

Wednesday, 9 December 2020

(2.00 pm)

SIR BRIAN LANGSTAFF: Good afternoon, professor. Can you see me?

THE WITNESS: I can see you, Sir Brian.

SIR BRIAN LANGSTAFF: Obviously, you can hear me as well, good. That's a promising start. We should have an uninterrupted technological connection. If we don't, well, we'll just have to bear with it.

Let me describe the scene for you because you won't have been, I suspect, in our hearing room in Fleetbank House. It's a very large room. It's capable of holding around 200 people when it's full and when Covid restrictions don't apply. At the moment, however, it has less than ten in it. I'm looking across the room to three members of the legal team, all wearing masks, except for Ms Richards, for obvious reasons. Then there are three other members of the Inquiry staff here. There is Soumik, whose job it is to make sure you can see the right document when it is referred to, two others, one of whom is Mary, who will ask you to swear the oath.

For those who are watching at home remotely, let me describe your position. You can tell us: are you at home? Are you at home? Can you hear me? You

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and research and about 50 per cent clinical general medicine, with haemophilia or bleeding disorder care and treatment representing only about 1 per cent of that; is that right?

A. That's correct. It was an academic unit, so I was expected to do teaching and research for half of my time throughout my career and the rest of the time I was training in general medicine, and that involved rotation amongst various specialties, coronary care et cetera, and in that three-year period I think I only assisted at the haemophilia centre for about six months.

Q. Then between January 1978 and September 1985, you were a lecturer and honorary senior registrar, still at the Royal Infirmary, and again with a similar division of responsibilities: 50 per cent teaching research; 50 per cent clinical medicine; with a very small proportion of that being haemophilia care, again, around 1 per cent you put it in your statement.

A. That is correct -- just really helping out if there was nobody else around to assist with a visiting haemophilia patient.

Q. Then from October 1985 through to September 2009, you continued to hold an academic post, in due course being appointed professor, and from December 1985 you

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can't.

THE WITNESS: Oh, I'm sorry. You're talking to me?

SIR BRIAN LANGSTAFF: Yes.

THE WITNESS: Yes, I'm sitting in my study at home, thank you.

SIR BRIAN LANGSTAFF: Your solicitor and your counsel are elsewhere. I think your counsel is Mr Bowie and we may hear from him in due course at the end of the hearings.

Ms Richards?

MS RICHARDS: I think Mary needs to swear Professor Lowe in first.

PROFESSOR GORDON DOUGLAS OGILVIE LOWE, sworn

Questioned by MS RICHARDS

MS RICHARDS: Professor Lowe, I'm going to start with a brief overview of your career, insofar as relevant for the Inquiry's purposes.

Between November 1974 and December 1977,

I understand from your statement that you were a registrar in general medicine at the Glasgow Royal Infirmary.

A. That's correct.

Q. You've told us in your statement that, in terms of the amount of time you spent on different responsibilities, it was about 50 per cent teaching

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were a consultant. Again, your responsibilities were approximately 50 per cent teaching and research, 50 per cent clinical medicine and, for this period of time, you have estimated the amount of time spent on the clinical side, in relation to haemophilia and bleeding disorders, as being in the region of about 10 per cent; is that right?

A. That is correct because I was, by that time, the second consultant on the unit assisting Dr Forbes as a co-director and I shared with him both reviewing patients on the wards who were admitted, patients at the review clinic, and consultant coverage.

Q. In terms of the directorship of the clinic, of the haemophilia centre, it was under Dr Forbes and Dr McDonald's directorship at that point, at the end of 1985, and you assisted them for the period through to the end of 1987, and then in 1988 you became co-director with Dr McDonald?

A. That is correct. The co-director at the centre was always a member -- a physician member of the Department of Medicine, initially Professor Douglas, Professor McNicol, and then Dr Forbes and Dr Prentice and, on the haematology side, which dealt with the laboratory service, the provision of blood products and reviewing many of the milder patients and the

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1 inhibitor patients, that would be staff in the
 2 Haematology Department of which Dr McDonald was head
 3 of department, Dr John Davidson ran the blood bank and
 4 blood products laboratory, and Dr Walker was
 5 consultant haematologist at the Royal Infirmary, and
 6 the Royal Maternity Hospital.

7 **Q.** Your statement says from 1991 onwards you were
 8 co-director with Dr Walker until 2009.

9 **A.** Sorry, it was -- I think, I checked -- June 1990.
 10 Dr McDonald retired as head of department, Dr David son
 11 succeeded him as head of the Haematology Department
 12 and he continued to run the blood products and
 13 transfusion laboratory but thought that Dr Walker was
 14 keen to be my co-director, and that was that.

15 **Q.** You refer in your statement to UKHCDO approving you
 16 appointment as director. What was the role of UKHC DO
 17 in terms of offering some form of approval?

18 **A.** I think my predecessor would suggest that I would be
 19 co-director, and I think Dr Forbes did propose that at
 20 UKHCDO and that was accepted. But before that could
 21 happen that had to be agreed between
 22 Professor McKillop, as my head of department, and
 23 Dr McDonald, as head of haematology.

24 **Q.** You became a member of UKHCDO and remained a member
 25 until 2009. You have listed in your statement

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1 **A.** That is correct. So I visited that less often,
 2 obviously, but maybe every year or two, usually
 3 because I had offered a presentation which they
 4 accepted.

5 **Q.** Can you recall whether, during the time that you
 6 remember of either society, you presented any findings
 7 in relation to research relating to patients with
 8 bleeding disorders?

9 **A.** I can't remember because my main research interest, as
 10 I think my written statement makes clear, is that my
 11 research was very much on the thrombotic and vascular
 12 disease. I cannot recall presenting any haemophili
 13 research findings. I did very little research in
 14 haemophilia.

15 **Q.** Now, I want to ask you next a little about the centre,
 16 the haemophilia centre, or service at the Glasgow
 17 Royal Infirmary. You've given us a very detailed
 18 history in your witness statement and I am not going
 19 to go through the detail of it, but I have a handful
 20 of questions about how it worked and then I want to
 21 ask you a little about the facilities and staffing.

22 What was the relationship, in particular in the
 23 1970s and 1980s, between the University of Glasgow and
 24 the Royal Infirmary?

25 **A.** Oh, very long-lasting. So the Royal Infirmary date

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1 a number of other societies and organisations of which
 2 you are a member. There are just two I wanted to ask
 3 you briefly about.

4 You refer to membership of the Scottish Society
 5 of Experimental Medicine between 1979 and 2009. Can
 6 you just tell us briefly what that is and what your
 7 role was?

8 **A.** Yes. So that is the Scottish equivalent of the
 9 Medical Research Society. So, basically, it's
 10 a professional society that holds regular meetings
 11 where you report research findings of all kinds. Since
 12 London being a long way away, from about the 1950s,
 13 I think, the Scottish Society of Experimental Medicine
 14 was its equivalent and it would meet about two or
 15 three times a year, alternating between Glasgow,
 16 Edinburgh, Dundee and Aberdeen which hosted it. In
 17 particular, it was the junior doctors who were doing
 18 research and training who gave the presentations, but
 19 occasionally at consultant level. So it was a wide
 20 variety of experimental studies, be it laboratory or
 21 clinical.

22 **Q.** The second organisation I was going to ask you about
 23 I think you may have already answered. It was the
 24 Medical Research Society. So that was the UK-wide
 25 body performing a similar function, was it?

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1 from about 1780, when it was set up as a charitable
 2 institution, and it was right beside the original
 3 medical school of Glasgow University, which was just
 4 down the road. So right from the start there's very
 5 close collaboration between Glasgow University Medical
 6 School and the physicians and surgeons who serve at
 7 the Royal Infirmary, and there was a lot of communication
 8 go between them. There's quite a detailed history of
 9 the medical faculty on the University of Glasgow
 10 website that my colleagues and I wrote, and I think
 11 I've given you the web link.

12 The university moved across to the west side of
 13 Glasgow in about the 1880s, and at that time the new
 14 Western Infirmary was built and the academics were
 15 split on two sides of town. So both at the
 16 Royal Infirmary and the Western Infirmary there was
 17 a department of medicine with a professor,
 18 a department of surgery with a professor, a department
 19 of obstetrics with a professor; so it was split across
 20 two sites and both sites were very active in research
 21 and in clinical care, working respectively in the
 22 Royal Infirmary in the east and in the Western
 23 Infirmary in the west.

24 The Royal Infirmary in particular was
 25 interested in obstetrics and gynaecology, and the

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1 Royal Maternity Hospital was just a short walk from
2 the Glasgow Royal Infirmary. That's where
3 Professor Walker developed an interest in perinatal
4 haemostasis and, in particular, the treatment of women
5 with congenital bleeding disorders, and carriers, and
6 looking after them during pregnancy and delivery. So
7 she was the haematological and haemophilia, if you
8 like, consultant from about 1978 there, as well as
9 with Dr Davidson and Dr McDonald in the
10 Royal Infirmary. So that was their contribution.

11 **Q.** What, if any, impact did that relationship and those
12 close links between the University and the Infirmary
13 have for the care and treatment of patients with
14 bleeding disorders?

15 **A.** So Professor Douglas -- sorry, Dr Douglas, in 1950,
16 was a registrar under Professor Davis, who was the
17 Professor of Medicine at the Royal Infirmary, and his
18 interest was in haematology and he wanted to set up
19 a haemophilia service for the west of Scotland.
20 In 1951, Dr Douglas went down to the Oxford
21 Haemophilia Centre (which you will know as the premium
22 centre in the country) and he trained for two years
23 with Drs Macfarlane and Biggs, and they invented a new
24 coagulation test which resulted in the two different
25 types of haemophilia: haemophilia A (Factor VIII

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1 a card to a general practitioner, the general
2 practitioner would know they were a patient with
3 haemophilia. They could ring the Royal Infirmary
4 haemophilia centre for advice about treatment, and
5 treatment could be given at the local hospital, of
6 which there were several which I've listed.

7 The patient could be referred to the local
8 physician with an interest in haematology who could
9 order appropriate treatment from the west of Scotland
10 Blood Transfusion Service, with advice if required
11 from the centre. So a lot of the patients throughout
12 the west of Scotland were treated, at least initially,
13 at the local hospital, and obviously there could be
14 correspondence between the local haematologist and the
15 haemophilia centre.

16 Now, initially this was run by the Department
17 of Medicine's physicians with an interest in
18 haemophilia, which was Professor Davis and
19 Dr Macfarlane, but then in -- by about 1960,
20 haematology was developing as a laboratory speciality
21 and departments of haematology were set up, and that
22 was when Dr McDonald came from Aberdeen to Glasgow and
23 he pioneered the Haematology Department. Its
24 responsibilities were, then, to not only provide the
25 laboratory service and the blood transfusion

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1 deficiency) and haemophilia B (Factor IX deficiency),
2 being distinct diseases needing different treatments,
3 ending up, of course, with Factor VIII and Factor IX
4 concentrates. So he made a big contribution.

5 He then came back in 1953 and, with
6 Professor Davis, spent ten years collecting all the
7 families in the west of Scotland, and he would
8 interview them all, take a family tree, take blood
9 samples and spend the rest of the day working out whether
10 they have Factor VIII or Factor IX deficiency, what
11 was the severity, and the Medical Research Council,
12 which organised haemophilia centres at that time,
13 would then have the patients registered.

14 Every affected patient would be given
15 a haemophilia card with their name, contact details
16 general practitioner, blood group and, very
17 importantly, the address and telephone number of the
18 centre. And they were educated about the disorder and
19 told if at any time they had a bleed or a trauma or
20 surgery or any other problem, ring the centre and the
21 centre would then arrange appropriate treatment.

22 Now, the west of Scotland was a very diverse
23 area, with many hospitals, and I think I sent you, as
24 an appendix to my written statement, a kind of diagram
25 which indicates that patients, obviously, would show

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1 laboratory locally but to start to look after the
2 clinical management of patients. And from this time,
3 haematologists were starting to train not as
4 pathologists, which they had been, but duly trained
5 and accredited in medicine.

6 At this time, Dr McDonald, who had done quite
7 a lot of blood coagulation research in Aberdeen, and
8 Dr McDonald agreed that they should share the centre.
9 So the patients -- sorry, going back to the facilities
10 now -- were reviewed on the University Department of
11 Medicine's wards 2 and 3, at the entrance to Glasgow
12 Royal Infirmary. They could turn up at any time of
13 day or night and the doctors and nurses knew how to
14 treat them and they had the index of what treatment
15 they needed.

16 The Haematology Department then took over --
17 continued to provide the blood transfusion and they
18 took over the routine blood tests for clotting
19 factors, which Dr Douglas had been doing in the
20 Department of Medicine. So they provided the routine
21 diagnostic measures, the monitoring of patients'
22 factor levels and inhibitors and of course the
23 haematology routine tests.

24 They also took over the blood clinic. Now, the
25 blood clinic had been set up by Professor Douglas and,

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basically, the Haematology Department, Dr McDonald and colleagues, took that over, particularly for review of the mild patients with haemophilia or von Willebrand's disease, who didn't need to, you know, turn up often for treatment of an acute bleed. So, by the time that I arrived at the Royal Infirmary in 1975, Dr Douglas's successors, Dr Forbes and Dr Prentice were the two consultant physicians who were still looking after most of the patients with severe haemophilia at the original centre.

At the blood clinic, that was Dr McDonald, Dr Davidson and Dr Walker and they continued to review many of the milder patients. But the centre was on in that they have had a common register, all the patients were registered at each, it's just that it was more convenient for the milder patients to attend the blood clinic, which was run by the consultant haematologist and the more severe patients would get their reviews often at the time they came up with severe bleeds.

So it was a close collaboration between the two departments.

The other -- sorry to be long-winded -- sometimes you get acquired haemophilia where a normal person suddenly starts bleeding. Their Factor VIII

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a statistical report prepared for the Penrose Inquiry, professor. If we go please, Soumik, to -- it's probably page 30. That's the one, I think.

So, if we could pick things up in 1975, we can see at Glasgow Royal Infirmary we have 103 patients with haemophilia A, 15 with haemophilia B, none at that stage registered -- no females with Factor VII or IX deficiency, one von Willebrand's disease, giving a total, I think, of 119 patients.

Then if we go to the next page please, Soumik, we can see for 1980 for the Royal Infirmary, we've got 197 patients with haemophilia A registered, 52 haemophilia B, there are now five females with Factor VIII or IX deficiency, 16 von Willebrand patients, and a total of 270.

Then for 1985, we see for the Royal Infirmary 211 patients with haemophilia A, 56 with haemophilia B, 10 in total female patients with Factor VIII or IX deficiency, 36 von Willebrand, and a total of 313.

I think the figures you give in your statement, professor, are very slightly different but it's a very marginal difference, so I think these are reasonably accurate.

SIR BRIAN LANGSTAFF: Can I just say that they cover five

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was normal when they were born but they have developed an inhibitor, so they bleed just like a severe haemophiliac and, in particular, Dr Davidson and Dr Walker would be interested in managing them because hopefully it was a curable condition and once you treated the inhibitor, they wouldn't have life-long haemophilia.

Now, they had beds on one of the other medical units, Professor Lawson's unit in my time, and they would look after these acquired inhibitor patients there using the various treatments. Basically, there was a sharing of the patients: the severely affected haemophiliacs continuing to come to wards 2 and 3, which they always had, and they knew it and liked coming there; the milder patients and the acquired inhibitors being reviewed at the blood clinic and only being referred to the haemophilia centre if they needed a special treatment; and, as I say, Dr Walker reviewing the women with bleeding disorders at the maternity hospital.

So it was spread over two departments in two hospitals but it was co-ordinated and all the patients were registered at UKHCDO.

Q. If we just have a look at the numbers, Soumik, could we have up on screen, please, PRSE0002887. This is

14

year spans.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: As a result, it can't be the case that each started with the number that we have and each finished with the number that we see for each five-year batch because there would then be a cliff-face change at the end of each five-year period. So it may reflect each and every patient who ever was registered during that period. It may reflect something else. It's not entirely clear from the wording.

MS RICHARDS: It's not.

SIR BRIAN LANGSTAFF: So I think I shall treat this, subject to any submissions later on made to me, as indicative of the overall numbers and of the trends but I don't think precision is what it's about.

MS RICHARDS: No, and I don't think we have any data beyond this that would assist in being more precise sir.

Professor, I do not know whether you can assist with this: do you know whether these figures would be likely to include patients who are from the broader west of Scotland area and are treated both at their local hospital and, from time to time, through the Royal Infirmary or would this just be patients who

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1 were seen at the Royal Infirmary?
 2 **A.** These would be patients who are registered at the
 3 Royal Infirmary, but that was the reference centre for
 4 the whole of the west of Scotland, and I think what
 5 you are seeing, in terms of the increased numbers of
 6 patients registered, is firstly that haemophilias were
 7 becoming more common because, as you may be aware, in
 8 the 1970s half of haemophiliacs died before they
 9 reached the age of 40 from bleeding. It was a very
 10 unfortunate disease if you didn't have adequate
 11 treatment.

12 So a number of patients surviving but also,
 13 increasingly, the number of patients registered who
 14 had been identified particularly with milder
 15 haemophilias by the various hospitals of the west of
 16 Scotland and some of them just hadn't been picked up.
 17 A mild haemophiliac can go for years and then suddenly
 18 have surgery and they bleed a lot and they are found
 19 to be a mild haemophiliac. So it's the increasing
 20 numbers of milder patients being identified and
 21 referred and definite diagnosis made and the patients
 22 are registered.

23 So that is the main increase.

24 **Q.** Thank you.

25 **A.** You will see also that von Willebrand's disease is

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1 So it was dependent -- the age of transfer we
 2 left very much to the haemophilia director at Yorkhill
 3 to decide. It would depend on the maturity of the
 4 child, the severity of the child and, often, there are
 5 haemophilic siblings, two brothers, for example, and
 6 you have to think do you want to transfer the older
 7 one first or should we wait until the younger one is
 8 of age and then ... so it was very much up to the
 9 children's director to decide and, at that point, they
 10 would have a discussion with the adult centre and then
 11 often a joint review, usually at Yorkhill with, "Ok ay,
 12 here we are, what do you feel about coming over", and
 13 transitions would be arranged.

14 **Q.** Do you know whether the Royal Infirmary haemophilia
 15 service was always adults only or were children
 16 initially treated there in the 1950s and 1960s?

17 **A.** I think they would be registered there but the Royal
 18 Hospital for Sick Children was always the place of
 19 care, as far as I recall, and I think -- my wife
 20 trained as a paediatrician there and as a medical
 21 student and I think that patients were usually looked
 22 after by the professor of child health with the
 23 assistance of the haematologist, and there was always
 24 a very close link between the Department of Child
 25 Health at Yorkhill, the University Department of Child

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1 increasingly being recognised by more modern tests and
 2 the numbers are increasing.

3 **Q.** Thank you. Soumik, you can take that down.

4 In terms of the adult/child divide, we heard
 5 yesterday and the day before from Dr Pettigrew and
 6 Professor Hann, the effect of their evidence was that
 7 there wasn't a precise age at which a patient would
 8 transfer from Yorkhill to Glasgow Royal Infirmary.
 9 Was that your experience too? It might depend upon
 10 a range of factors but, broadly, it was mid, sometimes
 11 late, teens?

12 **A.** That's correct. So, in Scotland, a child becomes
 13 an adult legally at 16 but, as I think Dr Pettigrew
 14 and Dr Hann have been saying in the past couple of
 15 days, the admission -- the arrangement between the
 16 Royal Hospital for Sick Children and adult hospitals,
 17 such as the Royal or the Western, was that around
 18 about the age of 12 or 13 you'd start thinking about
 19 it but Dr Pettigrew, I think, made the very valid
 20 point that, particularly for patients with severe
 21 haemophilia who were often admitted to hospital,
 22 education was very important and Yorkhill, of course,
 23 had teachers to carry on the education of the child
 24 whereas we didn't, at the Royal Infirmary, have any
 25 such thing.

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1 Health, and the University Department of Medicine at
 2 the Royal Infirmary.

3 For example, the professor when I arrived in
 4 1975 was Professor McGirr and his interest was
 5 endocrinology and Professor Hutchison had quite a lot
 6 of interest but the two of them collaborated closely
 7 on studies of thyroid disease in -- familial thyroid
 8 disease. So there was a very close connection between
 9 the two departments.

10 **Q.** When a bleeding disorder patient transferred from
 11 Yorkhill to the care of the Royal Infirmary, what
 12 happened in terms of the treatment regime, would the
 13 patient be kept, as far as possible, on the same
 14 treatment regime, in terms of home treatment or type
 15 of product, or would there be changes?

16 **A.** I think that would be discussed. As you have heard
 17 from colleagues in the last two days, a lot of the
 18 patients at Yorkhill were on home treatments and,
 19 obviously, the first question on transfer would be,
 20 with the parents and the patients, what is the home
 21 treatment situation you've been having? As you heard
 22 from Professor Hann yesterday, it would be usually
 23 a concentrate at that time, for patients on home
 24 treatment and you heard about the changes at different
 25 times of type of concentrate, and then: so what is the

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current concentrate, what is the current pattern of treatment? That would be reviewed.

A point I would like to make is that one of the many advantages of the haemophilia centre at the Royal Infirmary, and I think probably uniquely across the UK, was that in our department we had not only the haemophilia doctors, Dr Forbes and Dr Prentice, we had endocrinologists, as I have mentioned, we had kidney disease specialists, but a very major part of it was the first academic rheumatology department in Glasgow, and it was a power house of development in the 1960s onwards.

So two of the consultants in the departments when I came were professors of rheumatology. They had an adjacent hospital at Baird Street which moved to join the Royal Infirmary in 1982, in a new university building, and Dr Roger Sturrock, who later became Professor of Haematology, was in charge. He had a very close collaboration with Dr Forbes and Dr Prentice, which intensified when they came to the Department of Medicine in 1982.

From that time, the rheumatologists were very closely involved with the monitoring of the patients. You will have gathered that haemophilic arthritis is by far the most disabling and crippling complication

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treatment there may be a case for continuing that and the question then, if you are on home treatment: is it intermittent, when you suspect a bleed, or should it be prophylaxis, which you have heard about, which is treating maybe twice a week to maintain a certain minimum level of clotting factor, at which you will get no bleeds, and that child will not grow up with arthritis, and that child will not grow up crippled and be able to complete their education and get a job. That was clearly very, very important.

So, in terms of home treatment, the rheumatologists were always very much involved in making the decision together with the physicians who were looking after the patients with haemophilia.

Q. If you had --

A. So it wouldn't be -- sorry, yes?

Q. If you had a child transferring from Yorkhill to the Royal Infirmary in 1980/1981 who had been treated with predominantly or perhaps exclusively commercial concentrates, reflecting Dr Willoughby's practice at the time, and it may be you can't answer this because of your limited involvement -- if you can't, please say so -- would there have been a presumption that the patient would continue to receive commercial concentrates in accordance with the treatment they had

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of severe haemophilia, and they were very active in investigation of haemophilic arthritis. So from about 1982 the rheumatologists were very closely involved in monitoring patients at the haemophilia clinic. And from that time they started doing detailed assessments of the arthritis developing in the knees, the ankles, the wrists and the elbows, the common sites of bleeding, and they would have x-ray measurements and measurements of function. And they had very specialised physiotherapists.

So we had, always, a consultant rheumatologist with an interest in haemophilia and a specialist haemophilia physiotherapist, and they reviewed all the patients at the clinic in great detail and studies were done between about -- well, from about 1982 by senior registrar in rheumatology, Dr Steven, and by registrar in rheumatology, Dr Madhok, and the two of them did a very -- probably the most detailed study of haemophilic arthritis ever published in Britain, about 150 patients. That was published in, I think, 1986

Now, coming back to the transfer, they would be very involved in the transfer of children, in assessing the child, talking to the patients and saying: well, this is the current condition of your joints or your child's joints. In terms of home

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been receiving at Yorkhill or was it a completely fresh decision?

A. Well, the answer, as you have guessed, is I don't know, because apart from a six-month spell in 1976, I was never the junior doctor assisting Dr Forbes --

Q. Don't worry.

A. -- and Dr Prentice at review of the clinic.

I think, having said that, if a child had been -- the commercial concentrate was being used by Dr Willoughby, as you've heard, but we used very little at the Royal Infirmary. We only used commercial concentrate for things like surgery, and tried, wherever possible, to use the NHS factor concentrate. So that I think would have been the general policy but I can't help you about any particular children involved at that time.

Q. Can you help a little more broadly with how care would be managed for the patients who were not Glasgow residents, whose local hospital was elsewhere in the west of Scotland, how patients would be managed as between the local hospital and the haemophilia service in the Royal Infirmary?

A. Okay. What we ideally -- what my predecessor directors I think ideally liked would have been a direct annual review, which is patients coming from

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as far away as the Isle of Skye in the north-west or Stranraer, which is almost Ireland, in the south-west. But obviously patients were reluctant to travel that distance. It was a whole day out. So there was a general preference to just go to your local hospital, and they had plasma, they had

cryoprecipitate. And in due course, if it was agreed with the reference centre that concentrate would be preferable, that could all be supplied by the local branch of the SNBTS, which in general would be the West of Scotland Blood Transfusion Service. But I think my predecessors were quite keen to have an annual review if possible, or at least a discussion with the local haematologist as to what was going on just so we could, you know, keep in touch with the patient in case in the middle of the night some emergency happened.

The local haematologists -- I mean, there was a good network amongst Scottish haematologists, and my impression is that the local haematologist wouldn't hesitate if they had a problem to ring up the centre or discuss. But in terms of treatments, many patients preferred their local hospital. I can remember at the Penrose Inquiry being asked the same question and I said, "Oh, well, patients preferred, if possible, to

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will know, it's transmitted by female carriers, and it skips generations. So if a patient, say, dies and the records department say, "Well, that's that", and destroy the records, the problem is that 40 years later some granddaughter becomes pregnant and wants to know if she is a carrier and what kind of haemophilia was it. So in general we tried to keep all the records in the haemophilia centre, and the number of filing cabinets increased from about I think one, when I arrived in 1975 -- at last count I think it's about 20 filing cabinets.

If a patient died, we would put them in a locked cupboard within the haemophilia centre, because we occasionally had the problem that the records department said seven years, or whatever is the current policy, and would destroy them. So we tried to retain them as much as we could.

But, in practical terms, we had a small folder in the unit, as I think many other centres did, which listed the basic details of the patient and what treatment they were on and information like the family tree and the UKHCDO registration number, so that if a patient turned up in the middle of the night and for some reason the case sheets had gone missing, they had attended another clinic, they had gone to a surgical

27

attend the local hospital rather than make the long and dangerous journey to Glasgow" at which Lord Penrose announced that he was from a town about 20 miles from Glasgow and he would agree that that was a long and dangerous journey and he would rather have stayed there.

Q. I wanted to ask you next about records and record-keeping at the haemophilia centre. As far as you can recall from your time there, how and where were records relating to bleeding disorder patients kept?

A. So every patient had case records, obviously. For a severe haemophiliac, these could become several volumes, several feet high, over the years from the number of submissions that they had. And we always wanted to keep all the records available in the haemophilia unit.

Now, as you know, records can be destroyed at intervals by managers and records departments just wanting to keep their shelves clear, but there was a general recommendation by the UK Genetic Disorder Society, or whatever it was called -- I can't remember -- that it was preferable that these records not be destroyed. And there was a very good reason for that in patients with haemophilia because, as you

26

ward for operation, we had the essential information that was needed to know what kind of haemophilia it was and what the treatment would be.

Q. When you retired in 2009, Professor Lowe, were the records, hard copy records that you've described that might be multiple files, still kept within the filing cabinets within the haemophilia centre?

A. Deceased patients would be in a locked cupboard in another room. We kept, obviously, only the -- well instantly accessible the recent records of patients who were alive, and then if they stretched back too far they were, again, put in a kind of storage cupboard but could be accessed if required.

Q. Do you know whether patient records were destroyed or lost through moves or through computerisation at any stage whilst you were director?

A. I think we were pretty good. So we had on the front of every case record a big stamp routinely saying "Please return notes to haemophilia centre - Do not destroy".

Q. I want to move on to the question of what products were used. And, again, I'm conscious that your involvement in decision-making in relation to products would have been non-existent or limited until 1988. But I am going to invite you to look with me at the

28

1 same report again, just so we can get some of the
 2 basic data.
 3 PRSE0002887, please, so the statistical report
 4 again, to start with.
 5 If we could go, please, Soumik, to I think it
 6 is probably page 20 electronically.
 7 So we have the records there for Glasgow Royal
 8 Infirmary. We can see if we look, for example, at
 9 1974, substantial volumes of cryoprecipitate being
 10 used, and then in terms of factor concentrates it's
 11 a range of different commercial concentrates in
 12 smaller volumes: Kryobulin, Travenol/Hyland/Hemofil
 13 FVIII.
 14 We can see, 1975, again a substantial volume of
 15 cryoprecipitate, but now, for the first time,
 16 Factor VIII, PFC Factor VIII, in large quantities
 17 I think we've seen it in smaller quantities in
 18 previous years. And, again, commercial concentrates,
 19 a range of different commercial concentrates, being
 20 used.
 21 1976, again, we can see substantial volumes of
 22 cryoprecipitate, but increasing volumes of the PFC
 23 Factor VIII and still a mix of different commercial
 24 concentrates.
 25 If we just go further down, please, Soumik.

29

1 situation Dr Forbes and Prentice would be using these
 2 so-called activated Factor IX concentrates. And
 3 Proplex I think might have been one of them.
 4 If you look just three lines above to FEIBA,
 5 that's Factor VIII inhibitor bypassing activity, which
 6 essentially is another type of activated Factor IX
 7 concentrate. The proportion of these FEIBA and
 8 Proplex-type commercial products is they are all
 9 commercial and they are all some kind of activated
 10 Factor IX concentrate and they are all used for
 11 patients with inhibitors.
 12 Now, the number of patients with inhibitors
 13 varies a lot from year to year, and some of these
 14 patients maybe acquired inhibitors, they appear and
 15 disappear, so it's a changing small population. And
 16 according to the state of knowledge, Dr Prentice and
 17 Dr Forbes, in the patients admitted to their wards or,
 18 indeed, the patients with acquired inhibitors admitted
 19 to Dr Davidson and Dr Walker's wards, they would make
 20 the appropriate choice of product, which would be
 21 based, I would guess, on a balance between efficacy
 22 cost and safety.
 23 One of the safety problems with these products
 24 is thrombosis. If you give people high Factor IX
 25 levels or activated Factor IX, there is a risk of

31

1 Could we go to the next page then.
 2 Again, if we look at 1978 we can see it's still
 3 substantial amount of cryoprecipitate but increasing
 4 amounts of the PFC Factor VIII.
 5 Can you assist, please, professor, with what
 6 Proplex was? It appears to have been a commercial
 7 Factor IX product; is that correct?
 8 A. Yes. It sounds like it was only used once. I think
 9 it was probably used for an inhibitor patient. So, as
 10 you may know, the treatment of Factor VIII inhibitors
 11 is very difficult. The treatment varied over the
 12 years. Porcine Factor VIII was used at one time but
 13 caused bad reactions. So from, I think about 1976,
 14 some patients were treated with what was called
 15 activated Factor IX concentrates, and the concept
 16 there is the manufacturer had not just plain Factor IX
 17 but something that was slightly activated, usually
 18 with a kind of secret recipe according to each
 19 company. And there were reports by, I think, the
 20 mid-1970s that this was a useful and effective agent
 21 in patients with inhibitors who were actively
 22 bleeding.
 23 Some centres in the UK tried to use the
 24 NHS Factor IX and there were mixed results and quite
 25 a lot of the times it didn't work. So I think in that

30

1 thrombosis. So the decision was constantly changing
 2 over the years.
 3 On that point, if you look at the UKHCDO
 4 minutes, which I'm sure you do, there was a special
 5 working party on inhibitors in which Dr Prentice was
 6 particularly active, and I think he ran that from
 7 about the mid-1970s until he left Glasgow in about
 8 1983. He had the very daunting task of trying to get
 9 unanimity across the UK in practice, for which the
 10 best evidence-based solution would be to take the two
 11 most promising treatments and see if they could
 12 organise a randomised control trial across the UK
 13 haemophilia centres in collaboration with the
 14 manufacturers, to see which might be the most
 15 effective and, at the same time, the most safe of
 16 these concentrates.
 17 Q. Then we can see in 1979 we see DDAVP appearing for the
 18 first time then, if we move down to 1980 and beyond
 19 we can see, and I'm not going to go to the precise
 20 figures, professor, but we can see the use of
 21 cryoprecipitate declining in the early part of the
 22 1980s, and the predominant treatment being the PFC
 23 Factor VIII, again still with some various commercial
 24 products being used.
 25 If we go then, please, over the page, Soumik,

32

and we look at the top half of the page, again we can see the volume in terms of the cryoprecipitate declining, although slightly increasing again in 1983 but not to the previous levels. Then we can see, although there's a line for DDAVP in 1983 and 1984, in fact no volumes there put in, and with the PFC again being the main product for the treatment of haemophilia A.

Sir, there is a table which shows this similar to the tables that we have produced for the other centres, if that is of assistance.

A. Ms Richards, could I ask you just to stay on that page, because I think this is actually more helpful in terms of the distribution and discussion of the products than the one which I've been receiving the last few days.

So the first thing I'd say is that the revised one is problematic because DDAVP is grouped with FEIBA and that is inappropriate because they are quite different products. So DDAVP, as you may know, is a synthetic drug and you give it by infusion to raise Factor VIII levels in patients with mild haemophilia or to raise von Willebrand factor levels in patient with mild von Willebrand's disease, and you use it so that you can avoid the use of any blood product.

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and that was almost enough to meet the needs of all haemophilia A patients. That was why cryoprecipitate use was decreasing, because cryoprecipitate, as you know, is a product which has many, many disadvantages, as you have heard in the Inquiry, and the PFC concentrate was taking over.

But then if you -- just to go to 1985, you have observed that there's a bit of an increase in cryoprecipitate use here and that is because, of course, that was -- '84/'85 was the period of time when AIDS was very much in the headlines, and there were various pronouncements from, in fact, 1983, from memory, by UKHCDO saying: oh, not sure about this AIDS risk, and in selected patients, infrequently treated, we should be using cryoprecipitate rather than concentrate. So that was my recollection and, again, I'm a historian here, not a direct observer. That would account, I think, for the increased use of cryoprecipitate.

Q. Could we just look at the top of the page, again, please, Soumik. Sorry, professor, I just want to go back to one observation you made. You suggested -- I think it was probably a surmise rather than your own direct knowledge, but please correct me if I'm wrong -- that the reason why there may be nothing, no

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Could I just say that, because it's a synthetic drug, it took quite a few years, even though it was starting to be used about 1977, for the UKHCDO database to include it and ask for use of DDAVP to be sent in the annual returns. It was probably only 1985, when you have it there 735, that it was, by that time, it was asked for in the annual returns. So it's not that we weren't using it in those years, it's just it doesn't feature in the returns, and that was a policy decision.

But could I say that my memory was that, from 1977 when we published the first infusion we gave with DDAVP, we were very keen to use it in Glasgow Royal Infirmary because, obviously, it spared patients from having blood products. FEIBA I've mentioned and it's used for treatment of patients with inhibitors and that fluctuated from year to year.

But most important, can I just comment on the shifting balance between cryoprecipitate and PFC Factor VIII concentrate. This, obviously, is the majority of patients who have mostly severe or moderate haemophilia A and, as you may know, the SNBTS Protein Fractionation Centre in Edinburgh was increasing its output and it was about 1983 that it approached the UK and Scotland aim of self-sufficiency

34

volumes of usage, of units for DDAVP in 1983/1984 was because annual runs didn't have to include that data. But we do, in fact, see that, for the years from 1979, and we can see above the example for 1982, Glasgow had included that data.

Are you able to say, as a matter of your own knowledge, or help us as a matter of your own knowledge, why we see no usage here recorded for DDAVP in 1983 and 1984?

A. I've no knowledge because, as I think you know, 1983/1984, I wasn't even on the Department of Medicine wards. I was transferred to another unit. But it does surprise me that, you know, it wouldn't have been used and I can't explain why it's not recorded.

SIR BRIAN LANGSTAFF: Two questions: the first is that there is an asterisk against DDAVP in both occasions when there is no entry made.

The second, which you may be able to explain while Ms Richards is looking to see what the answer to that one is, 538 units of DDAVP. Now, the units, this may be an attempt in one column to put a standard measure of comparison as between all these various products. Is it appropriate to regard that as the same sort of unit as the international units of Factor VIII or Factor IX activity used in the other?

36

- 1 A. Well, thank you, Sir Brian. It's completely different
2 because, as a synthetic drug, these, from memory, are
3 micrograms. So it's the micrograms that you are
4 infusing from a vial, having been diluted with saline
5 and given by slow intravenous infusion of about
6 30 minutes. So my guess is, oh, I think it's
7 micrograms but I will probably get into trouble for
8 getting the units wrong. But it's that kind of thing
9 and that is completely different, as you say, to
10 an international unit of Factor VIII or Factor IX,
11 which is what you see in all the blood products.
- 12 **SIR BRIAN LANGSTAFF:** So, although the table may give us
13 a measure of comparison between cryoprecipitate, on
14 the assumption that a bag contains so many units and
15 the calculation, so far as Factor VIII and Factor IX
16 PFC are concerned, and Travenol, for that matter,
17 Hyland Hemofil, it would be wrong to think that
18 because DDAVP, for instance in 1982, is 538, that it
19 shows how little use was made of DDAVP, compared to
20 the others. It's not easy to work it out, is it, from
21 that?
- 22 A. I think, Sir Brian, the most appropriate measure would
23 probably be the number of DDAVP infusions given
24 because it's dependent on the weight of the patient
25 and I'd be more interested in the number of infusions

37

- 1 A. You mean how many years was it recorded that year?
- 2 Q. No. How did you capture -- as the director
3 responsible for the submission of the return to Oxford
4 and then Manchester, how did you capture DDAVP usage,
5 as far as you can recall, in the returns?
- 6 A. I think it was the total number of micrograms infused
7 to all the patients. Sorry, is that what you are
8 asking or --
- 9 Q. Yes.
- 10 A. The haemophilia sister would keep a record in every
11 patients' notes of the dose infused and then she would
12 add them up monthly and give the total number of
13 micrograms given to all the patients, is my
14 recollection, yes.
- 15 Q. Sir, in answer to your question about the asterisk,
16 the asterisk we're told, in relation to each of the
17 tables, means not included in the usage per diagnosis
18 figures, but we don't see it just as an asterisk
19 against DDAVP. For example, in relation to the
20 Edinburgh tables, we see it appearing against factor
21 concentrate. So quite what it means, we probably have
22 to ask Professor Hay or subsequently ask UKHCDO?
- 23 **SIR BRIAN LANGSTAFF:** Well, this is a statistical report
24 prepared for the purposes of the Penrose Inquiry,
25 isn't it?

39

- 1 which would tell me how many patients with mild
2 haemophilia A or mild von Willebrand's disease have
3 been appropriately given a synthetic product, rather
4 than have to use a blood product which, in those
5 years, would probably be cryoprecipitate.
- 6 **SIR BRIAN LANGSTAFF:** It follows that, because you are
7 viewing this as an historian, you can't really help us
8 with anything impressionistic as to the amount at that
9 time, or can you?
- 10 A. I wasn't really involved in the completion of the
11 annual returns of product use at the haemophilia
12 centre until I succeeded Dr Forbes in 1988. 1988 is
13 the first year that the haemophilia sister would
14 complete the forms and I would check them and sign
15 them off. So I never did this before 1988.
- 16 **MS RICHARDS:** If we just go to the next page, because we
17 will see the data for 1988 onwards, we can see, if we
18 just take by way of example, 1988 DDAVP, 1,400.
19 Although it's obviously larger than the earlier years,
20 it would seem as though it may be using the same unit
21 of measurement.
- 22 **SIR BRIAN LANGSTAFF:** Yes.
- 23 **MS RICHARDS:** Can you recall how, in the period of time
24 when you were director, Professor Lowe, DDAVP usage
25 was reflected in the returns?

38

- 1 **MS RICHARDS:** It was and we're making our own
2 investigations.
- 3 **SIR BRIAN LANGSTAFF:** It's really work done by others on
4 the basis of raw material or factual material. This
5 is a comment, in effect, and it doesn't -- on the face
6 of it, it appears to equate the usage of DDAVP in the
7 same sort of basis as the use of concentrates; in
8 others, it just doesn't.
- 9 **MS RICHARDS:** Soumik, that can come down now.
10 Professor Lowe, your statement suggests that,
11 in terms of how products were obtained at the
12 haemophilia centre, they were obtained through what
13 you've described as the Glasgow Royal Infirmary blood
14 bank and blood products laboratory. Can you explain
15 what the difference is? What was the blood product
16 laboratory as opposed to the blood bank at the
17 Royal Infirmary?
- 18 A. So they were both really set up by Dr Davidson in,
19 I think, the early 1970s when he became a consultant
20 haematologist and Dr McDonald said, Right, you're
21 running the blood bank in Glasgow Royal Infirmary. So
22 the blood bank received all the blood and blood
23 products that were produced by the west of Scotland
24 branch of the Scottish National Blood Transfusion
25 Service and that was based initially out of Law

40

Hospital in Lanarkshire and they co-ordinated the preparation of blood, of plasma, of cryoprecipitate, which was prepared locally, and they would obtain from the Protein Fractionation Centre in Edinburgh the concentrates that were made by SNBTS, which was the Factor VIII concentrate and the Factor IX concentrate.

So it was a bit of a journey. Starting with the patient arriving on the ward at the haemophilia centre, and the haemophilia centre would order, and that would usually be the haemophilia sister or the haemophilia registrar. They'd ring up the Glasgow Royal Infirmary blood bank, which was run by Dr Davidson, and usually, of course, they would have a stock of the appropriate product and they would have to order it.

Sorry, they would issue it from stock. They would reconstitute the product and then have the blood porter bring it over to the haemophilia centre, where it would be infused by the haemophilia sister or haemophilia doctor.

They had stocks of the PFC concentrate, which I think had to come from Law Hospital, that's the first stage of the journey. The second stage of the journey is for Dr Davidson to get that on, I think, a weekly basis, generally, from Law Hospital and put

41

laboratory, which would have been at the time we're most concerned with, up to 1996, Dr Davidson. That, at first blush, seems at least a slightly unusual arrangement, that the ultimate decision about what products to be kept and used by the service, or for the purposes of the service's patients, was in the hands of someone other than the primary treating clinician.

- A. I think you are right because, in a haemophilia centre, generally it would be the same consultant haematologist who was assessing and reviewing the patients who was in charge of the blood bank. So he or she would order it from themselves, as it were. But, by law, it has to be an accredited haematologist running -- in charge of a blood bank or blood products laboratory, who is in charge of the stock taking and the issuing. So all the products issued would have to be approved and recorded by a laboratory haematologist.

It couldn't be done by a consultant physician, like my predecessors, and that would be, in order, Dr Douglas, Dr McNicol, Dr Forbes and Dr Prentice, and it couldn't be done by me. So right up to my retirement in 2009 I couldn't order it myself. I had to go through the duty haematologist to request it.

43

it into the blood bank.

Now, a section of the blood bank didn't deal with blood, it dealt with the blood products. I think it was in the same building. That was where Dr Davidson was very meticulous in obviously the stock control, in the making up process and he was very keen, I think, to have a process by which, if a new batch arrived, he would check that the stated dose on that batch in the vial was what it was. You know, he was always very keen, whether it was a commercial concentrate or an NHS concentrate as quality control, to keep an eye on that. So that was the process.

At times of increased demand, I think Dr Davidson was quite busy, because he would say, right, a patient's developed an inhibitor, send us more than we usually need or a patient's having major surgery, I need an extra 50,000 units of Factor VII just to have there to cover that operation. So the demand would fluctuate, so it was a very interactive process.

- Q. Your statement says that you and your predecessors as directors could not make the final choice of and could not order blood products. This, your statement says, could only be done by consultant haematologists in the Royal Infirmary's blood bank and blood products

42

- Q. Your statement might give the impression, and we'll look in a moment at a bit of Professor Forbes' evidence in the Penrose Inquiry which might strengthen that impression, that it's not just a question of the mechanics of the ordering or quality control system but that the actual decisions as to shall we have a Hyland product or a Travenol product, how much SNBTS product shall we keep for use, were not being taken by the primary treating clinician but by Dr Davidson in the lab; is that correct?

- A. It would be a discussion. It would have to be a discussion. So if, say, you have a patient with an inhibitor and it needs an unusual product, one of these products that you need to treat a patient with inhibitors, there would be discussion if a patient, presented to the haemophilia centre, right, we've got an inhibitor patient, this is the situation, you measure the inhibitor, and then we'll have a discussion as to what we think the best treatment would be.

Now, in terms of treatment of patients with inhibitors, I think that the decision would very much be with Dr Davidson and Dr Walker, because they were treating all the patients with acquired inhibitors and they had lots of experience. But it would essentially

44

(11) Pages 41 - 44

1 be a consultation between the clinician and the
2 haematologist. But by law it has to be the
3 haematologist who does the ordering.

4 So I don't think there was ever any problem
5 with it because UKHCDO guidelines were always
6 consulted and they gave a fairly clear guidance as to
7 what were the advantages and disadvantages of
8 different patients having different treatments.

9 **Q.** Yes, you're right, of course, that there were UKHCD
10 guidelines for most if not all, I think, of the time
11 when you were a director, but the guidelines that you
12 may be referring to, which set out the detailed
13 products and the pros and cons of each, I think were
14 first drafted in the second half of the 1980s. So
15 there weren't similar guidelines before.

16 I just want to ask your observation on a piece
17 of Dr Forbes' evidence in relation to this, please.

18 Soumik, it's PRSE0006017.

19 It's an extract from Professor Forbes' evidence
20 to the Penrose Inquiry in April 2011.

21 Soumik, could we go to page 130, please.

22 If we pick it up in the bottom half of the
23 page, at line 17, we can see the question that's put
24 to Professor Forbes:

25 "... can I just ask you about the situation as

45

1 As far as you're aware, from your own knowledge
2 of how the centre and how decision-making worked, at
3 least by the time you became director, is that an
4 accurate description?

5 **A.** So Dr Forbes is talking, I think, at some distance,
6 because he was long retired, and his memory was not
7 very clear, as you probably gathered from the Penrose
8 descriptions. I think there was always a very close
9 collaboration between Dr Forbes and Dr Prentice and
10 the haematologists. After all, the history was that
11 Dr Douglas and Dr McNicol in 1962 agreed to run
12 a joint service, and throughout the 1960s they trained
13 their successors, and their successors in the
14 department of medicine were Dr Forbes and Dr Prentice,
15 and in the department of haematology were Dr Davidson
16 and Dr Walker.

17 So they all knew each other, they all worked
18 together, they all wrote papers together about the
19 development of cryoprecipitate and other products. So
20 they were very, very closely linked, and I think it
21 probably wouldn't have involved much discussion as to
22 what type of product was appropriate for a particular
23 patient.

24 I think what Dr Forbes does refer to, however,
25 is that there were times, particularly for the PFC

47

1 far as the decision-making in relation to acquiring
2 concentrates and prescribing them to patients. Were
3 you responsible for making the decision as to whether
4 to use concentrates? Was that one of your
5 responsibilities?

6 "Answer: I don't think it ever was. The only
7 time that we insisted on a concentrate was where there
8 was major surgery. For all the other situations,
9 which were not as severe that, we were happy to be
10 told what was available."

11 Then the next question:

12 "Right. And as far as what concentrates to use
13 were concerned, was that your responsibility or --

14 "Answer: No, never."

15 Then there's a discussion about it being mostly
16 NHS concentrates, and the answer is at line 8:

17 "Very little of the commercial material was
18 ever purchased, I'm told."

19 Then at line 10 the question is:

20 "And again, that's as a result of being told by
21 others as to what was being used or not being used?"

22 "Answer: Well, we were guided by SNBTS."

23 Then, at line 14:

24 "We were told what they had in store and in
25 stock."

46

1 Factor VIII concentrate, the NHS concentrate, when
2 there was a shortage, and I think that's probably what
3 Dr Forbes was referring to when he's saying it was
4 in stock. So the general preference, for example,
5 might have been to always have NHS concentrate. And
6 Dr Forbes is absolutely right, if somebody's having
7 major surgery, you must have concentrate. You can't
8 rely on cryoprecipitate or plasma. The patient's just
9 going to bleed.

10 But regarding the choice between SNBTS
11 Factor VIII concentrate and a commercial one, I think
12 there were times before SNBTS became self-sufficient
13 when sometimes there was no alternative but to use
14 a commercial source of Factor VIII, because, you know,
15 there was nothing else available. I think if you look
16 at the figures, it's particularly during those years
17 of maybe 1979 to 1983 period -- because '83 was the
18 year that PFC could produce, I think, for just about
19 all the patients in Scotland, an NHS Factor VIII
20 concentrate -- that -- where there's a shortfall, and
21 that was when, occasionally, you had to use
22 a commercial Factor VIII concentrate. I suspect that
23 was what he was referring to.

24 **Q.** The system that you have described, and indeed that
25 Professor Forbes described, taken together with what

48

we see from the statistical report which suggests that a number of different commercial concentrates were used in various years, might suggest that there was no batch dedication system or batch dedication policy in operation, and certainly I don't think I've seen an reference to there being such a policy at the Royal Infirmary. Are you in a position to assist with that?

- A.** So batch dedication I think was a separate issue. From what I understand, the batch dedication system probably started maybe about '83/'84, and that was the distribution within the PFC Factor VIII concentrate. It was produced in batches and I think the arrangement was that it would be useful to reduce donor exposure if, when a batch arrived, you could use it -- you could allocate it to, say, a third of the patients on your books, and then the next batch was the second third, and the next batch was the third third, and that was something like the letters of the alphabet for patients' names, so A to H would get batch 1 and cetera, et cetera.

The idea of that was not about having enough versus commercial concentrate, I think the idea of that was that batch dedication reduced the number of blood donors or plasma donors to whom the individual

49

patients on the same product.

- Q.** You're not aware of any system then of batch dedication prior to the one that you have just described?

- A.** Sorry, no. No, I'm not. I think -- sorry, I think you would have to ask Professor Walker.

- Q.** Could we look then at a document --

SIR BRIAN LANGSTAFF: Are we turning away from this particular issue?

MS RICHARDS: Looking at questions of allocation as between different centres is the next topic, sir.

SIR BRIAN LANGSTAFF: Yes.

Let me just ask you this: your description of how the system worked in the Royal Infirmary was that it depended, to an extent, upon what was in stock in the stores at the GRI; is that right?

- A.** Yes, I think in particular in my time, from memory it was about middle of 1988 when, as you will see well documented in the Penrose Inquiry report, there was a shortfall of manufactured PFC Factor VIII concentrate that affected the whole of Scotland. That was partly due to less being produced and partly because of an increased demand of patient use, being surgery or whatever.

At that time there had to be a decision as to,

51

patient was exposed.

- Q.** Yes, the description you have just given us echoes the evidence that Professor Ludlam gave, and the documents we have seen would suggest that that is late '84 or early '85.

Is it right then to understand that at the Royal Infirmary, first of all, there wasn't, prior to that arrangement, any express policy of keeping a patient, first of all, on the same type of concentrate at all times?

- A.** Well, I think the policy at Glasgow Royal Infirmary haemophilia centre was very much that of UKHCDO as a whole, in that -- or, indeed, international haemophilia care -- changing a product always was undesirable if possible, because if you keep patients on the same product, that was thought to be good haemophilia care. You needed a good reason to change a product. To have to switch from one product to another was, I think, principally a problem because it seemed to increase the risk of inhibitor formation, which was the most dreaded complication of treatment traditionally, that if you switched products around for some reason the immune system in the patient would be triggered to produce inhibitors. I think that was the main reason for trying if possible to keep

50

okay, we're going to have to supplement the PFC concentrate by purchase of the commercial concentrate, and the general policy agreed by the Haemophilia Centre Directors in Scotland is, bearing in mind what I have just been saying, we want to minimise the number of patients switched from one product to another, so we want to limit the number of patients who go on to a commercial virally inactivated product compared to an NHS virally inactivated Factor VIII concentrate, and who should those patients be. So the general decision, and you will see it in the minute of the Scottish haemophilia directors, is that it would be highly desirable to keep children and the infrequently treated patients and patients in the smaller centres, Dundee, Aberdeen and Inverness, keep them going on the NHS product, and then Edinburgh and Glasgow, as the bigger centres, some of whose patients had previously been on commercial concentrates, those will be the patients, the minimum number if possible, that would have to switch for a period of time to the commercial ones. And that's the best way of ensuring that the patients in Scotland with Factor VIII deficiency are kept on the same product.

That's important not only because of a general principle of avoiding inhibitors, it's -- sorry, I

52

1 trying to -- I'm sorry, Sir Brian, getting a little
 2 tired but let me just think for a minute longer.
 3 Yes, in 1988, as you probably know, we were
 4 very keen to set up a previously untreated patient
 5 study or minimally treated patient study, and we
 6 wanted to have the maximum number of patients who had
 7 had little or no treatment available to be invited to
 8 join the study of viral safety of the SNBTS products.
 9 So we wanted very much to not mess things up by
 10 throwing commercial product around at these patients,
 11 because it was very important to monitor the safety of
 12 the virally inactivated SNBTS products.

13 **SIR BRIAN LANGSTAFF:** Suppose that for particular reasons,
 14 if there were any, it had been thought desirable that
 15 the patients at the GRI should have commercial
 16 concentrate in preference to PFC. The effect of what
 17 you're saying, I think, is that wouldn't be feasible
 18 because the SNBTS wouldn't stock the product in the
 19 GRI, and therefore you wouldn't be able to use it and
 20 you had to use what you were given. Am I right?

21 **A.** I don't quite understand. Are you saying that --

22 **SIR BRIAN LANGSTAFF:** I'm exploring the question of the
 23 degree to which the treating consultant had the choice
 24 of product.

25 **A.** Well --

53

1 allocation of PFC Factor VIII between Edinburgh and
 2 Glasgow and we agree that the distribution for the
 3 financial year 1989/90 should be as follows ..."

4 Then it's set out, and then there's further
 5 reference to an agreement with you for a transfer
 6 between Edinburgh and Glasgow, and then it concludes:
 7 "For the time being I should be grateful if you
 8 could arrange for the Factor VIII to be distributed as
 9 above."

10 Now, this would suggest that by 1989 the
 11 question of allocation between different parts of
 12 Scotland of PFC product was largely being determined
 13 by you and Dr Ludlam. Is that correct, is that
 14 a correct reading of this letter?

15 **A.** No, not just the two of us because all decisions would
 16 be made with our fellow directors. So, for example
 17 I would have to discuss this with Dr Gibson at
 18 Yorkhill at the children's centre and Dr Ludlam would
 19 discuss it with his colleagues on the east coast in
 20 Aberdeen, Dundee and Inverness. This, I think, was
 21 a joint agreement. It wasn't just Dr Ludlam and
 22 I agreeing it as a cosy chat between two people. We
 23 had discussed this across Scottish Haemophilia Centre
 24 Directors.

25 So, basically, the commercial concentrate would

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1 **SIR BRIAN LANGSTAFF:** Is it, in other words, deliberate or
 2 accidental that the commercial product was used when
 3 it was, in the GRI?

4 **A.** In the GRI, as I've indicated, when I became
 5 co-director with Dr McDonald and Dr Davidson in the
 6 blood bank, these would always be joint decisions that
 7 we would have to make. They had to order the product
 8 and agree to its use in different patients. So it was
 9 a joint decision. We would have a discussion on what
 10 the policy should be. And everybody was agreed,
 11 I think across Scotland in haemophilia centres, that
 12 we tried to keep as many patients as possible on the
 13 NHS concentrate, particularly the children and the
 14 patients who had had little treatment.

15 The relatively few patients who had to be
 16 transferred to the commercial concentrate would be
 17 patients who had already had a commercial concentrate.
 18 That seemed an equitable way to do it.

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

20 **MS RICHARDS:** Professor, perhaps just one document to look
 21 at before, perhaps, we take a break. It's on
 22 a similar theme. It's SBT0000687_127 please, Soumik.
 23 This is a letter, 16 May 1989, from Dr Ludlam to
 24 Professor Cash and we can see he says in it:
 25 "I have discussed with Gordon Lowe the

54

1 have to be purchased by the two largest centres in
 2 Edinburgh Royal Infirmary and Glasgow Royal Infirmary
 3 and then the division of the financing would then have
 4 to be arranged between Lothian Health Board for
 5 Edinburgh and Greater Glasgow Health Board for Glasgow
 6 with the finance people. So this is talking about
 7 what Haemophilia Centre Directors uniformly across
 8 Scotland want to do and what this would involve with
 9 how do we buy commercial because the commercial has to
 10 come out of the budgets of the two health boards and
 11 they have to agree with that. The details of that
 12 would be negotiated by Dr Davidson in Glasgow Royal
 13 Infirmary, who was in charge of ordering the product,
 14 and with Dr Ludlam in Edinburgh, who would have to
 15 order the commercial product. So this was across the
 16 board.

17 **Q.** You've said you would have spoken to Dr Gibson in
 18 relation to the position at Yorkhill. Do you know --
 19 and, again, it may be you can't answer this because of
 20 your limited involvement at the time -- but do you
 21 know how, prior to you and Dr Gibson respectively
 22 taking over as directors at the Royal Infirmary in
 23 Yorkhill, how the allocation, as between the two
 24 Glasgow services, the two Glasgow centres, was
 25 determined?

56

I ask you that, professor, if I can just explain it, because we have heard from Dr Pettigrew that in the early 1980s Yorkhill would have liked a lot more PFC product, she said, or was her impression, and she suggested that might have been one of the reasons they were using so much commercial, whereas we can see the Royal Infirmary did seem to have a substantial quantity of PFC product available to it at most times.

Do you know anything about how the allocation arrangements between the two Glasgow hospitals worked in the years prior to your directorship?

A. No, I don't, because I wasn't a consultant and I wasn't a co-director.

Sorry, just to finish the Dr Gibson -- just to finish what you had up on the screen, Ms Richards, I think I have recently had correspondence between myself and Dr Gibson discussing this very issue and she's explaining about the problems of having to turn to commercial concentrate on her patients, very understandably, to which I stay sympathetic.

I think this correspondence, from memory, is Dr Gibson writing to the financial directors in Glasgow explaining that, if at all possible, Dr Gibson wants to keep all the children at Yorkhill on the NHS

57

Would that be all right?

A. Thank you, sir.

SIR BRIAN LANGSTAFF: During that period, as in any break, you must not discuss the evidence you have given or anything that you think you may yet be asked to say, with anyone, whoever they are, your wife, anyone else. You can talk about whatever else you like. I look forward to seeing you back at 4.20.

A. Thank you.

(3.33 pm)

(A short break)

(4.20 pm)

SIR BRIAN LANGSTAFF: Professor, if you feel that you need a break at any time just ask, won't you?

A. Thank you, Sir Brian. I will.

Before we start, could I just clarify what we were discussing at the end of the last session? We were discussing my involvement as the clinician in choice of one treatment product over another, and I've stated in my written statement that I would always discuss this with my co-director, initially Dr McDonald, thereafter Dr Walker, and we would both discuss with Dr Davidson, who ran the blood product laboratory and would have to do the ordering, and I would like to just add to that that I cannot recall

59

factor concentrate and, basically, that I was agreeable to saying, well, if somebody has to get commercial in the west of Scotland, I can agree that there's a strong case for that being the adult patients who have previously had commercial concentrate and agreeing with that.

Concerning -- so going back to relationships in previous years between Glasgow Royal Infirmary and Yorkhill, I don't know. I think in the Dr Willoughby period -- I never met Dr Willoughby and I think he certainly communicated particularly with Dr Prentice, who was the haemophilia co-director at the time, about children and adults, but I had no direct knowledge of that. When it came to Dr Hann, again, I think he had a fairly close relationship with Dr Forbes who had become the co-director and I think there's a lot more dialogue between the two but that is really only my impression. I wasn't involved.

MS RICHARDS: Sir, note the time. Would this be a convenient point at which to take a break.

SIR BRIAN LANGSTAFF: Yes. Well, we will take a break for, let's say, about 45 minutes. Would that be long enough for you to have a stretch and a cup of tea?

A. Yes, please.

SIR BRIAN LANGSTAFF: We will come back at 20 past 4.

58

any disagreement between us on choice of one product over another.

MS RICHARDS: Thank you.

Professor Lowe, there are a couple of points in your statement I wanted to ask you about before we leave issues about products and treatment policies.

In your statement at paragraph 8.5.2.7, which is page 21, I can put it up on screen -- it's WITN3496013, please, Soumik -- we can see in the paragraph about six or seven lines down, and you are talking here about the 1970s, you say that:

"Drs Prentice, Forbes, McDonald and Davidson had written protocols for assessment and management, updated regularly, including the type of product and usual calculated dose for each patient (duplicated in the Blood Bank, from which the product had to be requested) ..." et cetera, et cetera.

Can I just ask you to explain a little more about what these written protocols were. Were they patient-specific protocols, individual to each patient, or were they broader protocols for the treatment of different categories of patient?

A. I think there were two separate protocols. So ever junior doctor who was involved on ward 3 with managing patients who came up to the centre, they were all

60

(15) Pages 57 - 60

given -- and these were updated annually, I think -- a written protocol about general assessment and management. So what the doctor had to do, they gave broad advice as to what would be the usual product, for example, a patient with severe haemophilia A, severe haemophilia B, mild, et cetera, and then there was a separate indication in each patient's case record as for that individual patient, what was the type of product currently being issued to the patient and the usual calculated dose and that, again, would be updated in the event of any change of treatment.

This information was duplicated in the blood bank and, as it says in the statement, the junior doctor, or indeed the doctor on the centre, would have to request by telephone that and that the blood bank, they would always check that, yes, that was it, prepare it, and deliver it.

- Q.** So, in principle at least, the patient-specific document should still exist in the patient records, if the records survived from the 1970s?
- A.** Well, it did change over time. So rather than look at the record, I think I said to you that we had, for each patient, a kind of thin folder which gave the diagnosis, the basic details of the patient and on that it would be written at that time what that

61

doctor, the JHO, who was on the ward and probably the first contact with the patient, would have these and then the middle-grade doctors, who would be involved in the cover of the haemophilia centre.

- Q.** We haven't seen these documents, which is why I'm having to ask you about it and I appreciate it's a long time ago, but can you recall if these more general documents would have said anything about the kind of information that should be provided to patients, if a patient with a particular condition is going to be given a particular type of product, would it advise the junior doctor what information might need to be provided by way of pros and cons and risks and benefits to the patient?
- A.** No, it wouldn't go into that level of detail because any change of product would have been, you know, discussed with the patient by the consultant, and that was just recording what that choice was.
- Q.** Then, separate topic but still just picking up on something about products in your statement, if we look at paragraph 8.5.2.3 -- so I think that's two pages earlier, please, Soumik -- last sentence in paragraph 8.5.2.3, towards the bottom of the page, you are talking about work undertaken by Drs Davidson and Walker, and you say:

63

product was. But if the product changed, that would be changed in that folder. There's no point in looking at a stack of case records to find that out. That was written on the patient's -- I think what was called it was a pink folder and that contained a few sheets, summarising the information for the patient and that had to be available at the centre at all times, in case the current case records would have gone off to some other part of the hospital.

- Q.** Would the pink sheet, or whatever document it was, for the individual patient say anything more than "Mr X, currently receiving Factor VIII concentrate PFC, X number of units", or would there be some more detailed description?
- A.** I think it would say the product and the usual dose.
- Q.** Then in terms of the more general document that you described, which might say the kind of treatment that should be provided, say, to a patient with severe haemophilia B, where were those documents kept? You said they were given to the junior doctors but were they actually given to the junior doctors to take away or were they documents that were kept on the centre, on wards 2 and 3, or somewhere else?
- A.** I think they were duplicated and copies given to each of the junior doctors. So, for example, the junior

62

"From 1980, they also investigated the potential use of freeze-dried SNBTS cryoprecipitate with the Centre."

Then if we just go to one further paragraph before I ask you about this, paragraph 17.4 -- page 51, please, Soumik -- towards the bottom of the page, you say:

"... the centre evaluated freeze-dried cryoprecipitate as a smaller-pool alternative treatment to factor concentrates."

Then you say you:

"... recall it was not progressed, because of the risk of severe anaphylactic reactions which precluded home treatment on safety grounds; and as SNBTS prioritised Factor VIII concentrates ... et cetera.

Do you have any direct knowledge yourself of the investigations and work that was being undertaken, I think, in around the early 1980s, into the possibility of producing freeze-dried cryoprecipitate or was this based on materials you have read later?

- A.** This is me just outlining the history of the unit and who was doing what in terms of developments at the time. The paper numbered 17, I have read and I have referenced and it was basically just a first stage

64

1 trial of the product. I think only one infusion was
 2 given to a number of patients and then the recovery of
 3 the product in terms of a rise in Factor VIII level
 4 was evaluated but it never progressed into more formal
 5 clinical trials. It's just outlining its potential
 6 But my impression -- and I think it is
 7 discussed in the Penrose Inquiry about the development
 8 of products -- was this was a product produced by the
 9 West of Scotland branch of SNBTS and they thought it
 10 was a good idea but at the top level of SNBTS it was
 11 decided no, because we're now totally concentrating on
 12 the development of more pure Factor VIII concentrates,
 13 lower risk of reactions, and they were working at that
 14 time, as you know, on viral inactivation by heat
 15 treatment.
 16 **Q.** Just for the benefit of others, the paper you have
 17 referenced -- well, for the benefit of those
 18 listening, I will just briefly put it up on screen.
 19 WITN4035008, please.
 20 We'll just look at the summary at the top of
 21 the page:
 22 "Freeze-dried cryoprecipitate was used in the
 23 treatment of 14 patients with haemophilia A.
 24 The in vivo recovery was 91.2% which is comparable to
 25 that reported from other parts of Europe. The product

65

1 **MS RICHARDS:** Page 51.
 2 **SIR BRIAN LANGSTAFF:** So the suggestion you appear to be
 3 making was that one of the reasons for not going any
 4 further with something which had been begun in 1980 --
 5 and we've seen the conclusion reached on a report in
 6 1983, which suggests that the material from the report
 7 must have been available at least some time prior to
 8 the publication -- that SNBTS was prioritising
 9 Factor VIII concentrates which had a lower risk of
 10 reactions and could be virally inactivated by
 11 heat treatment.
 12 So is it your recollection or is it your view
 13 of the history that SNBTS were working on heat
 14 treatment in 1981/1982?
 15 **A.** Thank you Sir Brian. I think there's a whole volume
 16 of the Penrose Inquiry report which discusses the
 17 aggressive development of these products by SNBTS.
 18 It's very complicated and I think that the
 19 heat treatment progress was progressed in stages.
 20 I have no direct knowledge of that, I was never
 21 involved, and I suggest you could ask SNBTS about the
 22 history of development of --
 23 **SIR BRIAN LANGSTAFF:** Just to find out if you'd any
 24 knowledge of your own as opposed to that which you've
 25 derived from, as it were, third party sources. But

67

1 was efficacious and no adverse effects were reported.
 2 "Freeze-dried cryoprecipitate is the high yield
 3 product of a low technology process and as such may be
 4 of value in reducing any possible shortfall in the
 5 Factor VIII requirements of the haemophilic
 6 population of the UK."
 7 You say in your statement, professor, that you
 8 think that it wasn't taken any further because of the
 9 risk of severe anaphylactic reactions. The
 10 documentation the Inquiry's seen suggests that in fact
 11 the investigation came to a halt because of the
 12 closure of the freeze drying plant at Law Hospital.
 13 Do you yourself have any direct knowledge one way or
 14 another about it?
 15 **A.** No, because I wasn't involved at all in the
 16 development or use of this product. I think the -- as
 17 I say, all I've read is the paper and there's some
 18 discussion in the Penrose Inquiry. That's all I know.
 19 **Q.** I want to move on to ask you about --
 20 **SIR BRIAN LANGSTAFF:** Just before you do, this paper
 21 is 1983. Your understanding is that it was from 1980
 22 that the possibility of freeze-dried concentrates was
 23 being investigated. At what time, looking at what you
 24 say in paragraph 17.4 -- if we can have that back up
 25 please, Soumik -- 3496013.

66

1 thank you very much.
 2 **MS RICHARDS:** We can take the statement down, thank you,
 3 Soumik.
 4 Professor Lowe, I wanted to ask you next about
 5 non-A, non-B hepatitis.
 6 In terms of your familiarising yourself with
 7 keeping up-to-date with information and development
 8 in the medical and scientific world, you have said in
 9 your statement that in the 70s your sources were
 10 literature but also updates from Drs Prentice and
 11 Forbes; is that right?
 12 **A.** That's correct.
 13 **Q.** Typically, what medical literature would you be
 14 reading in the 70s and 80s?
 15 **A.** I think from the 70s it would be the British Medical
 16 Journal, at least from the late 70s I remember
 17 subscribing to that, and then when I became
 18 a lecturer, in 1978, I think that's when I took out my
 19 subscription to The Lancet. So those were the two
 20 main general medical journals that I read.
 21 I would like to add that in 1975, at a time
 22 when Drs Forbes and Prentice suggested I learned a bit
 23 more about haemophilia because it was my turn to come
 24 on the six-monthly slot, they registered me for
 25 a conference in Glasgow. And I think that -- I have

68

(17) Pages 65 - 68

the programme here -- this is the document that may be available to the Inquiry. So it's Royal College of Physicians and Surgeons of Glasgow, 19 September 1975, and it has a reference number of SNB.001.6951. And I remember this meeting very clearly and it does include, I think, one of the early descriptions of non-A, non-B hepatitis. Would you like me to talk about that?

Q. I am slight handicapped in not having the document, professor, so it may be we can arrange for you to provide a copy of that or we can obtain it overnight and perhaps ask you specifically about that document tomorrow.

A. Sorry, could I just say that I think that would be the first date that I heard it discussed, because one of the speakers at this meeting was Dr Craske, whom you know well, who was the UKHCDO Hepatitis Working Party Chairman, I think. He discusses virus hepatitis complicating replacement therapy, and from memory he was reporting on one of the first outbreaks of that following the very early use of concentrate. I remember him saying that it wasn't only hepatitis B, you could get hepatitis from non-A, non-B. And I think that was the first time I heard about that. Obviously that was then -- I think you have a fair

69

A. Well, I have a very clear memory of that because on 1 November 1974, when I joined the unit, I met all the consultants and Dr Forbes took me aside and said, "Right, just to let you know, I'm the consultant on the unit who is on the Education Committee of the Royal College of Physicians and Surgeons of Glasgow". He said, "You've come to the right place because this is the best place for any junior doctor to keep updated" on what we now call continuing medical education. And he said, "Right, you're the registrar in general medicine. I would advise you to join the college, keep up-to-date with all of these programmes, which are more or less weekly going on at the college. There's preparation courses for the MRCB. Now you've just got that, you don't need that. This more about updates on the various specialties within general medicine", and he said, "You should go to all of those that will extend your knowledge of general medicine because this is a unique college, it represents physicians and surgeons and dentists, and there are regular updates on all that a trainee doctor needs to know".

So he said, "Think of the major specialties that your knowledge needs updating on and go to the all". So that was on day 1. Then I think it was

71

voluminous literature, which you have circulated, about the development from about that year.

So I do remember Dr Craske talking about that.

Q. More generally, what was the system, if any, or what were the means by which junior doctors, such as yourself, could in the 1970s and early 1980s receive or obtain information about medical and scientific developments, other than through reading the BMJ or The Lancet or similar periodicals?

A. Well, I had a pretty intensive day at this meeting hearing about all the developments in haemophilia, and the programme which I have in front of me was very detailed. Do you want a summary of what we were to do or do you want to stick to the non-A, non-B hepatitis?

Q. I think I may ask you to go back to that once we've got the document before us because it's easier, but for me to ask questions but for those listening to follow, if we can display the document.

I'm just interested more generally, this conference was obviously one means by which you, as a junior doctor, learnt more. Was attendance at such conferences a regular feature or what were the other ways in which, as a junior at the Glasgow Royal Infirmary in the 1970s and early 1980s, you would keep up-to-date or be provided with information?

70

almost exactly a year later he said, "Oh, here's one on haemophilia, this is one you must go to".

So, firstly, within the Department of Medicine, I've mentioned that we had several specialties that covered a broad range. There was a weekly meeting where people would present patients and talk about developments in their specialties. So that was on the unit level. There were also weekly general meetings in the Royal Infirmary where all the specialties took it in turn to give an update often with a patient demonstration.

So Glasgow Royal Infirmary, and more generally the college in Glasgow for the west of Scotland, was the kind of epicentre of keeping doctors up-to-date and it was very good.

Q. In terms of materials produced either by one of the working parties of UKHCDO, such as the hepatitis working party, or the minutes produced of Reference Centre Directors' meetings, we've heard from other clinicians, other directors, non-Reference Centre Directors, that they weren't routinely disseminated more widely. Can you recall whether in the 1970s or 1980s Dr Forbes, who of course was effectively a Reference Centre Director, did he share with you and your colleagues documents from the reference centre

72

1 meetings or the working party meetings?
 2 **A.** No, I don't think it would be appropriate for them to
 3 disseminate boring 20-minute minutes of meetings.
 4 That was internal debate to try and unify and
 5 co-ordinate haemophilia care, as in any other
 6 specialty.
 7 I think what they were very good at doing was,
 8 after the ward rounds, we would all congregate in the
 9 coffee room and then not only Dr Forbes and
 10 Dr Prentice talking about developments in haemophilia
 11 but all the specialties were represented there and
 12 they would often informally say, oh, you know, the
 13 latest news is, and they would give us an update.
 14 So on an almost daily basis you were getting
 15 new information and then, as I say, when you were
 16 going to do a slot in a particular specialty it would
 17 send you to a meeting at which local, national and
 18 sometimes international speakers would give you the
 19 state of the art. So I think there was a whole
 20 network of continued communication. But in
 21 haemophilia they would, I think, just summarise any
 22 important developments rather than throw minutes at
 23 you.
 24 **Q.** Now in terms of non-A, non-B hepatitis specifically,
 25 you have said in your statement, in part by reference

73

1 hepatitis B was identified, that for every case of
 2 jaundice, you know, maybe, what -- there's maybe two
 3 cases of jaundice, one would be hepatitis B and one
 4 wouldn't be, and that was non-A, non-B. So although
 5 the terminology may have changed, I think the general
 6 feeling was: that there is hepatitis, and not only
 7 hepatitis B.
 8 My recollection is that's what patients were
 9 told: there's a risk of hepatitis. It doesn't matter
 10 if it's B or whatever.
 11 **Q.** Now, you weren't, I know, seeing very many patients
 12 with haemophilia in the period 1978 to 1984, so
 13 I don't know whether non-A, non-B hepatitis as
 14 a discrete issue was in the forefront of your mind at
 15 all, but you have listed in your statement a number of
 16 papers, in particular from the early 1980s through to
 17 1985; you don't mention in that Professor Preston's
 18 1978 Sheffield study which other clinicians have
 19 identified as significant in their developing
 20 knowledge.
 21 Do you know whether you read it at the time and
 22 were aware of it at the time?
 23 **A.** I'm trying to remember what journal it was published
 24 in.
 25 **Q.** The Lancet.

75

1 to what is set out in the Penrose report, that your
 2 understanding was that non-A, non-B hepatitis was -
 3 and I'm talking here about the second half of the 70s,
 4 early 80s -- a chronic but mild condition. Is that
 5 correct? That was your thinking at the time?
 6 **A.** Well, could I say at the start, the unit always talked
 7 about "hepatitis". I think I described to the Penrose
 8 Inquiry, when I first arrived on the haemophilia unit
 9 I thought: there's a big sign on the wall saying
 10 "hepatitis" and it doesn't say "hepatitis B" or
 11 "non-B", it just says "hepatitis". And I think as
 12 medical students we were all taught that. You have,
 13 I think, circulated a 1964 Scottish Home and Health
 14 Department memo to all doctors talking about blood
 15 transfusion, blood products, where they are at the
 16 different centres, including the haemophilia centre
 17 and including the haemophilia products, and it talks
 18 very plainly about the adverse effects. Number one is
 19 the most serious complication, is serum hepatitis, or
 20 jaundice, and that's because the prevalence is thought
 21 to be about 1 in 200 of the general population of
 22 Scotland, and blood donors. So all blood and blood
 23 products are going to carry a risk of hepatitis.
 24 This was before hepatitis B was discovered but
 25 I think it was fairly rapidly realised, once

74

1 **A.** That was 1978?
 2 **Q.** 1978, yes.
 3 **A.** It depends if I took out my subscription in any
 4 particular month in 1978. I think that the first time
 5 I heard about it was, in fact, the second Glasgow
 6 College symposium that Dr Forbes organised, which was
 7 in 1980. I think that was presented and discussed
 8 there. I do have the book.
 9 **Q.** Yes, I'm going to ask you about that next, in fact, so
 10 we can perhaps move straight to that. It's
 11 RLIT0001242, please, Soumik. We can see this is the
 12 publication that arose out of the conference, as I
 13 understand it, "Unresolved problems in Haemophilia"
 14 edited by Dr Forbes and by you. If we go over two
 15 pages, please, Soumik, we can see it's described there
 16 as being "Proceedings of an international symposium
 17 held at the Royal College of Physicians and Surgeons,
 18 Glasgow, September 1980", and then if we go on another
 19 two pages, please, to the list of contents, we can see
 20 liver disease in haemophilia is the first topic of
 21 discussion and a number of papers there referenced.
 22 Then we can see it goes on to discuss therapy for
 23 haemophilia. If we go over the page, a number of
 24 other issues were then discussed at the symposium.
 25 Could we go to the next page, please, Soumik,

76

the foreword, and see what's written here. So this is a foreword which has your name and Dr Forbes' name at the bottom. We can see, picking it up in the third line:

"The purpose of the meeting was to highlight the growing areas of haemophilia care and research as they serve as a model for the study of other disorders. In particular a major section of these proceedings is devoted to the investigation of live disease in haemophilia -- an area which offers unique opportunities for both basic, applied and clinical research."

Then it goes on to set out what the various other sections of this symposium was.

What was your involvement, first of all, in the organisation of this symposium, Professor Lowe?

- A. Well, none at all. This -- 1980 was a complicated year for me and I'll explain. So in February I had a very painful episode of a slipped lumbar disc and required to lie flat on my back for a few months. I then gradually mobilised, had a relapse about April and was referred for surgical laminectomy, which I think was performed about July. My colleagues visited to sympathise with me, including Dr Forbes, and I think it was probably after my operation in

77

- Q. I'm just going to invite you to look with at a few extracts from it, professor, not least because this isn't material that we have looked at in any of the oral hearings so far.

Soumik, if we go on, please, probably four pages. That's it: "Opening remarks".

We can pick up here "Opening remarks", by RNM MacSween, and then we can pick it up in the second and third paragraphs, where it's said in terms:

"It was anticipated that the screening of blood donors for [Hep B] would substantially reduce the incidence of post-transfusion hepatitis. However, this was not the course of events and, while some reduction did occur, post-transfusion hepatitis remained and remains a significant clinical hazard. It is now established that there are other transmissible agents capable of causing post-transfusion hepatitis, and there is good evidence that more than one virus is involved in what has become defined as non-A, non-B hepatitis."

Then it says this:

"Of particular interest has been the discovery that non-A, non-B hepatitis is a hazard in haemophilia patients and, as you will hear this afternoon, has been particularly associated with the use of the

79

August, when I was still having bed rest and convalescence, he brought me round proofs that he had received -- he organised it -- of the papers and he said could you do some proofreading for me because I'm busy organising this symposium, if you could read the proofs and make any proof corrections of technical things, he said this would also be another CME continuing medical education update for you on haemophilia.

So I did that and I read the papers. I didn't attend the meeting, which was, I think, at the end of September, for the very good reason that I was on honeymoon in the Lake District with my wife. So I didn't go to the meeting, and all I did was the pro of correction of the papers. And obviously once the book was published, I think a year later, I read through it and saw the discussion.

I don't recollect being involved in preparation of the foreword and I think it was kind for Dr Forbes to say that I was a co-editor, because I had no role in organising the meeting. I did proofreading of the papers. It was valuable education for me but that was my involvement. Dr Forbes I think was just very kind to us juniors in trying to get them their names on publications.

78

various concentrates with which these patients are now managed. Thus, while the use of these concentrates has represented a major advance in the therapy of haemophilia, it is unfortunate for the patients that this may be accompanied by an increased risk of acute and, possibly, chronic liver disease."

So we have that, and then I think the first paper is a paper by Dr Craske -- if we move on two pages, please, Soumik.

We can see "Epidemiology of Factor VIII and IX associated hepatitis in the UK", and it's Public Health Laboratory, Withington, which is Dr Craske.

We won't look at all of it, obviously, but if we could move on five pages, Soumik, I just want to -- if you go back a page, sorry. The pagination's not very clear on the copy I have. That's it.

So we can see under "Non-A, Non-B Hepatitis", Dr Craske says:

"The acute illness is clinically mild ..."

He refers to the incubation period, saying it's "clinically indistinguishable from hepatitis A and B".

Then if we go two pages further on, please, Soumik, we can see under the heading "Complications" that there's a discussion of non-A, non-B hepatitis

Again, I think, Professor Lowe, talking about

80

the acute stage there, so:

"Most cases of non-A, non-B hepatitis are mild illnesses. Six cases have been reported as 'severe'. Two patients have died in the acute stage[s] ... but there were complicating factors in both instances."

Then he goes on to talk about acute fulminating hepatitis.

Then he turns to consider chronic liver disease.

So if we look at the bottom half of the page please, Soumik.

If we pick it up in the third line, after he says most of the patients are symptomless, he says:

"... a few have clinical features suggestive of chronic liver disease ..."

And then he talks about the ethical problems associated with liver biopsy.

"About 40 patients have undergone biopsy in the UK and approximately 50% of these have histological evidence of chronic persistent hepatitis. Other patients showed evidence of chronic liver disease or cirrhosis."

He talks about the lack of correlation between the histological changes and the degree of disturbance of the serum enzyme levels. The only common factor

81

Factor VIII preparations (96 per cent), but slightly lower in those who had received cryoprecipitate only (80 per cent), untreated patients, if you had normal liver function tests."

I was looking back at the previous publications from the Royal Free Hospital, and I think it was 1976, Dr Levine from Worcester, Massachusetts, and Dr Katharine Dormandy, at the Royal Free Hospital, did a combined study of American and London patients, and in 1976, when only cryoprecipitate was used at the Royal Free, 50 per cent of patients had abnormal liver function tests. So at first the comment that I would like to make is that it would seem that before concentrates appeared in Britain, people were getting non-A, non-B hepatitis just from the use of cryoprecipitate or plasma from relatively small pools.

Then by 1980, at the time of this symposium, that figure has gone up at the Royal Free, from about 50 per cent to 80 per cent in people who received only cryoprecipitate. I think the other paper that I've been looking at recently is one from Morfini and colleagues in 1986 and that was a serial study done in Italy. That was the first study to really look at liver function tests every few weeks following a first treatment, and it went up fairly quickly in those who

83

was regular treatment with Factor VIII. Then he says, two lines further down:

"It seems likely that some patients will develop severe chronic liver disease over the next 10 years."

Professor, I don't know whether you have reread this recently, but would you agree, if you have, that in terms of both what Dr Craske says and what Dr Howard Thomas goes on to say in later papers, one of the themes is that this is going to be something that is potentially going to be highly problematic in years to come for patients. That was one of the key messages of this symposium, was it not?

A. Yes, indeed. And so I have been reading these. Could I maybe ask you to go to page 27 of the book.

Q. Is that the internal pagination that you have there

A. Yes, it is.

Q. Is that Dr Thomas' presentation?

A. That's correct.

Q. I think it is page 33 probably, Soumik.

A. So round about the middle of the first paragraph, I was interested in this sentence -- that's fine:

"The prevalence of abnormalities was similar in patients who had received NHS concentrate only (100 per cent) and those who had received commercial

82

had concentrate but, basically, in patients who had cryoprecipitate, there was 100 per cent risk of elevation. It took a bit longer with cryoprecipitate because you're being exposed to a lower pool.

So I think in terms of the aetiology of this disease, it came to prominence at the time when concentrates were used, but it would seem to me that if you put all this data together, if you have relatively mild haemophilia and are getting only concentrate at fairly long intervals, sooner or later you're going to get hepatitis.

I agree that the evidence from the increasing number of biopsy studies was that the pattern was looking gloomy and I think that Dr Thomas's prediction is correct. There are going to be some patients who, in ten years' time, are going to get the disease. I think the other page I'd just like to use to finish my comments is that there is discussion on what the book says is page 36, so you probably have to add a couple of pages to that.

Q. Yes, try page 42, Soumik.

A. Yes. So just maybe about six lines from the bottom Dr Thomas is saying:

"It is really now a question of how long it takes. Just because we have not seen it in this

84

six-year period, it does not mean that it will not happen. I think the thinking is that it takes ten or 20 years, or even 30 years for these lesions to progress. I think we have to realise that these are young patients, with many years ahead, when we are considering the significance of these lesions."

If you could just go on a couple more lines top of next page:

"Chronic persistent hepatitis in these patients, from what we know of other groups of such patients, has a much better prognosis, and one would not anticipate that they should come to grief from liver disease."

Yes, he is predicting that some patients are going to get liver disease but it is actually going to take quite a long time.

While we're on this page, and I'm sorry to be lengthy, but could I just make one other point, because if we turn to, okay, some of these patients will have got it from plasma or cryoprecipitate, the question now is, amongst the concentrates, is there any different risk from the NHS concentrate or the commercial concentrate? He is saying about line 5:

"The point is that the advantage accrued by volunteer donations is probably eliminated by havin

85

concentrate was never invented and we'd carried on treating patients with plasma or cryoprecipitate, the end result would have been the same.

Now, I think, in terms of practical management, the dilemma for the treaters is, yes, we know there's a problem but what's the alternative? If you want to treat with concentrate, in general terms NHS might be preferred for all kinds of reasons, but it's the size of the pool that's probably going to be the main determinant of people getting this infection and ending up with liver disease from it.

While it may be very sensible, and was the policy, I think, that my colleagues in Glasgow Royal Infirmary, and all the other haemophilia centres in the UK was, if you have mild patients try and get a way for as long as you can with cryoprecipitate or plasma for the haemophilia B patients because, hopefully, it's only a matter of time before you can get viral inactivation of the concentrates.

So, in terms of decisions about choice of product, which I think is something the Inquiry is almost certainly wanting to address, is this -- very sadly, this goes back to that 1964 Scottish Home & Health Department message saying 1 in 200 people has a virus that will give you jaundice and, no

87

to use a large pool."

Then the final sentence of this paragraph:

"The end result of this is that the risk of the large pool NHS concentrate and the commercial concentrate may be similar."

I'm sorry, if you could just go down to the end of the final paragraph:

"The other thing I should perhaps like to say is that there is evidence that a small number of haemophiliacs who have come to post-mortem have evidence of having had chronic liver disease, probably contracted years back from long-term exposure acquired in the years before commercial concentrate was ever thought of, when plasma or cryoprecipitate was used. No-one should take away the idea that commercial concentrate is the sole causative agent. We must assume that the large pool NHS concentrate is equally involved."

So to summarise all that, I think the literature looking back over the late '70s, up until about 1985 was, yes, there's a problem. Is it all due to commercial concentrate? No. If commercial concentrate had never been used and it was NHS concentrate, would the problem still be of the same size? Yes. You could go further back and say, if

86

matter what you get, plasma, cryoprecipitate, concentrate, NHS or commercial, you are going to get it at some time.

So what decision do you make in 1980 about changing the treatment for the majority of patients who have got it because, by this time, we know from the studies, such as the Royal Free, that just about everybody, regardless of their treatment, has abnormal liver function tests.

I think that the discussion, and I'm very sorry I missed it because I was on my honeymoon, between Dr Thomas and Dr Craske on these two pages, is very far-sighted and I think their predictions are correct that, yes, it's going to be a problem and we, I think from memory, were starting to see evidence of liver disease in our patients that the Royal Infirmary by about 1986, from memory.

Our colleagues that I mentioned earlier, Dr Steven and Dr Madhok, did a very systematic review of liver function tests over the first half of the 1980s in our patients, and I think there was about a 60 per cent prevalence of abnormal liver function tests. It couldn't be related to previous treatment, but all patients at this time were carefully examined for any clinical signs of liver

88

disease and none -- none -- had evidence of that, and then I think it was about a year or so after that paper was published that we saw our first patient, who had clinical non-A, non-B hepatitis progressing to cirrhosis, and they probably acquired that in the 1950s from plasma or in the 1960s from cryoprecipitate.

So I think that the prediction was correct. The question is clearly what should haemophilia treaters have done because this evidence is now emerging when most patients with severe haemophilia (a) have stayed alive, because mortality is now approaching that of a non-haemophiliac, unlike in the era of cryoprecipitate and plasma when half of patients died before they were 40 and, secondly, because there were unquestionable benefits from home treatment. In the case of the Glasgow patients, I refer you to the paper I've quoted by Professor Ivana Markova and her colleagues at the Department of Psychology at Stirling University, as she did a prospective study of the psychosocial benefits to both children at Yorkhill Hospital and to the adult patients at Glasgow Royal Infirmary that all of them said it was a life-changing treatment and only concentrates could do that.

89

SIR BRIAN LANGSTAFF: Thank you. My fault in notation.

Yes, I just want to understand what at the bottom of the page, please, what Dr Thomas was saying in the last couple of sentences, full sentences, on the page where he says: "I think the thinking is that it takes ten or 20 years, or even 30 years for these lesions to progress. I think we have to realise that these are young patients, with many years ahead, when we are considering the significance of these lesions."

Trying to unpick that, concentrating not so much upon what caused it but what sort of problem it was, is he recognising there that haemophilia is something which most patients who have it are born with it and, therefore, they are treated fairly early in life?

A. Yes, let me think about this.

SIR BRIAN LANGSTAFF: Therefore, the argument would go on -- I just want to see what it conveyed to you. The point he is making may go on to say: this is really significant because, in particular, they are young, we can expect them to live 10, 20, 30 or even more years. That's what it says to me at the moment but that may be a wrong way of reading it and you will probably know better than I do on this.

91

So, I'm sorry to be lengthy, but I think, yes, I agree with what you are saying, it was a bad disease but the question for the Inquiry is at what time should haemophilia directors have stopped using concentrates, stopped using home treatment and face the possibility that patients might start dying again prematurely of bleeding.

Q. Professor --

SIR BRIAN LANGSTAFF: May I just --

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: I think what counsel was focusing on, although you are right the other issues do arise, but I think what she was focusing on was how serious a disease it was or wasn't and what the knowledge about that was. Now, you have told us you agree it was a bad disease and I take it you are saying it was known to be in 1980. But can I just go back to page 27, that's 0033, Soumik.

No, it wasn't that. It was the page we were talking about the highly problematic in years to come.

MS RICHARDS: It's, I think, sir, page --

SIR BRIAN LANGSTAFF: It's page 36.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: 0042, is it?

MS RICHARDS: Try page 42, Soumik.

90

A. He's saying these are young patients. Yes, the other issue that was raised -- I mean the problem with these biopsy studies, it's a very selected population of patients. Many haemophilia directors, including Dr Forbes in my unit, thought it was unethical to biopsy patients with haemophilia because there had been fatalities and, if you look at the, I think the Alidort paper in 1985, that is basically the largest and best systematic study of all the biopsy studies, or at least all the studies where people collaborated with reviewing the liver biopsy specimens. So it was American and European studies, where biopsy samples were independently examined by expert histopathologists, a panel of them. They looked at what the original pathologist had said and discovered, not unusually for medical investigations reported in different places by different pathologists, that there is inconsistent grading of the severity.

So what they had was the independent adjudication of all the biopsies that were sent to them, which is, from memory, about maybe 90 per cent of all the biopsy studies and they said, right, we'll categorise them not into some subject of pathologist viewpoint but by a panel-agreed series of definitions, and they just said no liver disease, mild liver

92

disease or severe liver disease.

Basically, the situation was that the instance of severe liver disease, cirrhosis or really bad leukaemia, hepatitis, was probably between 12 and 15 per cent. So that's the summary of it. But the you have to consider what is the age of the patient but more importantly how long had they been exposed to the agent.

So what I'm trying to say, Sir Brian, is that there are many factors to consider when you are looking back over ten years of biopsy studies in about 1985 to say, well, what was the general message coming through? The general message is, yes, about something, 12 to 15 per cent of these patients are getting a nasty-looking disease but from what we know about the natural history of progression of cirrhosis from alcohol, or anything else, it's going to be quite some time before they get the disease. Now, that's a good thing initially but I agree with you in saying that for a young person in 10, 20, however many years, there's going to be nasty liver disease.

Sorry, I'm trying to generalise from what we know --

SIR BRIAN LANGSTAFF: I think what my question, if I can just rephrase it, perhaps, it was about what the

93

be bad news, yes.

SIR BRIAN LANGSTAFF: Thank you very much. I'm sorry I interrupted your line of questioning.

MS RICHARDS: Professor, the question I asked you was about what your actual knowledge was at the time and what you said in your statement your knowledge and understanding was. Can I just, before I go back to that question, check this with you. You have made out what might be regarded as a submission or an argument as to why treating clinicians should not be criticised for not taking a different course. You were not at the time we're talking about, as I understand it, and we're talking here the second half of the 1970s, the early part of the 1980s, you were not a clinician taking treatment decisions in relation to what concentrates or products to use for patients with haemophilia, were you?

A. No, I wasn't.

Q. So if we go back to the question of what you knew in 1980, as someone who we know, because your name is on it and you have told us, read this -- you weren't actually at the symposium but you read the papers beforehand, you read the papers in discussion afterwards -- it's clear, isn't it, from what we've looked at, and I haven't taken you further on but I'm

95

information was there to be known in 1980 when this symposium took place, and one way of putting it is that he appears that he may well be saying that it's serious but all the more serious because these patients are young. Is that a fair reading?

A. It is a fair point --

SIR BRIAN LANGSTAFF: No, it's not a point. It's a question of what he means to say.

A. Oh, I see. Right.

SIR BRIAN LANGSTAFF: That's what I think he may well be saying and I just want to have your comment on that if you have one.

A. It strikes me, just reading, because of the Inquiry, all these reports that there was a spectrum of opinion about what the severity is, what the number of patients with severe disease, how long and how long it's going to take but I think Dr Thomas makes a very good point in that, as a hepatologist, most of his patients hitherto had been people who had been drinking for many years and are getting old. The young patients with haemophilia have a much higher life expectancy and I think the point you're making -- well, the interpretation you're looking at here, Sir Brian, is that for a young person this is bad news. It may take years to happen but it is going to

94

anticipating you have read, there's a discussion then presentation by Dr Preston and Dr Triger from Sheffield. Then if we perhaps just pick it up one further section, if we go through to -- it's probably page 60 or so, Soumik. If we go back two pages.

So this is a discussion that follows the presentation by Dr Preston, Dr Triger and Dr Underwood, and we can see this halfway down the second half of the page, Dr Triger says:

"We are dealing with chronic liver disease, in which five to seven years is a very short time ... Ten to 20 years may be a long time, but we have been looking at liver biopsies of children under the age of ten years, and what we are concerned with is what is likely to happen to them when they should be fit, healthy 25-year olds. I was shown in Pittsburgh two horrendous cases of 18 and 21-year olds with large, juicy oesophageal varices, that the physician just hopes he is in Europe when they burst, because he does not know what he will do, I think we are just building up trouble."

Then Dr Thomas says, and these are two hepatologists:

"I think your view is the same. If we draw the analogy to hepatitis B infection, many of these

96

patients are infected at birth, at least in Africa. They do not get problems till the third decade of life. One might reasonably justify an analogy to that sort of infection. As Dr Triger has said, it is in 10 years' time that we shall see the problems. Bearing in mind the proportion of the patients that are infected, or have persistent abnormal liver function tests, anything from 60 to 80 per cent. I will be an enormous problem when it happens."

Now, in light of that -- and there are other references to similar effect from Dr Triger and Dr Preston and Dr Thomas. In light of that, on what basis can you say that it was regarded by you or regarded generally at this time as a mild condition, professor?

A. Well, in my statement -- sorry, which part of my statement are you referring to?

Q. You say in Section 30 of your statement, bottom of page 63, is where it starts, but if we go over the page -- Soumik, if we go back to WITN3496013, and we go to page 64.

In paragraph 30.3, you say that:
 "[Your] recollection of the evolution of [your] understanding parallels ..."
 Essentially what is summarised in the Penrose

97

five-year period."
 The Mannucci liver biopsy paper, 1982, non-progression was the general theme.
 The White study ... I then quote 1982 again:
 "... the frequent exposure to factor VIII concentrates is not accompanied by the development of more severe forms of liver disease."
 The Stevens et al --

SIR BRIAN LANGSTAFF: It does say, to be fair, "for many transfusion-requiring haemophiliacs the frequent exposure", so it means that for others it is. That's how I read it.

A. Okay. Then the Stevens paper and then the Hay paper, 1985, turning the statement from an overstated problem to an understated problem. And then the Aledort study, which I think is the definitive analysis of many of these previous studies.

It took some time before a consensus could be reached on the extent of severe liver disease in all these biopsy studies, and then I think the Penrose Inquiry report, final report:

"Knowledge of AIDS/HIV and Hepatitis C, concludes - 'There was no generally accepted view prior to 1985 that [non-A, non-B] Hepatitis had other than a generally benign prognosis. 1985 was a turning

99

Inquiry preliminary report.

Then if we go to the next page, please, Soumik, paragraph 30.6, bottom of the page, you quote your evidence to the Penrose Inquiry and you say:

'... 'the general feeling was that over that period of time very few patients with haemophilia had developed any clinical liver disease and that there were biopsy studies that showed that the changes in the liver tended to be relatively mild. So it was thought to be a chronic but mild condition' ..."

Then you refer to various pieces of literature over the page which, as we have already discussed, doesn't include Professor Preston's report and obviously doesn't include this symposium.

The question really, Professor Lowe, is: what was the basis for saying in terms, positively, it was a mild condition, in light of precisely the kind of concerns that we see expressed in the symposium?

A. I think -- so if you turn to page 66 of my written statement, the evidence I gave was the report, I think from the UKHCDO, that I think Dr Biggs and then Dr Rizza were reporting five-yearly -- "treatment of haemophilia 1976-1980":

"... it is interesting to note that only two deaths were attributed to hepatitis during the

98

point: this was when information began to emerge that would lead to changing views' ..."

I think this was particularly the Aledort paper which said: well, it's been a bit -- from small studies of biopsies in selected patients, it's a bit uncertain as to what the overall result is, but:
 "... 'From 1985 it became increasingly understood that [non-A, non-B] Hepatitis infection could be associated with serious disease' ..."

So I'm sorry I've not done a systematic review, because I haven't had time to do that, and I've had limited documentation available to me due to Covid lockdown access to papers. But at the time I wrote my written statement in September, this was me trying to give an overview of what the emerging evidence from biopsy studies was.

SIR BRIAN LANGSTAFF: I think, to be fair, you're being too hard on yourself, professor, because this is really a question of what one makes of the various studies and the information that I have as to what people thought at the time.

I understood that what you were saying to me earlier, when you told counsel it that you agreed it was a bad disease, by reference to questions about the 1980s symposium, that that was your personal view a

100

(25) Pages 97 - 100

1 the time. These papers you are referring to I think
2 are probably an attempt to see after the event,
3 perhaps, how the land lies rather than at the time.
4 But let me just ask you, for instance, about
5 the Stevens paper. They quote Aledort in 1981, where
6 he shows the incidence of chronic active hepatitis and
7 cirrhosis was 16 per cent. Just to put that in
8 context, cirrhosis is generally progressive, is it
9 not?

10 A. Yes, it is.

11 **SIR BRIAN LANGSTAFF:** If it goes on progressing, the
12 ultimate conclusion is that there will have to be
13 a liver transplant because continued cirrhosis is not,
14 ultimately, compatible with life. Is that correct?

15 A. Yes.

16 **SIR BRIAN LANGSTAFF:** Here it is saying that there is
17 a 16 per cent chance. That's about 1 in 6, isn't it,
18 people?

19 A. That's correct.

20 **SIR BRIAN LANGSTAFF:** Would you -- what's your watershed?
21 Do you have a threshold as to whether that's serious
22 or not if out of every six people one is suffering
23 from a seriously progressive disease which will end in
24 death or transplant? Presumably you would regard that
25 as serious? But don't let me put words in your mouth.

101

1 That, I think, is all argument, and I am in no
2 position at the moment to conclude the argument one
3 way or the other. I'm just interested into what goes
4 into it in order to be able to determine it properly
5 and fairly in due course, whatever the arguments may
6 be.

7 But your evidence is really -- it helps if it's
8 about what you knew at the time, what you thought at
9 the time, what you heard other people saying at the
10 time. That's what really is of assistance to me. So
11 I'm sorry for that but -- taking time to tell you
12 that.

13 A. I'm sorry, could I just briefly say that I think I did
14 my best in what I think was limited time at the
15 Penrose Inquiry to look at the evidence. And then
16 I quote the final report of the Penrose Inquiry, which
17 had a very detailed look at the evidence, and tried to
18 distil for you what I thought was happening at the
19 time, maybe even in 1980. And then you asked me the
20 question 30.10:

21 "Do you consider that haemophilia doctors prior
22 to circa 1985 adopted an unreasonable and/or
23 over-optimistic view on the long-term risks of NANB
24 hepatitis given the limited information that was
25 available to them at that time?"

103

1 I mean, would you regard that as serious?

2 A. So this really comes about by you asking me the
3 question:

4 "In your oral evidence to the Penrose Inquiry
5 ... you stated ... 'the general perception ... was
6 that very few patients were developing chronic liver
7 disease' ..."

8 In retrospect, it might have been better to say
9 "were developing clinical evidence of chronic liver
10 disease".

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

12 A. So perhaps the Penrose Inquiry I didn't do enough
13 homework in reading.

14 **SIR BRIAN LANGSTAFF:** I really wouldn't blame yourself
15 because -- we, here, can read -- we have our expert
16 group, we can read what the experts tell us and we can
17 read what the papers say. The issue for me will be
18 a mixture of the degree to which a risk that hepatitis
19 non-A, non-B might be caused by therapy, the degree to
20 which that risk was appreciated, and part of that is
21 an appreciation of the severity of the risk as a risk,
22 not, as it seems to me at the moment, but this is
23 a matter for submission, as a matter of conclusion as
24 to whether the risk was properly identified as one or
25 whether it was simply overstated. But there we are

102

1 My answer was:

2 "As I was little involved with haemophilia care
3 between 1978 and 1985, I do not think that I can give
4 an informed opinion on this. It appears from the
5 literature cited above that the long-term risks were
6 evolving."

7 So I think that's in a way what you are trying
8 to ask me. I've looked at the literature of 1980 and
9 it appeared to me at that time, in response to your
10 first question: yes, there was increasing evidence
11 from biopsies that the studies -- there was a lot of
12 room for doubt as to what the extent and severity was.

13 And then I'm now looking back, at your request,
14 to look at this information again.

15 I'll just go back to -- there's two important
16 questions here, Sir Brian. There's, you know, what
17 are we knowing about the evolution of the risks? And,
18 yes, the predictions are gloomy. Against the liver
19 biopsy study information, there was a lack of clinical
20 evidence of liver disease, and that I think must have
21 been, surely, the factor which was influencing my
22 colleagues.

23 So when you ask me the question, do you
24 consider that haemophilia doctors prior to circa 1985
25 adopted an unreasonable and/or overoptimistic view

104

(26) Pages 101 - 104

given the limited information available at the time, I'd say two things: it was limited information. They knew that lots of patients had had abnormal liver function tests but we now know retrospectively that the association of abnormal liver function tests was very misleading. It bore no relationship at all to the severity of the biopsy studies. So it may have been that my predecessors were saying: well, liver function tests have gone down a bit but they're not that bad, you know. We see alcoholics in Glasgow all the time with these and we know it will take years for some of them to develop the disease. But also my predecessors, as haemophilia directors, would have had in mind that, having seen the enormous benefits of concentrates, people were living longer. Perhaps living longer to get cirrhosis but they were living longer. They are not dying of bleeding. There were enormous psychosocial and family benefits from giving concentrates to home treatment.

No matter if a judge says at some point, "Right, it was 1980 you should have stopped treatment", or 1982 or whatever, that is an awful decision for both patients and families and doctors to make. "You're telling me", the patient and parents would say, "do I just not take any blood products ever

105

Haemophilia Centre Directors, had to cope with.

And I'm so glad I wasn't born five years earlier because I don't know what I would have done much.

SIR BRIAN LANGSTAFF: That's very helpful. Thank you very much.

MS RICHARDS: Professor Lowe, the question I was asking you was about your actual knowledge at the time. Before we leave this symposium, is there anything else about the symposium that you wanted to make an observation about? I think I've shown you the passages I wanted to explore with you.

A. The unsolved problems in haemophilia --

Q. Yes.

A. Other than to repeat that I am a bit mortified that Dr Forbes put me down as a co-editor when all I did was alleviate my sore back by reading the proofs. I think it was a great book. And could I say that the first symposium in 1975 was mostly people from Scotland. So that was very useful for people like me. But Dr Forbes I think was the first member of UKHCD to offer to put on a two-day meeting as the annual general meeting of UKHCDO and make it: okay, half day for the business, and let's have a one and a half day symposium in the Glasgow College, which will be published, which will address all the challenges, the

107

because I might get cirrhosis?"

The problem is most of them have already got severe liver disease that's going to progress. And that's -- you know, it may have been overoptimistic, looking through the retrospectoscope, as one tends to do, particularly 40 years on, but, you know, I think the question is: did the haemophilia doctors and their patients at the time make the right decision to carry on looking for the eventuality that viral inactivation of concentrates -- which are the accepted standard of haemophilia treatment care worldwide -- your own expert group on treatment of haemophilia says that, you know.

It was established by the 1980s that the only way to successfully treat the morbidity and the mortality of haemophilia is appropriate provision rapidly, especially to a young person, of something that will prevent them dying of intracranial bleeding or developing crippling arthritis. You know, it's a very difficult decision to make, and it's not surprising that, to my knowledge, hardly any haemophilia directors in Europe or North America said, "Right, I believe that Eric Preston's biopsy paper is terrible and therefore will stop treating patients". That is the difficulty that my predecessors, as

106

unsolved problems of haemophilia care.

That was the first meeting that led to subsequent UKHCDO meetings every year or two having not only a scientific symposium but an open one. It's not just a few boring haemophilia directors; anybody can register, anybody can come -- patients, people in other specialties. I think that was a great institution.

20 years after that, in 2000, Professor Walker and I put on a repeat performance, saying, "Can we celebrate 20 years of these symposiums", which have been a great success in advertising the challenges and inviting debate about which they come.

Q. Professor Lowe, you referred a few moments ago to difficult decisions having to be taken by clinician and patient, and I want to focus on the position of the patient.

Would you accept, as a matter of principle, that it's the responsibility of the clinician to inform his or her patient of the risks of treatment

A. Correct.

Q. It's not the responsibility of the patient to find it out for themselves, whether by reading literature or books or anything like that; they are entitled to be told by their treating doctor what the risks and

108

(27) Pages 105 - 108

benefits are?

A. Yes.

Q. Now, do you know if there are any contemporaneous materials from the second half of the 70s or the first half of the 1980s which show what was discussed by clinicians at the Glasgow Royal Infirmary with patients about the risks of hepatitis and in particular non-A, non-B hepatitis?

A. Well, as I said to the Penrose Inquiry, and repeated here, my first exposure to the haemophilia unit was big signs on the wall saying "hepatitis" that nobody could miss. I think that patients very well knew that there was a risk of getting at least jaundice, which was the initial manifestation of hepatitis. In 1975/1976, when I was assisting with putting up the infusions of the patients, up to four severe haemophiliacs would ring up in the morning saying: can I come up and have my cryo or plasma or whatever. They would come and sit around and then have four packs of cryoprecipitate or whatever put up. While I was doing that, the patients said, "Right, be careful, doctor, don't jab yourself with those needles because we've all had jaundice, you know, and I don't want his jaundice or my jaundice to do that". There was a wide knowledge, at least amongst the frequently

109

you as, again, part of your continuing medical education, we had a very good meeting of the Scottish branch of The Haemophilia Society", and I think that was about March 1980.

So, independently of the UK Haemophilia Society, there was a very active Scottish branch of The Haemophilia Society. It met every six months. He gave me a copy of the minutes of the meeting. And the speaker had been Dr Alistair Parker, who was Dr Ludlam's colleague in 1980, and I think he was treating the patients with haemophilia maybe before or just around the time that Dr Ludlam arrived to join him in Edinburgh, and he is reporting to the Scottish Haemophilia Society that he's just been to spend some time in Seattle, in the United States, where there was a very active investigation of hepatitis of the type which I think is summarised in this Unsolved Problems book that you see there.

He gave the talk solely on the topic of hepatitis to quite a large group of patients from across the different parts of Scotland. Now, I don't know what he said but the whole presentation was called hepatitis and the minutes record that he gave a very full update on the evolving knowledge about hepatitis internationally, and he was thanked

111

attending patients, that jaundice and hepatitis, whatever subtype you want to call it, was a problem.

I remember my patients saying, "Well, he's only had jaundice once I had it the twice, because it's two different ones, you know". I think the general perception was that hepatitis was a risk. I don't recall that in 1975 Dr Forbes and Dr Prentice did anything to -- anything other than to warn patients of the risk repeatedly.

I think it was mentioned in many Haemophilia Society publications, the Bulletin, the Peter Jones booklets which many patients read, Living with Haemophilia, frequent reference to it. For the Penrose Inquiry, you might remember that we had a collective response. We asked, you know, haemophilia directors from all over Scotland from all different eras: have you any collective recollection of what was told? And what information we had we would submit.

Now, I think you have copies of this, and could I direct you particularly to one of the annexes of that collective response. We're talking about -- we're going back to 1980, because on a previous visit to me on my bed of pain, in I think about April 1980, Dr Forbes came round and he said, "Could I just tell

110

profusely for the talk.

At the end of the meeting -- at the end of the minutes of this meeting it says "date of next meeting" and it was -- sorry, this meeting was in Glasgow Royal Infirmary, organised by Dr Forbes. That's why there's a copy of the minutes. The next meeting was to be held in the autumn in Edinburgh Royal Infirmary and the newly appointed Dr Ludlam was going to give a talk on something, and six months after that was Dr Willoughby at Yorkhill. I would guess that in 1981 he would almost certainly talk about the benefits of home treatment to his patients because he had been giving home treatment, as you know, for about a couple of years.

So, certainly in Scotland, I think we have evidence that patients were regularly updated on all the developments in haemophilia and that, I think, is a good example in March 1980 at this time, and you asked me what information was given to patients.

So what I tried to say to you, Ms Richards, is two things: certainly in my brief involvement with haemophilia care in 1975, the risk of jaundice and hepatitis was the talk of the steamie, as we say in Glasgow. People knew about it, they knew about the risks. That didn't stop them wanting to have the

112

(28) Pages 109 - 112

1 treatment.

2 Then in 1980, the patients who come to Scottish
3 Haemophilia Society meetings on a general education
4 programme are told in detail about hepatitis.

5 **Q.** Professor Lowe, my question to you was not about wh at
6 patients might have learnt from talking to each other
7 or what those who read Peter Jones' book, which was
8 published in 1974 and makes no mention of anything
9 other than hepatitis B for obvious reasons, might h ave
10 learned, or what might have been available to patients
11 from other sources, those who attended a particular
12 meeting.

13 My question to you is about what information is
14 there to tell this Inquiry what the advice about
15 non-A, non-B hepatitis and the risks of it that was ,
16 as a matter of fact, provided by clinicians at the
17 Royal Infirmary to their patients.

18 **A.** No, in addition as I think I said in my statement, for
19 this period of time, when I was getting my haemophi lia
20 experience, Dr Forbes or Dr Prentice, whoever was
21 doing the ward round, would come over and see these
22 patients when they came up for treatment and do the
23 reviews, and one of them would take me in from time to
24 time and we would review, which meant, okay, how ar
25 you doing, what's new, any problems since I saw you

113

1 haemophilia doctor or the haemophilia sister, and that
2 was where blood would be taken. I think that was
3 a general warning to patients and staff.

4 **Q.** Would you accept that, whilst no doubt a very sensi ble
5 precaution to have, to put that on the wall, that's
6 not really going to assist individual patients with
7 understanding the risks to them from their treatmen
8 as individuals, to take an informed decision about
9 what treatment they want, is it?

10 **A.** Well, as I've said, the message from my consultants
11 was: what do you think of your treatment, are you
12 happy with it? That would include, I assume, both the
13 benefits and the risks.

14 **Q.** You have referred in your statement, also, to the
15 request forms and laboratory blood samples having
16 yellow dangerous specimen labels on. The purpose o
17 that was to protect staff, however, wasn't it. Tha t's
18 not a means of providing advice to patients to enable
19 them to give informed consent, is it?

20 **A.** It was a request from all of the laboratories.
21 I think it followed the widely publicised hepatitis
22 outbreaks, particularly in Edinburgh, in Scotland i
23 1972. That was the time -- and I think you've seen
24 some of these circulars, you know, take great care in
25 treating patients who have multiple infusions wheth er

115

1 last. In particular, have you had jaundice, have you
2 had hepatitis, and then they would, in the
3 examination, examine the liver and the spleen and
4 discuss the treatment and how happy are you about t he
5 treatments -- and this was long before home
6 treatments, they just come up and had the treatment

7 Hepatitis was not something that was hidden.

8 You know, they are having -- they are being asked
9 about jaundice and hepatitis and that, to me,
10 indicated that the patients were being told by thei
11 consultant physician about the risks. Whether they
12 could -- it was quantified, I don't know, but there
13 was a risk.

14 **Q.** So your own factual knowledge is based upon some
15 consultations that you would have sat in on as part of
16 your training in 1975 --

17 **A.** Yes.

18 **Q.** -- where conversations along the lines you have
19 discussed, at which jaundice and the word "hepatiti s"
20 were mentioned; is that correct?

21 **A.** Correct.

22 **Q.** Now, you have referred to these warnings signs or t he
23 word "hepatitis". What was the purpose of that and
24 where exactly was it displayed?

25 **A.** In the room in which patients came in to speak to t he

114

1 that be in renal transplant units, in liver units, in
2 haemophilia units.

3 Yes, you're right. When I started, Dr Forbes
4 took me aside and would say, "Just to take blood of
5 you, Gordon, and check you out for hepatitis B"
6 because all the staff involved in giving treatment to
7 these patients are told be very careful with dispos al
8 of your needles. As you can see from what I've
9 reported of my conversations with the patients, it
10 was, you know, the four patients sitting there with
11 their drips, "Aye, doctor, you know it's the jaundi ce
12 and don't prick yourself". It was the talk of the
13 steamie, as we say in Glasgow. It was so widely
14 known, at least amongst the regular patients.

15 **Q.** Last question on this topic, professor, at least fo
16 now: was it in the '70s and first part of the '80s, to
17 your knowledge, the practice of the clinicians at the
18 Royal Infirmary to record any discussions they had
19 with patients about the risks of treatment in the
20 patients' notes?

21 **A.** At the reviews -- well, some were done when they we re
22 in-patients, which is the obvious time to do it (they
23 were in anyway, they're are having blood taken
24 anyway). The answer is I can't remember. On ward
25 rounds, these would be teaching ward rounds; the

116

1 consultant is spending some of the time with the
 2 patient talking to him, some of the time talking to
 3 the junior doctors or the students who are
 4 accompanying them, and it's my knowledge that it would
 5 normally be the junior doctor, like me, who would be
 6 writing in the notes "reviewed by" -- sometimes the
 7 consultant would write it themselves and sometimes it
 8 would be the junior doctor who would write down what
 9 was the consultant's view, opinion, or information to
 10 patients.

11 **Q.** Okay.

12 **A.** There wasn't the kind of tick box which you might see
 13 now when people wander round with some kind of smart
 14 thing and tick boxes saying "I have discussed with
 15 patients".

16 **MS RICHARDS:** Sir, I am going to move on to another topic;
 17 so I note the time and wonder whether we should pick
 18 that up tomorrow afternoon.

19 **SIR BRIAN LANGSTAFF:** I am sure Professor Lowe could do
 20 with a break and we will take a break until --
 21 2 o'clock tomorrow, is it?

22 **MS RICHARDS:** Yes.

23 **SIR BRIAN LANGSTAFF:** So 2 o'clock tomorrow, if you
 24 please, doctor. I look forward to -- professor, I'
 25 sorry. I look forward to seeing you again at that

1 time. The same rules apply, of course, about what you
 2 may say or may not say overnight. 2 o'clock tomorrow.

3 **(5.50 pm)**

4 **(Adjourned until 2.00 pm the following day)**

117

118

INDEX

1	PROFESSOR GORDON DOUGLAS OGILVIE	2
2	LOWE, sworn	
3	Questioned by MS RICHARDS	2

119

(31) MS RICHARDS: - age

A	57/10 agent [3] 30/20 86/16 93/8 agents [1] 79/17 aggressive [1] 67/17 ago [2] 63/7 108/14 agree [10] 26/4 54/8 55/2 56/11 58/3 82/7 84/12 90/2 90/15 93/19 agreeable [1] 58/2 agreed [8] 5/21 12/8 25/7 47/11 52/3 54/10 92/24 100/23 agreeing [2] 55/22 58/6 agreement [2] 55/5 55/21 ahead [2] 85/5 91/9 AIDS [3] 35/11 35/13 99/22 AIDS/HIV [1] 99/22 aim [1] 34/25 al [1] 99/8 alcohol [1] 93/17 alcoholics [1] 105/10 Aledort [3] 99/15 100/3 101/5 Alidort [1] 92/8 Alistair [1] 111/9 alive [2] 28/11 89/12 all [82] 1/17 6/11 10/6 10/8 13/14 14/22 22/13 25/9 26/16 27/7 31/8 31/9 31/10 35/1 36/22 37/11 39/7 39/13 40/22 43/17 44/24 45/10 46/8 47/10 47/17 47/17 47/18 48/19 50/7 50/9 50/10 55/15 57/24 57/25 59/1 60/25 62/7 66/15 66/17 66/18 70/11 71/2 71/12 71/17 71/21 71/25 72/9 73/8 73/11 74/12 74/14 74/22 75/15 77/15 77/17 78/14 80/13 84/8 86/19 86/21 87/8 87/14 88/24 89/23 92/9 92/10 92/20 92/22 94/4 94/14 99/19 103/1 105/6 105/10 107/15 107/25 109/23 110/16 110/16 112/16 115/20 116/6 alleviate [1] 107/16 allocate [1] 49/16 allocation [5] 51/10 55/1 55/11 56/23	172/1 73/14 87/22 112/11 along [1] 114/18 alphabet [1] 49/19 already [4] 6/23 54/17 98/12 106/2 also [9] 12/24 17/12 17/25 64/1 68/10 72/8 78/7 105/12 115/14 alternating [1] 6/15 alternative [3] 48/13 64/9 87/6 although [6] 33/3 33/5 37/12 38/19 75/4 90/12 always [17] 4/20 14/14 19/15 19/18 19/23 22/11 23/12 26/15 42/10 45/5 47/8 48/5 50/14 54/6 59/20 61/16 74/6 am [8] 7/18 28/25 53/20 69/9 103/1 107/14 117/16 117/19 America [1] 106/22 American [2] 83/9 92/12 amongst [5] 3/9 25/19 85/21 109/25 116/14 amount [4] 2/24 4/4 30/3 38/8 amounts [1] 30/4 an academic [1] 3/24 an accredited [1] 43/14 an acute [1] 13/5 an adjacent [1] 21/15 an adult [1] 18/13 an agreement [1] 55/5 an analogy [1] 97/3 an area [1] 77/10 an argument [1] 95/9 an enormous [1] 97/9 an historian [1] 38/7 an increase [1] 35/8 an inhibitor [3] 14/2 44/13 44/17 an international [2] 37/10 76/16 an uninterrupted [1] 1/8 an unusual [1] 44/13 an update [2] 72/10 73/13 analogy [2] 96/25 97/3 analysis [1] 99/16 anaphylactic [2] 64/13 66/9	ankles [1] 22/6 annexes [1] 110/21 announced [1] 26/3 annual [7] 24/25 25/13 34/5 34/7 36/2 38/11 107/21 annually [1] 61/1 another [12] 27/25 28/9 31/6 36/12 50/19 52/7 59/19 60/2 66/14 76/18 78/7 117/16 answer [11] 23/21 24/3 36/19 39/15 46/6 46/14 46/16 46/22 56/19 104/1 116/24 answered [1] 6/23 anticipate [1] 85/12 anticipated [1] 79/10 anticipating [1] 96/1 any [44] 7/6 7/12 9/11 10/19 10/20 12/12 16/14 16/17 18/24 24/15 28/15 33/25 45/4 49/5 50/8 51/2 53/14 59/3 59/14 60/1 61/11 63/16 64/17 66/4 66/8 66/13 67/3 67/23 70/4 71/8 73/5 73/21 76/3 78/6 79/3 85/22 88/25 98/7 105/25 106/21 109/3 110/17 113/25 116/18 anybody [2] 108/5 108/6 anyone [2] 59/6 59/6 anything [12] 38/8 57/10 59/5 62/11 63/8 93/17 97/8 107/8 108/24 110/8 110/8 113/8 anyway [2] 116/23 116/24 apart [1] 24/4 appear [2] 31/14 67/2 appeared [2] 83/14 104/9 appearing [2] 32/17 39/20 appears [4] 30/6 40/6 94/3 104/4 appendix [1] 10/24 applied [1] 77/11 apply [2] 1/14 118/1 appointed [2] 3/25 112/8 appointment [1] 5/16 appreciate [1] 63/6 appreciated [1] 102/20 appreciation [1] 102/21 approached [1] 34/25	approaching [1] 89/13 appropriate [9] 10/21 11/9 31/20 36/23 37/22 41/14 47/22 73/2 106/16 appropriately [1] 38/3 approval [1] 5/17 approved [1] 43/18 approving [1] 5/15 approximately [2] 4/2 81/19 April [3] 45/20 77/21 110/24 April 1980 [1] 110/24 April 2011 [1] 45/20 are [97] 1/18 1/23 1/24 1/25 2/6 6/2 6/2 15/13 15/22 15/23 16/22 16/23 17/2 17/5 17/18 17/22 18/2 19/4 19/12 23/2 31/8 31/9 31/10 33/19 36/6 37/2 37/3 37/16 38/6 39/7 43/9 49/7 51/8 52/23 53/21 59/6 60/4 60/10 63/24 71/13 71/20 74/15 74/23 79/16 80/1 81/2 81/13 84/9 84/15 84/16 85/4 85/5 85/14 88/2 88/13 90/2 90/12 90/16 91/8 91/9 91/14 91/15 91/21 92/1 93/10 93/10 93/14 94/5 94/20 96/10 96/14 96/20 96/22 97/1 97/7 97/10 97/17 101/1 101/2 102/25 104/7 104/17 104/18 105/17 106/10 108/24 109/1 109/3 113/4 113/24 114/4 114/8 114/8 115/11 116/7 116/23 117/3 area [3] 10/23 16/23 77/10 areas [1] 77/6 argument [4] 91/18 95/9 103/1 103/2 arguments [1] 103/5 arise [1] 90/12 arose [1] 76/12 around [9] 1/13 3/19 3/21 18/17 50/22 53/10 64/19 109/19 111/12 arrange [3] 10/21 55/8 69/10 arranged [2] 19/13 56/4 arrangement [4] 18/15 43/4 49/13 50/8	arrangements [1] 57/11 arrived [7] 13/6 20/3 27/10 42/8 49/15 74/8 111/12 arriving [1] 41/8 art [1] 73/19 arthritis [6] 21/24 22/2 22/6 22/19 23/8 106/19 as [169] aside [2] 71/3 116/4 ask [31] 1/22 6/2 6/22 7/15 7/21 26/7 33/12 34/4 39/22 39/22 45/16 45/25 51/6 51/13 57/1 59/14 60/5 60/18 63/6 64/5 66/19 67/21 68/4 69/12 70/15 70/17 76/9 82/15 101/4 104/8 104/23 asked [8] 25/24 34/7 59/5 95/4 103/19 110/15 112/19 114/8 asking [3] 39/8 102/2 107/6 aspect [1] 88/22 assessing [2] 22/23 43/11 assessment [3] 22/5 60/13 61/2 assist [6] 3/21 16/18 16/20 30/5 49/7 115/6 assistance [3] 19/23 33/11 103/10 assisted [2] 3/11 4/16 assisting [3] 4/9 24/5 109/15 associated [4] 79/25 80/11 81/17 100/9 association [1] 105/5 assume [2] 86/17 115/12 assumption [1] 37/14 asterisk [4] 36/16 39/15 39/16 39/18 attempt [2] 36/21 101/2 attend [3] 13/16 26/1 78/11 attendance [1] 70/21 attended [2] 27/25 113/11 attending [1] 110/1 attributed [1] 98/25 August [1] 78/1 autumn [1] 112/7 available [12] 26/16 46/10 48/15 53/7 57/8 62/7 67/7 69/2 100/12 103/25 105/1 113/10	avoid [1] 33/25 avoiding [1] 52/25 aware [4] 17/7 47/1 51/2 75/22 away [6] 6/12 25/1 51/8 62/21 86/15 87/15 awful [1] 105/22 Aye [1] 116/11
	B					
	back [27] 10/5 12/9 22/21 28/11 35/22 58/7 58/25 59/8 66/24 70/15 77/20 80/15 83/5 86/12 86/20 86/25 87/23 90/17 93/11 95/7 95/19 96/5 97/20 104/13 104/15 107/16 110/23 bad [8] 30/13 90/2 90/16 93/3 94/24 95/1 100/24 105/10 bag [1] 37/14 Baird [1] 21/15 Baird Street [1] 21/15 balance [2] 31/21 34/19 bank [15] 5/3 40/14 40/16 40/21 40/22 41/12 42/1 42/2 42/25 43/12 43/15 54/6 60/16 61/13 61/15 based [5] 31/21 32/10 40/25 64/21 114/14 basic [4] 27/20 29/2 61/24 77/11 basically [9] 6/9 13/1 14/11 55/25 58/1 64/25 84/1 92/8 93/2 basis [6] 40/4 40/7 41/25 73/14 97/13 98/16 batch [13] 16/6 42/8 42/9 49/4 49/4 49/9 49/10 49/15 49/17 49/18 49/20 49/24 51/2 batches [1] 49/13 be [178] bear [1] 1/9 bearing [2] 52/4 97/6 became [9] 4/17 5/24 21/17 40/19 47/3 48/12 54/4 68/17 100/7 because [85] 1/10 4/8 7/3 7/9 14/4 16/6 17/7 23/21 24/4 26/25 27/14 33/13 33/18 33/19 34/1 34/14 35/3 35/9 36/2 36/10 37/2					

B	33/7 44/8 46/15 46/20 46/21 46/21 49/6 51/22 51/23 55/7 55/12 58/4 61/9 64/18 66/23 76/16 78/18 84/4 100/17 114/8 114/10 believe [1] 106/23 benefit [2] 65/16 65/17 benefits [8] 63/14 89/16 89/22 105/14 105/18 109/1 112/11 115/13 benign [1] 99/25 beside [1] 8/2 best [6] 32/10 44/19 52/21 71/8 92/9 103/14 better [3] 85/11 91/25 102/8 between [39] 2/18 3/13 5/21 6/5 6/15 7/23 8/5 8/8 9/12 11/14 13/21 18/15 19/24 20/8 22/15 24/21 31/21 34/19 36/22 37/13 45/1 47/9 48/10 51/11 55/1 55/6 55/11 55/22 56/4 56/23 57/11 57/17 58/8 58/17 60/1 81/23 88/11 93/4 104/3 beyond [2] 16/18 32/18 big [4] 10/4 28/18 74/9 109/11 bigger [1] 52/17 Biggs [2] 9/23 98/21 biopsies [4] 92/20 96/13 100/5 104/11 biopsy [17] 81/17 81/18 84/13 92/3 92/6 92/9 92/11 92/12 92/22 93/11 98/8 99/2 99/20 100/16 104/19 105/7 106/23 birth [1] 97/1 bit [9] 35/8 41/7 44/2 68/22 84/3 100/4 100/5 105/9 107/14 blame [1] 102/14 bleed [6] 10/19 13/5 14/2 17/18 23/3 48/9 bleeding [15] 3/2 4/6 7/8 9/5 9/14 13/25 14/19 17/9 20/10 22/8 26/10 30/22 90/7 105/17 106/18 bleeds [2] 13/20 23/7 blood [60] 4/24 5/3 5/4 5/12 10/8 10/16	11/10 11/25 12/7 12/17 12/18 12/24 12/25 13/11 13/17 14/16 25/11 33/25 34/15 37/11 38/4 40/13 40/14 40/15 40/16 40/21 40/22 40/22 40/22 40/24 41/2 41/12 41/17 42/1 42/2 42/3 42/3 42/23 42/25 42/25 43/12 43/15 43/15 49/25 54/6 59/23 60/16 61/12 61/15 74/14 74/15 74/22 74/22 74/22 79/10 105/25 115/2 115/15 116/4 116/23 blush [1] 43/3 BMJ [1] 70/8 board [3] 56/4 56/5 56/16 boards [1] 56/10 body [1] 6/25 book [7] 76/8 78/15 82/15 84/19 107/17 111/18 113/7 booklets [1] 110/12 books [2] 49/17 108/24 bore [1] 105/6 boring [2] 73/3 108/5 born [3] 14/1 91/14 107/2 both [14] 4/10 8/15 8/20 16/23 36/16 40/18 59/22 70/16 77/11 81/5 82/8 89/22 105/23 115/12 bottom [9] 45/22 63/23 64/6 77/3 81/10 84/22 91/3 97/18 98/3 Bowie [1] 2/7 box [1] 117/12 boxes [1] 117/14 branch [5] 25/10 40/24 65/9 111/3 111/6 break [8] 54/21 58/20 58/21 59/3 59/11 59/14 117/20 117/20 Brian [9] 1/5 37/1 37/22 53/1 59/15 67/15 93/9 94/24 104/16 brief [2] 2/16 112/21 briefly [4] 6/3 6/6 65/18 103/13 bring [1] 41/18 Britain [2] 22/19 83/14 British [1] 68/15	broad [2] 61/4 72/5 broader [2] 16/22 60/21 broadly [2] 18/10 24/17 brothers [1] 19/5 brought [1] 78/2 budgets [1] 56/10 building [3] 21/17 42/4 96/20 built [1] 8/14 Bulletin [1] 110/11 burst [1] 96/19 business [1] 107/23 busy [2] 42/14 78/5 but [121] buy [1] 56/9 by [94] 2/14 4/8 11/16 11/19 12/25 13/5 13/17 17/15 18/1 19/22 21/25 22/15 22/16 24/9 25/9 26/19 26/21 27/1 30/19 33/21 34/6 35/13 37/5 38/18 40/3 40/18 40/23 41/5 41/12 41/19 42/7 42/24 43/5 43/14 43/18 43/20 43/23 44/8 44/9 45/2 46/20 46/22 47/3 52/2 52/3 53/9 55/10 55/13 56/1 56/12 61/15 63/13 63/17 63/24 65/8 65/14 67/10 67/17 70/5 70/20 72/16 73/25 76/14 76/14 79/7 80/5 80/8 83/17 85/24 85/25 88/6 88/16 89/18 92/13 92/17 92/24 96/2 96/7 97/13 99/6 100/24 102/2 102/19 106/14 107/16 108/15 108/23 108/25 109/5 112/5 113/16 114/10 117/6 119/3 bypassing [1] 31/5	can [83] 1/3 1/5 1/6 1/20 1/24 1/25 6/5 7/5 15/4 15/11 15/25 16/20 17/17 18/3 24/17 25/23 26/9 26/18 29/1 29/8 29/14 29/21 30/2 30/5 32/17 32/19 32/20 33/1 33/4 33/25 34/18 36/4 38/9 38/17 38/23 39/5 40/9 40/14 45/23 45/25 54/24 57/1 57/7 58/3 59/7 60/8 60/9 60/18 63/7 66/24 68/2 69/10 69/11 70/18 72/22 76/10 76/11 76/15 76/19 76/22 77/3 79/7 79/8 80/10 80/17 80/23 87/16 87/18 90/17 91/22 93/24 95/7 96/8 97/13 102/15 102/16 102/16 104/3 108/6 108/6 108/10 109/17 116/8 can't [12] 2/1 7/9 16/3 23/21 23/22 24/15 26/22 36/14 38/7 48/7 56/19 116/24 cannot [2] 7/12 59/25 capable [2] 1/13 79/17 capture [2] 39/2 39/4 card [2] 10/15 11/1 care [17] 3/2 3/9 3/18 8/21 9/13 19/19 20/11 24/17 50/14 50/17 73/5 77/6 104/2 106/11 108/1 112/22 115/24 career [2] 2/16 3/7 careful [2] 109/22 116/7 carefully [1] 88/25 carried [1] 87/1 carrier [1] 27/6 carriers [2] 9/5 27/1 carry [3] 18/23 74/23 106/8 case [13] 16/3 23/1 25/16 26/12 27/24 28/18 58/4 61/7 62/3 62/8 62/8 75/1 89/17 cases [4] 75/3 81/2 81/3 96/17 Cash [1] 54/24 categories [1] 60/22 categorise [1] 92/23 causative [1] 86/16 caused [3] 30/13 91/12 102/19 causing [1] 79/17 celebrate [1] 108/11	cent [23] 2/25 3/1 3/3 3/16 3/17 3/19 4/2 4/3 4/7 82/25 83/1 83/3 83/11 83/19 83/19 84/2 88/22 92/21 93/5 93/14 97/8 101/7 101/17 centre [54] 3/11 4/14 4/19 7/15 7/16 9/21 9/22 10/18 10/20 10/21 11/4 11/11 11/15 12/8 13/10 13/13 14/17 17/3 19/10 21/4 25/8 25/21 26/8 27/8 27/13 28/7 28/19 34/23 38/12 40/12 41/4 41/9 41/9 41/18 43/10 44/16 47/2 50/12 52/4 55/18 55/23 56/7 60/25 61/14 62/7 62/22 63/4 64/3 64/8 72/19 72/20 72/24 72/25 107/1 centres [14] 10/12 27/19 30/23 32/13 33/11 51/11 52/15 52/17 54/11 56/1 56/24 74/16 74/16 87/14 certain [1] 23/5 certainly [6] 49/5 58/11 87/22 112/11 112/15 112/21 cetera [7] 3/10 49/21 49/21 60/17 60/17 61/6 64/16 Chairman [1] 69/18 challenges [2] 107/25 108/12 chance [1] 101/17 change [5] 16/7 50/17 61/11 61/21 63/16 changed [3] 62/1 62/2 75/5 changes [4] 20/15 20/24 81/24 98/8 changing [6] 31/15 32/1 50/14 88/5 89/24 100/2 charge [5] 21/18 43/12 43/15 43/16 56/13 charitable [1] 8/1 chat [1] 55/22 check [5] 38/14 42/8 61/16 95/8 116/5 checked [1] 5/9 child [13] 18/4 18/12 18/23 19/4 19/4 19/22 19/24 19/25 22/23 23/7 23/8 23/17 24/8 child's [1] 22/25
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(33) because... - child's

<p>C</p> <p>children [11] 18/16 19/15 19/18 22/22 24/16 52/13 54/13 57/25 58/13 89/22 96/13</p> <p>children's [2] 19/9 55/18</p> <p>choice [8] 31/20 42/22 48/10 53/23 59/19 60/1 63/18 87/20</p> <p>chronic [14] 74/4 80/6 81/8 81/15 81/20 81/21 82/4 85/9 86/11 96/10 98/10 101/6 102/6 102/9</p> <p>circa [2] 103/22 104/24</p> <p>circulars [1] 115/24</p> <p>circulated [2] 70/1 74/13</p> <p>cirrhosis [9] 81/22 89/5 93/3 93/16 101/7 101/8 101/13 105/16 106/1</p> <p>cited [1] 104/5</p> <p>clarify [1] 59/16</p> <p>clear [8] 7/10 16/10 26/20 45/6 47/7 71/1 80/16 95/24</p> <p>clearly [3] 23/10 69/5 89/9</p> <p>cliff [1] 16/7</p> <p>clinic [11] 4/12 4/13 12/24 12/25 13/11 13/17 14/16 22/4 22/14 24/7 27/25</p> <p>clinical [16] 3/1 3/17 4/3 4/5 6/21 8/21 12/2 65/5 77/11 79/15 81/14 88/25 89/4 98/7 102/9 104/19</p> <p>clinically [2] 80/19 80/21</p> <p>clinician [7] 43/8 44/9 45/1 59/18 95/14 108/15 108/19</p> <p>clinicians [6] 72/20 75/18 95/10 109/6 113/16 116/17</p> <p>close [8] 8/5 9/12 13/21 19/24 20/8 21/19 47/8 58/15</p> <p>closely [4] 20/6 21/23 22/3 47/20</p> <p>closure [1] 66/12</p> <p>clotting [2] 12/18 23/6</p> <p>CME [1] 78/7</p> <p>co [16] 4/10 4/18 4/19 5/8 5/14 5/19 14/22</p>	<p>41/1 54/5 57/14 58/12 58/16 59/21 73/5 78/20 107/15</p> <p>co-director [10] 4/10 4/18 4/19 5/8 5/14 5/19 54/5 58/12 58/16 59/21</p> <p>co-editor [1] 107/15</p> <p>co-ordinate [1] 73/5</p> <p>co-ordinated [2] 14/22 41/1</p> <p>coagulation [2] 9/24 12/7</p> <p>coast [1] 55/19</p> <p>coffee [1] 73/9</p> <p>collaborated [2] 20/6 92/10</p> <p>collaboration [5] 8/5 13/21 21/19 32/13 47/9</p> <p>colleague [1] 111/10</p> <p>colleagues [11] 8/10 13/2 20/17 55/19 72/25 77/23 83/22 87/13 88/18 89/19 104/22</p> <p>collecting [1] 10/6</p> <p>collective [3] 110/15 110/17 110/22</p> <p>college [9] 69/2 71/6 71/12 71/13 71/19 72/13 76/6 76/17 107/24</p> <p>column [1] 36/21</p> <p>combined [1] 83/9</p> <p>come [19] 8/7 14/13 40/9 41/22 56/10 58/25 68/23 71/7 82/12 85/12 86/10 90/20 108/6 108/13 109/18 109/19 113/2 113/21 114/6</p> <p>comes [1] 102/2</p> <p>coming [5] 14/15 19/12 22/21 24/25 93/12</p> <p>comment [4] 34/18 40/5 83/12 94/11</p> <p>comments [1] 84/18</p> <p>commercial [44] 23/19 23/24 24/9 24/12 29/11 29/18 29/19 29/23 30/6 31/8 31/9 32/23 42/10 46/17 48/11 48/14 48/22 49/2 49/23 52/2 52/8 52/18 52/21 53/10 53/15 54/2 54/16 54/17 55/25 56/9 56/9 56/15 57/6 57/20 58/3 58/5 82/25 85/23 86/4 86/13</p>	<p>86/15 86/22 86/22 88/2</p> <p>Committee [1] 71/5</p> <p>common [4] 13/14 17/7 22/7 81/25</p> <p>communicated [1] 58/11</p> <p>communication [1] 73/20</p> <p>company [1] 30/19</p> <p>comparable [1] 65/24</p> <p>compared [2] 37/19 52/9</p> <p>comparison [2] 36/22 37/13</p> <p>compatible [1] 101/14</p> <p>complete [2] 23/9 38/14</p> <p>completely [3] 24/1 37/1 37/9</p> <p>completion [1] 38/10</p> <p>complicated [2] 67/18 77/17</p> <p>complicating [2] 69/19 81/5</p> <p>complication [3] 21/25 50/21 74/19</p> <p>Complications [1] 80/23</p> <p>computerisation [1] 28/15</p> <p>concentrate [59] 20/23 20/25 21/1 24/9 24/12 24/14 25/8 31/7 31/10 34/20 35/6 35/16 39/21 41/6 41/6 41/21 42/11 42/11 46/7 48/1 48/1 48/5 48/7 48/11 48/20 48/22 49/12 49/23 50/10 51/21 52/2 52/2 52/10 53/16 54/13 54/16 54/17 55/25 57/20 58/1 58/6 62/12 69/21 82/24 84/1 84/10 85/22 85/23 86/4 86/5 86/13 86/16 86/17 86/22 86/23 86/24 87/1 87/7 88/2</p> <p>concentrates [37] 10/4 23/20 23/25 29/10 29/11 29/18 29/19 29/24 30/15 31/2 32/16 40/7 41/5 46/2 46/4 46/12 46/16 49/2 52/18 64/10 64/15 65/12 66/22 67/9 80/1 80/2 83/14 84/7 85/21 87/19 89/25 90/5 95/16 99/6 105/15 105/19 106/10</p> <p>concentrating [2]</p>	<p>65/11 91/11</p> <p>concept [1] 30/15</p> <p>concerned [4] 37/16 43/2 46/13 96/14</p> <p>Concerning [1] 58/7</p> <p>concerns [1] 98/18</p> <p>conclude [1] 103/2</p> <p>concludes [2] 55/6 99/23</p> <p>conclusion [3] 67/5 101/12 102/23</p> <p>condition [6] 14/5 22/24 63/10 74/4 97/14 98/17</p> <p>condition' [1] 98/10</p> <p>conference [3] 68/25 70/20 76/12</p> <p>conferences [1] 70/22</p> <p>congenital [1] 9/5</p> <p>congregate [1] 73/8</p> <p>connection [2] 1/8 20/8</p> <p>cons [2] 45/13 63/13</p> <p>conscious [1] 28/22</p> <p>consensus [1] 99/18</p> <p>consent [1] 115/19</p> <p>consider [5] 81/8 93/6 93/10 103/21 104/24</p> <p>considering [2] 85/6 91/10</p> <p>constantly [1] 32/1</p> <p>consultant [20] 4/1 4/9 4/12 5/5 6/19 9/8 13/8 13/17 22/11 40/19 42/24 43/10 43/20 53/23 57/13 63/17 71/4 114/11 117/1 117/7</p> <p>consultant's [1] 117/9</p> <p>consultants [3] 21/13 71/3 115/10</p> <p>consultation [1] 45/1</p> <p>consultations [1] 114/15</p> <p>consulted [1] 45/6</p> <p>contact [2] 10/15 63/2</p> <p>contained [1] 62/5</p> <p>contains [1] 37/14</p> <p>contemporaneous [1] 109/3</p> <p>contents [1] 76/19</p> <p>context [1] 101/8</p> <p>continue [1] 23/24</p> <p>continued [6] 3/24 5/12 12/17 13/12 73/20 101/13</p> <p>continuing [5] 14/13 23/1 71/9 78/8 111/1</p> <p>contracted [1] 86/12</p> <p>contribution [2] 9/10 10/4</p> <p>control [4] 32/12 42/6</p>	<p>42/11 44/5</p> <p>convalescence [1] 78/2</p> <p>convenient [2] 13/16 58/20</p> <p>conversations [2] 114/18 116/9</p> <p>conveyed [1] 91/19</p> <p>cope [1] 107/1</p> <p>copies [2] 62/24 110/20</p> <p>copy [5] 28/5 69/11 80/16 111/8 112/6</p> <p>coronary [1] 3/9</p> <p>correct [23] 2/22 3/5 3/20 4/8 4/19 7/1 18/12 30/7 35/24 44/10 55/13 55/14 68/12 74/5 82/19 84/15 88/13 89/8 101/14 101/19 108/21 114/20 114/21</p> <p>correction [1] 78/15</p> <p>corrections [1] 78/6</p> <p>correlation [1] 81/23</p> <p>correspondence [3] 11/14 57/17 57/22</p> <p>cost [1] 31/22</p> <p>cosy [1] 55/22</p> <p>could [56] 5/20 11/3 11/5 11/7 11/8 11/13 12/12 14/24 15/4 25/9 25/15 26/13 27/17 28/13 29/5 30/1 32/11 33/12 34/1 34/11 35/20 42/22 42/22 42/24 45/21 48/18 49/15 49/16 51/7 55/8 59/16 67/10 67/21 69/14 69/23 70/6 74/6 76/25 78/4 78/5 80/14 82/14 85/7 85/18 86/6 86/25 89/25 99/18 100/9 103/13 107/17 109/12 110/20 110/25 114/12 117/19</p> <p>couldn't [4] 43/20 43/23 43/24 88/23</p> <p>Council [1] 10/11</p> <p>counsel [4] 2/6 2/7 90/11 100/23</p> <p>count [1] 27/10</p> <p>country [1] 9/22</p> <p>couple [6] 18/14 60/4 112/13</p> <p>course [14] 2/8 3/24 10/3 12/22 18/22 25/7 35/10 41/13 45/9 72/23 79/13 95/11 103/5 118/1</p> <p>courses [1] 71/14</p>	<p>cover [3] 15/25 42/18 63/4</p> <p>coverage [1] 4/12</p> <p>covered [1] 72/5</p> <p>Covid [2] 1/14 100/12</p> <p>Craske [7] 69/16 70/3 80/8 80/12 80/18 82/8 88/12</p> <p>crippled [1] 23/8</p> <p>crippling [2] 21/25 106/19</p> <p>criticised [1] 95/10</p> <p>cryo [1] 109/18</p> <p>cryoprecipitate [37] 25/7 29/9 29/15 29/22 30/3 32/21 33/2 34/19 35/2 35/3 35/9 35/15 35/19 37/13 38/5 41/2 47/19 48/8 64/2 64/9 64/20 65/22 66/2 83/2 83/10 83/16 83/20 84/2 84/3 85/20 86/14 87/2 87/16 88/1 89/7 89/14 109/20</p> <p>cup [1] 58/23</p> <p>cupboard [3] 27/13 28/8 28/13</p> <p>curable [1] 14/5</p> <p>current [5] 21/1 21/1 22/24 27/16 62/8</p> <p>currently [2] 61/9 62/12</p> <hr/> <p>D</p> <p>daily [1] 73/14</p> <p>dangerous [3] 26/2 26/5 115/16</p> <p>data [6] 16/17 29/2 36/2 36/5 38/17 84/8</p> <p>database [1] 34/4</p> <p>date [6] 68/7 69/15 70/25 71/12 72/14 112/3</p> <p>dates [1] 7/25</p> <p>daunting [1] 32/8</p> <p>Davidson [20] 5/3 5/10 9/9 13/12 14/3 31/19 40/18 41/13 41/24 42/5 42/14 43/2 44/9 44/23 47/15 54/5 56/12 59/23 60/12 63/24</p> <p>Davis [3] 9/16 10/6 11/18</p> <p>day [10] 10/9 12/13 18/5 25/4 70/10 71/25 107/21 107/22 107/23 118/4</p> <p>days [3] 18/15 20/17 33/16</p> <p>DDAVP [18] 32/17 33/5 33/18 33/20 34/4</p>
---	--	---	--	--	---

D	21/21 27/3 27/15 36/11 47/14 47/15 72/3 74/14 87/24 89/20 departments [6] 11/21 13/22 14/21 20/9 21/13 26/19 depend [2] 18/9 19/3 depended [1] 51/15 dependent [2] 19/1 37/24 depends [1] 76/3 derived [1] 67/25 describe [2] 1/10 1/24 described [8] 28/5 40/13 48/24 48/25 51/4 62/17 74/7 76/15 description [4] 47/4 50/2 51/13 62/14 descriptions [2] 47/8 69/6 desirable [2] 52/13 53/14 destroy [3] 27/4 27/16 28/20 destroyed [3] 26/18 26/24 28/14 detail [4] 7/19 22/14 63/15 113/4 detailed [8] 7/17 8/8 22/5 22/18 45/12 62/14 70/13 103/17 details [4] 10/15 27/20 56/11 61/24 determinant [1] 87/10 determine [1] 103/4 determined [2] 55/12 56/25 develop [2] 82/4 105/12 developed [4] 9/3 14/1 42/15 98/7 developing [6] 11/20 22/6 75/19 102/6 102/9 106/19 development [9] 21/11 47/19 65/7 65/12 66/16 67/17 67/22 70/2 99/6 developments [8] 64/23 68/7 70/8 70/11 72/7 73/10 73/22 112/17 devoted [1] 77/9 diagnosis [3] 17/21 39/17 61/24 diagnostic [1] 12/21 diagram [1] 10/24 dialogue [1] 58/17 did [23] 5/19 7/13 9/11 10/9 22/18 27/19 38/15 39/2 39/4 57/7	61/21 72/24 78/10 78/14 78/21 79/14 83/8 88/19 89/21 103/13 106/7 107/15 110/7 didn't [10] 13/4 17/10 18/24 30/25 36/2 42/2 78/10 78/14 102/12 112/25 died [4] 17/8 27/12 81/4 89/15 dies [1] 27/2 difference [2] 15/23 40/15 different [26] 2/24 9/24 10/2 15/22 20/24 29/11 29/19 29/23 33/20 37/1 37/9 45/8 45/8 49/2 51/11 54/8 55/11 60/22 74/16 85/22 92/17 92/17 95/11 110/5 110/17 111/21 difficult [3] 30/11 106/20 108/15 difficulty [1] 106/25 dilemma [1] 87/5 diluted [1] 37/4 direct [8] 24/25 35/17 35/24 58/13 64/17 66/13 67/20 110/21 director [20] 4/10 4/18 4/19 5/8 5/14 5/16 5/19 19/2 19/9 28/16 38/24 39/2 45/11 47/3 54/5 57/14 58/12 58/16 59/21 72/24 directors [18] 24/24 42/22 52/4 52/12 55/16 55/24 56/7 56/22 57/23 72/20 72/21 90/4 92/4 105/13 106/22 107/1 108/5 110/16 Directors' [1] 72/19 directorship [3] 4/13 4/15 57/12 disabling [1] 21/25 disadvantages [2] 35/4 45/7 disagreement [1] 60/1 disappear [1] 31/15 disc [1] 77/19 discovered [2] 74/24 92/15 discovery [1] 79/22 discrete [1] 75/14 discuss [8] 25/22 55/17 55/19 59/4 59/21 59/23 76/22	114/4 discussed [12] 20/16 54/25 55/23 63/17 65/7 69/15 76/7 76/24 98/12 109/5 114/19 117/14 discusses [2] 67/16 69/18 discussing [3] 57/18 59/17 59/18 discussion [19] 19/10 25/13 33/14 44/11 44/12 44/15 44/19 46/15 47/21 54/9 66/18 76/21 78/17 80/24 84/18 88/10 95/23 96/1 96/6 discussions [1] 116/18 disease [46] 7/12 13/4 15/8 17/10 17/25 20/7 20/8 21/9 33/24 38/2 76/20 77/10 80/6 81/9 81/15 81/21 82/4 84/6 84/16 85/13 85/15 86/11 87/11 88/16 89/1 90/2 90/14 90/16 92/25 93/1 93/1 93/3 93/15 93/18 93/21 94/16 96/10 98/7 99/7 99/19 100/24 101/23 102/10 104/20 105/12 106/3 disease' [2] 100/9 102/7 diseases [1] 10/2 disorder [4] 3/2 10/18 20/10 26/10 disorders [7] 4/6 7/8 9/5 9/14 14/19 26/21 77/8 display [1] 70/18 displayed [1] 114/24 disposal [1] 116/7 disseminate [1] 73/3 disseminated [1] 72/21 distance [2] 25/4 47/5 distil [1] 103/18 distinct [1] 10/2 distributed [1] 55/8 distribution [3] 33/14 49/12 55/2 District [1] 78/13 disturbance [1] 81/24 diverse [1] 10/22 divide [1] 18/4 division [2] 3/15 56/3 do [48] 3/6 16/20 16/21 19/6 19/12 19/14 28/14 28/19 32/4 36/3 54/18 56/8	56/9 56/18 56/20 57/10 59/24 61/3 64/17 66/13 66/20 70/3 70/13 70/14 73/16 75/21 76/8 78/4 88/4 89/25 90/12 91/25 96/20 97/2 100/11 101/21 102/12 103/21 104/3 104/23 105/25 106/6 109/3 109/24 113/22 115/11 116/22 117/19 doctor [18] 24/5 41/20 60/24 61/3 61/14 61/14 63/1 63/12 70/21 71/8 71/21 108/25 109/22 115/1 116/11 117/5 117/8 117/24 doctors [15] 6/17 12/13 21/7 62/20 62/21 62/25 63/3 70/5 72/14 74/14 103/21 104/24 105/23 106/7 117/3 document [11] 1/20 51/7 54/20 61/19 62/10 62/16 69/1 69/9 69/12 70/16 70/18 documentation [2] 66/10 100/12 documented [1] 51/19 documents [6] 50/3 62/19 62/22 63/5 63/8 72/25 does [7] 36/13 45/3 47/24 69/5 85/1 96/19 99/9 doesn't [7] 34/9 40/5 40/8 74/10 75/9 98/13 98/14 doing [8] 6/17 12/19 22/5 64/23 73/7 109/21 113/21 113/25 don't [27] 1/9 1/14 16/16 16/17 24/3 24/6 39/18 45/4 46/6 49/5 53/21 57/13 58/9 71/15 73/2 75/13 75/17 78/18 82/6 101/25 107/3 109/22 109/23 110/6 111/21 114/12 116/12 donations [1] 85/25 done [11] 12/6 22/15 40/3 42/24 43/20 43/23 83/22 89/10 100/10 107/3 116/21 donor [1] 49/14 donors [4] 49/25 49/25 74/22 79/11	Dormandy [1] 83/8 dose [5] 39/11 42/8 60/15 61/10 62/15 doubt [2] 104/12 115/4 DOUGLAS [10] 2/13 4/21 9/15 9/15 9/20 12/19 12/25 43/22 47/11 119/2 Douglas [1] 13/6 down [14] 8/4 9/20 18/3 29/25 32/18 40/9 60/10 68/2 82/2 86/6 96/8 105/9 107/15 117/8 Dr [163] Dr Alistair Parker [1] 111/9 Dr Biggs [1] 98/21 Dr Craske [7] 69/16 70/3 80/8 80/12 80/18 82/8 88/12 Dr Davidson [17] 5/10 9/9 13/12 14/3 31/19 40/18 41/13 41/24 42/5 42/14 43/2 44/9 44/23 47/15 54/5 56/12 59/23 Dr Douglas [5] 9/15 9/20 12/19 43/22 47/11 Dr Douglas' [1] 13/6 Dr Forbes [35] 4/9 4/14 4/22 5/19 13/7 21/7 21/19 24/5 31/1 31/17 38/12 43/22 47/5 47/9 47/14 47/24 48/3 48/6 58/15 71/3 72/23 73/9 76/6 76/14 77/24 78/19 78/23 92/5 107/15 107/20 110/7 110/25 112/5 113/20 116/3 Dr Forbes' [2] 45/17 77/2 Dr Gibson [7] 55/17 56/17 56/21 57/15 57/18 57/23 57/24 Dr Hann [2] 18/14 58/14 Dr Howard [1] 82/9 Dr John [1] 5/3 Dr Katharine Dormandy [1] 83/8 Dr Levine [1] 83/7 Dr Ludlam [7] 54/23 55/13 55/18 55/21 56/14 111/12 112/8 Dr Ludlam's [1] 111/10 Dr Macfarlane [1] 11/19
----------	--	--	--	---	---

D	51/22 86/21 100/12 103/5 duly [1] 12/4 Dundee [3] 6/16 52/15 55/20 duplicated [3] 60/15 61/12 62/24 during [6] 7/5 9/6 16/9 48/16 59/3 98/25 duty [1] 43/25 dying [3] 90/6 105/17 106/18	emergency [1] 25/17 emerging [2] 89/11 100/15 enable [1] 115/18 end [12] 2/8 4/15 4/17 16/7 59/17 78/11 86/3 86/6 87/3 101/23 112/2 112/2 ending [2] 10/3 87/11 endocrinologists [1] 21/8 endocrinology [1] 20/5 enormous [3] 97/9 105/14 105/18 enough [4] 35/1 49/22 58/23 102/12 ensuring [1] 52/21 entirely [1] 16/10 entitled [1] 108/24 entrance [1] 12/11 entry [1] 36/17 enzyme [1] 81/25 epicentre [1] 72/14 Epidemiology [1] 80/10 episode [1] 77/19 equally [1] 86/17 equate [1] 40/6 equitable [1] 54/18 equivalent [2] 6/8 6/14 era [1] 89/14 eras [1] 110/17 eras: have [1] 110/17 Eric [1] 106/23 Eric Preston's [1] 106/23 especially [1] 106/17 essential [1] 28/1 essentially [3] 31/6 44/25 97/25 established [2] 79/16 106/14 estimated [1] 4/4 et [8] 3/10 49/21 49/21 60/17 60/17 61/6 64/16 99/8 et cetera [7] 3/10 49/21 49/21 60/17 60/17 61/6 64/16 ethical [1] 81/16 Europe [3] 65/25 96/19 106/22 European [1] 92/12 evaluated [2] 64/8 65/4 even [6] 34/2 36/11 85/3 91/7 91/22 103/19 event [2] 61/11 101/2 events [1] 79/13	eventuality [1] 106/9 ever [7] 16/9 22/19 45/4 46/6 46/18 86/13 105/25 every [12] 7/2 10/14 16/8 26/12 28/18 39/10 60/23 75/1 83/24 101/22 108/3 111/7 everybody [2] 54/10 88/8 evidence [27] 18/6 32/10 44/3 45/17 45/19 50/3 59/4 79/18 81/20 81/21 84/12 86/9 86/11 88/15 89/1 89/10 98/4 98/20 100/15 102/4 102/9 103/7 103/15 103/17 104/10 104/20 112/16 evidence-based [1] 32/10 evolution [2] 97/23 104/17 evolving [2] 104/6 111/24 exactly [2] 72/1 114/24 examination [1] 114/3 examine [1] 114/3 examined [2] 88/25 92/13 example [11] 19/5 20/3 29/8 36/4 38/18 39/19 48/4 55/16 61/5 62/25 112/18 except [1] 1/17 exclusively [1] 23/19 exist [1] 61/19 existent [1] 28/24 expect [1] 91/22 expectancy [1] 94/22 expected [1] 3/6 experience [3] 18/9 44/25 113/20 experimental [3] 6/5 6/13 6/20 expert [3] 92/13 102/15 106/12 experts [1] 102/16 explain [6] 36/14 36/18 40/14 57/2 60/18 77/18 explaining [2] 57/19 57/24 explore [1] 107/11 exploring [1] 53/22 exposed [3] 50/1 84/4 93/7 exposure [5] 49/14 86/12 99/5 99/11 109/10	express [1] 50/8 expressed [1] 98/18 extend [1] 71/18 extent [3] 51/15 99/19 104/12 extra [1] 42/17 extract [1] 45/19 extracts [1] 79/2 eye [1] 42/12	F face [2] 16/7 40/5 faced [1] 90/5 facilities [2] 7/21 12/9 fact [7] 33/6 35/12 36/3 66/10 76/5 76/9 113/16 factor [69] 9/25 10/1 10/3 10/3 10/10 10/10 12/22 13/25 15/7 15/14 15/19 23/6 24/13 29/10 29/16 29/16 29/23 30/4 30/7 30/10 30/12 30/15 30/16 30/24 31/2 31/5 31/6 31/10 31/24 31/25 32/23 33/22 33/23 34/20 36/25 36/25 37/10 37/10 37/15 37/15 39/20 41/6 41/6 42/17 48/1 48/11 48/14 48/19 48/22 49/12 51/20 52/9 52/22 55/1 55/8 58/1 62/12 64/10 64/15 65/3 65/12 66/5 67/9 80/10 81/25 82/1 83/1 99/5 104/21 Factor IX [14] 10/1 10/3 10/10 30/7 30/15 30/16 31/2 31/6 31/10 31/24 31/25 36/25 37/10 41/6 factor VIII [42] 9/25 10/3 10/10 13/25 15/7 15/14 15/19 29/16 29/16 29/23 30/4 30/10 30/12 31/5 32/23 33/22 34/20 36/25 37/10 37/15 37/15 41/6 42/17 48/1 48/11 48/14 48/19 49/12 51/20 52/9 52/22 55/1 55/8 62/12 64/15 65/3 65/12 66/5 67/9 82/1 83/1 99/5 factors [4] 12/19 18/10 81/5 93/10 factual [2] 40/4 114/14 faculty [1] 8/9 fair [4] 94/5 94/6 99/9	100/17 fairly [8] 45/6 58/15 69/25 74/25 83/25 84/10 91/15 103/5 familial [1] 20/7 familiarising [1] 68/6 families [2] 10/7 105/23 family [3] 10/8 27/21 105/18 far [13] 19/19 20/13 21/25 25/1 26/8 28/12 37/15 39/5 46/1 46/12 47/1 79/4 88/13 far-sighted [1] 88/13 fatalities [1] 92/7 fault [1] 91/1 feasible [1] 53/17 feature [2] 34/9 70/22 features [1] 81/14 February [1] 77/18 feel [2] 19/12 59/13 feeling [2] 75/6 98/5 feet [1] 26/14 FEIBA [4] 31/4 31/7 33/18 34/15 fellow [1] 55/16 female [2] 15/18 27/1 females [2] 15/7 15/13 few [12] 33/16 34/2 54/15 62/5 77/20 79/1 81/14 83/24 98/6 102/6 108/5 108/14 figure [1] 83/18 figures [5] 15/21 16/21 32/20 39/18 48/16 files [1] 28/6 filing [3] 27/9 27/11 28/6 final [5] 42/22 86/2 86/7 99/21 103/16 finance [1] 56/6 financial [2] 55/3 57/23 financing [1] 56/3 find [3] 62/3 67/23 108/22 findings [3] 6/11 7/6 7/13 fine [1] 82/22 finish [3] 57/15 57/16 84/17 finished [1] 16/5 first [38] 2/12 19/7 20/19 21/10 29/15 32/18 33/17 34/12 36/15 38/13 41/23 43/3 45/14 50/7 50/9 63/2 64/25 69/15 69/20 69/24 74/8 76/4
----------	---	--	---	---	---	---

F first... [16] 76/20 77/15 80/7 82/21 83/12 83/23 83/24 88/20 89/3 104/10 107/18 107/20 108/2 109/4 109/10 116/16 firstly [2] 17/6 72/3 fit [1] 96/15 five [9] 15/13 15/25 16/6 16/7 80/14 96/11 98/22 99/1 107/2 five years [1] 107/2 five-year [3] 16/6 16/7 99/1 five-yearly [1] 98/22 flat [1] 77/20 Fleetbank [1] 1/12 fluctuate [1] 42/19 fluctuated [1] 34/17 focus [1] 108/16 focusing [2] 90/11 90/13 folder [4] 27/18 61/23 62/2 62/5 follow [1] 70/18 followed [1] 115/21 following [3] 69/21 83/24 118/4 follows [3] 38/6 55/3 96/6 Forbes [40] 4/9 4/14 4/22 5/19 13/7 21/7 21/19 24/5 31/1 31/17 38/12 43/22 45/24 47/5 47/9 47/14 47/24 48/3 48/6 48/25 58/15 60/12 68/11 68/22 71/3 72/23 73/9 76/6 76/14 77/24 78/19 78/23 92/5 107/15 107/20 110/7 110/25 112/5 113/20 116/3 Forbes' [4] 44/2 45/17 45/19 77/2 forefront [1] 75/14 foreword [3] 77/1 77/2 78/19 form [1] 5/17 formal [1] 65/4 formation [1] 50/20 forms [3] 38/14 99/7 115/15 forward [3] 59/8 117/24 117/25 found [1] 17/18 four [4] 79/5 109/16 109/19 116/10 Fractionation [2] 34/23 41/4 Free [5] 83/6 83/8	83/11 83/18 88/7 freeze [7] 64/2 64/8 64/20 65/22 66/2 66/12 66/22 freeze-dried [6] 64/2 64/8 64/20 65/22 66/2 66/22 frequent [3] 99/5 99/10 110/13 frequently [1] 109/25 fresh [1] 24/2 from [130] front [2] 28/17 70/12 full [3] 1/13 91/4 111/24 fulminating [1] 81/6 function [12] 6/25 22/9 83/4 83/12 83/24 88/9 88/20 88/23 97/8 105/4 105/5 105/9 further [10] 29/25 55/4 64/4 66/8 67/4 80/22 82/2 86/25 95/25 96/4 FVIII [1] 29/13 G gathered [2] 21/24 47/7 gave [10] 6/18 34/12 45/6 50/3 61/3 61/23 98/20 111/8 111/19 111/23 general [35] 2/20 3/1 3/8 10/16 11/1 11/1 24/15 25/5 25/10 26/21 27/7 48/4 52/3 52/11 52/24 61/2 62/16 63/8 68/20 71/11 71/16 71/18 72/8 74/21 75/5 87/7 93/12 93/13 98/5 99/3 102/5 107/22 110/5 113/3 115/3 generalise [1] 93/22 generally [9] 41/25 43/10 70/4 70/19 72/12 97/14 99/23 99/25 101/8 generations [1] 27/2 Genetic [1] 26/21 get [23] 13/18 13/24 23/7 23/9 29/1 32/8 37/7 41/24 49/20 58/2 69/23 78/24 84/11 84/16 85/15 87/15 87/18 88/1 88/2 93/18 97/2 105/16 106/1 getting [10] 37/8 53/1 73/14 83/14 84/9 87/10 93/15 94/20 109/13 113/19	Gibson [7] 55/17 56/17 56/21 57/15 57/18 57/23 57/24 give [14] 15/21 31/24 33/21 37/12 39/12 44/1 72/10 73/13 73/18 87/25 100/15 104/3 112/8 115/19 given [20] 7/17 8/11 10/14 11/5 37/5 37/23 38/3 39/13 50/2 53/20 59/4 61/1 62/20 62/21 62/24 63/11 65/2 103/24 105/1 112/19 giving [4] 15/8 105/18 112/13 116/6 glad [1] 107/2 Glasgow [54] 2/20 6/15 7/16 7/23 8/3 8/5 8/9 8/13 9/2 11/22 12/11 15/5 18/8 21/10 24/18 26/2 26/4 29/7 32/7 34/13 36/4 40/13 40/21 41/11 50/11 52/17 55/2 55/6 56/2 56/5 56/5 56/12 56/24 56/24 57/11 57/24 58/8 68/25 69/3 70/23 71/6 72/12 72/13 76/5 76/18 87/13 89/17 89/23 105/10 107/24 109/6 112/4 112/24 116/13 gloomy [2] 84/14 104/18 go [47] 7/19 8/8 15/2 15/10 17/17 25/5 29/5 29/25 30/1 32/19 32/25 35/7 35/21 38/16 43/25 45/21 52/8 63/15 64/4 70/15 71/17 71/24 72/2 76/14 76/18 76/23 76/25 78/14 79/5 80/15 80/22 82/15 85/7 86/6 86/25 90/17 91/18 91/20 95/7 95/19 96/4 96/5 97/19 97/20 97/21 98/2 104/15 goes [7] 76/22 77/13 81/6 82/9 87/23 101/11 103/3 going [37] 2/15 6/22 7/18 12/9 25/14 28/25 32/19 48/9 52/1 52/16 58/7 63/11 67/3 71/13 73/16 74/23 76/9 79/1 82/10 82/11 84/11 84/15 84/16 85/15 85/15 87/9 88/2 88/14 93/17 93/21 94/17	94/25 106/3 110/23 112/8 115/6 117/16 gone [5] 27/24 27/25 62/9 83/18 105/9 good [16] 1/3 1/7 25/19 26/24 28/17 50/16 50/17 65/10 72/15 73/7 78/12 79/18 93/19 94/18 111/2 112/18 GORDON [4] 2/13 54/25 116/5 119/2 Gordon Lowe [1] 54/25 got [7] 15/11 44/16 70/16 71/15 85/20 88/6 106/2 grade [1] 63/3 grading [1] 92/18 gradually [1] 77/21 granddaughter [1] 27/5 grateful [1] 55/7 great [5] 22/14 107/17 108/7 108/12 115/24 Greater [1] 56/5 GRI [5] 51/16 53/15 53/19 54/3 54/4 grief [1] 85/12 grounds [1] 64/14 group [4] 10/16 102/16 106/12 111/20 grouped [1] 33/18 groups [1] 85/10 grow [2] 23/7 23/8 growing [1] 77/6 guess [3] 31/21 37/6 112/10 guessed [1] 24/3 guidance [1] 45/6 guided [1] 46/22 guided by [1] 46/22 guidelines [4] 45/5 45/10 45/11 45/15 gynaecology [1] 8/25 H had [118] 5/21 7/3 10/19 12/4 12/6 12/14 12/19 12/25 13/14 14/8 14/14 17/14 18/23 20/5 21/6 21/7 21/8 21/14 21/18 22/9 22/11 23/15 23/17 23/18 23/25 24/8 25/6 25/6 25/21 26/12 26/15 27/14 27/18 27/24 27/24 27/25 28/1 28/17 30/16 32/8 36/4 41/21 41/22 43/24 44/25 46/24 48/21 51/25 52/18	53/6 53/7 53/14 53/20 53/23 54/7 54/14 54/14 54/15 54/17 54/17 55/23 57/16 57/17 58/5 58/13 58/14 58/15 60/13 60/16 61/3 61/22 62/7 67/4 67/9 70/10 72/4 77/18 77/21 78/2 78/20 82/24 82/25 83/2 83/3 83/11 84/1 84/1 86/11 86/23 89/1 89/4 92/6 92/15 92/19 93/7 94/19 94/19 98/6 99/24 100/11 100/11 103/17 105/3 105/3 105/13 107/1 109/23 110/4 110/4 110/14 110/18 111/2 111/9 112/12 114/1 114/2 114/6 116/18 hadn't [1] 17/16 haematological [1] 9/7 haematologist [13] 5/5 11/14 13/18 19/23 25/14 25/20 40/20 43/11 43/14 43/19 43/25 45/2 45/3 haematologists [5] 12/3 25/18 25/19 42/24 47/10 haematology [14] 4/23 5/2 5/11 5/23 9/18 11/8 11/20 11/21 11/23 12/16 12/23 13/1 21/18 47/15 haemophilia [145] haemophilia A [9] 15/6 15/12 15/17 33/8 34/22 35/2 38/2 61/5 65/23 haemophilia B [6] 10/1 15/6 15/18 61/6 62/19 87/17 haemophiliac [7] 14/3 17/17 17/19 21/24 26/13 66/5 89/13 haemophiliacs [5] 14/13 17/8 86/10 99/10 109/17 haemophilias [2] 17/6 17/15 haemophilic [3] 19/5 22/2 22/19 haemostasis [1] 9/4 half [15] 3/6 17/8 33/1 45/14 45/22 74/3 81/10 88/20 89/14 95/13 96/9 107/22 107/23 109/4 109/5 halfway [1] 96/8	halt [1] 66/11 handful [1] 7/19 handicapped [1] 69/9 hands [1] 43/7 Hann [4] 18/6 18/14 20/22 58/14 happen [4] 5/21 85/2 94/25 96/15 happened [2] 20/12 25/17 happening [1] 103/18 happens [1] 97/9 happy [3] 46/9 114/4 115/12 hard [2] 28/5 100/18 hardly [1] 106/21 has [17] 1/15 35/4 43/14 45/2 56/9 58/2 69/4 77/2 79/19 79/22 79/24 80/3 83/18 85/11 87/25 88/8 97/4 have [190] haven't [3] 63/5 95/25 100/11 having [20] 20/21 24/8 34/15 37/4 42/16 45/8 48/6 49/22 57/19 63/6 69/9 78/1 85/25 86/11 105/14 108/3 108/15 114/8 115/15 116/23 Hay [2] 39/22 99/13 hazard [2] 79/15 79/23 he [69] 5/12 9/18 9/22 10/4 10/5 10/7 11/23 21/18 26/3 26/4 26/5 32/6 32/7 32/8 40/19 42/6 42/8 42/9 42/14 43/12 47/6 48/23 54/24 58/10 58/14 69/18 69/19 71/7 71/10 71/17 71/23 72/1 72/24 78/2 78/2 78/3 78/3 78/7 80/20 81/6 81/8 81/12 81/13 81/16 81/23 82/1 85/14 85/23 91/5 91/13 91/20 94/3 94/3 94/8 94/10 96/19 96/19 96/20 101/6 110/25 111/7 111/10 111/13 111/19 111/22 111/23 111/25 112/11 112/12 he's [4] 48/3 92/1 110/3 111/14 head [5] 5/2 5/10 5/11 5/22 5/23 heading [1] 80/23 headlines [1] 35/11 health [9] 19/22 19/25
--	--	---	---	---	--

H	her [4] 57/4 57/20 89/19 108/20 here [16] 1/19 19/12 35/9 35/17 36/8 60/11 69/1 74/3 77/1 79/7 94/23 95/13 101/16 102/15 104/16 109/10 here's [1] 72/1 hesitate [1] 25/21 hidden [1] 114/7 high [3] 26/14 31/24 66/2 higher [1] 94/21 highlight [1] 77/5 highly [3] 52/13 82/11 90/20 him [6] 2/8 4/10 5/11 69/22 111/13 117/2 his [8] 9/17 20/4 47/6 55/19 94/18 108/20 109/24 112/12 histological [2] 81/19 81/24 histopathologists [1] 92/14 historian [2] 35/17 38/7 history [7] 7/18 8/8 47/10 64/22 67/13 67/22 93/16 hitherto [1] 94/19 HIV [1] 99/22 hold [1] 3/24 holding [1] 1/13 holds [1] 6/10 home [20] 1/23 1/25 1/25 2/4 20/14 20/18 20/20 20/23 22/25 23/2 23/11 64/14 74/13 87/24 89/16 90/5 105/19 112/12 112/13 114/5 homework [1] 102/13 honeymoon [2] 78/13 88/11 honorary [1] 3/14 hopefully [2] 14/5 87/17 hopes [1] 96/19 horrendous [1] 96/17 hospital [23] 5/6 9/1 11/5 11/13 14/20 16/24 18/16 18/21 19/18 21/15 24/19 24/21 25/6 25/23 26/1 41/1 41/22 41/25 62/9 66/12 83/6 83/8 89/22 hospitals [5] 10/23 14/22 17/15 18/16 57/11 hosted [1] 6/16 house [2] 1/12 21/11	how [29] 7/20 12/13 24/17 24/20 26/9 37/19 38/1 38/23 39/1 39/2 39/4 40/11 44/7 47/2 47/2 51/14 56/9 56/21 56/23 57/10 84/24 90/13 93/7 94/16 94/16 99/12 101/3 113/24 114/4 Howard [1] 82/9 however [5] 1/15 47/24 79/12 93/20 115/17 Hutchison [1] 20/5 Hyland [3] 29/12 37/17 44/7 I I agree [3] 84/12 90/2 93/19 I agreeing [1] 55/22 I am [7] 7/18 28/25 69/9 103/1 107/14 117/16 117/19 I appreciate [1] 63/6 I arrived [3] 13/6 20/3 27/10 I ask [2] 33/12 57/1 I asked [1] 95/4 I assume [1] 115/12 I became [2] 54/4 68/17 I came [1] 21/14 I can [6] 1/5 25/23 57/1 58/3 60/8 93/24 I can't [5] 7/9 24/15 26/22 36/14 116/24 I cannot [2] 7/12 59/25 I checked [1] 5/9 I couldn't [1] 43/24 I described [1] 74/7 I did [6] 7/13 78/10 78/14 78/21 103/13 107/15 I didn't [2] 78/10 102/12 I direct [1] 110/21 I do [3] 70/3 76/8 91/25 I don't [17] 16/16 24/3 45/4 46/6 49/5 53/21 57/13 58/9 73/2 75/13 78/18 82/6 107/3 109/23 110/6 111/21 114/12 I first [1] 74/8 I gave [1] 98/20 I go [1] 95/7 I had [6] 7/3 58/13 70/10 77/18 78/20 110/4	I have [13] 7/19 21/8 52/5 64/24 64/24 67/20 68/25 70/12 71/1 80/16 82/14 100/20 117/14 I haven't [2] 95/25 100/11 I heard [3] 69/15 69/24 76/5 I interrupted [1] 95/3 I joined [1] 71/2 I just [14] 34/1 35/21 45/16 59/16 69/14 80/14 85/18 90/9 91/2 91/19 94/11 103/13 105/25 110/25 I know [2] 66/18 75/11 I learned [1] 68/22 I look [3] 59/7 117/24 117/25 I may [1] 70/15 I maybe [1] 82/15 I mean [3] 25/18 92/2 102/1 I mentioned [1] 88/18 I met [1] 71/2 I might [1] 106/1 I missed [1] 88/11 I need [1] 42/17 I never [2] 38/15 58/10 I note [1] 117/17 I only [1] 3/11 I put [1] 108/10 I quote [1] 103/16 I read [4] 68/20 78/10 78/16 99/12 I really [1] 102/14 I remember [4] 68/16 69/5 69/22 110/3 I right [1] 53/20 I said [4] 25/25 61/22 109/9 113/18 I saw [1] 113/25 I say [6] 14/18 34/11 66/17 73/15 74/6 107/17 I see [1] 94/9 I sent [1] 10/23 I shall [1] 16/13 I shared [1] 4/10 I should [2] 55/7 86/8 I started [1] 116/3 I stay [1] 57/21 I succeeded [1] 38/12 I suggest [1] 67/21 I suspect [2] 1/11 48/22 I take [1] 90/16 I then [2] 77/21 99/4 I think [162] I thought [1] 103/18	I thought: there's [1] 74/9 I took [2] 68/18 76/3 I tried [1] 112/20 I understand [3] 2/19 49/10 95/12 I understood [1] 100/22 I visited [1] 7/1 I want [4] 7/15 7/20 28/21 66/19 I wanted [5] 6/2 26/7 60/5 68/4 107/11 I was [19] 3/5 3/8 4/8 6/22 24/5 36/12 58/1 67/20 78/1 78/12 78/20 82/22 83/5 88/11 96/16 104/2 107/6 109/21 113/19 I wasn't [8] 36/11 38/10 57/13 57/14 58/18 66/15 95/18 107/2 I will [1] 59/15 I would [12] 5/18 21/3 31/21 38/14 55/17 59/20 59/25 68/21 71/11 83/12 107/3 112/10 I wrote [2] 8/10 100/13 I'd [5] 33/17 37/25 84/17 89/17 105/2 I'll [2] 77/18 104/15 I'm [37] 1/15 2/2 2/4 2/15 28/22 32/4 32/19 35/17 35/24 46/18 51/5 52/25 53/1 53/22 63/5 70/19 71/4 74/3 75/23 76/9 78/4 79/1 85/17 86/6 88/10 90/1 93/9 93/22 95/2 95/25 100/10 103/3 103/11 103/13 104/13 107/2 117/24 I've [18] 8/11 11/6 33/15 34/15 36/10 49/5 54/4 59/19 66/17 72/4 83/20 89/18 100/10 100/11 104/8 107/10 115/10 116/8 I've looked [1] 104/8 idea [4] 49/22 49/23 65/10 86/15 ideally [2] 24/23 24/24 identified [5] 17/14 17/20 75/1 75/19 102/24 if [114] 1/8 3/20 9/7 9/11 10/19 11/10 14/17 14/24 15/2 15/4	15/10 17/10 23/2 23/15 23/17 23/22 24/8 25/7 25/13 25/21 25/25 27/2 27/6 27/12 27/22 28/11 28/13 29/5 29/8 29/25 30/2 31/4 31/24 32/3 32/11 32/18 32/25 33/11 35/7 35/24 38/16 38/17 42/7 44/12 44/15 45/10 45/22 48/3 48/6 48/15 49/15 50/15 50/15 50/22 50/25 52/19 53/14 55/7 57/1 57/24 58/2 59/13 61/19 62/1 63/7 63/10 63/20 64/4 66/24 67/23 70/4 70/18 75/10 76/3 76/14 76/18 76/23 78/5 79/5 80/8 80/13 80/15 80/22 81/10 81/12 82/7 83/3 84/8 84/8 85/7 85/19 86/6 86/22 86/25 87/6 87/15 92/7 93/24 94/11 95/19 96/3 96/4 96/5 96/24 97/19 97/20 98/2 98/19 101/11 101/22 103/7 105/20 109/3 117/23 illness [1] 80/19 illnesses [1] 81/3 immune [1] 50/23 impact [1] 9/11 important [7] 18/22 23/10 34/18 52/24 53/11 73/22 104/15 importantly [2] 10/17 93/7 impression [6] 25/20 44/1 44/4 57/5 58/18 65/6 impressionistic [1] 38/8 inactivated [4] 52/8 52/9 53/12 67/10 inactivation [3] 65/14 87/19 106/9 inappropriate [1] 33/19 incidence [2] 79/12 101/6 include [7] 16/22 34/4 36/2 69/6 98/13 98/14 115/12 included [2] 36/5 39/17 including [5] 60/14 74/16 74/17 77/24 92/4 inconsistent [1] 92/18
----------	--	--	---	--	--

I	100/1 100/20 103/24 104/14 104/19 105/1 105/2 110/18 112/19 113/13 117/9 informed [3] 104/4 115/8 115/19 infrequently [2] 35/14 52/14 infused [3] 39/6 39/11 41/19 infusing [1] 37/4 infusion [4] 33/21 34/12 37/5 65/1 infusions [4] 37/23 37/25 109/16 115/25 inhibitor [11] 5/1 14/2 14/6 14/10 30/9 31/5 42/15 44/13 44/17 44/18 50/20 inhibitors [15] 12/22 14/16 30/10 30/21 31/11 31/12 31/14 31/18 32/5 34/16 44/15 44/22 44/24 50/24 52/25 initial [1] 109/14 initially [7] 4/21 11/12 11/16 19/16 40/25 59/21 93/19 Inquiry [26] 1/19 15/1 25/24 35/5 39/24 44/3 45/20 51/19 65/7 66/18 67/16 69/2 74/8 87/21 90/3 94/13 98/1 98/4 99/21 102/4 102/12 103/15 103/16 109/9 110/14 113/14 Inquiry's [2] 2/17 66/10 insisted [1] 46/7 insofar [1] 2/16 instance [3] 37/18 93/2 101/4 instances [1] 81/5 instantly [1] 28/10 institution [2] 8/2 108/8 intensified [1] 21/20 intensive [1] 70/10 interactive [1] 42/19 interest [9] 7/9 9/3 9/18 11/8 11/17 20/4 20/6 22/12 79/22 interested [6] 8/25 14/4 37/25 70/19 82/22 103/3 interesting [1] 98/24 intermittent [1] 23/3 internal [2] 73/4 82/16 international [5] 36/24 37/10 50/13 73/18 76/16	internationally [1] 111/25 interpretation [1] 94/23 interrupted [1] 95/3 intervals [2] 26/19 84/10 interview [1] 10/8 into [8] 37/7 42/1 63/15 64/19 65/4 92/23 103/3 103/4 intracranial [1] 106/18 intravenous [1] 37/5 invented [2] 9/23 87/1 Inverness [2] 52/15 55/20 investigated [2] 64/1 66/23 investigation [4] 22/2 66/11 77/9 111/16 investigations [3] 40/2 64/18 92/16 invite [2] 28/25 79/1 invited [1] 53/7 inviting [1] 108/13 involve [1] 56/8 involved [18] 3/8 21/23 22/3 22/22 23/12 24/16 38/10 47/21 58/18 60/24 63/3 66/15 67/21 78/18 79/19 86/18 104/2 116/6 involvement [7] 23/22 28/23 56/20 59/18 77/15 78/23 112/21 Ireland [1] 25/2 is: [1] 98/15 is: what [1] 98/15 Isle [1] 25/1 isn't [4] 39/25 79/3 95/24 101/17 issue [7] 41/16 49/9 51/9 57/18 75/14 92/2 102/17 issued [2] 43/17 61/9 issues [3] 60/6 76/24 90/12 issuing [1] 43/17 it's [73] 1/12 1/12 1/13 6/9 13/15 15/2 15/22 16/10 16/12 16/16 17/19 27/1 27/10 29/10 30/2 31/15 34/1 34/7 34/8 34/15 36/14 37/1 37/3 37/6 37/8 37/20 37/24 38/19 40/3 44/4 45/18 45/19 48/16 52/25 54/21 54/22 55/4 60/8 63/6 65/5 67/18 69/2 70/16	75/10 76/10 76/15 79/9 80/11 80/20 87/8 87/18 88/14 90/21 90/22 92/3 93/17 94/3 94/7 94/7 94/17 95/24 96/4 100/4 100/5 103/7 106/19 106/20 108/4 108/19 108/22 110/4 116/11 117/4 Italy [1] 83/23 its [5] 6/14 11/23 34/24 54/8 65/5 Ivana [1] 89/19 IX [19] 10/1 10/3 10/10 15/8 15/14 15/19 30/7 30/15 30/16 30/24 31/2 31/6 31/10 31/24 31/25 36/25 37/10 41/6 80/10 J jab [1] 109/22 January [1] 3/13 jaundice [15] 74/20 75/2 75/3 87/25 109/13 109/23 109/24 109/24 110/1 110/4 112/22 114/1 114/9 114/19 116/11 JHO [1] 63/1 job [2] 1/19 23/9 John [1] 5/3 join [4] 21/16 53/8 71/11 111/12 joined [1] 71/2 joint [5] 19/11 47/12 54/6 54/9 55/21 joints [2] 22/25 22/25 Jones [1] 110/11 Jones' [1] 113/7 journal [2] 68/16 75/23 journals [1] 68/20 journey [5] 26/2 26/5 41/7 41/23 41/24 judge [1] 105/20 juicy [1] 96/18 July [1] 77/23 June [1] 5/9 June 1990 [1] 5/9 junior [16] 6/17 24/5 60/24 61/13 62/20 62/21 62/25 62/25 63/12 70/5 70/21 70/23 71/8 117/3 117/5 117/8 juniors [1] 78/24 just [103] 1/9 3/20 6/2 6/6 8/3 9/1 13/15 14/2 14/24 15/25 16/25 17/16 25/5 25/15	26/19 29/1 29/25 30/16 31/4 33/12 34/1 34/8 34/18 35/7 35/20 35/21 38/16 38/18 39/18 40/8 42/18 44/4 45/16 45/25 48/8 48/18 50/2 51/3 51/13 52/5 53/2 54/20 55/15 55/21 57/1 57/15 57/15 59/14 59/16 59/25 60/18 63/18 63/19 64/4 64/22 64/25 65/5 65/16 65/18 65/20 66/20 67/23 69/14 70/19 71/4 71/15 73/21 74/11 78/23 79/1 80/14 83/15 84/17 84/22 84/25 85/7 85/18 86/6 88/7 90/9 90/17 91/2 91/19 92/25 93/25 94/11 94/13 95/7 96/3 96/18 96/20 101/4 101/7 103/3 103/13 104/15 105/25 108/5 110/25 111/12 111/14 114/6 116/4 justify [1] 97/3 K Katharine [1] 83/8 keen [6] 5/14 25/12 34/13 42/7 42/10 53/4 keep [16] 25/15 26/16 26/20 27/7 39/10 42/12 44/8 50/15 50/25 52/13 52/15 54/12 57/25 70/24 71/8 71/12 keeping [4] 26/8 50/8 68/7 72/14 kept [8] 20/13 26/11 28/6 28/9 43/5 52/23 62/19 62/22 key [1] 82/12 kidney [1] 21/8 kind [16] 10/24 27/6 28/2 28/12 30/18 31/9 37/8 61/23 62/17 63/9 72/14 78/19 78/23 98/17 117/12 117/13 kinds [2] 6/11 87/8 knees [1] 22/6 knew [9] 12/13 14/14 47/17 95/19 103/8 105/3 109/12 112/24 112/24 know [66] 9/21 11/2 13/4 16/20 16/21 19/14 24/4 25/15 26/18 27/1 27/6 28/2	28/14 30/10 33/20 34/22 35/4 36/10 36/13 42/9 48/14 53/3 56/18 56/21 57/10 58/9 63/16 65/14 66/18 69/17 71/4 71/22 73/12 75/2 75/11 75/13 75/21 82/6 85/10 87/5 88/6 91/25 93/15 93/23 95/20 96/20 104/16 105/4 105/10 105/11 106/4 106/6 106/13 106/19 107/3 109/3 109/23 110/5 110/15 111/22 112/13 114/8 114/12 115/24 116/10 116/11 knowing [1] 104/17 knowledge [25] 31/16 35/24 36/7 36/8 36/10 47/1 58/13 64/17 66/13 67/20 67/24 71/18 71/24 75/20 90/14 95/5 95/6 99/22 106/21 107/7 109/25 111/24 114/14 116/17 117/4 known [3] 90/17 94/1 116/14 Kryobulin [1] 29/12 L lab [1] 44/10 labels [1] 115/16 laboratories [1] 115/20 laboratory [15] 4/24 5/4 5/13 6/20 11/20 11/25 12/1 40/14 40/16 43/1 43/16 43/18 59/24 80/12 115/15 lack [2] 81/23 104/19 Lake [1] 78/13 laminectomy [1] 77/22 Lanarkshire [1] 41/1 Lancet [3] 68/19 70/9 75/25 land [1] 101/3 large [7] 1/12 29/16 86/1 86/4 86/17 96/17 111/20 largely [1] 55/12 larger [1] 38/19 largest [2] 56/1 92/8 last [8] 20/17 27/10 33/16 59/17 63/22 91/4 114/1 116/15 lasting [1] 7/25 late [4] 18/11 50/4
----------	--	---	---	--	---

(39) increase - late

L	likely [3] 16/22 82/3 96/15 limit [1] 52/7 limited [8] 23/22 28/24 56/20 100/12 103/14 103/24 105/1 105/2 line [9] 33/5 45/23 46/16 46/19 46/23 77/4 81/12 85/23 95/3 line 10 [1] 46/19 line 14 [1] 46/23 line 17 [1] 45/23 line 5 [1] 85/23 line 8 [1] 46/16 lines [6] 31/4 60/10 82/2 84/22 85/7 114/18 link [2] 8/11 19/24 linked [1] 47/20 links [1] 9/12 list [1] 76/19 listed [4] 5/25 11/6 27/20 75/15 listening [2] 65/18 70/17 literature [8] 68/10 68/13 70/1 86/20 98/11 104/5 104/8 108/23 little [12] 7/13 7/15 7/21 24/11 24/17 37/19 46/17 53/1 53/7 54/14 60/18 104/2 live [1] 91/22 liver [45] 76/20 77/9 80/6 81/8 81/15 81/17 81/21 82/4 83/4 83/11 83/24 85/13 85/15 86/11 87/11 88/9 88/15 88/20 88/22 88/25 92/11 92/25 92/25 93/1 93/3 93/21 96/10 96/13 97/7 98/7 98/9 99/2 99/7 99/19 101/13 102/6 102/9 104/18 104/20 105/3 105/5 105/8 106/3 114/3 116/1 living [4] 105/15 105/16 105/16 110/12 local [15] 11/5 11/7 11/13 11/14 16/24 24/19 24/21 25/5 25/9 25/14 25/18 25/20 25/23 26/1 73/17 locally [2] 12/1 41/3 lockdown [1] 100/13 locked [2] 27/13 28/8 London [2] 6/12 83/9 long [21] 6/12 7/25 13/23 14/6 26/1 26/5	47/6 58/22 63/7 84/10 84/24 85/16 86/12 87/16 93/7 94/16 94/16 96/12 103/23 104/5 114/5 long-lasting [1] 7/25 long-term [3] 86/12 103/23 104/5 long-winded [1] 13/23 longer [5] 53/2 84/3 105/15 105/16 105/17 look [28] 12/1 14/10 14/24 28/25 29/8 30/2 31/4 32/3 33/1 35/20 44/2 48/15 51/7 54/20 59/7 61/21 63/20 65/20 79/1 80/13 81/10 83/23 92/7 103/15 103/17 104/14 117/24 117/25 looked [5] 19/21 79/3 92/14 95/25 104/8 looking [19] 1/16 9/6 13/8 23/14 36/19 51/10 62/3 66/23 83/5 83/21 84/14 86/20 93/11 93/15 94/23 96/13 104/13 106/5 106/9 Lord [1] 26/3 Lord Penrose [1] 26/3 lost [1] 28/15 lot [11] 8/7 11/11 12/7 17/18 20/5 20/17 30/25 31/13 57/4 58/16 104/11 Lothian [1] 56/4 lots [2] 44/25 105/3 low [1] 66/3 Lowe [17] 2/11 2/13 2/15 28/4 38/24 40/10 54/25 60/4 68/4 77/16 80/25 98/15 107/6 108/14 113/5 117/19 119/2 lower [4] 65/13 67/9 83/2 84/4 Ludlam [8] 50/3 54/23 55/13 55/18 55/21 56/14 111/12 112/8 Ludlam's [1] 111/10 lumbar [1] 77/19	M Macfarlane [2] 9/23 11/19 MacSween [1] 79/8 made [10] 10/4 16/14 17/21 18/19 35/22 36/17 37/19 41/5 55/16 95/8 Madhok [2] 22/17	88/19 main [6] 7/9 17/23 33/7 50/25 68/20 87/9 maintain [1] 23/5 major [7] 21/9 42/16 46/8 48/7 71/23 77/8 80/3 majority [2] 34/21 88/5 make [15] 1/20 21/3 26/1 31/19 42/22 54/7 78/6 83/13 85/18 88/4 105/24 106/8 106/20 107/9 107/22 makes [4] 7/10 94/17 100/19 113/8 making [10] 23/13 28/23 40/1 42/6 46/1 46/3 47/2 67/3 91/20 94/22 managed [3] 24/18 24/20 80/2 management [4] 12/2 60/13 61/3 87/4 managers [1] 26/19 managing [2] 14/4 60/24 Manchester [1] 39/4 manifestation [1] 109/14 Mannucci [1] 99/2 manufactured [1] 51/20 manufacturer [1] 30/16 manufacturers [1] 32/14 many [24] 4/25 10/23 13/13 21/4 25/22 27/19 35/4 35/4 37/14 38/1 39/1 54/12 75/11 85/5 91/9 92/4 93/10 93/20 94/20 96/25 99/9 99/17 110/10 110/12 March [2] 111/4 112/18 March 1980 [2] 111/4 112/18 marginal [1] 15/23 Markova [1] 89/19 Mary [2] 1/21 2/11 masks [1] 1/17 Massachusetts [1] 83/7 material [5] 40/4 40/4 46/17 67/6 79/3 materials [3] 64/21 72/16 109/4 maternity [3] 5/6 9/1 14/20 matter [11] 36/6 36/7	37/16 75/9 87/18 88/1 102/23 102/23 105/20 108/18 113/16 maturity [1] 19/3 maximum [1] 53/6 may [39] 2/8 6/23 16/8 16/9 17/7 23/1 23/21 30/10 33/20 34/22 35/25 36/18 36/21 37/12 38/20 45/12 54/23 56/19 59/5 66/3 69/1 69/10 70/15 75/5 80/5 86/5 87/12 90/9 91/20 91/23 94/3 94/10 94/25 96/12 103/5 105/7 106/4 118/2 118/2 maybe [12] 7/2 23/5 31/14 48/17 49/11 75/2 75/2 82/15 84/22 92/21 103/19 111/11 McDonald [14] 4/18 5/2 5/10 5/23 9/9 11/22 12/6 12/8 13/1 13/11 40/20 54/5 59/22 60/12 McDonald's [1] 4/15 McGirr [1] 20/4 McKillop [1] 5/22 McNicol [3] 4/22 43/22 47/11 me [52] 1/4 1/6 1/10 1/24 1/25 2/2 16/14 28/25 35/24 36/13 38/1 43/23 51/13 53/2 64/22 68/24 69/7 70/12 70/17 71/3 77/18 77/24 78/2 78/4 78/22 84/7 91/17 91/23 94/13 100/12 100/14 100/22 101/4 101/25 102/2 102/17 102/22 103/10 103/19 104/8 104/9 104/23 105/24 107/15 107/19 110/24 111/8 112/19 113/23 114/9 116/4 117/5 mean [5] 25/18 39/1 85/1 92/2 102/1 means [7] 39/17 39/21 70/5 70/20 94/8 99/11 115/18 meant [1] 113/24 measure [4] 36/22 37/13 37/22 44/18 measurement [1] 38/21 measurements [2] 22/8 22/9 measures [1] 12/21	mechanics [1] 44/5 medical [18] 6/9 6/24 8/3 8/5 8/9 10/11 14/8 19/20 68/8 68/13 68/15 68/20 70/7 71/9 74/12 78/8 92/16 111/1 medicine [20] 2/20 3/2 3/8 3/17 4/3 4/21 6/5 6/13 8/17 9/17 12/5 12/20 20/1 21/21 36/11 47/14 71/11 71/17 71/18 72/3 Medicine's [2] 11/17 12/11 meet [2] 6/14 35/1 meeting [20] 69/5 69/16 70/10 72/5 73/17 77/5 78/11 78/14 78/21 107/21 107/22 108/2 111/2 111/8 112/2 112/3 112/3 112/4 112/6 113/12 meetings [8] 6/10 72/8 72/19 73/1 73/1 73/3 108/3 113/3 member [6] 4/20 4/20 5/24 5/24 6/2 107/20 members [2] 1/16 1/18 membership [1] 6/4 memo [1] 74/14 memory [11] 34/11 35/13 37/2 47/6 51/17 57/22 69/19 71/1 88/15 88/17 92/21 mention [2] 75/17 113/8 mentioned [6] 21/8 34/15 72/4 88/18 110/10 114/20 mess [1] 53/9 message [4] 87/24 93/12 93/13 115/10 messages [1] 82/13 met [3] 58/10 71/2 111/7 meticulous [1] 42/5 micrograms [5] 37/3 37/3 37/7 39/6 39/13 mid [3] 18/10 30/20 32/7 mid-1970s [2] 30/20 32/7 middle [5] 25/16 27/23 51/18 63/3 82/21 middle-grade [1] 63/3 might [23] 18/9 28/6 31/3 32/14 44/1 44/3 48/5 49/3 57/5 62/17
----------	--	---	--	--	---	---

(40) late... - might

<p>M</p> <p>might... [13] 63/12 87/7 90/6 95/9 97/3 102/8 102/19 106/1 110/14 113/6 113/9 113/10 117/12</p> <p>mild [18] 13/3 17/17 17/19 33/22 33/24 38/1 38/2 61/6 74/4 80/19 81/2 84/9 87/15 92/25 97/14 98/9 98/10 98/17</p> <p>milder [6] 4/25 13/13 13/16 14/15 17/14 17/20</p> <p>miles [1] 26/4</p> <p>mind [4] 52/4 75/14 97/6 105/14</p> <p>minimally [1] 53/5</p> <p>minimise [1] 52/5</p> <p>minimum [2] 23/6 52/19</p> <p>minute [2] 53/2 73/3</p> <p>minutes [11] 32/4 37/6 52/11 58/22 72/18 73/3 73/22 111/8 111/23 112/3 112/6</p> <p>misleading [1] 105/6</p> <p>miss [1] 109/12</p> <p>missed [1] 88/11</p> <p>missing [1] 27/24</p> <p>mix [1] 29/23</p> <p>mixed [1] 30/24</p> <p>mixture [1] 102/18</p> <p>mobilised [1] 77/21</p> <p>model [1] 77/7</p> <p>moderate [1] 34/22</p> <p>modern [1] 18/1</p> <p>moment [5] 1/15 44/2 91/23 102/22 103/2</p> <p>moments [1] 108/14</p> <p>monitor [1] 53/11</p> <p>monitoring [3] 12/21 21/23 22/4</p> <p>month [2] 24/4 76/4</p> <p>monthly [2] 39/12 68/24</p> <p>months [4] 3/12 77/20 111/7 112/9</p> <p>morbidity [1] 106/15</p> <p>more [32] 13/16 13/18 16/18 17/7 18/1 24/17 33/13 37/25 42/16 57/4 58/16 60/18 62/11 62/13 62/16 63/7 65/4 65/12 68/23 70/4 70/19 70/21 71/13 71/15 72/12 72/22 79/19 85/7 91/22 93/7 94/4 99/7</p>	<p>Morfini [1] 83/21</p> <p>morning [1] 109/17</p> <p>mortality [2] 89/12 106/16</p> <p>mortem [1] 86/10</p> <p>mortified [1] 107/14</p> <p>most [19] 13/9 21/25 22/18 32/11 32/14 32/15 34/18 37/22 43/2 45/10 50/21 57/9 74/19 81/2 81/13 89/11 91/14 94/18 106/2</p> <p>mostly [3] 34/21 46/15 107/18</p> <p>mouth [1] 101/25</p> <p>move [7] 28/21 32/18 66/19 76/10 80/8 80/14 117/16</p> <p>moved [2] 8/12 21/15</p> <p>moves [1] 28/15</p> <p>Mr [2] 2/7 62/11</p> <p>Mr Bowie [1] 2/7</p> <p>Mr X [1] 62/11</p> <p>MRCB [1] 71/14</p> <p>Ms [8] 1/17 2/10 2/14 33/12 36/19 57/16 112/20 119/3</p> <p>Ms Richards [5] 1/17 2/10 33/12 36/19 57/16</p> <p>much [19] 7/11 19/2 19/8 23/12 27/17 35/11 44/7 44/22 47/21 50/12 53/9 54/19 57/6 68/1 85/11 91/12 94/21 95/2 107/5</p> <p>multiple [2] 28/6 115/25</p> <p>must [6] 48/7 59/4 67/7 72/2 86/16 104/20</p> <p>my [68] 2/4 3/6 3/7 5/14 5/18 5/22 7/9 7/10 7/10 8/10 10/24 14/9 19/19 24/23 25/12 25/19 34/11 35/16 37/6 39/13 43/21 43/23 51/17 58/17 59/18 59/20 59/21 65/6 68/18 68/23 75/8 76/3 77/20 77/23 77/25 78/13 78/23 84/18 87/13 88/11 91/1 92/5 93/24 97/16 97/16 98/19 100/13 103/14 104/1 104/21 105/8 105/12 106/21 106/25 107/16 109/10 109/18 109/24 110/3 110/24 112/21</p>	<p>113/5 113/13 113/18 113/19 115/10 116/9 117/4</p> <p>myself [2] 43/24 57/18</p> <p>N</p> <p>name [4] 10/15 77/2 77/2 95/20</p> <p>names [2] 49/20 78/24</p> <p>NANB [1] 103/23</p> <p>nasty [2] 93/15 93/21</p> <p>national [2] 40/24 73/17</p> <p>natural [1] 93/16</p> <p>need [7] 13/4 42/16 42/17 44/14 59/13 63/13 71/15</p> <p>needed [4] 12/15 14/18 28/2 50/17</p> <p>needing [1] 10/2</p> <p>needles [2] 109/22 116/8</p> <p>needs [5] 2/11 35/1 44/13 71/21 71/24</p> <p>negotiated [1] 56/12</p> <p>network [2] 25/19 73/20</p> <p>never [8] 24/5 38/15 46/14 58/10 65/4 67/20 86/23 87/1</p> <p>new [6] 8/13 9/23 21/16 42/7 73/15 113/25</p> <p>newly [1] 112/8</p> <p>news [3] 73/13 94/25 95/1</p> <p>next [17] 7/15 15/10 26/7 30/1 38/16 46/11 49/17 49/18 51/11 68/4 76/9 76/25 82/4 85/8 98/2 112/3 112/6</p> <p>NHS [18] 24/13 30/24 42/11 46/16 48/1 48/5 48/19 52/9 52/16 54/13 57/25 82/24 85/22 86/4 86/17 86/23 87/7 88/2</p> <p>NHS Factor IX [1] 30/24</p> <p>night [3] 12/13 25/16 27/23</p> <p>no [40] 15/7 16/17 23/7 33/6 35/25 36/8 36/10 36/17 39/2 46/14 48/13 49/3 51/5 51/5 53/7 55/15 57/13 58/13 62/2 63/15 65/11 66/1 66/15 67/20 73/2 78/20 86/15 86/22 87/25</p>	<p>90/19 92/25 94/7 95/18 99/23 103/1 105/6 105/20 113/8 113/18 115/4</p> <p>No-one [1] 86/15</p> <p>nobody [2] 3/21 109/11</p> <p>non [45] 28/24 68/5 68/5 69/7 69/7 69/23 69/23 70/14 70/14 72/20 73/24 73/24 74/2 74/2 74/11 75/4 75/4 75/13 75/13 79/20 79/20 79/23 79/23 80/17 80/17 80/24 80/24 81/2 81/2 83/15 83/15 89/4 89/4 89/13 99/3 99/24 99/24 100/8 100/8 102/19 102/19 109/8 109/8 113/15 113/15</p> <p>non-A [20] 68/5 69/7 69/23 70/14 73/24 74/2 75/4 75/13 79/20 79/23 80/17 80/24 81/2 83/15 89/4 99/24 100/8 102/19 109/8 113/15</p> <p>non-B [21] 68/5 69/7 69/23 70/14 73/24 74/2 74/11 75/4 75/13 79/20 79/23 80/17 80/24 81/2 83/15 89/4 99/24 100/8 102/19 109/8 113/15</p> <p>non-existent [1] 28/24</p> <p>non-progression [1] 99/3</p> <p>non-Reference [1] 72/20</p> <p>none [4] 15/6 77/17 89/1 89/1</p> <p>normal [4] 13/24 14/1 83/3 88/22</p> <p>normally [1] 117/5</p> <p>north [2] 25/1 106/22</p> <p>North America [1] 106/22</p> <p>north-west [1] 25/1</p> <p>not [78] 7/18 11/24 12/3 16/10 16/12 16/20 21/6 23/7 23/8 24/18 26/24 28/19 30/16 32/19 33/4 34/8 35/13 35/17 36/14 37/20 39/17 42/22 42/23 44/4 44/8 45/10 46/9 46/21 47/6 49/22 51/2 51/5 52/24 53/9 55/15 59/4 64/12 67/3 69/9 73/9 75/6 79/2</p>	<p>79/13 80/15 82/13 84/25 85/1 85/1 85/12 91/11 92/16 92/23 94/7 95/10 95/11 95/11 95/14 96/20 97/2 99/6 100/10 101/9 101/13 101/22 102/22 104/3 105/9 105/17 105/25 106/20 108/4 108/5 108/22 113/5 114/7 115/6 115/18 118/2</p> <p>notation [1] 91/1</p> <p>note [3] 58/19 98/24 117/17</p> <p>notes [4] 28/19 39/11 116/20 117/6</p> <p>nothing [2] 35/25 48/15</p> <p>November [2] 2/18 71/2</p> <p>November 1974 [1] 2/18</p> <p>now [40] 7/15 10/22 11/16 12/10 12/24 14/8 15/13 22/21 26/18 29/15 31/12 36/20 40/9 42/2 44/21 55/10 65/11 71/9 71/14 73/24 75/11 79/16 80/1 84/24 85/21 87/4 89/10 89/12 90/15 93/18 97/10 104/13 105/4 108/16 109/3 110/20 111/21 114/22 116/16 117/13</p> <p>number [30] 6/1 10/17 16/4 16/5 17/12 17/13 26/15 27/8 27/22 31/12 37/23 37/25 39/6 39/12 49/2 49/24 52/6 52/7 52/19 53/6 62/13 65/2 69/4 74/18 75/15 76/21 76/23 84/13 86/9 94/15</p> <p>numbered [1] 64/24</p> <p>numbers [5] 14/24 16/15 17/5 17/20 18/2</p> <p>nurses [1] 12/13</p> <p>O</p> <p>o'clock [3] 117/21 117/23 118/2</p> <p>oath [1] 1/22</p> <p>observation [3] 35/22 45/16 107/10</p> <p>observed [1] 35/8</p> <p>observer [1] 35/17</p> <p>obstetrics [2] 8/19 8/25</p> <p>obtain [3] 41/3 69/11</p>	<p>70/7</p> <p>obtained [2] 40/11 40/12</p> <p>obvious [3] 1/18 113/9 116/22</p> <p>obviously [17] 1/6 7/2 10/25 11/13 20/19 25/3 26/12 28/9 34/14 34/20 38/19 42/5 69/25 70/20 78/15 80/13 98/14</p> <p>occasionally [3] 6/19 27/14 48/21</p> <p>occasions [1] 36/16</p> <p>occur [1] 79/14</p> <p>October [1] 3/23</p> <p>oesophageal [1] 96/18</p> <p>off [3] 38/15 62/9 116/4</p> <p>offer [1] 107/21</p> <p>offered [1] 7/3</p> <p>offering [1] 5/17</p> <p>offers [1] 77/10</p> <p>often [8] 7/1 13/4 13/19 18/21 19/4 19/11 72/10 73/12</p> <p>OGILVIE [2] 2/13 119/2</p> <p>oh [8] 2/2 7/25 25/25 35/13 37/6 72/1 73/12 94/9</p> <p>okay [8] 19/11 24/23 52/1 85/19 99/13 107/22 113/24 117/11</p> <p>old [1] 94/20</p> <p>older [1] 19/6</p> <p>olds [2] 96/16 96/17</p> <p>once [6] 14/5 30/8 70/15 74/25 78/15 110/4</p> <p>one [61] 1/21 13/13 14/8 15/3 15/8 19/7 19/7 21/3 27/9 30/12 31/3 31/23 33/15 33/18 35/22 36/20 36/21 44/13 46/4 48/11 50/18 51/3 52/6 54/20 57/5 59/19 60/1 64/4 65/1 66/13 67/3 69/6 69/15 69/20 70/20 72/1 72/2 72/16 74/18 75/3 75/3 79/19 82/9 82/12 83/21 85/11 85/18 86/15 94/2 94/12 96/3 97/3 100/19 101/22 102/24 103/2 106/5 107/23 108/4 110/21 113/23</p> <p>ones [2] 52/21 110/5</p> <p>only [30] 3/3 3/11 11/24 14/16 19/15</p>
---	---	--	---	--	---

(41) might... - only

<p>O</p> <p>only... [25] 21/6 24/11 28/9 30/8 34/5 42/24 46/6 52/24 58/17 65/1 69/22 73/9 75/6 81/25 82/24 83/2 83/10 83/19 84/9 87/18 89/24 98/24 106/14 108/4 110/3</p> <p>onwards [3] 5/7 21/12 38/17</p> <p>open [1] 108/4</p> <p>Opening [2] 79/6 79/7</p> <p>operation [4] 28/1 42/18 49/5 77/25</p> <p>opinion [3] 94/14 104/4 117/9</p> <p>opportunities [1] 77/11</p> <p>opposed [2] 40/16 67/24</p> <p>optimistic [1] 103/23 or [147]</p> <p>oral [2] 79/4 102/4</p> <p>order [10] 11/9 41/9 41/15 42/23 43/13 43/21 43/24 54/7 56/15 103/4</p> <p>ordering [4] 44/5 45/3 56/13 59/24</p> <p>ordinate [1] 73/5</p> <p>ordained [2] 14/22 41/1</p> <p>organisation [2] 6/22 77/16</p> <p>organisations [1] 6/1</p> <p>organise [1] 32/12</p> <p>organised [4] 10/12 76/6 78/3 112/5</p> <p>organising [2] 78/5 78/21</p> <p>original [3] 8/2 13/10 92/15</p> <p>other [43] 1/18 6/1 10/20 13/23 14/8 27/19 33/10 43/7 46/8 47/17 47/19 54/1 62/9 65/25 70/8 70/22 72/19 72/20 73/5 75/18 76/24 77/7 77/14 79/16 81/20 83/20 84/17 85/10 85/18 86/8 87/14 90/12 92/1 97/10 99/24 103/3 103/9 107/14 108/7 110/8 113/6 113/9 113/11</p> <p>others [8] 1/21 36/25 37/20 40/3 40/8 46/21 65/16 99/11</p> <p>our [9] 1/11 21/6 40/1</p>	<p>55/16 88/16 88/18 88/21 89/3 102/15</p> <p>out [19] 3/20 10/9 25/4 37/20 40/25 45/12 55/4 56/10 62/3 67/23 68/18 74/1 76/3 76/12 77/13 95/8 101/22 108/23 116/5</p> <p>outbreaks [2] 69/20 115/22</p> <p>outlining [2] 64/22 65/5</p> <p>output [1] 34/24</p> <p>over [28] 12/16 12/18 12/24 13/2 14/21 19/12 26/14 30/11 32/2 32/25 35/6 41/18 56/22 59/19 60/2 61/21 76/14 76/23 82/4 86/20 88/20 93/11 97/19 98/5 98/12 103/23 110/16 113/21</p> <p>over-optimistic [1] 103/23</p> <p>overall [2] 16/15 100/6</p> <p>overnight [2] 69/11 118/2</p> <p>overoptimistic [2] 104/25 106/4</p> <p>overstated [2] 99/14 102/25</p> <p>overview [2] 2/16 100/15</p> <p>own [8] 35/23 36/6 36/7 40/1 47/1 67/24 106/11 114/14</p> <p>Oxford [2] 9/20 39/3</p>	<p>90/18</p> <p>page 30 [1] 15/3</p> <p>page 33 [1] 82/20</p> <p>page 36 [2] 84/19 90/22</p> <p>page 42 [2] 84/21 90/25</p> <p>page 51 [2] 64/6 67/1</p> <p>page 60 [1] 96/5</p> <p>page 63 [1] 97/19</p> <p>page 64 [1] 97/21</p> <p>page 66 [1] 98/19</p> <p>pages [10] 63/21 76/15 76/19 79/6 80/9 80/14 80/22 84/20 88/12 96/5</p> <p>pagination [1] 82/16</p> <p>pagination's [1] 80/15</p> <p>pain [1] 110/24</p> <p>painful [1] 77/19</p> <p>panel [2] 92/14 92/24</p> <p>paper [16] 64/24 65/16 66/17 66/20 80/8 80/8 83/20 89/3 89/18 92/8 99/2 99/13 99/13 100/3 101/5 106/23</p> <p>papers [13] 47/18 75/16 76/21 78/3 78/10 78/15 78/22 82/9 95/22 95/23 100/13 101/1 102/17</p> <p>paragraph [12] 60/7 60/10 63/21 63/23 64/4 64/5 66/24 82/21 86/2 86/7 97/22 98/3</p> <p>paragraph 17.4 [2] 64/5 66/24</p> <p>paragraph 30.3 [1] 97/22</p> <p>paragraph 30.6 [1] 98/3</p> <p>paragraph 8.5.2.3 [2] 63/21 63/23</p> <p>paragraph 8.5.2.7 [1] 60/7</p> <p>paragraphs [1] 79/9</p> <p>parallels [1] 97/24</p> <p>parents [2] 20/20 105/24</p> <p>Parker [1] 111/9</p> <p>part [10] 21/9 32/21 62/9 73/25 95/14 97/16 102/20 111/1 114/15 116/16</p> <p>particular [21] 6/17 7/22 8/24 9/4 14/3 24/16 47/22 51/9 51/17 53/13 63/10 63/11 73/16 75/16 76/4 77/8 79/22 91/21 109/8 113/11 114/1</p>	<p>particularly [13] 13/2 17/14 18/20 32/6 47/25 48/16 54/13 58/11 79/25 100/3 106/6 110/21 115/22</p> <p>parties [1] 72/17</p> <p>partly [2] 51/22 51/22</p> <p>parts [3] 55/11 65/25 111/21</p> <p>party [5] 32/5 67/25 69/17 72/18 73/1</p> <p>passages [1] 107/11</p> <p>past [2] 18/14 58/25</p> <p>pathologist [2] 92/15 92/23</p> <p>pathologists [2] 12/4 92/17</p> <p>patient [57] 3/22 10/14 11/2 11/7 16/8 18/7 20/10 20/13 23/24 25/16 26/12 27/2 27/12 27/20 27/23 28/14 30/9 37/24 41/8 44/12 44/14 44/15 44/17 47/23 50/1 50/9 50/23 51/23 53/4 53/5 60/15 60/20 60/21 60/22 61/5 61/8 61/9 61/18 61/19 61/23 61/24 62/6 62/11 62/18 63/2 63/10 63/14 63/17 72/10 89/3 93/6 105/24 108/16 108/17 108/20 108/22 117/2</p> <p>patient's [5] 42/15 42/16 48/8 61/7 62/4</p> <p>patient-specific [2] 60/20 61/18</p> <p>patients [193]</p> <p>patients' [4] 12/21 39/11 49/20 116/20</p> <p>pattern [2] 21/1 84/13</p> <p>Penrose [22] 15/1 25/24 26/3 39/24 44/3 45/20 47/7 51/19 65/7 66/18 67/16 74/1 74/7 97/25 98/4 99/20 102/4 102/12 103/15 103/16 109/9 110/14</p> <p>people [21] 1/13 31/24 55/22 56/6 72/6 83/14 83/19 87/10 87/25 92/10 94/19 100/21 101/18 101/22 103/9 105/15 107/18 107/19 108/6 112/24 117/13</p> <p>per [24] 2/25 3/1 3/3 3/16 3/17 3/19 4/2 4/3 4/7 39/17 82/25 83/1 83/3 83/11 83/19</p>	<p>83/19 84/2 88/22 92/21 93/5 93/14 97/8 101/7 101/17</p> <p>perception [2] 102/5 110/6</p> <p>performance [1] 108/10</p> <p>performed [1] 77/23</p> <p>performing [1] 6/25</p> <p>perhaps [11] 23/19 54/20 54/21 69/12 76/10 86/8 93/25 96/3 101/3 102/12 105/15</p> <p>perinatal [1] 9/3</p> <p>period [17] 3/10 4/3 4/16 16/8 16/9 35/10 38/23 48/17 52/20 58/10 59/3 75/12 80/20 85/1 98/6 99/1 113/19</p> <p>periodicals [1] 70/9</p> <p>persistent [3] 81/20 85/9 97/7</p> <p>person [4] 13/25 93/20 94/24 106/17</p> <p>personal [1] 100/25</p> <p>Peter [2] 110/11 113/7</p> <p>Peter Jones' [1] 113/7</p> <p>Pettigrew [4] 18/5 18/13 18/19 57/2</p> <p>PFC [20] 29/16 29/22 30/4 32/22 33/6 34/19 35/5 37/16 41/21 47/25 48/18 49/12 51/20 52/1 53/16 55/1 55/12 57/4 57/8 62/12</p> <p>physician [5] 4/20 11/8 43/20 96/18 114/11</p> <p>physicians [8] 8/6 11/17 13/8 23/13 69/3 71/6 71/20 76/17</p> <p>physiotherapist [1] 22/13</p> <p>physiotherapists [1] 22/10</p> <p>pick [7] 15/4 45/22 79/7 79/8 81/12 96/3 117/17</p> <p>picked [1] 17/16</p> <p>picking [2] 63/19 77/3</p> <p>piece [1] 45/16</p> <p>pieces [1] 98/11</p> <p>pink [2] 62/5 62/10</p> <p>pioneered [1] 11/23</p> <p>Pittsburgh [1] 96/16</p> <p>place [4] 19/18 71/7 71/8 94/2</p> <p>places [1] 92/17</p> <p>plain [1] 30/16</p> <p>plainly [1] 74/18</p> <p>plant [1] 66/12</p>	<p>plasma [13] 25/6 41/2 48/8 49/25 83/16 85/20 86/14 87/2 87/16 88/1 89/6 89/14 109/18</p> <p>please [32] 14/25 15/2 15/10 23/22 28/19 29/3 29/5 29/25 30/5 32/25 35/21 35/24 45/17 45/21 54/22 58/24 60/9 63/22 64/6 65/19 66/25 76/11 76/15 76/19 76/25 79/5 80/9 80/22 81/11 91/3 98/2 117/24</p> <p>pm [5] 1/2 59/10 59/12 118/3 118/4</p> <p>point [16] 4/15 18/20 19/9 21/3 32/3 58/20 62/2 85/18 85/24 91/20 94/6 94/7 94/18 94/22 100/1 105/20</p> <p>points [1] 60/4</p> <p>policies [1] 60/6</p> <p>policy [10] 24/15 27/16 34/10 49/4 49/6 50/8 50/11 52/3 54/10 87/13</p> <p>pool [6] 64/9 84/4 86/1 86/4 86/17 87/9</p> <p>pools [1] 83/16</p> <p>population [4] 31/15 66/6 74/21 92/3</p> <p>Porcine [1] 30/12</p> <p>porter [1] 41/18</p> <p>position [5] 1/24 49/7 56/18 103/2 108/16</p> <p>positively [1] 98/16</p> <p>possibility [3] 64/20 66/22 90/6</p> <p>possible [10] 20/13 24/13 25/13 25/25 50/15 50/25 52/19 54/12 57/24 66/4</p> <p>possibly [1] 80/6</p> <p>post [5] 3/24 79/12 79/14 79/18 86/10</p> <p>post-mortem [1] 86/10</p> <p>post-transfusion [3] 79/12 79/14 79/18</p> <p>potential [2] 64/2 65/5</p> <p>potentially [1] 82/11</p> <p>power [1] 21/11</p> <p>practical [2] 27/18 87/4</p> <p>practice [3] 23/20 32/9 116/17</p> <p>practitioner [3] 10/16 11/1 11/2</p> <p>precaution [1] 115/5</p>
---	--	---	---	--	---

(42) only... - precaution

<p>P</p> <p>precise [3] 16/18 18/7 32/19</p> <p>precisely [1] 98/17</p> <p>precision [1] 16/16</p> <p>precluded [1] 64/14</p> <p>predecessor [2] 5/18 24/23</p> <p>predecessors [6] 25/12 42/21 43/21 105/8 105/13 106/25</p> <p>predicting [1] 85/14</p> <p>prediction [2] 84/14 89/8</p> <p>predictions [2] 88/13 104/18</p> <p>predominant [1] 32/22</p> <p>predominantly [1] 23/19</p> <p>preferable [2] 25/9 26/23</p> <p>preference [3] 25/5 48/4 53/16</p> <p>preferred [3] 25/23 25/25 87/8</p> <p>pregnancy [1] 9/6</p> <p>pregnant [1] 27/5</p> <p>preliminary [1] 98/1</p> <p>prematurely [1] 90/7</p> <p>premium [1] 9/21</p> <p>Prentice [18] 4/22 13/7 21/7 21/20 24/7 31/1 31/16 32/5 43/22 47/9 47/14 58/11 60/12 68/10 68/22 73/10 110/7 113/20</p> <p>preparation [3] 41/2 71/14 78/18</p> <p>preparations [1] 83/1</p> <p>prepare [1] 61/17</p> <p>prepared [3] 15/1 39/24 41/3</p> <p>prescribing [1] 46/2</p> <p>present [1] 72/6</p> <p>presentation [5] 7/3 82/18 96/2 96/7 111/22</p> <p>presentations [1] 6/18</p> <p>presented [3] 7/6 44/16 76/7</p> <p>presenting [1] 7/12</p> <p>Preston [3] 96/2 96/7 97/12</p> <p>Preston's [3] 75/17 98/13 106/23</p> <p>Presumably [1] 101/24</p> <p>presumption [1] 23/23</p>	<p>pretty [2] 28/17 70/10</p> <p>prevalence [3] 74/20 82/23 88/22</p> <p>prevent [1] 106/18</p> <p>previous [7] 29/18 33/4 58/8 83/5 88/23 99/17 110/23</p> <p>previously [3] 52/18 53/4 58/5</p> <p>prick [1] 116/12</p> <p>primary [2] 43/7 44/9</p> <p>principally [1] 50/19</p> <p>principle [3] 52/25 61/18 108/18</p> <p>prior [8] 50/7 51/3 56/21 57/12 67/7 99/24 103/21 104/24</p> <p>prioritised [1] 64/15</p> <p>prioritising [1] 67/8</p> <p>probably [29] 15/3 21/5 22/18 29/6 30/9 34/5 35/23 37/7 37/23 38/5 39/21 47/7 47/21 48/2 49/11 53/3 63/1 77/25 79/5 82/20 84/19 85/25 86/11 87/9 89/5 91/24 93/4 96/4 101/2</p> <p>problem [17] 10/20 25/21 27/4 27/14 45/4 50/19 86/21 86/24 87/6 88/14 91/12 92/2 97/9 99/14 99/15 106/2 110/2</p> <p>problematic [3] 33/18 82/11 90/20</p> <p>problems [10] 31/23 57/19 76/13 81/16 97/2 97/5 107/12 108/1 111/17 113/25</p> <p>proceedings [2] 76/16 77/9</p> <p>process [5] 42/6 42/7 42/12 42/20 66/3</p> <p>produce [2] 48/18 50/24</p> <p>produced [7] 33/10 40/23 49/13 51/22 65/8 72/16 72/18</p> <p>producing [1] 64/20</p> <p>product [53] 20/15 30/7 31/20 33/7 33/25 35/4 38/3 38/4 38/11 41/14 41/17 44/7 44/7 44/8 44/13 47/22 50/14 50/16 50/18 50/18 51/1 52/6 52/8 52/16 52/23 53/10 53/18 53/24 54/2 54/7 55/12 56/13 56/15 57/4 57/8 59/19 60/1 60/14 60/16 61/4 61/9</p>	<p>62/1 62/1 62/15 63/11 63/16 65/1 65/3 65/8 65/25 66/3 66/16 87/21</p> <p>products [39] 4/24 5/4 5/12 28/21 28/23 31/8 31/23 32/24 33/15 33/20 34/15 36/23 37/11 40/11 40/14 40/15 40/23 42/3 42/23 42/25 43/5 43/15 43/17 44/14 45/13 47/19 50/22 53/8 53/12 59/23 60/6 63/20 65/8 67/17 74/15 74/17 74/23 95/16 105/25</p> <p>professional [1] 6/10</p> <p>professor [70] 1/3 2/11 2/13 2/15 3/25 4/21 4/22 5/22 8/17 8/18 8/19 9/3 9/15 9/16 9/17 10/6 11/18 12/25 14/9 15/2 15/22 16/20 18/6 19/22 20/3 20/4 20/5 20/22 21/18 28/4 30/5 32/20 35/21 38/24 39/22 40/10 44/2 45/19 45/24 48/25 50/3 51/6 54/20 54/24 57/1 59/13 60/4 66/7 68/4 69/10 75/17 77/16 79/2 80/25 82/6 89/19 90/8 95/4 97/15 98/13 98/15 100/18 107/6 108/9 108/14 113/5 116/15 117/19 117/24 119/2</p> <p>Professor Cash [1] 54/24</p> <p>Professor Davis [2] 10/6 11/18</p> <p>Professor Douglas [1] 12/25</p> <p>Professor Forbes [2] 45/24 48/25</p> <p>Professor Forbes' [2] 44/2 45/19</p> <p>Professor Hann [2] 18/6 20/22</p> <p>Professor Hay [1] 39/22</p> <p>Professor Ivana Markova [1] 89/19</p> <p>Professor Lowe [14] 2/11 2/15 28/4 38/24 40/10 60/4 68/4 77/16 80/25 98/15 107/6 108/14 113/5 117/19</p> <p>Professor Ludlam [1] 50/3</p> <p>Professor McGirr [1] 20/4</p>	<p>Professor McKillop [1] 5/22</p> <p>Professor McNicol [1] 4/22</p> <p>Professor Preston's [2] 75/17 98/13</p> <p>Professor Walker [3] 9/3 51/6 108/9</p> <p>professors [1] 21/14</p> <p>profusely [1] 112/1</p> <p>prognosis [2] 85/11 99/25</p> <p>programme [3] 69/1 70/12 113/4</p> <p>programmes [1] 71/12</p> <p>progress [4] 67/19 85/4 91/8 106/3</p> <p>progressed [3] 64/12 65/4 67/19</p> <p>progressing [2] 89/4 101/11</p> <p>progression [2] 93/16 99/3</p> <p>progressive [2] 101/8 101/23</p> <p>prominence [1] 84/6</p> <p>promising [2] 1/7 32/11</p> <p>pronouncements [1] 35/12</p> <p>proof [2] 78/6 78/14</p> <p>proofreading [2] 78/4 78/21</p> <p>proofs [3] 78/2 78/6 107/16</p> <p>properly [2] 102/24 103/4</p> <p>prophylaxis [1] 23/4</p> <p>Proplex [3] 30/6 31/3 31/8</p> <p>Proplex-type [1] 31/8</p> <p>proportion [3] 3/18 31/7 97/6</p> <p>propose [1] 5/19</p> <p>pros [2] 45/13 63/13</p> <p>prospective [1] 89/21</p> <p>protect [1] 115/17</p> <p>Protein [2] 34/23 41/4</p> <p>protocol [1] 61/2</p> <p>protocols [5] 60/13 60/19 60/20 60/21 60/23</p> <p>provide [3] 11/24 12/17 69/11</p> <p>provided [6] 12/20 62/18 63/9 63/13 70/25 113/16</p> <p>providing [1] 115/18</p> <p>provision [2] 4/24 106/16</p>	<p>PRSE0002887 [2] 14/25 29/3</p> <p>PRSE0006017 [1] 45/18</p> <p>Psychology [1] 89/20</p> <p>psychosocial [2] 89/21 105/18</p> <p>Public [1] 80/11</p> <p>publication [2] 67/8 76/12</p> <p>publications [3] 78/25 83/5 110/11</p> <p>publicised [1] 115/21</p> <p>published [8] 22/19 22/20 34/12 75/23 78/16 89/3 107/25 113/8</p> <p>purchase [1] 52/2</p> <p>purchased [2] 46/18 56/1</p> <p>pure [1] 65/12</p> <p>purpose [3] 77/5 114/23 115/16</p> <p>purposes [3] 2/17 39/24 43/6</p> <p>put [17] 3/19 27/12 28/12 33/6 36/21 41/25 45/23 60/8 65/18 84/8 101/7 101/25 107/15 107/21 108/10 109/20 115/5</p> <p>putting [2] 94/2 109/15</p> <p>Q</p> <p>quality [2] 42/11 44/5</p> <p>quantified [1] 114/12</p> <p>quantities [2] 29/16 29/17</p> <p>quantity [1] 57/8</p> <p>question [30] 20/19 23/2 25/24 28/21 39/15 44/4 45/23 46/11 46/19 53/22 55/11 84/24 85/21 89/9 90/3 93/24 94/8 95/4 95/8 95/19 98/15 100/19 102/3 103/20 104/23 106/7 107/6 113/5 113/13 116/15</p> <p>question: [1] 104/10</p> <p>question: yes [1] 104/10</p> <p>Questioned [2] 2/14 119/3</p> <p>questioning [1] 95/3</p> <p>questions [6] 7/20 36/15 51/10 70/17 100/24 104/16</p> <p>quickly [1] 83/25</p> <p>quite [13] 8/8 12/6 20/5 25/12 30/24</p>	<p>33/19 34/2 39/21 42/14 53/21 85/16 93/17 111/20</p> <p>quote [4] 98/3 99/4 101/5 103/16</p> <p>quoted [1] 89/18</p> <p>R</p> <p>raise [2] 33/21 33/23</p> <p>raised [1] 92/2</p> <p>ran [3] 5/3 32/6 59/23</p> <p>randomised [1] 32/12</p> <p>range [4] 18/10 29/11 29/19 72/5</p> <p>rapidly [2] 74/25 106/17</p> <p>rather [8] 26/1 26/5 35/15 35/23 38/3 61/21 73/22 101/3</p> <p>raw [1] 40/4</p> <p>ray [1] 22/8</p> <p>reached [3] 17/9 67/5 99/19</p> <p>reactions [5] 30/13 64/13 65/13 66/9 67/10</p> <p>read [18] 64/21 64/24 66/17 68/20 75/21 78/5 78/10 78/16 95/21 95/22 95/23 96/1 99/12 102/15 102/16 102/17 110/12 113/7</p> <p>reading [10] 55/14 68/14 70/8 82/14 91/24 94/5 94/13 102/13 107/16 108/23</p> <p>realise [2] 85/4 91/8</p> <p>realised [1] 74/25</p> <p>really [17] 3/20 38/7 38/10 40/3 40/18 58/17 83/23 84/24 91/20 93/3 98/15 100/19 102/2 102/14 103/7 103/10 115/6</p> <p>reason [7] 26/24 27/24 35/25 50/17 50/23 50/25 78/12</p> <p>reasonably [2] 15/23 97/3</p> <p>reasons [6] 1/18 53/13 57/6 67/3 87/8 113/9</p> <p>recall [11] 7/5 7/12 19/19 26/9 38/23 39/5 59/25 63/7 64/12 72/22 110/7</p> <p>receive [2] 23/24 70/6</p> <p>received [6] 40/22 78/3 82/24 82/25 83/2 83/19</p> <p>receiving [3] 24/1</p>
--	---	---	--	---	---

R	97/13 97/14 regarding [1] 48/10 regardless [1] 88/8 regime [2] 20/12 20/14 region [1] 4/6 register [2] 13/14 108/6 registered [12] 10/13 13/15 14/23 15/7 15/12 16/9 17/2 17/6 17/13 17/22 19/17 68/24 registrar [7] 2/20 3/14 9/16 22/16 22/17 41/11 71/10 registration [1] 27/22 regular [5] 6/10 70/22 71/21 82/1 116/14 regularly [2] 60/14 112/16 relapse [1] 77/21 related [1] 88/23 relating [2] 7/7 26/10 relation [9] 4/5 7/7 28/23 39/16 39/19 45/17 46/1 56/18 95/15 relationship [4] 7/22 9/11 58/15 105/6 relationships [1] 58/7 relatively [4] 54/15 83/16 84/9 98/9 relevant [1] 2/16 reluctant [1] 25/3 rely [1] 48/8 remained [2] 5/24 79/15 remains [1] 79/15 remarks [2] 79/6 79/7 remember [12] 7/6 7/9 25/23 26/23 68/16 69/5 69/22 70/3 75/23 110/3 110/14 116/24 remotely [1] 1/23 renal [1] 116/1 repeat [2] 107/14 108/10 repeated [1] 109/9 repeatedly [1] 110/9 rephrase [1] 93/25 replacement [1] 69/19 report [17] 6/11 15/1 29/1 29/3 39/23 49/1 51/19 67/5 67/6 67/16 74/1 98/1 98/13 98/20 99/21 99/21 103/16 reported [5] 65/25 66/1 81/3 92/16 116/9 reporting [3] 69/20 98/22 111/13 reports [2] 30/19	94/14 represented [2] 73/11 80/3 representing [1] 3/3 represents [1] 71/19 request [5] 43/25 61/15 104/13 115/15 115/20 requested [1] 60/17 required [3] 11/10 28/13 77/20 requirements [1] 66/5 requiring [1] 99/10 reread [1] 82/6 research [18] 3/1 3/6 3/16 4/2 6/9 6/11 6/18 6/24 7/7 7/9 7/11 7/13 7/13 8/20 10/11 12/7 77/6 77/12 residents [1] 24/19 respectively [2] 8/21 56/21 response [3] 104/9 110/15 110/22 responsibilities [5] 2/25 3/16 4/1 11/24 46/5 responsibility [3] 46/13 108/19 108/22 responsible [2] 39/3 46/3 rest [3] 3/7 10/9 78/1 restrictions [1] 1/14 result [5] 16/3 46/20 86/3 87/3 100/6 102/21 102/24 109/13 110/6 110/9 112/22 114/13 risks [13] 63/13 103/23 104/5 104/17 108/20 108/25 109/7 112/25 113/15 114/11 115/7 115/13 116/19 Rizza [1] 98/22 RLIT0001242 [1] 76/11 RNM [1] 79/8 RNM MacSween [1] 79/8 road [1] 8/4 Roger [1] 21/17 role [3] 5/16 6/7 78/20 room [7] 1/11 1/12 1/16 28/9 73/9 104/12 114/25 rotation [1] 3/9 round [5] 78/2 82/21 110/25 113/21 117/13 rounds [3] 73/8 116/25 116/25 routine [3] 12/18 12/20 12/23 routinely [2] 28/18 72/21 Royal [73] 2/20 3/15 5/5 5/6 7/17 7/24 7/25 8/7 8/16 8/22 8/24 9/1 9/2 9/10 9/17 11/3 12/12 13/6 15/5 15/11 15/16 16/25 17/1 17/3	18/8 18/16 18/17 18/24 19/14 19/17 20/2 20/11 21/5 21/16 23/18 24/11 24/22 29/7 34/13 40/13 40/17 40/21 41/12 42/25 49/7 50/7 50/11 51/14 56/2 56/2 56/12 56/22 57/7 58/8 69/2 70/23 71/6 72/9 72/12 76/17 83/6 83/8 83/11 83/18 87/13 88/7 88/16 89/23 109/6 112/4 112/7 113/17 116/18 Royal Free [5] 83/6 83/8 83/11 83/18 88/7 Royal Infirmary [33] 8/16 9/10 9/17 11/3 12/12 13/6 15/11 15/16 16/25 17/1 17/3 18/24 19/14 20/2 20/11 21/5 21/16 23/18 24/11 24/22 40/17 49/7 50/7 51/14 56/2 56/22 57/7 72/9 88/16 109/6 112/7 113/17 116/18 rules [1] 118/1 run [5] 5/12 11/16 13/17 41/12 47/11 running [2] 40/21 43/15 runs [1] 36/2	113/25 say [56] 14/18 15/25 23/23 27/2 27/3 33/17 34/1 34/11 36/6 37/9 42/14 44/12 49/16 58/22 59/5 60/11 62/11 62/15 62/17 62/18 63/25 64/7 64/11 66/7 66/17 66/24 69/14 73/12 73/15 74/6 74/10 78/20 82/9 86/8 86/25 91/20 93/9 93/12 94/8 97/13 97/18 97/22 98/4 99/9 102/8 102/17 103/13 105/2 105/25 107/17 112/20 112/23 116/4 116/13 118/2 118/2 saying [31] 18/14 22/24 28/18 35/13 48/3 52/5 53/17 53/21 58/2 69/22 74/9 80/20 84/23 85/23 87/24 90/2 90/16 91/3 92/1 93/19 94/3 94/11 98/16 100/22 101/16 103/9 108/10 109/11 109/17 110/3 117/14 saying: [1] 105/8 saying: well [1] 105/8 says [20] 5/7 42/21 42/23 54/24 61/13 74/11 79/21 80/18 81/13 81/13 82/1 82/8 84/19 91/5 91/23 96/9 96/22 105/20 106/12 112/3 SBTS0000687 [1] 54/22 scene [1] 1/10 school [2] 8/3 8/6 scientific [3] 68/8 70/7 108/4 Scotland [29] 9/19 10/7 10/22 11/9 11/12 16/23 17/4 17/16 18/12 24/20 25/11 34/25 40/23 48/19 51/21 52/4 52/22 54/11 55/12 56/8 58/3 65/9 72/13 74/22 107/19 110/16 111/21 112/15 115/22 Scottish [13] 6/4 6/8 6/13 25/19 40/24 52/12 55/23 74/13 87/23 111/2 111/6 111/13 113/2 screen [4] 14/25 57/16 60/8 65/18 screening [1] 79/10
----------	---	--	--	--

(44) receiving... - screening

S	3/23 69/3 76/18 78/12 100/14	61/19 62/18 63/9 71/17 85/12 86/8 86/15 89/9 90/4 95/10 96/15 105/21 117/17	slow [1] 37/5 small [6] 3/17 27/18 31/15 83/16 86/9 100/4 smaller [4] 29/12 29/17 52/15 64/9 smart [1] 117/13 SNB.001.6951 [1] 69/4 SNBTS [18] 25/10 34/22 41/5 44/7 46/22 48/10 48/12 53/8 53/12 53/18 64/2 64/15 65/9 65/10 67/8 67/13 67/17 67/21 so [169] so-called [1] 31/2 societies [1] 6/1 society [13] 6/4 6/9 6/10 6/13 6/24 7/6 26/22 110/11 111/3 111/6 111/7 111/14 113/3 sole [1] 86/16 solely [1] 111/19 solicitor [1] 2/6 solution [1] 32/10 some [37] 5/17 17/16 25/16 27/5 27/24 29/1 30/14 30/23 31/9 31/13 32/23 47/5 50/23 52/17 62/9 62/13 66/17 67/7 78/4 79/13 82/3 84/15 85/14 85/19 88/3 92/23 93/18 99/18 105/12 105/20 111/14 114/14 115/24 116/21 117/1 117/2 117/13 somebody [1] 58/2 somebody's [1] 48/6 someone [2] 43/7 95/20 something [12] 16/10 30/17 49/19 63/20 67/4 82/10 87/21 91/14 93/14 106/17 112/9 114/7 sometimes [6] 13/24 18/10 48/13 73/18 117/6 117/7 somewhere [1] 62/23 sooner [1] 84/10 sore [1] 107/16 sorry [28] 2/2 5/9 9/15 12/9 13/23 23/16 35/21 39/7 41/16 51/5 51/5 52/25 53/1 57/15 69/14 80/15 85/17 86/6 88/10 90/1 93/22 95/2 97/16 100/10 103/11 103/13 112/4	117/25 sort [4] 36/24 40/7 91/12 97/4 Soumik [33] 1/19 14/24 15/2 15/10 18/3 29/5 29/25 32/25 35/21 40/9 45/18 45/21 54/22 60/9 63/22 64/6 66/25 68/3 76/11 76/15 76/25 79/5 80/9 80/14 80/23 81/11 82/20 84/21 90/18 90/25 96/5 97/20 98/2 sounds [1] 30/8 source [1] 48/14 sources [3] 67/25 68/9 113/11 south [1] 25/2 south-west [1] 25/2 spans [1] 16/1 spared [1] 34/14 speak [1] 114/25 speaker [1] 111/9 speakers [2] 69/16 73/18 special [2] 14/18 32/4 specialised [1] 22/10 specialist [1] 22/12 specialists [1] 21/9 specialties [8] 3/9 71/16 71/23 72/4 72/7 72/9 73/11 108/7 specialty [3] 11/20 73/6 73/16 specific [2] 60/20 61/18 specifically [2] 69/12 73/24 specimen [1] 115/16 specimens [1] 92/11 spectrum [1] 94/14 spell [1] 24/4 spend [2] 10/9 111/14 spending [1] 117/1 spent [3] 2/24 4/4 10/6 spleen [1] 114/3 split [2] 8/15 8/19 spoken [1] 56/17 spread [1] 14/21 stack [1] 62/3 staff [5] 1/19 5/1 115/3 115/17 116/6 staffing [1] 7/21 stage [7] 15/7 28/16 41/23 41/23 64/25 81/1 81/4 stages [1] 67/19 stamp [1] 28/18 standard [2] 36/21 106/10	start [9] 1/7 2/15 8/4 12/1 18/18 29/4 59/16 74/6 90/6 started [4] 16/4 22/5 49/11 116/3 starting [4] 12/3 34/3 41/7 88/15 starts [2] 13/25 97/19 state [2] 31/16 73/19 stated [3] 42/8 59/20 102/5 statement [33] 2/19 2/23 3/19 5/7 5/15 5/25 7/10 7/18 10/24 15/21 40/10 42/21 42/23 44/1 59/20 60/5 60/7 61/13 63/20 66/7 68/2 68/9 73/25 75/15 95/6 97/16 97/17 97/18 98/20 99/14 100/14 113/18 115/14 States [1] 111/15 statistical [4] 15/1 29/3 39/23 49/1 stay [2] 33/12 57/21 stayed [2] 26/6 89/12 steamie [2] 112/23 116/13 Steven [2] 22/16 88/19 Stevens [3] 99/8 99/13 101/5 stick [1] 70/14 still [10] 3/14 13/8 28/6 29/23 30/2 32/23 61/19 63/19 78/1 86/24 Stirling [1] 89/20 stock [8] 41/14 41/16 42/5 43/16 46/25 48/4 51/15 53/18 stocks [1] 41/21 stop [2] 106/24 112/25 stopped [3] 90/4 90/5 105/21 storage [1] 28/12 store [1] 46/24 stores [1] 51/16 straight [1] 76/10 Stranraer [1] 25/2 Street [1] 21/15 strengthen [1] 44/3 stretch [1] 58/23 stretched [1] 28/11 strikes [1] 94/13 strong [1] 58/4 student [1] 19/21 students [2] 74/12 117/3 studies [19] 6/20 20/7 22/14 84/13 88/7 92/3
----------	---------------------------------	--	--	--	---

S	<p>studies... [13] 92/9 92/10 92/12 92/22 93/11 98/8 99/17 99/20 100/5 100/16 100/20 104/11 105/7</p> <p>study [15] 2/4 22/18 53/5 53/5 53/8 75/18 77/7 83/9 83/22 83/23 89/21 92/9 99/4 99/16 104/19</p> <p>Sturrock [1] 21/17</p> <p>subject [2] 16/14 92/23</p> <p>submission [3] 39/3 95/9 102/23</p> <p>submissions [2] 16/14 26/15</p> <p>submit [1] 110/19</p> <p>subscribing [1] 68/17</p> <p>subscription [2] 68/19 76/3</p> <p>subsequent [1] 108/3</p> <p>subsequently [1] 39/22</p> <p>substantial [5] 29/9 29/14 29/21 30/3 57/8</p> <p>substantially [1] 79/11</p> <p>subtype [1] 110/2</p> <p>succeeded [2] 5/11 38/12</p> <p>success [1] 108/12</p> <p>successfully [1] 106/15</p> <p>successors [3] 13/7 47/13 47/13</p> <p>such [9] 18/17 18/25 49/6 66/3 70/5 70/21 72/17 85/10 88/7</p> <p>suddenly [2] 13/25 17/17</p> <p>suffering [1] 101/22</p> <p>sufficiency [1] 34/25</p> <p>sufficient [1] 48/12</p> <p>suggest [5] 5/18 49/3 50/4 55/10 67/21</p> <p>suggested [3] 35/22 57/5 68/22</p> <p>suggestion [1] 67/2</p> <p>suggestive [1] 81/14</p> <p>suggests [4] 40/10 49/1 66/10 67/6</p> <p>summarise [2] 73/21 86/19</p> <p>summarised [2] 97/25 111/17</p> <p>summarising [1] 62/6</p> <p>summary [3] 65/20 70/13 93/5</p> <p>supplement [1] 52/1</p>	<p>supplied [1] 25/9</p> <p>Suppose [1] 53/13</p> <p>sure [4] 1/20 32/4 35/13 117/19</p> <p>surely [1] 104/21</p> <p>surgeons [5] 8/6 69/3 71/6 71/20 76/17</p> <p>surgery [8] 8/18 10/20 17/18 24/12 42/17 46/8 48/7 51/24</p> <p>surgical [2] 27/25 77/22</p> <p>surmise [1] 35/23</p> <p>surprise [1] 36/13</p> <p>surprising [1] 106/21</p> <p>survived [1] 61/20</p> <p>surviving [1] 17/12</p> <p>suspect [3] 1/11 23/3 48/22</p> <p>swear [2] 1/22 2/11</p> <p>switch [2] 50/18 52/20</p> <p>switched [2] 50/22 52/6</p> <p>sworn [2] 2/13 119/2</p> <p>sympathetic [1] 57/21</p> <p>sympathise [1] 77/24</p> <p>symposium [18] 76/6 76/16 76/24 77/14 77/16 78/5 82/13 83/17 94/2 95/22 98/14 98/18 100/25 107/8 107/9 107/18 107/24 108/4</p> <p>symposiums [1] 108/11</p> <p>symptomless [1] 81/13</p> <p>synthetic [4] 33/21 34/1 37/2 38/3</p> <p>system [8] 44/5 48/24 49/4 49/10 50/23 51/2 51/14 70/4</p> <p>systematic [3] 88/19 92/9 100/10</p>	<p>taking [6] 35/6 43/16 56/22 95/11 95/15 103/11</p> <p>talk [10] 59/7 69/7 72/6 81/6 111/19 112/1 112/8 112/11 112/23 116/12</p> <p>talked [1] 74/6</p> <p>talking [18] 2/2 22/23 47/5 56/6 60/11 63/24 70/3 73/10 74/3 74/14 80/25 90/20 95/12 95/13 110/22 113/6 117/2 117/2</p> <p>talks [3] 74/17 81/16 81/23</p> <p>task [1] 32/8</p> <p>taught [1] 74/12</p> <p>tea [1] 58/23</p> <p>teachers [1] 18/23</p> <p>teaching [5] 2/25 3/6 3/16 4/2 116/25</p> <p>team [1] 1/17</p> <p>technical [1] 78/6</p> <p>technological [1] 1/8</p> <p>technology [1] 66/3</p> <p>teens [1] 18/11</p> <p>telephone [2] 10/17 61/15</p> <p>tell [7] 1/24 6/6 38/1 102/16 103/11 110/25 113/14</p> <p>telling [1] 105/24</p> <p>ten [8] 1/15 10/6 84/16 85/2 91/6 93/11 96/11 96/14</p> <p>tended [1] 98/9</p> <p>tends [1] 106/5</p> <p>term [3] 86/12 103/23 104/5</p> <p>terminology [1] 75/5</p> <p>terms [29] 2/23 4/13 5/17 17/5 18/4 20/12 20/14 22/25 23/11 25/22 27/18 29/10 33/2 33/14 40/11 44/21 62/16 64/23 65/3 68/6 72/16 73/24 79/9 82/8 84/5 87/4 87/7 87/20 98/16</p> <p>terrible [1] 106/24</p> <p>test [1] 9/24</p> <p>tests [13] 12/18 12/23 18/1 83/4 83/12 83/24 88/9 88/20 88/23 97/8 105/4 105/5 105/9</p> <p>than [20] 1/15 26/1 33/15 35/15 35/23 38/4 38/19 42/16 43/7 61/21 62/11 70/8 73/22 79/19 91/25 99/25 101/3 107/14</p>	<p>110/8 113/9</p> <p>thank [15] 2/4 17/24 18/3 37/1 54/19 59/2 59/9 59/15 60/3 67/15 68/1 68/2 91/1 95/2 107/4</p> <p>thanked [1] 111/25</p> <p>that [532]</p> <p>that's [42] 1/7 2/22 3/5 9/2 15/3 18/12 27/3 31/5 41/22 45/23 46/20 48/2 52/21 52/24 63/21 66/18 68/12 68/18 74/20 75/8 79/6 80/16 82/19 82/22 87/9 90/18 91/23 93/5 93/18 94/10 99/11 101/17 101/19 101/21 103/10 104/7 106/3 106/4 107/4 112/5 115/5 115/17</p> <p>their [23] 9/10 10/15 13/19 13/25 16/23 18/6 23/9 25/23 26/20 31/17 47/13 47/13 72/7 75/19 78/24 88/8 88/13 106/7 108/25 113/17 114/10 115/7 116/11</p> <p>them [36] 4/16 8/8 9/6 10/8 12/14 14/4 17/16 20/6 22/18 27/12 27/16 27/17 31/3 38/14 38/15 39/12 46/2 52/16 71/24 73/2 78/24 89/24 91/22 92/14 92/21 92/23 96/15 103/25 105/12 106/2 106/18 112/25 113/23 115/7 115/19 117/4</p> <p>theme [2] 54/22 99/3</p> <p>themes [1] 82/10</p> <p>themselves [3] 43/13 108/23 117/7</p> <p>then [92] 1/18 3/13 3/23 4/17 4/22 7/20 10/5 10/13 10/21 11/19 11/24 12/16 15/10 15/16 16/6 17/17 19/8 19/10 20/25 23/2 28/11 29/10 30/1 32/17 32/18 32/25 33/4 35/7 39/4 39/11 41/17 44/18 46/11 46/15 46/19 46/23 49/17 50/6 51/2 51/7 52/16 55/4 55/4 55/6 56/3 56/3 61/6 62/16 63/3 63/19 64/4 64/11 65/2</p>	<p>68/17 69/25 71/25 73/9 73/15 76/18 76/22 76/24 77/13 77/21 79/8 79/21 80/7 80/22 81/6 81/8 81/16 82/1 83/17 86/2 89/2 93/5 96/1 96/3 96/22 98/2 98/11 98/21 99/4 99/13 99/13 99/15 99/20 103/15 103/19 104/13 109/19 113/2 114/2</p> <p>then ... so [1] 19/8</p> <p>therapy [4] 69/19 76/22 80/3 102/19</p> <p>there [112] 1/18 1/19 3/20 6/2 8/7 8/16 9/8 11/6 11/13 14/11 14/11 14/15 15/13 16/6 18/7 19/4 19/16 19/17 19/20 19/23 20/8 20/15 23/1 23/23 25/4 25/18 26/6 26/9 26/20 26/24 29/7 30/16 30/19 30/24 31/25 32/4 33/6 33/9 34/6 35/11 35/25 36/16 36/17 42/18 44/15 45/4 45/9 45/15 46/7 47/8 47/25 48/2 48/12 48/13 48/15 49/3 49/6 50/7 51/19 51/25 53/14 60/4 60/23 61/6 62/13 71/20 72/5 72/8 73/11 73/19 75/6 76/8 76/15 76/21 79/16 79/18 81/1 81/5 82/16 84/2 84/15 84/18 85/21 86/9 88/21 89/16 91/13 92/6 92/17 93/10 94/1 94/14 97/10 98/7 101/12 101/16 102/25 104/10 104/11 104/19 105/17 107/8 109/3 109/13 109/24 111/6 111/15 111/18 113/14 114/12 116/10 117/12</p> <p>there's [24] 8/4 8/8 33/5 35/8 46/15 48/20 55/4 58/4 58/16 62/2 66/17 67/15 71/14 74/9 75/2 75/9 80/24 86/21 87/5 93/21 96/1 104/15 104/16 112/5</p> <p>thereafter [1] 59/22</p> <p>therefore [4] 53/19 91/15 91/18 106/24</p> <p>these [55] 14/10 15/23 16/21 17/2 26/13 26/23 31/1 31/7</p>	<p>31/13 31/23 32/16 36/22 37/2 39/16 44/14 53/10 54/6 60/19 61/1 63/2 63/5 63/7 67/17 71/12 77/8 80/1 80/2 81/19 82/14 85/3 85/4 85/6 85/9 85/19 88/12 91/7 91/8 91/10 92/1 92/2 93/14 94/4 94/14 96/22 96/25 99/17 99/20 101/1 105/11 108/11 113/21 114/22 115/24 116/7 116/25</p> <p>they [132]</p> <p>They'd [1] 41/11</p> <p>they're [2] 105/9 116/23</p> <p>thin [1] 61/23</p> <p>thing [6] 18/25 33/17 37/8 86/8 93/19 117/14</p> <p>things [6] 15/4 24/12 53/9 78/7 105/2 112/21</p> <p>think [204]</p> <p>thinking [4] 18/18 74/5 85/2 91/6</p> <p>third [9] 49/16 49/18 49/18 49/18 67/25 77/3 79/9 81/12 97/2</p> <p>this [115] 4/3 11/16 12/2 12/6 14/25 16/13 16/18 16/21 16/25 22/24 23/21 30/20 33/9 33/13 34/20 35/13 36/20 38/7 38/15 39/23 40/4 42/23 44/17 45/17 51/8 51/13 54/23 55/10 55/14 55/17 55/20 55/23 56/6 56/8 56/15 56/19 57/18 57/22 58/19 59/21 61/12 64/5 64/21 64/22 65/8 66/16 66/20 69/1 69/5 69/16 70/10 70/19 71/7 71/15 71/19 72/2 74/24 76/11 77/1 77/14 77/16 77/17 78/5 78/7 79/2 79/13 79/21 79/24 80/5 82/7 82/10 82/13 82/22 83/17 84/5 84/8 84/25 85/17 86/2 86/3 87/10 87/22 87/23 88/6 88/24 89/10 91/17 91/20 91/25 94/1 94/24 95/8 95/21 96/6 96/8 97/14 98/14 100/1 100/3 100/14</p>
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T	75/21 75/22 76/4 83/17 84/6 84/16 85/16 87/18 88/3 88/6 88/24 90/3 93/18 95/5 95/12 96/11 96/12 97/5 97/14 98/6 99/18 100/11 100/13 100/21 101/1 101/3 103/8 103/9 103/10 103/11 103/14 103/19 103/25 104/9 105/1 105/11 106/8 107/7 111/12 111/15 112/18 113/19 113/23 113/24 115/23 116/22 117/1 117/2 117/17 118/1 times [9] 6/15 20/25 30/25 42/13 47/25 48/12 50/10 57/9 62/8 tired [1] 53/2 to [601] together [5] 23/13 47/18 47/18 48/25 84/8 told [17] 2/23 10/19 39/16 46/10 46/18 46/20 46/24 70/13 75/9 90/15 95/21 100/23 108/25 110/18 113/4 114/10 116/7 tomorrow [5] 69/13 117/18 117/21 117/23 118/2 too [3] 18/9 28/11 100/18 took [13] 12/16 12/18 12/24 13/2 34/2 68/18 71/3 72/9 76/3 84/3 94/2 99/18 116/4 top [6] 33/1 35/20 60/9 65/10 65/20 85/7 topic [6] 51/11 63/19 76/20 111/19 116/15 117/16 total [6] 15/9 15/15 15/18 15/20 39/6 39/12 totally [1] 65/11 touch [1] 25/15 towards [2] 63/23 64/6 town [2] 8/15 26/3 traditionally [1] 50/22 train [1] 12/3 trained [4] 9/22 12/4 19/20 47/12 trainee [1] 71/21 training [3] 3/8 6/18 114/16 transfer [7] 18/8 19/1 19/6 20/19 22/21 22/22 55/5	transferred [3] 20/10 36/12 54/16 transferring [1] 23/17 transfusion [11] 5/13 11/10 11/25 12/17 25/11 40/24 74/15 79/12 79/14 79/18 99/10 transfusion-requiring [1] 99/10 transitions [1] 19/13 transmissible [1] 79/17 transmitted [1] 27/1 transplant [3] 101/13 101/24 116/1 trauma [1] 10/19 travel [1] 25/3 Travenol [3] 29/12 37/16 44/7 Travenol/Hyland/Hem ofil [1] 29/12 treat [5] 12/14 16/13 44/14 87/7 106/15 treated [10] 11/12 14/6 16/23 19/16 23/18 30/14 35/14 52/14 53/5 91/15 treaters [2] 87/5 89/10 treating [11] 23/5 43/7 44/9 44/24 53/23 87/2 95/10 106/24 108/25 111/11 115/25 treatment [71] 3/3 9/4 9/13 10/21 11/4 11/5 11/9 12/14 13/5 14/18 17/11 20/12 20/14 20/14 20/21 20/24 21/2 23/1 23/2 23/11 23/25 27/21 28/3 30/10 30/11 32/22 33/7 34/16 44/19 44/21 50/21 53/7 54/14 59/19 60/6 60/22 61/11 62/17 64/10 64/14 65/15 65/23 67/11 67/14 67/19 82/1 83/25 88/5 88/8 88/24 89/17 89/24 90/5 95/15 98/22 105/19 105/22 106/11 106/12 108/20 112/12 112/13 113/1 113/22 114/4 114/6 115/7 115/9 115/11 116/6 116/19 treatments [8] 10/2 14/11 20/18 25/22 32/11 45/8 114/5 114/6 tree [2] 10/8 27/22 trends [1] 16/15	trial [2] 32/12 65/1 trials [1] 65/5 tried [7] 24/13 27/7 27/17 30/23 54/12 103/17 112/20 Triger [5] 96/2 96/7 96/9 97/4 97/11 triggered [1] 50/24 trouble [2] 37/7 96/21 try [4] 73/4 84/21 87/15 90/25 trying [10] 32/8 50/25 53/1 75/23 78/24 91/11 93/9 93/22 100/14 104/7 turn [7] 12/12 13/4 57/19 68/23 72/10 85/19 98/19 turned [1] 27/23 turning [3] 51/8 99/14 99/25 turns [1] 81/8 twice [2] 23/5 110/4 two [49] 1/21 6/2 6/14 7/2 8/15 8/20 9/22 9/24 13/7 13/21 14/21 14/21 19/5 20/6 20/9 20/17 21/13 22/17 32/10 36/15 55/15 55/22 56/1 56/10 56/23 56/24 57/11 58/17 60/23 63/21 68/19 75/2 76/14 76/19 80/8 80/22 81/4 82/2 88/12 96/5 96/16 96/22 98/24 104/15 105/2 107/21 108/3 110/4 112/21 type [10] 20/14 20/25 31/6 31/8 47/22 50/9 60/14 61/9 63/11 111/16 types [1] 9/25 Typically [1] 68/13	uncertain [1] 100/6 under [5] 4/14 9/16 80/17 80/23 96/13 undergone [1] 81/18 understand [7] 2/19 49/10 50/6 53/21 76/13 91/2 95/12 understandably [1] 57/21 understanding [5] 66/21 74/2 95/7 97/24 115/7 understated [1] 99/15 understood [2] 100/8 100/22 undertaken [2] 63/24 64/18 Underwood [1] 96/8 undesirable [1] 50/15 unethical [1] 92/5 unfortunate [2] 17/10 80/4 uniformly [1] 56/7 unify [1] 73/4 uninterrupted [1] 1/8 unique [2] 71/19 77/10 uniquely [1] 21/5 unit [17] 3/5 4/9 14/9 26/17 27/19 36/12 36/24 37/10 38/20 64/22 71/2 71/5 72/8 74/6 74/8 92/5 109/10 United [1] 111/15 United States [1] 111/15 units [12] 14/9 36/1 36/20 36/20 36/24 37/8 37/14 42/17 62/13 116/1 116/1 116/2 university [11] 7/23 8/3 8/5 8/9 8/12 9/12 12/10 19/25 20/1 21/16 89/20 unlike [1] 89/13 unpick [1] 91/11 unquestionable [1] 89/16 unreasonable [2] 103/22 104/25 Unresolved [1] 76/13 unsolved [3] 107/12 108/1 111/17 until [9] 5/8 5/25 19/7 28/24 32/7 38/12 86/20 117/20 118/4 untreated [2] 53/4 83/3 unusual [2] 43/3 44/13 unusually [1] 92/16	up [53] 8/1 9/18 10/3 11/21 12/12 12/25 13/4 13/19 14/25 15/4 17/16 19/8 23/7 23/8 25/21 27/23 39/12 40/18 41/11 42/6 43/2 43/23 45/22 53/4 53/9 57/16 60/8 60/25 63/19 65/18 66/24 68/7 70/25 71/12 72/14 77/3 79/7 79/8 81/12 83/18 83/25 86/20 87/11 96/3 96/21 109/15 109/16 109/17 109/18 109/20 113/22 114/6 117/18 up-to-date [4] 68/7 70/25 71/12 72/14 update [4] 72/10 73/13 78/8 111/24 updated [5] 60/14 61/1 61/11 71/9 112/16 updates [3] 68/10 71/16 71/21 updating [1] 71/24 upon [4] 18/9 51/15 91/12 114/14 us [17] 1/24 2/23 6/6 7/17 36/7 37/12 38/7 42/15 50/2 55/15 60/1 70/16 73/13 78/24 90/15 95/21 102/16 usage [6] 36/1 36/8 38/24 39/4 39/17 40/6 use [33] 24/13 30/23 32/20 33/24 33/25 34/4 34/13 35/3 35/9 35/18 37/19 38/4 38/11 40/7 44/8 46/4 46/12 48/13 48/21 49/15 51/23 53/19 53/20 54/8 64/2 66/16 69/21 79/25 80/2 83/15 84/17 86/1 95/16 used [25] 24/9 24/10 24/11 28/22 29/10 29/20 30/8 30/9 30/12 31/10 32/24 34/3 34/16 36/14 36/25 43/5 46/21 46/21 49/3 54/2 65/22 83/10 84/7 86/14 86/23 useful [3] 30/20 49/14 107/19 using [8] 14/11 31/1 34/8 35/15 38/20 57/6 90/4 90/5 usual [4] 60/15 61/4 61/10 62/15 usually [8] 7/2 19/11
----------	--	--	--	---	---

(47) this... - usually

<p>U</p> <p>usually... [6] 19/21 20/22 30/17 41/10 41/13 42/16</p> <p>V</p> <p>valid [1] 18/19 valuable [1] 78/22 value [1] 66/4 varices [1] 96/18 varied [1] 30/11 varies [1] 31/13 variety [1] 6/20 various [12] 3/9 14/11 17/15 32/23 35/12 36/22 49/3 71/16 77/13 80/1 98/11 100/19 vascular [1] 7/11 versus [1] 49/23 very [91] 1/12 3/17 7/11 7/13 7/17 7/25 8/4 8/20 10/16 10/22 15/22 15/22 17/9 18/19 18/22 19/2 19/8 19/24 20/8 21/9 21/19 21/22 22/1 22/3 22/9 22/18 22/22 23/10 23/10 23/12 24/10 26/24 30/11 32/8 34/13 35/11 42/5 42/6 42/10 42/19 44/22 46/17 47/7 47/8 47/20 47/20 50/12 53/4 53/9 53/11 54/19 57/18 57/20 67/18 68/1 69/5 69/21 70/12 71/1 72/15 73/7 74/18 75/11 77/19 78/12 78/23 80/16 87/12 87/22 88/10 88/12 88/19 92/3 94/17 95/2 96/11 98/6 102/6 103/17 105/6 106/20 107/4 107/4 107/19 109/12 111/2 111/6 111/16 111/24 115/4 116/7 vial [2] 37/4 42/9 view [7] 67/12 96/24 99/23 100/25 103/23 104/25 117/9 viewing [1] 38/7 viewpoint [1] 92/24 views' [1] 100/2 VIII [44] 9/25 10/3 10/10 13/25 15/7 15/14 15/19 29/16 29/16 29/23 30/4 30/10 30/12 31/5 32/23 33/22 34/20</p>	<p>36/25 37/10 37/15 37/15 41/6 42/17 48/1 48/11 48/14 48/19 48/22 49/12 51/20 52/9 52/22 55/1 55/8 62/12 64/15 65/3 65/12 66/5 67/9 80/10 82/1 83/1 99/5 viral [4] 53/8 65/14 87/18 106/9 virally [4] 52/8 52/9 53/12 67/10 virus [3] 69/18 79/19 87/25 visit [1] 110/23 visited [2] 7/1 77/24 visiting [1] 3/21 vivo [1] 65/24 volume [3] 29/14 33/2 67/15 volumes [6] 26/14 29/9 29/21 29/22 33/6 36/1 volumes: [1] 29/12 volumes: Kryobulin [1] 29/12 voluminous [1] 70/1 volunteer [1] 85/25 von [8] 13/3 15/8 15/14 15/19 17/25 33/23 33/24 38/2 von Willebrand [3] 15/14 15/19 33/23 von Willebrand's [5] 13/3 15/8 17/25 33/24 38/2</p> <p>W</p> <p>wait [1] 19/7 walk [1] 9/1 Walker [13] 5/4 5/8 5/13 9/3 13/12 14/4 14/18 44/23 47/16 51/6 59/22 63/25 108/9 Walker's [1] 31/19 wall [3] 74/9 109/11 115/5 wander [1] 117/13 want [21] 7/15 7/20 19/6 28/21 35/21 45/16 52/5 52/7 56/8 66/19 70/13 70/14 80/14 87/6 91/2 91/19 94/11 108/16 109/24 110/2 115/9 wanted [10] 6/2 9/18 26/7 26/16 53/6 53/9 60/5 68/4 107/9 107/11 wanting [3] 26/20 87/22 112/25</p>	<p>wants [2] 27/5 57/25 ward [8] 28/1 41/8 60/24 63/1 73/8 113/21 116/24 116/25 wards [7] 4/11 12/11 14/13 31/17 31/19 36/12 62/23 warn [1] 110/8 warning [1] 115/3 warnings [1] 114/22 was [435] was: [1] 75/6 was: that [1] 75/6 wasn't [17] 18/7 36/11 38/10 50/7 55/21 57/13 57/14 58/18 66/8 66/15 69/22 90/14 90/19 95/18 107/2 115/17 117/12 watching [1] 1/23 watershed [1] 101/20 way [11] 6/12 38/18 52/21 54/18 63/13 66/13 91/24 94/2 103/3 104/7 106/15 ways [1] 70/23 we [209] we'd [1] 87/1 we'll [5] 1/9 44/1 44/18 65/20 92/22 we're [10] 39/16 40/1 43/1 52/1 65/11 85/17 95/12 95/13 110/22 110/23 we've [8] 15/11 29/17 44/16 67/5 70/15 72/19 95/24 109/23 wearing [1] 1/17 web [1] 8/11 website [1] 8/10 Wednesday [1] 1/1 week [1] 23/5 weekly [4] 41/25 71/13 72/5 72/8 weeks [1] 83/24 weight [1] 37/24 well [36] 1/6 1/9 9/8 22/15 22/24 24/3 25/25 27/3 28/9 37/1 39/23 46/22 50/11 51/18 53/25 58/2 58/21 61/21 65/17 69/17 70/10 71/1 74/6 77/17 93/12 94/3 94/10 94/23 97/16 100/4 105/8 109/9 109/12 110/3 115/10 116/21 went [2] 9/20 83/25 were [145] weren't [5] 34/8 45/15 72/21 75/11 95/21</p>	<p>west [18] 8/12 8/23 9/19 10/7 10/22 11/9 11/12 16/23 17/4 17/15 24/20 25/1 25/2 25/11 40/23 58/3 65/9 72/13 Western [4] 8/14 8/16 8/22 18/17 what [158] what's [4] 77/1 87/6 101/20 113/25 whatever [11] 26/22 27/15 51/24 59/7 62/10 75/10 103/5 105/22 109/18 109/20 110/2 when [58] 1/13 1/14 1/20 8/1 11/22 14/1 20/3 20/10 21/14 21/20 23/3 27/9 28/4 34/6 34/12 35/11 36/17 38/24 40/19 45/11 48/1 48/3 48/13 48/21 49/15 51/18 54/2 54/4 58/14 68/17 68/18 68/22 71/2 73/15 74/8 78/1 83/10 84/6 85/5 86/14 89/11 89/14 91/9 93/10 94/1 96/15 96/19 97/9 100/1 100/23 104/23 107/15 109/15 113/19 113/22 116/3 116/21 117/13 where [22] 6/11 9/2 13/24 26/9 41/18 42/4 46/7 48/20 62/19 72/6 72/9 74/15 79/9 91/5 92/10 92/12 97/19 101/5 111/15 114/18 114/24 115/2 whereas [2] 18/24 57/7 wherever [1] 24/13 whether [18] 7/5 16/20 16/21 19/14 28/14 42/10 46/3 72/22 75/13 75/21 82/6 101/21 102/24 102/25 108/23 114/11 115/25 117/17 which [110] 4/23 5/2 6/1 6/16 7/3 8/3 9/21 9/24 10/12 10/25 11/6 11/6 11/18 12/4 12/19 13/17 14/14 18/7 21/15 21/20 23/4 23/4 23/6 24/25 25/2 25/10 26/2 27/19 31/5 31/20 32/4 32/5 32/9 32/14 33/9 33/15 35/4 36/18 37/11 38/1 38/4 41/3</p>	<p>41/5 41/12 41/21 42/7 43/1 44/3 45/12 46/9 49/1 50/21 53/23 57/21 58/20 60/7 60/16 61/23 62/17 63/5 64/13 65/24 67/4 67/6 67/9 67/16 67/24 70/1 70/5 70/12 70/20 70/23 71/13 73/17 75/18 76/6 77/2 77/10 77/22 78/11 80/1 80/12 87/21 91/14 92/21 96/11 97/16 98/12 99/16 100/4 101/23 102/18 102/20 103/16 104/21 106/10 107/24 107/25 108/11 108/13 109/5 109/13 110/12 111/17 113/7 113/24 114/19 114/25 116/22 117/12 while [6] 36/19 79/13 80/2 85/17 87/12 109/20 whilst [2] 28/16 115/4 White [1] 99/4 who [69] 1/22 1/23 4/11 6/17 6/18 8/6 9/16 11/8 12/6 13/4 13/8 16/8 16/22 16/25 17/2 17/13 18/21 21/17 23/13 23/18 24/18 28/11 30/21 34/21 43/11 43/12 43/16 45/3 52/8 52/10 53/6 54/14 54/15 54/17 56/13 56/14 58/5 58/12 58/15 59/23 60/24 60/25 63/1 63/3 64/23 69/17 71/5 72/23 82/24 82/25 83/2 83/19 83/25 84/1 84/15 86/10 88/6 89/3 91/14 94/19 95/20 111/9 113/2 113/7 113/11 115/25 117/3 117/5 117/8 whoever [2] 59/6 113/20 whole [7] 17/4 25/4 50/13 51/21 67/15 73/19 111/22 whom [3] 1/21 49/25 69/16 whose [3] 1/19 24/19 52/17 why [7] 35/2 35/25 36/8 36/14 63/5 95/10 112/5 wide [3] 6/19 6/24 109/25</p>	<p>widely [3] 72/22 115/21 116/13 wife [3] 19/19 59/6 78/13 will [35] 1/22 9/21 17/25 21/24 23/6 23/7 23/8 27/1 37/7 38/17 51/18 52/11 52/19 58/21 58/25 59/15 65/18 71/18 79/24 82/3 85/1 85/20 87/25 91/24 96/20 97/9 101/12 101/23 102/17 105/11 106/18 106/24 107/24 107/25 117/20 Willebrand [3] 15/14 15/19 33/23 Willebrand's [5] 13/3 15/8 17/25 33/24 38/2 Willoughby [4] 24/10 58/9 58/10 112/10 Willoughby's [1] 23/20 winded [1] 13/23 with [177] within [6] 27/13 28/6 28/7 49/12 71/16 72/3 Withington [1] 80/12 WITN3496013 [2] 60/9 97/20 WITN4035008 [1] 65/19 witness [1] 7/18 women [2] 9/4 14/19 won't [3] 1/11 59/14 80/13 wonder [1] 117/17 Worcester [1] 83/7 word [2] 114/19 114/23 wording [1] 16/11 words [2] 54/1 101/25 work [5] 30/25 37/20 40/3 63/24 64/18 worked [5] 7/20 47/2 47/17 51/14 57/11 working [9] 8/21 10/9 32/5 65/13 67/13 69/17 72/17 72/18 73/1 world [1] 68/8 worldwide [1] 106/11 worry [1] 24/6 would [182] would substantially [1] 79/11 wouldn't [11] 14/6 23/16 25/20 36/13 47/21 53/17 53/18 53/19 63/15 75/4 102/14 wrists [1] 22/7</p>
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(48) usually... - wrists

<p>W</p> <p>write [2] 117/7 117/8</p> <p>writing [2] 57/23 117/6</p> <p>written [11] 7/10 10/24 59/20 60/13 60/19 61/2 61/25 62/4 77/1 98/19 100/14</p> <p>wrong [4] 35/25 37/8 37/17 91/24</p> <p>wrote [3] 8/10 47/18 100/13</p> <hr/> <p>X</p> <p>X number [1] 62/13</p> <p>x-ray [1] 22/8</p> <hr/> <p>Y</p> <p>year [24] 3/10 6/15 7/2 16/1 16/6 16/7 31/13 31/13 34/17 34/17 38/13 39/1 48/18 55/3 70/2 72/1 77/18 78/16 85/1 89/2 96/16 96/17 99/1 108/3</p> <p>yearly [1] 98/22</p> <p>years [44] 9/22 10/6 17/17 26/14 27/4 27/15 29/18 30/12 32/2 34/2 34/8 36/3 38/5 38/19 39/1 48/16 49/3 57/12 58/8 82/5 82/12 85/3 85/3 85/5 86/12 86/13 90/20 91/7 91/7 91/9 91/22 93/11 93/20 94/20 94/25 96/11 96/12 96/14 105/11 106/6 107/2 108/9 108/11 112/14</p> <p>years' [2] 84/16 97/5</p> <p>yellow [1] 115/16</p> <p>yes [46] 2/3 2/4 6/8 16/2 23/16 30/8 38/22 39/9 39/14 45/9 50/2 51/12 51/17 53/3 58/21 58/24 61/16 76/2 76/9 82/14 82/17 84/21 84/22 85/14 86/21 86/25 87/5 88/14 90/1 90/10 90/23 91/2 91/17 92/1 93/13 95/1 101/10 101/15 102/11 104/10 104/18 107/13 109/2 114/17 116/3 117/22</p> <p>yesterday [2] 18/5 20/22</p> <p>yet [1] 59/5</p> <p>yield [1] 66/2</p> <p>Yorkhill [17] 18/8</p>	<p>18/22 19/2 19/11 19/25 20/11 20/18 23/17 24/1 55/18 56/18 56/23 57/3 57/25 58/9 89/22 112/10</p> <p>you [390]</p> <p>you'd [2] 18/18 67/23</p> <p>you're [14] 2/2 40/20 45/9 47/1 51/2 53/17 71/10 84/4 84/11 94/22 94/23 100/17 105/24 116/3</p> <p>you've [11] 2/23 7/17 20/21 24/10 28/5 40/13 56/17 67/24 71/7 71/14 115/23</p> <p>young [9] 85/5 91/9 91/21 92/1 93/20 94/5 94/21 94/24 106/17</p> <p>younger [1] 19/7</p> <p>your [89] 1/24 2/6 2/6 2/7 2/16 2/19 2/23 3/19 4/1 5/7 5/15 5/15 5/25 6/6 7/18 15/21 18/9 22/24 22/25 23/22 25/5 26/9 28/22 35/23 36/6 36/7 39/15 40/10 42/21 42/21 42/23 44/1 45/16 46/4 46/13 47/1 49/17 51/13 56/20 57/12 59/6 60/5 60/7 63/20 66/7 66/21 67/12 67/12 67/24 68/6 68/9 68/9 71/18 71/24 72/25 73/25 74/1 74/5 75/14 75/15 77/2 77/15 94/11 95/3 95/5 95/6 95/6 95/20 96/24 97/18 97/23 97/23 98/3 100/25 101/20 101/25 102/4 103/7 104/9 104/13 106/11 107/7 111/1 114/14 114/16 115/11 115/14 116/8 116/17</p> <p>yourself [8] 64/17 66/13 68/6 70/6 100/18 102/14 109/22 116/12</p>				
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(49) write - yourself