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**Wednesday, 26th February 2020**

1  
2 **(10.39 am)**  
3 **SIR BRIAN LANGSTAFF:** My apologies, though I think  
4 perhaps no apology is needed, for the slight  
5 delay to the start this morning. As you'll  
6 hear, when the panel start to speak, there is  
7 what one might describe as something of  
8 a Scottish accent to it, and a flight from  
9 Scotland, as some of you who are here will know,  
10 was delayed this morning in arrival. It  
11 emphasises the difficulties in scheduling an  
12 event such as this, particularly with very busy  
13 and prominent experts who are also at the moment  
14 heavily engaged in fighting the Covid 19 virus  
15 and considering its consequences for us.  
16 **Ms Richards. May they be sworn?**  
17 **MS RICHARDS:** Sir, yes. We're having a slight  
18 technical issue behind us with an echo, which is  
19 very disconcerting and is going to have to be  
20 switched off. Perhaps Mary can do the  
21 honours -- oh great, I think it's just been  
22 switched off at the socket, which makes life  
23 much easier.  
24 **PROFESSOR JOHN DILLON (sworn)**  
25 **DR KATIE JEFFEREY (sworn)**

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1 the main aspects of this would be liver  
2 transplantation, primary liver cancers and  
3 autoimmune hepatitis.  
4 **DR JAMIESON:** Hi there, I'm Scott Jamieson. I'm  
5 a GP up in Kirriemuir in Scotland. I also have  
6 a role within the Royal College of General  
7 Practitioners in Scotland. I'm the executive  
8 officer for quality improvement in Scotland.  
9 I have a strong interest in improving the  
10 quality of services across Scotland in the  
11 clusters and improving detection and treatments,  
12 access to hepatitis treatments in Scotland as  
13 well.  
14 **DR JEFFERY:** My name is Katie Jeffery. I am based  
15 at the John Radcliffe Hospital in Oxford.  
16 I divide my time -- I work 100 per cent  
17 clinically, my time is divided being  
18 a laboratory microbiologist and virologist,  
19 working as an infection consultant, seeing  
20 patients with a broad variety of infections, but  
21 I also have 20 years of experience of working in  
22 the viral hepatitis clinic, looking after  
23 patients with both hepatitis B and hepatitis C.  
24 I also work as the director of infection  
25 prevention and control for Oxford University

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1 **DR SCOTT JAMIESON (sworn)**  
2 **DR AILEEN MARSHALL (affirmed)**  
3 **PROFESSOR GRAHAM COOKE (sworn)**  
4 **Examined by MS RICHARDS**  
5 **MS RICHARDS:** Can I ask you to start by introducing  
6 yourselves and saying a little about yourselves,  
7 perhaps starting with you, Professor Cooke, and  
8 then working your way down the table.  
9 **PROFESSOR COOKE:** I'm Graham Cooke. I've worked in  
10 the care of patients with HIV and hepatitis for  
11 over 25 years and I'm currently based at  
12 St Mary's hospital in London. There I lead the  
13 HIV-hepatitis service but the majority of my  
14 time now is spent on research, and my research  
15 focuses particularly on new hepatitis C  
16 treatments and how they work, but also how we  
17 improve access to those treatments, both within  
18 the UK and internationally.  
19 **DR MARSHALL:** I'm Aileen Marshall. I'm a hepatology  
20 consultant and I'm based at the Royal Free  
21 Hospital in London. It is a centre  
22 for specialist treatments for liver diseases and  
23 so most of my time is spent in the care of  
24 patients who have complications of chronic liver  
25 diseases or acute and sudden liver diseases, so

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1 Hospitals.  
2 **PROFESSOR DILLON:** I'm John Dillon, I'm a professor  
3 of hepatology and gastroenterology at the  
4 University of Dundee, and I am a consultant  
5 hepatologist and gastroenterologist at  
6 Ninewells Hospital in Dundee. I lead the  
7 clinical hepatitis and blood-borne virus  
8 services for NHS Tayside and I have spent  
9 30 years researching various aspects of  
10 hepatitis C and clinical liver diseases.  
11 **MS RICHARDS:** Thank you.  
12 The report which you produced was  
13 co-authored by you and by a number of other  
14 experts who are not here today, but whose names  
15 are detailed and qualifications detailed in the  
16 report. It's my understanding that there are no  
17 significant areas of disagreement amongst those  
18 who contributed to the report about its content;  
19 is that right?  
20 **PROFESSOR DILLON:** That's correct, yes.  
21 **MS RICHARDS:** And your report has been produced in  
22 response to two letters of instruction, and you  
23 have sought to address the questions in both the  
24 original and the second letter of instruction in  
25 this report, so there's no further report

<p style="text-align: right;">5</p> <p>1 currently expected or awaited?</p> <p>2 <b>PROFESSOR DILLON:</b> That's correct.</p> <p>3 <b>MS RICHARDS:</b> Can I start by asking you to address</p> <p>4 some fairly basic concepts. First of all, what</p> <p>5 is hepatitis and what is viral hepatitis?</p> <p>6 <b>PROFESSOR COOKE:</b> Maybe I'll start and then others</p> <p>7 will come in, I think.</p> <p>8 So in the first section of the report, we've</p> <p>9 outlined this very briefly and I think it's</p> <p>10 important because people use the term</p> <p>11 "hepatitis" in different ways, both as doctors</p> <p>12 and as patients and others. I think when we</p> <p>13 talk about hepatitis we try to be precise in the</p> <p>14 report, and in general terms we're talking about</p> <p>15 hepatitis meaning inflammation of the liver.</p> <p>16 And the most common way that that's picked up is</p> <p>17 with blood tests. So often we'll do a set of</p> <p>18 blood tests which will include liver function</p> <p>19 tests, and these are some specific tests which</p> <p>20 look at evidence of inflammation in the liver,</p> <p>21 and one which I expect we'll come back to in</p> <p>22 particular is ALT, and there are levels of what</p> <p>23 we expect to be normal in a normal patient and</p> <p>24 we define hepatitis when those are outside of</p> <p>25 those normal ranges; and there is various</p>	<p style="text-align: right;">6</p> <p>1 discussion about what normal ranges should be.</p> <p>2 So viral hepatitis in that sense doesn't</p> <p>3 tell you the cause of that viral -- sorry,</p> <p>4 hepatitis in that sense doesn't tell you the</p> <p>5 cause of that, and there are many different</p> <p>6 causes of hepatitis, some of which are</p> <p>7 infection, and amongst the infections, some of</p> <p>8 those are viral infections, and those will be</p> <p>9 obviously the focus of much of what we talk</p> <p>10 about today. But hepatitis can be caused by</p> <p>11 drugs, it can be caused by fat in the liver, it</p> <p>12 can be caused by genetic conditions, it can be</p> <p>13 caused by metabolic conditions. So there's</p> <p>14 a very wide range of causes, and often the</p> <p>15 assessment of hepatitis is trying to work out,</p> <p>16 both from questions and tests, which of those</p> <p>17 causes is likely to be the main issue.</p> <p>18 So within the viral infectious causes of</p> <p>19 hepatitis we have five main viruses: A, B, C, D</p> <p>20 and E. And hepatitis B and hepatitis C as</p> <p>21 chronic viruses will be the focus of this, and</p> <p>22 globally the majority of -- sort of 95% of viral</p> <p>23 hepatitis and the problems related to it comes</p> <p>24 from those two particular viruses. So in the</p> <p>25 report we haven't really dealt with</p>
<p style="text-align: right;">7</p> <p>1 hepatitis A and E.</p> <p>2 <b>MS RICHARDS:</b> No, and I'm not going to ask you with</p> <p>3 those today. I will ask you to deal a little</p> <p>4 with hepatitis D and with hepatitis G at a later</p> <p>5 stage.</p> <p>6 Again, dealing with some of the basics, how</p> <p>7 does inflammation of the liver, hepatitis,</p> <p>8 result from exposure to viruses? What's the</p> <p>9 mechanism that causes that inflammation?</p> <p>10 <b>PROFESSOR DILLON:</b> So if the cellular processes are</p> <p>11 disrupted by the virus -- the virus is</p> <p>12 a parasite, it uses the cell's own replication</p> <p>13 systems to replicate itself, and so as it does</p> <p>14 that it disrupts the normal function of the</p> <p>15 cell. The different viruses do things in</p> <p>16 different ways but they will change protein</p> <p>17 production. That will lead to damage in the</p> <p>18 cells. They can increase the amount of damaging</p> <p>19 toxins that are produced in the cell and cause</p> <p>20 damage to the cells.</p> <p>21 Ideally, the virus doesn't want to destroy</p> <p>22 the cell because it wants to carry on using the</p> <p>23 cell to replicate more of itself but viruses</p> <p>24 aren't clever so they can sometimes damage the</p> <p>25 cells. The chronic viruses tend to be better at</p>	<p style="text-align: right;">8</p> <p>1 maintaining a better relationship with the</p> <p>2 cells, so hepatitis B and C are sometimes less</p> <p>3 damaging in the short-term, which allows them to</p> <p>4 replicate chronically -- or better at evading</p> <p>5 the immune system, whereas the A and E viruses</p> <p>6 are more damaging acutely but are cleared away</p> <p>7 by the immune system.</p> <p>8 And the virus itself can damage the cell or</p> <p>9 else the immune response to clearing the virus</p> <p>10 can be the process that damages the cell. So</p> <p>11 it's two separate processes. It can be directly</p> <p>12 from the virus. Hepatitis B is perhaps</p> <p>13 more damaging to the hepatocyte than hepatitis C</p> <p>14 is, but the immune responses can be more</p> <p>15 damaging, which is why some people have much</p> <p>16 more florid illnesses than other people when</p> <p>17 they're infected with the same virus, and it</p> <p>18 depends on the immune response to those viruses.</p> <p>19 <b>MS RICHARDS:</b> You mentioned ALT and AST levels.</p> <p>20 We've heard quite a lot of evidence from</p> <p>21 individuals, looking at their records, seeing</p> <p>22 test results that relate to these, so it would</p> <p>23 be very useful, I think, for our communal</p> <p>24 understanding, for you to explain what is meant</p> <p>25 by AST and ALT levels, what the significance of</p>

9

1 the raised levels is, and what that can tell us  
 2 about the condition of the liver.  
 3 **PROFESSOR DILLON:** So ALT and AST are two enzymes  
 4 that are -- they are representative of a vast  
 5 number of enzymes that live within the  
 6 hepatocyte, okay? And those, they have  
 7 particular cellular functions but they are  
 8 particularly focused in the liver, the ALT more  
 9 so than the AST, the AST can also appear quite  
 10 commonly in muscles. And when those cells are  
 11 broken down and turned over, those enzymes leak  
 12 out into the bloodstream and we can measure them  
 13 in the bloodstream. If there is more damage to  
 14 the liver cells than normal, more of that ALT  
 15 and AST will appear in the bloodstream and will  
 16 show that hepatocytes are being damaged and more  
 17 hepatocytes are dying and being damaged that day  
 18 than the previous days when the values were  
 19 lower.  
 20 **PROFESSOR COOKE:** It's probably just worth  
 21 emphasising that you can see those raised levels  
 22 of those enzymes in the blood and the patient  
 23 may have no symptoms, and equally you can have  
 24 someone who is quite unwell where the  
 25 abnormalities are not that dramatically

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1 **PROFESSOR DILLON:** No. If I can perhaps explain?  
 2 **MS RICHARDS:** Yes.  
 3 **PROFESSOR DILLON:** If you think of the liver, it's  
 4 about a kilo and a half, and if there's 10% of  
 5 that turning over in a day, then that's how high  
 6 your ALT will be. If, over years, you've lost  
 7 two-thirds of that liver and you only have  
 8 500 grams left, the natural turnover of the ALT  
 9 will be much lower because there will be less  
 10 of it to escape into the serum, and therefore,  
 11 you'd have to have a lot more damage for it to  
 12 raise the levels, and so it doesn't correlate.  
 13 And with the hepatocytes that die, it's  
 14 a question of whether they die and are replaced  
 15 by new hepatocytes, which is what happens most  
 16 of the time, or they die and are replaced by  
 17 scarring and fibrosis, which then leads to  
 18 chronic damage and the fibrosis and cirrhosis  
 19 that we'll get on to talk about later.  
 20 **MS RICHARDS:** Thank you.  
 21 If I can just ask you to touch again, by way  
 22 of introduction, on hepatitis D, our  
 23 understanding from your report is that  
 24 hepatitis D, sometimes referred to as "delta  
 25 virus", only infects those who already have

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1 different. So when we're talking about the  
 2 tests, we tend to call it a biochemical  
 3 hepatitis with the evidence from these enzymes,  
 4 to distinguish it from what we might call  
 5 a clinical hepatitis, when a patient might have  
 6 symptoms which might involve tenderness over the  
 7 liver, for example.  
 8 **PROFESSOR DILLON:** Just to follow up, these  
 9 abnormalities are very, very common. 20% of all  
 10 liver blood tests measured have an abnormality  
 11 of their ALT levels, and so they are very  
 12 common, from a multitude of causes that  
 13 Professor Cooke alluded to his opening  
 14 statements.  
 15 **MS RICHARDS:** So is this right, and if it's not,  
 16 please correct me: raised ALT or AST levels will  
 17 not themselves be diagnostic of hepatitis B  
 18 or C, but they may be an indication that further  
 19 investigation, including the diagnostic tests  
 20 that we'll come on to, will be required?  
 21 **DR JAMIESON:** Absolutely.  
 22 **PROFESSOR DILLON:** Yes.  
 23 **MS RICHARDS:** Is there any indication between those  
 24 raised levels and the condition of the liver in  
 25 terms of fibrosis or cirrhosis?

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1 hepatitis B. And perhaps you could just outline  
 2 that for us.  
 3 **PROFESSOR COOKE:** That's right. And so the  
 4 terminology is used interchangeably sometimes,  
 5 so hepatitis D, delta virus, HDV as well. But  
 6 on its own, hepatitis D isn't able to replicate  
 7 and produce new virus, it relies on the presence  
 8 of hepatitis B and what that does to the cell  
 9 for it to be able to replicate. And it may  
 10 infect patients who already have hepatitis B,  
 11 and there are many examples of that, or -- and  
 12 particularly in the setting of  
 13 blood transfusion, perhaps, it might be at the  
 14 same time, and there are well documented cases  
 15 of that. And it's only able to maintain its  
 16 replication after that point. So I think in  
 17 terms of patients affected, we see that the --  
 18 what we would call hepatitis B delta  
 19 co-infection as a subset of hepatitis B overall.  
 20 **MS RICHARDS:** We asked you I think one of the  
 21 supplemental questions a specific question about  
 22 hepatitis G. Can I just ask you again by way of  
 23 introduction, just to tell us what hepatitis G  
 24 is, and what its significance is.  
 25 **PROFESSOR COOKE:** Katie, do you want to? I'll

<p style="text-align: right;">13</p> <p>1 just -- so hepatitis G was associated with                  2 co-infection, particularly with HIV, in the                  3 early stages, and there was a suggestion that it                  4 would influence the progression of HIV, and                  5 so -- and then there is an increased prevalence                  6 of hepatitis G in the setting of HIV in                  7 particular, and it was around the time of the                  8 discovery of hepatitis C we discovered the                  9 hepatitis G genotype as well. We thought it was                  10 our next hepatitis, and but we haven't found                  11 a significant clinical illness associated with                  12 hepatitis G. It appears that it can live in the                  13 liver but it doesn't seem to cause much damage,                  14 and it seems to be quite common in the                  15 population so it seems to be a commensal rather                  16 than a disease at the moment.                  17 <b>MS RICHARDS:</b> Now you've set out in your report in                  18 a little more detail, then, information about                  19 the viruses and I'm going to focus for present                  20 purposes on hepatitis B and hepatitis C and may                  21 ask you a little bit more about hepatitis D                  22 later. You tell us in the report that                  23 hepatitis B is a DNA virus, and there's                  24 a distinction between that and hepatitis C which                  25 is an RNA virus.</p>	<p style="text-align: right;">14</p> <p>1 Could you explain what those differences                  2 are?                  3 <b>PROFESSOR COOKE:</b> So DNA many people dealing with --                  4 it will be familiar to many people from common                  5 parlance, but deoxyribonucleic acid is different                  6 from ribonucleic acid and in general RNA can be                  7 converted into DNA and so these are different                  8 types of chemical entity that are different                  9 between the virus and I think it's one example                  10 highlighting how, although there are many                  11 similarities between the viruses they                  12 fundamentally are very different viruses and                  13 behave in specifically different ways.                  14 DNA clearly is part of our human body, has                  15 in its cells, and that DNA then produces RNA as                  16 a message to the cell to make proteins and, for                  17 example, hepatitis B can integrate into that DNA                  18 in a cell and that, we'll come back to later, is                  19 related to ability to clear the virus, whereas                  20 RNA viruses don't -- well hepatitis C doesn't do                  21 that and that's an important distinction between                  22 the two. Others may want to add other aspects                  23 of that.                  24 <b>MS RICHARDS:</b> In relation to hepatitis B, you've                  25 told us in the report there are eight recognised</p>
<p style="text-align: right;">15</p> <p>1 genotypes, and those are identified as A through                  2 to H. You've explained in the report that the                  3 clinical relevance of those genotypes is                  4 limited, in contrast with hepatitis C. Could                  5 you just again explain shortly why the different                  6 genotypes have relatively little clinical                  7 significance for hepatitis B?                  8 <b>PROFESSOR COOKE:</b> I think, it's difficult to explain                  9 why they don't have a lot of difference. One of                  10 the things to say is that there's a very wide                  11 geographic distribution of these different                  12 genotypes and obviously if you want to ask the                  13 question about anything, about whether A is                  14 different from B, you need to have studies where                  15 you can have groups of patients in a similar                  16 setting where you can look at how those                  17 different viruses behave in a similar population                  18 and tease out differences. There are relatively                  19 few big studies able to do that in different                  20 parts of the world.                  21 So you need an area where there's a lot of                  22 patients who have different genotypes within                  23 that, so it may be that there are things that we                  24 don't know and but, in general, there have been                  25 relatively few studies which have shown</p>	<p style="text-align: right;">16</p> <p>1 a difference in a particular population and we                  2 have mentioned one or two examples where there                  3 has been a suggestion in the report.                  4 <b>MS RICHARDS:</b> Your report explains, however, that                  5 there are pathogenic differences between the                  6 genotypes in relation to hepatitis B, and that                  7 those differences can explain progression to                  8 liver cirrhosis and to liver cancer. Could you                  9 elaborate on that?                  10 <b>PROFESSOR COOKE:</b> There are some examples, for                  11 example suggesting that maybe genotype C could                  12 be associated with a more aggressive course of                  13 liver disease than genotype B, but in general                  14 there isn't a big enough difference that that's                  15 a very useful part of a discussion with                  16 a patient or in planning management of                  17 a patient.                  18 But I mean there is one exception which is                  19 potentially in relation to response to in the                  20 interferon so although interferon was always                  21 historically really used for hepatitis C                  22 treatment, there is a small area of use still in                  23 hepatitis B, and some genotypes may respond                  24 differently in terms of their response to                  25 interferon. That's, you know, it's a relatively</p>

17

1 small part of practice for hepatitis B.

2 **MS RICHARDS:** And in the United Kingdom, genotype D,

3 I think, is the most common, in hepatitis B.

4 **PROFESSOR COOKE:** I think it would be fair to say we

5 don't have great information on the distribution

6 of genotypes in the UK, and I think both for B

7 and C, this is a reflection on both

8 transmissions within the UK but also migrant

9 populations moving in and out of the UK from

10 areas of very high prevalence. So what we have

11 seen is one fairly large study which tried to

12 look at this, is to number different genotypes,

13 and genotype D would seem to be one of the more

14 common ones but it's not the majority. There

15 are others that are present.

16 **MS RICHARDS:** Then in relation to hepatitis D before

17 we move on to hepatitis C, your report indicates

18 that it's around 3% of those in the

19 United Kingdom with hepatitis B will also have

20 hepatitis D. Hepatitis D itself has eight

21 genotypes but there's limited data available on

22 any clinical significance of those genotypes; is

23 that right?

24 **PROFESSOR COOKE:** Absolutely. And we looked quite

25 hard to try to find the best data we could from

19

1 explained as an RNA virus, has eight genotypes

2 and then in excess of 80 subtypes, and we'll

3 look at the genotypes in a little more detail in

4 a moment, but can you tell us what the subtypes

5 are?

6 **PROFESSOR COOKE:** Katie, do you want to take that?

7 **DR JEFFERY:** So, one of the things we talk about

8 also is quasispecies and the subtypes. So RNA

9 viruses, when they multiply they don't replicate

10 faithfully, you don't get exactly the same

11 genetic make-up of the RNA every time, and a lot

12 of the time that doesn't matter but sometimes it

13 introduces subtle changes, and that is how,

14 historically, the genotypes have arisen, and

15 then there are further subbranches of the

16 genotype, so within each genotype there may be

17 subtypes. So, for example, within genotype 1,

18 we have two big subtypes, 1A and 1B, but there

19 are other further subtypes. So it's almost like

20 a family tree where you start out with

21 genotype 1 and then different species, subtypes,

22 as the virus evolves.

23 **MS RICHARDS:** And in the United Kingdom it's

24 genotypes 1 and 3 that account for some 40% of

25 hepatitis C infections; is that right?

18

1 the UK, and others may have found some more, but

2 there isn't very good data to tell us, but

3 I think, as an overall view -- and remember

4 we're talking about everybody with hepatitis B

5 from all causes of infection -- we think the

6 prevalence is probably around 3 per cent, and we

7 don't have very much data at all on which

8 genotype is more common. And again, in terms of

9 relevance of genotype and its setting to

10 a patient and the patient's management, it's

11 relatively less important to know what that

12 genotype would be, although there are

13 potentially some exceptions, and then we're

14 getting into quite small print about, you

15 know ...

16 **MS RICHARDS:** Professor Dillon.

17 **PROFESSOR DILLON:** So in terms of that rate of delta

18 infection, it's only in people who have been

19 infected with hepatitis B and who have become

20 chronic carriers of the surface antigen, so its

21 that combination. So it's even -- it's a much

22 smaller set of dolls, if you like, Russian

23 dolls, in terms of number of patients that are

24 actually affected.

25 **MS RICHARDS:** Now hepatitis C, which you've

20

1 **PROFESSOR COOKE:** Each, yes. So I think that -- so

2 genotype 1 remains just about the most common.

3 And I think one of the things that's a little

4 bit different in the UK from perhaps some other

5 similar northern European countries is we have

6 a relatively high proportion of genotype 3

7 infection, and that in some ways reflects

8 migration back and forth to the Indian

9 subcontinent. And if people have the report, in

10 figure 15.2 we tried to illustrate how different

11 genotypes distribute across the world.

12 **MS RICHARDS:** We'll put that onscreen, I think. It

13 will be easier for those people to follow. So

14 it's EXPG000001, and page 5, it should be,

15 Henry.

16 **PROFESSOR COOKE:** So I think, if I may, just to make

17 the point that I think -- we had a lot of

18 supplemental questions about hepatitis C

19 genotypes, and clearly -- both from a patient

20 perspective and a decision-making perspective

21 about treatment -- genotypes have been a really

22 important part of that discussion for a long

23 time, and that's changing, and we can talk about

24 that a little bit, but there are very clear

25 differences both in the genotypes and some of

21

1 the sub-genotypes that Dr Jeffery mentioned. So  
 2 I think that's obviously been a greater focus in  
 3 terms of trying to describe that.  
 4 **MS RICHARDS:** We've got the figure up onscreen. It  
 5 should be onscreen in front of you. Could you  
 6 perhaps just talk us through what it shows us.  
 7 **PROFESSOR COOKE:** I think what this figure is trying  
 8 to show is to illustrate two things, really. So  
 9 each of these pies, if you like, is  
 10 proportionate in size to the number of patients  
 11 we think have been exposed to hepatitis C in  
 12 different parts of the world, in terms of  
 13 numbers. So you can see obviously very large  
 14 numbers in Indian subcontinents and South East  
 15 Asia and substantial numbers in many parts of  
 16 the world. And then we've tried to estimate and  
 17 colour-code each of those pies according to  
 18 which types of genotypes are most common in  
 19 those areas.  
 20 If you look at the European chart as  
 21 a whole, red, being genotype 1, is the most  
 22 common. And as I mentioned, the UK is slightly  
 23 different from that, because of the green area,  
 24 genotype 3 being a bit bigger. And if you look  
 25 at India and the Indian subcontinent, you can

23

1 a greater focus on the numbers of patients who  
 2 remain with virus and need treatment. So  
 3 broadly speaking, I think the figure for the UK  
 4 that I last saw was about 210,000 patients with  
 5 antibody prevalence, about 160,000 in England,  
 6 and that's changing, but the proportion of that  
 7 who have -- the proportion of that number who  
 8 still have the virus is obviously diminishing  
 9 quite rapidly with roll-out of treatment.  
 10 And you might want to comment on the  
 11 numbers, John, in terms of Scotland and where  
 12 things are.  
 13 **PROFESSOR DILLON:** I think things have changed over  
 14 the 20, 30 years. It depends on how much  
 15 monitoring we do, and we don't have perfect  
 16 monitoring, we don't screen everybody in the  
 17 country for hepatitis C, so we don't know  
 18 precisely, but from the estimates and the  
 19 studies we thought, back in 2006, 2007, that  
 20 perhaps 1% of the Scottish population, about  
 21 50,000 people, were infected. About 0.5% of the  
 22 English population were infected, and  
 23 a proportion of that. What has happened over  
 24 time is those numbers have come down, so  
 25 Scotland is now probably around 21,000 people

22

1 see very much dominated by genotype 3. That's  
 2 part of the explanation. And overall, in the  
 3 world, we would say about 45% of hepatitis C is  
 4 due to genotype 1, based on the estimates we  
 5 have.  
 6 **MS RICHARDS:** Do we have an estimate of the numbers  
 7 of people in the UK who are infected with  
 8 hepatitis C?  
 9 **PROFESSOR COOKE:** That's a kind of important  
 10 question that I don't want to give a very  
 11 specific answer to -- John may do that -- but  
 12 I think -- the good thing is that's a dynamic  
 13 number, because things are changing very quickly  
 14 at the moment. And I think there's an important  
 15 distinction in all these numbers about patients  
 16 who have antibodies, and I think this is an  
 17 issue that has come up in a lot of the  
 18 testimony, and we heard on Monday again, the  
 19 difference between patients who have antibodies  
 20 who may or may not actually still harbour the  
 21 virus, and people who actually have the virus or  
 22 would be viremic, as we would say.  
 23 Often the estimates we've had historically  
 24 have been based on antibody tests and exposure,  
 25 whereas I think at the moment we're having

24

1 left with the virus. That's both those that  
 2 know they have the virus and those that don't  
 3 know they have the virus.  
 4 There's a similar proportion in Scotland,  
 5 and that's the effect of both treatment, death  
 6 with the virus, and new people not becoming  
 7 infected, because if you think of the prevalent  
 8 cases, it's dependent on all three of those  
 9 things, and so that's a dynamic number. And  
 10 with the new treatments that have become  
 11 available, that number is shifting downwards  
 12 very rapidly, and with both England and Scotland  
 13 and Wales being committed to elimination, that  
 14 number will continue to fall rapidly in the next  
 15 couple of years, so it's a dynamic number.  
 16 **MS RICHARDS:** Then sticking, if we can, with  
 17 genotypes because there were number of  
 18 supplemental questions asked of you in relation  
 19 to genotypes, is there any information about the  
 20 prevalence of particular genotypes amongst those  
 21 who were infected in the United Kingdom through  
 22 transfusion of blood or blood products? Has  
 23 that been the subject of research or studies, as  
 24 far as you know?  
 25 **PROFESSOR COOKE:** So there is data. We weren't

25

1 asked that question, and so we haven't provided  
 2 that data. I mean we could provide that data if  
 3 it's helpful.  
 4 **MS RICHARDS:** We might ask you to do that. I've  
 5 been asked to ask that question by core  
 6 participants, which is why --  
 7 **PROFESSOR COOKE:** I understand.  
 8 **PROFESSOR DILLON:** If I can -- so the genotype won't  
 9 identify your route of transmission reliably.  
 10 While you are more likely to be genotype 1 if  
 11 you are infected through a blood transfusion,  
 12 you could equally be genotype 2, 3, 4 or 5, and  
 13 if you acquired it through another route,  
 14 proportions may change slightly but they will  
 15 vary more geographically than they will by route  
 16 of infection, so it's not a reliable -- it's not  
 17 an absolute rule that if you've got this  
 18 genotype it must have come from a blood  
 19 transfusion or from some other route, so the  
 20 genotype isn't useful in predicting that.  
 21 **MS RICHARDS:** You've said in the report it's not  
 22 known if certain genotypes are more likely to be  
 23 associated with spontaneous clearance of the  
 24 virus.  
 25 **PROFESSOR COOKE:** Yeah, so just for sort of context,

27

1 early introduction of treatment was more  
 2 effective in genotype 3 than genotype 1 and so  
 3 it became difficult to do the studies to work  
 4 out the natural history because people weren't  
 5 being left untreated.  
 6 **PROFESSOR COOKE:** If I may, it's probably helpful to  
 7 pause for a moment with genotype 3 because as  
 8 John was saying, it can cause a bit of confusion  
 9 that when -- in the era of treatment for  
 10 hepatitis C, genotype 3 was referred to, and  
 11 I think many people wouldn't like this phrase  
 12 but it was referred to as "easier to treat", now  
 13 for people who had six months of interferon that  
 14 won't necessarily be "easy to treat" but it was  
 15 comparatively higher cure rates for interferon  
 16 therapy for genotype 3 compared to genotype 1,  
 17 for example.  
 18 As we may come back to later, in the current  
 19 era of treatment actually it's probably a little  
 20 bit harder to treat genotype 3 than genotype 1.  
 21 So I think when people talk about easy and hard  
 22 it becomes a little more confusing, so  
 23 genotype 3 has clearly changed in its relative  
 24 ease of treatment over time.  
 25 **MS RICHARDS:** It's possible, as I understand it from

26

1 then, a large number of patients who get  
 2 infected with hepatitis C can clear that virus  
 3 without any treatment. And it sort of goes back  
 4 to the question of it doesn't necessarily mean  
 5 there isn't -- it isn't an effect, but it's hard  
 6 to get data to show that effect. There is some  
 7 suggestion in some settings, for example, that  
 8 genotype 1 may have a slightly higher clearance  
 9 rate, particularly in patients who have got HIV,  
 10 based on some studies. But there isn't a lot of  
 11 comparative data, because it's not a very common  
 12 problem to study.  
 13 **MS RICHARDS:** In terms of progression to liver  
 14 damage, liver disease, cancer, what data, if  
 15 any, exists about the significance of the  
 16 genotype in relation to that?  
 17 **PROFESSOR DILLON:** So the evidence is not perfect,  
 18 but there is a suggestion that genotype 3 is  
 19 more likely to progress more rapidly, not vastly  
 20 more rapidly but that a higher proportion of  
 21 patients with genotype 3 than, say, genotype 1  
 22 would have cirrhosis at each time point that you  
 23 followed them up for, and so there does seem to  
 24 be that effect.  
 25 That was counterbalanced because of -- the

28

1 your report, to be infected with more than one  
 2 genotype, but typically someone will have  
 3 a dominant genotype.  
 4 **PROFESSOR COOKE:** Yes, I think we put a section in  
 5 about that and I think that was one of the  
 6 supplemental questions. So there are a number  
 7 of issues, so if you are infected with  
 8 hepatitis C, whether or not you're cleared or  
 9 cured, that doesn't give you the same level of  
 10 protection that a vaccination might give so it's  
 11 very -- it's possible to be reinfected after  
 12 you're treated, but that also means that if you  
 13 have an active infection you can get an active  
 14 infection on top, and the older tests for  
 15 detecting genotype would tend not to detect all  
 16 of that difference in virus. They tend to  
 17 defect the more common one, and so you'd often  
 18 just get one of those reported.  
 19 What we can see more clearly now with modern  
 20 techniques in sequencing that others are better  
 21 qualified to talk about is that we can see the  
 22 relative different proportions of different  
 23 virus that a patient may harbour. So I think  
 24 there is evidence clearly that patients infected  
 25 with multiple exposures can have different

29

1 genotypes within one person and we can come on  
 2 to the relevance of that if it's helpful.  
 3 I don't know if anybody wants to add to that.  
 4 **PROFESSOR DILLON:** I think just to add, the  
 5 relevance of that was in the past when we had  
 6 treatments that were -- if say genotype 3  
 7 appeared to be the genotype that the person was  
 8 infected with, if they were treated with the  
 9 shortened courses of treatment that we were  
 10 using at that stage for genotype 3, we might  
 11 then see a genotype 1 infection appear because  
 12 we'd cured the genotype 3 but the genotype 1 had  
 13 appeared, so that was the problem back then.  
 14 With the modern therapies that becomes less of  
 15 an issue because they are very effective against  
 16 all genotypes.  
 17 **PROFESSOR COOKE:** So we were asked a specific  
 18 question about whether having multiple genotype  
 19 infections was associated with a worse outcome,  
 20 so we looked quite hard to find that data. Now,  
 21 we didn't find clear data to show that, and  
 22 that's not to say that that's not the case, it's  
 23 just that we weren't able to find the evidence  
 24 to show that, but I think we can know from first  
 25 principles that it's -- there are potential

31

1 difficult to find in the literature evidence  
 2 going beyond those number of thousands of years,  
 3 but they probably have been around for a very  
 4 significant amount of time, and obviously we'll  
 5 never get a clear data on that, but they have  
 6 both been around for thousands of years, and  
 7 they have spread more widely around the world in  
 8 recent years and, of course, we have the ability  
 9 to diagnose them now so we've become much more  
 10 aware of them.  
 11 **MS RICHARDS:** Now, in section 15.3 of your report,  
 12 you were asked by the Inquiry to provide a short  
 13 history, a short chronology, and Professor Cooke  
 14 you're going to talk through that a little but  
 15 with a number of qualifications. First of all,  
 16 we've asked you to focus on current knowledge  
 17 and understanding, not the question of what was  
 18 known by whom, or what should have been known by  
 19 whom and when. This is not intended by any  
 20 stretch of the imagination to be comprehensive  
 21 or exhaustive.  
 22 In particular, I'm not going to ask you to  
 23 address the questions that might arise in  
 24 relation to the second half of the eighties and  
 25 early nineties about whether things could have

30

1 risks there and I think John has highlighted one  
 2 of the main ones there, which is that you may  
 3 get inappropriate -- you may not get the  
 4 treatment you would have had otherwise if it had  
 5 been known that you had these other genotypes.  
 6 **MS RICHARDS:** And does exposure to multiple  
 7 genotypes or having multiple genotypes make  
 8 spontaneous clearance less likely?  
 9 **PROFESSOR COOKE:** I'm not aware of evidence of that.  
 10 It's -- I think unusual to be exposed to more  
 11 than one at the same time.  
 12 **MS RICHARDS:** You've explained in your report that  
 13 both hepatitis B and hepatitis C are viruses at  
 14 least now known to have been around for several  
 15 thousand years. The figures you've given in  
 16 your report is hepatitis B has been found in  
 17 human remains up to four and a half thousand  
 18 years old, and that it's estimated that  
 19 hepatitis C first emerged over 3,000 years ago,  
 20 but it's in the last 100 years that both viruses  
 21 have spread geographically. That's due to,  
 22 I think in particular you identified to  
 23 migration and geographical factors; is that  
 24 right?  
 25 **DR JEFFERY:** Yes, that's correct. I think it was

32

1 been done earlier, should have been done  
 2 earlier, in relation to non-A non-B hepatitis,  
 3 hepatitis C. So with all those qualifications,  
 4 because those are matters of fact which the  
 5 Inquiry is investigating for itself for  
 6 determination by Sir Brian on the basis of  
 7 a very wide range of contemporaneous materials  
 8 that we have not provided to you, could I just  
 9 ask you to talk us through some elements of --  
 10 some milestones in the emergence of -- that  
 11 informs modern science.  
 12 **PROFESSOR COOKE:** Yeah, certainly. So the question  
 13 put to us is as it's in the report, and I think  
 14 we had a lot of discussion as to how we would  
 15 best present this and in the end we felt this  
 16 was probably quite a helpful way to present  
 17 a chronology. You will notice tomorrow as well  
 18 that we've tried to harmonise this a little bit  
 19 with the HIV chronology as well, so we haven't  
 20 dealt with a lot of things that may be relevant,  
 21 particularly from HIV, in this list.  
 22 The first point is where do you start?  
 23 Although we've chosen the point of discovery of  
 24 hepatitis B as the point to start, clearly it  
 25 was recognised before that for decades that



<p style="text-align: right;">33</p> <p>1 hepatitis existed as we described it already,  2 and that there were different forms of  3 hepatitis.</p> <p>4       There was what was then called infectious  5 hepatitis, which we now know to be hepatitis A  6 and then serum hepatitis which we now determine  7 as hepatitis B. So really the beginning of the  8 era of understanding hepatitis better began with  9 that discovery of what was first called  10 Australia antigen and we now call hepatitis B  11 surface antigen.</p> <p>12       I think just to make a general point about  13 dates, we've put a date in here which references  14 a paper that reported it, but I think there's  15 a general issue about when was something  16 actually discovered that we haven't really gone  17 into, and this is probably more relevant for  18 other things later, but clearly although a paper  19 comes out at a certain point, there's a process  20 before that, where knowledge is evolving, and  21 being shared, and that then leads finally to  22 a public presentation, so we have just chosen  23 a date we can reference.</p> <p>24       But obviously, once a virus is discovered  25 and hepatitis B in that case in the mid-sixties,</p>	<p style="text-align: right;">34</p> <p>1 that then leads to the ability to develop  2 a diagnostic test and I'm sure we'll come on to  3 that in more detail, and those tests were  4 introduced in the UK in the 1970s and, as you  5 say, we've been deliberately non-specific about  6 the precise dates because we understand the  7 Inquiry will look at that in more detail, both  8 for hepatitis B and hepatitis C.</p> <p>9       But once tests are available, that allows  10 surveillance, it allows a structure from  11 a public health perspective to go into place,  12 which happened during the 1970s for hepatitis B,  13 and of course, at that time it was then possible  14 to distinguish patients who had biochemical  15 hepatitis who didn't test positive for hepatitis  16 A, the virus which was discovered in the early  17 1970s, or hepatitis B. That's where this term,  18 non-A non-B hepatitis developed until the  19 discovery of hepatitis C.</p> <p>20       So really we see through that first period  21 the understanding, an improved understanding of  22 non-A non-B hepatitis, introduction of  23 hepatitis B vaccination for those at risk, and  24 obviously in the background of an emerging HIV  25 epidemic that was really important and I think</p>
<p style="text-align: right;">35</p> <p>1 that, you know, for the diagnostic side of  2 things, the discovery of hepatitis C as the main  3 cause of non-A non-B hepatitis was crucial at  4 the end of the 1980s and then led to the ability  5 to introduce tests very rapidly that could be  6 used to diagnose that initially, and antibody  7 based tests which we can come back to.</p> <p>8       So then, after that period, we then see,  9 sort of, what we might characterise as a sort of  10 developing field of hepatitis in terms of  11 treatment in particular, through the early  12 nineties, and better reporting with the ability  13 to detect both hepatitis B and hepatitis C by  14 this stage, and more international recognition  15 of the challenge of viral hepatitis and  16 introduction of various committees and public  17 health bodies that were focused on trying to  18 address that.</p> <p>19       With some treatment available, largely with  20 interferon at that point, and it was really in  21 the later nineties, at the same time that HIV  22 treatment was developing, that treatment --  23 specific treatments for hepatitis B and C became  24 more commonplace, and so the first -- the first  25 what we would call directly acting treatment for</p>	<p style="text-align: right;">36</p> <p>1 hepatitis B with Lamivudine in 1998, an HIV  2 drug, and subsequently other drugs we can come  3 on to, help to manage a group of patients with  4 chronic hepatitis B, and at the same time we  5 were seeing improvements, although it's an  6 improvement from a low base, in terms of  7 interferon treatment, both with the addition of  8 pegylated interferon, which could be given less  9 frequently with some improvement in side effect  10 profiles and better cure rates, and the  11 combination of that with ribavirin through the  12 nineties, which then allowed a sort of growing  13 evidence base around how best to manage and  14 treat hepatitis C and hepatitis B, but  15 hepatitis C in particular developing through  16 that phase.</p> <p>17       And to the point of sort of around the turn  18 of the millennium there was a much greater  19 public health focus on what needed to be done to  20 both prevent and treat viral hepatitis B and C  21 in particular. We've listed a number of key  22 events in terms of creating bodies and  23 structures that allowed that to happen. I think  24 we saw in the first decade of this millennium an  25 increasing international awareness of the</p>

37

1 importance of viral hepatitis and more  
 2 international involvement which led to more  
 3 investment, until the point about 5 years ago  
 4 now where there was rule transformation driven  
 5 by the changes in hepatitis C treatment which  
 6 really were transformative in terms of what that  
 7 meant for medicine, and it's one of the biggest  
 8 areas of medicine as a whole that's changed in  
 9 the last decade.

10 It transformed the ambition of what people  
 11 had towards viral hepatitis as a whole, both  
 12 nationally and internationally, and we've seen  
 13 since then very ambitious international targets  
 14 for the elimination of viral hepatitis with  
 15 funding in some cases following that, and very  
 16 much more ambitious programs throughout the home  
 17 nations in terms of trying to address  
 18 hepatitis C in particular. But also more  
 19 recently scaling up hepatitis B vaccination for  
 20 example, and other aspects of tackling viral  
 21 hepatitis.

22 So I think that's hopefully a kind of broad  
 23 overview without going through the individual  
 24 points but we can go back to individual points  
 25 if it's a help.

39

1 the Inquiry's work, and you've set out an  
 2 explanation of current screening measures in  
 3 relation to blood donation and I'm not going to  
 4 ask you to deal with that in any more detail.  
 5 Again, in particular, the historic position in  
 6 that regard is going to be a central part of the  
 7 Inquiry's later hearings. But there is just one  
 8 question that I want to ask being picked up by  
 9 a number of core participants, it's page 9 of  
 10 your report, and it's in the section which gives  
 11 a narrative overview of the current practice in  
 12 relation to screening and testing of blood  
 13 donations.

14 You've picked up in the second paragraph  
 15 this:

16 "Data from SHOT [and SHOT is Serious Hazards  
 17 of Transfusion] demonstrate that there has not  
 18 been a confirmed case of transfusion transmitted  
 19 HCV in the UK since 1997 and one confirmed and  
 20 two probable cases of transfusion transmitted  
 21 HBV in the last 10 years."

22 Now, that's something that a sample of core  
 23 participants have been particularly interested  
 24 to see but it may be something that you're not  
 25 able to shed any further light on and it's

38

1 **MS RICHARDS:** In setting out that overview, you  
 2 weren't asked to and you haven't, drawn any  
 3 conclusions one way or another about the  
 4 adequacy or otherwise of measures that were  
 5 taken or not taken, whether things could have  
 6 been done earlier or should have been done  
 7 earlier, because that's not the exercise you've  
 8 been asked to do.

9 **PROFESSOR COOKE:** Yes.

10 **MS RICHARDS:** So it's important that what you've set  
 11 out there is understood in that context.

12 **PROFESSOR COOKE:** That's correct and also we've  
 13 tried to reference dates where we can  
 14 objectively do that and I think it's important  
 15 to recognise that even around treatment  
 16 introduction there may be practice that's  
 17 different from those dates, and so we wouldn't  
 18 want that to be sort of taken too rigidly.

19 **MS RICHARDS:** Now I want to move to the question of  
 20 how blood borne viral hepatitis, how hepatitis B  
 21 and hepatitis C are transmitted.

22 You have dealt with that in section 15.5 of  
 23 your report. You first identified transfusion  
 24 of blood and blood products, as a means of  
 25 transmission and, obviously, that's the focus of

40

1 a question that needs to be directed to JPAC but  
 2 do you have any more information about those  
 3 cases, given the dates of them?

4 **PROFESSOR COOKE:** I think I would say that one of  
 5 the experts who -- our main expert in this area  
 6 is not here, and I think I'd be reluctant to go  
 7 too much further but I don't know if others have  
 8 more insight as to that.

9 **DR JAMIESON:** I suspect from a confidentiality  
 10 perspective in general, with numbers as small as  
 11 that, I don't know how much more detail you  
 12 would be given, because obviously you'd be  
 13 identifying them, they're such unique cases but  
 14 I'm sure they'd do that with due prudence to the  
 15 confidentiality of the individuals unfortunately  
 16 involved in that but I'm sure the details from  
 17 the JPAC guys would be more interesting.

18 **MS RICHARDS:** The SHOT report itself, I think,  
 19 doesn't give any more information --

20 **DR JAMIESON:** Yes, I think that's probably for that  
 21 reason. Usually -- in these kind of things  
 22 that's sometimes for those kinds of reasons.

23 **PROFESSOR DILLON:** My understanding is there was  
 24 a system failure within the laboratory testing  
 25 that the test was performed but didn't detect

41

1 the positive virus for whatever reason, now  
 2 whether that was the-- there was concern about  
 3 the quality of control of the testing and dates,  
 4 etc, but it's a reflection of if you've got tens  
 5 of thousands of tests being done there is always  
 6 the potential for one of the tests not to  
 7 function as it is supposed to and expected to  
 8 test. So that's the likely outcome that was  
 9 associated with that but it's a constant quality  
 10 control and audit process that they are  
 11 constantly checking and back checking all -- all  
 12 of their processes, and the fact the hundreds of  
 13 thousands of tests have only failed on that  
 14 small number of occasions is reassuring.  
 15 **MS RICHARDS:** Thank you for that, and we'll perhaps  
 16 direct those queries elsewhere to see if we can  
 17 find out any more about that information.  
 18 The other routes of transmission, for the  
 19 sake of completeness, you've identified in your  
 20 report, first of all mother to child, what's  
 21 often referred to as vertical transmission.  
 22 That can occur in both hepatitis B and  
 23 hepatitis C.  
 24 **PROFESSOR DILLON:** Mm-hm.  
 25 **MS RICHARDS:** And that can occur both during

43

1 **SIR BRIAN LANGSTAFF:** That is of the cases  
 2 transmitted vertically, is it?  
 3 **PROFESSOR DILLON:** Yes.  
 4 **PROFESSOR COOKE:** Yes.  
 5 **SIR BRIAN LANGSTAFF:** I thought that was clear, but  
 6 I thought I'd make it clear.  
 7 **MS RICHARDS:** And then, again, in this section of  
 8 the report, you've gone on to talk about  
 9 horizontal transmission between children and  
 10 I wonder if you could, although it's not  
 11 a significant area of focus for the Inquiry,  
 12 again so we can understand all routes of  
 13 transmission, could you explain briefly what  
 14 that refers to?  
 15 **PROFESSOR COOKE:** Yes, so this is particularly an  
 16 issue for hepatitis B and it's really a well  
 17 recognised issue in low-resource countries,  
 18 particularly high prevalence countries in  
 19 western Africa where it's been very well  
 20 described of hepatitis B negative children  
 21 becoming positive during childhood, presumed by  
 22 contact with other hepatitis B positive  
 23 children. Although we didn't really know fully  
 24 that means of transmission, and it's important  
 25 to emphasise we're in an era where hepatitis B

42

1 pregnancy and around the time of delivery.  
 2 **PROFESSOR DILLON:** Yes.  
 3 **MS RICHARDS:** Breastfeeding does not transmit  
 4 hepatitis B or C, as I understand it, unless  
 5 there is significant skin damage, skin breakage;  
 6 is that right?  
 7 Certainly, transmission of both hepatitis B  
 8 and hepatitis C can occur vertically from mother  
 9 to child during pregnancy and around the time of  
 10 delivery; is that correct?  
 11 **PROFESSOR DILLON:** Yes.  
 12 **MS RICHARDS:** Thank you.  
 13 Breastfeeding, by contrast, is not a route  
 14 of transmission in either hepatitis B or  
 15 hepatitis C, unless there is clear breakage to  
 16 the skin and bleeding?  
 17 **PROFESSOR DILLON:** Yes.  
 18 **SIR BRIAN LANGSTAFF:** Can I just understand, while  
 19 we're on this section of your report, how -- or  
 20 that my understanding of the percentages quoted  
 21 is correct, you say at the bottom of page 9 that  
 22 up to 40% of transmission of HBV is before the  
 23 onset of labour and you quote 30% I think for  
 24 HCV.  
 25 **PROFESSOR DILLON:** Mm-hm.

44

1 vaccination even in the poorest countries is  
 2 being scaled up very substantially and that's  
 3 becoming less of an issue, but it is nonetheless  
 4 still an important mode of transmission but less  
 5 so in our own setting, I think.  
 6 **MS RICHARDS:** And you've explained that infants  
 7 infected in early life are much more likely to  
 8 develop long-term chronic infection than adults.  
 9 First of all, is that true both for hepatitis B  
 10 and hepatitis C? Or is it just one?  
 11 **PROFESSOR COOKE:** It's well described for  
 12 hepatitis B and I think it's generally an  
 13 important issue to understand it in that at the  
 14 younger ages, the likelihood of becoming  
 15 a chronic infection is higher, you know, maybe  
 16 as high as 90 per cent, as opposed to when you  
 17 get infected in adulthood where that might be as  
 18 low as 25 per cent, so really quite a big  
 19 difference and that has long term implications  
 20 for the health of an individual infected.  
 21 In terms of hepatitis C it's a little bit  
 22 less clear-cut.  
 23 **PROFESSOR DILLON:** I don't think there's clear  
 24 evidence. I mean the rate of chronic infection  
 25 is already high and we don't have sufficient

45

1 cases to measure how much higher it is.

2 **MS RICHARDS:** The next route of transmission you've

3 identified is transmission through contaminated

4 needles and syringes. That's not just

5 recreational drug use; that can be medical use,

6 tattoos and piercings. That's more common with

7 hepatitis C than hepatitis B; is that right?

8 **PROFESSOR DILLON:** Yes.

9 **MS RICHARDS:** Then lastly sexual transmission.

10 There are important distinctions between

11 hepatitis B and hepatitis C in this respect, and

12 perhaps I can ask one of you to just identify

13 what those differences are.

14 **PROFESSOR COOKE:** Well, I'll start and let others

15 come in. One of the key differences is the

16 availability of vaccination so for an individual

17 at risk of infection there is an effective

18 vaccination for hepatitis B, which can reduce

19 the risk of transmission in all ways but sexual

20 transmission in particular, but without that and

21 with an infectious partner, there is quite

22 a significant risk of sexual transmission from

23 hepatitis B and we still see cases particularly

24 in adults of sexual transmission of hepatitis B.

25 For hepatitis C, and I realise this is an

47

1 with what happens to the mucosa. So in general,

2 we can say within heterosexual sexual activity

3 then the risk is very, very low, but in other

4 forms of sexual activity it may be different.

5 **MS RICHARDS:** The figures you've given, because not

6 everyone will have read the report but it is an

7 important issue, you've put it this way:

8 "Sexual transmission of HCV between

9 heterosexual couples is rare, estimated at 0.07%

10 per year or one in 190,000 occurrences of

11 intercourse."

12 **PROFESSOR COOKE:** I think the general issue is

13 trying to produce a single figure that covers

14 all eventualities is difficult and I think that

15 doesn't necessarily mean that that applies to an

16 individual.

17 **MS RICHARDS:** Can I then come on to ask you about

18 diagnosis and -- oh, I've noted the time, sir

19 and I know how much you like the breaks to be on

20 time after yesterday. It's another topic, and

21 not a particularly quick one, so perhaps this

22 would be a convenient point at which to stop.

23 **SIR BRIAN LANGSTAFF:** In that case this will be

24 a convenient point.

25 Shall we say 12 o'clock, please.

46

1 issue of particular concern to many people, then

2 there are good estimates of what the

3 transmission risk of hepatitis C is, and we know

4 it's very, very low, but it's not zero.

5 Obviously this can be an issue in terms of

6 messaging to a patient what that means, and

7 we'll talk probably tomorrow in a little bit

8 more detail about HIV where we're moving to an

9 environment now with HIV where if you're

10 suppressed on treatment we can give patients

11 very clear messages to say you're not infectious

12 and there are studies to show that the risk is

13 as close to zero as we can estimate it to be.

14 With hepatitis C, that risk is very, very low in

15 heterosexual transmission, and I know that's an

16 issue we will probably come back to, and we have

17 put an estimate in the report of what we think

18 that rate is based on the published literature.

19 It's worth making the point that we do see

20 sexual transmission at the moment particularly

21 for men who have sex with men, and we're seeing

22 quite a lot of transmission of hepatitis C in

23 that way, so that's a different nature of sexual

24 activity which is probably associated with

25 a higher risk of transmission, probably to do

48

1 **(11.32 am)**

2 **(A short break)**

3 **(12.05 pm)**

4 **SIR BRIAN LANGSTAFF:** Yes.

5 **MS RICHARDS:** The next topic I want to ask you about

6 is about the diagnostic testing.

7 Can I ask you first of all just to give an

8 overview, absolutely as you've done in the

9 report but a summary, of the distinction between

10 the assays, the EIAs and what you've described

11 as the NAT tests and what their different

12 functions are, please.

13 **DR JEFFERY:** Okay. The majority of diagnosis is

14 what is done by what we call enzyme immunoassay,

15 and in general they are looking actually at the

16 body's response to the virus; so the body's

17 immune response, which produces antibodies. But

18 in fact both for hepatitis B and hepatitis C

19 there are also enzyme immunoassays which have

20 been designed to look at protein components

21 directly of the virus, which is very helpful,

22 and the best example of that is hepatitis B

23 surface antigen which is a surface protein of

24 the virus.

25 So enzyme immunoassays have been around for

49

1 a long time. They've been used certainly for  
 2 diagnosing hepatitis B from the 1970s, and they  
 3 are very much what we would call the workhorse  
 4 for diagnosis. For both hepatitis B and  
 5 hepatitis C, we're often not making the  
 6 diagnosis in the acute phase of the infection,  
 7 in the early period after the first contact with  
 8 the virus, so these assays are very good at  
 9 picking up what we call prevalent infection or  
 10 chronic infection, looking at either protein  
 11 components of the virus or the immune response  
 12 to the virus.

13 The NAT assays that we were talking about,  
 14 or you may hear about them as PCR assays or  
 15 virus load assays, those are actually looking  
 16 directly at the DNA or the RNA of the virus, and  
 17 we heard Professor Cooke talk about that  
 18 earlier.

19 So those assays are looking in general after  
 20 someone has had a positive reaction on one of  
 21 our EIA assays, and they're used to characterise  
 22 whether that person actually has active  
 23 infection, certainly in the case of hepatitis C,  
 24 because we've also heard it's possible to  
 25 completely clear the virus, so if hepatitis C,

51

1 some to ask you to explain exactly what is meant  
 2 by the infection being "active".

3 **DR JEFFERY:** So from my point of view, as a -- if  
 4 you look at the diagnostic tests, and if I just  
 5 deal first of all with hepatitis C, what I mean  
 6 about the infection being active is in fact that  
 7 our RNA test, our virus load test, shows that  
 8 there's detectable virus in the body. And it's  
 9 as simple as that, really, because a significant  
 10 percentage of individuals will clear the virus  
 11 spontaneously, so they will have positive  
 12 antibody tests as evidence that their body has  
 13 seen the virus at some point, but when we use  
 14 our viral load test we won't find any virus.  
 15 And of course an individual who has had  
 16 a successful treatment, again, we won't be  
 17 finding any virus.

18 So active infection for hepatitis C just  
 19 from the purely diagnostic point of view is easy  
 20 to define: it's the presence or absence of  
 21 whether there's RNA.

22 For hepatitis B, that is a different way of  
 23 looking at things. Active infection in terms of  
 24 hepatitis B is most easily defined as whether or  
 25 not you have hepatitis B surface antigen,

50

1 we use them to define whether someone has active  
 2 infection and we use them to define whether  
 3 treatment has also been successful.

4 For hepatitis B, we use viral load type  
 5 assays to work out the phase of somebody's  
 6 infection and also to guide us on treatment and  
 7 to whether that treatment is working. So  
 8 they're complementary, and together, we use them  
 9 to get a picture of somebody's stage of disease,  
 10 of where they're at just in terms of their  
 11 virology.

12 They don't tell us anything about the actual  
 13 pathology going on in the liver, they are purely  
 14 diagnostic assays and assays that we're using to  
 15 help us guide treatment.

16 **MS RICHARDS:** So it will be through other techniques  
 17 that the presence of cirrhosis or fibrosis will  
 18 be detected and we'll come on to that later.

19 **DR JEFFERY:** Yes.

20 **MS RICHARDS:** But these techniques will tell a  
 21 clinician and a patient if the patient has or  
 22 has had hepatitis B or hepatitis C.

23 **DR JEFFERY:** That's correct.

24 **MS RICHARDS:** You used the phrase about the  
 25 infection being active, and I have been asked by

52

1 because it is perfectly possible to control the  
 2 virus with your immune system very well, such  
 3 that you have undetectable viral load but you  
 4 still have active hepatitis B infection.

5 **MS RICHARDS:** You've talked in your report in  
 6 relation to hepatitis B diagnosis about the  
 7 window periods, and could you please explain  
 8 what is meant and understood by that, and what  
 9 its significance has been and now currently is?

10 **DR JEFFERY:** So the usual definition of a window  
 11 period is that period of time between when you  
 12 are infected and potentially -- and when the  
 13 diagnostic tests become positive. So the -- for  
 14 hepatitis B that's actually quite a long period  
 15 of time, maybe even up to a couple of months but  
 16 sometimes shorter. So it is possible that --  
 17 before diagnostic tests become positive  
 18 potentially to be infectious, as the virus level  
 19 will initially be very low.

20 In general, if you were able to test  
 21 somebody daily after they'd been infected with  
 22 hepatitis B, the first thing you would probably  
 23 pick up would be some hepatitis B DNA using one  
 24 of our molecular assays. But very -- in a very  
 25 short period of time, a very short delay, you'd

53

1 also pick up hepatitis B surface antigen; that  
 2 is usually taken as being our earliest marker of  
 3 hepatitis B.  
 4 Theoretically there has -- historically much  
 5 has been made of a second window period. When  
 6 an individual clears hepatitis B, which as we've  
 7 said is quite common if you acquire hepatitis B,  
 8 as an adult, you lose your hepatitis B surface  
 9 antigens, so you lose the main marker of having  
 10 an infection. But you may not become completely  
 11 negative on your virus load, you may still have  
 12 some low-level virus before your immune system  
 13 fully kicks in and gets rid of that last bit of  
 14 virus. So there is a potential for a second  
 15 window period, but as our diagnostic tests have  
 16 got much, much better, that, I think, has really  
 17 gone away as a major concern.  
 18 **MS RICHARDS:** What about hepatitis C? Do window  
 19 periods have any particular significance in  
 20 relation to hepatitis C?  
 21 **DR JEFFERY:** Not in terms of the diagnostics, no,  
 22 but again, there is a window period whereby the  
 23 usual diagnostic tests that we're using, which  
 24 would be detection of hepatitis C surface  
 25 antibody, do lag behind the virus load test. So

55

1 because an individual presents with clinical  
 2 features that could be consistent with the  
 3 condition and so a clinician would arrange or  
 4 ought to arrange tests. And the second is if  
 5 they meet an indication for screening. And  
 6 you've listed in your report the NICE guidelines  
 7 for hepatitis B screening.  
 8 Am I right in understanding that the NICE  
 9 guidelines in relation to hepatitis B don't  
 10 include those who have received a blood  
 11 transfusion or blood products as an at-risk  
 12 group in contrast with the guidelines in  
 13 relation to hepatitis C? So we've got  
 14 guidelines for the hepatitis B screening at the  
 15 bottom of page 15 and top of page 16 of the  
 16 report and they don't include that cohort. But  
 17 hepatitis C they do.  
 18 **DR JEFFERY:** As long as I have transcribed that  
 19 correctly, that is the case, yes.  
 20 **PROFESSOR DILLON:** The rationale for that is because  
 21 hepatitis B testing for blood transfusion dates  
 22 back to the 1970s. The chances of anyone having  
 23 had a blood transfusion that would then be hep B  
 24 positive would be infinitesimally small, whereas  
 25 for hepatitis C, clearly anyone transfused

54

1 again, if you were to test somebody daily who  
 2 had just been infected with hepatitis C, the  
 3 first test that would become positive would be  
 4 the hepatitis C RNA test, and then the  
 5 hepatitis C antibody test would become positive  
 6 later. In fact if we know that somebody has  
 7 been at risk of hepatitis C infection -- the  
 8 particular setting that I deal with quite  
 9 frequently would be potentially a needle stick  
 10 or other exposure in the healthcare setting --  
 11 we would actually do hepatitis C RNA tests first  
 12 to make sure that we could identify that  
 13 individual as soon as possible.  
 14 **MS RICHARDS:** In relation to the hepatitis C and the  
 15 kind of window period you've described, what's  
 16 its magnitude?  
 17 **DR JEFFERY:** For hepatitis C RNA in general you  
 18 would expect to pick that up within a couple of  
 19 weeks after infection, and then the antibody can  
 20 sometimes lag a little bit, it may be a week or  
 21 two later.  
 22 **MS RICHARDS:** In terms of the criteria for testing  
 23 for hepatitis B, you've explained in your report  
 24 that there will be two approaches to the  
 25 decision to test for hepatitis B. One might be

56

1 before 1991 or blood products before 1987 would  
 2 be at risk. It's the age of the populations and  
 3 the guidelines for screening are written on the  
 4 basis of cost effectiveness rather than risk of  
 5 detection alone.  
 6 **PROFESSOR COOKE:** I think it might be just worth  
 7 emphasising one other point before we go on,  
 8 which is about how these tests developed in  
 9 time, most of the first tests were based, as we  
 10 were hearing, on the presence of an antibody,  
 11 and it was later that the tests were developed  
 12 that could detect virus directly and were  
 13 introduced later. So in relation to window  
 14 periods, then that changed over time, and the  
 15 development of those later tests was able to  
 16 narrow the window periods, I think that's  
 17 probably relevant for a number of questions.  
 18 **MS RICHARDS:** Again, a question I've been asked to  
 19 ask is whether it's possible to have a rough  
 20 timeline of the introduction of the different  
 21 generations of tests, I'm not asking you to do  
 22 it on the hoof today but is that information you  
 23 would be able to provide to the Inquiry?  
 24 **DR JEFFERY:** It was something I did try to provide  
 25 and I found it quite difficult to provide the

57

1 evidence, and clearly individual diagnostic  
 2 laboratories so these tests have been described,  
 3 as you may well have heard, as generations so --  
 4 and it's similar for HIV, so certainly for  
 5 hepatitis C we've got what are called the first  
 6 generation tests, second generation tests, third  
 7 generation tests, and they may have been  
 8 introduced at slightly different rates and  
 9 slightly different places, and I did find it  
 10 difficult to find accurate dates. I have, where  
 11 I could find them, put that in.  
 12 We could look at that again if you would  
 13 like us to try to narrow that window down  
 14 a little bit further.  
 15 **MS RICHARDS:** Thank you.  
 16 **DR JAMIESON:** I might add just for clarity,  
 17 I suppose, that as much as we've divided it into  
 18 the two groups, the ones with symptoms and the  
 19 higher risk groups, there are public campaigns  
 20 to try and obviously increase the visibility of  
 21 the issue with regard to those who have had  
 22 blood transfusions in the past, but moreover  
 23 with regards to increasing professionals in  
 24 general practice setting I suppose I would  
 25 suggest with regards to our awareness of being

59

1 with looking at high risk groups and the  
 2 symptoms. There is this other cohort that we  
 3 are picking up through that and we do have  
 4 patients we're picking up through that change.  
 5 But this is an evolving area.  
 6 **MS RICHARDS:** Thank you. I'm certainly going to  
 7 come back after lunch to the position in  
 8 relation to general practice because, as I know,  
 9 you're aware, and you've heard some of the  
 10 evidence, particularly the evidence given in  
 11 Edinburgh, delays in GPs arranging for tests for  
 12 hepatitis C has been a common theme, in a lot of  
 13 the evidence we've heard.  
 14 Just then turning to hepatitis C. You've  
 15 identified in your report, and I'm looking for  
 16 those who have the report at the top of page 17,  
 17 that in the mid-seventies it was clear there  
 18 were cases of hepatitis occurring  
 19 post-transfusion attributable to neither  
 20 hepatitis A nor hepatitis B, hence the term  
 21 non-A non-B hepatitis.  
 22 Again, I'm not going to ask you about the  
 23 details of the developments in relation to non-A  
 24 non-B and what should have been known, or what  
 25 was as a matter of fact known by clinicians.

58

1 mindful of minor changes in liver function  
 2 testing, to prompt the change. So they might  
 3 not have symptoms, but that GPs should be -- are  
 4 now even more acutely reminded of that.  
 5 We have developed systems in Scotland now  
 6 which will be national within this year,  
 7 developed based on research of Professor Dillon,  
 8 that we will be automatically far more proactive  
 9 about that. So this is an evolving area, more  
 10 than, you know, the two distinct groups which  
 11 somebody coming in jaundiced and somebody who is  
 12 a high risk, there is a third area where in  
 13 order to deliver the national policy agreements  
 14 with regards to elimination of hep C, that we  
 15 need to be more proactive. It's not just about  
 16 the screening at risk groups, nor those with  
 17 symptoms. There is another population that we  
 18 were readily identifying.  
 19 We have intimated that and referenced  
 20 Professor Dillon's work which started from our  
 21 area in Tayside and in GP -- it's done in  
 22 general practice, so -- and that's been rolled  
 23 out now across Scotland.  
 24 So that's a great innovation but if you want  
 25 to eliminate hep C you're not going to do it just

60

1 But is this fair: what was being recognised as  
 2 non-A non-B is what we now term hepatitis C?  
 3 **PROFESSOR DILLON:** So almost all non-A non-B  
 4 hepatitis was hepatitis C, so we were in the  
 5 situation in the early 1970s where we could test  
 6 for hepatitis B. There were patients who were  
 7 receiving a blood transfusion and they were  
 8 still getting what had been described as serum  
 9 hepatitis. We knew it wasn't hepatitis B  
 10 because their tests were negative. It was  
 11 about 30 per cent, I think, at the time of those  
 12 patients. The disease appeared to be milder  
 13 than the hepatitis B related ones that we'd seen  
 14 before, and seemed to be the self-limiting at  
 15 that time was our understanding. But we knew it  
 16 wasn't hepatitis B.  
 17 Those patients were put into cohorts and  
 18 followed up for the -- from the 1970s onwards to  
 19 see what happened to them, and it was in the  
 20 late 1980s those cohorts started to notice an  
 21 increased incidence of liver disease and when  
 22 the hepatitis C virus was discovered the tests  
 23 were applied to those cohorts and about 80% to  
 24 90% of them were hepatitis C positive.  
 25 The other hepatitises that had been noticed,

61

1 as we alluded to at the very start of the  
 2 Inquiry, there are lots of things that can cause  
 3 an inflammation of the liver and when patients  
 4 are having blood transfusions they are having  
 5 them because they are ill for multiple different  
 6 reasons so there are other causes of hepatitis  
 7 amongst them, but the majority of the disease we  
 8 called non-A non-B hepatitis was hepatitis C.  
 9 **MS RICHARDS:** Thank you. There is one other issue  
 10 you've alluded to there which I'm not going to  
 11 ask you further about but I'm just going to  
 12 explain why, which is the question of whether  
 13 it's correct to say that non-A non-B was  
 14 regarded as something that was mild and  
 15 self-limiting. Again, that is a very important  
 16 area of factual investigation for the Inquiry as  
 17 to what was or should have been understood about  
 18 non-A non-B from the seventies onwards.  
 19 **SIR BRIAN LANGSTAFF:** Can we just establish as  
 20 a matter of known facts, so far as fact is known  
 21 today, that a significant proportion of those --  
 22 the natural history is that a significant  
 23 proportion of those who come into contact with  
 24 blood which carries the virus or hepatitis C  
 25 will themselves develop an infection of

63

1 per year, it averages out at 1% or 2% per year  
 2 over a 20 or 30-year time frame, but many more  
 3 people will develop the problem in the later  
 4 time period.  
 5 **SIR BRIAN LANGSTAFF:** So after 20 years you say that  
 6 30 per cent or roughly one in three of those who  
 7 have been infected will develop cirrhosis.  
 8 **PROFESSOR DILLON:** Indeed.  
 9 **SIR BRIAN LANGSTAFF:** And that after 40 years it  
 10 will be 60 per cent.  
 11 **PROFESSOR DILLON:** Indeed.  
 12 **SIR BRIAN LANGSTAFF:** And I think after that you  
 13 haven't got the figures?  
 14 **PROFESSOR DILLON:** No, we're still -- those cohorts  
 15 are still being followed up, and clearly,  
 16 depending on the age of infection, the cohorts  
 17 get smaller and smaller.  
 18 **SIR BRIAN LANGSTAFF:** But there may be some, for  
 19 instance those who had transfusions at an early  
 20 age, very early age, because they suffered from  
 21 haemophilia, transfusions in the sense that they  
 22 received blood products --  
 23 **PROFESSOR DILLON:** Yes.  
 24 **SIR BRIAN LANGSTAFF:** -- who might have been in  
 25 contact with hepatitis C, of whom therefore it

62

1 hepatitis C? You're nodding.  
 2 **PROFESSOR DILLON:** Yes, I'm agreeing with you.  
 3 **SIR BRIAN LANGSTAFF:** That of those who develop that  
 4 infection, some will clear, but the others will  
 5 remain chronically infected. What sort of  
 6 proportion clear?  
 7 **PROFESSOR DILLON:** So approximately 20 per cent. It  
 8 varies on perhaps the dose and perhaps on other  
 9 factors about the person themselves, but roughly  
 10 20 per cent will clear spontaneously and 80%  
 11 will carry the virus long-term.  
 12 **SIR BRIAN LANGSTAFF:** So four out of five develop  
 13 chronic infection?  
 14 **PROFESSOR DILLON:** Yes.  
 15 **SIR BRIAN LANGSTAFF:** And in your report you quote  
 16 that the rate of development from chronic  
 17 infection to cirrhosis, unless it is treated, is  
 18 between 1% and 2% per year.  
 19 **PROFESSOR DILLON:** So we quote the rate at 1% or 2%  
 20 per year. It is probably not a linear increase  
 21 and -- so that the risk of cirrhosis in the  
 22 first couple of years is virtually zero because  
 23 you've got the fibrosis accumulating and then it  
 24 becomes much steeper as you become older, so  
 25 rather than it being a straight line of 1% or 2%

64

1 would follow that -- follow in the natural  
 2 progression, that four out of five would have  
 3 chronic infection, and after 40 years,  
 4 two-thirds at least would be suffering from  
 5 cirrhosis.  
 6 **PROFESSOR DILLON:** Yes.  
 7 **SIR BRIAN LANGSTAFF:** What proportion of those who  
 8 have cirrhosis develop cancer?  
 9 **PROFESSOR DILLON:** So the rate of cancer  
 10 development -- so the literature -- the field  
 11 and the knowledge has changed recently. For  
 12 those with a definite diagnosis of cirrhosis of  
 13 the rate of conversion to development of cancer  
 14 is probably up to 4% per year. It depends on  
 15 co-factors: being male is more likely to push  
 16 you forward for cancer than female; other  
 17 co-factors such as obesity and alcohol intake  
 18 will also accelerate that rate potentially.  
 19 But it's about between 2% and 4% per year,  
 20 but the more advanced your liver disease  
 21 becomes, the higher the risk. So again, it's  
 22 not a straight line. The risk increases  
 23 exponentially for the longer that you've been  
 24 cirrhotic.  
 25 **SIR BRIAN LANGSTAFF:** So that is per year, so if we



65

1 take -- suppose we had someone who, after  
 2 20 years of chronic infection, developed  
 3 cirrhosis, after another 10 years, they would  
 4 have had, on those figures, a 30-40% chance of  
 5 developing cancer?  
 6 **PROFESSOR DILLON:** Yes.  
 7 **SIR BRIAN LANGSTAFF:** Unless there was treatment?  
 8 **PROFESSOR DILLON:** Yes.  
 9 **PROFESSOR COOKE:** I think that's reasonable.  
 10 I think we have to be slightly careful to  
 11 remember that we're looking at populations here  
 12 and trying to produce numbers related to  
 13 a population, whereas when you're having  
 14 a discussion with a patient and -- what the  
 15 patient wants to know is what is going to happen  
 16 to them, and that's not the same, and that is  
 17 obviously one of the difficult issues for  
 18 communication, and Aileen may want to come in on  
 19 this.  
 20 **DR MARSHALL:** There was one point I wanted to make  
 21 earlier about your comment about the duration of  
 22 infection and the relationship with age.  
 23 So, many people who were exposed to blood  
 24 products would have a longer duration of  
 25 infection, but there was an indication that

67

1 development of cirrhosis, the development of  
 2 liver failure, and of liver cancer.  
 3 **SIR BRIAN LANGSTAFF:** Thank you.  
 4 **MS RICHARDS:** There's just one point of  
 5 clarification I wanted to ask arising out of  
 6 what you've set out in your report about  
 7 diagnosis and testing, which you've set out in  
 8 some detail and so I'm not going to ask you to  
 9 go through the details of it. But if we look  
 10 towards the top of page 20 of the report, to the  
 11 second paragraph -- it's a short one so I'll  
 12 just read, it out, it says:  
 13 "Over the last two decades, 1996 to 2017,  
 14 there's been a more than eightfold increase in  
 15 the number of laboratory reports of HCV,  
 16 positive HCV antibody, and/or HCV RNA in  
 17 England."  
 18 And again, a question that has been asked,  
 19 me to ask you, is do we know what the  
 20 explanation is for that eightfold increase?  
 21 **PROFESSOR DILLON:** Yes.  
 22 **MS RICHARDS:** Thank you.  
 23 **PROFESSOR DILLON:** That's because we've managed to  
 24 educate doctors and nurses and the public to do  
 25 the test, to ask for the test, and it reflects

66

1 people who are exposed to hepatitis C at an  
 2 older age, that the older they are, the more  
 3 susceptible the liver is to damage and that  
 4 those patients infected at an older age had  
 5 a more rapid progression to liver fibrosis and  
 6 cirrhosis.  
 7 There is also a strong relationship with age  
 8 and liver cancer independent of cirrhosis or not  
 9 cirrhosis.  
 10 **SIR BRIAN LANGSTAFF:** Thank you.  
 11 **PROFESSOR COOKE:** Just a final point from me, we may  
 12 be coming back to this in more detail but  
 13 I think it's important to recognise that there  
 14 are, as we've heard, a wide range of factors for  
 15 an individual which modified that risk of  
 16 progression, and we've listed a number of those  
 17 in the report.  
 18 But that does create a wide variability for  
 19 an individual in terms of how quickly they may  
 20 progress, both to getting cirrhosis or not and  
 21 getting cancer or not.  
 22 **DR MARSHALL:** If I could make just one further point  
 23 about the different viruses, the combination of  
 24 hepatitis B and hepatitis D is the virus that's  
 25 associated with the higher risk of both the

68

1 a vast increase in the number of tests being  
 2 performed.  
 3 **MS RICHARDS:** Perhaps we could just put the figure  
 4 onscreen, because sometimes seeing the  
 5 document -- thank you, Henry, you're ahead of  
 6 me.  
 7 So we see it there, the chart which maps out  
 8 that increase.  
 9 **DR JAMIESON:** And I would think, in -- you know, in  
 10 the past three years, that all -- again, that  
 11 sort of pattern of increase will be continuing.  
 12 It will be -- in particular with the strategies  
 13 that -- national strategies that we've already  
 14 alluded to.  
 15 **MS RICHARDS:** Can you then, before we leave the  
 16 question of testing and look at symptoms, can  
 17 I just ask about the reliability of the tests?  
 18 Your report alludes to issues in relation to  
 19 false negatives and false positives. Again,  
 20 you've gone into it in some detail in the  
 21 report, but could you perhaps summarise for us  
 22 what the position is in particular in relation  
 23 to current generation of testing, and false  
 24 positives and false negatives?  
 25 **DR JEFFERY:** So this is a really important concept

69

1 around diagnostic tests. So we described  
 2 diagnostic tests in terms of their sensitivity,  
 3 and the sensitivity is the proportion of people  
 4 who have the disease in question who will be  
 5 diagnosed by that test. So we're looking for  
 6 tests that have 100% sensitivity. And the  
 7 situation that we're in with our current enzyme  
 8 immunoassays is that we're very, very close  
 9 to 100% sensitivity, and some studies report  
 10 100% sensitivity. And that's what we're looking  
 11 for.

12 In fact, we are -- that is a major priority.  
 13 It's -- we want to pick up everybody who may  
 14 have the disease that we're looking for. And we  
 15 actually don't mind -- as a diagnostic person,  
 16 I don't mind if it even says somebody has the  
 17 disease who doesn't, because I, before I'm going  
 18 report that test, have ways of working out  
 19 whether that is a true positive result or not.

20 Now, the other big concept in terms of  
 21 diagnostic testing is specificity. So that is  
 22 not creating false positives. I might just go  
 23 back to where I talk about that to make sure  
 24 I get the phrase here absolutely right, because  
 25 these are quite tricky concepts to understand

71

1 patients with acute HCV infection before the  
 2 antibody has appeared ..."

3 Which we've already alluded to.  
 4 And then this:  
 5 "... persons with major immunosuppression,  
 6 advanced HIV infection or organ transplantation  
 7 recipients and persons with chronic renal  
 8 failure on long-term haemodialysis."

9 What systems or processes exist to try to  
 10 ensure that those false negatives don't result  
 11 in diagnosis being missed in individual  
 12 patients?

13 **DR JEFFERY:** So it's a really important question.  
 14 So these false negatives relate to individuals  
 15 who produce poor antibody responses. And it is  
 16 a difficult issue. We would want to be using  
 17 our PCR virus load-based assays to try to pick  
 18 up those individuals, and certainly around renal  
 19 dialysis programmes, transplant programmes, we  
 20 are doing a number of assays that are virus  
 21 load-based to pick up the virus rather than  
 22 looking for antibody responses.

23 **PROFESSOR COOKE:** This will often be an issue that  
 24 the clinician needs to think about and be  
 25 recognising that they're dealing with

70

1 even though I'm dealing with them all the time.  
 2 So a test with 100% specificity correctly  
 3 identifies all those without the condition of  
 4 interest. So again, we're looking for that to  
 5 be close to 100% and the current diagnostic  
 6 tests are very close to 100 per cent.

7 It does depend what population you're  
 8 looking at, and in general, the rate of  
 9 positivity of diagnostic tests for hepatitis B  
 10 and hepatitis C in routine diagnostic labs is  
 11 very low. So we're asking a lot of our tests.  
 12 It is quite unusual on a daily basis in my  
 13 laboratory to have somebody with a newly  
 14 positive test. So we are looking at -- in fact,  
 15 I believe current tests, they're very, very good  
 16 in that they are picking out the right people.  
 17 As we discussed, there are a number of  
 18 supplementary tests that we do to ensure that  
 19 we're giving the individual the right diagnosis,  
 20 and that we haven't generated false positive  
 21 information or missed an important diagnosis.

22 **MS RICHARDS:** You say in the report, and this is in  
 23 the bottom half of page 21, about false  
 24 negatives:  
 25 "Reasons for a false negative result include

72

1 a situation where there may be a poor antibody  
 2 response, and recognise that that's an issue,  
 3 and then actively do a test that they may not  
 4 otherwise have done to look directly for the  
 5 virus.

6 **DR JAMIESON:** Moreover, you know, we would be  
 7 screening for these before -- prior to  
 8 transplant and prior to haemodialysis, as part  
 9 of routine kind of -- you know, before you get  
 10 to the point where you're going to cause  
 11 immunosuppression, providing there's not then  
 12 future exposure of risk.

13 **MS RICHARDS:** Can I then come on to the question of  
 14 signs and symptoms of hepatitis. The questions  
 15 that you were asked were essentially divided  
 16 into three stages, the signs or symptoms that an  
 17 individual may manifest when first infected, and  
 18 then looking at acute -- the acute period of the  
 19 illness and then looking at the chronic period  
 20 of the illness. Could you please talk us  
 21 through, first of all, the signs and symptoms  
 22 that maybe manifested in that -- when the person  
 23 is first infected?

24 **PROFESSOR COOKE:** I'll start and I'll ask others to  
 25 come in, I think, but I think part of this

73

1 relates to what we were saying at the start, is  
 2 I think some of the questions reflect some  
 3 confusion in the terminology, and for one person  
 4 to say they have hepatitis, they may mean they  
 5 were unwell, but as we've already discussed,  
 6 actually, you can have hepatitis without any --  
 7 without feeling any symptoms at all. So I think  
 8 a majority of patients who are affected both  
 9 with hepatitis B and hepatitis C may not  
 10 actually get clinical symptoms at all. And as  
 11 we discuss in here, age in particular can be an  
 12 important determinant of whether or not you get  
 13 symptoms when you get that first infection, and  
 14 when you're older you're more likely to get more  
 15 significant symptoms. Which may be quite  
 16 non-specific, they might just be fatigue, off  
 17 your food, which we would refer to as anorexia  
 18 in that sense, and in the most severe cases you  
 19 may get pain over your liver and may be tender  
 20 if someone examines you and you may have  
 21 jaundice, but that's not necessarily the most  
 22 common situation. So many of those affections  
 23 may go unnoticed.  
 24 **MS RICHARDS:** What you've said in the report at  
 25 section 50.8 is there's a very wide range of

75

1 from the point of infection to where we are with  
 2 the patient. So particularly for -- when we  
 3 talk about chronic hepatitis we define that as  
 4 a window of six months from the acute phase to  
 5 the chronic phase and that's distinction based  
 6 on time rather than severity of symptoms.  
 7 **MS RICHARDS:** Again, you've said that acute  
 8 hepatitis may be associated, again, with a range  
 9 of signs and symptoms, or people may have none.  
 10 **PROFESSOR COOKE:** Yeah.  
 11 **MS RICHARDS:** You described those as ranging in  
 12 severity from a minor flu-like illness  
 13 accompanied by mild jaundice through to a severe  
 14 illness characterised by abdominal pain, deep  
 15 jaundice, joint and muscle pains, and in a very  
 16 small number of cases, even in this acute stage,  
 17 signs of liver failure such as confusion or  
 18 coma; is that right?  
 19 **PROFESSOR COOKE:** Yes, those are obviously  
 20 incredibly important consequences but they are  
 21 rare. We tend to see it with hepatitis B but  
 22 really not very common.  
 23 **MS RICHARDS:** Then can I turn to chronic hepatitis.  
 24 Again, looking at both hepatitis B and  
 25 hepatitis C, and any relevant distinctions

74

1 signs and symptoms, many patients do not have  
 2 any. In particular, you say, children under the  
 3 age of five, more than 90 per cent will be free  
 4 from signs and symptoms. In older children, so  
 5 that's presumably 5 to 17, and adults, you've  
 6 indicated there may be signs and symptoms in 30  
 7 per cent of those with hepatitis B and 20% to  
 8 35% of those with hepatitis C.  
 9 **PROFESSOR COOKE:** That's correct and that also talks  
 10 a little bit about the risk of what we were  
 11 discussing about the risk of being chronically  
 12 infected and not clearing so we do think there's  
 13 an association between having profound  
 14 inflammation and symptoms and actually clearing  
 15 the virus paradoxically, so that partly reflects  
 16 what we see across different age groups as well.  
 17 **MS RICHARDS:** Can you then explain what is meant and  
 18 understood by the acute phase of hepatitis,  
 19 hepatitis B and hepatitis C, and chronic.  
 20 **PROFESSOR COOKE:** So I think, as I say, we're  
 21 explaining here, then, we're talking here about  
 22 acute in terms of the timing infection, and  
 23 I think sometimes that can be interpreted to  
 24 mean the severity or acuteness of it and that's  
 25 not really what is meant. It's about the time

76

1 between the two. What you've said in your  
 2 report is that the vast majority of patients  
 3 with chronic HBV or HCV have no symptoms at all;  
 4 is that right?  
 5 **PROFESSOR COOKE:** That is generally -- I think it's  
 6 important to distinguish between hepatitis B and  
 7 hepatitis C and I think we very clearly  
 8 recognise and we've heard a lot of testimony  
 9 about what we might call the non-liver  
 10 consequences of chronic infection, particularly  
 11 with hepatitis C, less so with hepatitis B.  
 12 So you can certainly have non-liver-based  
 13 symptoms from both infections but the wider  
 14 range of things we recognise is with  
 15 hepatitis C.  
 16 **MS RICHARDS:** Certainly the evidence that the  
 17 Inquiry has heard from individuals who have  
 18 subsequently learnt that they were infected with  
 19 hepatitis C, they have described a range of  
 20 really very significant non-liver related  
 21 symptoms.  
 22 You've discussed here that some patients  
 23 with chronic HCV will experience neuro-cognitive  
 24 symptoms, and we will perhaps just list those  
 25 because they will resonate with a number of

77

1 individuals who have given evidence. They can  
 2 include fatigue, anxiety, depression, problems  
 3 with cognition known as brain fog, attention  
 4 deficit and memory impairment.  
 5 **PROFESSOR COOKE:** Correct.  
 6 **MS RICHARDS:** Is it possible to give any figures as  
 7 to the proportion of those with chronic  
 8 hepatitis C who might experience or may be more  
 9 likely to experience those range of symptoms?  
 10 **PROFESSOR DILLON:** I think it's important to  
 11 differentiate between if you're looking at this  
 12 from a perspective of diagnosis, many people, if  
 13 asked, "Are you well", would say they are well  
 14 and for many people, because it's become  
 15 a chronic part of their being, think it's  
 16 normality. For some people it was only after  
 17 they cured their virus that they felt  
 18 differently that they knew they had problems  
 19 associated before.  
 20 So often I think it's the differentiation  
 21 between people who would declare themselves as,  
 22 "Oh, how are you today?"  
 23 "I'm okay", as opposed to people who have  
 24 underlying chronic symptoms they have regarded  
 25 as having become part of their normality and

79

1 symptoms in somebody who is experiencing it  
 2 themselves to say that there's causation,  
 3 because an experience of a symptom is very  
 4 person-dependent and it's an experience that  
 5 they describe.  
 6 We have the same issue with chronic pain,  
 7 for example. It's their experience of it, it's  
 8 not a definition per se. It's how they describe  
 9 it to you. On reflection and on retrospect,  
 10 some people have chronic pain for their whole  
 11 lives and don't describe themselves as unwell or  
 12 having a disease. Other people, it's what --  
 13 their lived experiences of that. So these  
 14 studies are to try to put it to numbers. As  
 15 much as that's very helpful for the Inquiry and  
 16 is really important, it's also -- belittles the  
 17 importance of it to the individuals as well.  
 18 **PROFESSOR COOKE:** Just to be clear, we do recognise  
 19 that hepatitis C seems to have direct effects  
 20 that cause this, so that is something we  
 21 recognise.  
 22 **MS RICHARDS:** Yes. Indeed, you say that that is  
 23 widely accepted, and that these symptoms are  
 24 associated with low level inflammation in the  
 25 brain, and with functional changes which can be

78

1 I think that's a differentiation here.  
 2 In terms of if you go looking for (with  
 3 specific questionnaires around the brain fog)  
 4 cognitive impairment in a representative group  
 5 of patients, you'll find symptoms in about  
 6 30-40% of patients. If you enquired of those  
 7 patients without those specific  
 8 questionnaire-based things as to whether they  
 9 were well or not, about 90% of them would have  
 10 told you they had no symptoms. So there is that  
 11 differentiation of how you measure things and  
 12 how you ask for them, which comes into what  
 13 we'll talk later on around treatment-related  
 14 side effects.  
 15 **DR JAMIESON:** This is not unique necessarily to  
 16 hepatitis as well, we do see it in other  
 17 diseases, in cancer or diabetes, thyroid  
 18 disease, patients will think its normal for them  
 19 to be a certain way or to have a certain symptom  
 20 and they don't regard themselves as unwell  
 21 per se but once you correct the high calcium or  
 22 the very low sodium or the hyperthyroid, it  
 23 suddenly unravels itself that it was different.  
 24 But it's very hard to study specifically to  
 25 put a specific attribute -- attribute specific

80

1 identified using specialised MRI scans. What is  
 2 it about hepatitis C that may lead to this  
 3 low-level inflammation of the brain? Is that  
 4 known?  
 5 **PROFESSOR DILLON:** So, I think in terms of the  
 6 MRI abnormalities, these are magnetic brain  
 7 scans, they show inflammation within the support  
 8 structures of the neurones of the brain, so they  
 9 are slightly more swollen. It's not a dramatic  
 10 change but it's enough to slow these -- these  
 11 cells within the brain help support the neurones  
 12 that are actually transmitting the information,  
 13 and that transmission of information doesn't  
 14 happen as quickly and as slickly as it happens  
 15 in someone without that inflammation.  
 16 Now, that's not a specific finding to  
 17 hepatitis C, it can happen in other illnesses as  
 18 well, but it's caused probably by the virus  
 19 being able to cross the blood-brain barrier.  
 20 There is very limited data beyond that because  
 21 that would require brain tissue to go looking  
 22 for it, and that's not available.  
 23 **MS RICHARDS:** You've identified a rare complication  
 24 of HCV, cryoglobulinemia, if I've pronounced it  
 25 correctly, and that is associated with a skin

81

1 rash, peripheral nerve damage and loss of  
 2 sensation in the fingers. And again, that's  
 3 certainly been something described by witnesses  
 4 to the Inquiry.  
 5 How rare is that or is that not known?  
 6 **PROFESSOR COOKE:** So actually the presence of these  
 7 cryoglobulins is not actually that uncommon but  
 8 some manifestations of that can be less common.  
 9 So it's not a test that's often done routinely  
 10 these days because it doesn't necessarily change  
 11 what we do in terms of treatment, but there's no  
 12 doubt that in the presence of those  
 13 cryoglobulins we can see some very dramatic  
 14 clinical manifestations, like vasculitis for  
 15 example, which can have serious both short-term  
 16 and long-term consequences for infection.  
 17 **MS RICHARDS:** You then go on to describe the  
 18 symptoms and signs that a patient can experience  
 19 if they have cirrhosis and damage to the liver,  
 20 and you've identified there ascites, jaundice,  
 21 encephalopathy, vomiting blood or passage of  
 22 altered blood in the stool due to bleeding veins  
 23 in the oesophagus, fatigue, breathlessness and  
 24 susceptibility to bruising due to loss of  
 25 clotting factors.

83

1 tissues and give them their structure.  
 2 The fact that -- the remaining black lines  
 3 on that image are the supporting structures for  
 4 the liver cells, the hepatocytes, and so they  
 5 have -- they're likewise supported by this  
 6 network of fine filaments.  
 7 So when the liver is inflamed, one of the  
 8 end results of any inflammatory process is the  
 9 laying down of larger bands of scar tissue, and  
 10 there is a gradual progression through  
 11 increasing amounts of fibrosis as liver disease  
 12 develops, a process that may take as we've said,  
 13 many years or even decades. So the next panel  
 14 on the top right shows that central area which  
 15 is called the portal tract that contains the  
 16 bile ducts and the blood vessels and it shows  
 17 a thickening of the structures around those, and  
 18 then you can begin to see lines of fibrosis  
 19 reaching out from the portal tracts.  
 20 The next image on the bottom left is the  
 21 next stage where fine strands of fibrous tissue  
 22 begin to join up these portal tracts to each  
 23 other, and then eventually, these form into  
 24 nodules that completely surround the liver  
 25 cells, and that's the end stage of cirrhosis,

82

1 And can I ask you to talk to some of those  
 2 physical conditions, please.  
 3 **DR MARSHALL:** These all represent liver failure of  
 4 chronic liver disease and they happen when the  
 5 functions in the liver or the pressure inside  
 6 the liver because of scarring reach a point that  
 7 the function is obvious in those symptoms.  
 8 **MS RICHARDS:** We'll come to talk about treatment of  
 9 those conditions at a later stage of your  
 10 evidence, but this I think is probably the right  
 11 point to ask you to describe how the liver may  
 12 become damaged and the different stages of  
 13 scarring, fibrosis, cirrhosis, and cancer,  
 14 please.  
 15 **DR MARSHALL:** There's an image that might be helpful  
 16 to show, which is page 27. What this image  
 17 shows it's a liver biopsy -- different live  
 18 biopsy samples and a special stain for the scar  
 19 tissue that occurs within the liver and the top  
 20 left panel is normal liver and the darker area  
 21 in the centre is the supporting structures  
 22 around the blood vessels that feed blood in and  
 23 out of the liver and to the bile duct tubes that  
 24 drain the bile from the liver. So there's  
 25 a fine network of proteins that support those

84

1 which we use in medical terminology as to mean  
 2 the most advanced stage of fibrosis.  
 3 Now, when cirrhosis happens, there is then  
 4 a way of stratifying how severely that affects  
 5 the liver function. We may talk about and hear  
 6 about the Child-Pugh scoring system, which is  
 7 one of the oldest means of assessing how the  
 8 cirrhosis is affecting the liver function,  
 9 because many patients with cirrhosis will  
 10 actually, the liver will still function well,  
 11 and the pressure hasn't yet reached the point to  
 12 cause those symptoms.  
 13 So there are five criteria that are within  
 14 the Child-Pugh score. One of them is the  
 15 presence of ascites, whether it's none, mild to  
 16 moderate, or severe. Similarly, whether  
 17 encephalopathy, this type of fluctuating  
 18 confusion, is present, and then based on three  
 19 blood tests, so the level of the serum  
 20 bilirubin, a compound that the liver removes  
 21 from the circulation, so if that goes up that  
 22 indicates worsening liver function, and then the  
 23 proteins that the liver makes, a protein called  
 24 albumen, and then a measure of the blood  
 25 clotting factors, so if the liver is not working

85

1 so well it will be making lots of these proteins  
 2 so a lower value of those is the -- gives you  
 3 a higher mark.  
 4 So if all of these factors are normal,  
 5 that's called Child-Pugh A cirrhosis and we also  
 6 term that as being compensated cirrhosis.  
 7 That's the time when somebody may not be aware  
 8 that they have liver disease because it's not  
 9 apparent on their symptoms or blood tests.  
 10 As time goes by, if the liver continues to  
 11 be injured or even just with normal aging the  
 12 function of the liver can get worse so they can  
 13 then develop abnormalities within these five  
 14 factors I've described and then if there's  
 15 moderate impairment that is termed Child-Pugh B  
 16 and then if there's severe impairment that's  
 17 termed Child-Pugh C.  
 18 **MS RICHARDS:** We then get to decompensated  
 19 cirrhosis.  
 20 **DR MARSHALL:** Yes.  
 21 **MS RICHARDS:** Because again we've seen that phrase  
 22 used in relation to individuals on a number of  
 23 occasions. What does that mean?  
 24 **DR MARSHALL:** It usually means the development of  
 25 one of these important symptoms of liver failure

87

1 agreement between pathologists if you're -- what  
 2 a liver biopsy means, whereas then you might  
 3 find pathologists disagreeing between stage two  
 4 and stage three out of a six-stage system, for  
 5 example, and the advantage of a greater number  
 6 of categories is you can have more definitive  
 7 estimate of progression within those.  
 8 It's fair to say that no scoring system is  
 9 agreed fully by pathologists, that there is some  
 10 observer variation within both of those systems,  
 11 but also you'll see on the image of cirrhosis  
 12 that shows one large nodule and a couple of  
 13 smaller nodules, so when a liver biopsy sample  
 14 is taken, there is what's called sampling error  
 15 and it depends if the biopsy needle happens to  
 16 sample a large nodule they may not see so much  
 17 scarring present and therefore the degree of  
 18 fibrosis may be underestimated, and if they  
 19 happen to hit an area where there's more  
 20 scarring it may be said no estimated so there is  
 21 an issue with accuracy as Dr Jeffery described  
 22 with blood tests.  
 23 **MS RICHARDS:** So we have fibrosis, cirrhosis, can  
 24 I ask you to talk a little about liver cancer,  
 25 HCC, hepatocellular cancer.

86

1 such as ascites or fluid retention,  
 2 encephalopathy, an episode of bleeding or just  
 3 worsening of the liver function to cause  
 4 jaundice.  
 5 **MS RICHARDS:** Just going back a stage to fibrosis,  
 6 the scarring before it's got to the stage of  
 7 cirrhosis. Are there any recognised stages of  
 8 fibrosis and, if so, what are they?  
 9 **DR MARSHALL:** Yes, there are two main  
 10 classifications that are used based on how much  
 11 fibrosis can be seen on a liver biopsy. One of  
 12 them is termed the METAVIR score which scores  
 13 from one to four, four being the most severe  
 14 with cirrhosis, and the other termed the Ishak  
 15 score, with stages one to six, with six as the  
 16 most severe. These have been in widespread use  
 17 for any years.  
 18 **MS RICHARDS:** What's the reason for having two  
 19 different systems of scoring with potential for  
 20 confusion for clinicians and patients?  
 21 **DR MARSHALL:** They're generated independently when  
 22 people wish to find a way of measuring the  
 23 severity of a condition and they have relative  
 24 advantages and disadvantages. For example, if  
 25 there are only four stages there's greater

88

1 **DR MARSHALL:** Certainly.  
 2 So hepatocellular cancer is a tumour which  
 3 arises from the hepatocytes within the liver  
 4 predominantly, and the major risk factor for  
 5 developing HCC is chronic liver disease of any  
 6 cause, so that approximately 80% of people  
 7 with -- who are diagnosed with HCC already have  
 8 cirrhosis, and of the remaining 20 per cent,  
 9 some of those have risk factors for liver  
 10 disease such as hepatitis B, or hepatitis C, or  
 11 fatty liver without cirrhosis.  
 12 It is an asymptomatic tumour as it develops  
 13 early, and there are guidelines from  
 14 professional societies that recommend that if  
 15 a person is known to have cirrhosis that  
 16 screening tests should be offered to diagnose  
 17 hepatocellular cancer early because there is  
 18 a big difference in the outcome of treatment  
 19 comparing early stage cancers with later stage  
 20 cancers.  
 21 **MS RICHARDS:** Can I ask you just a little more about  
 22 the guidelines. What is the recommendation  
 23 if -- if one has a patient who is known to have  
 24 cirrhosis, in what circumstances then should the  
 25 clinician be testing for HCC, and what kind of

89

1 time period should there -- should elapse or  
 2 rather not elapse?  
 3 **DR MARSHALL:** So this is something which has evolved  
 4 very much over the years. And if we're talking  
 5 about the guidelines from the present day, there  
 6 are three that would be relevant to the UK. So  
 7 the first is that the National Institute for  
 8 Health and Clinical(sic) Excellence has issued  
 9 guidance on cirrhosis, and within that guidance,  
 10 they recommend that any patient with cirrhosis  
 11 who is not in the end stage of their life should  
 12 be offered surveillance testing, and the most  
 13 commonly used surveillance tests are an  
 14 ultrasound scan of the liver performed every six  
 15 months, and a blood test for a tumour marker,  
 16 alpha-fetoprotein.  
 17 Now, again, both of these tests are very  
 18 limited in their accuracy, they're affected by  
 19 low sensitivity and the lack of specificity. So  
 20 there certainly are cases where people have had  
 21 surveillance tests that have not detected  
 22 a cancer and then they've been diagnosed later  
 23 on.  
 24 The other two sets of guidelines that are  
 25 relevant are, firstly, produced by the European

91

1 cause a variety of problems such as skin rash,  
 2 joint pains or kidney damage, and that can be  
 3 both in hepatitis B and hepatitis C as  
 4 I understand it, you have described a variety of  
 5 problems. Is there a range of severity? How  
 6 serious can, for example, the kidney damage be  
 7 in consequence of this?  
 8 **PROFESSOR COOKE:** I mean, these conditions can be  
 9 very serious so that example could lead to  
 10 kidney failure and requiring dialysis, and there  
 11 are treatments that you can give to try to  
 12 reduce that, but they can be very severe  
 13 consequences, certainly.  
 14 **MS RICHARDS:** Then the second rarer complication  
 15 you've identified associated with chronic  
 16 hepatitis C is a small increased risk of  
 17 lymphomas, blood cancer, effectively. Is it  
 18 possible to quantify that risk other than small?  
 19 **PROFESSOR DILLON:** It is very small. There is an  
 20 association, and so a particular type of  
 21 lymphoma is more common in people with  
 22 hepatitis C, and there is some evidence that if  
 23 hepatitis C is cured the lymphoma regresses.  
 24 The lymphoma can occur in the absence of  
 25 hepatitis C, but it seems to occur more commonly

90

1 Association for the Study of Liver Disease(sic)  
 2 and the American Association for the Study of  
 3 Liver Diseases, whose recommendations differ  
 4 very slightly but essentially they will  
 5 recommend ultrasound as being the main  
 6 diagnostic test, with or without measurement of  
 7 the alpha-fetoprotein. And in those patients  
 8 with cirrhosis, where there is known to be  
 9 a high enough risk of liver cancer, in excess of  
 10 1.5% per year in the case of the American  
 11 guidelines -- and that would -- it -- cover  
 12 patients who have cirrhosis due to viral  
 13 hepatitis, fatty liver or alcohol-related  
 14 cirrhosis. Other rarer types of liver disease,  
 15 there may not be enough information to be  
 16 included in those guidelines.  
 17 The UK is in the process of writing some  
 18 specific HCC guidelines but those -- there are  
 19 some in existence that were published many years  
 20 ago and these need to be updated.  
 21 **MS RICHARDS:** Can I also just ask you about two  
 22 rarer potential complications you've identified  
 23 in your report. This is at the bottom of  
 24 page 27.  
 25 Cryoglobulins, which you've indicated can

92

1 if there is hepatitis C present but it is still  
 2 a very rare complication. So in 4,000  
 3 hepatitis C patients in Tayside, in my practice,  
 4 I've seen one.  
 5 **MS RICHARDS:** Okay.  
 6 **PROFESSOR DILLON:** That's the level of --  
 7 **MS RICHARDS:** So it's a recognised complication,  
 8 albeit one that is -- occurs in a small number  
 9 of patients.  
 10 **PROFESSOR DILLON:** Yes.  
 11 **PROFESSOR COOKE:** Correct.  
 12 **MS RICHARDS:** You've then talked in your report  
 13 about rates of progression, and obviously,  
 14 that's already been touched on in some of the  
 15 evidence you've given, but given the importance  
 16 of these issues to the matters that the Inquiry  
 17 is investigating, could I ask you to give,  
 18 again, an oral summary of what you've set out in  
 19 the report in terms of rates of progression for  
 20 both hepatitis B and hepatitis C?  
 21 **DR MARSHALL:** I think I wasn't the person who wrote  
 22 this particular part of the section.  
 23 **PROFESSOR COOKE:** Shall I speak to her then?  
 24 **PROFESSOR DILLON:** I can.  
 25 Hepatitis B, for those patients that have

93

1 active infection, which is the minority of  
 2 hepatitis B patients, will have a more rapid  
 3 progression. And so, over a five to ten-year  
 4 time frame, you can get significant liver damage  
 5 in the very active infections. Clearly those  
 6 patients who are what's called low-level  
 7 carriers, or immune tolerant phases of  
 8 hepatitis B will have much, much slower rates of  
 9 progression and may not progress at all. So it  
 10 depends very much on your stage of virus, but if  
 11 you have active viral replication going on, then  
 12 you have a much more rapid progression to  
 13 cirrhosis, and that's on a five to 10-year  
 14 horizon.

15 **MS RICHARDS:** Just pausing there and sticking with  
 16 hepatitis B there, are a number of different  
 17 factors, as I understand it, from your report --

18 **PROFESSOR DILLON:** Yes.

19 **MS RICHARDS:** -- that can influence that. The  
 20 extent of the inflammation of the liver, age,  
 21 alcohol intake, co-infections, particularly with  
 22 HDV -- so hepatitis delta -- and HIV.

23 **PROFESSOR DILLON:** Yes. So all of those factors  
 24 will accelerate progression of hepatitis B and  
 25 the more -- and of the different stages of

95

1 rate of progression from a normal liver towards  
 2 cirrhosis is about 1 to 2% per year, but it's  
 3 not a straight line. It's a sort of curve that  
 4 goes upwards. So the longer you've had it, the  
 5 more likely you are to progress, and the rate  
 6 goes up. And as Sir Brian alluded to earlier  
 7 on, that rate, by about 20 years, it's up at  
 8 20-30 per cent, and up at 30 years it's up at  
 9 about 40 per cent, and beyond that it goes on.

10 Other co-factors will push that forward, as  
 11 Professor Cooke alluded to earlier on. And so  
 12 individually, that's the average progression for  
 13 the average patient with hepatitis C. Some  
 14 patients will progress more rapidly, some  
 15 patients will progress more slowly. And we've  
 16 alluded to the impact that virus may have on  
 17 that in terms of the natural history.

18 **PROFESSOR COOKE:** Just one point which I think  
 19 you'll probably come back to, but it's worth  
 20 emphasising: that we know, both for hepatitis B  
 21 and hepatitis C, that by controlling virus, in  
 22 the case of hepatitis B suppressing it, or in  
 23 the case of hepatitis C, removing it, that those  
 24 risks change very, very substantially. So even  
 25 if you have scarring in your liver, the risks of

94

1 hepatitis B. Those with higher viral loads and  
 2 the more active disease will have a higher --  
 3 a faster rate of progression.

4 **PROFESSOR COOKE:** I think it's just worth  
 5 emphasising again that, although we understand  
 6 from the research over the last 20 or 30 years,  
 7 those factors quite well in terms of what they  
 8 mean, trying to use that for an individual  
 9 prognostic prediction is still very limited by  
 10 the science, and we're still not very good at  
 11 doing that.

12 **PROFESSOR DILLON:** But that's a conversation that  
 13 you have with an individual person, as you  
 14 discuss the numbers that apply to the average,  
 15 and then whether that individual person is  
 16 completely average, or is likely to be more at  
 17 risk or less at risk. Equally, it's an  
 18 important conversation around what's modifiable  
 19 in terms of obesity, alcohol and other things  
 20 that you can do to reduce your risk.

21 **MS RICHARDS:** Then hepatitis C rates of progression.  
 22 Again, you've touched on this in answer to  
 23 questions already from the chair, but could you  
 24 perhaps summarise that for us?

25 **PROFESSOR DILLON:** So, as I said before, the overall

96

1 progression in the absence of the virus are very  
 2 much lower, particularly for hepatitis C, where  
 3 the risks may fall 70% plus. I think it's  
 4 helpful to emphasise that.

5 **PROFESSOR DILLON:** We talk about the natural history  
 6 of these viruses, but they are now historical,  
 7 because neither of these viruses will have  
 8 a natural history any more, because if they are  
 9 identified they will be intervened with, and  
 10 those complications will be treated. Or the  
 11 viruses will be treated, and that will therefore  
 12 prevent those complications and that  
 13 development, and there is good evidence to show  
 14 that that's what happens. Those risks are  
 15 reduced substantially.

16 **MS RICHARDS:** That reduction will take place,  
 17 however, presumably for those who are presenting  
 18 with -- or developing hepatitis C/hepatitis B  
 19 for the first time, rather than for the cohorts  
 20 with whom the Inquiry is primarily concerned,  
 21 most of whom, or many of whom, may have had  
 22 hepatitis C, for example, for very long periods  
 23 of time.

24 **PROFESSOR DILLON:** Treatment intervention, even at  
 25 the late stages of fibrosis, will change the



97

1 natural history. Clearly, at the moment we  
 2 can't be certain that that would put their risks  
 3 back to those of someone uninfected with  
 4 hepatitis C. They will still carry some risks,  
 5 but they will carry substantially less risks of  
 6 progression, and so their risk of progressing to  
 7 liver failure, from data that we've published  
 8 this week from Scotland, shows that that risk of  
 9 liver failure falls dramatically and very  
 10 quickly.

11 The risk of cancer falls, but doesn't return  
 12 back to normal over a 3-year period yet. So  
 13 what will happen over a longer time frame will  
 14 remain to be seen. So there will still be, if  
 15 you are diagnosed or treated when you have more  
 16 fibrosis, some of the risks will still be there,  
 17 but the risks will be less than the natural  
 18 history risks that we're describing here in the  
 19 untreated or untreatable populations.

20 **PROFESSOR COOKE:** And I think we know from evidence  
 21 that's been received that there are patients  
 22 still who haven't embarked on that treatment  
 23 course for the reasons that have been explored.  
 24 And the message is very clear: that there is  
 25 benefit, even at a late stage, to getting that

99

1 probably about 350 million people actively  
 2 infected, and the number of deaths attributable  
 3 to viral hepatitis is similar to HIV, and  
 4 certainly higher than malaria, and that in some  
 5 respects reflects progress in malaria which has  
 6 been lacking in viral hepatitis.

7 **MS RICHARDS:** You've identified in your report that,  
 8 in general, death certificates tend to under  
 9 report deaths due to viral hepatitis. Is there  
 10 any reason for that that you're aware of, or any  
 11 guidance, about when death certificates should  
 12 record hepatitis?

13 **PROFESSOR COOKE:** So, I mean, this is obviously  
 14 a really important issue, and I think we heard  
 15 on Monday in particular a number of pieces about  
 16 evidence about how that can be dealt with in the  
 17 real world. The guidance is very clear in my  
 18 understanding, I think others will confirm, that  
 19 if viral hepatitis is related to a death it  
 20 should be on the death certificate.

21 And I think generally -- historically, there  
 22 have been different issues with that, more  
 23 related to HIV but I think also to hepatitis,  
 24 where, for example, you may be involved in  
 25 managing a patient where the diagnosis has not

98

1 treatment.

2 **MS RICHARDS:** Yes, and we will come on to treatment  
 3 after lunch.

4 Sir, I note the time.

5 **SIR BRIAN LANGSTAFF:** Yes.

6 **MS RICHARDS:** Again. I'm sorry, I've overrun.

7 **SIR BRIAN LANGSTAFF:** I've noted it too.

8 Shall we say two o'clock.

9 **(1.04 pm)**  
 10 **(The luncheon adjournment)**  
 11 **(2.04 pm)**

12 **MS RICHARDS:** Before we turn to treatments for liver  
 13 disease and for the viruses themselves, can  
 14 I just touch on what you say in your report at  
 15 page 28 under the heading "Prognosis and life  
 16 expectancy". You've already addressed a number  
 17 of these matters in your evidence but just  
 18 couple of points. Firstly, earlier in your  
 19 report you've explained that both hepatitis B  
 20 and hepatitis C are leading causes of mortality  
 21 world-wide, more so than malaria or HIV.

22 **PROFESSOR COOKE:** That's correct. I mean, I think a  
 23 similar sort of magnitude. If you look at viral  
 24 hepatitis as a whole, we think there's probably  
 25 about 1.4 million deaths each year and there are

100

1 been disclosed to the family, where it becomes  
 2 quite difficult -- which is not to say it  
 3 shouldn't happen, but it can be quite difficult  
 4 to have those conversations with family after  
 5 death, and sometimes there are reasons that it's  
 6 easier not to put things on a death certificate  
 7 but that's very clearly not what should happen.

8 There can also be issues about attributing  
 9 a death to a virus, when patients often die of  
 10 other things, and so causality can also be  
 11 a question in terms of how that death  
 12 certificate is filled out, but I think the  
 13 guidance now is very clear about what should  
 14 happen.

15 **DR JAMIESON:** That also assumes that they died from  
 16 consequences of the hep infection. If they died  
 17 of other causes -- you know, clearly there was  
 18 a large population that didn't know they had it,  
 19 historically, therefore, you might well be  
 20 attributing it to other causes where it wasn't  
 21 known that that was the cause, so it could also  
 22 under-report in that regard.

23 **MS RICHARDS:** You explain in your report the  
 24 difficulties of estimating the prognosis and  
 25 life expectancy for an individual for reasons

<p style="text-align: right;">101</p> <p>1 you've already touched on, and you've set them</p> <p>2 out in your report. Can I just ask you to deal</p> <p>3 briefly with two studies that you do reference</p> <p>4 in the report, an Australian study and a Dutch</p> <p>5 study, and if you could briefly relate what</p> <p>6 those found.</p> <p>7 <b>PROFESSOR COOKE:</b> Yes, I think it's fair to say that</p> <p>8 we haven't provided a comprehensive review of</p> <p>9 all of that literature but it actually was quite</p> <p>10 difficult to find a lot of data to really give</p> <p>11 robust estimates of what it means in terms of</p> <p>12 life expectancy. As you say, the couple that we</p> <p>13 could find that seemed more relevant, was</p> <p>14 a study from Australia, where there was a very</p> <p>15 clear reduction in life expectancy on average</p> <p>16 across a group of patients by about six years,</p> <p>17 and that was taking out other causes of death.</p> <p>18 For example, as Scott was just saying, often --</p> <p>19 you know, there are many other reasons people</p> <p>20 die, even if they have a chronic virus, and what</p> <p>21 you want to try to understand is the effect that</p> <p>22 virus is having. So if you take out -- and this</p> <p>23 is talking about a general population of</p> <p>24 hepatitis C patients now, where injecting drug</p> <p>25 use is more common, then you want to subtract</p>	<p style="text-align: right;">102</p> <p>1 out that component to understand the effect of</p> <p>2 the virus, and that was what they tried to do in</p> <p>3 the Australian study.</p> <p>4 The Dutch study I think you mentioned of</p> <p>5 haemophiliacs found that there was a similar</p> <p>6 life expectancy to those who got HIV but there</p> <p>7 was a very substantially increased mortality</p> <p>8 related to hepatitis C in that group compared to</p> <p>9 a general population, and the challenge always</p> <p>10 in these studies is to try and match that</p> <p>11 population as well as you can. But, I mean,</p> <p>12 I think very clear evidence that there's an</p> <p>13 excess of mortality there.</p> <p>14 <b>MS RICHARDS:</b> The way you've described it in the</p> <p>15 report in relation to the Dutch study was:</p> <p>16 "Those without hepatitis or HIV co-infection</p> <p>17 had a similar life expectancy to the general</p> <p>18 population, but those haemophiliacs infected</p> <p>19 with HCV had mortality rates 16 times higher."</p> <p>20 <b>PROFESSOR COOKE:</b> Yes, thank you, that's the correct</p> <p>21 phrasing, yes.</p> <p>22 <b>PROFESSOR DILLON:</b> I think it's important to stress</p> <p>23 that this is the untreated impact and it's not</p> <p>24 now the expectation, and the 16 -- the mortality</p> <p>25 rate, it's the increase in the rate. The rate</p>
<p style="text-align: right;">103</p> <p>1 overall was low, it was higher with hepatitis C,</p> <p>2 but the rate was still low and, therefore,</p> <p>3 16 times higher while it sounds dramatic is not</p> <p>4 a very large number of people that would be</p> <p>5 dying from the hepatitis C early.</p> <p>6 <b>MS RICHARDS:</b> I should just say because some of</p> <p>7 those sitting behind me have asked for copies of</p> <p>8 the Dutch study, that is being disclosed in</p> <p>9 relativity so core participants would be able to</p> <p>10 have a look at that.</p> <p>11 <b>PROFESSOR COOKE:</b> Sorry, just one other point that</p> <p>12 might be helpful is that clearly, as we showed</p> <p>13 earlier, overall, a lot of patients with viral</p> <p>14 hepatitis live in South East Asia, for example,</p> <p>15 and so some of the biggest studies come from</p> <p>16 that region but it's difficult to extrapolate</p> <p>17 what that means for life expectancy in a region</p> <p>18 like that where there are the competing causes</p> <p>19 of death, so I think we have to be a bit careful</p> <p>20 about transposing that.</p> <p>21 <b>DR JAMIESON:</b> We'd be very hesitant in any context</p> <p>22 of medical care to translate -- you would make</p> <p>23 far too many assumptions about other</p> <p>24 socioeconomic factors and other</p> <p>25 multi-morbidities and other co-morbidities that</p>	<p style="text-align: right;">104</p> <p>1 might affect the -- sorry, apologies -- you</p> <p>2 would -- we can't do that in other aspects of</p> <p>3 medical care. We don't translate prognosis</p> <p>4 absolutely across to other populations because</p> <p>5 there are multiple other factors which can</p> <p>6 affect that with regards to socioeconomic health</p> <p>7 and other co-morbidities, where -- very famous</p> <p>8 examples in epidemiology of, for example,</p> <p>9 Japanese, post-World War II, moving across to</p> <p>10 the USA, and it wasn't the genetics that</p> <p>11 determined their life expectancy, it was where</p> <p>12 they lived. So that's reasonably well</p> <p>13 established in other areas.</p> <p>14 <b>SIR BRIAN LANGSTAFF:</b> Could I just understand, and</p> <p>15 have on the record so that others can</p> <p>16 understand, what the 16 times relates to. It's</p> <p>17 a rate, a rate over what period?</p> <p>18 <b>PROFESSOR DILLON:</b> So the rate is over the lifetime</p> <p>19 of the study, and so --</p> <p>20 <b>SIR BRIAN LANGSTAFF:</b> Everyone dies over a lifetime.</p> <p>21 <b>PROFESSOR DILLON:</b> Yes, so it's an age-standardised</p> <p>22 mortality rate, and so if you think of that,</p> <p>23 because everyone dies over a lifetime, the age</p> <p>24 standardised mortality rate, there would be</p> <p>25 very, very few deaths in the healthy people at,</p>

<p style="text-align: right;">105</p> <p>1 say, aged 30 or 40 or 50, and those who are                  2 hepatitis C positive there would be several more                  3 deaths. Because of the way the age standardised                  4 mortality rate is worked out, it would look like                  5 a very large-fold increase, so if there was one                  6 person dying at the age of 30 in the study -- in                  7 the control population and five dying in the --                  8 at the same age in the intervention arm, it's                  9 still only five deaths out of the thousand                  10 people but the age-standardised mortality ratio                  11 for that would be a factor of five or ten,                  12 whereas if it's 50 people dying at the age of 50                  13 in the control arm, and 100 people dying at the                  14 age of 50 in the other arm, it would only be an                  15 age-standardised mortality ratio of two. So                  16 while it's the correct way of doing it, it                  17 sounds very dramatic but it does depend -- and                  18 clearly there is an excess risk of hepatitis C,                  19 but it makes it sound like a death sentence,                  20 which it's not, it's the way the statistics                  21 work, so that's the point I was trying to make.                  22 <b>PROFESSOR COOKE:</b> And it's the clear distinction                  23 between absolute risks and relative risks, and                  24 often in terms of public discussion of risk                  25 those are blurred, and as you're saying, the</p>	<p style="text-align: right;">106</p> <p>1 relative risks can sometimes be used to try to                  2 exaggerate rate what might be there. I think                  3 for this particular study it would be possible                  4 to go back to that study and they do have those                  5 absolute rates in both groups, which may be more                  6 helpful. I think it just illustrates that                  7 between different studies the risks are                  8 expressed in different ways and that can make it                  9 quite hard to sort of synthesise a single                  10 figure, if you like.                  11 <b>MS RICHARDS:</b> Okay, I wanted to move on next to the                  12 question of treatment, to start with treatment                  13 for liver disease, so for liver cirrhosis, liver                  14 failure and liver cancer, and then turn and look                  15 at the treatments, and in particular the side                  16 effects and adverse consequences of treatments                  17 for hepatitis in the interferon era.                  18 So starting with the treatment options for                  19 cirrhosis and liver failure, you've set out in                  20 your report the treatment options in relation,                  21 first of all, to ascites, and I wondered if you                  22 could perhaps summarise those for us, tell us                  23 what the condition is. Many here will know from                  24 first-hand experience, sadly.                  25 <b>DR MARSHALL:</b> All right.</p>
<p style="text-align: right;">107</p> <p>1 So, ascites is one of the symptoms that                  2 develops when the liver function is impaired and                  3 there is fluid which collects within the                  4 abdomen, surrounding the abdominal organs, and                  5 may also cause some swelling in the lower limbs                  6 as well. Liver disease is one of the causes of                  7 this condition; it can also be caused by heart                  8 disease or kidney disease or cancers that are                  9 affecting the abdominal organs.                  10 In a patient who develops ascites, then                  11 there is a stepwise treatment which starts off                  12 with advice about general measures. The fluid                  13 retention is driven by salt retention, so                  14 restricting dietary salt intake, giving tablets                  15 which help the body to get rid of the extra salt                  16 and water, and this may be all that's needed for                  17 many patients. If they don't respond to these                  18 treatments or have some side effects which might                  19 be affecting the blood salts or an adverse                  20 effect on the kidneys, then they are termed as                  21 having refractory ascites or resistant ascites,                  22 and the next level of treatment should be                  23 considered.                  24 The fluid can be drained off, especially if                  25 there is a large volume of fluid. This is</p>	<p style="text-align: right;">108</p> <p>1 merely to relieve the symptoms, it doesn't stop                  2 the fluid from reforming, and drainage may be                  3 required to be repeated at regular intervals to                  4 treat that symptom. And then if -- sometimes                  5 there may be something else which is damaging                  6 the liver so general advice such as avoiding                  7 alcohol or any other factor would be given. And                  8 if the ascites remains present despite these                  9 simple measures, then there are a number of                  10 other treatments that can be considered.                  11 So for someone with ascites who has not                  12 responded to regular treatment, it's important                  13 to ask whether they would be a suitable                  14 candidate for a liver transplant because this                  15 will give the best long-term outcome in suitable                  16 patients. There may be a number of reasons why                  17 somebody might not be suitable to have a liver                  18 transplant, and there are other -- two other                  19 main treatments that are given for this.                  20 So I've outlined one, which is a shunt,                  21 which can be placed inside the liver, which                  22 reduces the high pressure caused by cirrhosis                  23 and can lead to reduction in the volume of                  24 ascites. That's called a TIP shunt. This                  25 doesn't stop the cirrhosis being present, so</p>

109

1 that patient may still go on to develop further  
 2 complications of cirrhosis, and in patients who  
 3 are having regular paracentesis, this is quite  
 4 a burden that requires hospital visits and  
 5 patients may prefer to have a catheter which is  
 6 placed in and remains in place and then the  
 7 fluid can be drained off regularly at home. And  
 8 this is a relatively recent development for the  
 9 treatment of ascites.

10 **MS RICHARDS:** You've next considered varices. Can  
 11 you, again, briefly explain what that is and  
 12 then outline the treatments for us.

13 **DR MARSHALL:** So varices is used to describe large  
 14 varicose veins that develop when the pressure  
 15 caused by cirrhosis in the blood which feeds  
 16 into the liver is increased. There are veins,  
 17 the normal circulation is that all the blood  
 18 from the stomach and the intestines will flow  
 19 together into a vein called the portal vein,  
 20 which then goes into the liver, then the blood  
 21 goes through the liver and then returns to the  
 22 heart via the hepatic vein. And when someone  
 23 has cirrhosis, the pressure in the portal vein  
 24 increases and that pressure feeds back to these  
 25 venous channels present in the intestines, and

111

1 they've no history of bleeding then there are  
 2 two treatments that can be offered, either  
 3 medical treatment with beta blocker medication,  
 4 which reduces the pressure inside the varices,  
 5 or to place rubber bands, which tie off the  
 6 varices and stop the blood from flowing through  
 7 them and reduce the risk of that.

8 **MS RICHARDS:** And if it gets to the stage of  
 9 variceal bleeding, that is an emergency and  
 10 a life-threatening condition?

11 **DR MARSHALL:** It is, yes, so patients with  
 12 cirrhosis, I would normally warn them that if  
 13 they were ever to experience symptoms such as  
 14 vomiting of blood or passing blood in their  
 15 stools or dark stools, that that's an emergency  
 16 and they need to attend hospital straight away,  
 17 and they may need blood transfusion supportive  
 18 treatments, and endoscopy is done in that  
 19 situation to try to stop the bleeding which is  
 20 usually done by placing rubber bands or  
 21 injecting the varices with glue to stop blood  
 22 flowing through them.

23 **MS RICHARDS:** The next complication you've discussed  
 24 is hepatic encephalopathy. Could you explain  
 25 how that might be treated as well please?

110

1 they can enlarge, and become under high  
 2 pressure, and that's when they're called  
 3 varices.

4 The risk -- when the pressure increases in  
 5 those varices, there's a risk that they may  
 6 bleed spontaneously and somebody would not  
 7 likely know that they had varices until such an  
 8 event happened unless a test is done  
 9 specifically to look for those.

10 The test that is done to look for those is  
 11 endoscopy, which is where a camera is placed  
 12 through the mouth into the stomach, and under  
 13 direct vision the oesophagus is visualised and  
 14 these varices can be seen.

15 So most guidelines will recommend that if  
 16 someone has cirrhosis that they would have one  
 17 of these procedures, an endoscopy, and if no  
 18 varices are present then it will be normal then  
 19 just to repeat the test as a screening test in  
 20 two to 3 years.

21 The risk of bleeding relates to the size of  
 22 the varices, so if small varices are noted  
 23 again, no specific treatment recommended but  
 24 monitoring to reassess at an earlier interval  
 25 and if somebody has medium or large varices but

112

1 **DR MARSHALL:** Yes, one of the jobs that the liver  
 2 does is remove toxins from the blood which are  
 3 produced by gut bacteria, and so either if the  
 4 liver function is impaired this process may not  
 5 happen correctly, or because of the cirrhosis  
 6 the body may develop channels that take the  
 7 blood away from the liver, so the toxins are not  
 8 getting to the liver to be removed.

9 It is a symptom that can be brought on by  
 10 any other illness so it may be something as  
 11 simple as being dehydrated or constipated that  
 12 leads to this symptom and it can start off as  
 13 mild with simple disorientation and confusion,  
 14 and then it can progress through various stages,  
 15 where the most advanced stage is effectively  
 16 a coma where the patient may be unconscious.

17 In the milder symptoms this can be managed  
 18 at home with medical treatments, but if somebody  
 19 is unable to be cared for at home, or they've  
 20 got more serious encephalopathy again they  
 21 should be admitted to hospital, and the other  
 22 causes can be things like variceal bleeding or  
 23 infections so these should be actively sought  
 24 for and treated if they're present.

25 To prevent encephalopathy, the first line

<p style="text-align: right;">113</p> <p>1 treatment is a drug called lactulose which helps  2 to prevent constipation and reduce the  3 production of toxins by these gut bacteria, but  4 if patients are still having symptoms despite  5 that there is a drug called rifaximin which  6 should be prescribed in patients who are having  7 recurrent encephalopathy.</p> <p>8 <b>MS RICHARDS:</b> If that's refractory to medical  9 treatment, again, that's an indication for liver  10 transplantation.</p> <p>11 <b>DR MARSHALL:</b> Yes, that's correct.</p> <p>12 <b>MS RICHARDS:</b> Can I ask you to tell us a little  13 about liver transplantation. We've heard  14 evidence from those who have undergone that  15 surgery, we've heard evidence from those who  16 have undergone it and ultimately -- the  17 relatives of those have undergone it and  18 ultimately not survived, so it's an important  19 issue for many people.</p> <p>20 <b>DR MARSHALL:</b> Certainly. In the UK there are seven  21 liver transplant centres and liver  22 transplantation is regulated by NHS Blood and  23 Transplant and there are policies in place for  24 the assessment of patients for transplant and  25 for the criteria which patients need to meet in</p>	<p style="text-align: right;">114</p> <p>1 order to be suitable for a transplant, and all  2 the centres would work to those. Again, this  3 has evolved over the time that the Inquiry is  4 interested in.</p> <p>5 So these policies are also freely available  6 via the NHS BT website if people are interested  7 to look. So there is a -- each transplant  8 centre has a network of referring hospitals and  9 because patients may be referred to us from very  10 far away and when we see patients who have had  11 an episode such as a decompensating event, and  12 they have not responded to the usual medical  13 treatment then these are the patients who should  14 be referred to their transplant centre for  15 consideration, as long as there's no other  16 obvious reason why they might not be fit for  17 that to happen.</p> <p>18 The process of transplant assessment is --  19 it involves many different medical  20 professionals, and allied health professionals,  21 and what we are aiming to do is to try to  22 establish the severity of the patient's liver  23 condition to ensure that it meets the criteria  24 set out in order for that patient to benefit  25 from a transplant but then also to look at their</p>
<p style="text-align: right;">115</p> <p>1 overall fitness, which may be due to other  2 health conditions or their frailty, or several  3 other issues that may impact on their outcome  4 after a transplant. So if the patient is deemed  5 to have a need for a transplant and they are fit  6 enough, then they would be offered that as  7 a treatment.</p> <p>8 <b>MS RICHARDS:</b> They would be placed on the transplant  9 list, presumably?</p> <p>10 <b>DR MARSHALL:</b> That's right.</p> <p>11 <b>MS RICHARDS:</b> 2018, you've described over 1,000  12 liver transplants being performed in the  13 United Kingdom.</p> <p>14 <b>DR MARSHALL:</b> Mm.</p> <p>15 <b>MS RICHARDS:</b> And the estimated survival rate 1 year  16 after a liver transplant is over 91 per cent,  17 5 years survival over 80 per cent.</p> <p>18 <b>DR MARSHALL:</b> Yes, that's correct. I should also  19 say we're talking about decompensated cirrhosis  20 as a reason for transplant, but there are other  21 reasons, for example early stage liver cancer or  22 some of the other complications of cirrhosis,  23 which are rarer but listed on the policies that  24 I've alluded to. I'm happy to talk more about  25 these if that's relevant.</p>	<p style="text-align: right;">116</p> <p>1 <b>MS RICHARDS:</b> Can I turn to liver cancer, and the  2 treatment options for liver cancer. Again,  3 you've set it out in some detail in the report,  4 but if you could summarise those for us, that  5 would be very useful.</p> <p>6 <b>DR MARSHALL:</b> So there's three -- as I mentioned  7 before, most patients with liver cancer already  8 have cirrhosis as well and so most centres will  9 use a guideline which involves three main  10 factors. One of these is the stage of the  11 cancer. That is the size of it, and the number,  12 because liver cancer may be multiple within the  13 liver. Secondly, the severity of the underlying  14 cirrhosis. And we talked about the Child-Pugh  15 system and the presence of decompensation.  16 That's important because if someone has  17 decompensated cirrhosis, they won't tolerate  18 some of the treatments very well.</p> <p>19 Then, thirdly, performance status, which is  20 a common parameter in cancer treatments, where  21 it -- it really describes the overall level of  22 physical functioning. So someone who is  23 undertaking normal activities would have a  24 performance status of zero, someone who is very  25 frail and unwell, spending most of the time in</p>

117

1 bed, would have a performance status of four.  
 2 That's summarised in the picture in figure  
 3 15.11b, where there's a staging system that's  
 4 commonly used by many centres and originally  
 5 it's from the Barcelona clinic.  
 6 **MS RICHARDS:** Page 33 of the report, please, Henry.  
 7 Thank you.  
 8 It's the top half of the page.  
 9 **DR MARSHALL:** So what this algorithm outlines is the  
 10 stage, according to these three factors, which  
 11 I've mentioned. And from the left, stage zero,  
 12 moving through to the right, to the more  
 13 advanced stages.  
 14 Then you follow through the algorithm,  
 15 looking at the different factors which  
 16 I mentioned, and on the early stages, the three  
 17 treatments which are associated with the best  
 18 long-term outcomes are -- of approximately  
 19 40-70% five-year survival, is: liver resection,  
 20 or removal of part of the liver with the cancer  
 21 in it; liver transplantation; and, in this  
 22 picture, RF or PEI are techniques which are --  
 23 in the report are thermal ablation, or ablation,  
 24 which is a local treatment for the cancer.  
 25 And then moving to the right, the patients

119

1 your report that in the United Kingdom, in  
 2 common with other parts of the western world,  
 3 liver cancer is generally only identified at  
 4 a late stage.  
 5 **DR MARSHALL:** That's right. There are two factors  
 6 that influence that. So first is that many  
 7 patients don't know that they have cirrhosis,  
 8 and they may be diagnosed with cirrhosis and  
 9 liver cancer at the same time, when they develop  
 10 symptoms of the cancer. And then it's usually  
 11 diagnosed at a more advanced stage.  
 12 The surveillance for cancer in patients with  
 13 cirrhosis we've mentioned earlier, and that --  
 14 people who are under a surveillance programme  
 15 are more likely to be identified at an early  
 16 stage but this is a very variable tumour and  
 17 some patients despite screening may be diagnosed  
 18 at a late stage, even though they've been  
 19 undergoing tests.  
 20 **MS RICHARDS:** Can I then turn, please, to  
 21 section 15.13 of your report, where you begin to  
 22 examine the different treatments that have been  
 23 provided for hepatitis B and hepatitis C over  
 24 a number of years. I'm going to spend most of  
 25 the time looking at interferon for reasons that

118

1 who have intermediate stage, so they may have  
 2 larger cancers, or in multiple parts of the  
 3 liver, the treatment applied there is called  
 4 embolisation or chemoembolisation. That's  
 5 blocking off the blood supply.  
 6 In contrast to the treatments on the left,  
 7 embolisation is not considered to be a curative  
 8 therapy but may prolong survival and may prevent  
 9 cancer progression.  
 10 Moving further right, to the advanced stage,  
 11 stage C, this is where drug therapies,  
 12 particularly over the last 10 years, and even in  
 13 the last 2 years, there's been a great deal of  
 14 progress made in systemic therapies for liver  
 15 cancer. The drug listed here, Sorafenib, was  
 16 the original drug shown to benefit survival in  
 17 people with advanced HCC, but the overall  
 18 survival is still in the order of months, even  
 19 in patients who respond to treatment.  
 20 Then furthest to the right, patients who may  
 21 be very frail or with poor liver function would  
 22 not be expected to tolerate any of these  
 23 treatments well, and palliative care or  
 24 supportive care would be given here.  
 25 **MS RICHARDS:** And I think you identify somewhere in

120

1 I think will be obvious to everybody in this  
 2 room, and the side effects and adverse events  
 3 associated with interferon. But could I ask one  
 4 of you just to talk us through first, briefly,  
 5 the treatments that have been available for  
 6 hepatitis B and what treatments are currently  
 7 available for hepatitis B.  
 8 **PROFESSOR COOKE:** Yes. And I think, again, to  
 9 emphasise that the objective of treatment is  
 10 different for hepatitis B and C. And it's  
 11 probably helpful to start with interferon, which  
 12 was really one of the first drugs used for  
 13 hepatitis B.  
 14 Now in contrast to hepatitis C, the  
 15 objective of using interferon is not to get rid  
 16 of the virus from the blood necessarily, but  
 17 there are a small group of patients who can  
 18 benefit from treatment which will turn them --  
 19 turn their virus from being very highly active  
 20 into a lower active state, which is better for  
 21 the long-term condition, and which can then lead  
 22 to benefit from the other treatments.  
 23 In general, because, as has been well  
 24 recognised, the side effects from interferon are  
 25 unpleasant and, in the setting of hepatitis B,

<p style="text-align: right;">121</p> <p>1 treatment would often be for 48 weeks, and the</p> <p>2 success of that treatment may be very, very low,</p> <p>3 under 10 per cent, it's generally not used.</p> <p>4 Although it is recommended as part of NICE</p> <p>5 recommendations for therapy, it's rarely used.</p> <p>6 So the mainstay of treatment now, and indeed</p> <p>7 for the last 20 years or so, has been what we</p> <p>8 call oral nucleoside or nucleotide analogue</p> <p>9 drugs which directly target the virus, and the</p> <p>10 first of those that was used widely was</p> <p>11 lamivudine which we will hear about tomorrow as</p> <p>12 well I imagine because it is also a common part</p> <p>13 of HIV treatment.</p> <p>14 Lamivudine is generally a very well</p> <p>15 tolerated drug. It has a relatively good side</p> <p>16 effect profile, certainly nothing like</p> <p>17 interferon, and was used for a number of years,</p> <p>18 and there may still be patients taking it today</p> <p>19 where it is working.</p> <p>20 The main drawback of lamivudine is that many</p> <p>21 patients would fail treatment within a few years</p> <p>22 with quite a high rate of resistant virus</p> <p>23 emerging quite quickly, in the order of maybe</p> <p>24 50% of patients within a couple of years, so it</p> <p>25 was good when it worked and, as I say, still is</p>	<p style="text-align: right;">122</p> <p>1 used occasionally but has generally given way to</p> <p>2 other treatments which are more durable, the</p> <p>3 first of those being adefovir, which we don't</p> <p>4 use so much now, but again there may be patients</p> <p>5 on it for whom it's working well. But with the</p> <p>6 drug that followed adefovir, which is a bit like</p> <p>7 it, which is tenofovir, of which there are now</p> <p>8 two forms, TDF and TAF, which are the mainstays</p> <p>9 of treatment we have available, tenofovir</p> <p>10 disproxil fumarate, TDF, is probably the most</p> <p>11 commonly used drug, it's a once daily used drug</p> <p>12 again also active against HIV and a lot of</p> <p>13 experience with it with HIV, and much lower rate</p> <p>14 of emergence of resistance with that drug, which</p> <p>15 means that many patients can manage to take that</p> <p>16 on a daily basis indefinitely and control their</p> <p>17 virus, and their virus becomes undetectable in</p> <p>18 the blood.</p> <p>19 The side effect profiles of that drug are</p> <p>20 relatively good, there are some important and</p> <p>21 well recognised side effects including effects</p> <p>22 on the kidney and potentially bones, for</p> <p>23 example. But compared to other treatments,</p> <p>24 generally well tolerated.</p> <p>25 There's an alternative first line treatment</p>
<p style="text-align: right;">123</p> <p>1 which we would use now, which is entecavir which</p> <p>2 is occasionally used, which is again another</p> <p>3 oral daily medication which has quite</p> <p>4 a relatively good side effect profile and is</p> <p>5 effective against suppressing hepatitis B.</p> <p>6 So at the moment we really have those two</p> <p>7 drugs as our main choices and we have this newer</p> <p>8 version of tenofovir coming through, which is</p> <p>9 not fully approved due to costs particularly,</p> <p>10 but which may have advantages in a better side</p> <p>11 effect profile for patients who need to be</p> <p>12 taking this medication long-term.</p> <p>13 The drugs we have now are generally, when</p> <p>14 they're taken on a daily basis very effective at</p> <p>15 suppressing the viral replication so again not</p> <p>16 getting rid of the virus completely but</p> <p>17 certainly clearing it from the blood, and</p> <p>18 allowing, be it the liver to recover or other</p> <p>19 manifestations of the infection to improve by</p> <p>20 controlling the virus that leads to longer term</p> <p>21 clinical improvement.</p> <p>22 <b>MS RICHARDS:</b> For those with hepatitis B who are on</p> <p>23 these treatments because the aim of the</p> <p>24 treatment is not cure, it's not clearing the</p> <p>25 virus, it's not a time limited treatment; it's</p>	<p style="text-align: right;">124</p> <p>1 a treatment you remain on, is that right?</p> <p>2 <b>PROFESSOR COOKE:</b> In general, yes. In general you</p> <p>3 would usually say to a patient, "You would need</p> <p>4 to expect to stay on this lifelong". There is</p> <p>5 a lot of work going on to identify, not</p> <p>6 everybody goes on treatment for hepatitis B,</p> <p>7 that's worth saying, so there's an assessment at</p> <p>8 the start to see which patients really need to,</p> <p>9 but once you start generally the case is that</p> <p>10 you carry on, and that can, in some cases, be</p> <p>11 reviewed, but that would be relatively uncommon.</p> <p>12 <b>MS RICHARDS:</b> Then just briefly with hepatitis D,</p> <p>13 delta hepatitis, you say there treatments are</p> <p>14 very limited and pegylated interferon remains</p> <p>15 the mainstay of treatment?</p> <p>16 <b>PROFESSOR COOKE:</b> That's correct and we heard</p> <p>17 earlier, that this is particularly important,</p> <p>18 where you have both infections and there is</p> <p>19 probably a more aggressive clinical course to</p> <p>20 that, treatment with interferon can lead to what</p> <p>21 we would call virological response, but often</p> <p>22 that's not carried on once that treatment stops.</p> <p>23 And so it is an area of active research and</p> <p>24 there are some potentially useful drugs coming</p> <p>25 through that might help with that but it's</p>

125

1 a relatively difficult condition to treat at  
 2 this point still.

3 **MS RICHARDS:** Turning to hepatitis C, Henry, can we  
 4 up from the report, the figure that's on page 41  
 5 of the report, please. Before we look at the  
 6 side effects and adverse events associated with  
 7 interferon, you were going to talk us through  
 8 this figure.

9 **PROFESSOR COOKE:** We thought this would be a helpful  
 10 figure to illustrate a number of different  
 11 issues and I think some of them we've touched on  
 12 already. As you say, here we're really just  
 13 looking at the cure rates, and so for those who  
 14 are not familiar with the terminology, one of  
 15 the challenges as many people will know of  
 16 knowing whether you're cured of hepatitis C is  
 17 it's very hard to tell when you're on the  
 18 treatment. It's only when you come off the  
 19 treatment you can be monitored and we can see if  
 20 that virus returns.

21 And so generally what we -- what we do now  
 22 is to monitor a patient who finishes for 12  
 23 weeks and if the virus is still not detectable  
 24 in the blood after that point, we call that  
 25 a sustained virological response at 12 weeks,

127

1 interferon treatment, and you can see that that  
 2 improved cure rates quite significantly and  
 3 we'll come on to the consequences of that in  
 4 terms of side effects.

5 With the advent of pegylated interferon, peg  
 6 in the graph here, again the cure rates improve  
 7 further particularly for the genotype 1  
 8 infections but also for the genotype 3  
 9 infections.

10 Then around 2011 we move into this new phase  
 11 of treatment for hepatitis C where we started to  
 12 get these new drugs called directly acting  
 13 anti-virals against the virus, and that's the  
 14 contrast with interferon. We haven't really  
 15 mentioned this but it's a product made by the  
 16 body naturally in response to infection and when  
 17 you get flu, for example, interferon is  
 18 something that's produced and that's why often  
 19 you get those symptoms from interferon, is that  
 20 what that compound does.

21 So those -- these newer drugs target the  
 22 virus directly rather than the body, and the  
 23 first generation of those from 2011 onwards,  
 24 were specific to particular genotypes, in  
 25 particular genotype 1. So you'll see that those

126

1 which is shortened to SVR12, so we throw around  
 2 the term SVR12 and we sort of use that as  
 3 a surrogate for cure.

4 So what we see in this graph on the  
 5 left-hand side is SVR12 rates. I think the  
 6 first thing just to emphasise is how those rates  
 7 have changed over time, so on the left-hand side  
 8 we're looking at the first treatments in 1991  
 9 through to where we are now on the right-hand  
 10 side, and you can see really those early  
 11 treatments with either 24 weeks or 48 weeks of  
 12 interferon were offering very low treatment cure  
 13 rates, and so it was a really difficult  
 14 discussion/decision, about whether it was even  
 15 worth having treatment given the prolonged  
 16 nature of treatment and the success rates.

17 And I think that also emphasises what we  
 18 talked about earlier which is the difference in  
 19 genotypes, so the black bars here being genotype  
 20 1 and the purple bars being genotype 3, you can  
 21 see there was quite a distinction in those early  
 22 days between how you would respond to those  
 23 treatments, depending on that genotype.

24 Then we move through an era where we had  
 25 interferon but we added ribavirin into that

128

1 cure rates for genotype 1 improved very  
 2 significantly but the genotype 3 cure rates  
 3 didn't change at that point because those new  
 4 drugs only had very specific activity.

5 Then what we've seen in the last 5 years,  
 6 really, is that advent of a wider range of these  
 7 directly acting anti-virals which have managed  
 8 to achieve very high cure rates, as you can see  
 9 in the region of 90% plus, without using  
 10 interferon, and that's what we now call the  
 11 interferon-free DAA era.

12 Really, the development in the drugs in the  
 13 last two or three years has been to have drugs  
 14 which are better against all of the genotypes,  
 15 so whereas having -- whereas we used to have  
 16 drugs that were very specifically genotype  
 17 dependent, we now talk about having  
 18 pan-genotypic drugs, which are not always  
 19 available everywhere but that's where we are  
 20 now.

21 Really I don't think we expect to see any  
 22 changes in hepatitis C treatment in the  
 23 foreseeable future. This has moved incredibly  
 24 fast but has kind of matured and we now have  
 25 a range of options available. I don't know if



129

1 anyone wants to add to that.

2 **PROFESSOR DILLON:** I think to put it in the context

3 of the discussions that were being had with

4 people affected by hepatitis C is as that

5 timeline evolved, clearly as we had interferon

6 and ribavirin available and particularly when

7 the interferon became pegylated we had therapies

8 that were curative and at that stage we were

9 aware of the natural history of hepatitis C and

10 how it was progressing, and there were

11 conversations with people around their choice of

12 treatment.

13 If they knew their diagnosis and knew their

14 stage of disease, they could have an informed

15 discussion about whether to go with interferon

16 or to wait. For a long period of that time

17 frame, while we knew there were new drugs

18 coming, them arriving in 2014 as the definitive

19 product, if you'd asked most hepatologists in

20 2013 whether that was going to happen, they

21 would have happily told you it would be 2020

22 before the drugs were here and there was a very

23 accelerated phase of drug development that is

24 unique at the speed at which these drugs arrived

25 for widespread use, so when people are thinking

131

1 comment upon that because that's a matter of

2 fact and policy decisions to which you're not

3 responsible, but we do have statements from NHS

4 England and from others that will be published

5 either towards the end of this week or next

6 week, which address those issues, because for

7 many, the speed that scientists may have

8 observed in terms of drug development was not

9 mapped for them as individuals when treatments

10 were not made available to them.

11 **PROFESSOR COOKE:** And I think it is worth just

12 probably spending a moment on it, because there

13 was a very big issue about the cost of these

14 drugs and there was -- I mean we knew that the

15 drugs were good and we knew we wanted to treat

16 everybody, and there was a major impact

17 potentially on the budget so the way it was

18 handled in different home nations is different.

19 **MS RICHARDS:** Yes.

20 **PROFESSOR COOKE:** I think in particular in England

21 there was a different system which caused quite

22 a lot of controversy. The way it was handled

23 was the patients -- the individual centres were

24 told how many patients they could treat in

25 a year and it was up for them to prioritise

130

1 about treatment decisions it's putting it in

2 that context.

3 We knew we had a fatal condition that was

4 curable with interferon, albeit with significant

5 side effects that we'll talk about in a while's

6 time but it was changing the natural history of

7 the disease and that we couldn't predict the

8 arrival of the DAA therapies as quickly as they

9 came.

10 **MS RICHARDS:** Just one observation, probably not

11 a question but simply because I know it's

12 a matter of some importance to many who are in

13 the room or may be listening.

14 You've talked about, from the clinician's

15 point of view, the speed of introduction of

16 these drugs. We know from other material that

17 the Inquiry has and indeed has disclosed in the

18 course of the week, from representatives of the

19 National Health Service and the four

20 jurisdictions of the United Kingdom, that

21 following NICE recommendations, and assessment,

22 drugs -- the drugs were not made immediately

23 universally available to all of those with

24 hepatitis C.

25 I'm not going to ask you particularly to

132

1 which patients were treated, there was no

2 guidance as to how you should prioritise, and

3 I think there's very different experiences of

4 how that worked in different centres and what

5 criteria were used to prioritise patients

6 initially. And, you know, experience at one

7 centre was different from another, but there

8 were very clear choices having to be made, and

9 we're really talking about a recent period here,

10 so we're really talking about 2015, 2016, 2017.

11 Fortunately, I think we're now through that

12 and really everybody should be able to get

13 treatment quickly if they need it, but there was

14 a period where there was a lot of -- where there

15 were -- there was discrepancy between practice

16 in different places, which I think would have

17 differentially affected people with different

18 routes of transmission in different places.

19 **DR MARSHALL:** Can I say as well about the impact on

20 viral hepatitis in patients who have had

21 transplants of these new treatments, because

22 what we've talked about is just general liver

23 cirrhosis and transplant, but in years gone by,

24 before there was effective treatment for either

25 hepatitis B and C, if a patient had a transplant

133

1 but yet the virus was still present in the blood  
 2 then it would affect the new liver as well, and  
 3 would often have a faster course of progressive  
 4 liver disease after a transplant and that had  
 5 a negative impact on the outcome after  
 6 transplants for those patients, but now there is  
 7 effective treatment for both hepatitis B and C  
 8 we very rarely see any problem like that and  
 9 it's really transformed the outcomes for  
 10 transplant patients.  
 11 **DR JAMIESON:** One of my interests is therapeutics  
 12 and I sit on a local drug and therapeutic  
 13 committee and we look at new drugs coming in  
 14 onto the market in a wide scope of areas, no  
 15 less including these types of drugs becoming  
 16 available. Obviously, these were national  
 17 decisions but at a local area, I would say that  
 18 the speed for which this has got to this point,  
 19 which from a patient's perspective is too long,  
 20 in the bigger scheme of the graph set out here,  
 21 it's good that we've got through those pinch  
 22 points so quickly in that time, but that's still  
 23 too long for some, but for other diseases, in  
 24 bigger scopes, for example, in rare cancers, for  
 25 example, trying to get these drugs progressed as

135

1 to be responsive to the clinical situation.  
 2 **MS RICHARDS:** Could we turn to the next page,  
 3 please, Henry, and we're going to look at  
 4 a table that you've produced, if we look at the  
 5 bottom half of the page, please, which talks us  
 6 through adverse events associated with  
 7 interferon and its associated toxicity.  
 8 Before we look at any of the detail of it  
 9 can I just ask you about the heading on the  
 10 right-hand side "Frequency not known". Do  
 11 I understand that to mean you're not suggesting  
 12 that there isn't an association, but there  
 13 simply isn't any available data to say any more  
 14 about it?  
 15 **PROFESSOR DILLON:** That is correct, yeah.  
 16 **MS RICHARDS:** Then we can see a number of conditions  
 17 here set out, you've identified them on the  
 18 left-hand column by reference to body system, so  
 19 under the heading "Infections and infestations",  
 20 we can see described as a common adverse event  
 21 a range of infections, bronchitis, respiratory  
 22 infections, herpes, viral and bacterial  
 23 infections and the like, and then uncommon and  
 24 rare, but still an association, a pneumo-skin  
 25 infection, endocarditis, otitis externa, and

134

1 quickly as they need to be for everybody,  
 2 Scottish Government and SMC have done a huge  
 3 amount of work in the past three to five years  
 4 to try to improve access to drugs as quickly as  
 5 they need to be there, and it takes a lot to get  
 6 these drugs available as widely as they could  
 7 be, because you have to work out who pays for  
 8 them, and that shouldn't be a limit from  
 9 a patient's perspective, but certainly in  
 10 a system where you don't have that money that  
 11 needs to be paid to the companies to pay for the  
 12 medicines, it's quite hard to make sure that  
 13 gets done.  
 14 Still it's too long, but the Government are  
 15 aware and they do -- there has been -- in the  
 16 time that I've seen medicine progressing to try  
 17 to get on to market, the way and the structure  
 18 for which drugs such as these are approved has  
 19 dramatically changed to try to make this as  
 20 quick as they can for this and many other  
 21 conditions.  
 22 It doesn't justify the delays that there  
 23 were there but things have changed I think as  
 24 a result of medicines such as this where the  
 25 transformation and access needed to improve and

136

1 then, frequency not known, but unaccepted  
 2 association sepsis.  
 3 **PROFESSOR COOKE:** That's correct and just to give  
 4 the context to this I think we were asked  
 5 directly about adverse events of interferon and  
 6 it was difficult to know how to synthesize that  
 7 and so what this draws on is what is provided  
 8 with one of the products for interferon, the  
 9 package insert for interferon, so this from the  
 10 manufacturer of this particular interferon how  
 11 they classify what is known about interferon.  
 12 We felt as a starting point that was probably as  
 13 good as any that we could deal with.  
 14 Now, I just want to emphasise that just  
 15 because something isn't on this list doesn't  
 16 mean it's not associated with interferon and  
 17 similarly, sometimes things are reported that  
 18 are not necessarily due to the drug but happen  
 19 at the same time, although that's less common.  
 20 But I think as a starting point, I think this is  
 21 helpful and for those who don't have the  
 22 document I think what we're looking at is  
 23 a quarter of a very large table of things.  
 24 **MS RICHARDS:** Yes.  
 25 **PROFESSOR COOKE:** So the coding on the left side is

<p style="text-align: right;">137</p> <p>1 from the manufacturers and classification, but                  2 as you say, even in that first line, there are                  3 some common side effects which are important,                  4 infections and inflammation.                  5 <b>DR JAMIESON:</b> These are based on a study population,                  6 I think, aren't they, so these would be based on                  7 people who were investigated and given the                  8 treatment in a study population which might not                  9 be representative of a wider normal population                  10 who have other co-morbidities.                  11 <b>MS RICHARDS:</b> I'm not going to deal with every                  12 single entry in it but I'm just going to pick                  13 out a few that may resonate particularly with                  14 some of the evidence that we've read and heard                  15 from individuals.                  16 Identified there on the left-hand column,                  17 blood and lymphatic system disorders. You've                  18 identified again a number of common -- or some                  19 common, rare, very rare, and frequency not                  20 known, but associated manifestations of that.                  21 <b>PROFESSOR COOKE:</b> One that's worth pulling out there                  22 is thrombocytopenia which means low platelet                  23 counts. Platelets are one of the parts of the                  24 blood system which helps blood clot and is often                  25 low in patients with advanced liver disease and</p>	<p style="text-align: right;">138</p> <p>1 cirrhosis, so that's an important issue if                  2 you're having interferon in the setting of                  3 advanced liver disease then your platelet count                  4 may drop and the tendency to bleeding may                  5 increase, and so that's an important side                  6 effect.                  7 <b>MS RICHARDS:</b> Then we see immune system disorders,                  8 and sarcoidosis, thyroiditis, and then                  9 anaphylaxis, SLE, rheumatoid arthritis, and                  10 others. Again, those resonate with the evidence                  11 that we've heard. Endocrine disorders,                  12 metabolism and nutrition disorders.                  13 Then I just wanted to pick up psychiatric                  14 disorders, because we've heard a significant                  15 amount of evidence in relation to that. So this                  16 says, "Very common", and if we look at the top                  17 of that, that's over one in ten, depression,                  18 anxiety, insomnia. Common: aggression, mood                  19 alteration, emotional disorders, nervousness,                  20 libido decreased. Uncommon but still                  21 recognised: suicidal ideation, hallucinations.                  22 Then we see suicide, psychotic disorder, mania,                  23 bipolar disorders, homicidal ideation.                  24 So a very, very significant range of very                  25 severe psychiatric conditions.</p>
<p style="text-align: right;">139</p> <p>1 <b>PROFESSOR COOKE:</b> Absolutely, and very well                  2 recognised and accepted that that is the case.                  3 Obviously, that was always one of the difficult                  4 conversations to be having with patients in                  5 terms of the pros and cons of embarking on                  6 therapy like this, and I think probably it's                  7 fair to say that the most common reason that                  8 patients stopped a treatment whilst having                  9 started it was related to the neuro psychiatric                  10 complications of interferon, and we've heard                  11 about the direct consequence to patients but                  12 also the indirect consequences of that to people                  13 around them.                  14 <b>MS RICHARDS:</b> Picking up on what you say about                  15 conversations and difficult conversations with                  16 patients, I'm not necessarily asking you to                  17 comment upon this but a common theme in the                  18 evidence that the Inquiry has received has been                  19 those conversations not taking place or not                  20 taking place with in any kind of depth, so mild                  21 flu-like symptoms, was a phrase that was used in                  22 the descriptions given by a number of patients.                  23 Now, what was known about side effects of                  24 interferon may have changed over the years and                  25 that may be a matter of fact for the Inquiry to</p>	<p style="text-align: right;">140</p> <p>1 investigate, but it's important to note the                  2 conversations you very properly say you would                  3 expect to take place may not have taken place.                  4 <b>PROFESSOR COOKE:</b> You're right to highlight how                  5 difficult it is in retrospect to know what was                  6 appropriate conversation at what point, but                  7 certainly in recent years when we were using                  8 interferon, then discussions around neuro                  9 psychiatric side effects would be a common one                  10 and patients may have had pre-existing                  11 conditions related to hepatitis C as well so                  12 that would often be part of the management                  13 before starting interferon. John, do you want                  14 to ...?                  15 <b>PROFESSOR DILLON:</b> Having been around this field for                  16 slightly longer than some of my colleagues, as                  17 they pointed out to me at lunchtime, the problem                  18 was that interferon wasn't a new drug when we                  19 were using it in hepatitis C. It had been used                  20 in chemotherapy for a decade or so before we                  21 started to use it, so we were aware of the                  22 problems.                  23 When we first started using it we were                  24 timing patients to hospital because of the fear                  25 of the psychology side effects, so we were aware</p>

141

1 of it and we had those conversations. We became  
 2 more confident with treating it. We would  
 3 sometimes use anti-depressants and start them at  
 4 the beginning of therapy and it was very much  
 5 a two-way conversation about the patients and  
 6 the discussion.

7 So I think those discussions, certainly they  
 8 were in the guidelines to be had. They may have  
 9 changed over the time from the early nineties  
 10 through into the naughties in terms of how  
 11 confident we were that all of those  
 12 conversations were being had by everybody, and  
 13 I can't guarantee that everything was being done  
 14 but it was aware at that time and the  
 15 conversation should have been had and it should  
 16 have been that conversation and practice  
 17 between, "You have advancing liver disease. We  
 18 have a treatment that works, but it comes with  
 19 these risks and problems".

20 Certainly the ones that are listed here at  
 21 the one in 100 rate would be part of the list  
 22 that would be discussed with the patient.

23 **MS RICHARDS:** If we go to the next page, please,  
 24 Henry, again we'll pick out some of the ones  
 25 that may be particularly significant for

143

1 disorders, ear and labyrinth disorders, cardiac  
 2 disorders. So in the common column,  
 3 tachycardia, edema, peripheral palpitations and  
 4 then a number of rarer but significant  
 5 complications.

6 Then if we could have the bottom half of the  
 7 page, please, Henry. Vascular disorders, and  
 8 you see there including hypertension, cerebral  
 9 haemorrhage, respiratory thoracic and  
 10 mediastinal disorders, again a number of  
 11 different complications there.

12 Can I particularly ask you in the rare  
 13 column there, we have reference to interstitial  
 14 pneumonitis, including fatal outcome, and  
 15 pulmonary embolism, so very, very significant  
 16 side effects, consequences, adverse events, even  
 17 if relatively rare ones.

18 **PROFESSOR DILLON:** I think it's important how this  
 19 data is drawn together, so every report of  
 20 a complication of interferon is added to the  
 21 SmPC. That's the way it's written. So there  
 22 will be co-factors in this, so if you have  
 23 someone with chronic obstructive pulmonary  
 24 disease, for instance, who then develops  
 25 interstitial pneumonitis on top, if the

142

1 individuals so if we could highlight the first  
 2 half of the page, for those of us with less than  
 3 brilliant eyesight. Nervous system disorders,  
 4 so we see a range of potential complications  
 5 there, headache, dizziness, impaired  
 6 concentration, memory impairment, and weakness,  
 7 tremors, nightmares, somnolence, then peripheral  
 8 neuropathy, something we've heard from a number  
 9 of statements, rare complications, coma  
 10 convulsions, facial palsy.

11 Again, any particular observations that you  
 12 have about those?

13 **PROFESSOR COOKE:** I suppose just two points to come  
 14 back to, which is first of all, the overlap in  
 15 this with what we've heard already about what  
 16 the virus can do, and the challenge that creates  
 17 for patient and carer alike, but also the  
 18 difference sometimes in reversibility, so coming  
 19 off treatment would often result in an  
 20 improvement in many of these symptoms but not  
 21 all of them and, for example, peripheral  
 22 neuropathy may be longer lasting after  
 23 treatment, so I think it just illustrates both  
 24 those kind of general issues.

25 **MS RICHARDS:** Then we have a number of eye

144

1 interstitial pneumonitis had occurred in someone  
 2 with a normal lung function it wouldn't have  
 3 been a significant problem. The interferon  
 4 would have been stopped and it would have  
 5 stabilised.

6 Clearly, someone with significant  
 7 co-morbidity and there were a substantial number  
 8 of patients that were not suitable for  
 9 interferon therapy because of the risks of these  
 10 drugs, so it was a question of balancing those  
 11 risks between them and so they were, you know,  
 12 it's not -- so it's putting it into that  
 13 context.

14 **PROFESSOR COOKE:** I think the other point worth  
 15 saying is that, you know, if you're looking  
 16 after a patient who is on interferon treatment  
 17 and they're describing a symptom that's not on  
 18 the list, you can report that and add it. It's  
 19 obviously, where that is a very severe thing and  
 20 the patient is very sick as a consequence of it,  
 21 that's more likely to get reported. So I think  
 22 you tend to see it in the rare things, more  
 23 severe things, and that kind of reflects what  
 24 gets collected.

25 **MS RICHARDS:** Then if I can just pick up skin and

145

1 subcutaneous tissue disorders because again  
 2 we've heard a lot of evidence about that, you've  
 3 listed there or there is listed there a range of  
 4 common -- very common and common symptoms,  
 5 including rash, sweating, skin disorders, photo  
 6 sensitivity, night sweats. Again, experiences  
 7 that we've heard a number of witnesses describe.  
 8 If you can then go over the page, please,  
 9 Henry to the last part of it. So we have  
 10 musculoskeletal and connective tissue disorders,  
 11 including myalgia and arthralgia, back pain,  
 12 arthritis, muscle weakness, bone pain, neck pain  
 13 musculoskeletal pain, muscle cramps. I'm just  
 14 looking here currently at the very common and  
 15 common disorders, and common complication in  
 16 terms of reproductive system: impotence. Then  
 17 general disorders, administration site  
 18 conditions. If you can just explain what  
 19 administration site conditions means.  
 20 **PROFESSOR COOKE:** This usually relates to injection  
 21 sites and infection in particular that can occur  
 22 there.  
 23 **MS RICHARDS:** But here again in the very common or  
 24 common columns we have pyrexia, rigours, pain,  
 25 asthenia, fatigue, infection site reaction,

147

1 ribavirin, and most important of those, or most  
 2 common of those, is anaemia, where red blood  
 3 cells are broken down by taking the ribavirin.  
 4 But the reason it was still used and still  
 5 is used, although less so than it used to be, is  
 6 because in some settings it does improve the  
 7 cure rate by taking it. So that was the  
 8 trade-off that was given, but clearly there is,  
 9 as we've said here, a long list of other  
 10 relatively common side effects, including  
 11 depression, insomnia, headache, altered  
 12 concentrations, and many of the things we've  
 13 already discussed.  
 14 So in contrast to some of the interferon  
 15 side effects, most of the side effects from  
 16 ribavirin are reversible, and particularly  
 17 anaemia tends to recover quite quickly, but  
 18 nonetheless can be quite significant during  
 19 treatment, leaving patients feeling very weak,  
 20 and very difficult to do daily activities.  
 21 **MS RICHARDS:** You've then set out in your report, in  
 22 some detail, a description of the first  
 23 generation of direct acting antivirals between  
 24 2011 and 2014. I'm not going to ask you to go  
 25 through those with the same level of detail.

146

1 irritability, chest pain, influenza-like  
 2 illness, malaise, lethargy, hot flushes and  
 3 thirst. Again, descriptions we've heard from  
 4 number of individuals that underwent this  
 5 treatment.  
 6 Can I then turn to ribavirin, please and we  
 7 can take this more shortly, but your report sets  
 8 out again a range of very common side effects,  
 9 and perhaps you could, for the benefit of those  
 10 who don't have the report just summarise some of  
 11 the key ones for us.  
 12 **PROFESSOR COOKE:** So we thought it was important to  
 13 try to be as comprehensive as we could be about  
 14 interferon side effects, and I think in response  
 15 to some of the supplementals we've been through  
 16 as well, specific questions about things we  
 17 are -- that are in the report.  
 18 Ribavirin is always, in the context of  
 19 hepatitis C treatment, is always used with  
 20 interferon. And so we haven't gone into detail  
 21 about all the side effects of ribavirin because  
 22 many of them overlap with interferon, because  
 23 they're always given together. It's hard to  
 24 know which is causing a problem. But there are  
 25 some key side effects that are related to

148

1 Although in some respects a significant  
 2 improvement on interferon and ribavirin,  
 3 a number of them did still carry with them  
 4 significant side effects.  
 5 **PROFESSOR COOKE:** That's correct, and I think the  
 6 important thing to remember is that these were  
 7 being added in on top of interferon and  
 8 ribavirin, so you're already dealing with quite  
 9 toxic combinations of treatment, and the only  
 10 reason they were used was because of the  
 11 improvement in cure rates that could be  
 12 achieved. But some in particular, telaprevir  
 13 and some issues of the itching and skin rash,  
 14 and quite severe skin rashes, were quite a big  
 15 issue. And this is sort of a reflection on  
 16 those drugs that actually none of them are used  
 17 now, even though they're only seven or  
 18 eight years old. Those three drugs in  
 19 particular.  
 20 **MS RICHARDS:** Yes, and it's not long ago.  
 21 **PROFESSOR COOKE:** No.  
 22 **MS RICHARDS:** -- 2018 -- that those are withdrawn  
 23 from the market.  
 24 Then finally, before we break, sir -- I am  
 25 watching the time -- interferon-free treatment.

<p style="text-align: right;">149</p> <p>1 So the current era. Again, you've listed the                  2 various combinations in the report, so I don't                  3 need to ask you to go through each of them, and                  4 those listening who have had the treatments will                  5 know them better than anyone.                  6 Two features I wanted to just ask you about.                  7 The duration of the treatments, which seems to                  8 be much, much shorter than the duration of                  9 interferon, and then the extent of side effects.                  10 <b>PROFESSOR COOKE:</b> I think it's really the three                  11 features. So it's those two you mentioned, in                  12 addition to the higher cure rates that can be                  13 achieved, with durations of therapy which are                  14 now two to three months, really, compared to                  15 what would have been at least six months of                  16 treatment with interferon, and side effect rates                  17 which really are very substantially lower. And                  18 I know from conversations that there's still                  19 suspicion about these drugs for some people.                  20 But really, the adverse events we see with these                  21 drugs are minimal, and I think -- I can't even                  22 think of somebody who has had a problem that                  23 I've treated.                  24 So all of those factors have transformed the                  25 discussion you can have with patients, what</p>	<p style="text-align: right;">150</p> <p>1 patients can be offered and expect from their                  2 therapy now.                  3 We mentioned about how availability of those                  4 treatments is different across the UK, but we're                  5 in a position, I think broadly speaking now,                  6 that anyone who has got an infection and needs                  7 treatment can get it relatively quickly. There                  8 may be local issues about which treatment they                  9 get, but that is now accessible and it's really                  10 only in the last year that we've been able to                  11 treat everybody we want to treat.                  12 <b>DR JAMIESON:</b> And to make it quite clear, the last                  13 one I diagnosed, from a GP's perspective, from                  14 seeing a slight rise in their blood test, to                  15 then getting confirmation of the diagnosis, to                  16 them starting treatment was in the order of                  17 weeks, you know. And to completing treatment,                  18 you know, at the three-month point, they'd gone                  19 from the point of not knowing they had it to                  20 completion of treatment in a very, very quick                  21 timescale which, even three or five years ago                  22 wouldn't even -- you know, even testing them,                  23 that can be discussed if you -- you know. But,                  24 you know, it's a very, very different                  25 perspective now from where we've got to.</p>
<p style="text-align: right;">151</p> <p>1 <b>MS RICHARDS:</b> Sir, I'm moving on to a slightly                  2 different topic, so I think that's probably                  3 a convenient point to stop.                  4 <b>SIR BRIAN LANGSTAFF:</b> Well, I think so too.                  5 <b>MS RICHARDS:</b> Just to say, for the benefit of those                  6 sitting behind me, as with yesterday, if there                  7 are questions arising out of the evidence of the                  8 panel that core participants want to suggest,                  9 I've tried to incorporate a number of them as we                  10 go, but if there are still further questions, if                  11 they let me know over the course of the next                  12 half hour.                  13 <b>SIR BRIAN LANGSTAFF:</b> Thank you. 3.30.                  14 (3.02 pm)                  15 (A short break)                  16 (3.36 pm)                  17 <b>SIR BRIAN LANGSTAFF:</b> Yes?                  18 <b>MS RICHARDS:</b> Just following on from the material we                  19 looked at about the side effects or adverse                  20 events associated with interferon, we also asked                  21 you to look at a number of other conditions,                  22 complications or potential consequences that                  23 were listed in annexes to the letter of                  24 instruction, and asked you to say whether there                  25 was a known association or suspected association</p>	<p style="text-align: right;">152</p> <p>1 with hepatitis B or C.                  2 You've dealt with that in your report so I'm                  3 not going to ask you to go through it in the                  4 same way as we've done with interferon but I am                  5 just going to put up onscreen those parts of                  6 your report so that those who want to have that                  7 information will know where to find it in the                  8 report.                  9 So if we could perhaps just have, first of                  10 all, Henry, page 49, again that's the internal                  11 pagination, so if we just look at fourth                  12 paragraph down, which refers to annex 2, in                  13 respect of annex 2, if you could highlight that,                  14 please.                  15 Just, again, for the benefit of those                  16 listening either here or elsewhere, your report                  17 is in full available on the Inquiry's website,                  18 as are the questions and the annexes, and they                  19 are all easily accessible there.                  20 And you've identified here that most of the                  21 conditions that we asked you about were reported                  22 for interferon, and you've summarised a number                  23 of them there and then you've picked out there:                  24 "Avascular necrosis is not listed, but there                  25 is some limited literature associated with HCV</p>

153

1 and/or interferon use."  
 2 Henry, if we could just go on, please, to  
 3 page 58, we can see the Inquiry asked you about  
 4 other health conditions or complications that  
 5 may have been caused or contributed to either by  
 6 the hepatitis infection or the treatment, and  
 7 you've dealt with those again in the report, so  
 8 if we look at the bottom third of the page --  
 9 please, Henry -- you've identified there under  
 10 the heading "Main extra hepatic manifestations  
 11 of hepatitis C virus infection: classified  
 12 according to the strength of the association".  
 13 Then you've said:  
 14 "... (adapted from Cacoub et al)."  
 15 Could you just explain what the  
 16 classification is.  
 17 **PROFESSOR DILLON:** So this a published paper and  
 18 they had reviewed the available literature and  
 19 grouped the level of evidence around the  
 20 literature, and put it into these categories.  
 21 So I think it's important to realise the way  
 22 evidence is collected in medicine and -- so  
 23 there is evidence -- there is evidence of  
 24 effect, where you start off by having an  
 25 association where you notice two things occur

155

1 literature and what's known. If they're not on  
 2 the list, it doesn't mean that they're not --  
 3 that it doesn't happen but we don't have  
 4 evidence that it's happening.  
 5 **MS RICHARDS:** So anyone who is looking at this  
 6 published report will see listed there  
 7 conditions with significance prevalence and  
 8 consistent pathogenic data, and we've got two  
 9 conditions listed there, in particular I draw  
 10 attention to B cell non-Hodgkin lymphoma,  
 11 because we've heard evidence in relation to  
 12 that. You've then listed a number of conditions  
 13 where it is recognised that there is a higher  
 14 prevalence in HCV infected populations compared  
 15 to controls. I won't go through them but we can  
 16 see a number listed there.  
 17 If we go over the page, Henry, we can see  
 18 a range of other conditions listed there.  
 19 We then have a category of "Conditions with  
 20 possible association with [hepatitis C]", and we  
 21 see three conditions listed there, and then  
 22 "Conditions with anecdotal reports of  
 23 association", and perhaps you can just explain  
 24 what's meant by anecdotal reports.  
 25 **PROFESSOR DILLON:** So anecdotal reports are where

154

1 more commonly than you would expect, you then  
 2 find a plausible biological mechanism that links  
 3 them together, and then you prove in a trial  
 4 that if you do one, the other thing happens, and  
 5 that proves causality.  
 6 For most -- for almost all of the  
 7 manifestations we don't have that level of  
 8 evidence, we have evidence of association, but  
 9 because of the way the evidence of association  
 10 is captured, if there is not evidence it doesn't  
 11 mean that it doesn't happen, it means there is  
 12 an absence of evidence and we just don't know  
 13 because the report hasn't been gathered or there  
 14 is not that level of data. So for syndromes and  
 15 things that are very specific and very  
 16 characteristic, it's easier to report those, and  
 17 they're more easily noticed in the literature.  
 18 For constellations of symptoms that are less  
 19 cohesive and less tied together, it's harder for  
 20 those to be reported in the literature, it's  
 21 therefore harder for people to notice the  
 22 associations and to start to explore them in  
 23 things.  
 24 So in this area, we've tried to plot out  
 25 those levels of what we have seen in the

156

1 people have noticed that these two conditions  
 2 occur together more commonly but they've got  
 3 a smaller number of cases and they have reported  
 4 those in the literature. On some occasions that  
 5 means there are another -- another one or two  
 6 other case reports of other people that have  
 7 noticed the two things together but there's not  
 8 a systematic review of all the evidence and  
 9 a population to try to work out what will  
 10 happen. That will be the next stage of those  
 11 investigations.  
 12 **MS RICHARDS:** If we look down the rest of the page,  
 13 please, Henry, we can see you've then gone on to  
 14 discuss a range of particular types of  
 15 complications we've dealt with liver disease and  
 16 cirrhosis. We see there a description in  
 17 relation to vascular disease, including vascular  
 18 dementia -- and I'm simply drawing attention to  
 19 that because I know it's a point that a number  
 20 of individuals have raised.  
 21 Then if we go to the next page we see  
 22 cancer. We've addressed, obviously, liver  
 23 cancer, but other -- increased risks of other  
 24 cancers you've addressed there, in the report,  
 25 and that's on page 60 of the report.

157

1 You've addressed a range of musculoskeletal  
 2 problems. And then if we continue down, a range  
 3 of autoimmune and multi-system disorders,  
 4 explaining that HCV infection causes immune cell  
 5 dysfunction, and you've identified there  
 6 a number of syndromes with which that's  
 7 associated.  
 8 "Mental health", and you've talked there  
 9 about the association, the strong association  
 10 between HCV infection and mental health  
 11 conditions.  
 12 And then -- thank you, Henry -- over the  
 13 page, "Respiratory conditions", and then you've  
 14 identified a handful of conditions in which  
 15 there is no evidence of association.  
 16 So for reasons of time, and because you've  
 17 answered the questions in the report, I'm not  
 18 going to ask you to go through each of them now,  
 19 but the report is there and provides that  
 20 information to those who would like to see it.  
 21 Can I then, before we look at the next part  
 22 of your report, just ask you this: many  
 23 individuals have reported that following the  
 24 cessation of treatment with interferon, or  
 25 interferon with ribavirin, pegylated interferon,

159

1 the next part of the report, which was looking  
 2 at the significance of co-infection.  
 3 I'm not going to ask you about the section  
 4 of the report that asks about hepatitis and the  
 5 relationship between hepatitis and haemophilia,  
 6 von Willebrand disease and thalassaemia. The  
 7 reason for that is that there is an expert  
 8 coming on Friday who will better be able to  
 9 answer those questions. That's what you've told  
 10 me, at least, that's not my subjective judgment  
 11 on you!  
 12 **PROFESSOR COOKE:** We're very grateful.  
 13 **MS RICHARDS:** Can I ask you to start with  
 14 co-infection with HIV and perhaps ask you,  
 15 Professor Cooke, to address that.  
 16 **PROFESSOR COOKE:** Certainly. And I think this is --  
 17 will come up again tomorrow, I'm sure. But it's  
 18 obviously relatively common to see co-infection  
 19 of both hepatitis B and HIV and hepatitis C and  
 20 HIV, through shared transmission routes. And  
 21 I think, in both cases, there are clear  
 22 interactions where the presence of HIV affects  
 23 what happens to the hepatitis B, at different  
 24 stages, so -- and hepatitis C.  
 25 So just to very briefly go through them,

158

1 the symptoms that they experienced, in  
 2 particular such as brain fog, depression,  
 3 fatigue, did not go away, and many of them  
 4 report that they have endured those for years.  
 5 Can I ask for any observations you have on that.  
 6 **PROFESSOR DILLON:** If we look at the trials overall,  
 7 that symptoms get less common after successful  
 8 treatment, and so a proportion of the people  
 9 affected by them it's clearly caused by  
 10 hepatitis C.  
 11 For the other residual symptoms that are  
 12 left after cure, it's a question of whether  
 13 there is something else going on that's causing  
 14 those symptoms, or alternatively, that the  
 15 hepatitis C had established some pattern of  
 16 damage within the brain, or the behaviours  
 17 associated with it, that didn't change after  
 18 treatment. And so we know that the treatment  
 19 reduces the incidence of those symptoms  
 20 substantially. A proportion of patients they  
 21 don't resolve, and it's either because of some  
 22 permanent damage the hep C has left behind in  
 23 the brain in terms of an adaptation, or there  
 24 was something else going on.  
 25 **MS RICHARDS:** Now I wanted to ask you to deal with

160

1 individuals with HIV are more likely to have  
 2 chronic infection once they've been infected  
 3 with hepatitis B. When chronic infection is  
 4 established, it's more likely to have a higher  
 5 replicating amount of hepatitis B, and that in  
 6 turn can be related to a more rapid progression  
 7 of liver disease as a consequence, with more  
 8 rapid progression to cirrhosis.  
 9 And indeed, in the HIV cohorts across Europe  
 10 and the UK in recent years, until relatively  
 11 recently liver disease was growing as  
 12 a relatively important cause of death among  
 13 patients with HIV.  
 14 And it's also worth saying that that has  
 15 changed quite a lot with the advances in  
 16 treatments, and I mentioned earlier one or two  
 17 treatments which treat both HIV and hepatitis B,  
 18 and with effective treatment a lot of that can  
 19 be reduced but for many years that wasn't  
 20 possible and that was a real problem.  
 21 And similarly, with hepatitis C and HIV,  
 22 the -- there's a similar issue where if your  
 23 immune response is weaker then you're more  
 24 likely to develop a chronic infection after  
 25 exposure. Again, you can see a more rapid



161

1 progression of that condition. The viral load  
 2 in hepatitis C is a little bit different but  
 3 nonetheless the disease can progress more  
 4 quickly. You're more likely to get advanced  
 5 fibrosis cirrhosis. And on top of that, in the  
 6 setting of the hepatitis C, then, we talked  
 7 about interferon stimulating the host immune  
 8 system; if you've got a weakened host immune  
 9 system because of HIV, that interferon is less  
 10 likely to be effective. And so some of the  
 11 guidelines, from European guidance for example,  
 12 recommended 72 weeks of interferon for patients  
 13 with HIV. So really very substantial durations  
 14 of therapy. And again, with lower success rates  
 15 as well, as a trade-off.

16 But equally, again, the newer treatments  
 17 that directly target the virus seem to be as  
 18 effective for patients with HIV as without, and  
 19 have been able to clear the virus for those  
 20 patients. So there's a number of different  
 21 interactions.

22 I think in the report -- those are the ones  
 23 we've highlighted, I think it's just worth  
 24 emphasising that, of course -- the psychosocial  
 25 element of both viruses we heard a lot about,

163

1 I think it's more about the discussion about the  
 2 risks and benefits. So I think, you know,  
 3 you're having a discussion about a much longer  
 4 course of treatment, with a lower chance of  
 5 success. So there may have been a choice that  
 6 would be more likely to be made in terms of  
 7 waiting to use that treatment for HIV patients.

8 Do you want to add to that, John?

9 **PROFESSOR DILLON:** I would agree. I think it was  
 10 a different discussion with -- and there were  
 11 also more risks associated with hepatitis C  
 12 interferon-based therapies in someone who is  
 13 co-infected with HIV with a much reduced chance  
 14 of benefit at that stage. And so it was this  
 15 play-off between -- how severe your liver  
 16 disease was became a much more significant  
 17 discussion during that development.

18 **MS RICHARDS:** And you've said in your report,  
 19 advanced HIV is associated with a worse outcome  
 20 for both HBV and HCV.

21 **PROFESSOR COOKE:** Yes, and by advanced HIV -- we'll  
 22 talk about this more tomorrow, but we mean  
 23 people with a weakened immune system, the  
 24 CD4 cell count that we tend to talk about being  
 25 low as a marker that you'll respond to less well

162

1 but it is -- it can be additive and there are  
 2 different effects for an individual patient as  
 3 to how they perceive those viruses and the  
 4 stigma that they might attach to different  
 5 viruses even though they have both.

6 And I think the other thing that we didn't  
 7 put in the report that's worth mentioning is  
 8 that some of the HIV medications, certainly --  
 9 even some of the ones we still use now can also  
 10 have neuropsychiatric side effects. So one drug  
 11 in particular, Efavirenz, which we use very  
 12 widely for HIV, is associated with depression,  
 13 and that can be an additional factor of  
 14 complication, particularly for patients with  
 15 hepatitis C who -- who may have further  
 16 problems.

17 So there's a range of important  
 18 interactions.

19 **MS RICHARDS:** Is this also right: that for some of  
 20 those who were co-infected with HCV and HIV,  
 21 they would not have been able to receive  
 22 treatment with interferon?

23 **PROFESSOR COOKE:** There are always a group of  
 24 patients who -- where that was difficult, but it  
 25 tended to relate to advanced liver disease.

164

1 to treatments like interferon.

2 **MS RICHARDS:** Then can I ask you next about  
 3 co-infection with other hepatic viruses.

4 **PROFESSOR COOKE:** Yes, so I think in the report  
 5 we've touched on quite a lot of these things  
 6 already. I think one of the -- we've mentioned  
 7 hepatitis G already and we've talked about  
 8 hepatitis D. I think one of the things that  
 9 will be of concern and interest to some people  
 10 is the idea of triple infection, and clearly  
 11 there are a number of patients, not  
 12 inconsiderable numbers, who have been infected  
 13 with HIV, hepatitis B and hepatitis C, and that  
 14 has different implications that are a little bit  
 15 complicated, so those viruses can have an  
 16 interaction in a patient as to what they -- what  
 17 that means, and often one virus will dominate  
 18 but may come back if the other virus is treated  
 19 and that's an issue that we still deal with  
 20 a little bit in practice.

21 Again, the hepatitis D can also be an  
 22 additional factor.

23 So, for a small number of patients there is  
 24 an additional complication of multiple  
 25 co-infection which is -- this is a --

165

1 **MS RICHARDS:** And treatment decisions obviously, for  
 2 the reasons you've given, may become much more  
 3 complicated for patients who are experiencing --  
 4 **PROFESSOR COOKE:** Yes, and there is an issue, which  
 5 is still an issue, which is about the issue of  
 6 hepatitis B, which can be less obvious before  
 7 you treat hepatitis C and then can flare  
 8 afterwards, and that's something we've  
 9 recognised more in recent years with some of the  
 10 treatments and that we can take measures to  
 11 prevent, but it does require a certain -- a  
 12 certain sort of more complicated management  
 13 approach.  
 14 **PROFESSOR DILLON:** I think it's fair to say that  
 15 things have become much easier with the arrival  
 16 of the DAAs. It has made the management of HIV  
 17 and hepatitis B and hepatitis C much more  
 18 straightforward and we've now spent the last  
 19 four years learning our way around those, and  
 20 I think it's become clearer and easier from  
 21 a patient's perspective.  
 22 **MS RICHARDS:** Can I move on to section 15.18 of your  
 23 report, pages 53 to 54 for those that have the  
 24 report.  
 25 The question you were asked was about

167

1 publicity when they published a report saying  
 2 that there was no evidence of cure. What that  
 3 meant was not that the virus didn't go away but  
 4 that the clinical consequences of that viral  
 5 infection didn't necessarily go away completely.  
 6 And the reason for that was that actually --  
 7 it was based on studies that hadn't really  
 8 looked at patients for a very long time after  
 9 they'd finished treatment, and we know, just as  
 10 the complications are slow to come on, the  
 11 benefits of treatment are relatively slow to  
 12 come on in terms of preventing advanced fibrosis  
 13 and liver cancer.  
 14 So I think it is right to talk about "cure".  
 15 It's cure of the virus, but it's not necessarily  
 16 cure of everything. And I think that's an  
 17 important distinction that I know for many  
 18 patients is important, both in terms of what  
 19 we've heard about the neurocognitive side  
 20 effects and the liver disease as well. So we do  
 21 talk about "cure", and we use these markers  
 22 we've talked about as a sort of surrogate for  
 23 that long-term cure in terms of the presence of  
 24 virus after treatment.  
 25 And as we've already mentioned, then, it is

166

1 whether hepatitis can be cured or whether it  
 2 remains dormant and is only undetectable, and  
 3 I think you've addressed that in relation to  
 4 hepatitis B already.  
 5 Can I just ask you to say a little bit more  
 6 about hepatitis C. One of the particular  
 7 questions that some core participants have asked  
 8 is whether it's right to talk about "cure" or  
 9 simply "suppression" of hepatitis C.  
 10 **PROFESSOR COOKE:** Yes, I think this is really  
 11 important, and it's worth going into a bit of  
 12 detail I think.  
 13 It is -- as we've said a number of times, it  
 14 is a very different approach to treatment, where  
 15 we are trying to get rid of the virus from the  
 16 body. Although that doesn't necessarily mean  
 17 there can't be traces of that virus found, which  
 18 sometimes can confuse things.  
 19 We've acknowledged, I think, in the report  
 20 that there's been a bit of controversy around  
 21 "cure", and part of this came because there was  
 22 a very high profile report that came out about  
 23 two or three years ago from the Cochrane group,  
 24 a very well respected group, who reviewed new  
 25 treatments for hepatitis C and got a lot of

168

1 also possible to get reinfected. So we have to  
 2 be careful, if we see a patient with virine to  
 3 work out whether this is an infection that has  
 4 come back or a new infection. And with the  
 5 newer tests we can do with the virus, we can be  
 6 more confident about that, and often we do find  
 7 that patients become reinfected rather than sort  
 8 of relapsing later on. And I think that's sort  
 9 of taken away some of the anxieties that people  
 10 had about relapsing infection. But I think --  
 11 I'm very comfortable with the idea that -- and  
 12 I think we're all are, but our -- I mean, there  
 13 is controversy outside the field a little bit  
 14 that we can talk about cure from this  
 15 perspective.  
 16 **MS RICHARDS:** Professor Dillon?  
 17 **PROFESSOR DILLON:** I think we should be unequivocal  
 18 that there is a cure. I think the Cochrane  
 19 report, for those people that want to think  
 20 about it in more detail, what the Cochrane  
 21 report were demanding was that we did trials  
 22 until death, and that we didn't treat people.  
 23 And that, I think, is unacceptable. And I think  
 24 the Cochrane report was rightly condemned by the  
 25 whole community and has, you know -- most of the

169

1 committee that produced it have retracted  
 2 themselves from it because of that purpose.  
 3 We have shown previously that SVR24 or 12 is  
 4 a very, very good surrogate for a cure in the  
 5 long-term, and we therefore don't need to not  
 6 treat people for decades to show that the people  
 7 that were treated were benefited.  
 8 Now, cure of the virus means that if you've  
 9 been detected early and most of the scarring  
 10 hasn't happened, then you have -- you can walk  
 11 away from the consequences of hepatitis C,  
 12 thankfully. If you're treated later, then there  
 13 is still some associated risk, which we will get  
 14 on to discussing how that's managed and looked  
 15 after. But even in those patients, the risk  
 16 falls substantially once you're cured of the  
 17 virus.  
 18 **MS RICHARDS:** Just dealing with that latter point,  
 19 in your report you say:  
 20 "There is a large body of evidence that  
 21 achieving SVR12/24 is associated in the longer  
 22 term with significant reductions in all cause  
 23 mortality, liver cancer and liver failure.  
 24 However these risks remain higher than in  
 25 patients never infected with HCV."

171

1 For those that have cirrhosis, which, if you  
 2 look at the whole population, there is a group  
 3 of people who will be carrying that scarring  
 4 with them, they still have those -- they still  
 5 have some risk but the risk is much reduced.  
 6 **MS RICHARDS:** And you've -- I think sought to  
 7 quantify, to the extent that you're able to on  
 8 the existing material, those risks on page 56 of  
 9 your report. You say:  
 10 "After cure, a person with cirrhosis would  
 11 expect some regeneration of the liver, which  
 12 would improve health and symptoms of liver  
 13 failure, but they may be left with residual  
 14 symptoms and signs of liver failure."  
 15 You say:  
 16 "This would be a small proportion of those  
 17 with cirrhosis and such people may require liver  
 18 transplantation."  
 19 You say:  
 20 "The majority of those with cirrhosis, who  
 21 have [not yet reached the stage of] ... liver  
 22 failure, are likely to get some improvement in  
 23 liver function ... after SVR."  
 24 But still have a long-term risk of  
 25 developing HCC.

170

1 And again, you've given more detail about  
 2 that in your report. It goes back to an answer  
 3 I think you gave before lunch: successful  
 4 treatment may reduce the risk of what would  
 5 otherwise have been the natural progression of  
 6 the liver damage but it doesn't reduce it to the  
 7 level that it would be if you had never had  
 8 hepatitis C.  
 9 **PROFESSOR DILLON:** So the evidence base at the  
 10 moment -- because we are, if you like, the first  
 11 generation of people who were cured of  
 12 hepatitis C by the DAAs -- were -- were of  
 13 advanced disease, but we cured them four or  
 14 five years ago, so we're still following them  
 15 up. What we know is that over those four or  
 16 five years in Scotland their risk of liver  
 17 failure has fallen dramatically. Their risk of  
 18 liver cancer has fallen but not as quickly but  
 19 it will carry on monitoring that so they're  
 20 left -- these are the patients who are left with  
 21 significant scarring and cirrhosis, and in  
 22 people who have minimal fibrosis or no fibrosis  
 23 when they're cured, their risks go back to  
 24 normal very quickly and they have no risk of  
 25 progression from what we can tell.

172

1 **PROFESSOR DILLON:** Yes and I think that's the  
 2 estimate at the moment, it's certainly fallen  
 3 over the three or four years that we've been  
 4 watching it and we've shown that we've just  
 5 published that data for Scotland at that  
 6 national level so the risk falls. How much more  
 7 the risk will continue to fall over the coming  
 8 years, we'll just have to monitor it, but  
 9 I think we will continue to monitor patients who  
 10 are risk of that, and it's patients with  
 11 significant scarring at the time that they're  
 12 cured.  
 13 I think for the people who have cirrhosis  
 14 but weren't in liver failure, there appears to  
 15 be no risk of progression to cirrhosis and liver  
 16 failure, unless there are other co-factors such  
 17 as metabolic obesity and alcohol playing in as  
 18 well.  
 19 **PROFESSOR COOKE:** I think it's worth emphasising  
 20 that we think in general that how you achieve  
 21 that cure it doesn't affect the benefit of it.  
 22 So if you achieved it with interferon,  
 23 antiviran, ribavirin, or the newer drugs, then  
 24 you still have that benefit of cure of similar  
 25 magnitude.

173

1 I think one of the questions that we just  
 2 touched on, it remains unclear as to how we help  
 3 patients who have been cured of the virus who  
 4 still have scarring or cirrhosis, to understand  
 5 the risks going forward, and those are studies  
 6 that are currently running in the UK trying to  
 7 understand that risk.

8 **MS RICHARDS:** Picking up on that point, and what  
 9 patients would be entitled to expect as a matter  
 10 of basic good practice, in terms of follow-up,  
 11 we have had evidence that suggests a patchy and  
 12 variable position for specific individuals.  
 13 Some who have not had, despite having liver  
 14 scarring, any form of follow-up.

15 So I wondered if you could just explain to  
 16 us what you say patients should be entitled to  
 17 as a matter of basic good practice.

18 **PROFESSOR DILLON:** So in terms of people who have  
 19 established cirrhosis, and I'd like to follow up  
 20 with a point about how you make that diagnosis  
 21 of cirrhosis, they should be followed up  
 22 regularly for hepatoma screening, they should be  
 23 followed up to look for oesophageal varices and  
 24 therapy should be arranged, if they have  
 25 varices, to reduce the risk of bleeding. That

175

1 that things may have been explained to people  
 2 along the line in terms of scarring and severe  
 3 scarring and cirrhosis needs to be clarified for  
 4 people as to what their risk actually is.

5 We know that quite a lot of those early  
 6 scars disappear out of a liver biopsy after  
 7 treatment as well and so there needs to be  
 8 a discussion as to when you were told you had  
 9 scarring on your liver, how bad the scarring  
 10 was, and whether you still need follow-up for  
 11 it. But I think that there has been some  
 12 uncertainty about what to do, and clearly some  
 13 people -- who has been treating, et cetera, and  
 14 who would follow people up, so hepatologists for  
 15 instance will spend their entire lives following  
 16 up people who are -- have some scarring on their  
 17 liver, whereas people from an infectious  
 18 diseases background might think the virus is  
 19 done it's over to the liver doctors to sort out  
 20 so there maybe some of that going on.

21 There should be clear guidelines for every  
 22 hepatitis C treatment service across the UK as  
 23 to who needs follow-up and who is going to do  
 24 the follow-up.

25 **MS RICHARDS:** You say there should be, are there?

174

1 clearly is with patient choice, and that -- the  
 2 pros and cons of follow-up and screening should  
 3 be discussed with the person involved and they  
 4 should make the decision as to whether they wish  
 5 to go through that screening, but that's what  
 6 should be offered.

7 In terms of the diagnosis of cirrhosis,  
 8 historically we made the diagnosis of cirrhosis  
 9 with liver biopsy which we now don't do because  
 10 it's a risky and unpleasant procedure. We use  
 11 other techniques to estimate the amount of  
 12 scarring in the liver, either blood tests or  
 13 imaging based techniques. With these imaging  
 14 based techniques, they are different in the way  
 15 they measure the scarring in the liver, and so  
 16 if we have uncertainty, we will trigger  
 17 screening, lower levels of scarring on the  
 18 liver. So patients who may not be fully  
 19 cirrhotic but carry a lot of scarring, we will  
 20 offer them screening as well so the system is  
 21 failsafe in that way.

22 I think it's important to remember  
 23 Dr Marshall's pictures about the progression of  
 24 liver disease, and there are lots of scars on  
 25 those pictures that she showed, and so the way

176

1 **PROFESSOR DILLON:** There is guidance and it clearly  
 2 says what it should do both for British  
 3 Association for the Study of the Liver, and for  
 4 EASL, which we all follow, and so those guidance  
 5 are there and practice should be instituted  
 6 appropriately.

7 **MS RICHARDS:** If I can ask you about three different  
 8 categories of patient then, the first category  
 9 are the patient who has achieved SVR, whether  
 10 it's SVR 12, SVR 24, and there is no evidence of  
 11 liver scarring, my understanding from your  
 12 report is you would expect they would be  
 13 discharged from care without any follow-up.

14 **DR MARSHALL:** To their GP.

15 **MS RICHARDS:** I'm sorry?

16 **DR MARSHALL:** To their GP.

17 **MS RICHARDS:** Yes.

18 **PROFESSOR COOKE:** That's not universal but I think  
 19 that would be what we'd say as group.

20 **MS RICHARDS:** What, if anything, would you expect  
 21 their GP to be doing in those circumstances?

22 **DR JAMIESON:** It depends on the individual. So it's  
 23 a discussion with an individual about what, you  
 24 know, obviously the causes of it in the first  
 25 place, and the ongoing lifestyle issues need to

177

1 be individualised and you need to cater for that  
 2 for the individual.  
 3 I think obviously we already discussed that  
 4 the lifetime risk is not going to end up being  
 5 zero and I don't think the evidence as yet  
 6 exists as to how exactly, if you were going to  
 7 monitor these patients lifelong, would you look  
 8 at that.  
 9 **PROFESSOR DILLON:** I think for the patient who has  
 10 no scarring, it is fairly clear there is no risk  
 11 in the long-term, no risk compared to the  
 12 general population.  
 13 **DR JAMIESON:** But I guess what I was hinting at is  
 14 what is the cause of hep C was in the first  
 15 place, it's a reinfection, I think that's what  
 16 I'm trying to --  
 17 **PROFESSOR DILLON:** Yes, if we're confining this to  
 18 the infected blood cohort, then -- which is the  
 19 purpose of this Inquiry, then there wouldn't be  
 20 on -- clearly, if there are other  
 21 multi-morbidities in a person's life we would  
 22 deal with those and move on from that point of  
 23 view. For someone who has acquired hepatitis C  
 24 from an infected blood route and they are cured,  
 25 there would be no ongoing transmission risk.

179

1 disease should be reviewing the patient  
 2 annually.  
 3 **MS RICHARDS:** That should be for the rest of their  
 4 life?  
 5 **PROFESSOR DILLON:** Yes, or until they grow tired and  
 6 make the choice that they don't wish us to go  
 7 forward with it.  
 8 **MS RICHARDS:** So the more difficult category may be  
 9 those who don't fall into either end of that  
 10 spectrum, the patient who has scarring,  
 11 fibrosis, but it's -- but not reached the stage  
 12 of cirrhosis, and it sounded from what you were  
 13 saying as though those may be matters where the  
 14 guidelines are less clear and there may be  
 15 questions of clinical judgment or have  
 16 I misunderstood?  
 17 **PROFESSOR DILLON:** There are issues of clinical  
 18 judgment, the measures, because we're not liver  
 19 biopsying anymore, the measures of fibrosis are  
 20 a little grey in those areas and so we would  
 21 divide those patients into those with quite  
 22 a lot of scarring and they might be on the verge  
 23 of cirrhosis, and we would discuss that with  
 24 them and offer them follow-up as if they had  
 25 cirrhosis, and most of them opt for that option

178

1 There would be no ongoing risk to them as  
 2 a individual if they have no fibrosis and  
 3 scarring and they could live their life as  
 4 a normal person and we would keen to get --  
 5 albeit there would still be the haemophilia  
 6 treatment, et cetera, that would be a part of  
 7 their background life.  
 8 **MS RICHARDS:** So we have that category, at the other  
 9 end of the spectrum we have the category of the  
 10 patient who has achieved SVR but who has  
 11 cirrhosis.  
 12 Am I right in understanding that whether  
 13 they have compensated or decompensated  
 14 cirrhosis, they should be receiving follow-up  
 15 monitoring?  
 16 **PROFESSOR COOKE:** That's correct.  
 17 **PROFESSOR DILLON:** Yes, they should.  
 18 **MS RICHARDS:** How frequent would you expect that to  
 19 be, in terms of scans and blood tests?  
 20 **PROFESSOR DILLON:** The guidelines suggest  
 21 six-monthly ultrasounds and probably annual  
 22 clinical review, be that with a nurse-led clinic  
 23 or consultant-led clinic or a GP or the  
 24 specialist interest, someone with a special  
 25 interest with the management of chronic liver

180

1 when they're given it. Or they have a little  
 2 bit of scarring it's not very much, but they do  
 3 need to be aware of keeping their weight down  
 4 and their alcohol intake for the future, as the  
 5 hep C scarring will never cause them any harm  
 6 but they are, if you like, one step up towards  
 7 cirrhosis, and if they add to that step they  
 8 could progress so it would be, as Scott was  
 9 alluding to, lifestyle advice about reducing the  
 10 risks of those progressions.  
 11 **MS RICHARDS:** What about something that's neither  
 12 very light scarring nor on the verge of  
 13 cirrhosis?  
 14 **PROFESSOR DILLON:** So if it's -- so I think we would  
 15 draw the line in -- split them in two.  
 16 **MS RICHARDS:** Okay.  
 17 **PROFESSOR DILLON:** If you want to stick one in the  
 18 middle and there was signature doubt, perhaps  
 19 because we had two fibrosis markers that  
 20 disagreed with each other, there would be  
 21 a discussion with the patient about how they  
 22 wanted to err on the cause and whether they  
 23 wanted six-monthly ultrasounds and endoscopic  
 24 examination or whether they were prepared to not  
 25 have that because it was of limited benefit and

181

1 that would be a discussion.

2 **DR JAMIESON:** I think, shared decision-making really

3 is a -- underpins that, though -- you know,

4 because we're really living in such uncertainty,

5 these drugs, we -- we -- you know, we're hopeful

6 of the long-term outcomes and we continue to

7 monitor that, but we're in this -- this grey

8 area in the middle with that massive amount of

9 uncertainty. Shared decision-making, you know,

10 explaining uncertainty, and then looking at the

11 patient's core values and their priorities and

12 bringing that into it, it's got to be key at

13 that stage. In my experience that's -- usually

14 helps shape that plan.

15 **PROFESSOR COOKE:** I think this is where it's

16 important that empowering and educating primary

17 care is an important part of this, because as

18 many people will know, often people are

19 travelling quite substantial distances for their

20 liver care, and to go every six months when

21 you're very well for a scan, quite some

22 distance, is difficult, and I think the closer

23 that care can be delivered to a patient going

24 forward, the better.

25 **MS RICHARDS:** Picking up on what you just said about

183

1 time given for explanation?

2 **PROFESSOR DILLON:** Shall I start? So I think it

3 depends on the context in which hepatitis C is

4 being diagnosed. If it is in a context where it

5 is expected and not unexpected, for instance in

6 an addiction, psychiatry setting, or a needle

7 exchange, for instance, then that's a very

8 different discussion to a diagnosis that's made

9 because of a blood transfusion that happened

10 25 years ago and you were in for an insurance

11 medical and had an abnormal ALT discovered. And

12 that would clearly be in a -- usually in

13 a hospital environment, because the patients

14 would be able to access this, having had some

15 preliminary information from their GP, and

16 hopefully the GP would have had access to online

17 information that they could pass to the patient,

18 and hopefully that suitable environment would be

19 with someone who was knowledgeable about the

20 condition and knowledgeable about the treatment,

21 and how that treatment plan would be evolved.

22 And I think that's moving forward quickly.

23 **MS RICHARDS:** If we turn on to the next page we can

24 see you flesh that out. You talk about giving

25 the opportunity for a full discussion. You talk

182

1 shared decision-making and the importance of

2 discussions between clinician and patient, just

3 going to ask to have up on the screen a section

4 of the report.

5 It's page 61 onwards. please, Henry.

6 Again, I'm not going to go through this in

7 detail, but it's to signpost where anyone who

8 wishes to read the report will find it.

9 If we look at the bottom half of the page,

10 please, Henry.

11 So you were asked the question about the

12 advice and information you would expect

13 a patient to be given now about hepatitis.

14 And you've set out a number of general

15 considerations about the kind of discussion that

16 should take place. In particular, you say that

17 there must be a suitable environment with

18 adequate time given for such an explanation.

19 I know those of you who heard some of the

20 psychosocial evidence yesterday will obviously

21 understand the importance of these issues.

22 Can I ask -- and recognising, as I do, you

23 distinguish between what the GP might do and

24 what might happen in secondary care, what do you

25 mean by a suitable environment with adequate

184

1 about the importance of effective shared

2 decision-making, of listening to patient

3 preferences, of ensuring the patient has the

4 information they need to make an informed

5 choice. You talk about an equal partnership

6 between patient and clinician, and then you set

7 out some of the kind of basic information you

8 would expect the clinician to be providing to

9 the patient.

10 **DR JAMIESON:** Yeah, these were kind of set out as --

11 almost at a primary care level, you know, for

12 the very core information that we -- we fully

13 appreciate -- I've highlighted there, you know,

14 different learning and literacy issues need to

15 be catered for, including the use of pictorial

16 explanation and patient's -- and supporting

17 patient self-recording as well. And we know

18 when you're giving important diagnosis that

19 patients will often not remember a lot of what

20 you say, and so trying to facilitate that in any

21 way you can, cognisant of the patient that is

22 sitting in front of you, you must have -- give

23 consideration to that, in particular if it is an

24 unexpected diagnosis, how are you going to help

25 manage that in a GP appointment when they're

<p style="text-align: right;">185</p> <p>1 going to be walking out of the door soon  2 afterwards? You know, after the discussion, how  3 can we make sure we support that properly?  4 Ensuring that I know that I'm referring, in  5 my case, I'm referring to Professor Dillon's  6 service, I know that from there on in it's a bit  7 of a snowball, it's a bit of a rollercoaster and  8 so we're making sure that we're adequately  9 preparing them for that process, and that  10 they've got the support surrounding them that  11 they need, and that they are being signposted to  12 the right sort of information and trying to give  13 them some caveats and hints on how to manage  14 that process.  15 But remembering that they remember very  16 little of what you say, barring the diagnosis,  17 which is an important thing to remember, which  18 all GPs are trained in discussing and hopefully  19 manage to implement effectively.  20 <b>PROFESSOR COOKE:</b> Just to add a couple of things,  21 I think you can see from looking at this that  22 there's potentially a lot of information that  23 would be needed to be shared, and I don't think  24 we would want to suggest that necessarily all  25 had to be done at one time. Sometimes that's</p>	<p style="text-align: right;">186</p> <p>1 broken over serial conversations and  2 particularly in secondary care. I think we've  3 heard a bit about the importance of specialist  4 nursing and often that conversation will be  5 shared between a specialist and the nursing  6 team, who may have more time allocated where  7 that can be done. Different services have  8 different levels of provision for that. I think  9 that's quite important.  10 The other thing to say is that it's quite  11 hard to find a single recommended list of things  12 that need to be told to people. What we've  13 included in the report is a couple of examples  14 of local patient information sheets that have  15 been developed for patients, and there's links  16 in the report. I think we felt that they were  17 quite good examples of what could be done,  18 rather than saying that was what needed to be  19 done. But I think if someone wanted to  20 a starting point, that would be quite a good  21 place to look.  22 <b>MS RICHARDS:</b> You've set out on page 63 some of the  23 particular kinds of information that should be  24 provided. The top half of the page deals with  25 hepatitis B, the bottom half with hepatitis C.</p>
<p style="text-align: right;">187</p> <p>1 This, I think, would typically be in secondary  2 care, as I understand the report, or could it  3 also be in primary care?  4 <b>DR JAMIESON:</b> It depends if the question gets asked.  5 I think I'm very mindful in these conversations  6 that the patient is not going to remember a huge  7 amount of what we discussed bar the diagnosis,  8 and I'm going to be wanting to offer that  9 referral and early access to treatment. So it's  10 patient-led as well as to what they want to know  11 and where they're at. So it's very  12 individualised. The information is there and we  13 can offer to discuss. But you've got to be led  14 by where that conversation is going.  15 The priority is to make sure that they're  16 very clear that I have offered treatment and we  17 have offered access to services, and to looking  18 at their values and their beliefs and their  19 priorities to see how we can make those match,  20 to distil down to what I suppose you would call  21 optimal care, which takes the combination of our  22 evidence and our guidelines and the patient's  23 beliefs and their core values and their  24 priorities and we'll distill it down to what  25 their priority is at that moment. That's the</p>	<p style="text-align: right;">188</p> <p>1 same for the conversation that I might have but  2 is equally transferable to the conversation my  3 colleagues might have in secondary care as well.  4 <b>MS RICHARDS:</b> Again, I flag that up because the  5 evidence that we have heard, not from everybody,  6 but from a number of individuals, describes  7 experience of being given information or not  8 being given information about, in particular,  9 hepatitis C, which is not consistent with the  10 model that you've set out here. What you've set  11 out is what you say should be done.  12 <b>DR JAMIESON:</b> Mm-hm.  13 <b>MS RICHARDS:</b> I'm not going to take time on it now,  14 because you've dealt with it fully in your  15 report, but you have dealt with issues about  16 advice about conception, if someone is infected  17 with hepatitis B or C or is undergoing  18 treatment, and implications for fertility in  19 your report from pages 64 and also page 70.  20 I just again draw attention to that because some  21 individuals had raised questions about that.  22 You were asked in the report just to comment  23 upon the World Health Organisation initiative.  24 (this is the initiative to eliminate  25 hepatitis C) and also to set out what was being</p>

<p style="text-align: right;">189</p> <p>1 done in the United Kingdom towards that. Your</p> <p>2 report covers England, Scotland and reference to</p> <p>3 Northern Ireland but not Wales. I wondered if</p> <p>4 that's simply because you didn't know the</p> <p>5 position or whether do we infer from that that</p> <p>6 steps are not being taken in Wales?</p> <p>7 <b>PROFESSOR COOKE:</b> So we looked for publicly</p> <p>8 available documents at the time we wrote this.</p> <p>9 My understanding is -- and I haven't checked</p> <p>10 this, I was told this yesterday -- I understand</p> <p>11 there is a document now on the Welsh website</p> <p>12 about the plans afoot there. So there are</p> <p>13 clearly different levels of complexity and</p> <p>14 progress in different home nations, and I think</p> <p>15 the Scottish example is probably the best at the</p> <p>16 moment. But there are plans in all the home</p> <p>17 nations to make progress with elimination, in</p> <p>18 line with the WHO targets which are really quite</p> <p>19 aggressive. There is an ambition to try to</p> <p>20 substantially reduce mortality and transmission</p> <p>21 of hepatitis, both B and C, by 2030 and I think</p> <p>22 certainly the UK Government -- sorry, the</p> <p>23 English health system I think has stated</p> <p>24 a target of 2025 for elimination of hepatitis C.</p> <p>25 I think the Scots may have said 2024. That may</p>	<p style="text-align: right;">190</p> <p>1 be coincidence.</p> <p>2 <b>DR JAMIESON:</b> I think they came up with theirs after</p> <p>3 2025.</p> <p>4 <b>SIR BRIAN LANGSTAFF:</b> The Scots are going one</p> <p>5 better.</p> <p>6 <b>DR JAMIESON:</b> I think that was Professor Dillon's</p> <p>7 doing.</p> <p>8 <b>PROFESSOR DILLON:</b> Certainly steps towards</p> <p>9 elimination are advancing well and within one</p> <p>10 region within Scotland we are likely to achieve</p> <p>11 elimination by the World Health definitions this</p> <p>12 year and Scotland is on track to achieve it by</p> <p>13 2024. But it does require more effort and</p> <p>14 public awareness around hepatitis C, the fact it</p> <p>15 can be cured, and where it is in our populations</p> <p>16 and how we have to bring people forward for</p> <p>17 diagnosis and cure.</p> <p>18 <b>PROFESSOR COOKE:</b> I think there's a helpful concept</p> <p>19 of micro-elimination that's being used a bit and</p> <p>20 that's where we look at particular risk groups</p> <p>21 and try and achieve up to 100 per cent cure of</p> <p>22 everybody in that risk group. Clearly I think</p> <p>23 people with certain blood disorders fall into</p> <p>24 a risk group where that can be achievable in</p> <p>25 reasonably short time. In HIV, we've got</p>
<p style="text-align: right;">191</p> <p>1 a national programme trying to achieve that and</p> <p>2 we've made progress with probably fewer than 10</p> <p>3 per cent of patients left to be cured of</p> <p>4 hepatitis C. So there is real genuine and high</p> <p>5 ambition for elimination, particularly in some</p> <p>6 key risk groups.</p> <p>7 <b>MS RICHARDS:</b> One question that I have been asked to</p> <p>8 raise with you is the explanation, if any, for</p> <p>9 the length of time it took from the development</p> <p>10 of the hepatitis B vaccine and its use for</p> <p>11 at-risk groups to universal vaccination in the</p> <p>12 United Kingdom in 2017. I think you are perhaps</p> <p>13 more than happy to answer that.</p> <p>14 <b>PROFESSOR DILLON:</b> I've spent 20 years standing</p> <p>15 in European, African and Asian meetings being</p> <p>16 embarrassed by being apparently from a country</p> <p>17 too poor to spend the money on hepatitis B</p> <p>18 vaccination. I think the fact that there hasn't</p> <p>19 been universal vaccination for hepatitis B in</p> <p>20 the UK has been a disgrace. I'm delighted it</p> <p>21 has now happened but it took 20 years and</p> <p>22 I think it's, you know, poor practice.</p> <p>23 <b>PROFESSOR COOKE:</b> To the best of our understanding,</p> <p>24 that was based on what was perceived to be the</p> <p>25 cost benefit of doing that and that calculation</p>	<p style="text-align: right;">192</p> <p>1 has changed.</p> <p>2 <b>SIR BRIAN LANGSTAFF:</b> What was put on the benefits</p> <p>3 side, that's obvious. What was the cost?</p> <p>4 <b>PROFESSOR COOKE:</b> Simply the numbers of people that</p> <p>5 would need the vaccine on an annual basis and</p> <p>6 even a relatively cheap and effective vaccine,</p> <p>7 like hepatitis B, if you're vaccinating every</p> <p>8 infant, that's a significant cost to the Health</p> <p>9 Service that needs to be traded against other</p> <p>10 things that money could be spent on.</p> <p>11 <b>PROFESSOR DILLON:</b> They believed that the number of</p> <p>12 people that would contract hepatitis B, need</p> <p>13 chronic treatment or die from it didn't justify</p> <p>14 the cost of vaccination.</p> <p>15 <b>SIR BRIAN LANGSTAFF:</b> And the cost of treating them</p> <p>16 for those conditions wouldn't justify the cost</p> <p>17 of vaccination.</p> <p>18 <b>PROFESSOR DILLON:</b> According to their health</p> <p>19 economics.</p> <p>20 <b>MS RICHARDS:</b> I think the penultimate topic arising</p> <p>21 out of your report I wanted to ask you about</p> <p>22 before I move on to a range of questions</p> <p>23 suggested by core participants, it's just about</p> <p>24 infection control. This is dealt with in</p> <p>25 page 78 onwards of your report. As I understand</p>



193

1 your report, its standard precautions are what  
 2 you would apply to hepatitis C care. Could you  
 3 explain what those are and what's meant by  
 4 standard precautions?  
 5 **DR JEFFERY:** Yes, so standard precautions are what  
 6 we would expect in only healthcare setting to  
 7 protect all of our patients, healthcare users,  
 8 staff, from infection. Be that a respiratory  
 9 infection, MRSA, hepatitis C, the precaution is  
 10 the same, and there are a range of standard  
 11 practices that we expect every healthcare worker  
 12 to practice between all patients without making  
 13 any assumptions about an infection that  
 14 individual might have.  
 15 **MS RICHARDS:** So you would not expect there to be  
 16 any additional precautions specific to the  
 17 treatment and care of those with hepatitis C?  
 18 **DR JEFFERY:** There is one particular area where  
 19 there is a difference, and that is in -- within  
 20 renal dialysis units. And that is largely  
 21 historical and dates from experience with  
 22 hepatitis B when a number of both patients and  
 23 healthcare workers became infected with  
 24 hepatitis B in the renal dialysis setting. And  
 25 so there are different provisions within renal

195

1 HIV?  
 2 **DR JEFFERY:** None whatsoever.  
 3 **MS RICHARDS:** There is then, as I say, a handful of  
 4 discrete matters I wanted to ask you about.  
 5 The first is perhaps best addressed to  
 6 Dr Jamieson. We have heard from a number of  
 7 witnesses who relate going to see their GP over  
 8 the years, reporting symptoms similar to the  
 9 neurocognitive symptoms that have been  
 10 described, both by you orally and in the  
 11 report -- fatigue, difficulties in concentration  
 12 and the like -- not being tested for  
 13 hepatitis C, not being asked about whether  
 14 they'd received a transfusion for many years,  
 15 and that leading inevitably to delays in  
 16 diagnosis and delays in treatment.  
 17 Can I ask you to comment, obviously not on  
 18 any individual case but on that generally. What  
 19 would you expect a GP to do in those kind of  
 20 circumstances?  
 21 **DR JAMIESON:** The road to a diagnosis is sometimes  
 22 very straight and short. I described a case  
 23 earlier that we had recently looked at, which  
 24 is: a model, a standard, a gold standard,  
 25 supported by secondary care and primary care, to

194

1 dialysis for hepatitis B and hepatitis C.  
 2 Within that setting, hepatitis B is much more  
 3 infectious than hepatitis C. And so hepatitis C  
 4 patients are dialysed together, as a group, but  
 5 not in an isolated part of the unit, in most  
 6 units. Although individual dialysis units may  
 7 be able to offer an individual room, whatever  
 8 their local provision is.  
 9 So there is a difference just, I think, in  
 10 renal dialysis units, and there are some  
 11 differences that Professor Cooke actually wrote  
 12 about in the section on assisted reproduction.  
 13 **MS RICHARDS:** I'm just going to ask you, because  
 14 you're not here tomorrow, briefly to deal with  
 15 infection control within the context of HIV,  
 16 because I think you wrote that part of the  
 17 HIV report --  
 18 **DR JEFFERY:** I did, yes.  
 19 **MS RICHARDS:** -- but you won't be attending  
 20 tomorrow.  
 21 Are there any particularly significant  
 22 differences between the infection control  
 23 measures you would expect for hepatitis C,  
 24 which, as you've described, subject to certain  
 25 limited exceptions, are the standard ones and

196

1 make sure that you're lab testing, make sure  
 2 that the awareness, make sure that the  
 3 education, they're sitting at a level whereby  
 4 a minor raise in a blood test is automatically  
 5 cascading me to -- to check for hepatitis C and  
 6 B and HIV, and lots of other diagnoses which  
 7 could be possibly causing that, and a model  
 8 whereby I've got access to treatments which are  
 9 readily and speedily available. And I would say  
 10 that that model that I described, as it is now,  
 11 is a model that I would say has not been -- in  
 12 my career as a doctor, from where I started  
 13 training, you know, 18 years ago, has -- has --  
 14 has changed remarkably, and I would say even in  
 15 the past 18 to 24 months is really where we've  
 16 got to in -- in having that type of model.  
 17 The symptoms you described are very common,  
 18 and arriving at Plymouth at a train station when  
 19 you were standing at Exeter might have been an  
 20 obvious choice, but when you started off on that  
 21 train journey in Inverness with one symptom in  
 22 attending the GP, there was multiple places you  
 23 could have been going with that. In fact there  
 24 were an infinite number of places you could have  
 25 been going on that journey. And the symptoms

197

1 that we described, through -- you know, you've  
 2 reflected on some of those symptoms to actually  
 3 be the exact common side effects of treatments  
 4 that are mentioned for the same -- for the same  
 5 conditions. And so trying to navigate that as  
 6 a GP I find a challenge. That doesn't justify  
 7 it. I think when patients are attending and  
 8 re-attending, we have to ask ourselves is that  
 9 because of a diagnosis of depression, or  
 10 fibromyalgia or of many of the other causes of  
 11 similar symptoms.

12 With regards to the issue in particular you  
 13 raise of previous blood transfusions, I think  
 14 that's a really important one. I am aware, and  
 15 I've seen myself, as a member of the public, the  
 16 campaigns that have tried to raise that profile  
 17 of the importance of that history. Only the  
 18 people in the room will be able to say whether  
 19 they've also seen those and whether that  
 20 potentially led them to a diagnosis. I don't --  
 21 I don't know. And I find that we've -- in  
 22 medicine we have lots of where we think we've  
 23 done the right thing with regards to raising the  
 24 profile of something.

25 The most recent one publicly, I suppose, has

199

1 And so in medicine, to keep going back and  
 2 improving our systems to try to reiterate and  
 3 re-educate, and make it as easy as possible to  
 4 be doing the right things, the sterling work  
 5 that's been done in Scotland led by  
 6 Professor Dillon and the team to try to make  
 7 sure that this work, and the visibility of this  
 8 diagnosis is there, is -- I see hep C results in  
 9 my in-box on a daily basis, and that is because  
 10 I am looking for it. I want to eliminate it to  
 11 zero, I want to get patients offered these  
 12 treatments, and the only way that I can do so is  
 13 by the hard work that's been put in, to make  
 14 sure that it's visible to me, because I'm --  
 15 because of the work of a GP, 10,000 patient  
 16 contacts a year or so that I might have, trying  
 17 to make sure that that's at the forefront of my  
 18 mind, with all the other important diagnoses  
 19 that I cannot miss, the cancers, the rare  
 20 things, the common things, is very difficult.  
 21 So I'm sorry to talk for so long and try not to  
 22 give -- you know, I'm trying to give as specific  
 23 answer as I can to the question, but it's very  
 24 difficult, but it is a continual effort as  
 25 opposed to what -- is what I would highlight,

198

1 been the valproate issue in pregnancy, and we  
 2 have known for many years that valproate use in  
 3 pregnancy could have been teratogenic, it could  
 4 have harmed babies. It's only been in the past  
 5 two years that we've really got our act together  
 6 when we thought we were telling people the right  
 7 thing and the only way that we proved that we  
 8 weren't was we went to patients and the MHRA  
 9 asked the patients, "By the way did anybody ever  
 10 tell you that this wasn't anything to become  
 11 pregnant on?" And it wasn't, not by the  
 12 specialist, not by the box, nor by the -- the  
 13 summary of characteristics told them, and it  
 14 said that this was a risk, but the patients  
 15 didn't know when they were asked individually.

16 And so when we think we're doing the right  
 17 thing and following the right guidelines and  
 18 trying to articulate the right issues, it isn't  
 19 until we unpick it and actually check and go  
 20 back to ourselves, that we then improve that,  
 21 and now, I would -- I've done audits in my area  
 22 and there's not a single patient that doesn't  
 23 know that that's a possibility on that drug.  
 24 And yet for a long time we've known that that  
 25 was a possibility.

200

1 and it's a continual work to make sure -- we're  
 2 continually making little tweaks to our systems  
 3 about how we can make it easier to do the right  
 4 things.

5 **MS RICHARDS:** Is this fair: that every GP now at  
 6 least should know that those who received  
 7 a blood transfusion or blood products prior to  
 8 the relevant dates fall within a category of  
 9 people who are at risk for hepatitis C?

10 **DR JAMIESON:** Yeah. And these patients should have  
 11 been offered treatments. And the way that we've  
 12 done that, trying to look through our medical  
 13 record, which is incomplete sometimes and is not  
 14 going back -- we don't automatically have a flag  
 15 on your notes to say, you know, this person  
 16 during childbirth in 19-whatever received  
 17 a blood transfusion. That's not an obvious  
 18 thing when they're in consulting about something  
 19 else. For, you know, the public side of that  
 20 campaign was really important to try to  
 21 highlight that. That said, if somebody was  
 22 coming in and I noticed -- so, in -- in my  
 23 practice, when I have noticed a raise in that  
 24 blood test and I'm -- I do ask the question,  
 25 "Have you ever had a major operation? Have you

201

1 ever been in a" -- because there are these  
 2 situations where patients might not have  
 3 realised that they -- you know, they might have  
 4 had it and they might have been told about it,  
 5 but consenting for a blood transfusion when it  
 6 was an emergency is a very different thing and  
 7 they might not have -- so it's always about  
 8 all -- looking round that and trying to make  
 9 sure that we've discussed the wider  
 10 possibilities of trying to unpick that.

11 I think the modes that we've described to  
 12 try to pick up and detect hep C with regards to  
 13 the screening of the high risk groups, the --  
 14 the screening of the high risk groups and the  
 15 look-back exercises with regards to those that  
 16 have had it, but importantly it's the detection.  
 17 The way that we're going to get the elimination  
 18 to zero is the detection of those cases where  
 19 they might not have known or might have been  
 20 horizontal transmission within a household  
 21 setting. Those are the cases that -- that now  
 22 I'm kind of relatively content as a GP that I'm  
 23 hopeful that I know that all my patients that  
 24 are -- I hope -- at higher risk should be  
 25 getting picked out. They should -- what I'm now

203

1 on that?

2 **PROFESSOR DILLON:** So doctors are taught to ask all  
 3 of those questions, including the blood  
 4 transfusion question and so, you know, all of  
 5 those risk factors for a hepatitis or a blood  
 6 born virus should be asked and I know some  
 7 people regard them as stigmatising and why would  
 8 they ask me that question? But if we normalise  
 9 the asking of the question and ask everybody, we  
 10 can then get on to getting people tested and  
 11 move forward with it. So I make no apologies  
 12 for asking everybody those questions, including  
 13 the blood transfusion question and the blood  
 14 product question.

15 That's the way we will find everybody that  
 16 needs to be found, and if that damages -- or  
 17 upsets some people's sensibilities, be reassured  
 18 that it's not happening to you alone, it's  
 19 happening to everybody, and if someone you know  
 20 hasn't been asked that question, it's because  
 21 the doctor they were seeing wasn't doing their  
 22 job properly.

23 **MS RICHARDS:** Does it depend in part upon how the  
 24 question is asked?

25 **PROFESSOR DILLON:** Exactly, there is always a way --

202

1 trying to look forward at is how am I going to  
 2 find that other group that are underneath that,  
 3 that are not pinging on everybody's radar, that  
 4 might have misused drugs in the eighties and  
 5 don't do so now? And that's -- you know, those  
 6 are the other groups we're looking at. So it's  
 7 very much trying to always improve ... yeah.

8 **MS RICHARDS:** Following on from the question, and  
 9 this is -- covers secondary care as well as  
 10 primary care -- following on from the question  
 11 I've just asked and your answer, again a number  
 12 of witnesses have described that whilst they're  
 13 not asked the question about blood transfusion,  
 14 they are asked the question, in circumstances  
 15 that might objectively seem entirely  
 16 inappropriate to their personal circumstances,  
 17 about drug use, being a sex worker, having  
 18 tattoos, having piercings, abusing alcohol. And  
 19 many have related that being the thrust of what  
 20 they are questioned about, not simply, as I say,  
 21 by GPs, but in hospitals as well, and the focus  
 22 being on that rather than looking to see whether  
 23 there is something in their history that may be  
 24 a more obvious explanation.

25 Does any of the panel have any observations

204

1 ways and means of asking those sorts of  
 2 questions, but they should be asked.

3 **DR MARSHALL:** It's very simple to say that when  
 4 you're meeting someone with the first time,  
 5 "I need to ask you some routine questions that  
 6 we ask to all patients coming here", and then go  
 7 ahead and ask them. That I --

8 **DR JAMIESON:** That's the phrasing I use as well when  
 9 I'm doing the tests themselves. I say "It will  
 10 be my routine practice -- you have a raised --  
 11 it is my routine practice to always check for  
 12 these other causes, to make you aware. Is that  
 13 okay?"

14 "Oh absolutely, doctor." I think if we're  
 15 normalising these types of conversations that  
 16 it's not stigmatising. Patients at the moment,  
 17 I don't have push-back from that, and the same  
 18 with sexual health screening. It's the exact  
 19 same thing. It's my routine practice. You  
 20 know, you've asked for a sexual health screen  
 21 today. It's also my routine practice: is it  
 22 okay if we check you for syphilis and HIV with  
 23 this? Would you be at risk of hepatitis? Only  
 24 by having it as routine course do you ever find  
 25 all the cases.

205

1 **MS RICHARDS:** There's then a number of specific  
 2 questions I've been asked by core participants  
 3 to ask. They won't necessarily follow  
 4 a particular sequence --

5 **SIR BRIAN LANGSTAFF:** Just before we go there, can  
 6 I ask one further question. It really arises  
 7 out of a comment which I think Professor Dillon  
 8 made earlier about the advice which a GP might  
 9 give these days to someone who has hepatitis;  
 10 that was you hope he would have access, online  
 11 access, to details, information. I was just  
 12 wondering (really, for you to deal with  
 13 principally, Dr Jamieson) how far that -- that  
 14 implies that the average GP will not know enough  
 15 from his usual practice to be able to deal with  
 16 that, and that may say something about the level  
 17 of hepatitis that doctor comes across or, for  
 18 that matter, the level he's looking for.

19 Is there, in your experience -- and I think  
 20 you may have to exclude Tayside from this -- but  
 21 is there in your general experience of talking  
 22 to other GPs, a lack of information about  
 23 diseases such as hepatitis?

24 **DR JAMIESON:** I think that is there standardised  
 25 information? I would say across the country I'm

207

1 patient for the first time to deliver the  
 2 knowledge that it is a positive test. If the GP  
 3 hasn't got the information readily available in  
 4 the back of his mind or her mind but has to go  
 5 online, that takes time.

6 **DR JAMIESON:** It takes time.

7 **SIR BRIAN LANGSTAFF:** But is there time in the usual  
 8 GP practice to deal with that, to prepare in  
 9 advance rather than say something and then try  
 10 and catch up later?

11 **DR JAMIESON:** No is the short answer. I would say  
 12 that I would hope that I would know in advance  
 13 why the patient was coming in and what we were  
 14 going to be discussing. With regards to the  
 15 time, the UK is amongst the shortest GP  
 16 consultation lengths in any developed country in  
 17 the world. 9.2 minutes is the average GP  
 18 consultation in the UK versus 23 minutes,  
 19 I think, in Sweden. So we do have amongst the  
 20 shortest amount of time.

21 Therefore, within that, I would say that in  
 22 an increasingly complex multi-morbid -- and  
 23 especially if we're talking about something  
 24 that's an unexpected diagnosis (such as  
 25 hepatitis may be for somebody that had

206

1 not aware that there is for general practice on  
 2 things that you could automatically turn to for  
 3 patients. I know the RCGP (for which I would  
 4 obviously declare that I'm a member), they have  
 5 done work in their liver toolkit which tries to  
 6 support a breadth of resources that we could  
 7 turn to. So I would say that that's probably  
 8 the closest you could get to a universal source  
 9 that you could turn to to try to signpost you to  
 10 areas where you could, if you wanted to improve  
 11 your knowledge and education, look at  
 12 specifically. If you wanted to find resources  
 13 to signpost patients to, that could also be  
 14 within there. Beyond that, patient information  
 15 leaflets then are integrated within the GP  
 16 system. There are ways to access those and most  
 17 GP systems have direct access into patient  
 18 information in printable format.

19 Beyond that, it's local.

20 **SIR BRIAN LANGSTAFF:** May I just ask, leading on  
 21 from that, presumably the problem of  
 22 transmitting information arises when you have,  
 23 as a GP, a test which is positive.

24 **DR JAMIESON:** Mm-hm.

25 **SIR BRIAN LANGSTAFF:** And you have to see that

208

1 a transfusion, you know, many years before),  
 2 I personally, you know, would shape my day and  
 3 my appointments around affording the opportunity  
 4 to make sure that we could have a proper  
 5 discussion about that. That obviously makes the  
 6 assumption that we've known in advance that's  
 7 what we were going to do.

8 Often now, as I've alluded to, we're trying  
 9 to find the cases where it might be unexpected  
 10 and therefore that that might not be. But if  
 11 that means I run late, well, that means I run  
 12 late.

13 So the resources are there. Trying to  
 14 immediately know where to bring them in,  
 15 I think, is the other challenge. As I alluded  
 16 to before, I know that they won't remember  
 17 a huge amount but I know that very quickly  
 18 they'll have a lot of questions and therefore  
 19 making sure that the processes for follow-up,  
 20 and often I will often say, "You will  
 21 immediately have quite a lot of questions. Come  
 22 back to me and, you know, we will instantly then  
 23 pick up where we've left when you've got  
 24 yourself to that point."

25 I'm fortunate in that, from where we work,

209

1 I work really hard to make sure that access to  
 2 GPs is timely, and that is hard, and I know in  
 3 all areas it's not as easy access as it could  
 4 be, and that's with lack of GP numbers. But we  
 5 work hard to make sure that you can get back in,  
 6 especially for these types of issues when it's  
 7 an important diagnosis, because often that  
 8 conversation might just be -- it might only take  
 9 the ten minutes to just explain what the initial  
 10 points are, but very quickly, in an  
 11 IT-accessible world, when the patient is walking  
 12 out the door and possibly already has access to  
 13 their phone in front of them to start to look  
 14 into these things, I must help and make sure  
 15 that I've appropriately signposted to resources  
 16 such as those we've referenced to make sure that  
 17 patients can start to look at things which have  
 18 some authority behind them to start to answer  
 19 some of their questions.

20 **SIR BRIAN LANGSTAFF:** Dr Jeffery, you were going to  
 21 add something.

22 **DR JEFFERY:** Yes, just as a couple of comments. So  
 23 in my role as a consultant microbiologist,  
 24 I mean, I'm dealing, as we've already heard,  
 25 with the diagnosis of hepatitis B and

211

1 **MS RICHARDS:** First of all, a couple of follow-up  
 2 questions relating to ongoing screening  
 3 post-SVR.

4 Picking up on something that was said by one  
 5 member of the panel earlier, when patients are  
 6 being regularly screened, their cancer may not  
 7 be picked up until a later stage. And the  
 8 question that I have been asked to raise with  
 9 you is: are there any investigations not  
 10 routinely used which might assist in earlier  
 11 detection, or would more regular screening make  
 12 a difference?

13 **DR MARSHALL:** There's research that shows more  
 14 frequent screening does not make a difference  
 15 and that six months seems to be the optimum  
 16 interval.

17 The reason why some cancers may not be  
 18 picked up relates to the concept of sensitivity  
 19 and specificity that we've heard before.  
 20 Ultrasound is the most commonly used type of  
 21 test, but if you look back -- think back to the  
 22 picture that I showed of the nodules, what we're  
 23 looking for is a nodule among nodules on  
 24 ultrasound, and that's why it can be very  
 25 difficult to detect.

210

1 hepatitis C all the time, but I think the  
 2 important thing to remember is that for any  
 3 individual GP, they may actually not have any  
 4 patients on their books, as it were, with  
 5 hepatitis B and hepatitis C. And something  
 6 that I personally do a lot of -- because GPs are  
 7 a sensible bunch, if they're faced with  
 8 something where they don't know exactly what  
 9 they should be telling the patient, they will  
 10 call for advice, and we do quite a lot of  
 11 signposting to GPs taking them through the  
 12 important things to talk about. But also,  
 13 signposting them to written advice, and often  
 14 physical pieces of paper as well as online  
 15 stuff, because patients don't remember what  
 16 they've heard in that initial discussion.

17 So Scott's got a lot of experience and  
 18 a relatively large cohort, I presume, of  
 19 patients, but there will be GPs who don't have  
 20 any patients with a blood-borne virus diagnosis  
 21 at all, and there are hopefully systems to  
 22 support those GPs to support their patients.  
 23 But providing signposts to good online advice is  
 24 really important, and good written advice.

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

212

1 There are other tests, such as CT or MRI,  
 2 which are -- there's no evidence to support  
 3 their use in screening or surveillance at the  
 4 moment. But it is very much a conversation with  
 5 the patient and about your level of suspicion.  
 6 So if you find something that the ultrasound  
 7 can't say clearly one way or the other whether  
 8 there is a problem, one of those situations  
 9 where it might be where the person doing the  
 10 ultrasound reports that they did not get  
 11 adequate views of the liver, then you would have  
 12 a relatively low threshold for doing a different  
 13 type of test. But even with MRI and CT, they  
 14 are not 100 per cent sensitive or specific at  
 15 picking up things. And it's simply because the  
 16 nodules of cancer can look very similar to  
 17 cirrhotic nodules on any test.

18 **MS RICHARDS:** And you've referred to ultrasound  
 19 scans. I've been asked to ask about fibroscans  
 20 and their use.

21 **DR MARSHALL:** This is one of the things that we want  
 22 to talk about because we didn't cover it in the  
 23 report.

24 So a fibroscan is one of the measures of  
 25 assessing liver fibrosis without the need for

213

1 a biopsy, which Professor Dillon alluded to when  
 2 he talked about imaging tests and blood tests to  
 3 look for fibrosis.  
 4 Now, a fibroscan is just one of a number of  
 5 techniques that can be used, and it's  
 6 a measurement of the liver stiffness using  
 7 soundwaves to interrogate the characteristics of  
 8 the liver. So that's the role of fibroscans.  
 9 And in the past, biopsies were used to try  
 10 to determine how much scarring was present, but  
 11 because it is associated with a risk and it may  
 12 be painful or uncomfortable for the patient,  
 13 tests such as fibroscan or other blood tests  
 14 have now superseded the use of biopsy. And so  
 15 all patients with various types of liver disease  
 16 might be offered one of these tests to help  
 17 establish where they are on that route.  
 18 **MS RICHARDS:** Do fibroscans play any part in the  
 19 screening process and monitoring process  
 20 post-SVR?  
 21 **PROFESSOR COOKE:** That's correct. And it's worth  
 22 making the point that access to fibroscan  
 23 testing is still relatively limited in some  
 24 parts of the country. It's improved quite a lot  
 25 over recent years but it's clearly a tool that's

215

1 **PROFESSOR DILLON:** Six months.  
 2 **MS RICHARDS:** The next question on my list,  
 3 hepatitis C and damage to other organs: what  
 4 other organs, in particular the kidney, may be  
 5 susceptible to damage in consequence of  
 6 hepatitis C or treatment for hepatitis C?  
 7 **PROFESSOR DILLON:** So the liver is the primary organ  
 8 of damage. The brain can be affected by  
 9 hepatitis C. The kidneys not directly affected  
 10 by hepatitis C but can be damaged because of the  
 11 formation of cryoglobulins which cause this  
 12 immune-mediated disease. And then in the report  
 13 we've listed the other associations with  
 14 hepatitis C.  
 15 **MS RICHARDS:** This is perhaps a question for  
 16 Dr Jamieson but it may be for others. At what  
 17 level of adverse liver function would a GP be  
 18 expected to take action to then move to the  
 19 question of diagnostic tests for hepatitis B  
 20 or C if the person is not otherwise showing  
 21 symptoms or is not otherwise in a high risk  
 22 group?  
 23 **DR JAMIESON:** I think that then depends why you're  
 24 doing the test.  
 25 So we do liver function testing for a vast

214

1 very beneficial for patients, it avoids  
 2 biopsies, which we've discussed are challenging,  
 3 and it allows them a closer monitoring, often,  
 4 on someone's liver condition. So there has been  
 5 some investment but it's been a bit patchy and  
 6 I think still some centres struggle to offer  
 7 that outside of the specialist centre. It's  
 8 different in different countries but it's an  
 9 area where I think there can still be some room  
 10 for improvement.  
 11 **MS RICHARDS:** Then I'll asked whether a fatty liver  
 12 is a symptom of HCV or a side effect of  
 13 interferon? Or neither?  
 14 **PROFESSOR DILLON:** Neither. Neither and both.  
 15 Fatty liver is a common descriptor, fatty  
 16 liver is very common. About 40% of the  
 17 population have fatty liver. And it simply  
 18 describes there is fat in the liver. And that  
 19 can occur in hepatitis C. It's more common with  
 20 genotype 3. But interferon therapy doesn't  
 21 particularly cause it, or make it any worse than  
 22 it was before.  
 23 **MS RICHARDS:** Natural clearance, spontaneous  
 24 clearance. Is there a timescale within which  
 25 that will typically occur, and if so what is it?

216

1 majority of varied -- wide varied reasons, most  
 2 commonly I will get liver function test results  
 3 potentially from monitoring certain medications  
 4 which I know will slightly increase liver  
 5 function abnormality. We might be using it in  
 6 patients who have other lifestyle -- diabetes,  
 7 cardiovascular disease, which is causing a raise  
 8 in liver function and we're monitoring that. It  
 9 might then be -- you've mentioned that -- with  
 10 the exception of the symptomatic patients,  
 11 I suspect that's the area actually to focus on.  
 12 That's the threshold where just now we think we  
 13 need to improve, where the evidence, as we  
 14 alluded to in our expert report, is changing,  
 15 where we suspect that our tolerance is for that  
 16 higher end. And remember these normal ranges,  
 17 how they're created, I'm not a clinical  
 18 scientist but I absolutely see blood tests that  
 19 are commonly at the higher ends of what was  
 20 reported as the normal range, but the normal  
 21 range is only covering a majority of the  
 22 population and not all the population.  
 23 Therefore, what we are now revising is  
 24 actually that this normal range possibly was too  
 25 generous in accepting some of the upper ranges

217

1 of that abnormality, because it was missing in  
 2 cases of abnormalities which would go on to  
 3 cause disease, and therefore we've brought that  
 4 threshold down.  
 5 One of the lessons that we've had to work  
 6 hard on in primary care in my area is explaining  
 7 to GPs that their tolerance of that higher end  
 8 of liver function is now cascading,  
 9 investigation and testing for hepatitis and HIV,  
 10 where they might have felt that previously they  
 11 might have tolerated that level within normal  
 12 ranges. In fact, on the lab report you get  
 13 through, it might still say that it is normal.  
 14 I suspect in the coming four or five years --  
 15 and I look to Professor and I'm sure he can  
 16 correct me and maybe give me an update as he  
 17 likes to -- that actually I don't know whether  
 18 we'll be reporting those as normal for very much  
 19 longer. I think that will start to change more  
 20 and more as our acknowledgment and acceptance of  
 21 that -- it's very hard to put a specific number  
 22 on it. It depends why you were doing the test  
 23 in the first place. But it's changing and  
 24 evolving. It's an area where we have improved,  
 25 and continue to improve.

219

1 known to be associated with infection with  
 2 hepatitis or its treatment?  
 3 **PROFESSOR DILLON:** Venous malformations are usually  
 4 congenital. Some of them can be acquired later  
 5 in life and grow as small atrial venous  
 6 malformations and fistulas. They are normally  
 7 considered congenital and there is no good  
 8 evidence of association with them. They are  
 9 very common in the liver and they are commonly  
 10 detected in the liver when people are found to  
 11 have hepatitis C because they have an  
 12 ultrasound.  
 13 **MS RICHARDS:** If low platelet count is a significant  
 14 problem in the context of advanced liver  
 15 disease, what is the significance of clotting  
 16 factor deficiencies in that context?  
 17 **PROFESSOR DILLON:** Clotting factors are produced by  
 18 the liver. Platelets are produced by the bone  
 19 marrow. The two of them working together causes  
 20 us to clot and stop us bleeding when we bleed.  
 21 If you have both low platelets and low clotting  
 22 factors you are more likely to bleed, and in the  
 23 context --  
 24 **PROFESSOR COOKE:** In the setting of advanced liver  
 25 failure, then often the clotting factors are

218

1 **PROFESSOR DILLON:** An abnormal liver test should  
 2 have an explanation, and that should trigger  
 3 a series of investigations of which hepatitis  
 4 screening is one of them, to see if that's the  
 5 cause of it.  
 6 **MS RICHARDS:** To what extent is jaundice an accurate  
 7 marker of hepatitis B or C infection?  
 8 **PROFESSOR DILLON:** Jaundice is the excess presence  
 9 of bilirubin in the liver (which we've talked  
 10 about earlier) and is the byproduct that's  
 11 produced by the liver and is excreted. So that  
 12 yellow colour is a sign of the liver not working  
 13 properly.  
 14 At an acute phase with hepatitis B or  
 15 hepatitis C, we can have jaundice as we talked  
 16 about earlier on, but it's not specific to those  
 17 two things. In the chronic end stage phases of  
 18 hepatitis B or C, you can become jaundiced  
 19 because the liver is failing, but it's a sign of  
 20 liver failure not necessarily a sign of  
 21 hepatitis B or C.  
 22 **MS RICHARDS:** Then, again this is a question I think  
 23 that's been specifically raised with one of the  
 24 recognised legal representatives by individuals  
 25 here, are venous malformations around the body

220

1 part of the supportive therapy that may be given  
 2 to the patient.  
 3 **MS RICHARDS:** When did it become known that  
 4 hepatitis B was sexually transmissible? I don't  
 5 know whether you have that information.  
 6 **PROFESSOR COOKE:** I think probably if you want  
 7 a precise answer we'd probably have to go away  
 8 and find one.  
 9 **PROFESSOR DILLON:** But it was certainly in the  
 10 textbooks by the 1980s at medical school and if  
 11 it was in the textbooks, they weren't new.  
 12 **MS RICHARDS:** I'm going to ask a question which  
 13 I think I've already partly asked, but there's  
 14 a second part to it, to which you may well not  
 15 be able to give the answer but the fact you  
 16 can't is relevant for us to know.  
 17 What is known now about the prevalence of  
 18 hepatitis B and hepatitis C infection: (a) in  
 19 the UK population as a whole; and then (b)  
 20 specifically in the UK blood donor population  
 21 since 1970?  
 22 **PROFESSOR DILLON:** I can give you figures for  
 23 Scotland. I'm not sure if you can reciprocate  
 24 for England.  
 25 **PROFESSOR COOKE:** I can try.

<p style="text-align: right;">221</p> <p>1 <b>PROFESSOR DILLON:</b> The hepatitis C prevalence in  2 Scotland is now around 20,000 people, probably  3 18,000, and we still have provisional figures  4 that the figure may have fallen to 16,000, but  5 those figures are still being internally worked  6 on and haven't been validated yet. That's the  7 impact of treatment and death as we talked about  8 before.</p> <p>9 Hepatitis B is very rare. Hepatitis B in  10 terms of active hepatitis B infection is about  11 ten times less common in Scotland than that, and  12 we are working on those figures at the moment,  13 and I don't have accurate figures for that --  14 but at least ten times less common.</p> <p>15 <b>MS RICHARDS:</b> The second part of the question was  16 prevalence in the UK blood donor population  17 since 1970 which I don't know whether you would  18 be able to answer?</p> <p>19 <b>PROFESSOR DILLON:</b> So from 1991 onwards clearly  20 anyone who is found positive is removed from the  21 blood donor pool. So "prevalence" isn't exactly  22 the right term because they would instantly be  23 removed and so the prevalence is zero because  24 there's no -- but if you want to talk about the  25 positivity detection rate of someone who is</p>	<p style="text-align: right;">222</p> <p>1 presenting to donate blood and is found to be  2 positive, it's less than one in a thousand at  3 the moment, and clearly that donation is not  4 used.</p> <p>5 <b>MS RICHARDS:</b> Professor Cooke?</p> <p>6 <b>PROFESSOR COOKE:</b> Yes, I mean, I think there's  7 similar estimates of hepatitis B prevalence in  8 England and obviously, as we've discussed  9 earlier, the numbers of patients with active  10 hepatitis C are falling, rapidly. NHS England  11 started by treating approximately 10,000  12 patients a year since 2015, which has been  13 successful and carried on with numbers  14 increasing in recent years. So tens of  15 thousands of patients have been treated in the  16 last three or four years and we think there are  17 still tens of thousands of patients left to  18 treat, but one of the becoming questions that we  19 are all grappling with is really to understand  20 how we work out exactly how many patients are  21 left to treat and where they are.</p> <p>22 That's a challenge, and I think for example  23 we saw the data on the numbers of tests being  24 done, but often we don't link up the numbers of  25 the tests to individuals, and many individuals</p>
<p style="text-align: right;">223</p> <p>1 have more than one test that can distort the  2 numbers we see, so we're trying to learn at the  3 moment as we go as to how many are left. In  4 certain key groups we have a clear  5 understanding, but as a population without  6 testing a population, it's hard to know.</p> <p>7 <b>MS RICHARDS:</b> Then the next question I have arises  8 out of some evidence you gave this morning,  9 Professor Cooke about genotypes and you said it  10 was unusual to be exposed to more than one  11 genotype of hepatitis C at once, words to that  12 effect.</p> <p>13 <b>PROFESSOR COOKE:</b> So I think to clarify that, I'm  14 talking in general terms rather than when  15 exposed to blood products and so clearly within  16 pooled blood products there's a greater chance  17 of pooling different genotypes from different  18 donors, and that can be the case that you could  19 be exposed to more than one genotype at once.</p> <p>20 <b>MS RICHARDS:</b> You anticipated the question and given  21 the answer, thank you.</p> <p>22 There's a reference in your report to occult  23 hepatitis and I'm asked to ask you what that is.</p> <p>24 <b>DR JEFFERY:</b> So occult hepatitis B is an unusual  25 scenario. We talked about the marker for</p>	<p style="text-align: right;">224</p> <p>1 hepatitis B infection being the presence of  2 hepatitis B surface antigen, and occult  3 hepatitis B is a situation where you don't have  4 surface antigen that's detectable by standard  5 tests but you have evidence of other hepatitis B  6 antibodies, in particular an antibody to the  7 hepatitis B core protein, and you have usually  8 very low level hepatitis B DNA which is  9 detectable. That is -- means that you have  10 viral -- hepatitis B infection and you are  11 potentially infectious, but quite difficult to  12 pick up.</p> <p>13 In general the level of hepatitis B DNA in  14 those individuals is very low, and they probably  15 did have a much more easily diagnosable  16 hepatitis B in the past, and this is a measure  17 of sort of incomplete clearance.</p> <p>18 <b>PROFESSOR COOKE:</b> It's worth saying it's relatively  19 uncommon but it is critically important if  20 you're screening products. You won't detect  21 occult hepatitis B unless you do a direct test  22 for the virus, which is usually a PCR. So tests  23 based on testing for antibody may not detect it.</p> <p>24 <b>DR JEFFERY:</b> But it would be picked up by the  25 processes of screening blood donation because</p>



225

1 they do do those direct tests.

2 **MS RICHARDS:** Then if someone with a bleeding

3 disorder has had repeated exposure to a viral

4 load through multiple treatments with factor

5 concentrates, does this have an increased early

6 effect, does it affect the speed of progression

7 of severity because of the haemophiliac's

8 baseline status? I don't know whether that's

9 a question you can answer or whether that's

10 something I would need to direct to the group on

11 Friday.

12 **PROFESSOR DILLON:** In terms of the evidence that we

13 have, there doesn't seem to be an increased

14 effect, that while -- so in terms of the

15 outcomes, compared to people who have acquired

16 the virus in other ways and have a single

17 infection, the outcomes appear to be similar,

18 and it's the difference of effective genotypes,

19 et cetera.

20 In terms of treatment outcomes once those

21 patients are treated, they appear to get the

22 same benefit. So there doesn't seem to be

23 a large effect but it's a difficult area to

24 gather evidence in because we don't have

25 evidence about how many viruses you have been

227

1 be in the need for blood products and hence the

2 quantity of exposure which might affect the

3 amount -- the risk of getting infected and the

4 amount of infection, but in terms of progression

5 at that point, I don't think there's evidence to

6 suggest that's the case.

7 **MS RICHARDS:** Then -- final question then, to some

8 extent we've touched on this, but it's an

9 important matter, so it's -- perhaps airing it

10 again: does a delay in diagnosis of the order of

11 20 to 30 years have any effect on the

12 usefulness, type of, and success of treatment

13 for hepatitis C and if so what effect?

14 **PROFESSOR DILLON:** So, yes, I think is the important

15 answer. Getting diagnosed early. I know

16 clearly getting diagnosed early now when we have

17 the correct treatments available is absolutely

18 vital. Getting diagnosed 20 or 30 years ago

19 would have enabled you to participate in the

20 conversations about interferon and ribavirin,

21 which cured many people, particularly those

22 people who had signs of progression of disease.

23 I think an early diagnosis of hepatitis is very,

24 very important.

25 **PROFESSOR COOKE:** One thing we didn't draw out

226

1 infected with. But if you've got a hepatitis C

2 infection and you already have 60 -- 80 million

3 copies of the virus per ml of your blood, having

4 a few other mls of infectious viruses coming in

5 is dwarfed by what you've already got and what

6 you're already manufacturing, so I think that's

7 another way of looking at it.

8 **MS RICHARDS:** Then, is someone with haemophilia more

9 likely to have a reduced level of resistance to

10 hepatitis C due to a depressed immune system

11 arising out of repeated treatment with blood

12 products?

13 **PROFESSOR DILLON:** There is no clear evidence of an

14 effect. Clearly, the chances -- we know the

15 chances of someone becoming infected must be

16 increased because they are recurrently infected,

17 but that's not an experiment that we would ever

18 want to do or be allowed to do in terms of

19 working that out. But there's no clear-cut

20 evidence one way or the other.

21 **MS RICHARDS:** This may be a question for Friday's

22 group but does the severity of the haemophilia

23 have any relationship with the progression or

24 severity of hepatitis?

25 **PROFESSOR COOKE:** I think the only association would

228

1 earlier which is helpful is that interferon, the

2 success rate of interferon is also affected by

3 the stage of liver disease, so we tended to see

4 less good cure rates with more advanced liver

5 disease, so that delay in diagnosis can not only

6 lead to the consequences of infection, but

7 certainly before the DAAs came along it could

8 also reduce your chance of then curing if you

9 were treated.

10 **MS RICHARDS:** Then this is the very final question.

11 Some people have described clearing hepatitis on

12 their second or third attempt at treatment with

13 interferon. Is there any reason why that is the

14 case, why it worked after two attempts but

15 didn't work the first or second time? And is it

16 possible that they might have in fact been

17 cleared of a one genotype but been left with

18 another?

19 **PROFESSOR DILLON:** So there is certainly some

20 evidence of, for instance, clearing genotype 3,

21 and then having genotype 1 emerge having --

22 because we used less treatment for genotype 3,

23 in the early days. It's possible that sometimes

24 people didn't tolerate the interferon as well

25 the first time, couldn't take as much of it, and

229

1 stopped therapy early. And therefore had  
 2 a second treatment. So there are multiple  
 3 reasons for why people would end up with three  
 4 treatments of interferon. Clearly, we had the  
 5 interferon before it became pegylated,  
 6 interferon before it became partnered with  
 7 ribavirin, and we then had interferon before it  
 8 became partnered with sofosbuvir and the  
 9 protease inhibitors. So many of the people who  
 10 endured three treatments of interferon started  
 11 with native interferon then had pegylated  
 12 interferon and then had pegylated interferon  
 13 plus the DAA in 2013, 2014, before the pure DAA  
 14 therapies came online.  
 15 **PROFESSOR COOKE:** This doesn't quite answer your  
 16 question but really only very late in the  
 17 interferon era did we understand quite  
 18 significant genetic differences between  
 19 individuals and how they respond to interferon,  
 20 and we now understand that very well, although  
 21 we're not using the drug so much these days, and  
 22 there clearly are some well understood genetic  
 23 types that affect very much how well that  
 24 interferon will work.  
 25 **MS RICHARDS:** Are there any other matters arising

231

1 [Laughter]  
 2 The first couple are really around the  
 3 question of transmission. I think we will hear  
 4 on tomorrow, and perhaps on Friday, but  
 5 certainly tomorrow, that so far as HIV is  
 6 concerned, U equals U. That is, undetectable  
 7 equals untransmissible.  
 8 When hepatitis B has been treated and is  
 9 undergoing treatment because it's -- effectively  
 10 the viral load has been reduced but it's still  
 11 there, does the same apply to hepatitis B?  
 12 **PROFESSOR DILLON:** So transmission -- if there is  
 13 still virus, a detectable virus in the serum  
 14 it's still transmissible. The risk of  
 15 transmission is related to the load, so the  
 16 higher the load, the more likely the virus is to  
 17 be transmitted. Most of the drugs will  
 18 eventually bring hepatitis B down to  
 19 undetectable levels and therefore  
 20 untransmissible.  
 21 **SIR BRIAN LANGSTAFF:** So someone receiving treatment  
 22 should be an undetectable level?  
 23 **PROFESSOR DILLON:** Yes.  
 24 **SIR BRIAN LANGSTAFF:** And that will be  
 25 untransmissible?

230

1 out of your report or indeed any of the  
 2 questions you have been asked that we haven't  
 3 addressed, that you think would be important to  
 4 address?  
 5 **PROFESSOR COOKE:** I think we all feel -- well, first  
 6 of all we're very grateful for the invitation to  
 7 come, and thank you for that, and we're very  
 8 grateful to be able to support the Inquiry in  
 9 its important work. I think if there's one  
 10 thing we would all like to see, it's that if  
 11 anybody does not yet have the ability to engage  
 12 with care and feels they still don't trust  
 13 services, that they revisit that in whatever way  
 14 that they can to try to engage with the many  
 15 possible pathways into care, particularly given  
 16 the advances that we've outlined that little bit  
 17 today and what's achievable, I think, with  
 18 treatment.  
 19 **MS RICHARDS:** Sir, I'm just going to turn my back  
 20 and see if there are any other particularly  
 21 pressing matters.  
 22 And I'm happy to say that no one is putting  
 23 their head above the parapet.  
 24 **SIR BRIAN LANGSTAFF:** Unfortunately I've got  
 25 a couple of questions.

232

1 **PROFESSOR DILLON:** Yes.  
 2 **PROFESSOR COOKE:** But we don't have quite the level  
 3 of evidence that we have for HIV in terms of the  
 4 study, so there's been some quite big randomised  
 5 trials in high-risk groups and HIV patients that  
 6 have established that very clearly  
 7 prospectively.  
 8 **PROFESSOR DILLON:** But the cut-off risk for  
 9 healthcare workers, for instance, who are  
 10 hepatitis B positive, their -- the level for  
 11 them allowed to undertake exposure-prone  
 12 procedures has been clearly defined and so  
 13 that's the level at which the Government  
 14 perceives there is no risk of transmission.  
 15 **SIR BRIAN LANGSTAFF:** You've told us that  
 16 hepatitis C is transmissible by blood, and in  
 17 practical terms only by blood. When a number of  
 18 those who have given evidence went to see their  
 19 GPs, they were told, and I think they still  
 20 would be told, not to share toothbrushes, not to  
 21 share razors, and presumably to have -- to use  
 22 protection for most sexual acts. Is the level,  
 23 so far as one can -- anyone can ever gauge it,  
 24 of transmission by razors or toothbrush sharing  
 25 or similar, the blood which isn't cleared up,

233

1 and someone with a cut -- a cut finger touches  
 2 it, something of that sort, is that of the same  
 3 sort of level, one in 190,000 cases,  
 4 transmission or does one simply not know?  
 5 **PROFESSOR DILLON:** I think it's one of those areas  
 6 that we have an absence of evidence, partly  
 7 because doing -- doing the trial to try to work  
 8 that out would be very difficult, to give you  
 9 a precise figure, and doing the experiment would  
 10 be highly unethical. And trying to capture the  
 11 data as to what the risk factor was for  
 12 someone's hepatitis C within the cohorts of  
 13 people that you could study are difficult as  
 14 well. So I think it's more theoretical, you  
 15 know, if the razor or the toothbrush is  
 16 contaminated with blood and was then used, it  
 17 could theoretically transmit the virus but the  
 18 rate would probably be infinitesimally small but  
 19 it would be a risk potentially.  
 20 **SIR BRIAN LANGSTAFF:** Presumably the rate of one in  
 21 190,000 will -- well, for acts of sexual  
 22 transmission, will be no -- it will be no higher  
 23 than that for the other forms of transmission,  
 24 because one assumes that some of the sexual  
 25 transmission would be the sort that might occur

235

1 possibilities that they might be transmitting or  
 2 have transmitted to people close to them through  
 3 one of these routes.  
 4 **PROFESSOR DILLON:** I think to -- to help reassure  
 5 that point, the early estimates of sexual  
 6 transmission were taken from the reports on  
 7 blood cards that people had filled in, and often  
 8 people were happy to disclose a sexual partner  
 9 as the risk factor of having acquired the  
 10 infection rather than another -- another risk,  
 11 and that may have pushed the apparent risk of  
 12 sexual transmission for hepatitis C much higher  
 13 than it really is, because people had other  
 14 risks that they were too stigmatised to  
 15 disclose.  
 16 **SIR BRIAN LANGSTAFF:** I see. I was at one stage  
 17 going to ask you, Professor Dillon, to tell us  
 18 more about the Tayside attack on hepatitis but  
 19 now is not the time. Now is the time to thank  
 20 you, and thank you collectively, for what has  
 21 been a most informative and authoritative day  
 22 telling us about hepatitis C. And can I thank  
 23 you, secondly, individually and collectively,  
 24 for taking the time and effort to come here.  
 25 You may have thanked us for the opportunity, but

234

1 when the participants don't bring an overnight  
 2 bag and a toothbrush.  
 3 (Laughter)  
 4 **PROFESSOR DILLON:** So I think the sexual  
 5 transmission data probably needs a few caveats.  
 6 So the frequency of sex was self-reported, and  
 7 so in the people that were participating in the  
 8 survey, how often they estimated they had sex as  
 9 opposed to how often they actually had sex would  
 10 have an impact on the rate. Considerably. And  
 11 so if they underestimated it by half, or doubled  
 12 it or tripled it, we don't know what the impact  
 13 could be on that rate. So I think that's -- so  
 14 it's a very small -- the rate is very small but  
 15 when you're in these very small numbers, a small  
 16 change will move the rate up and down by  
 17 a couple of decimal points.  
 18 **PROFESSOR COOKE:** I think trying to tease apart  
 19 those different routes of transmission in  
 20 a couple or a family is very difficult. We  
 21 can't tell from the virus how it was transmitted  
 22 very well.  
 23 **SIR BRIAN LANGSTAFF:** The reason I asked it in  
 24 particular was because of the number of those  
 25 who have been very worried about the

236

1 we certainly thank you for taking it. Thank you  
 2 very much.  
 3 [Applause]  
 4 Tomorrow, 10.30.  
 5 **MS RICHARDS:** Yes, Professor Cooke is back for  
 6 another round.  
 7 **(5.10 pm)**  
 8 **(The hearing adjourned until 10.30 the**  
 9 **following day)**  
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<p><b>DR JAMIESON: [29]</b> 3/3 10/20 40/8 40/19 57/15 68/8 72/5 78/14 100/14 103/20 133/10 137/4 150/11 176/21 177/12 181/1 184/9 187/3 188/11 190/1 190/5 195/20 200/9 204/7 205/23 206/23 207/5 207/10 215/22 <b>DR JEFFERY: [21]</b> 3/13 19/6 30/24 48/12 50/18 50/22 51/2 52/9 53/20 54/16 55/17 56/23 68/24 71/12 193/4 193/17 194/17 195/1 209/21 223/23 224/23 <b>DR MARSHALL: [30]</b> 2/18 65/19 66/21 82/2 82/14 85/19 85/23 86/8 86/20 87/25 89/2 92/20 106/24 109/12 111/10 111/25 113/10 113/19 115/9 115/13 115/17 116/5 117/8 119/4 132/18 176/13 176/15 204/2 211/12 212/20 <b>MS RICHARDS: [193]</b> 1/16 2/4 4/10 4/20 5/2 7/1 8/18 10/14 10/22 11/1 11/19 12/19 13/16 14/23 16/3 17/1 17/15 18/15 18/24 19/22 20/11 21/3 22/5 24/15 25/3 25/20 26/12 27/24 30/5 30/11 31/10 37/25 38/9 38/18 40/17 41/14 41/24 42/2 42/11 43/6 44/5 45/1 45/8 47/4 47/16 48/4 50/15 50/19 50/23 52/4 53/17 54/13 54/21 56/17 57/14 59/5 61/8 67/3 67/21 68/2 68/14 70/21 72/12 73/23 74/16 75/6 75/10 75/22 76/15 77/5 79/21 80/22 81/16 82/7 85/17 85/20 86/4 86/17 87/22 88/20 90/20 91/13 92/4 92/6 92/11 93/14 93/18 94/20 96/15 98/1 98/5 98/11 99/6 100/22 102/13 103/5 106/10 109/9 111/7 111/22 113/7 113/11 115/7 115/10 115/14 115/25</p>	<p>117/5 118/24 119/19 123/21 124/11 125/2 130/9 131/18 135/1 135/15 136/23 137/10 138/6 139/13 141/22 142/24 144/24 145/22 147/20 148/19 148/21 150/25 151/4 151/17 155/4 156/11 158/24 159/12 162/18 163/17 164/1 164/25 165/21 168/15 169/17 171/5 173/7 175/24 176/6 176/14 176/16 176/19 178/7 178/17 179/2 179/7 180/10 180/15 181/24 183/22 186/21 188/3 188/12 191/6 192/19 193/14 194/12 194/18 195/2 200/4 202/7 203/22 204/25 210/25 212/17 213/17 214/10 214/22 215/1 215/14 218/5 218/21 219/12 220/2 220/11 221/14 222/4 223/6 223/19 225/1 226/7 226/20 227/6 228/9 229/24 230/18 236/4 <b>PROFESSOR</b> <b>COOKE: [103]</b> 2/8 5/5 9/19 12/2 12/24 14/2 15/7 16/9 17/3 17/23 19/5 19/25 20/15 21/6 22/8 24/24 25/6 25/24 27/5 28/3 29/16 30/8 32/11 38/8 38/11 40/3 43/3 43/14 44/10 45/13 47/11 56/5 65/8 66/10 71/22 72/23 74/8 74/19 75/9 75/18 76/4 77/4 79/17 81/5 91/7 92/10 92/22 94/3 95/17 97/19 98/21 99/12 101/6 102/19 103/10 105/21 120/7 124/1 124/15 125/8 131/10 131/19 136/2 136/24 137/20 138/25 140/3 142/12 144/13 145/19 146/11 148/4 148/20 149/9 159/11 159/15 162/22 163/20 164/3 165/3 166/9 172/18 176/17 178/15 181/14 185/19 189/6 190/17 191/22 192/3 213/20 219/23 220/5 220/24 222/5 223/12 224/17 226/24 227/24 229/14 230/4 232/1 234/17 <b>PROFESSOR</b> <b>DILLON: [105]</b> 4/1</p>	<p>4/19 5/1 7/9 9/2 10/7 10/21 10/25 11/2 18/16 23/12 25/7 26/16 29/3 40/22 41/23 42/1 42/10 42/16 42/24 43/2 44/22 45/7 55/19 60/2 62/1 62/6 62/13 62/18 63/7 63/10 63/13 63/22 64/5 64/8 65/5 65/7 67/20 67/22 77/9 80/4 91/18 92/5 92/9 92/23 93/17 93/22 94/11 94/24 96/4 96/23 102/21 104/17 104/20 129/1 135/14 140/14 143/17 153/16 155/24 158/5 163/8 165/13 168/16 170/8 171/25 173/17 175/25 177/8 177/16 178/16 178/19 179/4 179/16 180/13 180/16 183/1 190/7 191/13 192/10 192/17 203/1 203/24 214/13 214/25 215/6 217/25 218/7 219/2 219/16 220/8 220/21 220/25 221/18 225/11 226/12 227/13 228/18 231/11 231/22 231/25 232/7 233/4 234/3 235/3 <b>SIR BRIAN</b> <b>LANGSTAFF: [43]</b> 1/2 42/17 42/25 43/4 47/22 48/3 61/18 62/2 62/11 62/14 63/4 63/8 63/11 63/17 63/23 64/6 64/24 65/6 66/9 67/2 98/4 98/6 104/13 104/19 151/3 151/12 151/16 190/3 192/1 192/14 205/4 206/19 206/24 207/6 209/19 210/24 230/23 231/20 231/23 232/14 233/19 234/22 235/15</p> <p>-</p> <p>-- you [1] 103/22</p> <p><b>0</b> 0.07 [1] 47/9 0.5 [1] 23/21</p> <p><b>1</b> 1,000 [1] 115/11 1.04 [1] 98/9 1.4 million [1] 98/25 1.5 [1] 90/10 10 [3] 11/4 12/1/3 191/2</p>	<p><b>10 years [3]</b> 39/21 65/3 118/12 <b>10,000 [2]</b> 199/15 222/11 <b>10-year [1]</b> 93/13 <b>10.30 [2]</b> 236/4 236/8 <b>10.39 [1]</b> 1/2 <b>100 [9]</b> 69/6 69/9 69/10 70/2 70/5 70/6 105/13 141/21 190/21 <b>100 per cent [2]</b> 3/16 212/14 <b>100 years [1]</b> 30/20 <b>11.32 [1]</b> 48/1 <b>12 [4]</b> 125/22 125/25 169/3 176/10 <b>12 o'clock [1]</b> 47/25 <b>12.05 [1]</b> 48/3 <b>15 [1]</b> 55/15 <b>15.11b [1]</b> 117/3 <b>15.13 [1]</b> 119/21 <b>15.18 [1]</b> 165/22 <b>15.2 [1]</b> 20/10 <b>15.3 [1]</b> 31/11 <b>15.5 [1]</b> 38/22 <b>16 [4]</b> 55/15 102/19 102/24 104/16 <b>16 times [1]</b> 103/3 <b>16,000 [1]</b> 221/4 <b>160,000 [1]</b> 23/5 <b>17 [2]</b> 59/16 74/5 <b>18 [1]</b> 196/15 <b>18 years [1]</b> 196/13 <b>18,000 [1]</b> 221/3 <b>19 [1]</b> 1/14 <b>19-whatever [1]</b> 200/16 <b>190,000 [3]</b> 47/10 233/3 233/21 <b>1970 [2]</b> 220/21 221/17 <b>1970s [7]</b> 34/4 34/12 34/17 49/2 55/22 60/5 60/18 <b>1980s [3]</b> 35/4 60/20 220/10 <b>1987 [1]</b> 56/1 <b>1991 [3]</b> 56/1 126/8 221/19 <b>1996 [1]</b> 67/13 <b>1997 [1]</b> 39/19 <b>1998 [1]</b> 36/1 <b>1A [1]</b> 19/18 <b>1B [1]</b> 19/18</p> <p><b>2</b> <b>2 years [1]</b> 118/13 <b>2.04 [1]</b> 98/11 <b>20 [11]</b> 10/9 23/14 62/7 62/10 63/2 67/10 74/7 88/8 94/6 227/11 227/18 <b>20 years [7]</b> 3/21 63/5</p>	<p>65/2 95/7 121/7 191/14 191/21 <b>20,000 [1]</b> 221/2 <b>20-30 [1]</b> 95/8 <b>2006 [1]</b> 23/19 <b>2007 [1]</b> 23/19 <b>2011 [3]</b> 127/10 127/23 147/24 <b>2013 [2]</b> 129/20 229/13 <b>2014 [3]</b> 129/18 147/24 229/13 <b>2015 [2]</b> 132/10 222/12 <b>2016 [1]</b> 132/10 <b>2017 [3]</b> 67/13 132/10 191/12 <b>2018 [2]</b> 115/11 148/22 <b>2020 [2]</b> 1/1 129/21 <b>2024 [2]</b> 189/25 190/13 <b>2025 [2]</b> 189/24 190/3 <b>2030 [1]</b> 189/21 <b>21 [1]</b> 70/23 <b>21,000 people [1]</b> 23/25 <b>210,000 [1]</b> 23/4 <b>23 [1]</b> 207/18 <b>24 [4]</b> 126/11 169/21 176/10 196/15 <b>25 [1]</b> 44/18 <b>25 years [2]</b> 2/11 183/10 <b>26th February [1]</b> 1/1 <b>27 [2]</b> 82/16 90/24 <b>28 [1]</b> 98/15</p> <p><b>3</b> <b>3 years [1]</b> 110/20 <b>3,000 years [1]</b> 30/19 <b>3.02 [1]</b> 151/14 <b>3.30 [1]</b> 151/13 <b>3.36 [1]</b> 151/16 <b>30 [7]</b> 42/23 60/11 63/6 74/6 95/8 105/1 105/6 <b>30 years [6]</b> 4/9 23/14 94/6 95/8 227/11 227/18 <b>30-40 [1]</b> 78/6 <b>30-year [1]</b> 63/2 <b>33 [1]</b> 117/6 <b>35 [1]</b> 74/8 <b>350 million [1]</b> 99/1</p> <p><b>4</b> <b>4,000 [1]</b> 92/2 <b>40 [7]</b> 19/24 42/22 65/4 78/6 95/9 105/1 214/16 <b>40 years [2]</b> 63/9 64/3 <b>40-70 [1]</b> 117/19</p>	<p><b>41 [1]</b> 125/4 <b>45 [1]</b> 22/3 <b>48 [1]</b> 126/11 <b>48 weeks [1]</b> 121/1 <b>49 [1]</b> 152/10</p> <p><b>5</b> <b>5 years [3]</b> 37/3 115/17 128/5 <b>5.10 [1]</b> 236/7 <b>50 [5]</b> 105/1 105/12 105/12 105/14 121/24 <b>50,000 [1]</b> 23/21 <b>50.8 [1]</b> 73/25 <b>500 grams [1]</b> 11/8 <b>53 [1]</b> 165/23 <b>54 [1]</b> 165/23 <b>56 [1]</b> 171/8 <b>58 [1]</b> 153/3</p> <p><b>6</b> <b>60 [3]</b> 63/10 156/25 226/2 <b>61 [1]</b> 182/5 <b>63 [1]</b> 186/22 <b>64 [1]</b> 188/19</p> <p><b>7</b> <b>70 [3]</b> 96/3 117/19 188/19 <b>72 [1]</b> 161/12 <b>78 [1]</b> 192/25</p> <p><b>8</b> <b>80 [5]</b> 19/2 60/23 62/10 88/6 115/17 <b>80 million [1]</b> 226/2</p> <p><b>9</b> <b>9.2 [1]</b> 207/17 <b>90 [5]</b> 44/16 60/24 74/3 78/9 128/9 <b>91 [1]</b> 115/16 <b>95 [1]</b> 6/22</p> <p><b>A</b> <b>a 20 [1]</b> 63/2 <b>a 3-year [1]</b> 97/12 <b>a 30-40 [1]</b> 65/4 <b>a better [2]</b> 8/1 123/10 <b>a big [4]</b> 16/14 44/18 88/18 148/14 <b>a biopsy [1]</b> 213/1 <b>a bit [8]</b> 21/24 27/8 166/11 166/20 185/7 186/3 190/19 214/5 <b>a bleeding [1]</b> 225/2 <b>a blood [12]</b> 25/11 25/18 55/10 55/23 60/7 89/15 183/9 196/4 200/7 200/17 201/5 203/5 <b>a blood-borne [1]</b> 210/20</p>
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<b>A</b>	<b>a cure [1]</b> 168/18 <b>a cut [1]</b> 233/1 <b>a daily [4]</b> 70/12 122/16 123/14 199/9 <b>a date [2]</b> 33/13 33/23 <b>a day [1]</b> 11/5 <b>a death [3]</b> 100/6 100/9 105/19 <b>a decade [1]</b> 140/20 <b>a decision-making [1]</b> 20/20 <b>a definite [1]</b> 64/12 <b>a definition [1]</b> 79/8 <b>a delay [1]</b> 227/10 <b>a description [2]</b> 147/22 156/16 <b>a detectable [1]</b> 231/13 <b>a diagnosis [3]</b> 183/8 197/9 197/20 <b>a diagnostic [2]</b> 34/2 69/15 <b>a difference [5]</b> 16/1 193/19 194/9 211/12 211/14 <b>a different [5]</b> 46/23 51/22 131/21 163/10 212/12 <b>a differentiation [1]</b> 78/1 <b>a difficult [2]</b> 71/16 225/23 <b>a direct [1]</b> 224/21 <b>a discussion [7]</b> 16/15 65/14 163/3 175/8 176/23 180/21 181/1 <b>a disease [2]</b> 13/16 79/12 <b>a disgrace [1]</b> 191/20 <b>a distinction [2]</b> 13/24 126/21 <b>a DNA [1]</b> 13/23 <b>a doctor [1]</b> 196/12 <b>a document [1]</b> 189/11 <b>a dominant [1]</b> 28/3 <b>a dramatic [1]</b> 80/9 <b>a drug [2]</b> 113/1 113/5 <b>a Dutch [1]</b> 101/4 <b>a dynamic [3]</b> 22/12 24/9 24/15 <b>a false [1]</b> 70/25 <b>a family [2]</b> 19/20 234/20 <b>a faster [2]</b> 94/3 133/3 <b>a fatal [1]</b> 130/3 <b>a fatty [1]</b> 214/11 <b>a few [4]</b> 121/21 137/13 226/4 234/5 <b>a final [1]</b> 66/11 <b>a fine [1]</b> 82/25 <b>a five [2]</b> 93/3 93/13	<b>a flag [1]</b> 200/14 <b>a flight [1]</b> 1/8 <b>a full [1]</b> 183/25 <b>a general [4]</b> 33/12 33/15 101/23 102/9 <b>a genotype 1 [1]</b> 29/11 <b>a gold [1]</b> 195/24 <b>a good [1]</b> 186/20 <b>a GP [9]</b> 3/5 178/23 184/25 195/19 197/6 199/15 201/22 206/23 215/17 <b>a GP's [1]</b> 150/13 <b>a gradual [1]</b> 83/10 <b>a great [2]</b> 58/24 118/13 <b>a greater [4]</b> 21/2 23/1 87/5 223/16 <b>a group [4]</b> 36/3 101/16 171/2 194/4 <b>a guideline [1]</b> 116/9 <b>a half [2]</b> 11/4 30/17 <b>a handful [2]</b> 157/14 195/3 <b>a help [1]</b> 37/25 <b>a helpful [3]</b> 32/16 125/9 190/18 <b>a hepatitis [1]</b> 203/5 <b>a hepatitis C [1]</b> 226/1 <b>a hepatology [1]</b> 2/19 <b>a high [4]</b> 58/12 90/9 121/22 215/21 <b>a higher [6]</b> 26/20 46/25 85/3 94/2 155/13 160/4 <b>a hospital [1]</b> 183/13 <b>a household [1]</b> 201/20 <b>a huge [3]</b> 134/2 187/6 208/17 <b>a individual [1]</b> 178/2 <b>a kilo [1]</b> 11/4 <b>a kind [2]</b> 22/9 37/22 <b>a known [1]</b> 151/25 <b>a laboratory [1]</b> 3/18 <b>a large [5]</b> 26/1 87/16 100/18 107/25 225/23 119/18 <b>a late [3]</b> 97/25 119/4 119/18 <b>a later [3]</b> 7/4 82/9 211/7 <b>a level [1]</b> 196/3 <b>a life-threatening [1]</b> 111/10 <b>a lifetime [2]</b> 104/20 104/23 <b>a linear [1]</b> 62/20 <b>a little [25]</b> 2/6 7/3 13/18 13/21 19/3 20/3 20/24 27/19 27/22 31/14 32/18 44/21	46/7 54/20 57/14 74/10 87/24 113/12 161/2 164/14 164/20 166/5 168/13 179/20 180/1 <b>a liver [8]</b> 82/17 86/11 87/2 87/13 108/14 108/17 115/16 175/6 <b>a local [2]</b> 133/12 133/17 <b>a long [6]</b> 20/22 49/1 52/14 129/16 147/9 198/24 <b>a long-term [1]</b> 171/24 <b>a longer [2]</b> 65/24 97/13 <b>a look [1]</b> 103/10 <b>a lot [33]</b> 8/20 11/11 15/9 15/21 20/17 22/17 26/10 32/14 46/22 59/12 70/11 76/8 101/10 122/12 124/5 131/22 134/5 145/2 160/15 160/18 161/25 166/25 174/19 175/5 179/22 184/19 185/22 208/18 208/21 210/6 210/10 210/17 213/24 <b>a low [1]</b> 36/6 <b>a lower [3]</b> 85/2 120/20 163/4 <b>a major [4]</b> 53/17 69/12 131/16 200/25 <b>a majority [2]</b> 73/8 216/21 <b>a marker [1]</b> 163/25 <b>a matter [6]</b> 61/20 130/12 131/1 139/25 173/9 173/17 <b>a means [1]</b> 38/24 <b>a measure [2]</b> 84/24 224/16 <b>a measurement [1]</b> 213/6 <b>a member [2]</b> 197/15 206/4 <b>a message [1]</b> 14/16 <b>a minor [2]</b> 75/12 196/4 <b>a model [3]</b> 195/24 196/7 196/11 <b>a moment [2]</b> 19/4 131/12 <b>a more [8]</b> 16/12 66/5 67/14 93/2 119/11 124/19 160/25 202/24 <b>a most [1]</b> 235/21 <b>a much [6]</b> 18/21 36/18 163/3 163/13 163/16 224/15 <b>a multitude [1]</b> 10/12	<b>a narrative [1]</b> 39/11 <b>a national [1]</b> 191/1 <b>a natural [1]</b> 96/8 <b>a need [1]</b> 115/5 <b>a needle [2]</b> 54/9 183/6 <b>a negative [1]</b> 133/5 <b>a network [1]</b> 114/8 <b>a new [2]</b> 140/18 168/4 <b>a newly [1]</b> 70/13 <b>a nodule [1]</b> 211/23 <b>a normal [3]</b> 5/23 95/1 178/4 <b>a number [34]</b> 4/13 28/6 36/21 39/9 66/16 70/17 71/20 93/16 99/15 108/9 108/16 119/24 121/17 125/10 135/16 137/18 139/22 142/8 142/25 143/4 143/10 148/3 151/9 151/21 155/16 157/6 166/13 182/14 188/6 193/22 195/6 205/1 213/4 232/17 <b>a nurse-led [1]</b> 178/22 <b>a one [1]</b> 228/17 <b>a paper [2]</b> 33/14 33/18 <b>a parasite [1]</b> 7/12 <b>a part [1]</b> 178/6 <b>a particular [3]</b> 16/1 91/20 205/4 <b>a particularly [1]</b> 47/21 <b>a patchy [1]</b> 173/11 <b>a patient [17]</b> 16/16 16/17 18/10 20/19 28/23 65/14 81/18 88/23 99/25 107/10 124/3 125/22 132/25 144/16 164/16 168/2 182/13 <b>a patient's [3]</b> 133/19 134/9 165/21 <b>a PCR [1]</b> 224/22 <b>a period [1]</b> 132/14 <b>a person [2]</b> 88/15 171/10 <b>a person's [1]</b> 177/21 <b>a perspective [1]</b> 77/12 <b>a phrase [1]</b> 139/21 <b>a picture [1]</b> 50/9 <b>a plausible [1]</b> 154/2 <b>a pneumo-skin [1]</b> 135/24 <b>a point [3]</b> 82/6 156/19 173/20 <b>a population [4]</b> 65/13 156/9 223/5 223/6	<b>a position [1]</b> 150/5 <b>a positive [2]</b> 49/20 207/2 <b>a possibility [2]</b> 198/23 198/25 <b>a potential [1]</b> 53/14 <b>a precise [2]</b> 220/7 233/9 <b>a primary [1]</b> 184/11 <b>a problem [3]</b> 146/24 149/22 212/8 <b>a process [2]</b> 33/19 83/12 <b>a product [1]</b> 127/15 <b>a professor [1]</b> 4/2 <b>a proper [1]</b> 208/4 <b>a proportion [3]</b> 23/23 158/8 158/20 <b>a protein [1]</b> 84/23 <b>a public [2]</b> 33/22 34/11 <b>a published [1]</b> 153/17 <b>a quarter [1]</b> 136/23 <b>a question [11]</b> 11/14 40/1 56/18 67/18 100/11 130/11 144/10 158/12 220/12 225/9 226/21 <b>a raise [2]</b> 200/23 216/7 <b>a range [14]</b> 76/19 91/5 128/25 135/21 142/4 145/3 146/8 155/18 156/14 157/1 157/2 162/17 192/22 193/10 <b>a rare [1]</b> 80/23 <b>a rate [2]</b> 104/17 104/17 <b>a real [1]</b> 160/20 <b>a really [6]</b> 20/21 68/25 71/13 99/14 126/13 197/14 <b>a reason [1]</b> 115/20 <b>a recent [1]</b> 132/9 <b>a recognised [1]</b> 92/7 <b>a reduced [1]</b> 226/9 <b>a reference [1]</b> 223/22 <b>a reflection [3]</b> 17/7 41/4 148/15 <b>a reinfection [1]</b> 177/15 <b>a relatively [9]</b> 16/25 20/6 109/8 123/4 125/1 160/12 192/6 210/18 212/12 <b>a reliable [1]</b> 25/16 <b>a report [1]</b> 167/1 <b>a representative [1]</b> 78/4 <b>a respiratory [1]</b> 193/8
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<b>A</b>	<b>a starting [3]</b> 136/12 136/20 186/20	61/15 73/25 75/15 92/2 101/14 102/7 103/4 105/5 119/16 121/14 129/22 131/13 136/23 138/24 144/19 150/20 150/24 166/14 166/22 166/24 167/8 169/4 183/7 201/6 234/14	34/5 37/3 38/3 40/2 41/2 41/17 43/8 46/8 47/17 48/5 48/6 49/13 49/14 49/17 50/12 50/24 51/6 52/6 53/18 56/8 58/9 58/15 59/22 60/11 60/23 61/11 61/17 62/9 64/19 65/21 65/21 66/23 67/6 68/17 69/23 70/23 71/24 74/10 74/11 74/21 74/25 75/3 76/9 78/5 78/9 80/2 82/8 84/5 84/6 87/24 88/21 89/5 90/21 92/13 95/2 95/7 95/9 96/5 98/25 99/1 99/11 99/15 99/16 100/8 100/13 101/16 101/23 103/20 103/23 107/12 113/13 115/19 115/24 116/14 121/11 126/14 126/18 128/17 129/15 130/1 130/5 130/14 131/13 132/9 132/10 132/19 132/22 135/9 135/14 136/5 136/11 139/11 139/14 139/23 141/5 142/12 142/15 145/2 146/13 146/16 146/21 149/6 149/19 150/3 150/8 151/19 152/21 153/3 157/9 159/3 159/4 161/7 161/25 163/1 163/1 163/3 163/22 163/24 164/2 164/7 165/5 165/25 166/6 166/8 166/22 167/14 167/19 167/21 167/22 168/6 168/10 168/14 168/20 170/1 173/20 174/23 175/12 176/7 176/23 180/9 180/11 180/21 181/25 182/11 182/13 182/15 183/19 183/20 183/24 184/1 184/5 186/3 188/8 188/15 188/16 188/21 189/12 192/21 192/23 193/13 194/12 195/4 195/13 200/3 200/18 201/4 201/7 202/13 202/17 202/20 205/8 205/16 205/22 207/23 208/5 210/12 212/5 212/19 212/22 213/2 214/16 218/10 218/16 220/17 221/7 221/10 221/24 223/9 223/25 225/25 227/20 234/25 235/18 235/22	<b>above [1]</b> 230/23 <b>absence [5]</b> 51/20 91/24 96/1 154/12 233/6 <b>absolute [3]</b> 25/17 105/23 106/5 <b>absolutely [9]</b> 10/21 17/24 48/8 69/24 104/4 139/1 204/14 216/18 227/17 <b>abusing [1]</b> 202/18 <b>ac [1]</b> 53/7 <b>accelerate [2]</b> 64/18 93/24 <b>accelerated [1]</b> 129/23 <b>accent [1]</b> 1/8 <b>acceptance [1]</b> 217/20 <b>accepted [2]</b> 79/23 139/2 <b>accepting [1]</b> 216/25 <b>access [17]</b> 2/17 3/12 134/4 134/25 183/14 183/16 187/9 187/17 196/8 205/10 205/11 206/16 206/17 209/1 209/3 209/12 213/22 <b>accessible [3]</b> 150/9 152/19 209/11 <b>accompanied [1]</b> 75/13 <b>according [4]</b> 21/17 117/10 153/12 192/18 <b>account [1]</b> 19/24 <b>accumulating [1]</b> 62/23 <b>accuracy [2]</b> 87/21 89/18 <b>accurate [3]</b> 57/10 218/6 221/13 <b>achievable [2]</b> 190/24 230/17 <b>achieve [6]</b> 128/8 172/20 190/10 190/12 190/21 191/1 <b>achieved [5]</b> 148/12 149/13 172/22 176/9 178/10 <b>achieving [1]</b> 169/21 <b>acid [2]</b> 14/5 14/6 <b>acknowledged [1]</b> 166/19 <b>acknowledgment [1]</b> 217/20 <b>acquired [5]</b> 25/13 177/23 219/4 225/15 235/9 <b>across [12]</b> 3/10 20/11 58/23 74/16 101/16 104/4 104/9 150/4 160/9 175/22 205/17 205/25	<b>act [1]</b> 198/5 <b>acting [4]</b> 35/25 127/12 128/7 147/23 <b>action [1]</b> 215/18 <b>active [20]</b> 28/13 28/13 49/22 50/1 50/25 51/2 51/6 51/18 51/23 52/4 93/1 93/5 93/11 94/2 120/19 120/20 122/12 124/23 221/10 222/9 <b>actively [3]</b> 72/3 99/1 112/23 <b>activities [2]</b> 116/23 147/20 <b>activity [4]</b> 46/24 47/2 47/4 128/4 <b>acts [2]</b> 232/22 233/21 <b>actual [1]</b> 50/12 <b>actually [30]</b> 18/24 22/20 22/21 27/19 33/16 48/15 49/15 49/22 52/14 54/11 69/15 73/6 73/10 74/14 80/12 81/6 81/7 84/10 101/9 148/16 167/6 175/4 194/11 197/2 198/19 210/3 216/11 216/24 217/17 234/9 <b>acute [11]</b> 2/25 49/6 71/1 72/18 72/18 74/18 74/22 75/4 75/7 75/16 218/14 <b>acutely [2]</b> 8/6 58/4 <b>acuteness [1]</b> 74/24 <b>adaptation [1]</b> 158/23 <b>adapted [1]</b> 153/14 <b>add [10]</b> 14/22 29/3 29/4 57/16 129/1 144/18 163/8 180/7 185/20 209/21 <b>added [3]</b> 126/25 143/20 148/7 <b>addiction [1]</b> 183/6 <b>addition [2]</b> 36/7 149/12 <b>additional [4]</b> 162/13 164/22 164/24 193/16 <b>additive [1]</b> 162/1 <b>address [8]</b> 4/23 5/3 31/23 35/18 37/17 131/6 159/15 230/4 <b>addressed [7]</b> 98/16 156/22 156/24 157/1 166/3 195/5 230/3 <b>adefovir [2]</b> 122/3 122/6 <b>adequacy [1]</b> 38/4 <b>adequate [3]</b> 182/18 182/25 212/11 <b>adequately [1]</b> 185/8
----------	---	--	--	--	--

<b>A</b>	158/7 158/12 158/17 160/24 167/8 167/24 169/15 171/10 171/23 175/6 185/2 190/2 228/14 <b>afterwards [2]</b> 165/8 185/2 <b>again [69]</b> 7/6 11/21 12/22 15/5 18/8 22/18 39/5 43/7 43/12 51/16 53/22 54/1 56/18 57/12 59/22 61/15 64/21 67/18 68/10 68/19 70/4 75/7 75/8 75/24 81/2 85/21 89/17 92/18 94/5 94/22 98/6 109/11 110/23 112/20 113/9 114/2 116/2 120/8 122/4 122/12 123/2 123/15 127/6 137/18 138/10 141/24 142/11 143/10 145/1 145/6 145/23 146/3 146/8 149/1 152/10 152/15 153/7 159/17 160/25 161/14 161/16 164/21 170/1 182/6 188/4 188/20 202/11 218/22 227/10 <b>against [6]</b> 29/15 122/12 123/5 127/13 128/14 192/9 <b>age [21]</b> 56/2 63/16 63/20 63/20 65/22 66/2 66/4 66/7 73/11 74/3 74/16 93/20 104/21 104/23 105/3 105/6 105/8 105/10 105/12 105/14 105/15 <b>age-standardised [3]</b> 104/21 105/10 105/15 <b>aged [1]</b> 105/1 <b>ages [1]</b> 44/14 <b>aggression [1]</b> 138/18 <b>aggressive [3]</b> 16/12 124/19 189/19 <b>aging [1]</b> 85/11 <b>ago [10]</b> 30/19 37/3 90/20 148/20 150/21 166/23 170/14 183/10 196/13 227/18 <b>agree [1]</b> 163/9 <b>agreed [1]</b> 87/9 <b>agreeing [1]</b> 62/2 <b>agreement [1]</b> 87/1 <b>agreements [1]</b> 58/13 <b>ahead [2]</b> 68/5 204/7 <b>AILEEN [3]</b> 2/2 2/19 65/18 <b>Aileen Marshall [1]</b> 2/19 <b>aim [1]</b> 123/23	<b>aiming [1]</b> 114/21 <b>airing [1]</b> 227/9 <b>al [1]</b> 153/14 <b>albeit [3]</b> 92/8 130/4 178/5 <b>albumen [1]</b> 84/24 <b>alcohol [8]</b> 64/17 90/13 93/21 94/19 108/7 172/17 180/4 202/18 <b>alcohol-related [1]</b> 90/13 <b>algorithm [2]</b> 117/9 117/14 <b>alike [1]</b> 142/17 <b>all [73]</b> 5/4 10/9 18/5 18/7 22/15 24/8 28/15 29/16 31/15 32/3 41/11 41/11 41/20 43/12 44/9 45/19 47/14 48/7 51/5 60/3 68/10 70/1 70/3 72/21 73/7 73/10 76/3 82/3 85/4 93/9 93/23 101/9 106/21 106/25 107/16 109/17 114/1 128/14 130/23 141/11 142/14 142/21 146/21 149/24 152/10 152/19 154/6 156/8 168/12 169/22 176/4 185/18 185/24 189/16 193/7 193/12 199/18 201/8 201/23 203/2 203/4 204/6 204/25 209/3 210/1 210/21 211/1 213/15 216/22 222/19 230/5 230/6 230/10 <b>allied [1]</b> 114/20 <b>allocated [1]</b> 186/6 <b>allowed [4]</b> 36/12 36/23 226/18 232/11 <b>allowing [1]</b> 123/18 <b>allows [4]</b> 8/3 34/9 34/10 214/3 <b>alluded [13]</b> 10/13 61/1 61/10 68/14 71/3 95/6 95/11 95/16 115/24 208/8 208/15 213/1 216/14 <b>alludes [1]</b> 68/18 <b>alluding [1]</b> 180/9 <b>almost [4]</b> 19/19 60/3 154/6 184/11 <b>alone [2]</b> 56/5 203/18 <b>along [2]</b> 175/2 228/7 <b>alpha [2]</b> 89/16 90/7 <b>alpha-fetoprotein [2]</b> 89/16 90/7 <b>already [28]</b> 11/25 12/10 33/1 44/25 68/13 71/3 73/5 88/7 92/14 94/23 98/16	101/1 116/7 125/12 142/15 147/13 148/8 164/6 164/7 166/4 167/25 177/3 209/12 209/24 220/13 226/2 226/5 226/6 <b>also [56]</b> 1/13 2/16 3/5 3/21 3/24 9/9 17/8 17/19 19/8 28/12 37/18 38/12 48/19 49/24 50/3 50/6 53/1 64/18 66/7 74/9 79/16 85/5 87/11 90/21 99/23 100/8 100/10 100/15 100/21 107/5 107/7 114/5 114/25 115/18 121/12 122/12 126/17 127/8 139/12 142/17 151/20 160/14 162/9 162/19 163/11 164/21 168/1 187/3 188/19 188/25 197/19 204/21 206/13 210/12 228/2 228/8 <b>ALT [11]</b> 5/22 8/19 8/25 9/3 9/8 9/14 10/11 10/16 11/6 11/8 183/11 <b>alteration [1]</b> 138/19 <b>altered [2]</b> 81/22 147/11 <b>alternative [1]</b> 122/25 <b>alternatively [1]</b> 158/14 <b>although [16]</b> 14/10 16/20 18/12 32/23 33/18 36/5 43/10 43/23 94/5 121/4 136/19 147/5 148/1 166/16 194/6 229/20 <b>always [13]</b> 16/20 41/5 102/9 128/18 139/3 146/18 146/19 146/23 162/23 201/7 202/7 203/25 204/11 <b>am [11]</b> 1/2 3/14 4/4 48/1 55/8 148/24 152/4 178/12 197/14 199/10 202/1 <b>ambition [3]</b> 37/10 189/19 191/5 <b>ambitious [2]</b> 37/13 37/16 <b>American [2]</b> 90/2 90/10 <b>among [2]</b> 160/12 211/23 <b>amongst [6]</b> 4/17 6/7 24/20 61/7 207/15 207/19 <b>amount [12]</b> 7/18 31/4 134/3 138/15 160/5 174/11 181/8 187/7	207/20 208/17 227/3 227/4 <b>amounts [1]</b> 83/11 <b>anaemia [2]</b> 147/2 147/17 <b>analogue [1]</b> 121/8 <b>anaphylaxis [1]</b> 138/9 <b>and/or [2]</b> 67/16 153/1 <b>anecdotal [3]</b> 155/22 155/24 155/25 <b>annex [2]</b> 152/12 152/13 <b>annex 2 [2]</b> 152/12 152/13 <b>annexes [2]</b> 151/23 152/18 <b>annual [2]</b> 178/21 192/5 <b>annually [1]</b> 179/2 <b>anorexia [1]</b> 73/17 <b>another [14]</b> 25/13 38/3 47/20 58/17 65/3 123/2 132/7 156/5 156/5 226/7 228/18 235/10 235/10 236/6 <b>answer [16]</b> 22/11 94/22 159/9 170/2 191/13 199/23 202/11 207/11 209/18 220/7 220/15 221/18 223/21 225/9 227/15 229/15 <b>answered [1]</b> 157/17 <b>anti [3]</b> 127/13 128/7 141/3 <b>anti-depressants [1]</b> 141/3 <b>anti-virals [2]</b> 127/13 128/7 <b>antibodies [4]</b> 22/16 22/19 48/17 224/6 <b>antibody [15]</b> 22/24 23/5 35/6 51/12 53/25 54/5 54/19 56/10 67/16 71/2 71/15 71/22 72/1 224/6 224/23 <b>anticipated [1]</b> 223/20 <b>antigen [8]</b> 18/20 33/10 33/11 48/23 51/25 53/1 224/2 224/4 <b>antigens [1]</b> 53/9 <b>antivirals [1]</b> 147/23 <b>antiviran [1]</b> 172/23 <b>anxieties [1]</b> 168/9 <b>anxiety [2]</b> 77/2 138/18 <b>any [66]</b> 10/23 17/22 24/19 26/3 26/15 31/19 38/2 39/4 39/25 40/2 40/19 41/17 51/14 51/17 53/19 73/6 73/7 74/2 75/25	77/6 83/8 86/7 86/17 88/5 89/10 96/8 99/10 99/10 103/21 108/7 112/10 118/22 128/21 133/8 135/8 135/13 135/13 136/13 139/20 142/11 158/5 173/14 176/13 180/5 184/20 191/8 193/13 193/16 194/21 195/18 202/25 202/25 207/16 210/2 210/3 210/20 211/9 212/17 213/18 214/21 226/23 227/11 228/13 229/25 230/1 230/20 <b>anybody [3]</b> 29/3 198/9 230/11 <b>anymore [1]</b> 179/19 <b>anyone [9]</b> 55/22 55/25 129/1 149/5 150/6 155/5 182/7 221/20 232/23 <b>anything [4]</b> 15/13 50/12 176/20 198/10 <b>apart [1]</b> 234/18 <b>apologies [3]</b> 1/3 104/1 203/11 <b>apology [1]</b> 1/4 <b>apparent [2]</b> 85/9 235/11 <b>apparently [1]</b> 191/16 <b>appear [5]</b> 9/9 9/15 29/11 225/17 225/21 <b>appeared [4]</b> 29/7 29/13 60/12 71/2 <b>appears [2]</b> 13/12 172/14 <b>Applause [1]</b> 236/3 <b>applied [2]</b> 60/23 118/3 <b>applies [1]</b> 47/15 <b>apply [3]</b> 94/14 193/2 231/11 <b>appointment [1]</b> 184/25 <b>appointments [1]</b> 208/3 <b>appreciate [1]</b> 184/13 <b>approach [2]</b> 165/13 166/14 <b>approaches [1]</b> 54/24 <b>appropriate [1]</b> 140/6 <b>appropriately [2]</b> 176/6 209/15 <b>approved [2]</b> 123/9 134/18 <b>approximately [4]</b> 62/7 88/6 117/18 222/11 <b>are [341]</b> <b>area [24]</b> 15/21 16/22 21/23 40/5 43/11 58/9 58/12 58/21 59/5
----------	--	--	---	---	---

<b>A</b>	101/2 108/13 113/12 120/3 130/25 135/9 143/12 147/24 149/3 149/6 152/3 157/18 157/22 158/5 158/25 159/3 159/13 159/14 164/2 166/5 176/7 182/3 182/22 192/21 194/13 195/4 195/17 197/8 200/24 203/2 203/8 203/9 204/5 204/6 204/7 205/3 205/6 206/20 212/19 220/12 223/23 235/17 <b>asked [46]</b> 12/20 24/18 25/1 25/5 29/17 31/12 31/16 38/2 38/8 50/25 56/18 67/18 72/15 77/13 103/7 129/19 136/4 151/20 151/24 152/21 153/3 165/25 166/7 182/11 187/4 188/22 191/7 195/13 198/9 198/15 202/11 202/13 202/14 203/6 203/20 203/24 204/2 204/20 205/2 211/8 212/19 214/11 220/13 223/23 230/2 234/23 <b>asking [7]</b> 5/3 56/21 70/11 139/16 203/9 203/12 204/1 <b>asks [1]</b> 159/4 <b>aspects [5]</b> 3/1 4/9 14/22 37/20 104/2 <b>assays [13]</b> 48/10 49/8 49/13 49/14 49/15 49/19 49/21 50/5 50/14 50/14 52/24 71/17 71/20 <b>assessing [2]</b> 84/7 212/25 <b>assessment [5]</b> 6/15 113/24 114/18 124/7 130/21 <b>assist [1]</b> 211/10 <b>assisted [1]</b> 194/12 <b>associated [31]</b> 13/1 13/11 16/12 25/23 29/19 41/9 46/24 66/25 75/8 77/19 79/24 80/25 91/15 117/17 120/3 125/6 135/6 135/7 136/16 137/20 151/20 152/25 157/7 158/17 162/12 163/11 163/19 169/13 169/21 213/11 219/1 <b>association [21]</b> 74/13 90/1 90/2 91/20 135/12 135/24 136/2 151/25 151/25 153/12	153/25 154/8 154/9 155/20 155/23 157/9 157/9 157/15 176/3 219/8 226/25 <b>associations [2]</b> 154/22 215/13 <b>assumes [2]</b> 100/15 233/24 <b>assumption [1]</b> 208/6 <b>assumptions [2]</b> 103/23 193/13 <b>AST [7]</b> 8/19 8/25 9/3 9/9 9/9 9/15 10/16 <b>asthenia [1]</b> 145/25 <b>asymptomatic [1]</b> 88/12 <b>at-risk [2]</b> 55/11 191/11 <b>atrial [1]</b> 219/5 <b>attach [1]</b> 162/4 <b>attack [1]</b> 235/18 <b>attempt [1]</b> 228/12 <b>attempts [1]</b> 228/14 <b>attend [1]</b> 111/16 <b>attending [4]</b> 194/19 196/22 197/7 197/8 <b>attention [4]</b> 77/3 155/10 156/18 188/20 <b>attributable [2]</b> 59/19 99/2 <b>attribute [2]</b> 78/25 78/25 <b>attributing [2]</b> 100/8 100/20 <b>audit [1]</b> 41/10 <b>audits [1]</b> 198/21 <b>Australia [2]</b> 33/10 101/14 <b>Australian [2]</b> 101/4 102/3 <b>authored [1]</b> 4/13 <b>authoritative [1]</b> 235/21 <b>authority [1]</b> 209/18 <b>autoimmune [2]</b> 3/3 157/3 <b>automatically [4]</b> 58/8 196/4 200/14 206/2 <b>availability [2]</b> 45/16 150/3 <b>available [23]</b> 17/21 24/11 34/9 35/19 80/22 114/5 120/5 120/7 122/9 128/19 128/25 129/6 130/23 131/10 133/16 134/6 135/13 152/17 153/18 189/8 196/9 207/3 227/17 <b>Avascular [1]</b> 152/24 <b>average [7]</b> 94/14 94/16 95/12 95/13 101/15 205/14 207/17	<b>averages [1]</b> 63/1 <b>avoiding [1]</b> 108/6 <b>avoids [1]</b> 214/1 <b>awaited [1]</b> 5/1 <b>aware [14]</b> 30/9 31/10 59/9 85/7 99/10 129/9 134/15 140/21 140/25 141/14 180/3 197/14 204/12 206/1 <b>awareness [4]</b> 36/25 57/25 190/14 196/2 <b>away [11]</b> 8/6 53/17 111/16 112/7 114/10 158/3 167/3 167/5 168/9 169/11 220/7	<b>B</b> <b>babies [1]</b> 198/4 <b>back [39]</b> 5/21 14/18 20/8 23/19 26/3 27/18 29/13 35/7 37/24 41/11 46/16 55/22 59/7 66/12 69/23 86/5 95/19 97/3 97/12 106/4 109/24 142/14 145/11 164/18 168/4 170/2 170/23 198/20 199/1 200/14 201/15 204/17 207/4 208/22 209/5 211/21 211/21 230/19 236/5 <b>background [3]</b> 34/24 175/18 178/7 <b>bacteria [2]</b> 112/3 113/3 <b>bacterial [1]</b> 135/22 <b>bad [1]</b> 175/9 <b>bag [1]</b> 234/2 <b>balancing [1]</b> 144/10 <b>bands [3]</b> 83/9 111/5 111/20 <b>bar [1]</b> 187/7 <b>Barcelona [1]</b> 117/5 <b>barrier [1]</b> 80/19 <b>barring [1]</b> 185/16 <b>bars [2]</b> 126/19 126/20 <b>base [3]</b> 36/6 36/13 170/9 <b>based [25]</b> 2/11 2/20 3/14 22/4 22/24 26/10 35/7 46/18 56/9 58/7 71/17 71/21 75/5 76/12 78/8 84/18 86/10 137/5 137/6 163/12 167/7 174/13 174/14 191/24 224/23 <b>baseline [1]</b> 225/8 <b>basic [4]</b> 5/4 173/10 173/17 184/7 <b>basics [1]</b> 7/6 <b>basis [7]</b> 32/6 56/4 70/12 122/16 123/14	192/5 199/9 <b>be [428]</b> <b>became [9]</b> 27/3 35/23 129/7 141/1 163/16 193/23 229/5 229/6 229/8 <b>because [124]</b> 5/10 7/22 11/9 21/23 22/13 24/7 24/17 26/11 26/25 27/4 27/7 29/11 29/15 32/4 34/6 38/7 40/12 47/5 49/24 51/9 52/1 55/1 55/20 59/8 60/10 61/5 62/22 63/20 67/23 68/4 69/17 69/24 76/25 77/14 79/3 80/20 81/10 82/6 84/9 85/8 85/21 88/17 96/7 96/8 103/6 104/4 104/23 105/3 108/14 112/5 114/9 116/12 116/16 120/23 121/12 123/23 128/3 130/11 131/1 131/6 131/12 132/21 134/7 136/15 138/14 140/24 144/9 145/1 146/21 146/22 147/6 148/10 154/9 154/13 155/11 156/19 157/16 158/21 161/9 166/21 169/2 170/10 174/9 179/18 180/19 180/25 181/4 181/17 183/9 183/13 188/4 188/14 188/20 189/4 194/13 194/16 197/9 199/9 199/14 199/15 201/1 203/20 209/7 210/6 210/15 212/15 212/22 213/11 215/10 217/1 218/19 219/11 221/22 221/23 224/25 225/7 225/24 226/16 228/22 231/9 233/7 233/24 234/24 235/13 <b>become [20]</b> 18/19 24/10 31/9 52/13 52/17 53/10 54/3 54/5 62/24 77/14 77/25 82/12 110/1 165/2 165/15 165/20 168/7 198/10 218/18 220/3 <b>becomes [6]</b> 27/22 29/14 62/24 64/21 100/1 122/17 <b>becoming [7]</b> 24/6 43/21 44/3 44/14 133/15 222/18 226/15 <b>bed [1]</b> 117/1 <b>been [130]</b> 1/21 4/21 15/24 16/3 18/18 20/21 21/2 21/11	22/24 24/23 25/5 30/5 30/14 30/16 31/3 31/6 31/18 32/1 32/1 34/5 38/6 38/6 38/8 39/18 39/23 43/19 48/20 48/25 49/1 50/3 50/25 52/9 52/21 53/5 54/2 54/7 56/18 57/2 57/7 58/22 59/12 59/24 60/8 60/25 61/17 63/7 63/24 64/23 67/14 67/18 81/3 86/16 89/22 92/14 97/21 97/23 99/6 99/22 100/1 118/13 119/18 119/22 120/5 120/23 121/7 128/13 134/15 139/18 140/15 140/19 141/15 141/16 144/3 144/4 146/15 149/15 150/10 153/5 154/13 160/2 161/19 162/21 163/5 164/12 166/20 169/9 170/5 172/3 173/3 175/1 175/11 175/13 186/15 191/7 191/19 191/20 195/9 196/11 196/19 196/23 196/25 198/1 198/3 198/4 199/5 199/13 200/11 201/1 201/4 201/19 203/20 205/2 211/8 212/19 214/4 214/5 218/23 221/6 222/12 222/15 225/25 228/16 228/17 230/2 231/8 231/10 232/4 232/12 234/25 235/21 <b>before [42]</b> 17/16 32/25 33/20 42/22 52/17 53/12 56/1 56/1 56/7 60/14 68/15 69/17 71/1 72/7 72/9 77/19 86/6 94/25 98/12 116/7 125/5 129/22 132/24 135/8 140/13 140/20 148/24 157/21 165/6 170/3 192/22 205/5 208/1 208/16 211/19 214/22 221/8 228/7 229/5 229/6 229/7 229/13 <b>began [1]</b> 33/8 <b>begin [3]</b> 83/18 83/22 119/21 <b>beginning [2]</b> 33/7 141/4 <b>behave [2]</b> 14/13 15/17 <b>behaviours [1]</b> 158/16 <b>behind [6]</b> 1/18 53/25 103/7 151/6 158/22 209/18
----------	---	--	--	---	--	---



<b>B</b>	88/18 131/13 148/14 232/4 <b>bigger</b> [3] 21/24 133/20 133/24 <b>biggest</b> [2] 37/7 103/15 <b>bile</b> [3] 82/23 82/24 83/16 <b>bilirubin</b> [2] 84/20 218/9 <b>biochemical</b> [2] 10/2 34/14 <b>biological</b> [1] 154/2 <b>biopsies</b> [2] 213/9 214/2 <b>biopsy</b> [10] 82/17 82/18 86/11 87/2 87/13 87/15 174/9 175/6 213/1 213/14 <b>biopsying</b> [1] 179/19 <b>bipolar</b> [1] 138/23 <b>bit</b> [29] 13/21 20/4 20/24 21/24 27/8 27/20 32/18 44/21 46/7 53/13 54/20 57/14 74/10 103/19 122/6 161/2 164/14 164/20 166/5 166/11 166/20 168/13 180/2 185/6 185/7 186/3 190/19 214/5 230/16 <b>black</b> [2] 83/2 126/19 <b>bleed</b> [3] 110/6 219/20 219/22 <b>bleeding</b> [12] 42/16 81/22 86/2 110/21 111/1 111/9 111/19 112/22 138/4 173/25 219/20 225/2 <b>blocker</b> [1] 111/3 <b>blocking</b> [1] 118/5 <b>blood</b> [98] 4/7 5/17 5/18 9/22 10/10 12/13 24/22 24/22 25/11 25/18 38/20 38/24 38/24 39/3 39/12 55/10 55/11 55/21 55/23 56/1 57/22 60/7 61/4 61/24 63/22 65/23 80/19 81/21 81/22 82/22 82/22 83/16 84/19 84/24 85/9 87/22 89/15 91/17 107/19 109/15 109/17 109/20 111/6 111/14 111/14 111/17 111/21 112/2 112/7 113/22 118/5 120/16 122/18 123/17 125/24 133/1 137/17 137/24 137/24 147/2 150/14 174/12 177/18 177/24 178/19 183/9 190/23	196/4 197/13 200/7 200/7 200/17 200/24 201/5 202/13 203/3 203/5 203/13 203/13 210/20 213/2 213/13 216/18 220/20 221/16 221/21 222/1 223/15 223/16 224/25 226/3 226/11 227/1 232/16 232/17 232/25 233/16 235/7 <b>blood transfusion</b> [1] 12/13 <b>blood-borne</b> [1] 4/7 <b>blood-brain</b> [1] 80/19 <b>bloodstream</b> [3] 9/12 9/13 9/15 <b>blurred</b> [1] 105/25 <b>bodies</b> [2] 35/17 36/22 <b>body</b> [11] 14/14 51/8 51/12 107/15 112/6 127/16 127/22 135/18 166/16 169/20 218/25 <b>body's</b> [2] 48/16 48/16 <b>bone</b> [2] 145/12 219/18 <b>bones</b> [1] 122/22 <b>books</b> [1] 210/4 <b>born</b> [1] 203/6 <b>borne</b> [3] 4/7 38/20 210/20 <b>both</b> [55] 2/17 3/23 4/23 5/11 6/16 17/6 17/7 20/19 20/25 24/1 24/5 24/12 30/13 30/20 31/6 34/7 35/13 36/7 36/20 37/11 41/22 41/25 42/7 44/9 48/18 49/4 66/20 66/25 73/8 75/24 76/13 81/15 87/10 89/17 91/3 92/20 95/20 98/19 106/5 124/18 133/7 142/23 159/19 159/21 160/17 161/25 162/5 163/20 167/18 176/2 189/21 193/22 195/10 214/14 219/21 <b>bottom</b> [10] 42/21 55/15 70/23 83/20 90/23 135/5 143/6 153/8 182/9 186/25 <b>box</b> [2] 198/12 199/9 <b>brain</b> [13] 77/3 78/3 79/25 80/3 80/6 80/8 80/11 80/19 80/21 158/2 158/16 158/23 215/8 <b>breadth</b> [1] 206/6 <b>break</b> [3] 48/2 148/24	151/15 <b>breakage</b> [2] 42/5 42/15 <b>breaks</b> [1] 47/19 <b>Breastfeeding</b> [2] 42/3 42/13 <b>breathlessness</b> [1] 81/23 <b>Brian</b> [2] 32/6 95/6 <b>briefly</b> [9] 5/9 43/13 101/3 101/5 109/11 120/4 124/12 159/25 194/14 <b>brilliant</b> [1] 142/3 <b>bring</b> [4] 190/16 208/14 231/18 234/1 <b>bringing</b> [1] 181/12 <b>British</b> [1] 176/2 <b>broad</b> [2] 3/20 37/22 <b>broadly</b> [2] 23/3 150/5 <b>broken</b> [3] 9/11 147/3 186/1 <b>bronchitis</b> [1] 135/21 <b>brought</b> [2] 112/9 217/3 <b>bruising</b> [1] 81/24 <b>BT</b> [1] 114/6 <b>budget</b> [1] 131/17 <b>bunch</b> [1] 210/7 <b>burden</b> [1] 109/4 <b>busy</b> [1] 1/12 <b>but</b> [341] <b>by</b> [113] 2/4 2/5 4/13 4/13 5/3 6/10 6/11 6/12 6/13 7/11 8/7 8/25 11/15 11/16 11/21 12/22 22/1 25/5 25/15 31/12 31/18 31/18 31/19 32/6 35/13 37/5 39/8 42/13 43/21 48/14 50/25 51/2 52/8 59/25 69/5 74/18 75/13 75/14 80/18 81/3 83/5 85/10 87/9 89/18 89/25 94/9 95/7 95/21 101/16 107/7 107/13 108/22 109/15 111/20 112/3 112/9 113/3 113/22 117/4 123/19 127/15 129/4 132/23 135/18 139/22 141/12 147/3 147/7 153/5 153/24 155/24 158/9 158/9 163/21 168/24 170/12 182/25 187/14 189/21 190/11 190/12 191/16 192/23 193/3 195/10 195/25 198/9 198/11 198/12 198/12 199/5 199/13 202/21 204/24 205/2 211/4 215/8 215/10 218/11 218/24	219/17 219/18 220/10 222/11 224/4 224/24 226/5 228/2 232/16 232/17 232/24 234/11 234/16 <b>byproduct</b> [1] 218/10 <b>C</b> <b>Cacoub</b> [1] 153/14 <b>calcium</b> [1] 78/21 <b>calculation</b> [1] 191/25 <b>call</b> [15] 10/2 10/4 12/18 33/10 35/25 48/14 49/3 49/9 76/9 121/8 124/21 125/24 128/10 187/20 210/10 <b>called</b> [16] 33/4 33/9 57/5 61/8 83/15 84/23 85/5 87/14 93/6 108/24 109/19 110/2 113/1 113/5 118/3 127/12 <b>came</b> [6] 130/9 166/21 166/22 190/2 228/7 229/14 <b>camera</b> [1] 110/11 <b>campaign</b> [1] 200/20 <b>campaigns</b> [2] 57/19 197/16 <b>can</b> [233] 1/20 2/5 5/3 6/10 6/11 6/12 6/12 7/18 7/24 8/8 8/10 8/11 8/14 9/1 9/9 9/12 9/21 9/23 11/1 11/21 12/22 13/12 14/6 14/17 15/15 15/16 16/7 19/4 20/23 21/13 21/25 24/16 25/8 26/2 27/8 28/13 28/19 28/21 28/25 29/1 29/24 33/23 35/7 36/2 37/24 38/13 41/16 41/22 41/25 42/8 42/18 43/12 45/5 45/12 45/18 46/5 46/10 46/13 47/2 47/17 48/7 54/19 61/2 61/19 68/15 68/16 72/13 73/6 73/11 74/17 74/23 75/23 76/12 77/1 79/25 80/17 81/8 81/13 81/15 81/18 82/1 83/18 85/12 85/12 86/11 87/6 87/23 88/21 90/21 90/25 91/2 91/6 91/8 91/11 91/12 91/24 92/24 93/4 93/19 94/20 98/13 99/16 100/3 100/8 100/10 101/2 102/11 104/5 104/15 106/1 106/8 107/7	107/24 108/10 108/21 108/23 109/7 109/10 110/1 110/14 111/2 112/9 112/12 112/14 112/17 112/22 113/12 116/1 119/20 120/17 120/21 122/15 124/10 124/20 125/3 125/19 125/19 126/10 126/20 127/1 128/8 132/19 134/20 135/9 135/16 135/20 142/16 143/12 144/18 144/25 145/8 145/18 145/21 146/6 146/7 147/18 149/12 149/25 150/1 150/7 150/23 153/3 155/15 155/17 155/23 156/13 157/21 158/5 159/13 160/6 160/18 160/25 161/3 162/1 162/9 162/13 164/2 164/15 164/21 165/6 165/7 165/10 165/22 166/1 166/5 166/18 168/5 168/5 168/14 169/10 170/25 176/7 181/23 182/22 183/23 184/21 185/3 185/21 186/7 187/13 187/19 190/15 190/24 195/17 199/12 199/23 200/3 203/10 205/5 209/5 209/17 211/24 212/16 213/5 214/9 214/19 215/8 215/10 217/15 218/15 218/18 219/4 220/22 220/23 220/25 223/1 223/18 225/9 228/5 230/14 232/23 232/23 235/22 <b>can't</b> [8] 97/2 104/2 141/13 149/21 166/17 212/7 220/16 234/21 <b>cancer</b> [43] 16/8 26/14 64/8 64/9 64/13 64/16 65/5 66/8 66/21 67/2 78/17 82/13 87/24 87/25 88/2 88/17 89/22 90/9 91/17 97/11 106/14 115/21 116/1 116/2 116/7 116/11 116/12 116/20 117/20 117/24 118/9 118/15 119/3 119/9 119/10 119/12 156/22 156/23 167/13 169/23 170/18 211/6 212/16 <b>cancers</b> [9] 3/2 88/19 88/20 107/8 118/2 133/24 156/24 199/19 211/17
----------	---	--	---	---	---

<p><b>C</b></p> <p><b>candidate</b> [1] 108/14</p> <p><b>cannot</b> [1] 199/19</p> <p><b>capture</b> [1] 233/10</p> <p><b>captured</b> [1] 154/10</p> <p><b>cardiac</b> [1] 143/1</p> <p><b>cardiovascular</b> [1] 216/7</p> <p><b>cards</b> [1] 235/7</p> <p><b>care</b> [26] 2/10 2/23 103/22 104/3 118/23 118/24 176/13 181/17 181/20 181/23 182/24 184/11 186/2 187/2 187/3 187/21 188/3 193/2 193/17 195/25 195/25 202/9 202/10 217/6 230/12 230/15</p> <p><b>cared</b> [1] 112/19</p> <p><b>career</b> [1] 196/12</p> <p><b>careful</b> [3] 65/10 103/19 168/2</p> <p><b>carer</b> [1] 142/17</p> <p><b>carried</b> [2] 124/22 222/13</p> <p><b>carriers</b> [2] 18/20 93/7</p> <p><b>carries</b> [1] 61/24</p> <p><b>carry</b> [8] 7/22 62/11 97/4 97/5 124/10 148/3 170/19 174/19</p> <p><b>carrying</b> [1] 171/3</p> <p><b>cascading</b> [2] 196/5 217/8</p> <p><b>case</b> [18] 29/22 33/25 39/18 47/23 49/23 55/19 90/10 95/22 95/23 124/9 139/2 156/6 185/5 195/18 195/22 223/18 227/6 228/14</p> <p><b>cases</b> [22] 12/14 24/8 37/15 39/20 40/3 40/13 43/1 45/1 45/23 59/18 73/18 75/16 89/20 124/10 156/3 159/21 201/18 201/21 204/25 208/9 217/2 233/3</p> <p><b>catch</b> [1] 207/10</p> <p><b>categories</b> [3] 87/6 153/20 176/8</p> <p><b>category</b> [6] 155/19 176/8 178/8 178/9 179/8 200/8</p> <p><b>cater</b> [1] 177/1</p> <p><b>catered</b> [1] 184/15</p> <p><b>catheter</b> [1] 109/5</p> <p><b>causality</b> [2] 100/10 154/5</p> <p><b>causation</b> [1] 79/2</p> <p><b>cause</b> [24] 6/3 6/5 7/19 13/13 27/8 35/3</p>	<p>61/2 72/10 79/20 84/12 86/3 88/6 91/1 100/21 107/5 160/12 169/22 177/14 180/5 180/22 214/21 215/11 217/3 218/5</p> <p><b>caused</b> [11] 6/10 6/11 6/12 6/13 80/18 107/7 108/22 109/15 131/21 153/5 158/9</p> <p><b>causes</b> [20] 6/6 6/14 6/17 6/18 7/9 10/12 18/5 61/6 98/20 100/17 100/20 101/17 103/18 107/6 112/22 157/4 176/24 197/10 204/12 219/19</p> <p><b>causing</b> [4] 146/24 158/13 196/7 216/7</p> <p><b>caveats</b> [2] 185/13 234/5</p> <p><b>CD4</b> [1] 163/24</p> <p><b>CD4 cell</b> [1] 163/24</p> <p><b>cell</b> [12] 7/15 7/19 7/22 7/23 8/8 8/10 12/8 14/16 14/18 155/10 157/4 163/24</p> <p><b>cell's</b> [1] 7/12</p> <p><b>cells</b> [11] 7/18 7/20 7/25 8/2 9/10 9/14 14/15 80/11 83/4 83/25 147/3</p> <p><b>cellular</b> [2] 7/10 9/7</p> <p><b>cent</b> [21] 3/16 18/6 44/16 44/18 60/11 62/7 62/10 63/6 63/10 70/6 74/3 74/7 88/8 95/8 95/9 115/16 115/17 121/3 190/21 191/3 212/14</p> <p><b>central</b> [2] 39/6 83/14</p> <p><b>centre</b> [6] 2/21 82/21 114/8 114/14 132/7 214/7</p> <p><b>centres</b> [7] 113/21 114/2 116/8 117/4 131/23 132/4 214/6</p> <p><b>cerebral</b> [1] 143/8</p> <p><b>certain</b> [11] 25/22 33/19 78/19 78/19 97/2 165/11 165/12 190/23 194/24 216/3 223/4</p> <p><b>certainly</b> [31] 32/12 42/7 49/1 49/23 57/4 59/6 71/18 76/12 76/16 81/3 88/1 89/20 91/13 99/4 113/20 121/16 123/17 134/9 140/7 141/7 141/20 159/16 162/8 172/2 189/22 190/8 220/9 228/7 228/19 231/5</p>	<p>236/1</p> <p><b>certificate</b> [3] 99/20 100/6 100/12</p> <p><b>certificates</b> [2] 99/8 99/11</p> <p><b>cessation</b> [1] 157/24</p> <p><b>cetera</b> [3] 175/13 178/6 225/19</p> <p><b>chair</b> [1] 94/23</p> <p><b>challenge</b> [6] 35/15 102/9 142/16 197/6 208/15 222/22</p> <p><b>challenges</b> [1] 125/15</p> <p><b>challenging</b> [1] 214/2</p> <p><b>chance</b> [5] 65/4 163/4 163/13 223/16 228/8</p> <p><b>chances</b> [3] 55/22 226/14 226/15</p> <p><b>change</b> [12] 7/16 25/14 58/2 59/4 80/10 81/10 95/24 96/25 128/3 158/17 217/19 234/16</p> <p><b>changed</b> [13] 23/13 27/23 37/8 56/14 64/11 126/7 134/19 134/23 139/24 141/9 160/15 192/1 196/14</p> <p><b>changes</b> [5] 19/13 37/5 58/1 79/25 128/22</p> <p><b>changing</b> [6] 20/23 22/13 23/6 130/6 216/14 217/23</p> <p><b>channels</b> [2] 109/25 112/6</p> <p><b>characterise</b> [2] 35/9 49/21</p> <p><b>characterised</b> [1] 75/14</p> <p><b>characteristic</b> [1] 154/16</p> <p><b>characteristics</b> [2] 198/13 213/7</p> <p><b>chart</b> [2] 21/20 68/7</p> <p><b>cheap</b> [1] 192/6</p> <p><b>check</b> [4] 196/5 198/19 204/11 204/22</p> <p><b>checked</b> [1] 189/9</p> <p><b>checking</b> [2] 41/11 41/11</p> <p><b>chemical</b> [1] 14/8</p> <p><b>chemoembolisation</b> [1] 118/4</p> <p><b>chemotherapy</b> [1] 140/20</p> <p><b>chest</b> [1] 146/1</p> <p><b>child</b> [8] 41/20 42/9 84/6 84/14 85/5 85/15 85/17 116/14</p> <p><b>Child-Pugh</b> [6] 84/6 84/14 85/5 85/15 85/17 116/14</p>	<p><b>childbirth</b> [1] 200/16</p> <p><b>childhood</b> [1] 43/21</p> <p><b>children</b> [5] 43/9 43/20 43/23 74/2 74/4</p> <p><b>choice</b> [6] 129/11 163/5 174/1 179/6 184/5 196/20</p> <p><b>choices</b> [2] 123/7 132/8</p> <p><b>chosen</b> [2] 32/23 33/22</p> <p><b>chronic</b> [39] 2/24 6/21 7/25 11/18 18/20 36/4 44/8 44/15 44/24 49/10 62/13 62/16 64/3 65/2 71/7 72/19 74/19 75/3 75/5 75/23 76/3 76/10 76/23 77/7 77/15 77/24 79/6 79/10 82/4 88/5 91/15 101/20 143/23 160/2 160/3 160/24 178/25 192/13 218/17</p> <p><b>chronically</b> [3] 8/4 62/5 74/11</p> <p><b>chronology</b> [3] 31/13 32/17 32/19</p> <p><b>circulation</b> [2] 84/21 109/17</p> <p><b>circumstances</b> [5] 88/24 176/21 195/20 202/14 202/16</p> <p><b>cirrhosis</b> [84] 10/25 11/18 16/8 26/22 50/17 62/17 62/21 63/7 64/5 64/8 64/12 65/3 66/6 66/8 66/9 66/20 67/1 81/19 82/13 83/25 84/3 84/8 84/9 85/5 85/6 85/19 86/7 86/14 87/11 87/23 88/8 88/11 88/15 88/24 89/9 89/10 90/8 90/12 90/14 93/13 95/2 106/13 106/19 108/22 108/25 109/2 109/15 109/23 110/16 111/12 112/5 115/19 115/22 116/8 116/14 116/17 119/7 119/8 119/13 132/23 138/1 156/16 160/8 161/5 170/21 171/1 171/10 171/17 171/20 172/13 172/15 173/4 173/19 173/21 174/7 174/8 175/3 178/11 178/14 179/12 179/23 179/25 180/7 180/13</p> <p><b>cirrhotic</b> [3] 64/24 174/19 212/17</p> <p><b>clarification</b> [1] 67/5</p>	<p><b>clarified</b> [1] 175/3</p> <p><b>clarify</b> [1] 223/13</p> <p><b>clarity</b> [1] 57/16</p> <p><b>classification</b> [2] 137/1 153/16</p> <p><b>classifications</b> [1] 86/10</p> <p><b>classified</b> [1] 153/11</p> <p><b>classify</b> [1] 136/11</p> <p><b>clear</b> [35] 14/19 20/24 26/2 29/21 31/5 42/15 43/5 43/6 44/22 44/23 46/11 49/25 51/10 59/17 62/4 62/6 62/10 79/18 97/24 99/17 100/13 101/15 102/12 105/22 132/8 150/12 159/21 161/19 175/21 177/10 179/14 187/16 223/4 226/13 226/19</p> <p><b>clear-cut</b> [2] 44/22 226/19</p> <p><b>clearance</b> [6] 25/23 26/8 30/8 214/23 214/24 224/17</p> <p><b>cleared</b> [4] 8/6 28/8 228/17 232/25</p> <p><b>clearer</b> [1] 165/20</p> <p><b>clearing</b> [7] 8/9 74/12 74/14 123/17 123/24 228/11 228/20</p> <p><b>clearly</b> [40] 14/14 20/19 27/23 28/19 28/24 32/24 33/18 55/25 57/1 63/15 76/7 93/5 97/1 100/7 100/17 103/12 105/18 129/5 144/6 147/8 158/9 164/10 174/1 175/12 176/1 177/20 183/12 189/13 190/22 212/7 213/25 221/19 222/3 223/15 226/14 227/16 229/4 229/22 232/6 232/12</p> <p><b>clears</b> [1] 53/6</p> <p><b>clever</b> [1] 7/24</p> <p><b>clinic</b> [4] 3/22 117/5 178/22 178/23</p> <p><b>clinical</b> [19] 4/7 4/10 10/5 13/11 15/3 15/6 17/22 55/1 73/10 81/14 89/8 123/21 124/19 135/1 167/4 178/22 179/15 179/17 216/17</p> <p><b>clinically</b> [1] 3/17</p> <p><b>clinician</b> [7] 50/21 55/3 71/24 88/25 182/2 184/6 184/8</p> <p><b>clinician's</b> [1] 130/14</p> <p><b>clinicians</b> [2] 59/25 86/20</p>	<p><b>close</b> [5] 46/13 69/8 70/5 70/6 235/2</p> <p><b>closer</b> [2] 181/22 214/3</p> <p><b>closest</b> [1] 206/8</p> <p><b>clot</b> [2] 137/24 219/20</p> <p><b>clotting</b> [6] 81/25 84/25 219/15 219/17 219/21 219/25</p> <p><b>clusters</b> [1] 3/11</p> <p><b>co</b> [21] 4/13 12/19 13/2 64/15 64/17 93/21 95/10 102/16 103/25 104/7 137/10 143/22 144/7 159/2 159/14 159/18 162/20 163/13 164/3 164/25 172/16</p> <p><b>co-authored</b> [1] 4/13</p> <p><b>co-factors</b> [5] 64/15 64/17 95/10 143/22 172/16</p> <p><b>co-infected</b> [2] 162/20 163/13</p> <p><b>co-infection</b> [8] 12/19 13/2 102/16 159/2 159/14 159/18 164/3 164/25</p> <p><b>co-infections</b> [1] 93/21</p> <p><b>co-morbidities</b> [3] 103/25 104/7 137/10</p> <p><b>co-morbidity</b> [1] 144/7</p> <p><b>Cochrane</b> [4] 166/23 168/18 168/20 168/24</p> <p><b>code</b> [1] 21/17</p> <p><b>coding</b> [1] 136/25</p> <p><b>cognisant</b> [1] 184/21</p> <p><b>cognition</b> [1] 77/3</p> <p><b>cognitive</b> [2] 76/23 78/4</p> <p><b>cohesive</b> [1] 154/19</p> <p><b>cohort</b> [4] 55/16 59/2 177/18 210/18</p> <p><b>cohorts</b> [8] 60/17 60/20 60/23 63/14 63/16 96/19 160/9 233/12</p> <p><b>coincidence</b> [1] 190/1</p> <p><b>colleagues</b> [2] 140/16 188/3</p> <p><b>collected</b> [2] 144/24 153/22</p> <p><b>collectively</b> [2] 235/20 235/23</p> <p><b>collects</b> [1] 107/3</p> <p><b>College</b> [1] 3/6</p> <p><b>colour</b> [2] 21/17 218/12</p> <p><b>colour-code</b> [1] 21/17</p> <p><b>column</b> [4] 135/18 137/16 143/2 143/13</p>
--	---	--	--	---	--

<b>C</b>	219/9	<b>conclusions [1]</b> 38/3	154/18	149/18 186/1 187/5	<b>counterbalanced [1]</b>
<b>columns [1]</b> 145/24	<b>commonplace [1]</b>	<b>condemned [1]</b>	<b>constipated [1]</b>	204/15 227/20	26/25
<b>coma [3]</b> 75/18	35/24	168/24	112/11	<b>conversion [1]</b> 64/13	<b>countries [5]</b> 20/5
112/16 142/9	<b>communal [1]</b> 8/23	<b>condition [15]</b> 9/2	<b>constipation [1]</b>	<b>converted [1]</b> 14/7	43/17 43/18 44/1
<b>combination [4]</b>	<b>communication [1]</b>	10/24 55/3 70/3 86/23	113/2	<b>convulsions [1]</b>	214/8
18/21 36/11 66/23	65/18	106/23 107/7 111/10	<b>consultant [5]</b> 2/20	142/10	<b>country [5]</b> 23/17
187/21	<b>community [1]</b> 168/25	114/23 120/21 125/1	3/19 4/4 178/23	<b>COOKE [12]</b> 2/3 2/7	191/16 205/25 207/16
<b>combinations [2]</b>	<b>companies [1]</b> 134/11	130/3 161/1 183/20	209/23	2/9 10/13 31/13 49/17	213/24
148/9 149/2	<b>comparative [1]</b> 26/11	214/4	<b>consultant-led [1]</b>	95/11 159/15 194/11	<b>counts [1]</b> 137/23
<b>come [36]</b> 5/7 5/21	<b>comparatively [1]</b>	<b>conditions [28]</b> 6/12	178/23	222/5 223/9 236/5	<b>couple [16]</b> 24/15
10/20 14/18 22/17	27/15	6/13 82/2 82/9 91/8	<b>consultation [2]</b>	<b>copies [2]</b> 103/7	52/15 54/18 62/22
23/24 25/18 27/18	<b>compared [7]</b> 27/16	115/2 134/21 135/16	207/16 207/18	226/3	87/12 98/18 101/12
29/1 34/2 35/7 36/2	102/8 122/23 149/14	138/25 140/11 145/18	<b>consulting [1]</b> 200/18	<b>core [12]</b> 25/5 39/9	121/24 185/20 186/13
45/15 46/16 47/17	155/14 177/11 225/15	145/19 151/21 152/21	<b>contact [4]</b> 43/22 49/7	39/22 103/9 151/8	209/22 211/1 230/25
50/18 59/7 61/23	<b>comparing [1]</b> 88/19	153/4 155/7 155/9	61/23 63/25	166/7 181/11 184/12	231/2 234/17 234/20
65/18 72/13 72/25	<b>compensated [2]</b> 85/6	155/12 155/18 155/19	<b>contacts [1]</b> 199/16	187/23 192/23 205/2	<b>couples [1]</b> 47/9
82/8 95/19 98/2	178/13	155/21 155/22 156/1	<b>contains [1]</b> 83/15	224/7	<b>course [12]</b> 16/12
103/15 125/18 127/3	<b>competing [1]</b> 103/18	157/11 157/13 157/14	<b>contaminated [2]</b>	<b>correct [26]</b> 4/20 5/2	31/8 34/13 51/15
142/13 159/17 164/18	<b>complementary [1]</b>	192/16 197/5	45/3 233/16	10/16 30/25 38/12	97/23 124/19 130/18
167/10 167/12 168/4	50/8	<b>confident [3]</b> 141/2	<b>contemporaneous [1]</b>	42/10 42/21 50/23	133/3 151/11 161/24
208/21 230/7 235/24	<b>completely [6]</b> 49/25	141/11 168/6	32/7	61/13 74/9 77/5 78/21	163/4 204/24
<b>comes [5]</b> 6/23 33/19	53/10 83/24 94/16	<b>confidentiality [2]</b>	<b>content [2]</b> 4/18	92/11 98/22 102/20	<b>courses [1]</b> 29/9
78/12 141/18 205/17	123/16 167/5	40/9 40/15	201/22	105/16 113/11 115/18	<b>cover [2]</b> 90/11
<b>comfortable [1]</b>	<b>completeness [1]</b>	<b>confining [1]</b> 177/17	<b>context [14]</b> 25/25	124/16 135/15 136/3	212/22
168/11	41/19	<b>confirm [1]</b> 99/18	38/11 103/21 129/2	148/5 178/16 213/21	<b>covering [1]</b> 216/21
<b>coming [14]</b> 58/11	<b>completing [1]</b> 150/17	<b>confirmation [1]</b>	130/2 136/4 144/13	217/16 227/17	<b>covers [3]</b> 47/13
66/12 123/8 124/24	<b>completion [1]</b> 150/20	150/15	146/18 183/3 183/4	<b>correctly [4]</b> 55/19	189/2 202/9
129/18 133/13 142/18	<b>complex [1]</b> 207/22	<b>confirmed [2]</b> 39/18	194/15 219/14 219/16	70/2 80/25 112/5	<b>Covid [1]</b> 1/14
159/8 172/7 200/22	<b>complexity [1]</b> 189/13	39/19	219/23	<b>correlate [1]</b> 11/12	<b>Covid 19 [1]</b> 1/14
204/6 207/13 217/14	<b>complicated [3]</b>	<b>confuse [1]</b> 166/18	<b>continual [2]</b> 199/24	<b>cost [8]</b> 56/4 131/13	<b>cramps [1]</b> 145/13
226/4	164/15 165/3 165/12	<b>confusing [1]</b> 27/22	200/1	191/25 192/3 192/8	<b>create [1]</b> 66/18
<b>commensal [1]</b> 13/15	<b>complication [9]</b>	<b>confusion [6]</b> 27/8	<b>continually [1]</b> 200/2	192/14 192/15 192/16	<b>created [1]</b> 216/17
<b>comment [7]</b> 23/10	80/23 91/14 92/2 92/7	73/3 75/17 84/18	<b>continue [6]</b> 24/14	<b>costs [1]</b> 123/9	<b>creates [1]</b> 142/16
65/21 131/1 139/17	111/23 143/20 145/15	86/20 112/13	157/2 172/7 172/9	<b>could [78]</b> 12/1 14/1	<b>creating [2]</b> 36/22
188/22 195/17 205/7	162/14 164/24	<b>congenital [2]</b> 219/4	181/6 217/25	15/4 16/8 16/11 17/25	69/22
<b>comments [1]</b> 209/22	<b>complications [15]</b>	219/7	<b>continues [1]</b> 85/10	21/5 25/2 25/12 31/25	<b>criteria [5]</b> 54/22
<b>committed [1]</b> 24/13	2/24 90/22 96/10	<b>connective [1]</b> 145/10	<b>continuing [1]</b> 68/11	32/8 35/5 36/8 38/5	84/13 113/25 114/23
<b>committee [2]</b> 133/13	96/12 109/2 115/22	<b>cons [2]</b> 139/5 174/2	<b>contract [1]</b> 192/12	43/10 43/13 52/7	132/5
169/1	139/10 142/4 142/9	<b>consenting [1]</b> 201/5	<b>contrast [7]</b> 15/4	54/12 55/2 56/12	<b>critically [1]</b> 224/19
<b>committees [1]</b> 35/16	143/5 143/11 151/22	<b>consequence [5]</b> 91/7	42/13 55/12 118/6	57/11 57/12 60/5	<b>cross [1]</b> 80/19
<b>common [57]</b> 5/16	153/4 156/15 167/10	139/11 144/20 160/7	120/14 127/14 147/14	66/22 68/3 68/21	<b>crucial [1]</b> 35/3
10/9 10/12 13/14 14/4	<b>component [1]</b> 102/1	215/5	<b>contributed [2]</b> 4/18	72/20 91/9 92/17	<b>cryoglobulinemia [1]</b>
17/3 17/14 18/8 20/2	<b>components [2]</b>	<b>consequences [14]</b>	153/5	94/23 100/21 101/5	80/24
21/18 21/22 26/11	48/20 49/11	1/15 75/20 76/10	<b>control [10]</b> 3/25 41/3	101/13 104/14 106/22	<b>cryoglobulins [4]</b>
28/17 45/6 53/7 59/12	<b>compound [2]</b> 84/20	81/16 91/13 100/16	41/10 52/1 105/7	111/24 116/4 120/3	81/7 81/13 90/25
73/22 75/22 81/8	127/20	106/16 127/3 139/12	105/13 122/16 192/24	129/14 131/24 134/6	215/11
91/21 101/25 116/20	<b>comprehensive [3]</b>	143/16 151/22 167/4	194/15 194/22	135/2 136/13 142/1	<b>CT [2]</b> 212/1 212/13
119/2 121/12 135/20	31/20 101/8 146/13	169/11 228/6	<b>controlling [2]</b> 95/21	143/6 146/9 146/13	<b>curable [1]</b> 130/4
136/19 137/3 137/18	<b>concentrates [1]</b>	<b>Considerably [1]</b>	123/20	148/11 152/9 152/13	<b>curative [2]</b> 118/7
137/19 138/16 138/18	225/5	234/10	<b>controls [1]</b> 155/15	153/2 153/15 173/15	129/8
139/7 139/17 140/9	<b>concentration [2]</b>	<b>consideration [2]</b>	<b>controversy [3]</b>	178/3 180/8 183/17	<b>cure [33]</b> 27/15 36/10
143/2 145/4 145/4	142/6 195/11	114/15 184/23	131/22 166/20 168/13	186/17 187/2 192/10	123/24 125/13 126/3
145/4 145/14 145/15	<b>concentrations [1]</b>	<b>considerations [1]</b>	<b>convenient [3]</b> 47/22	193/2 196/7 196/23	126/12 127/2 127/6
145/15 145/23 145/24	147/12	182/15	47/24 151/3	196/24 198/3 198/3	128/1 128/2 128/8
146/8 147/2 147/10	<b>concept [4]</b> 68/25	<b>considered [5]</b> 107/23	<b>conversation [12]</b>	206/2 206/6 206/8	147/7 148/11 149/12
158/7 159/18 196/17	69/20 190/18 211/18	108/10 109/10 118/7	94/12 94/18 140/6	206/9 206/10 206/13	158/12 166/8 166/21
197/3 199/20 214/15	<b>conception [1]</b> 188/16	219/7	141/5 141/15 141/16	208/4 209/3 223/18	167/2 167/14 167/15
214/16 214/19 219/9	<b>concepts [2]</b> 5/4	<b>considering [1]</b> 1/15	186/4 187/14 188/1	228/7 233/13 233/17	167/16 167/21 167/23
221/11 221/14	69/25	<b>consistent [3]</b> 55/2	188/2 209/8 212/4	234/13	168/14 168/18 169/4
<b>commonly [11]</b> 9/10	<b>concern [4]</b> 41/2 46/1	155/8 188/9	<b>conversations [14]</b>	<b>couldn't [2]</b> 130/7	169/8 171/10 172/21
89/13 91/25 117/4	53/17 164/9	<b>constant [1]</b> 41/9	100/4 129/11 139/4	228/25	172/24 190/17 190/21
122/11 154/1 156/2	<b>concerned [2]</b> 96/20	<b>constantly [1]</b> 41/11	139/15 139/15 139/19	<b>count [3]</b> 138/3	228/4
211/20 216/2 216/19	231/6	<b>constellations [1]</b>	140/2 141/1 141/12	163/24 219/13	<b>cured [16]</b> 28/9 29/12

<b>C</b>	51/5 54/8 101/2 118/13 136/13 137/11 158/25 164/19 177/22 194/14 205/12 205/15 207/8 <b>dealing [7]</b> 7/6 14/3 70/1 71/25 148/8 169/18 209/24 <b>deals [1]</b> 186/24 <b>dealt [10]</b> 6/25 32/20 38/22 99/16 152/2 153/7 156/15 188/14 188/15 192/24 <b>death [15]</b> 24/5 99/8 99/11 99/19 99/20 100/5 100/6 100/9 100/11 101/17 103/19 105/19 160/12 168/22 221/7 <b>deaths [6]</b> 98/25 99/2 99/9 104/25 105/3 105/9 <b>decade [3]</b> 36/24 37/9 140/20 <b>decades [4]</b> 32/25 67/13 83/13 169/6 <b>decimal [1]</b> 234/17 <b>decision [8]</b> 20/20 54/25 126/14 174/4 181/2 181/9 182/1 184/2 <b>decision-making [4]</b> 181/2 181/9 182/1 184/2 <b>decisions [4]</b> 130/1 131/2 133/17 165/1 <b>declare [2]</b> 77/21 206/4 <b>decompensated [4]</b> 85/18 115/19 116/17 178/13 <b>decompensating [1]</b> 114/11 <b>decompensation [1]</b> 116/15 <b>decreased [1]</b> 138/20 <b>deemed [1]</b> 115/4 <b>deep [1]</b> 75/14 <b>defect [1]</b> 28/17 <b>deficiencies [1]</b> 219/16 <b>deficit [1]</b> 77/4 <b>define [5]</b> 5/24 50/1 50/2 51/20 75/3 <b>defined [2]</b> 51/24 232/12 <b>definite [1]</b> 64/12 <b>definition [2]</b> 52/10 79/8 <b>definitions [1]</b> 190/11 <b>definitive [2]</b> 87/6 129/18 <b>degree [1]</b> 87/17	<b>dehydrated [1]</b> 112/11 <b>delay [4]</b> 1/5 52/25 227/10 228/5 <b>delayed [1]</b> 1/10 <b>delays [4]</b> 59/11 134/22 195/15 195/16 <b>deliberately [1]</b> 34/5 <b>delighted [1]</b> 191/20 <b>deliver [2]</b> 58/13 207/1 <b>delivered [1]</b> 181/23 <b>delivery [2]</b> 42/1 42/10 <b>delta [6]</b> 11/24 12/5 12/18 18/17 93/22 124/13 <b>demanding [1]</b> 168/21 <b>dementia [1]</b> 156/18 <b>demonstrate [1]</b> 39/17 <b>deoxyribonucleic [1]</b> 14/5 <b>depend [3]</b> 70/7 105/17 203/23 <b>dependent [3]</b> 24/8 79/4 128/17 <b>depending [2]</b> 63/16 126/23 <b>depends [10]</b> 8/18 23/14 64/14 87/15 93/10 176/22 183/3 187/4 215/23 217/22 <b>depressants [1]</b> 141/3 <b>depressed [1]</b> 226/10 <b>depression [6]</b> 77/2 138/17 147/11 158/2 162/12 197/9 <b>depth [1]</b> 139/20 <b>describe [9]</b> 1/7 21/3 79/5 79/8 79/11 81/17 82/11 109/13 145/7 <b>described [26]</b> 33/1 43/20 44/11 48/10 54/15 57/2 60/8 69/1 75/11 76/19 81/3 85/14 87/21 91/4 102/14 115/11 135/20 194/24 195/10 195/22 196/10 196/17 197/1 201/11 202/12 228/11 <b>describes [3]</b> 116/21 188/6 214/18 <b>describing [2]</b> 97/18 144/17 <b>description [2]</b> 147/22 156/16 <b>descriptions [2]</b> 139/22 146/3 <b>descriptor [1]</b> 214/15 <b>designed [1]</b> 48/20 <b>despite [4]</b> 108/8 113/4 119/17 173/13	<b>destroy [1]</b> 7/21 <b>detail [19]</b> 13/18 19/3 34/3 34/7 39/4 40/11 46/8 66/12 67/8 68/20 116/3 135/8 146/20 147/22 147/25 166/12 168/20 170/1 182/7 <b>detailed [2]</b> 4/15 4/15 <b>details [4]</b> 40/16 59/23 67/9 205/11 <b>detect [8]</b> 28/15 35/13 40/25 56/12 201/12 211/25 224/20 224/23 <b>detectable [5]</b> 51/8 125/23 224/4 224/9 231/13 <b>detected [4]</b> 50/18 89/21 169/9 219/10 <b>detecting [1]</b> 28/15 <b>detection [7]</b> 3/11 53/24 56/5 201/16 201/18 211/11 221/25 <b>determinant [1]</b> 73/12 <b>determination [1]</b> 32/6 <b>determine [2]</b> 33/6 213/10 <b>determined [1]</b> 104/11 <b>develop [14]</b> 34/1 44/8 61/25 62/3 62/12 63/3 63/7 64/8 85/13 109/1 109/14 112/6 119/9 160/24 <b>developed [8]</b> 34/18 56/8 56/11 58/5 58/7 65/2 186/15 207/16 <b>developing [7]</b> 35/10 35/22 36/15 65/5 88/5 96/18 171/25 <b>development [14]</b> 56/15 62/16 64/10 64/13 67/1 67/1 85/24 96/13 109/8 128/12 129/23 131/8 163/17 191/9 <b>developments [1]</b> 59/23 <b>develops [5]</b> 83/12 88/12 107/2 107/10 143/24 <b>diabetes [2]</b> 78/17 216/6 <b>diagnosable [1]</b> 224/15 <b>diagnose [3]</b> 31/9 35/6 88/16 <b>diagnosed [12]</b> 69/5 88/7 89/22 97/15 119/8 119/11 119/17 150/13 183/4 227/15 227/16 227/18 <b>diagnoses [2]</b> 196/6	199/18 <b>diagnosing [1]</b> 49/2 <b>diagnosis [35]</b> 47/18 48/13 49/4 49/6 52/6 64/12 67/7 70/19 70/21 71/11 77/12 99/25 129/13 150/15 173/20 174/7 174/8 183/8 184/18 184/24 185/16 187/7 190/17 195/16 195/21 197/9 197/20 199/8 207/24 209/7 209/25 210/20 227/10 227/23 228/5 <b>diagnostic [22]</b> 10/17 10/19 34/2 35/1 48/6 50/14 51/4 51/19 52/13 52/17 53/15 53/23 57/1 69/1 69/2 69/15 69/21 70/5 70/9 70/10 90/6 215/19 <b>diagnostics [1]</b> 53/21 <b>dialysed [1]</b> 194/4 <b>dialysis [7]</b> 71/19 91/10 193/20 193/24 194/1 194/6 194/10 <b>did [11]</b> 56/24 57/9 148/3 158/3 168/21 194/18 198/9 212/10 220/3 224/15 229/17 <b>didn't [18]</b> 29/21 34/15 40/25 43/23 100/18 128/3 158/17 162/6 167/3 167/5 168/22 189/4 192/13 198/15 212/22 227/25 228/15 228/24 <b>die [6]</b> 11/13 11/14 11/16 100/9 101/20 192/13 <b>died [2]</b> 100/15 100/16 <b>dies [2]</b> 104/20 104/23 <b>dietary [1]</b> 107/14 <b>differ [1]</b> 90/3 <b>difference [14]</b> 15/9 16/1 16/14 22/19 28/16 44/19 88/18 126/18 142/18 193/19 194/9 211/12 211/14 225/18 <b>differences [10]</b> 14/1 15/18 16/5 16/7 20/25 45/13 45/15 194/11 194/22 229/18 <b>different [88]</b> 5/11 6/5 7/15 7/16 10/1 14/5 14/7 14/8 14/12 14/13 15/5 15/11 15/14 15/17 15/19 15/22 17/12 19/21 20/4 20/10 21/12 21/23	28/22 28/22 28/25 33/2 38/17 46/23 47/4 48/11 51/22 56/20 57/8 57/9 61/5 66/23 74/16 78/23 82/12 82/17 86/19 93/16 93/25 99/22 106/7 106/8 114/19 117/15 119/22 120/10 125/10 131/18 131/18 131/21 132/3 132/4 132/7 132/16 132/17 132/18 143/11 150/4 150/24 151/2 159/23 161/2 161/20 162/2 162/4 163/10 164/14 166/14 174/14 176/7 183/8 184/14 186/7 186/8 189/13 189/14 193/25 201/6 212/12 214/8 214/8 223/17 223/17 234/19 <b>differentially [1]</b> 132/17 <b>differentiate [1]</b> 77/11 <b>differentiation [3]</b> 77/20 78/1 78/11 <b>differently [2]</b> 16/24 77/18 <b>difficult [30]</b> 15/8 27/3 31/1 47/14 56/25 57/10 65/17 71/16 100/2 100/3 101/10 103/16 125/1 126/13 136/6 139/3 139/15 140/5 147/20 162/24 179/8 181/22 199/20 199/24 211/25 224/11 225/23 233/8 233/13 234/20 <b>difficulties [3]</b> 1/11 100/24 195/11 <b>DILLON [9]</b> 1/24 4/2 18/16 58/7 168/16 199/6 205/7 213/1 235/17 <b>Dillon's [3]</b> 58/20 185/5 190/6 <b>diminishing [1]</b> 23/8 <b>direct [9]</b> 41/16 79/19 110/13 139/11 147/23 206/17 224/21 225/1 225/10 <b>directed [1]</b> 40/1 <b>directly [13]</b> 8/11 35/25 48/21 49/16 56/12 72/4 121/9 127/12 127/22 128/7 136/5 161/17 215/9 <b>director [1]</b> 3/24 <b>disadvantages [1]</b> 86/24 <b>disagreed [1]</b> 180/20
----------	---	---	---	--	---

<b>D</b>	90/3 133/23 175/18 205/23 <b>disagreeing [1]</b> 87/3 <b>disagreement [1]</b> 4/17 <b>disappear [1]</b> 175/6 <b>discharged [1]</b> 176/13 <b>disclose [2]</b> 235/8 235/15 <b>disclosed [3]</b> 100/1 103/8 130/17 <b>disconcerting [1]</b> 1/19 <b>discovered [6]</b> 13/8 33/16 33/24 34/16 60/22 183/11 <b>discovery [5]</b> 13/8 32/23 33/9 34/19 35/2 <b>discrepancy [1]</b> 132/15 <b>discrete [1]</b> 195/4 <b>discuss [5]</b> 73/11 94/14 156/14 179/23 187/13 <b>discussed [13]</b> 70/17 73/5 76/22 111/23 141/22 147/13 150/23 174/3 177/3 187/7 201/9 214/2 222/8 <b>discussing [4]</b> 74/11 169/14 185/18 207/14 <b>discussion [24]</b> 6/1 16/15 20/22 32/14 65/14 105/24 126/14 129/15 141/6 149/25 163/1 163/3 163/10 163/17 175/8 176/23 180/21 181/1 182/15 183/8 183/25 185/2 208/5 210/16 <b>discussion/decision</b> <b>[1]</b> 126/14 <b>discussions [4]</b> 129/3 140/8 141/7 182/2 <b>disease [53]</b> 13/16 16/13 26/14 50/9 60/12 60/21 61/7 64/20 69/4 69/14 69/17 78/18 79/12 82/4 83/11 85/8 88/5 88/10 90/1 90/14 94/2 98/13 106/13 107/6 107/8 107/8 129/14 130/7 133/4 137/25 138/3 141/17 143/24 156/15 156/17 159/6 160/7 160/11 161/3 162/25 163/16 167/20 170/13 174/24 179/1 213/15 215/12 216/7 217/3 219/15 227/22 228/3 228/5 <b>diseases [9]</b> 2/22 2/25 2/25 4/10 78/17	202/5 204/24 207/19 208/7 210/6 210/10 213/18 215/25 224/21 225/1 225/1 226/18 226/18 <b>doctor [4]</b> 196/12 203/21 204/14 205/17 <b>doctors [4]</b> 5/11 67/24 175/19 203/2 <b>document [3]</b> 68/5 136/22 189/11 <b>documented [1]</b> 12/14 <b>documents [1]</b> 189/8 <b>does [25]</b> 7/7 7/13 12/8 26/23 30/6 42/3 66/18 70/7 85/23 105/17 112/2 127/20 147/6 165/11 190/13 202/25 203/23 211/14 225/5 225/6 226/22 227/10 230/11 231/11 233/4 <b>does it [2]</b> 203/23 225/6 <b>doesn't [32]</b> 6/2 6/4 7/21 11/12 13/13 14/20 19/12 26/4 28/9 40/19 47/15 69/17 80/13 81/10 97/11 108/1 108/25 134/22 136/15 154/10 154/11 155/2 155/3 166/16 170/6 172/21 197/6 198/22 214/20 225/13 225/22 229/15 <b>doing [17]</b> 71/20 94/11 105/16 176/21 190/7 191/25 198/16 199/4 203/21 204/9 212/9 212/12 215/24 217/22 233/7 233/7 233/9 <b>dolls [2]</b> 18/22 18/23 <b>dominant [1]</b> 28/3 <b>dominate [1]</b> 164/17 <b>dominated [1]</b> 22/1 <b>don't [66]</b> 14/20 15/9 15/24 17/5 18/7 19/9 19/10 22/10 23/15 23/16 23/17 24/2 29/3 40/7 40/11 44/23 44/25 50/12 55/9 55/16 69/15 69/16 71/10 78/20 79/11 104/3 107/17 119/7 122/3 128/21 128/25 134/10 136/21 146/10 149/2 154/7 154/12 155/3 158/21 169/5 174/9 177/5 179/6 179/9 185/23 197/20 197/21 200/14 202/5	204/17 210/8 210/15 210/19 217/17 220/4 221/13 221/17 222/24 224/3 225/8 225/24 227/5 230/12 232/2 234/1 234/12 <b>donate [1]</b> 222/1 <b>donation [3]</b> 39/3 222/3 224/25 <b>donations [1]</b> 39/13 <b>done [32]</b> 32/1 32/1 36/19 38/6 38/6 41/5 48/8 48/14 58/21 72/4 81/9 110/8 110/10 111/18 111/20 134/2 134/13 141/13 152/4 175/19 185/25 186/7 186/17 186/19 188/11 189/1 197/23 198/21 199/5 200/12 206/5 222/24 <b>donor [3]</b> 220/20 221/16 221/21 <b>donors [1]</b> 223/18 <b>door [2]</b> 185/1 209/12 <b>dormant [1]</b> 166/2 <b>dose [1]</b> 62/8 <b>doubled [1]</b> 234/11 <b>doubt [2]</b> 81/12 180/18 <b>down [15]</b> 2/8 9/11 23/24 57/13 83/9 147/3 152/12 156/12 157/2 180/3 187/20 187/24 217/4 231/18 234/16 <b>downwards [1]</b> 24/11 <b>DR [10]</b> 1/25 2/1 2/2 2/1 87/21 174/23 195/6 205/13 209/20 215/16 <b>DR AILEEN [1]</b> 2/2 <b>Dr Jamieson [3]</b> 195/6 205/13 215/16 <b>Dr Jeffery [3]</b> 21/1 87/21 209/20 <b>DR KATIE [1]</b> 1/25 <b>Dr Marshall's [1]</b> 174/23 <b>DR SCOTT [1]</b> 2/1 <b>drain [1]</b> 82/24 <b>drainage [1]</b> 108/2 <b>drained [2]</b> 107/24 109/7 <b>dramatic [4]</b> 80/9 81/13 103/3 105/17 <b>dramatically [4]</b> 9/25 97/9 134/19 170/17 <b>draw [4]</b> 155/9 180/15 188/20 227/25 <b>drawback [1]</b> 121/20 <b>drawing [1]</b> 156/18 <b>drawn [2]</b> 38/2 143/19	<b>draws [1]</b> 136/7 <b>driven [2]</b> 37/4 107/13 <b>drop [1]</b> 138/4 <b>drug [23]</b> 36/2 45/5 101/24 113/1 113/5 118/11 118/15 118/16 121/15 122/6 122/11 122/11 122/14 122/19 129/23 131/8 133/12 136/18 140/18 162/10 198/23 202/17 229/21 <b>drugs [37]</b> 6/11 36/2 120/12 121/9 123/7 123/13 124/24 127/12 127/21 128/4 128/12 128/13 128/16 128/18 129/17 129/22 129/24 130/16 130/22 130/22 131/14 131/15 133/13 133/15 133/25 134/4 134/6 134/18 144/10 148/16 148/18 149/19 149/21 172/23 181/5 202/4 231/17 <b>duct [1]</b> 82/23 <b>ducts [1]</b> 83/16 <b>due [11]</b> 22/4 30/21 40/14 81/22 81/24 90/12 99/9 115/1 123/9 136/18 226/10 <b>Dundee [2]</b> 4/4 4/6 <b>durable [1]</b> 122/2 <b>duration [4]</b> 65/21 65/24 149/7 149/8 <b>durations [2]</b> 149/13 161/13 <b>during [7]</b> 34/12 41/25 42/9 43/21 147/18 163/17 200/16 <b>Dutch [4]</b> 101/4 102/4 102/15 103/8 <b>dwarfed [1]</b> 226/5 <b>dying [6]</b> 9/17 103/5 105/6 105/7 105/12 105/13 <b>dynamic [3]</b> 22/12 24/9 24/15 <b>dysfunction [1]</b> 157/5	<b>earliest [1]</b> 53/2 <b>early [30]</b> 13/3 27/1 31/25 34/16 35/11 44/7 49/7 60/5 63/19 63/20 88/13 88/17 88/19 103/5 115/21 117/16 119/15 126/10 126/21 141/9 169/9 175/5 187/9 225/5 227/15 227/16 227/23 228/23 229/1 235/5 <b>ease [1]</b> 27/24 <b>easier [8]</b> 1/23 20/13 27/12 100/6 154/16 165/15 165/20 200/3 <b>easily [4]</b> 51/24 152/19 154/17 224/15 <b>EASL [1]</b> 176/4 <b>East [2]</b> 21/14 103/14 <b>easy [5]</b> 27/14 27/21 51/19 199/3 209/3 <b>echo [1]</b> 1/18 <b>economics [1]</b> 192/19 <b>edema [1]</b> 143/3 <b>Edinburgh [1]</b> 59/11 <b>educate [2]</b> 67/24 199/3 <b>educating [1]</b> 181/16 <b>education [2]</b> 196/3 206/11 <b>Efavirenz [1]</b> 162/11 <b>effect [23]</b> 24/5 26/5 26/6 26/24 36/9 101/21 102/1 107/20 121/16 122/19 123/4 123/11 138/6 149/16 153/24 214/12 223/12 225/6 225/14 225/23 226/14 227/11 227/13 <b>effective [13]</b> 27/2 29/15 45/17 123/5 123/14 132/24 133/7 160/18 161/10 161/18 184/1 192/6 225/18 <b>effectively [4]</b> 91/17 112/15 185/19 231/9 <b>effectiveness [1]</b> 56/4 <b>effects [30]</b> 78/14 79/19 106/16 107/18 120/2 120/24 122/21 122/21 125/6 127/4 130/5 137/3 139/23 140/9 140/25 143/16 146/8 146/14 146/21 146/25 147/10 147/15 147/15 148/4 149/9 151/19 162/2 162/10 167/20 197/3 <b>effort [3]</b> 190/13 199/24 235/24 <b>EIA [1]</b> 49/21 <b>EIAs [1]</b> 48/10 <b>eight [4]</b> 14/25 17/20
----------	---	---	--	--	---

<p><b>E</b></p> <p><b>eight...</b> [2] 19/1 148/18</p> <p><b>eight years</b> [1] 148/18</p> <p><b>eightfold</b> [2] 67/14 67/20</p> <p><b>eighties</b> [2] 31/24 202/4</p> <p><b>either</b> [12] 42/14 49/10 111/2 112/3 126/11 131/5 132/24 152/16 153/5 158/21 174/12 179/9</p> <p><b>elaborate</b> [1] 16/9</p> <p><b>elapse</b> [2] 89/1 89/2</p> <p><b>element</b> [1] 161/25</p> <p><b>elements</b> [1] 32/9</p> <p><b>eliminate</b> [3] 58/25 188/24 199/10</p> <p><b>elimination</b> [10] 24/13 37/14 58/14 189/17 189/24 190/9 190/11 190/19 191/5 201/17</p> <p><b>else</b> [5] 8/9 108/5 158/13 158/24 200/19</p> <p><b>elsewhere</b> [2] 41/16 152/16</p> <p><b>embarked</b> [1] 97/22</p> <p><b>embarking</b> [1] 139/5</p> <p><b>embarrassed</b> [1] 191/16</p> <p><b>embolisation</b> [2] 118/4 118/7</p> <p><b>embolism</b> [1] 143/15</p> <p><b>emerge</b> [1] 228/21</p> <p><b>emerged</b> [1] 30/19</p> <p><b>emergence</b> [2] 32/10 122/14</p> <p><b>emergency</b> [3] 111/9 111/15 201/6</p> <p><b>emerging</b> [2] 34/24 121/23</p> <p><b>emotional</b> [1] 138/19</p> <p><b>emphasise</b> [5] 43/25 96/4 120/9 126/6 136/14</p> <p><b>emphasises</b> [2] 1/11 126/17</p> <p><b>emphasising</b> [6] 9/21 56/7 94/5 95/20 161/24 172/19</p> <p><b>empowering</b> [1] 181/16</p> <p><b>enabled</b> [1] 227/19</p> <p><b>encephalopathy</b> [7] 81/21 84/17 86/2 111/24 112/20 112/25 113/7</p> <p><b>end</b> [13] 32/15 35/4 83/8 83/25 89/11 131/5 177/4 178/9 179/9 216/16 217/7 218/17 229/3</p>	<p><b>endocarditis</b> [1] 135/25</p> <p><b>Endocrine</b> [1] 138/11</p> <p><b>endoscopic</b> [1] 180/23</p> <p><b>endoscopy</b> [3] 110/11 110/17 111/18</p> <p><b>ends</b> [1] 216/19</p> <p><b>endured</b> [2] 158/4 229/10</p> <p><b>engage</b> [2] 230/11 230/14</p> <p><b>engaged</b> [1] 1/14</p> <p><b>England</b> [9] 23/5 24/12 67/17 131/4 131/20 189/2 220/24 222/8 222/10</p> <p><b>English</b> [2] 23/22 189/23</p> <p><b>enlarge</b> [1] 110/1</p> <p><b>enough</b> [6] 16/14 80/10 90/9 90/15 115/6 205/14</p> <p><b>enquired</b> [1] 78/6</p> <p><b>ensure</b> [3] 70/18 71/10 114/23</p> <p><b>ensuring</b> [2] 184/3 185/4</p> <p><b>entecavir</b> [1] 123/1</p> <p><b>entire</b> [1] 175/15</p> <p><b>entirely</b> [1] 202/15</p> <p><b>entitled</b> [2] 173/9 173/16</p> <p><b>entity</b> [1] 14/8</p> <p><b>entry</b> [1] 137/12</p> <p><b>environment</b> [5] 46/9 182/17 182/25 183/13 183/18</p> <p><b>enzyme</b> [4] 48/14 48/19 48/25 69/7</p> <p><b>enzymes</b> [5] 9/3 9/5 9/11 9/22 10/3</p> <p><b>epidemic</b> [1] 34/25</p> <p><b>epidemiology</b> [1] 104/8</p> <p><b>episode</b> [2] 86/2 114/11</p> <p><b>equal</b> [1] 184/5</p> <p><b>equally</b> [5] 9/23 25/12 94/17 161/16 188/2</p> <p><b>equals</b> [2] 231/6 231/7</p> <p><b>era</b> [9] 27/9 27/19 33/8 43/25 106/17 126/24 128/11 149/1 229/17</p> <p><b>err</b> [1] 180/22</p> <p><b>error</b> [1] 87/14</p> <p><b>escape</b> [1] 11/10</p> <p><b>especially</b> [3] 107/24 207/23 209/6</p> <p><b>essentially</b> [2] 72/15 90/4</p>	<p><b>establish</b> [3] 61/19 114/22 213/17</p> <p><b>established</b> [5] 104/13 158/15 160/4 173/19 232/6</p> <p><b>estimate</b> [7] 21/16 22/6 46/13 46/17 87/7 172/2 174/11</p> <p><b>estimated</b> [5] 30/18 47/9 87/20 115/15 234/8</p> <p><b>estimates</b> [7] 22/4 22/23 23/18 46/2 101/11 222/7 235/5</p> <p><b>estimating</b> [1] 100/24</p> <p><b>et</b> [4] 153/14 175/13 178/6 225/19</p> <p><b>etc</b> [1] 41/4</p> <p><b>Europe</b> [1] 160/9</p> <p><b>European</b> [5] 20/5 21/20 89/25 161/11 191/15</p> <p><b>evading</b> [1] 8/4</p> <p><b>even</b> [31] 18/21 38/15 44/1 52/15 58/4 69/16 70/1 75/16 83/13 85/11 95/24 96/24 97/25 101/20 118/12 118/18 119/18 126/14 137/2 143/16 148/17 149/21 150/21 150/22 150/22 162/5 162/9 169/15 192/6 196/14 212/13</p> <p><b>event</b> [4] 1/12 110/8 114/11 135/20</p> <p><b>events</b> [8] 36/22 120/2 125/6 135/6 136/5 143/16 149/20 151/20</p> <p><b>eventualities</b> [1] 47/14</p> <p><b>eventually</b> [2] 83/23 231/18</p> <p><b>ever</b> [7] 111/13 198/9 200/25 201/1 204/24 226/17 232/23</p> <p><b>every</b> [9] 19/11 89/14 137/11 143/19 175/21 181/20 192/7 193/11 200/5</p> <p><b>everybody</b> [16] 18/4 23/16 69/13 120/1 124/6 131/16 132/12 134/1 141/12 150/11 188/5 190/22 203/9 203/12 203/15 203/19</p> <p><b>everybody's</b> [1] 202/3</p> <p><b>everyone</b> [3] 47/6 104/20 104/23</p> <p><b>everything</b> [2] 141/13 167/16</p> <p><b>everywhere</b> [1]</p>	<p>128/19</p> <p><b>evidence</b> [70] 5/20 8/20 10/3 26/17 28/24 29/23 30/9 31/1 36/13 44/24 51/12 57/1 59/10 59/10 59/13 76/16 77/1 82/10 91/22 92/15 96/13 97/20 98/17 99/16 102/12 113/14 113/15 137/14 138/10 138/15 139/18 145/2 151/7 153/19 153/22 153/23 153/23 154/8 154/8 154/9 154/10 154/12 155/4 155/11 156/8 157/15 167/2 169/20 170/9 173/11 176/10 177/5 182/20 187/22 188/5 212/2 216/13 219/8 223/8 224/5 225/12 225/24 225/25 226/13 226/20 227/5 228/20 232/3 232/18 233/6</p> <p><b>evolved</b> [4] 89/3 114/3 129/5 183/21</p> <p><b>evolves</b> [1] 19/22</p> <p><b>evolving</b> [4] 33/20 58/9 59/5 217/24</p> <p><b>exact</b> [2] 197/3 204/18</p> <p><b>exactly</b> [7] 19/10 51/1 177/6 203/25 210/8 221/21 222/20</p> <p><b>exaggerate</b> [1] 106/2</p> <p><b>examination</b> [1] 180/24</p> <p><b>examine</b> [1] 119/22</p> <p><b>Examined</b> [1] 2/4</p> <p><b>examines</b> [1] 73/20</p> <p><b>example</b> [29] 10/7 14/9 14/17 16/11 19/17 26/7 27/17 37/20 48/22 79/7 81/15 86/24 87/5 91/6 91/9 96/22 99/24 101/18 103/14 104/8 115/21 122/23 127/17 133/24 133/25 142/21 161/11 189/15 222/22</p> <p><b>examples</b> [6] 12/11 16/2 16/10 104/8 186/13 186/17</p> <p><b>Excellence</b> [1] 89/8</p> <p><b>exception</b> [2] 16/18 216/10</p> <p><b>exceptions</b> [2] 18/13 194/25</p> <p><b>excess</b> [5] 19/2 90/9 102/13 105/18 218/8</p> <p><b>excess risk</b> [1] 105/18</p>	<p><b>exchange</b> [1] 183/7</p> <p><b>exclude</b> [1] 205/20</p> <p><b>excreted</b> [1] 218/11</p> <p><b>executive</b> [1] 3/7</p> <p><b>exercise</b> [1] 38/7</p> <p><b>exercises</b> [1] 201/15</p> <p><b>Exeter</b> [1] 196/19</p> <p><b>exhaustive</b> [1] 31/21</p> <p><b>exist</b> [1] 71/9</p> <p><b>existed</b> [1] 33/1</p> <p><b>existence</b> [1] 90/19</p> <p><b>existing</b> [2] 140/10 171/8</p> <p><b>exists</b> [2] 26/15 177/6</p> <p><b>expect</b> [20] 5/21 5/23 54/18 124/4 128/21 140/3 150/1 154/1 171/11 173/9 176/12 176/20 178/18 182/12 184/8 193/6 193/11 193/15 194/23 195/19</p> <p><b>expectancy</b> [8] 98/16 100/25 101/12 101/15 102/6 102/17 103/17 104/11</p> <p><b>expectation</b> [1] 102/24</p> <p><b>expected</b> [5] 5/1 41/7 118/22 183/5 215/18</p> <p><b>experience</b> [18] 3/21 76/23 77/8 77/9 79/3 79/4 79/7 81/18 106/24 111/13 122/13 132/6 181/13 188/7 193/21 205/19 205/21 210/17</p> <p><b>experienced</b> [1] 158/1</p> <p><b>experiences</b> [3] 79/13 132/3 145/6</p> <p><b>experiencing</b> [2] 79/1 165/3</p> <p><b>experiment</b> [2] 226/17 233/9</p> <p><b>expert</b> [3] 40/5 159/7 216/14</p> <p><b>experts</b> [3] 1/13 4/14 40/5</p> <p><b>EXPG0000001</b> [1] 20/14</p> <p><b>explain</b> [20] 8/24 11/1 14/1 15/5 15/8 16/7 43/13 51/1 52/7 61/12 74/17 100/23 109/11 111/24 145/18 153/15 155/23 173/15 193/3 209/9</p> <p><b>explained</b> [7] 15/2 19/1 30/12 44/6 54/23 98/19 175/1</p> <p><b>explaining</b> [4] 74/21 157/4 181/10 217/6</p> <p><b>explains</b> [1] 16/4</p> <p><b>explanation</b> [9] 22/2</p>	<p>39/2 67/20 182/18 183/1 184/16 191/8 202/24 218/2</p> <p><b>explore</b> [1] 154/22</p> <p><b>explored</b> [1] 97/23</p> <p><b>exponentially</b> [1] 64/23</p> <p><b>exposed</b> [7] 21/11 30/10 65/23 66/1 223/10 223/15 223/19</p> <p><b>exposure</b> [9] 7/8 22/24 30/6 54/10 72/12 160/25 225/3 227/2 232/11</p> <p><b>exposure-prone</b> [1] 232/11</p> <p><b>exposures</b> [1] 28/25</p> <p><b>expressed</b> [1] 106/8</p> <p><b>extent</b> [5] 93/20 149/9 171/7 218/6 227/8</p> <p><b>externa</b> [1] 135/25</p> <p><b>extra</b> [2] 107/15 153/10</p> <p><b>extrapolate</b> [1] 103/16</p> <p><b>eye</b> [1] 142/25</p> <p><b>eyesight</b> [1] 142/3</p> <hr/> <p><b>F</b></p> <p><b>faced</b> [1] 210/7</p> <p><b>facial</b> [1] 142/10</p> <p><b>facilitate</b> [1] 184/20</p> <p><b>fact</b> [18] 32/4 41/12 48/18 51/6 54/6 59/25 61/20 69/12 70/14 83/2 131/2 139/25 190/14 191/18 196/23 217/12 220/15 228/16</p> <p><b>factor</b> [9] 88/4 105/11 108/7 162/13 164/22 219/16 225/4 233/11 235/9</p> <p><b>factors</b> [27] 30/23 62/9 64/15 64/17 66/14 81/25 84/25 85/4 85/14 88/9 93/17 93/23 94/7 95/10 103/24 104/5 116/10 117/10 117/15 119/5 143/22 149/24 172/16 203/5 219/17 219/22 219/25</p> <p><b>facts</b> [1] 61/20</p> <p><b>factual</b> [1] 61/16</p> <p><b>fail</b> [1] 121/21</p> <p><b>failed</b> [1] 41/13</p> <p><b>failing</b> [1] 218/19</p> <p><b>failsafe</b> [1] 174/21</p> <p><b>failure</b> [20] 40/24 67/2 71/8 75/17 82/3 85/25 91/10 97/7 97/9 106/14 106/19 169/23 170/17 171/13 171/14 171/22 172/14 172/16</p>
--	---	--	--	--	---

<b>F</b>	213/4 213/13 213/22 <b>fibroscans</b> [3] 212/19 213/8 213/18 <b>fibrosis</b> [27] 10/25 11/17 11/18 50/17 62/23 66/5 82/13 83/11 83/18 84/2 86/5 86/8 86/11 87/18 87/23 96/25 97/16 161/5 167/12 170/22 170/22 178/2 179/11 179/19 180/19 212/25 213/3 <b>fibrous</b> [1] 83/21 <b>field</b> [4] 35/10 64/10 140/15 168/13 <b>fighting</b> [1] 1/14 <b>figure</b> [13] 20/10 21/4 21/7 23/3 47/13 68/3 106/10 117/2 125/4 125/8 125/10 221/4 233/9 <b>figures</b> [10] 30/15 47/5 63/13 65/4 77/6 220/22 221/3 221/5 221/12 221/13 <b>filaments</b> [1] 83/6 <b>filled</b> [2] 100/12 235/7 <b>final</b> [3] 66/11 227/7 228/10 <b>finally</b> [2] 33/21 148/24 <b>find</b> [29] 17/25 29/20 29/21 29/23 31/1 41/17 51/14 57/9 57/10 57/11 78/5 86/22 87/3 101/10 101/13 152/7 154/2 168/6 182/8 186/11 197/6 197/21 202/2 203/15 204/24 206/12 208/9 212/6 220/8 <b>finding</b> [2] 51/17 80/16 <b>fine</b> [3] 82/25 83/6 83/21 <b>finger</b> [1] 233/1 <b>fingers</b> [1] 81/2 <b>finished</b> [1] 167/9 <b>finishes</b> [1] 125/22 <b>first</b> [60] 5/4 5/8 29/24 30/19 31/15 32/22 33/9 34/20 35/24 35/24 36/24 38/23 41/20 44/9 48/7 49/7 51/5 52/22 54/3 54/11 56/9 57/5 62/22 72/17 72/21 72/23 73/13 89/7 96/19 106/21 106/24 112/25 119/6 120/4 120/12 121/10 122/3 122/25 126/6 126/8 127/23 137/2	140/23 142/1 142/14 147/22 152/9 170/10 176/8 176/24 177/14 195/5 204/4 207/1 211/1 217/23 228/15 228/25 230/5 231/2 <b>first-hand</b> [1] 106/24 <b>firstly</b> [2] 89/25 98/18 <b>fistulas</b> [1] 219/6 <b>fit</b> [2] 114/16 115/5 <b>fitness</b> [1] 115/1 <b>five</b> [17] 6/19 62/12 64/2 74/3 84/13 85/13 93/3 93/13 105/7 105/9 105/11 117/19 134/3 150/21 170/14 170/16 217/14 <b>five years</b> [3] 170/14 170/16 217/14 <b>five-year</b> [1] 117/19 <b>flag</b> [2] 188/4 200/14 <b>flare</b> [1] 165/7 <b>flesh</b> [1] 183/24 <b>flight</b> [1] 1/8 <b>florid</b> [1] 8/16 <b>flow</b> [1] 109/18 <b>flowing</b> [2] 111/6 111/22 <b>flu</b> [3] 75/12 127/17 139/21 <b>flu-like</b> [2] 75/12 139/21 <b>fluctuating</b> [1] 84/17 <b>fluid</b> [7] 86/1 107/3 107/12 107/24 107/25 108/2 109/7 <b>flushes</b> [1] 146/2 <b>focus</b> [11] 6/9 6/21 13/19 21/2 23/1 31/16 36/19 38/25 43/11 202/21 216/11 <b>focused</b> [2] 9/8 35/17 <b>focuses</b> [1] 2/15 <b>fog</b> [3] 77/3 78/3 158/2 <b>fold</b> [1] 105/5 <b>follow</b> [20] 10/8 20/13 64/1 64/1 117/14 173/10 173/14 173/19 174/2 175/10 175/14 175/23 175/24 176/4 176/13 178/14 179/24 205/3 208/19 211/1 <b>follow-up</b> [11] 173/10 173/14 174/2 175/10 175/23 175/24 176/13 178/14 179/24 208/19 211/1 <b>followed</b> [6] 26/23 60/18 63/15 122/6 173/21 173/23 <b>following</b> [10] 37/15 130/21 151/18 157/23	170/14 175/15 198/17 202/8 202/10 236/9 <b>following day</b> [1] 236/9 <b>food</b> [1] 73/17 <b>for specialist</b> [1] 2/22 <b>forefront</b> [1] 199/17 <b>foreseeable</b> [1] 128/23 <b>form</b> [2] 83/23 173/14 <b>format</b> [1] 206/18 <b>formation</b> [1] 215/11 <b>forms</b> [4] 33/2 47/4 122/8 233/23 <b>forth</b> [1] 20/8 <b>fortunate</b> [1] 208/25 <b>Fortunate</b> [1] 132/11 <b>forward</b> [9] 64/16 95/10 173/5 179/7 181/24 183/22 190/16 202/1 203/11 <b>found</b> [11] 13/10 18/1 30/16 56/25 101/6 102/5 166/17 203/16 219/10 221/20 222/1 <b>four</b> [14] 30/17 62/12 64/2 86/13 86/13 86/25 117/1 130/19 165/19 170/13 170/15 172/3 217/14 222/16 <b>four years</b> [3] 165/19 172/3 222/16 <b>fourth</b> [1] 152/11 <b>frait</b> [2] 116/25 118/21 <b>frailty</b> [1] 115/2 <b>frame</b> [4] 63/2 93/4 97/13 129/17 <b>free</b> [4] 2/20 74/3 128/11 148/25 <b>freely</b> [1] 114/5 <b>frequency</b> [4] 135/10 136/1 137/19 234/6 <b>frequent</b> [2] 178/18 211/14 <b>frequently</b> [2] 36/9 54/9 <b>Friday</b> [3] 159/8 225/11 231/4 <b>Friday's</b> [1] 226/21 <b>from</b> [154] 1/8 6/16 6/24 7/8 8/12 8/20 10/3 10/4 10/12 11/23 14/4 14/6 15/14 17/9 17/25 18/5 20/4 20/19 21/23 23/18 25/18 25/19 27/25 29/24 32/21 34/10 36/6 38/17 39/16 40/9 40/16 42/8 45/22 49/2 51/3 51/19 58/20 60/18 61/18 62/16 63/20 64/4 66/11 74/4	75/1 75/4 75/12 76/13 76/17 77/12 82/24 83/19 84/21 86/13 88/3 88/13 89/5 93/17 94/6 94/23 95/1 97/7 97/8 97/20 100/15 101/14 103/5 103/15 106/23 108/2 109/18 111/6 112/2 112/7 113/14 113/15 114/9 114/25 117/5 117/11 120/16 120/18 120/19 120/22 120/24 123/17 125/4 127/19 127/23 130/14 130/16 130/18 131/3 131/4 132/7 133/19 134/8 136/9 137/1 137/15 141/9 142/8 146/3 147/15 148/23 149/18 150/1 150/13 150/13 150/19 150/25 151/18 153/14 161/11 165/20 166/15 166/23 168/14 169/2 169/11 170/25 175/17 176/11 176/13 177/22 177/24 179/12 183/15 185/6 185/21 188/5 188/6 188/19 189/5 191/9 191/16 192/13 193/8 193/21 195/6 196/12 202/8 202/10 204/17 205/15 205/20 206/21 208/25 216/3 221/19 221/20 223/17 234/21 235/6 <b>front</b> [3] 21/5 184/22 209/13 <b>full</b> [2] 152/17 183/25 <b>fully</b> [7] 43/23 53/13 87/9 123/9 174/18 184/12 188/14 <b>fumarate</b> [1] 122/10 <b>function</b> [22] 5/18 7/14 41/7 58/1 82/7 84/5 84/8 84/10 84/22 85/12 86/3 107/2 112/4 118/21 144/2 171/23 215/17 215/25 216/2 216/5 216/8 217/8 <b>functional</b> [1] 79/25 <b>functioning</b> [1] 116/22 <b>functions</b> [3] 9/7 48/12 82/5 <b>fundamentally</b> [1] 14/12 <b>funding</b> [1] 37/15 <b>further</b> [15] 4/25 10/18 19/15 19/19 39/25 40/7 57/14 61/11 66/22 109/1	118/10 127/7 151/10 162/15 205/6 <b>furthest</b> [1] 118/20 <b>future</b> [3] 72/12 128/23 180/4
				<b>G</b>	
				<b>gastroenterologist</b> [1] 4/5 <b>gastroenterology</b> [1] 4/3 <b>gather</b> [1] 225/24 <b>gathered</b> [1] 154/13 <b>gauge</b> [1] 232/23 <b>gave</b> [2] 170/3 223/8 <b>general</b> [37] 3/6 5/14 14/6 15/24 16/13 33/12 33/15 40/10 47/1 47/12 48/15 49/19 52/20 54/17 57/24 58/22 59/8 70/8 99/8 101/23 102/9 102/17 107/12 108/6 120/23 124/2 124/2 132/22 142/24 145/17 172/20 177/12 182/14 205/21 206/1 223/14 224/13 <b>generally</b> [12] 44/12 76/5 99/21 119/3 121/3 121/14 122/1 122/24 123/13 124/9 125/21 195/18 <b>generated</b> [2] 70/20 86/21 <b>generation</b> [7] 57/6 57/6 57/7 68/23 127/23 147/23 170/11 <b>generations</b> [2] 56/21 57/3 <b>generous</b> [1] 216/25 <b>genetic</b> [4] 6/12 19/11 229/18 229/22 <b>genetics</b> [1] 104/10 <b>genotype</b> [63] 13/9 16/11 16/13 17/2 17/13 18/8 18/9 18/12 19/16 19/16 19/17 19/21 20/2 20/6 21/21 21/24 22/1 22/4 25/8 25/10 25/12 25/18 25/20 26/8 26/16 26/18 26/21 26/21 27/2 27/2 27/7 27/10 27/16 27/16 27/20 27/20 27/23 28/2 28/3 28/15 29/6 29/7 29/10 29/11 29/12 29/12 29/18 126/19 126/20 126/23 127/7 127/8 127/25 128/1 128/2 128/16 214/20 223/11 223/19 228/17 228/20	

<b>G</b>	77/1 92/15 92/15 108/7 108/19 118/24 122/1 126/15 137/7 139/22 146/23 147/8 165/2 170/1 180/1 182/13 182/18 183/1 188/7 188/8 220/1 223/20 230/15 232/18 <b>gives [2]</b> 39/10 85/2 <b>giving [4]</b> 70/19 107/14 183/24 184/18 <b>globally [1]</b> 6/22 <b>glue [1]</b> 111/21 <b>go [40]</b> 34/11 37/24 40/6 56/7 67/9 69/22 73/23 78/2 80/21 81/17 106/4 109/1 129/15 141/23 145/8 147/24 149/3 151/10 152/3 153/2 155/15 155/17 156/21 157/18 158/3 159/25 167/3 167/5 170/23 174/5 179/6 181/20 182/6 198/19 204/6 205/5 207/4 217/2 220/7 223/3 <b>goes [10]</b> 26/3 84/21 85/10 95/4 95/6 95/9 109/20 109/21 124/6 170/2 <b>going [66]</b> 1/19 7/2 13/19 31/2 31/14 31/22 37/23 39/3 39/6 50/13 58/25 59/6 59/22 61/10 61/11 65/15 67/8 69/17 72/10 86/5 93/11 119/24 124/5 125/7 129/20 130/25 135/3 137/11 137/12 147/24 152/3 152/5 157/18 158/13 158/24 159/3 166/11 173/5 175/20 175/23 177/4 177/6 181/23 182/3 182/6 184/24 185/1 187/6 187/8 187/14 188/13 190/4 194/13 195/7 196/23 196/25 199/1 200/14 201/17 202/1 207/14 208/7 209/20 220/12 230/19 235/17 <b>gold [1]</b> 195/24 <b>gone [8]</b> 33/16 43/8 53/17 68/20 132/23 146/20 150/18 156/13 <b>good [23]</b> 18/2 22/12 46/2 49/8 70/15 94/10 96/13 121/15 121/25 122/20 123/4 131/15 133/21 136/13 169/4 173/10 173/17 186/17	186/20 210/23 210/24 219/7 228/4 <b>got [33]</b> 21/4 25/17 26/9 41/4 53/16 55/13 57/5 62/23 63/13 86/6 102/6 112/20 133/18 133/21 150/6 150/25 155/8 156/2 161/8 166/25 181/12 185/10 187/13 190/25 196/8 196/16 198/5 207/3 208/23 210/17 226/1 226/5 230/24 <b>Government [4]</b> 134/2 134/14 189/22 232/13 <b>GP [29]</b> 3/5 58/21 176/14 176/16 176/21 178/23 182/23 183/15 183/16 184/25 195/7 195/19 196/22 197/6 199/15 200/5 201/22 205/8 205/14 206/15 206/17 206/23 207/2 207/8 207/15 207/17 209/4 210/3 215/17 <b>GP's [1]</b> 150/13 <b>GPs [12]</b> 58/3 59/11 185/18 202/21 205/22 209/2 210/6 210/11 210/19 210/22 217/7 232/19 <b>gradual [1]</b> 83/10 <b>GRAHAM [2]</b> 2/3 2/9 <b>grams [1]</b> 11/8 <b>graph [3]</b> 126/4 127/6 133/20 <b>grappling [1]</b> 222/19 <b>grateful [3]</b> 159/12 230/6 230/8 <b>great [4]</b> 1/21 17/5 58/24 118/13 <b>greater [6]</b> 21/2 23/1 36/18 86/25 87/5 223/16 <b>green [1]</b> 21/23 <b>grey [2]</b> 179/20 181/7 <b>group [18]</b> 36/3 55/12 78/4 101/16 102/8 120/17 162/23 166/23 166/24 171/2 176/19 190/22 190/24 194/4 202/2 215/22 225/10 226/22 <b>grouped [1]</b> 153/19 <b>groups [16]</b> 15/15 57/18 57/19 58/10 58/16 59/1 74/16 106/5 190/20 191/6 191/11 201/13 201/14 202/6 223/4 232/5 <b>grow [2]</b> 179/5 219/5 <b>growing [2]</b> 36/12 160/11	<b>guarantee [1]</b> 141/13 <b>guess [1]</b> 177/13 <b>guidance [9]</b> 89/9 89/9 99/11 99/17 100/13 132/2 161/11 176/1 176/4 <b>guide [2]</b> 50/6 50/15 <b>guideline [1]</b> 116/9 <b>guidelines [20]</b> 55/6 55/9 55/12 55/14 56/3 88/13 88/22 89/5 89/24 90/11 90/16 90/18 110/15 141/8 161/11 175/21 178/20 179/14 187/22 198/17 <b>gut [2]</b> 112/3 113/3 <b>guys [1]</b> 40/17	<b>had [84]</b> 20/17 22/23 27/13 29/5 29/12 30/4 30/4 30/5 32/14 34/14 37/11 49/20 50/22 51/15 54/2 55/23 57/21 60/8 60/25 63/19 65/1 65/4 66/4 77/18 78/10 89/20 95/4 96/21 100/18 102/17 102/19 110/7 114/10 126/24 128/4 129/3 129/5 129/7 130/3 132/20 132/25 133/4 140/10 140/19 141/1 141/8 141/12 141/15 144/1 149/4 149/22 150/19 153/18 158/15 168/10 170/7 170/7 173/11 173/13 175/8 179/24 180/19 183/11 183/14 183/16 185/25 188/21 195/23 200/25 201/4 201/16 207/25 217/5 225/3 227/22 229/1 229/4 229/7 229/11 229/12 234/8 234/9 235/7 235/13 <b>hadn't [1]</b> 167/7 <b>haemodialysis [2]</b> 71/8 72/8 <b>haemophilia [5]</b> 63/21 159/5 178/5 226/8 226/22 <b>haemophilic's [1]</b> 225/7 <b>haemophiliacs [2]</b> 102/5 102/18 <b>haemorrhage [1]</b> 143/9 <b>half [13]</b> 11/4 30/17 31/24 70/23 117/8 135/5 142/2 143/6 151/12 182/9 186/24	186/25 234/11 <b>hallucinations [1]</b> 138/21 <b>hand [7]</b> 106/24 126/5 126/7 126/9 135/10 135/18 137/16 <b>handful [2]</b> 157/14 195/3 <b>handled [2]</b> 131/18 131/22 <b>happen [18]</b> 36/23 65/15 80/14 80/17 82/4 87/19 97/13 100/3 100/7 100/14 112/5 114/17 129/20 136/18 154/11 155/3 156/10 182/24 <b>happened [7]</b> 23/23 34/12 60/19 110/8 169/10 183/9 191/21 <b>happening [3]</b> 155/4 203/18 203/19 <b>happens [8]</b> 11/15 47/1 80/14 84/3 87/15 96/14 154/4 159/23 <b>happily [1]</b> 129/21 <b>happy [4]</b> 115/24 191/13 230/22 235/8 <b>harbour [2]</b> 22/20 28/23 <b>hard [17]</b> 17/25 26/5 27/21 29/20 78/24 106/9 125/17 134/12 146/23 186/11 199/13 209/1 209/2 209/5 217/6 217/21 223/6 <b>harder [3]</b> 27/20 154/19 154/21 <b>harm [1]</b> 180/5 <b>harmed [1]</b> 198/4 <b>harmonise [1]</b> 32/18 <b>has [97]</b> 4/21 14/14 16/3 17/20 19/1 22/17 23/23 24/22 27/23 30/1 30/16 39/17 44/19 49/20 49/22 50/1 50/3 50/21 50/22 51/12 51/15 52/9 53/4 53/5 53/16 54/6 59/12 64/11 67/18 69/16 71/2 76/17 88/23 89/3 89/8 99/5 99/25 108/11 109/23 110/16 110/25 114/3 114/8 116/16 120/23 121/7 121/15 122/1 123/3 128/13 128/23 128/24 130/17 130/17 133/18 134/15 134/18 139/18 139/18 149/22 150/6 158/22 160/14 164/14 165/16 168/3 168/25 170/17 170/18 175/11	175/13 176/9 177/9 177/23 178/10 178/10 179/10 184/3 189/23 191/20 191/21 192/1 196/11 196/13 196/13 196/14 197/25 205/9 207/4 209/12 214/4 222/12 225/3 231/8 231/10 232/12 235/20 <b>hasn't [6]</b> 84/11 154/13 169/10 191/18 203/20 207/3 <b>have [413]</b> <b>haven't [15]</b> 6/25 13/10 25/1 32/19 33/16 38/2 63/13 70/20 97/22 101/8 127/14 146/20 189/9 221/6 230/2 <b>having [38]</b> 1/17 22/25 29/18 30/7 53/9 55/22 61/4 61/4 65/13 74/13 77/25 79/12 86/18 101/22 107/21 109/3 113/4 113/6 126/15 128/15 128/17 132/8 138/2 139/4 139/8 140/15 153/24 163/3 173/13 183/14 196/16 202/17 202/18 204/24 226/3 228/21 228/21 235/9 <b>Hazards [1]</b> 39/16 <b>HBV [4]</b> 39/21 42/22 76/3 163/20 <b>HCC [7]</b> 87/25 88/5 88/7 88/25 90/18 118/17 171/25 <b>HCV [19]</b> 39/19 42/24 47/8 67/15 67/16 67/16 71/1 76/3 76/23 80/24 102/19 152/25 155/14 157/4 157/10 162/20 163/20 169/25 214/12 <b>HDV [2]</b> 12/5 93/22 <b>he [4]</b> 205/10 213/2 217/15 217/16 <b>he's [1]</b> 205/18 <b>head [1]</b> 230/23 <b>headache [2]</b> 142/5 147/11 <b>heating [4]</b> 98/15 135/9 135/19 153/10 <b>health [20]</b> 34/11 35/17 36/19 44/20 89/8 104/6 114/20 115/2 130/19 153/4 157/8 157/10 171/12 188/23 189/23 190/11 192/8 192/18 204/18 204/20 <b>healthcare [6]</b> 54/10
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<p><b>H</b></p> <p><b>healthcare...</b> [5] 193/6 193/7 193/11 193/23 232/9</p> <p><b>healthy</b> [1] 104/25</p> <p><b>hear</b> [5] 1/6 49/14 84/5 121/11 231/3</p> <p><b>heard</b> [33] 8/20 22/18 49/17 49/24 57/3 59/9 59/13 66/14 76/8 76/17 99/14 113/13 113/15 124/16 137/14 138/11 138/14 139/10 142/8 142/15 145/2 145/7 146/3 155/11 161/25 167/19 182/19 186/3 188/5 195/6 209/24 210/16 211/19</p> <p><b>hearing</b> [2] 56/10 236/8</p> <p><b>hearings</b> [1] 39/7</p> <p><b>heart</b> [2] 107/7 109/22</p> <p><b>heavily</b> [1] 1/14</p> <p><b>help</b> [11] 36/3 37/25 50/15 80/11 107/15 124/25 173/2 184/24 209/14 213/16 235/4</p> <p><b>helpful</b> [15] 25/3 27/6 29/2 32/16 48/21 79/15 82/15 96/4 103/12 106/6 120/11 125/9 136/21 190/18 228/1</p> <p><b>helps</b> [3] 113/1 137/24 181/14</p> <p><b>hence</b> [2] 59/20 227/1</p> <p><b>Henry</b> [16] 20/15 68/5 117/6 125/3 135/3 141/24 143/7 145/9 152/10 153/2 153/9 155/17 156/13 157/12 182/5 182/10</p> <p><b>hep</b> [9] 55/23 58/14 58/25 100/16 158/22 177/14 180/5 199/8 201/12</p> <p><b>hep B</b> [1] 55/23</p> <p><b>hep C</b> [1] 201/12</p> <p><b>hepatic</b> [4] 109/22 111/24 153/10 164/3</p> <p><b>hepatitis</b> [467]</p> <p><b>hepatitis A and E</b> [1] 7/1</p> <p><b>hepatitis B</b> [162] 3/23 6/20 8/2 8/12 12/1 12/8 12/10 12/18 12/19 13/20 13/23 14/17 14/24 15/7 16/6 16/23 17/1 17/3 17/19 18/4 18/19 30/13 30/16 32/24 33/7 33/10 33/25 34/8 34/12 34/17 34/23</p>	<p>35/13 35/23 36/1 36/4 36/14 37/19 38/20 41/22 42/4 42/7 42/14 43/16 43/20 43/22 43/25 44/9 44/12 45/7 45/11 45/18 45/23 45/24 48/18 48/22 49/2 49/4 50/4 50/22 51/22 51/24 51/25 52/4 52/6 52/14 52/22 52/23 53/1 53/3 53/6 53/7 54/23 54/25 55/7 55/9 55/14 55/21 59/20 60/6 60/9 60/13 60/16 66/24 70/9 73/9 74/7 74/19 75/21 75/24 76/6 76/11 88/10 91/3 92/20 92/25 93/2 93/8 93/16 93/24 94/1 95/20 95/22 98/19 119/23 120/6 120/7 120/10 120/13 120/25 123/5 123/22 124/6 132/25 133/7 152/1 159/19 159/23 160/3 160/5 160/17 164/13 165/6 165/17 166/4 186/25 188/17 191/10 191/17 191/19 192/7 192/12 193/22 193/24 194/1 194/2 209/25 210/5 215/19 218/7 218/14 218/18 218/21 220/4 220/18 221/9 221/9 221/10 222/7 223/24 224/1 224/2 224/3 224/5 224/7 224/8 224/10 224/16 224/21 231/8 231/11 231/18 232/10</p> <p><b>hepatitis B DNA</b> [1] 224/13</p> <p><b>hepatitis C</b> [180] 2/15 3/23 4/10 6/20 8/13 13/8 13/20 13/24 14/20 15/4 16/21 17/17 18/25 19/25 20/18 21/11 22/3 22/8 23/17 26/2 27/10 28/8 30/13 30/19 32/3 34/8 34/19 35/2 35/13 36/14 36/15 37/5 37/18 38/21 41/23 42/8 42/15 44/10 44/21 45/7 45/11 45/25 46/3 46/14 46/22 48/18 49/5 49/23 50/22 51/5 51/18 53/18 53/20 53/24 54/2 54/4 54/5 54/7 54/11 54/14 54/17 55/13 55/17</p>	<p>55/25 57/5 59/12 59/14 60/2 60/4 60/22 61/8 61/24 62/1 63/25 66/1 70/10 73/9 74/8 74/19 75/25 76/7 76/11 76/15 76/19 77/8 79/19 80/2 80/17 88/10 91/3 91/16 91/22 91/23 91/25 92/1 92/3 92/20 94/21 95/13 95/21 95/23 96/2 96/22 97/4 98/20 101/24 102/8 103/1 103/5 105/2 119/23 120/14 125/3 125/16 127/11 128/22 129/4 129/9 130/24 140/11 140/19 146/19 153/11 155/20 158/10 158/15 159/19 159/24 160/21 161/2 161/6 162/15 163/11 164/13 165/7 165/17 166/6 166/25 169/11 170/8 170/12 175/22 177/23 183/3 186/25 188/9 188/25 189/24 190/14 191/4 193/2 193/9 193/17 194/1 194/3 194/3 194/23 195/13 196/5 200/9 210/1 210/5 214/19 215/3 215/6 215/6 215/9 215/10 215/14 219/11 220/18 221/1 222/10 223/11 226/10 227/13 232/16 233/12 235/12 235/22</p> <p><b>hepatitis C/hepatitis B</b> [1] 96/18</p> <p><b>hepatitis D</b> [10] 7/4 11/24 12/5 12/6 13/21 17/16 17/20 66/24 124/12 164/21</p> <p><b>hepatitis G</b> [8] 7/4 12/22 12/23 13/1 13/6 13/9 13/12 164/7</p> <p><b>hepatitises</b> [1] 60/25</p> <p><b>hepatocellular</b> [3] 87/25 88/2 88/17</p> <p><b>hepatocyte</b> [2] 8/13 9/6</p> <p><b>hepatocytes</b> [6] 9/16 9/17 11/13 11/15 83/4 88/3</p> <p><b>hepatologist</b> [1] 4/5</p> <p><b>hepatologists</b> [2] 129/19 175/14</p> <p><b>hepatology</b> [2] 2/19 4/3</p> <p><b>hepatoma</b> [1] 173/22</p> <p><b>her</b> [2] 92/23 207/4</p> <p><b>here</b> [33] 1/9 4/14 33/13 40/6 65/11</p>	<p>69/24 73/11 74/21 74/21 76/22 78/1 97/18 106/23 118/15 118/24 125/12 126/19 127/6 129/22 132/9 133/20 135/17 141/20 145/14 145/23 147/9 152/16 152/20 188/10 194/14 204/6 218/25 235/24</p> <p><b>herpes</b> [1] 135/22</p> <p><b>hesitant</b> [1] 103/21</p> <p><b>heterosexual</b> [3] 46/15 47/2 47/9</p> <p><b>Hi</b> [1] 3/4</p> <p><b>high</b> [20] 11/5 17/10 20/6 43/18 44/16 44/25 58/12 59/1 78/21 90/9 108/22 110/1 121/22 128/8 166/22 191/4 201/13 201/14 215/21 232/5</p> <p><b>high-risk</b> [1] 232/5</p> <p><b>higher</b> [27] 26/8 26/20 27/15 44/15 45/1 46/25 57/19 64/21 66/25 85/3 94/1 94/2 99/4 102/19 103/1 103/3 149/12 155/13 160/4 169/24 201/24 216/16 216/19 217/7 231/16 233/22 235/12</p> <p><b>highlight</b> [5] 140/4 142/1 152/13 199/25 200/21</p> <p><b>highlighted</b> [3] 30/1 161/23 184/13</p> <p><b>highlighting</b> [1] 14/10</p> <p><b>highly</b> [2] 120/19 233/10</p> <p><b>hinting</b> [1] 177/13</p> <p><b>hints</b> [1] 185/13</p> <p><b>his</b> [3] 10/13 205/15 207/4</p> <p><b>historic</b> [1] 39/5</p> <p><b>historical</b> [2] 96/6 193/21</p> <p><b>historically</b> [7] 16/21 19/14 22/23 53/4 99/21 100/19 174/8</p> <p><b>history</b> [13] 27/4 31/13 61/22 95/17 96/5 96/8 97/1 97/18 111/1 129/9 130/6 197/17 202/23</p> <p><b>hit</b> [1] 87/19</p> <p><b>HIV</b> [55] 2/10 2/13 13/2 13/4 13/6 26/9 32/19 32/21 34/24 35/21 36/1 46/8 46/9 57/4 71/6 93/22 98/21 99/3 99/23 102/6 102/16 121/13 122/12</p>	<p>122/13 159/14 159/19 159/20 159/22 160/1 160/9 160/13 160/17 160/21 161/9 161/13 161/18 162/8 162/12 162/20 163/7 163/13 163/19 163/21 164/13 165/16 190/25 194/15 194/17 195/1 196/6 204/22 217/9 231/5 232/3 232/5</p> <p><b>HIV report</b> [1] 194/17</p> <p><b>HIV-hepatitis</b> [1] 2/13</p> <p><b>hm</b> [4] 41/24 42/25 188/12 206/24</p> <p><b>Hodgkin</b> [1] 155/10</p> <p><b>home</b> [7] 37/16 109/7 112/18 112/19 131/18 189/14 189/16</p> <p><b>homicidal</b> [1] 138/23</p> <p><b>honours</b> [1] 1/21</p> <p><b>hoof</b> [1] 56/22</p> <p><b>hope</b> [3] 201/24 205/10 207/12</p> <p><b>hopeful</b> [2] 181/5 201/23</p> <p><b>hopefully</b> [5] 37/22 183/16 183/18 185/18 210/21</p> <p><b>horizon</b> [1] 93/14</p> <p><b>horizontal</b> [2] 43/9 201/20</p> <p><b>hospital</b> [9] 2/12 2/21 3/15 4/6 109/4 111/16 112/21 140/24 183/13</p> <p><b>hospitals</b> [3] 4/1 114/8 202/21</p> <p><b>host</b> [2] 161/7 161/8</p> <p><b>hot</b> [1] 146/2</p> <p><b>hour</b> [1] 151/12</p> <p><b>household</b> [1] 201/20</p> <p><b>how</b> [76] 2/16 2/16 7/6 11/5 14/10 15/16 19/13 20/10 23/14 32/14 36/13 38/20 38/20 40/11 42/19 45/1 47/19 56/8 66/19 77/22 78/11 78/12 79/8 81/5 82/11 84/4 84/7 86/10 91/5 99/16 100/11 111/25 126/6 126/22 129/10 131/24 132/2 132/4 136/6 136/10 140/4 141/10 143/18 150/3 162/3 163/15 169/14 172/6 172/20 173/2 173/20 175/9 177/6 178/18 180/21 183/21 184/24 185/2 185/13 187/19 190/16 200/3 202/1 203/23 205/13 213/10 216/17 222/20 222/20</p>	<p>223/3 225/25 229/19 229/23 234/8 234/9 234/21</p> <p><b>however</b> [3] 16/4 96/17 169/24</p> <p><b>huge</b> [3] 134/2 187/6 208/17</p> <p><b>human</b> [2] 14/14 30/17</p> <p><b>hundreds</b> [1] 41/12</p> <p><b>hypertension</b> [1] 143/8</p> <p><b>hyperthyroid</b> [1] 78/22</p> <hr/> <p><b>I</b></p> <p><b>I absolutely</b> [1] 216/18</p> <p><b>I alluded</b> [1] 208/15</p> <p><b>I also</b> [3] 3/5 3/24 90/21</p> <p><b>I am</b> [4] 148/24 152/4 197/14 199/10</p> <p><b>I ask</b> [9] 82/1 87/24 88/21 92/17 113/12 120/3 164/2 195/17 205/6</p> <p><b>I asked</b> [1] 234/23</p> <p><b>I believe</b> [1] 70/15</p> <p><b>I can</b> [10] 11/1 11/21 25/8 45/12 144/25 176/7 199/12 199/23 220/22 220/25</p> <p><b>I can't</b> [2] 141/13 149/21</p> <p><b>I could</b> [2] 57/11 66/22</p> <p><b>I described</b> [1] 195/22</p> <p><b>I diagnosed</b> [1] 150/13</p> <p><b>I did</b> [3] 56/24 57/9 194/18</p> <p><b>I divide</b> [1] 3/16</p> <p><b>I do</b> [2] 182/22 200/24</p> <p><b>I don't</b> [10] 22/10 29/3 44/23 69/16 128/21 149/2 197/21 204/17 221/13 227/5</p> <p><b>I draw</b> [1] 155/9</p> <p><b>I expect</b> [1] 5/21</p> <p><b>I find</b> [2] 197/6 197/21</p> <p><b>I flag</b> [1] 188/4</p> <p><b>I found</b> [1] 56/25</p> <p><b>I get</b> [1] 69/24</p> <p><b>I going</b> [1] 202/1</p> <p><b>I guess</b> [1] 177/13</p> <p><b>I have</b> [10] 3/9 4/8 50/25 55/18 57/10 187/16 191/7 200/23 211/8 223/7</p> <p><b>I haven't</b> [1] 189/9</p> <p><b>I just</b> [13] 12/22 32/8 42/18 51/4 68/17</p>
--	---	---	--	--	--

<b>I</b>	30/10 30/22 30/25 32/13 33/14 34/25 36/23 37/22 38/14 40/4 40/6 40/20 42/23 44/5 44/12 47/12 53/16 56/16 60/11 63/12 65/9 65/10 66/13 73/7 74/20 74/23 76/5 76/7 77/10 77/20 78/1 82/10 92/21 94/4 95/18 96/3 98/22 99/14 99/18 99/21 99/23 100/12 101/7 102/4 102/12 102/22 106/6 118/25 120/1 120/8 125/11 126/5 126/17 131/11 131/20 132/3 132/16 134/23 136/4 136/20 136/20 136/22 137/6 139/6 141/7 142/23 143/18 144/14 144/21 148/5 149/10 149/21 150/5 151/2 151/4 153/21 159/16 159/21 161/22 162/6 163/1 163/2 163/9 164/8 165/20 166/3 166/10 166/12 166/19 167/14 167/16 168/8 168/10 168/12 168/17 168/18 168/23 168/23 170/3 171/6 172/1 172/9 172/13 172/19 173/1 174/22 175/11 177/3 177/9 180/14 181/2 181/15 181/22 183/2 183/22 185/21 186/2 186/16 186/19 187/1 187/5 189/14 189/21 189/23 189/25 190/2 190/6 190/18 190/22 191/12 191/18 191/22 192/20 194/9 194/16 197/7 197/13 201/11 205/19 205/24 207/19 208/15 210/1 214/6 214/9 215/23 217/19 218/22 220/13 222/22 223/13 226/25 227/14 227/23 230/9 230/17 231/3 232/19 233/5 233/14 234/4 234/13 234/18 235/4	<b>I want [4]</b> 38/19 39/8 48/5 199/10 <b>I wanted [6]</b> 65/20 67/5 149/6 158/25 192/21 195/4 <b>I was [4]</b> 105/21 177/13 205/11 235/16 <b>I wasn't [1]</b> 92/21 <b>I will [3]</b> 7/3 208/20 216/2 <b>I won't [1]</b> 155/15 <b>I wonder [1]</b> 43/10 <b>I wondered [2]</b> 173/15 189/3 <b>I work [1]</b> 209/1 <b>I would [15]</b> 57/24 111/12 133/17 163/9 196/9 196/14 198/21 199/25 205/25 206/3 206/7 207/11 207/12 207/21 225/10 <b>I'd [3]</b> 40/6 43/6 173/19 <b>I'll [7]</b> 5/6 12/25 45/14 67/11 72/24 72/24 214/11 <b>I'm [75]</b> 2/9 2/11 2/19 2/19 2/20 3/4 3/4 3/7 4/2 4/2 7/2 13/19 30/9 31/22 34/2 39/3 40/14 40/16 56/21 59/6 59/15 59/22 61/10 61/11 62/2 67/8 69/17 70/1 77/23 98/6 115/24 119/24 130/25 137/11 137/12 139/16 145/13 147/24 151/1 152/2 156/18 157/17 159/3 159/17 168/11 176/15 177/16 182/6 185/4 185/5 187/5 187/8 188/13 191/20 194/13 199/14 199/21 199/22 200/24 201/22 201/22 201/25 204/9 205/25 206/4 208/25 209/24 216/17 217/15 220/12 220/23 223/13 223/23 230/19 230/22	<b>identified [22]</b> 15/1 30/22 38/23 41/19 45/3 59/15 80/1 80/23 81/20 90/22 91/15 96/9 99/7 119/3 119/15 135/17 137/16 137/18 152/20 153/9 157/5 157/14 <b>identifies [1]</b> 70/3 <b>identify [5]</b> 25/9 45/12 54/12 118/25 124/5 <b>identifying [2]</b> 40/13 58/18 <b>if [217]</b> 7/10 9/13 10/15 11/1 11/3 11/4 11/6 11/21 15/12 18/22 20/9 20/16 21/9 21/20 21/24 24/7 24/16 25/2 25/8 25/10 25/13 25/17 25/22 26/14 27/6 28/7 28/12 29/2 29/3 29/6 29/8 30/4 37/25 40/7 41/4 41/16 43/10 46/9 49/25 50/21 51/3 51/4 52/20 53/7 54/1 54/6 55/4 57/12 58/24 64/25 66/22 67/9 69/16 73/20 77/11 77/12 78/2 78/6 80/24 81/19 84/21 84/25 85/4 85/10 85/14 85/16 86/8 86/24 87/1 87/15 87/18 88/14 88/23 88/23 89/4 91/22 92/1 93/10 95/25 96/8 97/14 98/23 99/19 100/16 101/5 101/20 101/22 104/22 105/5 105/12 106/10 106/21 107/17 107/24 108/4 108/8 110/15 110/17 110/22 110/25 111/8 111/12 112/3 112/18 112/24 113/4 113/8 114/6 115/4 115/25 116/4 116/16 125/19 125/23 128/25 129/13 129/19 132/13 132/25 135/4 138/1 138/16 141/23 142/1 143/6 143/17 143/22 143/25 144/15 144/25 145/8 145/18 150/23 151/6 151/10 151/10 152/9 152/11 152/13 153/2 153/8 154/4 154/10 155/1 155/17 156/12 156/21 157/2 158/6 160/22 161/8 164/18 168/2 169/8 169/12 170/7 170/10 171/1 172/22	173/15 173/24 174/16 176/7 176/20 177/6 177/17 177/20 178/2 179/24 180/6 180/7 180/14 180/17 182/9 183/4 183/23 184/23 186/19 187/4 188/16 189/3 191/8 192/7 200/21 203/8 203/16 203/19 204/14 204/22 206/10 206/12 207/2 207/23 208/10 210/7 211/21 212/6 214/25 215/20 218/4 219/13 219/21 220/6 220/10 220/23 221/24 224/19 225/2 226/1 227/13 228/8 230/9 230/10 230/20 231/12 233/15 234/11 <b>II [1]</b> 104/9 <b>ill [1]</b> 61/5 <b>illness [7]</b> 13/11 72/19 72/20 75/12 75/14 112/10 146/2 <b>illnesses [2]</b> 8/16 80/17 <b>illustrate [3]</b> 20/10 21/8 125/10 <b>illustrates [2]</b> 106/6 142/23 <b>image [5]</b> 82/15 82/16 83/3 83/20 87/11 <b>imagination [1]</b> 31/20 <b>imagine [1]</b> 121/12 <b>imaging [3]</b> 174/13 174/13 213/2 <b>immediately [3]</b> 130/22 208/14 208/21 <b>immune [18]</b> 8/5 8/7 8/9 8/14 8/18 48/17 49/11 52/2 53/12 93/7 138/7 157/4 160/23 161/7 161/8 163/23 215/12 226/10 <b>immune-mediated [1]</b> 215/12 <b>immunoassay [1]</b> 48/14 <b>immunoassays [3]</b> 48/19 48/25 69/8 <b>immunosuppression</b> <b>[2]</b> 71/5 72/11 <b>impact [9]</b> 95/16 102/23 115/3 131/16 132/19 133/5 221/7 234/10 234/12 <b>impaired [3]</b> 107/2 112/4 142/5 <b>impairment [5]</b> 77/4 78/4 85/15 85/16 142/6 <b>implement [1]</b> 185/19	<b>implications [3]</b> 44/19 164/14 188/18 <b>implies [1]</b> 205/14 <b>importance [9]</b> 37/1 79/17 92/15 130/12 182/1 182/21 184/1 186/3 197/17 <b>important [66]</b> 5/10 14/21 18/11 20/22 22/9 22/14 34/25 38/10 38/14 43/24 44/4 44/13 45/10 47/7 61/15 66/13 68/25 70/21 71/13 73/12 75/20 76/6 77/10 79/16 85/25 94/18 99/14 102/22 108/12 113/18 116/16 122/20 124/17 137/3 138/1 138/5 140/1 143/18 146/12 147/1 148/6 153/21 160/12 162/17 166/11 167/17 167/18 174/22 181/16 181/17 184/18 185/17 186/9 197/14 199/18 200/20 209/7 210/2 210/12 210/24 224/19 227/9 227/14 227/24 230/3 230/9 <b>importantly [1]</b> 201/16 <b>impotence [1]</b> 145/16 <b>improve [12]</b> 2/17 123/19 127/6 134/4 134/25 147/6 171/12 198/20 202/7 206/10 216/13 217/25 <b>improved [5]</b> 34/21 127/2 128/1 213/24 217/24 <b>improvement [9]</b> 3/8 36/6 36/9 123/21 142/20 148/2 148/11 171/22 214/10 <b>improvements [1]</b> 36/5 <b>improving [3]</b> 3/9 3/11 199/2 <b>in European [1]</b> 191/15 <b>in-box [1]</b> 199/9 <b>inappropriate [2]</b> 30/3 202/16 <b>incidence [2]</b> 60/21 158/19 <b>include [5]</b> 5/18 55/10 55/16 70/25 77/2 <b>included [2]</b> 90/16 186/13 <b>including [12]</b> 10/19 122/21 133/15 143/8 143/14 145/5 145/11
----------	---	--	--	---	---

<b>I</b>	137/15 142/1 146/4 156/20 157/23 160/1 173/12 188/6 188/21 218/24 222/25 222/25 224/14 229/19 <b>inevitably [1]</b> 195/15 <b>infant [1]</b> 192/8 <b>infants [1]</b> 44/6 <b>infect [1]</b> 12/10 <b>infected [42]</b> 8/17 18/19 22/7 23/21 23/22 24/7 24/21 25/11 26/2 28/1 28/7 28/24 29/8 44/7 44/17 44/20 52/12 52/21 54/2 62/5 63/7 66/4 72/17 72/23 74/12 76/18 99/2 102/18 155/14 160/2 162/20 163/13 164/12 169/25 177/18 177/24 188/16 193/23 226/1 226/15 226/16 227/3 <b>infection [90]</b> 3/19 3/24 6/7 12/19 13/2 18/5 18/18 20/7 25/16 28/13 28/14 29/11 44/8 44/15 44/24 45/17 49/6 49/9 49/10 49/23 50/2 50/6 50/25 51/2 51/6 51/18 51/23 52/4 53/10 54/7 54/19 61/25 62/4 62/13 62/17 63/16 64/3 65/2 65/22 65/25 71/1 71/6 73/13 74/22 75/1 76/10 81/16 93/1 100/16 102/16 123/19 127/16 135/25 145/21 145/25 150/6 153/6 153/11 157/4 157/10 159/2 159/14 159/18 160/2 160/3 160/24 164/3 164/10 164/25 167/5 168/3 168/4 168/10 192/24 193/8 193/9 193/13 194/15 194/22 218/7 219/1 220/18 221/10 224/1 224/10 225/17 226/2 227/4 228/6 235/10 <b>infectious [17]</b> 3/20 6/7 6/8 19/25 29/19 76/13 93/5 93/21 112/23 124/18 127/8 127/9 135/19 135/21 135/22 135/23 137/4 <b>infectious [9]</b> 6/18 33/4 45/21 46/11 52/18 175/17 194/3 224/11 226/4 <b>infects [1]</b> 11/25 <b>infer [1]</b> 189/5	<b>infestations [1]</b> 135/19 <b>infinite [1]</b> 196/24 <b>infinitesimally [2]</b> 55/24 233/18 <b>inflamed [1]</b> 83/7 <b>inflammation [12]</b> 5/15 5/20 7/7 7/9 61/3 74/14 79/24 80/3 80/7 80/15 93/20 137/4 <b>inflammatory [1]</b> 83/8 <b>influence [3]</b> 13/4 93/19 119/6 <b>influenza [1]</b> 146/1 <b>influenza-like [1]</b> 146/1 <b>information [34]</b> 13/18 17/5 24/19 40/2 40/19 41/17 56/22 70/21 80/12 80/13 90/15 152/7 157/20 182/12 183/15 183/17 184/4 184/7 184/12 185/12 185/22 186/14 186/23 187/12 188/7 188/8 205/11 205/22 205/25 206/14 206/18 206/22 207/3 220/5 <b>informative [1]</b> 235/21 <b>informed [2]</b> 129/14 184/4 <b>informs [1]</b> 32/11 <b>inhibitors [1]</b> 229/9 <b>initial [2]</b> 209/9 210/16 <b>initially [3]</b> 35/6 52/19 132/6 <b>initiative [2]</b> 188/23 188/24 <b>injecting [2]</b> 101/24 111/21 <b>injection [1]</b> 145/20 <b>injured [1]</b> 85/11 <b>innovation [1]</b> 58/24 <b>Inquiry [19]</b> 31/12 32/5 34/7 43/11 56/23 61/2 61/16 76/17 79/15 81/4 92/16 96/20 114/3 130/17 139/18 139/25 153/3 177/19 230/8 <b>Inquiry's [3]</b> 39/1 39/7 152/17 <b>insert [1]</b> 136/9 <b>inside [3]</b> 82/5 108/21 111/4 <b>insight [1]</b> 40/8 <b>insomnia [2]</b> 138/18 147/11 <b>instance [7]</b> 63/19 143/24 175/15 183/5 183/7 228/20 232/9	<b>instantly [2]</b> 208/22 221/22 <b>Institute [1]</b> 89/7 <b>instituted [1]</b> 176/5 <b>instruction [3]</b> 4/22 4/24 151/24 <b>insurance [1]</b> 183/10 <b>intake [4]</b> 64/17 93/21 107/14 180/4 <b>integrate [1]</b> 14/17 <b>integrated [1]</b> 206/15 <b>intended [1]</b> 31/19 <b>interaction [1]</b> 164/16 <b>interactions [3]</b> 159/22 161/21 162/18 <b>interchangeably [1]</b> 12/4 <b>intercourse [1]</b> 47/11 <b>interest [5]</b> 3/9 70/4 164/9 178/24 178/25 <b>interested [3]</b> 39/23 114/4 114/6 <b>interested in [1]</b> 114/4 <b>interesting [1]</b> 40/17 <b>interests [1]</b> 133/11 <b>interferon [89]</b> 16/20 16/20 16/25 27/13 27/15 35/20 36/7 36/8 106/17 119/25 120/3 120/11 120/15 120/24 121/17 124/14 124/20 125/7 126/12 126/25 127/1 127/5 127/14 127/17 127/19 128/10 128/11 129/5 129/7 129/15 130/4 135/7 136/5 136/8 136/9 136/10 136/11 136/16 138/2 139/10 139/24 140/8 140/13 140/18 143/20 144/3 144/9 144/16 146/14 146/20 146/22 147/14 148/2 148/7 148/25 149/9 149/16 151/20 152/4 152/22 153/1 157/24 157/25 157/25 161/7 161/9 161/12 162/22 163/12 164/1 172/22 214/13 214/20 227/20 228/1 228/2 228/13 228/24 229/4 229/5 229/6 229/7 229/10 229/11 229/12 229/12 229/17 229/19 229/24 <b>interferon-based [1]</b> 163/12 <b>interferon-free [2]</b> 128/11 148/25 <b>intermediate [1]</b> 118/1 <b>internal [1]</b> 152/10	<b>internally [1]</b> 221/5 <b>international [4]</b> 35/14 36/25 37/2 37/13 <b>internationally [2]</b> 2/18 37/12 <b>interpreted [1]</b> 74/23 <b>interrogate [1]</b> 213/7 <b>interstitial [3]</b> 143/13 143/25 144/1 <b>interval [2]</b> 110/24 211/16 <b>intervals [1]</b> 108/3 <b>intervened [1]</b> 96/9 <b>intervention [2]</b> 96/24 105/8 <b>intestines [2]</b> 109/18 109/25 <b>intimated [1]</b> 58/19 <b>into [33]</b> 9/12 11/10 14/7 14/17 18/14 33/17 34/11 57/17 60/17 61/23 68/20 72/16 78/12 83/23 109/16 109/19 109/20 110/12 120/20 126/25 127/10 141/10 144/12 146/20 153/20 166/11 179/9 179/21 181/12 190/23 206/17 209/14 230/15 <b>introduce [1]</b> 35/5 <b>introduced [3]</b> 34/4 56/13 57/8 <b>introduces [1]</b> 19/13 <b>introducing [1]</b> 2/5 <b>introduction [8]</b> 11/22 12/23 27/1 34/22 35/16 38/16 56/20 130/15 <b>Inverness [1]</b> 196/21 <b>investigate [1]</b> 140/1 <b>investigated [1]</b> 137/7 <b>investigating [2]</b> 32/5 92/17 <b>investigation [3]</b> 10/19 61/16 217/9 <b>investigations [3]</b> 156/11 211/9 218/3 <b>investment [2]</b> 37/3 214/5 <b>invitation [1]</b> 230/6 <b>involve [1]</b> 10/6 <b>involved [3]</b> 40/16 99/24 174/3 <b>involvement [1]</b> 37/2 <b>involves [2]</b> 114/19 116/9 <b>Ireland [1]</b> 189/3 <b>irritability [1]</b> 146/1 <b>is done [1]</b> 110/8 <b>Ishak [1]</b> 86/14 <b>isn't [13]</b> 12/6 16/14	18/2 25/20 26/5 26/5 26/10 135/12 135/13 136/15 198/18 221/21 232/25 <b>isolated [1]</b> 194/5 <b>issue [33]</b> 1/18 6/17 22/17 29/15 33/15 43/16 43/17 44/3 44/13 46/1 46/5 46/16 47/7 47/12 57/21 61/9 71/16 71/23 72/2 79/6 87/21 99/14 113/19 131/13 138/1 148/15 160/22 164/19 165/4 165/5 165/5 197/12 198/1 <b>issued [1]</b> 89/8 <b>issues [19]</b> 28/7 65/17 68/18 92/16 99/22 100/8 115/3 125/11 131/6 142/24 148/13 150/8 176/25 179/17 182/21 184/14 188/15 198/18 209/6 <b>it's [250]</b> <b>IT-accessible [1]</b> 209/11 <b>itching [1]</b> 148/13 <b>its [17]</b> 1/15 4/18 12/6 12/15 12/24 14/15 18/9 18/20 27/23 52/9 54/16 78/18 135/7 191/10 193/1 219/2 230/9 <b>itself [7]</b> 7/13 7/23 8/8 17/20 32/5 40/18 78/23
<b>J</b>					<b>JAMIESON [5]</b> 2/1 3/4 195/6 205/13 215/16 <b>Japanese [1]</b> 104/9 <b>jaundice [8]</b> 73/21 75/13 75/15 81/20 86/4 218/6 218/8 218/15 <b>jaundiced [2]</b> 58/11 218/18 <b>JEFFEREY [1]</b> 1/25 <b>Jeffery [4]</b> 3/14 21/1 87/21 209/20 <b>job [1]</b> 203/22 <b>jobs [1]</b> 112/1 <b>JOHN [9]</b> 1/24 3/15 4/2 22/11 23/11 27/8 30/1 140/13 163/8 <b>join [1]</b> 83/22 <b>joint [2]</b> 75/15 91/2 <b>journey [2]</b> 196/21 196/25 <b>JPAC [2]</b> 40/1 40/17 <b>judgment [3]</b> 159/10 179/15 179/18

<b>J</b>	40/21 54/15 72/9 88/25 128/24 139/20 142/24 144/23 182/15 184/7 184/10 195/19 201/22 <b>kinds [2]</b> 40/22 186/23 <b>Kingdom [9]</b> 17/2 17/19 19/23 24/21 115/13 119/1 130/20 189/1 191/12 <b>Kirriemuir [1]</b> 3/5 <b>knew [9]</b> 60/9 60/15 77/18 129/13 129/13 129/17 130/3 131/14 131/15 <b>know [118]</b> 1/9 15/24 16/25 18/11 18/15 23/17 24/2 24/3 24/24 29/3 29/24 33/5 35/1 40/7 40/11 43/23 44/15 46/3 46/15 47/19 54/6 58/10 59/8 65/15 67/19 68/9 72/6 72/9 95/20 97/20 100/17 100/18 101/19 106/23 110/7 119/7 125/15 128/25 130/11 130/16 132/6 136/6 140/5 144/11 144/15 146/24 149/5 149/18 150/17 150/18 150/22 150/23 150/24 151/11 152/7 154/12 156/19 158/18 163/2 167/9 167/17 168/25 170/15 175/5 176/24 181/3 181/5 181/9 181/18 182/19 184/11 184/13 184/17 185/2 185/4 185/6 187/10 189/4 191/22 196/13 197/1 197/21 198/15 198/23 199/22 200/6 200/15 200/19 201/3 201/23 202/5 203/4 203/6 203/19 204/20 205/14 206/3 207/12 208/1 208/2 208/14 208/16 208/17 208/22 209/2 210/8 216/4 217/17 220/5 220/16 221/17 223/6 225/8 226/14 227/15 233/4 233/15 234/12 <b>knowing [2]</b> 125/16 150/19 <b>knowledge [5]</b> 31/16 33/20 64/11 206/11 207/2 <b>knowledgeable [2]</b> 183/19 183/20 <b>known [30]</b> 25/22	30/5 30/14 31/18 31/18 59/24 59/25 61/20 61/20 77/3 80/4 81/5 88/15 88/23 90/8 100/21 135/10 136/1 136/11 137/20 139/23 151/25 155/1 198/2 198/24 201/19 208/6 219/1 220/3 220/17	<b>L</b> <b>lab [2]</b> 196/1 217/12 <b>laboratories [1]</b> 57/2 <b>laboratory [4]</b> 3/18 40/24 67/15 70/13 <b>labour [1]</b> 42/23 <b>labs [1]</b> 70/10 <b>labyrinth [1]</b> 143/1 <b>lack [3]</b> 89/19 205/22 209/4 <b>lacking [1]</b> 99/6 <b>lactulose [1]</b> 113/1 <b>lag [2]</b> 53/25 54/20 <b>lamivudine [4]</b> 36/1 121/11 121/14 121/20 <b>large [15]</b> 17/11 21/13 26/1 87/12 87/16 100/18 103/4 105/5 107/25 109/13 110/25 136/23 169/20 210/18 225/23 <b>large-fold [1]</b> 105/5 <b>largely [2]</b> 35/19 193/20 <b>larger [2]</b> 83/9 118/2 <b>last [17]</b> 23/4 30/20 37/9 39/21 53/13 67/13 94/6 118/12 118/13 121/7 128/5 128/13 145/9 150/10 150/12 165/18 222/16 <b>lasting [1]</b> 142/22 <b>lastly [1]</b> 45/9 <b>late [8]</b> 60/20 96/25 97/25 119/4 119/18 208/11 208/12 229/16 <b>later [24]</b> 7/4 11/19 13/22 14/18 27/18 33/18 35/21 39/7 50/18 54/6 54/21 56/11 56/13 56/15 63/3 78/13 82/9 88/19 89/22 168/8 169/12 207/10 211/7 219/4 <b>latter [1]</b> 169/18 <b>Laughter [2]</b> 231/1 234/3 <b>laying [1]</b> 83/9 <b>lead [9]</b> 2/12 4/6 7/17 80/2 91/9 108/23 120/21 124/20 228/6 <b>leading [3]</b> 98/20 195/15 206/20	<b>leads [5]</b> 11/17 33/21 34/1 112/12 123/20 <b>leaflets [1]</b> 206/15 <b>leak [1]</b> 9/11 <b>learn [1]</b> 223/2 <b>learning [2]</b> 165/19 184/14 <b>learnt [1]</b> 76/18 <b>least [6]</b> 30/14 64/4 149/15 159/10 200/6 221/14 <b>leave [1]</b> 68/15 <b>leaving [1]</b> 147/19 <b>led [8]</b> 35/4 37/2 178/22 178/23 187/10 187/13 197/20 199/5 <b>left [23]</b> 11/8 24/1 27/5 82/20 83/20 117/11 118/6 126/5 126/7 135/18 136/25 137/16 158/12 158/22 170/20 170/20 171/13 191/3 208/23 222/17 222/21 223/3 228/17 <b>left-hand [4]</b> 126/5 126/7 135/18 137/16 <b>legal [1]</b> 218/24 <b>length [1]</b> 191/9 <b>lengths [1]</b> 207/16 <b>less [30]</b> 8/2 11/9 18/11 29/14 30/8 36/8 44/3 44/4 44/22 76/11 81/8 94/17 97/5 97/17 133/15 136/19 142/2 147/5 154/18 154/19 158/7 161/9 163/25 165/6 179/14 221/11 221/14 222/2 228/4 228/22 <b>lessons [1]</b> 217/5 <b>let [2]</b> 45/14 151/11 <b>lethargy [1]</b> 146/2 <b>letter [2]</b> 4/24 151/23 <b>letters [1]</b> 4/22 <b>level [32]</b> 28/9 52/18 53/12 79/24 80/3 84/19 92/6 93/6 107/22 116/21 147/25 153/19 154/7 154/14 170/7 172/6 184/11 196/3 205/16 205/18 212/5 215/17 217/11 224/8 224/13 226/9 231/22 232/2 232/10 232/13 232/22 233/3 <b>levels [14]</b> 5/22 8/19 8/25 9/1 9/21 10/11 10/16 10/24 11/12 154/25 174/17 186/8 189/13 231/19 <b>libido [1]</b> 138/20 <b>life [17]</b> 1/22 44/7 89/11 98/15 100/25	101/12 101/15 102/6 102/17 103/17 104/11 111/10 177/21 178/3 178/7 179/4 219/5 <b>lifelong [2]</b> 124/4 177/7 <b>lifestyle [3]</b> 176/25 180/9 216/6 <b>lifetime [4]</b> 104/18 104/20 104/23 177/4 <b>light [2]</b> 39/25 180/12 <b>like [28]</b> 18/22 19/19 21/9 27/11 47/19 57/13 75/12 81/14 103/18 105/4 105/19 106/10 112/22 121/16 122/6 133/8 135/23 139/6 139/21 146/1 157/20 164/1 170/10 173/19 180/6 192/7 195/12 230/10 <b>likelihood [1]</b> 44/14 <b>likely [26]</b> 6/17 25/10 25/22 26/19 30/8 41/8 44/7 64/15 73/14 77/9 94/16 95/5 110/7 119/15 144/21 160/1 160/4 160/24 161/4 161/10 163/6 171/22 190/10 219/22 226/9 231/16 <b>likes [1]</b> 217/17 <b>likewise [1]</b> 83/5 <b>limbs [1]</b> 107/5 <b>limit [1]</b> 134/8 <b>limited [11]</b> 15/4 17/21 80/20 89/18 94/9 123/25 124/14 152/25 180/25 194/25 213/23 <b>limiting [2]</b> 60/14 61/15 <b>line [9]</b> 62/25 64/22 95/3 112/25 122/25 137/2 175/2 180/15 189/18 <b>linear [1]</b> 62/20 <b>lines [2]</b> 83/2 83/18 <b>link [1]</b> 222/24 <b>links [2]</b> 154/2 186/15 <b>list [10]</b> 32/21 76/24 115/9 136/15 141/21 144/18 147/9 155/2 186/11 215/2 <b>listed [18]</b> 36/21 55/6 66/16 115/23 118/15 141/20 145/3 145/3 149/1 151/23 152/24 155/6 155/9 155/12 155/16 155/18 155/21 215/13 <b>listening [4]</b> 130/13 149/4 152/16 184/2	<b>literacy [1]</b> 184/14 <b>literature [11]</b> 31/1 46/18 64/10 101/9 152/25 153/18 153/20 154/17 154/20 155/1 156/4 <b>little [30]</b> 2/6 7/3 13/18 13/21 15/6 19/3 20/3 20/24 27/19 27/22 31/14 32/18 44/21 46/7 54/20 57/14 74/10 87/24 88/21 113/12 161/2 164/14 164/20 166/5 168/13 179/20 180/1 185/16 200/2 230/16 <b>live [5]</b> 9/5 13/12 82/17 103/14 178/3 <b>lived [2]</b> 79/13 104/12 <b>liver [202]</b> 2/22 2/24 2/25 3/1 3/2 4/10 5/15 5/18 5/20 6/11 7/7 9/2 9/8 9/14 10/7 10/10 10/24 11/3 11/7 13/13 16/8 16/8 16/13 26/13 26/14 50/13 58/1 60/21 61/3 64/20 66/3 66/5 66/8 67/2 67/2 73/19 75/17 76/9 76/12 76/20 81/19 82/3 82/4 82/5 82/6 82/11 82/17 82/19 82/20 82/23 82/24 83/4 83/7 83/11 83/24 84/5 84/8 84/10 84/20 84/22 84/23 84/25 85/8 85/10 85/12 85/25 86/3 86/11 87/2 87/13 87/24 88/3 88/5 88/9 88/11 89/14 90/1 90/3 90/9 90/13 90/14 93/4 93/20 95/1 95/25 97/7 97/9 98/12 106/13 106/13 106/13 106/14 106/19 107/2 107/6 108/6 108/14 108/17 108/21 109/16 109/20 109/21 112/1 112/4 112/7 112/8 113/9 113/13 113/21 113/21 114/22 115/12 115/16 115/21 116/1 116/2 116/7 116/12 116/13 117/19 117/20 117/21 118/3 118/14 118/21 119/3 119/9 123/18 132/22 133/2 133/4 137/25 138/3 141/17 156/15 156/22 160/7 160/11 162/25 163/15 167/13 167/20 169/23 169/23 170/6 170/16 170/18 171/11
----------	--	---	--	---	---	---

<p><b>L</b></p> <p><b>liver...</b> [54] 171/12 171/14 171/17 171/21 171/23 172/14 172/15 173/13 174/9 174/12 174/15 174/18 174/24 175/6 175/9 175/17 175/19 176/3 176/11 178/25 179/18 181/20 206/5 212/11 212/25 213/6 213/8 213/15 214/4 214/11 214/15 214/16 214/17 214/18 215/7 215/17 215/25 216/2 216/4 216/8 217/8 218/1 218/9 218/11 218/12 218/19 218/20 219/9 219/10 219/14 219/18 219/24 228/3 228/4</p> <p><b>lives</b> [2] 79/11 175/15</p> <p><b>living</b> [1] 181/4</p> <p><b>load</b> [14] 49/15 50/4 51/7 51/14 52/3 53/11 53/25 71/17 71/21 161/1 225/4 231/10 231/15 231/16</p> <p><b>load-based</b> [2] 71/17 71/21</p> <p><b>loads</b> [1] 94/1</p> <p><b>local</b> [7] 117/24 133/12 133/17 150/8 186/14 194/8 206/19</p> <p><b>London</b> [2] 2/12 2/21</p> <p><b>long</b> [29] 20/22 44/8 44/19 49/1 52/14 55/18 62/11 71/8 81/16 96/22 108/15 114/15 117/18 120/21 123/12 129/16 133/19 133/23 134/14 147/9 148/20 167/8 167/23 169/5 171/24 177/11 181/6 198/24 199/21</p> <p><b>long-term</b> [12] 44/8 62/11 71/8 81/16 108/15 117/18 120/21 123/12 167/23 169/5 177/11 181/6</p> <p><b>longer</b> [10] 64/23 65/24 95/4 97/13 123/20 140/16 142/22 163/3 169/21 217/19</p> <p><b>look</b> [49] 5/20 15/16 17/12 19/3 21/20 21/24 34/7 48/20 51/4 57/12 67/9 68/16 72/4 98/23 103/10 105/4 106/14 110/9 110/10 114/7 114/25 125/5 133/13 135/3 135/4 135/8 138/16 151/21 152/11 153/8 156/12</p>	<p>157/21 158/6 171/2 173/23 177/7 182/9 186/21 190/20 200/12 201/15 202/1 206/11 209/13 209/17 211/21 212/16 213/3 217/15 <b>look-back</b> [1] 201/15</p> <p><b>looked</b> [7] 17/24 29/20 151/19 167/8 169/14 189/7 195/23</p> <p><b>looked at</b> [3] 151/19 167/8 195/23</p> <p><b>looking</b> [42] 3/22 8/21 48/15 49/10 49/15 49/19 51/23 59/1 59/15 65/11 69/5 69/10 69/14 70/4 70/8 70/14 71/22 72/18 72/19 75/24 77/11 78/2 80/21 117/15 119/25 125/13 126/8 136/22 144/15 145/14 155/5 159/1 181/10 185/21 187/17 199/10 201/8 202/6 202/22 205/18 211/23 226/7</p> <p><b>lose</b> [2] 53/8 53/9</p> <p><b>loss</b> [2] 81/1 81/24</p> <p><b>lost</b> [1] 11/6</p> <p><b>lot</b> [38] 8/20 11/11 15/9 15/21 19/11 20/17 22/17 26/10 32/14 32/20 46/22 59/12 70/11 76/8 101/10 103/13 122/12 124/5 131/22 132/14 134/5 145/2 160/15 160/18 161/25 164/5 166/25 174/19 175/5 179/22 184/19 185/22 208/18 208/21 210/6 210/10 210/17 213/24</p> <p><b>lots</b> [5] 61/2 85/1 174/24 196/6 197/22</p> <p><b>low</b> [27] 36/6 43/17 44/18 46/4 46/14 47/3 52/19 53/12 70/11 78/22 79/24 80/3 89/19 93/6 103/1 103/2 121/2 126/12 137/22 137/25 163/25 212/12 219/13 219/21 219/21 224/8 224/14</p> <p><b>low-level</b> [3] 53/12 80/3 93/6</p> <p><b>low-resource</b> [1] 43/17</p> <p><b>lower</b> [11] 9/19 11/9 85/2 96/2 107/5 120/20 122/13 149/17 161/14 163/4 174/17</p> <p><b>lunch</b> [3] 59/7 98/3 170/3</p>	<p><b>luncheon</b> [1] 98/10</p> <p><b>lunchtime</b> [1] 140/17</p> <p><b>lung</b> [1] 144/2</p> <p><b>lymphatic</b> [1] 137/17</p> <p><b>lymphoma</b> [4] 91/21 91/23 91/24 155/10</p> <p><b>lymphomas</b> [1] 91/17</p> <p><b>M</b></p> <p><b>made</b> [12] 53/5 118/14 127/15 130/22 131/10 132/8 163/6 165/16 174/8 183/8 191/2 205/8</p> <p><b>magnetic</b> [1] 80/6</p> <p><b>magnitude</b> [3] 54/16 98/23 172/25</p> <p><b>main</b> [14] 3/1 6/17 6/19 30/2 35/2 40/5 53/9 86/9 90/5 108/19 116/9 121/20 123/7 153/10</p> <p><b>mainstay</b> [2] 121/6 124/15</p> <p><b>mainstays</b> [1] 122/8</p> <p><b>maintain</b> [1] 12/15</p> <p><b>maintaining</b> [1] 8/1</p> <p><b>major</b> [6] 53/17 69/12 71/5 88/4 131/16 200/25</p> <p><b>majority</b> [10] 2/13 6/22 17/14 48/13 61/7 73/8 76/2 171/20 216/1 216/21</p> <p><b>make</b> [44] 14/16 19/11 20/16 30/7 33/12 43/6 54/12 65/20 66/22 69/23 103/22 105/21 106/8 134/12 134/19 150/12 173/20 174/4 179/6 184/4 185/3 187/15 187/19 189/17 196/1 196/1 196/2 199/3 199/6 199/13 199/17 200/1 200/3 201/8 203/11 204/12 208/4 209/1 209/5 209/14 209/16 211/11 211/14 214/21</p> <p><b>make-up</b> [1] 19/11</p> <p><b>makes</b> [4] 1/22 84/23 105/19 208/5</p> <p><b>making</b> [13] 20/20 46/19 49/5 85/1 181/2 181/9 182/1 184/2 185/8 193/12 200/2 208/19 213/22</p> <p><b>malaise</b> [1] 146/2</p> <p><b>malaria</b> [3] 98/21 99/4 99/5</p> <p><b>male</b> [1] 64/15</p> <p><b>malformations</b> [3]</p>	<p>218/25 219/3 219/6</p> <p><b>manage</b> [6] 36/3 36/13 122/15 184/25 185/13 185/19</p> <p><b>managed</b> [4] 67/23 112/17 128/7 169/14</p> <p><b>management</b> [6] 16/16 18/10 140/12 165/12 165/16 178/25</p> <p><b>managing</b> [1] 99/25</p> <p><b>mania</b> [1] 138/22</p> <p><b>manifest</b> [1] 72/17</p> <p><b>manifestations</b> [6] 81/8 81/14 123/19 137/20 153/10 154/7</p> <p><b>manifested</b> [1] 72/22</p> <p><b>manufacturer</b> [1] 136/10</p> <p><b>manufacturers</b> [1] 137/1</p> <p><b>manufacturing</b> [1] 226/6</p> <p><b>many</b> [53] 6/5 12/11 14/3 14/4 14/10 21/15 27/11 46/1 63/2 65/23 73/22 74/1 77/12 77/14 83/13 84/9 90/19 96/21 101/19 103/23 106/23 107/17 113/19 114/19 117/4 119/6 121/20 122/15 125/15 130/12 131/7 131/24 134/20 142/20 146/22 147/12 157/22 158/3 160/19 167/17 181/18 195/14 197/10 198/2 202/19 208/1 222/20 222/25 223/3 225/25 227/21 229/9 230/14</p> <p><b>mapped</b> [1] 131/9</p> <p><b>maps</b> [1] 68/7</p> <p><b>mark</b> [1] 85/3</p> <p><b>marker</b> [6] 53/2 53/9 89/15 163/25 218/7 223/25</p> <p><b>markers</b> [2] 167/21 180/19</p> <p><b>market</b> [3] 133/14 134/17 148/23</p> <p><b>marrow</b> [1] 219/19</p> <p><b>MARSHALL</b> [2] 2/2 2/19</p> <p><b>Marshall's</b> [1] 174/23</p> <p><b>Mary</b> [1] 1/20</p> <p><b>Mary's</b> [1] 2/12</p> <p><b>massive</b> [1] 181/8</p> <p><b>match</b> [2] 102/10 187/19</p> <p><b>material</b> [3] 130/16 151/18 171/8</p> <p><b>materials</b> [1] 32/7</p> <p><b>matter</b> [10] 19/12</p>	<p>59/25 61/20 130/12 131/1 139/25 173/9 173/17 205/18 227/9</p> <p><b>matters</b> [7] 32/4 92/16 98/17 179/13 195/4 229/25 230/21</p> <p><b>matured</b> [1] 128/24</p> <p><b>may</b> [140] 1/16 9/23 10/18 12/9 13/20 14/22 15/23 16/23 18/1 19/16 20/16 22/11 22/20 22/20 25/14 26/8 27/6 27/18 28/23 30/2 30/3 32/20 38/16 39/24 47/4 49/14 53/10 53/11 54/20 57/3 57/7 63/18 65/18 66/11 66/19 69/13 72/1 72/3 72/17 73/4 73/9 73/15 73/19 73/19 73/20 73/23 74/6 75/8 75/9 77/8 80/2 82/11 83/12 84/5 85/7 87/16 87/18 87/20 90/15 93/9 95/16 96/3 96/21 99/24 106/5 107/5 107/16 108/2 108/5 108/16 109/1 109/5 110/5 111/17 112/4 112/6 112/10 112/16 114/9 115/1 115/3 116/12 118/1 118/8 118/8 118/20 119/8 119/17 121/2 121/18 122/4 123/10 130/13 131/7 137/13 138/4 138/4 139/24 139/25 140/3 140/10 141/8 141/25 142/22 150/8 153/5 162/15 163/5 164/18 165/2 170/4 171/13 171/17 174/18 175/1 179/8 179/13 179/14 186/6 189/25 189/25 194/6 202/23 205/16 205/20 206/20 207/25 210/3 211/6 211/17 213/11 215/4 215/16 220/1 220/14 221/4 224/23 226/21 235/11 235/25</p> <p><b>maybe</b> [8] 5/6 16/11 44/15 52/15 72/22 121/23 175/20 217/16</p> <p><b>me</b> [15] 10/16 66/11 67/19 68/6 103/7 140/17 151/6 151/11 159/10 196/5 199/14 203/8 208/22 217/16 217/16</p> <p><b>me to</b> [2] 67/19 196/5</p> <p><b>mean</b> [26] 16/18 25/2</p>	<p>26/4 44/24 47/15 51/5 73/4 74/24 84/1 85/23 91/8 94/8 98/22 99/13 102/11 131/14 135/11 136/16 154/11 155/2 163/22 166/16 168/12 182/25 209/24 222/6</p> <p><b>meaning</b> [1] 5/15</p> <p><b>means</b> [20] 28/12 38/24 43/24 46/6 84/7 85/24 87/2 101/11 103/17 122/15 137/22 145/19 154/11 156/5 164/17 169/8 204/1 208/11 208/11 224/9</p> <p><b>meant</b> [9] 8/24 37/7 51/1 52/8 74/17 74/25 155/24 167/3 193/3</p> <p><b>measure</b> [6] 9/12 45/1 78/11 84/24 174/15 224/16</p> <p><b>measured</b> [1] 10/10</p> <p><b>measurement</b> [2] 90/6 213/6</p> <p><b>measures</b> [9] 38/4 39/2 107/12 108/9 165/10 179/18 179/19 194/23 212/24</p> <p><b>measuring</b> [1] 86/22</p> <p><b>mechanism</b> [2] 7/9 154/2</p> <p><b>mediastinal</b> [1] 143/10</p> <p><b>mediated</b> [1] 215/12</p> <p><b>medical</b> [12] 45/5 84/1 103/22 104/3 111/3 112/18 113/8 114/12 114/19 183/11 200/12 220/10</p> <p><b>medication</b> [3] 111/3 123/3 123/12</p> <p><b>medications</b> [2] 162/8 216/3</p> <p><b>medicine</b> [6] 37/7 37/8 134/16 153/22 197/22 199/1</p> <p><b>medicines</b> [2] 134/12 134/24</p> <p><b>medium</b> [1] 110/25</p> <p><b>meet</b> [2] 55/5 113/25</p> <p><b>meeting</b> [1] 204/4</p> <p><b>meetings</b> [1] 191/15</p> <p><b>meets</b> [1] 114/23</p> <p><b>member</b> [3] 197/15 206/4 211/5</p> <p><b>memory</b> [2] 77/4 142/6</p> <p><b>men</b> [2] 46/21 46/21 157/10</p> <p><b>mentioned</b> [17] 8/19 16/2 21/1 21/22 102/4 116/6 117/11 117/16</p>
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<b>M</b>	199/18 207/4 207/4	<b>morbidity [1]</b> 144/7	<b>most [41]</b> 2/23 5/16 11/15 17/3 20/2 21/18 21/21 51/24 56/9 73/18 73/21 84/2 86/13 86/16 89/12 96/21 110/15 112/15 116/7 116/8 116/25 119/24 122/10 129/19 139/7 147/1 147/1 147/15 152/20 154/6 168/25 169/9 179/25 194/5 197/25 206/16 211/20 216/1 231/17 232/22 235/21	229/2	175/10 176/25 177/1 180/3 184/4 184/14 185/11 186/12 192/5 192/12 204/5 212/25 216/13 225/10 227/1 <b>needed [6]</b> 1/4 36/19 107/16 134/25 185/23 186/18
<b>mentioned... [9]</b> 119/13 127/15 149/11 150/3 160/16 164/6 167/25 197/4 216/9	<b>mindful [2]</b> 58/1 187/5	<b>morbidity [1]</b> 144/7	<b>mother [2]</b> 41/20 42/8	<b>multiply [1]</b> 19/9	<b>needle [3]</b> 54/9 87/15 183/6
<b>mentioning [1]</b> 162/7	<b>minimal [2]</b> 149/21 170/22	<b>more [145]</b> 7/23 8/6 8/13 8/14 8/16 9/8 9/13 9/14 9/16 11/11 13/18 13/21 16/12 17/13 18/1 18/8 19/3 25/10 25/15 25/22 26/19 26/19 26/20 27/1 27/22 28/1 28/17 28/19 30/10 31/7 31/9 33/17 34/3 34/7 35/14 35/24 37/1 37/2 37/16 37/18 39/4 40/2 40/8 40/11 40/17 40/19 41/17 44/7 45/6 46/8 58/4 58/8 58/9 58/15 63/2 64/15 64/20 66/2 66/5 66/12 67/14 73/14 73/14 74/3 77/8 80/9 87/6 87/19 88/21 91/21 91/25 93/2 93/12 93/25 94/2 94/16 95/5 95/14 95/15 96/8 97/15 98/21 99/22 101/13 101/25 105/2 106/5 112/20 115/24 117/12 119/11 119/15 122/2 124/19 135/13 141/2 144/21 144/22 146/7 154/1 154/17 156/2 160/1 160/4 160/6 160/7 160/23 160/25 161/3 161/4 163/1 163/6 163/11 163/16 163/22 165/2 165/9 165/12 165/17 166/5 168/6 168/20 170/1 172/6 179/8 186/6 190/13 191/13 194/2 202/24 211/11 211/13 214/19 217/19 217/20 219/22 223/1 223/10 223/19 224/15 226/8 228/4 231/16 233/14 235/18	<b>mouth [1]</b> 110/12	<b>multitude [1]</b> 10/12	<b>negate [5]</b> 43/20 53/11 60/10 70/25 133/5
<b>merely [1]</b> 108/1	<b>minor [3]</b> 58/1 75/12 196/4	<b>more as [1]</b> 217/20	<b>move [11]</b> 17/17 38/19 106/11 126/24 127/10 165/22 177/22 192/22 203/11 215/18 234/16	<b>muscle [3]</b> 75/15 145/12 145/13	<b>negatives [5]</b> 68/19 68/24 70/24 71/10 71/14
<b>message [2]</b> 14/16 97/24	<b>minority [1]</b> 93/1	<b>more damage [1]</b> 9/13	<b>Ms [2]</b> 1/16 2/4	<b>muscles [1]</b> 9/10	<b>neither [6]</b> 59/19 96/7 180/11 214/13 214/14 214/14
<b>messages [1]</b> 46/11	<b>minutes [3]</b> 207/17 207/18 209/9	<b>more damaging [1]</b> 8/13	<b>Ms Richards [1]</b> 1/16	<b>musculoskeletal [3]</b> 145/10 145/13 157/1	<b>nerve [1]</b> 81/1
<b>messaging [1]</b> 46/6	<b>miss [1]</b> 199/19	<b>moreover [2]</b> 57/22 72/6	<b>much [57]</b> 1/23 6/9 8/15 11/9 13/13 18/7 18/21 22/1 23/14 31/9 36/18 37/16 40/7 40/11 44/7 45/1 47/19 49/3 53/4 53/16 53/16 57/17 62/24 79/15 86/10 87/16 89/4 93/8 93/8 93/10 93/12 96/2 122/4 122/13 141/4 149/8 149/8 163/3 163/13 163/16 165/2 165/15 165/17 171/5 172/6 180/2 194/2 202/7 212/4 213/10 217/18 224/15 228/25 229/21 229/23 235/12 236/2	<b>must [5]</b> 25/18 182/17 184/22 209/14 226/15	<b>nervousness [1]</b> 138/19
<b>metabolic [2]</b> 6/13 172/17	<b>missed [2]</b> 70/21 71/11	<b>mortality [12]</b> 98/20 102/7 102/13 102/19 102/24 104/22 104/24 105/4 105/10 105/15 169/23 189/20	<b>MRI [4]</b> 80/1 80/6 212/1 212/13	<b>my [38]</b> 1/3 2/13 2/14 2/23 3/14 3/16 3/17 4/16 40/23 42/20 51/3 70/12 92/3 99/17 133/11 140/16 159/10 176/11 181/13 185/5 188/2 189/9 196/12 198/21 199/9 199/17 200/22 201/23 204/10 204/11 204/19 204/21 208/2 208/3 209/23 215/2 217/6 230/19	<b>nervous [1]</b> 142/3
<b>metabolism [1]</b> 138/12	<b>misused [1]</b> 202/4		<b>MRI abnormalities [1]</b> 80/6	<b>myalgia [1]</b> 145/11	<b>network [3]</b> 82/25 83/6 114/8
<b>META VIR [1]</b> 86/12	<b>ml [1]</b> 226/3		<b>MRSA [1]</b> 193/9	<b>myself [1]</b> 197/15	<b>neuro [3]</b> 76/23 139/9 140/8
<b>MHRA [1]</b> 198/8	<b>mls [1]</b> 226/4		<b>Ms [2]</b> 1/16 2/4		<b>neuro-cognitive [1]</b> 76/23
<b>micro [1]</b> 190/19	<b>Mm [5]</b> 41/24 42/25 115/14 188/12 206/24		<b>Ms Richards [1]</b> 1/16		<b>neurocognitive [2]</b> 167/19 195/9
<b>micro-elimination [1]</b> 190/19	<b>Mm-hm [4]</b> 41/24 42/25 188/12 206/24		<b>much [57]</b> 1/23 6/9 8/15 11/9 13/13 18/7 18/21 22/1 23/14 31/9 36/18 37/16 40/7 40/11 44/7 45/1 47/19 49/3 53/4 53/16 53/16 57/17 62/24 79/15 86/10 87/16 89/4 93/8 93/8 93/10 93/12 96/2 122/4 122/13 141/4 149/8 149/8 163/3 163/13 163/16 165/2 165/15 165/17 171/5 172/6 180/2 194/2 202/7 212/4 213/10 217/18 224/15 228/25 229/21 229/23 235/12 236/2	<b>national [8]</b> 58/6 58/13 68/13 89/7 130/19 133/16 172/6 191/1	<b>neurons [2]</b> 80/8 80/11
<b>microbiologist [2]</b> 3/18 209/23	<b>mode [1]</b> 44/4		<b>Moved [1]</b> 128/23	<b>nationally [1]</b> 37/12	<b>neuropathy [2]</b> 142/8 142/22
<b>mid [2]</b> 33/25 59/17	<b>model [6]</b> 188/10 195/24 196/7 196/10 196/11 196/16		<b>moving [8]</b> 17/9 46/8 104/9 117/12 117/25 118/10 151/1 183/22	<b>nations [4]</b> 37/17 131/18 189/14 189/17 229/11	<b>neuropsychiatric [1]</b> 162/10
<b>mid-seventies [1]</b> 59/17	<b>moderate [2]</b> 84/16 85/15		<b>MRI [4]</b> 80/1 80/6 212/1 212/13	<b>native [1]</b> 229/11	<b>never [4]</b> 31/5 169/25 170/7 180/5
<b>mid-sixties [1]</b> 33/25	<b>modern [3]</b> 28/19 29/14 32/11		<b>Ms [2]</b> 1/16 2/4	<b>natural [13]</b> 11/8 27/4 61/22 64/1 95/17 96/5 96/8 97/1 97/17 129/9 130/6 170/5 214/23	<b>new [16]</b> 2/15 11/15 12/7 24/6 24/10 127/10 127/12 128/3 129/17 132/21 133/2 133/13 140/18 166/24 168/4 220/11
<b>middle [2]</b> 180/18 181/8	<b>modes [1]</b> 201/11		<b>Ms Richards [1]</b> 1/16	<b>naturally [1]</b> 127/16	<b>newer [5]</b> 123/7 127/21 161/16 168/5 172/23
<b>might [68]</b> 1/7 10/4 10/5 10/6 12/13 23/10 25/4 28/10 29/10 31/23 35/9 44/17 54/25 56/6 57/16 58/2 63/24 69/22 73/16 76/9 77/8 82/15 87/2 100/19 103/12 104/1 106/2 107/18 108/17 111/25 114/16 124/25 137/8 162/4 175/18 179/22 182/23 182/24 188/1 188/3 193/14 196/19 199/16 201/2 201/3 201/4 201/7 201/19 201/19 202/4 202/15 205/8 208/9 208/10 209/8 209/8 211/10 212/9 213/16 216/5 216/9 217/10 217/11 217/13 227/2 228/16 233/25 235/1	<b>modified [1]</b> 66/15		<b>Ms Richards [1]</b> 1/16	<b>nature [2]</b> 46/23 126/16	<b>newly [1]</b> 70/13
<b>mid-seventies [1]</b> 59/17	<b>moment [19]</b> 1/13 13/16 19/4 22/14 22/25 27/7 46/20 97/1 123/6 131/12 170/10 172/2 187/25 189/16 204/16 212/4 221/12 222/3 223/3		<b>Much [57]</b> 1/23 6/9 8/15 11/9 13/13 18/7 18/21 22/1 23/14 31/9 36/18 37/16 40/7 40/11 44/7 45/1 47/19 49/3 53/4 53/16 53/16 57/17 62/24 79/15 86/10 87/16 89/4 93/8 93/8 93/10 93/12 96/2 122/4 122/13 141/4 149/8 149/8 163/3 163/13 163/16 165/2 165/15 165/17 171/5 172/6 180/2 194/2 202/7 212/4 213/10 217/18 224/15 228/25 229/21 229/23 235/12 236/2	<b>needed [6]</b> 1/4 36/19 107/16 134/25 185/23 186/18	<b>next [23]</b> 13/10 24/14 45/2 48/5 83/13 83/20 83/21 106/11 107/22 109/10 111/23 131/5 135/2 141/23 151/11 156/10 156/21 157/21 159/1 164/2 183/23 215/2 223/7
<b>mid-sixties [1]</b> 33/25	<b>Monday [2]</b> 22/18 99/15		<b>MRI [4]</b> 80/1 80/6 212/1 212/13	<b>neither [6]</b> 59/19 96/7 180/11 214/13 214/14 214/14	<b>NHS [5]</b> 4/8 113/22
<b>middle [2]</b> 180/18 181/8	<b>money [3]</b> 134/10 191/17 192/10		<b>MRI abnormalities [1]</b> 80/6	<b>neuro [3]</b> 76/23 139/9 140/8	
<b>might [68]</b> 1/7 10/4 10/5 10/6 12/13 23/10 25/4 28/10 29/10 31/23 35/9 44/17 54/25 56/6 57/16 58/2 63/24 69/22 73/16 76/9 77/8 82/15 87/2 100/19 103/12 104/1 106/2 107/18 108/17 111/25 114/16 124/25 137/8 162/4 175/18 179/22 182/23 182/24 188/1 188/3 193/14 196/19 199/16 201/2 201/3 201/4 201/7 201/19 201/19 202/4 202/15 205/8 208/9 208/10 209/8 209/8 211/10 212/9 213/16 216/5 216/9 217/10 217/11 217/13 227/2 228/16 233/25 235/1	<b>monitor [5]</b> 125/22 172/8 172/9 177/7 181/7		<b>Ms [2]</b> 1/16 2/4	<b>nationally [1]</b> 37/12	
<b>mild [5]</b> 61/14 75/13 84/15 112/13 139/20	<b>monitored [1]</b> 125/19		<b>Ms Richards [1]</b> 1/16	<b>nations [4]</b> 37/17 131/18 189/14 189/17 229/11	
<b>milder [2]</b> 60/12 112/17	<b>monitoring [9]</b> 23/15 23/16 110/24 170/19 178/15 213/19 214/3 216/3 216/8		<b>Much [57]</b> 1/23 6/9 8/15 11/9 13/13 18/7 18/21 22/1 23/14 31/9 36/18 37/16 40/7 40/11 44/7 45/1 47/19 49/3 53/4 53/16 53/16 57/17 62/24 79/15 86/10 87/16 89/4 93/8 93/8 93/10 93/12 96/2 122/4 122/13 141/4 149/8 149/8 163/3 163/13 163/16 165/2 165/15 165/17 171/5 172/6 180/2 194/2 202/7 212/4 213/10 217/18 224/15 228/25 229/21 229/23 235/12 236/2	<b>native [1]</b> 229/11	
<b>milestones [1]</b> 32/10	<b>months [11]</b> 27/13 52/15 75/4 89/15 118/18 149/14 149/15 181/20 196/15 211/15 215/1		<b>Moved [1]</b> 128/23	<b>natural [13]</b> 11/8 27/4 61/22 64/1 95/17 96/5 96/8 97/1 97/17 129/9 130/6 170/5 214/23	
<b>millennium [2]</b> 36/18 36/24	<b>mood [1]</b> 138/18		<b>moving [8]</b> 17/9 46/8 104/9 117/12 117/25 118/10 151/1 183/22	<b>naughties [1]</b> 141/10	
<b>million [3]</b> 98/25 99/1 226/2	<b>morbid [1]</b> 207/22		<b>MRI [4]</b> 80/1 80/6 212/1 212/13	<b>navigate [1]</b> 197/5	
<b>mind [5]</b> 69/15 69/16			<b>Ms [2]</b> 1/16 2/4	<b>necessarily [15]</b> 26/4 27/14 47/15 73/21 78/15 81/10 120/16 136/18 139/16 166/16 167/5 167/15 185/24 205/3 218/20	

<b>N</b>	180/12 198/12	152/3 152/24 154/10	213/14 216/12 216/23	192/3 196/20 200/17	142/19 164/17 168/6
<b>NHS...</b> [3] 114/6 131/3	<b>normal</b> [26] 5/23 5/23	154/14 155/1 155/2	217/8 220/17 221/2	202/24	181/18 184/19 186/4
222/10	5/25 6/1 7/14 9/14	156/7 157/17 158/3	227/16 229/20 235/19	<b>obviously</b> [29] 6/9	208/8 208/20 208/20
<b>NICE</b> [4] 55/6 55/8	78/18 82/20 85/4	159/3 159/10 162/21	235/19	15/12 21/2 21/13 23/8	209/7 210/13 214/3
121/4 130/21	85/11 95/1 97/12	164/11 167/3 167/15	<b>nucleoside</b> [1] 121/8	31/4 33/24 34/24	219/25 222/24 234/8
<b>night</b> [1] 145/6	109/17 110/18 116/23	169/5 170/18 171/21	<b>nucleotide</b> [1] 121/8	38/25 40/12 46/5	234/9 235/7
<b>nightmares</b> [1] 142/7	137/9 144/2 170/24	173/13 174/18 176/18	<b>number</b> [76] 4/13 9/5	57/20 65/17 75/19	<b>oh</b> [4] 1/21 47/18
<b>nineties</b> [5] 31/25	178/4 216/16 216/20	177/4 179/11 179/18	17/12 18/23 21/10	92/13 99/13 133/16	77/22 204/14
35/12 35/21 36/12	216/20 216/24 217/11	180/2 180/24 182/6	22/13 23/7 24/9 24/11	139/3 144/19 156/22	<b>okay</b> [8] 9/6 48/13
141/9	217/13 217/18	183/5 184/19 187/6	24/14 24/15 24/17	159/18 165/1 176/24	77/23 92/5 106/11
<b>Ninewells</b> [1] 4/6	<b>normalise</b> [1] 203/8	188/5 188/7 188/9	26/1 28/6 31/2 31/15	177/3 182/20 195/17	180/16 204/13 204/22
<b>Ninewells Hospital</b> [1]	<b>normalising</b> [1]	188/13 189/3 189/6	36/21 39/9 41/14	206/4 208/5 222/8	<b>old</b> [2] 30/18 148/18
4/6	204/15	193/15 194/5 194/14	56/17 66/16 67/15	<b>occasionally</b> [2]	<b>older</b> [7] 28/14 62/24
<b>no</b> [43] 1/4 4/16 4/25	<b>normality</b> [2] 77/16	195/12 195/13 195/17	68/1 70/17 71/20	122/1 123/2	66/2 66/2 66/4 73/14
7/2 9/23 11/1 53/21	77/25	196/11 198/11 198/12	75/16 76/25 85/22	<b>occasions</b> [3] 41/14	74/4
63/14 76/3 78/10	<b>normally</b> [2] 111/12	198/22 199/21 200/13	87/5 92/8 93/16 98/16	85/23 156/4	<b>oldest</b> [1] 84/7
81/11 87/8 87/20	219/6	200/17 201/2 201/7	99/2 99/15 103/4	<b>occult</b> [4] 223/22	<b>once</b> [11] 33/24 34/9
110/17 110/23 111/1	<b>northern</b> [2] 20/5	201/19 202/3 202/13	108/9 108/16 116/11	223/24 224/2 224/21	78/21 122/11 124/9
114/15 132/1 133/14	189/3	202/20 203/18 204/16	119/24 121/17 125/10	<b>occur</b> [11] 41/22	124/22 160/2 169/16
148/21 157/15 167/2	<b>not</b> [229] 4/14 7/2	205/14 206/1 208/10	135/16 137/18 139/22	41/25 42/8 91/24	223/11 223/19 225/20
170/22 170/24 172/15	9/25 10/15 10/17	209/3 210/3 211/6	142/8 142/25 143/4	91/25 145/21 153/25	<b>one</b> [124] 1/7 5/21
176/10 177/10 177/10	17/14 22/20 24/6	211/9 211/14 211/17	143/10 144/7 145/7	156/2 214/19 214/25	12/20 14/9 15/9 16/2
177/11 177/25 178/1	25/16 25/16 25/21	212/10 212/14 215/9	146/4 148/3 151/9	233/25	16/18 17/11 17/13
178/2 203/11 207/11	26/11 26/17 26/19	215/20 215/21 216/17	151/21 152/22 155/12	<b>occurred</b> [1] 144/1	19/7 20/3 28/1 28/5
212/2 219/7 221/24	28/8 28/15 29/22	216/22 218/12 218/16	155/16 156/3 156/19	<b>occurrences</b> [1]	28/17 28/18 29/1 30/1
226/13 226/19 230/22	29/22 30/3 30/9 31/17	218/20 220/14 220/23	157/6 161/20 164/11	47/10	30/11 37/7 38/3 39/7
232/14 233/22 233/22	31/19 31/22 32/8 38/5	222/3 224/23 226/17	164/23 166/13 182/14	<b>occurring</b> [1] 59/18	39/19 40/4 41/6 44/10
<b>nodding</b> [1] 62/1	38/7 39/3 39/17 39/24	228/5 229/21 230/11	188/6 192/11 193/22	<b>occurs</b> [2] 82/19 92/8	45/12 45/15 47/10
<b>nodule</b> [3] 87/12	40/6 41/6 42/3 42/13	232/20 232/20 233/4	195/6 196/24 202/11	<b>oesophageal</b> [1]	47/21 49/20 52/23
87/16 211/23	43/10 45/4 46/4 46/11	235/19	205/1 213/4 217/21	173/23	54/25 56/7 61/9 63/6
<b>nodules</b> [6] 83/24	47/5 47/21 49/5 51/25	<b>note</b> [2] 98/4 140/1	232/17 234/24	<b>oesophagus</b> [2] 81/23	65/17 65/20 66/22
87/13 211/22 211/23	53/10 53/21 56/21	<b>noted</b> [3] 47/18 98/7	<b>numbers</b> [21] 21/13	110/13	67/4 67/11 73/3 83/7
212/16 212/17	58/3 58/15 58/25	110/22	21/14 21/15 22/6	<b>of it</b> [13] 11/10 26/4	84/7 84/14 85/25
<b>non</b> [28] 32/2 32/2	59/22 61/10 62/20	<b>notes</b> [1] 200/15	22/15 23/1 23/11	67/9 74/24 79/7 79/17	86/11 86/13 86/15
34/5 34/18 34/18	64/22 65/16 66/8	<b>nothing</b> [1] 121/16	23/24 40/10 65/12	116/11 141/1 144/20	87/12 88/23 92/4 92/8
34/22 34/22 35/3 35/3	66/20 66/21 67/8	<b>notice</b> [4] 32/17 60/20	79/14 94/14 164/12	172/21 176/24 218/5	95/18 103/11 105/5
59/21 59/21 59/23	69/19 69/22 72/3	153/25 154/21	192/4 209/4 222/9	228/25	107/1 107/6 108/20
59/24 60/2 60/2 60/3	72/11 73/9 73/12	<b>noticed</b> [6] 60/25	222/13 222/23 222/24	<b>of liver</b> [1] 67/2	110/16 112/1 116/10
60/3 61/8 61/8 61/13	73/21 74/1 74/12	154/17 156/1 156/7	223/2 234/15	<b>of number</b> [1] 18/23	120/3 120/12 125/14
61/13 61/18 61/18	74/25 75/22 78/9	200/22 200/23	<b>nurse</b> [1] 178/22	<b>of treatments</b> [1]	130/10 132/6 133/11
73/16 76/9 76/12	78/15 79/8 80/9 80/16	<b>now</b> [81] 2/14 13/17	<b>nurses</b> [1] 67/24	197/3	136/8 137/21 137/23
76/20 155/10	80/22 81/5 81/7 81/9	18/25 23/25 27/12	<b>nursing</b> [2] 186/4	<b>off</b> [17] 1/20 1/22	138/17 139/3 140/9
<b>non-A</b> [11] 32/2 34/18	84/25 85/7 85/8 87/16	28/19 29/20 30/14	186/5	73/16 107/11 107/24	141/21 150/13 154/4
34/22 35/3 59/21	89/2 89/11 89/21	31/9 31/11 33/5 33/6	<b>nutrition</b> [1] 138/12	109/7 111/5 112/12	156/5 160/16 162/10
59/23 60/2 60/3 61/8	90/15 93/9 94/10 95/3	33/10 37/4 38/19		118/5 125/18 142/19	164/6 164/8 164/17
61/13 61/18	99/25 100/2 100/6	39/22 41/1 46/9 52/9	<b>O</b>	147/8 153/24 161/15	166/6 173/1 180/6
<b>non-B</b> [11] 32/2 34/18	100/7 102/23 103/3	58/4 58/5 58/23 60/2	<b>o'clock</b> [2] 47/25 98/8	163/15 196/20 232/8	180/17 185/25 190/4
34/22 35/3 59/21	105/20 108/11 108/17	69/20 80/16 84/3	<b>obesity</b> [3] 64/17	<b>offer</b> [6] 174/20	190/9 191/7 193/18
59/24 60/2 60/3 61/8	110/6 112/4 112/7	89/17 96/6 100/13	94/19 172/17	179/24 187/8 187/13	196/21 197/14 197/25
61/13 61/18	113/18 114/12 114/16	101/24 102/24 120/14	<b>objective</b> [2] 120/9	194/7 214/6	205/6 211/4 212/7
<b>non-Hodgkin</b> [1]	118/7 118/22 120/15	121/6 122/4 122/7	120/15	<b>offered</b> [11] 88/16	212/8 212/21 212/24
155/10	121/3 123/9 123/15	123/1 123/13 125/21	<b>objectively</b> [2] 38/14	89/12 111/2 115/6	213/4 213/16 217/5
<b>non-liver</b> [2] 76/9	123/24 123/24 123/25	126/9 128/10 128/17	202/15	150/1 174/6 187/16	218/4 218/23 220/8
76/20	124/5 124/22 125/14	128/20 128/24 132/11	<b>observation</b> [1]	187/17 199/11 200/11	222/2 222/18 223/1
<b>non-liver-based</b> [1]	125/23 128/18 130/10	133/6 136/14 139/23	130/10	213/16	223/10 223/19 226/20
76/12	130/22 130/25 131/2	148/17 149/14 150/2	<b>observations</b> [3]	<b>offering</b> [1] 126/12	227/25 228/17 230/9
<b>non-specific</b> [2] 34/5	131/8 131/10 135/10	150/5 150/9 150/25	142/11 158/5 202/25	<b>officer</b> [1] 3/8	230/22 232/23 233/3
73/16	135/11 136/1 136/16	157/18 158/25 162/9	<b>observed</b> [1] 131/8	<b>often</b> [35] 5/17 6/14	233/4 233/5 233/20
<b>none</b> [4] 75/9 84/15	136/18 137/8 137/11	165/18 169/8 174/9	<b>observer</b> [1] 87/10	22/23 28/17 41/21	233/24 235/3 235/16
148/16 195/2	137/19 139/16 139/19	182/13 188/13 189/11	<b>obstructive</b> [1]	49/5 71/23 77/20 81/9	<b>ones</b> [11] 17/14 30/2
<b>nonetheless</b> [3] 44/3	139/19 140/3 142/20	191/21 196/10 198/21	143/23	100/9 101/18 105/24	57/18 60/13 141/20
147/18 161/3	144/8 144/12 144/17	200/5 201/21 201/25	<b>obvious</b> [8] 82/7	121/1 124/21 127/18	141/24 143/17 146/11
<b>nor</b> [4] 58/16 59/20	147/24 148/20 150/19	202/5 208/8 213/4	114/16 120/1 165/6	133/3 137/24 140/12	161/22 162/9 194/25

<p><b>O</b></p> <p><b>ongoing</b> [4] 176/25 177/25 178/1 211/2</p> <p><b>online</b> [6] 183/16 205/10 207/5 210/14 210/23 229/14</p> <p><b>only</b> [28] 11/7 11/25 12/15 18/18 41/13 77/16 86/25 105/9 105/14 119/3 125/18 128/4 148/9 148/17 150/10 166/2 193/6 197/17 198/4 198/7 199/12 204/23 209/8 216/21 226/25 228/5 229/16 232/17</p> <p><b>onscreen</b> [5] 20/12 21/4 21/5 68/4 152/5</p> <p><b>onset</b> [1] 42/23</p> <p><b>onto</b> [1] 133/14</p> <p><b>onwards</b> [6] 60/18 61/18 127/23 182/5 192/25 221/19</p> <p><b>opening</b> [1] 10/13</p> <p><b>operation</b> [1] 200/25</p> <p><b>opportunity</b> [3] 183/25 208/3 235/25</p> <p><b>opposed</b> [4] 44/16 77/23 199/25 234/9</p> <p><b>opt</b> [1] 179/25</p> <p><b>optimal</b> [1] 187/21</p> <p><b>optimum</b> [1] 211/15</p> <p><b>option</b> [1] 179/25</p> <p><b>options</b> [4] 106/18 106/20 116/2 128/25</p> <p><b>or</b> [236] 2/25 5/1 8/4 8/8 10/16 10/18 10/25 11/16 12/11 16/2 16/16 22/20 22/21 24/22 24/23 25/12 25/19 28/8 28/8 30/7 31/18 31/21 34/17 38/3 38/4 38/5 38/6 42/4 42/14 42/19 44/10 47/10 49/9 49/11 49/14 49/14 49/16 50/17 50/21 50/22 51/20 51/24 54/10 54/20 55/3 55/11 56/1 59/24 61/17 61/24 62/19 62/25 63/1 63/2 63/6 66/8 66/20 66/21 67/16 69/19 70/21 71/6 71/9 72/16 73/12 74/24 75/9 75/17 76/3 77/8 78/9 78/17 78/19 78/21 78/22 79/11 81/5 81/21 82/5 83/13 84/16 85/9 85/11 86/1 86/2 88/10 88/10 89/1 90/6 90/13 91/2 93/7 94/6 94/16 94/17</p>	<p>95/22 96/10 96/18 96/21 97/15 97/19 98/21 99/10 102/16 105/1 105/1 105/11 107/8 107/8 107/18 107/19 107/21 108/7 110/25 111/5 111/14 111/15 111/20 112/5 112/11 112/19 112/22 115/2 115/2 115/21 117/20 117/22 117/23 118/2 118/4 118/21 118/23 121/7 121/8 123/18 126/11 128/13 129/16 130/13 131/5 137/18 139/19 140/20 145/3 145/23 147/1 148/17 150/21 151/19 151/22 151/25 152/1 152/16 153/1 153/4 153/5 153/6 154/13 156/5 157/24 158/14 158/16 158/23 160/16 166/1 166/8 166/23 168/4 169/3 170/13 170/15 170/22 172/3 172/23 173/4 174/12 178/13 178/23 178/23 178/23 179/5 179/15 180/1 180/24 183/6 187/2 188/7 188/17 188/17 189/5 192/13 197/9 197/10 199/16 200/7 201/19 203/5 203/16 205/17 207/4 211/11 212/1 212/3 212/7 212/14 213/12 213/13 214/12 214/13 214/21 215/6 215/20 215/21 217/14 218/7 218/14 218/18 218/21 219/2 222/16 225/9 226/18 226/20 226/23 227/18 228/12 228/15 230/1 232/24 232/25 233/4 233/15 234/11 234/12 234/20 235/1</p> <p><b>or C</b> [2] 10/18 215/20</p> <p><b>oral</b> [3] 92/18 121/8 123/3</p> <p><b>orally</b> [1] 195/10</p> <p><b>order</b> [7] 58/13 114/1 114/24 118/18 121/23 150/16 227/10</p> <p><b>organ</b> [2] 71/6 215/7</p> <p><b>Organisation</b> [1] 188/23</p> <p><b>organs</b> [4] 107/4 107/9 215/3 215/4</p> <p><b>original</b> [2] 4/24 118/16</p> <p><b>originally</b> [1] 117/4</p> <p><b>other</b> [112] 4/13 8/16</p>	<p>14/22 19/19 20/4 25/19 30/5 33/18 36/2 37/20 41/18 43/22 47/3 50/16 54/10 56/7 59/2 60/25 61/6 61/9 62/8 64/16 69/20 78/16 79/12 80/17 83/23 86/14 89/24 90/14 91/18 94/19 95/10 100/10 100/17 100/20 101/17 101/19 103/11 103/23 103/24 103/25 104/2 104/4 104/5 104/7 104/13 105/14 108/7 108/10 108/18 108/18 112/10 112/21 114/15 115/1 115/3 115/20 115/22 119/2 120/22 122/2 122/23 123/18 130/16 133/23 134/20 137/10 144/14 147/9 151/21 153/4 154/4 155/18 156/6 156/6 156/23 156/23 158/11 162/6 164/3 164/18 172/16 174/11 177/20 178/8 180/20 186/10 192/9 196/6 197/10 199/18 202/2 202/6 204/12 205/22 208/15 212/1 212/7 213/13 215/3 215/4 215/13 216/6 224/5 225/16 226/4 226/20 229/25 230/20 233/23 235/13</p> <p><b>others</b> [15] 5/6 5/12 14/22 17/15 18/1 28/20 40/7 45/14 62/4 72/24 99/18 104/15 131/4 138/10 215/16</p> <p><b>otherwise</b> [6] 30/4 38/4 72/4 170/5 215/20 215/21</p> <p><b>otitis</b> [1] 135/25</p> <p><b>ought</b> [1] 55/4</p> <p><b>our</b> [34] 8/23 11/22 13/10 14/14 40/5 44/5 49/21 51/7 51/7 51/14 52/24 53/2 53/15 57/25 58/20 60/15 69/7 70/11 71/17 123/7 165/19 168/12 187/21 187/22 190/15 191/23 193/7 198/5 199/2 200/2 200/12 216/14 216/15 217/20</p> <p><b>ourselves</b> [2] 197/8 198/20</p> <p><b>out</b> [76] 6/15 9/12 13/17 15/18 17/9 19/20 23/9 27/4 33/19 38/1 38/11 39/1 41/17</p>	<p>50/5 58/23 62/12 63/1 64/2 67/5 67/6 67/7 67/12 68/7 69/18 70/16 82/23 83/19 87/4 92/18 100/12 101/2 101/17 101/22 102/1 105/4 105/9 106/19 114/24 116/3 133/20 134/7 135/17 137/13 137/21 140/17 141/24 146/8 147/21 151/7 152/23 154/24 156/9 166/22 168/3 175/6 175/19 182/14 183/24 184/7 184/10 185/1 186/22 188/10 188/11 188/25 192/21 201/25 205/7 209/12 222/20 223/8 226/11 226/19 227/25 230/1 233/8</p> <p><b>outcome</b> [8] 29/19 41/8 88/18 108/15 115/3 133/5 143/14 163/19</p> <p><b>outcomes</b> [6] 117/18 133/9 181/6 225/15 225/17 225/20</p> <p><b>outline</b> [2] 12/1 109/12</p> <p><b>outlined</b> [3] 5/9 108/20 230/16</p> <p><b>outlines</b> [1] 117/9</p> <p><b>outside</b> [3] 5/24 168/13 214/7</p> <p><b>over</b> [43] 2/11 9/11 10/6 11/5 11/6 23/13 23/23 27/24 30/19 56/14 63/2 67/13 73/19 89/4 93/3 94/6 97/12 97/13 104/17 104/18 104/20 104/23 114/3 115/11 115/16 115/17 118/12 119/23 126/7 138/17 139/24 141/9 145/8 151/11 155/17 157/12 170/15 172/3 172/7 175/19 186/1 195/7 213/25</p> <p><b>overall</b> [10] 12/19 18/3 22/2 94/25 103/1 103/13 115/1 116/21 118/17 158/6</p> <p><b>overlap</b> [2] 142/14 146/22</p> <p><b>overnight</b> [1] 234/1</p> <p><b>overrun</b> [1] 98/6</p> <p><b>overview</b> [4] 37/23 38/1 39/11 48/8</p> <p><b>own</b> [3] 7/12 12/6 44/5</p> <p><b>Oxford</b> [2] 3/15 3/25</p>	<p><b>P</b></p> <p><b>package</b> [1] 136/9</p> <p><b>page</b> [36] 20/14 39/9 42/21 55/15 55/15 59/16 67/10 70/23 82/16 90/24 98/15 117/6 117/8 125/4 135/2 135/5 141/23 142/2 143/7 145/8 152/10 153/3 153/8 155/17 156/12 156/21 156/25 157/13 171/8 182/5 182/9 183/23 186/22 186/24 188/19 192/25</p> <p><b>page 15</b> [1] 55/15</p> <p><b>page 16</b> [1] 55/15</p> <p><b>page 17</b> [1] 59/16</p> <p><b>page 20</b> [1] 67/10</p> <p><b>page 21</b> [1] 70/23</p> <p><b>page 27</b> [2] 82/16 90/24</p> <p><b>page 28</b> [1] 98/15</p> <p><b>Page 33</b> [1] 117/6</p> <p><b>page 41</b> [1] 125/4</p> <p><b>page 5</b> [1] 20/14</p> <p><b>page 56</b> [1] 171/8</p> <p><b>page 58</b> [1] 153/3</p> <p><b>page 60</b> [1] 156/25</p> <p><b>page 61</b> [1] 182/5</p> <p><b>page 63</b> [1] 186/22</p> <p><b>page 70</b> [1] 188/19</p> <p><b>page 78</b> [1] 192/25</p> <p><b>page 9</b> [2] 39/9 42/21</p> <p><b>pages</b> [2] 165/23 188/19</p> <p><b>pages 53</b> [1] 165/23</p> <p><b>pages 64</b> [1] 188/19</p> <p><b>pagination</b> [1] 152/11</p> <p><b>paid</b> [1] 134/11</p> <p><b>pain</b> [10] 73/19 75/14 79/6 79/10 145/11 145/12 145/12 145/13 145/24 146/1</p> <p><b>painful</b> [1] 213/12</p> <p><b>pains</b> [2] 75/15 91/2</p> <p><b>palliative</b> [1] 118/23</p> <p><b>palpitations</b> [1] 143/3</p> <p><b>palsy</b> [1] 142/10</p> <p><b>pan</b> [1] 128/18</p> <p><b>pan-genotypic</b> [1] 128/18</p> <p><b>panel</b> [6] 1/6 82/20 83/13 151/8 202/25 211/5</p> <p><b>paper</b> [4] 33/14 33/18 153/17 210/14</p> <p><b>paracentesis</b> [1] 109/3</p> <p><b>paradoxically</b> [1] 74/15</p> <p><b>paragraph</b> [3] 39/14 67/11 152/12</p>	<p><b>parameter</b> [1] 116/20</p> <p><b>parapet</b> [1] 230/23</p> <p><b>parasite</b> [1] 7/12</p> <p><b>parlance</b> [1] 14/5</p> <p><b>part</b> [29] 14/14 16/15 17/1 20/22 22/2 39/6 72/8 72/25 77/15 77/25 92/22 117/20 121/4 121/12 140/12 141/21 145/9 157/21 159/1 166/21 178/6 181/17 194/5 194/16 203/23 213/18 220/1 220/14 221/15</p> <p><b>participants</b> [9] 25/6 39/9 39/23 103/9 151/8 166/7 192/23 205/2 234/1</p> <p><b>participate</b> [1] 227/19</p> <p><b>participating</b> [1] 234/7</p> <p><b>particular</b> [50] 5/22 6/24 9/7 13/7 16/1 24/20 30/22 31/22 35/11 36/15 36/21 37/18 39/5 45/20 46/1 53/19 54/8 68/12 68/22 73/11 74/2 91/20 92/22 99/15 106/3 106/15 127/24 127/25 131/20 136/10 142/11 145/21 148/12 148/19 155/9 156/14 158/2 162/11 166/6 182/16 184/23 186/23 188/8 190/20 193/18 197/12 205/4 215/4 224/6 234/24</p> <p><b>particularly</b> [36] 1/12 2/15 9/8 12/12 13/2 26/9 32/21 39/23 43/15 43/18 45/23 46/20 47/21 59/10 75/2 76/10 93/21 96/2 118/12 123/9 124/17 127/7 129/6 130/25 137/13 141/25 143/12 147/16 162/14 186/2 191/5 194/21 214/21 227/21 230/15 230/20</p> <p><b>partly</b> [3] 74/15 220/13 233/6</p> <p><b>partner</b> [2] 45/21 235/8</p> <p><b>partnered</b> [2] 229/6 229/8</p> <p><b>partnership</b> [1] 184/5</p> <p><b>parts</b> [8] 15/20 21/12 21/15 118/2 119/2 137/23 152/5 213/24</p> <p><b>pass</b> [1] 183/17</p> <p><b>passage</b> [1] 81/21</p> <p><b>passing</b> [1] 111/14</p>
--	---	--	---	--	--



<p><b>P</b></p> <p><b>past [8]</b> 29/5 57/22 68/10 134/3 196/15 198/4 213/9 224/16</p> <p><b>patchy [2]</b> 173/11 214/5</p> <p><b>pathogenic [2]</b> 16/5 155/8</p> <p><b>pathologists [3]</b> 87/1 87/3 87/9</p> <p><b>pathology [1]</b> 50/13</p> <p><b>pathways [1]</b> 230/15</p> <p><b>patient [66]</b> 5/23 9/22 10/5 16/16 16/17 18/10 20/19 28/23 46/6 50/21 50/21 65/14 65/15 75/2 81/18 88/23 89/10 95/13 99/25 107/10 109/1 112/16 114/24 115/4 124/3 125/22 132/25 141/22 142/17 144/16 144/20 162/2 164/16 168/2 174/1 176/8 176/9 177/9 178/10 179/1 179/10 180/21 181/23 182/2 182/13 183/17 184/2 184/3 184/6 184/9 184/17 184/21 186/14 187/6 187/10 198/22 199/15 206/14 206/17 207/1 207/13 209/11 210/9 212/5 213/12 220/2</p> <p><b>patient's [8]</b> 18/10 114/22 133/19 134/9 165/21 181/11 184/16 187/22</p> <p><b>patient-led [1]</b> 187/10</p> <p><b>patients [164]</b> 2/10 2/24 3/20 3/23 5/12 12/10 12/17 15/15 15/22 18/23 21/10 22/15 22/19 23/1 23/4 26/1 26/9 26/21 28/24 34/14 36/3 46/10 59/4 60/6 60/12 60/17 61/3 66/4 71/1 71/12 73/8 74/1 76/2 76/22 78/5 78/6 78/7 78/18 84/9 86/20 90/7 90/12 92/3 92/9 92/25 93/2 93/6 95/14 95/15 97/21 100/9 101/16 101/24 103/13 107/17 108/16 109/2 109/5 111/11 113/4 113/6 113/24 113/25 114/9 114/10 114/13 116/7 117/25 118/19 118/20 119/7 119/12 119/17 120/17 121/18 121/21 121/24</p>	<p>122/4 122/15 123/11 124/8 131/23 131/24 132/1 132/5 132/20 133/6 133/10 137/25 139/4 139/8 139/11 139/16 139/22 140/10 140/24 141/5 144/8 147/19 149/25 150/1 158/20 160/13 161/12 161/18 161/20 162/14 162/24 163/7 164/11 164/23 165/3 167/8 167/18 168/7 169/15 169/25 170/20 172/9 172/10 173/3 173/9 173/16 174/18 177/7 179/21 183/13 184/19 186/15 191/3 193/7 193/12 193/22 194/4 197/7 198/8 198/9 198/14 199/11 200/10 201/2 201/23 204/6 204/16 206/3 206/13 209/17 210/4 210/15 210/19 210/20 210/22 211/5 213/15 214/1 216/6 216/10 222/9 222/12 222/15 222/17 222/20 225/21 232/5</p> <p><b>pattern [2]</b> 68/11 158/15</p> <p><b>pause [1]</b> 27/7</p> <p><b>pausing [1]</b> 93/15</p> <p><b>pay [1]</b> 134/11</p> <p><b>pays [1]</b> 134/7</p> <p><b>PCR [3]</b> 49/14 71/17 224/22</p> <p><b>peg [1]</b> 127/5</p> <p><b>pegylated [8]</b> 36/8 124/14 127/5 129/7 157/25 229/5 229/11 229/12</p> <p><b>PEI [1]</b> 117/22</p> <p><b>penultimate [1]</b> 192/20</p> <p><b>people [105]</b> 5/10 8/15 8/16 14/3 14/4 18/18 20/9 20/13 22/7 22/21 23/21 23/25 24/6 27/4 27/11 27/13 27/21 27/10 46/1 63/3 65/23 66/1 69/3 70/16 75/9 77/12 77/14 77/16 77/21 77/23 79/10 79/12 86/22 88/6 89/20 91/21 99/1 101/19 103/4 104/25 105/10 105/12 105/13 113/19 114/6 118/17 119/14 125/15 129/4 129/11 129/25 132/17 137/7 139/12 149/19 154/21 156/1 156/6</p>	<p>158/8 163/23 164/9 168/9 168/19 168/22 169/6 169/6 170/11 170/22 171/3 171/17 172/13 173/18 175/1 175/4 175/13 175/14 175/16 175/17 181/18 181/18 186/12 190/16 190/23 192/4 192/12 197/18 198/6 200/9 203/7 203/10 219/10 221/2 225/15 227/21 227/22 228/11 228/24 229/3 229/9 233/13 234/7 235/2 235/7 235/8 235/13</p> <p><b>people's [1]</b> 203/17</p> <p><b>per [34]</b> 3/16 18/6 44/16 44/18 47/10 60/11 62/7 62/10 62/18 62/20 63/1 63/1 63/6 63/10 64/14 64/19 64/25 70/6 74/3 74/7 78/21 79/8 88/8 90/10 95/2 95/8 95/9 115/16 115/17 121/3 190/21 191/3 212/14 226/3</p> <p><b>per cent [17]</b> 44/16 44/18 60/11 62/7 62/10 63/6 63/10 70/6 74/3 74/7 88/8 95/8 95/9 115/16 121/3 190/21 191/3</p> <p><b>per se [2]</b> 78/21 79/8</p> <p><b>perceive [1]</b> 162/3</p> <p><b>perceived [1]</b> 191/24</p> <p><b>perceives [1]</b> 232/14</p> <p><b>percentage [1]</b> 51/10</p> <p><b>percentages [1]</b> 42/20</p> <p><b>perfect [2]</b> 23/15 26/17</p> <p><b>perfectly [1]</b> 52/1</p> <p><b>performance [3]</b> 116/19 116/24 117/1</p> <p><b>performed [4]</b> 40/25 68/2 89/14 115/12</p> <p><b>perhaps [30]</b> 1/4 1/20 2/7 8/12 11/1 12/1 12/13 20/4 21/6 23/20 41/15 45/12 47/21 62/8 62/8 68/3 68/21 76/24 94/24 106/22 146/9 152/9 155/23 159/14 180/18 191/12 195/5 215/15 227/9 231/4</p> <p><b>period [20]</b> 34/20 35/8 49/7 52/11 52/11 52/14 52/25 53/5 53/15 53/22 54/15 63/4 72/18 72/19 89/1 97/12 104/17 129/16</p>	<p>132/9 132/14</p> <p><b>periods [5]</b> 52/7 53/19 56/14 56/16 96/22</p> <p><b>peripheral [4]</b> 81/1 142/7 142/21 143/3</p> <p><b>permanent [1]</b> 158/22</p> <p><b>person [19]</b> 29/1 29/7 49/22 62/9 69/15 72/22 73/3 79/4 88/15 92/21 94/13 94/15 105/6 171/10 174/3 178/4 200/15 212/9 215/20</p> <p><b>person's [1]</b> 177/21</p> <p><b>person-dependent [1]</b> 79/4</p> <p><b>personal [1]</b> 202/16</p> <p><b>personally [2]</b> 208/2 210/6</p> <p><b>persons [2]</b> 71/5 71/7</p> <p><b>perspective [11]</b> 20/20 20/20 34/11 40/10 77/12 133/19 134/9 150/13 150/25 165/21 168/15</p> <p><b>phase [9]</b> 36/16 49/6 50/5 74/18 75/4 75/5 127/10 129/23 218/14</p> <p><b>phases [2]</b> 93/7 218/17</p> <p><b>phone [1]</b> 209/13</p> <p><b>photo [1]</b> 145/5</p> <p><b>phrase [5]</b> 27/11 50/24 69/24 85/21 139/21</p> <p><b>phrasing [2]</b> 102/21 204/8</p> <p><b>physical [3]</b> 82/2 116/22 210/14</p> <p><b>pick [13]</b> 52/23 53/1 54/18 69/13 71/17 71/21 137/12 138/13 141/24 144/25 201/12 208/23 224/12</p> <p><b>picked [8]</b> 5/16 39/8 39/14 152/23 201/25 211/7 211/18 224/24</p> <p><b>picking [9]</b> 49/9 59/3 59/4 70/16 139/14 173/8 181/25 211/4 212/15</p> <p><b>pictorial [1]</b> 184/15</p> <p><b>picture [4]</b> 50/9 117/2 117/22 211/22</p> <p><b>pictures [2]</b> 174/23 174/25</p> <p><b>pieces [2]</b> 99/15 210/14</p> <p><b>piercings [2]</b> 45/6 202/18</p> <p><b>pies [2]</b> 21/9 21/17</p> <p><b>pinch [1]</b> 133/21</p> <p><b>pinging [1]</b> 202/3</p>	<p><b>place [14]</b> 34/11 96/16 109/6 111/5 113/23 139/19 139/20 140/3 140/3 176/25 177/15 182/16 186/21 217/23</p> <p><b>placed [4]</b> 108/21 109/6 110/11 115/8</p> <p><b>places [5]</b> 57/9 132/16 132/18 196/22 196/24</p> <p><b>placing [1]</b> 111/20</p> <p><b>plan [2]</b> 181/14 183/21</p> <p><b>planning [1]</b> 16/16</p> <p><b>plans [2]</b> 189/12 189/16</p> <p><b>platelet [3]</b> 137/22 138/3 219/13</p> <p><b>platelets [3]</b> 137/23 219/18 219/21</p> <p><b>plausible [1]</b> 154/2</p> <p><b>play [2]</b> 163/15 213/18</p> <p><b>play-off [1]</b> 163/15</p> <p><b>playing [1]</b> 172/17</p> <p><b>please [23]</b> 10/16 47/25 48/12 52/7 72/20 82/2 82/14 111/25 117/6 119/20 125/5 135/3 135/5 141/23 143/7 145/8 146/6 152/14 153/2 153/9 156/13 182/5 182/10</p> <p><b>plot [1]</b> 154/24</p> <p><b>plus [3]</b> 96/3 128/9 229/13</p> <p><b>Plymouth [1]</b> 196/18</p> <p><b>pm [6]</b> 48/3 98/9 98/11 151/14 151/16 236/7</p> <p><b>pneumo [1]</b> 135/24</p> <p><b>pneumonitis [3]</b> 143/14 143/25 144/1</p> <p><b>point [52]</b> 12/16 20/17 26/22 32/22 32/23 32/24 33/12 33/19 35/20 36/17 37/3 46/19 47/22 47/24 51/3 51/13 51/19 56/7 65/20 66/11 66/22 67/4 72/10 75/1 82/6 82/11 84/11 95/18 103/11 105/21 125/2 125/24 128/3 130/15 133/18 136/12 136/20 140/6 144/14 150/18 150/19 151/3 156/19 169/18 173/8 173/20 177/22 186/20 208/24 213/22 227/5 235/5</p> <p><b>pointed [1]</b> 140/17</p>	<p><b>points [7]</b> 37/24 37/24 98/18 133/22 142/13 209/10 234/17</p> <p><b>policies [3]</b> 113/23 114/5 115/23</p> <p><b>policy [2]</b> 58/13 131/2</p> <p><b>pool [1]</b> 221/21</p> <p><b>pooled [1]</b> 223/16</p> <p><b>pooling [1]</b> 223/17</p> <p><b>poor [5]</b> 71/15 72/1 118/21 191/17 191/22</p> <p><b>poorest [1]</b> 44/1</p> <p><b>population [28]</b> 13/15 15/17 16/1 23/20 23/22 58/17 65/13 70/7 100/18 101/23 102/9 102/11 102/18 105/7 137/5 137/8 137/9 156/9 171/2 177/12 214/17 216/22 216/22 220/19 220/20 221/16 223/5 223/6</p> <p><b>populations [7]</b> 17/9 56/2 65/11 97/19 104/4 155/14 190/15</p> <p><b>portal [5]</b> 83/15 83/19 83/22 109/19 109/23</p> <p><b>position [6]</b> 39/5 59/7 68/22 150/5 173/12 189/5</p> <p><b>positive [22]</b> 34/15 41/1 43/21 43/22 49/20 51/11 52/13 52/17 54/3 54/5 55/24 60/24 67/16 69/19 70/14 70/20 105/2 206/23 207/2 221/20 222/2 232/10</p> <p><b>positives [3]</b> 68/19 68/24 69/22</p> <p><b>positivity [2]</b> 70/9 221/25</p> <p><b>possibilities [2]</b> 201/10 235/1</p> <p><b>possibility [2]</b> 198/23 198/25</p> <p><b>possible [18]</b> 27/25 28/11 34/13 49/24 52/1 52/16 54/13 56/19 77/6 91/18 106/3 155/20 160/20 168/1 199/3 228/16 228/23 230/15</p> <p><b>possibly [3]</b> 196/7 209/12 216/24</p> <p><b>post [4]</b> 59/19 104/9 211/3 213/20</p> <p><b>post-SVR [2]</b> 211/3 213/20</p> <p><b>post-transfusion [1]</b> 59/19</p> <p><b>post-World [1]</b> 104/9</p> <p><b>potential [7]</b> 29/25</p>
--	--	---	---	---	---

<p><b>P</b></p> <p><b>potential...</b> [6] 41/6 53/14 86/19 90/22 142/4 151/22</p> <p><b>potentially</b> [14] 16/19 18/13 52/12 52/18 54/9 64/18 122/22 124/24 131/17 185/22 197/20 216/3 224/11 233/19</p> <p><b>practical</b> [1] 232/17</p> <p><b>practice</b> [23] 17/1 38/16 39/11 57/24 58/22 59/8 92/3 132/15 141/16 164/20 173/10 173/17 176/5 191/22 193/12 200/23 204/10 204/11 204/19 204/21 205/15 206/1 207/8</p> <p><b>practices</b> [1] 193/11</p> <p><b>Practitioners</b> [1] 3/7</p> <p><b>pre</b> [1] 140/10</p> <p><b>pre-existing</b> [1] 140/10</p> <p><b>precaution</b> [1] 193/9</p> <p><b>precautions</b> [4] 193/1 193/4 193/5 193/16</p> <p><b>precise</b> [4] 5/13 34/6 220/7 233/9</p> <p><b>precisely</b> [1] 23/18</p> <p><b>predict</b> [1] 130/7</p> <p><b>predicting</b> [1] 25/20</p> <p><b>prediction</b> [1] 94/9</p> <p><b>predominantly</b> [1] 88/4</p> <p><b>prefer</b> [1] 109/5</p> <p><b>preferences</b> [1] 184/3</p> <p><b>pregnancy</b> [4] 42/1 42/9 198/1 198/3</p> <p><b>pregnant</b> [1] 198/11</p> <p><b>preliminary</b> [1] 183/15</p> <p><b>prepare</b> [1] 207/8</p> <p><b>prepared</b> [1] 180/24</p> <p><b>preparing</b> [1] 185/9</p> <p><b>prescribed</b> [1] 113/6</p> <p><b>presence</b> [12] 12/7 50/17 51/20 56/10 81/6 81/12 84/15 116/15 159/22 167/23 218/8 224/1</p> <p><b>present</b> [15] 13/19 17/15 32/15 32/16 84/18 87/17 89/5 92/1 108/8 108/25 109/25 110/18 112/24 133/1 213/10</p> <p><b>presentation</b> [1] 33/22</p> <p><b>presenting</b> [2] 96/17 222/1</p> <p><b>presents</b> [1] 55/1</p>	<p><b>pressing</b> [1] 230/21</p> <p><b>pressure</b> [9] 82/5 84/11 108/22 109/14 109/23 109/24 110/2 110/4 111/4</p> <p><b>presumably</b> [6] 74/5 96/17 115/9 206/21 232/21 233/20</p> <p><b>presume</b> [1] 210/18</p> <p><b>presumed</b> [1] 43/21</p> <p><b>prevalence</b> [14] 13/5 17/10 18/6 23/5 24/20 43/18 155/7 155/14 220/17 221/1 221/16 221/21 221/23 222/7</p> <p><b>prevalent</b> [2] 24/7 49/9</p> <p><b>prevent</b> [6] 36/20 96/12 112/25 113/2 118/8 165/11</p> <p><b>preventing</b> [1] 167/12</p> <p><b>prevention</b> [1] 3/25</p> <p><b>previous</b> [2] 9/18 197/13</p> <p><b>previously</b> [2] 169/3 217/10</p> <p><b>primarily</b> [1] 96/20</p> <p><b>primary</b> [8] 3/2 181/16 184/11 187/3 195/25 202/10 215/7 217/6</p> <p><b>principally</b> [1] 205/13</p> <p><b>principles</b> [1] 29/25</p> <p><b>print</b> [1] 18/14</p> <p><b>printable</b> [1] 206/18</p> <p><b>prior</b> [3] 72/7 72/8 200/7</p> <p><b>priorities</b> [3] 181/11 187/19 187/24</p> <p><b>prioritise</b> [3] 131/25 132/2 132/5</p> <p><b>priority</b> [3] 69/12 187/15 187/25</p> <p><b>proactive</b> [2] 58/8 58/15</p> <p><b>probable</b> [1] 39/20</p> <p><b>probably</b> [40] 9/20 18/6 23/25 27/6 27/19 31/3 32/16 33/17 40/20 46/7 46/16 46/24 46/25 52/22 56/17 62/20 64/14 80/18 82/10 95/19 98/24 99/1 120/11 122/10 124/19 130/10 131/12 136/12 139/6 151/2 178/21 189/15 191/2 206/7 220/6 220/7 221/2 224/14 233/18 234/5</p> <p><b>problem</b> [12] 26/12 29/13 63/3 133/8 140/17 144/3 146/24 149/22 160/20 206/21</p>	<p>212/8 219/14</p> <p><b>problems</b> [9] 6/23 77/2 77/18 91/1 91/5 140/22 141/19 157/2 162/16</p> <p><b>procedure</b> [1] 174/10</p> <p><b>procedures</b> [2] 110/17 232/12</p> <p><b>process</b> [12] 8/10 33/19 41/10 83/8 83/12 90/17 112/4 114/18 185/9 185/14 213/19 213/19</p> <p><b>processes</b> [6] 7/10 8/11 41/12 71/9 208/19 224/25</p> <p><b>produce</b> [4] 12/7 47/13 65/12 71/15</p> <p><b>produced</b> [11] 4/12 4/21 7/19 89/25 112/3 127/18 135/4 169/1 218/11 219/17 219/18</p> <p><b>produces</b> [2] 14/15 48/17</p> <p><b>product</b> [3] 127/15 129/19 203/14</p> <p><b>production</b> [2] 7/17 113/3</p> <p><b>products</b> [13] 24/22 38/24 55/11 56/1 63/22 65/24 136/8 200/7 223/15 223/16 224/20 226/12 227/1</p> <p><b>professional</b> [1] 88/14</p> <p><b>professionals</b> [3] 57/23 114/20 114/20</p> <p><b>professor</b> [24] 1/24 2/3 2/7 4/2 10/13 18/16 31/13 49/17 58/7 58/20 95/11 159/15 168/16 185/5 190/6 194/11 199/6 205/7 213/1 217/15 222/5 223/9 235/17 236/5</p> <p><b>Professor and</b> [1] 217/15</p> <p><b>Professor Cooke</b> [10] 2/7 10/13 31/13 49/17 95/11 159/15 194/11 222/5 223/9 236/5</p> <p><b>Professor Dillon</b> [6] 18/16 58/7 168/16 199/6 205/7 235/17</p> <p><b>Professor Dillon's</b> [3] 58/20 185/5 190/6</p> <p><b>PROFESSOR GRAHAM</b> [1] 2/3</p> <p><b>PROFESSOR JOHN</b> [1] 1/24</p> <p><b>profile</b> [6] 121/16 123/4 123/11 166/22</p>	<p>197/16 197/24</p> <p><b>profiles</b> [2] 36/10 122/19</p> <p><b>profound</b> [1] 74/13</p> <p><b>prognosis</b> [3] 98/15 100/24 104/3</p> <p><b>prognostic</b> [1] 94/9</p> <p><b>programme</b> [2] 119/14 191/1</p> <p><b>programmes</b> [2] 71/19 71/19</p> <p><b>programs</b> [1] 37/16</p> <p><b>progress</b> [14] 26/19 66/20 93/9 95/5 95/14 95/15 99/5 112/14 118/14 161/3 180/8 189/14 189/17 191/2</p> <p><b>progressed</b> [1] 133/25</p> <p><b>progressing</b> [3] 97/6 129/10 134/16</p> <p><b>progression</b> [32] 13/4 16/7 26/13 64/2 66/5 66/16 83/10 87/7 92/13 92/19 93/3 93/9 93/12 93/24 94/3 94/21 95/1 95/12 96/1 97/6 118/9 160/6 160/8 161/1 170/5 170/25 172/15 174/23 225/6 226/23 227/4 227/22</p> <p><b>progressions</b> [1] 180/10</p> <p><b>progressive</b> [1] 133/3</p> <p><b>prolong</b> [1] 118/8</p> <p><b>prolonged</b> [1] 126/15</p> <p><b>prominent</b> [1] 1/13</p> <p><b>prompt</b> [1] 58/2</p> <p><b>prone</b> [1] 232/11</p> <p><b>pronounced</b> [1] 80/24</p> <p><b>proper</b> [1] 208/4</p> <p><b>properly</b> [4] 140/2 185/3 203/22 218/13</p> <p><b>proportion</b> [15] 20/6 23/6 23/7 23/23 24/4 26/20 61/21 61/23 62/6 64/7 69/3 77/7 158/8 158/20 171/16</p> <p><b>proportionate</b> [1] 21/10</p> <p><b>proportions</b> [2] 25/14 28/22</p> <p><b>pros</b> [2] 139/5 174/2</p> <p><b>prospectively</b> [1] 232/7</p> <p><b>protease</b> [1] 229/9</p> <p><b>protect</b> [1] 193/7</p> <p><b>protection</b> [2] 28/10 232/22</p> <p><b>protein</b> [6] 7/16 48/20 48/23 49/10 84/23 224/7</p>	<p><b>proteins</b> [4] 14/16 82/25 84/23 85/1</p> <p><b>prove</b> [1] 154/3</p> <p><b>proved</b> [1] 198/7</p> <p><b>proves</b> [1] 154/5</p> <p><b>provide</b> [5] 25/2 31/12 56/23 56/24 56/25</p> <p><b>provided</b> [6] 25/1 32/8 101/8 119/23 136/7 186/24</p> <p><b>provides</b> [1] 157/19</p> <p><b>providing</b> [3] 72/11 184/8 210/23</p> <p><b>provision</b> [2] 186/8 194/8</p> <p><b>provisional</b> [1] 221/3</p> <p><b>provisions</b> [1] 193/25</p> <p><b>prudence</b> [1] 40/14</p> <p><b>psychiatric</b> [4] 138/13 138/25 139/9 140/9</p> <p><b>psychiatry</b> [1] 183/6</p> <p><b>psychology</b> [1] 140/25</p> <p><b>psychosocial</b> [2] 161/24 182/20</p> <p><b>psychotic</b> [1] 138/22</p> <p><b>public</b> [10] 33/22 34/11 35/16 36/19 57/19 67/24 105/24 190/14 197/15 200/19</p> <p><b>publicity</b> [1] 167/1</p> <p><b>publicly</b> [2] 189/7 197/25</p> <p><b>published</b> [8] 46/18 90/19 97/7 131/4 153/17 155/6 167/1 172/5</p> <p><b>Pugh</b> [6] 84/6 84/14 85/5 85/15 85/17 116/14</p> <p><b>pulling</b> [1] 137/21</p> <p><b>pulmonary</b> [2] 143/15 143/23</p> <p><b>pure</b> [1] 229/13</p> <p><b>purely</b> [2] 50/13 51/19</p> <p><b>purple</b> [1] 126/20</p> <p><b>purpose</b> [2] 169/2 177/19</p> <p><b>purposes</b> [1] 13/20</p> <p><b>push</b> [3] 64/15 95/10 204/17</p> <p><b>push-back</b> [1] 204/17</p> <p><b>pushed</b> [1] 235/11</p> <p><b>put</b> [20] 20/12 28/4 32/13 33/13 46/17 47/7 57/11 60/17 68/3 78/25 79/14 97/2 100/6 129/2 152/5 153/20 162/7 192/2 199/13 217/21</p> <p><b>putting</b> [3] 130/1 144/12 230/22</p> <p><b>pyrexia</b> [1] 145/24</p>	<p><b>Q</b></p> <p><b>qualifications</b> [3] 4/15 31/15 32/3</p> <p><b>qualified</b> [1] 28/21</p> <p><b>quality</b> [4] 3/8 3/10 41/3 41/9</p> <p><b>quantify</b> [2] 91/18 171/7</p> <p><b>quantity</b> [1] 227/2</p> <p><b>quarter</b> [1] 136/23</p> <p><b>quasispecies</b> [1] 19/8</p> <p><b>queries</b> [1] 41/16</p> <p><b>question</b> [58] 11/14 12/21 15/13 22/10 25/1 25/5 26/4 29/18 31/17 32/12 38/19 39/8 40/1 56/18 61/12 67/18 68/16 69/4 71/13 72/13 100/11 106/12 130/11 144/10 158/12 165/25 182/11 187/4 191/7 199/23 200/24 202/8 202/10 202/13 202/14 203/4 203/8 203/9 203/13 203/14 203/20 203/24 205/6 211/8 215/2 215/15 215/19 218/22 220/12 221/15 223/7 223/20 225/9 226/21 227/7 228/10 229/16 231/3</p> <p><b>questioned</b> [1] 202/20</p> <p><b>questionnaire</b> [1] 78/8</p> <p><b>questionnaire-based</b> [1] 78/8</p> <p><b>questionnaires</b> [1] 78/3</p> <p><b>questions</b> [34] 4/23 6/16 12/21 20/18 24/18 28/6 31/23 56/17 72/14 73/2 94/23 146/16 151/7 151/10 152/18 157/17 159/9 166/7 173/1 179/15 188/21 192/22 203/3 203/12 204/2 204/5 205/2 208/18 208/21 209/19 211/2 222/18 230/2 230/25</p> <p><b>quick</b> [3] 47/21 134/20 150/20</p> <p><b>quickly</b> [18] 22/13 66/19 80/14 97/10 121/23 130/8 132/13 133/22 134/1 134/4 147/17 150/7 161/4 170/18 170/24 183/22 208/17 209/10</p> <p><b>quire</b> [1] 53/7</p> <p><b>quite</b> [57] 8/20 9/9 9/24 13/14 17/24</p>
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<b>Q</b>	<b>rashes [1]</b> 148/14	128/21 132/9 132/10	110/23 121/4 161/12	108/12 109/3 211/11	<b>remaining [2]</b> 83/2
<b>quite... [52]</b> 18/14	<b>rate [38]</b> 18/17 26/9	132/12 133/9 149/10	186/11	<b>regularly [3]</b> 109/7	88/8
23/9 29/20 32/16	44/24 46/18 62/16	149/14 149/17 149/20	<b>record [3]</b> 99/12	173/22 211/6	<b>remains [7]</b> 20/2
44/18 45/21 46/22	62/19 64/9 64/13	150/9 161/13 166/10	104/15 200/13	<b>regulated [1]</b> 113/22	30/17 108/8 109/6
52/14 53/7 54/8 56/25	64/18 70/8 94/3 95/1	167/7 181/2 181/4	<b>recording [1]</b> 184/17	<b>reinfected [3]</b> 28/11	124/14 166/2 173/2
69/25 70/12 73/15	95/5 95/7 102/25	189/18 196/15 197/14	<b>records [1]</b> 8/21	168/1 168/7	<b>remarkably [1]</b> 196/14
94/7 100/2 100/3	102/25 102/25 103/2	198/5 200/20 205/6	<b>recover [2]</b> 123/18	<b>reinfection [1]</b> 177/15	<b>remember [12]</b> 18/3
101/9 106/9 109/3	104/17 104/17 104/18	205/12 209/1 210/24	147/17	<b>reiterate [1]</b> 199/2	65/11 148/6 174/22
121/22 121/23 123/3	104/22 104/24 105/4	222/19 229/16 231/2	<b>recreational [1]</b> 45/5	<b>relapsing [2]</b> 168/8	184/19 185/15 185/17
126/21 127/2 131/21	106/2 115/15 121/22	235/13	<b>recurrent [1]</b> 113/7	168/10	187/6 208/16 210/2
134/12 147/17 147/18	122/13 141/21 147/7	<b>really very [1]</b> 161/13	<b>recurrently [1]</b> 226/16	<b>relate [5]</b> 8/22 71/14	210/15 216/16
148/8 148/14 148/14	221/25 228/2 233/18	<b>reason [14]</b> 40/21	<b>red [2]</b> 21/21 147/2	101/5 162/25 195/7	<b>remembering [1]</b>
150/12 160/15 164/5	233/20 234/10 234/13	41/1 86/18 99/10	<b>reduce [10]</b> 45/18	<b>related [16]</b> 6/23	185/15
175/5 179/21 181/19	234/14 234/16	114/16 115/20 139/7	91/12 94/20 111/7	14/19 60/13 65/12	<b>reminded [1]</b> 58/4
181/21 186/9 186/10	<b>rates [24]</b> 27/15 36/10	147/4 148/10 159/7	113/2 170/4 170/6	76/20 78/13 90/13	<b>removal [1]</b> 117/20
186/17 186/20 189/18	57/8 92/13 92/19 93/8	167/6 211/17 228/13	173/25 189/20 228/8	99/19 99/23 102/8	<b>remove [1]</b> 112/2
208/21 210/10 213/24	94/21 102/19 106/5	234/23	<b>reduced [6]</b> 96/15	139/9 140/11 146/25	<b>removed [3]</b> 112/8
224/11 229/15 229/17	125/13 126/5 126/6	<b>reasonable [1]</b> 65/9	160/19 163/13 171/5	160/6 202/19 231/15	221/20 221/23
232/2 232/4	126/13 126/16 127/2	<b>reasonably [2]</b> 104/12	226/9 231/10	<b>relates [5]</b> 73/1	<b>removes [1]</b> 84/20
<b>quote [3]</b> 42/23 62/15	127/6 128/1 128/2	190/25	<b>reduces [3]</b> 108/22	104/16 110/21 145/20	<b>removing [1]</b> 95/23
62/19	128/8 148/11 149/12	<b>reasons [14]</b> 40/22	111/4 158/19	211/18	<b>renal [6]</b> 71/7 71/18
<b>quoted [1]</b> 42/20	149/16 161/14 228/4	61/6 70/25 97/23	<b>reducing [1]</b> 180/9	<b>relating [1]</b> 211/2	193/20 193/24 193/25
<b>R</b>	<b>rather [14]</b> 13/15 56/4	100/5 100/25 101/19	<b>reduction [3]</b> 96/16	<b>relation [27]</b> 14/24	194/10
<b>radar [1]</b> 202/3	62/25 71/21 75/6 89/2	108/16 115/21 119/25	101/15 108/23	16/6 16/19 17/16	<b>repeat [1]</b> 110/19
<b>Radcliffe [1]</b> 3/15	96/19 127/22 168/7	157/16 165/2 216/1	<b>reductions [1]</b> 169/22	24/18 26/16 31/24	<b>repeated [3]</b> 108/3
<b>raise [8]</b> 11/12 191/8	186/18 202/22 207/9	229/3	<b>refer [1]</b> 73/17	32/2 39/3 39/12 52/6	225/3 226/11
196/4 197/13 197/16	223/14 235/10	<b>reassess [1]</b> 110/24	<b>reference [7]</b> 33/23	53/20 54/14 55/9	<b>replaced [2]</b> 11/14
200/23 211/8 216/7	<b>ratio [2]</b> 105/10	<b>reassure [1]</b> 235/4	38/13 101/3 135/18	55/13 56/13 59/8	11/16
<b>raised [8]</b> 9/1 9/21	105/15	<b>reassured [1]</b> 203/17	143/13 189/2 223/22	59/23 68/18 68/22	<b>replicate [6]</b> 7/13 7/23
10/16 10/24 156/20	<b>rationale [1]</b> 55/20	<b>reassuring [1]</b> 41/14	<b>referenced [2]</b> 58/19	85/22 102/15 106/20	8/4 12/6 12/9 19/9
188/21 204/10 218/23	<b>razor [1]</b> 233/15	<b>receive [1]</b> 162/21	209/16	138/15 155/11 156/17	<b>replicating [1]</b> 160/5
<b>raising [1]</b> 197/23	<b>razors [2]</b> 232/21	<b>received [7]</b> 55/10	<b>references [1]</b> 33/13	166/3	<b>replication [4]</b> 7/12
<b>randomised [1]</b> 232/4	232/24	63/22 97/21 139/18	<b>referral [1]</b> 187/9	<b>relationship [5]</b> 8/1	12/16 93/11 123/15
<b>range [26]</b> 6/14 32/7	<b>RCGP [1]</b> 206/3	195/14 200/6 200/16	<b>referred [7]</b> 11/24	65/22 66/7 159/5	<b>report [130]</b> 4/12 4/16
66/14 73/25 75/8	<b>re [2]</b> 197/8 199/3	<b>receiving [3]</b> 60/7	27/10 27/12 41/21	226/23	4/18 4/21 4/25 4/25
76/14 76/19 77/9 91/5	<b>re-attending [1]</b> 197/8	178/14 231/21	114/9 114/14 212/18	<b>relative [5]</b> 27/23	5/8 5/14 6/25 11/23
128/6 128/25 135/21	<b>re-educate [1]</b> 199/3	<b>recent [9]</b> 31/8 109/8	<b>referring [3]</b> 114/8	28/22 86/23 105/23	13/17 13/22 14/25
138/24 142/4 145/3	<b>reach [1]</b> 82/6	132/9 140/7 160/10	185/4 185/5	106/1	15/2 16/3 16/4 17/17
146/8 155/18 156/14	<b>reached [3]</b> 84/11	165/9 197/25 213/25	<b>refers [2]</b> 43/14	<b>relatively [25]</b> 15/6	20/9 25/21 28/1 30/12
157/1 157/2 162/17	171/21 179/11	222/14	152/12	15/18 15/25 16/25	30/16 31/11 32/13
192/22 193/10 216/20	<b>reaching [1]</b> 83/19	<b>recently [4]</b> 37/19	<b>reflect [1]</b> 73/2	18/11 20/6 109/8	38/23 39/10 40/18
216/21 216/24	<b>reaction [2]</b> 49/20	64/11 160/11 195/23	<b>reflected [1]</b> 197/2	121/15 122/20 123/4	41/20 42/19 43/8
<b>ranges [5]</b> 5/25 6/1	145/25	<b>recipients [1]</b> 71/7	<b>reflection [4]</b> 17/7	124/11 125/1 143/17	46/17 47/6 48/9 52/5
216/16 216/25 217/12	<b>read [4]</b> 47/6 67/12	<b>reciprocate [1]</b>	41/4 79/9 148/15	147/10 150/7 159/18	54/23 55/6 55/16
<b>ranging [1]</b> 75/11	137/14 182/8	220/23	<b>reflects [5]</b> 20/7 67/25	160/10 160/12 167/11	59/15 59/16 62/15
<b>rapid [6]</b> 66/5 93/2	<b>readily [3]</b> 58/18	<b>recognise [7]</b> 38/15	74/15 99/5 144/23	192/6 201/22 210/18	66/17 67/6 67/10
93/12 160/6 160/8	196/9 207/3	66/13 72/2 76/8 76/14	<b>reforming [1]</b> 108/2	212/12 213/23 224/18	68/18 68/21 69/9
160/25	<b>real [3]</b> 99/17 160/20	79/18 79/21	<b>refractory [2]</b> 107/21	<b>relatives [1]</b> 113/17	69/18 70/22 73/24
<b>rapidly [8]</b> 23/9 24/12	191/4	<b>recognised [13]</b> 14/25	113/8	<b>relativity [1]</b> 103/9	76/2 90/23 92/12
24/14 26/19 26/20	<b>realise [2]</b> 45/25	32/25 43/17 60/1 86/7	<b>regard [5]</b> 39/6 57/21	<b>relevance [4]</b> 15/3	92/19 93/17 98/14
35/5 95/14 222/10	153/21	92/7 120/24 122/21	78/20 100/22 203/7	18/9 29/2 29/5	98/19 99/7 99/9
<b>rare [15]</b> 47/9 75/21	<b>realised [1]</b> 201/3	138/21 139/2 155/13	<b>regarded [2]</b> 61/14	<b>relevant [10]</b> 32/20	100/22 100/23 101/2
80/23 81/5 92/2	<b>really [61]</b> 6/25 16/21	165/9 218/24	77/24	33/17 56/17 75/25	101/4 102/15 106/20
133/24 135/24 137/19	20/21 21/8 33/7 33/16	<b>recognising [2]</b> 71/25	<b>regards [9]</b> 57/23	89/6 89/25 101/13	116/3 117/6 117/23
137/19 142/9 143/12	34/20 34/25 35/20	182/22	57/25 58/14 104/6	115/25 200/8 220/16	119/1 119/21 125/4
143/17 144/22 199/19	37/6 43/16 43/23	<b>recognition [1]</b> 35/14	197/12 197/23 201/12	<b>reliability [1]</b> 68/17	125/5 143/19 144/18
221/9	44/18 51/9 53/16	<b>recommend [4]</b> 88/14	201/15 207/14	<b>reliable [1]</b> 25/16	146/7 146/10 146/17
<b>rarely [2]</b> 121/5 133/8	68/25 71/13 74/25	89/10 90/5 110/15	<b>regeneration [1]</b>	<b>reliably [1]</b> 25/9	147/21 149/2 152/2
<b>rarer [5]</b> 90/14 90/22	75/22 76/20 79/16	<b>recommendation [1]</b>	171/11	<b>relies [1]</b> 12/7	152/6 152/8 152/16
91/14 115/23 143/4	99/14 101/10 116/21	88/22	<b>region [4]</b> 103/16	<b>relieve [1]</b> 108/1	153/7 154/13 154/16
<b>rash [4]</b> 81/1 91/1	120/12 123/6 124/8	<b>recommendations [3]</b>	103/17 128/9 190/10	<b>reluctant [1]</b> 40/6	155/6 156/24 156/25
145/5 148/13	125/12 126/10 126/13	90/3 121/5 130/21	<b>regresses [1]</b> 91/23	<b>remain [5]</b> 23/2 62/5	157/17 157/19 157/22
	127/14 128/6 128/12	<b>recommended [4]</b>	<b>regular [4]</b> 108/3	97/14 124/1 169/24	158/4 159/1 159/4

<b>R</b>	107/17 118/19 126/22 163/25 229/19 <b>responded [2]</b> 108/12 114/12 <b>response [14]</b> 4/22 8/9 8/18 16/19 16/24 48/16 48/17 49/11 72/2 124/21 125/25 127/16 146/14 160/23 <b>responses [3]</b> 8/14 71/15 71/22 <b>responsible [1]</b> 131/3 <b>responsive [1]</b> 135/1 <b>rest [2]</b> 156/12 179/3 <b>restricting [1]</b> 107/14 <b>result [6]</b> 7/8 69/19 70/25 71/10 134/24 142/19 <b>results [4]</b> 8/22 83/8 199/8 216/2 <b>retention [3]</b> 86/1 107/13 107/13 <b>retracted [1]</b> 169/1 <b>retrospect [2]</b> 79/9 140/5 <b>return [1]</b> 97/11 <b>returns [2]</b> 109/21 125/20 <b>reversibility [1]</b> 142/18 <b>reversible [1]</b> 147/16 <b>review [3]</b> 101/8 156/8 178/22 <b>reviewed [3]</b> 124/11 153/18 166/24 <b>reviewing [1]</b> 179/1 <b>revising [1]</b> 216/23 <b>revisit [1]</b> 230/13 <b>RF [1]</b> 117/22 <b>rheumatoid [1]</b> 138/9 <b>ribavirin [15]</b> 36/11 126/25 129/6 146/6 146/18 146/21 147/1 147/3 147/16 148/2 148/8 157/25 172/23 227/20 229/7 <b>ribonucleic [1]</b> 14/6 <b>Richards [2]</b> 1/16 2/4 <b>rid [5]</b> 53/13 107/15 120/15 123/16 166/15 <b>rifaximin [1]</b> 113/5 <b>right [40]</b> 4/19 10/15 12/3 17/23 19/25 30/24 42/6 45/7 55/8 69/24 70/16 70/19 75/18 76/4 82/10 83/14 106/25 115/10 117/12 117/25 118/10 118/20 119/5 124/1 126/9 135/10 140/4 162/19 166/8 167/14 178/12 185/12 197/23 198/6 198/16 198/17	198/18 199/4 200/3 221/22 <b>right-hand [2]</b> 126/9 135/10 <b>rightly [1]</b> 168/24 <b>rigidly [1]</b> 38/18 <b>rigours [1]</b> 145/24 <b>rise [1]</b> 150/14 <b>risk [87]</b> 34/23 45/17 45/19 45/22 46/3 46/12 46/14 46/25 47/3 54/7 55/11 56/2 56/4 57/19 58/12 58/16 59/1 62/21 64/21 64/22 66/15 66/25 72/12 74/10 74/11 88/4 88/9 90/9 91/16 91/18 94/17 94/17 94/20 97/6 97/8 97/11 105/18 105/24 110/4 110/5 110/21 111/7 169/13 169/15 170/4 170/16 170/17 170/24 171/5 171/5 171/24 172/6 172/7 172/10 172/15 173/7 173/25 175/4 177/4 177/10 177/11 177/25 178/1 190/20 190/22 190/24 191/6 191/11 198/14 200/9 201/13 201/14 201/24 203/5 204/23 213/11 215/21 227/3 231/14 232/5 232/8 232/14 233/11 233/19 235/9 235/10 235/11 <b>risks [27]</b> 30/1 95/24 95/25 96/3 96/14 97/2 97/4 97/5 97/16 97/17 97/18 105/23 105/23 106/1 106/7 141/19 144/9 144/11 156/23 163/2 163/11 169/24 170/23 171/8 173/5 180/10 235/14 <b>risky [1]</b> 174/10 <b>RNA [14]</b> 13/25 14/6 14/15 14/20 19/1 19/8 19/11 49/16 51/7 51/21 54/4 54/11 54/17 67/16 <b>road [1]</b> 195/21 <b>robust [1]</b> 101/11 <b>role [3]</b> 3/6 209/23 213/8 <b>roll [1]</b> 23/9 <b>roll-out [1]</b> 23/9 <b>rolled [1]</b> 58/22 <b>rollercoaster [1]</b> 185/7 <b>room [5]</b> 120/2 130/13 194/7 197/18 214/9	<b>rough [1]</b> 56/19 <b>roughly [2]</b> 62/9 63/6 <b>round [2]</b> 201/8 236/6 <b>route [8]</b> 25/9 25/13 25/15 25/19 42/13 45/2 177/24 213/17 <b>routes [6]</b> 41/18 43/12 132/18 159/20 234/19 235/3 <b>routine [8]</b> 70/10 72/9 204/5 204/10 204/11 204/19 204/21 204/24 <b>routinely [2]</b> 81/9 211/10 <b>Royal [2]</b> 2/20 3/6 <b>rubber [2]</b> 111/5 111/20 <b>rule [2]</b> 25/17 37/4 <b>run [2]</b> 208/11 208/11 <b>running [1]</b> 173/6 <b>Russian [1]</b> 18/22	169/19 171/9 171/15 171/19 173/16 175/25 176/19 182/16 184/20 185/16 186/10 188/11 195/3 196/9 196/11 196/14 197/18 200/15 202/20 204/3 204/9 205/16 205/25 206/7 207/9 207/11 207/21 208/20 212/7 217/13 230/22 <b>saying [12]</b> 2/6 27/8 73/1 101/18 105/25 124/7 144/15 160/14 167/1 179/13 186/18 224/18 <b>says [4]</b> 67/12 69/16 138/16 176/2 <b>scaled [1]</b> 44/2 <b>scaling [1]</b> 37/19 <b>scan [2]</b> 89/14 181/21 <b>scans [4]</b> 80/1 80/7 178/19 212/19 <b>scar [2]</b> 82/18 83/9 <b>scarring [31]</b> 11/17 82/6 82/13 86/6 87/17 87/20 95/25 169/9 170/21 171/3 172/11 173/4 173/14 174/12 174/15 174/17 174/19 175/2 175/3 175/9 175/9 175/16 176/11 177/10 178/3 179/10 179/22 180/2 180/5 180/12 213/10 <b>scars [2]</b> 174/24 175/6 <b>scenario [1]</b> 223/25 <b>scheduling [1]</b> 1/11 <b>scheme [1]</b> 133/20 <b>school [1]</b> 220/10 <b>science [2]</b> 32/11 94/10 <b>scientist [1]</b> 216/18 <b>scientists [1]</b> 131/7 <b>scope [1]</b> 133/14 <b>scopes [1]</b> 133/24 <b>score [3]</b> 84/14 86/12 86/15 <b>scores [1]</b> 86/12 <b>scoring [3]</b> 84/6 86/19 87/8 <b>Scotland [22]</b> 1/9 3/5 3/7 3/8 3/10 3/12 23/11 23/25 24/4 24/12 58/5 58/23 97/8 170/16 172/5 189/2 190/10 190/12 199/5 220/23 221/2 221/11 <b>Scots [2]</b> 189/25 190/4 <b>SCOTT [4]</b> 2/1 3/4 101/18 180/8	<b>Scott's [1]</b> 210/17 <b>Scottish [4]</b> 1/8 23/20 134/2 189/15 <b>screen [3]</b> 23/16 182/3 204/20 <b>screened [1]</b> 211/6 <b>screening [27]</b> 39/2 39/12 55/5 55/7 55/14 56/3 58/16 72/7 88/16 110/19 119/17 173/22 174/2 174/5 174/17 174/20 201/13 201/14 204/18 211/2 211/11 211/14 212/3 213/19 218/4 224/20 224/25 <b>se [2]</b> 78/21 79/8 <b>second [14]</b> 4/24 31/24 39/14 53/5 53/14 55/4 57/6 67/11 91/14 220/14 221/15 228/12 228/15 229/2 <b>secondary [6]</b> 182/24 186/2 187/1 188/3 195/25 202/9 <b>secondly [2]</b> 116/13 235/23 <b>section [14]</b> 5/8 28/4 31/11 38/22 39/10 42/19 43/7 73/25 92/22 119/21 159/3 165/22 182/3 194/12 <b>section 15.13 [1]</b> 119/21 <b>section 15.18 [1]</b> 165/22 <b>section 15.3 [1]</b> 31/11 <b>section 15.5 [1]</b> 38/22 <b>see [68]</b> 9/21 12/17 21/13 22/1 28/19 28/21 29/11 34/20 35/8 39/24 41/16 45/23 46/19 60/19 68/7 74/16 75/21 78/16 81/13 83/18 87/11 87/16 114/10 124/8 125/19 126/4 126/10 126/21 127/1 127/25 128/8 128/21 133/8 135/16 135/20 138/7 138/22 142/4 143/8 144/22 149/20 153/3 155/6 155/16 155/17 155/21 156/13 156/16 156/21 157/20 159/18 160/25 168/2 183/24 185/21 187/19 195/7 199/8 202/22 206/25 216/18 218/4 223/2 228/3 230/10 230/20 232/18 235/16 <b>seeing [7]</b> 3/19 8/21 36/5 46/21 68/4 150/14 203/21
----------	--	--	---	--	---

<b>S</b>	<b>settings [2]</b> 26/7 147/6	89/11 99/11 99/20 100/7 100/13 103/6 107/22 112/21 112/23 113/6 114/13 115/18 132/2 132/12 141/15 141/15 168/17 173/16 173/21 173/22 173/24 174/2 174/4 174/6 175/21 175/25 176/2 176/5 178/14 178/17 179/1 179/3 182/16 186/23 188/11 200/6 200/10 201/24 201/25 203/6 204/2 210/9 218/1 218/2 231/22	163/16 169/22 170/21 172/11 192/8 194/21 219/13 229/18	42/16 80/25 91/1 135/24 144/25 145/5 148/13 148/14	162/19 164/9 165/9 166/7 168/9 169/13 171/5 171/11 171/22 173/13 175/11 175/12 175/16 175/20 181/21 182/19 183/14 184/7 185/13 186/22 188/20 191/5 194/10 197/2 203/6 203/17 204/5 209/18 209/19 211/17 213/23 214/5 214/6 214/9 216/25 219/4 223/8 227/7 228/11 228/19 229/22 232/4 233/24
<b>seem [7]</b> 13/13 17/13 26/23 161/17 202/15 225/13 225/22	<b>seven [2]</b> 113/20 148/17	<b>shouldn't [2]</b> 100/3 134/8	<b>significantly [2]</b> 127/2 128/2	<b>SLE [1]</b> 138/9	<b>somebody [16]</b> 52/21 54/1 54/6 58/11 58/11 69/16 70/13 79/1 85/7 108/17 110/6 110/25 112/18 149/22 200/21 207/25
<b>seemed [2]</b> 60/14 101/13	<b>seventies [2]</b> 59/17 61/18	<b>show [10]</b> 9/16 21/8 26/6 29/21 29/24 46/12 80/7 82/16 96/13 169/6	<b>signpost [3]</b> 182/7 206/9 206/13	<b>slightly [11]</b> 21/22 25/14 26/8 57/8 57/9 65/10 80/9 90/4 140/16 151/1 216/4	<b>somebody's [2]</b> 50/5 50/9
<b>seems [6]</b> 13/14 13/15 79/19 91/25 149/7 211/15	<b>several [3]</b> 30/14 105/2 115/2	<b>showed [3]</b> 103/12 174/25 211/22	<b>signposted [2]</b> 185/11 209/15	<b>slight [3]</b> 1/4 1/17 150/14	<b>someone [32]</b> 9/24 28/2 49/20 50/1 65/1 73/20 80/15 97/3 108/11 109/22 110/16 116/16 116/22 116/24 143/23 144/1 144/6 163/12 177/23 178/24 183/19 186/19 188/16 203/19 204/4 205/9 221/25 225/2 226/8 226/15 231/21 233/1
<b>seen [14]</b> 17/11 37/12 51/13 60/13 85/21 86/11 92/4 97/14 110/14 128/5 134/16 154/25 197/15 197/19	<b>severe [13]</b> 73/18 75/13 84/16 85/16 86/13 86/16 91/12 138/25 144/19 144/23 148/14 163/15 175/2	<b>shown [4]</b> 15/25 118/16 169/3 172/4	<b>signposting [2]</b> 210/11 210/13	<b>slow [3]</b> 80/10 167/10 167/11	<b>someone's [2]</b> 214/4 233/12
<b>self [4]</b> 60/14 61/15 184/17 234/6	<b>severely [1]</b> 84/4	<b>shows [8]</b> 21/6 51/7 82/17 83/14 83/16 87/12 97/8 211/13	<b>signposts [1]</b> 210/23	<b>slower [1]</b> 93/8	<b>something [31]</b> 1/7 33/15 39/22 39/24 56/24 61/14 79/20 81/3 89/3 108/5 112/10 127/18 136/15 142/8 158/13 158/24 165/8 180/11 197/24 200/18 202/23 205/16 207/9 207/23 209/21 210/5 210/8 211/4 212/6 225/10 233/2
<b>self-limiting [1]</b> 61/15	<b>severity [10]</b> 74/24 75/6 75/12 86/23 91/5 114/22 116/13 225/7 226/22 226/24	<b>sick [1]</b> 144/20	<b>signs [11]</b> 72/14 72/16 72/21 74/1 74/4 74/6 75/9 75/17 81/18 171/14 227/22	<b>slowly [1]</b> 95/15	<b>sometimes [21]</b> 7/24 8/2 11/24 12/4 19/12 40/22 52/16 54/20 68/4 74/23 100/5 106/1 108/4 136/17 141/3 142/18 166/18 185/25 195/21 200/13 228/23
<b>self-recording [1]</b> 184/17	<b>sex [5]</b> 46/21 202/17 234/6 234/8 234/9	<b>side [43]</b> 35/1 36/9 78/14 106/15 107/18 120/2 120/24 121/15 122/19 122/21 123/4 123/10 125/6 126/5 126/7 126/10 127/4 130/5 135/10 136/25 137/3 138/5 139/23 140/9 140/25 143/16 146/8 146/14 146/21 146/25 147/10 147/15 147/15 148/4 149/9 149/16 151/19 162/10 167/19 192/3 197/3 200/19 214/12	<b>similar [17]</b> 15/15 15/17 20/5 24/4 57/4 98/23 99/3 102/5 102/17 160/22 172/24 195/8 197/11 212/16 222/7 225/17 232/25	<b>small [21]</b> 16/22 17/1 18/14 40/10 41/14 55/24 75/16 91/16 91/18 91/19 92/8 110/22 120/17 164/23 171/16 219/5 233/18 234/14 234/14 234/15 234/15	<b>soon [2]</b> 54/13 185/1
<b>self-reported [1]</b> 234/6	<b>sexual [18]</b> 45/9 45/19 45/22 45/24 46/20 46/23 47/2 47/4 47/8 204/18 204/20 232/22 233/21 233/24 234/4 235/5 235/8 235/12	<b>signed [1]</b> 180/18	<b>similarities [1]</b> 14/11	<b>smaller [5]</b> 18/22 63/17 63/17 87/13 156/3	<b>sorry [7]</b> 6/3 98/6 103/11 104/1 176/15 189/22 199/21
<b>sensation [1]</b> 81/2	<b>sexually [1]</b> 220/4	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>similarly [3]</b> 84/16 136/17 160/21	<b>SmC [1]</b> 134/2	
<b>sense [4]</b> 6/2 6/4 63/21 73/18	<b>Shall [4]</b> 47/25 92/23 98/8 183/2	<b>significance [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>SmPC [1]</b> 143/21	
<b>sensibilities [1]</b> 203/17	<b>shape [2]</b> 181/14 208/2	<b>sign [3]</b> 218/12 218/19 218/20	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>snowball [1]</b> 185/7	
<b>sensible [1]</b> 210/7	<b>share [2]</b> 232/20 232/21	<b>signed [1]</b> 180/18	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>so [438]</b>	
<b>sensitive [1]</b> 212/14	<b>shared [8]</b> 33/21 159/20 181/2 181/9 182/1 184/1 185/23 186/5	<b>signature [1]</b> 180/18	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>societies [1]</b> 88/14	
<b>sensitivity [8]</b> 69/2 69/3 69/6 69/9 69/10 89/19 145/6 211/18	<b>sharing [1]</b> 232/24	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>socioeconomic [2]</b> 103/24 104/6	
<b>sequence [1]</b> 205/4	<b>she [1]</b> 174/25	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>socket [1]</b> 1/22	
<b>sequencing [1]</b> 28/20	<b>shed [1]</b> 39/25	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>sodium [1]</b> 78/22	
<b>serial [1]</b> 186/1	<b>sheets [1]</b> 186/14	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>sofosbuvir [1]</b> 229/8	
<b>series [1]</b> 218/3	<b>shifting [1]</b> 24/11	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>some [132]</b> 1/9 5/4 5/19 6/6 6/7 7/6 8/15 16/10 16/23 18/1 18/13 19/24 20/4 20/7 20/25 25/19 26/6 26/7 26/10 32/9 32/10 35/19 36/9 37/15 51/1 51/13 52/23 53/12 59/9 62/4 63/18 67/8 68/20 69/9 73/2 73/2 76/22 77/16 79/10 81/8 81/13 82/1 87/9 88/9 90/17 90/19 91/22 92/14 95/13 95/14 97/4 97/16 99/4 103/6 103/15 107/5 107/18 115/22 116/3 116/18 119/17 122/20 124/10 124/24 125/11 130/12 133/23 137/3 137/14 137/18 140/16 141/24 146/10 146/15 146/25 147/6 147/14 147/22 148/1 148/12 148/13 149/19 152/25 156/4 158/15 158/21 161/10 162/8 162/9	
<b>serious [5]</b> 39/16 81/15 91/6 91/9 112/20	<b>short [12]</b> 8/3 31/12 31/13 48/2 52/25 52/25 67/11 81/15 151/15 190/25 195/22 207/11	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>somebody [16]</b> 52/21 54/1 54/6 58/11 58/11 69/16 70/13 79/1 85/7 108/17 110/6 110/25 112/18 149/22 200/21 207/25	
<b>serum [5]</b> 11/10 33/6 60/8 84/19 231/13	<b>short-term [2]</b> 8/3 81/15	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>somebody's [2]</b> 50/5 50/9	
<b>service [5]</b> 2/13 130/19 175/22 185/6 192/9	<b>shortened [2]</b> 29/9 126/1	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>someone's [2]</b> 214/4 233/12	
<b>services [5]</b> 3/10 4/8 186/7 187/17 230/13	<b>shorter [2]</b> 52/16 149/8	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>something [31]</b> 1/7 33/15 39/22 39/24 56/24 61/14 79/20 81/3 89/3 108/5 112/10 127/18 136/15 142/8 158/13 158/24 165/8 180/11 197/24 200/18 202/23 205/16 207/9 207/23 209/21 210/5 210/8 211/4 212/6 225/10 233/2	
<b>set [22]</b> 5/17 13/17 18/22 38/10 39/1 67/6 67/7 92/18 101/1 106/19 114/24 116/3 133/20 135/17 147/21 182/14 184/6 184/10 186/22 188/10 188/10 188/25	<b>shortest [2]</b> 207/15 207/20	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>so [438]</b>	
<b>sets [2]</b> 89/24 146/7	<b>shortly [2]</b> 15/5 146/7	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>societies [1]</b> 88/14	
<b>setting [18]</b> 12/12 13/6 15/16 18/9 38/1 44/5 54/8 54/10 57/24 120/25 138/2 161/6 183/6 193/6 193/24 194/2 201/21 219/24	<b>SHOT [3]</b> 39/16 39/16 40/18	<b>signature [10]</b> 8/25 12/24 15/7 17/22 26/15 52/9 53/19 155/7 159/2 219/15	<b>simple [5]</b> 51/9 108/9 112/11 112/13 204/3	<b>socioeconomic [2]</b> 103/24 104/6	

<b>S</b>	51/11 62/10 110/6	<b>step [2]</b> 180/6 180/7	<b>struggle [1]</b> 214/6	<b>suggest [5]</b> 57/25	224/2 224/4
<b>sort [25]</b> 6/22 25/25	<b>spread [2]</b> 30/21 31/7	<b>steps [2]</b> 189/6 190/8	<b>studies [16]</b> 15/14	151/8 178/20 185/24	<b>surface antigen [1]</b>
26/3 35/9 35/9 36/12	<b>St [1]</b> 2/12	<b>stepwise [1]</b> 107/11	15/19 15/25 23/19	227/6	48/23
36/17 38/18 62/5	<b>St Mary's [1]</b> 2/12	<b>sterling [1]</b> 199/4	24/23 26/10 27/3	<b>suggested [1]</b> 192/23	<b>surgery [1]</b> 113/15
68/11 95/3 98/23	<b>stabilised [1]</b> 144/5	<b>stick [2]</b> 54/9 180/17	46/12 69/9 79/14	<b>suggesting [2]</b> 16/11	<b>surrogate [3]</b> 126/3
106/9 126/2 148/15	<b>staff [1]</b> 193/8	<b>sticking [2]</b> 24/16	101/3 102/10 103/15	135/11	167/22 169/4
165/12 167/22 168/7	<b>stage [43]</b> 7/5 29/10	93/15	106/7 167/7 173/5	<b>suggestion [4]</b> 13/3	<b>surround [1]</b> 83/24
168/8 175/19 185/12	35/14 50/9 75/16 82/9	<b>stiffness [1]</b> 213/6	<b>study [21]</b> 17/11	16/3 26/7 26/18	<b>surrounding [2]</b> 107/4
224/17 233/2 233/3	83/21 83/25 84/2 86/5	<b>stigma [1]</b> 162/4	26/12 78/24 90/1 90/2	<b>suggests [1]</b> 173/11	185/10
233/25	86/6 87/3 87/4 87/4	<b>stigmatised [1]</b>	101/4 101/5 101/14	<b>suicidal [1]</b> 138/21	<b>surveillance [7]</b> 34/10
<b>sorts [1]</b> 204/1	88/19 88/19 89/11	235/14	102/3 102/4 102/15	<b>suicide [1]</b> 138/22	89/12 89/13 89/21
<b>sought [3]</b> 4/23	93/10 97/25 111/8	<b>stigmatising [2]</b> 203/7	103/8 104/19 105/6	<b>suitable [8]</b> 108/13	119/12 119/14 212/3
112/23 171/6	112/15 115/21 116/10	204/16	106/3 106/4 137/5	108/15 108/17 114/1	<b>survey [1]</b> 234/8
<b>sound [1]</b> 105/19	117/10 117/11 118/1	<b>still [61]</b> 16/22 22/20	137/8 176/3 232/4	144/8 182/17 182/25	<b>survival [6]</b> 115/15
<b>sounded [1]</b> 179/12	118/10 118/11 119/4	23/8 44/4 45/23 52/4	233/13	183/18	115/17 117/19 118/8
<b>sounds [2]</b> 103/3	119/11 119/16 119/18	53/11 60/8 63/14	<b>stuff [1]</b> 210/15	<b>summarise [5]</b> 68/21	118/16 118/18
105/17	129/8 129/14 156/10	63/15 84/10 92/1 94/9	<b>sub [1]</b> 21/1	94/24 106/22 116/4	<b>survived [1]</b> 113/18
<b>soundwaves [1]</b>	163/14 171/21 179/11	94/10 97/4 97/14	<b>sub-genotypes [1]</b>	146/10	<b>susceptibility [1]</b>
213/7	181/13 211/7 218/17	97/16 97/22 103/2	21/1	<b>summarised [2]</b> 117/2	81/24
<b>source [1]</b> 206/8	228/3 235/16	105/9 109/1 113/4	<b>subbranches [1]</b>	152/22	<b>susceptible [2]</b> 66/3
<b>South [2]</b> 21/14	<b>stages [12]</b> 13/3	118/18 121/18 121/25	19/15	<b>summary [3]</b> 48/9	215/5
103/14	72/16 82/12 86/7	125/2 125/23 133/1	<b>subcontinent [2]</b> 20/9	92/18 198/13	<b>suspect [4]</b> 40/9
<b>speak [2]</b> 1/6 92/23	86/15 86/25 93/25	133/22 134/14 135/24	21/25	<b>superseded [1]</b>	216/11 216/15 217/14
<b>speaking [2]</b> 23/3	96/25 112/14 117/13	138/20 147/4 147/4	<b>subcontinents [1]</b>	213/14	<b>suspected [1]</b> 151/25
150/5	117/16 159/24	148/3 149/18 151/10	21/14	<b>supplemental [4]</b>	<b>suspicion [2]</b> 149/19
<b>special [2]</b> 82/18	<b>staging [1]</b> 117/3	162/9 164/19 165/5	<b>subcutaneous [1]</b>	12/21 20/18 24/18	212/5
178/24	<b>stain [1]</b> 82/18	169/13 170/14 171/4	145/1	28/6	<b>sustained [1]</b> 125/25
<b>specialised [1]</b> 80/1	<b>standard [8]</b> 193/1	171/4 171/24 172/24	<b>subject [2]</b> 24/23	<b>supplementals [1]</b>	<b>SVR [7]</b> 171/23 176/9
<b>specialist [6]</b> 2/22	193/4 193/5 193/10	173/4 175/10 178/5	194/24	146/15	176/10 176/10 178/10
178/24 186/3 186/5	194/25 195/24 195/24	213/23 214/6 214/9	<b>subjective [1]</b> 159/10	<b>supplementary [1]</b>	211/3 213/20
198/12 214/7	224/4	217/13 221/3 221/5	<b>subsequently [2]</b> 36/2	70/18	<b>SVR12 [4]</b> 126/1
<b>species [1]</b> 19/21	<b>standardised [6]</b>	222/17 230/12 231/10	76/18	<b>supply [1]</b> 118/5	126/2 126/5 169/21
<b>specific [25]</b> 5/19	104/21 104/24 105/3	231/13 231/14 232/19	<b>subset [1]</b> 12/19	<b>support [10]</b> 80/7	<b>SVR12/24 [1]</b> 169/21
12/21 22/11 29/17	105/10 105/15 205/24	<b>stimulating [1]</b> 161/7	<b>substantial [4]</b> 21/15	80/11 82/25 185/3	<b>SVR24 [1]</b> 169/3
34/5 35/23 73/16 78/3	<b>standing [2]</b> 191/14	<b>stomach [2]</b> 109/18	144/7 161/13 181/19	185/10 206/6 210/22	<b>sweating [1]</b> 145/5
78/7 78/25 78/25	196/19	110/12	<b>substantially [9]</b> 44/2	210/22 212/2 230/8	<b>sweats [1]</b> 145/6
80/16 90/18 110/23	<b>start [26]</b> 1/5 1/6 2/5	<b>stool [1]</b> 81/22	95/24 96/15 97/5	<b>supported [2]</b> 83/5	<b>Sweden [1]</b> 207/19
127/24 128/4 146/16	5/3 5/6 19/20 32/22	<b>stools [2]</b> 111/15	102/7 149/17 158/20	195/25	<b>swelling [1]</b> 107/5
154/15 173/12 193/16	32/24 45/14 61/1	111/15	169/16 189/20	<b>supporting [3]</b> 82/21	<b>switched [2]</b> 1/20
199/22 205/1 212/14	72/24 73/1 106/12	<b>stop [8]</b> 47/22 108/1	<b>subtle [1]</b> 19/13	83/3 184/16	1/22
217/21 218/16	112/12 120/11 124/8	108/25 111/6 111/19	<b>subtract [1]</b> 101/25	<b>supportive [3]</b> 111/17	<b>swollen [1]</b> 80/9
<b>specifically [7]</b> 14/13	124/9 141/3 153/24	111/21 151/3 219/20	<b>subtypes [7]</b> 19/2	118/24 220/1	<b>sworn [5]</b> 1/16 1/24
78/24 110/9 128/16	154/22 159/13 183/2	<b>stopped [3]</b> 139/8	19/4 19/8 19/17 19/18	<b>suppose [6]</b> 57/17	1/25 2/1 2/3
206/12 218/23 220/20	209/13 209/17 209/18	144/4 229/1	19/19 19/21	57/24 65/1 142/13	<b>symptom [8]</b> 78/19
<b>specificity [4]</b> 69/21	217/19	<b>stops [1]</b> 124/22	<b>success [6]</b> 121/2	187/20 197/25	79/3 108/4 112/9
70/2 89/19 211/19	<b>started [10]</b> 58/20	<b>straight [5]</b> 62/25	126/16 161/14 163/5	<b>supposed [1]</b> 41/7	112/12 144/17 196/21
<b>spectrum [2]</b> 178/9	60/20 127/11 139/9	64/22 95/3 111/16	227/12 228/2	<b>suppressed [1]</b> 46/10	214/12
179/10	140/21 140/23 196/12	195/22	<b>successful [5]</b> 50/3	<b>suppressing [3]</b>	<b>symptomatic [1]</b>
<b>speed [5]</b> 129/24	196/20 222/11 229/10	<b>straightforward [1]</b>	51/16 158/7 170/3	95/22 123/5 123/15	216/10
130/15 131/7 133/18	<b>starting [7]</b> 2/7 106/18	165/18	222/13	<b>suppression [1]</b>	<b>symptoms [60]</b> 9/23
225/6	136/12 136/20 140/13	<b>strands [1]</b> 83/21	<b>such [24]</b> 1/12 40/13	166/9	10/6 57/18 58/3 58/17
<b>speedily [1]</b> 196/9	150/16 186/20	<b>strategies [2]</b> 68/12	52/2 64/17 75/17 86/1	<b>sure [26]</b> 34/2 40/14	59/2 68/16 72/14
<b>spend [3]</b> 119/24	<b>starts [1]</b> 107/11	68/13	88/10 91/1 108/6	40/16 54/12 69/23	72/16 72/21 73/7
175/15 191/17	<b>state [1]</b> 120/20	<b>stratifying [1]</b> 84/4	110/7 111/13 114/11	134/12 159/17 185/3	73/10 73/13 73/15
<b>spending [2]</b> 116/25	<b>stated [1]</b> 189/23	<b>strength [1]</b> 153/12	134/18 134/24 158/2	185/8 187/15 196/1	74/1 74/4 74/6 74/14
131/12	<b>statements [3]</b> 10/14	<b>stress [1]</b> 102/22	171/17 172/16 181/4	196/1 196/2 199/7	75/6 75/9 76/3 76/13
<b>spent [6]</b> 2/14 2/23	131/3 142/9	<b>stretch [1]</b> 31/20	182/18 205/23 207/24	199/14 199/17 200/1	76/21 76/24 77/9
4/8 165/18 191/14	<b>station [1]</b> 196/18	<b>strong [3]</b> 3/9 66/7	209/16 212/1 213/13	201/9 208/4 208/19	77/24 78/5 78/10 79/1
192/10	<b>statistics [1]</b> 105/20	157/9	<b>sudden [1]</b> 2/25	209/1 209/5 209/14	79/23 81/18 82/7
<b>split [1]</b> 180/15	<b>status [4]</b> 116/19	<b>structure [3]</b> 34/10	<b>suddenly [1]</b> 78/23	209/16 217/15 220/23	84/12 85/9 85/25
<b>spontaneous [3]</b>	116/24 117/1 225/8	83/1 134/17	<b>suffered [1]</b> 63/20	<b>surface [10]</b> 18/20	107/1 108/1 111/13
25/23 30/8 214/23	<b>stay [1]</b> 124/4	<b>structures [5]</b> 36/23	<b>suffering [1]</b> 64/4	33/11 48/23 48/23	112/17 113/4 119/10
<b>spontaneously [3]</b>	<b>steeper [1]</b> 62/24	80/8 82/21 83/3 83/17	<b>sufficient [1]</b> 44/25	51/25 53/1 53/8 53/24	127/19 139/21 142/20

<b>S</b>	168/14 183/24 183/25 184/5 199/21 210/12 212/22 221/24 <b>talked [15]</b> 52/5 92/12 116/14 126/18 130/14 132/22 157/8 161/6 164/7 167/22 213/2 218/9 218/15 221/7 223/25 <b>talking [13]</b> 5/14 10/1 18/4 49/13 74/21 89/4 101/23 115/19 132/9 132/10 205/21 207/23 223/14 <b>talks [2]</b> 74/9 135/5 <b>target [4]</b> 121/9 127/21 161/17 189/24 <b>targets [2]</b> 37/13 189/18 <b>tattoos [2]</b> 45/6 202/18 <b>taught [1]</b> 203/2 <b>Tayside [5]</b> 4/8 58/21 92/3 205/20 235/18 <b>TDF [2]</b> 122/8 122/10 <b>team [2]</b> 186/6 199/6 <b>tease [2]</b> 15/18 234/18 <b>technical [1]</b> 1/18 <b>techniques [8]</b> 28/20 50/16 50/20 117/22 174/11 174/13 174/14 213/5 <b>telaprevir [1]</b> 148/12 <b>tell [16]</b> 6/3 6/4 9/1 12/23 13/22 18/2 19/4 50/12 50/20 106/22 113/12 125/17 170/25 198/10 234/21 235/17 <b>telling [3]</b> 198/6 210/9 235/22 <b>ten [6]</b> 93/3 105/11 138/17 209/9 221/11 221/14 <b>ten-year [1]</b> 93/3 <b>tend [8]</b> 7/25 10/2 28/15 28/16 75/21 99/8 144/22 163/24 <b>tended [2]</b> 162/25 228/3 <b>tendency [1]</b> 138/4 <b>tender [1]</b> 73/19 <b>tenderness [1]</b> 10/6 <b>tends [1]</b> 147/17 <b>tenofovir [3]</b> 122/7 122/9 123/8 <b>tens [3]</b> 41/4 222/14 222/17 <b>teratogenic [1]</b> 198/3 <b>term [25]</b> 5/10 8/3 34/17 44/8 44/19 59/20 60/2 62/11 71/8 81/15 81/16 85/6	108/15 117/18 120/21 123/12 123/20 126/2 167/23 169/5 169/22 171/24 177/11 181/6 221/22 <b>termed [5]</b> 85/15 85/17 86/12 86/14 107/20 <b>terminology [4]</b> 12/4 73/3 84/1 125/14 <b>terms [60]</b> 5/14 10/25 12/17 16/24 18/8 18/17 18/23 21/3 21/12 23/11 26/13 35/10 36/6 36/22 37/6 37/17 44/21 46/5 50/10 51/23 53/21 54/22 66/19 69/2 69/20 74/22 78/2 80/5 81/11 92/19 94/7 94/19 95/17 100/11 101/11 105/24 127/4 131/8 139/5 141/10 145/16 158/23 163/6 167/12 167/18 167/23 173/10 173/18 174/7 175/2 178/19 221/10 223/14 225/12 225/14 225/20 226/18 227/4 232/3 232/17 <b>test [44]</b> 8/22 34/2 34/15 40/25 41/8 51/7 51/7 51/14 52/20 53/25 54/1 54/3 54/4 54/5 54/25 60/5 67/25 67/25 69/5 69/18 70/2 70/14 72/3 81/9 89/15 90/6 110/8 110/10 110/19 110/19 150/14 196/4 200/24 206/23 207/2 211/21 212/13 212/17 215/24 216/2 217/22 218/1 223/1 224/21 <b>tested [2]</b> 195/12 203/10 <b>testimony [2]</b> 22/18 76/8 <b>testing [20]</b> 39/12 40/24 41/3 48/6 54/22 55/21 58/2 67/7 68/16 68/23 69/21 88/25 89/12 150/22 196/1 213/23 215/25 217/9 223/6 224/23 <b>tests [73]</b> 5/17 5/18 5/19 5/19 6/16 10/2 10/10 10/19 22/24 28/14 34/3 34/9 35/5 35/7 41/5 41/6 41/13 48/11 51/4 51/12 52/13 52/17 53/15 53/23 54/11 55/4 56/8	56/9 56/11 56/15 56/21 57/2 57/6 57/6 57/7 59/11 60/10 60/22 68/1 68/17 69/1 69/2 69/6 70/6 70/9 70/11 70/15 70/18 84/19 85/9 87/22 88/16 89/13 89/17 89/21 119/19 168/5 174/12 178/19 204/9 212/1 213/2 213/2 213/13 213/13 213/16 215/19 216/18 222/23 222/25 224/5 224/22 225/1 <b>textbooks [2]</b> 220/10 220/11 <b>thalassaemia [1]</b> 159/6 <b>than [54]</b> 8/13 8/16 9/9 9/14 9/18 13/16 16/13 25/15 26/21 27/2 27/20 28/1 30/11 44/8 45/7 56/4 58/10 60/13 62/25 64/16 67/14 71/21 74/3 75/6 91/18 96/19 97/17 98/21 99/4 127/22 140/16 142/2 147/5 149/5 149/8 154/1 168/7 169/24 186/18 191/2 191/13 194/3 202/22 207/9 214/21 221/11 222/2 223/1 223/10 223/14 223/19 233/23 235/10 235/13 <b>thank [23]</b> 4/11 11/20 41/15 42/12 57/15 59/6 61/9 66/10 67/3 67/22 68/5 102/20 117/7 151/13 157/12 210/25 223/21 230/7 235/19 235/20 235/22 236/1 236/1 <b>thanked [1]</b> 235/25 <b>thankfully [1]</b> 169/12 <b>that [1186]</b> <b>that I [13]</b> 23/4 54/8 167/17 185/4 196/10 196/11 199/16 199/19 201/23 204/7 207/12 210/6 211/22 <b>that's [175]</b> 4/20 5/2 5/16 11/5 12/3 14/21 16/14 16/25 20/3 20/23 21/2 22/1 22/9 22/12 23/6 24/1 24/5 24/9 29/22 29/22 30/21 30/25 34/17 37/8 37/22 38/7 38/12 38/16 38/25 39/22 40/20 40/22 41/8 44/2 45/4 45/6 46/15 46/23	50/23 52/14 56/16 58/22 58/24 65/9 65/16 66/24 67/23 69/10 72/2 73/21 74/5 74/9 74/24 75/5 78/1 79/15 80/16 80/22 81/2 81/9 83/25 85/5 85/7 85/16 92/6 92/14 93/13 94/12 95/12 96/14 97/21 98/22 100/7 102/20 104/12 105/21 107/16 108/24 110/2 111/15 113/8 113/9 113/11 115/10 115/18 115/25 116/16 117/2 117/3 118/4 119/5 124/7 124/16 124/22 125/4 127/13 127/18 127/18 128/10 128/19 131/1 133/22 136/3 136/19 137/21 138/1 138/5 138/17 143/21 144/17 144/21 148/5 151/2 152/10 156/25 157/6 158/13 159/9 159/10 162/7 164/19 165/8 167/16 168/8 169/14 172/1 174/5 176/18 177/15 178/16 180/11 181/13 183/7 183/8 183/22 185/25 186/9 187/25 189/4 190/19 190/20 192/3 192/8 197/14 198/23 199/5 199/13 199/17 200/17 202/5 203/15 204/8 206/7 207/24 208/6 209/4 211/24 213/8 213/21 213/25 216/11 216/12 218/4 218/10 218/23 221/6 222/22 224/4 225/8 225/9 226/6 226/17 227/6 232/13 234/13 <b>the cellular [1]</b> 7/10 <b>the proportion [2]</b> 23/6 23/7 <b>the self-limiting [1]</b> 60/14 <b>their [77]</b> 8/21 10/11 16/24 41/12 48/11 50/10 51/12 60/10 69/2 77/15 77/17 77/25 79/7 79/10 79/13 83/1 85/9 89/11 89/18 97/2 97/6 104/11 111/14 114/14 114/25 115/2 115/3 120/19 122/16 122/17 129/11 129/13 129/13 150/1 150/14 170/16 170/17 170/23 175/4	175/15 175/16 176/14 176/16 176/21 178/3 178/7 179/3 180/3 180/4 181/11 181/19 183/15 187/18 187/18 187/18 187/23 187/23 187/25 192/18 194/8 195/7 202/16 202/23 203/21 206/5 209/13 209/19 210/4 210/22 211/6 212/3 212/20 217/7 228/12 230/23 232/10 232/18 <b>theirs [1]</b> 190/2 <b>them [87]</b> 8/3 9/12 26/23 31/9 31/10 40/3 40/13 49/14 50/1 50/2 50/8 57/11 60/19 60/24 61/5 61/7 65/16 70/1 78/9 78/12 78/18 83/1 84/14 86/12 101/1 111/7 111/12 111/22 120/18 125/11 129/18 131/9 131/10 131/25 134/8 135/17 139/13 141/3 142/21 144/11 146/22 148/3 148/3 148/16 149/3 149/5 150/16 150/22 151/9 152/23 154/3 154/22 155/15 157/18 158/3 158/9 159/25 170/13 170/14 171/4 174/20 178/1 179/24 179/24 179/25 180/5 180/15 185/9 185/10 185/13 192/15 197/20 198/13 203/7 204/7 208/14 209/13 209/18 210/11 210/13 214/3 218/4 219/4 219/8 219/19 232/11 235/2 <b>theme [2]</b> 59/12 139/17 <b>themselves [10]</b> 10/17 61/25 62/9 77/21 78/20 79/2 79/11 98/13 169/2 204/9 <b>then [176]</b> 2/8 5/6 11/5 11/17 13/5 13/18 14/15 17/16 18/13 19/2 19/15 19/21 21/16 24/16 26/1 29/11 29/13 33/4 33/6 33/21 34/1 34/13 35/4 35/8 35/8 36/12 37/13 43/7 45/9 46/1 47/3 47/17 54/4 54/19 55/23 56/14 59/14 62/23 68/15 71/4 72/3 72/11 72/13 72/18 72/19 74/17 74/21
<b>T</b>	<b>table [3]</b> 2/8 135/4 136/23 <b>tablets [1]</b> 107/14 <b>tachycardia [1]</b> 143/3 <b>tackling [1]</b> 37/20 <b>TAF [1]</b> 122/8 <b>take [15]</b> 19/6 65/1 83/12 96/16 101/22 112/6 122/15 140/3 146/7 165/10 182/16 188/13 209/8 215/18 228/25 <b>taken [10]</b> 38/5 38/5 38/18 53/2 87/14 123/14 140/3 168/9 189/6 235/6 <b>takes [4]</b> 134/5 187/21 207/5 207/6 <b>taking [10]</b> 101/17 121/18 123/12 139/19 139/20 147/3 147/7 210/11 235/24 236/1 <b>talk [40]</b> 5/13 6/9 11/19 19/7 20/23 21/6 27/21 28/21 31/14 32/9 43/8 46/7 49/17 69/23 72/20 75/3 78/13 82/1 82/8 84/5 87/24 96/5 115/24 120/4 125/7 128/17 130/5 163/22 163/24 166/8 167/14 167/21				

<b>T</b>	15/21 17/21 22/14 24/4 33/14 33/19 44/23 51/8 51/21 67/4 67/14 72/11 73/25 74/12 79/2 81/11 82/15 82/24 85/14 85/16 86/25 87/19 98/24 102/12 110/5 114/15 116/6 117/3 118/13 122/25 124/7 132/3 149/18 156/7 160/22 161/20 162/17 166/20 185/22 186/15 190/18 198/22 205/1 211/13 212/2 220/13 221/24 222/6 223/16 223/22 226/19 227/5 230/9 232/4	29/15 31/3 31/5 31/7 41/10 48/15 49/2 50/12 50/13 51/11 55/5 55/16 55/17 57/7 58/2 60/7 61/4 61/5 63/20 63/21 65/3 66/2 66/19 70/16 72/3 73/4 73/4 73/4 73/16 75/20 76/18 76/19 76/25 77/1 77/13 77/17 77/17 77/18 77/18 77/24 78/8 78/10 78/20 79/5 79/8 80/7 80/8 81/19 82/4 83/4 85/8 85/12 86/8 86/23 87/16 87/18 89/10 90/4 91/12 94/7 96/6 96/8 96/9 97/4 97/5 100/15 100/16 100/18 101/20 102/2 104/12 106/4 107/17 107/20 108/13 110/1 110/5 110/7 110/16 111/13 111/16 111/17 112/20 114/12 114/16 115/5 115/6 115/8 116/17 118/1 119/7 119/8 119/9 129/13 129/14 129/20 130/8 131/24 132/13 134/1 134/5 134/6 134/15 134/20 136/11 137/6 140/17 141/7 141/8 144/11 148/10 150/8 150/19 151/11 152/18 153/18 156/3 158/1 158/4 158/20 162/3 162/4 162/5 162/21 164/16 167/1 170/24 171/4 171/4 171/13 173/21 173/22 173/24 174/3 174/4 174/14 174/15 176/12 177/24 178/2 178/3 178/13 178/14 178/17 179/5 179/6 179/22 179/24 180/1 180/2 180/6 180/7 180/7 180/21 180/22 180/24 183/17 184/4 185/11 185/11 185/15 186/16 187/10 190/2 192/11 198/15 201/3 201/3 201/4 201/7 201/19 201/25 202/14 202/20 203/8 203/21 204/2 205/3 206/4 208/16 210/3 210/8 210/9 210/9 212/10 212/13 213/17 217/10 217/10 219/6 219/8 219/9 219/11 220/11 221/22 222/21 224/14 225/1 225/21 226/16	228/16 229/19 230/12 230/13 230/14 232/19 232/19 234/8 234/8 234/9 234/11 235/1 235/14 <b>they'd</b> [5] 40/14 52/21 150/18 167/9 195/14 <b>they'll</b> [1] 208/18 <b>they're</b> [31] 8/17 40/13 49/21 50/8 50/10 70/15 71/25 83/5 86/21 89/18 110/2 112/24 123/14 144/17 146/23 148/17 154/17 155/1 155/2 170/19 170/23 172/11 180/1 184/25 187/11 187/15 196/3 200/18 202/12 210/7 216/17 <b>they've</b> [10] 49/1 89/22 111/1 112/19 119/18 156/2 160/2 185/10 197/19 210/16 <b>thickening</b> [1] 83/17 <b>thing</b> [18] 22/12 52/22 126/6 144/19 148/6 154/4 162/6 185/17 186/10 197/23 198/7 198/17 200/18 201/6 204/19 210/2 227/25 230/10 <b>things</b> [55] 7/15 15/10 15/23 19/7 20/3 21/8 22/13 23/12 23/13 24/9 31/25 32/20 33/18 35/2 38/5 40/21 51/23 61/2 76/14 78/8 78/11 94/19 100/6 100/10 112/22 134/23 136/17 136/23 144/22 144/23 146/16 147/12 153/25 154/15 154/23 156/7 164/5 164/8 165/15 166/18 175/1 185/20 186/11 192/10 199/4 199/20 199/20 200/4 206/2 209/14 209/17 210/12 212/15 212/21 218/17 <b>think</b> [253] <b>thinking</b> [1] 129/25 <b>third</b> [4] 57/6 58/12 153/8 228/12 <b>thirdly</b> [1] 116/19 <b>thirds</b> [2] 11/7 64/4 <b>thirst</b> [1] 146/3 <b>this</b> [167] 1/5 1/10 1/12 3/1 4/25 5/9 6/21 10/15 17/7 17/12 21/7 22/16 25/17 27/11 31/19 32/15 32/15 32/18 32/21 33/17 34/17 35/14 36/24	39/15 40/5 42/19 43/7 43/15 45/11 45/25 46/5 47/7 47/21 47/23 58/6 58/9 59/2 59/5 60/1 65/19 66/12 68/25 70/22 71/4 71/23 72/25 75/16 77/11 78/15 79/20 80/2 82/10 82/16 83/5 84/17 89/3 90/23 91/7 92/22 94/22 97/8 99/13 101/22 102/23 106/3 107/7 107/16 107/25 108/14 108/19 108/24 109/3 109/8 112/4 112/12 112/17 114/2 117/9 117/21 118/11 119/16 120/1 123/7 123/12 124/4 124/17 125/2 125/8 125/9 126/4 127/10 127/15 128/23 131/5 133/18 133/18 134/19 134/20 134/24 136/4 136/7 136/9 136/10 136/15 136/20 138/15 139/6 139/17 140/15 142/15 143/18 143/22 145/20 146/4 146/7 148/15 153/17 154/24 155/5 157/22 159/16 162/19 163/14 163/22 164/25 166/10 166/21 168/3 168/14 171/16 177/17 177/19 181/7 181/7 181/15 181/17 182/6 183/14 185/21 187/1 188/24 189/8 189/10 189/10 190/11 192/24 198/10 198/14 199/7 199/7 200/5 200/15 202/9 204/23 205/20 212/21 215/11 215/15 216/24 218/22 223/8 224/16 225/5 226/21 227/8 228/10 229/15 <b>thoracic</b> [1] 143/9 <b>those</b> [235] 2/17 4/17 5/24 5/25 6/8 6/8 6/16 6/24 7/3 8/18 9/6 9/10 9/11 9/21 9/22 10/23 11/25 14/1 15/1 15/3 15/16 16/7 17/18 17/22 20/13 21/17 21/19 23/24 24/1 24/2 24/8 24/20 28/18 31/2 32/3 32/4 34/3 34/23 38/17 40/2 40/22 41/16 45/13 49/15 49/19 55/10 56/15 57/21 58/16 59/16 60/11 60/17 60/20	60/23 61/21 61/23 62/3 63/6 63/14 63/19 64/7 64/12 65/4 66/4 66/16 70/3 71/10 71/18 73/22 74/7 74/8 75/11 75/19 76/24 77/7 77/9 78/6 78/7 81/12 82/1 82/7 82/9 82/25 83/17 84/12 85/2 87/7 87/10 88/9 90/7 90/16 90/18 92/25 93/5 93/23 94/1 94/7 95/23 96/10 96/12 96/14 96/17 97/3 100/4 101/6 102/6 102/16 102/18 103/7 105/1 105/25 106/4 106/22 110/5 110/9 110/10 113/14 113/15 113/17 114/2 116/4 121/10 122/3 123/6 123/22 125/13 126/6 126/10 126/21 126/22 127/19 127/21 127/23 127/25 128/3 130/23 131/6 133/6 133/21 136/21 138/10 139/19 141/1 141/7 141/11 142/2 142/12 142/24 144/10 146/9 147/1 147/2 147/25 148/16 148/18 148/22 149/4 149/11 149/24 150/3 151/5 152/5 152/6 152/15 153/7 154/16 154/20 154/25 156/4 156/10 157/20 158/4 158/14 158/19 159/9 161/19 161/22 162/3 162/20 164/15 165/19 165/23 168/19 169/15 170/15 171/11 171/4 171/8 171/16 171/20 173/5 174/25 175/5 176/4 176/21 177/22 179/9 179/13 179/20 179/21 179/21 180/10 182/19 187/19 192/16 193/3 193/17 195/19 197/2 197/19 200/6 201/15 201/18 201/21 202/5 203/3 203/5 203/12 204/1 206/16 209/16 210/22 212/8 217/18 218/16 221/5 221/12 224/14 225/1 225/20 227/21 232/18 233/5 234/19 234/24 <b>though</b> [7] 1/3 70/1 119/18 148/17 162/5 179/13 181/3 <b>thought</b> [7] 13/9
----------	---	---	---	--	---



<b>T</b>	74/25 75/6 85/7 85/10 89/1 93/4 96/19 96/23 97/13 98/4 114/3 116/25 119/9 119/25 123/25 126/7 129/16 130/6 133/22 134/16 136/19 141/9 141/14 148/25 157/16 167/8 172/11 182/18 183/1 185/25 186/6 188/13 189/8 190/25 191/9 198/24 204/4 207/1 207/5 207/6 207/7 207/15 207/20 210/1 228/15 228/25 235/19 235/19 235/24 <b>timeline [2]</b> 56/20 129/5 <b>timely [1]</b> 209/2 <b>times [6]</b> 102/19 103/3 104/16 166/13 221/11 221/14 <b>timescale [2]</b> 150/21 214/24 <b>timing [2]</b> 74/22 140/24 <b>TIP [1]</b> 108/24 <b>tired [1]</b> 179/5 <b>tissue [6]</b> 80/21 82/19 83/9 83/21 145/1 145/10 <b>tissues [1]</b> 83/1 <b>to [1251]</b> <b>to 100 [1]</b> 69/9 <b>today [9]</b> 4/14 6/10 7/3 56/22 61/21 77/22 121/18 204/21 230/17 <b>together [11]</b> 50/8 109/19 143/19 146/23 154/3 154/19 156/2 156/7 194/4 198/5 219/19 <b>told [13]</b> 14/25 78/10 129/21 131/24 159/9 175/8 186/12 189/10 198/13 201/4 232/15 232/19 232/20 <b>tolerance [2]</b> 216/15 217/7 <b>tolerant [1]</b> 93/7 <b>tolerate [3]</b> 116/17 118/22 228/24 <b>tolerated [3]</b> 121/15 122/24 217/11 <b>tomorrow [10]</b> 32/17 46/7 121/11 159/17 163/22 194/14 194/20 231/4 231/5 236/4 <b>too [11]</b> 38/18 40/7 98/7 103/23 133/19 133/23 134/14 151/4 191/17 216/24 235/14 <b>took [2]</b> 191/9 191/21	<b>tool [1]</b> 213/25 <b>toolkit [1]</b> 206/5 <b>toothbrush [3]</b> 232/24 233/15 234/2 <b>toothbrushes [1]</b> 232/20 <b>top [12]</b> 28/14 55/15 59/16 67/10 82/19 83/14 117/8 138/16 143/25 148/7 161/5 186/24 <b>topic [4]</b> 47/20 48/5 151/2 192/20 <b>touch [2]</b> 11/21 98/14 <b>touched [7]</b> 92/14 94/22 101/1 125/11 164/5 173/2 227/8 <b>touches [1]</b> 233/1 <b>towards [7]</b> 37/11 67/10 95/1 131/5 180/6 189/1 190/8 <b>toxic [1]</b> 148/9 <b>toxicity [1]</b> 135/7 <b>toxins [4]</b> 7/19 112/2 112/7 113/3 <b>traces [1]</b> 166/17 <b>track [1]</b> 190/12 <b>tract [1]</b> 83/15 <b>tracts [2]</b> 83/19 83/22 <b>trade [2]</b> 147/8 161/15 <b>trade-off [1]</b> 147/8 <b>traded [1]</b> 192/9 <b>train [2]</b> 196/18 196/21 <b>trained [1]</b> 185/18 <b>training [1]</b> 196/13 <b>transcribed [1]</b> 55/18 <b>transferable [1]</b> 188/2 <b>transformation [2]</b> 37/4 134/25 <b>transformative [1]</b> 37/6 <b>transformed [3]</b> 37/10 133/9 149/24 <b>transfused [1]</b> 55/25 <b>transfusion [23]</b> 12/13 24/22 25/11 25/19 38/23 39/17 39/18 39/20 55/11 55/21 55/23 59/19 60/7 111/17 183/9 195/14 200/7 200/17 201/5 202/13 203/4 203/13 208/1 <b>transfusions [5]</b> 57/22 61/4 63/19 63/21 197/13 <b>translate [2]</b> 103/22 104/3 <b>transmissible [3]</b> 220/4 231/14 232/16 <b>transmission [43]</b> 25/9 38/25 41/18	41/21 42/7 42/14 42/22 43/9 43/13 43/24 44/4 45/2 45/3 45/9 45/19 45/20 45/22 45/24 46/3 46/15 46/20 46/22 46/25 47/8 80/13 132/18 159/20 177/25 189/20 201/20 231/3 231/12 231/15 232/14 232/24 233/4 233/22 233/23 233/25 234/5 234/19 235/6 235/12 <b>transmissions [1]</b> 17/8 <b>transmit [2]</b> 42/3 233/17 <b>transmitted [7]</b> 38/21 39/18 39/20 43/2 231/17 234/21 235/2 <b>transmitting [3]</b> 80/12 206/22 235/1 <b>transplant [21]</b> 71/19 72/8 108/14 108/18 113/21 113/23 113/24 114/1 114/7 114/14 114/18 114/25 115/4 115/5 115/8 115/16 115/20 132/23 132/25 133/4 133/10 <b>transplantation [7]</b> 3/2 71/6 113/10 113/13 113/22 117/21 171/18 <b>transplants [3]</b> 115/12 132/21 133/6 <b>transposing [1]</b> 103/20 <b>travelling [1]</b> 181/19 <b>treat [17]</b> 27/12 27/14 27/20 36/14 36/20 108/4 125/1 131/15 131/24 150/11 150/11 160/17 165/7 168/22 169/6 222/18 222/21 <b>treated [17]</b> 28/12 29/8 62/17 96/10 96/11 97/15 111/25 112/24 132/1 149/23 164/18 169/7 169/12 222/15 225/21 228/9 231/8 <b>treating [4]</b> 141/2 175/13 192/15 222/11 <b>treatment [137]</b> 16/22 20/21 23/2 23/9 24/5 26/3 27/1 27/9 27/19 27/24 29/9 30/4 35/11 35/19 35/22 35/22 35/25 36/7 37/5 38/15 46/10 50/3 50/6 50/7 50/15 51/16 65/7 78/13 81/11 82/8	88/18 96/24 97/22 98/1 98/2 106/12 106/12 106/18 106/20 107/11 107/22 108/12 109/9 110/23 111/3 113/1 113/9 114/13 115/7 116/2 117/24 118/3 118/19 120/9 120/18 121/1 121/2 121/6 121/13 121/21 122/9 122/25 123/24 123/25 124/1 124/6 124/15 124/20 124/22 125/18 125/19 126/12 126/15 126/16 127/1 127/11 128/22 129/12 130/1 132/13 132/24 133/7 137/8 139/8 141/18 142/19 142/23 144/16 146/5 146/19 147/19 148/9 148/25 149/16 150/7 150/8 150/16 150/17 150/20 153/6 157/24 158/8 158/18 158/18 160/18 162/22 163/4 163/7 165/1 166/14 167/9 167/11 167/24 170/4 175/7 175/22 178/6 183/20 183/21 187/9 187/16 188/18 192/13 193/17 195/16 215/6 219/2 221/7 225/20 226/11 227/12 228/12 228/22 229/2 230/18 231/9 231/21 <b>treatment-related [1]</b> 78/13 <b>treatments [54]</b> 2/16 2/17 2/22 3/11 3/12 24/10 29/6 35/23 91/11 98/12 106/15 106/16 107/18 108/10 108/19 109/12 111/2 111/18 112/18 116/18 116/20 117/17 118/6 118/23 119/22 120/5 120/6 120/22 122/2 122/23 123/23 124/13 126/8 126/11 126/23 131/9 132/21 149/4 149/7 150/4 160/16 160/17 161/16 164/1 165/10 166/25 196/8 197/3 199/12 200/11 225/4 227/17 229/4 229/10 <b>tree [1]</b> 19/20 <b>tremors [1]</b> 142/7 <b>trial [2]</b> 154/3 233/7 <b>trials [3]</b> 158/6 168/21 232/5 <b>tricky [1]</b> 69/25	<b>tried [9]</b> 17/11 20/10 21/16 32/18 38/13 102/2 151/9 154/24 197/16 <b>tries [1]</b> 206/5 <b>trigger [2]</b> 174/16 218/2 <b>triple [1]</b> 164/10 <b>tripled [1]</b> 234/12 <b>true [2]</b> 44/9 69/19 <b>trust [1]</b> 230/12 <b>try [32]</b> 5/13 17/25 56/24 57/13 57/20 71/9 71/17 79/14 91/11 101/21 102/10 106/1 111/19 114/21 134/4 134/16 134/19 146/13 156/9 189/19 190/21 199/2 199/6 199/21 200/20 201/12 206/9 207/9 213/9 220/25 230/14 233/7 <b>trying [28]</b> 21/7 35/17 37/17 47/13 65/12 94/8 105/21 133/25 166/15 173/6 177/16 184/20 185/12 191/1 197/5 198/18 199/16 199/22 200/12 201/8 201/10 202/1 202/7 208/8 208/13 223/2 233/10 234/18 <b>tubes [1]</b> 82/23 <b>tumour [4]</b> 88/2 88/12 89/15 119/16 <b>turn [16]</b> 36/17 75/23 98/12 106/14 116/1 119/20 120/18 120/19 135/2 146/6 160/6 183/23 206/2 206/7 206/9 230/19 <b>turned [1]</b> 9/11 <b>turning [3]</b> 11/5 59/14 125/3 <b>turnover [1]</b> 11/8 <b>tweaks [1]</b> 200/2 <b>two [50]</b> 4/22 6/24 8/11 9/3 11/7 14/22 16/2 19/18 21/8 39/20 54/21 54/24 57/18 58/10 64/4 67/13 76/1 86/9 86/18 87/3 89/24 90/21 98/8 101/3 105/15 108/18 110/20 111/2 119/5 122/8 123/6 128/13 141/5 142/13 149/6 149/11 149/14 153/25 155/8 156/1 156/5 156/7 160/16 166/23 180/15 180/19 198/5 218/17 219/19 228/14 <b>two o'clock [1]</b> 98/8
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<b>T</b>	<b>understand [25]</b> 25/7 27/25 34/6 42/4 42/18 43/12 44/13 69/25 91/4 93/17 94/5 101/21 102/1 104/14 104/16 135/11 173/4 173/7 182/21 187/2 189/10 192/25 222/19 229/17 229/20	179/5 198/19 211/7 236/8	141/3 153/1 162/9 162/11 163/7 167/21 174/10 184/15 191/10 198/2 202/17 204/8 212/3 212/20 213/14 232/21	110/22 110/22 110/25 111/4 111/6 111/21 173/23 173/25	123/14 124/14 125/17 126/12 128/1 128/4 128/8 128/16 129/22 131/13 132/3 132/8 133/8 136/23 137/19 138/16 138/24 138/24 138/24 139/1 140/2 141/4 143/15 143/15 144/19 144/20 145/4 145/14 145/23 146/8 147/19 147/20 149/17 150/20 150/20 150/24 150/24 154/15 154/15 159/12 159/25 161/13 162/11 166/14 166/22 166/24 167/8 168/11 169/4 169/4 170/24 180/2 180/12 181/21 183/7 184/12 185/15 187/5 187/11 187/16 195/22 196/17 199/20 199/23 201/6 202/7 204/3 208/17 209/10 211/24 212/4 212/16 214/1 214/16 217/18 217/21 219/9 221/9 224/8 224/14 227/23 227/24 228/10 229/16 229/20 229/23 230/6 230/7 232/6 233/8 234/14 234/14 234/15 234/20 234/22 234/25 236/2
<b>two years [1]</b> 198/5	<b>understanding [17]</b> 4/16 8/24 11/23 31/17 33/8 34/21 34/21 40/23 42/20 55/8 60/15 99/18 176/11 178/12 189/9 191/23 223/5	<b>untransmissible [3]</b> 231/7 231/20 231/25	<b>used [39]</b> 12/4 16/21 35/6 49/1 49/21 50/24 85/22 86/10 89/13 106/1 109/13 117/4 120/12 121/3 121/5 121/10 121/17 122/1 122/11 122/11 123/2 128/15 132/5 139/21 140/19 146/19 147/4 147/5 147/5 148/10 148/16 190/19 211/10 211/20 213/5 213/9 222/4 228/22 233/16	<b>varicose [1]</b> 109/14	<b>vessels [2]</b> 82/22 83/16
<b>two-thirds [2]</b> 11/7 64/4	<b>understood [5]</b> 38/11 52/8 61/17 74/18 229/22	<b>untreatable [1]</b> 97/19	<b>useful [5]</b> 8/23 16/15 25/20 116/5 124/24	<b>various [6]</b> 4/9 5/25 35/16 112/14 149/2 213/15	<b>vias [2]</b> 109/22 114/6
<b>tying [2]</b> 6/15 21/3	<b>undertake [1]</b> 232/11	<b>untreated [3]</b> 27/5 97/19 102/23	<b>usefulness [1]</b> 227/12	<b>various [2]</b> 216/1 216/1	<b>view [5]</b> 18/3 51/3 51/19 130/15 177/23
<b>type [7]</b> 50/4 84/17 91/20 196/16 211/20 212/13 227/12	<b>undertaking [1]</b> 116/23	<b>unusual [4]</b> 30/10 70/12 223/10 223/24	<b>users [1]</b> 193/7	<b>varies [1]</b> 62/8	<b>views [1]</b> 212/11
<b>types [9]</b> 14/8 21/18 90/14 133/15 156/14 204/15 209/6 213/15 229/23	<b>underwent [1]</b> 146/4	<b>unwell [5]</b> 9/24 73/5 78/20 79/11 116/25	<b>uses [1]</b> 7/12	<b>varies [3]</b> 3/20 91/1 91/4	<b>viral [34]</b> 3/22 5/5 6/2 6/3 6/8 6/18 6/22 35/15 36/20 37/1 37/11 37/14 37/20 38/20 50/4 51/14 52/3 90/12 93/11 94/1 98/23 99/3 99/6 99/9 99/19 103/13 123/15 132/20 135/22 161/1 167/4 224/10 225/3 231/10
<b>typically [3]</b> 28/2 187/1 214/25	<b>undetected [6]</b> 52/3 122/17 166/2 231/6 231/19 231/22	<b>up [77]</b> 3/5 5/16 10/8 19/11 21/4 22/17 26/23 30/17 37/19 39/8 39/14 42/22 44/2 49/9 52/15 52/23 53/1 54/18 59/3 59/4 60/18 63/15 64/14 69/13 71/18 71/21 83/22 84/21 95/6 95/7 95/8 95/8 125/4 131/25 138/13 139/14 144/25 152/5 159/17 170/15 173/8 173/10 173/14 173/19 173/21 173/23 174/2 175/10 175/14 175/16 175/23 175/24 176/13 177/4 178/14 179/24 180/6 181/25 182/3 188/4 190/2 190/21 201/12 207/10 208/19 208/23 211/1 211/4 211/7 211/18 212/15 222/24 224/12 224/24 229/3 232/25 234/16	<b>using [15]</b> 7/22 29/10 50/14 52/23 53/23 71/16 80/1 120/15 128/9 140/7 140/19 140/23 213/6 216/5 229/21	<b>vascular [3]</b> 143/7 156/17 156/17	<b>virals [2]</b> 127/13 128/7
<b>U</b>	<b>unequivocal [1]</b> 168/17	<b>update [1]</b> 217/16	<b>usual [5]</b> 52/10 53/23 114/12 205/15 207/7	<b>vasculitis [1]</b> 81/14	<b>viremic [1]</b> 22/22
<b>UK [25]</b> 2/18 17/6 17/8 17/9 18/1 20/4 21/22 22/7 23/3 34/4 39/19 89/6 90/17 113/20 150/4 160/10 173/6 175/22 189/22 191/20 207/15 207/18 220/19 220/20 221/16	<b>unethical [1]</b> 233/10	<b>updated [1]</b> 90/20	<b>usually [12]</b> 40/21 53/2 85/24 111/20 119/10 124/3 145/20 181/13 183/12 219/3 224/7 224/22	<b>vast [4]</b> 9/4 68/1 76/2 215/25	<b>virine [1]</b> 168/2
<b>ultimately [2]</b> 113/16 113/18	<b>unexpected [4]</b> 183/5 184/24 207/24 208/9	<b>upon [4]</b> 131/1 139/17 188/23 203/23	<b>users [1]</b> 193/7	<b>vastly [1]</b> 26/19	<b>virological [2]</b> 124/21 125/25
<b>ultrasound [8]</b> 89/14 90/5 211/20 211/24 212/6 212/10 212/18 219/12	<b>unfortunately [2]</b> 40/15 230/24	<b>upper [1]</b> 216/25	<b>uses [1]</b> 7/12	<b>vein [3]</b> 109/19 109/22 109/23	<b>virologist [1]</b> 3/18
<b>ultrasounds [2]</b> 178/21 180/23	<b>uninfected [1]</b> 97/3	<b>upsets [1]</b> 203/17	<b>using [15]</b> 7/22 29/10 50/14 52/23 53/23 71/16 80/1 120/15 128/9 140/7 140/19 140/23 213/6 216/5 229/21	<b>veins [3]</b> 81/22 109/14 109/16	<b>virtually [1]</b> 62/22
<b>unable [1]</b> 112/19	<b>unique [3]</b> 40/13 78/15 129/24	<b>upwards [1]</b> 95/4	<b>usual [5]</b> 52/10 53/23 114/12 205/15 207/7	<b>venous [4]</b> 109/25 218/25 219/3 219/5	<b>virus [114]</b> 1/14 4/7 7/11 7/11 7/21 8/8 8/9 8/12 8/17 11/25 12/5 12/7 13/23 13/25 14/9
<b>unacceptable [1]</b> 168/23	<b>unit [1]</b> 194/5	<b>us [40]</b> 1/15 1/18 9/1 12/2 12/23 13/22 14/25 18/2 19/4 21/6 21/6 32/9 32/13 50/6 50/12 50/15 57/13 68/21 72/20 94/24 106/22 106/22 109/12 113/12 114/9 116/4 120/4 125/7 135/5 142/2 146/11 173/16 179/6 219/20 219/20 220/16 232/15 235/17 235/22 235/25	<b>usual [5]</b> 52/10 53/23 114/12 205/15 207/7	<b>verge [2]</b> 179/22 180/12	<b>virtually [1]</b> 62/22
<b>unaccepted [1]</b> 136/1	<b>United [9]</b> 17/2 17/19 19/23 24/21 115/13 119/1 130/20 189/1 191/12	<b>USA [1]</b> 104/10	<b>usually [12]</b> 40/21 53/2 85/24 111/20 119/10 124/3 145/20 181/13 183/12 219/3 224/7 224/22	<b>version [1]</b> 123/8	<b>virtually [1]</b> 62/22
<b>uncertainty [5]</b> 174/16 175/12 181/4 181/9 181/10	<b>United Kingdom [8]</b> 17/2 17/19 24/21 115/13 119/1 130/20 189/1 191/12	<b>use [35]</b> 5/10 16/22 45/5 45/5 50/1 50/2 50/4 50/8 51/13 84/1 86/16 94/8 101/25 116/9 122/4 123/1 126/2 129/25 140/21	<b>users [1]</b> 193/7	<b>versus [1]</b> 207/18	<b>virtually [1]</b> 62/22
<b>unclear [1]</b> 173/2	<b>unfortunately [2]</b> 40/15 230/24	<b>update [1]</b> 217/16	<b>uses [1]</b> 7/12	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22
<b>uncomfortable [1]</b> 213/12	<b>uninfected [1]</b> 97/3	<b>updated [1]</b> 90/20	<b>using [15]</b> 7/22 29/10 50/14 52/23 53/23 71/16 80/1 120/15 128/9 140/7 140/19 140/23 213/6 216/5 229/21	<b>vertically [2]</b> 42/8 43/2	<b>virtually [1]</b> 62/22
<b>uncommon [5]</b> 81/7 124/11 135/23 138/20 224/19	<b>unique [3]</b> 40/13 78/15 129/24	<b>upon [4]</b> 131/1 139/17 188/23 203/23	<b>users [1]</b> 193/7	<b>version [1]</b> 123/8	<b>virtually [1]</b> 62/22
<b>unconscious [1]</b> 112/16	<b>unit [1]</b> 194/5	<b>upper [1]</b> 216/25	<b>uses [1]</b> 7/12	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22
<b>under [10]</b> 74/2 98/15 99/8 100/22 110/1 110/12 119/14 121/3 135/19 153/9	<b>United [9]</b> 17/2 17/19 19/23 24/21 115/13 119/1 130/20 189/1 191/12	<b>upsets [1]</b> 203/17	<b>using [15]</b> 7/22 29/10 50/14 52/23 53/23 71/16 80/1 120/15 128/9 140/7 140/19 140/23 213/6 216/5 229/21	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22
<b>under-report [1]</b> 100/22	<b>United Kingdom [8]</b> 17/2 17/19 24/21 115/13 119/1 130/20 189/1 191/12	<b>upwards [1]</b> 95/4	<b>usual [5]</b> 52/10 53/23 114/12 205/15 207/7	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22
<b>underestimated [2]</b> 87/18 234/11	<b>units [4]</b> 193/20 194/6 194/6 194/10	<b>us [40]</b> 1/15 1/18 9/1 12/2 12/23 13/22 14/25 18/2 19/4 21/6 21/6 32/9 32/13 50/6 50/12 50/15 57/13 68/21 72/20 94/24 106/22 106/22 109/12 113/12 114/9 116/4 120/4 125/7 135/5 142/2 146/11 173/16 179/6 219/20 219/20 220/16 232/15 235/17 235/22 235/25	<b>usually [12]</b> 40/21 53/2 85/24 111/20 119/10 124/3 145/20 181/13 183/12 219/3 224/7 224/22	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22
<b>undergoing [3]</b> 119/19 188/17 231/9	<b>universal [4]</b> 176/18 191/11 191/19 206/8	<b>USA [1]</b> 104/10	<b>users [1]</b> 193/7	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22
<b>undergone [3]</b> 113/14 113/16 113/17	<b>universally [1]</b> 130/23	<b>use [35]</b> 5/10 16/22 45/5 45/5 50/1 50/2 50/4 50/8 51/13 84/1 86/16 94/8 101/25 116/9 122/4 123/1 126/2 129/25 140/21	<b>using [15]</b> 7/22 29/10 50/14 52/23 53/23 71/16 80/1 120/15 128/9 140/7 140/19 140/23 213/6 216/5 229/21	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22
<b>underlying [2]</b> 77/24 116/13	<b>University [2]</b> 3/25 4/4	<b>update [1]</b> 217/16	<b>users [1]</b> 193/7	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22
<b>underneath [1]</b> 202/2	<b>unless [7]</b> 42/4 42/15 62/17 65/7 110/8 172/16 224/21	<b>updated [1]</b> 90/20	<b>using [15]</b> 7/22 29/10 50/14 52/23 53/23 71/16 80/1 120/15 128/9 140/7 140/19 140/23 213/6 216/5 229/21	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22
<b>underpins [1]</b> 181/3	<b>unnoticed [1]</b> 73/23	<b>upon [4]</b> 131/1 139/17 188/23 203/23	<b>usual [5]</b> 52/10 53/23 114/12 205/15 207/7	<b>vertical [1]</b> 41/21	<b>virtually [1]</b> 62/22

<b>V</b>	<b>walk [1]</b> 169/10 <b>walking [2]</b> 185/1 209/11 <b>want [33]</b> 7/21 12/25 14/22 15/12 19/6 22/10 23/10 38/18 38/19 39/8 48/5 58/24 65/18 69/13 71/16 101/21 101/25 136/14 140/13 150/11 151/8 152/6 163/8 168/19 180/17 185/24 187/10 199/10 199/11 212/21 220/6 221/24 226/18 <b>wanted [14]</b> 65/20 67/5 106/11 131/15 138/13 149/6 158/25 180/22 180/23 186/19 192/21 195/4 206/10 206/12 <b>wanting [1]</b> 187/8 <b>wants [4]</b> 7/22 29/3 65/15 129/1 <b>War [1]</b> 104/9 <b>warn [1]</b> 111/12 <b>was [186]</b> 1/10 4/12 13/1 13/3 13/7 13/9 16/20 23/4 26/25 27/1 27/8 27/10 27/12 27/14 28/5 29/5 29/7 29/13 29/19 30/25 31/17 32/16 32/25 33/4 33/4 33/9 33/15 34/13 34/16 34/25 35/3 35/20 35/22 36/18 37/4 40/23 40/25 41/2 41/2 41/8 43/5 56/11 56/15 56/24 59/17 59/25 60/1 60/4 60/10 60/15 60/19 60/22 61/8 61/13 61/14 61/17 65/7 65/20 65/25 77/16 78/23 100/17 100/21 101/9 101/13 101/14 101/17 101/18 102/2 102/5 102/7 102/15 103/1 103/1 103/2 104/11 105/5 105/21 118/15 120/12 121/10 121/10 121/17 121/25 126/13 126/14 126/21 129/10 129/20 129/22 130/3 130/6 131/8 131/13 131/14 131/16 131/17 131/21 131/22 131/23 131/25 132/1 132/7 132/13 132/14 132/15 132/24 133/1 136/6 136/12 139/3 139/9 139/21 139/21 139/23 140/5 140/18 141/4 141/13	141/14 144/10 146/12 147/4 147/7 147/8 148/10 150/16 151/25 158/24 159/1 160/11 160/20 162/24 163/9 163/14 163/16 165/25 166/21 167/2 167/3 167/6 167/7 168/21 168/24 175/10 177/13 177/14 180/8 180/18 180/25 183/19 186/18 188/25 189/10 190/6 191/24 191/24 192/2 192/3 196/22 198/8 198/14 198/25 200/20 200/21 201/6 205/10 205/11 207/13 211/4 213/10 214/22 216/19 216/24 217/1 220/4 220/9 220/11 221/15 223/10 233/11 233/16 234/6 234/21 234/24 235/16 <b>was discrepancy [1]</b> 132/15 <b>wasn't [10]</b> 60/9 60/16 92/21 100/20 104/10 140/18 160/19 198/10 198/11 203/21 <b>watching [2]</b> 148/25 172/4 <b>water [1]</b> 107/16 <b>way [41]</b> 2/8 5/16 11/21 12/22 32/16 38/3 46/23 47/7 51/22 78/19 84/4 86/22 102/14 105/3 105/16 105/20 122/1 131/17 131/22 134/17 141/5 143/21 152/4 153/21 154/9 165/19 174/14 174/21 174/25 184/21 198/7 198/9 199/12 200/11 201/17 203/15 203/25 212/7 226/7 226/20 230/13 <b>ways [10]</b> 5/11 7/16 14/13 20/7 45/19 69/18 106/8 204/1 206/16 225/16 <b>we [470]</b> <b>we'd [5]</b> 29/12 60/13 103/21 176/19 220/7 <b>we'll [21]</b> 5/17 5/21 10/20 11/19 14/18 19/2 20/12 31/4 34/2 41/15 46/7 50/18 78/13 82/8 127/3 130/5 141/24 163/21 172/8 187/24 217/18 <b>we're [61]</b> 1/17 5/14 10/1 18/4 18/13 22/25 42/19 43/25 46/8	46/21 49/5 50/14 53/23 59/4 63/14 65/11 69/5 69/7 69/8 69/10 69/14 70/4 70/11 70/19 74/20 74/21 89/4 94/10 97/18 115/19 125/12 126/8 132/9 132/10 132/11 135/3 136/22 150/4 159/12 168/12 170/14 177/17 179/18 181/4 181/5 181/7 185/8 185/8 198/16 200/1 201/17 202/6 204/14 207/23 208/8 211/22 216/8 223/2 229/21 230/6 230/7 <b>we've [97]</b> 5/8 8/20 21/4 21/16 22/23 31/9 31/16 32/18 32/23 33/13 34/5 36/21 37/12 38/12 49/24 53/6 55/13 57/5 57/17 59/13 66/14 66/16 67/23 68/13 71/3 73/5 76/8 83/12 85/21 95/15 97/7 113/13 113/15 119/13 125/11 128/5 132/22 133/21 137/14 138/11 138/14 139/10 142/8 142/15 145/2 145/7 146/3 146/15 147/9 147/12 150/10 150/25 152/4 154/24 155/8 155/11 156/15 156/22 161/23 164/5 164/6 164/7 165/8 165/18 166/13 166/19 167/19 167/22 167/25 172/3 172/4 172/4 186/2 186/12 190/25 191/2 196/15 197/21 197/22 198/5 198/24 200/11 201/9 201/11 208/6 208/23 209/16 209/24 211/19 214/2 215/13 217/3 217/5 218/9 222/8 227/8 230/16 <b>weak [1]</b> 147/19 <b>weakened [2]</b> 161/8 163/23 <b>weaker [1]</b> 160/23 <b>weakness [2]</b> 142/6 145/12 <b>website [3]</b> 114/6 152/17 189/11 <b>Wednesday [1]</b> 1/1 <b>week [5]</b> 54/20 97/8 130/18 131/5 131/6 <b>weeks [8]</b> 54/19 121/1 125/23 125/25 126/11 126/11 150/17 161/12	<b>weight [1]</b> 180/3 <b>well [69]</b> 3/13 12/5 12/14 13/9 14/20 32/17 32/19 43/16 43/19 44/11 45/14 52/2 57/3 74/16 77/13 77/13 78/9 78/16 79/17 80/18 84/10 85/1 94/7 100/19 102/11 104/12 107/6 111/25 116/8 116/18 118/23 120/23 121/12 121/14 122/5 122/21 122/24 132/19 133/2 139/1 140/11 146/16 151/4 161/15 163/25 166/24 167/20 172/18 174/20 175/7 181/21 184/17 187/10 188/3 190/9 202/9 202/21 204/8 208/11 210/14 220/14 228/24 229/20 229/22 229/23 230/5 233/14 233/21 234/22 <b>Welsh [1]</b> 189/11 <b>went [2]</b> 198/8 232/18 <b>were [116]</b> 9/18 23/21 23/22 24/17 24/21 29/6 29/8 29/9 29/17 31/12 33/2 34/3 35/17 36/5 37/6 38/4 49/13 52/20 54/1 56/9 56/10 56/11 56/12 58/18 59/18 60/4 60/6 60/6 60/7 60/10 60/17 60/23 60/24 65/23 72/15 72/15 73/1 73/5 74/10 76/18 78/9 90/19 111/13 125/7 126/12 127/24 128/16 129/3 129/8 129/8 129/10 129/17 129/22 130/22 131/10 131/15 131/23 132/1 132/5 132/8 132/15 133/16 134/23 136/4 137/7 140/7 140/19 140/21 140/23 140/25 141/8 141/11 141/12 144/7 144/8 144/11 148/6 148/10 148/14 151/23 152/21 162/20 163/10 165/25 168/21 169/7 169/7 170/11 170/12 170/12 175/8 177/6 179/12 180/24 182/11 183/10 184/10 186/16 188/22 196/19 196/24 198/6 198/15 203/21 207/13 208/7 209/20 210/4 213/9 217/22 228/9 232/19 234/7 235/6 235/8 235/14	<b>weren't [7]</b> 24/25 27/4 29/23 38/2 172/14 198/8 220/11 <b>western [2]</b> 43/19 119/2 <b>what [208]</b> 1/7 5/4 5/5 5/22 6/1 6/9 8/24 8/25 9/1 10/4 11/15 12/8 12/18 12/23 12/24 14/1 17/10 18/11 19/4 21/6 21/7 23/23 26/14 28/19 31/17 31/18 33/4 33/9 35/9 35/25 36/19 37/6 37/10 38/10 43/13 45/13 46/2 46/6 46/17 47/1 48/10 48/11 48/14 48/14 49/3 49/9 51/1 51/5 52/8 52/8 53/18 57/5 59/24 59/24 60/1 60/2 60/8 60/19 61/17 62/5 64/7 65/14 65/15 67/6 67/19 68/22 69/10 70/7 71/9 73/1 73/24 74/10 74/16 74/17 74/25 76/1 76/9 78/12 79/12 80/1 81/11 82/16 85/23 86/8 87/1 88/22 88/24 88/25 92/18 94/7 96/14 97/13 98/14 100/7 100/13 101/5 101/11 101/20 102/2 103/17 104/16 104/17 106/2 106/23 109/11 114/21 117/9 120/6 121/7 124/20 125/21 125/21 126/4 126/17 127/20 128/5 128/10 132/4 132/22 136/7 136/7 136/11 136/22 139/14 139/23 140/5 140/6 142/15 142/15 144/23 145/18 149/15 149/25 153/15 154/25 156/9 159/9 159/23 164/16 164/16 167/2 167/18 168/20 170/4 170/15 170/25 173/8 173/16 174/5 175/4 175/12 176/2 176/19 176/20 176/23 177/13 177/14 177/15 179/12 180/11 181/25 182/23 182/24 182/24 184/19 185/16 186/12 186/17 186/18 187/7 187/10 187/20 187/24 188/10 188/11 188/25 191/24 192/2 192/3 193/1 193/3 193/5 195/18 199/25 199/25 201/25 202/19 207/13 208/7
<b>W</b>	<b>wait [1]</b> 129/16 <b>waiting [1]</b> 163/7 <b>Wales [3]</b> 24/13 189/3 189/6				

<b>W</b>	150/25 152/7 153/24 153/25 155/13 155/25 159/22 160/22 162/24 166/14 179/13 181/15 182/7 183/4 186/6 187/11 187/14 190/15 190/20 190/24 193/18 196/12 196/15 197/22 201/2 201/18 206/10 208/9 208/14 208/23 208/25 210/8 212/9 212/9 213/17 214/9 216/12 216/13 216/15 217/10 217/24 222/21 224/3	109/20 110/11 111/4 111/5 111/19 112/2 113/1 113/5 113/25 115/1 115/23 116/9 116/19 117/10 117/15 117/17 117/22 117/24 120/11 120/18 120/20 120/21 121/9 121/11 122/2 122/3 122/6 122/7 122/7 122/8 122/14 123/1 123/1 123/1 123/2 123/3 123/8 123/10 124/8 126/1 126/18 128/7 128/14 128/18 129/24 131/2 131/6 131/21 132/1 132/16 133/18 133/19 134/18 135/5 137/3 137/8 137/22 137/24 142/14 146/24 149/7 149/13 149/17 150/8 150/21 152/12 157/6 157/14 159/1 160/17 162/11 164/25 165/4 165/5 165/6 166/17 169/13 171/1 171/11 174/9 176/4 177/18 183/3 185/17 185/17 187/21 188/9 189/18 194/24 195/23 196/6 196/8 200/13 205/7 205/8 206/3 206/5 206/23 209/17 211/10 212/2 213/1 214/2 214/24 215/11 216/4 216/7 217/2 218/3 218/9 220/12 220/14 221/17 222/12 224/8 224/22 227/2 227/21 228/1 232/13 232/25	88/7 88/23 89/11 90/12 92/21 93/6 96/17 97/22 102/6 105/1 107/10 108/11 109/2 113/6 113/14 113/15 114/10 114/13 116/22 116/24 118/1 118/19 118/20 119/14 120/17 123/11 123/22 125/13 125/22 130/12 132/20 134/7 136/21 137/7 137/10 143/24 144/16 146/10 149/4 149/22 150/6 152/6 155/5 157/20 159/8 162/15 162/15 162/20 162/24 163/12 164/12 165/3 166/24 170/11 170/20 170/22 171/3 171/20 172/9 172/13 173/3 173/3 173/13 173/18 174/18 175/13 175/14 175/16 175/23 175/23 176/9 177/9 177/23 178/10 178/10 179/9 179/10 182/7 182/19 183/19 186/6 189/18 195/7 200/6 200/9 205/9 210/19 216/6 221/20 221/25 225/15 227/22 229/9 232/9 232/18 234/25 <b>whole [8]</b> 21/21 37/8 37/11 79/10 98/24 168/25 171/2 220/19 <b>whom [7]</b> 31/18 31/19 63/25 96/20 96/21 96/21 122/5 <b>whose [2]</b> 4/14 90/3 <b>why [17]</b> 8/15 15/5 15/9 25/6 61/12 108/16 114/16 127/18 203/7 207/13 211/17 211/24 215/23 217/22 228/13 228/14 229/3 <b>wide [9]</b> 6/14 15/10 32/7 66/14 66/18 73/25 98/21 133/14 216/1 <b>widely [5]</b> 31/7 79/23 121/10 134/6 162/12 <b>wider [4]</b> 76/13 128/6 137/9 201/9 <b>widespread [2]</b> 86/16 129/25 <b>will [137]</b> 1/9 5/7 5/18 6/8 6/21 7/3 7/16 7/17 9/15 9/15 10/16 10/20 11/6 11/9 11/9 14/4 17/19 20/13 24/14 25/14 25/15 28/2 32/17 34/7 46/16 47/6 47/23 50/16 50/17	50/20 51/10 51/11 52/19 54/24 58/6 58/8 61/25 62/4 62/4 62/10 62/11 63/3 63/7 63/10 64/18 68/11 68/12 69/4 71/23 74/3 76/23 76/24 76/25 78/18 84/9 84/10 85/1 90/4 93/2 93/8 93/24 94/2 95/10 95/14 95/15 96/7 96/9 96/10 96/11 96/11 96/16 96/25 97/4 97/5 97/13 97/13 97/14 97/16 97/17 98/2 99/18 106/23 108/15 109/18 110/15 110/18 116/8 120/1 120/18 121/11 125/15 131/4 143/22 149/4 152/7 155/6 156/9 156/10 159/8 159/17 164/9 164/17 169/13 170/19 171/3 172/7 172/9 174/16 174/19 175/15 180/5 181/18 182/8 182/20 184/19 186/4 197/18 203/15 204/9 205/14 208/20 208/20 208/22 210/9 210/19 214/25 216/2 216/4 217/19 229/24 231/3 231/17 231/24 233/21 233/22 233/22 234/16 <b>Willebrand [1]</b> 159/6 <b>window [11]</b> 52/7 52/10 53/5 53/15 53/18 53/22 54/15 56/13 56/16 57/13 75/4 <b>wish [3]</b> 86/22 174/4 179/6 <b>wishes [1]</b> 182/8 <b>with [379]</b> <b>with it [4]</b> 158/17 179/7 188/14 203/11 <b>withdrawn [1]</b> 148/22 <b>within [42]</b> 2/17 3/6 6/18 9/5 15/22 17/8 19/16 19/17 29/1 40/24 47/2 54/18 58/6 80/7 80/11 82/19 84/13 85/13 87/7 87/10 88/3 89/9 107/3 116/12 121/21 121/24 158/16 190/9 190/10 193/19 193/25 194/2 194/15 200/8 201/20 206/14 206/15 207/21 214/24 217/11 223/15 233/12 <b>without [17]</b> 26/3 37/23 45/20 70/3 73/6	73/7 78/7 80/15 88/11 90/6 102/16 128/9 161/18 176/13 193/12 212/25 223/5 <b>witnesses [4]</b> 81/3 145/7 195/7 202/12 <b>won't [10]</b> 25/8 27/14 51/14 51/16 116/17 155/15 194/19 205/3 208/16 224/20 <b>wonder [1]</b> 43/10 <b>wondered [3]</b> 106/21 173/15 189/3 <b>wondering [1]</b> 205/12 <b>words [1]</b> 223/11 <b>work [30]</b> 2/16 3/16 3/24 6/15 27/3 39/1 50/5 58/20 105/21 114/2 124/5 134/3 134/7 156/9 168/3 199/4 199/7 199/13 199/15 200/1 206/5 208/25 209/1 209/5 217/5 222/20 228/15 229/24 230/9 233/7 <b>worked [6]</b> 2/9 105/4 121/25 132/4 221/5 228/14 <b>worker [2]</b> 193/11 202/17 <b>workers [2]</b> 193/23 232/9 <b>workhorse [1]</b> 49/3 <b>working [12]</b> 2/8 3/19 3/21 50/7 69/18 84/25 121/19 122/5 218/12 219/19 221/12 226/19 <b>works [1]</b> 141/18 <b>world [14]</b> 15/20 20/11 21/12 21/16 22/23 31/7 98/21 99/17 104/9 119/2 188/23 190/11 207/17 209/11 <b>world-wide [1]</b> 98/21 <b>worried [1]</b> 234/25 <b>worse [4]</b> 29/19 85/12 163/19 214/21 <b>worsening [2]</b> 84/22 86/3 <b>worth [17]</b> 9/20 46/19 56/6 94/4 95/19 124/7 126/15 131/11 137/21 144/14 160/14 161/23 162/7 166/11 172/19 213/21 224/18 <b>would [187]</b> 3/1 8/22 12/18 13/4 17/4 17/13 18/12 22/3 22/22 22/22 26/22 28/15 30/4 32/14 35/25 40/4 40/12 40/17 47/22 49/3 52/22 52/23 53/24 54/3 54/3 54/5
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<p><b>W</b></p> <p>would... [161] 54/9 54/11 54/18 55/3 55/23 55/24 56/1 56/23 57/12 57/24 64/1 64/2 64/4 65/3 65/24 68/9 71/16 72/6 73/17 77/13 77/21 78/9 80/21 89/6 90/11 97/2 103/4 103/9 103/22 104/2 104/24 105/2 105/4 105/11 105/14 106/3 108/7 108/13 110/6 110/16 111/12 114/2 115/6 115/8 116/5 116/23 117/1 118/21 118/24 121/1 121/21 123/1 124/3 124/3 124/11 124/21 125/9 126/22 129/21 129/21 132/16 133/2 133/3 133/17 137/6 140/2 140/9 140/12 141/2 141/21 141/22 142/19 144/4 144/4 149/15 154/1 157/20 162/21 163/6 163/9 170/4 170/7 171/10 171/12 171/16 173/9 175/14 176/12 176/12 176/19 176/20 177/7 177/21 177/25 178/1 178/4 178/5 178/6 178/18 179/20 179/23 180/8 180/14 180/20 181/1 182/12 183/12 183/14 183/16 183/18 183/21 184/8 185/23 185/24 186/20 187/1 187/20 192/5 192/12 193/2 193/6 193/15 194/23 195/19 196/9 196/11 196/14 198/21 199/25 203/7 204/23 205/10 205/25 206/3 206/7 207/11 207/12 207/12 207/21 208/2 211/11 212/11 215/17 217/2 221/17 221/22 224/24 225/10 226/17 226/25 227/19 229/3 230/3 230/10 232/20 233/8 233/9 233/18 233/19 233/25 234/9 wouldn't [6] 27/11 38/17 144/2 150/22 177/19 192/16 writing [1] 90/17 written [4] 56/3 143/21 210/13 210/24 wrote [4] 92/21 189/8 194/11 194/16</p>	<p><b>Y</b></p> <p>yeah [7] 25/25 32/12 75/10 135/15 184/10 200/10 202/7 year [23] 47/10 58/6 62/18 62/20 63/1 63/1 63/2 64/14 64/19 64/25 90/10 93/3 93/13 95/2 97/12 98/25 115/15 117/19 131/25 150/10 190/12 199/16 222/12 years [72] 2/11 3/21 4/9 11/6 23/14 24/15 30/15 30/18 30/19 30/20 31/2 31/6 31/8 37/3 39/21 62/22 63/5 63/9 64/3 65/2 65/3 68/10 83/13 86/17 89/4 90/19 94/6 95/7 95/8 101/16 110/20 115/17 118/12 118/13 119/24 121/7 121/17 121/21 121/24 128/5 128/13 132/23 134/3 139/24 140/7 148/18 150/21 158/4 160/10 160/19 165/9 165/19 166/23 170/14 170/16 172/3 172/8 183/10 191/14 191/21 195/8 195/14 196/13 198/2 198/5 208/1 213/25 217/14 222/14 222/16 227/11 227/18 yellow [1] 218/12 yes [66] 1/17 4/20 10/22 11/2 20/1 28/4 30/25 38/9 40/20 42/2 42/11 42/17 43/3 43/4 43/15 45/8 48/4 50/19 55/19 62/2 62/14 63/23 64/6 65/6 65/8 67/21 75/19 79/22 85/20 86/9 92/10 93/18 93/23 98/2 98/5 101/7 102/20 102/21 104/21 111/11 112/1 113/11 115/18 120/8 124/2 131/19 136/24 148/20 151/17 163/21 164/4 165/4 166/10 172/1 176/17 177/17 178/17 179/5 193/5 194/18 209/22 222/6 227/14 231/23 232/1 236/5 yesterday [4] 47/20 151/6 182/20 189/10 yet [8] 84/11 97/12 133/1 171/21 177/5 198/24 221/6 230/11 you [478]</p>	<p>you'd [5] 11/11 28/17 40/12 52/25 129/19 you'll [6] 1/5 78/5 87/11 95/19 127/25 163/25 you're [43] 28/8 28/12 31/14 39/24 46/9 46/11 58/25 59/9 62/1 65/13 68/5 70/7 72/10 73/14 73/14 77/11 87/1 99/10 105/25 125/16 125/17 131/2 135/11 138/2 140/4 144/15 148/8 160/23 161/4 163/3 169/12 169/16 171/7 181/21 184/18 192/7 194/14 196/1 204/4 215/23 224/20 226/6 234/15 you've [105] 11/6 13/17 14/24 15/2 18/25 25/17 25/21 30/12 30/15 38/7 38/10 39/1 39/14 41/4 41/19 43/8 44/6 45/2 47/5 47/7 48/8 48/10 52/5 54/15 54/23 55/6 59/9 59/14 61/10 62/23 64/23 67/6 67/7 68/20 73/24 74/5 75/7 76/1 76/22 80/23 81/20 90/22 90/25 91/15 92/12 92/15 92/18 94/22 95/4 98/16 98/19 99/7 101/1 101/1 102/14 106/19 109/10 111/23 115/11 116/3 130/14 135/4 135/17 137/17 145/2 147/21 149/1 152/2 152/20 152/22 152/23 153/7 153/9 153/13 155/12 156/13 156/24 157/1 157/5 157/8 157/13 157/16 159/9 161/8 163/18 165/2 166/3 169/8 170/1 171/6 182/14 186/22 187/13 188/10 188/10 188/14 194/24 197/1 204/20 208/23 212/18 216/9 226/1 226/5 232/15 younger [1] 44/14 your [81] 2/8 4/21 11/6 11/23 13/17 16/4 17/17 25/9 28/1 30/12 30/16 31/11 38/23 39/10 41/19 42/19 52/2 52/5 53/8 53/11 53/12 54/23 55/6 59/15 62/15 64/20 65/21 67/6 68/18</p>	<p>73/17 73/19 76/1 82/9 90/23 92/12 93/10 93/17 94/20 95/25 98/14 98/17 98/18 99/7 100/23 101/2 106/20 119/1 119/21 138/3 146/7 147/21 152/2 152/6 152/16 157/22 160/22 163/15 163/18 165/22 169/19 170/2 171/9 175/9 176/11 188/14 188/19 189/1 192/21 192/25 193/1 200/15 202/11 205/19 205/21 206/11 212/5 223/22 226/3 228/8 229/15 230/1 yourself [1] 208/24 yourselves [2] 2/6 2/6</p> <p><b>Z</b></p> <p>zero [9] 46/4 46/13 62/22 116/24 117/11 177/5 199/11 201/18 221/23</p>		
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