

Thursday, 3 March 2022

(10.03 am)

SIR BRIAN LANGSTAFF: Good morning, Professor, if I may call you that. You are, I think, technically Professor Dame Sally Davies.

You are talking not just to those who are here in this room but to something in the region of 100,000 -- sorry -- 100 or so -- I'm overstating the importance of this Inquiry. How could I -- but 100 or so people who will be watching remotely. Bear that in mind when you are giving evidence.

In a moment, Mary will ask you to take the oath, and then Ms Fraser Butlin will ask you the questions.

Mary.

PROFESSOR DAME SALLY CLAIRE DAVIES (sworn)

Questioned by MS FRASER BUTLIN

MS FRASER BUTLIN: Professor Davies, I just want to start with a brief overview of your career before we talk about some of the detail.

You qualified in 1972, and then undertook two years of training until 1974; is that right?

A. Yes.

Q. And then you took a career break until 1978, returning to undertake further training in London in paediatrics and then haematology training in 1979 to 1982.

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Q. In 2004, you were then appointed as Director General of Research and Development and Chief Scientific Adviser to the Department of Health --

A. Yes.

Q. -- where your primary work was setting up the National Institute for Health Research.

A. Which I did in 2006.

Q. And then in 2010, you became interim Chief Medical Officer, and Chief Medical Officer in 2011 --

A. Yes.

Q. -- until you retired in 2019 --

A. Yes.

Q. -- from that post.

A. September 30th.

Q. I want to take you all the way back to your training before your career break, if I may, so up until 1974.

What were you taught during your training about when a transfusion should be given?

A. I think I was very well taught that no medical intervention is risk-free and that you had to think very hard about why you were doing something and that blood and its products was an intervention that had risks.

At the time, we were concerned particularly with alloimmunisation and febrile risks and, therefore,

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A. Yes.

Q. You then undertook a molecular biology research post until 1985 before being appointed as a consultant haematologist at the Central Middlesex Hospital in 1985.

A. Yes.

Q. And that consultant post held a specific remit in relation to sickle cell disease.

A. Yes.

Q. You remained there until 1996 when you were then seconded to the NHS executive as director of a research and development for the North Thames Regional Health Authority.

A. Yes.

Q. And during that time, is it right that you continued with some work in sickle cell outpatient clinics -- advising on inpatients and mentoring younger consultants?

A. Yes.

Q. Then from 1999 to 2002, you worked as the director of research and development for London at the DHSC.

A. Yes.

Q. And then the deputy director for research and development for the Department of Health.

A. Yes.

2

they should only be used when really needed, and so we would judge the patients and when they really needed them.

One of my house jobs, or kind of allocated, was actually to work with a vascular surgeon for a few months and, of course, during some vascular surgery, the patients do bleed immensely and need significant transfusions, so we would give them what was reckoned to be appropriate.

Q. Could we turn to HCDO0000861, please. It will appear on your screen. Thank you.

This is a booklet that the Inquiry has looked at a number of times. It is called *Notes on Transfusion*, and this edition was revised in 1973.

During your house officer years, do you recall ever being provided with a copy of this?

A. No, I don't believe I was. I think it's useful to understand that, at that period, medicine was pretty hierarchical, and so the practice of the junior docs was based on what the more senior doctors and the consultant wanted. But I do not recall it.

Q. And could we turn to page 4, please. We pick up the second and third paragraphs:

"A transfusion should never be given without a definite indication. Not only is this in the

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patient's interest, since an element of risk is associated with every transfusion, but supplies of blood are not unlimited, and with the ever-growing demand for blood, it is imperative that it should not be used unnecessarily.

"The use of transfusion to correct moderate or slight degrees of anaemia that could be overcome as effectively if more slowly by other means seems unjustifiable unless some cogent reason for speed of recovery exists. In some instances, failure to institute simpler and safer but equally effective treatment earlier leads to the quite unnecessary use of blood transfusion."

I understand you haven't seen the document at the time when you were training, but does this accord with what you were told in your training?

A. Yes, and with my practice.

Q. And broadly, was that the approach taken by your colleagues as well?

A. Yes, it was normal practice, as I remember it.

I don't remember being out of the ordinary. Everyone in my hospital -- it was called Withington Hospital; it later became the University Hospital of South Manchester, and it's now been knocked down, but that was practice as I remember it.

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bacterial infections could be, malaria could be, but I don't recall discussions of viruses. But, you know, as a houseman and then an SHO, you were not -- I was not involved in the policy discussions, nor was I going to meetings around transfusion.

Q. During your training, what was your understanding of the risks of hepatitis? Was that something that crossed your radar as a junior?

A. I trained in Manchester and did those first two years in Manchester, and the most common cause of hepatitis, sadly, was alcohol. Following behind, we saw hepatitis A, and we were only beginning to be aware of hepatitis B.

Q. And when you returned from your career break in 1978 and returned to that training period before your consultancy, again, did you receive any training in relation to viral transmission via blood transfusion in that period?

A. When I was a paediatric senior house officer, my first role, the first year back, no, I don't recall any specific training on that. But of course, once I moved into haematology training, there was discussion about viral transmission and the need to both be able to diagnose hepatitis B -- and the query about, we knew there was non-A, non-B hepatitis, but

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Q. Then if we turn to page 18, please. We see the heading "Transfusion records", and it notes:

"A record of every transfusion should be made in the patient's case notes, in addition to the details recorded in the transfusion laboratory. It is not always appreciated that the main reason for accurate recording is the protection of the patient."

Again, does that accord with your training and practice in your early years?

A. Absolutely. We always recorded that a transfusion was made and, generally on the wards, why. The anaesthetist would do it in theatre.

Q. And was that something that your senior colleagues drilled into you, the need to record it, or checked up that it had been done in any way?

A. I -- my first six months were working for an amazing, considerate clinician who was highly regarded, and I think he did drill it into me, but my values are transparency and that you should record things.

Q. In terms of the risks of viral transmission from blood transfusion, what were you taught about that during your early years?

A. I actually do not remember discussion of viral transmission in those early years. We were aware that infections could be transmitted by transfusion because

6

what was it? And of course donors or units were excluded if the liver function tests were abnormal in order to try to minimise any transmission.

Q. What was your understanding and how did the understanding develop during that training period in relation to the seriousness of non-A, non-B?

A. I find it difficult to recall. The knowledge clearly grew steadily. I have always been very bad at recalling dates, I'm afraid. Family dates, any dates. I failed the eleven-plus, I am dyslexic. So I apologise that I find it difficult to remember dates and put things in dates.

We heard about hepatitis B, we heard about the hunt. I personally knew a certain amount about it because as a haematologist in training I spent six months at the Regional Transfusion Centre in northwest London, and I must have received more training at that stage there, and I will have visited the laboratories where they did the testing. But the detail and the way that it slowly grew in my knowledge, I don't really know.

And I was actually focusing much more on two areas: one which was sickle cell disease, which I came to specialise in, and the other was paediatric haematology and looking after children with blood

8

1 disorders. So my focus was less on the transfusion.
 2 And I felt then and I felt all the way through my
 3 career, that I could rely on the expertise of our
 4 Regional Transfusion Centre to give us the best
 5 products that they could at that time. And I think my
 6 six months there convinced me that they were doing
 7 their best to stay on top of the latest science and
 8 deliver the best they could.

9 **SIR BRIAN LANGSTAFF:** But whatever the date was, you have
 10 a recollection from what you have already said that,
 11 at that stage, tests were being done on donors to
 12 exclude those with raised LFTs.

13 **A.** That is my memory.

14 **SIR BRIAN LANGSTAFF:** So plainly whatever the seriousness
 15 was thought to be, it was serious enough to take those
 16 steps to exclude donations.

17 **A.** Yes, everyone wanted blood transfusion to be as safe
 18 as possible. But as any medical intervention, nothing
 19 is truly safe, there are always risks.

20 **MS FRASER BUTLIN:** Bearing in mind your difficulty with
 21 dates, when do you think you first became aware of
 22 AIDS as a risk?

23 **A.** I actually think I became aware of it in the
 24 homosexual population well before I became aware of
 25 the risks in the transfusion supply. I don't think,

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1 Sickle cell disease has patients in that group
 2 who are SS, the sickle gene from both parents, or S
 3 from one parent and another haemoglobin abnormality
 4 from the other. C is quite common. D, various
 5 others. They are all part of sickle cell disease.

6 So, if you have inherited this, why does it
 7 matter? Well, our red blood cells that are made in
 8 the bone marrow and circulate in the blood are there
 9 to take oxygen from the lungs to the tissues. And as
 10 those red blood cells go through the tiny blood
 11 vessels called capillaries, and through the spleen, as
 12 a matter of fact, they have to be flexible and distort
 13 in order to squeeze through. And sickle haemoglobin,
 14 when it gives up its oxygen, goes into crystals, and
 15 the crystals align and distort the red blood cell into
 16 that classic sickle banana shape, and that's why it is
 17 called that.

18 We can look down microscopes and we can see
 19 these bananas of sickle red blood cells. They are
 20 crystals. They are stiff, they can't get through the
 21 tiny blood vessels, and some of them stick to the
 22 blood vessel walls, the bigger ones, and they make
 23 blockages. The blockages means that no oxygen,
 24 because no red blood cells can go past that blockage,
 25 so you get no oxygen to the tissues.

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1 along with many others, that I made that connection
 2 particularly at the time. But that doesn't mean that
 3 those experts were not making the connection, it is
 4 just that I don't recall making that connection before
 5 it was highlighted by the transfusion service.

6 **Q.** Moving on to when you became a consultant in 1985.
 7 You've said your post was the first in the UK to
 8 be established specialising in sickle cell disease.
 9 Many of those listening to the evidence will be aware
 10 of what sickle cell disease is but some won't be.
 11 Could you give us just a brief layman's explanation of
 12 it, for those who are less familiar with the
 13 condition.

14 **A.** Thank you. So sickle cell disease is an inherited
 15 anaemia, and you have to inherit the sickle gene from
 16 both parents to have the disease. If you only have
 17 one gene you are called a sickle cell carrier.

18 And there is an advantage to that: if you live
 19 in a malaria area that during the first year of life,
 20 it seems to protect against infection, against
 21 malaria. So that explains why this gene has reached
 22 quite high levels in Sub-Saharan Africa, Nigeria,
 23 Ghana and places. It is also present in the Middle
 24 East and India and wherever those populations have
 25 migrated to.

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1 So it is a bit like a heart attack. You get
 2 a blockage in a blood vessel, no oxygen to the heart
 3 muscle, you get pain. And sickle cell painful crisis
 4 is when there is pain in the muscles or bones because
 5 the blockages don't let the oxygen-carrying red blood
 6 cells through.

7 Of course, the blockage can go away and then the
 8 flow starts again, but if it persists you will get, as
 9 in a heart attack, scarring. And if it is
 10 overwhelming, as in a heart attack, it can kill.

11 And there are horrible sequelae, so dreadful
 12 pain crises that -- I mean, I only understood how bad
 13 when I asked one of my sickle women who had had a baby
 14 how was the pain at parturition, at delivery of the
 15 baby, and she said, "Nothing on sickle cell". I have
 16 to say my respect was always there for my patients but
 17 it went a lot higher.

18 It can be very bad but also you can get sickling
 19 in the lungs when you -- it's called the sickle chest
 20 syndrome, when of course you get a vicious cycle
 21 because you then can't -- you are blocking blood
 22 vessels so you can't pick up the oxygen to take round.

23 You can get pooling of sickle cells in the
 24 spleen, and then suddenly they can drop their
 25 haemoglobin to dreadfully low levels, 2g, and actually

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die of it in the space of a few hours.

You can get pooling in the liver, you can get priapisms, so a prolonged painful erection that can go on for days and means they will get scarring and impotence later.

And about 15% of SS children get some degree of damage to their brain that ranges from actual stroke to just cognitive changes and maybe some learning disabilities. So it can affect anywhere in the body and it can be catastrophic.

One of the difficulties for the patients is that you don't know who is going to be severely affected and who isn't. So it is very difficult.

And all we can do -- all we could do when I was practising was advise the patients to keep warm, to keep hydrated, to use painkillers, and come to hospital if it was bad. Now there are some anti-sickling agents, and towards the end of my practice we had hydroxyurea that raised another haemoglobin -- foetal haemoglobin -- levels in the red blood cells, which made it more difficult for the crystals to happen and to align. But in the '80s and until the late '90s, essentially all treatment was symptomatic.

SC patients had fewer complications but

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'80s, the median survival was 44.

Q. The Inquiry has got an expert report dealing with a number of different conditions, and in that report it also addresses sickle cell disease. It estimates that there are about 15,000 patients in the UK with sickle cell. Do you recall roughly how many sickle cell patients you were treating at the Central Middlesex when you were a consultant there?

A. It came and went. And I think by the time I left we had about 600 patients on our books. But some of them didn't turn up for outpatients because they felt well and couldn't see the point of coming when they were well. I always hoped they would because to look after patients when they are ill, it is very helpful to know how they function and who they are when they are well, and we could talk about prevention and other things. But interestingly, when I reviewed the paper I sent you, it looks as if at the beginning we had rather fewer patients. Probably under a hundred.

Q. But over time that built up?

A. Yes.

Q. You think that the Central Middlesex clinic was probably one of the biggest clinics for sickle cell disease in the UK at that time?

A. It was, alongside King's, University College Hospital,

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pregnancy could be particularly difficult. SD

patients, there aren't many of them, were as severely affected as SS.

And then, of course, you could get an interaction of the sickle gene, so haemoglobin, with a beta thalassemia gene. And if it was a beta thalassemia gene that made no haemoglobin, it was equivalent of SS. If it was a beta thalassemia gene that made a lot of ordinary haemoglobin A for adult, it could be quite mild.

Q. In terms of your post being established in 1985, do you know why your post was established at that particular time as a specialist sickle cell post?

A. They at Central Middlesex established my post because we were one of the hospitals that had a large clinic of patients with sickle cell and we wanted -- I was a senior registrar there, so when I say "we", I was part of the discussions -- we wanted to really major on it and make sure that our patients in Brent got the best treatment they could, and so that meant we needed to focus on it. And I was appointed because I wanted to do that but also I had not only the haematology training but some paediatric training. And of course that meant I could look after them from birth right through to death. I should say at that time, in the

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Birmingham.

Q. And in terms of those with the SS gene, what sort of proportion of your patients had that most serious version?

A. I would have known that, absolutely. It was the majority. Yes.

Q. The Inquiry has heard quite a lot of evidence about the UKHCDO, the Haemophilia Centre Directors' Organisation, the group of haemophilia clinicians who met. Was there a UK-wide specialty group for sickle cell clinicians?

A. There was not when I started but it kind of developed, and it developed in two ways. One we had the Brent Sickle Cell and Thalassemia Centre manned, if I can use that word, by wonderful specialist nurses, who in fact then trained most of the other nurses and kind of trained the trainer who set up counselling services round the country.

So through that counselling and nurse network, there was a lot of sharing, and we would, between us, have various meetings. But then -- and I'm trying to remember when, I think in the '90s, but quite when -- we did start to meet as multidisciplinary teams, it was never doctors without nurses, it was all of us together, to discuss patients and issues, probably

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1 from the late '80s, early '90s, thinking about when
2 the SMAC -- the Standing Medical Advisory Committee
3 report came out, we must have been meeting before
4 that.

5 **Q.** And in those discussions, as a group of clinicians, as
6 nurses, were there discussions about protocols and
7 guidelines for treatment?

8 **A.** So, we talked about treatment. We had at
9 Central Middlesex very strict guidelines for managing
10 sickle cell crises and what should be done.

11 I'm sure you're aware it's very easy to write
12 a guideline. It is not too difficult to send it out
13 and disseminate it. The problem comes -- and it's all
14 in the social sciences, and I can bull for Britain on
15 the evidence up till about the mid-teens of this
16 decade -- the difficulty of getting people to follow
17 them.

18 We were strong in Central Middlesex on
19 guidelines. Ours existed. The sickle cell ones were
20 followed more than any other. When we asked the young
21 doctors why they followed ours, they said two things.
22 The first was, they hadn't been exposed to sickle cell
23 in their training, so they didn't know what to do, so
24 it was really helpful. The second was, I was given to
25 stalking the wards and finding the doctors and saying,

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1 functioning well because of regular transfusions, but
2 then they were dying of iron overload, giving them
3 hepatitis, diabetes, cardiomyopathy, and we didn't
4 want our sickle cell patients to have transfusions
5 just because it make them feel good for a week or two
6 and then have this problem of iron overload.

7 There is a treatment. It is called chelation
8 therapy. Essentially, you give a treatment,
9 a chemical, that will wrap round the iron molecule and
10 make it soluble so you can either wee it out or poo it
11 out. The standard while I was working was
12 desferrioxamine. In fact, for most of those years, it
13 was the only one. It could only be given by infusion.
14 You needed for the thalassemia patients, all those
15 sickle patients on regular transfusions to use it as
16 an infusion with a needle under the skin for a minimum
17 of 6 hours, and ideally 8 to 10 hours, 5 to 7 nights
18 a week, and it was irritant. It was horrible. That
19 treatment was not what you wanted. But if you give
20 them lots of blood and you didn't solve the iron
21 overload, then you were going to kill them anyway with
22 the iron overload years later.

23 There are now oral chelators. And now
24 transfusions are not done manually; they are for
25 people who have regular transfusions done as exchange

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1 "You didn't abide by the guidelines." That's fine if
2 you had a good reason not to, but if you didn't have
3 a good reason, then that's not right, and make sure
4 you do next time or I'll be around again. So
5 I stalked the wards about our guidelines and supported
6 them when they departed from them for good, clinical
7 reasons.

8 **Q.** Can you give an overview for the Inquiry as to what
9 the circumstances would be where a sickle cell patient
10 would require a blood transfusion.

11 **A.** So we didn't want to use blood transfusions for sickle
12 cell patients. First of all, they normally run
13 a haemoglobin around 7/8g if they are SS, but then
14 blood viscosity is normal. So if you add to it,
15 thinking that they need it because they're anaemic,
16 you increase the blood viscosity. And there are cases
17 in the literature of stroke being caused by that
18 raising the blood viscosity.

19 Of course, there are risks with transfusion, not
20 only the immediate risks but the longer term risks.
21 Alloimmunisation, transmission of infection. But the
22 one that very much exercised us was iron overload. So
23 with every bag of blood you give, you give 250mg of
24 iron that the body cannot get rid of, and the
25 thalassemia patients were kept alive and well and

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1 transfusions on machines where they take out the old
2 blood. So they're trying to take iron out as they put
3 in fresh blood, and that reduces the iron overload.
4 Though maybe they still need some oral chelation. I'm
5 not up to date.

6 **SIR BRIAN LANGSTAFF:** When they put in fresh blood now, is
7 that largely red blood cells rather than whole blood?

8 **A.** Yes. In my day, it would have been an optimal
9 additive solution, and I presume it still is, yes.

10 **SIR BRIAN LANGSTAFF:** But if it is in optimal additive
11 solution, can you explain, going back to the question
12 of viscosity, why that should make the circulation
13 more viscous.

14 **A.** The red cells themselves add to the viscosity. It's
15 not just a plasma; it's a whole blood viscosity that
16 I'm worrying about.

17 **SIR BRIAN LANGSTAFF:** Yes.

18 **A.** So if you up their haemoglobin, you're adding red
19 cells, and you're increasing the whole blood
20 viscosity.

21 **SIR BRIAN LANGSTAFF:** But you are also increasing the
22 fluid in which the blood is transported.

23 **A.** No, you aren't. As you -- we have, what, eight litres
24 of blood in us, of which a certain amount is red
25 cells, white cells, platelets and plasma. If you pour

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1 blood in, then most people will pee out the excess
 2 fluid.
 3 **SIR BRIAN LANGSTAFF:** Yes, so it's a question of the
 4 retention of the red blood cells, getting rid of the
 5 excess fluid.
 6 **A.** Yes. We balance ourselves out quite quickly actually.
 7 **MS FRASER BUTLIN:** So in what circumstances would
 8 a transfusion, red cell concentrates, be given to
 9 a sickle cell patient?
 10 **A.** So only generally if it was life saving. So, you
 11 know, they -- if they were infected with parvovirus,
 12 that would stop them producing red blood cells for
 13 two, three weeks, then their haemoglobins would drop
 14 dramatically. The red cell lifespan in sickle cell
 15 disease, as I remember it, it's about right, is about
 16 9 to 15 days, whereas it's 110 days normally. So if
 17 you don't produce any red blood cells, your
 18 haemoglobin goes into your boots. So that's aplastic
 19 anaemia. We would top them up; a straightforward
 20 transfusion.
 21 Splenic sequestration, we would top them up.
 22 Hepatic sequestration, we would try and do
 23 an exchange. Sick chest syndrome, we would do
 24 an exchange. Concern for the brain, we would do
 25 an exchange acutely, but then if we were going to go

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1 there for a whole day, 6 to 8 hours, just steadily
 2 trying to do this because what you were trying to do
 3 was get the sickle haemoglobin definitely below 30%.
 4 And reading some of the documents maybe -- this is
 5 a number that I don't remember -- maybe it was below
 6 20%. But we -- ideally, we would break it into
 7 sessions, and you would try and do, you know, 6 units
 8 one day and another 4 to 6 the next day because it
 9 was -- I mean, I got blisters on my hands sometimes
 10 doing it. It was really hard work. And for the
 11 patient, it must have been dreadful. But it was life
 12 saving.
 13 **Q.** In those contexts, generally, how many units were
 14 transfused?
 15 **A.** For an adult, somewhere between 8 and 10 units
 16 usually, as I remember it.
 17 **Q.** You've said in your statement that some severely
 18 affected patients were given transfusions every two to
 19 four weeks. Roughly what proportion of your patients
 20 were in that category?
 21 **A.** It was quite a low number that we had on regular
 22 transfusions because of the iron overload worry.
 23 I mean, you know, I'd love to have had more on
 24 transfusions to give them good quality life, but
 25 you're always balancing risk with advantage, and there

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1 on long-term, we would generally transfuse them.
 2 Well, at the beginning of our practice, we transfuse
 3 them every six weeks, but that time became shorter as
 4 we understood how, if you gave them a top-up, that
 5 suppressed their own production of cells. So,
 6 therefore, you could try and keep the viscosity low
 7 and the sickling low, but that was all as practice
 8 developed. And, as I say, now they do it generally on
 9 machines.
 10 **MS FRASER BUTLIN:** And you spoke about an exchange
 11 transfusion. Again, could you just briefly explain
 12 what that involves?
 13 **A.** So you would have a sick patient, adult or child, and
 14 we would sit there, and I even did it as a consultant,
 15 and you would essentially try and get as big a needle
 16 as you could into the vein, but sickle cell patients
 17 have dreadful veins, so it would be very difficult to
 18 find vascular access. You'd have a three-way tap, and
 19 you would have the bag of blood one side and an empty
 20 bag the other side. You'd suck out 10-20mls, and it
 21 would be quite hard work. You would turn the tap,
 22 push that into the empty bag, turn the tap around and
 23 drip in 20mls or suck 20mls fresh donated blood into
 24 the syringe, give it to the patient and start again.
 25 And if a patient was very sick, we could sit

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1 was no way I could recommend regular transfusions to
 2 someone if I didn't think it was the best thing for
 3 them, despite the risks. And we would sit and debate
 4 it, sometimes over periods of weeks, to come to
 5 a conclusion that they felt they could live with.
 6 **Q.** And when you became a consultant in 1985, and during
 7 your registrar years, were you aware of any
 8 significant changes in practice, in terms of the
 9 amount or frequency of transfusion?
 10 **A.** Well, we did develop at the Central Middlesex probably
 11 the exchange transfusion protocols and everything
 12 early. And my colleague Dr Mischa Brozovic -- who
 13 sadly died in December -- and I wrote one of the
 14 earliest papers on sick chest syndrome, which was in
 15 The Lancet, and how exchange transfusion could save
 16 their lives. So I think we developed it steadily, but
 17 we were at the cutting edge. But we were careful.
 18 I didn't like doing it.
 19 **Q.** And so, would it be fair that during the early '80s
 20 and through the '80s, there was an increase in
 21 transfusion with sickle cell patients?
 22 **A.** Yes, there will have been.
 23 **Q.** Could we turn to RLIT0000806, please. These are a set
 24 of guidelines on red cell transfusion in sickle cell
 25 disease. I'm very conscious, Professor Davies, that

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1 these were published in 2016, so only very recently.
2 Before we look at some of the detail of them,
3 were you aware of any national guidelines before 2016
4 in relation to sickle cell?

5 A. No, I'm not aware of any national guidelines. Of
6 course, Kate Ryan was, first of all, my senior
7 registrar and then my colleague consultant. Gavin Cho
8 took over when I left, so I know many of these people.

9 Q. But you're not aware of any national guidelines before
10 these?

11 A. No.

12 Q. If we could just pick up on the bottom right-hand
13 column of this page:

14 "Key recommendations.

15 "Consideration of sickle cell patients for
16 transfusion, particularly long-term regimens, should
17 weigh up the potential benefits against potential
18 risks."

19 Then it deals with cerebrovascular disease:

20 "Regular transfusion to maintain HbS less than
21 30% should be offered as initial treatment to children
22 with SS or S/β thalassemia aged 2-16 years judged to
23 be at high risk for a first stroke on this basis of
24 Transcranial Doppler ultrasonography."

25 Does that represent or accord with the practice

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1 Just pausing there. In terms of those two
2 recommendations, does that accord with your practice?

3 A. The first, yes. This one, "surgery" for me is
4 interesting.

5 The world -- the medical world split in two.

6 Those who believed in transfusion preoperatively and
7 those like me who were very wary of it, but there were
8 no -- there was one study from Vichinsky. I mean, it
9 wasn't a very good study. And we, because our
10 anaesthetists and surgeons were used to sickle, did do
11 less pre-op transfusion than many people actually.
12 And then I helped Dr Jo Howard set up the study that
13 happened after I stopped looking after patients that
14 has given rise to this.

15 I still worry because I think if you've got
16 minor surgery like a tonsillectomy, you may not need
17 it, but I do think for a replacement joint, you give
18 the new joint the best opportunity of healing if it's
19 getting lots of oxygen rather than getting sickling in
20 the -- in it to start with.

21 Q. So would it be fair that in the 1980s and 1990s when
22 you were practising, you weren't undertaking as much
23 preoperative transfusion as might be suggested by
24 these guidelines?

25 A. Probably a bit less.

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1 when you were in practice?

2 A. That was what we developed. I was quite au fait with
3 what the Americans were doing. I went to the American
4 Society of Haematology, to the sickle cell sessions.
5 One of the people who did a lot of the work on this
6 was Vichinsky at -- just north of Berkeley, Oakland,
7 and I knew what they were doing. I read their things,
8 and, yes, that was our practice.

9 Q. And then if we turn to the next page. I'm going to
10 just read out a number of chunks of the guidelines and
11 then ask you a question about it, Professor Davies.

12 First of all, on the left-hand column:

13 "Long-term transfusion to maintain HbS at less
14 than 30% is recommended for the prevention of
15 recurrent ischaemic stroke due to sickle cell disease
16 in both children and adults."

17 Then if we go down to the heading "Surgery":

18 "Preoperative transfusion is recommended for SS
19 patients undergoing medium risk surgery (eg abdominal,
20 tonsillectomy, orthopaedic).

21 "Preoperative transfusion is recommended for SC
22 patients undergoing medium risk surgery, and
23 transfusion is recommended for sickle cell patients of
24 all genotypes requiring high-risk surgery --
25 cardiovascular or brain."

26

1 Q. Then if we go down, the guideline addresses emergency
2 surgery:

3 "For patients requiring emergency surgery, the
4 urgency and complexity of the procedure should be
5 taken into account in the timing of perioperative
6 transfusion. Simple transfusion should be given
7 preoperatively if Hb is less than 90, provided this
8 will not result in undue delay to surgery. If
9 transfusion is likely to cause an unacceptable delay
10 to surgery, it is reasonable to proceed to surgery
11 while arranging to transfuse the patient intra- or
12 post-operatively if necessary."

13 Again, in terms of your practice in the '80s and
14 '90s --

15 A. We would have blood ready, but the operation, if it's
16 emergency, would have gone ahead, and we would have
17 looked at the bleeding level.

18 As I've said, I would not be pushing or
19 sanctioning transfusion if the haemoglobin was 9.
20 That's a normal haemoglobin for a sickle patient, and
21 I would want to see whether there was bleeding or any
22 other reason why that patient should receive
23 a transfusion. And that depends on why they were
24 having surgery and everything.

25 Q. Then if we go to the bottom of this column and over to

28

the next column:

"Acutely ill patients. Transfusion is recommended and may be life-saving in acute sickle complications such as splenic sequestration, hepatic sequestration, aplastic crisis and severe acute chest syndrome. Transfusion should be considered in the unwell patient with acute multi-organ failure, mesenteric syndrome and patients with severe sepsis. Such cases should be discussed with a specialist haemoglobinopathy team.

"Transfusion for other causes of acute anaemia requires individual assessment and should be discussed with the SHT. Transfusion may be given by simple transfusion (top up) or exchange, depending on clinical severity, under the guidance of the SHT."

Again, same question, during the 1980s and 1990s, how similar was your practice?

A. This reflects my practice then, and it was very difficult. I mean, there are some patients that live with us throughout our lives, and I still remember one where he had multi-organ failure, and we had exchanged him and he had less than 20% haemoglobin S, but he was still dying in front of us. And he did die, and we don't know why he died because once you've exchanged the blood, you hope that you have washed out the

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steadily made that shorter and shorter, and I think I was well aware of that.

Q. Do you recall any discussions with the staff of the Regional Transfusion Centre about limiting the use of transfusion or about the advice about transfusion-related hepatitis?

A. So, I mean, I think we all wanted to limit transfusion at a certain point, but I can't date it. Transfusion committees were set up, and I remember that ours was probably one of the early ones because my senior colleague was seen as being a leader in transfusion in district generals, and that was one way to bring other clinicians into the discussion and update them.

Did I answer all your question? No?

Q. The Inquiry has heard evidence that for certain Regional Transfusion Centres, they have indicated that they came into the hospital and did talks or seminars or workshops with clinical staff at the hospital or they went on grand rounds. Do you recall anything of that happening at the Central Middlesex?

A. No, I don't recall, but that doesn't mean it didn't happen. They didn't come to a grand round. We had regular training sessions for the haematology department including the technicians, the MLSOs. They

31

sickle. And most of his blood tests were normal, yet he died. It's a horrible disease at its worst.

Q. In terms of the risks of blood transfusion, you've said today and in your statement that you took the view that experts were ensuring the blood supply was as low-risk as possible.

Were you aware then of when screening of blood, for example for hepatitis C, was introduced?

A. I will have been, but with my problem with dates, I can't date it for you. But, of course, through the general haematology education sessions I attended, the fact that haematologists of our region met together for audits three times a year and therefore talked about changes, I will have been aware.

Q. Did you have any discussions within that group of people or with the Regional Transfusion Director about the extent and limits of screening? So difficulties with screening.

A. I don't recall any. But, I mean, clearly we all are aware that if you're doing antibody screening, you can have an infection and be infective before the antibodies start. That if you are looking for the actual infective organism, you can get it earlier, but actually you can still be infective. There is an infective, non-pickable-up area, and science has

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may well have come but I don't recall it. And we did -- we were supported by one of the best transfusion centres in the country. So if that was happening, it would be odd if we weren't part of it.

Q. You have said in your statement that the department was scrupulous about following the British Committee for Haematology guidelines, it may seem a very obvious question but how did you come to know that a guideline had been published?

A. Well, I was not in charge of the blood bank. For most of my time, Dr Brozovic was. But, I mean, we would scan the British Journal of Haematology. Most of them were published in that. Some were published in other journals but she kept an eye on those. And of course the network would be -- I mean, the guidelines were all written by colleagues, so we knew what they were working on and we knew when to expect them.

I expect also that the transfusion centre sent them round everyone, but I don't -- I would not have been the one that received them.

Q. You would have relied on your colleague to pass them on to you?

A. To take the action that our hospital needed to take. You can't do everything.

Q. In terms of the supplies of red cells for transfusion,

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1 and indeed also fresh frozen plasma, you say in your
 2 statement that the department held supplies. Very
 3 practically were those supplies held in the
 4 haematology unit or were they held in the hospital
 5 blood bank?

6 **A.** The hospital blood bank was part of our laboratory, so
 7 you worked in and the blood bank was on the right, the
 8 main haematology lab was next and then there was
 9 a haemoglobin lab, and then initially there was
 10 a chemical pathology lab at the end of the corridor.

11 **Q.** In terms of the paperwork that was used to obtain
 12 blood, you have said that if you were requesting blood
 13 or platelets from the blood bank then there would be
 14 a written form that was sent to the blood bank. Was
 15 the reason for the transfusion recorded on that form
 16 as far as you can recall?

17 **A.** No, I'm not sure it was.

18 **Q.** What records did the blood bank keep, in relation to
 19 blood that was supplied?

20 **A.** The blood bank kept the records of the request which
 21 was the details of the patient, the patient hospital
 22 number -- we didn't use NHS numbers -- name, date of
 23 birth, the consultant in charge, the ward that they
 24 were on. The blood bank would keep the cross-matching
 25 records, what they tested, and then what they had

33

1 **Q.** I want to move on to the information you gave to
 2 patients about transfusions.

3 When a patient needed either a top-up
 4 transfusion or an exchange transfusion, what
 5 information did you give them about the risks of
 6 a transfusion, particularly the viral risks?

7 **A.** Well, the discussion was always about risk/benefit.
 8 You know? And if you've got an aplastic crisis or
 9 a splenic sequestration or chest syndrome, then you
 10 are very likely to die without transfusion. So the
 11 conversation was shorter but the benefits were very
 12 much more clear.

13 I think we went much more into the long-term
 14 consequences, including particularly iron overload and
 15 mentioning infection, but the infection risk was quite
 16 low, the blood was tested, and so we did not make
 17 a big issue of that. But I believe we said, "And of
 18 course infection can be transmitted."

19 **Q.** You have said in your statement that there wasn't
 20 a process of formal consent to the transfusion. By
 21 that, do you mean there wasn't written consent or
 22 there wasn't consent -- can you help us with what you
 23 meant by that?

24 **A.** There was no form, there was no set number of things
 25 that one should discuss. It was an informal

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1 marked up for that patient and then whether it was
 2 dispensed, which meant that it was taken from the
 3 fridge by someone who was allowed to but they had
 4 matched the numbers of the patient with the units.
 5 And we would know who had picked it up and at what
 6 time because they had to sign a book and that was
 7 kept. There were sticky labels that then had to be
 8 put in the patient's notes.

9 If the blood was not used, which was a rare
 10 event, then, they were expected to send it back to the
 11 blood bank and it was recorded as received back, and
 12 I think returned to the transfusion centre, but I'm
 13 not -- for disposal -- but I'm not certain.

14 **Q.** In terms of what was then in the patient's notes of
 15 having received a transfusion, there would be
 16 a sticky label indicating the unit details?

17 **A.** Yes.

18 **Q.** Was there any handwritten note as well?

19 **A.** Well, that depends on the clinician. For our patients
 20 it would be a handwritten note of why we were doing
 21 a transfusion, how many units and what our objective
 22 was. And then the nurses who put the blood up would
 23 have to sign the sheet and date and time it for -- the
 24 medication sheet. So that would also be kept in the
 25 notes for years to come.

34

1 conversation between treating clinician and the
 2 patient that was, I don't think, recorded in that way
 3 in the notes. I think we would say -- you know,
 4 I would go and write in the notes, "Transfuse" -- or,
 5 "Exchange/transfuse. Aim: [this]."

6 But we would not give a treatment to
 7 a patient -- and blood and its products are
 8 treatments -- without discussing it with a conscious
 9 patient and making sure that they were accepting of
 10 it.

11 **Q.** You have again said in your statement that no sickle
 12 cell patients at the Central Middlesex who had been
 13 transfused in the UK were infected with HIV. Is that
 14 right?

15 **A.** I'm not aware of any patients in our clinic who
 16 acquired HIV, or hepatitis C for that matter.

17 **Q.** That was my next question.

18 I just want to understand the hepatitis C point
 19 a little more, or explore that a little more with you,
 20 Professor Davies.

21 In terms of the following up of sickle cell
 22 patients in clinic on a routine basis, putting just to
 23 one side when they are in a crisis, but on a routine
 24 basis how frequently would you see a sickle cell
 25 patient? Assuming they attend when they should.

36

1 A. Well, we asked them to come every six months. Many of
 2 them didn't. And I absolutely understand why they
 3 didn't. They saw enough of us when they were sick,
 4 they didn't want to see us when they were well. So
 5 some would disappear for years and then reappear
 6 because they were ill. Some would move out of the
 7 area and then re-appear and say, "I'm back visiting so
 8 I have come to see you". I mean, it was not as kind
 9 of regular as it was for, say, leukaemia patients or
 10 other patients. But of course there were the frequent
 11 fliers who we saw very regularly because they needed
 12 our support and care.

13 Q. Before hepatitis C testing was available, were liver
 14 function tests routinely undertaken?

15 A. Our patients would have their liver function test
 16 checked at least annually if not every six months.
 17 But classically in sickle cell they are not normal.
 18 They will have raised bilirubins, quite often
 19 an abnormal gamma-GT or ALT and things. So they're
 20 not -- the fact that they were abnormal doesn't make
 21 you think, "Oh, something's new". What we were
 22 interested in is how abnormal, and particularly
 23 compared to before, so that when we saw them when
 24 acutely ill you would know if they had changed. But
 25 regularly or quite often they were abnormal.

37

1 recall receiving any at all to do with my sickle
 2 patients.

3 Q. Did that surprise you?

4 A. No.

5 Q. In the context of patients who have received regular
 6 blood transfusions and quite significant quantities of
 7 blood, might one have expected some of those units to
 8 have been identified in the look-back?

9 A. Well, I think you and the experts will be much more on
 10 top of the data than I am. I was not surprised at the
 11 time.

12 Q. At the time.

13 And in terms of your awareness of the look-back
 14 exercise, did you have or did the department have
 15 discussions with the Regional Transfusion Centre about
 16 the extent and perhaps the limitations of the
 17 look-back exercise?

18 A. My colleagues in charge of the blood bank may have had
 19 those conversations. I was not party to it. That
 20 I remember. But I don't think I was.

21 Q. We will continue on until one more topic before we
 22 take a break. The Inquiry has heard some evidence or
 23 read some evidence about the significant stigma for
 24 some communities around having sickle cell disease.
 25 What was your experience in that regard?

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1 Q. Within that assessment of the abnormality of liver
 2 function tests, were you looking for anything in
 3 relation to possible hepatitis C infection?

4 A. No.

5 Q. Once hepatitis C testing was available, was there any
 6 routine testing of patients with sickle cell for
 7 hepatitis C?

8 A. No, I'm not aware of anyone who set out to test their
 9 whole clinic.

10 Q. Why was that?

11 A. Well, I think that we had a group think that the blood
 12 was tested and therefore the risk was low.

13 Q. But for those patients who had received transfusions
 14 before hepatitis C screening came in, was there any
 15 consideration given to testing those patients for
 16 hepatitis C?

17 A. Not that I recall, but I thought that with the
 18 look-backs that were going on, if any were, at
 19 particular risk, that we would pick them up.

20 Q. And do you recall whether any patients in the clinic
 21 were identified in the look-back?

22 A. I recall that some look-back letters came to
 23 Central Middlesex that my colleagues then went to find
 24 the notes and the clinicians and it was all sorted
 25 out, but I did not receive any of those and I don't

38

1 A. I think there are two issues here. Is having
 2 an inherited disease a cause of stigma? And I think
 3 it can be. It can be a cause of guilt for parents.
 4 It can be very difficult. And so within families and
 5 communities you can have that. But then you get into
 6 the issue of race. And it is very interesting, or it
 7 was to me at the time, that the big hospitals that had
 8 significant sickle cell populations, the teaching
 9 hospitals, did very little research on it. The
 10 haematologists were all either doing clotting
 11 disorders or leukaemias and lymphomas, and somehow it
 12 was the Cinderella speciality.

13 I and my patients and community -- we had a very
 14 active patient support group in Central Middlesex --
 15 worried that that might be institutional racism and
 16 that this might be stopping patients getting bone
 17 marrow transplants as curative therapy in -- as time
 18 went on, in the '90s. In order to try to explore
 19 that, I actually set up a moot. So I persuaded
 20 three QCs to give their time for free, and on
 21 a Saturday we tried the case that more transplants
 22 should be available for sickle cell. Diseased
 23 patients, we had a jury where the mother of a child
 24 had died of sepsis, a public health doctor and
 25 a patient, we flew in some experts from the States and

40

we had two witnesses on either side that were really put under interrogation by the QCs. And at the end -- and with a big audience from the community as well as medical, nursing and everything. And at the end the view was that actually the professions were being very careful and that one shouldn't go forward to bone marrow transplant like that. What we needed to do was studies and do it very carefully.

Of course, different ways of doing transplants have come since and now they are practiced much more. So I did try to test the racism and get this kind of discussion opened up to make sure my patients were getting the best -- it was actually written up in the British Medical Journal -- to try to make sure that everyone thought about these issues.

Does that answer your question?

- Q.** I'm going to return to my previous question in just a moment. I want to carry on in relation to the race issues that you have raised. I have also been asked to ask you whether you think that the funding for and care of sickle cell patients was influenced by the fact that the majority of sufferers are from a Sub-Saharan African or Caribbean background?
- A.** I feared it might be, because if you looked at the money spent on haemophilia patients and the numbers,

41

you need to be well hydrated, you need to be kept warm. And to live in accommodation that was crowded, stressful and drafty, was not good for the disease.

So, it kind of played out in those ways. It was difficult, yes. Poverty and inequalities do not help.

- Q.** Could we turn then to the report of the working party, the Standing Medical Advisory Committee.

It is SCGV0000267_152, please.

Again, it will appear on your screen. We can see on the subsequent page that this was published in 1993. I want to turn to page 6, please, of the -- it is page 9 internally if you want to go to your own copy, but it is on the screen. The "Executive Summary".

We see here that:

"The Secretary of State for Health invited the Standing Medical Advisory Committee ... to consider various aspects of haemoglobinopathies, in order to ensure more even provision of health care."

A few paragraphs down:

"This working party has sparked a tremendous amount of interest, from health professionals, (both individuals and professional bodies), people with haemoglobinopathies and their families, members of populations at risk and relevant voluntary

43

the discrepancy was unfair. If you looked at cystic fibrosis patients, they had specialist centres and much more funding. It seemed unfair. So I was concerned about the fairness of it and did my best to make sure that our patients, and nationally, we gave the best we could.

And that, of course, was some of the thinking underpinning that Standing Medical Advisory Committee report that you have uncovered.

- Q.** Which I'm going to go to in one moment. But before I do, were other health inequalities associated with ethnicity and race? Do you think they were fed into the treatment options for sickle cell?

A. I know quite a lot about health inequalities as a result of being CMO, but I'm not sure I understand quite what you are getting at there.

- Q.** I'm sorry, it is a question I have been asked to ask you: whether other health inequalities associated with ethnicity and race fed into the treatment options for sickle cell?

A. So many of my patients lived in poor conditions. They lived in housing that was not satisfactory. And of course it is difficult with any chronic disease to live in poor conditions, but if, actually, you have got sickle cell, you need to try to prevent infection,

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organisations. This concern was reflected by the large number of people and organisations who submitted written evidence."

If we could go further down, please:

"It was clear from both oral and written evidence that care for patients with haemoglobinopathies, and genetic counselling of populations at risk, is not always of the highest quality, even where these disorders are frequently seen."

Professor Davies, do you have any views on those findings of the advisory committee?

- A.** I agreed.
- Q.** There's no reference whatsoever in the working party report to HIV, hepatitis B or hepatitis C either in terms of diagnosis or recommendations for treatment. It might be suggested, therefore, that blood-borne viruses were not really on the radar for this group of patients. Was that the situation or is there some other explanation of what was happening?

A. Well, I was not on the Committee, though my senior colleague Dr Brozovic was. There is concern mentioned I think on iron overload. I think what was going on was trying to pick off the priority issues. Get attention on this group, improve services. You know?

44

And it was pretty patchy across the country. A lot of patients from around the country would come and see me once a year or something and my standard consultation started with, "This is really difficult for you because not only are you ill but you know more about your illness than your doctors will ever know. And by the time we have finished you will know an increasing amount, and what we have to discuss is: how do you handle a doctor when you know more than they do?"

That was a routine. I saw a lot of people who were children of diplomats here in London and other patients who came from abroad to see me.

But what I think this SMAC report was getting at was: we haven't even got to the starting base for these patients, and let's get there and then you can begin to focus on less common issues.

So it is a mission -- it is, now, very interesting with a retrospectroscope, but actually the priority was to get decent services in place and then start to look at other things.

Q. Going back to my first question in relation to stigma. You spoke about the difficulties of having a genetic disease. Were you aware of any other individual and personal experience of stigma for those suffering from sickle cell?

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their behalf. I actually wrote on behalf of a number of patients to the police when they seemed to be picking up my patients who had not been misbehaving.

So we would do our best to support on housing, on welfare. There were some benefits that if the children or adults were badly affected they could get and we would write the appropriate letters if it seemed right.

Q. And within the Brent Centre, how involved was the centre in providing additional information and advice about the risks of transfusion, beyond what you had done in clinic?

A. I'm not aware that they were involved over and above what we did in clinic, though they will have known what they did in clinic because nurses often sat with us to make sure that the patients were not overawed by the doctor or that they remembered in the heat of the moment to say things.

I should also say that I got the grants to start a psychosocial support system with counselling support and everything too for them, which started in the early 1990s.

MS FRASER BUTLIN: Sir, I'm about to move away from sickle cell care to a different topic, and I note it is almost 11.15. I wonder if now is a convenient

47

A. Yes. It happened every few years, every couple of years, that I would meet a family where the mother had been accused of hitting her child or not caring for her child properly, because one of the first presentations, up to 18 months of life, is sickle crises in the long bones, the metacarpals, or the metatarsals in the feet, and then you get red swelling over it. It is called the hand-foot syndrome.

Now, if you don't know it happens and you are not thinking about it and you don't test for sickle, then you think that child has been damaged. And so a number of mothers would be falsely accused. And, you know, it would only be discovered time later.

So, yeah, there were difficulties in drawing it to people's attention and making sure the patients were effectively diagnosed at first presentation.

Q. In terms of psychosocial support for those patients, what was provided within Central Middlesex?

A. We from the Brent Sickle Cell Centre, which was the first in the country, provided a counselling service manned -- staffed by wonderful expert nurses, who would interact with the families, explaining, helping, they would go into schools to explain and support and ask for extra education. They would elicit what the problems were. And so I often wrote to Housing on

46

moment to break?

SIR BRIAN LANGSTAFF: Yes.

Just before we do, if I may, one of the features of some of the evidence which we have had early in this Inquiry, indeed it was raised with me three and a half years ago when we had preliminary hearings by at least one of the representatives of Core Participants, was that the real expert -- they were talking about haemophilia -- was the person who had haemophilia, and it was very difficult to persuade doctors that they knew something about haemophilia. You asked or raised the question: how do you handle a doctor when you know more than they do? What is the answer?

A. Well, it isn't easy. And doctors often don't like to be corrected. So I would talk to them about ways of raising issues with -- and how to be assertive rather than aggressive, and how to bring different issues in. And how to use me as a bulwark to protect them. You know, "Well, Dr Davies said ..." and things. So I would try and do that.

There are two differences between the haemophilia group and my sickle group. My sickle group lived with the disease as it -- in its raw nature and only had transfusions to modify it.

48

1 Whereas the haemophilia patients at this period were
2 generally getting Factor VIII in one form or another
3 and may not have seen what it was like to have
4 haemophilia before treatment and the horrors of that.

5 The same would be said of thalassemia major.

6 I mean I have seen thalassemia major in Greece
7 untreated and in Africa and how horrible it is, but
8 the thalassemia major patients who were transfused had
9 lost that kind of social memory of both diseases, what
10 it is like if you don't treat, and the doctors now
11 don't have that social memory either.

12 **SIR BRIAN LANGSTAFF:** In that discussion of how you deal
13 with a doctor who -- when you know more than they do,
14 the underlying assumption is that the doctor is
15 saying, "Look do this, do that, take this treatment".
16 Is there an issue here about the extent to which
17 medicine, at least then, was more dictated to the
18 patient than discussed with the patient?

19 **A.** Yes, I think we have changed over the decades to more
20 transparent, no decision without me, and putting the
21 patient there. Why would I have been earlier in this?
22 I came from an academic background where debate and
23 discussion really mattered. And I respected my
24 patients. I respect them awfully. To live with what
25 they live with, they are amazing.

49

1 **SIR BRIAN LANGSTAFF:** Thank you. We will take a break and
2 it is until 11.50.

3 This is the first break. You are giving
4 evidence, you may not discuss the evidence you have
5 given or any evidence which you think you may yet be
6 asked to give with anyone, whoever that person is, but
7 you are free to talk about anything else you like.

8 **A.** Thank you very much.

9 **SIR BRIAN LANGSTAFF:** 11.50 am, please.
10 (11.20 am)

(A short break)

12 (11.52 am)

13 **SIR BRIAN LANGSTAFF:** Yes.

14 **MS FRASER BUTLIN:** Before I move on from sickle cell care,
15 I have just been asked to ask you a question.

16 Very few sickle cell and indeed thalassemia
17 patients have given statements to the Inquiry. Is
18 there anything you can draw on from your experience
19 treating patients with haemoglobinopathies to explain
20 this?

21 **A.** Well, it may well be that my experience is mirrored
22 across the country, that very few did acquire
23 transfusion-related infections. I don't think they
24 will have been undertaking other activities that could
25 have given them those infections particularly because

51

1 **SIR BRIAN LANGSTAFF:** It brings me back to what has been
2 a theme in recent weeks in particular, which is the
3 extent to which clinical freedom enfranchises or frees
4 the patient rather than it gives the doctor liberty to
5 do what he wants to the patient. You have
6 a particular perspective as having been CMO on this,
7 I have no doubt. Do you want to comment?

8 **A.** I think we have an interesting balance between
9 clinical freedom and trying to do the best thing for
10 that individual patient, which should be a discussion,
11 and may, if innovation is there, be different from the
12 guideline, which is what we -- the best evidence that
13 we should be using for the majority of patients. But
14 you will remember that when I talked about going on
15 the hunt every morning for the doctors who had
16 admitted my patients overnight, I said if they
17 departed from the guideline for good reason,
18 I congratulated them. That's clinical freedom. It is
19 knowing what is the best evidence and then saying at
20 the time, "But does that work for this patient?" And
21 if the patient is able to, to discuss it and say,
22 "Well, normally we would do this, but this is where we
23 are."

24 But I do think that transparency and debate has
25 shifted over the decades for the better.

50

1 of all their other problems, so I can only work on
2 that assumption, I think.

3 **Q.** Might stigma have also played a role in a hesitance to
4 engage?

5 **A.** It might. I mean, as we sat over coffee, I reflected
6 on another story. I remember one of my patients
7 standing up and saying, "It's good that you are our
8 doctor because you understand what it's like to be
9 a second-class citizen." And when I enquired, "In
10 what way?" He said, "Well, you're a woman." So
11 clearly there was perceived stigma.

12 **Q.** I want to move on then from sickle cell care --

13 **SIR BRIAN LANGSTAFF:** Just before you do. Are you aware
14 of any physiological reason why someone from the
15 communities who suffer from -- principally from sickle
16 cell and thalassemia should not be affected in the
17 same way as those who don't come from those
18 communities?

19 **A.** No. I mean, they -- the sickle patients SS and SB to
20 O, SD lose their splenic function. That makes them
21 more at risk of bacterial infection, but that's quite
22 a different matter.

23 **SIR BRIAN LANGSTAFF:** Because I wanted again, if I can
24 just say this to those who are listening, we clearly
25 understood that it is entirely up to anyone to make

52

1 their own decision as to whether they want to come
2 forward and give evidence, either directly to us or
3 through an intermediary. If they do, they are very
4 welcome, and they ought not to be afraid if they are
5 afraid or worried if they are worried that it in some
6 way the Inquiry is an official body. They are
7 welcome. And I can just repeat my request to those
8 who may feel moved to give evidence to do so. Thank
9 you.

10 **MS FRASER BUTLIN:** Thank you, sir.

11 I want to move on then to your work with
12 clinicians outside of sickle cell care.

13 You, as a haematologist, also provided advice to
14 clinicians elsewhere in the hospital outside of the
15 haematology department; is that right?

16 **A.** Yes, particularly when on call.

17 **Q.** That would only be when those other clinicians sought
18 your advice.

19 **A.** Generally when they sought our advice but, of course,
20 as routine blood tests went through the laboratory, if
21 they were abnormal, then they were usually flagged to
22 the doctors, and sometimes we would just write
23 a comment, but sometimes we would be moved to ring up
24 or go and see the patient. And if anyone wanted
25 platelets or blood products, they would need to ask

53

1 anaesthetics?

2 **A.** They were flagged up to them. So they -- I don't
3 think they could reasonably claim they were not shown.
4 But as you heard it, the evidence is -- it's very
5 difficult to change people's behaviours. And I have,
6 through my R&D role, understood that evidence is
7 a social construct, and people's attitudes matter as
8 well in how they hear the evidence and whether they
9 take action.

10 **Q.** You have said in your statement that you think there
11 was a hospital transfusion committee --

12 **A.** There was.

13 **Q.** -- but you didn't sit on it.

14 **A.** I think I did for a period, but I -- apart from
15 knowing it was there and not knowing the date, of
16 course, I don't remember the content. I also remember
17 that someone from the Regional Transfusion Service
18 came to it.

19 **Q.** Do you recall which other specialities were on the
20 committee?

21 **A.** No.

22 **Q.** And in terms of the role of that committee in
23 promulgating or disseminating guidelines to other
24 specialities and saying, "Look there's a new guideline
25 on platelet usage or red cell concentrates," what role

55

1 for our agreement. And if anyone ordered abnormal
2 amounts of blood, you know, over routine, or there was
3 a problem, a big massive haemorrhage in theatre or
4 A&E, blood bank would be informed, and they would
5 probably tell us if we were around. So sometimes we
6 were proactive.

7 **Q.** In terms of that proactivity, did that extend to
8 a more educative role of clinicians outside of the
9 haematology department about reducing the use of
10 particularly red cell concentrates?

11 **A.** Yes. I was given to chuntering around the hospital,
12 "Blood is a dangerous drug. Every drug has side
13 effects. Don't use it unless you need it." I was
14 well known for going on about that at surgeons and
15 people.

16 **Q.** And were any audits carried out to assess the use of
17 blood by other departments?

18 **A.** I think there were audits, but I don't recall them,
19 and the world of audit has gone up steadily through
20 the '90s and into this century, so I can't recall
21 them.

22 **Q.** You have spoken about the haematology department
23 following the relevant guidelines that had been
24 published. How would your colleagues, if at all,
25 access those guidelines, say, in obstetrics or

54

1 did the committee play in that regard?

2 **A.** I think the committee must have played a role, but
3 I would be wrong to say it did because my memory
4 doesn't recall, I'm sorry.

5 **Q.** In terms of the use of red cell concentrates, in
6 non-sickle contexts, you have said in your statement
7 that you advised other clinicians that transfusion was
8 contraindicated if the haemoglobin was over 10. Was
9 that the level, the rule of thumb that you used
10 throughout your practice?

11 **A.** For the non-sickle cell patients, it was the rule of
12 thumb. That didn't mean that if it was 8 that you
13 needed a transfusion. It depends on why you are
14 anaemic and how long you have been anaemic because as
15 you become anaemic, a certain enzyme, I think it is
16 23DPG, which is packaged with the haemoglobin changes
17 how much oxygen you can pick up and how you deliver
18 it. So if you are anaemic over a period of time, it's
19 like going high altitude. Over time, you become
20 accustomed because you alter this enzyme.

21 So, first of all, how long has it been there?

22 Then, is there a way you can treat it, particularly
23 with iron and other haematinics, that will sort it?

24 **Q.** Could we turn to RLIT0001564, please. This is a copy
25 of the *ABC of Transfusion* edited by Marcela Contreras

56

1 with a chapter in it that you wrote. This is from
2 1990.
3 If we could then turn on to page 16, please. We
4 pick up your chapter on transfusion of red cells. And
5 it starts in this way:

6 "The term "blood transfusion" is often used
7 rather loosely by doctors when what they really mean
8 is the transfusion of red cells. Symptomatic of this
9 linguistic laxity is that blood is often transfused
10 without sufficient regard either to the specific
11 requirements of the patient or to the potentially
12 harmful effects of the transfusion."

13 Was that your experience at the Central
14 Middlesex at around this time?

15 A. It -- I think in Central Middlesex, Mischa Brozovic
16 had been there for some years and had been educating
17 people, and I came and added more energy and newness
18 to it. They were rarely misused, if at all. But
19 I think there was still misuse across the country, so
20 I stand by this at that time.

21 Q. And then if we turn the page, please, we pick up under
22 the heading "Indications for transfusion of red
23 cells", and the chapter says this:

24 "The only true indication for the transfusion of
25 red cells is the need to improve the delivery of

57

1 transfuse is made."

2 Here, a haemoglobin of 80 is given -- sorry, 8
3 or less, rather than 10 or less. When do you think
4 that change came into play?

5 A. It must have come into play in the '80s, mustn't it?

6 Q. And does that accord with what you were advising
7 clinicians at the time?

8 A. Yes.

9 Q. When you advised clinicians about particularly
10 pre-operative or post-operative transfusion needs and
11 the shift from the haemoglobin of 10 to haemoglobin of
12 8, was that advice generally followed by your clinical
13 colleagues, or did you face resistance to it?

14 A. The anaesthetists found it difficult and worrying,
15 but, I mean, we steadily moved. So I wouldn't say
16 anyone was resistant; just it took time. Change
17 always takes time in the NHS.

18 Q. And you have mentioned the anaesthetist being
19 particularly worried. Were there other specialities
20 where you tended to find that they found it more
21 difficult?

22 A. Well, the orthopaedic surgeons found change difficult,
23 but -- and we didn't have any of the other
24 specialities like open heart surgery or major liver
25 surgery or anything that might have different views,

59

1 oxygen to the tissues within a short time. A low
2 haemoglobin concentration should not be the only
3 reason for transfusion, as many other factors are
4 important. These include the patient's age and
5 general state and the rate and fall of the haemoglobin
6 concentration. A patient whose haemoglobin
7 concentration falls suddenly feels ill and may well
8 require transfusion, and equally low haemoglobin
9 concentration (for example 80g/l), however, may be
10 well tolerated by a patient whose body has had time to
11 adapt because the fall has taken place gradually over
12 weeks or months, so such patients are generally better
13 treated in other ways."

14 If we turn the page, please, to pick up the
15 preoperative blood transfusion situation where it
16 says:

17 "It is usually safer to correct anaemia with
18 appropriate haematinics if its cause is known. If
19 preoperative anaemia cannot be corrected in this way
20 (for example if the operation is an emergency, or the
21 patient has failed to respond to haematinics) and the
22 haemoglobin concentration is 80g/l or less, the
23 patient may be transfused. When the haemoglobin
24 concentration is between 80 and 100g/l, each patient
25 should be assessed individually before the decision to

58

1 and I'm not expert at that, and I wasn't then either,
2 so I can't comment.

3 Q. I want to then move on to your role when you were
4 Chief Medical Officer.

5 We have spoken, but just so that we put it into
6 context, you were appointed as interim CMO in 2010,
7 and then CMO in 2011. What did the role of CMO
8 entail?

9 A. It is -- it has many roles. You are there to advise
10 ministers and policymakers on the issues of the time,
11 to write an annual report, to be, as we called it in
12 inverted commas, the nation's doctor when there were
13 emergencies, or when there are big campaigns that need
14 a medical face because it's a medical issue. So it
15 has a number of roles in it together.

16 Q. When you talk about being the nation's doctor, what do
17 you mean by that?

18 A. Well, if I went on the television or the radio, then
19 I was the one who, as one of the most senior
20 clinicians in the country, was speaking to the public
21 on behalf of the medical profession rather than
22 actually the government. I was independent. Our
23 Chief Medical Adviser and Chief Scientific Adviser are
24 independent.

25 Q. Was there a formal job description for the CMO role?

60

1 A. There was. I have not brought it with me.
 2 Q. Perhaps it's something we can be provided with
 3 subsequently.
 4 In terms of oversight of blood transfusion
 5 services, what role did you play as CMO in that
 6 regard?
 7 A. None at all.
 8 Q. And why was that?
 9 A. Well, there will be two reasons. The first, it
 10 hadn't -- it did not come up as an issue while I was
 11 CMO. The second was, of course, that the Lansley
 12 reforms of 2011 separated a public health function and
 13 the Department of Health, where I sat, from the NHS
 14 who had a senior medical director. So while
 15 I reserved the right to comment or act on or in the
 16 NHS, I generally focused on the public health and the
 17 cross-government role, and I did much more
 18 cross-government work than my predecessors had done.
 19 I argued that I was the Chief Medical Officer for the
 20 whole of government, not the NHS.
 21 **SIR BRIAN LANGSTAFF:** By "cross-government", do you mean
 22 across all four nations, or just across government
 23 insofar as England was concerned?
 24 A. Across government in Whitehall, I was the UK
 25 government's most senior medical adviser, but if it

61

1 clinicians. What role, if at all, does the CMO play
 2 in assisting that?
 3 A. I mean -- so I think my predecessor did it a bit
 4 differently. There was a CMO letter to all doctors,
 5 not frequently but more than once a year, and he would
 6 highlight a number of things. However, I did not do
 7 that. We were in a phase of government reducing the
 8 size of the civil service and therefore the amount of
 9 support, and it seemed to me that when I had been on
 10 the receiving end, that getting too much from all
 11 sorts of places left you kind of wondering, "Which has
 12 supremacy and when am I going to find time to read
 13 that and look after my patients?" So I left the
 14 dissemination essentially to NICE of their own
 15 guidelines, and the specialists to them.
 16 But we all know you have got to have the experts
 17 write it but it needs to be grounded in reality.
 18 I mean, I could write a guideline that no one could
 19 do, but it might be perfection. It needs to be
 20 grounded in reality. It then has to be disseminated.
 21 But the big problem is not dissemination: you can
 22 email it, you can post it, you can put it on the wall,
 23 but how do you change the hearts and minds so people
 24 do things differently? And it is extraordinarily
 25 difficult.

63

1 was something that strayed into -- so Foreign Office,
 2 Home Office, it would be me. Development. But, for
 3 instance, when I was asked by the then Prime Minister
 4 to update the guidelines on safe alcohol consumption,
 5 I asked the other CMOs to join in so that it was from
 6 all of us. When I felt we needed to update the
 7 guidelines on physical activity, I asked them to join
 8 with me, so that it was all of us together. So I was
 9 the primus inter pares.
 10 **MS FRASER BUTLIN:** In terms of guidelines and guidance,
 11 was it part of your role to provide guidance or
 12 guidelines for clinicians on a national basis about
 13 policies and practices?
 14 A. No. It was not part of my role to write or prepare
 15 guidelines because those sit with experts, and of
 16 course the -- one route is NICE. Not only bring in
 17 the experts but the patients, and consult. Another is
 18 the specialist societies who produce quite a lot of
 19 guidelines. So there are many routes for experts to
 20 input. And my expertise was sickle cell becoming out
 21 of date and of being able to integrate different areas
 22 and think about it, and of course research strategy.
 23 Q. One of the themes of the evidence that the Inquiry has
 24 heard has been about the difficulties of information
 25 and guidelines being disseminated to different

62

1 Q. What involvement as a CMO did you have in that aspect
 2 of changing hearts and minds?
 3 A. I played a bit of a role in antimicrobial resistance
 4 because I chose that as one of the issues of my time,
 5 but essentially that has to be the role of the NHS and
 6 their system, and I was not actually part of their
 7 system. They had a senior medical director who
 8 assured me that all was fine.
 9 Q. What was your view of the ethical principles
 10 underpinning the role of CMO, as a civil servant
 11 answerable to the government but also a public servant
 12 with particular responsibilities for the public's
 13 health and also a doctor subject to the usual ethical
 14 and regulatory duties? What was your view of how all
 15 of that came together within the role of CMO?
 16 A. Quite simple: I have very strong moral values that
 17 were developed through a childhood where a father was
 18 a theologian, and I stick to them. They fit with
 19 the Nolan principles and I told truth to power when
 20 I felt it was needed.
 21 Q. What, in your view, then would be an ethical response
 22 for a CMO if they felt that the government or
 23 ministers were acting in a way that wasn't transparent
 24 or fully candid to the general public about an
 25 emerging or present public crisis?

64

1 A. So one example would be Ebola, and we had a debate
2 between myself, the minister and the
3 communications people about was Ebola going to reach
4 England and, if it was, how are we going to handle it?
5 But actually should we warn the public? I did tell
6 the public that I expected us to get up to a handful
7 of imported cases, and we did.

8 Q. You talked in your statement about --

9 SIR BRIAN LANGSTAFF: Just one moment.
10 What was the counterargument? What was the
11 argument that you shouldn't?

12 A. I think it is sort of a kind of paternalistic "Don't
13 worry the people because it may not happen". Whereas
14 the evidence, of course, about scientific
15 communication is that you should be very
16 straightforward, tell the truth, what you do know and
17 what you don't know, and then update as you learn
18 more. And that's where I come from.

19 SIR BRIAN LANGSTAFF: Thank you.

20 MS FRASER BUTLIN: That might suggest some tension between
21 the role of advising ministers and the public, as you
22 have put it in your statement, without fear. Is that
23 fair? That there was some tension in those two roles?

24 A. Not often. And it was always resolved. I did what
25 I thought was right.

65

1 where I said, "If you don't follow my advice I will
2 resign". The public would have known had it been --
3 had they not listened.

4 Q. And to what extent do you think other health-related
5 special advisory committee advice should be public and
6 published?

7 A. I think that the protocol for scientific advisory
8 committees to government is quite clear, the minutes
9 are published and I expect them to be.

10 Q. During your time as CMO, in your statement, you have
11 spoken about three public health emergencies: the
12 flu pandemic, Ebola and the Novichok poisonings.
13 What is the CMO's role in those sorts of
14 situations?

15 A. So, it is quite a pivotal role because you sit
16 understanding the science, because if you don't you
17 have to get the right people in to make sure you do;
18 knowing where the NHS is and therefore reality of what
19 can be done; and working with the politicians and
20 across government. So in the '09/'10 flu pandemic, it
21 was wave 3, and I needed to review the data and see
22 where it was going and try to help push the country
23 into understanding the importance of the role of
24 vaccination. And indeed, I was on holiday at the new
25 year and the levels went up alarmingly and I came back

67

1 Q. And are you aware of whether there had been tensions
2 in that regard between those two roles for previous
3 CMOs?

4 A. I never discussed it.

5 Q. To what extent do you think that CMO advice to
6 ministers should be published for the public to see
7 and understand?

8 A. Well, my main advice came through reports or me
9 speaking very publicly. I think you have to recognise
10 that the relationship to be effective is built on
11 trust. Trust that I would tell them the truth, trust
12 that I knew what I was telling them, and trust that
13 I would help them get to the best answer. And as
14 we -- as seen played out at the moment, advisers are
15 there to advise and the politicians at the end of the
16 day have to decide. So, there are discussions which
17 don't need making public. It would not be helpful.
18 It is about building trust and developing that
19 relationship so that when the issue is difficult they
20 listen. And they did.

21 Q. The counter to that might be that the public have
22 a right if there are health concerns and health
23 consequences to understand the debate and be aware of
24 the advice that's being given.

25 A. I accept that and there were a couple of occasions

66

1 from holiday to make sure I was there to advise both
2 politicians and the nation, going on television.
3 So that was the role I played there.

4 My predecessor in waves 1 and 2 played a more
5 active role, because that was when the pandemic was
6 starting.

7 In Ebola --

8 Q. Just before you move to Ebola, can I just pick up one
9 point you just mentioned there. You talked about
10 discussing with politicians. Who particularly would
11 you be dealing with and how much would you liaise with
12 the Secretary of State for Health?

13 A. Secretary of State for Health regularly, more than
14 weekly, often daily. Permanent secretary and all the
15 senior policy officials and the minister for public
16 health.

17 Q. Thank you. You are very welcome to continue in
18 relation to Ebola.

19 A. Ebola was different. I was kind of responsible in
20 that same sort of way within the UK and England, kind
21 of -- I co-chaired the SAGE, Scientific Advisory Group
22 for Emergencies, with the Chief Scientific Adviser.
23 And as CMO, I go to the Cabinet Office briefing rooms
24 COBRA meetings to give my opinion and views to the
25 ministers, chaired often by the Prime Minister or

68

1 others, and take into that, sitting alongside the
2 Minister of Health, issues from Public Health England,
3 Public Health, SAGE and the NHS to try to make sure we
4 get to the right place.

5 I also did a number of televised briefings to
6 the nation. I played a role through that, working
7 with the minister without portfolio on -- and the
8 present Chief Medical Officer, who was the Chief
9 Scientific Adviser for the Department for
10 International Development, on advising how we
11 responded as we took the lead for Ebola in
12 Sierra Leone and on pushing to make sure that the NHS
13 had appropriate PPE, appropriate training and things
14 like that.

15 **Q.** As CMO in an emerging pandemic, what role did you play
16 to ensure that NHS clinicians have the relevant
17 information and guidance that they need?

18 **A.** The NHS leadership dealt with the guidance. Well,
19 I made sure that there are various scientific
20 committees and they needed to be brought in into
21 contribute to the guidance. I made sure the right
22 scientific advisory committees were convened, asked
23 the right questions, and that the advice went to the
24 NHS who could then disseminate it and do it, but I did
25 not do the advice.

69

1 **Q.** Did infected blood come up with you at all?

2 **A.** Well, I was aware that there was a cross-party
3 agreement to set up this investigation, and I waited
4 to see how it worked through. I was secluded from
5 those discussions as a haematologist.

6 **Q.** And in terms of hepatitis C more generally, was there
7 any consideration given to running a national health
8 campaign in relation to hepatitis C broadly?

9 **A.** Not that I'm aware of, but I might not have been made
10 aware. I didn't know all the policies, issues that
11 were going on in the department. I knew about those
12 that I was interested in and worked on and those where
13 they asked my advice, either on developing the policy
14 or in discussing it with ministers. So plenty went on
15 that I didn't know about and, you know, I couldn't
16 cover properly all the work of the department, and
17 I didn't set out to.

18 **MS FRASER BUTLIN:** Sir, those are the questions I have for
19 Professor Davies. I obviously need a little bit of
20 time to establish whether there are further questions
21 from the lawyers behind me.

22 I wonder if we can take a break for say --

23 I think probably 15 minutes will be ample.

24 **SIR BRIAN LANGSTAFF:** Let me deal with it this way. Let
25 me say not before 12.40 pm.

71

1 **Q.** In terms of those other committees needing to consider
2 and decide matters, another issue that's arisen in the
3 evidence before the Inquiry is that of delay, in terms
4 of the time taken to discuss matters, working through
5 advisory groups and further discussions before actions
6 can be taken. Do you think that the current system is
7 flexible and speedy enough to make decisions quickly
8 on issues within a pandemic?

9 **A.** What I saw in the flu pandemic, waves one, two and
10 three, and Ebola and Novichok, yes, we were agile. We
11 responded quickly.

12 **Q.** And it may be something you haven't discussed with
13 previous CMOs or others. Had that system changed
14 significantly over the years?

15 **A.** It has developed over the years, yes, and I'm sure, as
16 we learn the lessons from this pandemic, it will
17 improve and develop again.

18 **Q.** You were CMO when this Inquiry was announced. Did you
19 ever consider, whilst you were CMO, running a campaign
20 to try and get those who had not been identified by
21 the look-back to be tested for hepatitis C?

22 **A.** No. And no one suggested it to me. No.

23 **Q.** Do you recall discussing anything in that regard with
24 health ministers or your staff?

25 **A.** No. It was not an issue that came up with me.

70

1 Let me just explain. In this Inquiry, there are
2 a number of Core Participants, many of whom are
3 represented by legal representatives. They have
4 a right through their legal representatives to invite
5 counsel to ask further questions, and she will, but
6 she has to know what the questions are that they
7 suggest, and they have been listening to you either
8 here in this chamber or online. So we need time for
9 that to happen. And then -- I can't tell you how long
10 you will be kept here for answering those questions
11 afterwards. I don't think it will eat significantly
12 into your lunchtime, but I can't be sure. We will
13 have to wait and see. But 12.40 pm, if you please.

14 **A.** Thank you.

15 (12.25 pm)

(A short break)

16
17 (12.40 pm)

18 **SIR BRIAN LANGSTAFF:** Yes.

19 **MS FRASER BUTLIN:** Thank you. Professor Davies, I just
20 have a handful of questions which do range across all
21 of your evidence, so it covers a variety of matters.

22 First of all, in one of your answers, you
23 referred to hepatitis being caused by alcohol. Is it
24 right that by that you mean inflammation of the liver
25 caused by alcohol, as distinct from infectious

72

1 hepatitis?

2 **A.** Yes. I was brought up to understand "itis" as

3 inflammation with many causes.

4 **Q.** Also in your evidence, you talked about liver function

5 tests. You talked about donors being excluded due to

6 abnormal liver function tests.

7 Other evidence to the Inquiry has indicated that

8 that wasn't routinely done in the North London centre;

9 it was only done if there was post-transfusion

10 hepatitis enquiries.

11 Can you assist us with why you thought liver

12 function tests were being done, how you came to that

13 understanding?

14 **A.** I apologise if I have misremembered. I warned you my

15 memory is not the world's best. But my training in

16 haematology was at the Middlesex, and the haematology

17 department was downstairs, and Dane, who discovered

18 the Dane particle of hepatitis B, was on the third

19 floor. So there were always discussions about non-A,

20 non-B, and that was how I understood about the LFTs,

21 and I had thought that that was the case, I apologise.

22 **Q.** In your evidence you spoke of patients losing the

23 social memory of haemophilia without treatment. Is it

24 right though that you have no first-hand knowledge of

25 what patients with haemophilia did or didn't

73

1 **Q.** Did you have any role or involvement in relation to

2 the Penrose Inquiry while you were CMO?

3 **A.** None at all.

4 **Q.** And did you or your team consider the Penrose Inquiry

5 report and its recommendation to offer tests for

6 hepatitis C to people who had received transfusions in

7 Scotland?

8 **A.** The policy team will have looked at that.

9 **Q.** But do you think it came across your desk?

10 **A.** I don't remember a formal discussion about it.

11 Clearly there were comments. And in fact I don't

12 remember that they recommended testing.

13 **Q.** We spoke -- you spoke about racial inequalities in

14 practice. Was that something you then examined or

15 looked at during your time as CMO at all?

16 **A.** To a certain extent. It took me some time to get on

17 top of all the public health issues that you will have

18 as CMO, not coming from that background, and then to

19 really understand, but you can see in my reports

20 concern about health equalities, a chapter for

21 instance on violence with women, and other things.

22 I have addressed it most since I stepped down and

23 wrote a book that was published in 2020.

24 **Q.** And finally, in relation to your evidence that you

25 would hold truth to power, how would you resolve

75

1 experience or indeed what social memory they may have

2 had or not had?

3 **A.** I did look after some haemophilia patients as

4 a trainee. So I remember seeing some of the dreadful

5 joints and hearing stories about relatives from them,

6 but I did not look after any as they deteriorated and

7 died.

8 **Q.** In relation though to your evidence in relation to the

9 social memory point, would it be fair that that was

10 probably no more than speculation or assumption in

11 relation to the later years?

12 **A.** When I talked to the patients, most of them were

13 remembering that it had been bad but they were in the

14 stage of prophylaxis.

15 **Q.** In terms of your CMO role, given that you had

16 previously and were a haematologist as a clinician,

17 why didn't you consider a health campaign in relation

18 to hepatitis C?

19 **A.** I have always worked extraordinarily hard, well

20 overtime, for my patients and the public, and you

21 can't do everything. And this was not put to me as

22 a suggestion and it did not arise from my background.

23 My sickle cell patients, as I've said, did not appear

24 to have hepatitis C. So it was not at the forefront

25 of my mind.

74

1 a situation where you disagreed with the government's

2 approach to an issue involving the health of the

3 nation?

4 **A.** So, you know, some -- I was there to advise, and

5 ministers had to decide. And some things, maybe

6 I would have done differently, but that was their

7 democratic right.

8 There were a couple of things, as I said

9 earlier, which I felt strongly about, but when we

10 discussed it and I explained how strongly I felt and

11 why, with the evidence, they accepted. So it didn't

12 get to a difficult -- well, that was tough, but it

13 didn't get to a parting of ways.

14 **MS FRASER BUTLIN:** Sir, those are the questions I have

15 from those behind me. I'm just going to check whether

16 Professor Davies' representative has anything they

17 would like me to raise.

18 Sir, do you have anything you would like to

19 raise?

Questions from SIR BRIAN LANGSTAFF

21 **SIR BRIAN LANGSTAFF:** Yes, I do. It really arises out of

22 your cri de cœur that it is very difficult to change

23 hearts and minds.

24 The reason I ask is that I remember in recent

25 times, having been to a health education forum with

76

which the subject for discussion, the seminar, was all about inquiries that there had been into the NHS. And I remember the Chair observing that it seemed that almost every inquiry had ended up saying that the culture needed to change.

Whether it is hearts and minds is the same as culture, certainly they are very close. You said it was difficult. You didn't say it was impossible. How do you go about it?

A. So I think it depends on the issue. So let me take one issue in sickle cell.

There was not antenatal screening for women who might have sickle cell or traits to see whether they had, and then whether the partner had, to offer prenatal diagnosis or at least the understanding that they could have a sickle cell child. We brought it in, and we talked about it, but it was not being picked up everywhere.

Then I was asked by patients or -- no, they aren't patients -- women who had sickle cell children that were not, and they expected to assist as an expert witness and speak to that, and I did. And they were -- you would know as lawyer -- wrongful birth cases. And I chose to do that because I felt that it was one way to shift hospital management to

77

You can do it through meetings. But you've got to change the culture, you've got to incentivise good behaviour, and you've got to help people to see that their patients will benefit. Because they are there for the patients and they believe that. But it is multi-pronged and there is no magic bullet.

SIR BRIAN LANGSTAFF: Essentially the three things you have mentioned are the effect of the legal system or legal condemnation in -- playing a role in ensuring that what is good practice becomes required practice.

Secondly, you have discussed training, making sure that doctors start off on the right foot, if I can put it that way.

And thirdly, incentivising those who are in the profession to do good for other people.

Is part of that incentive process producing material which will show empirically that "If you do this, you get better results than if you do that"?

A. I think it is. After all, I was the director general of R&D, and I was the one who set up NIHR so we could generate much more evidence to move things forward to improve patient outcomes. In the NIHR I was the one who made sure that the patients and the public were part of the decisions about what studies we did. Because I believe totally in the value of evidence as

79

saying, ah they have been talking about this, but now we could lose a case and have to pay out money. We would be better paying it to provide that service.

So you can do things what I would call structurally. You can do things structurally through now IT systems which say, you know, you want to do this. Well, you can't unless you have done that.

But in general, it's much more about culture, and that's partly how we train our clinicians much more multidisciplinary, which is good, but we also need to train our clinicians to ask questions and be open to challenge.

I was very lucky, I had a visit for three weeks from one of the top sickle cell doctors in the States, Professor Charache, who was at Johns Hopkins, and he not only went on the ward rounds with us and gave us advice then, at the end of every ward round he would sit down one-to-one with me and say, "Now ...", and interrogate me and advise me about the interactions and the evidence. So he helped train me to be much more open to the team about the interaction and the team and the patient challenging me and asking me.

You know, so there are ways you can train people and help them. My way of going round about the guidelines for sickle was another way of doing it.

78

the basis for changing and moving forward and improving patient outcomes and experience.

SIR BRIAN LANGSTAFF: So it is presenting the evidence and hoping that evidence isn't, as you described it earlier, too much of a social construct, but is actually listened to?

A. Yes, and trying to make it a norm for that part of our medical system, as it were, because people cleave to the norms, so, "If that's what everyone else is doing, why are you the outlier?" And hence the role of audit.

SIR BRIAN LANGSTAFF: So is there a competitive element in this? "They're doing it over there, and they're the leaders, we ought to be doing it here"?

A. Most doctors are a bit competitive, yes.

SIR BRIAN LANGSTAFF: We have seen signs of some of that on occasion.

So, you, at the moment, I think, have a role or have a great interest in antimicrobial resistance?

A. Yes.

Q. And that is essentially the problem of too many drugs causing infections to become resistant to those drugs?

A. Yes, overuse of antibiotics, for instance, push resistance higher.

SIR BRIAN LANGSTAFF: There must be a considerable

80

1 reluctance, which one might have described at some
2 stages as cultural, to not giving drugs, particularly
3 if the patient is coming and saying, "Look, I have got
4 this, give me something to deal with it?"

5 **A.** Yes.

6 **SIR BRIAN LANGSTAFF:** How are you managing it across the
7 world, how are you convincing people to change their
8 culture on that?

9 **A.** So through evidence and stories, there are the two
10 lines. So I felt we needed more evidence about the
11 harm and persuaded the Department, the Wellcome Trust
12 and the Gates Foundation to fund a big study of the
13 burden of disease. It came out two weeks ago.
14 1.27 million people die each year across the
15 world of untreatable infections. 5 million, which
16 includes that 1.3, die with antimicrobial resistance.
17 It's contributed, so it's one of the top three
18 contributors to death, with stroke and heart disease.
19 That's been very powerful.

20 But then what do you do about it? Well, in
21 low-income countries, there's access issues, but what
22 we're talking about I think is misuse of antibiotics.
23 So you then have to look at how can you steward what
24 we've got? It is called stewardship programmes, and
25 some of that is education. And pharmacists can play

81

1 interesting, is run by Public Health England in the
2 northwest was, the general view is: patients ask for
3 antibiotics and make doctors' lives difficult. Well,
4 then, why do they want them, and if you do focus
5 groups, they want to be able to ring up work and say,
6 "You see? I am ill. I've got an antibiotic." They
7 need that, and they are ill.

8 So they developed special prescription sheets
9 where the patient's name was handwritten, a tick for
10 what was wrong, a tick for what should happen, going
11 through, but not an antibiotic because it wasn't
12 needed, signed and dated by the doctor, torn off and
13 handed over. And that worked really well at reducing
14 them because a patient could ring up and say, "I've
15 got a prescription. I am ill", and the patient got
16 something out of that consultation.

17 So there are behavioural ways, and we have to do
18 a lot more work on that side of evidence and what
19 works.

20 **SIR BRIAN LANGSTAFF:** When you say, "We have to do a lot
21 more work", that's, again, going back perhaps to
22 an aspect of research and development, it is certainly
23 research. Who is doing it and or should be doing it?

24 **A.** Well, in general it is the NIHR. When I left
25 I endowed Chris Whitty with an annual budget of

83

1 a big role in holding doctors to account.

2 You know, I would sit in outpatients, and the
3 pharmacist would ring up and say, "Dr Davies, we don't
4 any longer have that drug," or, "We don't use for
5 community pneumonia this antibiotic; we use that. May
6 we change it?" So they can play quite a useful role
7 in this.

8 Guidelines have a role, but behavioural things
9 play a role too. So, for instance, I wrote -- it went
10 over my name; Public Health England ran it -- a letter
11 to half, randomly chosen, of the top 25% prescribing
12 GPs and said, "You are in the top 25% of prescribing."
13 That year, prescribing went down 13% in that group, as
14 compared with the control group, and we went on and it
15 continued to decline. Australia copied it, and they
16 got an even bigger rise.

17 So you can put in place behavioural things.

18 A lovely study about delayed prescriptions done out of
19 Southampton. So a mum takes a child. "My child needs
20 an antibiotic. Look. Ill. High temperature." The GP
21 says, "I think it's viral. I think your child is
22 going to be all right, but here is a prescription. If
23 he is worse in 24 hours, you can cash it in." Use of
24 antibiotics goes down dramatically. Not totally.

25 Another behavioural one, which I think is quite

82

1 1.3 billion each year to spend on clinical and health
2 research, and it included trials. Those trials were
3 funded by that.

4 And that was why I thought up the idea of the
5 NIHR and argued so successfully for money, because we
6 had to do research of a type that the Medical Research
7 Council never funded.

8 **SIR BRIAN LANGSTAFF:** Yes.

9 Well, thank you very much. I don't know if
10 there are any further questions from anyone which
11 arise out of that?

12 **MS FRASER BUTLIN:** No, sir.

13 Professor Davies, is there anything else you
14 would like to say?

15 **A.** If I may?

16 **MS FRASER BUTLIN:** Please do.

17 **A.** I wanted to say, we all ask ourselves: can I do more?
18 Could I do more? I know for myself, and I think it is
19 true for others, or many others, that we have worked
20 as hard as we can to do our best for individual
21 patients and the public. But I also want to
22 highlight, I think that Covid and these events have
23 shown us both the power and the insidiousness of
24 infectious diseases. When I became CMO I was told
25 about the American Surgeon General Dr William Stewart,

84

who said in 1967 that we could close the book on infectious diseases. That was wrong, and you've talked about why I am championing, still, this cause of antimicrobial resistance. Yet, as we have seen with the infected blood and the pandemic, it is not only difficult to find new and different infections, it takes us too, too long to develop diagnostics, even when we know it is there. And also, and I think importantly, in the minds of both doctors and politicians, we find it difficult to understand something new is afoot and shift how we do things.

I think the other learning from this episode has, for all of us, been the truth that no medical intervention is risk-free. Everything from aspirin to simple tonsil removal or catching measles has risks. And I chose those three examples because I have seen deaths from all three.

And I have spoken about that today, but we have to remember and help everyone understand that.

This has been so tragic with dreadful suffering for the patients and their families. I'm glad the pain has been laid bare for all to see and learn from but I am sad and sorry for the suffering. It was a tragedy for everyone who knows someone infected, but it is a tragic episode for our society as a whole,

85

generally speaking, it has been about 100 or so this week. So they are the people who also need to hear what you have to say. Bear that in mind when you are answering the questions.

The questions will be asked in a moment or two by Ms Fraser Butlin, but first, Mary will invite you to take the oath.

Mary.

MS ELIZABETH EMMA PRESCOTT (sworn)

Questioned by MS FRASER BUTLIN

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: Ms Prescott, first of all, I would just like to work through a brief overview of your career.

You qualified as a registered general nurse in 1988; is that right?

A. Yes.

Q. And you worked then as a staff nurse specialising in oncology nursing from 1989 until 1995.

A. Yes.

Q. And then you became a thalassemia nurse specialist at the Whittington Hospital, and you have remained in that role since then.

A. Yes.

Q. You also took on a hepatitis C nurse specialist role at the Whittington Hospital between 2006 and 2009.

87

I believe, and I hope and pray that we all can learn and heal from this as a result of the Inquiry.

Thank you for doing it.

SIR BRIAN LANGSTAFF: Well, thank you very much for the energetic evidence which you have given, the way in which you have described and illuminated sickle cell disease, and what you can tell us about that as having been the first or one of the first consultants to be dealing with that in the NHS.

And on your observations from your time as CMO, all your evidence has been of very great value to us and I want to thank you for your time and your words in coming to deliver it. Thank you.

2.00 pm then.

MS FRASER BUTLIN: Thank you, sir.

SIR BRIAN LANGSTAFF: 2.00 pm.

(1.04 pm)

(The short adjournment)

(2.03 pm)

SIR BRIAN LANGSTAFF: Good afternoon, Ms Prescott.

THE WITNESS: Afternoon.

SIR BRIAN LANGSTAFF: Now, you are talking to the people you see here, that's obvious, and the lawyers to your left, but there is a much bigger audience out there watching remotely, I don't know quite how many, but,

86

A. Yes.

Q. And we will come back to that in a moment.

First of all, in terms of your training as

a nurse, what were you taught about the risks of viral transmission in blood transfusion?

A. In my basic training, general nursing, I don't remember actually being taught anything about viral hepatitis at that stage. My knowledge came really more from media itself, hospital sort of infection control measures, and literally just reading up on papers myself.

Q. And what were you taught about record-keeping when a transfusion was given?

A. I think that was quite thorough. Obviously, it's -- you know, it's vital to document everything that you are doing with the transfusion. So we would obviously -- prescriptions, correct prescriptions, collect documentation of collection of blood products from the laboratory, documentation of receipt of blood products onto the unit, obviously after, you know, the cross-checking documentation that it has been checked, patient observation documentation, how -- any issues during the transfusion, post-transfusion, you know, how the patients were prior to being discharged.

Q. And when you were working in oncology nursing, so

88

1 between 1989 and 1995, what involvement did you have
2 in giving blood transfusions?

3 **A.** Not much at all. Very rarely. I was in solid
4 tumours, particularly breast cancer and head and neck
5 tumours which, on the whole, didn't, you know, require
6 blood transfusions.

7 **Q.** So you then became a clinical nurse specialist in
8 thalassemia in 1995.

9 **A.** Yes.

10 **Q.** The Inquiry has heard evidence about what β
11 thalassemia is, and there is an expert report dealing
12 with it, but for those listening who perhaps haven't
13 heard that previous evidence, could you tell us in
14 layman's terms what β thalassemia is.

15 **A.** β thalassemia is a genetic inherited disorder. Both
16 parents have to carry the faulty gene, if you like, to
17 pass that on to the affected child. So any pregnancy
18 with mum as a carrier, dad has a carrier, there is a 1
19 in 4 chance that that pregnancy will result in
20 a thalassemia major child, so two inherited genes.

21 It stems really from the years of malaria. So
22 if you look at the malaria belt across the world,
23 these tend to be where -- the countries that have been
24 affected by thalassemia because the thalassemia
25 carrier we believe holds some protection against

89

1 have mentioned this -- there's lots of different
2 mutations, lots of different types of that β
3 thalassemia; over 200. So, again, depending on what
4 they've inherited from mum and what they've inherited
5 from dad will determine how severe their thalassemia
6 is.

7 Thalassemia in the old days used to be
8 categorised into two main areas. One would be
9 thalassemia major, and one would be thalassemia
10 intermedia. Thalassemia major would be those that at
11 three months are not thriving, so they have no option
12 but to receive blood transfusions.

13 Thalassemia intermedia not that long ago would
14 be termed as those who are managing to grow, managing
15 to survive without blood transfusions. It's now
16 become clear that that's not so clear cut, and we
17 don't have a clear definition between a major and
18 an intermedia.

19 So we now call them transfusion-dependent
20 thalassemia and non-transfusion-dependent thalassemia.
21 And the non-transfusion-dependent thalassemia really
22 need very careful monitoring because -- just because
23 they're living doesn't necessarily mean that they are
24 thriving or they are not going to get long-term
25 complications.

91

1 malaria.

2 So the main countries would be really -- it's
3 not indigenous to north Europe. It's really coming
4 down the Mediterranean countries, moving across then
5 into the sort of Middle Eastern countries, then across
6 to the Indian subcontinent, and then across to the
7 Far East.

8 When -- basically, the upshot is with these
9 patients, they don't produce enough or any at all
10 haemoglobin A, which is adult haemoglobin, so this is
11 the oxygen-transporting mechanism that we have to get
12 oxygen to the rest of our body.

13 When you're first born, a baby -- the majority
14 of a baby's haemoglobin would be the haemoglobin F,
15 the foetal haemoglobin, which is not affected by β
16 thalassemia. You don't need the beta-globin for that
17 production. So, unless you are screening children,
18 a child would be born, you wouldn't actually know that
19 they have thalassemia until that F level naturally
20 comes down. So usually around three to six months is
21 when you'll first see that these children become weak
22 and anaemic, and they become pale. They may not be
23 feeding. They are obviously unhappy. They are
24 failing to thrive.

25 So depending on the severity because -- I should

90

1 For the sake of the Inquiry, I look after
2 thalassemia -- the old thalassemia major, the
3 transfusion-dependent, so all of these chaps require
4 blood transfusions in order to survive.

5 **Q.** And roughly how many patients are treated within the
6 Whittington Hospital?

7 **A.** We have 140 regular transfusions. So those are guys
8 that actually come to my day unit every two to four
9 weeks. And then because we are a tertiary centre, we
10 have probably between 50 and 100 that come from other
11 parts of the UK, but we do not transfuse them; they
12 just come for specialist advice. That's changed now
13 with the new haemoglobinopathy coordinating centres
14 and -- so satellite centres. So hopefully these
15 patients will be managed more locally and get the care
16 they need in their old centres.

17 **Q.** Can you tell us broadly what your role at the
18 Whittington Hospital involves, particularly on
19 a day-to-day basis?

20 **A.** Day-to-day basis, basically I'm the manager for the
21 transfusion day unit. So I'm pretty much, with my
22 nursing colleagues, the first point of call for these
23 patients. So it is very important that obviously,
24 from an observation point of view, we are the first
25 really to actually see whether there are any problems

92

1 arising with these patients, whether it be clinical or
2 whether it be psychological.

3 So they can't -- obviously 140 patients cannot
4 see the consultants every three weeks to monitor their
5 blood results and check how they are taking their
6 medications. So that's a very important role for me.
7 So each time a patient comes for their pre-blood test,
8 which I would arrange, it is obviously my
9 responsibility to check that -- is everything all
10 right, is their kidney function all right, is their
11 liver function all right. I have to monitor their
12 iron. And I should have probably mentioned that in
13 the first bit. Thalassaemia isn't so straightforward,
14 unfortunately, as simply having blood transfusions.

15 Any time you give a blood transfusion to
16 anybody, you give between 200 and 250mg of iron. Our
17 daily intake is 1mg. Our daily excretion is 1mg. So
18 if you have an average man having three units of red
19 blood cells every three weeks, he's having between 600
20 and 750 milligrams of iron in a three-week period. So
21 as time goes on, after a year or so, this iron
22 becomes -- it is unsafe, if you like, and it is
23 unbound, and this is what creates the problems for our
24 thalasseemics -- in developed countries where we have
25 the blood and -- to keep them alive.

93

1 fertility. It also affects the pancreas, which if
2 damaged we are now looking at diabetes. So iron
3 overload in the developed countries is the
4 major killer in thalassaemia.

5 Moving on to the mid-1990s, a new novel tablet
6 form of chelator came in. Not without its complete
7 side effects but a very, very welcome extension to
8 Desferal, and this drug is given three times a day
9 every day.

10 Then, moving into the mid-2000s, we have now had
11 a once-a-day formula, which is obviously far more
12 tolerable to these patients. But again, as with most
13 things, it is not 100 per cent without its side
14 effects, and even those who do tolerate it, for one
15 reason or another, compliance or concordance to taking
16 the medication is not always 100 per cent. So we
17 still are having battles with treating iron overload
18 and other patients have allergies or severe side
19 effects. So again that is an issue.

20 So, going back to your question, a major part of
21 my role would be to monitor the compliance, the
22 issues, the side effects, their toxicities, the
23 dosage, you know, the reduction or increase of these
24 chelators.

25 And then obviously the psychological support

95

1 Unfortunately there is no natural way of giving
2 this iron so we have to mechanically get rid of it by
3 what we call iron chelating agents. Up until the sort
4 of 1990s, the only treatment available was a drug
5 called -- or is a drug called desferrioxamine, which
6 cannot be taken orally, it has to be given either
7 intravenously or subcutaneously, and it cannot be
8 given in one quick injection, it doesn't work like
9 that, it has to be slowly infused, mopping up the iron
10 as it goes through the body. So usually the treatment
11 is given over around 10 to 12 hours over 5 to 6 nights
12 a week. But it is painful, it's -- you imagine
13 a small child having this thick sort of syrupy
14 infusion going into their tummy. It is not optimal.
15 If you are looking outside the UK it is also quite
16 expensive, with all the syringes and the medication.
17 So a lot of patients up until the 1990s were dying at
18 a very young age of iron overload, particularly iron
19 in the heart.

20 It also affects the liver, and if you don't
21 treat the iron appropriately you will get fibrosis,
22 cirrhosis and eventually cancer of the liver. It also
23 affects the endocrine gland, so your pituitary gland,
24 which is our gland that is responsible for our growth,
25 for our energy levels, for our hormones, for our

94

1 because, as you have heard, it is not particularly
2 pleasant treatment. So they do need support. They do
3 need sometimes to sort of discuss issues, that maybe
4 we can sort of work out ways to resolve it. So that
5 I see as a very major part of my role.

6 Also education. I do a lot of nursing and
7 medical education, not just here but also in other
8 parts of the world. We have been very fortunate to
9 travel to other clinics and develop services abroad.

10 What else? Clinical research. We have been
11 an active centre in clinical research for many, many
12 years, particularly revolving around the iron overload
13 issues and iron chelation issues.

14 **Q.** So, in terms of the transfusion -- the provision of
15 the transfusion to a patient, who would decide when
16 a transfusion would be given? Would that be your
17 decision or it would be a clinician's decision?

18 **A.** No, it would be a clinician. As I say, this is from
19 birth. Even in the non-transfusion -- you know, the
20 milder phenotypes, usually they are presenting in
21 childhood in some form or another. So at the
22 Whittington, which has been going on for many years,
23 we don't just have a paediatrician who is generically
24 looking after kids. It is a paediatrician with
25 a thalassaemia doctor, haematology consultants, so they

96

1 would be the ones who -- usually the patients are
 2 referred either by a GP or by a local hospital. And
 3 usually it is a watch and wait sort of thing to begin
 4 with: how is the child thriving? What's happening?
 5 What's he -- obviously, you know, get the genetic
 6 profile to see. But it would be ultimately the
 7 haematology consultants and the paediatric consultant.
 8 **Q.** When they make a decision that a transfusion needs to
 9 be given would they decide, "We need to give one
 10 today", or would they decide, "Right, we need
 11 transfusions this -- regularly with this patient?"
 12 **A.** Yes, I think by the stage you have decided -- when you
 13 know this child is now transfusion-dependent, then
 14 yes, you know this is ongoing. So that the family
 15 would be prepared that this is now -- you know, it is
 16 very rare that you can say, "Well, we will give one
 17 transfusion but your child is going to be okay",
 18 unless there was a specific reason why, a virus or
 19 something that suddenly plummeted that child's
 20 haemoglobin, but on the whole you are making really
 21 a lifelong plan for that child at this stage.
 22 **Q.** So each time a patient comes in to clinic to see you,
 23 comes to the day unit, would they also see the doctor
 24 to decide yes, there is going to be a transfusion
 25 today?

97

1 adjust our package to suit that individual patient.
 2 But on the whole, you know, once they're adult
 3 it doesn't tend to vary too much. If you come in for
 4 two units every three weeks, that is usually your
 5 pattern.
 6 **Q.** What is the usual pattern, obviously with some
 7 variation?
 8 **A.** Yes, it is variation. So I would say, if you would
 9 average it out, it is probably three packs of red
 10 blood cells every three weeks, some two units and
 11 occasionally some four units, but depending on various
 12 variables.
 13 **Q.** Would those units be given as a day patient or do
 14 people come in for longer periods?
 15 **A.** No. We try and make it -- because this is part of
 16 their life and these are busy working mums, dads, you
 17 know, nurses, doctors themselves. So we try to make
 18 it as streamlined as we possibly can. We try to fit
 19 in with their diaries. You know, haemoglobins
 20 allowing. They will come in in the morning or
 21 afternoon. And with those now, we audited this along
 22 with UCLH and we found that it is quite safe, the red
 23 blood cells, they are leukocyte depleted, the
 24 reaction -- transfusion reactions are, very, very
 25 minimal, if at all. The unit sizes are -- it's quite

99

1 **A.** No.
 2 **Q.** Or would it be part of a protocol for that patient?
 3 **A.** No, it is part of the protocol. I mean, obviously
 4 every patient is individual. Even if you had
 5 a patient who has inherited exactly the same mutation
 6 as their Greek Cypriot friend, they are going to be
 7 different, they are going to be different in their
 8 requirements, they are different in their lifestyles,
 9 they are different in their body weight, they're
 10 different in all sorts of ways. Some patients had
 11 their -- in the old days we used to routinely remove
 12 the spleen because, you know, giving blood wasn't
 13 appropriate or we didn't want to give so much blood,
 14 we had no way of getting rid of the iron, so by
 15 removing these enlarged spleens we were reducing the
 16 amount of red blood cells that they needed. So those
 17 patients tend to have slightly less blood transfusion
 18 requirements. And our youngsters that we really do
 19 want to keep the spleens in. So, again, it is
 20 an individual care package, if you like, for each
 21 patient.
 22 This can change also. So a patient may, as
 23 a child, go every four weeks, but as they are getting
 24 older and they're getting bigger, they may -- the
 25 haemoglobin may drop after 14, 15, 21 days. So we

98

1 packed, they're quite small. These patients we know
 2 if they have got healthy hearts, healthy kidneys, that
 3 they can tolerate three units of blood over a three to
 4 four-hour period. In the old days they may have been
 5 admitted for 24 hours, which is a heck of burden if
 6 you are trying to get on with a normal life. So it is
 7 very much an informal -- you come in, you have your
 8 blood.
 9 If a patient says, "I feel uncomfortable, I'd
 10 rather have it over six hours", that's completely
 11 fine. But the idea is we are trying to minimise any
 12 disruption to their lives.
 13 **Q.** And in terms of the groups of patients who are not
 14 transfusion-dependent, what's your understanding of
 15 the clinical indicators for needing a transfusion?
 16 Does it sometimes happen that they do need
 17 a transfusion?
 18 **A.** It can do. I don't want to say too much because
 19 I don't have so much experience with the
 20 non-transfusion-dependent, but sometimes for whatever
 21 reason they will reduce their -- they will drop their
 22 haemoglobin, and thereby, you know, if it drops to
 23 a level -- you wouldn't -- if they suddenly dropped
 24 from 90 to 80, I don't think any clinician would say
 25 we're going to rush in with a transfusion. It is

100

1 a watch and monitor. But if they severely drop, then
2 yes -- you know, substitution is certainly not what
3 they need. So yes, they may do. If something like
4 parvovirus or something this will make -- plummet it.

5 And occasionally as a -- you know, if someone
6 has been non-transfusion-dependent and for whatever
7 reason their clinician will notice that actually they
8 may be getting increased pressure in their lungs or
9 their heart may be running into issues or they may be
10 getting expansion of the bone marrow to a degree which
11 is deemed to be clinically not safe for that patient,
12 so they may then switch over to transfusions.

13 Q. So for those that need transfusion only irregularly,
14 how is that administered? Would they come into your
15 day unit or would they stay at a sort of standard
16 haematology centre?

17 A. If it was at the Whittington, we have a handful of the
18 non-transfusion-dependent, they would be very closely
19 monitored by the haematology consultants and it would
20 be the haematology consultant who made the decision of
21 whether or not to transfuse.

22 Q. Could we turn to WITN6979003. It will appear on your
23 screen.

24 We can see here a document from the Whittington
25 which is the blood policy. And it is dated from

101

1 adult haematology consultant, obviously everything
2 would be explained to that patient. So you are
3 looking at the benefits of the blood transfusion. So
4 in the case of the non-transfusion-dependent, to maybe
5 reduce his pressure in the lungs or maybe to reduce
6 this excessive bone marrow expansion, maybe to improve
7 quality of life, but also the cons of blood
8 transfusion, which -- iron overload being the main one
9 nowadays, and obviously explanations on how we would
10 treat the iron overload.

11 Alloimmunisation is a huge issue with these
12 patients. As I mentioned, the countries where these
13 patients originate from, we know that the majority of
14 donors in the UK are from white Caucasian northern
15 European, so there is a risk of -- when I say
16 "alloimmunisation", I mean developing antibodies
17 against the blood that they are receiving. The more
18 antibodies they develop, the more difficult it is in
19 the long-term to find safe, very, very -- 100 per cent
20 cross-matched blood, which is what we aim to do every
21 time. And all our patients, their blood is -- we
22 genotype them, we phenotype them on -- at regular
23 intervals to make sure we are giving them the correct
24 blood for them.

25 Bacterial infection is a risk. It shouldn't

103

1 October 2019. We can see it is version 6. Do you
2 recall when the sort of first set of guidelines were
3 produced in the Whittington?

4 A. There would have been guidelines when I was there at
5 '95. I cannot recall unfortunately. You know,
6 I can't imagine it is greatly different from the one
7 we actually see now. But unfortunately I can't recall
8 exactly.

9 Q. But throughout your time in practice, as far as you
10 are aware, there has been a set of guidelines --

11 A. Absolutely.

12 Q. -- in relation to blood policy?

13 A. Yes.

14 Q. Thank you.

15 You can take it down, thank you.

16 Just in terms of real practicalities of when
17 a transfusion is given to a patient, what would be
18 written in the patient record in relation to the
19 giving of that transfusion?

20 A. When they first start or ongoing?

21 Q. Both. If we start with when they first start.

22 A. Okay.

23 So when they first start and they have been seen
24 by the haematology paediatrician or, if they are
25 a non-transfusion-dependent, have been seen by the

102

1 happen, but it is something that we will explain. And
2 even nowadays viral infections would still be -- there
3 is, albeit exceptionally slim, but it would still be
4 discussed with them.

5 Q. Just staying with that first interaction and the first
6 time transfusions would be needed. You were obviously
7 only involved in thalassemia care from 1995. But
8 what's your understanding of what your patients were
9 told previously about viral risks of transfusion?

10 A. I obviously wasn't there but they would have been
11 informed from -- that there is a risk of transmission
12 of hepatitis C, hepatitis B and HIV. Even in those
13 days -- I don't know exactly when the hepatitis B
14 vaccination came out, it certainly was out when
15 I started and patients were vaccinated against
16 hepatitis B, anybody prior to starting a transfusion
17 programme, and we still monitor their antibody levels
18 each year to make sure they are up to date with
19 booster vaccines.

20 As far as I'm aware, all patients would have
21 been informed that there was a risk of transmission in
22 those days.

23 Q. Have you had conversations with current patients about
24 what they were told historically about what they were
25 told about viral --

104

1 A. No, I haven't. No.
 2 Q. So it is just an assumption that that's what they
 3 would have been told?
 4 A. Yes.
 5 Q. Then once you come to the sort of frequent
 6 transfusions, what information is given to a patient
 7 on each occasion that they then receive a transfusion?
 8 A. Probably not a great deal because this is something
 9 that is literally happening every three weeks for
 10 them. Iron, as I say, is the major issue, so we
 11 constantly are updating them on what their iron levels
 12 are doing.
 13 I don't think, from my point of view, things
 14 have changed dramatically from the transfusion
 15 perspective. The only thing that's changed more
 16 recently is the audit we did regarding the actual --
 17 how quickly, if you like, they can have the blood
 18 which is a benefit to most of the patients.
 19 But I think -- and they're expert patients as
 20 well. I think it's very important to remember that.
 21 You know, these patients have lived with this all
 22 their lives. They are a very, very educated group,
 23 so, you know -- and we are very open to discussion if
 24 anybody has any particular concerns, whatever it may
 25 be.

105

1 along with the UK Thalassaemia Society. Really we want
 2 these children and these adolescents to become the
 3 expert patients and, you know -- so they are very,
 4 very informed about their treatments, even from
 5 a young age. But I'm not sure whether the actual
 6 consent is ...
 7 Q. You spoke a moment ago about the psychological burden
 8 of the illness -- of the disease. Can you tell us --
 9 of the condition, I should say.
 10 Can you tell us more about what that is like for
 11 patients with thalassaemia?
 12 A. It is improving, thankfully, a great deal, but it --
 13 in some parts of the world, it actually was -- causes
 14 stigma. And you will see, you know, people, older
 15 generations will still refer to thalassaemia as "the
 16 child with the stigma". That sits with these guys
 17 even when they're in their 50s.
 18 Many of the patients were told -- so we're
 19 looking at patients now in their 50s, and they were
 20 told, their families were told when they were, you
 21 know, six or seven, "Don't bother sending them to
 22 school. They are not going to live long enough. Just
 23 spoil the child. Let the child ..." So some of them
 24 didn't get the education. Some of them were actually
 25 put in special schools that they used to for -- so if

107

1 Q. And in terms of providing information and obtaining
 2 consent for transfusions, again, I'm aware you only
 3 became a specialist in 1995, but from your
 4 discussions, if you've had any, with the patients, has
 5 there been any change in relation to the consent
 6 process for transfusion?
 7 A. Not as far as I'm aware that there has been any
 8 change. As far as I'm aware, they would have -- the
 9 consent would have been the same. Consent form would
 10 have been completed and signed by the parent or
 11 guardian of the child or by the patient themselves,
 12 and that's obviously documented in the notes. The
 13 discussion with the patient would have been documented
 14 in the notes, and that remains the same to this day.
 15 Q. And what happens when a patient becomes an adolescent?
 16 Perhaps their parents have given consent as a child.
 17 What happens in relation to information and consent
 18 for those patients as they reach adolescence?
 19 A. That's a very good point. I actually cannot answer
 20 that. I don't know whether the consent is re-sought.
 21 By the time they come to have transition, they
 22 are actually into the -- they are adults by the time
 23 they -- I think probably they -- you know, more
 24 information is constantly given to them, and we do
 25 a lot of educational seminars for these patients,

106

1 you had any disability, if you were deaf, or diabetes
 2 I think they classed, and thalassaemia. So some of the
 3 patients were -- so, again, they were sort of
 4 discriminated against in their eyes.
 5 In some families, you know, when you are looking
 6 at sort of introduced marriages, you will see that
 7 some people don't want to disclose that there is
 8 thalassaemia in the family. So, again, it is sort of
 9 evolving around this stigma, that there is a problem
 10 in that family, there's a genetic problem. So that
 11 still sits strongly in some of the patients.
 12 A lot of barriers have been bashed down, and
 13 I think there is a lot more awareness out there now,
 14 you know, particularly in the sort of -- in this part
 15 of the UK, there's a -- you know, people are not
 16 frightened so much to say that they have thalassaemia.
 17 But, you know, throughout the years, you know --
 18 I will give you an example. One of the patients
 19 always jokes that he has to pay insurance on
 20 absolutely everything, but he can't get life
 21 insurance, you know. Trying for them to get
 22 a mortgage, that sort of thing. So we were on the one
 23 hand telling them, "You go to school. You go to
 24 university. You do whatever you would have done
 25 normally. You live a normal life," but then they are

108

1 going out into the real world, and they're not being
 2 able to live a normal life. So there is
 3 discrimination and to a certain degree still and
 4 patients have definitely said that they feel
 5 stigmatised.

6 **Q.** In terms of hepatitis C, are you aware of whether
 7 routine testing for hepatitis C, of all thalassemia
 8 patients, was carried out at the Whittington before
 9 you arrived?

10 **A.** It definitely was before I arrived. I'm not sure when
 11 it was actually introduced. Knowing the lead
 12 consultant at the time, she was incredibly -- you
 13 know, so proactive. I can imagine as soon as any
 14 risks were alerted to, that the patients would have
 15 been screened.

16 **Q.** So you are assuming it was early, but you know that
 17 they were certainly tested before 1995?

18 **A.** Yes, certainly. Yes.

19 **Q.** Do you have any awareness from perhaps conversations
 20 with patients, what they were told, what information
 21 was provided to them before they were tested for
 22 hepatitis C?

23 **A.** Not then, no.

24 **Q.** And in your statement, you've said that there were
 25 nine Whittington thalassemia patients in total who

109

1 who have come in from abroad.

2 **A.** There were definitely 5 from abroad. I don't know
 3 about those 5 missing patients. But 5 out of the
 4 initial 20 were from abroad.

5 **Q.** You then became a part-time specialist hepatitis C
 6 clinical nurse specialist. How did that come about?

7 **A.** Well, I obviously was working very closely with the
 8 pegylated interferon, the yearly trial that we did on
 9 the 11 patients at the end that remained hepatitis C
 10 positive despite previous interferon treatments.

11 So I had been working with the haematology and
 12 hepatology consultant with this, and I was closely
 13 monitoring them on a weekly basis throughout this
 14 year. So working closely, obviously, with the drug
 15 company as well that was providing the interferon, and
 16 they were very supportive in things they could offer.

17 Then our gastroenterology department in the
 18 hospital were trying to sort of -- there were a lot of
 19 general hepatitis C patients out there that weren't
 20 really -- they didn't have the resources or the time
 21 to actually, you know, put in a proper programme. So
 22 they wanted somebody to sort of run alongside them,
 23 the clinic, to try and get as many of these patients
 24 treated as well. So Schering-Plough, the drug
 25 company, sponsored my post with the hospital for one

111

1 were hepatitis C RNA positive, and then six other
 2 patients were referred to the Whittington from other
 3 UK centres.

4 **A.** Yes.

5 **Q.** But since your statement, I think you found an old
 6 presentation that gave a different set of figures.

7 **A.** Yes.

8 **Q.** And you think that, in fact, 25 patients were
 9 identified as hepatitis C positive; is that right?

10 **A.** In 1995 when I started -- not necessarily then, but
 11 when I started to get involved in the hepatitis
 12 management, I set up my own database. We had nine, as
 13 you say, Whittington, six from other UK centres, and
 14 I think it was five from -- who had come in from
 15 abroad.

16 When I presented in the BSH in 2005, after we
 17 did the pegylated interferon on these patients -- and
 18 I clearly said on the slide there we had 25 --
 19 previously we'd had 25 patients; there weren't 25
 20 involved in that pilot study. Now, that figure
 21 I would have got from the existing probably
 22 haematologist database or the hepatology database, but
 23 I don't know who those missing 5 patients were, I'm
 24 afraid.

25 **Q.** And within that 25, some of those would be patients

110

1 day a week for three years to try and get as many of
 2 these general hepatitis C patients. So it was four
 3 days thalassemia, and one day as hepatitis.

4 **Q.** Just tracking back to when you just had the β
 5 thalassemia role. During that role, were you also
 6 providing support to patients undergoing hepatitis C
 7 treatment?

8 **A.** The general patients?

9 **Q.** The β thalassemia patients?

10 **A.** Sorry. Clarify that again.

11 **Q.** Before you took on the hepatitis C specialist role,
 12 and you just had your thalassemia role, were you also
 13 then supporting thalassemia patients receiving
 14 hepatitis C treatments?

15 **A.** Yes.

16 **Q.** So were all patients with β thalassemia at the
 17 Whittington who had hepatitis C seen by you in dealing
 18 with their hepatitis C?

19 **A.** Along with the haematology and the consultant. But we
 20 found with this group because -- we know with the
 21 interferon in the general population without
 22 thalassemia that it does drop their neutrophil, the
 23 bacteria-fighting cells, and so they needed to be
 24 monitored. And I think the general protocols were
 25 they were monitored after two weeks, and then

112

1 monitored monthly.

2 We found because our patients -- either because
3 they had slightly enlarged spleens which were chewing
4 up their neutrophils more quickly than our spleens
5 would, or they were taking one of the oral chelators
6 which also coincidentally had the side effect of
7 dropping the neutrophils.

8 Now, obviously, if you drop the neutrophils too
9 low, you are putting that patient at extreme risk of
10 severe infection and potential death. So we decided
11 initially we would monitor them weekly to make sure
12 that they were safe on the interferon drug. We found
13 that actually they were dropping their neutrophils
14 very, very rapidly. I think 7 out of 11 were
15 frequently dropping their neutrophil counts. So
16 throughout that year, I continued to monitor them on
17 a weekly basis to make sure -- check their bloods to
18 make sure that they weren't -- they were in the safe
19 zone.

20 And there were also other issues; you know, the
21 psychological impact of this treatment. One of the
22 other things which was problematic is that the tablet
23 form of antiviral, the ribavirin, even in the
24 non-transfused population caused what's known as
25 haemolysis, an early destruction of the red blood

113

1 they were going through, the side effects or their
2 blood results, we were doing a sort of one-stop shop,
3 if you like. So that is how we reviewed them.

4 So they would come in Thursday clinic, primarily
5 to see me, because some of them didn't need to see the
6 consultant every week, but there was a consultant
7 haematologist, the lead consultant, you know, there if
8 there were any worries.

9 **Q.** Was a hepatologist available as well?

10 **A.** Not in that clinic. At that time we didn't have a --
11 we had a gastroenterology service but not a specific
12 hepatology service at the Whittington. The Royal Free
13 Hospital is a renowned hepatology service, so we had
14 very close links. All our patients were reviewed
15 prior to starting treatment by the hepatologist. All
16 the sort of preliminary investigations that they
17 needed. Then they were reviewed, depending on need,
18 but I think it was on a three-monthly basis. And that
19 goes on to this day. Any patient who did sustain
20 liver damage, which was unfortunately the majority,
21 would still be seen by the hepatologist at the Royal
22 Free if need be.

23 **Q.** You have spoken a little bit about the particular
24 difficulties in providing treatment for hepatitis C
25 for these with beta thalassemia. You have mentioned

115

1 cells, which was a bit disastrous in our patient group
2 that also had this haemolytic anaemia. So, again,
3 that was very important to monitor weekly to make sure
4 their haemoglobins weren't plummeting, obviously
5 having to transfuse them instead of every three weeks,
6 it might have been every eight to ten days.

7 So, again, a lot of, you know, active monitoring
8 to make sure that they were safe going through the
9 treatment.

10 **Q.** So in terms of the thalassemia patients you were
11 seeing who were having their hepatitis C treatment,
12 you saw them weekly?

13 **A.** Yes.

14 **Q.** And the haematology consultant saw them regularly?

15 **A.** Now what -- how we did this, we used to run an evening
16 clinic on a Thursday. This was because the patients
17 are working, they are in school, we didn't want them
18 to come in on a Tuesday afternoon. So for the general
19 thalasseemics, for their usual screening, clinical
20 appointments, they would come in on a Thursday
21 evening. So I would set myself up in a clinic room
22 next to the haematology who was running the general
23 thalassemia clinic so if there were any concerns or if
24 the patient just wanted to have a talk to the
25 haematologist, or I was concerned about anything that

114

1 the neutropenia --

2 **A.** Yes.

3 **Q.** -- and the difficulties with enlarged spleens. What
4 else did the interferon cause difficulties with in
5 relation to patients with thalassemia?

6 **A.** Interferon is an absolutely horrible drug in my
7 opinion. I think it is probably the worst drug I have
8 ever had to use on patients. It has terrible side
9 effects. It can turn a very mild mannered person into
10 the most -- into -- spontaneous bouts of aggression,
11 through no control of their own. It causes severe
12 depression. It makes you extremely tired, very, very
13 fatigued. And you think about the haemoglobins also,
14 they have anaemia, they feel tired, you know, for
15 probably a third of their life as it is. It causes
16 weight loss. And our thalassemia group on the whole
17 tend to be on the slimmer side. So one guy I think
18 dropped down to about 40/41kg from about 58kg, and
19 he -- you know, he was literally wasting away. He has
20 no energy. He is feeling absolutely lousy. So it was
21 a horrible, horrible treatment for them to go through.
22 And it was a year long. And then the side effects
23 tend to last for a period after the treatment as well.

24 **Q.** In relation to the impact of liver iron on the success
25 or not of the treatment, what can you tell us about

116

1 that?

2 **A.** Well, obviously liver iron on its own, taking away any

3 virus or any other aggravator, if you don't treat it

4 appropriately and you allow it to mount up, will cause

5 scarring of the liver, which will eventually turn into

6 cirrhosis, which will eventually turn into a cancer.

7 You put something like a virus on top to

8 aggravate that liver, then you are speeding up that

9 process two, three, four, fivefold.

10 We also know from previous studies that the

11 response to interferon treatment, for getting in at

12 the liver and attacking the virus, if you have

13 a build-up of iron in the liver then your response to

14 the antibiotic treatment is not going to be as good as

15 well. So they are really -- having a double whammy,

16 really.

17 So, again, before we started the treatment we

18 had to sort of intensively, intensively chelate them

19 to try to and get the livers out, to give them the

20 best possible chance of clearing the virus. But many

21 of these patients were in their 30s at this stage.

22 They had contracted the virus possibly 20 years before

23 we -- maybe even longer, before we started it. So

24 their livers were damaged at that stage. So it was

25 imperative that we try to, you know, get that virus

117

1 probably only getting about 50-60% of the optimal

2 dose. So they weren't really standing in a very good

3 stead.

4 **Q.** Prior to treatment being started what were patients

5 being told about the likely side effects of the

6 interferon?

7 **A.** All of these patients who started the treatment that

8 I was working with had already previously been on the

9 intermittent interferon. So the standard treatment

10 before would be the non-pegylated form. So this was

11 given an injection three times a week and it was given

12 combined with ribavirin and it was given for six

13 months. The pegylated was a once-a-week sort of

14 longer acting injection, and it was given for a year.

15 So the patients were -- when I was treating them, were

16 well rehearsed. They knew exactly what was ahead.

17 And not all of them, I would say, would -- took it on

18 lightly, because it was such an awful treatment. But

19 they were obviously informed, reiterated again about

20 the side effects, about the risks involved, about the

21 importance of proper monitoring and, you know,

22 reporting of side effects.

23 **Q.** From your conversations with those patients, did you

24 have any sense of the information that had been

25 provided when they first had interferon? Whether they

119

1 under control.

2 **Q.** And what was your experience of the success of the

3 treatments in the beta thalassemia group?

4 **A.** It wasn't as good as the non-general population.

5 I think 4 out of 11 initially responded. This is the

6 genotype 1, so the core group. Two of them later

7 relapsed, after three months of stopping treatment, so

8 we had two. I think when you look at the large

9 studies, the -- in those days, with the interferon and

10 pegylated interferon and ribavirin they had

11 a sustained rate of 48%, so ours was actually

12 significantly lower.

13 And I think that's probably a few reasons. One

14 that we probably had issues with the liver, so were we

15 optimally getting that virus? But probably most

16 importantly it's because we couldn't optimally treat

17 them because we were having to dose reduce the

18 majority of the time. I think, looking at the slide,

19 7 out of the 11 patients we frequently had to halve

20 the dose of the interferon because of the neutrophils,

21 and there were two patients who dropped their

22 platelets significantly, so they were -- I think there

23 were only -- there was only one patient who sustained

24 the optimal dosing throughout the whole year. All the

25 others, and I think the majority of them, were

118

1 had been prepared sufficiently for the side effects

2 the first time round?

3 **A.** I think, knowing the team that I worked for, they

4 definitely were. You know, we knew what had happened

5 in the general population. We knew that the side

6 effects were very well documented. Also, again, they

7 were monitored so regularly, there was a lot of, you

8 know -- they had a lot of interaction to sort of

9 report back how they were feeling, how they were

10 coping. So I think they were given, you know, more

11 than adequate information.

12 **Q.** And in terms of your role with patients and the -- you

13 have talked about the side effects including

14 significant depression and other mental health

15 impacts, how much of your role involved psychological

16 support of patients going through the treatments?

17 **A.** It was a lot. A lot of my role. And I remember those

18 Thursday clinics -- even though they are 16/17 years

19 ago -- very, very clearly, because, you know, you

20 would see patients who were so sort of upbeat normally

21 and they were coming in and absolutely drained. You

22 know? Two -- at least two patients lost relationships

23 with partners during that time because of the --

24 either the way they were feeling or maybe because of

25 sort of aggressive outbursts. So -- you know, a lot

120

1 of time was spent with them and I really gained a lot
 2 of insight into it.

3 **Q.** And did you have any specific training in
 4 psychological support or counselling before you
 5 started dealing with the patients?

6 **A.** Yes, in the Royal Marsden I did a psychosocial
 7 counselling sort of module there. Not particularly in
 8 relation to anything like that but generally about
 9 sort of counselling skills.

10 **Q.** Was there any specialist psychological support and
 11 counselling available to those patients?

12 **A.** Yes. We had and still do have a psychologist who is
 13 dedicated to the Thalassaemia and Sickle Group and
 14 I think they have about four sessions a week at the
 15 Whittington. So any patient -- and she would sit in
 16 on the MDT meetings so was very knowledgeable about
 17 the thalassaemia generally and what they are going
 18 through. And we would have, you know, genned her up,
 19 if you like, on what was happening with the hepatitis
 20 patients. So any patient who was really struggling or
 21 wanted to had easy access to our psychologist.

22 **Q.** Would that require a referral from you --

23 **A.** Yes.

24 **Q.** -- or could they access that themselves?

25 **A.** No, it would be a referral from us but it would be

121

1 just -- to actually now, "I'm out there, I have
 2 hepatitis C on top". And I have even had patients
 3 feel -- say that they felt dirty with hepatitis C.

4 So a tremendous impact psychologically. And
 5 I think still to this day very few of them would
 6 openly discuss that they had hepatitis C.

7 I have also had patients say to me, "That's
 8 a part of my life I don't ever want to re-visit". And
 9 you know, considering what they have been through
 10 through their life, that is the bit that really does
 11 stand out as the tough bit.

12 **Q.** From your perspective as a specialist nurse, how
 13 important do you think your role was to helping
 14 patients get through the hepatitis C treatments?

15 **A.** Well, I think that obviously it was a completely team
 16 approach, and I think all of us had parts to play.
 17 And fortunately with the Whittington team it always
 18 has been and will be a very close knit group, and
 19 everybody had their own part.

20 I do think the nurse role was significantly
 21 important, but simply because of point of access. I'm
 22 always there, if you like. Obviously consultants have
 23 their busy clinics, they have other things. They are
 24 contactable and they are always eager to be available,
 25 but I'm a point where basically everybody knows where

123

1 a relatively quick turnover. You know, as I say, the
 2 psychologist sat in the MDT meetings, so these were --
 3 you know, where we discussed patients, any issues. So
 4 it would have been picked up then and the next
 5 available slot they would have been seen.

6 And they would also come to the transfusion unit
 7 to see them so they didn't have to drag themselves out
 8 on a Thursday with a transfusion on Tuesday, so we
 9 would arrange for them to come into the quiet room and
 10 then the two could have their session together then.

11 **Q.** You spoke a moment ago about the stigma involved in
 12 having thalassaemia, and the Inquiry has heard evidence
 13 about the significant stigma involved in having
 14 hepatitis C. What was your experience of that in the
 15 patients that you saw?

16 **A.** I think it is tremendous and I think it still is the
 17 impact. Only the other day I was asking a patient
 18 why, you know, they hadn't sort of come forward to the
 19 Inquiry and the first thing they said was, "I don't
 20 want people to know I had hepatitis C". And
 21 I understand that.

22 They have lived through their life, as
 23 I mentioned, with this stigma of thalassaemia, and in
 24 some cases actually hiding it from their partner's
 25 families or from their work colleagues. And then

122

1 I am. I would see them once a week. So I think it
 2 was an essential part of the role. And now you will
 3 see there are more and more of these nurse supportive
 4 roles in various disciplines for patients having
 5 issues.

6 **Q.** If a patient didn't clear the virus in that first
 7 treatment, can you recall what practices or policies
 8 were in place in terms of additional courses of
 9 treatment?

10 **A.** Well, after that final course, until the recent
 11 antivirals, there has been nothing in between. So --
 12 and 9 out of that 11, so 9 out of the original 25 --
 13 we're now an aging population, if you like, with
 14 liver/iron preceding many, many years. So damage --
 15 we knew they had fibrosis and some of them had
 16 cirrhosis. We've had a patient who has gone on to
 17 have a liver transplant directly because of the
 18 hepatitis C combined with the iron. We have lost four
 19 patients out of that cohort from liver-related
 20 problems. And we also have one or two who we know
 21 have oesophageal viruses as a secondary -- from the
 22 virus and from the iron overload. So they are still
 23 not without their problems. So hepatology follow-up
 24 is essential. Obviously the haematology follow-up
 25 they get all the time. So it has remained at the

124

1 Royal Free Hospital and the liver unit there and they
 2 will -- they are under surveillance since --
 3 throughout they have been, and up to this day.
 4 **Q.** So whether a patient cleared the virus in the first
 5 tranche or whether it required the direct antivirals?
 6 **A.** Yes. So we have -- there is one girl who -- her liver
 7 isn't too bad but she does -- did have some evidence
 8 of liver disease. Now, she was -- in the very first
 9 cohort she cleared, she was a genotype 2, it was nice
 10 and smooth. But she had already sustained -- and she
 11 would only have been in her 20s then. She is now
 12 coming up to 50. She will still be -- we still
 13 will -- we ultrasound our patients for other reasons
 14 anyway, but we do the hepatology screening, and she
 15 still sees the Royal Free team I think probably on
 16 a yearly basis.

17 We also have the FibroScan which has replaced
 18 the liver biopsies, so again all these patients will
 19 be routinely screened with the FibroScan to see --
 20 fortunately those who did sustain damage, as long as
 21 we've kept their iron liver -- they don't seem to have
 22 progressed, provided they have cleared the virus,
 23 thankfully.

24 **Q.** So that liver screening is for both the hepatitis C
 25 damage and also the iron overload issues?

125

1 sickle population as they are now.
 2 **Q.** But as a hepatitis C clinical nurse specialist, you
 3 didn't see any sickle cell patients --
 4 **A.** No, they weren't referred -- no, there wasn't any
 5 referred.
 6 **Q.** Finally, when a patient with thalassemia and
 7 hepatitis C was seen by you, were you involved at all
 8 in telling them about the ex gratia financial
 9 assistance schemes?
 10 **A.** I was not really involved. I was aware of it. The UK
 11 Thalassemia Society, which is the UK charity for --
 12 more than a charity, they're -- they're in -- you
 13 know, a tremendous amount of knowledge that they pass
 14 out there, and awareness. They were heavily involved
 15 and they were literally information givers to all the
 16 UK members. So I think that's primarily -- I think
 17 the consultants were also -- were giving -- in the
 18 clinics were giving out the information about the
 19 funds as well.

20 **MS FRASER BUTLIN:** Sir, those are the questions I have for
 21 Ms Prescott. I should just ask for a break to see if
 22 there's anyone behind me who has questions that they
 23 would like me to put to her.

24 **SIR BRIAN LANGSTAFF:** Yes, of course. This is to give
 25 people who are represented and are Core

127

1 **A.** Yes.
 2 **Q.** Thinking then about your broader hepatitis C nurse
 3 specialist role. The patients you were seeing in that
 4 clinic, were there others who had contracted
 5 hepatitis C through transfusions?
 6 **A.** There was only one I remember. I think the majority
 7 were through drug use at some point. There was one
 8 patient that the only risk factor we could find
 9 I think was a transfusion in Egypt several years
 10 before that.
 11 **Q.** You mentioned sickle cell patients. We heard evidence
 12 this morning about sickle cell patients.
 13 **A.** Yes.
 14 **Q.** Did you see any sickle cell patients who had
 15 contracted hepatitis C and required treatment?
 16 **A.** No. I don't primarily look after sickle. I do look
 17 after sickle patients that are being transfused. In
 18 the old days we would do what we'd call manual
 19 exchanges and they would come to our transfusion unit.
 20 We now have the automated exchanges and they came --
 21 I don't know of any, and I asked our senior consultant
 22 who also worked at UCLH, she had not seen the sickle
 23 patients. And when I asked her why we thought this
 24 was -- I think transfusions back in the day, pre-1990,
 25 weren't so widely used in -- in our experience, in the

126

1 Participants -- their representatives are entitled to
 2 ask through counsel questions of you, if any arise
 3 from your evidence so far.
 4 So we take a break to allow them to forward
 5 their questions to counsel. Now, this is a break.
 6 You are giving evidence. The rule is that you must
 7 not discuss anything you have said already in
 8 evidence, or, for that matter, discuss anything you
 9 think you might yet be asked about what you have been
 10 talking about, but you can talk about anything else
 11 you like.
 12 **A.** Thank you.
 13 **SIR BRIAN LANGSTAFF:** We will take a break. How long do
 14 you think you might need?
 15 **MS FRASER BUTLIN:** Probably just ten minutes, sir.
 16 **SIR BRIAN LANGSTAFF:** We will take a break. Let's say not
 17 before 3.05 pm. I say not before 3.05 because if
 18 there are more questions than counsel anticipates, we
 19 will start just a little bit later, but we won't start
 20 before 3.05 pm.

21 **(2.55 pm)**
 22 **(A short break)**
 23 **(3.10 pm)**
 24 **SIR BRIAN LANGSTAFF:** Yes.
 25 **MS FRASER BUTLIN:** I just have a handful of further

128

1 questions to ask you.

2 You spoke about the stigma that you were aware
3 of, of having -- of patients having thalassemia. Are
4 you aware of any work that the hospital has done,
5 perhaps with the Thalassemia Society, in terms of
6 outreach to a particular community to seek to lessen
7 that stigma?

8 **A.** Many years ago, the UKTS ran an Asian awareness group.
9 This was mainly about getting young people to be aware
10 of thalassemia so you could get screening and, you
11 know, testing before perhaps you met your life
12 partner. But, obviously, on the back of that, that
13 actually brought a lot of awareness to the population,
14 what thalassemia was. Many thalassemia patients would
15 go and talk to these communities, along with the UK
16 Thalassemia Society, about what thalassemia was.
17 Thalassemia is improving all the time. Patients are
18 living hopefully normal lives now, so that was a huge
19 sort of boost.

20 As I say, it still hasn't cracked all
21 communities, but it did have a -- quite a major
22 breakthrough in this population.

23 **Q.** You discuss in your statement your own presentations
24 that you've given at Thalassemia Society conferences.
25 Can you recall ever discussing the risks of

129

1 information leaflet about side effects and management
2 of side effects. The drug companies also had provided
3 information about the treatment, but I don't think
4 there was specifically one about hepatitis C itself.
5 It would be more about the treatment.

6 **Q.** And you spoke about one patient who -- one thalassemia
7 patient who had required a liver transplant. Is that
8 proportion reflective of the proportion of thalassemia
9 patients who require liver transplants in any event,
10 or was it something --

11 **A.** No. We've never had a patient require a liver
12 transplant for iron overload alone.

13 Even -- I mean, the one good thing about liver
14 iron, if you like, if you intensively chelate, you can
15 remove liver iron quite quickly. You can, to
16 a certain extent, slightly improve the scarring,
17 provided they haven't got so far down the road. So
18 this is what we're constantly telling our younger
19 patients, "Please don't get into that area."

20 With our experience with the liver iron, if you
21 have had previous liver iron and you have got
22 a scarred liver, you get rid of the liver iron, you
23 will not miraculously remove the scarring; it will be
24 slightly ameliorated, but you will stop it
25 progressing.

131

1 transfusion transmitted infection, or perhaps the
2 signs and symptoms to look out for to consider if
3 someone has been infected. Was that something that
4 was done with the society?

5 **A.** Not specifically, because by that stage -- by the time
6 I was in the post, the blood was -- is safe, and
7 patients are screened or should be screened annually
8 anyway and vaccinated appropriately.

9 I think a lot of the talks I gave -- so if you
10 went to maybe a small centre somewhere in the north of
11 England, where you are talking to the nurses or the
12 doctors there, we go through the whole sort of remit
13 of thalassemia. So, again, viral screening, liver
14 screening, all of that would come into it.

15 I have obviously presented quite a few -- about
16 hepatitis C patients, but it wouldn't have been
17 specifically about what to look out for but really the
18 screening that those medical professionals should be
19 doing anyway for their patients.

20 **Q.** When you started work as a specialist nurse in
21 thalassemia, were there any leaflets available about
22 hepatitis C, or any information, written information,
23 available?

24 **A.** No. When it came to the treatments, there were --
25 I think we did our own hospital sort of basic patient

130

1 Unfortunately, when you put the virus in with
2 that -- when you -- I looked at the data actually on
3 the slides of this one particular patient who had the
4 liver transplant, his liver iron actually was very
5 low, so it didn't take much for -- with the virus to
6 attack his liver.

7 **Q.** You've mentioned a multidisciplinary team approach to
8 care and treatment at various points in your evidence.
9 From your perspective as a clinical nurse specialist,
10 what are the benefits of that sort of team working?

11 **A.** Tremendous benefits. I mean, we are trying to grab
12 any team that will come on board. So, obviously,
13 psychological support is vital for these patients.

14 We have cardiology. We are joint clinics with
15 the cardiologists, which is extremely important for
16 their heart problems.

17 We now have a guy, a liver expert at the
18 Whittington, who's taken a great interest, and he is
19 doing joint clinics at UCLH, and soon to do them at
20 the Whittington, so we can monitor not just the hep C
21 but also the general liver patients.

22 We have an endocrine joint clinic, so looking at
23 growth development, pituitary issues, fertility
24 issues.

25 We have a diabetes joint clinic for those who

132

1 have developed diabetes.
 2 We have two excellent obstetricians who have
 3 actually come on board with us, so it's a massive
 4 thing. It really is looking after the patient from
 5 head to toe in the best possible care.
 6 **Q.** And finally, in your role as a hepatitis C clinical
 7 nurse specialist, what's your view of the need for
 8 hepatitis C screening more generally?
 9 **A.** Well, I think nowadays even more so than ever because
 10 we have these treatments now. I know from our
 11 patients that went through it, compared to the
 12 previous treatments, they said it was a walk in the
 13 park. It's three months. They are all -- you know,
 14 were cured.
 15 Personally, I would say anybody who could get
 16 tested, get tested. The treatment is now available.
 17 It is very tolerable, and, you know, looking at the
 18 prevention of long-term problems, it's vital.
 19 **Q.** I'm just going to check behind me, sir.
 20 They are all the questions that I have been
 21 asked to raise, sir. Do you have any further
 22 questions?
 23 **SIR BRIAN LANGSTAFF:** No, I don't. Thank you very much.
 24 **MS FRASER BUTLIN:** Ms Prescott, is there anything else you
 25 would like to add to your evidence?

133

1 What I didn't say, of course, in the short
 2 mention which I made this morning was that if they are
 3 worried about giving evidence -- because one of the
 4 matters you raised was people are worried about
 5 putting their head above the parapet. They have
 6 suffered so much stigma, they cannot bring themselves
 7 to identify as someone. That statements are in
 8 writing -- that's evidence to the Inquiry -- and they
 9 can be anonymous.
 10 If someone doesn't want to go even that far,
 11 there are people I have mentioned, intermediaries this
 12 morning -- somebody suggested that I might want to say
 13 what intermediaries are. They are people, trained
 14 social workers, who work for the Inquiry, who will
 15 come on an entirely confidential basis and pick up
 16 what someone has to say and relay it in a report in
 17 due course to the Inquiry, without mentioning any
 18 names, and so there will be nothing to identify anyone
 19 who does that. But the essence of what people have to
 20 say, if they want to contribute, will be there.
 21 Now, they don't have to contribute. I want to
 22 thank you for encouraging people to do so, but as you
 23 have said, some have very good reasons -- they don't
 24 want to be reminded of what happened, or they may have
 25 other very good reasons for not wishing to. They

135

1 **A.** No. The only thing I would really like to get out on
 2 behalf of the patients is really, you know, how it did
 3 impact on their lives. They have had such a terrible
 4 tough time in their youth before treatments changed,
 5 and I think then this on top of it really has
 6 significantly impacted on their lives. And just
 7 talking to one of the patients only yesterday, you
 8 know, he really -- that's the bit of his thalassemia
 9 that sticks out the most. So I think, you know, I'm
 10 very glad that people are sort of taking so much sort
 11 of heed to this.
 12 **SIR BRIAN LANGSTAFF:** Well, it certainly has been very
 13 important to us, as the evidence today will have
 14 shown, that we looked at both sickle cell in
 15 particular in the morning, and thalassemia in
 16 particular in the afternoon. And you have been
 17 thoroughly illuminating in that, and I wanted to thank
 18 you for that and for your support of the patients in
 19 the ways that you have.
 20 If I can just comment, since I'm talking and for
 21 those who are listening, earlier on today I repeated
 22 the plea that I made earlier for those who have
 23 hepatitis C, or, for that matter, HIV infections, who
 24 also suffer from thalassemia or from sickle cell, to,
 25 if they can, come forward.

134

1 don't have to have a reason not to. They have to want
 2 to give a statement. But I want to make it absolutely
 3 clear, as far as we are concerned, we will treat any
 4 offering which they have with the respect which it
 5 deserves.

6 But thank you for your part in that and for
 7 coming today to talk to us. Thank you very much.
 8 Tomorrow.

9 **MS FRASER BUTLIN:** Tomorrow, sir, in the morning, we will
 10 be hearing from the Palliative Care in Advanced Liver
 11 Disease expert group. That's Dr Hazel Woodland,
 12 Dr Ben Hudson and Dr Fiona Finlay. Then in the
 13 afternoon, we will be hearing from Ms Samantha May
 14 from the Hepatitis C Trust.

15 **SIR BRIAN LANGSTAFF:** So tomorrow 10.00.
 16 (3.20 pm)

17 (The Inquiry adjourned until 10.00 am on Friday,
 18 4 March 2022)
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 20
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 23
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 25

136

INDEX

PROFESSOR DAME SALLY CLAIRE DAVIES	2
(sworn)	
Questioned by MS FRASER BUTLIN	2
Questions from SIR BRIAN LANGSTAFF	77
MS ELIZABETH EMMA PRESCOTT (sworn)	88
Questioned by MS FRASER BUTLIN	88

MS FRASER BUTLIN: [21] 1/17 9/20 21/7 22/10 47/23 51/14 53/10 62/10 65/20 71/18 72/19 76/14 84/12 84/16 86/15 87/12 127/20 128/15 128/25 133/24 136/9 SIR BRIAN LANGSTAFF: [42] 1/3 9/9 9/14 20/6 20/10 20/17 20/21 21/3 48/2 49/12 50/1 51/1 51/9 51/13 52/13 52/23 61/21 65/9 65/19 71/24 72/18 76/21 79/7 80/3 80/12 80/16 80/25 81/6 83/20 84/8 86/4 86/16 86/20 86/22 87/11 127/24 128/13 128/16 128/24 133/23 134/12 136/15 THE WITNESS: [1] 86/21 * '09 [1] 67/20 '09/'10 [1] 67/20 '10 [1] 67/20 '80s [7] 13/22 15/1 17/1 24/19 24/20 28/13 59/5 '90s [6] 13/23 16/22 17/1 28/14 40/18 54/20 '95 [1] 102/5 1 1.04 pm [1] 86/17 1.27 million [1] 81/14 1.3 [1] 81/16 1.3 billion [1] 84/1 10 [5] 23/15 56/8 59/3 59/11 94/11 10 hours [1] 19/17 10-20mls [1] 22/20 10.00 [2] 136/15 136/17 10.03 [1] 1/2 100 [4] 1/8 1/9 87/1 92/10 100 per cent [3] 95/13 95/16 103/19 100,000 [1] 1/8 100g/l [1] 58/24 11 [5] 111/9 113/14 118/5 118/19 124/12 11.15 [1] 47/25 11.20 [1] 51/10 11.50 [2] 51/2 51/9	11.52 [1] 51/12 110 [1] 21/16 12 hours [1] 94/11 12.25 pm [1] 72/15 12.40 [1] 71/25 12.40 pm [2] 72/13 72/17 13 [1] 82/13 14 [1] 98/25 140 [1] 92/7 140 patients [1] 93/3 15 [3] 13/6 21/16 98/25 15 minutes [1] 71/23 15,000 patients [1] 15/5 152 [1] 43/8 16 [1] 57/3 16/17 years [1] 120/18 18 [1] 6/1 18 months [1] 46/5 1967 [1] 85/1 1972 [1] 1/20 1973 [1] 4/14 1974 [2] 1/21 3/16 1978 [2] 1/23 7/14 1979 [1] 1/25 1980s [2] 27/21 29/16 1982 [1] 1/25 1985 [5] 2/3 2/5 10/6 14/11 24/6 1988 [1] 87/15 1989 [2] 87/18 89/1 1990 [2] 57/2 126/24 1990s [6] 27/21 29/17 47/22 94/4 94/17 95/5 1993 [1] 43/11 1995 [7] 87/18 89/1 89/8 104/7 106/3 109/17 110/10 1996 [1] 2/10 1999 [1] 2/20 1mg [2] 93/17 93/17 2 2-16 years [1] 25/22 2.00 [2] 86/14 86/16 2.03 pm [1] 86/19 2.55 pm [1] 128/21 20 [3] 23/6 29/22 111/4 20 years [1] 117/22 200 [2] 91/3 93/16 2000s [1] 95/10 2002 [1] 2/20 2004 [1] 3/1 2005 [1] 110/16 2006 [2] 3/7 87/25 2009 [1] 87/25 2010 [2] 3/8 60/6 2011 [3] 3/9 60/7	61/12 2016 [2] 25/1 25/3 2019 [2] 3/11 102/1 2020 [1] 75/23 2022 [2] 1/1 136/18 20mls [3] 22/20 22/23 22/23 20s [1] 125/11 21 days [1] 98/25 23DPG [1] 56/16 24 hours [2] 82/23 100/5 25 [8] 82/11 82/12 110/8 110/18 110/19 110/19 110/25 124/12 250mg [2] 18/23 93/16 2g [1] 12/25 3 3 March 2022 [1] 1/1 3.05 [1] 128/17 3.05 pm [2] 128/17 128/20 3.10 pm [1] 128/23 3.20 pm [1] 136/16 30 [3] 23/3 25/21 26/14 30s [1] 117/21 30th [1] 3/14 4 4 March 2022 [1] 136/18 40/41kg [1] 116/18 41kg [1] 116/18 44 [1] 15/1 48 [1] 118/11 5 5 million [1] 81/15 50 [2] 92/10 125/12 50-60 [1] 119/1 50s [2] 107/17 107/19 58kg [1] 116/18 6 6 nights [1] 94/11 60 [1] 119/1 600 [1] 93/19 600 patients [1] 15/10 7 7/8g [1] 18/13 750 milligrams [1] 93/20 8 8 hours [1] 23/1 80 [3] 58/24 59/2 100/24 80g/l [2] 58/9 58/22	8g [1] 18/13 9 90 [2] 28/7 100/24 A ABC [1] 56/25 abdominal [1] 26/19 abide [1] 18/1 able [5] 7/24 50/21 62/21 83/5 109/2 abnormal [8] 8/2 37/19 37/20 37/22 37/25 53/21 54/1 73/6 abnormality [2] 11/3 38/1 about [144] above [2] 47/13 135/5 abroad [6] 45/12 96/9 110/15 111/1 111/2 111/4 absolutely [9] 6/10 16/5 37/2 102/11 108/20 116/6 116/20 120/21 136/2 academic [1] 49/22 accept [1] 66/25 accepted [1] 76/11 accepting [1] 36/9 access [6] 22/18 54/25 81/21 121/21 121/24 123/21 accommodation [1] 43/2 accord [5] 5/15 6/8 25/25 27/2 59/6 account [2] 28/5 82/1 accurate [1] 6/6 accused [2] 46/3 46/12 accustomed [1] 56/20 acquire [1] 51/22 acquired [1] 36/16 acquired HIV [1] 36/16 across [15] 45/1 51/22 57/19 61/22 61/22 61/24 67/20 72/20 75/9 81/6 81/14 89/22 90/4 90/5 90/6 act [1] 61/15 acting [2] 64/23 119/14 action [2] 32/23 55/9 actions [1] 70/5 active [4] 40/14 68/5 96/11 114/7 activities [1] 51/24 activity [1] 62/7 actual [4] 13/7 30/23 105/16 107/5 actually [38] 4/5 6/23	8/22 9/23 12/25 21/6 27/11 30/24 40/19 41/5 41/13 42/24 45/18 47/1 60/22 64/6 65/5 80/6 88/7 90/18 92/8 92/25 101/7 102/7 106/19 106/22 107/13 107/24 109/11 111/21 113/13 118/11 122/24 123/1 129/13 132/2 132/4 133/3 acute [4] 29/3 29/5 29/7 29/11 acutely [3] 21/25 29/2 37/24 adapt [1] 58/11 add [3] 18/14 20/14 133/25 added [1] 57/17 adding [1] 20/18 addition [1] 6/4 additional [2] 47/10 124/8 additive [2] 20/9 20/10 addressed [1] 75/22 addresses [2] 15/4 28/1 adequate [1] 120/11 adjourned [1] 136/17 adjournment [1] 86/18 adjust [1] 99/1 administered [1] 101/14 admitted [2] 50/16 100/5 adolescence [1] 106/18 adolescent [1] 106/15 adolescents [1] 107/2 adult [6] 14/9 22/13 23/15 90/10 99/2 103/1 adults [3] 26/16 47/6 106/22 Advanced [1] 136/10 advantage [2] 10/18 23/25 advice [16] 31/5 47/10 53/13 53/18 53/19 59/12 66/5 66/8 66/24 67/1 67/5 69/23 69/25 71/13 78/17 92/12 advise [6] 13/15 60/9 66/15 68/1 76/4 78/19 advised [2] 56/7 59/9 adviser [6] 3/3 60/23 60/23 61/25 68/22 69/9 advisers [1] 66/14	advising [4] 2/17 59/6 65/21 69/10 advisory [10] 17/2 42/8 43/7 43/17 44/12 67/5 67/7 68/21 69/22 70/5 affect [1] 13/9 affected [8] 13/12 14/3 23/18 47/6 52/16 89/17 89/24 90/15 affects [3] 94/20 94/23 95/1 afoot [1] 85/11 afraid [4] 8/9 53/4 53/5 110/24 Africa [2] 10/22 49/7 African [1] 41/23 after [22] 8/25 14/24 15/13 27/13 27/13 63/13 74/3 74/6 79/19 88/20 92/1 93/21 96/24 98/25 110/16 112/25 116/23 118/7 124/10 126/16 126/17 133/4 afternoon [6] 86/20 86/21 99/21 114/18 134/16 136/13 afterwards [1] 72/11 again [28] 6/8 7/16 12/8 18/4 22/11 22/24 28/13 29/16 36/11 43/9 52/23 70/17 83/21 91/3 95/12 95/19 98/19 106/2 108/3 108/8 112/10 114/2 114/7 117/17 119/19 120/6 125/18 130/13 against [7] 10/20 10/20 25/17 89/25 103/17 104/15 108/4 age [3] 58/4 94/18 107/5 aged [1] 25/22 agents [2] 13/18 94/3 aggravate [1] 117/8 aggravator [1] 117/3 aggression [1] 116/10 aggressive [2] 48/18 120/25 agile [1] 70/10 aging [1] 124/13 ago [7] 48/6 81/13 91/13 107/7 120/19 122/11 129/8 agreed [1] 44/13 agreement [2] 54/1 71/3 ah [1] 78/1 ahead [2] 28/16 119/16
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------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A	95/1 96/6 96/7 97/23 98/22 103/7 112/5 112/12 113/6 113/20 114/2 116/13 117/10 120/6 122/6 123/7 124/20 125/17 125/25 126/22 127/17 131/2 132/21 134/24 ALT [1] 37/19 alter [1] 56/20 altitude [1] 56/19 always [18] 6/6 6/10 8/8 9/19 12/16 15/13 23/25 35/7 44/8 59/17 65/24 73/19 74/19 95/16 108/19 123/17 123/22 123/24 am [13] 1/2 8/10 39/10 51/9 51/10 51/12 63/12 83/6 83/15 85/3 85/23 124/1 136/17 amazing [2] 6/16 49/25 ameliorated [1] 131/24 American [2] 26/3 84/25 Americans [1] 26/3 amount [8] 8/14 20/24 24/9 43/22 45/8 63/8 98/16 127/13 amounts [1] 54/2 ample [1] 71/23 an abnormal [1] 37/19 an absolutely [1] 116/6 an academic [1] 49/22 an active [1] 96/11 an adolescent [1] 106/15 an adult [1] 23/15 an advantage [1] 10/18 an aging [1] 124/13 an amazing [1] 6/16 an annual [2] 60/11 83/25 an antibiotic [1] 83/11 an aplastic [1] 35/8 an Asian [1] 129/8 an aspect [1] 83/22 an assumption [1] 105/2 an average [1] 93/18 an awful [1] 119/18 an early [1] 113/25 an element [1] 5/1 an emergency [1] 58/20	an emerging [1] 69/15 an empty [1] 22/19 an endocrine [1] 132/22 an entirely [1] 135/15 an essential [1] 124/2 an ethical [1] 64/21 an even [1] 82/16 an evening [1] 114/15 an example [1] 108/18 an exchange [4] 21/23 21/24 21/25 35/4 an expert [3] 15/2 77/22 89/11 an eye [1] 32/14 an increase [1] 24/20 an increasing [1] 45/7 an individual [1] 98/20 an infection [1] 30/21 an informal [1] 35/25 an infusion [1] 19/16 an inherited [2] 10/14 40/2 an injection [1] 119/11 an interesting [1] 50/8 an intermedia [1] 91/18 an intermediary [1] 53/3 an intervention [1] 3/22 an issue [5] 49/16 61/10 70/25 76/2 95/19 an observation [1] 92/24 an official [1] 53/6 an old [1] 110/5 an optimal [1] 20/8 an overview [1] 18/8 an SHO [1] 7/3 anaemia [8] 5/7 10/15 21/19 29/11 58/17 58/19 114/2 116/14 anaemic [6] 18/15 56/14 56/14 56/15 56/18 90/22 anaesthetics [1] 55/1 anaesthetist [2] 6/12 59/18 anaesthetists [2] 27/10 59/14 announced [1] 70/18 annual [2] 60/11 83/25 annually [2] 37/16	130/7 anonymous [1] 135/9 another [11] 11/3 13/19 23/8 49/2 52/6 62/17 70/2 78/25 82/25 95/15 96/21 answer [5] 31/15 41/16 48/14 66/13 106/19 answerable [1] 64/11 answering [2] 72/10 87/4 answers [1] 72/22 antenatal [1] 77/12 anti [1] 13/18 anti-sickling [1] 13/18 antibiotic [5] 82/5 82/20 83/6 83/11 117/14 antibiotics [4] 80/23 81/22 82/24 83/3 antibodies [3] 30/22 103/16 103/18 antibody [2] 30/20 104/17 anticipates [1] 128/18 antimicrobial [4] 64/3 80/19 81/16 85/4 antiviral [1] 113/23 antivirals [2] 124/11 125/5 any [74] 6/15 7/16 7/20 8/3 8/9 9/18 17/20 21/17 24/7 25/3 25/5 25/9 28/21 30/15 30/19 31/3 34/18 36/15 38/5 38/14 38/18 38/20 38/25 39/1 42/23 44/11 45/23 51/5 52/14 54/16 59/23 71/7 74/6 75/1 82/4 84/10 88/22 89/17 90/9 92/25 93/15 100/11 100/24 105/24 106/4 106/5 106/7 108/1 109/13 109/19 114/23 115/8 115/19 117/2 117/3 119/24 121/3 121/10 121/15 121/20 122/3 126/14 126/21 127/3 127/4 128/2 129/4 130/21 130/22 131/9 132/12 133/21 135/17 136/3 anybody [4] 93/16 104/16 105/24 133/15 anyone [9] 38/8 51/6 52/25 53/24 54/1 59/16 84/10 127/22 135/18 anything [16] 31/20	38/2 51/7 51/18 59/25 70/23 76/16 76/18 84/13 88/7 114/25 121/8 128/7 128/8 128/10 133/24 anyway [4] 19/21 125/14 130/8 130/19 anywhere [1] 13/9 apart [1] 55/14 aplastic [3] 21/18 29/5 35/8 apologise [3] 8/11 73/14 73/21 appear [5] 4/10 37/7 43/9 74/23 101/22 appointed [4] 2/3 3/1 14/21 60/6 appointments [1] 114/20 appreciated [1] 6/6 approach [4] 5/18 76/2 123/16 132/7 appropriate [6] 4/9 47/7 58/18 69/13 69/13 98/13 appropriately [3] 94/21 117/4 130/8 are [185] area [4] 10/19 30/25 37/7 131/19 areas [3] 8/23 62/21 91/8 aren't [3] 14/2 20/23 77/20 argued [2] 61/19 84/5 argument [1] 65/11 arise [3] 74/22 84/11 128/2 arisen [1] 70/2 arises [1] 76/21 arising [1] 93/1 around [13] 7/5 18/4 18/13 22/22 39/24 45/2 54/5 54/11 57/14 90/20 94/11 96/12 108/9 arrange [2] 93/8 122/9 arranging [1] 28/11 arrived [2] 109/9 109/10 as [183] as exchange [1] 19/25 Asian [1] 129/8 ask [16] 1/12 1/13 26/11 41/20 42/17 46/24 51/15 53/25 72/5 76/24 78/11 83/2 84/17 127/21 128/2 129/1 asked [19] 12/13 17/20 37/1 41/19	42/17 48/12 51/6 51/15 62/3 62/5 62/7 69/22 71/13 77/19 87/5 126/21 126/23 128/9 133/21 asking [2] 78/22 122/17 aspect [2] 64/1 83/22 aspects [1] 43/18 aspirin [1] 85/14 assertive [1] 48/17 assess [1] 54/16 assessed [1] 58/25 assessment [2] 29/12 38/1 assist [2] 73/11 77/21 assistance [1] 127/9 assisting [1] 63/2 associated [3] 5/2 42/11 42/18 assuming [2] 36/25 109/16 assumption [4] 49/14 52/2 74/10 105/2 assured [1] 64/8 attack [4] 12/1 12/9 12/10 132/6 attacking [1] 117/12 attend [1] 36/25 attended [1] 30/11 attention [2] 44/25 46/15 attitudes [1] 55/7 au [1] 26/2 audience [2] 41/3 86/24 audit [3] 54/19 80/11 105/16 audited [1] 99/21 audits [3] 30/13 54/16 54/18 Australia [1] 82/15 Authority [1] 2/13 automated [1] 126/20 available [11] 37/13 38/5 40/22 94/4 115/9 121/11 122/5 123/24 130/21 130/23 133/16 average [2] 93/18 99/9 aware [35] 6/24 7/12 9/21 9/23 9/24 10/9 17/11 24/7 25/3 25/5 25/9 30/7 30/14 30/20 31/2 36/15 38/8 45/23 47/13 52/13 66/1 66/23 71/2 71/9 71/10 102/10 104/20 106/2 106/7 106/8 109/6 127/10 129/2 129/4 129/9 awareness [6] 39/13
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A	9/21 9/23 9/24 10/6 22/3 24/6 84/24 87/20 89/7 106/3 111/5 because [76] 6/25 8/15 11/24 12/4 12/21 14/14 14/21 15/11 15/13 18/15 19/1 19/5 23/2 23/8 23/22 27/9 27/15 29/24 31/10 34/6 37/6 37/11 41/24 45/5 46/4 47/15 51/25 52/8 52/23 56/3 56/14 56/20 58/11 60/14 62/15 64/4 65/13 67/15 67/16 68/5 77/24 79/4 79/25 80/8 83/11 83/14 84/5 85/16 89/24 90/25 91/22 91/22 92/9 96/1 98/12 99/15 100/18 105/8 112/20 113/2 113/2 114/16 115/5 118/16 118/17 118/20 119/18 120/19 120/23 120/24 123/21 124/17 128/17 130/5 133/9 135/3 become [7] 56/15 56/19 80/22 90/21 90/22 91/16 107/2 becomes [3] 79/10 93/22 106/15 becoming [1] 62/20 been [85] 5/24 6/15 8/8 17/3 17/22 20/8 23/11 24/22 30/9 30/14 32/9 32/20 36/12 39/8 41/19 42/17 46/3 46/11 49/21 50/1 50/6 51/15 51/24 54/23 56/14 56/21 57/16 57/16 62/24 63/9 66/1 67/2 70/20 71/9 72/7 74/13 76/25 77/2 78/1 81/19 85/13 85/20 85/22 86/8 86/11 87/1 88/21 89/23 96/8 96/10 96/22 100/4 101/6 102/4 102/10 102/23 102/25 104/10 104/21 105/3 106/5 106/7 106/9 106/10 106/13 108/12 109/15 111/11 114/6 119/8 119/24 120/1 122/4 122/5 123/9 123/18 124/11 125/3 125/11 128/9 130/3 130/16 133/20 134/12 134/16 before [41] 1/18 2/3 3/16 7/15 9/24 10/4	17/3 25/2 25/3 25/9 30/21 37/13 37/23 38/14 39/21 42/10 48/3 49/4 51/14 52/13 58/25 68/8 70/3 70/5 71/25 109/8 109/10 109/17 109/21 112/11 117/17 117/22 117/23 119/10 121/4 126/10 128/17 128/17 128/20 129/11 134/4 begin [2] 45/16 97/3 beginning [3] 7/12 15/18 22/2 behalf [4] 47/1 47/1 60/21 134/2 behaviour [1] 79/3 behavioural [4] 82/8 82/17 82/25 83/17 behaviours [1] 55/5 behind [5] 7/11 71/21 76/15 127/22 133/19 being [26] 2/3 4/16 5/21 9/11 14/11 18/17 31/11 41/5 42/15 47/3 59/18 60/16 62/21 62/25 66/24 72/23 73/5 73/12 77/17 88/7 88/24 103/8 109/1 119/4 119/5 126/17 believe [6] 4/17 35/17 79/5 79/25 86/1 89/25 believed [1] 27/6 below [2] 23/3 23/5 belt [1] 89/22 Ben [1] 136/12 benefit [3] 35/7 79/4 105/18 benefits [6] 25/17 35/11 47/5 103/3 132/10 132/11 Berkeley [1] 26/6 best [19] 9/4 9/7 9/8 14/20 24/2 27/18 32/2 41/13 42/4 42/6 47/4 50/9 50/12 50/19 66/13 73/15 84/20 117/20 133/5 beta [6] 14/6 14/6 14/8 90/16 115/25 118/3 beta-globin [1] 90/16 better [4] 50/25 58/12 78/3 79/18 between [16] 16/20 23/15 36/1 48/22 50/8 58/24 65/2 65/20 66/2 87/25 89/1 91/17 92/10 93/16 93/19 124/11 beyond [1] 47/11 big [9] 22/15 35/17	40/7 41/3 54/3 60/13 63/21 81/12 82/1 bigger [4] 11/22 82/16 86/24 98/24 biggest [1] 15/23 bilirubins [1] 37/18 billion [1] 84/1 biology [1] 2/2 biopsies [1] 125/18 Birmingham [1] 16/1 birth [4] 14/24 33/23 77/24 96/19 bit [13] 12/1 27/25 63/3 64/3 71/19 80/15 93/13 114/1 115/23 123/10 123/11 128/19 134/8 bleed [1] 4/7 bleeding [2] 28/17 28/21 blisters [1] 23/9 blockage [3] 11/24 12/2 12/7 blockages [3] 11/23 11/23 12/5 blocking [1] 12/21 blood [117] 3/22 5/3 5/4 5/13 6/20 7/17 8/25 9/17 11/7 11/8 11/10 11/10 11/15 11/19 11/21 11/22 11/24 12/2 12/5 12/21 13/21 18/10 18/11 18/14 18/16 18/18 18/23 19/20 20/2 20/3 20/6 20/7 20/7 20/15 20/19 20/22 20/24 21/1 21/4 21/12 21/17 22/19 22/23 28/15 29/25 30/1 30/3 30/5 30/7 32/10 33/5 33/6 33/7 33/12 33/12 33/13 33/14 33/18 33/19 33/20 33/24 34/9 34/11 34/22 35/16 36/7 38/11 39/6 39/7 39/18 44/17 53/20 53/25 54/2 54/4 54/12 54/17 57/6 57/9 58/15 61/4 71/1 85/5 88/5 88/18 88/19 89/2 89/6 91/12 91/15 92/4 93/5 93/7 93/14 93/15 93/19 93/25 98/12 98/13 98/16 98/17 99/10 99/23 100/3 100/8 101/25 102/12 103/3 103/7 103/17 103/20 103/21 103/24 105/17 113/25 115/2 130/6 blood-borne [1] 44/17	bloods [1] 113/17 board [2] 132/12 133/3 bodies [1] 43/23 body [7] 13/9 18/24 53/6 58/10 90/12 94/10 98/9 bone [5] 11/8 40/16 41/7 101/10 103/6 bone marrow [1] 41/7 bones [2] 12/4 46/6 book [3] 34/6 75/23 85/1 booklet [1] 4/12 books [1] 15/10 boost [1] 129/19 booster [1] 104/19 boots [1] 21/18 born [2] 90/13 90/18 borne [1] 44/17 both [14] 7/24 10/16 11/2 26/16 43/23 44/5 49/9 68/1 84/23 85/9 89/15 102/21 125/24 134/14 both individuals [1] 43/23 bother [1] 107/21 bottom [2] 25/12 28/25 bouts [1] 116/10 brain [3] 13/7 21/24 26/25 break [17] 1/23 3/16 7/14 23/6 39/22 48/1 51/1 51/3 51/11 71/22 72/16 127/21 128/4 128/5 128/13 128/16 128/22 breakthrough [1] 129/22 breast [1] 89/4 Brent [4] 14/19 16/13 46/19 47/9 BRIAN [2] 76/20 137/4 brief [3] 1/18 10/11 87/13 briefing [1] 68/23 briefings [1] 69/5 briefly [1] 22/11 bring [4] 31/13 48/18 62/16 135/6 brings [1] 50/1 Britain [1] 17/14 British [3] 32/6 32/12 41/14 broader [1] 126/2 broadly [3] 5/18 71/8 92/17 brought [5] 61/1 69/20 73/2 77/16	129/13 Brozovic [4] 24/12 32/11 44/22 57/15 BSH [1] 110/16 budget [1] 83/25 build [1] 117/13 building [1] 66/18 built [2] 15/20 66/10 bull [1] 17/14 bullet [1] 79/6 bulwark [1] 48/19 burden [3] 81/13 100/5 107/7 busy [2] 99/16 123/23 but [211] Butlin [6] 1/13 1/16 87/6 87/10 137/3 137/6 by [67] 1/16 5/8 5/18 6/25 10/5 15/9 16/15 18/1 18/17 19/13 27/23 29/13 32/2 32/16 34/3 35/20 35/23 41/2 41/21 44/1 45/6 46/21 47/16 48/6 54/17 56/25 57/7 57/20 58/10 59/12 60/17 61/21 62/3 68/25 70/20 72/3 72/23 72/24 72/25 77/19 83/1 83/12 84/3 87/6 87/10 89/24 90/15 94/2 97/2 97/2 97/12 98/14 101/19 102/24 102/25 106/10 106/11 106/21 106/22 112/17 115/15 115/21 127/7 130/5 130/5 137/3 137/6
				C	
				Cabinet [1] 68/23 call [7] 1/4 53/16 78/4 91/19 92/22 94/3 126/18 called [12] 4/13 5/22 10/17 11/11 11/17 12/19 19/7 46/8 60/11 81/24 94/5 94/5 came [23] 8/23 15/9 17/3 31/18 38/14 38/22 45/12 49/22 55/18 57/17 59/4 64/15 66/8 67/25 70/25 73/12 75/9 81/13 88/8 95/6 104/14 126/20 130/24 campaign [3] 70/19 71/8 74/17 campaigns [1] 60/13 can [87] 11/18 11/18 11/24 12/7 12/10	

C	89/18 89/18 89/25 can... [82] 12/18 12/18 12/23 12/24 13/2 13/2 13/3 13/9 13/10 13/14 16/14 17/14 18/8 19/10 20/11 30/20 30/23 30/24 33/16 35/18 35/22 40/3 40/3 40/4 40/5 43/9 45/15 51/18 52/1 52/23 53/7 56/17 56/22 61/2 63/21 63/22 63/22 67/19 68/8 70/6 71/22 73/11 75/19 78/4 78/5 78/23 79/1 79/13 81/23 81/25 82/6 82/17 82/23 84/17 84/20 86/1 86/7 92/17 96/4 97/16 98/22 99/18 100/3 100/18 101/24 102/1 102/15 105/17 107/8 107/10 109/13 116/9 116/25 124/7 128/10 129/25 131/14 131/15 132/20 134/20 134/25 135/9 can't [16] 11/20 12/21 12/22 30/10 31/8 32/24 54/20 60/2 72/9 72/12 74/21 78/7 93/3 102/6 102/7 108/20 cancer [3] 89/4 94/22 117/6 candid [1] 64/24 cannot [8] 18/24 58/19 93/3 94/6 94/7 102/5 106/19 135/6 capillaries [1] 11/11 cardiologists [1] 132/15 cardiology [1] 132/14 cardiomyopathy [1] 19/3 cardiovascular [1] 26/25 care [14] 37/12 41/21 43/19 44/6 47/24 51/14 52/12 53/12 92/15 98/20 104/7 132/8 133/5 136/10 career [6] 1/18 1/23 3/16 7/14 9/3 87/13 careful [3] 24/17 41/6 91/22 carefully [1] 41/8 Caribbean [1] 41/23 caring [1] 46/3 carried [2] 54/16 109/8 carrier [4] 10/17	25/18 25/18 25/25 carry [2] 41/18 89/16 carrying [1] 12/5 case [5] 6/4 40/21 73/21 78/2 103/4 cases [5] 18/16 29/9 65/7 77/24 122/24 cash [1] 82/23 catastrophic [1] 13/10 catching [1] 85/15 categorised [1] 91/8 category [1] 23/20 Caucasian [1] 103/14 cause [8] 7/10 28/9 40/2 40/3 58/18 85/3 116/4 117/4 caused [4] 18/17 72/23 72/25 113/24 causes [5] 29/11 73/3 107/13 116/11 116/15 causing [1] 80/22 cell [77] 2/8 2/16 8/23 10/8 10/10 10/14 10/17 11/1 11/5 11/15 12/3 12/15 14/13 14/16 15/4 15/6 15/7 15/23 16/11 16/14 17/10 17/19 17/22 18/9 18/12 19/4 21/8 21/9 21/14 21/14 22/16 24/21 24/24 24/24 25/4 25/15 26/4 26/15 26/23 36/12 36/21 36/24 37/17 38/6 39/24 40/8 40/22 41/21 42/13 42/20 42/25 45/25 46/19 47/24 51/14 51/16 52/12 52/16 53/12 54/10 55/25 56/5 56/11 62/20 74/23 77/11 77/13 77/16 77/20 78/14 86/6 126/11 126/12 126/14 127/3 134/14 134/24 cells [27] 11/7 11/10 11/19 11/24 12/6 12/23 13/21 20/7 20/14 20/19 20/25 20/25 21/4 21/12 21/17 22/5 32/25 57/4 57/8 57/23 57/25 93/19 98/16 99/10 99/23 112/23 114/1 cent [3] 95/13 95/16 103/19 Central [14] 2/4 14/14 15/7 15/22 17/9 17/18 24/10 31/21 36/12 38/23 40/14 46/18 57/13 57/15	Central Middlesex [2] 17/9 38/23 centre [16] 8/16 9/4 16/8 16/14 31/4 32/18 34/12 39/15 46/19 47/9 47/10 73/8 92/9 96/11 101/16 130/10 centres [8] 31/17 32/3 42/2 92/13 92/14 92/16 110/3 110/13 century [1] 54/20 cerebrovascular [1] 25/19 certain [9] 8/14 20/24 31/8 31/16 34/13 56/15 75/16 109/3 131/16 certainly [7] 77/7 83/22 101/2 104/14 109/17 109/18 134/12 Chair [1] 77/3 chaired [2] 68/21 68/25 challenge [1] 78/12 challenging [1] 78/22 chamber [1] 72/8 championing [1] 85/3 chance [2] 89/19 117/20 change [13] 55/5 59/4 59/16 59/22 63/23 76/22 77/5 79/2 81/7 82/6 98/22 106/5 106/8 changed [7] 37/24 49/19 70/13 92/12 105/14 105/15 134/4 changes [4] 13/8 24/8 30/14 56/16 changing [2] 64/2 80/1 chaps [1] 92/3 chapter [4] 57/1 57/4 57/23 75/20 Charache [1] 78/15 charge [3] 32/10 33/23 39/18 charity [2] 127/11 127/12 check [5] 76/15 93/5 93/9 113/17 133/19 checked [3] 6/14 37/16 88/21 checking [1] 88/21 chelate [2] 117/18 131/14 chelating [1] 94/3 chelation [3] 19/7 20/4 96/13 chelator [1] 95/6 chelators [3] 19/23 95/24 113/5	chemical [2] 19/9 33/10 chest [5] 12/19 21/23 24/14 29/5 35/9 chewing [1] 113/3 Chief [10] 3/2 3/8 3/9 60/4 60/23 60/23 61/19 68/22 69/8 69/8 Chief Medical [1] 69/8 child [23] 22/13 40/23 46/3 46/4 46/11 77/16 82/19 82/19 82/21 89/17 89/20 90/18 94/13 97/4 97/13 97/17 97/21 98/23 106/11 106/16 107/16 107/23 107/23 child's [1] 97/19 childhood [2] 64/17 96/21 children [10] 8/25 13/6 25/21 26/16 45/11 47/6 77/20 90/17 90/21 107/2 Cho [1] 25/7 chose [3] 64/4 77/24 85/16 chosen [1] 82/11 Chris [1] 83/25 Chris Whitty [1] 83/25 chronic [1] 42/23 chunks [1] 26/10 chuntering [1] 54/11 Cinderella [1] 40/12 circulate [1] 11/8 circulation [1] 20/12 circumstances [2] 18/9 21/7 cirrhosis [3] 94/22 117/6 124/16 citizen [1] 52/9 civil [2] 63/8 64/10 claim [1] 55/3 CLAIRE [2] 1/15 137/2 Clarify [1] 112/10 class [1] 52/9 classified [1] 108/2 classic [1] 11/16 classically [1] 37/17 clear [8] 35/12 44/5 67/8 91/16 91/16 91/17 124/6 136/3 cleared [3] 125/4 125/9 125/22 clearing [1] 117/20 clearly [7] 8/7 30/19 52/11 52/24 75/11 110/18 120/19 cleave [1] 80/8 clinic [19] 14/15 15/22 36/15 36/22	38/9 38/20 47/12 47/14 47/15 97/22 111/23 114/16 114/21 114/23 115/4 115/10 126/4 132/22 132/25 clinical [18] 18/6 29/15 31/19 50/3 50/9 50/18 59/12 84/1 89/7 93/1 96/10 96/11 100/15 111/6 114/19 127/2 132/9 133/6 clinically [1] 101/11 clinician [7] 6/17 34/19 36/1 74/16 96/18 100/24 101/7 clinician's [1] 96/17 clinicians [18] 16/9 16/11 17/5 31/13 38/24 53/12 53/14 53/17 54/8 56/7 59/7 59/9 60/20 62/12 63/1 69/16 78/9 78/11 clinics [8] 2/16 15/23 96/9 120/18 123/23 127/18 132/14 132/19 close [4] 77/7 85/1 115/14 123/18 closely [4] 101/18 111/7 111/12 111/14 clotting [1] 40/10 CMO [26] 42/15 50/6 60/6 60/7 60/7 60/25 61/5 61/11 63/1 63/4 64/1 64/10 64/15 64/22 66/5 67/10 68/23 69/15 70/18 70/19 74/15 75/2 75/15 75/18 84/24 86/10 CMO's [1] 67/13 CMOs [3] 62/5 66/3 70/13 co [1] 68/21 COBRA [1] 68/24 coffee [1] 52/5 cogent [1] 5/9 cognitive [1] 13/8 cohort [2] 124/19 125/9 coincidentally [1] 113/6 colleague [5] 24/12 25/7 31/11 32/21 44/22 colleagues [9] 5/19 6/13 32/16 38/23 39/18 54/24 59/13 92/22 122/25 collect [1] 88/18 collection [1] 88/18 College [1] 15/25 column [4] 25/13	26/12 28/25 29/1 combined [2] 119/12 124/18 come [42] 13/16 24/4 31/23 32/1 32/8 34/25 37/1 37/8 41/10 45/2 52/17 53/1 59/5 61/10 65/18 71/1 88/2 92/8 92/10 92/12 99/3 99/14 99/20 100/7 101/14 105/5 106/21 110/14 111/1 111/6 114/18 114/20 115/4 122/6 122/9 122/18 126/19 130/14 132/12 133/3 134/25 135/15 comes [5] 17/13 90/20 93/7 97/22 97/23 coming [8] 15/12 75/18 81/3 86/13 90/3 120/21 125/12 136/7 commas [1] 60/12 comment [5] 50/7 53/23 60/2 61/15 134/20 comments [1] 75/11 committee [13] 17/2 32/6 42/8 43/7 43/17 44/12 44/21 55/11 55/20 55/22 56/1 56/2 67/5 committees [5] 31/9 67/8 69/20 69/22 70/1 common [3] 7/10 11/4 45/16 communication [1] 65/15 communications [1] 65/3 communications people [1] 65/3 communities [6] 39/24 40/5 52/15 52/18 129/15 129/21 community [4] 40/13 41/3 82/5 129/6 companies [1] 131/2 company [2] 111/15 111/25 compared [3] 37/23 82/14 133/11 competitive [2] 80/12 80/15 complete [1] 95/6 completed [1] 106/10 completely [2] 100/10 123/15 complexity [1] 28/4 compliance [2] 95/15 95/21 complications [3]
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(39) can... - complications

C	97/7 101/20 103/1 109/12 111/12 112/19 114/14 115/6 115/6 115/7 126/21 consultants [8] 2/18 86/8 93/4 96/25 97/7 101/19 123/22 127/17 consultation [2] 45/3 83/16 consumption [1] 62/4 contactable [1] 123/24 content [1] 55/16 context [2] 39/5 60/6 contexts [2] 23/13 56/6 continue [2] 39/21 68/17 continued [3] 2/15 82/15 113/16 contracted [3] 117/22 126/4 126/15 contraindicated [1] 56/8 Contreras [1] 56/25 contribute [3] 69/21 135/20 135/21 contributed [1] 81/17 contributors [1] 81/18 control [4] 82/14 88/10 116/11 118/1 convened [1] 69/22 convenient [1] 47/25 conversation [2] 35/11 36/1 conversations [4] 39/19 104/23 109/19 119/23 convinced [1] 9/6 convincing [1] 81/7 coordinating [1] 92/13 copied [1] 82/15 coping [1] 120/10 copy [3] 4/16 43/13 56/24 core [4] 48/7 72/2 118/6 127/25 correct [4] 5/6 58/17 88/17 103/23 corrected [2] 48/16 58/19 corridor [1] 33/10 could [53] 1/9 4/10 4/22 5/7 6/25 7/1 7/1 9/3 9/5 9/8 10/11 13/14 14/1 14/4 14/10 14/20 14/24 15/16 19/13 22/6 22/11 22/16 22/25 24/1 24/5 24/15 24/23 25/12 42/6 43/6 44/4 47/6	51/24 55/3 56/24 57/3 63/18 63/18 69/24 77/16 78/2 79/20 83/14 84/18 85/1 89/13 101/22 111/16 121/24 122/10 126/8 129/10 133/15 couldn't [3] 15/12 71/15 118/16 Council [1] 84/7 counsel [4] 72/5 128/2 128/5 128/18 counselling [9] 16/17 16/19 44/7 46/20 47/20 121/4 121/7 121/9 121/11 counter [1] 66/21 counterargument [1] 65/10 countries [8] 81/21 89/23 90/2 90/4 90/5 93/24 95/3 103/12 country [9] 16/18 32/3 45/1 45/2 46/20 51/22 57/19 60/20 67/22 counts [1] 113/15 couple [3] 46/1 66/25 76/8 course [26] 4/6 7/21 8/1 12/7 12/20 14/4 14/23 18/19 25/6 30/10 32/14 35/18 37/10 41/9 42/7 42/23 53/19 55/16 61/11 62/16 62/22 65/14 124/10 127/24 135/1 135/17 courses [1] 124/8 cover [1] 71/16 covers [1] 72/21 Covid [1] 84/22 cracked [1] 129/20 creates [1] 93/23 cri [1] 76/22 crises [3] 12/12 17/10 46/6 crisis [5] 12/3 29/5 35/8 36/23 64/25 cross [7] 33/24 61/17 61/18 61/21 71/2 88/21 103/20 cross-checking [1] 88/21 cross-government [3] 61/17 61/18 61/21 cross-matched [1] 103/20 cross-matching [1] 33/24 crossed [1] 7/8 crowded [1] 43/2 crystals [4] 11/14	11/15 11/20 13/22 cultural [1] 81/2 culture [5] 77/5 77/7 78/8 79/2 81/8 curative [1] 40/17 cured [1] 133/14 current [2] 70/6 104/23 cut [1] 91/16 cutting [1] 24/17 cycle [1] 12/20 Cypriot [1] 98/6 cystic [1] 42/2 cystic fibrosis [1] 42/2 cœur [1] 76/22	118/9 126/18 de [1] 76/22 deaf [1] 108/1 deal [5] 49/12 71/24 81/4 105/8 107/12 dealing [6] 15/2 68/11 86/9 89/11 112/17 121/5 deals [1] 25/19 dealt [1] 69/18 death [3] 14/25 81/18 113/10 deaths [1] 85/17 debate [5] 24/3 49/22 50/24 65/1 66/23 decade [1] 17/16 decades [2] 49/19 50/25 December [1] 24/13 decent [1] 45/19 decide [7] 66/16 70/2 76/5 96/15 97/9 97/10 97/24 decided [2] 97/12 113/10 decision [7] 49/20 53/1 58/25 96/17 96/17 97/8 101/20 decisions [2] 70/7 79/24 decline [1] 82/15 dedicated [1] 121/13 deemed [1] 101/11 definite [1] 4/25 definitely [5] 23/3 109/4 109/10 111/2 120/4 definition [1] 91/17 degree [3] 13/6 101/10 109/3 degrees [1] 5/7 delay [3] 28/8 28/9 70/3 delayed [1] 82/18 deliver [3] 9/8 56/17 86/13 delivery [2] 12/14 57/25 demand [1] 5/4 democratic [1] 76/7 departed [2] 18/6 50/17 department [16] 2/24 3/3 31/25 32/5 33/2 39/14 53/15 54/9 54/22 61/13 69/9 71/11 71/16 73/17 81/11 111/17 departments [1] 54/17 dependent [11] 91/19 91/20 91/21 92/3	97/13 100/14 100/20 101/6 101/18 102/25 103/4 depending [5] 29/14 90/25 91/3 99/11 115/17 depends [4] 28/23 34/19 56/13 77/10 depleted [1] 99/23 depression [2] 116/12 120/14 deputy [1] 2/23 described [3] 80/4 81/1 86/6 description [1] 60/25 deserves [1] 136/5 Desferal [1] 95/8 desferrioxamine [2] 19/12 94/5 desk [1] 75/9 despite [2] 24/3 111/10 destruction [1] 113/25 detail [3] 1/19 8/20 25/2 details [3] 6/4 33/21 34/16 deteriorated [1] 74/6 determine [1] 91/5 develop [6] 8/5 24/10 70/17 85/7 96/9 103/18 developed [11] 16/12 16/13 22/8 24/16 26/2 64/17 70/15 83/8 93/24 95/3 133/1 developing [3] 66/18 71/13 103/16 development [8] 2/12 2/21 2/24 3/2 62/2 69/10 83/22 132/23 DHSC [1] 2/21 diabetes [5] 19/3 95/2 108/1 132/25 133/1 diagnose [1] 7/24 diagnosed [1] 46/16 diagnosis [2] 44/16 77/15 diagnostics [1] 85/7 diaries [1] 99/19 dictated [1] 49/17 did [77] 3/7 6/18 7/9 7/16 8/4 8/19 16/23 22/14 24/10 26/5 27/10 29/23 30/15 31/15 31/18 32/2 32/8 33/18 35/5 35/16 38/25 39/3 39/14 39/14 40/9 41/11 42/4 47/14 47/15 51/22 54/7 55/14 56/1 56/3
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(40) complications... - did

D	director [8] 2/11 2/20 2/23 3/1 30/16 61/14 64/7 79/19 Directors' [1] 16/8 dirty [1] 123/3 disabilities [1] 13/9 disability [1] 108/1 disagreed [1] 76/1 disappear [1] 37/5 disastrous [1] 114/1 discharged [1] 88/24 disciplines [1] 124/4 disclose [1] 108/7 discovered [2] 46/13 73/17 discrepancy [1] 42/1 discriminated [1] 108/4 discrimination [1] 109/3 discuss [11] 16/25 35/25 45/8 50/21 51/4 70/4 96/3 123/6 128/7 128/8 129/23 discussed [9] 29/9 29/12 49/18 66/4 70/12 76/10 79/11 104/4 122/3 discussing [5] 36/8 68/10 70/23 71/14 129/25 discussion [12] 6/23 7/23 31/13 35/7 41/12 49/12 49/23 50/10 75/10 77/1 105/23 106/13 discussions [13] 7/2 7/4 14/18 17/5 17/6 30/15 31/3 39/15 66/16 70/5 71/5 73/19 106/4 disease [27] 2/8 8/23 10/8 10/10 10/14 10/16 11/1 11/5 15/4 15/24 21/15 24/25 25/19 26/15 30/2 39/24 40/2 42/23 43/3 45/23 48/24 81/13 81/18 86/7 107/8 125/8 136/11 Diseased [1] 40/22 diseases [3] 49/9 84/24 85/2 disorder [1] 89/15 disorders [3] 9/1 40/11 44/9 dispensed [1] 34/2 disposal [1] 34/13 disruption [1] 100/12 disseminate [2] 17/13 69/24 disseminated [2]	62/25 63/20 disseminating [1] 55/23 dissemination [2] 63/14 63/21 distinct [1] 72/25 distort [2] 11/12 11/15 district [1] 31/12 do [119] 4/7 4/15 4/21 6/12 6/23 9/21 13/14 13/14 14/11 14/22 15/6 17/23 18/4 21/22 21/23 21/24 22/8 23/2 23/2 23/7 27/10 27/17 31/3 31/20 32/24 35/21 38/20 39/1 41/8 41/8 42/11 42/12 43/5 44/11 45/8 45/9 47/4 48/3 48/12 48/13 48/21 49/13 49/15 49/15 50/5 50/7 50/9 50/22 50/24 52/13 53/3 53/8 55/19 59/3 60/16 61/21 63/6 63/19 63/23 63/24 65/16 66/5 67/4 67/17 69/24 69/25 70/6 70/23 72/20 74/21 75/9 76/18 76/21 77/9 77/24 78/4 78/5 78/6 79/1 79/15 79/17 79/18 81/20 81/20 83/4 83/4 83/17 83/20 84/6 84/16 84/17 84/18 84/20 85/11 92/11 95/14 96/2 96/2 96/6 98/18 99/13 100/16 100/18 101/3 102/1 103/20 106/24 108/24 109/19 121/12 123/13 123/20 125/14 126/16 126/18 128/13 132/19 133/21 135/22 docs [1] 4/19 doctor [14] 40/24 45/9 47/17 48/13 49/13 49/14 50/4 52/8 60/12 60/16 64/13 83/12 96/25 97/23 doctors [19] 4/20 16/24 17/21 17/25 45/6 48/11 48/15 49/10 50/15 53/22 57/7 63/4 78/14 79/12 80/15 82/1 85/9 99/17 130/12 doctors' [1] 83/3 document [3] 5/14 88/15 101/24 documentation [4] 88/18 88/19 88/21 88/22	documented [3] 106/12 106/13 120/6 documents [1] 23/4 does [14] 5/15 6/8 11/6 25/25 27/2 41/16 50/20 59/6 63/1 100/16 112/22 123/10 125/7 135/19 doesn't [8] 10/2 31/22 37/20 56/4 91/23 94/8 99/3 135/10 doing [22] 3/21 9/6 23/10 24/18 26/3 26/7 30/20 34/20 40/10 41/9 78/25 80/9 80/13 80/14 83/23 83/23 86/3 88/16 105/12 115/2 130/19 132/19 don't [70] 4/17 5/21 7/2 7/20 8/21 9/25 10/4 12/5 13/12 21/17 23/5 29/24 30/19 31/22 32/1 32/19 36/2 38/25 39/20 46/9 46/10 48/15 49/10 49/11 51/23 52/17 54/13 54/18 55/2 55/16 65/12 65/17 66/17 67/1 67/16 72/11 75/10 75/11 82/3 82/4 84/9 86/25 88/6 90/9 90/16 91/17 94/20 96/23 100/18 100/19 100/24 104/13 105/13 106/20 107/21 108/7 110/23 111/2 117/3 122/19 123/8 125/21 126/16 126/21 131/3 131/19 133/23 135/21 135/23 136/1 donated [1] 22/23 donations [1] 9/16 done [17] 6/15 9/11 17/10 19/24 19/25 47/12 61/18 67/19 73/8 73/9 73/12 76/6 78/7 82/18 108/24 129/4 130/4 donors [4] 8/1 9/11 73/5 103/14 Doppler [1] 25/24 dosage [1] 95/23 dose [3] 118/17 118/20 119/2 dosing [1] 118/24 double [1] 117/15 doubt [1] 50/7 down [16] 5/24 11/18 26/17 28/1 43/20 44/4 75/22 78/18 82/13 82/24 90/4 90/20 102/15 108/12 116/18	131/17 downstairs [1] 73/17 Dr [10] 24/12 27/12 32/11 44/22 48/20 82/3 84/25 136/11 136/12 136/12 Dr Ben Hudson [1] 136/12 Dr Brozovic [2] 32/11 44/22 Dr Davies [2] 48/20 82/3 Dr Fiona Finlay [1] 136/12 Dr Hazel [1] 136/11 Dr Jo [1] 27/12 Dr Mischa Brozovic [1] 24/12 Dr William [1] 84/25 drafty [1] 43/3 drag [1] 122/7 drained [1] 120/21 dramatically [3] 21/14 82/24 105/14 draw [1] 51/18 drawing [1] 46/14 dreadful [5] 12/11 22/17 23/11 74/4 85/20 dreadfully [1] 12/25 drill [1] 6/18 drilled [1] 6/14 drip [1] 22/23 drop [7] 12/24 21/13 98/25 100/21 101/1 112/22 113/8 dropped [3] 100/23 116/18 118/21 dropping [3] 113/7 113/13 113/15 drops [1] 100/22 drug [13] 54/12 54/12 82/4 94/4 94/5 95/8 111/14 111/24 113/12 116/6 116/7 126/7 131/2 drugs [3] 80/21 80/22 81/2 due [3] 26/15 73/5 135/17 during [16] 2/15 3/17 4/6 4/15 6/21 7/6 8/5 10/19 24/6 24/19 29/16 67/10 75/15 88/23 112/5 120/23 duties [1] 64/14 dying [3] 19/2 29/23 94/17 dyslexic [1] 8/10 E	84/1 93/7 97/22 98/20 104/18 105/7 eager [1] 123/24 earlier [7] 5/12 30/23 49/21 76/9 80/5 134/21 134/22 earliest [1] 24/14 early [11] 6/9 6/22 6/24 17/1 24/12 24/19 31/10 47/22 48/4 109/16 113/25 early 1990s [1] 47/22 East [2] 10/24 90/7 Eastern [1] 90/5 easy [3] 17/11 48/15 121/21 eat [1] 72/11 Ebola [9] 65/1 65/3 67/12 68/7 68/8 68/18 68/19 69/11 70/10 edge [1] 24/17 edited [1] 56/25 edition [1] 4/14 educated [1] 105/22 educating [1] 57/16 education [7] 30/11 46/24 76/25 81/25 96/6 96/7 107/24 educational [1] 106/25 educative [1] 54/8 effect [2] 79/8 113/6 effective [2] 5/11 66/10 effectively [2] 5/8 46/16 effects [17] 54/13 57/12 95/7 95/14 95/19 95/22 115/1 116/9 116/22 119/5 119/20 119/22 120/1 120/6 120/13 131/1 131/2 eg [1] 26/19 Egypt [1] 126/9 eight [2] 20/23 114/6 either [15] 19/10 35/3 40/10 41/1 44/15 49/11 53/2 57/10 60/1 71/13 72/7 94/6 97/2 113/2 120/24 element [2] 5/1 80/12 eleven [1] 8/10 eleven-plus [1] 8/10 elicit [1] 46/24 ELIZABETH [2] 87/9 137/5 else [7] 51/7 80/9 84/13 96/10 116/4 128/10 133/24 elsewhere [1] 53/14 email [1] 63/22
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E	42/19 Europe [1] 90/3 European [1] 103/15 even [20] 22/14 43/19 44/9 45/14 82/16 85/7 95/14 96/19 98/4 104/2 104/12 107/4 107/17 113/23 117/23 120/18 123/2 131/13 133/9 135/10 evening [2] 114/15 114/21 event [2] 34/10 131/9 events [1] 84/22 eventually [3] 94/22 117/5 117/6 ever [8] 4/16 5/3 45/6 70/19 116/8 123/8 129/25 133/9 ever-growing [1] 5/3 every [26] 5/2 6/3 18/23 22/3 23/18 37/1 37/16 46/1 46/1 50/15 54/12 77/4 78/17 92/8 93/4 93/19 95/9 98/4 98/23 99/4 99/10 103/20 105/9 114/5 114/6 115/6 everybody [2] 123/19 123/25 everyone [7] 5/21 9/17 32/19 41/15 80/9 85/19 85/24 everything [11] 24/11 28/24 32/24 41/4 47/21 74/21 85/14 88/15 93/9 103/1 108/20 everywhere [1] 77/18 evidence [53] 1/11 10/9 16/7 17/15 31/16 39/22 39/23 44/3 44/6 48/4 50/12 50/19 51/4 51/4 51/5 53/2 53/8 55/4 55/6 55/8 62/23 65/14 70/3 72/21 73/4 73/7 73/22 74/8 75/24 76/11 78/20 79/21 79/25 80/3 80/4 81/9 81/10 83/18 86/5 86/11 89/10 89/13 122/12 125/7 126/11 128/3 128/6 128/8 132/8 133/25 134/13 135/3 135/8 evolving [1] 108/9 ex [1] 127/8 exactly [4] 98/5 102/8 104/13 119/16 examined [1] 75/14 example [5] 30/8 58/9 58/20 65/1 108/18	examples [1] 85/16 excellent [1] 133/2 exceptionally [1] 104/3 excess [2] 21/1 21/5 excessive [1] 103/6 exchange [10] 19/25 21/23 21/24 21/25 22/10 24/11 24/15 29/14 35/4 36/5 Exchange/transfuse [1] 36/5 exchanged [2] 29/21 29/24 exchanges [2] 126/19 126/20 exclude [2] 9/12 9/16 excluded [2] 8/2 73/5 excretion [1] 93/17 executive [2] 2/11 43/13 exercise [2] 39/14 39/17 exercised [1] 18/22 existed [1] 17/19 existing [1] 110/21 exists [1] 5/10 expansion [2] 101/10 103/6 expect [3] 32/17 32/18 67/9 expected [4] 34/10 39/7 65/6 77/21 expensive [1] 94/16 experience [12] 39/25 45/24 51/18 51/21 57/13 74/1 80/2 100/19 118/2 122/14 126/25 131/20 expert [10] 15/2 46/21 48/8 60/1 77/22 89/11 105/19 107/3 132/17 136/11 expertise [2] 9/3 62/20 experts [8] 10/3 30/5 39/9 40/25 62/15 62/17 62/19 63/16 explain [6] 20/11 22/11 46/23 51/19 72/1 104/1 explained [2] 76/10 103/2 explaining [1] 46/22 explains [1] 10/21 explanation [2] 10/11 44/20 explanations [1] 103/9 explore [2] 36/19 40/18 exposed [1] 17/22	extend [1] 54/7 extension [1] 95/7 extent [8] 30/17 39/16 49/16 50/3 66/5 67/4 75/16 131/16 extra [1] 46/24 extraordinarily [2] 63/24 74/19 extreme [1] 113/9 extremely [2] 116/12 132/15 eye [1] 32/14 eyes [1] 108/4 F face [2] 59/13 60/14 fact [8] 11/12 16/16 19/12 30/12 37/20 41/22 75/11 110/8 factor [2] 49/2 126/8 Factor VIII [1] 49/2 factors [1] 58/3 failed [2] 8/10 58/21 failing [1] 90/24 failure [3] 5/10 29/7 29/21 fair [4] 24/19 27/21 65/23 74/9 fairness [1] 42/4 fait [1] 26/2 fall [2] 58/5 58/11 falls [1] 58/7 falsely [1] 46/12 familiar [1] 10/12 families [7] 40/4 43/24 46/22 85/21 107/20 108/5 122/25 family [5] 8/9 46/2 97/14 108/8 108/10 far [11] 33/16 90/7 95/11 102/9 104/20 106/7 106/8 128/3 131/17 135/10 136/3 Far East [1] 90/7 father [1] 64/17 fatigued [1] 116/13 faulty [1] 89/16 fear [1] 65/22 feared [1] 41/24 features [1] 48/3 febrile [1] 3/25 fed [2] 42/12 42/19 feeding [1] 90/23 feel [6] 19/5 53/8 100/9 109/4 116/14 123/3 feeling [3] 116/20 120/9 120/24 feels [1] 58/7 feet [1] 46/7 felt [12] 9/2 9/2 15/11 24/5 62/6 64/20 64/22	76/9 76/10 77/24 81/10 123/3 fertility [2] 95/1 132/23 few [9] 4/5 13/1 43/20 46/1 51/16 51/22 118/13 123/5 130/15 fewer [2] 13/25 15/19 FibroScan [2] 125/17 125/19 fibrosis [3] 42/2 94/21 124/15 fighting [1] 112/23 figure [1] 110/20 figures [1] 110/6 final [1] 124/10 finally [3] 75/24 127/6 133/6 financial [1] 127/8 find [10] 8/7 8/11 22/18 38/23 59/20 63/12 85/6 85/10 103/19 126/8 finding [1] 17/25 findings [1] 44/12 fine [3] 18/1 64/8 100/11 finished [1] 45/7 Finlay [1] 136/12 Fiona [1] 136/12 first [44] 6/16 7/9 7/19 7/20 9/21 10/7 10/19 17/22 18/12 25/6 25/23 26/12 27/3 45/21 46/4 46/16 46/20 51/3 56/21 61/9 72/22 73/24 86/8 86/8 87/6 87/12 88/3 90/13 90/21 92/22 92/24 93/13 102/2 102/20 102/21 102/23 104/5 104/5 119/25 120/2 122/19 124/6 125/4 125/8 first-hand [1] 73/24 fit [2] 64/18 99/18 five [1] 110/14 fivefold [1] 117/9 flagged [2] 53/21 55/2 flew [1] 40/25 flexible [2] 11/12 70/7 fliers [1] 37/11 floor [1] 73/19 flow [1] 12/8 flu [3] 67/12 67/20 70/9 flu pandemic [1] 67/12 fluid [3] 20/22 21/2 21/5 focus [4] 9/1 14/21 45/16 83/4	focused [1] 61/16 focusing [1] 8/22 foetal [2] 13/20 90/15 follow [4] 17/16 67/1 124/23 124/24 follow-up [2] 124/23 124/24 followed [3] 17/20 17/21 59/12 following [4] 7/11 32/6 36/21 54/23 foot [2] 46/8 79/12 forefront [1] 74/24 Foreign [1] 62/1 form [9] 33/14 33/15 35/24 49/2 95/6 96/21 106/9 113/23 119/10 format [3] 35/20 60/25 75/10 formula [1] 95/11 fortunate [1] 96/8 fortunately [2] 123/17 125/20 forum [1] 76/25 forward [7] 41/6 53/2 79/21 80/1 122/18 128/4 134/25 found [8] 59/14 59/20 59/22 99/22 110/5 112/20 113/2 113/12 Foundation [1] 81/12 four [10] 23/19 61/22 92/8 98/23 99/11 100/4 112/2 117/9 121/14 124/18 four weeks [1] 98/23 four-hour [1] 100/4 Fraser [6] 1/13 1/16 87/6 87/10 137/3 137/6 free [8] 3/20 40/20 51/7 85/14 115/12 115/22 125/1 125/15 freedom [3] 50/3 50/9 50/18 frees [1] 50/3 frequency [1] 24/9 frequent [2] 37/10 105/5 frequently [5] 36/24 44/9 63/5 113/15 118/19 fresh [4] 20/3 20/6 22/23 33/1 Friday [1] 136/17 fridge [1] 34/3 friend [1] 98/6 frightened [1] 108/16 from [115] 2/20 3/13 6/20 7/14 9/10 10/15 11/2 11/3 11/4 11/9 13/7 14/24 17/1 18/6
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F	Gavin [1] 25/7 Gavin Cho [1] 25/7 gene [10] 10/15 10/17 10/21 11/2 14/5 14/6 14/7 14/8 16/2 89/16 general [21] 3/1 30/11 58/5 64/24 78/8 79/19 83/2 83/24 84/25 87/14 88/6 111/19 112/2 112/8 112/21 112/24 114/18 114/22 118/4 120/5 132/21 generally [15] 6/11 21/10 22/1 22/8 23/13 49/2 53/19 58/12 59/12 61/16 71/6 87/1 121/8 121/17 133/8 generals [1] 31/12 generate [1] 79/21 generations [1] 107/15 generically [1] 96/23 genes [1] 89/20 genetic [5] 44/7 45/22 89/15 97/5 108/10 genned [1] 121/18 genotype [3] 103/22 118/6 125/9 genotypes [1] 26/24 get [56] 11/20 11/25 12/1 12/3 12/8 12/18 12/20 12/23 13/2 13/2 13/4 13/6 14/4 18/24 22/15 23/3 30/23 40/5 41/11 44/24 45/15 45/19 46/7 47/6 65/6 66/13 67/17 69/4 70/20 75/16 76/12 76/13 79/18 90/11 91/24 92/15 94/2 94/21 97/5 100/6 107/24 108/20 108/21 110/11 111/23 112/1 117/19 117/25 123/14 124/25 129/10 131/19 131/22 133/15 133/16 134/1 getting [19] 17/16 21/4 27/19 27/19 40/16 41/13 42/16 45/13 49/2 63/10 98/14 98/23 98/24 101/8 101/10 117/11 118/15 119/1 129/9 Ghana [1] 10/23 girl [1] 125/6 give [28] 4/8 9/4 10/11 18/8 18/23 18/23 19/8 19/19 22/24 23/24 27/17 35/5 36/6 40/20 51/6 53/2 53/8 68/24 81/4	93/15 93/16 97/9 97/16 98/13 108/18 117/19 127/24 136/2 given [37] 3/18 4/24 17/24 19/13 21/8 23/18 27/14 28/6 29/13 38/15 51/5 51/17 51/25 54/11 59/2 66/24 71/7 74/15 86/5 88/13 94/6 94/8 94/11 95/8 96/16 97/9 99/13 102/17 105/6 106/16 106/24 119/11 119/11 119/12 119/14 120/10 129/24 givers [1] 127/15 gives [2] 11/14 50/4 giving [13] 1/11 19/2 51/3 81/2 89/2 94/1 98/12 102/19 103/23 127/17 127/18 128/6 135/3 glad [2] 85/21 134/10 gland [3] 94/23 94/23 94/24 globin [1] 90/16 go [24] 11/10 11/24 12/7 13/3 21/25 26/17 28/1 28/25 36/4 41/6 42/10 43/12 44/4 46/23 53/24 68/23 77/9 98/23 108/23 108/23 116/21 129/15 130/12 135/10 goes [6] 11/14 21/18 82/24 93/21 94/10 115/19 going [42] 7/5 13/12 19/21 20/11 21/25 26/9 38/18 41/17 42/10 44/23 45/21 50/14 54/14 56/19 63/12 65/3 65/4 67/22 68/2 71/11 76/15 78/24 82/22 83/10 83/21 91/24 94/14 95/20 96/22 97/17 97/24 98/6 98/7 100/25 107/22 109/1 114/8 115/1 117/14 120/16 121/17 133/19 gone [3] 28/16 54/19 124/16 good [22] 1/3 18/2 18/3 18/6 19/5 23/24 27/9 43/3 50/17 52/7 78/10 79/2 79/10 79/15 86/20 106/19 117/14 118/4 119/2 131/13 135/23 135/25 got [22] 14/19 15/2 23/9 27/15 35/8 42/25	45/14 47/19 63/16 79/1 79/2 79/3 81/3 81/24 82/16 83/6 83/15 83/15 100/2 110/21 131/17 131/21 government [12] 60/22 61/17 61/18 61/20 61/21 61/22 61/24 63/7 64/11 64/22 67/8 67/20 government's [2] 61/25 76/1 GP [2] 82/20 97/2 GPs [1] 82/12 grab [1] 132/11 gradually [1] 58/11 grand [2] 31/20 31/23 grants [1] 47/19 gratia [1] 127/8 great [5] 80/19 86/11 105/8 107/12 132/18 greatly [1] 102/6 Greece [1] 49/6 Greek [1] 98/6 grew [2] 8/8 8/20 grounded [2] 63/17 63/20 group [25] 11/1 16/9 16/10 17/5 30/15 38/11 40/14 44/18 44/25 48/23 48/23 48/24 68/21 82/13 82/14 105/22 112/20 114/1 116/16 118/3 118/6 121/13 123/18 129/8 136/11 groups [3] 70/5 83/5 100/13 grow [1] 91/14 growing [1] 5/3 growth [2] 94/24 132/23 GT [1] 37/19 guardian [1] 106/11 guidance [6] 29/15 62/10 62/11 69/17 69/18 69/21 guideline [7] 17/12 28/1 32/8 50/12 50/17 55/24 63/18 guidelines [29] 17/7 17/9 17/19 18/1 18/5 24/24 25/3 25/5 25/9 26/10 27/24 32/7 32/15 54/23 54/25 55/23 62/4 62/7 62/10 62/12 62/15 62/19 62/25 63/15 78/25 82/8 102/2 102/4 102/10 guilt [1] 40/3 guy [2] 116/17 132/17	guys [2] 92/7 107/16 H had [130] 3/20 3/22 6/15 12/13 12/13 13/19 13/25 14/15 14/22 15/10 15/18 16/3 16/13 17/8 18/2 23/21 23/23 29/21 29/21 29/22 31/23 32/9 33/25 34/3 34/5 34/6 34/7 36/12 37/24 38/11 38/13 39/18 40/7 40/13 40/23 40/24 41/1 42/2 46/2 47/3 47/11 48/4 48/6 48/9 48/25 49/8 50/15 54/23 57/16 57/16 58/10 61/14 61/18 63/9 64/7 65/1 66/1 67/2 67/3 69/13 70/13 70/20 73/21 74/2 74/2 74/13 74/15 75/6 76/5 77/2 77/4 77/14 77/14 77/20 78/13 84/6 95/10 98/4 98/10 98/14 104/23 106/4 108/1 110/12 110/14 110/18 110/19 111/11 112/4 112/12 112/17 113/3 113/6 114/2 115/11 115/13 116/8 117/18 117/22 118/8 118/10 118/14 118/19 119/8 119/24 119/25 120/1 120/4 120/8 121/12 121/21 122/20 123/2 123/6 123/7 123/16 123/19 124/15 124/15 124/16 125/10 126/4 126/14 126/22 131/2 131/7 131/11 131/21 132/3 134/3 hadn't [3] 17/22 61/10 122/18 haematinics [3] 56/23 58/18 58/21 haematologist [8] 2/4 8/15 53/13 71/5 74/16 110/22 114/25 115/7 haematologists [2] 30/12 40/10 haematology [27] 1/25 7/22 8/25 14/22 26/4 30/11 31/24 32/7 33/4 33/8 53/15 54/9 54/22 73/16 73/16 96/25 97/7 101/16 101/19 101/20 102/24 103/1 111/11 112/19 114/14 114/22 124/24 haemoglobin [35]	11/3 11/13 12/25 13/20 13/20 14/5 14/7 14/9 18/13 20/18 21/18 23/3 28/19 28/20 29/22 33/9 56/8 56/16 58/2 58/5 58/6 58/8 58/22 58/23 59/2 59/11 59/11 90/10 90/10 90/14 90/14 90/15 97/20 98/25 100/22 haemoglobin A [1] 14/9 haemoglobinopathies [4] 43/18 43/24 44/7 51/19 haemoglobinopathy [2] 29/10 92/13 haemoglobins [4] 21/13 99/19 114/4 116/13 haemolysis [1] 113/25 haemolytic [1] 114/2 haemophilia [12] 16/8 16/9 41/25 48/9 48/10 48/11 48/23 49/1 49/4 73/23 73/25 74/3 haemorrhage [1] 54/3 Haematology [1] 32/12 half [2] 48/6 82/11 halve [1] 118/19 hand [5] 25/12 26/12 46/8 73/24 108/23 hand-foot [1] 46/8 handed [1] 83/13 handful [4] 65/6 72/20 101/17 128/25 handle [3] 45/9 48/12 65/4 hands [1] 23/9 handwritten [3] 34/18 34/20 83/9 happen [7] 13/22 31/23 65/13 72/9 83/10 100/16 104/1 happened [4] 27/13 46/1 120/4 135/24 happening [6] 31/21 32/4 44/20 97/4 105/9 121/19 happens [3] 46/9 106/15 106/17 hard [5] 3/21 22/21 23/10 74/19 84/20 harm [1] 81/11 harmful [1] 57/12 has [63] 4/12 10/21 11/1 15/2 16/7 27/14 30/25 31/16 39/22 43/21 46/11 50/1
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H	70/24 71/7 74/17 75/17 75/20 76/2 76/25 82/10 83/1 84/1 120/14 health-related [1] 67/4 healthy [2] 100/2 100/2 hear [2] 55/8 87/2 heard [12] 8/13 8/13 16/7 31/16 39/22 55/4 62/24 89/10 89/13 96/1 122/12 126/11 hearing [3] 74/5 136/10 136/13 hearings [1] 48/6 heart [9] 12/1 12/2 12/9 12/10 59/24 81/18 94/19 101/9 132/16 hearts [5] 63/23 64/2 76/23 77/6 100/2 heat [1] 47/17 heavily [1] 127/14 heck [1] 100/5 heed [1] 134/11 held [4] 2/7 33/2 33/3 33/4 help [7] 35/22 43/5 66/13 67/22 78/24 79/3 85/19 helped [2] 27/12 78/20 helpful [3] 15/14 17/24 66/17 helping [2] 46/22 123/13 hence [1] 80/10 hep [1] 132/20 hep C [1] 132/20 hepatic [2] 21/22 29/4 hepatitis [75] 7/7 7/10 7/12 7/13 7/24 7/25 8/13 19/3 30/8 31/6 36/16 36/18 37/13 38/3 38/5 38/7 38/14 38/16 44/15 44/15 70/21 71/6 71/8 72/23 73/1 73/10 73/18 74/18 74/24 75/6 87/24 88/8 104/12 104/12 104/13 104/16 109/6 109/7 109/22 110/1 110/9 110/11 111/5 111/9 111/19 112/2 112/3 112/6 112/18 114/11 115/24 121/19 122/14 122/20 123/2 123/3 123/6 123/14 124/18 125/24 126/2 126/5 126/15	127/2 127/7 130/16 130/22 131/4 133/6 133/8 134/23 136/14 hepatitis A [1] 7/12 hepatitis B [8] 7/13 7/24 8/13 44/15 73/18 104/12 104/13 104/16 hepatitis C [50] 30/8 36/16 36/18 37/13 38/3 38/5 38/7 38/14 38/16 44/15 70/21 71/6 71/8 74/18 74/24 75/6 104/12 109/6 109/7 109/22 110/1 110/9 111/5 111/9 111/19 112/2 112/6 112/11 112/14 112/17 112/18 114/11 115/24 122/14 122/20 123/2 123/3 123/6 123/14 125/24 126/2 126/5 126/15 127/7 130/16 130/22 131/4 133/8 134/23 136/14 hepatologist [3] 115/9 115/15 115/21 hepatology [6] 110/22 111/12 115/12 115/13 124/23 125/14 her [7] 46/3 46/4 121/18 125/6 125/11 126/23 127/23 here [13] 1/6 40/1 43/15 45/11 49/16 59/2 72/8 72/10 80/14 82/22 86/23 96/7 101/24 hesitance [1] 52/3 hiding [1] 122/24 hierarchial [1] 4/19 high [5] 10/22 25/23 26/24 56/19 82/20 high-risk [1] 26/24 higher [2] 12/17 80/24 highest [1] 44/8 highlight [2] 63/6 84/22 highlighted [1] 10/5 highly [1] 6/17 him [1] 29/22 his [5] 30/1 103/5 132/4 132/6 134/8 historically [1] 104/24 hitting [1] 46/3 HIV [5] 36/13 36/16 44/15 104/12 134/23 hold [1] 75/25 holding [1] 82/1 holds [1] 89/25 holiday [2] 67/24 68/1 Home [1] 62/2 Home Office [1] 62/2	homosexual [1] 9/24 hope [2] 29/25 86/1 hoped [1] 15/13 hopefully [2] 92/14 129/18 hoping [1] 80/4 Hopkins [1] 78/15 hormones [1] 94/25 horrible [7] 12/11 19/18 30/2 49/7 116/6 116/21 116/21 horrors [1] 49/4 hospital [28] 2/4 5/22 5/22 5/23 13/17 15/25 31/18 31/19 32/23 33/4 33/6 33/21 53/14 54/11 55/11 77/25 87/21 87/25 88/9 92/6 92/18 97/2 111/18 111/25 115/13 125/1 129/4 130/25 hospitals [3] 14/15 40/7 40/9 hour [1] 100/4 hours [8] 13/1 19/17 19/17 23/1 82/23 94/11 100/5 100/10 house [3] 4/4 4/15 7/19 houseman [1] 7/3 housing [3] 42/22 46/25 47/4 how [64] 1/9 8/4 12/12 12/14 15/6 15/15 22/4 23/13 24/15 29/17 32/8 34/21 36/24 37/22 45/8 47/9 48/12 48/17 48/18 48/19 49/7 49/12 54/24 55/8 56/14 56/17 56/17 56/21 63/23 64/14 65/4 68/11 69/10 71/4 72/9 73/12 73/20 75/25 76/10 77/8 78/9 81/6 81/7 81/23 85/11 86/25 88/22 88/24 91/5 92/5 93/5 97/4 101/14 103/9 105/17 111/6 114/15 115/3 120/9 120/9 120/15 123/12 128/13 134/2 Howard [1] 27/12 however [2] 58/9 63/6 Hudson [1] 136/12 huge [2] 103/11 129/18 hundred [1] 15/19 hunt [2] 8/14 50/15 hydrated [2] 13/16 43/1 hydroxyurea [1] 13/19	I I absolutely [1] 37/2 I accept [1] 66/25 I actually [5] 6/23 9/23 40/19 47/1 106/19 I agreed [1] 44/13 I also [3] 55/16 69/5 84/21 I always [1] 15/13 I am [7] 8/10 39/10 83/6 83/15 85/3 85/23 124/1 I and [1] 40/13 I answer [1] 31/15 I apologise [3] 8/11 73/14 73/21 I argued [1] 61/19 I arrived [1] 109/10 I ask [1] 76/24 I asked [5] 12/13 62/5 62/7 126/21 126/23 I attended [1] 30/11 I became [3] 9/23 9/24 84/24 I believe [3] 35/17 79/25 86/1 I came [4] 8/23 49/22 57/17 67/25 I can [8] 16/14 17/14 52/1 52/23 53/7 79/13 109/13 134/20 I can't [8] 30/10 31/8 54/20 60/2 72/9 72/12 102/6 102/7 I cannot [1] 102/5 I chose [3] 64/4 77/24 85/16 I clearly [1] 110/18 I co-chaired [1] 68/21 I come [1] 65/18 I congratulated [1] 50/18 I continued [1] 113/16 I could [4] 9/3 14/24 24/1 63/18 I couldn't [1] 71/15 I did [13] 3/7 38/25 41/11 55/14 61/17 63/6 65/5 65/24 69/24 74/3 74/6 77/22 121/6 I didn't [6] 24/2 24/18 71/10 71/15 71/17 135/1 I do [10] 4/21 27/17 42/11 50/24 76/21 84/17 84/18 96/6 123/20 126/16 I don't [39] 4/17 5/21 7/2 7/20 8/21 9/25 10/4 23/5 30/19 31/22	32/1 32/19 36/2 38/25 39/20 51/23 54/18 55/2 55/16 72/11 75/10 75/11 84/9 86/25 88/6 100/18 100/19 100/24 104/13 105/13 106/20 110/23 111/2 122/19 123/8 126/16 126/21 131/3 133/23 I endowed [1] 83/25 I enquired [1] 52/9 I even [1] 22/14 I expect [2] 32/18 67/9 I expected [1] 65/6 I explained [1] 76/10 I failed [1] 8/10 I feared [1] 41/24 I felt [8] 9/2 9/2 62/6 64/20 76/9 76/10 77/24 81/10 I find [2] 8/7 8/11 I gave [1] 130/9 I generally [1] 61/16 I go [1] 68/23 I going [2] 7/5 63/12 I got [2] 23/9 47/19 I had [6] 14/22 63/9 73/21 78/13 111/11 122/20 I have [28] 8/8 12/15 37/8 41/19 42/17 49/6 49/21 50/7 51/15 55/5 61/1 64/16 71/18 74/19 75/22 76/14 81/3 85/16 85/18 93/11 116/7 123/1 123/2 123/7 127/20 130/15 133/20 135/11 I haven't [1] 105/1 I helped [1] 27/12 I hope [1] 86/1 I just [5] 1/17 36/18 68/8 72/19 128/25 I knew [3] 26/7 66/12 71/11 I know [4] 25/8 42/14 84/18 133/10 I left [4] 15/9 25/8 63/13 83/24 I look [1] 92/1 I looked [1] 132/2 I made [5] 10/1 69/19 69/21 134/22 135/2 I may [4] 1/3 3/16 48/3 84/15 I mean [15] 12/12 23/9 23/23 27/8 29/19 30/19 37/8 49/6 52/5 52/19 59/15 63/3 63/18 103/16 132/11
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------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

I	34/12 35/13 36/3	28/18 28/21 32/19	improve [6] 44/25	inflammation [2]	interested [2] 37/22
I mentioned [2]	38/11 39/9 40/1 40/2	36/4 46/2 48/16 48/21	57/25 70/17 79/22	72/24 73/3	71/12
103/12 122/23	44/23 44/23 49/19	56/3 66/11 66/13 76/6	103/6 131/16	influenced [1] 41/21	interesting [5] 27/4
I might [1] 135/12	50/8 52/2 54/18 55/14	78/4 82/2 87/12 93/8	improving [3] 80/2	informal [2] 35/25	40/6 45/18 50/8 83/1
I move [1] 51/14	56/2 56/15 57/15	99/8 110/21 114/21	107/12 129/17	100/7	interestingly [1]
I moved [1] 7/22	57/19 63/3 65/12 66/9	119/17 124/1 133/15	incentive [1] 79/16	information [18] 35/1	15/17
I must [1] 8/17	67/7 71/23 77/10	134/1	incentivise [1] 79/2	35/5 47/10 62/24	interferon [15] 110/17
I needed [1] 67/21	79/19 80/18 81/22	I wouldn't [1] 59/15	incentivising [1]	69/17 105/6 106/1	111/8 111/10 111/15
I never [1] 66/4	82/21 82/21 82/25	I wrote [2] 24/13 82/9	79/14	106/17 106/24 109/20	112/21 113/12 116/4
I note [1] 47/24	84/18 84/22 85/8	I'd [2] 23/23 100/9	include [1] 58/4	119/24 120/11 127/15	116/6 117/11 118/9
I obviously [3] 71/19	88/14 97/12 105/19	I'll [1] 18/4	included [1] 84/2	127/18 130/22 130/22	118/10 118/20 119/6
104/10 111/7	105/20 106/23 108/2	I'm [42] 1/8 8/9 16/21	includes [1] 81/16	131/1 131/3	119/9 119/25
I often [1] 46/25	108/13 110/5 110/14	17/11 20/4 20/16	including [3] 31/25	informed [5] 54/4	interim [2] 3/8 60/6
I only [1] 12/12	112/24 115/18 116/7	24/25 25/5 26/9 33/17	35/14 120/13	104/11 104/21 107/4	intermedia [3] 91/10
I personally [1] 8/14	118/5 118/8 118/13	34/12 34/13 36/15	income [1] 81/21	119/19	91/13 91/18
I persuaded [1] 40/19	118/25 120/3 120/10	37/7 38/8 41/17 42/10	increase [3] 18/16	infused [1] 94/9	intermediaries [2]
I played [3] 64/3 68/3	121/14 122/16 123/5	42/15 42/17 47/13	24/20 95/23	infusion [3] 19/13	135/11 135/13
69/6	123/15 123/16 124/1	47/23 56/4 60/1 70/15	increased [1] 101/8	19/16 94/14	intermediary [1] 53/3
I presented [1] 110/16	126/6 126/9 126/24	71/9 76/15 85/21	increasing [3] 20/19	inherit [1] 10/15	intermittent [1] 119/9
I presume [1] 20/9	127/16 127/16 130/9	92/20 92/21 104/20	20/21 45/7	inherited [8] 10/14	internally [1] 43/12
I read [1] 26/7	130/25 133/9 134/9	106/2 106/7 106/8	incredibly [1] 109/12	11/6 40/2 89/15 89/20	International [1]
I really [1] 121/1	I thought [3] 38/17	107/5 109/10 110/23	indeed [5] 33/1 48/5	91/4 91/4 98/5	69/10
I recall [2] 38/17	65/25 84/4	123/1 123/21 123/25	51/16 67/24 74/1	initial [2] 25/21 111/4	interrogate [1] 78/19
38/22	I told [1] 64/19	133/19 134/9 134/20	independent [2]	initially [3] 33/9	interrogation [1] 41/2
I reflected [1] 52/5	I trained [1] 7/9	I've [4] 28/18 74/23	60/22 60/24	113/11 118/5	intervals [1] 103/23
I remember [12] 5/20	I understand [3] 5/14	83/6 83/14	INDEX [1] 136/19	injection [3] 94/8	intervention [4] 3/20
5/25 21/15 23/16 31/9	42/15 122/21	idea [2] 84/4 100/11	India [1] 10/24	119/11 119/14	3/22 9/18 85/14
39/20 52/6 74/4 76/24	I understood [1]	ideally [2] 19/17 23/6	Indian [1] 90/6	innovation [1] 50/11	into [44] 6/14 6/18
77/3 120/17 126/6	73/20	identified [4] 38/21	indicated [2] 31/17	inpatients [1] 21/7	7/22 11/14 11/15
I repeated [1] 134/21	I waited [1] 71/3	39/8 70/20 110/9	73/7	input [1] 62/20	21/18 22/16 22/22
I reserved [1] 61/15	I want [10] 3/15 35/1	identify [2] 135/7	indicating [1] 34/16	inquiries [1] 77/2	22/23 23/6 28/5 31/13
I respect [1] 49/24	41/18 43/11 52/12	135/18	indication [2] 4/25	inquiry [27] 1/9 4/12	31/18 35/13 40/5
I respected [1] 49/23	53/11 60/3 86/12	if [159]	57/24	15/2 16/7 18/8 31/16	42/13 42/19 46/23
I reviewed [1] 15/17	135/21 136/2	ill [10] 15/14 29/2 37/6	Indications [1] 57/22	39/22 48/5 51/17 53/6	54/20 59/4 59/5 60/5
I said [3] 50/16 67/1	I wanted [4] 14/21	37/24 45/5 58/7 82/20	indicators [1] 100/15	62/23 70/3 70/18 72/1	62/1 67/23 69/1 69/20
76/8	52/23 84/17 134/17	83/6 83/7 83/15	indigenous [1] 90/3	73/7 75/2 75/4 77/4	72/12 77/2 90/5 91/8
I sat [1] 61/13	I warned [1] 73/14	illness [2] 45/6 107/8	individual [7] 29/12	86/2 89/10 92/1	94/14 95/10 101/9
I saw [2] 45/10 70/9	I was [54] 3/19 4/17	illuminated [1] 86/6	45/23 50/10 84/20	122/12 122/19 135/8	101/14 106/22 109/1
I say [8] 14/17 22/8	7/3 7/19 8/22 13/14	illuminating [1]	98/4 98/20 99/1	135/14 135/17 136/17	116/9 116/10 117/5
96/18 103/15 105/10	14/16 14/17 14/21	134/17	individually [1] 58/25	insidiousness [1]	117/6 121/2 122/9
122/1 128/17 129/20	17/24 19/11 26/2 31/2	imagine [3] 94/12	individuals [1] 43/23	84/23	130/14 131/19
I see [1] 96/5	32/10 39/10 39/19	102/6 109/13	inequalities [5] 42/11	insight [1] 121/2	intra [1] 28/11
I sent [1] 15/17	39/20 42/3 44/21	immediate [1] 18/20	42/14 42/18 43/5	insofar [1] 61/23	intravenously [1]
I set [1] 110/12	54/11 54/13 60/19	immensely [1] 4/7	75/13	instance [4] 62/3	94/7
I should [6] 14/25	60/22 61/10 61/19	impact [5] 113/21	infected [6] 21/11	75/21 80/23 82/9	introduced [3] 30/8
47/19 90/25 93/12	61/24 62/3 62/8 64/6	116/24 122/17 123/4	36/13 71/1 85/5 85/24	instances [1] 5/10	108/6 109/11
107/9 127/21	66/12 67/24 68/1	134/3	130/3	instead [1] 114/5	inverted [1] 60/12
I spent [1] 8/15	68/19 71/2 71/4 71/12	impacted [1] 134/6	infection [13] 10/20	institute [2] 3/6 5/11	investigation [1] 71/3
I stalked [1] 18/5	73/2 76/4 77/19 78/13	impacts [1] 120/15	18/21 30/21 35/15	institutional [1] 40/15	investigations [1]
I stand [1] 57/20	79/19 79/20 79/22	imperative [2] 5/4	35/15 35/18 38/3	insurance [2] 108/19	115/16
I started [4] 16/12	84/24 89/3 102/4	117/25	42/25 52/21 88/9	108/21	invite [2] 72/4 87/6
104/15 110/10 110/11	111/12 114/25 119/8	importance [3] 1/9	103/25 113/10 130/1	intake [1] 93/17	invited [1] 43/16
I stepped [1] 75/22	119/15 122/17 127/10	67/23 119/21	infections [9] 6/25 7/1	integrate [1] 62/21	involved [13] 7/4 47/9
I stick [1] 64/18	127/10 130/6	important [9] 58/4	51/23 51/25 80/22	intensively [3] 117/18	47/13 104/7 110/11
I still [2] 27/15 29/20	I wasn't [1] 60/1	92/23 93/6 105/20	81/15 85/6 104/2	117/18 131/14	110/20 119/20 120/15
I stopped [1] 27/13	I went [2] 26/3 60/18	114/3 123/13 123/21	134/23	inter [1] 62/9	122/11 122/13 127/7
I talked [2] 50/14	I will [5] 8/18 30/9	132/15 134/13	infections would [1]	interact [1] 46/22	127/10 127/14
74/12	30/14 67/1 108/18	importantly [2] 85/9	104/2	interaction [4] 14/5	involvement [3] 64/1
I think [76] 1/4 3/19	I wonder [2] 47/25	118/16	infectious [3] 72/25	78/21 104/5 120/8	75/1 89/1
4/17 6/18 9/5 15/9	71/22	imported [1] 65/7	84/24 85/2	interactions [1] 78/19	involves [2] 22/12
16/22 27/15 31/1 31/7	I worked [1] 120/3	impossible [1] 77/8	infective [4] 30/21	interest [4] 5/1 43/22	92/18
	I would [23] 16/5	impotence [1] 13/5	30/23 30/24 30/25	80/19 132/18	involving [1] 76/2

(45) I mentioned - involving

<p>I</p> <p>iron [47] 18/22 18/24 19/2 19/6 19/9 19/20 19/22 20/2 20/3 23/22 35/14 44/23 56/23 93/12 93/16 93/20 93/21 94/2 94/3 94/9 94/18 94/18 94/21 95/2 95/17 96/12 96/13 98/14 103/8 103/10 105/10 105/11 116/24 117/2 117/13 124/14 124/18 124/22 125/21 125/25 131/12 131/14 131/15 131/20 131/21 131/22 132/4</p> <p>irregularly [1] 101/13</p> <p>irritant [1] 19/18</p> <p>is: [1] 45/8</p> <p>is: how [1] 45/8</p> <p>ischaemic [1] 26/15</p> <p>isn't [5] 13/13 48/15 80/4 93/13 125/7</p> <p>issue [14] 35/17 40/6 49/16 60/14 61/10 66/19 70/2 70/25 76/2 77/10 77/11 95/19 103/11 105/10</p> <p>issues [28] 16/25 40/1 41/15 41/19 44/24 45/16 48/17 48/18 60/10 64/4 69/2 70/8 71/10 75/17 81/21 88/22 95/22 96/3 96/13 96/13 101/9 113/20 118/14 122/3 124/5 125/25 132/23 132/24</p> <p>it's [35] 4/17 5/24 12/19 17/11 17/13 20/14 20/15 21/3 21/15 21/16 27/18 28/15 30/2 52/7 52/8 55/4 56/18 60/14 61/2 78/8 81/17 81/17 82/21 88/14 88/15 90/2 90/3 91/15 94/12 99/25 105/20 118/16 133/3 133/13 133/18</p> <p>it's a [1] 30/2</p> <p>itis [1] 73/2</p> <p>its [10] 3/22 11/14 30/2 36/7 48/24 58/18 75/5 95/6 95/13 117/2</p> <p>itself [2] 88/9 131/4</p>	<p>join [2] 62/5 62/7</p> <p>joint [6] 27/17 27/18 132/14 132/19 132/22 132/25</p> <p>joints [1] 74/5</p> <p>jokes [1] 108/19</p> <p>Journal [2] 32/12 41/14</p> <p>journals [1] 32/14</p> <p>judge [1] 4/2</p> <p>judged [1] 25/22</p> <p>junior [2] 4/19 7/8</p> <p>jury [1] 40/23</p> <p>just [55] 1/6 1/17 10/4 10/11 13/8 19/5 20/15 22/11 23/1 25/12 26/6 26/10 27/1 36/18 36/22 41/17 48/3 51/15 52/13 52/24 53/7 53/22 59/16 60/5 61/22 65/9 68/8 68/8 68/9 72/1 72/19 76/15 87/12 88/10 91/22 92/12 96/7 96/23 102/16 104/5 105/2 107/22 112/4 112/4 112/12 114/24 123/1 127/21 128/15 128/19 128/25 132/20 133/19 134/6 134/20</p> <p>K</p> <p>Kate [1] 25/6</p> <p>Kate Ryan [1] 25/6</p> <p>keep [7] 13/15 13/16 22/6 33/18 33/24 93/25 98/19</p> <p>keeping [1] 88/12</p> <p>kept [8] 18/25 32/14 33/20 34/7 34/24 43/1 72/10 125/21</p> <p>Key [1] 25/14</p> <p>kidney [1] 93/10</p> <p>kidneys [1] 100/2</p> <p>kids [1] 96/24</p> <p>kill [2] 12/10 19/21</p> <p>killer [1] 95/4</p> <p>kind [11] 4/4 16/12 16/16 37/8 41/11 43/4 49/9 63/11 65/12 68/19 68/20</p> <p>King's [1] 15/25</p> <p>knew [12] 7/25 8/14 26/7 32/16 32/17 48/11 66/12 71/11 119/16 120/4 120/5 124/15</p> <p>knit [1] 123/18</p> <p>knocked [1] 5/24</p> <p>know [115] 7/2 8/21 13/12 14/12 15/14 17/23 21/11 23/7</p>	<p>23/23 25/8 29/24 32/8 34/5 35/8 36/3 37/24 42/14 44/25 45/5 45/6 45/7 45/9 46/9 46/13 48/13 48/20 49/13 54/2 63/16 65/16 65/17 71/10 71/15 71/15 72/6 76/4 77/23 78/6 78/23 82/2 84/9 84/18 85/8 86/25 88/15 88/20 88/23 89/5 90/18 95/23 96/19 97/5 97/13 97/14 97/15 98/12 99/2 99/17 99/19 100/1 100/22 101/2 101/5 102/5 103/13 104/13 105/21 105/23 106/20 106/23 107/3 107/14 107/21 108/5 108/14 108/15 108/17 108/17 108/21 109/13 109/16 110/23 111/2 111/21 112/20 113/20 114/7 115/7 116/14 116/19 117/10 117/25 119/21 120/4 120/8 120/10 120/19 120/22 120/25 121/18 122/1 122/3 122/18 122/20 123/9 124/20 126/21 127/13 129/11 133/10 133/13 133/17 134/2 134/8 134/9</p> <p>knowing [6] 50/19 55/15 55/15 67/18 109/11 120/3</p> <p>knowledge [5] 8/7 8/21 73/24 88/8 127/13</p> <p>knowledgeable [1] 121/16</p> <p>known [6] 16/5 47/14 54/14 58/18 67/2 113/24</p> <p>knows [2] 85/24 123/25</p> <p>L</p> <p>lab [3] 33/8 33/9 33/10</p> <p>label [1] 34/16</p> <p>labels [1] 34/7</p> <p>laboratories [1] 8/19</p> <p>laboratory [4] 6/5 33/6 53/20 88/19</p> <p>laid [1] 85/22</p> <p>Lancet [1] 24/15</p> <p>LANGSTAFF [2] 76/20 137/4</p> <p>Lansley [1] 61/11</p> <p>large [3] 14/15 44/2</p>	<p>118/8</p> <p>largely [1] 20/7</p> <p>last [1] 116/23</p> <p>late [2] 13/23 17/1</p> <p>later [7] 5/23 13/5 19/22 46/13 74/11 118/6 128/19</p> <p>latest [1] 9/7</p> <p>lawyer [1] 77/23</p> <p>lawyers [2] 71/21 86/23</p> <p>laxity [1] 57/9</p> <p>layman's [2] 10/11 89/14</p> <p>lead [3] 69/11 109/11 115/7</p> <p>leader [1] 31/11</p> <p>leaders [1] 80/14</p> <p>leadership [1] 69/18</p> <p>leads [1] 5/12</p> <p>leaflet [1] 131/1</p> <p>leaflets [1] 130/21</p> <p>learn [4] 65/17 70/16 85/22 86/1</p> <p>learning [2] 13/8 85/12</p> <p>least [5] 37/16 48/7 49/17 77/15 120/22</p> <p>left [7] 15/9 25/8 26/12 63/11 63/13 83/24 86/24</p> <p>left-hand [1] 26/12</p> <p>legal [4] 72/3 72/4 79/8 79/9</p> <p>Leone [1] 69/12</p> <p>less [13] 9/1 10/12 25/20 26/13 27/11 27/25 28/7 29/22 45/16 58/22 59/3 59/3 98/17</p> <p>lessen [1] 129/6</p> <p>lessons [1] 70/16</p> <p>let [6] 12/5 71/24 71/24 72/1 77/10 107/23</p> <p>let's [2] 45/15 128/16</p> <p>letter [2] 63/4 82/10</p> <p>letters [2] 38/22 47/7</p> <p>leukaemia [1] 37/9</p> <p>leukaemias [1] 40/11</p> <p>leukocyte [1] 99/23</p> <p>level [4] 28/17 56/9 90/19 100/23</p> <p>levels [7] 10/22 12/25 13/20 67/25 94/25 104/17 105/11</p> <p>LFTs [2] 9/12 73/20</p> <p>liaise [1] 68/11</p> <p>liberty [1] 50/4</p> <p>life [17] 10/19 21/10 23/11 23/24 29/3 46/5 99/16 100/6 103/7</p>	<p>108/20 108/25 109/2 116/15 122/22 123/8 123/10 129/11</p> <p>life-saving [1] 29/3</p> <p>lifelong [1] 97/21</p> <p>lifespan [1] 21/14</p> <p>lifestyles [1] 98/8</p> <p>lightly [1] 119/18</p> <p>like [35] 12/1 24/18 27/7 27/16 41/7 48/15 49/3 49/10 51/7 52/8 56/19 59/24 69/14 76/17 76/18 84/14 87/13 89/16 93/22 94/8 98/20 101/3 105/17 107/10 115/3 117/7 121/8 121/19 123/22 124/13 127/23 128/11 131/14 133/25 134/1</p> <p>likely [3] 28/9 35/10 119/5</p> <p>limit [1] 31/7</p> <p>limitations [1] 39/16</p> <p>limiting [1] 31/4</p> <p>limits [1] 30/17</p> <p>lines [1] 81/10</p> <p>linguistic [1] 57/9</p> <p>links [1] 115/14</p> <p>listen [1] 66/20</p> <p>listened [2] 67/3 80/6</p> <p>listening [5] 10/9 52/24 72/7 89/12 134/21</p> <p>literally [4] 88/10 105/9 116/19 127/15</p> <p>literature [1] 18/17</p> <p>litres [1] 20/23</p> <p>little [6] 36/19 36/19 40/9 71/19 115/23 128/19</p> <p>live [10] 10/18 24/5 29/19 42/24 43/2 49/24 49/25 107/22 108/25 109/2</p> <p>lived [5] 42/21 42/22 48/24 105/21 122/22</p> <p>liver [46] 8/2 13/2 37/13 37/15 38/1 59/24 72/24 73/4 73/6 73/11 93/11 94/20 94/22 115/20 116/24 117/2 117/5 117/8 117/12 117/13 118/14 124/14 124/17 124/19 125/1 125/6 125/8 125/18 125/21 125/24 130/13 131/7 131/9 131/11 131/13 131/15 131/20 131/21 131/22 131/22 132/4 132/4 132/6 132/17 132/21</p>	<p>136/10</p> <p>liver-related [1] 124/19</p> <p>liver/iron [1] 124/14</p> <p>livers [2] 117/19 117/24</p> <p>lives [8] 24/16 29/20 83/3 100/12 105/22 129/18 134/3 134/6</p> <p>living [2] 91/23 129/18</p> <p>local [1] 97/2</p> <p>locally [1] 92/15</p> <p>London [5] 1/24 2/21 8/17 45/11 73/8</p> <p>long [17] 22/1 25/16 26/13 35/13 46/6 56/14 56/21 72/9 85/7 91/13 91/24 103/19 107/22 116/22 125/20 128/13 133/18</p> <p>long-term [7] 22/1 25/16 26/13 35/13 91/24 103/19 133/18</p> <p>longer [5] 18/20 82/4 99/14 117/23 119/14</p> <p>look [27] 11/18 14/24 15/13 25/2 38/18 38/21 38/22 39/8 39/13 39/17 45/20 49/15 55/24 63/13 70/21 74/3 74/6 81/3 81/23 82/20 89/22 92/1 118/8 126/16 126/16 130/2 130/17</p> <p>look-back [6] 38/21 38/22 39/8 39/13 39/17 70/21</p> <p>look-backs [1] 38/18</p> <p>looked [8] 4/12 28/17 41/24 42/1 75/8 75/15 132/2 134/14</p> <p>looking [14] 8/25 27/13 30/22 38/2 94/15 95/2 96/24 103/3 107/19 108/5 118/18 132/22 133/4 133/17</p> <p>looks [1] 15/18</p> <p>loosely [1] 57/7</p> <p>lose [2] 52/20 78/2</p> <p>losing [1] 73/22</p> <p>loss [1] 116/16</p> <p>lost [3] 49/9 120/22 124/18</p> <p>lot [26] 12/17 14/9 16/7 16/20 26/5 42/14 45/1 45/10 62/18 83/18 83/20 94/17 96/6 106/25 108/12 108/13 111/18 114/7 120/7 120/8 120/17</p>
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L	79/11 97/20 malaria [6] 7/1 10/19 10/21 89/21 89/22 90/1 man [1] 93/18 managed [1] 92/15 management [3] 77/25 110/12 131/1 manager [1] 92/20 managing [4] 17/9 81/6 91/14 91/14 Manchester [3] 5/24 7/9 7/10 manned [2] 16/14 46/21 mannered [1] 116/9 manual [1] 126/18 manually [1] 19/24 many [30] 10/1 10/9 14/2 15/6 23/13 25/8 27/11 34/21 37/1 42/21 58/3 60/9 62/19 72/2 73/3 80/21 84/19 86/25 92/5 96/11 96/11 96/22 107/18 111/23 112/1 117/20 124/14 124/14 129/8 129/14 Marcela [1] 56/25 March [2] 1/1 136/18 marked [1] 34/1 marriages [1] 108/6 marrow [5] 11/8 40/17 41/7 101/10 103/6 Marsden [1] 121/6 Mary [4] 1/12 1/14 87/6 87/8 massive [2] 54/3 133/3 matched [2] 34/4 103/20 matching [1] 33/24 material [1] 79/17 matter [7] 11/7 11/12 36/16 52/22 55/7 128/8 134/23 mattered [1] 49/23 matters [4] 70/2 70/4 72/21 135/4 may [36] 1/3 3/16 27/16 29/3 29/13 32/1 32/7 39/18 48/3 49/3 50/11 51/4 51/5 51/21 53/8 58/7 58/9 58/23 65/13 70/12 74/1 82/5 84/15 90/22 98/22 98/24 98/25 100/4 101/3 101/8 101/9 101/9 101/12 105/24 135/24 136/13 maybe [12] 13/8 20/4 23/4 23/5 76/5 96/3	103/4 103/5 103/6 117/23 120/24 130/10 MDT [2] 121/16 122/2 me [41] 6/18 9/6 27/3 27/7 40/7 45/2 45/12 48/5 48/19 49/20 50/1 61/1 62/2 62/8 63/9 64/8 66/8 70/22 70/25 71/21 71/24 71/25 72/1 74/21 75/16 76/15 76/17 77/10 78/18 78/19 78/19 78/20 78/22 78/22 81/4 93/6 115/5 123/7 127/22 127/23 133/19 mean [29] 10/2 12/12 23/9 23/23 27/8 29/19 30/19 31/7 31/22 32/11 32/15 35/21 37/8 49/6 52/5 52/19 56/12 57/7 59/15 60/17 61/21 63/3 63/18 72/24 91/23 98/3 103/16 131/13 132/11 means [3] 5/8 11/23 13/4 meant [4] 14/20 14/24 34/2 35/23 measles [1] 85/15 measures [1] 88/10 mechanically [1] 94/2 mechanism [1] 90/11 media [1] 88/9 median [1] 15/1 medical [26] 3/8 3/9 3/19 9/18 17/2 27/5 41/4 41/14 42/8 43/7 43/17 60/4 60/14 60/14 60/21 60/23 61/14 61/19 61/25 64/7 69/8 80/8 84/6 85/13 96/7 130/18 medication [3] 34/24 94/16 95/16 medications [1] 93/6 medicine [2] 4/18 49/17 Mediterranean [1] 90/4 medium [2] 26/19 26/22 meet [2] 16/23 46/2 meeting [1] 17/3 meetings [6] 7/5 16/21 68/24 79/1 121/16 122/2 members [2] 43/24 127/16 memory [8] 9/13 49/9 49/11 56/3 73/15 73/23 74/1 74/9	mental [1] 120/14 mentioned [12] 44/22 59/18 68/9 79/8 91/1 93/12 103/12 115/25 122/23 126/11 132/7 135/11 mentioning [2] 35/15 135/17 mentoring [1] 2/17 mesenteric [1] 29/8 met [3] 16/10 30/12 129/11 metacarpals [1] 46/6 metatarsals [1] 46/7 microscopes [1] 11/18 mid [3] 17/15 95/5 95/10 mid-1990s [1] 95/5 mid-2000s [1] 95/10 mid-teens [1] 17/15 Middle [2] 10/23 90/5 Middlesex [15] 2/4 14/14 15/8 15/22 17/9 17/18 24/10 31/21 36/12 38/23 40/14 46/18 57/14 57/15 73/16 might [19] 27/23 39/7 40/15 40/16 41/24 44/17 52/3 52/5 59/25 63/19 65/20 66/21 71/9 77/13 81/1 114/6 128/9 128/14 135/12 migrated [1] 10/25 mild [2] 14/10 116/9 milder [1] 96/20 milligrams [1] 93/20 million [2] 81/14 81/15 mind [4] 1/11 9/20 74/25 87/3 minds [5] 63/23 64/2 76/23 77/6 85/9 minimal [1] 99/25 minimise [2] 8/3 100/11 minimum [1] 19/16 minister [6] 62/3 65/2 68/15 68/25 69/2 69/7 ministers [8] 60/10 64/23 65/21 66/6 68/25 70/24 71/14 76/5 minor [1] 27/16 minutes [3] 67/8 71/23 128/15 miraculously [1] 131/23 mirrored [1] 51/21 misbehaving [1] 47/3	Mischa [2] 24/12 57/15 misremembered [1] 73/14 missing [2] 110/23 111/3 mission [1] 45/17 misuse [2] 57/19 81/22 misused [1] 57/18 MLSOs [1] 31/25 moderate [1] 5/6 modify [1] 48/25 module [1] 121/7 molecular [1] 2/2 molecule [1] 19/9 moment [12] 1/12 41/18 42/10 47/18 48/1 65/9 66/14 80/18 87/5 88/2 107/7 122/11 money [3] 41/25 78/2 84/5 monitor [9] 93/4 93/11 95/21 101/1 104/17 113/11 113/16 114/3 132/20 monitored [5] 101/19 112/24 112/25 113/1 120/7 monitoring [4] 91/22 111/13 114/7 119/21 monthly [2] 113/1 115/18 months [13] 4/6 6/16 8/16 9/6 37/1 37/16 46/5 58/12 90/20 91/11 118/7 119/13 133/13 moot [1] 40/19 mopping [1] 94/9 moral [1] 64/16 more [62] 4/20 5/8 8/17 8/22 13/21 17/20 20/13 23/23 35/12 35/13 36/19 36/19 39/9 39/21 40/21 41/10 42/3 43/19 45/5 45/9 48/13 49/13 49/17 49/19 52/21 54/8 57/17 59/20 61/17 63/5 65/18 68/4 68/13 71/6 74/10 78/8 78/10 78/21 79/21 81/10 83/18 83/21 84/17 84/18 88/9 92/15 95/11 103/17 103/18 105/15 106/23 107/10 108/13 113/4 120/10 124/3 124/3 127/12 128/18 131/5 133/8 133/9	morning [8] 1/3 50/15 99/20 126/12 134/15 135/2 135/12 136/9 mortgage [1] 108/22 most [18] 7/10 16/3 16/16 19/12 21/1 30/1 32/10 32/12 60/19 61/25 74/12 75/22 80/15 95/12 105/18 116/10 118/15 134/9 mother [2] 40/23 46/2 mothers [1] 46/12 mount [1] 117/4 move [9] 35/1 37/6 47/23 51/14 52/12 53/11 60/3 68/8 79/21 moved [4] 7/22 53/8 53/23 59/15 moving [5] 10/6 80/1 90/4 95/5 95/10 Ms [13] 1/13 1/16 86/20 87/6 87/9 87/10 87/12 127/21 133/24 136/13 137/3 137/5 137/6 MS ELIZABETH [2] 87/9 137/5 Ms Fraser [6] 1/13 1/16 87/6 87/10 137/3 137/6 Ms Prescott [4] 86/20 87/12 127/21 133/24 Ms Samantha [1] 136/13 much [35] 8/22 18/22 27/22 35/12 35/13 39/9 41/10 42/3 51/8 56/17 61/17 63/10 68/11 78/8 78/9 78/20 79/21 80/5 84/9 86/4 86/24 89/3 92/21 98/13 99/3 100/7 100/18 100/19 108/16 120/15 132/5 133/23 134/10 135/6 136/7 multi [3] 29/7 29/21 79/6 multi-organ [2] 29/7 29/21 multi-pronged [1] 79/6 multidisciplinary [3] 16/23 78/10 132/7 mum [3] 82/19 89/18 91/4 mums [1] 99/16 muscle [1] 12/3 muscles [1] 12/4 must [7] 8/17 17/3 23/11 56/2 59/5 80/25 128/6 mustn't [1] 59/5
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(47) lot... - mustn't

M	14/20 19/14 32/23 35/3 37/11 41/7 56/13 62/6 64/20 67/21 69/20 77/5 81/10 83/12 98/16 104/6 112/23 115/17 needing [2] 70/1 100/15 needle [2] 19/16 22/15 needs [5] 59/10 63/17 63/19 82/19 97/8 network [2] 16/19 32/15 neutropenia [1] 116/1 neutrophil [2] 112/22 113/15 neutrophils [5] 113/4 113/7 113/8 113/13 118/20 never [5] 4/24 16/24 66/4 84/7 131/11 new [8] 27/18 37/21 55/24 67/24 85/6 85/11 92/13 95/5 newness [1] 57/17 next [8] 18/4 23/8 26/9 29/1 33/8 36/17 114/22 122/4 NHS [15] 2/11 33/22 59/17 61/13 61/16 61/20 64/5 67/18 69/3 69/12 69/16 69/18 69/24 77/2 86/9 nice [3] 62/16 63/14 125/9 Nigeria [1] 10/22 nights [2] 19/17 94/11 NIHR [4] 79/20 79/22 83/24 84/5 nine [2] 109/25 110/12 no [59] 3/19 4/17 7/20 11/23 11/24 11/25 12/2 14/7 20/23 24/1 25/5 25/11 27/8 31/15 31/22 33/17 35/24 35/24 36/11 38/4 38/8 39/4 44/14 49/20 50/7 52/19 55/21 62/14 63/18 70/22 70/22 70/22 70/25 73/24 74/10 77/19 79/6 84/12 85/13 91/11 94/1 96/18 98/1 98/3 98/14 99/15 105/1 105/1 109/23 116/11 116/20 121/25 126/16 127/4 127/4 130/24 131/11 133/23 134/1 Nolan [1] 64/19 non [20] 7/25 7/25 8/6	8/6 30/25 56/6 56/11 73/19 73/20 91/20 91/21 96/19 100/20 101/6 101/18 102/25 103/4 113/24 118/4 119/10 non-A [3] 7/25 8/6 73/19 non-B [3] 7/25 8/6 73/20 non-general [1] 118/4 non-pegylated [1] 119/10 non-pickable-up [1] 30/25 non-sickle [2] 56/6 56/11 non-transfused [1] 113/24 non-transfusion [1] 96/19 non-transfusion-depe ndent [6] 91/20 91/21 100/20 101/6 101/18 103/4 None [2] 61/7 75/3 nor [1] 7/4 norm [1] 80/7 normal [9] 5/20 18/14 28/20 30/1 37/17 100/6 108/25 109/2 129/18 normally [5] 18/12 21/16 50/22 108/25 120/20 norms [1] 80/9 north [5] 2/12 26/6 73/8 90/3 130/10 northern [1] 103/14 northwest [2] 8/17 83/2 not [144] note [3] 34/18 34/20 47/24 notes [11] 4/13 6/2 6/4 34/8 34/14 34/25 36/3 36/4 38/24 106/12 106/14 nothing [4] 9/18 12/15 124/11 135/18 notice [1] 101/7 novel [1] 95/5 Novichok [2] 67/12 70/10 now [42] 5/24 13/17 19/23 19/23 20/6 22/8 41/10 45/17 46/9 47/25 49/10 78/1 78/6 78/18 86/22 91/15 91/19 92/12 95/2 95/10 97/13 97/15 99/21 102/7 107/19	108/13 110/20 113/8 114/15 123/1 124/2 124/13 125/8 125/11 126/20 127/1 128/5 129/18 132/17 133/10 133/16 135/21 nowadays [3] 103/9 104/2 133/9 number [14] 4/13 15/3 23/5 23/21 26/10 33/22 35/24 44/2 46/12 47/1 60/15 63/6 69/5 72/2 numbers [3] 33/22 34/4 41/25 nurse [16] 16/19 87/14 87/17 87/20 87/24 88/4 89/7 111/6 123/12 123/20 124/3 126/2 127/2 130/20 132/9 133/7 nurses [9] 16/15 16/16 16/24 17/6 34/22 46/21 47/15 99/17 130/11 nursing [6] 41/4 87/18 88/6 88/25 92/22 96/6	odd [1] 32/4 oesophageal [1] 124/21 off [3] 44/24 79/12 83/12 offer [3] 75/5 77/14 111/16 offered [1] 25/21 offering [1] 136/4 Office [3] 62/1 62/2 68/23 officer [7] 3/9 3/9 4/15 7/19 60/4 61/19 69/8 official [1] 53/6 officials [1] 68/15 often [10] 37/18 37/25 46/25 47/15 48/15 57/6 57/9 65/24 68/14 68/25 Oh [1] 37/21 okay [2] 97/17 102/22 old [8] 20/1 91/7 92/2 92/16 98/11 100/4 110/5 126/18 older [2] 98/24 107/14 once [10] 7/21 29/24 38/5 45/3 63/5 95/11 99/2 105/5 119/13 124/1 oncology [2] 87/18 88/25 one [85] 4/4 8/23 10/17 11/3 12/13 13/11 14/15 15/23 16/13 18/22 19/13 22/19 23/8 24/13 26/5 27/3 27/8 29/20 31/10 31/12 32/2 32/20 35/25 36/23 39/7 39/21 41/6 42/10 46/4 48/3 48/7 49/2 52/6 60/19 60/19 62/16 62/23 63/18 64/4 65/1 65/9 68/8 70/9 70/22 72/22 77/11 77/25 78/14 78/18 78/18 79/20 79/22 81/1 81/17 82/25 86/8 91/8 91/9 94/8 95/14 97/9 97/16 102/6 103/8 108/18 108/22 111/25 112/3 113/5 113/21 115/2 116/17 118/13 118/23 124/20 125/6 126/6 126/7 131/4 131/6 131/6 131/13 132/3 134/7 135/3 one-stop [1] 115/2 one-to-one [1] 78/18 ones [4] 11/22 17/19 31/10 97/1 ongoing [2] 97/14	102/20 online [1] 72/8 only [36] 4/1 4/25 7/12 10/16 12/12 14/22 18/20 19/13 19/13 21/10 25/1 45/5 46/13 48/25 52/1 53/17 57/24 58/2 62/16 73/9 78/16 85/6 94/4 101/13 104/7 105/15 106/2 118/23 118/23 119/1 122/17 125/11 126/6 126/8 134/1 134/7 onto [1] 88/20 op [1] 27/11 open [4] 59/24 78/12 78/21 105/23 opened [1] 41/12 openly [1] 123/6 operation [2] 28/15 58/20 operative [2] 59/10 59/10 operatively [1] 28/12 opinion [2] 68/24 116/7 opportunity [1] 27/18 optimal [5] 20/8 20/10 94/14 118/24 119/1 optimally [2] 118/15 118/16 option [1] 91/11 options [2] 42/13 42/19 or [165] oral [4] 19/23 20/4 44/5 113/5 orally [1] 94/6 order [5] 8/3 11/13 40/18 43/18 92/4 ordered [1] 54/1 ordinary [2] 5/21 14/9 organ [2] 29/7 29/21 Organisation [1] 16/9 organisations [2] 44/1 44/2 organism [1] 30/23 original [1] 124/12 originate [1] 103/13 orthopaedic [2] 26/20 59/22 other [52] 5/8 8/24 11/4 15/16 16/16 17/20 22/20 28/22 29/11 31/13 32/13 37/10 42/11 42/18 44/20 45/11 45/20 45/23 51/24 52/1 53/17 54/17 55/19 55/23 56/7 56/23 58/3 58/13 59/19 59/23
N	name [3] 33/22 82/10 83/9 names [1] 135/18 nation [3] 68/2 69/6 76/3 nation's [2] 60/12 60/16 national [6] 3/5 25/3 25/5 25/9 62/12 71/7 nationally [1] 42/5 nations [1] 61/22 natural [1] 94/1 naturally [1] 90/19 nature [1] 48/25 necessarily [2] 91/23 110/10 necessary [1] 28/12 neck [1] 89/4 need [35] 4/7 6/14 7/23 18/15 20/4 27/16 42/25 43/1 43/1 53/25 54/13 57/25 60/13 66/17 69/17 71/19 72/8 78/11 83/7 87/2 90/16 91/22 92/16 96/2 96/3 97/9 97/10 100/16 101/3 101/13 115/5 115/17 115/22 128/14 133/7 needed [20] 4/1 4/2		O Oakland [1] 26/6 oath [2] 1/12 87/7 objective [1] 34/21 observation [2] 88/22 92/24 observations [1] 86/10 observing [1] 77/3 obstetricians [1] 133/2 obstetrics [1] 54/25 obtain [1] 33/11 obtaining [1] 106/1 obvious [2] 32/7 86/23 obviously [30] 71/19 88/14 88/17 88/20 90/23 92/23 93/3 93/8 95/11 95/25 97/5 98/3 99/6 103/1 103/9 104/6 104/10 106/12 111/7 111/14 113/8 114/4 117/2 119/19 123/15 123/22 124/24 129/12 130/15 132/12 occasion [2] 80/17 105/7 occasionally [2] 99/11 101/5 occasions [1] 66/25 October [1] 102/1 October 2019 [1] 102/1		

<p>O</p> <p>other... [22] 62/5 67/4 70/1 73/7 75/21 79/15 85/12 92/10 95/18 96/7 96/9 110/1 110/2 110/13 113/20 113/22 117/3 120/14 122/17 123/23 125/13 135/25</p> <p>others [8] 10/1 11/5 69/1 70/13 84/19 84/19 118/25 126/4</p> <p>ought [2] 53/4 80/14</p> <p>our [56] 9/3 11/7 14/19 15/10 18/5 19/4 22/2 26/8 27/9 29/20 30/12 32/23 33/6 34/19 34/21 36/15 37/12 37/15 42/5 47/4 52/7 53/19 54/1 60/22 78/9 78/11 80/7 84/20 85/25 90/12 93/16 93/17 93/23 94/24 94/24 94/25 94/25 94/25 98/18 99/1 103/21 111/17 113/2 113/4 114/1 115/14 116/16 121/21 125/13 126/19 126/21 126/25 130/25 131/18 131/20 133/10</p> <p>ours [4] 17/19 17/21 31/10 118/11</p> <p>ourselves [1] 21/6</p> <p>ourselves: [1] 84/17</p> <p>ourselves: can [1] 84/17</p> <p>out [52] 5/21 17/3 17/12 19/10 19/11 20/1 20/2 21/1 21/6 22/20 26/10 29/25 37/6 38/8 38/25 43/4 54/16 62/20 66/14 71/17 76/21 78/2 81/13 82/18 83/16 84/11 86/24 96/4 99/9 104/14 104/14 108/13 109/1 109/8 111/3 111/19 113/14 117/19 118/5 118/19 122/7 123/1 123/11 124/12 124/12 124/19 127/14 127/18 130/2 130/17 134/1 134/9</p> <p>outbursts [1] 120/25</p> <p>outcomes [2] 79/22 80/2</p> <p>outlier [1] 80/10</p> <p>outpatient [1] 2/16</p> <p>outpatients [2] 15/11 82/2</p> <p>outreach [1] 129/6</p>	<p>outside [4] 53/12 53/14 54/8 94/15</p> <p>over [25] 15/20 24/4 25/8 28/25 46/8 47/13 49/19 50/25 52/5 54/2 56/8 56/18 56/19 58/11 70/14 70/15 80/13 82/10 83/13 91/3 94/11 94/11 100/3 100/10 101/12</p> <p>overawed [1] 47/16</p> <p>overawed by [1] 47/16</p> <p>overcome [1] 5/7</p> <p>overload [18] 18/22 19/2 19/6 19/21 19/22 20/3 23/22 35/14 44/23 94/18 95/3 95/17 96/12 103/8 103/10 124/22 125/25 131/12</p> <p>overnight [1] 50/16</p> <p>oversight [1] 61/4</p> <p>overstating [1] 1/8</p> <p>overtime [1] 74/20</p> <p>overuse [1] 80/23</p> <p>overview [3] 1/18 18/8 87/13</p> <p>overwhelming [1] 12/10</p> <p>own [10] 22/5 43/12 53/1 63/14 110/12 116/11 117/2 123/19 129/23 130/25</p> <p>oxygen [12] 11/9 11/14 11/23 11/25 12/2 12/5 12/22 27/19 56/17 58/1 90/11 90/12</p> <p>oxygen-carrying [1] 12/5</p> <p>oxygen-transporting [1] 90/11</p>	<p>page 6 [1] 43/11</p> <p>page 9 [1] 43/12</p> <p>pain [5] 12/3 12/4 12/12 12/14 85/22</p> <p>painful [3] 12/3 13/3 94/12</p> <p>painkillers [1] 13/16</p> <p>pale [1] 90/22</p> <p>Palliative [1] 136/10</p> <p>pancreas [1] 95/1</p> <p>pandemic [8] 67/12 67/20 68/5 69/15 70/8 70/9 70/16 85/5</p> <p>paper [1] 15/17</p> <p>papers [2] 24/14 88/11</p> <p>paperwork [1] 33/11</p> <p>paragraphs [2] 4/23 43/20</p> <p>parapet [1] 135/5</p> <p>parent [2] 11/3 106/10</p> <p>parents [5] 10/16 11/2 40/3 89/16 106/16</p> <p>pares [1] 62/9</p> <p>park [1] 133/13</p> <p>part [21] 11/5 14/18 32/4 33/6 62/11 62/14 64/6 79/16 79/24 80/7 95/20 96/5 98/2 98/3 99/15 108/14 111/5 123/8 123/19 124/2 136/6</p> <p>Participants [3] 48/8 72/2 128/1</p> <p>particle [1] 73/18</p> <p>particular [11] 14/13 38/19 50/2 50/6 64/12 105/24 115/23 129/6 132/3 134/15 134/16</p> <p>particularly [22] 3/24 10/2 14/1 25/16 35/6 35/14 37/22 51/25 53/16 54/10 56/22 59/9 59/19 68/10 81/2 89/4 92/18 94/18 96/1 96/12 108/14 121/7</p> <p>parting [1] 76/13</p> <p>partly [1] 78/9</p> <p>partner [2] 77/14 129/12</p> <p>partner's [1] 122/24</p> <p>partners [1] 120/23</p> <p>parts [4] 92/11 96/8 107/13 123/16</p> <p>parturition [1] 12/14</p> <p>party [5] 39/19 43/6 43/21 44/14 71/2</p> <p>parvovirus [2] 21/11 101/4</p> <p>pass [3] 32/21 89/17 127/13</p> <p>past [1] 11/24</p>	<p>patchy [1] 45/1</p> <p>paternalistic [1] 65/12</p> <p>pathology [1] 33/10</p> <p>patient [83] 6/7 18/9 21/9 22/13 22/24 22/25 23/11 28/11 28/20 28/22 29/7 33/21 33/21 34/1 34/4 35/3 36/2 36/7 36/9 36/25 40/14 40/25 49/18 49/18 49/21 50/4 50/5 50/10 50/20 50/21 53/24 57/11 58/6 58/10 58/21 58/23 58/24 78/22 79/22 80/2 81/3 83/14 83/15 88/22 93/7 96/15 97/11 97/22 98/2 98/4 98/5 98/21 98/22 99/1 99/13 100/9 101/11 102/17 102/18 103/2 105/6 106/11 106/13 106/15 113/9 114/1 114/24 115/19 118/23 121/15 121/20 122/17 124/6 124/16 125/4 126/8 127/6 130/25 131/6 131/7 131/11 132/3 133/4</p> <p>patient's [6] 5/1 6/4 34/8 34/14 58/4 83/9</p> <p>patients [201]</p> <p>pattern [2] 99/5 99/6</p> <p>pausing [1] 27/1</p> <p>pay [2] 78/2 108/19</p> <p>paying [1] 78/3</p> <p>pee [1] 21/1</p> <p>pegylated [5] 110/17 111/8 118/10 119/10 119/13</p> <p>Penrose [2] 75/2 75/4</p> <p>Penrose Inquiry [1] 75/2</p> <p>people [39] 1/10 17/16 19/25 21/1 25/8 26/5 27/11 30/16 43/23 44/2 45/10 54/15 57/17 63/23 65/3 65/13 67/17 75/6 78/23 79/3 79/15 80/8 81/7 81/14 86/22 87/2 99/14 107/14 108/7 108/15 122/20 127/25 129/9 134/10 135/4 135/11 135/13 135/19 135/22</p> <p>people's [3] 46/15 55/5 55/7</p> <p>per [3] 95/13 95/16 103/19</p> <p>perceived [1] 52/11</p>	<p>perfection [1] 63/19</p> <p>perhaps [9] 39/16 61/2 83/21 89/12 106/16 109/19 129/5 129/11 130/1</p> <p>period [10] 4/18 7/15 7/18 8/5 49/1 55/14 56/18 93/20 100/4 116/23</p> <p>periods [2] 24/4 99/14</p> <p>perioperative [1] 28/5</p> <p>Permanent [1] 68/14</p> <p>persists [1] 12/8</p> <p>person [3] 48/9 51/6 116/9</p> <p>personal [1] 45/24</p> <p>personally [2] 8/14 133/15</p> <p>perspective [4] 50/6 105/15 123/12 132/9</p> <p>persuade [1] 48/10</p> <p>persuaded [2] 40/19 81/11</p> <p>pharmacist [1] 82/3</p> <p>pharmacists [1] 81/25</p> <p>phase [1] 63/7</p> <p>phenotype [1] 103/22</p> <p>phenotypes [1] 96/20</p> <p>physical [1] 62/7</p> <p>physiological [1] 52/14</p> <p>pick [11] 4/22 12/22 25/12 38/19 44/24 56/17 57/4 57/21 58/14 68/8 135/15</p> <p>pickable [1] 30/25</p> <p>picked [3] 34/5 77/18 122/4</p> <p>picking [1] 47/3</p> <p>pilot [1] 110/20</p> <p>pituitary [2] 94/23 132/23</p> <p>pivotal [1] 67/15</p> <p>place [5] 45/19 58/11 69/4 82/17 124/8</p> <p>places [2] 10/23 63/11</p> <p>plainly [1] 9/14</p> <p>plan [1] 97/21</p> <p>plasma [3] 20/15 20/25 33/1</p> <p>platelet [1] 55/25</p> <p>platelets [4] 20/25 33/13 53/25 118/22</p> <p>play [10] 56/1 59/4 59/5 61/5 63/1 69/15 81/25 82/6 82/9 123/16</p> <p>played [8] 43/4 52/3 56/2 64/3 66/14 68/3 68/4 69/6</p> <p>playing [1] 79/9</p>	<p>plea [1] 134/22</p> <p>pleasant [1] 96/2</p> <p>please [15] 4/10 4/22 6/1 24/23 43/8 43/11 44/4 51/9 56/24 57/3 57/21 58/14 72/13 84/16 131/19</p> <p>plenty [1] 71/14</p> <p>Plough [1] 111/24</p> <p>plummet [1] 101/4</p> <p>plummeted [1] 97/19</p> <p>plummetering [1] 114/4</p> <p>plus [1] 8/10</p> <p>pm [13] 71/25 72/13 72/15 72/17 86/14 86/16 86/17 86/19 128/17 128/20 128/21 128/23 136/16</p> <p>pneumonia [1] 82/5</p> <p>point [12] 15/12 31/8 36/18 68/9 74/9 92/22 92/24 105/13 106/19 123/21 123/25 126/7</p> <p>points [1] 132/8</p> <p>poisonings [1] 67/12</p> <p>police [1] 47/2</p> <p>policies [3] 62/13 71/10 124/7</p> <p>policy [6] 7/4 68/15 71/13 75/8 101/25 102/12</p> <p>polymakers [1] 60/10</p> <p>politicians [5] 66/15 67/19 68/2 68/10 85/10</p> <p>poo [1] 19/10</p> <p>pooling [2] 12/23 13/2</p> <p>poor [2] 42/21 42/24</p> <p>population [9] 9/24 112/21 113/24 118/4 120/5 124/13 127/1 129/13 129/22</p> <p>populations [4] 10/24 40/8 43/25 44/8</p> <p>portfolio [1] 69/7</p> <p>positive [3] 110/1 110/9 111/10</p> <p>possible [5] 9/18 30/6 38/3 117/20 133/5</p> <p>possibly [2] 99/18 117/22</p> <p>post [15] 2/2 2/7 3/13 10/7 14/11 14/12 14/13 14/14 28/12 59/10 63/22 73/9 88/23 111/25 130/6</p> <p>post-operative [1] 59/10</p> <p>post-operatively [1] 28/12</p> <p>post-transfusion [2]</p>
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(49) other... - post-transfusion

<p>P</p> <p>post-transfusion... [2] 73/9 88/23</p> <p>potential [3] 25/17 25/17 113/10</p> <p>potentially [1] 57/11</p> <p>pour [1] 20/25</p> <p>Poverty [1] 43/5</p> <p>power [3] 64/19 75/25 84/23</p> <p>powerful [1] 81/19</p> <p>PPE [1] 69/13</p> <p>practicalities [1] 102/16</p> <p>practically [1] 33/3</p> <p>practice [21] 4/19 5/17 5/20 5/25 6/9 13/19 22/2 22/7 24/8 25/25 26/1 26/8 27/2 28/13 29/17 29/18 56/10 75/14 79/10 79/10 102/9</p> <p>practiced [1] 41/10</p> <p>practices [2] 62/13 124/7</p> <p>practising [2] 13/15 27/22</p> <p>pray [1] 86/1</p> <p>pre [4] 27/11 59/10 93/7 126/24</p> <p>pre-1990 [1] 126/24</p> <p>pre-blood [1] 93/7</p> <p>pre-op [1] 27/11</p> <p>pre-operative [1] 59/10</p> <p>preceding [1] 124/14</p> <p>predecessor [2] 63/3 68/4</p> <p>predecessors [1] 61/18</p> <p>pregnancy [3] 14/1 89/17 89/19</p> <p>preliminary [2] 48/6 115/16</p> <p>prenatal [1] 77/15</p> <p>preoperative [5] 26/18 26/21 27/23 58/15 58/19</p> <p>preoperatively [2] 27/6 28/7</p> <p>prepare [1] 62/14</p> <p>prepared [2] 97/15 120/1</p> <p>Prescott [6] 86/20 87/9 87/12 127/21 133/24 137/5</p> <p>prescribing [3] 82/11 82/12 82/13</p> <p>prescription [3] 82/22 83/8 83/15</p> <p>prescriptions [3]</p>	<p>82/18 88/17 88/17</p> <p>present [3] 10/23 64/25 69/8</p> <p>presentation [2] 46/16 110/6</p> <p>presentations [2] 46/5 129/23</p> <p>presented [2] 110/16 130/15</p> <p>presenting [2] 80/3 96/20</p> <p>pressure [2] 101/8 103/5</p> <p>presume [1] 20/9</p> <p>pretty [3] 4/18 45/1 92/21</p> <p>prevent [1] 42/25</p> <p>prevention [3] 15/16 26/14 133/18</p> <p>previous [8] 41/17 66/2 70/13 89/13 111/10 117/10 131/21 133/12</p> <p>previously [4] 74/16 104/9 110/19 119/8</p> <p>priapisms [1] 13/3</p> <p>primarily [3] 115/4 126/16 127/16</p> <p>primary [1] 3/5</p> <p>Prime [2] 62/3 68/25</p> <p>primus [1] 62/9</p> <p>principally [1] 52/15</p> <p>principles [2] 64/9 64/19</p> <p>prior [4] 88/24 104/16 115/15 119/4</p> <p>priority [2] 44/24 45/19</p> <p>proactive [2] 54/6 109/13</p> <p>proactivity [1] 54/7</p> <p>probably [23] 15/19 15/23 16/25 24/10 27/25 31/10 54/5 71/23 74/10 92/10 93/12 99/9 105/8 106/23 110/21 116/7 116/15 118/13 118/14 118/15 119/1 125/15 128/15</p> <p>problem [8] 17/13 19/6 30/9 54/3 63/21 80/21 108/9 108/10</p> <p>problematic [1] 113/22</p> <p>problems [8] 46/25 52/1 92/25 93/23 124/20 124/23 132/16 133/18</p> <p>procedure [1] 28/4</p> <p>proceed [1] 28/10</p> <p>process [4] 35/20</p>	<p>79/16 106/6 117/9</p> <p>produce [3] 21/17 62/18 90/9</p> <p>produced [1] 102/3</p> <p>producing [2] 21/12 79/16</p> <p>production [2] 22/5 90/17</p> <p>products [6] 3/22 9/5 36/7 53/25 88/18 88/20</p> <p>profession [2] 60/21 79/15</p> <p>professional [1] 43/23</p> <p>professionals [2] 43/22 130/18</p> <p>professions [1] 41/5</p> <p>Professor [14] 1/3 1/5 1/15 1/17 24/25 26/11 36/20 44/11 71/19 72/19 76/16 78/15 84/13 137/2</p> <p>Professor Charache [1] 78/15</p> <p>PROFESSOR DAME [2] 1/15 137/2</p> <p>Professor Dame Sally Davies [1] 1/5</p> <p>Professor Davies [8] 1/17 24/25 26/11 36/20 44/11 71/19 72/19 84/13</p> <p>Professor Davies' [1] 76/16</p> <p>profile [1] 97/6</p> <p>programme [2] 104/17 111/21</p> <p>programmes [1] 81/24</p> <p>progressed [1] 125/22</p> <p>progressing [1] 131/25</p> <p>prolonged [1] 13/3</p> <p>promulgating [1] 55/23</p> <p>pronged [1] 79/6</p> <p>proper [2] 111/21 119/21</p> <p>properly [2] 46/4 71/16</p> <p>prophylaxis [1] 74/14</p> <p>proportion [4] 16/3 23/19 131/8 131/8</p> <p>protect [2] 10/20 48/19</p> <p>protection [2] 6/7 89/25</p> <p>protocol [3] 67/7 98/2 98/3</p> <p>protocols [3] 17/6</p>	<p>24/11 112/24</p> <p>provide [2] 62/11 78/3</p> <p>provided [11] 4/16 28/7 46/18 46/20 53/13 61/2 109/21 119/25 125/22 131/2 131/17</p> <p>providing [5] 47/10 106/1 111/15 112/6 115/24</p> <p>provision [2] 43/19 96/14</p> <p>psychological [8] 93/2 95/25 107/7 113/21 120/15 121/4 121/10 132/13</p> <p>psychologically [1] 123/4</p> <p>psychologist [3] 121/12 121/21 122/2</p> <p>psychosocial [3] 46/17 47/20 121/6</p> <p>public [25] 40/24 60/20 61/12 61/16 64/11 64/24 64/25 65/5 65/6 65/21 66/6 66/17 66/21 67/2 67/5 67/11 68/15 69/2 69/3 74/20 75/17 79/23 82/10 83/1 84/21</p> <p>public's [1] 64/12</p> <p>publicly [1] 66/9</p> <p>published [10] 25/1 32/9 32/13 32/13 43/10 54/24 66/6 67/6 67/9 75/23</p> <p>push [3] 22/22 67/22 80/23</p> <p>pushing [2] 28/18 69/12</p> <p>put [17] 8/12 20/2 20/6 34/8 34/22 41/2 60/5 63/22 65/22 74/21 79/13 82/17 107/25 111/21 117/7 127/23 132/1</p> <p>putting [4] 36/22 49/20 113/9 135/5</p>	<p>question: [1] 48/12</p> <p>question: how [1] 48/12</p> <p>Questioned [4] 1/16 87/10 137/3 137/6</p> <p>questions [23] 1/13 69/23 71/18 71/20 72/5 72/6 72/10 72/20 76/14 76/20 78/11 84/10 87/4 87/5 127/20 127/22 128/2 128/5 128/18 129/1 133/20 133/22 137/4</p> <p>quick [2] 94/8 122/1</p> <p>quickly [6] 21/6 70/7 70/11 105/17 113/4 131/15</p> <p>quiet [1] 122/9</p> <p>quite [32] 5/12 10/22 11/4 14/10 16/7 16/22 21/6 22/21 23/21 26/2 35/15 37/18 37/25 39/6 42/14 42/16 52/21 62/18 64/16 67/8 67/15 82/6 82/25 86/25 88/14 94/15 99/22 99/25 100/1 129/21 130/15 131/15</p>	<p>reached [1] 10/21</p> <p>reaction [1] 99/24</p> <p>reactions [1] 99/24</p> <p>read [4] 26/7 26/10 39/23 63/12</p> <p>reading [2] 23/4 88/10</p> <p>ready [1] 28/15</p> <p>real [3] 48/8 102/16 109/1</p> <p>reality [3] 63/17 63/20 67/18</p> <p>really [37] 4/1 4/2 8/21 14/18 17/24 23/10 41/1 44/18 45/4 49/23 57/7 75/19 76/21 83/13 88/8 89/21 90/2 90/3 91/21 92/25 97/20 98/18 107/1 111/20 117/15 117/16 119/2 121/1 121/20 123/10 127/10 130/17 133/4 134/1 134/2 134/5 134/8</p> <p>reappear [1] 37/5</p> <p>reason [15] 5/9 6/6 18/2 18/3 28/22 33/15 50/17 52/14 58/3 76/24 95/15 97/18 100/21 101/7 136/1</p> <p>reasonable [1] 28/10</p> <p>reasonably [1] 55/3</p> <p>reasons [6] 18/7 61/9 118/13 125/13 135/23 135/25</p> <p>recall [27] 4/15 4/21 7/2 7/20 8/7 10/4 15/6 30/19 31/3 31/20 31/22 32/1 33/16 38/17 38/20 38/22 39/1 54/18 54/20 55/19 56/4 70/23 102/2 102/5 102/7 124/7 129/25</p> <p>recalling [1] 8/9</p> <p>receipt [1] 88/19</p> <p>receive [5] 7/16 28/22 38/25 91/12 105/7</p> <p>received [7] 8/17 32/20 34/11 34/15 38/13 39/5 75/6</p> <p>receiving [4] 39/1 63/10 103/17 112/13</p> <p>recent [3] 50/2 76/24 124/10</p> <p>recently [2] 25/1 105/16</p> <p>reckoned [1] 4/8</p> <p>reclused [1] 71/4</p> <p>recognise [1] 66/9</p> <p>recollection [1] 9/10</p> <p>recommend [1] 24/1</p> <p>recommendation [1]</p>
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R	39/5 92/7 103/22 regularly [6] 37/11 37/25 68/13 97/11 114/14 120/7 regulatory [1] 64/14 rehearsed [1] 119/16 reiterated [1] 119/19 relapsed [1] 118/7 related [4] 31/6 51/23 67/4 124/19 relation [23] 2/8 7/17 8/6 25/4 33/18 38/3 41/18 45/21 68/18 71/8 74/8 74/8 74/11 74/17 75/1 75/24 102/12 102/18 106/5 106/17 116/5 116/24 121/8 relationship [2] 66/10 66/19 relationships [1] 120/22 relatively [1] 122/1 relatives [1] 74/5 relay [1] 135/16 relevant [3] 43/25 54/23 69/16 relied [1] 32/21 reluctance [1] 81/1 rely [1] 9/3 remained [4] 2/10 87/21 111/9 124/25 remains [1] 106/14 remember [26] 5/20 5/21 5/25 6/23 8/11 16/22 21/15 23/5 23/16 29/20 31/9 39/20 50/14 52/6 55/16 55/16 74/4 75/10 75/12 76/24 77/3 85/19 88/7 105/20 120/17 126/6 remembered [1] 47/17 remembering [1] 74/13 reminded [1] 135/24 remit [2] 2/7 130/12 remotely [2] 1/10 86/25 removal [1] 85/15 remove [3] 98/11 131/15 131/23 removing [1] 98/15 renowned [1] 115/13 repeat [1] 53/7 repeated [1] 134/21 replaced [1] 125/17 replacement [1] 27/17 report [12] 15/2 15/3 17/3 42/9 43/6 44/15 45/13 60/11 75/5	89/11 120/9 135/16 reporting [1] 119/22 reports [2] 66/8 75/19 represent [1] 25/25 representative [1] 76/16 representatives [4] 48/7 72/3 72/4 128/1 represented [2] 72/3 127/25 request [2] 33/20 53/7 requesting [1] 33/12 require [7] 18/10 58/8 89/5 92/3 121/22 131/9 131/11 required [4] 79/10 125/5 126/15 131/7 requirements [3] 57/11 98/8 98/18 requires [1] 29/12 requiring [2] 26/24 28/3 research [15] 2/2 2/12 2/21 2/23 3/2 3/6 40/9 62/22 83/22 83/23 84/2 84/6 84/6 96/10 96/11 reserved [1] 61/15 resign [1] 67/2 resistance [6] 59/13 64/3 80/19 80/24 81/16 85/4 resistant [2] 59/16 80/22 resolve [2] 75/25 96/4 resolved [1] 65/24 resources [1] 111/20 respect [3] 12/16 49/24 136/4 respected [1] 49/23 respond [1] 58/21 responded [3] 69/11 70/11 118/5 response [3] 64/21 117/11 117/13 responsibilities [1] 64/12 responsibility [1] 93/9 responsible [2] 68/19 94/24 rest [1] 90/12 result [4] 28/8 42/15 86/2 89/19 results [3] 79/18 93/5 115/2 retention [1] 21/4 retired [1] 3/11 retrospectoscope [1] 45/18 return [1] 41/17 returned [3] 7/14 7/15	34/12 returning [1] 1/23 review [1] 67/21 reviewed [4] 15/17 115/3 115/14 115/17 revised [1] 4/14 revolving [1] 96/12 ribavirin [3] 113/23 118/10 119/12 rid [5] 18/24 21/4 94/2 98/14 131/22 right [29] 1/21 2/15 14/24 18/3 21/15 25/12 33/7 36/14 47/8 53/15 61/15 65/25 66/22 67/17 69/4 69/21 69/23 72/4 72/24 73/24 76/7 79/12 82/22 87/15 93/10 93/10 93/11 97/10 110/9 right-hand [1] 25/12 ring [4] 53/23 82/3 83/5 83/14 rise [2] 27/14 82/16 risk [23] 3/20 5/1 9/22 23/25 25/23 26/19 26/22 26/24 30/6 35/7 35/15 38/12 38/19 43/25 44/8 52/21 85/14 103/15 103/25 104/11 104/21 113/9 126/8 risk-free [2] 3/20 85/14 risk/benefit [1] 35/7 risks [21] 3/23 3/25 6/20 7/7 9/19 9/25 18/19 18/20 18/20 24/3 25/18 30/3 35/5 35/6 47/11 85/15 88/4 104/9 109/14 119/20 129/25 RLIT0000806 [1] 24/23 RLIT0001564 [1] 56/24 RNA [1] 110/1 road [1] 131/17 role [54] 7/20 52/3 54/8 55/6 55/22 55/25 56/2 60/3 60/7 60/25 61/5 61/17 62/11 62/14 63/1 64/3 64/5 64/10 64/15 65/21 67/13 67/15 67/23 68/3 68/5 69/6 69/15 74/15 75/1 79/9 80/10 80/18 82/1 82/6 82/8 82/9 87/22 87/24 92/17 93/6 95/21 96/5 112/5 112/5 112/11	112/12 120/12 120/15 120/17 123/13 123/20 124/2 126/3 133/6 roles [5] 60/9 60/15 65/23 66/2 124/4 room [3] 1/7 114/21 122/9 rooms [1] 68/23 roughly [3] 15/6 23/19 92/5 round [8] 12/22 16/18 19/9 31/23 32/19 78/17 78/24 120/2 rounds [2] 31/20 78/16 route [1] 62/16 routes [1] 62/19 routine [7] 36/22 36/23 38/6 45/10 53/20 54/2 109/7 routinely [4] 37/14 73/8 98/11 125/19 Royal [5] 115/12 115/21 121/6 125/1 125/15 rule [3] 56/9 56/11 128/6 run [4] 18/12 83/1 111/22 114/15 running [4] 70/19 71/7 101/9 114/22 rush [1] 100/25 Ryan [1] 25/6	106/9 106/14 sanctioning [1] 28/19 sat [4] 47/15 52/5 61/13 122/2 satellite [1] 92/14 satisfactory [1] 42/22 Saturday [1] 40/21 save [1] 24/15 saving [3] 21/10 23/12 29/3 saw [9] 7/11 37/3 37/11 37/23 45/10 70/9 114/12 114/14 122/15 say [49] 12/16 14/17 14/25 22/8 33/1 36/3 37/7 37/9 47/18 47/19 50/21 52/24 54/25 56/3 59/15 71/22 71/25 77/8 78/6 78/18 82/3 83/5 83/14 83/20 84/14 84/17 87/3 96/18 97/16 99/8 100/18 100/24 103/15 105/10 107/9 108/16 110/13 119/17 122/1 123/3 123/7 128/16 128/17 129/20 133/15 135/1 135/12 135/16 135/20 saying [8] 17/25 49/15 50/19 52/7 55/24 77/4 78/1 81/3 says [4] 57/23 58/16 82/21 100/9 SB [1] 52/19 SC [2] 13/25 26/21 scan [1] 32/12 scarred [1] 131/22 scarring [5] 12/9 13/4 117/5 131/16 131/23 SCGV0000267 [1] 43/8 schemes [1] 127/9 Schering [1] 111/24 Schering-Plough [1] 111/24 school [3] 107/22 108/23 114/17 schools [2] 46/23 107/25 science [3] 9/7 30/25 67/16 sciences [1] 17/14 scientific [9] 3/2 60/23 65/14 67/7 68/21 68/22 69/9 69/19 69/22 Scotland [1] 75/7 screen [4] 4/11 43/9 43/13 101/23 screened [4] 109/15
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(51) recommendation... - screened

S	September [1] 3/14 September 30th [1] 3/14 sequelae [1] 12/11 sequestration [5] 21/21 21/22 29/4 29/5 35/9 serious [2] 9/15 16/3 seriousness [2] 8/6 9/14 servant [2] 64/10 64/11 service [8] 10/5 46/20 55/17 63/8 78/3 115/11 115/12 115/13 services [5] 16/17 44/25 45/19 61/5 96/9 session [1] 122/10 sessions [5] 23/7 26/4 30/11 31/24 121/14 set [15] 16/17 24/23 27/12 31/9 35/24 38/8 40/19 71/3 71/17 79/20 102/2 102/10 110/6 110/12 114/21 setting [1] 3/5 seven [1] 107/21 several [1] 126/9 severe [6] 29/5 29/8 91/5 95/18 113/10 116/11 severely [4] 13/12 14/2 23/17 101/1 severity [2] 29/15 90/25 shape [1] 11/16 sharing [1] 16/20 she [16] 12/15 32/14 72/5 72/6 109/12 121/15 125/7 125/8 125/9 125/9 125/10 125/10 125/11 125/12 125/14 126/22 sheet [2] 34/23 34/24 sheets [1] 83/8 shift [3] 59/11 77/25 85/11 shifted [1] 50/25 SHO [1] 7/3 shop [1] 115/2 short [6] 51/11 58/1 72/16 86/18 128/22 135/1 shorter [4] 22/3 31/1 31/1 35/11 should [38] 3/18 4/1 4/24 5/4 6/3 6/19 14/25 17/10 20/12 25/16 25/21 28/4 28/6 28/22 29/6 29/9 29/12 35/25 36/25 40/22 47/19 50/10 50/13 52/16 58/2 58/25 65/5 65/15 66/6 67/5 83/10 83/23 90/25 93/12 107/9 127/21 130/7 130/18 shouldn't [3] 41/6 65/11 103/25 show [1] 79/17 shown [3] 55/3 84/23 134/14 SHT [2] 29/13 29/15 sick [3] 22/13 22/25 37/3 sickle [100] 2/8 2/16 8/23 10/8 10/10 10/14 10/15 10/17 11/1 11/2 11/5 11/13 11/16 11/19 12/3 12/13 12/15 12/19 12/23 14/5 14/13 14/16 15/4 15/6 15/6 15/23 16/10 16/14 17/10 17/19 17/22 18/9 18/11 19/4 19/15 21/9 21/14 21/23 22/16 23/3 24/14 24/21 24/24 25/4 25/15 26/4 26/15 26/23 27/10 28/20 29/3 30/1 36/11 36/21 36/24 37/17 38/6 39/1 39/24 40/8 40/22 41/21 42/13 42/20 42/25 45/25 46/5 46/10 46/19 47/24 48/23 48/23 51/14 51/16 52/12 52/15 52/19 53/12 56/6 56/11 62/20 74/23 77/11 77/13 77/16 77/20 78/14 78/25 86/6 121/13 126/11 126/12 126/14 126/16 126/17 126/22 127/1 127/3 134/14 134/24 sickle cell [2] 15/6 47/24 sickling [4] 12/18 13/18 22/7 27/19 side [23] 22/19 22/20 36/23 41/1 54/12 83/18 95/7 95/13 95/18 95/22 113/6 115/1 116/8 116/17 116/22 119/5 119/20 119/22 120/1 120/5 120/13 131/1 131/2 Sierra [1] 69/12 Sierra Leone [1] 69/12 sign [2] 34/6 34/23 signed [2] 83/12	106/10 significant [7] 4/7 24/8 39/6 39/23 40/8 120/14 122/13 significantly [6] 70/14 72/11 118/12 118/22 123/20 134/6 signs [2] 80/16 130/2 similar [1] 29/17 simple [4] 28/6 29/13 64/16 85/15 simpler [1] 5/11 simply [2] 93/14 123/21 since [7] 5/1 41/10 75/22 87/22 110/5 125/2 134/20 sir [14] 47/23 53/10 71/18 76/14 76/18 76/20 84/12 86/15 127/20 128/15 133/19 133/21 136/9 137/4 sit [9] 22/14 22/25 24/3 55/13 62/15 67/15 78/18 82/2 121/15 sits [2] 107/16 108/11 sitting [1] 69/1 situation [3] 44/19 58/15 76/1 situations [1] 67/14 six [12] 6/16 8/16 9/6 22/3 37/1 37/16 90/20 100/10 107/21 110/1 110/13 119/12 six months [2] 8/16 37/1 size [1] 63/8 sizes [1] 99/25 skills [1] 121/9 skin [1] 19/16 slide [2] 110/18 118/18 slides [1] 132/3 slight [1] 5/7 slightly [4] 98/17 113/3 131/16 131/24 slim [1] 104/3 slimmer [1] 116/17 slot [1] 122/5 slowly [3] 5/8 8/20 94/9 SMAC [2] 17/2 45/13 SMAC report [1] 45/13 small [3] 94/13 100/1 130/10 smooth [1] 125/10 so [287] social [9] 17/14 49/9 49/11 55/7 73/23 74/1 74/9 80/5 135/14	societies [1] 62/18 society [8] 26/4 85/25 107/1 127/11 129/5 129/16 129/24 130/4 solid [1] 89/3 soluble [1] 19/10 solution [2] 20/9 20/11 solve [1] 19/20 some [62] 1/19 2/16 4/6 5/9 5/10 10/10 11/21 13/6 13/8 13/17 14/23 15/10 20/4 23/4 23/17 25/2 29/19 32/13 37/5 37/6 38/22 39/7 39/22 39/23 39/24 40/25 42/7 44/19 47/5 48/4 53/5 57/16 65/20 65/23 74/3 74/4 75/16 76/4 76/5 80/16 81/1 81/25 89/25 96/21 98/10 99/6 99/10 99/11 107/13 107/23 107/24 108/2 108/5 108/7 108/11 110/25 115/5 122/24 124/15 125/7 126/7 135/23 somebody [2] 111/22 135/12 somehow [1] 40/11 someone [10] 24/2 34/3 52/14 55/17 85/24 101/5 130/3 135/7 135/10 135/16 something [21] 1/7 3/21 6/13 7/7 45/3 48/11 61/2 62/1 70/12 75/14 81/4 83/16 85/11 97/19 101/3 101/4 104/1 105/8 117/7 130/3 131/10 something's [1] 37/21 sometimes [8] 23/9 24/4 53/22 53/23 54/5 96/3 100/16 100/20 somewhere [2] 23/15 130/10 soon [2] 109/13 132/19 sorry [6] 1/8 42/17 56/4 59/2 85/23 112/10 sort [37] 16/2 56/23 65/12 68/20 88/9 90/5 94/3 94/13 96/3 96/4 97/3 101/15 102/2 105/5 108/3 108/6 108/8 108/14 108/22 111/18 111/22 115/2 115/16 117/18 119/13 120/8 120/20 120/25	121/7 121/9 122/18 129/19 130/12 130/25 132/10 134/10 134/10 sorted [1] 38/24 sorts [3] 63/11 67/13 98/10 sought [3] 53/17 53/19 106/20 South [1] 5/23 Southampton [1] 82/19 space [1] 13/1 sparked [1] 43/21 speak [1] 77/22 speaking [3] 60/20 66/9 87/1 special [3] 67/5 83/8 107/25 specialise [1] 8/24 specialising [2] 10/8 87/17 specialist [20] 14/13 16/15 29/9 42/2 62/18 87/20 87/24 89/7 92/12 106/3 111/5 111/6 112/11 121/10 123/12 126/3 127/2 130/20 132/9 133/7 specialists [1] 63/15 specialities [4] 55/19 55/24 59/19 59/24 speciality [1] 40/12 specialty [1] 16/10 specific [6] 2/7 7/21 57/10 97/18 115/11 121/3 specifically [3] 130/5 130/17 131/4 speculation [1] 74/10 speed [1] 5/9 speeding [1] 117/8 speedy [1] 70/7 spend [1] 84/1 spent [3] 8/15 41/25 121/1 spleen [3] 11/11 12/24 98/12 spleens [5] 98/15 98/19 113/3 113/4 116/3 splenic [4] 21/21 29/4 35/9 52/20 split [1] 27/5 spoil [1] 107/23 spoke [9] 22/10 45/22 73/22 75/13 75/13 107/7 122/11 129/2 131/6 spoken [5] 54/22 60/5 67/11 85/18 115/23 sponsored [1] 111/25 spontaneous [1]
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S	stiff [1] 11/20 stigma [15] 39/23 40/2 45/21 45/24 52/3 52/11 107/14 107/16 108/9 122/11 122/13 122/23 129/2 129/7 135/6 stigmatised [1] 109/5 still [24] 20/4 20/9 27/15 29/20 29/23 30/24 57/19 85/3 95/17 104/2 104/3 104/17 107/15 108/11 109/3 115/21 121/12 122/16 123/5 124/22 125/12 125/12 125/15 129/20 stop [3] 21/12 115/2 131/24 stopped [1] 27/13 stopping [2] 40/16 118/7 stories [2] 74/5 81/9 story [1] 52/6 straightforward [3] 21/19 65/16 93/13 strategy [1] 62/22 strayed [1] 62/1 streamlined [1] 99/18 stressful [1] 43/3 strict [1] 17/9 stroke [5] 13/7 18/17 25/23 26/15 81/18 strong [2] 17/18 64/16 strongly [3] 76/9 76/10 108/11 structurally [2] 78/5 78/5 struggling [1] 121/20 studies [4] 41/8 79/24 117/10 118/9 study [6] 27/8 27/9 27/12 81/12 82/18 110/20 Sub [2] 10/22 41/23 Sub-Saharan [1] 10/22 subcontinent [1] 90/6 subcutaneously [1] 94/7 subject [2] 64/13 77/1 submitted [1] 44/2 subsequent [1] 43/10 subsequently [1] 61/3 substitution [1] 101/2 success [2] 116/24 118/2 successfully [1] 84/5 such [5] 29/4 29/9 58/12 119/18 134/3 suck [2] 22/20 22/23 suddenly [4] 12/24	58/7 97/19 100/23 suffer [2] 52/15 134/24 suffered [1] 135/6 sufferers [1] 41/22 suffering [3] 45/24 85/20 85/23 sufficient [1] 57/10 sufficiently [1] 120/1 suggest [2] 65/20 72/7 suggested [4] 27/23 44/17 70/22 135/12 suggestion [1] 74/22 suit [1] 99/1 Summary [1] 43/14 supplied [1] 33/19 supplies [4] 5/2 32/25 33/2 33/3 supply [2] 9/25 30/5 support [16] 37/12 40/14 46/17 46/23 47/4 47/20 47/20 63/9 95/25 96/2 112/6 120/16 121/4 121/10 132/13 134/18 supported [2] 18/5 32/2 supporting [1] 112/13 supportive [2] 111/16 124/3 suppressed [1] 22/5 supremacy [1] 63/12 sure [30] 14/19 17/11 18/3 33/17 36/9 41/12 41/14 42/5 42/15 46/15 47/16 67/17 68/1 69/3 69/12 69/19 69/21 70/15 72/12 79/12 79/23 103/23 104/18 107/5 109/10 113/11 113/17 113/18 114/3 114/8 surgeon [2] 4/5 84/25 surgeons [3] 27/10 54/14 59/22 surgery [15] 4/6 26/17 26/19 26/22 26/24 27/3 27/16 28/2 28/3 28/8 28/10 28/10 28/24 59/24 59/25 surprise [1] 39/3 surprised [1] 39/10 surveillance [1] 125/2 survival [1] 15/1 survive [2] 91/15 92/4 sustain [2] 115/19 125/20 sustained [3] 118/11 118/23 125/10 swelling [1] 46/7 switch [1] 101/12	sworn [4] 1/15 87/9 137/2 137/5 symptomatic [2] 13/24 57/8 symptoms [1] 130/2 syndrome [7] 12/20 21/23 24/14 29/6 29/8 35/9 46/8 syringe [1] 22/24 syringes [1] 94/16 syrupy [1] 94/13 system [7] 47/20 64/6 64/7 70/6 70/13 79/8 80/8 systems [1] 78/6	tell [11] 54/5 65/5 65/16 66/11 72/9 86/7 89/13 92/17 107/8 107/10 116/25 telling [4] 66/12 108/23 127/8 131/18 temperature [1] 82/20 ten [2] 114/6 128/15 tend [5] 89/23 98/17 99/3 116/17 116/23 tended [1] 59/20 tension [2] 65/20 65/23 tensions [1] 66/1 term [9] 18/20 22/1 25/16 26/13 35/13 57/6 91/24 103/19 133/18 termed [1] 91/14 terms [34] 6/20 14/11 16/2 24/8 27/1 28/13 30/3 32/25 33/11 34/14 36/21 39/13 44/16 46/17 54/7 55/22 56/5 61/4 62/10 70/1 70/3 71/6 74/15 88/3 89/14 96/14 100/13 102/16 106/1 109/6 114/10 120/12 124/8 129/5 terrible [2] 116/8 134/3 tertiary [1] 92/9 test [5] 37/15 38/8 41/11 46/10 93/7 tested [8] 33/25 35/16 38/12 70/21 109/17 109/21 133/16 133/16 testing [8] 8/19 37/13 38/5 38/6 38/15 75/12 109/7 129/11 tests [10] 8/2 9/11 30/1 37/14 38/2 53/20 73/5 73/6 73/12 75/5 thalassemia [81] 14/6 14/7 14/8 16/14 18/25 19/14 25/22 49/5 49/6 49/8 51/16 52/16 87/20 89/8 89/11 89/14 89/15 89/20 89/24 89/24 90/16 90/19 91/3 91/5 91/7 91/9 91/9 91/10 91/13 91/20 91/20 91/21 92/2 92/2 93/13 95/4 96/25 104/7 107/1 107/11 107/15 108/2 108/8 108/16 109/7 109/25 112/3 112/5 112/9 112/12 112/13 112/16 112/22 114/10 114/23 115/25 116/5	116/16 118/3 121/13 121/17 122/12 122/23 127/6 127/11 129/3 129/5 129/10 129/14 129/14 129/16 129/16 129/17 129/24 130/13 130/21 131/6 131/8 134/8 134/15 134/24 thalassemics [2] 93/24 114/19 Thames [1] 2/12 than [28] 17/20 20/7 25/20 26/14 27/11 27/19 28/7 29/22 39/10 45/6 45/9 48/13 48/18 49/13 49/18 50/4 59/3 60/21 61/18 63/5 68/13 74/10 79/18 113/4 120/11 127/12 128/18 133/9 thank [24] 4/11 10/14 51/1 51/8 53/8 53/10 65/19 68/17 72/14 72/19 84/9 86/3 86/4 86/12 86/13 86/15 102/14 102/15 128/12 133/23 134/17 135/22 136/6 136/7 thankfully [2] 107/12 125/23 that [587] that's [29] 11/16 18/1 18/3 21/18 28/20 50/18 52/21 65/18 66/24 70/2 78/9 80/9 81/19 83/21 86/23 91/16 92/12 93/6 100/10 105/2 105/15 106/12 106/19 118/13 123/7 127/16 134/8 135/8 136/11 that: [1] 10/18 that: if [1] 10/18 theatre [2] 6/12 54/3 their [90] 9/7 12/24 13/7 17/23 20/18 21/13 22/5 24/16 26/7 37/15 38/8 40/20 43/24 47/1 52/1 52/20 53/1 63/14 64/6 64/6 72/4 76/6 79/4 81/7 85/21 91/5 92/16 93/4 93/5 93/7 93/10 93/10 93/11 94/14 95/22 98/6 98/7 98/8 98/9 98/11 99/16 99/19 100/12 100/21 100/21 101/7 101/8 101/9 103/21 104/17 105/11 105/22 106/16 107/4 107/17 107/19 107/20 108/4 112/18 112/22
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(53) spontaneous... - their

T	38/23 40/5 43/6 45/15 45/19 46/7 46/11 49/17 50/19 52/12 53/11 53/21 56/22 57/3 57/21 60/1 60/3 60/7 60/18 62/3 63/20 64/21 65/17 69/24 72/9 75/14 75/18 77/14 77/19 78/17 81/20 81/23 83/4 86/14 87/17 87/20 87/22 89/7 90/4 90/5 90/6 92/9 95/10 95/25 97/13 101/1 101/12 105/5 105/7 108/25 109/23 110/1 110/10 111/5 111/17 112/13 112/25 115/17 116/22 117/8 117/13 122/4 122/10 122/10 122/25 125/11 126/2 134/5 136/12 theologian [1] 64/18 therapy [2] 19/8 40/17 there [172] there's [7] 44/14 55/24 81/21 91/1 108/10 108/15 127/22 thereby [1] 100/22 therefore [7] 3/25 22/6 30/13 38/12 44/17 63/8 67/18 these [42] 11/19 24/23 25/1 25/8 25/10 27/24 41/15 44/9 45/15 58/4 84/22 89/23 90/8 90/21 92/3 92/14 92/22 93/1 95/12 95/23 98/15 99/16 100/1 103/11 103/12 105/21 106/25 107/2 107/2 107/16 110/17 111/23 112/2 115/25 117/21 119/7 122/2 124/3 125/18 129/15 132/13 133/10 they [320] they're [15] 18/15 20/2 37/19 80/13 80/13 91/23 98/9 98/24 99/2 100/1 105/19 107/17 109/1 127/12 127/12 they've [2] 91/4 91/4 thick [1] 94/13 thing [9] 24/2 50/9 97/3 105/15 108/22 122/19 131/13 133/4 134/1 things [28] 6/19 8/12 15/16 17/21 26/7 35/24 37/19 45/20	47/18 48/20 63/6 63/24 69/13 75/21 76/5 76/8 78/4 78/5 79/7 79/21 82/8 82/17 85/11 95/13 105/13 111/16 113/22 123/23 think [121] 1/4 3/19 3/20 4/17 6/18 9/5 9/21 9/23 9/25 15/9 15/22 16/22 24/2 24/16 27/15 27/17 31/1 31/7 34/12 35/13 36/2 36/3 37/21 38/11 38/11 39/9 39/20 40/1 40/2 41/20 42/12 44/23 44/23 45/13 46/11 49/19 50/8 50/24 51/5 51/23 52/2 54/18 55/3 55/10 55/14 56/2 56/15 57/15 57/19 59/3 62/22 63/3 65/12 66/5 66/9 67/4 67/7 70/6 71/23 72/11 75/9 77/10 79/19 80/18 81/22 82/21 82/21 82/25 84/18 84/22 85/8 85/12 88/14 97/12 100/24 105/13 105/19 105/20 106/23 108/2 108/13 110/5 110/8 110/14 112/24 113/14 115/18 116/7 116/13 116/17 118/5 118/8 118/13 118/18 118/22 118/25 120/3 120/10 121/14 122/16 122/16 123/5 123/13 123/15 123/16 123/20 124/1 125/15 126/6 126/9 126/24 127/16 127/16 128/9 128/14 130/9 130/25 131/3 133/9 134/5 134/9 thinking [5] 17/1 18/15 42/7 46/10 126/2 third [3] 4/23 73/18 116/15 thirdly [1] 79/14 this [122] 1/7 1/9 4/12 4/14 4/16 4/25 5/15 10/21 11/6 17/15 19/6 23/2 23/4 25/13 25/23 26/5 27/3 27/14 28/7 28/25 29/18 36/5 40/16 41/11 43/10 43/21 44/1 44/18 44/25 45/4 45/13 48/5 49/1 49/15 49/15 49/21 50/6 50/20 50/22 50/22 51/3	51/20 52/24 54/20 56/20 56/24 57/1 57/5 57/8 57/14 57/20 57/23 58/19 70/16 70/18 71/3 71/24 72/1 72/8 74/21 78/1 78/7 79/18 80/13 81/4 82/5 82/7 85/3 85/12 85/20 86/2 87/1 90/10 91/1 93/21 93/23 94/2 94/13 95/8 96/18 97/11 97/11 97/13 97/14 97/15 97/21 98/22 99/15 99/21 101/4 103/6 105/8 105/21 106/14 108/9 108/14 111/12 111/13 112/20 113/21 114/2 114/15 114/16 115/19 117/21 118/5 119/10 122/23 123/5 125/3 126/12 126/23 127/24 128/5 129/9 129/22 131/18 132/3 134/5 134/11 135/2 135/11 thorough [1] 88/14 thoroughly [1] 134/17 those [78] 1/6 6/24 7/9 9/12 9/15 10/3 10/9 10/12 10/24 11/10 16/2 17/5 19/12 19/14 23/13 27/1 27/6 27/7 32/14 33/3 38/13 38/15 38/25 39/7 39/19 43/4 44/11 45/24 46/17 51/25 52/17 52/17 52/24 53/7 53/17 54/25 62/15 65/23 66/2 67/13 70/1 70/20 71/5 71/11 71/12 71/18 72/10 76/14 76/15 79/14 80/22 84/2 85/16 89/12 91/10 91/14 92/7 95/14 98/16 99/13 99/21 101/13 104/12 104/22 106/18 110/23 110/25 111/3 118/9 119/23 120/17 121/11 125/20 127/20 130/18 132/25 134/21 134/22 though [6] 20/4 44/21 47/14 73/24 74/8 120/18 thought [8] 9/15 38/17 41/15 65/25 73/11 73/21 84/4 126/23 three [32] 21/13 22/18 30/13 40/20 48/5 67/11 70/10 78/13	79/7 81/17 85/16 85/17 90/20 91/11 93/4 93/18 93/19 93/20 95/8 99/4 99/9 99/10 100/3 100/3 105/9 112/1 114/5 115/18 117/9 118/7 119/11 133/13 three months [1] 118/7 three QCs [1] 40/20 three units [1] 100/3 three weeks [2] 21/13 99/10 thrive [1] 90/24 thriving [3] 91/11 91/24 97/4 through [41] 9/2 11/10 11/11 11/13 11/20 12/6 14/25 16/19 24/20 30/10 53/3 53/20 54/19 55/6 64/17 66/8 69/6 70/4 71/4 72/4 78/5 79/1 81/9 83/11 87/13 94/10 114/8 115/1 116/11 116/21 120/16 121/18 122/22 123/9 123/10 123/14 126/5 126/7 128/2 130/12 133/11 throughout [8] 29/20 56/10 102/9 108/17 111/13 113/16 118/24 125/3 thumb [2] 56/9 56/12 Thursday [6] 1/1 114/16 114/20 115/4 120/18 122/8 tick [2] 83/9 83/10 till [1] 17/15 time [64] 2/15 3/24 5/15 9/5 10/2 14/13 14/25 15/9 15/20 15/24 18/4 22/3 32/11 34/6 34/23 39/11 39/12 40/7 40/17 40/20 45/7 46/13 50/20 56/18 56/19 57/14 57/20 58/1 58/10 59/7 59/16 59/17 60/10 63/12 64/4 67/10 70/4 71/20 72/8 75/15 75/16 86/10 86/12 93/7 93/15 93/21 97/22 102/9 103/21 104/6 106/21 106/22 109/12 111/5 111/20 115/10 118/18 120/2 120/23 121/1 124/25 129/17 130/5 134/4	times [5] 4/13 30/13 76/25 95/8 119/11 timing [1] 28/5 tiny [2] 11/10 11/21 tired [2] 116/12 116/14 tissues [3] 11/9 11/25 58/1 to [737] to 50 [1] 125/12 today [7] 30/4 85/18 97/10 97/25 134/13 134/21 136/7 toe [1] 133/5 together [6] 16/25 30/12 60/15 62/8 64/15 122/10 told [12] 5/16 64/19 84/24 104/9 104/24 104/25 105/3 107/18 107/20 107/20 109/20 119/5 tolerable [2] 95/12 133/17 tolerate [2] 95/14 100/3 tolerated [1] 58/10 tomorrow [3] 136/8 136/9 136/15 tonsil [1] 85/15 tonsillectomy [2] 26/20 27/16 too [12] 17/12 47/21 63/10 80/5 80/21 82/9 85/7 85/7 99/3 100/18 113/8 125/7 took [9] 1/23 25/8 30/4 59/16 69/11 75/16 87/24 112/11 119/17 top [15] 9/7 21/19 21/21 22/4 29/14 35/3 39/10 75/17 78/14 81/17 82/11 82/12 117/7 123/2 134/5 topic [2] 39/21 47/24 torn [1] 83/12 total [1] 109/25 totally [2] 79/25 82/24 tough [3] 76/12 123/11 134/4 towards [1] 13/18 toxicities [1] 95/22 tracking [1] 112/4 tragedy [1] 85/24 tragic [2] 85/20 85/25 train [4] 78/9 78/11 78/20 78/23 trained [4] 7/9 16/16 16/17 135/13 trainee [1] 74/4 trainer [1] 16/17
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(54) their... - trainer

T	Transfusion	tremendous [5] 43/21 122/16 123/4 127/13 132/11 trial [1] 111/8 trials [2] 84/2 84/2 tried [1] 40/21 true [2] 57/24 84/19 truly [1] 9/19 trust [7] 66/11 66/11 66/11 66/12 66/18 81/11 136/14 truth [5] 64/19 65/16 66/11 75/25 85/13 try [20] 8/3 21/22 22/6 22/15 23/7 40/18 41/11 41/14 42/25 48/21 67/22 69/3 70/20 99/15 99/17 99/18 111/23 112/1 117/19 117/25 trying [12] 16/21 20/2 23/2 23/2 44/24 50/9 80/7 100/6 100/11 108/21 111/18 132/11 Tuesday [2] 114/18 122/8 tummy [1] 94/14 tumours [2] 89/4 89/5 turn [18] 4/10 4/22 6/1 15/11 22/21 22/22 24/23 26/9 43/6 43/11 56/24 57/3 57/21 58/14 101/22 116/9 117/5 117/6 turnover [1] 122/1 two [35] 1/20 7/9 8/22 16/13 17/21 19/5 21/13 23/18 27/1 27/5 40/1 41/1 48/22 61/9 65/23 66/2 70/9 81/9 81/13 87/5 89/20 91/8 92/8 99/4 99/10 112/25 117/9 118/6 118/8 118/21 120/22 120/22 122/10 124/20 133/2 type [1] 84/6 types [1] 91/2	UKTS [1] 129/8 ultimately [1] 97/6 ultrasonography [1] 25/24 ultrasound [1] 125/13 unacceptable [1] 28/9 unbound [1] 93/23 uncomfortable [1] 100/9 uncovered [1] 42/9 under [7] 15/19 19/16 29/15 41/2 57/21 118/1 125/2 undergoing [3] 26/19 26/22 112/6 underlying [1] 49/14 underpinning [2] 42/8 64/10 understand [13] 4/18 5/14 36/18 37/2 42/15 52/8 66/7 66/23 73/2 75/19 85/10 85/19 122/21 understanding [9] 7/6 8/4 8/5 67/16 67/23 73/13 77/15 100/14 104/8 understood [5] 12/12 22/4 52/25 55/6 73/20 undertake [1] 1/24 undertaken [1] 37/14 undertaking [2] 27/22 51/24 undertook [2] 1/20 2/2 undue [1] 28/8 unfair [2] 42/1 42/3 unfortunately [6] 93/14 94/1 102/5 102/7 115/20 132/1 unhappy [1] 90/23 unit [11] 33/4 34/16 88/20 92/8 92/21 97/23 99/25 101/15 122/6 125/1 126/19 unit sizes [1] 99/25 units [13] 8/1 23/7 23/13 23/15 34/4 34/21 39/7 93/18 99/4 99/10 99/11 99/13 100/3 university [3] 5/23 15/25 108/24 unjustifiable [1] 5/9 unless [5] 5/9 54/13 78/7 90/17 97/18 unlimited [1] 5/3 unnecessarily [1] 5/5 unnecessary [1] 5/12 unsafe [1] 93/22 until [15] 1/21 1/23 2/3 2/10 3/11 3/16	13/23 39/21 51/2 87/18 90/19 94/3 94/17 124/10 136/17 untreatable [1] 81/15 untreated [1] 49/7 unwell [1] 29/7 up [74] 3/5 3/16 4/22 6/14 11/14 12/22 15/11 15/20 16/17 17/15 20/5 20/18 21/19 21/21 22/4 25/12 25/17 27/12 29/14 30/25 31/9 34/1 34/5 34/22 35/3 36/21 38/19 40/19 41/12 41/13 46/5 47/3 52/7 52/25 53/23 54/19 55/2 56/17 57/4 57/21 58/14 61/10 65/6 67/25 68/8 70/25 71/1 71/3 73/2 77/4 77/18 79/20 82/3 83/5 83/14 84/4 88/10 94/3 94/9 94/17 104/18 110/12 113/4 114/21 117/4 117/8 117/13 121/18 122/4 124/23 124/24 125/3 125/12 135/15 upbeat [1] 120/20 update [4] 31/14 62/4 62/6 65/17 updating [1] 105/11 upshot [1] 90/8 urgency [1] 28/4 us [35] 9/4 10/11 16/20 16/24 18/22 20/24 29/20 29/23 35/22 37/3 37/4 47/16 53/2 54/5 62/6 62/8 65/6 73/11 78/16 78/16 84/23 85/7 85/13 86/7 86/11 89/13 92/17 107/8 107/10 116/25 121/25 123/16 133/3 134/13 136/7 usage [1] 55/25 use [18] 5/6 5/12 13/16 16/15 18/11 19/15 31/4 33/22 48/19 54/9 54/13 54/16 56/5 82/4 82/5 82/23 116/8 126/7 used [12] 4/1 5/5 27/10 33/11 34/9 56/9 57/6 91/7 98/11 107/25 114/15 126/25 useful [2] 4/17 82/6 using [1] 50/13 usual [3] 64/13 99/6 114/19 usually [9] 23/16	53/21 58/17 90/20 94/10 96/20 97/1 97/3 99/4 V vaccinated [2] 104/15 130/8 vaccination [2] 67/24 104/14 vaccines [1] 104/19 value [2] 79/25 86/11 values [2] 6/18 64/16 variables [1] 99/12 variation [2] 99/7 99/8 variety [1] 72/21 various [7] 11/4 16/21 43/18 69/19 99/11 124/4 132/8 vary [1] 99/3 vascular [3] 4/5 4/6 22/18 vein [1] 22/16 veins [1] 22/17 version [2] 16/4 102/1 version 6 [1] 102/1 very [93] 3/19 3/21 8/8 12/18 13/13 15/14 17/9 17/11 18/22 22/17 22/25 24/25 25/1 27/7 27/9 29/18 32/7 33/2 35/10 35/11 37/11 40/4 40/6 40/9 40/13 41/5 41/8 45/17 48/10 51/8 51/16 51/22 53/3 55/4 64/16 65/15 66/9 68/17 76/22 77/7 78/13 81/19 84/9 86/4 86/11 89/3 91/22 92/23 93/6 94/18 95/7 95/7 96/5 96/8 97/16 99/24 99/24 100/7 101/18 103/19 103/19 105/20 105/22 105/22 105/23 106/19 107/3 107/4 111/7 111/16 113/14 113/14 114/3 115/14 116/9 116/12 116/12 119/2 120/6 120/19 120/19 121/16 123/5 123/18 125/8 132/4 133/17 133/23 134/10 134/12 135/23 135/25 136/7 vessel [2] 11/22 12/2 vessels [3] 11/11 11/21 12/22 via [1] 7/17 Vichinsky [2] 26/6 27/8 vicious [1] 12/20 view [9] 30/5 41/5
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V	warned [1] 73/14 wary [1] 27/7 was [370] washed [1] 29/25 wasn't [12] 27/9 35/19 35/21 35/22 60/1 64/23 73/8 83/11 98/12 104/10 118/4 127/4 wasting [1] 116/19 watch [2] 97/3 101/1 watching [2] 1/10 86/25 wave [1] 67/21 wave 3 [1] 67/21 waves [2] 68/4 70/9 way [25] 3/15 6/15 8/20 9/2 22/18 24/1 31/12 36/2 52/10 52/17 53/6 56/22 57/5 58/19 64/23 68/20 71/24 77/25 78/24 78/25 79/13 86/5 94/1 98/14 120/24 ways [11] 16/13 41/9 43/4 48/16 58/13 76/13 78/23 83/17 96/4 98/10 134/19 we [322] we'd [2] 110/19 126/18 we're [5] 81/22 100/25 107/18 124/13 131/18 we've [4] 81/24 124/16 125/21 131/11 weak [1] 90/21 wee [1] 19/10 week [11] 19/5 19/18 87/2 93/20 94/12 112/1 115/6 119/11 119/13 121/14 124/1 weekly [6] 68/14 111/13 113/11 113/17 114/3 114/12 weeks [17] 21/13 22/3 23/19 24/4 50/2 58/12 78/13 81/13 92/9 93/4 93/19 98/23 99/4 99/10 105/9 112/25 114/5 weigh [1] 25/17 weight [2] 98/9 116/16 welcome [4] 53/4 53/7 68/17 95/7 welfare [1] 47/5 well [65] 3/19 5/19 9/24 11/7 15/11 15/13 15/15 18/25 19/1 22/2 24/10 31/2 32/1 32/10 34/18 34/19 35/7 37/1 37/4 38/11 39/9 41/3	43/1 44/21 48/15 48/20 50/22 51/21 51/21 52/10 54/14 55/8 58/7 58/10 59/22 60/18 61/9 66/8 69/18 71/2 74/19 76/12 78/7 81/20 83/3 83/13 83/24 84/9 86/4 97/16 105/20 111/7 111/15 111/24 115/9 116/23 117/2 117/15 119/16 120/6 123/15 124/10 127/19 133/9 134/12 Wellcome [1] 81/11 went [18] 12/17 15/9 26/3 31/20 35/13 38/23 40/18 53/20 60/18 67/25 69/23 71/14 78/16 82/9 82/13 82/14 130/10 133/11 were [226] weren't [9] 27/22 32/4 110/19 111/19 113/18 114/4 119/2 126/25 127/4 whammy [1] 117/15 what [143] what's [6] 97/4 97/5 100/14 104/8 113/24 133/7 whatever [6] 9/9 9/14 100/20 101/6 105/24 108/24 whatsoever [1] 44/14 when [110] 1/11 2/10 3/18 4/1 4/2 5/15 7/14 7/19 9/21 10/6 11/14 12/4 12/13 12/19 12/20 13/14 14/17 15/8 15/12 15/14 15/15 15/17 16/12 16/22 16/22 17/1 17/20 18/6 20/6 24/6 25/8 26/1 27/21 30/7 32/17 35/3 36/23 36/25 37/3 37/4 37/23 37/23 45/9 47/2 48/6 48/13 49/13 50/14 52/9 53/16 53/17 53/19 57/7 58/23 59/3 59/9 60/3 60/12 60/13 60/16 62/3 62/6 63/9 63/12 64/19 66/19 68/5 70/18 74/12 76/9 83/20 83/24 84/24 85/8 87/3 88/12 88/25 90/8 90/13 90/21 96/15 97/8 97/12 102/2 102/4 102/16 102/20 102/21 102/23 103/15 104/13 104/14	106/15 107/17 107/20 108/5 109/10 110/10 110/11 110/16 112/4 118/8 119/15 119/25 126/23 127/6 130/20 130/24 132/1 132/2 where [28] 3/5 8/19 18/9 20/1 29/21 40/23 44/9 46/2 49/22 50/22 58/15 59/20 61/13 64/17 65/18 67/1 67/18 67/22 71/12 76/1 83/9 89/23 93/24 103/12 122/3 123/25 123/25 130/11 whereas [3] 21/16 49/1 65/13 wherever [1] 10/24 whether [23] 28/21 34/1 38/20 41/20 42/18 53/1 55/8 66/1 71/20 76/15 77/6 77/13 77/14 92/25 93/1 93/2 101/21 106/20 107/5 109/6 119/25 125/4 125/5 which [64] 3/7 8/23 8/23 13/21 20/22 20/24 24/14 33/20 34/2 34/9 42/10 46/19 47/21 48/4 49/16 50/2 50/3 50/10 50/12 51/5 55/19 56/16 63/11 66/16 72/20 76/9 77/1 78/6 78/10 79/17 81/1 81/15 82/25 84/10 86/5 86/6 89/5 90/10 90/15 93/8 94/5 94/24 95/1 95/11 96/22 100/5 101/10 101/25 103/8 103/20 105/18 113/3 113/6 113/22 114/1 115/20 117/5 117/6 125/17 127/11 132/15 135/2 136/4 136/4 while [5] 19/11 28/11 61/10 61/14 75/2 whilst [1] 70/19 white [2] 20/25 103/14 Whitehall [1] 61/24 Whittington [18] 87/21 87/25 92/6 92/18 96/22 101/17 101/24 102/3 109/8 109/25 110/2 110/13 112/17 115/12 121/15 123/17 132/18 132/20 Whitty [1] 83/25 who [104] 1/6 1/10 6/17 10/12 11/2 12/13 13/12 13/13 15/15	16/9 16/15 16/17 19/25 24/12 26/5 27/6 27/7 34/3 34/5 34/22 36/12 36/15 37/11 38/8 38/13 39/5 44/2 45/10 45/12 46/21 47/3 48/9 49/8 49/13 50/15 52/15 52/17 52/24 53/8 60/19 61/14 62/18 64/7 68/10 69/8 69/24 70/20 73/17 75/6 77/12 77/20 78/15 79/14 79/20 79/23 83/23 85/1 85/24 87/2 89/12 91/14 95/14 96/15 96/23 97/1 98/5 100/13 101/20 109/25 110/14 110/23 111/1 112/17 114/11 114/22 115/19 118/21 118/23 119/7 120/20 121/12 121/20 124/16 124/20 125/6 125/20 126/4 126/14 126/22 127/22 127/25 131/6 131/7 131/9 132/3 132/25 133/2 133/15 134/21 134/22 134/23 135/14 135/14 135/19 who's [1] 132/18 whoever [1] 51/6 whole [13] 20/7 20/15 20/19 23/1 38/9 61/20 85/25 89/5 97/20 99/2 116/16 118/24 130/12 whom [1] 72/2 whose [2] 58/6 58/10 why [28] 3/21 6/11 10/21 11/6 11/16 14/12 17/21 20/12 28/22 28/23 29/24 34/20 37/2 38/10 49/21 52/14 56/13 61/8 73/11 74/17 76/11 80/10 83/4 84/4 85/3 97/18 122/18 126/23 wide [1] 16/10 widely [1] 126/25 will [79] 1/10 1/12 1/13 4/10 8/18 10/9 12/8 13/4 19/9 21/1 24/22 28/8 30/9 30/14 37/18 39/9 39/21 43/9 45/6 45/7 47/14 50/14 51/1 51/24 56/23 61/9 67/1 70/16 71/23 72/5 72/10 72/11 72/12 75/8 75/17 79/4 79/17 87/5 87/6 88/2 89/19 91/5 92/15 94/21	97/16 99/20 100/21 100/21 101/4 101/7 101/22 104/1 107/14 107/15 108/6 108/18 117/4 117/5 117/6 123/18 124/2 125/2 125/12 125/13 125/18 128/13 128/16 128/19 131/23 131/23 131/24 132/12 134/13 135/14 135/18 135/20 136/3 136/9 136/13 will -- we [1] 125/13 William [1] 84/25 wishing [1] 135/25 with [192] with ethnicity [2] 42/12 42/19 within [11] 30/15 38/1 40/4 46/18 47/9 58/1 64/15 68/20 70/8 92/5 110/25 Withington [1] 5/22 without [15] 4/24 16/24 35/10 36/8 49/20 57/10 65/22 69/7 73/23 91/15 95/6 95/13 112/21 124/23 135/17 WITN6979003 [1] 101/22 witness [1] 77/22 witnesses [1] 41/1 woman [1] 52/10 women [4] 12/13 75/21 77/12 77/20 won't [2] 10/10 128/19 wonder [2] 47/25 71/22 wonderful [2] 16/15 46/21 wondering [1] 63/11 Woodland [1] 136/11 word [1] 16/15 words [1] 86/12 work [21] 2/16 3/5 4/5 22/21 23/10 26/5 50/20 52/1 53/11 61/18 71/16 83/5 83/18 83/21 87/13 94/8 96/4 122/25 129/4 130/20 135/14 worked [10] 2/20 33/7 71/4 71/12 74/19 83/13 84/19 87/17 120/3 126/22 workers [1] 135/14 working [17] 6/16 19/11 32/17 43/6 43/21 44/14 67/19 69/6 70/4 88/25 99/16 111/7 111/11 111/14
W	wait [2] 72/13 97/3 waited [1] 71/3 walk [1] 133/12 wall [1] 63/22 walls [1] 11/22 want [36] 1/17 3/15 18/11 19/4 28/21 35/1 36/18 37/4 41/18 43/11 43/12 50/7 52/12 53/1 53/11 60/3 78/6 83/4 83/5 84/21 86/12 98/13 98/19 100/18 107/1 108/7 114/17 122/20 123/8 135/10 135/12 135/20 135/21 135/24 136/1 136/2 wanted [14] 4/21 9/17 14/16 14/18 14/21 19/19 31/7 52/23 53/24 84/17 111/22 114/24 121/21 134/17 wants [1] 50/5 ward [3] 33/23 78/16 78/17 wards [3] 6/11 17/25 18/5 warm [2] 13/15 43/2 warn [1] 65/5				

W working... [3] 114/17 119/8 132/10 works [1] 83/19 workshops [1] 31/19 world [9] 27/5 27/5 54/19 81/7 81/15 89/22 96/8 107/13 109/1 world's [1] 73/15 worried [6] 40/15 53/5 53/5 59/19 135/3 135/4 worries [1] 115/8 worry [3] 23/22 27/15 65/13 worrying [2] 20/16 59/14 worse [1] 82/23 worst [2] 30/2 116/7 would [181] wouldn't [4] 59/15 90/18 100/23 130/16 wrap [1] 19/9 write [8] 17/11 36/4 47/7 53/22 60/11 62/14 63/17 63/18 writing [1] 135/8 written [8] 32/16 33/14 35/21 41/13 44/3 44/5 102/18 130/22 wrong [3] 56/3 83/10 85/2 wrongful [1] 77/23 wrote [6] 24/13 46/25 47/1 57/1 75/23 82/9	16/6 20/8 20/9 20/17 21/3 21/6 24/22 26/8 27/3 34/17 43/5 46/1 48/2 49/19 51/13 53/16 54/11 59/8 70/10 70/15 72/18 73/2 76/21 80/7 80/15 80/20 80/23 81/5 84/8 87/11 87/16 87/19 87/23 88/1 89/9 97/12 97/14 97/24 99/8 101/2 101/3 102/13 105/4 109/18 109/18 110/4 110/7 112/15 114/13 116/2 121/6 121/12 121/23 125/6 126/1 126/13 127/24 128/24 yesterday [1] 134/7 yet [4] 30/1 51/5 85/4 128/9 you [590] You'd [2] 22/18 22/20 you'll [1] 90/21 you're [8] 17/11 20/18 20/19 23/25 25/9 30/20 52/10 90/13 you've [14] 10/7 23/17 27/15 29/24 30/3 35/8 79/1 79/2 79/3 85/2 106/4 109/24 129/24 132/7 young [4] 17/20 94/18 107/5 129/9 younger [2] 2/17 131/18 youngsters [1] 98/18 your [124] 1/18 3/5 3/15 3/16 3/17 4/11 4/15 5/16 5/18 6/8 6/9 6/13 6/22 7/6 7/6 7/8 7/14 7/15 8/4 9/20 10/7 14/11 14/12 16/3 21/17 21/18 23/17 23/19 24/7 27/2 28/13 29/17 30/4 31/15 32/5 32/21 33/1 35/19 36/11 39/13 39/25 41/16 43/9 43/12 45/6 45/6 51/18 53/11 53/18 54/24 55/10 56/6 56/10 57/4 57/13 59/12 60/3 62/11 64/9 64/14 64/21 65/8 65/22 67/10 67/10 70/24 72/12 72/21 72/22 73/4 73/22 74/8 74/15 75/4 75/9 75/15 75/24 76/22 82/21 86/10 86/10 86/11 86/12 86/12 86/23 87/13 88/3 92/17	94/23 95/20 96/16 97/17 99/4 100/7 100/14 101/14 101/22 102/9 104/8 104/8 106/3 109/24 110/5 112/12 117/13 118/2 119/23 120/12 120/15 122/14 123/12 123/13 126/2 128/3 129/11 129/23 129/23 132/8 132/9 133/6 133/7 133/25 134/18 136/6 youth [1] 134/4			
Y yeah [1] 46/14 year [16] 7/20 10/19 30/13 45/3 63/5 67/25 81/14 82/13 84/1 93/21 104/18 111/14 113/16 116/22 118/24 119/14 yearly [2] 111/8 125/16 years [29] 1/21 4/15 6/9 6/22 6/24 7/9 19/12 19/22 24/7 25/22 34/25 37/5 46/1 46/2 48/6 57/16 70/14 70/15 74/11 89/21 96/12 96/22 108/17 112/1 117/22 120/18 124/14 126/9 129/8 yes [73] 1/22 2/1 2/6 2/9 2/14 2/19 2/22 2/25 3/4 3/10 3/12 5/17 5/20 9/17 15/21		Z zone [1] 113/19			

(57) working... - zone