 22/8 22/12 22/17 23/12 82/7 94/19 128/9 130/19 131/6 131/25 134/15 138/14 140/2 155/16</p> <p>doing [3] 140/8 151/4 167/15</p> <p>don't [26] 9/15 10/4 10/5 15/20 22/13 25/23 28/19 38/8 39/25 60/18 61/10 73/16 89/24 95/11 95/16 111/25 125/19 145/4 151/7 155/3 160/24 161/22 162/3 162/22 163/23 164/19</p> <p>donation [1] 101/9</p> <p>donations [2] 101/6 139/9</p> <p>done [10] 17/22 18/24 20/8 24/6 39/23 55/15 71/7 82/1 102/13 116/14</p> <p>donor [6] 47/1 119/24 120/11 125/10 128/3 128/8</p> <p>donors [4] 114/5 120/2 122/12 124/5</p> <p>dosage [11] 48/25 73/23 73/25 74/3 98/1 105/5 147/8 147/15 147/18 148/19 148/20</p> <p>dosages [3] 149/6 150/3 151/11</p> <p>dose [24] 4/18 4/19 5/1 5/9 6/1 97/20 97/23 98/8 98/10</p> <p>104/14 104/15 105/12 105/15 105/19 107/4 107/21 111/24 148/1 150/15 150/18 150/20 152/5 153/2 154/10</p> <p>doses [8] 4/5 5/25 98/4 98/7 105/24 106/14 106/19 148/10</p> <p>double [12] 6/1 68/22 76/15 89/10 102/1 102/18 103/2 147/8 147/17 147/23 147/25 148/9</p> <p>double-blind [5] 89/10 147/8 147/17 147/23 147/25</p> <p>doubt [2] 23/16 165/12</p> <p>down [17] 7/17 15/1 32/23 46/22 47/23 50/8 57/17 97/4 109/23 119/19 122/1 125/20 125/23 133/15 136/13 154/2 162/5</p> <p>downplaying [1] 22/8</p> <p>Dr [242]</p> <p>Dr Arblaster [8] 40/20 67/20 70/14 80/2 82/19 85/17 95/2 95/8</p> <p>Dr Arblaster's [1] 70/9</p> <p>Dr Aronstam [48] 1/14 2/2 3/22 3/25 7/8 10/7 10/15 15/18 16/13 19/2 24/12 26/4 29/14 34/5 34/18 38/4 40/20 40/22 70/19 74/8 80/2 82/19 83/23 86/7 91/5 91/7 94/3 95/3 97/11 97/15 97/20 101/21 105/8 139/17 148/17 152/25 153/14 155/10 155/15 155/24 157/16 161/20 162/15 162/18 163/9 163/12 163/24 164/23</p> <p>Dr Aronstam's [5] 14/7 15/24 19/11 29/9 164/24</p> <p>Dr Bidwell [5] 80/14 82/20 84/20 85/25 86/13</p> <p>Dr Biggs [12] 54/22 55/10 59/23 66/1 70/24 71/13 71/23 73/8 73/16 78/9 78/17 80/1</p> <p>Dr Biggs' [1] 56/18</p> <p>Dr Blecher [1] 109/25</p> <p>Dr Bunje [1] 82/21</p> <p>Dr Cash [1] 97/25</p> <p>Dr Cossart [4] 59/9</p> <p>99/9 112/19 125/24</p> <p>Dr Craske [10] 50/23 100/15 139/17 140/5 141/4 141/6 143/16 143/22 143/23 144/14</p> <p>Dr Diana [1] 168/17</p> <p>Dr Holborow [1] 64/12</p> <p>Dr Hugh Platt [1] 133/10</p> <p>Dr Ingram [1] 95/21</p> <p>Dr Jones [4] 145/16 146/2 153/14 156/18</p> <p>Dr Jones's [1] 146/23</p> <p>Dr Kirk [34] 40/16 41/11 51/7 51/24 52/5 52/11 52/19 65/10 97/11 98/17 99/5 100/12 100/16 109/10 118/9 118/12 120/12 120/22 125/25 128/12 129/3 129/12 130/1 130/6 130/25 131/9 132/6 137/17 137/20 137/24 138/16 141/22 142/19 145/1</p> <p>Dr Kirk's [4] 51/16 53/5 109/4 136/3</p> <p>Dr Mann [2] 130/5 138/8</p> <p>Dr Matthews [2] 26/25 73/24</p> <p>Dr Maycock [7] 79/6 79/12 79/20 80/1 80/14 100/20 143/20</p> <p>Dr McGrath [1] 138/17</p> <p>Dr Metters [2] 70/11 82/20</p> <p>Dr Painter [3] 148/17 149/13 151/16</p> <p>Dr PC Arblaster [1] 42/4</p> <p>Dr Peter [1] 51/4</p> <p>Dr PG Arblaster [2] 65/20 102/3</p> <p>Dr Rainsford [35] 40/12 43/5 43/14 43/23 44/3 48/19 52/16 55/14 55/24 56/8 56/9 56/16 56/20 58/17 60/1 60/3 60/8 65/11 66/9 66/13 70/20 82/19 83/16 91/5 91/6 95/3 96/2 96/13 97/12 100/12 100/21 102/4 110/9 112/19 118/7</p> <p>Dr Rainsford's [4] 56/15 66/15 66/25 67/11</p> <p>Dr Rosemary [1] 68/8</p> <p>Dr Rosemary Biggs [4] 58/19 65/21 76/16 129/7</p> <p>Dr Sharrard [1] 59/2</p> <p>Dr Stewart [2] 82/20 98/6</p> <p>Dr Swinburne [2] 130/24 153/1</p> <p>Dr Tomlinson [7] 23/3 23/8 25/9 54/6 91/10 91/11 91/15</p> <p>Dr Wallsley [1] 161/8</p> <p>Dr Wassef [9] 26/25 31/25 32/2 33/1 33/11 33/14 33/23 161/8 161/20</p> <p>Dr Whitfield [1] 31/10</p> <p>Dr Yvonne [1] 59/6</p> <p>Dr. [1] 142/1</p> <p>Dr. Kirk [1] 142/1</p> <p>draft [2] 69/7 159/15</p> <p>drain [1] 17/15</p> <p>draw [3] 29/2 136/13 165/2</p> <p>drawn [5] 35/5 76/16 84/6 137/4 168/3</p> <p>dried [6] 72/20 90/10 124/1 140/11 142/6 144/10</p> <p>dropped [1] 105/18</p> <p>Drs [2] 71/8 81/11</p> <p>Drs Arblaster [1] 71/8</p> <p>drug [1] 68/12</p> <p>drugs [1] 70/1</p> <p>due [10] 35/7 35/7 46/6 76/22 121/7 144/10 165/13 167/1 167/2 167/18</p> <p>duration [3] 46/5 68/19 75/20</p> <p>during [28] 17/16 43/20 44/2 46/3 51/23 73/21 73/22 74/4 75/17 77/15 87/9 90/8 90/11 91/21 94/5 104/18 104/21 111/12 111/15 111/17 111/17 114/21 115/15 115/17 123/13 126/16 126/19 141/15</p> <p>duties [1] 45/2</p> <p>dying [2] 17/9 17/12</p>	<p>154/6 154/16 157/5</p> <p>earlier [14] 7/3 53/7 61/16 66/1 69/6 82/22 94/15 105/8 107/3 112/2 129/4 135/11 137/1 160/21</p> <p>early [9] 1/17 86/16 94/23 95/10 117/16 118/8 140/19 144/17 161/6</p> <p>easier [2] 49/5 129/17</p> <p>easily [2] 105/21 123/21</p> <p>Easter [1] 126/20</p> <p>easy [5] 39/6 39/19 76/7 82/11 138/3</p> <p>EB [3] 119/4 121/9 135/9</p> <p>Edinburgh [2] 132/22 142/3</p> <p>educate [1] 16/24</p> <p>education [4] 16/16 20/18 21/8 23/24</p> <p>Education/Conferences [1] 21/8</p> <p>effect [6] 33/10 37/23 88/9 122/17 124/6 151/21</p> <p>effective [4] 98/4 105/23 152/3 152/5</p> <p>effectiveness [1] 74/11</p> <p>effects [7] 47/19 49/23 50/2 88/19 89/1 151/1 151/25</p> <p>efficacy [1] 151/2</p> <p>efficiently [1] 133/14</p> <p>effort [1] 164/12</p> <p>efforts [1] 55/18</p> <p>eg [1] 119/4</p> <p>eight [2] 4/10 128/19</p> <p>eighteen [3] 41/24 123/10 127/11</p> <p>eighteen months [1] 123/10</p> <p>eighteen years [1] 41/24</p> <p>eighties [1] 38/16</p> <p>either [13] 6/6 6/24 7/3 23/12 25/7 26/10 37/9 77/25 79/5 91/22 106/15 139/3 152/3</p> <p>elective [1] 87/15</p> <p>elevated [3] 134/22 136/9 144/7</p> <p>eleven [1] 41/23</p> <p>elevenths [2] 42/16 42/17</p> <p>elicit [2] 128/25 155/5</p> <p>eligibility [8] 84/23 86/23 88/3 89/23 90/3 91/18 103/23 122/21</p>	<p>104/14 104/15 105/12 105/15 105/19 107/4 107/21 111/24 148/1 150/15 150/18 150/20 152/5 153/2 154/10</p> <p>doses [8] 4/5 5/25 98/4 98/7 105/24 106/14 106/19 148/10</p> <p>double [12] 6/1 68/22 76/15 89/10 102/1 102/18 103/2 147/8 147/17 147/23 147/25 148/9</p> <p>double-blind [5] 89/10 147/8 147/17 147/23 147/25</p> <p>doubt [2] 23/16 165/12</p> <p>down [17] 7/17 15/1 32/23 46/22 47/23 50/8 57/17 97/4 109/23 119/19 122/1 125/20 125/23 133/15 136/13 154/2 162/5</p> <p>downplaying [1] 22/8</p> <p>Dr [242]</p> <p>Dr Arblaster [8] 40/20 67/20 70/14 80/2 82/19 85/17 95/2 95/8</p> <p>Dr Arblaster's [1] 70/9</p> <p>Dr Aronstam [48] 1/14 2/2 3/22 3/25 7/8 10/7 10/15 15/18 16/13 19/2 24/12 26/4 29/14 34/5 34/18 38/4 40/20 40/22 70/19 74/8 80/2 82/19 83/23 86/7 91/5 91/7 94/3 95/3 97/11 97/15 97/20 101/21 105/8 139/17 148/17 152/25 153/14 155/10 155/15 155/24 157/16 161/20 162/15 162/18 163/9 163/12 163/24 164/23</p> <p>Dr Aronstam's [5] 14/7 15/24 19/11 29/9 164/24</p> <p>Dr Bidwell [5] 80/14 82/20 84/20 85/25 86/13</p> <p>Dr Biggs [12] 54/22 55/10 59/23 66/1 70/24 71/13 71/23 73/8 73/16 78/9 78/17 80/1</p> <p>Dr Biggs' [1] 56/18</p> <p>Dr Blecher [1] 109/25</p> <p>Dr Bunje [1] 82/21</p> <p>Dr Cash [1] 97/25</p> <p>Dr Cossart [4] 59/9</p>	<p>99/9 112/19 125/24</p> <p>Dr Craske [10] 50/23 100/15 139/17 140/5 141/4 141/6 143/16 143/22 143/23 144/14</p> <p>Dr Diana [1] 168/17</p> <p>Dr Holborow [1] 64/12</p> <p>Dr Hugh Platt [1] 133/10</p> <p>Dr Ingram [1] 95/21</p> <p>Dr Jones [4] 145/16 146/2 153/14 156/18</p> <p>Dr Jones's [1] 146/23</p> <p>Dr Kirk [34] 40/16 41/11 51/7 51/24 52/5 52/11 52/19 65/10 97/11 98/17 99/5 100/12 100/16 109/10 118/9 118/12 120/12 120/22 125/25 128/12 129/3 129/12 130/1 130/6 130/25 131/9 132/6 137/17 137/20 137/24 138/16 141/22 142/19 145/1</p> <p>Dr Kirk's [4] 51/16 53/5 109/4 136/3</p> <p>Dr Mann [2] 130/5 138/8</p> <p>Dr Matthews [2] 26/25 73/24</p> <p>Dr Maycock [7] 79/6 79/12 79/20 80/1 80/14 100/20 143/20</p> <p>Dr McGrath [1] 138/17</p> <p>Dr Metters [2] 70/11 82/20</p> <p>Dr Painter [3] 148/17 149/13 151/16</p> <p>Dr PC Arblaster [1] 42/4</p> <p>Dr Peter [1] 51/4</p> <p>Dr PG Arblaster [2] 65/20 102/3</p> <p>Dr Rainsford [35] 40/12 43/5 43/14 43/23 44/3 48/19 52/16 55/14 55/24 56/8 56/9 56/16 56/20 58/17 60/1 60/3 60/8 65/11 66/9 66/13 70/20 82/19 83/16 91/5 91/6 95/3 96/2 96/13 97/12 100/12 100/21 102/4 110/9 112/19 118/7</p> <p>Dr Rainsford's [4] 56/15 66/15 66/25 67/11</p> <p>Dr Rosemary [1] 68/8</p>	<p>Dr Rosemary Biggs [4] 58/19 65/21 76/16 129/7</p> <p>Dr Sharrard [1] 59/2</p> <p>Dr Stewart [2] 82/20 98/6</p> <p>Dr Swinburne [2] 130/24 153/1</p> <p>Dr Tomlinson [7] 23/3 23/8 25/9 54/6 91/10 91/11 91/15</p> <p>Dr Wallsley [1] 161/8</p> <p>Dr Wassef [9] 26/25 31/25 32/2 33/1 33/11 33/14 33/23 161/8 161/20</p> <p>Dr Whitfield [1] 31/10</p> <p>Dr Yvonne [1] 59/6</p> <p>Dr. [1] 142/1</p> <p>Dr. Kirk [1] 142/1</p> <p>draft [2] 69/7 159/15</p> <p>drain [1] 17/15</p> <p>draw [3] 29/2 136/13 165/2</p> <p>drawn [5] 35/5 76/16 84/6 137/4 168/3</p> <p>dried [6] 72/20 90/10 124/1 140/11 142/6 144/10</p> <p>dropped [1] 105/18</p> <p>Drs [2] 71/8 81/11</p> <p>Drs Arblaster [1] 71/8</p> <p>drug [1] 68/12</p> <p>drugs [1] 70/1</p> <p>due [10] 35/7 35/7 46/6 76/22 121/7 144/10 165/13 167/1 167/2 167/18</p> <p>duration [3] 46/5 68/19 75/20</p> <p>during [28] 17/16 43/20 44/2 46/3 51/23 73/21 73/22 74/4 75/17 77/15 87/9 90/8 90/11 91/21 94/5 104/18 104/21 111/12 111/15 111/17 111/17 114/21 115/15 115/17 123/13 126/16 126/19 141/15</p> <p>duties [1] 45/2</p> <p>dying [2] 17/9 17/12</p>	<p>E</p> <p>e 5 [1] 70/21</p> <p>each [23] 3/3 16/20 40/19 41/22 42/1 68/18 74/9 76/21 85/22 89/7 91/21 104/10 111/21 112/21 113/9 113/11 122/2 123/8 128/3 140/24</p>
--	---	---	--	--	---

(51) discussion... - eligibility

<p>E</p> <p>eligible [6] 86/25 87/4 87/11 87/14 104/1 122/23</p> <p>eloquent [1] 37/20</p> <p>else [8] 11/18 21/11 21/21 44/15 62/18 78/20 98/3 134/15</p> <p>else's [1] 146/1</p> <p>elsewhere [5] 15/19 26/13 78/25 91/15 132/13</p> <p>Elstree [5] 99/2 121/3 121/22 128/20 137/5</p> <p>emerge [1] 120/25</p> <p>emergency [2] 43/18 136/20</p> <p>emerges [4] 9/3 11/4 39/11 40/9</p> <p>emotional [3] 11/18 27/9 37/20</p> <p>emotionally [1] 6/21</p> <p>emphasising [1] 31/10</p> <p>employed [2] 42/14 42/15</p> <p>employment [1] 89/10</p> <p>enable [8] 20/16 21/6 21/8 55/21 149/7 152/4 168/5 168/8</p> <p>enabled [2] 3/4 13/21</p> <p>enclose [4] 68/2 102/13 145/20 153/4</p> <p>enclosed [1] 156/23</p> <p>encompass [1] 28/6</p> <p>encountered [1] 97/21</p> <p>encountering [1] 16/15</p> <p>encouraged [1] 161/12</p> <p>end [6] 38/19 39/14 50/14 62/20 77/17 118/21</p> <p>energy [1] 56/12</p> <p>engaged [1] 52/1</p> <p>England [1] 73/9</p> <p>enhanced [2] 21/2 92/24</p> <p>enlarged [1] 142/14</p> <p>enormous [1] 102/8</p> <p>enough [5] 34/9 72/25 73/6 119/2 162/8</p> <p>ensure [7] 25/2 49/18 49/23 49/24 83/3 126/20 132/25</p> <p>ensuring [3] 11/8 45/2 127/10</p> <p>enter [1] 17/1</p> <p>entered [2] 110/7 134/5</p>	<p>entering [1] 104/23</p> <p>enthusiastic [1] 151/4</p> <p>entire [2] 6/25 91/21</p> <p>entirely [5] 1/22 5/15 20/21 22/9 129/11</p> <p>entitled [3] 45/22 61/14 112/14</p> <p>entries [2] 25/23 37/11</p> <p>entry [6] 39/8 117/4 123/6 127/11 128/5 132/12</p> <p>envisaged [1] 64/25</p> <p>envisages [1] 121/20</p> <p>enzyme [2] 142/7 144/7</p> <p>epidemiological [2] 57/3 57/13</p> <p>episode [4] 3/3 89/1 94/11 105/18</p> <p>episodes [2] 87/9 92/8</p> <p>equipped [4] 14/1 42/6 43/9 65/1</p> <p>equivalent [1] 78/9</p> <p>equivocal [1] 11/23</p> <p>essential [4] 18/20 20/6 55/15 72/11</p> <p>essentially [10] 9/1 10/4 20/10 32/3 36/12 119/11 121/14 128/6 141/2 166/7</p> <p>establish [4] 81/11 102/14 107/4 140/9</p> <p>established [5] 42/5 42/23 56/3 62/4 77/1</p> <p>establishment [5] 41/18 44/11 61/21 62/14 76/18</p> <p>estimate [2] 66/10 157/8</p> <p>et [8] 47/25 119/9 120/5 125/22 144/11 144/11 162/10 162/10</p> <p>et al [2] 119/9 120/5</p> <p>et cetera [1] 125/22</p> <p>etc [2] 37/1 37/1</p> <p>ethical [10] 69/4 78/19 82/9 84/25 85/1 155/1 165/16 165/22 165/24 167/6</p> <p>ethically [2] 78/24 79/1</p> <p>ethics [2] 74/24 154/19</p> <p>evaluate [2] 76/12 89/15</p> <p>Evans [2] 58/10 60/21</p> <p>even [10] 4/22 6/18 16/22 17/6 24/10 27/20 35/14 40/8 68/23 98/5</p>	<p>event [13] 4/21 4/22 4/23 5/1 22/15 30/15 33/6 60/19 91/16 100/22 128/11 132/17 134/16</p> <p>events [1] 82/24</p> <p>eventually [2] 15/15 24/11</p> <p>ever [1] 8/18</p> <p>every [6] 24/24 48/6 52/8 74/1 113/20 113/20</p> <p>everyday [1] 3/10</p> <p>everyone [1] 168/8</p> <p>everything [3] 37/17 37/18 37/22</p> <p>evidence [66] 1/10 5/16 5/19 5/21 7/20 7/22 8/1 8/4 9/4 9/6 9/24 10/8 10/16 10/18 10/21 10/22 11/2 11/4 11/5 11/9 11/15 11/21 11/24 12/1 12/14 12/19 12/25 15/7 22/13 31/5 31/16 32/15 34/24 35/2 35/8 35/17 36/1 36/2 36/6 36/15 36/20 37/10 37/20 57/3 57/13 57/19 91/14 93/21 97/18 110/8 114/25 128/22 134/4 140/3 142/11 142/23 144/12 148/4 159/11 159/19 159/24 160/18 160/25 168/17 168/19 169/2</p> <p>evident [1] 140/25</p> <p>evolution [1] 14/12</p> <p>exacerbated [1] 30/18</p> <p>exactly [1] 38/13</p> <p>examination [3] 33/1 59/10 167/4</p> <p>examinations [5] 4/13 5/5 36/24 37/2 51/22</p> <p>examine [1] 113/20</p> <p>examined [5] 57/22 58/6 58/21 64/12 84/15</p> <p>examining [3] 37/10 114/1 145/2</p> <p>example [9] 39/7 86/17 88/20 92/25 93/23 93/23 93/24 155/21 162/25</p> <p>examples [11] 21/12 35/20 36/23 37/2 37/4 129/1 130/3 157/21 160/22 162/20 162/24</p> <p>exceed [1] 90/17</p> <p>excellent [1] 51/17</p> <p>except [2] 150/20 150/23</p>	<p>exception [3] 36/1 57/1 167/17</p> <p>exceptional [1] 51/12</p> <p>exceptions [1] 130/10</p> <p>exchange [2] 45/10 73/1</p> <p>exchanges [2] 141/14 159/24</p> <p>excitement [1] 4/25</p> <p>exclude [2] 68/23 135/7</p> <p>excluded [1] 135/21</p> <p>excluding [1] 135/21</p> <p>exclusion [2] 122/25 167/7</p> <p>execution [1] 87/17</p> <p>exemplary [1] 31/12</p> <p>exert [2] 14/14 88/24</p> <p>exist [1] 89/19</p> <p>existence [1] 46/24</p> <p>exists [1] 64/22</p> <p>expensive [1] 66/12</p> <p>experience [4] 2/14 3/16 13/25 20/5</p> <p>experienced [1] 128/4</p> <p>experiences [1] 27/12</p> <p>experimentation [1] 17/3</p> <p>expert [2] 17/5 34/20</p> <p>expertise [2] 2/21 14/24</p> <p>explain [4] 13/16 22/9 128/9 162/22</p> <p>explained [11] 33/2 33/9 58/25 91/18 103/25 107/24 118/23 146/5 155/10 155/15 155/24</p> <p>explanation [3] 44/16 152/7 152/8</p> <p>expose [1] 119/22</p> <p>exposed [1] 167/13</p> <p>exposure [13] 114/25 115/11 122/11 122/12 122/14 125/10 128/3 128/8 134/12 161/22 162/10 162/12 166/5</p> <p>express [1] 125/12</p> <p>expressed [5] 51/4 73/15 80/23 110/14 159/2</p> <p>expresses [1] 161/21</p> <p>expressing [2] 149/10 151/5</p> <p>expressly [1] 122/19</p> <p>extend [2] 5/6 67/10</p> <p>extended [4] 47/4 50/5 84/2 85/12</p> <p>extending [1] 14/23</p> <p>extension [3] 44/2 97/22 127/16</p> <p>extensive [3] 6/14</p>	<p>44/13 62/15</p> <p>extent [3] 17/25 122/20 137/22</p> <p>external [1] 26/12</p> <p>extolled [1] 89/13</p> <p>extra [1] 86/7</p> <p>extracts [1] 28/15</p> <p>extrapolation [1] 3/10</p> <p>extremely [5] 10/20 24/8 24/14 59/8 146/11</p> <p>F</p> <p>f.VIII [1] 137/14</p> <p>face [2] 25/10 102/8</p> <p>faced [1] 2/18</p> <p>faceted [1] 16/7</p> <p>facilities [7] 42/7 44/13 45/4 45/12 51/12 62/15 89/19</p> <p>facility [2] 12/2 12/15</p> <p>fact [12] 10/3 29/20 105/18 112/10 128/18 130/9 147/13 149/12 151/4 151/20 162/5 163/1</p> <p>factor [104] 4/19 6/10 14/17 33/8 45/3 45/24 46/10 46/11 46/25 48/12 48/25 50/11 57/6 58/14 58/23 62/24 62/25 63/5 64/2 64/9 66/12 69/21 70/2 74/14 75/22 79/9 79/17 79/25 80/13 81/12 82/13 84/11 84/21 85/12 85/22 86/1 86/4 86/13 87/3 87/13 88/20 89/9 90/10 94/6 97/20 98/2 99/2 100/3 101/5 101/6 101/13 103/3 103/7 106/15 107/21 108/22 108/23 111/14 111/22 111/23 118/15 119/14 119/21 119/25 119/25 120/16 121/2 121/24 127/25 129/16 131/16 139/13 139/25 140/11 144/5 145/23 147/15 148/1 148/19 150/3 150/7 151/3 151/23 152/1 153/25 154/11 155/15 155/24 156/3 158/12 158/21 158/24 159/4 160/11 161/22 162/12</p> <p>Factor VIII-containing [1] 106/12</p> <p>Factorate [4] 153/18 153/20 153/24 154/8</p> <p>factors [1] 46/7</p> <p>facts [2] 16/1 116/23</p> <p>failure [1] 118/22</p> <p>failures [1] 2/11</p> <p>faint [2] 46/13 48/21</p> <p>fairly [3] 58/11 129/23 163/25</p> <p>fall [1] 112/2</p> <p>fallen [1] 39/24</p> <p>families [3] 16/3 16/14 18/16</p> <p>family [4] 25/19 26/11 27/20 87/2</p> <p>far [9] 2/20 7/11 80/6 84/20 102/7 122/13 133/16 144/5 151/24</p> <p>fashion [1] 166/4</p> <p>fatal [2] 8/3 8/3</p> <p>fault [1] 20/21</p> <p>fear [1] 16/18</p> <p>feature [1] 40/2</p> <p>February [4] 28/16 81/5 131/17 132/23</p> <p>February 1976 [1] 132/23</p> <p>February 1986 [1] 28/16</p>	<p>Factor VII [1] 142/17</p> <p>factor VIII [91] 4/19 6/10 14/17 45/3 46/10 46/25 48/12 48/25 50/11 57/6 62/24 62/25 63/5 64/2 64/9 66/12 69/21 70/2 74/14 75/22 79/9 79/17 79/25 80/13 81/12 82/13 84/11 84/21 85/12 85/22 86/1 86/4 86/13 87/13 88/20 89/9 90/10 94/6 97/20 98/2 99/2 100/3 101/5 101/6 101/13 103/3 103/7 106/15 107/21 108/22 108/23 111/22 111/23 118/15 119/14 119/21 119/25 120/16 121/2 121/24 127/25 129/16 131/16 139/13 139/25 140/11 144/5 145/23 147/15 148/1 148/19 150/3 150/7 151/3 151/23 152/1 153/25 154/11 155/15 155/24 156/3 158/12 158/21 158/24 159/4 160/11 161/22 162/12</p> <p>Factor VIII-containing [1] 106/12</p> <p>Factorate [4] 153/18 153/20 153/24 154/8</p> <p>factors [1] 46/7</p> <p>facts [2] 16/1 116/23</p> <p>failure [1] 118/22</p> <p>failures [1] 2/11</p> <p>faint [2] 46/13 48/21</p> <p>fairly [3] 58/11 129/23 163/25</p> <p>fall [1] 112/2</p> <p>fallen [1] 39/24</p> <p>families [3] 16/3 16/14 18/16</p> <p>family [4] 25/19 26/11 27/20 87/2</p> <p>far [9] 2/20 7/11 80/6 84/20 102/7 122/13 133/16 144/5 151/24</p> <p>fashion [1] 166/4</p> <p>fatal [2] 8/3 8/3</p> <p>fault [1] 20/21</p> <p>fear [1] 16/18</p> <p>feature [1] 40/2</p> <p>February [4] 28/16 81/5 131/17 132/23</p> <p>February 1976 [1] 132/23</p> <p>February 1986 [1] 28/16</p>
--	--	---	--	--	---

<p>F</p> <p>feel [9] 6/16 6/18 13/11 55/3 56/5 102/9 146/13 148/21 149/7</p> <p>Feinstone [1] 119/8</p> <p>fell [2] 83/22 161/15</p> <p>fellow [21] 40/13 42/25 43/14 43/20 44/5 44/17 45/13 45/16 45/19 46/1 51/2 53/9 53/9 55/22 56/9 64/20 64/23 65/5 67/12 76/23 77/15</p> <p>fellowship [5] 42/22 62/4 64/22 164/11 164/18</p> <p>felt [8] 71/13 73/8 97/22 99/12 99/14 100/13 100/17 110/6</p> <p>few [6] 28/3 46/9 51/10 74/8 128/14 157/20</p> <p>few' [1] 29/3</p> <p>fibrinolysis [1] 63/7</p> <p>field [2] 24/8 108/9</p> <p>Fifteen [1] 142/8</p> <p>fifth [1] 116/21</p> <p>fifty [2] 2/5 41/18</p> <p>fifty boys [1] 41/18</p> <p>figure [2] 40/5 115/16</p> <p>figures [2] 116/23 137/3</p> <p>final [8] 4/23 51/18 86/16 88/10 90/2 102/12 109/2 109/19</p> <p>Finally [1] 136/16</p> <p>finance [3] 19/6 79/24 81/18</p> <p>financial [13] 14/21 21/15 45/18 62/6 69/8 77/6 79/14 83/13 86/2 107/1 108/5 164/10 164/18</p> <p>financing [1] 163/15</p> <p>find [6] 6/5 28/21 39/1 118/2 138/3 156/23</p> <p>finding [1] 124/13</p> <p>findings [9] 44/10 46/17 62/12 103/19 107/3 107/3 113/6 116/19 134/24</p> <p>fine [1] 32/8</p> <p>finish [1] 136/11</p> <p>firm [1] 79/11</p> <p>first [35] 25/1 27/22 28/18 38/10 38/20 41/9 48/23 50/10 52/13 53/8 61/18 62/21 66/14 69/19 80/11 89/5 95/13 103/10 105/25 106/20</p>	<p>106/22 129/2 133/23 134/12 139/19 141/19 146/20 148/20 149/14 152/10 152/18 153/1 159/20 165/15 166/24</p> <p>fit [5] 5/15 5/18 5/20 54/15 134/15</p> <p>five [15] 2/1 15/12 19/12 19/13 41/5 100/25 108/25 111/11 111/16 114/23 121/22 128/21 142/3 142/15 168/24</p> <p>fixed [1] 4/9</p> <p>flavour [4] 41/1 41/13 117/15 148/13</p> <p>Florence [1] 42/18</p> <p>focus [3] 144/25 166/13 166/16</p> <p>fold [1] 120/9</p> <p>follow [3] 16/19 113/4 116/2</p> <p>follow-up [1] 16/19</p> <p>followed [2] 115/12 126/4</p> <p>following [19] 33/16 72/8 75/23 81/15 83/7 91/20 95/21 95/24 97/20 97/24 98/22 104/9 118/23 120/15 122/20 125/7 126/22 145/6 168/25</p> <p>follows [2] 20/11 141/25</p> <p>fore [1] 161/12</p> <p>foregoing [1] 62/8</p> <p>foremost [2] 166/23 166/24</p> <p>forerunner [1] 144/18</p> <p>foreseen [1] 84/21</p> <p>forgotten [1] 110/5</p> <p>form [30] 9/8 12/19 25/21 26/3 26/12 39/8 45/25 49/16 69/6 76/15 88/5 88/7 104/12 126/2 129/23 146/14 149/3 153/18 155/8 155/12 155/21 159/14 159/15 159/18 159/18 159/20 162/22 163/2 164/10 164/17</p> <p>formal [3] 69/25 77/9 141/15</p> <p>format [1] 155/21</p> <p>forming [1] 153/16</p> <p>forms [5] 86/22 93/17 139/25 157/21 162/20</p> <p>formulated [1] 96/23</p> <p>forthcoming [1] 56/1</p> <p>fortnightly [1] 125/16</p> <p>forty [2] 114/23 142/3</p> <p>Forty-five [1] 142/3</p>	<p>forward [1] 164/12</p> <p>forwarded [1] 54/9</p> <p>found [6] 14/1 126/9 140/10 142/15 150/10 151/23</p> <p>foundation [1] 43/22</p> <p>four [14] 17/12 42/17 57/10 57/12 63/12 74/1 75/17 83/7 90/8 92/12 105/13 106/13 128/20 135/2</p> <p>four years [1] 75/17</p> <p>fourteen [1] 43/8</p> <p>fourth [3] 63/21 72/8 104/11</p> <p>fraction [1] 93/5</p> <p>fractionated [1] 119/24</p> <p>fractionation [2] 79/7 101/4</p> <p>fractions [1] 47/1</p> <p>framework [2] 45/9 106/3</p> <p>Francis [1] 42/11</p> <p>Fraser [1] 26/6</p> <p>FRCS [1] 60/21</p> <p>free [6] 93/5 93/8 93/9 93/10 126/23 163/17</p> <p>freeze [6] 72/20 90/10 124/1 140/11 142/6 144/10</p> <p>freeze-dried [5] 72/20 90/10 124/1 140/11 142/6</p> <p>frequencies [1] 108/2</p> <p>frequency [19] 4/5 46/5 63/2 63/6 64/3 73/23 73/25 74/10 75/19 85/13 87/8 103/9 103/10 103/17 106/19 107/23 108/19 113/6 116/7</p> <p>frequent [6] 4/13 16/20 48/24 99/14 113/22 132/25</p> <p>frequently [3] 63/14 74/2 115/9</p> <p>fresh [3] 18/23 79/15 154/15</p> <p>Friday [1] 1/1</p> <p>friends [1] 36/11</p> <p>from [188]</p> <p>frozen [1] 79/15</p> <p>fulfil [2] 22/3 88/1</p> <p>full [10] 17/8 20/11 42/14 64/20 65/2 67/7 92/12 100/5 105/1 164/7</p> <p>full-blown [1] 17/8</p> <p>fully [10] 27/6 43/9 43/13 64/22 65/1 65/3 88/6 91/18 103/25</p>	<p>142/17</p> <p>function [18] 36/9 46/11 47/25 75/21 100/1 100/14 100/17 123/6 126/4 126/10 131/13 133/13 134/23 136/10 139/24 143/2 143/5 143/12</p> <p>Fund [5] 42/24 43/1 56/19 76/25 96/24</p> <p>fundamental [3] 39/12 46/8 57/20</p> <p>funded [1] 21/13</p> <p>funding [13] 19/7 20/14 20/14 20/16 20/17 21/2 21/6 21/8 41/10 54/24 60/16 66/5 82/2</p> <p>funds [3] 79/23 81/18 157/10</p> <p>further [39] 1/9 15/8 15/10 19/10 20/11 25/5 28/13 30/23 31/9 32/10 32/23 50/6 61/11 70/15 81/25 82/8 88/12 92/13 97/4 99/25 108/9 112/5 118/9 119/17 121/7 125/23 131/22 133/15 134/19 135/4 137/7 141/9 143/6 147/20 148/4 153/11 154/2 158/17 163/3</p> <p>Furthermore [3] 59/15 119/25 133/1</p> <p>future [17] 16/10 20/13 20/24 20/25 34/7 46/21 50/16 52/11 62/20 64/18 65/7 75/16 100/13 105/22 110/11 127/16 133/19</p> <p>Future Research [1] 62/20</p>	<p>getting [2] 18/23 137/2</p> <p>gist [1] 32/7</p> <p>give [21] 17/20 40/4 41/1 44/4 48/8 53/3 53/10 69/24 90/1 103/6 104/2 117/15 125/7 138/3 140/14 140/24 148/21 160/15 161/25 163/1 163/20</p> <p>given [38] 4/9 4/11 10/14 11/7 11/8 11/16 11/22 12/18 15/8 31/19 32/10 34/11 35/14 36/1 36/10 38/19 44/22 48/3 52/14 74/3 79/22 87/25 91/14 103/5 104/15 105/20 107/8 108/4 111/14 113/10 115/5 128/20 131/1 133/23 151/3 152/5 161/17 162/8</p> <p>gives [7] 14/9 41/11 57/12 148/13 151/6 155/8 165/5</p> <p>giving [8] 4/19 71/19 105/19 124/9 130/16 149/8 149/23 162/18</p> <p>Glenarthur [1] 168/19</p> <p>gloomier [1] 15/13</p> <p>go [111] 1/19 1/25 3/23 4/17 8/14 12/9 13/4 13/7 14/6 15/1 15/5 16/8 16/24 19/9 20/12 21/11 26/16 27/18 27/21 27/21 28/14 28/22 31/7 32/20 33/21 41/3 43/6 46/22 47/13 47/23 54/20 58/15 60/15 61/13 62/20 63/10 64/13 67/17 69/10 69/14 70/21 72/1 75/13 77/23 81/5 82/10 83/14 85/11 85/23 86/24 88/14 89/24 90/4 91/3 93/1 96/16 97/12 99/25 100/24 101/11 101/19 102/23 104/10 104/16 105/6 106/1 106/6 106/21 107/16 108/19 109/2 109/7 110/3 112/13 114/12 114/18 115/22 115/25 116/21 117/5 117/10 117/19 117/20 125/19 125/23 127/4 128/13 128/16 128/17 131/8 132/5 133/15 137/1 143/7 143/23 147/16 148/3</p>	<p>152/19 154/10 155/6 155/11 156/9 156/17 157/9 158/24 158/25 159/17 160/14 160/23 164/3 164/7</p> <p>goes [1] 143/7</p> <p>going [33] 6/4 26/6 27/18 36/11 37/19 39/2 39/16 39/25 46/16 53/13 67/13 67/17 88/14 91/6 93/6 93/12 102/23 106/1 111/7 112/7 115/22 116/22 128/8 128/16 134/18 136/11 138/9 147/2 148/3 152/19 157/11 158/1 160/14</p> <p>gone [3] 102/7 141/15 149/22</p> <p>good [9] 53/15 56/2 73/5 110/4 112/25 136/2 140/14 146/7 146/24</p> <p>got [17] 31/24 32/14 33/7 86/14 93/21 93/23 93/24 112/6 121/19 128/25 131/8 155/12 155/21 160/4 160/21 162/23 162/25</p> <p>governing [4] 23/7 28/16 28/18 28/20</p> <p>graduating [1] 51/20</p> <p>grant [10] 55/3 60/22 60/23 61/8 65/6 67/24 76/24 143/16 143/22 156/15</p> <p>granted [1] 51/4</p> <p>grateful [4] 34/8 54/8 67/23 149/18</p> <p>great [8] 43/20 51/24 66/8 66/10 68/25 70/25 111/7 164/11</p> <p>greater [6] 29/16 84/8 87/5 101/9 101/13 127/25</p> <p>greatly [3] 59/18 67/2 160/24</p> <p>groundwork [1] 106/3</p> <p>group [18] 8/20 10/2 17/7 50/12 60/10 70/7 72/5 72/12 74/12 74/13 82/4 92/3 97/19 103/17 113/2 123/2 139/4 166/14</p> <p>groups [4] 19/22 50/9 71/13 144/4</p> <p>guardian [2] 87/24 91/19</p> <p>guardians [2] 104/1 125/6</p> <p>guidelines [1] 165/16</p> <p>Guthrie [3] 56/18</p>
--	---	--	--	--	--

G	78/18 79/18 80/3 80/22 81/7 86/11 86/20 87/1 88/17 89/2 90/22 94/23 95/1 96/7 97/7 98/20 101/23 102/2 102/5 102/18 106/9 109/4 109/6 111/5 111/12 112/23 116/4 118/14 121/18 122/22 127/17 128/15 129/7 129/8 130/1 130/19 131/6 138/1 141/7 141/12 141/16 143/14 144/3 146/9 147/10 148/3 150/18 152/22 153/8 153/21 158/14 160/13 163/11 166/3	54/12 58/2 69/5 82/3 hand [7] 23/11 106/24 107/10 107/17 107/18 111/8 147/5 handful [9] 1/9 40/25 67/17 129/1 137/7 145/8 147/3 148/7 152/20 handicaps [1] 24/1 handle [1] 31/14 handwritten [2] 155/22 160/5 Hants [1] 55/2 happened [1] 9/11 happens [1] 61/11 happy [3] 129/20 146/12 150/4 harbouring [1] 27/10 hard [1] 162/3 Harwood [1] 69/15 has [94] 2/9 9/4 9/6 9/24 14/12 14/20 17/2 23/18 24/3 26/6 26/9 31/17 33/2 34/23 37/24 39/7 42/23 43/2 43/7 44/18 44/22 46/25 51/4 51/16 51/18 51/24 55/14 55/15 55/17 55/24 56/2 56/9 57/8 59/6 59/9 59/23 63/5 63/15 64/19 66/8 66/17 66/19 68/2 68/6 77/8 77/10 78/7 78/12 87/8 94/11 94/18 96/23 97/5 102/5 102/13 103/3 112/25 113/13 113/19 113/22 114/5 118/17 119/16 120/4 122/8 128/24 129/14 130/20 133/12 133/13 134/1 135/13 135/16 135/21 138/7 142/23 143/2 144/5 146/7 146/10 149/3 149/17 149/22 151/21 151/22 151/25 154/17 155/17 155/22 156/3 156/6 159/2 159/5 162/15	141/19 HCDO0001015 [1] 70/17 HCV [3] 33/3 33/17 34/7 he [83] 2/4 4/8 4/17 7/10 8/9 11/11 12/24 12/25 13/8 14/23 15/5 15/9 15/25 17/19 17/21 18/19 19/11 19/16 19/16 19/18 19/21 19/23 19/24 20/2 20/10 20/12 20/25 20/25 21/2 21/4 21/13 21/18 22/9 23/5 27/6 29/22 30/8 30/18 30/19 30/24 32/1 33/2 40/13 40/15 40/18 51/16 51/17 52/5 52/8 53/5 57/12 57/17 67/22 79/13 83/5 88/23 88/25 91/25 92/2 92/3 95/13 97/17 97/18 97/21 98/21 101/23 104/23 105/8 129/15 129/17 131/14 131/21 131/23 134/1 137/14 138/4 138/7 138/12 142/23 143/2 150/7 150/18 153/2 he's [3] 20/14 131/19 137/16 he/she [1] 30/24 head [1] 38/9 headed [5] 75/15 86/19 101/23 115/24 159/14 heading [37] 3/25 15/2 16/12 20/23 21/3 21/7 28/25 39/3 41/15 45/20 47/14 62/19 63/24 64/16 69/18 74/21 90/5 91/16 96/18 103/21 107/10 107/15 107/16 111/9 114/14 116/15 116/21 125/18 126/1 136/12 141/23 143/24 147/7 154/3 154/19 156/14 158/9 headmaster [8] 11/6 12/22 22/19 25/7 29/1 30/2 30/10 30/14 headmaster's [1] 12/4 Health [22] 19/3 31/14 44/1 59/5 63/16 64/19 67/21 69/16 72/24 73/3 75/3 76/3 77/7 77/25 78/14 81/16 81/20 81/24 82/3 106/5 141/4 168/18 hear [3] 6/20 156/2	169/2 heard [15] 5/16 5/21 7/19 7/20 9/7 9/24 10/1 10/8 10/18 11/5 35/1 37/18 37/21 37/22 160/25 hearing [2] 13/3 168/16 hearings [3] 167/22 168/11 168/12 heavy [2] 4/24 84/18 held [4] 68/7 76/10 82/15 128/14 help [7] 23/12 42/25 64/24 66/10 117/18 130/8 136/19 helpful [2] 6/20 150/4 Hemofil [16] 109/17 121/23 121/23 128/20 131/16 133/18 134/17 137/4 139/1 142/22 143/1 150/12 154/1 154/9 157/13 157/19 hepatitis [147] 6/6 6/13 6/24 7/25 8/1 8/3 8/7 8/10 8/17 31/17 32/1 32/7 32/10 32/19 32/25 33/5 34/13 34/15 35/25 36/5 36/8 36/12 47/6 48/4 48/9 50/22 50/22 52/4 52/23 59/14 59/22 76/2 92/24 93/5 93/8 93/9 93/10 93/16 93/17 96/16 97/2 98/16 98/19 100/1 100/6 100/9 101/15 104/20 104/22 112/9 114/16 114/17 115/1 115/2 115/9 115/14 115/17 116/3 116/8 116/20 116/22 117/7 117/11 117/16 117/24 118/8 118/14 118/18 118/20 118/23 119/2 119/4 119/7 119/11 119/12 119/23 120/3 120/3 120/10 120/14 120/19 120/22 121/5 121/6 121/7 121/8 121/11 121/14 121/15 122/12 126/2 126/5 126/7 129/6 129/18 130/24 131/4 131/11 131/14 131/18 131/20 132/4 132/9 133/22 134/2 134/4 134/5 134/18 134/22 135/1 135/6 135/7 135/8 135/8 135/10 135/12 136/7 136/9 137/2 137/13 137/21 138/13	138/20 138/23 138/24 139/23 140/9 140/19 140/25 141/18 141/20 141/22 141/24 142/2 142/21 142/22 143/1 143/8 144/3 144/12 144/13 144/19 144/20 144/22 144/23 145/6 167/8 hepatitis 'A' [1] 121/8 hepatitis A [2] 135/10 135/12 hepatitis B [15] 8/17 48/4 93/10 93/16 101/15 118/20 119/2 119/11 121/5 121/11 131/18 134/18 135/8 142/22 144/13 hepatitis C [7] 31/17 32/1 32/7 32/10 32/19 33/5 34/13 hepatology [1] 34/21 her [5] 8/8 9/18 54/22 60/3 66/4 here [22] 2/3 7/8 13/3 20/23 20/25 29/8 54/21 55/10 56/23 57/3 57/14 98/12 98/12 107/5 108/17 131/9 137/3 147/17 152/25 155/6 155/13 158/9 hers [1] 26/7 hesitate [1] 25/7 hesitation [1] 67/6 HHFT0000053 [2] 112/13 117/20 HHFT0000145 [1] 161/2 HHFT0000332 [1] 115/23 HHFT0000925 [1] 139/17 HHFT0001073 [1] 14/9 HHFT0001161 [1] 159/11 HHFT0001201 [2] 153/13 156/17 HHFT0001430 [1] 160/4 high [13] 4/21 4/22 5/3 59/8 66/15 104/14 148/2 150/19 153/2 153/5 153/17 153/24 154/8 high-dose [1] 104/14 higher [8] 4/5 120/9 142/5 148/19 148/20 149/6 150/20 151/11 highest [2] 5/24 66/21 highlighted [1] 49/3
----------	---	---	--	--	---

<p>H</p> <p>highly [1] 74/15</p> <p>him [15] 5/10 27/10 32/2 33/2 51/20 53/7 53/8 88/23 129/15 131/1 131/22 131/24 150/19 151/4 162/8</p> <p>himself [4] 19/23 56/10 56/16 88/24</p> <p>hindsight [1] 13/11</p> <p>his [53] 3/17 3/18 3/18 3/19 8/4 10/21 11/24 13/7 19/17 19/21 21/19 22/5 22/7 24/13 27/6 27/16 30/9 31/10 32/1 35/17 42/16 43/20 44/2 44/3 51/6 51/21 51/23 56/11 65/7 66/16 68/18 76/23 77/12 86/8 87/24 88/23 89/7 94/7 94/13 122/5 127/10 128/4 131/12 134/12 137/15 140/1 142/24 150/8 150/12 150/25 162/9 162/10 162/11</p> <p>historically [1] 60/23</p> <p>history [5] 41/12 41/12 48/13 87/2 116/25</p> <p>HIV [19] 9/5 12/16 13/13 13/17 14/3 14/4 14/13 14/20 15/3 15/7 16/2 16/21 19/21 19/24 22/4 25/13 27/8 27/16 27/25</p> <p>HIV situation [1] 19/21</p> <p>HIV/AIDS [2] 13/17 14/4</p> <p>HL [2] 155/17 155/22</p> <p>Holborow [1] 64/12</p> <p>hold [1] 48/20</p> <p>holiday [3] 45/5 73/21 74/20</p> <p>holidays [5] 73/23 74/4 94/5 126/17 150/10</p> <p>home [22] 1/18 17/14 20/17 21/7 30/24 31/21 37/4 71/20 90/22 91/2 93/25 99/15 104/6 104/6 119/18 121/2 123/11 124/10 130/1 130/18 131/5 136/12</p> <p>home-produced [1] 121/2</p> <p>homes [1] 2/20</p> <p>hope [7] 18/10 80/8</p>	<p>149/20 156/3 163/20 165/4 169/1</p> <p>hoped [9] 45/10 90/21 94/12 113/9 116/11 120/24 121/12 133/17 159/8</p> <p>horizons [1] 47/5</p> <p>hormone [1] 151/20</p> <p>horrific [1] 11/19</p> <p>Horsham [2] 131/10 131/24</p> <p>hospital [17] 17/11 17/13 19/15 30/24 33/24 34/19 55/19 58/2 68/4 69/5 71/20 81/4 81/10 94/3 113/21 130/6 133/12</p> <p>hourly [1] 107/20</p> <p>hours [4] 97/20 105/14 106/20 163/18</p> <p>house [2] 51/23 53/6</p> <p>household [2] 95/19 96/5</p> <p>housemaster [4] 11/10 11/17 12/10 13/6</p> <p>housemasters [1] 11/10</p> <p>how [9] 9/22 15/21 31/14 32/2 60/4 103/22 116/5 166/19 166/20</p> <p>Howell [1] 68/3</p> <p>however [13] 3/14 3/15 6/16 6/20 20/4 48/7 64/25 72/12 79/21 119/21 127/24 150/4 164/13</p> <p>HTLV [5] 9/5 9/23 36/17 37/12 37/13</p> <p>HTLV-III [4] 9/23 36/17 37/12 37/13</p> <p>HTLV-III/HIV [1] 9/5</p> <p>Hugh [1] 133/10</p> <p>human [4] 46/25 93/5 107/1 108/5</p> <p>Humanate [2] 163/17 163/21</p> <p>humane [1] 25/3</p> <p>hundred [1] 2/5</p> <p>hydrotherapy [1] 43/17</p> <p>Hyland [2] 73/4 159/4</p> <p>hypotheses [1] 118/23</p> <p>I</p> <p>I agree [1] 148/19</p> <p>I am [6] 5/5 69/6 115/22 139/2 145/19 158/24</p> <p>I and [1] 17/22</p>	<p>I approve [1] 67/10</p> <p>I attended [1] 78/4</p> <p>I believe [4] 3/10 18/20 66/25 102/12</p> <p>I can [8] 6/5 39/1 40/2 118/2 148/21 152/12 158/8 167/14</p> <p>I can't [3] 26/5 40/4 51/11</p> <p>I come [1] 1/7</p> <p>I discovered [1] 80/2</p> <p>I do [5] 8/18 18/5 21/18 148/20 163/20</p> <p>I don't [11] 22/13 25/23 38/8 60/18 61/10 89/24 95/16 111/25 125/19 161/22 162/3</p> <p>I enclose [4] 68/2 102/13 145/20 153/4</p> <p>I explained [1] 33/2</p> <p>I feel [3] 6/16 55/3 102/9</p> <p>I found [1] 14/1</p> <p>I had [2] 135/24 139/20</p> <p>I have [8] 19/25 22/2 22/18 33/8 66/15 129/7 131/12 161/22</p> <p>I haven't [1] 6/25</p> <p>I hope [1] 18/10</p> <p>I just [4] 2/2 118/1 136/13 148/7</p> <p>I let [1] 5/9</p> <p>I look [1] 161/3</p> <p>I looked [1] 28/22</p> <p>I may [1] 102/8</p> <p>I mean [1] 40/12</p> <p>I move [1] 145/7</p> <p>I note [1] 70/6</p> <p>I now [1] 67/7</p> <p>I ought [1] 56/21</p> <p>I pick [2] 14/11 107/17</p> <p>I predict [1] 15/12</p> <p>I raise [1] 166/25</p> <p>I received [1] 13/10</p> <p>I referred [3] 15/1 31/2 137/1</p> <p>I saw [1] 146/4</p> <p>I say [10] 6/23 11/1 19/4 37/24 39/19 52/13 88/8 128/13 147/2 147/16</p> <p>I see [2] 18/12 146/13</p> <p>I should [5] 3/14 19/9 20/22 145/4 168/1</p> <p>I start [1] 53/15</p> <p>I suppose [1] 21/17</p> <p>I take [1] 70/11</p> <p>I then [1] 34/23</p> <p>I think [45] 1/19 1/20</p>	<p>19/8 20/19 23/2 26/8 31/2 38/24 40/6 40/16 41/9 43/5 49/2 56/21 62/1 75/11 77/20 77/24 80/15 82/18 82/21 102/25 109/3 109/7 110/17 117/19 129/4 132/16 135/11 140/12 141/17 145/14 147/11 147/12 152/20 157/20 157/22 158/8 158/16 160/8 161/25 162/4 163/9 168/13 168/14</p> <p>I tried [1] 37/25</p> <p>I turn [1] 38/1</p> <p>I understand [4] 54/1 70/3 136/14 139/5</p> <p>I use [1] 39/3</p> <p>I view [1] 20/3</p> <p>I want [1] 163/4</p> <p>I wanted [1] 3/23</p> <p>I was [6] 2/18 8/16 8/16 8/17 8/17 57/2</p> <p>I will [3] 98/11 146/11 158/3</p> <p>I won't [6] 108/19 128/13 128/17 143/7 147/16 160/23</p> <p>I wonder [2] 130/15 146/13</p> <p>I would [11] 5/1 13/9 34/8 37/21 38/16 67/23 129/20 138/12 148/23 148/25 162/12</p> <p>I'd [2] 112/5 124/7</p> <p>I'll [12] 38/25 48/19 53/8 86/17 98/16 98/24 108/15 109/19 112/7 118/2 118/4 165/11</p> <p>I'm [37] 1/22 20/21 26/6 27/18 32/22 33/4 37/19 39/2 39/16 39/25 46/16 49/5 49/10 53/4 53/13 54/8 58/4 67/13 67/17 69/19 88/14 102/23 105/25 107/15 111/7 112/7 116/22 117/22 128/6 128/16 143/24 148/3 152/19 156/9 160/14 162/2 162/2</p> <p>I've [6] 23/13 37/17 54/5 103/19 165/12 168/3</p> <p>idea [3] 39/22 123/24 140/13</p> <p>ideal [4] 47/8 77/2 89/12 89/14</p> <p>ideas [1] 56/11</p> <p>identification [2]</p>	<p>132/2 153/5</p> <p>identified [7] 6/25 30/7 31/8 92/25 134/9 135/17 143/11</p> <p>identify [2] 8/6 165/11</p> <p>identifying [1] 136/8</p> <p>if [179]</p> <p>ignore [2] 20/5 88/22</p> <p>II [1] 153/19</p> <p>iii [6] 9/5 9/23 36/17 37/12 37/13 95/25</p> <p>ill [4] 14/1 30/20 126/12 131/21</p> <p>illness [5] 18/4 113/6 116/6 126/1 126/9</p> <p>illness' [1] 30/18</p> <p>illuminating [1] 80/20</p> <p>immediate [3] 2/22 23/24 110/11</p> <p>immediately [1] 24/15</p> <p>immense [1] 56/11</p> <p>immune [2] 36/25 64/8</p> <p>immunity [1] 115/1</p> <p>immuno [2] 72/22 121/10</p> <p>immunoglobulins [2] 58/16 58/21</p> <p>immunological [1] 18/18</p> <p>impact [3] 14/13 16/2 37/17</p> <p>implementation [1] 110/12</p> <p>implication [1] 155/2</p> <p>implications [11] 14/21 16/11 26/2 27/7 77/21 82/9 106/25 151/10 165/22 165/24 167/6</p> <p>importance [4] 41/14 57/20 66/8 66/21</p> <p>important [21] 5/7 5/8 14/18 17/10 46/7 47/17 55/11 55/25 66/14 66/24 68/24 71/2 71/14 72/9 77/18 99/13 107/2 134/25 135/7 137/14 141/11</p> <p>imposes [1] 21/20</p> <p>impossible [2] 18/2 24/17</p> <p>improve [2] 67/2 151/2</p> <p>improved [1] 47/3</p> <p>inadequate [1] 75/21</p> <p>inaudible [1] 34/22</p> <p>incidence [14] 59/7 63/12 81/13 98/19 100/5 103/13 109/13 112/15 113/1 117/7 118/8 120/18 139/23</p>	<p>144/23</p> <p>include [7] 5/6 52/2 97/23 100/14 105/23 143/17 149/1</p> <p>included [15] 45/8 74/5 77/13 84/14 85/8 87/19 88/4 95/23 108/22 132/21 133/18 150/5 152/9 152/17 167/12</p> <p>includes [1] 167/6</p> <p>including [5] 74/23 97/2 101/8 119/18 139/7</p> <p>inclusion [5] 87/11 87/14 90/23 122/24 167/7</p> <p>inconveniences [1] 69/2</p> <p>inconvenient [1] 3/15</p> <p>increase [4] 19/19 79/21 120/18 124/17</p> <p>increased [9] 19/19 20/14 47/3 47/7 48/22 48/24 103/15 151/11 166/5</p> <p>increases [2] 20/15 21/4</p> <p>increasing [2] 17/2 162/10</p> <p>increasingly [1] 17/15</p> <p>indeed [7] 60/2 93/22 108/17 128/1 146/23 165/19 167/19</p> <p>index [1] 6/7</p> <p>indexed [1] 6/23</p> <p>indicate [4] 58/22 75/22 94/18 164/21</p> <p>indicated [3] 6/2 6/19 135/5</p> <p>indicates [4] 11/11 115/1 151/16 159/19</p> <p>indicating [2] 7/2 163/2</p> <p>indication [11] 4/16 32/13 34/1 59/25 60/16 141/24 145/4 149/6 149/21 163/7 165/5</p> <p>indications [2] 104/4 163/4</p> <p>indicative [1] 144/16</p> <p>indistinguishable [2] 72/10 93/6</p> <p>individual [15] 7/22 9/22 10/17 14/2 23/1 27/15 27/20 78/17 89/8 90/7 127/12 160/22 160/22 165/24 166/23</p> <p>individuals [4] 4/14 30/14 166/20 166/21</p>
---	--	--	--	--	--

(55) highly - individuals

<p>I</p> <p>individuals' [1] 37/24</p> <p>inducing [4] 160/19 161/4 161/11 161/11</p> <p>inert [1] 105/20</p> <p>inevitable [1] 133/4</p> <p>inevitably [1] 21/20</p> <p>infancy [1] 115/10</p> <p>infected [8] 8/10 8/17 13/22 15/15 29/20 30/15 36/4 101/8</p> <p>infection [15] 14/13 22/4 24/4 24/14 31/4 31/25 32/6 33/18 35/13 48/6 92/24 115/12 124/17 140/24 166/6</p> <p>infections [1] 29/21</p> <p>infectiousness [1] 17/4</p> <p>infective [1] 134/8</p> <p>inference [2] 29/2 84/6</p> <p>Infirmary [1] 156/12</p> <p>influence [4] 14/14 63/1 101/3 160/10</p> <p>influences [2] 14/19 89/1</p> <p>information [53] 2/9 3/7 5/22 7/25 9/19 10/10 11/7 11/9 11/22 12/11 13/16 14/10 19/11 20/8 22/23 22/25 25/5 30/9 31/22 32/11 33/11 35/15 36/2 36/10 37/14 54/9 56/14 88/5 94/21 110/10 121/7 128/24 129/21 137/8 143/18 145/11 149/7 149/23 150/2 151/18 152/9 152/16 153/6 153/7 153/9 155/4 155/8 156/6 159/11 159/16 160/1 160/2 164/19</p> <p>informed [16] 5/22 8/16 9/23 31/25 34/25 37/12 87/25 90/1 91/16 92/16 125/5 125/7 152/14 154/20 155/5 165/17</p> <p>informed X [1] 37/12</p> <p>informing [1] 36/7</p> <p>infusion [6] 6/9 91/22 103/6 103/11 105/15 131/15</p> <p>infusions [7] 48/2 90/9 90/12 91/12 103/5 104/14 105/12</p> <p>Ingram [3] 95/21 101/2 101/4</p>	<p>inhibitor [4] 104/18 158/18 158/22 159/13</p> <p>inhibitors [9] 58/14 58/23 87/13 104/17 111/11 113/16 117/14 160/19 161/5</p> <p>initially [2] 2/23 157/10</p> <p>initiate [1] 4/6</p> <p>initiated [1] 55/24</p> <p>initiative [2] 51/25 151/14</p> <p>injected [1] 152/4</p> <p>injection [1] 18/5</p> <p>injections [2] 57/5 145/23</p> <p>injustice [1] 37/25</p> <p>innovations [1] 3/5</p> <p>Inquiry [8] 1/5 9/4 9/6 9/24 26/9 31/17 31/19 170/2</p> <p>Inquiry's [1] 168/4</p> <p>insight [3] 17/20 80/20 121/12</p> <p>instance [4] 48/6 90/17 152/10 152/18</p> <p>instances [1] 5/5</p> <p>Institute [1] 138/18</p> <p>institution [1] 3/10</p> <p>instruction [1] 13/20</p> <p>intake [1] 151/22</p> <p>integrated [1] 23/25</p> <p>intellectual [1] 7/11</p> <p>intend [1] 152/2</p> <p>intended [1] 56/8</p> <p>intends [1] 70/7</p> <p>intense [1] 17/5</p> <p>intention [2] 92/11 110/11</p> <p>interaction [4] 128/23 130/18 148/8 148/14</p> <p>interactions [1] 163/5</p> <p>interest [9] 23/18 51/4 54/12 54/13 63/23 74/15 75/12 78/6 149/18</p> <p>interested [3] 140/8 162/13 168/5</p> <p>interested in [1] 162/13</p> <p>interesting [4] 134/7 152/12 156/13 161/7</p> <p>interfere [3] 50/16 87/16 131/3</p> <p>interferes [1] 105/19</p> <p>interferon [2] 33/17 33/20</p> <p>interim [5] 63/17 95/6 115/22 115/25 116/17</p> <p>Intermediate [1] 154/1</p> <p>internal [2] 125/2</p>	<p>164/4</p> <p>internationally [1] 21/10</p> <p>interpret [1] 100/19</p> <p>interpretation [1] 143/4</p> <p>intervals [5] 48/1 64/3 71/21 125/17 139/22</p> <p>intervention [1] 97/25</p> <p>interview [3] 38/3 38/6 170/4</p> <p>intimate [1] 24/20</p> <p>into [28] 12/16 14/24 17/11 17/20 18/6 42/24 43/1 44/8 50/9 55/16 56/19 59/20 61/8 62/10 76/25 83/22 92/15 110/7 119/15 121/13 122/16 123/6 147/16 153/17 159/3 164/8 164/16 165/8</p> <p>introduced [2] 12/16 159/3</p> <p>introducing [1] 98/18</p> <p>introduction [5] 41/16 61/19 118/16 119/14 119/18</p> <p>introductory [1] 3/21</p> <p>invaluable [1] 133/12</p> <p>investigate [1] 147/14</p> <p>investigated [2] 134/19 142/18</p> <p>investigation [11] 57/24 58/9 61/1 75/23 75/25 108/13 141/23 143/10 150/5 153/17 164/7</p> <p>investigations [9] 35/22 46/12 46/14 58/22 59/4 59/15 116/25 143/13 154/13</p> <p>investigators [1] 154/24</p> <p>invited [1] 9/18</p> <p>invoice [1] 157/12</p> <p>involve [2] 4/24 143/17</p> <p>involved [18] 6/21 11/6 11/7 11/11 17/4 17/17 18/9 40/22 58/22 70/4 80/18 83/10 107/12 107/13 137/12 146/21 160/23 166/17</p> <p>involvement [14] 2/17 19/11 19/21 53/5 53/6 106/4 137/23 146/19 152/22 156/11 156/20 157/17 160/5 165/25</p> <p>involves [2] 58/3 71/21</p>	<p>IPSN000331 [1] 163/8</p> <p>iron [2] 130/16 138/10</p> <p>irrespective [1] 111/24</p> <p>irresponsible [1] 20/5</p> <p>issue [7] 34/23 75/12 139/8 164/20 165/15 165/22 166/10</p> <p>issues [9] 1/10 1/11 7/6 13/17 27/9 80/11 165/11 166/25 167/3</p> <p>issuing [1] 101/14</p> <p>It'll [1] 35/6</p> <p>it's [111] 1/15 1/15 1/25 6/6 9/1 14/7 14/9 19/7 20/22 23/12 26/18 26/21 27/17 27/20 28/2 28/3 28/6 28/7 29/19 33/22 33/24 33/25 38/3 38/9 38/16 38/24 39/19 41/8 41/10 45/9 49/5 49/10 49/12 53/2 53/10 54/11 58/25 61/15 61/15 69/11 69/12 69/15 75/14 75/15 76/6 78/2 78/23 78/24 78/24 78/25 82/11 85/1 86/15 86/19 87/23 88/9 88/16 93/12 93/24 95/5 96/13 101/20 101/23 102/20 102/24 102/24 103/8 109/3 109/6 114/2 115/19 115/19 115/23 115/24 115/24 118/1 124/1 124/2 125/2 125/14 126/8 127/16 128/6 128/23 129/23 129/23 132/1 132/7 136/8 136/13 138/16 143/16 143/19 145/16 149/22 149/24 152/12 153/8 155/9 158/1 158/13 158/20 159/14 161/6 161/25 162/7 162/14 163/9 163/12 168/6 168/13</p> <p>items [1] 78/6</p> <p>its [16] 13/10 13/17 14/23 26/2 27/6 59/14 62/23 63/1 63/5 69/6 70/10 77/21 83/4 118/17 124/4 124/13</p> <p>itself [3] 55/17 62/9 91/1</p> <p>IX [3] 128/21 137/6 158/10</p> <p>IX' [1] 45/24</p>	<p>J</p> <p>Jane [3] 25/25 26/19 27/3</p> <p>Jane Kershaw [2] 25/25 26/19</p> <p>Jane Kershaw's [1] 27/3</p> <p>January [7] 61/6 69/11 95/2 96/13 97/5 109/7 157/7</p> <p>January '75 [1] 97/5</p> <p>January 1971 [1] 61/6</p> <p>January 1975 [1] 96/13</p> <p>January 1977 [1] 109/7</p> <p>January 1981 [1] 157/7</p> <p>jaundice [4] 63/13 100/3 114/17 117/1</p> <p>John [3] 10/21 51/4 136/18</p> <p>John Peach [1] 10/21</p> <p>join [1] 78/22</p> <p>joined [1] 132/23</p> <p>joint [5] 4/6 7/14 58/9 61/3 94/25</p> <p>joints [2] 4/11 109/15</p> <p>Jones [5] 145/16 146/2 153/14 156/18 164/8</p> <p>Jones's [1] 146/23</p> <p>jostling [1] 4/25</p> <p>Journal [2] 49/15 102/20</p> <p>journey [1] 4/24</p> <p>judgment [1] 35/7</p> <p>July [12] 32/21 33/4 56/17 60/24 101/22 102/22 162/14 162/17 163/9 168/13 169/4 169/7</p> <p>July '75 [1] 102/22</p> <p>July '83 [2] 162/14 162/17</p> <p>July 1967 [1] 60/24</p> <p>July 1970 [1] 56/17</p> <p>July 1980 [1] 163/9</p> <p>July 1991 [1] 33/4</p> <p>June [1] 1/1</p> <p>just [71] 1/25 2/2 3/21 3/24 17/11 25/15 26/15 27/21 28/13 28/24 31/1 32/8 32/9 32/18 34/23 38/3 40/25 41/1 47/23 48/23 57/17 63/21 67/17 67/17 69/18 71/16 76/11 78/23 85/11 86/17 95/16 98/24 100/11 100/25</p>	<p>101/19 103/20 106/21 107/14 108/15 109/2 110/25 111/9 114/18 115/25 117/15 118/1 122/10 128/25 131/12 132/2 136/11 136/12 136/13 140/2 141/5 141/17 145/9 147/2 148/7 155/9 155/19 156/13 157/20 157/20 158/9 158/19 160/15 161/2 163/3 163/4 163/9</p> <p>justice [1] 37/21</p> <p>justified [2] 105/21 118/1</p> <p>K</p> <p>keen [2] 140/6 140/18</p> <p>keep [3] 21/9 98/22 99/21</p> <p>Kenneth [1] 169/3</p> <p>kept [3] 42/10 66/9 150/7</p> <p>Kershaw [2] 25/25 26/19</p> <p>Kershaw's [1] 27/3</p> <p>key [1] 168/19</p> <p>kidney [1] 64/15</p> <p>kill [1] 32/2</p> <p>kind [15] 8/3 8/3 8/25 9/13 21/12 22/14 28/4 28/5 34/9 36/10 37/14 38/3 137/10 155/3 160/3</p> <p>kinds [4] 37/2 44/14 62/16 141/14</p> <p>Kingdom [2] 44/12 146/11</p> <p>Kirk [39] 40/16 41/11 51/4 51/7 51/24 52/5 52/11 52/19 65/10 97/11 98/17 99/5 100/12 100/16 109/10 110/1 118/9 118/12 120/12 120/22 125/25 128/12 129/3 129/12 130/1 130/6 130/25 131/9 132/6 137/17 137/20 137/24 138/16 139/20 139/25 141/22 142/1 142/19 145/1</p> <p>Kirk's [4] 51/16 53/5 109/4 136/3</p> <p>kits [1] 163/17</p> <p>knew [2] 28/17 138/15</p> <p>Knight [1] 160/12</p> <p>know [22] 10/14 11/5 15/21 23/22 30/11 38/8 70/13 71/15 72/11 93/9 96/6 108/19 108/20 130/13</p>
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(56) individuals' - know

<p>K know... [8] 131/11 131/21 134/15 147/4 148/24 149/19 157/14 159/23 knowing [2] 30/14 135/25 knowledge [4] 67/2 121/13 131/5 151/14 known [8] 46/7 89/18 98/21 108/4 116/14 119/3 131/7 159/7 Kryobulin [12] 99/1 107/13 109/17 121/21 128/19 131/1 133/24 134/11 137/4 139/2 139/7 139/9</p>	<p>latter [1] 124/7 lay [1] 135/15 leading [1] 24/7 leaflet [2] 159/16 160/2 learn [1] 150/17 learned [2] 2/10 59/13 least [18] 6/1 7/11 7/11 11/25 15/20 15/23 29/5 35/11 37/15 53/5 84/14 93/10 93/10 103/7 129/22 142/9 145/25 146/22 leave [3] 30/9 41/23 91/2 leaving [2] 93/14 95/15</p>	<p>levelled [1] 80/4 levels [11] 47/17 52/3 57/21 62/25 63/5 63/20 85/22 98/8 98/10 144/8 148/1 LFT [1] 99/12 LFT's [1] 142/25 LFTs [1] 126/14 liaison [1] 44/19 liberal [2] 5/6 46/25 life [8] 16/18 32/8 57/6 115/13 152/3 153/24 155/17 155/23 lifelong [1] 17/18 light [1] 82/8 like [13] 29/21 38/20 39/7 49/12 49/14 76/19 94/11 99/4 110/5 112/5 129/23 148/23 148/23 likely [10] 15/10 18/14 54/6 58/21 58/23 67/1 67/8 77/16 103/16 115/12 likewise [1] 35/24 limit [3] 64/23 142/9 144/8 limitation [1] 84/9 limitations [1] 108/5 limited [13] 4/8 4/10 4/16 11/1 31/18 31/23 36/10 106/25 108/10 111/15 124/4 160/1 162/19 limiting [9] 122/11 122/12 122/14 125/9 125/13 129/15 133/2 145/1 167/9 line [3] 58/4 72/8 108/13 lines [7] 71/10 75/23 75/25 92/16 101/1 162/21 162/24 linked [1] 118/18 list [1] 5/6 listed [1] 21/11 listening [1] 165/3 Lister [3] 35/18 137/5 139/4 lists [1] 19/18 litres [2] 101/7 120/1 little [4] 56/14 65/25 130/22 154/2 live [1] 16/17 lived [1] 7/7 lively [1] 79/16 liver [29] 33/1 34/16 36/9 47/25 100/1 100/14 100/17 123/6 126/4 126/10 131/12 133/13 134/23 135/3 136/10 139/24 140/15</p>	<p>141/24 142/7 142/11 142/14 142/23 143/2 143/4 143/5 143/9 143/10 143/12 144/17 lives [1] 37/24 living [1] 3/11 LMT [1] 8/16 load [5] 17/2 18/11 21/22 21/24 21/25 local [3] 18/7 55/19 124/23 locality [1] 43/24 locally [1] 86/9 locate [1] 151/9 location [3] 89/13 89/14 89/21 loco [1] 11/18 logistical [1] 18/22 London [1] 124/13 long [15] 3/19 4/1 4/4 4/24 10/10 11/13 32/2 33/10 58/11 62/21 64/21 85/5 102/24 109/23 158/2 long-term [2] 4/1 4/4 longer [2] 15/23 25/20 Longstaff [1] 145/18 look [40] 2/3 8/12 8/14 28/24 31/1 32/23 40/25 48/23 67/13 69/18 86/17 90/19 91/9 94/22 95/15 97/4 107/9 107/14 108/17 111/8 118/4 118/11 118/16 118/25 119/13 120/20 121/25 122/21 129/2 130/2 141/6 145/7 147/5 148/7 155/20 160/4 161/3 162/5 163/4 166/11 looked [27] 1/13 9/12 14/7 20/22 28/22 36/22 36/24 37/9 53/23 54/7 61/18 66/4 76/11 82/22 96/12 96/15 103/20 106/4 127/20 129/4 132/17 155/19 161/24 162/4 162/22 162/25 164/16 looked at [18] 1/13 14/7 20/22 36/24 37/9 53/23 54/7 61/18 66/4 76/11 106/4 127/20 132/17 155/19 161/24 162/4 162/22 162/25 looking [13] 7/18 37/1 53/13 54/21 55/8 65/9 117/22 152/24 158/19 161/1 161/8 166/7 168/10 looks [7] 39/7 49/12 49/14 52/15 52/22</p>	<p>129/23 136/1 Lord [45] 1/6 2/6 26/22 41/17 42/18 43/7 46/3 55/1 60/5 60/21 60/25 61/1 61/7 68/8 69/21 71/7 71/24 72/19 74/6 75/5 75/18 76/19 77/2 77/11 78/20 79/1 81/9 82/13 83/12 89/12 89/21 97/16 99/5 103/4 112/17 112/22 117/12 123/2 126/18 144/6 145/21 146/14 168/19 169/3 170/2 Lord Kenneth Clarke [1] 169/3 Lord Mayor [2] 26/22 60/21 Lord Mayor Treloar [2] 1/6 170/2 loss [1] 37/1 lost [1] 166/19 lot [8] 4/24 4/25 7/3 21/19 27/10 27/19 31/18 148/24 lots [1] 54/3 low [3] 104/15 105/12 105/15 low-dose [2] 104/15 105/12 lower [1] 85/13 lowest [1] 107/4 Ltd [1] 156/16 lunch [2] 110/18 127/20 luncheon [1] 110/23 lymph [1] 37/1 lymph nodes [1] 37/1</p>	<p>maintained [2] 43/4 76/22 maintaining [1] 19/17 major [7] 4/23 14/14 14/17 18/13 55/17 112/8 123/1 majority [1] 11/12 make [14] 22/18 24/17 31/13 75/7 77/20 79/8 81/21 92/2 92/19 93/2 102/11 164/22 165/13 167/2 makes [5] 6/13 18/2 27/23 55/6 66/2 making [3] 20/10 122/8 163/14 male [1] 87/7 manage [2] 123/20 123/21 management [9] 1/17 2/12 33/15 43/14 69/5 89/20 119/15 153/20 158/11 Manchester [1] 124/12 Mann [2] 130/5 138/8 manufacture [1] 86/3 manufactured [1] 156/3 manufacturers [2] 122/8 127/6 many [21] 2/10 3/5 4/14 15/6 15/21 16/6 16/7 19/25 27/7 40/3 42/1 52/1 55/9 56/11 74/9 80/7 99/13 112/21 118/19 166/12 168/2 March [2] 10/16 82/16 March of [1] 10/16 margin [1] 35/10 mark [3] 8/6 78/11 78/13 mark 2 [1] 78/13 marked [2] 8/9 88/11 markers [1] 18/21 Martin [2] 58/19 59/1 material [52] 35/6 35/20 37/11 66/13 72/5 72/10 72/16 72/17 72/18 72/22 72/25 73/6 73/8 73/8 78/24 79/13 81/12 84/11 98/20 99/8 99/16 101/3 101/15 103/16 104/15 105/12 105/16 105/20 108/1 108/21 114/6 122/3 123/9 123/12 125/9 125/14 126/25 127/2 127/11 127/23 129/16 132/19 134/8 137/15</p>
<p>L labelled [1] 134/1 laboratories [4] 18/22 127/7 159/6 164/4 laboratory [28] 20/15 21/2 42/7 44/10 45/4 47/11 47/14 47/16 47/22 48/15 50/19 50/24 51/18 59/5 59/6 62/12 63/16 63/17 76/4 79/7 79/8 84/18 99/10 133/7 133/10 134/4 141/4 166/15 lack [4] 13/21 62/6 77/5 149/6 lacking [1] 13/12 Lancet [1] 147/6 lapse [4] 62/6 73/22 74/4 77/5 large [13] 4/25 43/7 47/1 83/19 89/16 110/7 119/14 120/1 122/8 127/8 130/15 133/13 134/12 largely [2] 57/5 62/1 larger [3] 119/22 150/15 152/6 last [26] 29/3 32/23 44/21 44/21 46/3 51/1 61/17 70/24 74/16 75/17 78/10 85/9 94/10 100/25 105/6 107/14 130/12 130/23 131/1 133/24 140/21 141/6 143/15 145/19 146/5 146/9 late [4] 7/4 38/16 38/18 165/7 later [10] 28/8 105/12 106/6 106/9 118/3 128/14 128/17 130/22 140/25 161/2 latest [1] 69/7</p>	<p>led [4] 24/3 46/25 82/24 166/2 Leeds [1] 124/13 left [5] 24/19 26/22 31/20 106/24 107/10 left-hand [2] 106/24 107/10 legal [1] 168/7 leisure [1] 105/19 lends [1] 62/9 length [1] 148/25 lengthened [1] 84/19 lengthy [1] 72/2 less [7] 87/3 98/5 113/24 115/5 128/4 137/21 166/4 lessen [1] 150/8 lessons [1] 2/10 let [4] 5/9 130/13 131/21 149/19 let's [1] 157/25 letter [52] 23/2 23/10 25/9 25/11 26/17 26/18 27/3 27/18 32/21 33/6 33/22 54/6 54/22 54/25 56/16 56/18 60/2 60/19 65/25 66/4 67/19 69/11 69/24 85/17 94/2 101/21 129/3 129/4 131/8 137/18 137/25 139/16 143/19 145/16 145/21 145/24 148/16 148/18 149/10 149/12 149/15 149/21 150/1 152/11 152/13 156/17 161/1 161/7 162/14 162/16 163/8 163/24 letters [2] 37/4 151/16 level [10] 7/11 65/8 87/3 106/1 106/15 107/22 151/23 154/12 161/21 162/12</p>	<p>levelled [1] 80/4 levels [11] 47/17 52/3 57/21 62/25 63/5 63/20 85/22 98/8 98/10 144/8 148/1 LFT [1] 99/12 LFT's [1] 142/25 LFTs [1] 126/14 liaison [1] 44/19 liberal [2] 5/6 46/25 life [8] 16/18 32/8 57/6 115/13 152/3 153/24 155/17 155/23 lifelong [1] 17/18 light [1] 82/8 like [13] 29/21 38/20 39/7 49/12 49/14 76/19 94/11 99/4 110/5 112/5 129/23 148/23 148/23 likely [10] 15/10 18/14 54/6 58/21 58/23 67/1 67/8 77/16 103/16 115/12 likewise [1] 35/24 limit [3] 64/23 142/9 144/8 limitation [1] 84/9 limitations [1] 108/5 limited [13] 4/8 4/10 4/16 11/1 31/18 31/23 36/10 106/25 108/10 111/15 124/4 160/1 162/19 limiting [9] 122/11 122/12 122/14 125/9 125/13 129/15 133/2 145/1 167/9 line [3] 58/4 72/8 108/13 lines [7] 71/10 75/23 75/25 92/16 101/1 162/21 162/24 linked [1] 118/18 list [1] 5/6 listed [1] 21/11 listening [1] 165/3 Lister [3] 35/18 137/5 139/4 lists [1] 19/18 litres [2] 101/7 120/1 little [4] 56/14 65/25 130/22 154/2 live [1] 16/17 lived [1] 7/7 lively [1] 79/16 liver [29] 33/1 34/16 36/9 47/25 100/1 100/14 100/17 123/6 126/4 126/10 131/12 133/13 134/23 135/3 136/10 139/24 140/15</p>	<p>141/24 142/7 142/11 142/14 142/23 143/2 143/4 143/5 143/9 143/10 143/12 144/17 lives [1] 37/24 living [1] 3/11 LMT [1] 8/16 load [5] 17/2 18/11 21/22 21/24 21/25 local [3] 18/7 55/19 124/23 locality [1] 43/24 locally [1] 86/9 locate [1] 151/9 location [3] 89/13 89/14 89/21 loco [1] 11/18 logistical [1] 18/22 London [1] 124/13 long [15] 3/19 4/1 4/4 4/24 10/10 11/13 32/2 33/10 58/11 62/21 64/21 85/5 102/24 109/23 158/2 long-term [2] 4/1 4/4 longer [2] 15/23 25/20 Longstaff [1] 145/18 look [40] 2/3 8/12 8/14 28/24 31/1 32/23 40/25 48/23 67/13 69/18 86/17 90/19 91/9 94/22 95/15 97/4 107/9 107/14 108/17 111/8 118/4 118/11 118/16 118/25 119/13 120/20 121/25 122/21 129/2 130/2 141/6 145/7 147/5 148/7 155/20 160/4 161/3 162/5 163/4 166/11 looked [27] 1/13 9/12 14/7 20/22 28/22 36/22 36/24 37/9 53/23 54/7 61/18 66/4 76/11 82/22 96/12 96/15 103/20 106/4 127/20 129/4 132/17 155/19 161/24 162/4 162/22 162/25 164/16 looked at [18] 1/13 14/7 20/22 36/24 37/9 53/23 54/7 61/18 66/4 76/11 106/4 127/20 132/17 155/19 161/24 162/4 162/22 162/25 looking [13] 7/18 37/1 53/13 54/21 55/8 65/9 117/22 152/24 158/19 161/1 161/8 166/7 168/10 looks [7] 39/7 49/12 49/14 52/15 52/22</p>	<p>129/23 136/1 Lord [45] 1/6 2/6 26/22 41/17 42/18 43/7 46/3 55/1 60/5 60/21 60/25 61/1 61/7 68/8 69/21 71/7 71/24 72/19 74/6 75/5 75/18 76/19 77/2 77/11 78/20 79/1 81/9 82/13 83/12 89/12 89/21 97/16 99/5 103/4 112/17 112/22 117/12 123/2 126/18 144/6 145/21 146/14 168/19 169/3 170/2 Lord Kenneth Clarke [1] 169/3 Lord Mayor [2] 26/22 60/21 Lord Mayor Treloar [2] 1/6 170/2 loss [1] 37/1 lost [1] 166/19 lot [8] 4/24 4/25 7/3 21/19 27/10 27/19 31/18 148/24 lots [1] 54/3 low [3] 104/15 105/12 105/15 low-dose [2] 104/15 105/12 lower [1] 85/13 lowest [1] 107/4 Ltd [1] 156/16 lunch [2] 110/18 127/20 luncheon [1] 110/23 lymph [1] 37/1 lymph nodes [1] 37/1</p>	<p>M Macfarlane [3] 38/11 38/19 38/21 Macpherson [4] 23/1 23/20 28/23 31/3 Macpherson's [1] 11/23 made [37] 2/11 3/22 19/2 46/2 46/9 47/16 48/5 48/11 50/20 60/17 60/23 60/24 61/6 65/7 67/9 73/9 73/13 75/17 81/18 83/4 90/14 91/20 96/1 96/1 100/10 119/17 120/1 123/11 124/2 125/8 126/24 131/18 136/16 139/6 145/11 164/8 168/6 main [3] 2/4 47/10 80/11 maintain [1] 123/15</p>

<p>M</p> <p>material... [8] 146/23 150/9 152/4 159/7 162/8 165/19 165/21 167/21</p> <p>materialised [1] 164/13</p> <p>materials [16] 1/9 59/11 74/24 77/8 79/22 103/15 103/21 106/12 107/11 108/4 133/2 133/5 136/19 136/24 161/13 165/1</p> <p>matter [12] 5/6 5/13 6/17 10/3 12/21 17/11 34/17 35/6 129/20 149/18 157/15 167/17</p> <p>matters [7] 14/10 31/15 83/9 83/11 92/18 97/7 165/12</p> <p>Matthews [2] 26/25 73/24</p> <p>maximal [1] 17/4</p> <p>maximum [2] 28/10 70/2</p> <p>may [57] 4/5 4/11 4/13 4/20 4/22 8/24 10/11 10/12 10/19 15/17 17/20 23/5 32/21 45/10 48/8 48/20 57/20 58/22 59/13 88/20 88/21 88/24 93/23 99/19 101/24 102/8 105/9 105/21 112/1 115/16 118/23 122/5 124/3 128/1 129/13 132/16 144/18 148/10 148/16 151/9 152/14 152/15 155/18 156/13 157/23 158/19 161/1 161/23 162/4 165/10 165/13 166/16 166/18 166/25 167/1 167/2 167/14</p> <p>May 1978 [1] 148/16</p> <p>maybe [3] 51/10 105/7 131/20</p> <p>Maycock [9] 73/5 73/14 79/6 79/12 79/20 80/1 80/14 100/20 143/20</p> <p>Mayor [43] 1/6 2/7 26/22 41/17 42/18 43/7 46/3 55/1 60/5 60/21 60/25 61/1 61/7 68/9 69/21 71/7 71/24 72/19 74/6 75/5 75/18 76/19 77/2 77/11 78/20 79/1 81/9 82/13 83/12 89/12 89/21 97/16 99/5 103/4</p>	<p>112/17 112/22 117/12 123/2 126/18 144/6 145/21 146/14 170/2</p> <p>McGrath [1] 138/17</p> <p>McLellan [3] 111/6 160/12 160/12</p> <p>me [13] 8/20 13/25 19/25 22/2 22/19 25/7 105/1 110/17 130/13 131/21 145/10 145/15 150/17</p> <p>mean [3] 14/4 40/12 124/21</p> <p>means [2] 13/17 71/19</p> <p>meant [1] 29/5</p> <p>measure [3] 49/25 50/1 50/2</p> <p>Measurement [1] 62/23</p> <p>media [3] 23/19 23/21 54/12</p> <p>medical [35] 13/16 18/18 21/3 21/4 25/10 25/24 36/23 41/25 42/13 42/14 42/17 42/19 43/3 43/12 51/19 59/2 61/23 67/20 68/13 69/12 70/6 77/9 77/25 78/15 80/21 81/24 82/17 90/21 101/22 101/25 106/5 143/20 146/10 146/19 168/17</p> <p>Medicine [1] 52/7</p> <p>meet [2] 25/21 69/25</p> <p>meeting [31] 9/14 9/18 29/3 30/1 32/6 68/6 70/18 70/25 72/3 76/8 78/1 78/2 78/4 78/10 80/22 81/3 82/15 82/18 82/25 86/10 94/25 97/8 101/24 109/6 127/18 127/20 128/15 141/7 146/9 159/9 164/4</p> <p>meetings [4] 21/13 23/7 141/13 141/16</p> <p>member [4] 24/18 26/11 54/8 141/22</p> <p>members [1] 144/2</p> <p>memo [1] 78/3</p> <p>memos [1] 82/22</p> <p>mention [3] 22/12 108/15 148/22</p> <p>mentioned [1] 64/19</p> <p>mentioning [1] 22/9</p> <p>merely [2] 30/5 50/12</p> <p>merits [1] 105/1</p> <p>met [1] 157/10</p> <p>method [3] 68/22 89/10 121/16</p>	<p>methods [3] 103/21 111/9 119/1</p> <p>meticulous [2] 43/3 76/21</p> <p>Metters [2] 70/11 82/20</p> <p>mickey [1] 68/25</p> <p>Microbiology [1] 50/24</p> <p>mid [6] 8/5 32/14 32/16 52/22 65/25 118/10</p> <p>mid-1970s [2] 8/5 65/25</p> <p>mid-1990 [1] 32/14</p> <p>mid-1991 [1] 32/16</p> <p>mid-seventies [2] 52/22 118/10</p> <p>Middlesex [1] 75/2</p> <p>might [43] 12/20 25/21 27/2 28/5 28/10 29/10 29/20 29/23 31/7 31/13 36/11 39/23 39/24 52/25 74/14 75/23 77/20 79/10 79/21 83/1 83/6 84/6 85/12 88/25 89/6 89/9 90/15 92/22 98/5 98/12 105/4 107/4 107/19 116/11 141/14 151/2 152/3 158/4 159/3 162/17 163/24 166/2 167/10</p> <p>mild [4] 48/7 134/14 135/3 151/23</p> <p>mind [3] 25/15 141/11 162/15</p> <p>mindset [2] 166/17 166/22</p> <p>mine [1] 26/7</p> <p>minimum [6] 123/7 123/9 150/8 154/3 154/5 157/5</p> <p>minister [1] 168/19</p> <p>Ministry [3] 72/24 75/3 77/7</p> <p>minor [2] 8/17 18/11</p> <p>Minute [1] 29/2</p> <p>minutes [12] 23/7 28/15 28/19 28/20 76/11 94/25 95/11 127/19 141/12 141/20 141/24 157/22</p> <p>missing [1] 41/4</p> <p>Mistakes [1] 2/11</p> <p>mix [1] 121/23</p> <p>ml [1] 103/7</p> <p>moderate [1] 103/11</p> <p>modern [2] 43/7 43/10</p> <p>modes [1] 71/18</p> <p>modifications [1] 102/11</p>	<p>monitor [2] 18/20 70/9</p> <p>monitored [1] 35/23</p> <p>monitoring [1] 149/17</p> <p>month [3] 125/1 127/13 149/25</p> <p>months [9] 42/1 80/7 122/6 123/7 123/10 123/16 127/11 138/21 144/9</p> <p>morbidity [1] 103/12</p> <p>more [46] 2/9 4/13 5/19 10/17 16/19 16/20 16/22 17/6 22/24 29/10 31/18 31/22 32/18 34/16 37/11 41/18 44/21 46/25 48/24 53/10 56/14 57/19 59/20 61/21 68/23 73/17 75/11 77/20 79/17 84/4 86/6 88/24 92/22 98/1 99/22 100/9 103/15 115/21 140/8 141/17 144/9 145/7 147/3 148/24 164/19 165/10</p> <p>Moreover [2] 52/9 74/11</p> <p>morning [2] 18/8 161/24</p> <p>mornings [1] 19/13</p> <p>most [16] 10/23 11/1 11/3 34/8 36/20 46/7 56/6 67/23 74/2 77/18 115/9 142/10 144/21 146/8 150/10 168/2</p> <p>mother [4] 8/18 9/17 33/12 94/7</p> <p>motive [2] 22/5 22/21</p> <p>move [3] 18/14 112/8 145/7</p> <p>Moynihan [1] 42/12</p> <p>Mr [23] 11/10 11/23 12/9 13/4 13/6 14/5 22/16 22/21 23/1 23/20 28/23 31/3 35/17 42/11 56/18 56/18 58/10 60/21 66/5 69/20 143/19 145/18 163/19</p> <p>Mr Evans [1] 60/21</p> <p>Mr Francis [1] 42/11</p> <p>Mr Guthrie [3] 56/18 56/18 66/5</p> <p>Mr Macpherson [4] 23/1 23/20 28/23 31/3</p> <p>Mr Macpherson's [1] 11/23</p> <p>Mr Peach [1] 35/17</p> <p>Mr Scott [5] 11/10 12/9 13/4 13/6 22/16</p>	<p>Mr Scott's [2] 14/5 22/21</p> <p>Mr Stanley [1] 58/10</p> <p>Mr Stewart [1] 69/20</p> <p>Mr Williams [1] 163/19</p> <p>MRC [5] 65/14 65/22 70/6 82/21 83/1</p> <p>MRCO0000065 [6] 69/10 77/23 82/10 86/18 100/24 101/19</p> <p>MRCP [1] 51/22</p> <p>Mrs [2] 57/25 145/18</p> <p>Mrs Longstaff [1] 145/18</p> <p>Mrs Richardson [1] 57/25</p> <p>Ms [3] 12/3 26/6 143/20</p> <p>Ms Burton [1] 12/3</p> <p>Ms Buxton [1] 143/20</p> <p>Ms Fraser Butlin [1] 26/6</p> <p>much [15] 10/16 16/19 16/20 28/12 29/9 31/18 46/25 47/4 59/13 77/10 94/12 119/22 145/7 147/2 162/21</p> <p>multi [1] 16/7</p> <p>multiple [7] 35/19 37/3 39/5 67/16 122/12 162/24 167/13</p> <p>multiplicity [1] 167/3</p> <p>muscle [1] 61/3</p> <p>must [18] 5/25 11/19 17/5 17/16 18/16 20/8 52/21 64/22 74/4 90/1 92/1 92/11 123/3 123/7 123/8 125/6 136/16 146/20</p> <p>my [16] 2/17 5/6 5/8 8/18 12/14 13/25 15/12 20/21 22/3 22/3 25/15 38/8 66/7 66/21 148/21 162/3</p> <p>myself [4] 14/1 18/12 58/11 102/3</p> <p>N</p> <p>name [2] 49/10 149/1</p> <p>named [1] 137/12</p> <p>namely [6] 41/19 44/9 62/11 68/19 121/3 135/8</p> <p>narrative [1] 104/12</p> <p>national [8] 42/24 43/1 56/19 59/19 76/25 96/24 137/13 138/17</p> <p>nationally [1] 21/9</p> <p>natural [1] 48/13</p>	<p>naturally [2] 16/10 18/9</p> <p>nature [7] 17/2 18/1 18/14 46/11 103/25 124/4 149/19</p> <p>near [3] 34/7 46/20 133/19</p> <p>nearly [1] 107/25</p> <p>necessarily [5] 5/20 30/12 39/18 117/25 124/22</p> <p>necessary [10] 20/7 65/18 79/22 85/6 90/15 92/19 125/15 126/13 150/15 157/16</p> <p>need [16] 16/15 16/18 16/21 18/17 21/1 21/5 48/20 50/15 68/10 85/8 101/10 107/25 112/1 125/19 154/25 157/14</p> <p>needed [6] 4/6 28/10 30/11 36/13 73/9 103/16</p> <p>needing [2] 112/25 113/22</p> <p>needs [2] 16/16 138/4</p> <p>negative [3] 27/11 104/22 131/19</p> <p>neighbourhood [1] 16/23</p> <p>neither [1] 36/16</p> <p>never [3] 8/19 86/6 124/5</p> <p>nevertheless [1] 102/12</p> <p>new [12] 44/5 44/17 45/9 48/20 67/12 94/13 96/22 99/17 140/14 155/14 155/24 156/2</p> <p>Newcastle [9] 98/23 121/18 121/22 124/12 126/23 133/16 145/16 156/13 157/3</p> <p>next [46] 13/14 13/23 15/5 15/11 18/15 20/12 31/8 43/25 46/22 47/13 49/7 51/10 62/7 81/14 83/20 90/4 92/6 96/22 101/10 108/12 111/13 114/3 114/13 116/15 117/6 117/8 117/10 117/20 117/21 117/21 117/21 119/13 125/4 125/18 134/20 135/5 136/11 136/12 139/2 140/16 142/19 144/14 146/17 163/19 168/5 168/10</p> <p>NHBT0000091 [1]</p>
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<p>N</p> <p>NHBT0000091... [1] 102/17</p> <p>NHBT0107241 [1] 96/10</p> <p>NHS [9] 35/18 45/10 45/15 73/7 73/14 101/5 108/22 109/18 111/22</p> <p>Nicholas [1] 58/18</p> <p>Nick [3] 8/1 8/11 8/25</p> <p>nine [5] 42/1 103/4 104/10 104/13 107/25</p> <p>Ninety [1] 104/14</p> <p>Ninety-seven [1] 104/14</p> <p>no [47] 6/9 12/15 15/23 17/24 19/7 21/15 21/15 21/17 23/16 25/20 26/7 29/16 29/25 29/25 35/11 36/6 57/4 57/9 67/6 70/3 78/17 79/13 87/4 87/11 88/3 88/10 90/17 92/20 104/18 104/20 123/17 127/25 133/16 135/15 138/25 142/11 142/16 146/22 146/25 151/3 151/24 154/1 155/1 155/8 159/19 160/2 165/12</p> <p>no-one [1] 151/24</p> <p>nodes [1] 37/1</p> <p>nods [1] 54/3</p> <p>non [22] 8/3 32/24 32/25 33/3 33/3 33/5 33/5 36/8 36/8 120/3 120/9 121/15 121/15 126/7 131/20 134/2 135/16 135/16 140/9 143/1 144/20 144/20</p> <p>non-'B' [2] 120/3 120/9</p> <p>non-A [5] 32/24 33/3 36/8 121/15 144/20</p> <p>non-A, non-B [2] 33/5 135/16</p> <p>non-B [10] 32/25 33/3 36/8 121/15 126/7 131/20 134/2 140/9 143/1 144/20</p> <p>non-fatal [1] 8/3</p> <p>None [1] 115/14</p> <p>nor [1] 36/16</p> <p>norm [1] 167/16</p> <p>normal [8] 106/16 123/5 128/1 136/20 142/10 142/25 144/9 153/2</p> <p>normally [1] 150/18</p> <p>North [3] 69/4 82/3</p>	<p>139/6</p> <p>not [159] 1/22 3/12 4/23 5/2 6/11 6/21 7/23 7/23 8/10 8/18 9/1 9/10 9/11 9/20 9/25 10/12 10/19 10/23 11/3 11/6 11/11 12/6 12/24 13/1 16/1 16/14 17/11 18/5 20/1 20/20 21/24 22/9 23/10 23/20 24/22 25/3 25/7 25/13 26/11 27/18 30/8 30/12 30/14 30/19 30/23 32/10 32/22 33/4 33/24 35/9 35/10 35/14 35/17 35/21 35/24 36/3 36/13 36/17 36/18 36/21 37/6 37/8 37/14 37/19 37/21 39/6 39/19 40/14 46/6 46/16 49/3 49/10 50/16 53/4 53/5 56/1 56/7 71/22 72/11 75/14 75/20 76/6 77/16 78/23 81/12 82/11 83/24 84/9 84/16 84/24 85/1 85/18 85/25 86/15 87/4 87/12 87/14 87/18 88/4 88/10 88/14 88/15 91/1 91/24 92/4 92/25 93/7 93/23 94/11 97/23 101/14 102/23 105/9 105/21 105/23 106/1 108/3 110/7 110/11 111/7 113/19 115/2 115/22 116/22 117/24 117/25 119/2 124/3 124/21 128/10 128/24 135/13 135/18 136/1 136/14 140/16 143/16 145/19 148/3 148/21 148/25 149/22 150/4 150/19 152/8 152/19 153/8 154/25 156/9 158/24 159/12 160/14 162/2 162/15 164/22 167/6 167/11 168/2 168/11</p> <p>note [14] 35/3 70/6 78/3 78/16 89/25 92/18 99/19 113/3 125/20 147/12 152/12 156/14 161/7 168/1</p> <p>noted [1] 82/5</p> <p>notes [2] 37/3 160/5</p> <p>nothing [4] 146/6 146/24 164/13 164/15</p> <p>notification [1] 69/25</p> <p>notify [1] 138/12</p>	<p>November [9] 33/22 34/17 53/24 53/25 54/4 66/1 66/6 78/3 132/22</p> <p>November '73 [2] 66/1 66/6</p> <p>November '87 [2] 53/25 54/4</p> <p>November 1987 [1] 53/24</p> <p>November 1995 [1] 34/17</p> <p>now [36] 15/6 16/19 17/23 20/19 24/3 26/18 41/4 42/5 43/19 45/15 51/21 53/14 56/22 63/15 64/4 65/1 67/7 67/13 71/9 77/1 77/19 80/8 81/20 96/20 102/3 102/7 109/16 128/17 140/1 143/8 146/18 155/7 161/11 161/16 164/16 165/11</p> <p>number [35] 10/15 12/23 26/17 35/3 39/16 39/23 40/1 40/1 40/4 40/5 45/5 53/13 55/4 71/1 76/1 83/24 83/25 84/9 85/7 86/5 89/16 112/12 116/16 117/23 124/5 134/22 136/9 154/4 154/6 155/7 156/10 157/5 160/18 160/21 165/20</p> <p>numbers [3] 121/19 133/13 154/3</p> <p>nursed [1] 30/19</p> <p>Nurses [2] 30/11 43/12</p> <p>nursing [12] 17/22 18/13 25/25 25/25 26/5 26/15 26/20 28/7 30/25 42/20 68/13 133/6</p>	<p>observations [15] 1/9 3/21 44/11 46/2 47/15 47/16 48/11 49/18 50/20 50/25 57/20 62/12 75/17 75/22 119/17</p> <p>observe [1] 47/19</p> <p>observed [2] 89/17 123/17</p> <p>observer [1] 68/23</p> <p>observes [1] 88/18</p> <p>obtain [6] 45/16 52/8 74/18 91/1 140/18 149/20</p> <p>obtained [8] 57/5 74/7 104/2 113/24 150/3 153/18 154/20 157/13</p> <p>obtaining [6] 5/22 41/10 56/12 90/18 90/23 165/17</p> <p>obvious [2] 5/5 76/17</p> <p>obviously [15] 7/10 18/11 31/4 35/1 35/6 36/18 38/9 73/7 115/19 124/21 131/5 157/18 165/4 165/18 168/6</p> <p>occasion [4] 4/21 105/13 129/22 141/10</p> <p>occasions [3] 5/2 39/5 155/7</p> <p>occur [4] 31/7 92/9 105/11 105/13</p> <p>occurred [2] 66/17 71/20</p> <p>occurring [2] 55/12 115/15</p> <p>occurs [1] 71/22</p> <p>October [8] 70/19 76/10 78/2 78/5 139/16 139/18 141/8 158/22</p> <p>October 1977 [1] 139/16</p> <p>oddity [1] 91/14</p> <p>off [2] 38/8 87/6</p> <p>off' [2] 4/20 34/8</p> <p>offer [5] 3/16 13/22 73/13 164/17 166/14</p> <p>offering [4] 14/24 163/15 163/17 163/18</p> <p>officer [9] 25/10 42/13 42/15 42/18 51/23 53/6 67/21 143/20 168/17</p> <p>officers [1] 42/19</p> <p>often [7] 42/1 59/13 86/15 98/4 100/18 101/6 112/10</p> <p>oh [3] 38/11 41/5 107/15</p> <p>once [9] 5/25 30/3</p>	<p>74/1 74/2 90/9 90/12 91/22 103/5 140/23</p> <p>once-weekly [2] 90/9 90/12</p> <p>one [93] 1/13 2/3 2/5 3/11 4/10 4/19 6/9 7/6 9/9 11/10 18/8 22/18 26/1 27/4 27/13 27/24 28/3 28/22 29/5 29/10 32/12 38/2 39/7 39/20 40/6 40/7 40/8 42/6 45/1 47/7 50/9 55/16 56/5 58/3 64/24 71/3 75/1 77/18 78/6 79/24 82/21 84/6 84/6 85/8 86/17 88/12 88/12 93/23 93/24 96/11 99/7 99/21 104/21 105/13 112/5 112/8 112/24 114/1 114/22 117/16 122/13 125/2 125/9 125/14 127/13 128/20 130/10 132/6 136/2 137/15 137/16 140/17 141/20 142/21 144/4 144/12 145/1 145/9 147/11 149/17 151/16 151/24 152/6 152/24 160/20 161/1 161/2 161/19 161/23 162/4 162/25 163/9 167/9</p> <p>ones [1] 39/21</p> <p>ongoing [6] 18/17 34/4 40/2 64/6 96/4 137/20</p> <p>only [34] 6/5 6/6 6/23 9/15 14/16 18/11 24/19 44/11 62/13 68/13 71/6 74/14 76/18 83/21 83/24 92/1 93/23 99/7 105/22 115/8 116/25 122/15 126/22 126/24 127/2 127/10 127/13 129/14 130/9 137/14 138/4 149/16 156/3 167/6</p> <p>onwards [2] 39/14 165/7</p> <p>opened [1] 142/1</p> <p>operation [4] 35/12 74/17 122/7 127/23</p> <p>operational [1] 65/1</p> <p>opinion [4] 45/14 66/7 66/21 162/13</p> <p>opportunistic [1] 29/21</p> <p>opportunities [1] 166/15</p> <p>opportunity [7] 44/12 47/8 51/8 55/6 62/15</p>	<p>94/5 113/1</p> <p>opposed [3] 22/25 30/5 167/16</p> <p>optimum [1] 147/15</p> <p>or [131] 1/23 3/17 6/6 6/24 7/4 7/22 7/23 10/3 10/17 11/7 11/10 11/17 11/17 12/6 13/13 15/11 16/14 17/25 18/15 22/18 24/18 25/6 25/7 25/8 25/18 25/19 26/4 26/11 26/13 30/13 30/24 34/21 34/25 35/11 35/11 35/14 35/22 35/22 36/8 37/10 38/18 39/8 39/9 39/9 39/20 39/23 40/5 40/8 40/9 45/24 52/25 53/9 71/3 71/16 71/20 71/22 77/20 77/25 78/3 79/6 79/8 79/18 80/14 81/11 84/3 84/3 84/5 86/16 87/3 87/5 87/15 87/24 90/13 91/13 91/19 91/23 94/20 104/1 105/9 105/12 106/15 110/1 111/22 112/23 113/10 118/17 121/8 121/9 125/6 125/14 127/9 130/10 130/20 131/7 131/20 132/1 135/2 136/23 137/9 137/22 138/15 139/4 139/4 139/11 140/3 143/17 143/19 144/9 144/19 145/5 145/11 145/12 147/1 148/10 148/11 150/14 151/14 151/17 152/4 154/21 155/5 156/7 157/22 159/4 160/2 164/22 165/23 165/23 165/25 166/4 166/4</p> <p>oral [5] 7/20 34/24 35/2 37/10 160/25</p> <p>orally [1] 9/7</p> <p>order [6] 4/4 84/1 85/8 105/5 120/14 122/4</p> <p>Orderlies [1] 43/12</p> <p>ordinarily [1] 88/22</p> <p>ordinary [1] 167/11</p> <p>organisation [11] 43/2 45/15 55/15 62/5 72/6 73/20 76/22 77/1 77/5 83/4 127/23</p> <p>organisational [3] 45/9 55/23 60/7</p> <p>organise [4] 44/23 71/5 71/10 78/18</p> <p>organised [3] 12/6</p>
--	---	---	--	--	--

<p>O</p> <p>organised... [2] 86/9 146/17</p> <p>organiser [1] 56/10</p> <p>organising [3] 45/7 71/12 97/21</p> <p>origin [1] 158/13</p> <p>original [6] 49/6 56/11 56/24 66/14 102/12 113/4</p> <p>orthopaedic [3] 42/11 42/12 87/15</p> <p>ostracised [1] 25/4</p> <p>other [69] 6/25 7/12 7/12 8/23 10/2 11/13 14/10 14/21 19/18 20/4 22/18 24/1 24/25 26/4 27/14 29/16 35/4 44/8 48/9 55/24 56/4 56/12 62/10 63/22 70/3 78/21 85/19 87/15 88/8 90/11 92/21 93/17 93/21 97/2 98/13 106/2 109/17 112/8 112/23 119/3 119/6 119/11 121/8 121/13 132/12 132/14 132/16 133/6 135/5 135/7 137/21 142/20 145/8 146/4 146/7 146/25 147/3 148/11 148/21 148/22 151/17 151/17 151/18 157/21 162/24 164/1 165/4 165/25 167/3</p> <p>others [11] 9/8 10/6 10/7 10/12 15/20 16/9 22/8 29/21 100/17 110/3 167/1</p> <p>otherwise [2] 88/25 92/22</p> <p>ought [1] 56/21</p> <p>our [35] 3/5 3/5 3/12 3/16 3/16 5/24 6/1 14/14 14/15 14/18 14/20 15/6 16/2 17/18 17/22 18/6 18/9 18/22 20/5 25/1 34/6 35/3 45/14 58/19 59/8 59/10 67/2 102/12 105/21 130/9 140/6 147/11 149/17 150/5 156/24</p> <p>out [56] 3/14 16/24 20/10 20/25 23/2 27/17 28/21 39/1 39/19 46/16 48/1 49/9 52/16 56/3 56/23 57/10 57/25 59/4 59/9 61/24 65/2 65/15 66/7 66/16 68/25 72/12</p>	<p>73/4 74/8 74/13 74/22 76/14 77/19 79/20 80/12 81/9 81/22 83/23 85/18 85/25 89/14 98/3 102/6 102/14 103/3 104/11 105/2 105/18 112/11 142/3 146/8 149/22 151/8 151/12 158/16 161/15 167/3</p> <p>outbreak [5] 8/5 36/2 96/16 120/2 126/6</p> <p>outcome [1] 59/14</p> <p>outcomes [1] 36/21</p> <p>outline [2] 56/24 153/13</p> <p>outlined [1] 95/9</p> <p>outside [3] 24/15 123/18 141/15</p> <p>over [40] 2/15 4/17 8/22 10/10 21/11 27/18 43/6 46/9 47/23 54/5 58/15 62/20 63/10 64/13 68/16 72/1 74/21 76/15 81/18 84/22 85/23 89/11 91/3 93/15 104/10 105/6 109/21 112/12 114/18 122/6 127/13 139/22 143/6 144/24 150/9 152/5 154/10 155/11 157/9 166/12</p> <p>overall [4] 9/4 103/8 103/11 133/3</p> <p>overlapping [1] 57/9</p> <p>overwhelmingly [1] 35/10</p> <p>own [14] 2/17 2/21 6/18 10/7 18/22 22/7 56/11 68/18 69/1 89/7 151/13 151/14 154/25 162/13</p> <p>Oxford [33] 26/20 26/23 44/18 44/19 45/1 45/9 45/11 45/12 45/18 50/25 51/14 51/15 54/23 56/5 57/10 61/2 65/13 65/14 65/23 66/3 66/18 66/24 76/10 98/24 121/3 121/18 121/23 121/23 126/22 129/8 132/21 141/8 146/9</p> <p>OXUH0000447 [1] 158/20</p> <p>OXUH0003735 [2] 97/9 101/11</p> <p>OXUH0003758 [1] 132/5</p>	<p>P</p> <p>pag [1] 70/21</p> <p>page [118] 1/20 3/24 4/17 6/4 6/7 8/14 8/15 13/7 15/1 16/8 19/9 20/12 20/19 20/22 21/11 27/18 27/22 28/22 31/2 31/8 32/23 33/14 43/6 47/13 47/23 51/1 58/15 61/12 61/17 62/20 63/10 64/13 69/14 72/1 74/16 74/21 81/6 81/14 83/15 85/16 85/23 86/24 89/11 90/4 90/19 91/3 92/6 93/2 95/4 95/16 95/18 96/16 96/17 97/10 97/13 97/13 98/15 99/3 99/25 100/2 101/10 101/12 103/21 104/10 104/11 104/16 105/6 106/21 106/24 107/8 107/10 107/14 107/15 107/18 109/7 109/8 109/21 111/8 111/20 114/1 114/13 114/13 114/18 116/1 116/21 117/6 117/8 117/10 117/21 117/21 117/21 117/21 117/21 122/20 125/4 126/16 127/5 127/21 132/9 134/6 136/11 137/1 143/6 143/23 143/24 154/2 154/7 154/10 154/18 155/12 156/1 156/14 157/9 159/1 159/17 162/6 163/16 163/19 164/6</p> <p>page 106 [1] 3/24</p> <p>page 11 [1] 137/1</p> <p>page 2 [1] 96/16</p> <p>page 3 [1] 86/24</p> <p>page 4 [3] 95/4 96/17 99/25</p> <p>page 5 [3] 101/12 132/9 164/6</p> <p>page 6 [2] 143/23 156/14</p> <p>page 7 [2] 19/9 104/16</p> <p>page 8 [2] 13/7 97/13</p> <p>page 9 [1] 109/7</p> <p>pages [5] 1/19 2/1 93/2 102/24 103/20</p> <p>paid [2] 44/1 120/2</p> <p>Painter [3] 148/17 149/13 151/16</p> <p>paints [2] 10/22 37/23</p> <p>palpability [1] 142/13</p>	<p>paper [4] 95/23 98/18 102/16 153/4</p> <p>papers [1] 63/22</p> <p>paperwork [1] 19/20</p> <p>paragraph [75] 4/2 6/3 6/5 8/15 13/8 13/14 13/23 15/2 15/5 15/9 20/2 27/4 28/23 31/9 32/24 46/22 47/24 49/7 50/9 50/14 58/5 61/25 62/3 62/7 62/21 64/11 68/17 69/18 69/23 72/8 74/16 76/2 76/5 83/20 85/9 85/15 88/18 91/9 94/4 94/10 94/15 95/5 95/25 103/23 105/6 106/22 107/18 109/23 111/13 114/3 118/21 119/13 119/19 122/1 125/20 127/4 130/7 130/12 131/2 133/25 134/20 136/13 139/19 140/16 140/21 141/6 142/19 144/15 153/1 159/1 161/9 162/6 162/7 163/13 164/6</p> <p>paragraph 2 [1] 68/17</p> <p>paragraph 3 [1] 159/1</p> <p>paragraph 4 [2] 27/4 91/9</p> <p>paragraph 41 [1] 13/8</p> <p>paragraph 6 [1] 76/2</p> <p>paragraph 7 [1] 76/5</p> <p>paragraph 8 [2] 20/2 164/6</p> <p>paragraph 9 [1] 8/15</p> <p>paraphrasing [1] 128/7</p> <p>parent [16] 11/17 23/3 87/20 93/25 129/22 148/16 149/4 149/7 149/11 150/1 151/5 151/12 152/14 152/15 162/23 163/1</p> <p>parental [1] 137/22</p> <p>parentis [1] 11/18</p> <p>parents [52] 1/11 7/23 10/23 11/2 11/8 16/21 22/24 23/1 23/9 23/15 25/12 25/19 27/13 28/1 30/10 31/3 32/5 35/10 35/12 35/14 35/21 36/1 36/3 36/7 36/16 36/20 85/17 87/24 91/19 94/19 104/1 125/6 125/15 128/23 130/21 137/8 138/15 145/12 145/25 146/1 146/4 148/9 148/14 149/22 151/12 152/10 152/17 153/10</p>	<p>155/5 156/1 156/7 159/25</p> <p>parents' [1] 74/18</p> <p>parents/guardians [1] 125/6</p> <p>Park [1] 82/15</p> <p>part [25] 2/3 2/4 10/23 11/1 11/3 19/5 36/20 39/12 43/21 43/25 52/17 65/2 80/17 118/8 135/15 139/22 148/20 149/14 150/12 155/14 155/23 157/3 161/6 163/21 166/17</p> <p>part-time [2] 43/25 52/17</p> <p>participant [1] 128/3</p> <p>participants [3] 128/8 165/13 168/7</p> <p>participate [4] 87/25 92/12 145/22 154/5</p> <p>participating [2] 87/20 91/10</p> <p>participation [5] 94/16 96/3 99/6 137/9 150/25</p> <p>participative [1] 7/4</p> <p>particular [35] 2/3 3/22 13/19 13/24 23/21 26/2 27/24 28/9 36/6 39/20 40/8 47/21 50/21 72/4 74/23 76/6 78/6 79/6 114/1 122/6 130/25 131/10 132/18 133/2 134/10 137/11 139/12 144/25 150/20 151/6 163/23 164/20 165/23 166/1 166/2</p> <p>particularly [12] 40/22 44/7 52/10 55/11 56/5 67/7 99/15 108/6 140/10 140/14 140/18 150/8</p> <p>parties [1] 19/22</p> <p>parts [1] 168/20</p> <p>Party [7] 141/21 141/22 144/3 158/18 158/22 159/5 159/13</p> <p>passage [3] 2/3 3/22 101/16</p> <p>passed [3] 2/6 24/18 25/13</p> <p>passing [1] 33/11</p> <p>past [6] 13/25 33/8 46/9 65/14 87/9 139/22</p> <p>pastoral [1] 11/19</p> <p>patch' [1] 4/14</p> <p>path [1] 107/5</p> <p>pathological [2] 46/2 58/10</p> <p>pathologist [1] 58/1</p>	<p>Pathology [1] 133/11</p> <p>patient [63] 5/9 14/18 17/5 18/3 32/13 34/8 34/12 37/8 43/9 86/23 86/25 87/1 87/5 87/7 87/8 87/13 87/24 88/21 89/7 89/8 90/7 90/9 91/19 91/21 91/24 92/2 94/7 94/11 98/2 99/7 99/21 119/22 121/6 122/2 122/5 123/8 123/15 126/1 126/12 126/15 127/10 130/20 130/25 131/7 132/3 134/14 134/17 137/11 137/12 137/22 138/4 142/25 149/1 149/14 151/5 154/3 156/6 159/11 159/14 159/15 160/2 165/15 165/17</p> <p>patient's [6] 7/15 91/17 91/19 94/9 130/21 154/11</p> <p>patients [77] 7/12 7/19 12/17 15/3 15/6 15/13 16/3 18/10 19/25 20/17 21/7 22/4 34/6 45/6 45/23 47/3 48/7 48/14 52/3 55/5 55/11 71/15 89/5 89/18 90/1 91/13 92/7 92/11 92/19 98/16 98/20 98/22 98/25 99/1 99/2 99/15 106/18 109/10 109/14 110/9 110/16 111/9 112/24 117/13 121/20 122/22 122/25 125/6 125/14 130/11 132/22 133/1 133/2 133/5 133/16 133/18 138/1 138/24 139/3 139/12 140/3 140/19 142/5 143/11 144/18 145/12 146/7 146/25 154/21 155/5 160/6 160/22 161/4 166/21 166/23 167/9 167/11</p> <p>pattern [4] 113/4 116/2 166/11 166/12</p> <p>patterns [1] 116/6</p> <p>pausing [3] 78/23 122/10 140/2</p> <p>pay [2] 20/15 21/4</p> <p>payments [1] 38/23</p> <p>PC [1] 42/4</p> <p>Peach [2] 10/21 35/17</p> <p>Peard [1] 131/9</p> <p>peculiar [2] 150/22 150/23</p> <p>penultimate [1] 85/15</p>
--	--	--	--	---	--

(60) organised... - penultimate

<p>P</p> <p>people [9] 8/23 9/10 9/12 9/15 15/21 15/22 80/8 83/2 158/4</p> <p>per [4] 87/9 98/2 98/2 114/23</p> <p>perfecting [1] 80/17</p> <p>performed [1] 136/22</p> <p>perhaps [18] 5/19 13/12 28/24 31/1 53/14 68/23 71/6 83/25 124/20 126/14 149/6 152/4 152/7 152/16 152/24 161/6 161/15 164/21</p> <p>period [17] 4/9 10/10 12/4 81/19 84/22 90/16 114/1 115/18 122/6 124/20 125/1 126/9 127/11 127/14 142/10 144/24 152/5</p> <p>periodically [1] 4/15</p> <p>periods [9] 4/12 17/13 74/12 76/20 90/14 90/16 108/11 111/15 144/9</p> <p>permanent [2] 30/25 64/21</p> <p>permanently [2] 134/22 136/9</p> <p>permission [3] 145/22 146/2 148/21</p> <p>permit [1] 59/20</p> <p>persistent [1] 114/22</p> <p>person [1] 29/19</p> <p>personal [1] 2/17</p> <p>personnel [1] 89/19</p> <p>persons [1] 71/2</p> <p>persuade [1] 105/17</p> <p>Peter [4] 51/4 139/20 139/25 145/22</p> <p>Peter Kirk [1] 139/20</p> <p>PFL [1] 79/18</p> <p>PG [2] 65/20 102/3</p> <p>pharmaceutical [4] 156/16 163/6 164/1 164/22</p> <p>philosophy [1] 5/8</p> <p>physician [5] 34/21 42/4 65/20 88/23 91/11</p> <p>physiotherapist [1] 43/16</p> <p>physiotherapy [1] 43/10</p> <p>pick [7] 3/24 14/11 96/9 97/7 98/12 106/23 107/17</p> <p>picking [2] 58/4 140/16</p> <p>picture [7] 10/22 11/3</p>	<p>34/2 37/23 40/8 110/25 166/11</p> <p>piece [5] 39/6 39/9 166/1 166/8 166/9</p> <p>pieces [3] 28/3 39/17 67/14</p> <p>pilot [4] 98/15 98/21 127/18 154/24</p> <p>pity [2] 73/23 77/4</p> <p>place [9] 27/7 28/6 30/2 47/8 71/6 75/10 78/2 150/14 161/6</p> <p>placebo [17] 68/21 72/4 72/7 72/9 89/9 90/12 90/14 91/13 91/23 92/3 93/4 93/11 97/23 102/9 105/21 105/24 147/1</p> <p>placebos [1] 146/21</p> <p>plagued [1] 16/22</p> <p>plainly [1] 135/16</p> <p>plan [5] 44/23 67/10 67/11 82/1 113/4</p> <p>planned [4] 57/8 68/19 87/16 123/1</p> <p>planning [4] 47/12 66/16 71/10 77/12</p> <p>plasma [13] 6/10 47/17 57/21 63/19 79/7 79/15 93/5 101/7 103/6 120/2 124/9 136/20 139/7</p> <p>plasma-cortisol [1] 57/21</p> <p>plate [1] 8/6</p> <p>platelet [1] 62/23</p> <p>platelets [1] 63/21</p> <p>Platt [1] 133/10</p> <p>play [5] 18/12 38/2 38/5 65/2 80/17</p> <p>played [2] 38/6 170/4</p> <p>playing [2] 4/23 22/7</p> <p>please [13] 2/1 3/24 8/12 16/9 21/21 25/6 38/5 70/17 106/24 117/20 130/13 131/21 156/23</p> <p>pleased [4] 130/8 131/24 138/12 156/2</p> <p>plural [1] 52/24</p> <p>plus [2] 50/11 87/6</p> <p>pm [3] 110/22 110/24 169/6</p> <p>point [10] 3/14 19/23 28/9 34/19 89/25 90/20 110/18 115/20 123/6 141/5</p> <p>pointed [8] 72/12 73/4 74/8 74/13 74/22 79/20 83/23 85/25</p> <p>points [9] 68/10 79/3 79/6 91/20 98/3</p>	<p>120/24 125/7 146/12 157/2</p> <p>policies [2] 14/14 14/19</p> <p>policy [2] 31/11 122/11</p> <p>pool [4] 101/3 113/10 119/14 134/12</p> <p>Poole [1] 161/8</p> <p>pools [5] 47/1 101/5 101/7 119/24 120/1</p> <p>popularity [1] 161/15</p> <p>population [4] 14/18 15/15 83/19 124/9</p> <p>porcine [1] 163/13</p> <p>portrayed [1] 36/12</p> <p>posed [4] 29/15 56/25 130/17 138/8</p> <p>poses [2] 17/19 144/14</p> <p>position [8] 12/17 28/21 36/18 65/24 114/10 138/21 139/14 164/17</p> <p>positive [12] 8/21 9/23 15/4 17/1 101/15 114/21 114/24 115/11 115/15 121/4 140/3 142/24</p> <p>possibility [2] 33/20 50/22</p> <p>possible [25] 3/20 24/20 33/9 47/5 58/13 72/23 74/18 79/21 80/6 84/16 86/15 92/20 92/23 99/14 108/4 108/10 113/19 122/3 122/14 124/1 127/16 131/19 140/19 144/5 151/11</p> <p>possibly [11] 6/9 10/7 10/16 19/1 31/18 34/10 53/11 59/11 110/4 159/15 162/11</p> <p>post [12] 63/4 64/11 67/1 103/6 103/11 115/17 117/24 118/22 119/7 119/12 120/9 121/14</p> <p>post-infusion [1] 103/11</p> <p>post-transfusion [5] 64/11 115/17 117/24 119/12 121/14</p> <p>potential [2] 89/4 153/17</p> <p>potentially [1] 84/5</p> <p>powerful [3] 10/20 37/20 37/23</p> <p>practicable [1] 123/14</p> <p>practical [3] 84/25 95/9 105/9</p>	<p>practicalities [1] 3/12</p> <p>practice [3] 3/5 3/9 74/3</p> <p>Practitioner [1] 51/19</p> <p>pre [3] 64/11 132/14 140/24</p> <p>pre-date [1] 132/14</p> <p>pre-infection [1] 140/24</p> <p>precautions [2] 24/16 25/6</p> <p>precipitated [1] 125/3</p> <p>precise [1] 53/4</p> <p>precisely [5] 1/23 1/23 54/14 100/9 162/15</p> <p>predated [1] 132/16</p> <p>predict [1] 15/12</p> <p>predictions [3] 15/14 20/13 20/24</p> <p>preface [1] 1/25</p> <p>preferably [1] 127/13</p> <p>preference [1] 123/5</p> <p>preferred [1] 110/1</p> <p>prejudice [3] 16/15 16/23 154/22</p> <p>preliminary [1] 97/1</p> <p>prepare [1] 70/25</p> <p>prepared [6] 7/3 13/25 47/1 85/18 96/21 97/17</p> <p>prescribed [1] 4/12</p> <p>presence [6] 58/6 59/21 63/13 75/21 113/7 116/7</p> <p>present [23] 42/25 43/13 43/19 44/4 44/6 44/14 45/18 46/11 52/2 57/8 57/10 59/19 62/17 65/5 70/20 79/5 82/18 83/21 88/11 97/12 127/24 134/23 164/5</p> <p>presentation [3] 1/5 167/24 170/2</p> <p>presented [3] 14/2 97/17 107/19</p> <p>presently [1] 164/19</p> <p>preserved [1] 18/16</p> <p>presumably [5] 7/3 38/9 93/10 156/22 167/5</p> <p>prevent [2] 4/4 118/22</p> <p>preventative [3] 86/20 88/17 94/13</p> <p>prevention [2] 55/13 59/14</p> <p>previous [8] 49/18 73/24 95/16 106/22 114/25 117/19 126/7 142/16</p> <p>previously [4] 95/20</p>	<p>96/12 96/15 107/7</p> <p>price [1] 163/16</p> <p>Primarily [1] 76/22</p> <p>primary [1] 18/4</p> <p>Prince's [1] 120/6</p> <p>principal [3] 58/1 67/20 143/20</p> <p>principle [2] 11/25 127/22</p> <p>prior [4] 90/2 117/4 128/4 142/25</p> <p>priorities [1] 14/16</p> <p>probability [1] 101/8</p> <p>probable [3] 59/12 128/3 134/7</p> <p>probably [22] 15/21 38/15 38/16 41/9 46/9 48/4 49/2 49/4 53/2 53/16 54/11 104/25 105/22 112/10 115/1 131/15 144/21 147/12 147/22 157/22 158/16 168/4</p> <p>problem [4] 16/2 100/6 135/6 159/7</p> <p>problematic [1] 78/25</p> <p>problems [7] 23/21 31/7 105/7 127/24 129/6 133/3 143/3 87/16 125/19 126/3</p> <p>procedures [1] 123/1</p> <p>proceed [1] 153/19</p> <p>Proceedings [1] 1/3</p> <p>process [13] 4/7 11/6 11/8 11/11 30/6 32/3 35/11 36/19 80/9 104/5 132/4 135/2 160/23</p> <p>processed [1] 119/24</p> <p>processing [1] 133/12</p> <p>produce [1] 78/10</p> <p>produced [8] 118/12 121/2 128/12 132/6 151/20 153/14 154/9 159/7</p> <p>producing [2] 79/13 86/1</p> <p>product [11] 6/10 80/24 119/24 133/6 145/1 155/15 155/16 155/24 157/19 157/19 163/13</p> <p>production [1] 79/22</p> <p>products [13] 40/5 63/15 79/8 111/19 113/8 113/10 116/9 121/22 127/7 133/4 142/6 154/8 164/24</p> <p>Prof [3] 100/8 101/4 110/5</p> <p>Prof Stewart [1] 100/8</p>	<p>professional [1] 65/8</p> <p>Professor [7] 33/23 58/18 59/1 68/3 75/2 101/2 162/17</p> <p>Professor Bloom [1] 162/17</p> <p>Professor Ingram [1] 101/2</p> <p>Professor J [1] 68/3</p> <p>Professor Martin [1] 59/1</p> <p>Profilate [2] 128/20 137/5</p> <p>profit [1] 51/8</p> <p>profound [1] 77/22</p> <p>profoundly [1] 16/5</p> <p>program [2] 57/8 96/22</p> <p>programme [11] 56/22 59/23 61/14 62/22 65/3 65/19 96/19 96/24 148/20 149/2 163/22</p> <p>programmed [1] 17/3</p> <p>progress [5] 15/21 15/22 52/2 70/10 96/9</p> <p>project [24] 44/18 45/21 45/22 47/10 51/5 51/17 57/13 58/3 58/3 58/12 58/15 58/25 59/3 60/6 63/18 63/19 64/6 67/4 76/3 82/2 94/6 97/3 149/14 149/16</p> <p>projects [17] 40/2 44/4 52/1 55/22 55/25 57/11 57/12 59/24 63/11 63/25 65/15 66/13 66/16 66/19 76/1 97/2 149/15</p> <p>prolong [1] 152/3</p> <p>prolonged [2] 76/20 144/24</p> <p>promised [1] 164/10</p> <p>promises [1] 164/8</p> <p>Promotion [1] 45/22</p> <p>prompted [1] 88/24</p> <p>promptly [2] 92/4 150/11</p> <p>proper [2] 7/8 87/17</p> <p>properly [2] 166/19 166/20</p> <p>prophylactic [49] 5/9 48/18 48/21 50/16 57/5 64/1 64/2 67/24 70/22 71/5 71/16 73/11 73/15 74/13 75/5 76/12 78/8 81/6 88/19 92/21 93/20 94/17 96/17 96/20 97/5 97/14 102/2 102/14 103/3 105/23</p>
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(61) people - prophylactic

<p>P</p> <p>prophylactic... [19] 106/8 106/10 106/22 107/7 107/11 107/20 108/16 109/9 109/11 109/12 110/3 110/6 110/10 111/2 111/14 112/4 138/10 145/10 153/20</p> <p>prophylaxis [39] 3/23 3/25 4/1 4/4 4/8 4/9 4/11 4/16 4/18 5/19 6/12 6/13 6/18 48/19 67/15 68/20 71/21 72/3 73/16 76/6 89/15 95/4 95/6 97/16 97/25 98/6 100/23 101/23 102/18 105/25 106/2 108/11 108/13 108/18 108/24 109/22 110/1 111/16 146/21</p> <p>proportion [5] 15/22 83/16 83/19 142/5 144/17</p> <p>proposal [3] 81/16 98/18 143/13</p> <p>proposals [1] 139/11</p> <p>propose [1] 89/24</p> <p>proposed [24] 44/17 44/25 45/12 48/8 48/16 52/5 61/14 62/22 65/3 65/17 66/13 67/1 75/1 78/7 81/8 83/3 98/6 98/15 120/13 127/17 135/4 138/1 149/24 153/16</p> <p>proposing [5] 64/18 98/21 139/3 156/9 158/24</p> <p>prospective [7] 40/10 88/16 118/14 120/14 137/13 139/23 142/2</p> <p>protected [1] 97/19</p> <p>protection [2] 47/4 121/5</p> <p>protective [1] 29/24</p> <p>protein [2] 62/24 93/5</p> <p>protocol [28] 68/2 69/6 70/9 70/22 70/25 71/8 71/11 76/15 78/10 78/12 80/4 80/7 81/25 83/8 83/15 92/16 102/1 102/12 118/13 125/18 128/12 132/13 153/13 155/19 156/21 156/23 160/20 162/9</p> <p>protocols [2] 161/4 161/11</p> <p>prove [1] 83/1</p> <p>proves [1] 156/4</p>	<p>provide [13] 9/17 11/18 32/12 44/12 49/19 49/21 49/22 62/14 64/20 79/10 110/10 116/12 121/12</p> <p>provided [21] 22/23 23/1 30/19 43/1 72/18 80/13 84/21 86/5 94/21 112/25 128/25 129/22 132/3 137/8 152/9 152/17 153/7 153/9 155/4 156/6 157/14</p> <p>provides [5] 19/10 34/1 43/8 47/8 151/17</p> <p>providing [4] 33/12 45/3 45/5 136/24</p> <p>provision [2] 5/21 136/20</p> <p>provisionally [2] 45/8 134/1</p> <p>provoke [1] 88/25</p> <p>PRSE0002268 [1] 109/5</p> <p>psychiatrist [1] 11/25</p> <p>psychological [2] 13/22 89/1</p> <p>public [7] 31/6 31/9 31/15 59/5 63/16 76/3 141/3</p> <p>publication [12] 1/21 46/18 49/11 49/15 97/18 102/22 106/7 111/19 120/7 147/6 147/20 158/15</p> <p>publications [2] 33/16 111/1</p> <p>published [7] 1/22 46/18 102/16 109/19 158/17 160/8 168/4</p> <p>Pugh [1] 164/9</p> <p>pupil [19] 8/8 8/13 9/9 26/2 26/10 27/24 29/15 30/4 30/7 30/17 30/22 33/25 34/1 94/19 131/7 131/10 138/15 150/17 166/3</p> <p>pupil's [2] 33/12 165/24</p> <p>pupils [41] 1/11 7/22 8/20 9/14 9/21 9/22 10/2 10/19 11/7 11/12 11/22 12/21 12/24 22/24 24/22 25/12 25/14 25/18 25/19 26/21 29/16 29/17 31/4 31/16 35/13 35/23 35/24 36/9 36/16 37/19 39/13 55/8 122/18 134/16 140/3 141/3 148/6 149/24 160/22 166/18</p>	<p>166/22</p> <p>purchase [1] 164/25</p> <p>purely [1] 55/22</p> <p>Purity [4] 153/18 153/24 154/1 154/8</p> <p>purpose [4] 19/8 37/10 69/24 120/20</p> <p>purpose' [1] 13/10</p> <p>purposes [10] 37/9 60/4 88/11 99/21 99/22 99/23 122/16 123/15 164/5 167/21</p> <p>pursued [2] 75/24 76/18</p> <p>put [6] 4/3 21/16 24/22 40/2 138/9 164/11</p> <p>putting [2] 122/16 164/12</p> <hr/> <p>Q</p> <p>qualifications [1] 51/18</p> <p>qualified [2] 51/8 51/19</p> <p>qualify [1] 52/11</p> <p>quality [1] 73/5</p> <p>quantitatively [1] 58/21</p> <p>quantities [2] 130/14 157/15</p> <p>quantity [1] 84/22</p> <p>Quarters [1] 43/8</p> <p>queries [2] 129/19 138/2</p> <p>question [27] 7/18 10/13 17/19 25/16 34/25 38/1 39/2 55/12 57/1 57/3 80/24 82/8 93/15 93/17 118/5 120/15 130/17 135/16 138/8 143/8 144/14 145/11 151/7 151/10 152/8 159/9 165/9</p> <p>questionable [1] 129/13</p> <p>questions [7] 14/3 56/25 73/20 74/24 80/16 152/15 166/19</p> <p>quickly [1] 133/14</p> <p>quite [11] 5/5 10/10 27/10 27/19 51/7 61/17 80/20 98/4 123/21 130/15 150/19</p> <hr/> <p>R</p> <p>R Harwood [1] 69/15</p> <p>radio [1] 121/10</p> <p>Rainsford [38] 40/12 43/5 43/14 43/23 44/3 48/19 49/9 52/16 55/14 55/24 56/8 56/9</p>	<p>56/16 56/20 58/17 60/1 60/3 60/8 60/9 65/11 66/9 66/13 70/20 71/9 82/19 83/16 91/5 91/6 95/3 96/2 96/13 97/12 100/12 100/21 102/4 110/9 112/19 118/7</p> <p>Rainsford's [4] 56/15 66/15 66/25 67/11</p> <p>raise [7] 106/14 107/22 118/2 118/2 151/23 152/15 166/25</p> <p>raised [2] 80/3 154/12</p> <p>raises [2] 10/13 151/9</p> <p>random [1] 90/14</p> <p>range [6] 9/6 39/24 154/14 160/16 163/10 165/19</p> <p>rare [1] 130/10</p> <p>rate [1] 115/13</p> <p>rates [1] 121/1</p> <p>rather [16] 4/5 28/7 28/8 29/7 31/22 33/5 34/19 46/13 79/19 79/23 104/7 105/1 122/16 157/23 161/2 166/23</p> <p>rationale [1] 167/15</p> <p>rationalisation [1] 128/2</p> <p>raw [1] 79/22</p> <p>re [2] 1/5 170/2</p> <p>reach [1] 7/14</p> <p>reached [1] 57/2</p> <p>reaching [1] 151/13</p> <p>read [12] 2/2 26/8 26/8 37/22 46/16 49/5 51/10 76/7 82/11 94/15 101/20 124/7</p> <p>readily [2] 86/1 133/1</p> <p>reading [3] 12/14 105/1 105/2</p> <p>reads [1] 161/10</p> <p>reagent [1] 116/13</p> <p>real [1] 21/20</p> <p>realise [1] 17/10</p> <p>realised [1] 64/22</p> <p>realistic [1] 29/10</p> <p>reality [1] 7/7</p> <p>really [13] 2/13 6/4 32/10 39/13 39/25 55/9 71/15 79/17 106/3 117/15 160/15 165/7 166/10</p> <p>reason [4] 6/3 18/4 71/3 155/11</p> <p>reasonably [1] 107/19</p> <p>reasons [6] 55/4 78/19 84/25 85/1 120/13 140/7</p> <p>reassess [1] 14/15</p>	<p>reassurance [1] 9/17</p> <p>reassure [2] 23/3 25/11</p> <p>recall [11] 8/1 8/4 8/18 10/2 10/6 10/20 11/13 11/23 23/20 26/5 35/16</p> <p>recalled [1] 9/13</p> <p>recalling [1] 11/2</p> <p>recalls [7] 8/8 9/9 9/18 12/5 31/24 32/5 32/9</p> <p>receipt [3] 35/18 147/1 157/11</p> <p>receive [11] 13/20 50/10 90/9 91/22 92/7 99/7 122/5 126/24 129/14 133/5 150/20</p> <p>received [15] 9/4 9/7 9/24 13/10 26/9 31/18 31/20 60/20 78/13 81/8 98/20 102/21 131/12 133/5 145/21</p> <p>receives [5] 127/10 127/13 137/14 150/7 150/18</p> <p>receiving [11] 31/21 71/17 72/13 92/20 92/21 98/25 99/1 99/2 134/17 137/16 151/10</p> <p>recent [6] 33/16 58/16 119/8 144/2 148/18 150/9</p> <p>recently [2] 26/22 120/4</p> <p>recipients [2] 120/8 120/10</p> <p>recognise [1] 3/11</p> <p>recognised [1] 62/11</p> <p>recognising [1] 7/10</p> <p>recognition [4] 44/23 46/10 119/10 125/12</p> <p>recollection [6] 8/10 8/25 14/5 23/21 26/7 32/1</p> <p>recommend [1] 98/9</p> <p>recommendations [3] 3/7 3/16 143/13</p> <p>record [3] 37/7 82/15 141/25</p> <p>recorded [10] 2/10 37/3 37/15 47/22 48/10 88/6 111/23 114/2 132/13 143/3</p> <p>recording [2] 125/23 143/24</p> <p>records [16] 25/24 35/5 36/23 37/6 37/9 37/15 39/8 43/3 49/8 49/17 66/9 76/21 83/16 98/22 109/16 116/23</p>	<p>recovery [1] 153/24</p> <p>recruit [1] 157/5</p> <p>recruiting [1] 84/6</p> <p>recruitment [1] 65/10</p> <p>recurred [1] 34/24</p> <p>recurrence [2] 150/14 150/16</p> <p>red [1] 8/5</p> <p>redacted [3] 27/20 149/1 152/11</p> <p>reduce [6] 64/3 81/12 103/13 103/17 107/22 108/18</p> <p>reduced [4] 103/8 103/11 128/9 151/22</p> <p>reduces [1] 109/12</p> <p>reduction [3] 103/12 106/18 106/19</p> <p>refer [7] 22/17 23/8 25/24 39/16 112/6 157/21 158/9</p> <p>reference [69] 6/23 18/17 18/25 21/14 22/10 28/18 29/13 30/6 31/6 31/9 32/25 33/19 43/5 43/16 45/4 49/11 49/14 50/3 51/6 51/20 52/21 59/5 61/16 61/20 62/21 63/11 63/16 64/10 67/4 68/11 68/15 78/7 91/9 95/17 95/20 96/17 97/1 98/23 99/10 109/8 109/23 113/12 113/25 114/9 117/2 117/22 118/20 120/6 121/16 121/17 123/5 126/6 131/18 133/10 134/10 135/10 142/13 144/11 144/20 146/4 146/19 146/20 146/22 146/25 147/17 154/13 160/20 161/23 162/2</p> <p>referenced [1] 6/7</p> <p>references [6] 7/1 39/4 40/1 53/7 114/16 127/15</p> <p>referral [1] 34/15</p> <p>referred [20] 15/1 15/3 15/19 19/10 19/25 23/2 28/2 31/2 32/22 35/3 35/21 37/18 39/10 53/8 61/11 98/18 112/10 137/1 137/3 166/14</p> <p>referring [11] 23/5 39/8 39/20 39/25 101/16 105/8 131/10 147/13 149/15 155/11 163/14</p> <p>refers [41] 6/5 14/23</p>
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<p>R</p> <p>refers... [39] 19/16 19/21 21/2 21/5 26/12 26/25 27/10 27/12 46/17 47/24 49/7 52/23 54/11 58/15 60/7 60/20 62/3 63/21 64/6 76/2 77/7 98/15 105/7 106/22 125/21 125/24 126/16 130/11 134/17 139/19 143/21 146/1 146/16 153/1 154/18 156/11 156/21 157/1 168/1</p> <p>refuse [1] 154/21</p> <p>refusing [1] 163/1</p> <p>regard [12] 10/21 15/8 27/2 28/21 35/4 54/10 57/2 66/15 112/3 119/18 130/21 161/9</p> <p>regarded [3] 39/12 99/20 112/11</p> <p>regarding [6] 9/14 27/8 33/15 34/5 111/1 135/5</p> <p>regardless [1] 71/22</p> <p>regards [4] 13/12 13/17 56/22 150/25</p> <p>regime [4] 98/7 109/25 147/18 167/11</p> <p>regimens [2] 105/23 147/9</p> <p>regimes [1] 2/12</p> <p>region [5] 14/8 19/3 24/13 29/9 45/8</p> <p>regional [9] 19/3 44/1 44/24 44/25 45/7 55/19 68/4 81/4 114/4</p> <p>register [1] 52/6</p> <p>registered [2] 43/12 133/17</p> <p>regular [9] 48/1 57/5 59/10 71/21 120/17 120/21 122/23 125/21 145/23</p> <p>Regulatory [1] 155/1</p> <p>reimburse [1] 157/11</p> <p>reintroduction [1] 161/17</p> <p>relate [1] 113/5</p> <p>related [8] 14/21 27/9 35/21 46/10 62/24 63/1 63/5 155/19</p> <p>relates [1] 129/10</p> <p>relating [7] 1/8 83/9 83/11 136/14 137/8 144/22 149/5</p> <p>relation [53] 5/19 5/22 6/7 8/5 9/5 9/22 12/6 14/25 20/13 21/4 27/4 27/14 31/16 33/24</p>	<p>33/25 35/13 35/25 39/13 50/6 53/23 55/1 63/7 63/20 67/5 67/16 73/2 75/12 106/2 108/20 111/1 114/11 114/15 116/19 118/7 128/18 130/2 130/25 135/14 137/20 141/18 148/6 148/9 148/11 149/5 159/10 159/23 159/25 161/3 163/11 164/1 165/2 165/17 165/20</p> <p>relations [3] 31/7 31/10 31/15</p> <p>relationship [10] 44/9 47/18 58/12 59/21 62/11 62/24 64/8 64/14 120/21 164/21</p> <p>relationships [1] 27/9</p> <p>relatively [6] 12/23 28/3 28/3 89/16 126/10 160/1</p> <p>relevance [3] 14/17 109/3 164/5</p> <p>relevant [1] 1/10</p> <p>relying [1] 80/9</p> <p>remain [2] 105/17 123/8</p> <p>remainder [1] 104/24</p> <p>remained [1] 17/17</p> <p>remaining [2] 117/3 117/13</p> <p>remains [1] 46/11</p> <p>remember [2] 101/24 158/4</p> <p>remembering [1] 8/4</p> <p>removing [1] 130/15</p> <p>renamed [1] 60/17</p> <p>repeated [1] 112/25</p> <p>repeatedly [2] 3/13 166/14</p> <p>repetition [1] 62/1</p> <p>replace [1] 65/5</p> <p>replacement [7] 50/11 50/13 120/17 122/23 128/2 132/19 133/2</p> <p>replied [2] 79/12 110/1</p> <p>reply [1] 151/15</p> <p>report [23] 14/8 14/16 19/2 19/5 24/13 29/9 58/16 64/5 95/7 95/21 96/1 96/21 97/15 102/13 102/24 109/19 112/17 115/22 115/25 132/7 136/7 158/8 158/21</p> <p>reported [7] 85/17 102/20 106/9 107/5 109/10 120/4 145/3</p> <p>reporting [2] 92/5</p>	<p>96/13</p> <p>reports [4] 63/17 96/11 132/6 147/13</p> <p>represent [1] 3/8</p> <p>representation [1] 164/12</p> <p>representatives [2] 163/6 168/7</p> <p>represented [1] 70/8</p> <p>request [7] 19/7 28/1 68/12 69/8 71/9 76/3 81/18</p> <p>require [5] 16/20 86/8 103/14 126/18 138/5</p> <p>required [13] 44/16 55/15 74/18 79/9 84/19 86/4 92/17 92/22 98/6 105/4 147/15 149/9 150/3</p> <p>requirement [3] 13/24 88/2 99/6</p> <p>requirements [10] 20/13 20/24 21/1 66/11 87/21 88/1 89/5 111/4 132/13 165/17</p> <p>requires [4] 16/24 129/15 131/23 149/16</p> <p>research [152] 1/8 24/6 38/2 39/3 39/4 39/9 39/11 39/17 40/5 40/7 40/10 40/13 40/23 41/2 41/13 41/14 42/21 42/22 42/24 42/25 43/1 43/13 43/20 43/22 44/4 44/5 44/7 44/17 44/24 45/7 45/12 45/13 45/16 45/17 45/21 45/22 45/25 45/25 46/20 51/1 51/3 51/5 51/8 51/17 52/1 52/10 53/9 53/9 54/19 54/24 55/17 55/21 55/22 55/24 55/25 56/1 56/4 56/9 56/19 56/22 56/24 57/8 57/11 59/20 59/25 60/6 60/11 60/18 61/2 61/8 61/14 62/3 62/9 62/17 62/20 62/22 64/6 64/18 64/20 64/20 64/23 64/24 65/5 65/14 65/15 65/17 65/22 66/5 66/7 66/17 66/22 66/24 67/12 67/14 67/24 68/4 69/12 69/16 70/3 70/6 75/16 76/1 76/23 76/25 77/3 77/9 77/15 77/19 78/1 78/15 80/21 81/3 81/18 81/24 82/17 84/8 94/6</p>	<p>96/19 96/22 96/25 98/13 99/21 99/22 101/22 101/25 106/5 112/9 136/14 143/16 143/22 145/8 146/10 146/19 147/3 148/5 148/11 153/11 157/10 160/16 163/15 164/11 165/2 165/6 165/10 165/23 165/25 166/2 166/8 166/9 166/11 166/22 167/4</p> <p>researcher [1] 40/17</p> <p>reservation [2] 3/13 110/13</p> <p>reservations [1] 79/5</p> <p>reserve [1] 127/8</p> <p>residence [3] 41/21 47/7 61/23</p> <p>resident [1] 116/5</p> <p>residential [2] 3/9 112/24</p> <p>resources [4] 16/11 17/15 107/1 108/5</p> <p>respect [4] 77/3 124/7 136/23 165/19</p> <p>respective [1] 91/4</p> <p>respectively [1] 58/2</p> <p>responding [1] 16/7</p> <p>response [2] 48/8 163/23</p> <p>responsibilities [1] 91/4</p> <p>responsibility [7] 2/18 17/18 25/2 51/25 74/25 90/20 154/25</p> <p>responsible [7] 43/21 45/2 90/23 91/8 91/11 119/4 127/9</p> <p>rest [1] 28/24</p> <p>restrict [2] 139/3 139/12</p> <p>restricted [7] 30/10 128/18 132/18 133/18 133/24 138/24 139/1</p> <p>result [9] 32/14 32/15 37/12 37/13 55/18 74/15 98/1 102/9 138/22</p> <p>resultant [1] 84/18</p> <p>resulting [1] 158/15</p> <p>results [26] 2/23 10/15 24/6 48/8 48/17 70/10 74/7 83/5 83/24 84/14 85/5 95/12 100/14 100/18 104/11 106/17 110/2 110/4 114/9 114/12 131/12 140/1 142/2 145/3 149/20 153/18</p> <p>resume [1] 168/13</p> <p>retirement [1] 13/7</p>	<p>retrospective [1] 40/11</p> <p>return [1] 54/18</p> <p>returning [1] 9/10</p> <p>reveal [2] 16/1 95/11</p> <p>revenue [1] 21/15</p> <p>reverting [1] 26/23</p> <p>review [2] 3/3 167/20</p> <p>revised [1] 156/24</p> <p>revision [1] 70/8</p> <p>revisions [1] 81/25</p> <p>revolutionised [1] 119/16</p> <p>rheumatoid [3] 58/7 58/12 67/5</p> <p>Richardson [1] 57/25</p> <p>right [12] 22/12 22/16 23/11 29/25 54/2 54/10 107/17 107/18 111/8 147/5 154/21 162/2</p> <p>right-hand [5] 23/11 107/17 107/18 111/8 147/5</p> <p>rise [2] 124/9 151/6</p> <p>risk [18] 4/21 4/22 5/3 6/12 7/24 24/3 24/19 24/23 29/20 119/23 120/9 134/18 148/2 150/8 150/16 153/5 162/19 166/5</p> <p>risks [7] 23/4 29/14 35/12 92/4 92/20 92/24 151/11</p> <p>RLIT0000084 [1] 106/6</p> <p>RLIT0000093 [1] 111/3</p> <p>RLIT0000098 [1] 147/21</p> <p>RLIT0000104 [1] 156/8</p> <p>RLIT0000110 [1] 158/8</p> <p>RLIT0000111 [1] 147/24</p> <p>RLIT0000124 [1] 160/8</p> <p>RLIT0000198 [1] 147/5</p> <p>RLIT0000663 [1] 23/6</p> <p>RLIT0000666 [1] 1/15</p> <p>role [8] 18/5 18/13 22/7 22/8 41/2 50/3 82/25 121/10</p> <p>roles [1] 40/21</p> <p>roommate [1] 9/9</p> <p>rooms [1] 43/11</p> <p>Rosemary [5] 58/19 65/21 68/8 76/16 129/7</p> <p>roughly [1] 53/11</p>	<p>routine [2] 72/19 154/22</p> <p>routinely [1] 57/22</p> <p>routines [1] 119/15</p> <p>Royal [3] 58/2 126/23 156/12</p> <p>rules [1] 24/22</p> <p>run [1] 80/8</p> <hr/> <p>S</p> <p>safe [2] 13/18 92/1</p> <p>safety [4] 24/25 125/13 161/13 161/16</p> <p>said [32] 6/11 29/8 30/1 58/8 63/22 70/24 73/8 73/24 78/17 86/3 86/7 92/19 96/15 97/18 97/21 100/15 100/18 100/20 101/4 103/8 105/10 110/9 112/2 116/10 125/14 126/8 127/16 128/6 130/20 134/17 147/11 164/6</p> <p>Sainsbury [1] 8/2</p> <p>salient [1] 144/21</p> <p>same [18] 6/11 26/7 35/13 103/17 106/1 115/24 122/2 122/5 123/16 123/25 123/25 124/5 129/11 138/8 147/22 149/12 149/25 153/9</p> <p>samples [23] 18/23 48/2 48/3 48/11 64/11 85/21 99/8 99/12 113/21 114/2 125/16 125/21 126/13 131/23 132/25 136/5 138/5 138/6 140/13 141/1 141/3 154/14 154/15</p> <p>satisfactory [1] 82/6</p> <p>satisfactory [2] 67/8 135/14</p> <p>satisfy [1] 77/13</p> <p>save [3] 73/17 89/25 125/20</p> <p>saved [1] 99/16</p> <p>saving [1] 79/10</p> <p>savings [1] 163/16</p> <p>saw [6] 30/13 37/11 79/13 86/11 146/4 160/20</p> <p>say [22] 6/23 11/1 12/23 19/4 22/16 25/20 37/11 37/24 39/19 40/6 52/13 81/20 88/8 102/8 108/7 128/13 145/4 147/2 147/16 152/12 155/16 168/1</p> <p>saying [16] 15/18</p>
--	---	---	--	---	--

<p>S</p> <p>saying... [15] 15/19 15/20 21/18 21/19 24/13 60/9 60/12 83/16 129/5 130/25 131/1 137/11 146/2 146/24 156/1</p> <p>says [64] 2/2 2/4 4/1 13/8 15/5 15/9 16/13 17/21 18/19 19/11 19/16 19/24 20/2 23/14 27/4 33/1 33/14 46/22 47/15 50/14 54/25 56/20 57/18 58/17 62/7 66/6 67/5 67/22 68/17 69/17 72/8 76/7 77/20 83/20 85/16 90/20 94/4 94/10 95/22 99/3 100/4 101/23 111/10 118/16 118/21 119/13 120/12 120/23 126/11 130/11 132/10 133/15 133/25 134/5 136/15 140/5 141/6 150/1 153/3 154/3 154/14 155/9 163/19 168/9</p> <p>scale [1] 110/7</p> <p>scans [2] 135/3 135/5</p> <p>scathing [1] 12/23</p> <p>scholastic [1] 69/1</p> <p>school [34] 1/6 9/10 12/2 12/5 12/16 16/23 17/21 22/11 22/15 22/24 23/18 23/23 24/19 25/1 25/10 25/12 25/14 26/13 30/13 41/2 42/19 43/24 54/12 55/6 55/16 59/2 70/13 87/9 87/20 90/8 90/17 104/13 112/22 170/2</p> <p>schooling [1] 105/20</p> <p>scientists [1] 56/13</p> <p>scope [3] 6/15 123/18 165/5</p> <p>Scott [5] 11/10 12/9 13/4 13/6 22/16</p> <p>Scott's [2] 14/5 22/21</p> <p>screen [3] 20/20 20/23 59/11</p> <p>screened [2] 90/10 93/14</p> <p>screening [5] 93/15 112/7 114/5 114/8 115/5</p> <p>seasonal [1] 57/14</p> <p>second [28] 4/2 8/14 15/2 28/22 31/9 49/10 50/12 61/25 63/19 69/18 69/23 80/13</p>	<p>81/5 94/4 103/20 107/8 107/18 115/25 125/20 130/6 134/3 142/25 147/23 149/16 158/25 163/13 165/22 167/5</p> <p>Secondly [1] 89/7</p> <p>secretarial [2] 42/25 68/13</p> <p>secretary [2] 12/4 76/24</p> <p>Secure [1] 65/7</p> <p>Security [6] 67/22 69/17 72/24 75/4 78/14 81/17</p> <p>see [126] 1/15 1/21 3/24 16/12 18/5 18/12 20/23 23/11 25/8 25/9 26/6 28/7 29/8 30/1 31/6 31/8 31/10 32/25 34/6 34/10 37/8 38/25 39/4 41/15 45/20 47/24 53/8 53/9 54/21 56/17 57/17 60/15 60/22 61/19 61/24 63/10 64/13 64/14 69/8 69/11 69/14 69/15 69/17 70/15 70/19 71/2 75/14 76/2 76/5 82/12 82/18 82/23 83/15 84/12 85/23 86/24 87/18 88/18 89/11 89/23 90/4 95/21 96/17 97/1 97/4 97/10 97/13 98/17 98/23 100/11 101/22 102/16 102/21 103/1 103/22 104/11 104/16 106/6 107/10 107/11 108/7 109/8 109/12 109/20 109/21 110/13 111/10 112/13 113/25 114/18 115/24 116/5 118/5 118/6 121/16 121/19 122/19 129/3 130/23 131/22 131/24 136/8 137/3 143/21 143/23 145/4 146/2 146/13 146/22 147/17 147/25 152/3 152/7 153/7 153/14 154/10 155/6 156/10 156/17 158/13 159/1 159/13 159/17 160/9 167/14 168/8</p> <p>seeing [1] 166/22</p> <p>seek [2] 34/20 67/11</p> <p>seeking [2] 33/15 157/18</p> <p>seem [3] 54/15 115/10 162/3</p> <p>seemed [1] 80/11</p>	<p>seemingly [1] 25/11</p> <p>seems [5] 11/14 136/3 150/17 151/12 164/14</p> <p>seen [28] 2/25 12/7 15/18 17/17 18/3 22/16 35/9 36/15 37/2 37/3 37/6 51/16 55/9 62/2 62/8 73/1 88/2 95/20 99/23 104/4 106/3 107/6 145/2 155/7 163/6 163/10 163/25 165/18</p> <p>selected [4] 77/14 126/22 127/1 129/14</p> <p>send [1] 34/9</p> <p>sending [1] 69/7</p> <p>senior [3] 30/2 30/11 51/23</p> <p>sense [7] 9/3 10/11 22/19 26/15 77/20 123/23 135/16</p> <p>sensible [1] 150/11</p> <p>sensitive [1] 119/2</p> <p>sent [12] 23/2 71/1 71/8 78/12 80/5 80/7 81/16 85/18 99/9 125/24 141/3 145/14</p> <p>sentence [6] 85/9 119/19 130/23 133/24 140/21 161/10</p> <p>separate [2] 57/10 141/5</p> <p>separated [1] 133/9</p> <p>separating [1] 89/20</p> <p>September [13] 23/13 26/18 54/7 54/11 54/13 54/16 97/8 97/11 118/13 127/19 128/13 130/6 137/19</p> <p>September 1975 [4] 97/8 127/19 128/13 137/19</p> <p>September 1985 [3] 54/11 54/13 54/16</p> <p>September 1989 [1] 26/18</p> <p>sequelae [1] 144/1</p> <p>sequentially [1] 122/4</p> <p>sera [7] 58/6 59/16 59/18 59/19 113/24 117/11 140/24</p> <p>serial [2] 126/13 140/12</p> <p>series [1] 112/11</p> <p>serious [3] 32/4 59/16 73/10</p> <p>seriously [1] 24/5</p> <p>Serological [1] 127/7</p> <p>serum [12] 58/19 59/13 76/2 114/25 116/3 116/8 116/12</p>	<p>116/19 117/7 117/10 140/13 144/7</p> <p>serves [1] 89/7</p> <p>service [10] 12/20 14/25 52/20 55/20 59/6 63/17 68/14 76/4 107/1 141/4</p> <p>sessions [2] 19/12 19/13</p> <p>set [13] 27/17 32/12 43/2 55/21 61/24 70/7 76/23 81/23 102/14 104/11 129/12 141/20 146/4</p> <p>setting [4] 20/25 38/11 71/13 141/15</p> <p>seven [4] 15/10 42/16 104/14 160/5</p> <p>Seventeen [1] 132/21</p> <p>seventies [2] 52/22 118/10</p> <p>Seventy [1] 111/11</p> <p>Seventy-five [1] 111/11</p> <p>several [6] 14/15 39/21 68/7 78/5 79/3 102/24</p> <p>severe [6] 2/19 103/4 103/14 111/5 152/2 160/11</p> <p>severely [6] 2/5 30/20 83/17 89/16 106/13 109/13</p> <p>severity [1] 3/18</p> <p>sexual [2] 17/3 24/20</p> <p>SGOT [3] 47/25 125/22 142/9</p> <p>SGPT [1] 47/25</p> <p>SH [1] 116/3</p> <p>shall [4] 45/1 90/17 141/7 157/25</p> <p>share [1] 21/21</p> <p>shared [1] 125/25</p> <p>sharp [1] 71/17</p> <p>Sharrard [1] 59/2</p> <p>shattered [1] 14/13</p> <p>Shaw [1] 57/25</p> <p>she [21] 8/19 8/20 18/9 18/13 27/4 27/10 27/12 30/24 54/25 60/3 60/7 66/6 67/5 70/24 70/25 71/1 71/4 71/7 73/8 85/25 86/3</p> <p>she's [4] 27/14 60/9 60/12 131/1</p> <p>sheet [1] 137/10</p> <p>SHO [1] 42/14</p> <p>shopping [1] 5/7</p> <p>short [7] 38/2 53/20 57/6 70/12 94/22 108/17 126/10</p> <p>short-term [1] 108/17</p>	<p>shortage [2] 59/16 133/3</p> <p>shortly [4] 64/5 105/11 145/7 147/3</p> <p>should [66] 3/14 6/17 7/13 17/19 19/9 20/22 21/13 25/3 25/13 27/15 30/3 30/10 45/13 46/19 51/3 52/6 55/3 55/21 56/8 57/9 64/5 64/18 65/4 68/14 71/23 72/11 72/21 75/3 75/7 76/13 76/14 80/12 80/13 84/13 84/14 92/3 97/23 99/5 99/7 99/16 100/9 100/13 105/22 105/23 108/9 110/7 122/4 125/10 125/15 126/3 126/3 126/12 127/12 128/4 129/17 131/22 140/24 145/4 149/14 149/24 150/7 152/16 164/7 164/16 167/16 168/1</p> <p>show [6] 28/4 39/17 57/4 106/18 135/3 148/8</p> <p>showing [4] 15/6 117/6 117/10 134/3</p> <p>shown [5] 51/24 56/10 59/6 132/19 144/6</p> <p>shows [3] 122/10 128/17 129/25</p> <p>sick [3] 30/19 43/8 105/14</p> <p>Sick Quarters [1] 43/8</p> <p>side [6] 106/24 107/10 107/17 107/18 111/8 147/6</p> <p>Sidney [1] 164/8</p> <p>sight [1] 166/19</p> <p>sign [1] 146/14</p> <p>signed [1] 137/17</p> <p>significance [10] 5/3 33/9 36/8 83/23 84/2 84/8 84/16 85/5 134/24 165/9</p> <p>significant [8] 14/19 74/7 74/15 106/18 115/6 119/7 138/22 138/25</p> <p>significantly [1] 120/18</p> <p>signs [1] 142/21</p> <p>similar [7] 35/20 61/18 71/10 88/9 107/23 129/4 149/10</p> <p>Simon [1] 168/19</p> <p>Simon Glenarthur [1]</p>	<p>168/19</p> <p>simple [1] 127/22</p> <p>simply [6] 22/9 37/14 83/1 105/2 124/3 162/22</p> <p>since [14] 2/7 4/6 41/18 42/22 55/11 72/10 74/13 84/17 114/4 115/10 119/23 128/3 133/21 135/17</p> <p>single [5] 4/18 9/25 79/24 89/8 111/23</p> <p>sir [53] 1/7 1/22 5/14 8/24 12/14 15/17 20/23 28/17 35/8 37/22 38/1 39/2 41/8 49/1 50/1 51/10 52/13 53/13 53/22 60/1 60/12 61/19 67/13 67/16 82/7 82/12 82/17 94/2 94/25 99/19 101/17 101/19 101/21 103/19 105/1 108/15 109/19 110/21 110/25 118/5 123/23 124/7 135/11 146/22 158/21 159/12 162/6 163/3 165/1 166/25 167/20 167/25 169/5</p> <p>sister [8] 8/7 17/22 18/13 25/25 25/25 26/16 26/20 28/7</p> <p>Sisters [1] 42/20</p> <p>site [1] 124/2</p> <p>sitting [2] 168/24 169/1</p> <p>situation [5] 4/20 17/5 19/21 27/11 29/11</p> <p>situations [1] 16/8</p> <p>six [7] 1/19 46/3 56/25 68/19 90/17 128/19 144/9</p> <p>six pages [1] 1/19</p> <p>six specific [1] 56/25</p> <p>six years [1] 46/3</p> <p>sixteen [1] 41/24</p> <p>size [1] 101/3</p> <p>skim [1] 6/24</p> <p>skip [1] 57/17</p> <p>slight [1] 100/11</p> <p>slightly [1] 155/12</p> <p>slim [1] 35/9</p> <p>small [5] 15/22 24/11 70/7 81/22 98/4</p> <p>smaller [1] 152/4</p> <p>so [192]</p> <p>social [11] 5/3 18/7 18/7 18/9 67/21 69/2 69/17 72/24 75/3 78/14 81/17</p> <p>Society [3] 33/13 54/9 75/7</p>
--	--	--	--	--	--

S	105/18 134/4 sooner [1] 105/12 sorry [21] 1/20 13/23 20/21 37/5 41/5 46/13 48/23 69/19 85/11 100/7 101/2 101/10 107/15 107/17 125/23 131/3 136/6 143/25 145/19 150/24 161/20 sort [2] 108/3 125/2 sought [4] 122/8 128/22 159/5 159/20 Soumik [8] 1/15 1/19 16/9 27/21 38/5 69/19 85/11 145/13 sounds [2] 38/20 54/10 source [4] 48/6 129/17 134/8 139/8 sources [2] 80/15 89/3 Southampton [3] 18/23 33/23 34/18 special [5] 38/21 38/23 78/7 126/18 145/23 specialised [2] 18/1 18/5 specialising [1] 42/8 specialist [2] 22/14 26/3 specialists [2] 24/7 55/19 specific [10] 12/15 26/21 34/11 34/20 44/7 56/25 62/9 67/14 67/14 89/4 specifically [6] 12/8 33/24 40/13 56/7 60/10 136/14 specified [1] 133/6 specimen [1] 140/23 specimens [3] 133/8 140/18 154/15 speed [1] 80/9 spelt [1] 151/12 spend [2] 18/8 79/24 spending [1] 21/14 spent [1] 77/10 Speywood [2] 163/8 163/10 spleen [1] 142/14 sponsored [1] 65/19 spontaneous [2] 46/5 75/20 sporting [1] 4/21 spread [1] 24/14 spring [3] 77/17 114/4 132/8 St [1] 59/2 St George's [1] 59/2 staff [26] 11/14 13/15	13/17 13/21 16/4 18/24 20/15 20/16 21/3 21/4 21/6 21/8 21/13 24/18 25/1 26/5 29/16 30/3 30/11 30/13 42/12 42/20 45/10 68/13 91/12 133/7 staffed [3] 42/6 43/11 65/1 stage [13] 9/14 29/6 29/22 30/6 30/7 30/16 30/21 116/17 116/18 139/2 146/15 153/16 153/19 stages [2] 15/20 114/24 stand [1] 166/10 standard [3] 6/1 129/23 159/18 standards [2] 136/21 138/18 Stanley [1] 58/10 start [8] 53/15 67/18 70/5 70/13 130/14 132/15 133/21 157/7 started [1] 132/11 starting [1] 67/15 state [2] 43/11 47/18 stated [2] 56/7 74/5 statement [6] 8/13 12/3 12/9 13/4 31/24 79/15 statements [6] 9/9 25/17 26/8 26/9 31/19 35/4 States [1] 159/8 statistical [1] 84/25 statistics [1] 100/13 status [3] 27/6 42/15 126/15 stay [2] 43/21 43/24 steady [1] 14/12 steering [1] 81/23 step [2] 107/5 108/12 Stewart [7] 69/12 69/20 75/2 82/20 98/6 100/8 110/5 stick [1] 123/25 stigmata [1] 35/23 still [15] 8/17 14/18 22/8 25/16 28/20 34/17 55/12 95/14 115/6 119/2 139/11 142/24 143/2 151/9 155/16 stimulus [1] 115/4 stop [4] 87/4 87/18 87/23 110/3 stored [2] 141/1 154/17 strategy [2] 2/22 16/7	strenuously [1] 88/24 stress [1] 4/12 stressed [3] 3/13 89/2 95/13 strict [1] 77/14 strongly [3] 6/16 46/4 75/19 structured [1] 12/6 student [1] 52/6 students [3] 12/7 13/22 160/18 studied [7] 58/14 104/13 111/12 116/16 142/4 142/10 144/24 studies [27] 3/6 39/5 39/23 40/1 40/3 40/6 40/9 48/15 48/16 48/20 49/8 49/17 77/19 87/21 112/11 117/16 135/17 143/8 144/22 145/6 145/10 147/12 147/13 147/14 152/23 165/20 166/12 study [89] 39/9 44/9 47/8 50/19 52/2 52/3 52/22 55/7 55/13 62/11 63/12 86/20 88/16 88/17 98/16 98/19 98/21 99/5 100/3 102/10 109/14 112/8 112/9 112/17 113/1 113/13 113/19 114/24 115/15 116/2 117/16 118/14 120/14 120/20 122/3 122/16 123/6 123/15 123/19 127/8 127/16 127/18 127/22 128/1 128/5 128/15 128/19 129/11 129/12 130/2 130/8 130/14 131/11 132/3 132/9 132/16 133/17 134/5 136/7 137/2 137/9 137/13 137/21 138/1 139/2 139/23 141/18 144/2 147/23 150/25 153/15 154/24 155/2 157/7 158/7 158/15 158/16 158/17 158/23 159/10 159/12 159/13 159/23 162/1 165/23 166/2 166/23 167/7 167/15 studying [2] 118/7 166/13 sub [1] 81/3 sub committee [1] 81/3 subclinical [1] 115/12 subject [4] 6/15 27/8 29/2 129/9 subjects [2] 6/8 83/7	submission [1] 167/17 submissions [3] 35/7 165/13 167/2 submitted [1] 46/1 subsequent [3] 78/11 128/16 158/23 subsequently [1] 60/17 substance [7] 94/20 148/22 149/23 151/1 151/17 151/18 151/25 substance' [2] 148/24 149/20 successful [2] 85/10 156/4 succumb [1] 15/16 such [25] 4/12 4/21 4/21 4/23 5/1 5/3 6/10 6/12 13/17 43/18 45/2 45/15 45/19 48/9 48/13 76/16 76/18 77/4 79/11 88/21 89/21 107/2 107/24 112/10 164/18 suddenly [2] 2/18 14/2 suffered [2] 22/4 115/8 sufferer [1] 17/14 suffering [16] 29/15 30/4 30/8 30/17 41/19 45/23 46/4 57/21 60/5 61/22 75/18 112/16 112/22 116/4 117/11 134/25 sufficient [6] 79/14 84/21 88/21 110/8 149/7 150/13 suggest [19] 12/1 15/14 22/13 34/14 35/9 36/6 36/16 52/25 75/19 78/15 81/25 94/16 109/18 126/4 140/23 155/18 161/14 162/17 167/16 suggested [7] 46/19 54/10 56/24 68/22 71/23 82/25 83/5 suggesting [6] 31/12 36/20 84/12 92/5 132/15 149/13 suggestion [7] 17/24 31/3 50/4 84/5 120/7 131/25 148/22 suggestive [1] 126/2 suggests [13] 9/25 10/19 12/19 32/15 36/3 46/5 57/14 91/15 93/21 106/17 107/24 135/20 145/24 suit [1] 69/1	suitable [3] 44/7 65/4 135/12 summarise [2] 37/20 37/25 summarised [1] 82/24 summary [5] 64/17 103/2 103/19 106/10 114/19 summer [11] 77/16 93/22 96/14 113/13 113/14 115/21 116/17 126/20 134/19 160/6 162/9 supervise [1] 74/19 supervision [3] 41/25 42/11 61/24 supplement [1] 65/10 supplied [1] 72/19 supply [8] 45/3 59/17 73/6 86/12 124/18 136/17 136/19 136/24 supplying [1] 114/6 support [24] 11/19 11/21 13/22 16/15 16/18 16/22 17/8 28/11 44/3 45/5 45/19 51/3 56/1 60/3 62/6 66/4 69/9 71/23 77/6 81/17 146/10 163/21 164/10 164/18 supported [2] 119/8 156/15 supporting [5] 12/18 13/12 54/23 67/6 75/4 suppose [1] 21/17 supra [2] 44/24 44/25 sure [8] 1/22 32/2 32/22 33/4 49/10 52/9 53/4 162/2 Surgeon [1] 42/12 surgery [1] 43/10 surgical [2] 87/15 123/1 surprising [1] 115/2 surveillance [2] 18/18 18/18 survey [9] 95/18 96/4 114/22 129/8 129/19 132/24 138/20 142/2 167/9 Survival [1] 160/10 suspected [1] 140/20 Swinburne [2] 130/24 153/1 Switch [1] 68/16 switched [1] 35/18 symptoms [5] 88/22 92/5 126/2 140/22 142/20 system [2] 35/11 36/25 systematic [1] 36/7
----------	---	---	--	--	--

S	tenure [2] 67/1 67/11	53/22	102/15 103/3 106/8	71/9 72/12 72/13 73/6	though [5] 27/20
systematically [1] 36/3	term [25] 3/19 4/1 4/4 9/10 33/4 33/10 40/8 58/11 70/13 77/16 77/17 96/14 96/14 104/24 108/17 113/9 113/20 114/4 132/8 132/8 132/12 134/19 135/5 140/23 146/17	that [529] that I [4] 137/3 146/5 157/21 165/2 that is [5] 5/11 15/23 93/9 102/14 151/2 that's [54] 2/1 9/3 11/3 19/2 20/21 23/13 28/2 29/25 30/12 31/1 34/25 41/7 43/5 48/4 54/1 57/24 58/3 58/25 59/25 61/11 64/14 65/24 75/9 87/6 88/2 88/7 91/14 100/15 100/20 103/19 105/25 108/12 112/4 117/15 117/16 120/20 123/25 124/11 126/3 128/9 128/10 128/12 129/10 129/11 136/6 137/17 147/19 158/15 162/2 166/5 166/7 167/17 168/21 168/23 that: [1] 21/19 that: AIDS [1] 21/19 their [54] 2/20 2/21 7/23 10/6 10/25 12/12 16/3 20/17 21/7 23/24 27/1 27/25 28/10 30/24 31/4 31/17 31/20 31/21 31/21 32/5 32/13 34/12 35/15 36/3 37/10 37/12 37/13 45/6 69/1 71/9 84/15 87/25 90/1 104/1 104/2 105/16 119/16 123/11 125/6 125/7 126/19 127/9 128/8 133/6 136/18 146/2 151/13 151/14 154/22 154/25 156/7 159/6 163/1 166/3 them [17] 12/7 12/18 14/4 17/3 24/11 25/20 40/3 40/19 60/11 80/6 88/11 105/17 148/4 152/19 160/24 161/18 165/11 themselves [3] 5/2 11/2 24/23 then [252] therapeutic [13] 14/19 66/12 74/24 91/12 99/16 103/15 105/5 108/1 108/4 108/21 123/9 126/25 136/19 therapy [30] 14/22 48/18 50/12 50/13 50/17 50/20 70/22 71/16 73/12 76/13 78/8 98/5 99/15 102/2	111/2 119/18 120/18 122/23 126/21 128/2 128/11 130/16 132/1 138/10 139/25 142/17 145/5 there [177] there's [91] 9/6 18/17 18/25 21/14 21/15 22/13 27/23 27/24 29/13 30/6 31/5 32/12 32/24 32/25 38/2 43/16 46/14 47/13 49/14 50/3 50/4 50/8 51/20 52/21 60/19 61/16 62/19 62/21 63/7 64/10 64/14 65/25 67/4 70/21 72/7 72/15 73/19 83/18 84/5 85/7 85/14 88/12 91/3 92/13 94/9 95/4 97/24 98/13 99/25 101/14 107/16 109/21 109/23 112/5 114/9 114/11 114/13 114/16 115/21 116/15 116/21 117/22 118/5 118/6 118/20 121/17 122/25 126/6 128/16 130/18 132/8 135/10 139/14 139/16 141/17 142/13 143/6 143/9 145/9 146/22 146/25 147/7 147/20 149/15 150/1 154/3 154/13 157/8 160/2 161/19 165/15 thereabouts [1] 53/1 thereby [1] 88/25 therefore [10] 15/10 21/21 41/25 46/19 59/18 65/18 77/4 86/17 135/25 157/14 these [39] 3/4 17/16 28/15 31/15 41/22 42/2 42/19 47/7 47/20 48/3 49/17 52/2 57/19 57/22 58/22 59/15 59/18 62/12 71/18 75/22 80/16 89/3 90/8 90/13 94/5 107/2 113/5 114/6 116/6 116/24 120/13 126/24 134/21 134/24 139/10 140/13 142/8 144/16 152/23 they [49] 2/7 6/18 7/13 9/15 9/19 9/23 11/13 12/12 14/2 16/15 16/18 16/22 23/23 23/25 25/12 31/20 36/11 36/13 40/3 41/24 71/2 71/3	73/7 86/15 87/14 92/8 94/8 95/10 95/11 105/15 108/8 113/8 116/9 126/25 132/3 134/25 135/1 141/13 142/10 150/10 160/24 161/14 162/22 165/12 166/18 they'd [1] 50/11 they're [4] 87/4 87/11 88/4 163/4 thing [2] 128/7 167/10 things [5] 12/23 18/14 19/18 146/16 166/7 think [60] 1/19 1/20 19/4 19/8 20/19 22/13 23/2 25/23 26/8 28/5 29/10 31/2 38/24 40/6 40/16 41/9 43/5 48/4 49/2 49/4 56/21 60/18 61/10 62/1 75/11 77/20 77/24 80/15 82/18 82/21 102/25 108/8 109/3 109/7 110/17 111/25 117/19 124/16 129/4 132/16 135/11 139/11 140/12 141/17 145/14 147/11 147/12 152/20 157/20 157/22 158/1 158/8 158/16 160/8 161/22 161/25 162/4 163/9 168/13 168/14 thinking [1] 25/16 thinks [2] 20/25 21/13 third [20] 16/8 20/15 21/5 58/4 62/3 63/20 88/18 103/23 108/16 108/20 109/3 109/10 111/2 111/13 112/4 127/4 134/14 159/17 161/9 166/10 Thirty [1] 114/23 this [300] thorough [2] 18/3 133/8 those [45] 2/13 2/15 2/16 3/21 5/16 6/7 13/12 14/16 17/9 17/17 21/20 22/3 25/18 25/18 25/19 28/4 31/19 36/21 37/2 37/8 48/15 53/22 57/12 58/23 60/4 66/18 66/23 71/11 76/10 83/1 85/13 87/21 93/19 99/15 117/2 124/19 127/1 127/19 140/14 141/3 144/21 165/1 165/3 166/25 168/5	52/15 100/17 136/1 142/17 thought [12] 38/17 57/19 71/2 72/9 73/6 78/24 100/8 113/23 130/16 140/14 163/24 167/10 three [43] 17/12 30/6 42/5 43/11 44/1 50/10 52/9 52/9 57/1 57/3 60/25 61/8 65/6 68/20 68/20 72/4 74/1 81/19 96/23 101/25 108/25 111/17 114/10 114/20 117/2 117/3 121/17 122/6 123/3 127/13 133/21 134/21 136/8 142/24 143/11 147/8 147/12 147/13 147/18 148/10 165/11 168/12 168/16 three days [2] 50/10 168/16 three years [6] 42/5 52/9 61/8 81/19 96/23 101/25 three-month [1] 127/13 through [22] 2/6 22/11 22/15 26/4 33/8 80/14 88/14 89/24 102/23 106/1 115/22 116/22 117/20 124/13 125/19 132/2 143/7 148/3 156/9 158/25 160/23 162/9 throughout [7] 34/24 39/14 57/22 113/19 122/3 123/17 165/7 thus [1] 137/13 time [49] 4/10 8/18 10/10 11/20 12/4 12/13 13/11 15/19 15/19 16/20 16/22 16/25 17/3 17/6 20/9 20/11 21/19 28/9 34/20 38/9 42/14 42/16 43/25 48/2 52/16 52/17 53/15 54/20 56/15 57/2 64/20 70/12 77/10 83/21 84/3 86/7 94/14 96/8 98/14 103/1 114/1 114/21 123/9 124/20 144/24 152/5 161/2 163/12 164/12 times [8] 2/9 14/7 17/16 107/25 108/25 111/17 142/9 144/8 timing [1] 162/14 to [1086]

T	129/15 transfusion [27] 63/4 64/2 64/11 95/1 111/4 111/21 111/24 113/6 113/11 113/22 113/24 114/2 114/5 115/17 116/7 117/24 118/17 118/22 119/7 119/12 119/23 120/10 120/19 120/22 121/14 142/22 152/1 transfusions [3] 33/8 112/25 115/5 transmission [3] 13/18 29/14 118/18 transportable [2] 124/1 124/3 Travenol [3] 127/6 154/9 159/6 treat [4] 55/16 110/16 147/15 166/20 treated [14] 2/8 2/25 25/3 50/12 113/8 116/9 122/2 124/19 142/5 142/7 149/24 150/11 154/15 166/3 treaters [1] 161/12 treating [3] 104/6 152/22 153/8 treatment [103] 1/10 2/15 2/22 3/15 3/15 3/20 5/12 7/5 18/25 23/17 23/24 24/2 32/19 33/20 34/3 34/15 35/1 35/15 42/17 43/9 43/14 44/14 44/24 47/2 47/3 47/9 47/20 49/23 50/2 55/20 61/3 62/1 62/16 68/7 69/1 71/17 71/18 71/19 71/19 71/21 72/10 73/10 73/17 73/21 73/22 74/4 74/11 74/12 74/14 75/5 76/9 76/13 77/21 79/19 86/20 88/17 88/22 89/13 90/13 90/16 91/7 91/25 92/8 92/23 94/13 97/14 97/19 99/8 99/23 106/10 108/16 109/9 109/11 109/12 109/16 110/3 110/6 112/5 114/6 119/16 119/21 120/21 122/17 123/12 124/21 124/22 124/23 126/19 127/2 128/1 136/12 138/4 138/7 144/5 145/1 145/6 147/9 148/2 150/15 154/23 157/21 163/21 167/11	treatments [2] 42/2 72/14 treble [1] 74/14 TREL000012 [1] 155/6 TREL0000064 [1] 137/10 TREL0000070 [1] 149/25 TREL0000103 [1] 131/8 TREL0000105 [1] 148/15 TREL0000108 [1] 155/20 TREL0000137 [1] 33/21 TREL0000147 [2] 149/11 151/15 TREL0000173 [1] 162/1 TREL0000211 [1] 130/22 TREL0000222 [1] 26/16 TREL0000225 [1] 129/2 TREL0000250 [1] 137/18 TREL0000280 [1] 130/4 TREL0000313 [1] 32/20 TREL0000318 [1] 94/1 TREL0000327 [1] 152/24 TREL0000365 [1] 28/14 TREL0000521 [1] 81/2 Treloar [61] 1/6 2/7 2/8 3/8 13/6 13/15 26/22 41/17 42/3 42/18 42/19 43/7 44/20 45/14 45/15 46/3 46/17 47/19 55/1 60/21 60/25 61/1 61/7 61/20 65/21 67/25 68/9 69/22 71/7 71/24 72/19 74/6 75/5 75/18 76/19 77/2 77/11 78/20 79/2 81/9 82/14 83/12 89/12 89/22 97/16 98/25 99/5 102/4 103/4 112/17 112/22 117/12 123/3 126/18 144/6 145/21 146/15 150/18 158/13 160/13 170/2 Treloar's [66] 1/8 5/13 7/21 8/8 8/14 10/24	20/6 26/10 31/20 32/6 33/25 35/6 35/16 39/13 54/19 54/24 60/6 66/3 91/1 96/4 98/14 98/23 98/24 104/8 108/14 121/18 121/21 122/18 124/11 124/14 126/7 128/11 128/18 136/25 141/2 143/9 143/17 143/18 144/22 144/24 145/9 145/25 147/4 147/14 148/7 148/12 148/14 149/4 149/22 151/8 152/21 153/12 156/12 156/22 159/12 159/22 159/25 160/6 160/17 161/5 163/5 164/23 165/6 166/12 166/18 167/4 trial [180] trialing [1] 160/19 trials [15] 39/5 39/21 40/9 44/13 62/16 67/14 105/22 106/2 111/1 148/6 148/10 148/11 158/7 160/16 161/3 tried [2] 37/25 151/25 trouble [2] 71/1 77/10 true [1] 35/13 truly [1] 67/8 trust [7] 18/2 24/22 38/12 55/2 60/21 60/25 61/7 trusts [1] 38/21 try [7] 23/3 28/21 37/19 140/8 152/2 160/15 162/9 trying [3] 66/10 140/13 146/16 Turk [1] 111/6 turn [1] 38/1 twenty [2] 15/12 15/12 twenty-five [1] 15/12 twice [7] 73/25 103/16 106/8 106/14 108/25 111/16 126/14 two [40] 8/2 9/15 15/11 18/15 43/12 43/25 47/10 50/9 63/17 71/18 72/14 80/11 87/9 89/4 90/8 90/11 95/13 98/7 98/13 105/18 110/20 110/20 117/13 130/10 130/11 132/22 139/22 140/7 141/17 142/9 142/20 144/8 147/13 148/1 148/10 149/15 154/5 163/3 168/16	168/18 two o'clock [2] 110/20 110/20 Tyne [1] 156/13 type [24] 44/7 44/22 62/9 62/16 77/3 78/19 80/12 99/7 99/21 120/4 122/2 122/13 125/10 125/14 129/16 131/20 132/18 132/24 137/15 144/5 145/1 148/5 153/11 156/2 types [5] 8/3 98/21 99/17 145/8 147/3 typical [1] 163/25	U U.K [1] 159/3 UK [6] 9/16 46/1 62/14 108/6 127/17 158/21 UKHCDO [1] 159/10 UKHCDO's [2] 158/18 159/13 ultimate [1] 6/19 ultimately [1] 5/13 unable [1] 30/22 unacceptable [1] 6/13 unanimously [1] 76/11 unclear [2] 54/7 116/15 uncommon [2] 62/13 115/2 undated [5] 41/8 52/13 61/15 115/19 162/24 undefined [1] 151/1 under [38] 3/20 15/2 21/7 28/25 41/25 42/3 42/8 42/11 47/14 55/13 59/24 61/23 62/19 68/8 69/19 74/21 76/19 81/10 94/14 96/6 96/18 103/21 107/14 111/9 113/15 116/15 116/18 126/1 136/17 141/4 141/23 143/24 144/25 154/2 154/18 156/14 158/17 159/21 under-treatment [1] 3/20 undergo [1] 4/15 underlined [1] 21/3 underlying [2] 147/22 162/18 underneath [1] 121/25 underpinning [1] 93/20 understand [4] 54/1 70/3 136/14 139/5	understanding [5] 11/24 18/4 128/10 155/4 160/15 understood [2] 13/1 92/1 undertake [3] 40/21 78/21 154/24 undertaken [31] 1/8 35/22 36/25 39/13 39/17 40/7 40/11 40/23 57/11 59/1 60/1 60/8 67/15 71/14 96/6 98/14 104/7 107/7 108/13 117/17 118/6 118/9 145/9 147/4 148/5 148/6 153/12 159/21 160/17 165/6 167/4 undertaking [1] 51/5 undesirable [1] 113/23 undue [1] 92/4 unfortunate [1] 62/5 unfortunately [4] 23/12 82/7 88/15 151/7 uniform [1] 9/25 uniformly [1] 135/13 unique [8] 8/11 20/6 41/17 55/6 61/20 77/3 166/14 166/15 unit [5] 18/6 61/2 65/14 65/23 150/12 United [3] 44/12 146/11 159/8 United Kingdom [2] 44/12 146/11 United States [1] 159/8 units [3] 90/22 98/1 127/24 University [3] 46/1 51/21 52/7 unjustifiably [1] 25/4 unknown [2] 119/6 121/8 unless [3] 18/3 22/9 132/25 unlike [1] 8/23 unnecessary [1] 6/11 unsafe [1] 166/4 unsurprisingly [1] 161/15 until [8] 10/13 13/7 67/11 84/13 85/19 110/7 110/19 169/7 unusually [1] 51/7 up [35] 3/24 7/7 14/11 15/14 16/19 17/23 21/19 22/7 38/11 43/2 55/21 56/21 58/4 70/2 70/7 71/13 76/16
----------	--	---	--	---	--	--

(67) to ensure - up

<p>U</p> <p>up... [18] 76/23 80/9 81/23 82/25 85/11 96/9 97/7 98/12 106/23 107/17 111/2 129/12 140/1 140/16 141/2 147/19 156/8 156/10</p> <p>up-playing [1] 22/7</p> <p>up-to-date [1] 56/21</p> <p>update [10] 3/5 65/24 94/9 94/22 95/4 97/14 100/22 109/4 138/16 139/14</p> <p>upon [6] 19/20 37/19 83/24 107/6 156/13 165/12</p> <p>upper [2] 142/9 144/8</p> <p>urgency [2] 3/18 157/15</p> <p>urgently [1] 73/9</p> <p>urine [1] 151/21</p> <p>us [22] 3/4 14/9 16/4 17/20 25/8 25/20 61/10 78/7 94/20 106/11 111/25 112/20 130/19 131/6 135/12 138/14 140/24 148/13 149/19 154/7 157/14 163/20</p> <p>usage [2] 74/14 103/15</p> <p>use [22] 39/3 46/25 72/19 72/22 73/16 79/19 80/25 81/12 85/12 101/15 108/1 109/22 118/15 130/9 136/20 144/10 147/1 158/10 159/4 161/21 161/21 163/21</p> <p>used [13] 33/5 70/1 72/5 72/21 74/10 101/3 108/21 109/18 111/20 112/1 113/3 127/25 154/8</p> <p>useful [2] 13/20 116/12</p> <p>using [3] 94/6 102/9 151/25</p> <p>usual [2] 92/5 92/8</p> <p>usually [2] 4/10 41/22</p>	<p>various [17] 19/22 41/19 44/14 47/17 47/21 61/22 62/16 63/21 75/25 76/9 85/14 86/14 113/12 117/5 141/12 157/2 162/20</p> <p>varying [1] 73/25</p> <p>vast [1] 11/12</p> <p>version [4] 78/11 78/13 80/5 88/10</p> <p>versions [3] 86/16 86/16 88/8</p> <p>versus [1] 158/24</p> <p>very [36] 6/16 6/20 15/22 24/5 24/11 28/12 37/23 39/3 40/21 48/21 48/23 53/2 54/8 66/8 66/12 66/15 66/17 71/4 71/14 72/9 76/6 94/12 101/20 103/20 109/2 113/22 120/1 129/4 135/3 136/2 137/14 147/2 155/12 156/2 160/16 162/21</p> <p>VI [1] 132/20</p> <p>via [1] 159/3</p> <p>Victoria [1] 156/12</p> <p>video [5] 38/2 38/6 38/25 53/23 170/4</p> <p>Vienna [1] 72/23</p> <p>view [14] 3/8 15/24 20/3 29/23 31/11 73/15 84/15 100/15 105/22 106/25 129/6 136/3 164/16 168/6</p> <p>viewed [1] 128/2</p> <p>views [2] 6/20 100/20</p> <p>VII [1] 142/17</p> <p>VIII [99] 4/19 6/10 14/17 33/8 45/3 45/24 46/10 46/25 48/12 48/25 50/11 57/6 58/14 58/24 62/24 62/25 63/5 64/2 64/9 66/12 69/21 70/2 74/14 75/22 79/9 79/17 79/25 80/13 81/12 82/13 84/11 84/21 85/12 85/22 86/1 86/4 86/13 87/3 87/13 88/20 89/9 90/10 94/6 97/20 98/2 99/2 100/3 101/5 101/6 101/13 103/3 103/7 106/12 106/15 107/21 108/22 108/23 111/14 111/22 111/23 118/15 119/14 119/21 119/25 120/16 121/2 121/24 127/25 129/16</p>	<p>131/16 132/19 133/4 139/6 139/13 139/25 140/11 144/5 144/11 145/23 147/15 148/1 148/19 150/3 150/7 151/3 151/23 152/1 153/25 154/11 155/15 155/24 156/3 158/12 158/21 158/24 159/4 160/11 161/22 162/12</p> <p>viral [8] 17/2 35/12 48/9 92/24 93/17 118/18 119/3 166/5</p> <p>virology [1] 99/9</p> <p>virtues [1] 89/12</p> <p>virus [17] 15/16 17/6 24/4 24/10 24/15 24/17 24/21 59/5 63/16 99/10 99/12 99/17 119/4 119/5 121/9 133/9 135/9</p> <p>viruses [4] 47/6 52/23 119/6 121/8</p> <p>visit [3] 16/20 20/16 21/6</p> <p>visits [1] 16/19</p> <p>vivo [1] 153/23</p> <p>viz [1] 127/6</p> <p>voice [1] 162/19</p> <p>volunteer [1] 120/10</p> <p>von [3] 41/20 46/15 113/17</p> <p>von Willebrand's [3] 41/20 46/15 113/17</p> <p>vote [1] 75/1</p> <p>vulnerable [1] 113/2</p>	<p>we'd [1] 111/8</p> <p>we'll [9] 27/21 38/8 38/24 39/4 47/23 69/15 107/14 121/19 122/19</p> <p>we're [12] 28/20 57/24 93/4 93/7 93/11 93/13 97/5 98/12 115/7 151/18 168/23 169/1</p> <p>we've [56] 5/16 5/21 7/19 9/7 10/18 14/6 15/18 23/22 26/8 26/8 26/11 28/2 31/24 32/14 35/3 35/20 36/15 36/22 36/23 37/2 37/3 37/9 37/18 55/9 62/2 76/11 86/14 93/21 93/24 95/20 96/11 99/23 104/4 106/3 106/4 121/19 123/16 128/25 131/8 132/17 145/2 147/11 155/7 155/12 155/20 160/4 160/21 162/20 162/21 162/23 162/25 162/25 163/6 163/10 163/25 165/18</p> <p>weak [1] 30/22</p> <p>weaker [1] 17/14</p> <p>website [2] 38/25 168/4</p> <p>Weddings [1] 5/4</p> <p>week [27] 5/16 7/22 9/8 10/8 10/18 18/8 19/12 19/14 34/24 35/2 36/23 37/19 98/7 113/24 123/17 129/5 135/11 146/5 160/21 168/3 168/5 168/10 168/21 168/23 168/24 168/25 168/25</p> <p>week's [1] 167/21</p> <p>weekly [13] 64/3 74/2 90/9 90/12 91/22 103/5 106/8 106/14 108/25 108/25 111/16 111/17 126/14</p> <p>weeks [4] 4/10 74/1 168/12 168/16</p> <p>weight [1] 37/1</p> <p>welcome [1] 78/22</p> <p>well [26] 5/15 5/18 19/19 23/25 31/1 32/7 48/20 51/7 52/15 59/14 59/24 60/9 65/1 65/1 82/19 93/1 98/12 102/24 110/15 123/24 142/11 157/25 165/4 165/8 167/5 167/23</p> <p>went [2] 40/4 151/8</p> <p>were [91] 2/11 2/25 7/22 7/23 7/23 7/23</p>	<p>8/2 8/20 8/21 8/22 9/10 9/15 9/19 9/22 11/8 11/13 12/12 12/24 14/2 25/18 25/19 28/9 30/14 31/4 31/21 35/10 35/14 35/17 35/22 35/23 36/3 36/4 36/16 36/17 36/18 36/21 40/9 54/20 56/25 67/15 71/9 71/12 71/17 72/13 73/7 73/21 74/24 77/14 78/6 78/21 78/22 79/4 80/6 80/23 83/21 95/3 97/19 98/4 99/17 100/18 101/16 102/9 103/5 104/1 104/5 105/11 105/14 106/12 108/12 111/12 111/20 112/1 113/8 114/21 114/23 115/15 116/9 132/18 132/21 137/3 138/24 138/25 142/10 144/4 145/3 147/4 151/13 160/16 161/14 165/18 166/1</p> <p>Wessex [5] 19/3 55/19 68/4 81/4 114/4</p> <p>what [91] 2/2 7/2 7/8 7/22 7/23 9/11 11/19 11/21 14/4 15/17 15/18 19/16 20/11 20/25 21/1 21/11 22/2 22/16 22/19 24/12 26/15 27/2 27/17 28/21 29/8 30/13 37/6 39/1 39/3 39/9 39/10 39/10 40/6 54/1 60/12 60/17 61/10 62/2 64/23 71/2 80/24 85/1 86/11 88/15 91/14 93/2 94/20 94/21 95/11 96/15 102/13 105/4 105/7 110/5 111/19 112/2 117/22 118/1 121/20 123/23 128/9 128/17 128/24 130/19 131/7 134/15 135/15 137/2 138/14 141/13 145/4 145/11 149/5 149/8 149/23 150/16 151/1 151/16 152/11 155/3 155/8 155/16 156/5 159/19 162/15 162/22 163/25 164/24 166/13 168/8 168/15</p> <p>what's [2] 30/1 164/6</p> <p>whatever [3] 84/3 149/21 152/17</p> <p>whatsoever [1]</p>	<p>164/15</p> <p>when [24] 1/22 1/23 2/17 4/13 4/22 12/12 14/2 17/14 28/9 28/17 30/7 30/17 30/22 52/16 53/8 92/8 101/25 105/8 105/20 117/3 129/15 130/13 138/4 146/13</p> <p>whenever [4] 50/11 71/20 138/6 151/22</p> <p>where [19] 18/19 31/24 36/24 66/6 68/19 71/6 76/19 76/21 82/1 89/15 89/17 89/19 102/5 122/3 126/8 127/2 137/3 155/13 164/9</p> <p>whereas [2] 101/6 115/12</p> <p>whereby [1] 89/6</p> <p>whenever [1] 74/18</p> <p>whether [33] 5/11 7/7 11/17 27/15 39/19 53/10 62/25 63/4 64/1 64/7 64/14 71/15 71/22 79/7 81/11 86/15 108/18 110/14 110/15 116/14 129/10 129/11 130/16 134/25 135/1 144/16 151/10 159/2 159/6 165/16 166/13 166/16 166/21</p> <p>which [133] 2/24 4/14 5/2 6/5 8/6 9/15 9/18 10/13 10/19 10/22 11/3 11/12 12/24 12/24 12/25 13/10 13/21 13/25 14/13 15/3 15/14 16/9 16/9 16/12 16/19 20/4 20/20 21/18 24/4 25/21 26/9 26/12 27/23 28/4 29/9 30/14 32/12 32/15 34/23 37/6 37/11 38/2 39/17 39/21 39/24 42/3 43/8 43/22 44/12 44/14 45/1 48/2 49/19 49/22 52/25 54/13 55/9 55/14 55/17 55/21 55/25 56/25 59/20 62/1 62/14 63/22 64/25 65/7 66/2 66/12 68/2 70/7 72/12 73/9 74/10 76/24 80/5 81/22 87/16 88/9 88/10 88/22 91/24 95/9 97/17 100/10 101/16 102/9 102/13 107/4 109/12 109/25 110/16 110/18 111/25</p>
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<p>W</p> <p>which... [38] 112/9 113/8 116/9 116/12 119/8 126/25 128/16 129/25 130/14 131/15 133/13 134/15 135/3 135/13 139/20 144/4 144/17 145/10 146/21 150/1 151/2 151/16 152/16 155/8 155/18 157/15 157/18 159/19 161/20 162/18 164/21 165/11 165/12 166/2 166/18 167/9 168/1 168/5</p> <p>which is [1] 20/20</p> <p>While [1] 8/16</p> <p>whilst [5] 40/4 98/12 132/22 141/12 148/19</p> <p>Whitfield [1] 31/10</p> <p>who [55] 5/17 6/21 7/20 8/8 10/1 10/6 10/11 10/12 12/3 12/5 17/9 17/18 17/19 18/8 20/1 22/3 22/4 25/18 25/18 25/19 25/19 26/21 27/24 29/20 30/11 31/19 42/9 42/13 42/15 49/10 50/9 52/11 53/22 54/9 69/15 78/21 80/8 82/21 83/2 83/22 84/9 98/20 99/4 102/3 133/23 137/2 142/6 151/12 152/10 152/13 152/21 154/21 166/14 167/11 168/8</p> <p>who is [1] 102/3</p> <p>whole [4] 5/8 12/3 23/4 39/18</p> <p>whom [4] 34/8 43/13 122/25 140/19</p> <p>whose [1] 37/8</p> <p>why [4] 33/4 78/24 128/9 152/8</p> <p>wide [1] 160/16</p> <p>wider [1] 143/8</p> <p>widespread [1] 59/20</p> <p>will [110] 5/13 14/14 14/16 15/15 15/21 15/22 16/5 16/10 17/9 18/8 18/9 18/10 21/1 23/16 24/22 24/24 26/22 30/18 32/8 33/15 43/24 44/3 45/25 47/10 47/16 48/1 48/3 48/5 48/10 48/11 49/16 49/17 50/15 50/20 50/23 51/16 55/21 56/1 59/18 59/20 62/8 65/2</p>	<p>65/6 65/17 65/18 69/25 70/4 70/7 70/11 82/2 87/20 90/7 90/9 90/14 90/22 91/12 91/18 91/20 91/21 91/24 92/7 92/18 93/4 94/13 98/11 105/13 110/19 120/15 120/24 121/12 121/22 122/2 122/7 123/11 125/8 125/15 126/12 127/9 127/24 127/25 129/16 130/15 130/15 131/3 133/5 133/18 138/3 138/6 140/12 140/24 145/13 145/20 146/11 153/18 154/5 154/12 154/15 154/20 154/21 157/3 157/5 157/7 157/10 158/3 159/9 163/20 168/4 168/5 168/8 168/15</p> <p>Willebrand's [3] 41/20 46/15 113/17</p> <p>Williams [1] 163/19</p> <p>willing [1] 81/21</p> <p>Wilson [1] 67/20</p> <p>win [1] 18/2</p> <p>Winwick [1] 136/18</p> <p>wish [6] 15/17 99/19 130/13 141/9 150/19 165/13</p> <p>wishes [2] 52/11 168/8</p> <p>with [211]</p> <p>with it [1] 71/1</p> <p>withdraw [1] 154/22</p> <p>withdrawn [1] 104/23</p> <p>within [7] 3/9 15/11 26/13 39/24 105/14 163/18 168/17</p> <p>without [3] 111/11 135/24 154/22</p> <p>WITN3224001 [1] 8/12</p> <p>WITN5314001 [1] 13/5</p> <p>witness [6] 8/7 9/9 9/17 31/24 32/5 35/4</p> <p>witnesses [6] 7/20 9/13 10/1 37/8 160/21 162/5</p> <p>won't [9] 27/21 39/18 108/19 128/13 128/17 141/13 143/7 147/16 160/23</p> <p>wonder [2] 130/15 146/13</p> <p>wondered [2] 74/7 118/1</p> <p>words [5] 11/13 51/10 92/21 113/3 165/25</p> <p>work [42] 12/12 18/8 18/9 18/24 22/1 39/12</p>	<p>39/19 43/25 44/2 44/16 45/16 50/3 50/5 50/22 51/23 55/14 55/18 56/3 56/4 56/6 56/15 60/1 60/7 65/10 65/17 66/17 67/1 78/25 97/1 107/5 107/7 108/9 118/6 118/9 119/8 133/10 134/23 140/8 156/8 156/15 160/16 168/12</p> <p>worked [1] 146/8</p> <p>worker [1] 18/7</p> <p>workers [1] 73/24</p> <p>working [11] 19/22 45/17 52/20 66/23 141/21 141/22 144/3 158/18 158/22 159/5 159/13</p> <p>workload [2] 14/20 84/18</p> <p>works [1] 102/15</p> <p>worldwide [1] 63/22</p> <p>worry [4] 9/2 9/11 9/15 9/21</p> <p>worth [4] 152/24 157/23 158/19 161/1</p> <p>worthwhile [1] 139/11</p> <p>would [106] 5/1 5/4 8/22 9/12 13/9 13/21 20/4 28/6 29/4 29/5 30/8 30/24 32/2 32/3 34/8 34/9 35/9 37/21 37/25 38/14 38/16 50/10 50/12 52/8 52/10 53/15 54/15 54/15 57/3 57/4 64/3 65/7 67/23 67/24 68/18 68/20 71/4 71/7 72/17 73/7 73/22 74/11 74/18 77/4 78/15 79/8 79/19 81/12 81/22 83/24 84/10 84/16 84/18 85/3 85/8 85/18 86/8 86/8 86/12 87/16 88/22 89/3 89/15 91/1 91/1 91/7 92/17 93/13 94/18 99/4 102/25 103/14 107/22 107/25 108/18 115/10 116/12 123/18 124/16 129/20 130/8 131/14 131/22 131/23 136/23 138/12 138/12 139/10 139/11 140/23 141/1 146/13 148/23 148/25 149/18 149/19 149/20 150/4 150/19 151/3 155/18 156/19 157/13 157/17 162/12 167/15</p> <p>write [1] 75/3</p>	<p>writing [5] 23/8 26/25 140/1 152/25 162/16</p> <p>written [16] 1/14 1/23 1/24 9/8 35/3 37/4 81/20 111/2 115/19 147/12 147/19 154/17 155/17 156/8 156/10 168/1</p> <p>wrong [1] 162/11</p> <p>Y</p> <p>Yeah [2] 1/20 109/8</p> <p>year [18] 10/17 15/11 18/15 32/17 40/8 41/22 42/1 44/22 54/7 57/23 60/25 63/12 65/6 78/10 84/2 98/2 112/21 126/7</p> <p>years [28] 2/16 14/15 16/6 17/12 26/17 40/4 41/24 42/1 42/5 44/1 44/21 46/3 46/9 52/9 52/9 61/8 75/17 81/19 87/5 94/12 96/23 101/25 111/12 112/12 118/19 139/22 142/24 166/12</p> <p>yellow [1] 36/11</p> <p>yes [57] 5/18 7/6 7/16 12/22 13/2 21/23 22/6 22/12 22/22 26/14 28/12 29/12 38/13 38/18 38/22 38/24 40/15 40/18 40/19 40/24 49/4 49/24 52/18 53/4 53/12 53/16 54/3 54/4 54/17 60/7 60/13 60/14 87/11 87/14 87/18 87/23 93/11 93/18 101/18 105/3 110/19 118/4 124/11 124/15 124/20 124/25 125/1 135/19 135/23 157/25 158/3 158/6 162/3 162/6 167/8 167/8 167/23</p> <p>yesterday [7] 11/5 15/2 22/19 28/17 28/23 30/13 32/22</p> <p>yet [6] 1/13 10/16 112/6 119/6 135/13 142/17</p> <p>you [90] 5/13 6/17 7/7 7/17 9/2 10/4 10/4 10/4 10/4 15/17 18/3 23/16 23/22 24/25 25/5 26/14 27/2 28/5 28/12 28/17 34/9 34/10 34/10 35/1 37/22 40/7 49/1 50/1 51/10 54/17 56/21</p>	<p>69/24 70/11 92/18 99/19 100/25 101/10 101/16 101/18 101/24 105/1 110/21 117/18 117/18 118/2 123/20 123/21 123/22 124/5 129/19 129/20 130/13 130/13 130/14 130/16 131/11 131/21 131/22 135/11 137/2 137/25 138/5 138/9 138/12 139/10 139/11 141/9 145/14 145/15 145/15 145/19 145/20 146/12 146/13 146/13 148/18 148/22 148/25 149/19 149/20 150/6 157/15 158/1 161/25 162/6 163/20 165/3 166/25 169/4 169/5</p> <p>you'd [3] 124/8 124/12 124/16</p> <p>you'll [16] 8/1 8/4 10/20 11/23 20/23 23/11 23/20 35/16 56/17 76/2 98/17 110/13 113/3 143/21 146/22 159/17</p> <p>you're [4] 20/19 22/12 22/16 41/4</p> <p>you've [6] 10/1 10/8 22/15 25/15 37/21 160/25</p> <p>young [3] 4/3 18/14 45/16</p> <p>your [19] 6/18 32/7 35/7 129/14 130/8 131/3 137/25 137/25 138/2 145/22 148/18 148/20 148/21 149/1 149/14 153/5 162/13 163/21 167/5</p> <p>yours [1] 6/19</p> <p>yourself [2] 6/22 34/5</p> <p>Yvonne [1] 59/6</p> <p>Z</p> <p>zeros [1] 41/5</p> <p>zoom [3] 69/10 82/11 101/20</p> <p>zooming [1] 23/11</p>
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