# OPUS<sub>2</sub>

Scottish Covid-19 Inquiry

Day 2

July 27, 2023

Opus 2 - Official Court Reporters

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1 Thursday, 27 July 2023 2 (10.00 am) LORD BRAILSFORD: There are two things that I want to do 3 4 before we start formally. 5 The first one is a little formal statement by 6 myself. 7 Now, I realise that some of you attending or 8 watching yesterday may have expected to see or hear more 9 in the way of acknowledgment of the impact the pandemic 10 had on individuals and families. The reason that didn't 11 happen is that this presentation was not designed as 12 a formal hearing of the Inquiry, but as a session on 13 epidemiology, on science. The focus of this session is 14 to help those interested in the work of the Inquiry 15 understand more about the underlying science which will 16 form the basis of much of our investigation and, of 17 course, deliberation throughout the coming no doubt many 18 months. 19 On 28 and 29 August, as I told you yesterday, we 20 will have a further hearing, or we will have a hearing, 21 and the focus will then shift from the science to the 22 people affected by the virus and the strategic response 23 to the virus. On those days, we will hold what we 24 consider to be our official preliminary hearing, and

that will constitute a formal opening to the Inquiry's

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1	evidence-gathering and hearings to follow, which I think
2	again, as you all know, will commence late in October.
3	At that stage, in August, there will be
4	an opportunity for core participants to the Inquiry $$
5	including, of course, bereaved families, care home
6	relatives and others affected $$ to participate. We
7	also plan to show a film at that hearing to highlight
8	the impact of COVID on people, to signal the beginning
9	of our hearings dealing with impacts on the people of
10	Scotland. I should say that I'm grateful to those
11	families and individuals who have provided photographs
12	which we've used in that film, and I thank them for
13	their contribution and their own going participation in
14	the Inquiry. They are and will continue to be at the
15	forefront of my mind when conducting the work of the
16	Inquiry and when it comes to deliberating and
17	considering the report.
18	As I said yesterday, core participants will receive
19	a communication from the Inquiry next week, providing
20	more and detailed information about what to expect from
21	the August hearings and how they should participate
22	therein .
22	Colline that also the matters

- 23 So I hope that clarifies matters.
- 24 That's the first thing I wanted to say.
- 25 The second thing is that Dr Croft has kindly told me

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1	that he's realised, on consideration last night, he made
2	an error of a technical nature, and he would like to
3	correct that. I think that's entirely appropriate.
4	Can I simply ask you to explain what the error was
5	and then correct it.
6	DR ASHLEY CROFT (continued)
7	THE WITNESS: Yes, thank you, my Lord.
8	If I could ask you, my Lord, to turn to page 463.
9	LORD BRAILSFORD: 463.
10	A. In fact, before that, let's turn $$ so sorry. We'll
11	come back to 463.
12	Let's turn to page 659. This is about gargling to
13	prevent COVID $-19$ . We were just using it as an example
14	of Cochrane reviews.
15	LORD BRAILSFORD: I remember that. 659, did you say?
16	A. 659.
17	LORD BRAILSFORD: Oh, yes. The Almanza-Reyes and
18	Gutiérrez—García papers.
19	A. Of course, yes. That's right. So we started
20	yesterday $$ well, we began by talking about Mr Gale's
21	hypothetical acne, and that Mr Gale went to his GP and
22	he said,"Right, doctor, what's the risk of my being
23	cured of my acne, my hypothetical acne, if I take this
24	antibiotic ?", and the doctor said, "The risk is $$ in
25	other words, the likelihood of you being cured, is 6,
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1	60%, because in the trial, of those who took the
2	antibiotic , 6 got better and 4 didn't get better. So
3	60% likelihood. What's the risk of your getting better
4	if you don't take the antibiotic?", and if you remember,
5	the risk was 30%. So, therefore, the risk ratio was 2,
6	meaning he was two times more likely to $$
7	LORD BRAILSFORD: Two times
8	A. Yes.
9	Right, so applying that same understanding to the
10	gargling, if you remember, Almanza—Reyes and
11	Gutiérrez-García were two randomised controlled trials,
12	both in Mexico, and they both involved healthcare
13	workers. They were quite small numbers, but produced
14	a very powerful effect from gargling.
15	The combined impact of $$ the combined pooled effect
16	measure gave a risk ratio of 0.07 $$ could you see that
17	in the third line down? $$ with a confidence interval of
18	0.02 to 0.23.
19	LORD BRAILSFORD: Yes.
20	A. In the heat of the moment, I said that means they're $93\%$
21	less likely to get COVID $-19$ if they were gargling than
22	if they weren't, and that's incorrect.
23	These were healthcare workers working in Mexico in
24	intense environments where the transmission of $COVID{-19}$
25	was very intense, so they were obviously quite alarmed

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mini—outbreaks.

group were gargling with a solution of silver
nanoparticles, and that was compared with a group who
just did conventional gargling. We don't know what
with.
The second group, Gutiérrez–García, they were all

and worried, and they did this gargling. The first

- 7 wearing PPE, which is interesting, both arms of the
- 8 trial, and the experimental arm were also gargling with
- 9 this neutral electrolysed water, and they did that three 10 times a day, and the other group did it for three times
- 11 a day.
- 12 The first group were followed for nine weeks,
- 13  $\hfill I think, and the second group were followed for$
- $14 \hfill two weeks.$  So they weren't very long trials . Again,
- 15 the pooled effect measure was 0.07. So what does that
- 16 mean? What is the risk ratio? It's actually 14. So
- 17 it's 100 divided by 7.
- 18 LORD BRAILSFORD: Okay.
- 19  $\,$  A. So in other words, the people who were gargling were
- 20 14 times less likely to acquire COVID-19 than the
- 21 doctors and nurses who weren't gargling, which is
- 22 impressive. You don't often get such good effect
- 23  $\,$  measures, but this is , I think, indisputable, because
- 24 they were randomised controlled trials, they were well
- 25 done, and the heterogeneity was 0, the I–squared was 0%,

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1	so it was reasonable to combine these two trials. And
2	the confidence interval there $$ you can see that along
3	that dark, bold line $$ ranged from 0.02 to 0.23. So,
4	therefore, we can have $95\%$ confidence that the true
5	measure lay somewhere between 50 times more protected,
6	which is 0.02, they might have been 50 times less likely
7	to acquire COVID $-19$ , or they might have been four times
8	less likely to acquire COVID, which is 0.23. So that,
9	I think, is a correct interpretation.
10	It might have been helpful if Jefferson had given
11	some interpretation, but they put this forest plot in
12	because they obviously found it interesting , but they
13	were so busy talking about other things, they didn't
14	interpret it.
15	So that $$ just to finish, my Lord $$ tells us
16	a couple of things. Firstly , there are very effective
17	measures that one can apply to prevent COVID $-19$ , such as
18	this one; simple, effective, cheap.
19	Oh, yes, in the Gutiérrez-García, the control group
20	were wearing full PPE, but nevertheless they still had
21	quite a high number of cases of COVID, 10 out of 79. So
22	it shows there may be some protective effect, but the
23	ones who were wearing full PPE and also gargling only
24	had one case out of 84. So much better to be gargling.
25	It shows you can do randomised controlled trials

- even at times of high COVID intensity, as long as 1 2 they're designed correctly. They don't have to be 3 expensive. The second group said they had no funding. 4 The doctors and nurses just decided to do it amongst 5 themselves. So this pre-empts the possible argument that might be used by the policymakers: well, we 6 7 couldn't do research at this time because everything was so fraught. But people were doing good trials. We may 8 9 later on discuss the Danish trial and the Bangladesh 10 trials that were done in this time. 11 So my last point -- sorry to go on -- is: what made 12 these doctors and nurses in Mexico do this? 13 LORD BRAILSFORD: Quite. A. Which seems odd, and the answer must be: they must have 14 15 read the science. They must have read Jefferson 1, 16 which is the precursor of this, and that was the 17 original systematic review that came out in 2011. 18 If we look at Jefferson 1, again, there's a 19 surprising -- page 463. That's the third forest plot 2.0 down called, "Analysis 1.9 ... Case-control studies, 21 Outcome 9 Nose wash". They must have looked at that 22 and thought: that's pretty impressive. 23 So they are looking at two studies there, Chinese 24 studies, that were done in China during SARS outbreaks,
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- 7 1 LORD BRAILSFORD Yes 2 A. And these are case-control studies. So they're not as 3 powerful as randomised controlled trials 4 Case-controlled studies are what they call 5 quasi-experimental studies, and they level IIb evidence 6 in that hierarchy. 7 But, essentially, what happened here was that Chen and Liu, Chinese investigators, they compared cases, 8 9 people who had got SARS and then they recovered -- they 10 were all healthcare workers, we think -- and they 11 matched them with equivalent age-matched and sex-matched 12 healthcare workers who didn't get SARS, and they worked 13 out: what was it that enabled one lot not to get SARS, 14 and the first lot to get SARS, and they found a powerful 15 protective effect from nasal gargling or nasal washing 16 of some sort. 17 Interestingly , the total -- the diamond there shows 18 an odds ratio which is similar to the risk ratio, which 19 is 0.3. So it's the same kind of order of magnitude as 2.0 the Mexicans found later on. 21 So that, I think, explains all of that, and it's of 2.2 interest, and I think of practical importance as well. 23 Thank you, my Lord. 24 LORD BRAILSFORD: No, thank you very much indeed. 25 Yes, now, Mr Gale, when you're ready. 8

1		Questions from COUNSEL TO THE INQUIRY (continued)
2	MF	R GALE: Thank you very much, my Lord.
3		Doctor, we had reached, at the conclusion yesterday
4		afternoon, page 11 of your report and section 2.3,
5		headed, "What are coronaviruses?"
6		I want to take quite a lot of this short because
7		it's there for everybody to read $$
8	Α.	Yes.
9	Q.	and those who wish to investigate it further will
10		have the opportunity to do so.
11		I think you indicated towards the bottom of page 11,
12		last paragraph, that the coronaviruses are further
13		categorised according to a classification scheme
14		developed in the 1970s by the Nobel laureate David
15		Baltimore.
16	Α.	Yes.
17	Q.	Then there are four features: the molecular
18		architecture, their genome, their replication strategy
19		and whether, in the case of RNA viruses, they are
20		positive or negative.
21	Α.	Yes.
22	Q.	Now, I'm slightly interested in what is said in the
23		second paragraph on page 12, where it is said that:
24		"RNA viruses [which I think we know COVID is one of
25		those viruses] have high error rates, with genomes
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		,
1		diverging by as much as 2% in the course of a year $-$
2		1 million times greater than the divergence rate of
3		eukaryotic cell genomes."
4		Now, can you translate that for me, please?
5	A.	Thank you, Mr Gale. That's a direct, word-for-word
6		transcription from a textbook, and it's in jargon, for
7		which I apologise.
8		Sorry, I have lost the place on the page. We're on
9		page 12 —
10	Q.	We are on page 12 of your report, the second full
11	-	paragraph on page 12. "RNA viruses", it begins.
10		Pielet

12	Α.	Right.
		·

13So RNA viruses are single-stranded nucleic acids,14and so they don't have that same, shall we say, property

- 15 of DNA viruses that has are double-stranded, and DNA
- 16 viruses, as they replicate, are less likely to have
- 17 slight changes in their molecular structure. So that's
- 18 my understanding of this concept.
- 19 So because they're more fragile, every time they
- $20 \qquad \qquad \text{replicate } -- \text{ and that's their whole purpose in} \\$
- 21  $\qquad$  existence, which is to replicate  $\,--$  there may be slight
- 22  $% \left( {{\left( {{{{\rm{ch}}}} \right)}_{\rm{ch}}}} \right)$  changes in the molecular structure, particularly in the
- 23  $\,$  ordering of the nitrogenous bases we were talking about
- 24 yesterday, the guanine, adenine, cytosine and uracil in
- 25 the case of -- so there's a slight ordering in those

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1		bases. The code for which they exist is different .
2		It's a bit like a computer code. It's similar to a kind
3		of virus that gets into your computer, makes it behave
4		slightly differently .
5		So the genome is the totality of their genetic
6		information, the total genetic profile , and that can
7		change with viruses, as said here, by 2%. So in the
8		course of one year of continuous replication, you may
9		end up with viruses at the end that are $2\%$ different to
10		the original parent virus. That's how I understand
11		this .
12		Quite what that means is hard for us to understand,
13		but the reference I have taken that from goes on to say
14		that this is 1 million times greater than the genetic
15		transformations that would be seen in eukaryotic cell
16		genomes. Eukaryotic cells are those that are found in
17		advanced organisms such as humans and mammals, and so
18		therefore our genomes are also undergoing slight
19		mutations all the time, or slight changes, but nothing
20		like the rate we see in viruses.
21	Q.	You go on in that paragraph to say:
22		"Many of these viral mutations are
23		non—functional"
24	Α.	Yes.
25	Q.	And then you qualify that:
		11
		**

1		" but some will allow the virus to evade host
2		immune responses and medical therapies."
3	Α.	Yes.
4	Q.	Is this effectively a mutation?
5	Α.	Yes. Yes, that is a mutation, yes. Every change in the
6		genetic structure will be a mutation. But in general,
7		mutations $$ and we undergo mutations ourselves,
8		particularly those, for example, on the skin that are
9		exposed to ultraviolet light. They may mutate. Some of
10		those mutations in ourselves may cause the cells to
11		become cancerous, to lose their normal properties.
12		So most mutations don't result in a functional
13		advantage for the cell or the organism, but some of them
14		might. Some of them might make the virus more
15		pathogenic, more easily transmissible and, therefore, if
16		they're more easily transmissible, they may get into
17		cells more easily, they may evade the immune response
18		more readily, and, therefore, they become more
19		pathogenic.
20	Q.	Perhaps, to put it simply, they become a moving target
21		so far as human $$
22	Α.	Yes, correct.
23	Q.	immune responses and medical therapies are concerned.
24	Α.	Of course. We see the same phenomenon with influenza
25		viruses, which again are RNA viruses. They are around

1		us all the time. And when conditions are particularly
2		good for their transmission, which means the winter,
3		they will cause disease, and all the time influenza
4		viruses are undergoing slight mutations. It's called
5		antigenic drift . So there's a tendency for them to
6		always be a bit different .
7		Occasionally, influenza viruses will undergo a major
8		mutation, and that's termed antigenic shift, and that
9		gives rise to a new subtype of influenza virus, which
10		often can be very dangerous, because the new subtype may
11		be one that people have never been exposed to because
12		it 's so different .
13		The same phenomenon, as I understand it $$ I'm
14		an epidemiologist, not a virologist $$ is seen in
15		coronaviruses where, as you say, Mr Gale, they are
16		a moving target.
17	Q.	Could you just read the final paragraph, so we have it
18		in the notes, that begins "In summary".
19	Α.	Yes:
20		"In summary, coronaviruses are enveloped,
21		single—stranded, positive—sense ribonucleic acid viruses
22		that infect mammals and birds and that typically (but
23		not exclusively) target the respiratory tract of their
24		hosts."
25	Q.	We move on now to what diseases are caused by
		13
1		coronaviruses. I think some of this we've already
2		looked at in the context of your appendices on SARS and

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2		looked at in the context of your appendices on SARS and
3		MERS.
4	Α.	Yes.
5	Q.	I think we can take that as read.
6		I think yesterday you indicated that there were
7		seven known human coronaviruses, and that is set out in
8		the table on page 13. I think the first four of those
9		coronaviruses are the ones that you didn't specifically
10		refer to, but I think they're there just simply for the
11		record.
12	Α.	Yes.
13	Q.	The ones with which you were concerned are the last
14		three: MERS, SARS and SARS-CoV-2.
15	Α.	Yes, those are the novel coronaviruses that emerged $$
16		we don't know with certainty how, but more likely than
17		not as a result of some kind of animal reservoir
18		spilling over into humans.
19	Q.	Can we move over now to 2.5 at page 14. There we'll
20		see, again, this is some material that we've already
21		looked at, and, as you say, the term is
22		"architecture" ——
23	Α.	Yes.
24	Q.	and that is shown in the figure.
25		Again, I think one of the things that probably most

1 of us do remember from general presentations during the 2 COVID pandemic was the significance of the spike, hence 3 the name "corona". 4 A. Yes.  $\mathsf{Q}.\;$  Can you just explain what the spike is and what it does? 5 A. Yes. The spike of SARS-CoV-2 -- this picture shows 6 7 SARS-CoV-2, which is very similar to the original SARS 8 virus, the coronavirus that caused SARS. First of all, 9 it's quite a large virus, so it's quite complex, so 10 potentially there's the possibility of it changing in unexpected directions and causing problems with 11 12 an immune response. But it's surrounded by these spike 13 proteins which project from the envelope. The spike 14 proteins are the means by which -- the surface proteins 15 by which the virus achieves entry into the target  $% \left( {{{\mathbf{r}}_{\mathbf{r}}}_{\mathbf{r}}} \right)$  cells 16 of the host, which may be an animal or it may be human, 17 and how the virus does this is through identifying and 18 fusing with a receptor, which is a protein, on the 19 surface of the cell called the ACE2 protein. So the 20 spike protein attaches to that receptor, undergoes 21 a slight transformation, and then the virus can then 2.2 enter the cell through that entrance. 23 So I consider it 's a little bit like a Yale key, 24 which will fit into a lock, it won't into other locks, 25 even though there are other locks, and it will open the

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1		lock and then you can go in.
2		Just to go back to the previous table, the receptor
3		that SARS $-2$ had $$ so the table on the previous page,
4		page 13. That's the table of the seven human
5		coronaviruses.
6	LO	RD BRAILSFORD: Yes.
7	Α.	That's right.
8		So if you look at the right—hand column, my Lord,
9		you can see that SARS-CoV-1, which was discovered in
10		2003 and caused the epidemic of SARS, has the same
11		receptor, the ACE2 receptor, angiotensin-converting
12		enzyme 2 receptor, as the SARS that we're preoccupied
13		with now, and that was quite helpful because a lot of
14		research had been done on the ACE2 receptor, exactly how
15		$SARS{-}CoV{-}1$ interacted with that. So quite a lot was
16		already understood about, if you like, the dynamics of
17		infection with regard to this novel coronavirus.
18	Q.	I think we can also see in that table that the virus
19		identified in 2004 had the same entry receptor.
20	Α.	Yes, that's right, yes.
21	Q.	Right. Can we go back to page 15, please.
22	Α.	Yes.
23	Q.	l'm interested $$ again, just taking various passages
24		from what you say $$ in what you say in the second
25		paragraph on page 15. What you say there is:
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1	"The mutations that SARS—CoV—2 accumulates

- 2 facilitate the phenomenon of immune escape meaning,
- 3 that re-infection with the virus can occur after natural
- 4 infection, and also after vaccination."
- 5 A. Yes.
- 6 Q. So is that essentially saying that we can expect to be 7 infected with COVID more than once, even if we are
- vaccinated?
   A. Yes, just as we can expect to get flu more than once.
   But there may be some degree of -- continuing with flu,
- 11 with every flu season, there will be a slightly
- 12 different flu variant, flu virus variant; in fact, there
- 13 are a number of influenza virus variants circulating all
- 14 the time. It will be slightly different to last year's
- 15 because the virus is mutating all the time.
- 16 Q. Yes.
- A. But often we will have a degree of cross-protection from
  the time that we last encountered that flu virus, so it
  won't affect us as badly.
- 20 The same we would expect to find with SARS-CoV. If 21 we've acquired it, especially if we've acquired it
- 22 naturally, we may well acquire it again after a period
- 23 of perhaps a year, but we are likely to not have such
- 24 significant illness the second time round.
- 25 Q. I think that's what you say in the following paragraph.

- 1 A. Of course, here  ${\sf I}\,{}^\prime{\sf m}$  quoting the indisputable scientific literature . That's my reading of what is set out as 2 3 indisputable facts. 4 Q. Yes 5 We move on to 2.6, and we are now looking at the 6 spread of the virus. You concentrate, first of all, on 7 airborne spread versus droplet spread of respiratory pathogens --8 9 A. Yes. 10 Q. -- and the distinction you then set out in the following 11 paragraph. I think you say that the distinction is 12 based on the size of the infecting particles . 13 A Yes 14 Q. And in airborne spread, very small particles  $\,--\,$  and 15 you've given the dimensions -- and then you move on to 16 droplet spread. 17 In very simple terms, what is the difference between 18 airborne spread and droplet spread? 19 A. Well, I'm not convinced there is a great difference, but 2.0 enormous arguments rage about the difference and what it 21 means. But, basically, they're transmitted through the 2.2 air, but some particles are heavy -- I guess they're 23 surrounded by mucous -- and they fall on the ground 24 around you, and others are very small and light and they 25 waft through the air for some distance.
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Ŧ		i guess, in practical terms, il most of the
2		transmission is occurring through the droplets that are
3		falling around you, then you want to focus on the
4		immediate environment, whereas if most is occurring at
5		a distance, the immediate environment may not be as
6		important.
7		But with most respiratory viruses, it does seem to
8		be the case that it's a combination of the two, the
9		airborne and the droplet spread, that results in
10		transmission.
11	Q.	I think in relation to airborne spread, you do say that:
12		"Being very small, the infective particles can
13		remain suspended in the air for long periods of time and
14		travel long distances and be inhaled into the air
15		passages of potential new hosts."
16	Α.	Yes.
17	Q.	Droplets, as you say, I think, to put it crudely, tend
18		to be perhaps more localised.
19		You make reference in your discussion on droplet
20		spread to droplets contaminating environmental
21		surfaces
22	Α.	Yes.
23	Q.	or inanimate objects, that is fomites. Now, I think
24		you do define $$ we don't need to look at it $$ what
25		"fomite" means.
		19
	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	2 3 4 5 6 7 7 8 9 9 10 Q. 11 Q. 12 13 14 15 16 A. 17 Q. 18 19 20 21 22 A. 23 Q. 24

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1		I think, again, we have probably all heard during
2		the pandemic of the need to wash surfaces and handrails,
3		etc. Is that what you're talking about?
4	Α.	Yes. Yes, that would seem to be quite a logical thing
5		to do and one that doesn't involve a great deal of
6		inconvenience or expense. It's all part and parcel of
7		basic hygiene.
8	Q.	The problem obviously is that if somebody touches
9		somewhere where there is an infected droplet, and then
10		puts their hand to their mouth $$
11	Α.	Yes, indeed.
12	Q.	—— that is a potential transmission.
13	Α.	Indeed, and your mask might become a fomite if either
14		you have put infectious droplets onto it by breathing
15		out or you've breathed in infectious droplets. It
16		potentially could be a fomite. So masks have to be worn
17		correctly and disposed of correctly.
18	Q.	I think then, in page 16, going on, you helpfully set
19		out:
20		" the range of infective particle size (and hence
21		the predominant mode of spread) will be affected by
22		factors such as "
23		And you list them: the volume, the character of the
24		secretions, the extent to which droplets are converted
25		to aerosol particles by evaporation.

<ul> <li>That's something perhaps you might explain: how is</li> <li>a droplet evaporated and converted into an aerosol</li> <li>particle?</li> <li>A. Well, if droplets are mainly fluid and they are landing</li> <li>on a surface, especially if they're exposed to the sun,</li> <li>they will evaporate in the way that fluids do.</li> <li>Q. Simple as that.</li> <li>A. They end up as minute airborne particles.</li> <li>Q. Then you refer to the duration of airborne suspension</li> <li>A. Yes.</li> <li>Q which is influenced by environmental factors, and we</li> <li>will come on to those environmental factors in a minute.</li> <li>A. Yes.</li> <li>Q. But that includes temperature, humidity and prevailing</li> <li>air currents.</li> <li>A. Yes.</li> <li>Q. And then, finally, the distance travelled, which again</li> <li>is obviously influenced by environmental factors.</li> <li>A. Yes.</li> </ul>			
<ul> <li>particle?</li> <li>A. Well, if droplets are mainly fluid and they are landing</li> <li>on a surface, especially if they're exposed to the sun,</li> <li>they will evaporate in the way that fluids do.</li> <li>Q. Simple as that.</li> <li>A. They end up as minute airborne particles.</li> <li>Q. Then you refer to the duration of airborne suspension</li> <li>A. Yes.</li> <li>Q which is influenced by environmental factors, and we</li> <li>will come on to those environmental factors in a minute.</li> <li>A. Yes.</li> <li>Q. But that includes temperature, humidity and prevailing</li> <li>air currents.</li> <li>A. Yes.</li> <li>Q. And then, finally, the distance travelled, which again</li> <li>is obviously influenced by environmental factors.</li> </ul>	1		That's something perhaps you might explain: how is
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<ul> <li>10 A. Yes.</li> <li>11 Q which is influenced by environmental factors, and we</li> <li>12 will come on to those environmental factors in a minute.</li> <li>13 A. Yes.</li> <li>14 Q. But that includes temperature, humidity and prevailing</li> <li>15 air currents.</li> <li>16 A. Yes.</li> <li>17 Q. And then, finally, the distance travelled, which again</li> <li>18 is obviously influenced by environmental factors.</li> </ul>	8	Α.	They end up as minute airborne particles.
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<ul> <li>Q. But that includes temperature, humidity and prevailing air currents.</li> <li>A. Yes.</li> <li>Q. And then, finally, the distance travelled, which again is obviously influenced by environmental factors.</li> </ul>	12		will come on to those environmental factors in a minute.
<ol> <li>air currents.</li> <li>A. Yes.</li> <li>Q. And then, finally, the distance travelled, which again</li> <li>is obviously influenced by environmental factors.</li> </ol>	13	Α.	Yes.
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<ul><li>Q. And then, finally, the distance travelled, which again</li><li>is obviously influenced by environmental factors.</li></ul>	15		air currents.
18 is obviously influenced by environmental factors.	16	Α.	Yes.
	17	Q.	And then, finally, the distance travelled, which again
19 A Yes	18		is obviously influenced by environmental factors.
19 / 103.	19	Α.	Yes.
20~ Q. If you just read from the bottom of page 16 to the end	20	Q.	If you just read from the bottom of page 16 to the end
21 of that section, doctor, so we just have, effectively,	21		of that section, doctor, so we just have, effectively ,
22 your summary.	22		your summary.
23 A. Thank you. So really this is the summary of the,	23	Α.	Thank you. So really this is the summary of the,
24 I think, undisputed knowledge about transmission:	24		I think, undisputed knowledge about transmission:
25 "In reality , both the size of respiratory particles	25		"In reality, both the size of respiratory particles
21			21
<u> </u>			21
1 produced by an infected person and the distance they can	1		produced by an infected person and the distance they can
2 travel are likely to fall within a spectrum; for any			
3 given respiratory pathogen, therefore, disease			
4 acquisition may occur through both the airborne and the	4		
5 droplet mechanisms of spread."	5		
6 Q. And, obviously, the same transmission can be occurring		Q.	
7 at the same time.	7	-	-
8 A. Indeed, yes.	8	Α.	Indeed, yes.
9 Q. You then go on to talk about what you say are the	9		

- 10 aerodynamic factors.
- 11 A. Yes.
- 12  $\mathsf{Q}.\;\;\mathsf{I}$  think you begin by prefacing this with the word  $"{\sf Perplexingly"}.$ 13
- A. Yes. 14
- 15 Q. You say:
- 16 "... and although COVID-19 is generally thought of 17 as an acute respiratory illness , there are very low
- 18 levels of SARS–CoV–2 in the respiratory tract during the
- 19 early phase of disease ... "
- 20 A. Yes.
- 21 Q. "... this is the case with all coronavirus infections." 22
- Is there an explanation for that?
- 23 A. Well, it does seem to be the case that the virus
- 24 particles are particularly trapped in the nasopharynx, 25
  - which is the next paragraph, and they don't go straight

1		into the lungs, which is the mode of transmission with
2		some airborne diseases, for example TB or asbestosis.
3		You have to be a particle that wafts straight into the
4		lungs and causes the problem there.
5		So the nasopharynx is acting, it would seem, as
6		a kind of filter and first line of defence by collecting
7		all these virus particles, and then, from there, they
8		disseminate to the rest of the body.
9		That ties in with what we were just talking about,
10		which is nasal washing and nasopharyngeal gargling.
11	Q.	If you go on, on that page, to the penultimate
12		paragraph:
13		"SARS-CoV-2 is primarily transmitted from person to
14		person following close ([less than] 6 feet, $\sim$ 2 metres)
15		exposure to respiratory fluids carrying infectious
16		viruses ."
17		Then you give examples; very simple examples of
18		somebody breathing, singing, talking, coughing or
19		sneezing, that:
20		" release large infective particles (droplet
21		nuclei) into the air; these particles may land on the
22		exposed mucous membranes of a host, causing
23		infection ."
24	Α.	Yes.
25	Q.	Then you go on to infection from touching contaminated
		23
1		surfaces, which you say is also possible, and then
2		perhaps you would just read what you say in the final
3		paragraph of this section at the top of page 18.
4	Α.	So the paragraph starting, "Finally"?
5	Q.	"Finally "
6	Α.	So:
7		"Finally, SARS-CoV-2 exposure can occur when very
8		small infective particles (aerosol particles), suspended
9		in the air, are inhaled directly. Aerosol-generating
10		procedures commonly take place in hospitals, and in

- procedures commonly take place in hospitals, and in 11 dental surgeries; hospital procedures in this category
- 12 include (but are not limited to) tracheal intubation,
- 13 manual ventilation, non-invasive ventilation and the use
- of certain high-flow oxygen treatments." 14
- 15 Q. Thank you.
- 16 You then go on to talk about something you prefaced in the previous section, the environmental factors, and
- 17 18  ${\sf I}$  think we can read what you say there.
- 19
- I think, on a practical level, it's quite 20
- interesting what you say, that in indoor settings,
- transmission is thought to be much less common. 21
- 22 A. I thought I said the opposite.
- 23 Q. I'm sorry.
- 24 A. Yes, the opposite. Yes, it's more common in --
- 25 Q. Yes, in outdoor settings, it's much less common.

- 1 A. In outdoor settings, much less common, yes. It is. And
- 2 this would be because the viruses are naturally fragile
- 3 and they are degraded by ultraviolet light coming from
- 4 the sun, and fresh air disperses them even more.
- 5 Of course, it immediately calls into question: what 6 do you do about people outdoors? And certainly in
- 7 England, the -- well, by way of comparison, in Scotland
- 8 during the lockdown, the golf courses were open; in
- 9 England, they were all closed all the time during every
- 10 lockdown. To me, that doesn't sound logical, because on
- $11 \qquad$  a golf course you're in the fresh air , you're physically
- 12 distanced from other people, and the risk of
- 13 transmission must be very low.
- 14  $\,$  Q. I think there was talk in the very early days of the
- 15 pandemic about the -- to use a buzzword --
- 16 super-spreader event, or potential super-spreader event,
- of the Cheltenham race meeting, which I think occurredvery early in the pandemic.
- 19 A. Yes.

25

- 20 Q. Now, obviously that was --
- 21 A. Out of doors, yes.
- 22 Q. -- outdoor, but it was presumably a lot of people in 23 close proximity to each other.
- 24 A. Yes. Yes. Sure, yes. Indeed. That foreseeably could
  - have been a super-spreader event, yes.

#### 25

- 1 Q. Thank you. 2 You make reference at the bottom of page 18 to 3 outbreaks on buses and trains. 4 A. Yes. Q. You then make reference to what are termed "attack 5 rates". Again, I think this is a term you define. 6 7 A. Mm-hm. 8  $\mathsf{Q}.\;$  But it's the proportion of people exposed who go on to 9 develop infection, and you say that that has been as 10 high as 36%. That's in relation to buses. I think you 11 give the citation for that in your footnote. Then, 12 similarly, you do that with trains. 13 Then on the top of page 19 you refer to transmission 14 during airline travel, and I think you say it can be as 15 high as 60% in subsections of an aircraft. It probably 16 is fairly obvious as to why that would be. 17 A. That section was probably packed. But, equally, it's 18 interesting that aircraft flights might result in a 0%19 transmission rate. 20 Q. Yes. 21 A. So it has to be interpreted cautiously, that piece of 2.2 information.
- 23 Q. I think you then mention Wuhan --
- 23 Q. 1 th 24 A. Yes.
- 25 Q. -- and that the experience in Wuhan shows that
  - 26

2		with thousands of new patients diagnosed daily.
3	Α.	Potentially, yes.
4	Q.	Then you have a section on patient-specific factors. In
5		this section, you introduce a qualification on,
6		I suppose, the degree of infection , and you say that:
7		" Individuals with mild to moderate COVID $-19$ may shed
8		infectious virus and respiratory secretions for up to
9		10 days following the onset of symptoms"
10		Just so that we understand, can you put in simple
11		terms what you mean when you qualify the infection as
12		being mild to moderate?
13	Α.	I can't, because it's a subjective term, but what
14		I presume is meant here is $$ generally, severe illness
15		is generally categorised as one where the person has to
16		seek medical advice from a GP or from a hospital. So
17		mild to moderate, I imagine, would be the person being
18		at home, not necessarily seeking medical advice, and
19		${\sf self-medicating}, {\sf or maybe not even self-medicating},$
20		just $$ but, on the other hand, not entirely well.
21	Q.	I think you say that that fact was known from early on
22		in the pandemic.
23	Α.	Yes, it was, and it was a factor that was also a feature
24		of SARS, so it was logically a feature also of
25		SARS-CoV-2.

transmission can be massive in a short space of time,

#### 27

- 1~ Q. I think you then go on to say:
- 2 "Immunocompromised people with severe disease may
- $3 \qquad$  shed the virus for longer ( potentially , for up to
- 4 [10] days)."
- 5 A. I think actually that's 20 days.
- 6 Q. Oh, I'm sorry.
- 7 A. I believe there's a transcription error which
- 8 I corrected. But it's longer because they're taking
   9 longer to clear the virus.
- 10~ Q. Yes. So that's the same figure as the one you've given
- 11 before.
- 12 A. Oh, right.
- 13  $\,$  Q. So it must be different. It must be 20 days.
- 14 A. Yes, of course. Yes, I beg your pardon.
- 15 Q. Then, again, something I think we probably can all 16 remember from the general presentations during the
- 17 pandemic. You say that:
- 18 " ... the concentrations of SARS–CoV–2 RNA are
- 19 highest one day before symptoms appear, leading to
- 20  $\qquad$  extensive spread of the virus by asymptomatic people not
- 21 yet showing any signs of illness ."
- 22 A. Yes.

24

- 23  $\,$  Q. Is that effectively one of the dangers of the situation?
  - A. It is, yes. Yes.
- 25 Q. I think in the next paragraph you do say that some

1		and the second
1 2		people may remain asymptomatic, albeit having acquired the virus and acquired the infection.
3	۸	Yes, especially if they're very young and healthy.
4		Yes. I think you make the point that, in the case of
5	ч.	infected children, at least one-third are likely to
6		remain asymptomatic during infection.
7	А	Yes.
8		You then give the example of the Diamond Princess cruise
9		ship ——
10	A.	Mm.
11	Q.	which was quarantined $$ I think we all remember the
12		footage on the television of this $$ off the coast of
13		Japan.
14	Α.	Yes.
15	Q.	What subsequently emerged from the research was that 52%
16		of the 634 people who were laboratory—confirmed cases
17		were initially asymptomatic $$
18	Α.	Yes.
19	Q.	and most began to show symptoms, but an estimated
20		almost 18% of infected individuals never showed any
21		symptoms of infection.
22	Α.	Indeed, even though, one imagines, they were middle-aged
23		and elderly passengers, but they were still
24		asymptomatic.
25	Q.	Right. Thank you, doctor.
		29
1		The next section of your report, 2.10, deals with
2		the origins of COVID-19.
2 3		the origins of COVID-19. Now, this is, I think, an area that probably
2 3 4		the origins of COVID-19. Now, this is, I think, an area that probably everybody is now or at least informed readers will
2 3 4 5		the origins of COVID-19. Now, this is, I think, an area that probably everybody is now — or at least informed readers will be — – relatively familiar with, and I'm not going to
2 3 4 5 6		the origins of COVID-19. Now, this is, I think, an area that probably everybody is now or at least informed readers will be relatively familiar with, and I'm not going to take you through it in any detail.
2 3 4 5 6 7		the origins of COVID-19. Now, this is, I think, an area that probably everybody is now or at least informed readers will be relatively familiar with, and I'm not going to take you through it in any detail. There are two things I would like to, however, ask
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q.	<pre>the origins of COVID_19. Now, this is, I think, an area that probably everybody is now or at least informed readers will be relatively familiar with, and I'm not going to take you through it in any detail. There are two things I would like to, however, ask you about. Mm-hm. At the top of page 21, you say that: "It is now believed by many that the novel Wuhan virus was transmitted to humans via horseshoe bats and potentially other intermediate hosts, to whom individuals may have been exposed at wild food markets in the centre of Wuhan" I think that was what was initially thought. You also say: " an alternative theory is that the virus resulted from a 'lab leak'." Yes. I think there is a lab in Wuhan which may have been seen as being the source of the infection. I take it you're not expressing any view on which</pre>

30

1 A. Indeed, those are two theories. I was a bit sceptical 2 about the lab leak theory, but it does seem that the 3 SARS -- if you remember, SARS 2002–2003, there were several subsequent mini-outbreaks, and three of those --4 we touched this yesterday -- seemed to come from lab 5 leaks of some sort, so clearly it's possible. 6 7 Q. I think, helpfully, we can see the progression over 8 about 20 days of the infection of persons with the virus 9 shown in the maps that you've shown on that page, and we 10 can all look at that. 11 A. Yes 12 Q. The other point that I would like to take from this 13 section on the history of the virus is what is said at 14 page 22 at the top, where you refer to the basic 15 reproductive rate, which I think we probably all 16 remember being referred to as the R number. 17 A. Yes 18 Q. I think you indicate that the original wild-type strain 19 of SARS-CoV-2 was estimated as having an R number of 20 2.8 21 A. Yes 2.2 Q. And, as you say: 23 "The R [number] denotes the number of persons 24 directly infected by an infectious case during his or 25 her entire infectious period, on entering a totally 31 susceptible population." 1 2 Then I think you've indicated, by comparison, the  ${\sf R}$ 3 of seasonal influenza is typically between 1 and 2. 4 A. Yes. 5  $\mathsf{Q}.\;\;\mathsf{So},\;\mathsf{in}\;\mathsf{simple}\;\mathsf{terms},\;\mathsf{the}\;\mathsf{R}\;\mathsf{number}\;\mathsf{represents}\;\mathsf{the}\;\mathsf{number}\;$ 6 of people who would be infected by one person. 7 A. Yes. 8  $\mathsf{Q}.\;$  Sorry, having said there were two things, there are in 9 fact three things I would like to just take from this 10 section, and this further matter follows on from what 11 we've just discussed. 12 If you go to page 25 at paragraph 2.13, you will see you deal with the emergence of variants, late 2020, and 13 14 I think you say there that: " ... new variants ... had emerged carrying several 15 16 amino acid substitutions." 17

- amino acid substitutions."
  A. Yes.
  Q. "The variants mostly had higher R ... numbers than the original wild-type strain and were said to be more transmissible due to mutations in the receptor-binding domain of the spike ... protein."
  You've explained the significance of the spike protein.
- 24 A. Yes.
- 25  $\,$   $\,$  Q. And then there are references to two of the variants

-		
1		that I think we are all, again, familiar with. The
2		Delta variant had an estimated R number of 5.1 $$
3	Α.	Mm-hm.
4	Q.	and the Omicron variant, which emerged in late 2021,
5		had an estimated R number of 9.5.
6	Α.	Yes.
7	Q.	${\sf I}$ think that was perhaps one of the alarming aspects as
8		that information came out.
9	Α.	Yes. Yes. Yes. Yes.
10	Q.	Yes.
11		Can we move on now, doctor, to 2.14 at page 26.
12		You deal at the bottom of that page with, "How
13		quickly does COVID-19 develop?" I think you say that
14		those exposed to an infected person typically develop
15		symptoms between four to five days post-exposure,
16		although obviously you've indicated that people can
17		remain asymptomatic during that period.
18	Α.	Of course. Yes.
19	Q.	You then say that:
20		"The median incubation period of ${ m COVID}{-19}$ (i.e. the
21		time interval between the individual becoming infected
22		and him or her then developing overt symptoms)
23		is 4 days (with an interquartile range of $2-7$ days).
24		The incubation period can be as long as 14 days."
25	Α.	Yes.

1	Q.	Now you deal with those who are at high risk for COVID
2		infection . Perhaps I can hand over to you just to read
3		through what you have said there, please. So 2.14 and
4		following.
5	Α.	2.15, "Who is at high risk" $$
6	Q.	l'm sorry, 2.15.
7	Α.	"Who is at high risk for severe COVID-19 infection?
8		"Individuals who are older, male, from deprived
9		areas, or from black, ethnic or minority groups are at
10		higher risk of severe disease and death from $\ensuremath{COVID}{-19."}$
11		If I could just qualify that, my Lord. Really the
12		key figure there is older. People who are older than
13		85 years are at very high risk . The others are at
14		increased risk , but those categories are not equivalent
15		in terms of risk . But they are all at higher risk .
16		"Substance use (e.g. alcohol, opioid or cocaine use
17		disorder), and current or former smoking both increase
18		the risk."
19	Q.	It is something that the Inquiry is going to look at in
20		due course: is there a particular reason why black,
21		ethnic or minority groups are at higher risk, do you
22		know?
23	Α.	Their genetic make-up is the same as ours, but it may be
24		that their home circumstances are different. They tend

<u> </u>	that their nome circumstances are uncrent.	They tend
25	to be multi-generational, more so than we are	e. We tend

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1 to live in nuclear families, compared to many ethnic 2 minority groups. So there could be societal reasons as opposed to physiological explanations for  $% \mathcal{T}_{\mathrm{s}}^{(1)}(\mathbf{r})$  it is the set of 3 4 an area that does really warrant further research. Q. Yes, because I think it's an area that has been 5 6 commented on --7 A. Yes, indeed. 8 Q. -- very considerably --9 A. Yes. 10 Q.  $\,--$  and data tends to suggest that there's substance for 11 that. A. Yes. Some of the ethnic groups do have a higher 12 13 prevalence of obesity, and that in itself is a risk 14 factor. So that could be another variable that explains 15 this. 16 Q. You go on to say: 17 "The risk of severe COVID ..." 18 And, again, you've got a qualification word there, 19 "severe", and I take it that you've indicated earlier 20 what "severe" is. It's somewhat subjective. 21 A. It is somewhat subjective, yes. 2.2  $\mathsf{Q}.\;$  But it's the sort of level of infection that would tend 23 to suggest that it's time to see your doctor? 24 A. I guess so, yes. Yes. 25 Q. And you say that there are further increasing risk 35

1	factors, and you list them there. I think they are
2	probably fairly obvious: obesity, diabetes,
3	hypertension, cardiac disease, frailty and impaired
4	immunity, and you go on to say reduced ability to cough
5	and clear bronchial secretions.
6	We have come across and will continue to come across
7	the concept of impaired immunity or immunosuppressed.
8	Can you just explain what that is?
9	A. Yes. The immune system is the body's way of combating
10	pathogens, combating infections. It's very complicated,
11	but there are two sides to the immune system.
12	There's the innate immune system that we're all born
13	with, and that's kind of a general kind of surveillance
14	system that surveys all the potential pathogens that
15	might have gone into the body. It's also called the
16	cellular immune system, confusingly, because there are
17	individual cells within that aspect of the immune system
18	that have particular functions, and that will go out and
19	seek and destroy pathogens. We're born with that, and
20	that tends to decline with age.
21	The other side of the immune system is what's called
22	the humoral immune system, which is based on antibodies.
23	That tends to be disease-specific. So we develop
24	antibodies for specific diseases when alerted by the
25	innate immune system, and that tends to get better as

1	you get older; you encounter more diseases, so your
2	stock of antibodies builds up. Furthermore, sometimes
3	antibodies may be cross-reactive. They may be effective
4	against one particular virus, and they may also be
5	partly effective against a different virus.
6	LORD BRAILSFORD: May I interrupt at this stage.
7	You indicated, doctor $$ I think, in fact, Mr Gale
8	indicated on your behalf $$ that the list you give is
9	pretty obvious, and also it's fairly objective. But
10	there's one word you use which I think is a little
11	subjective: "frailty".
12	A. Yes.
13	LORD BRAILSFORD: "Frailty", I think many of us or we would
14	
	all have different interpretations. Perhaps we
15	automatically think of an old person.
16	A. Yes.
17	LORD BRAILSFORD: But what do you mean by "frailty" there?
18	Are you able to be a little bit more objective?
19	A. Yes, it is subjective, and there are frailty indices
20	that will be used in care homes. My wife is a nurse,
21	was for a long time staff nurse in charge of nursing
22	homes, and actually there's an important distinction
23	between nursing homes and residential homes there. So
24	when new residents come into the nursing home or the
25	residential home, they will be assessed for frailty .
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1	There are different measures, but they combine various
2	factors, mainly based on mobility.
3	LORD BRAILSFORD: Okay.
4	A. Beyond that, I'm a bit out of my depth, actually. But
5	clearly people have found that there are people who are
6	old but very robust and there are people who are old but
7	very frail, and it is the ones who are old and frail who
8	are particularly at risk of $COVID-19$ . Presumably this
9	
9 10	is because their innate immune system has gradually
	diminished with the passage of time, whereas their
11	adaptive or humoral immune system is still all right.
12	They've still got antibodies to a range the diseases
13	they've encountered during their life .
14	LORD BRAILSFORD: Thank you.
15	Sorry, Mr Gale.
16	A. Just $$ we were talking yesterday about the swine flu
17	epidemic. That was striking because older people seem
18	not to acquire swine flu , if you remember $$
19	LORD BRAILSFORD: Yes, you said that.

- 19 LORD BRAILSFORD: Yes, you said that.
- 20 A. -- because they had encountered the same influenza virus 21 in the 1950s, but the younger people were getting it
- 22 because they hadn't.
- 23 MR GALE: I think, just to complete the list, you say that
- 24 people with chronic liver disease, especially cirrhosis, 25
  - are at a high risk of severe COVID.

1 A. Yes.

3

- 2  $\mathsf{Q}.~\mathsf{I}$  think as was apparent from your papers that you
  - referred to --
- 4 A. Yes.
- 5  $\mathsf{Q}.\ --$  this is an area with which you have a particular
- 6 interest .
- A. Yes. 7
- 8 Q. Could you just read the final paragraph and perhaps
- 9 expand on it a little , page 28. It's the final
- 10 paragraph of 2.15, please.
- 11 Α. "In the early stages of the pandemic the crude (i.e. 12 all-age) [average] case-fatality rate ... from COVID-19 13 was reported [in the medical literature and the press] 14 as ranging from 1% to 13%–14%; this very wide variation 15 in a key measure of pathogenicity was explained at the 16 time as being possibly due to different case definitions 17 used and, to some extent, the intensive care capacity of 18 hospitals." 19 Q. Right. Can you explain -- because obviously 20 an explanation is being given as to that wide range, and 21 at the moment I'm, I have to say, slightly struggling to 2.2 understand that. 23 A. Yes. So when the pandemic came along, everyone was 24 taken by surprise, and some centres were reporting, 25 "13 or 14% of our patients that we've admitted are dying

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1		of COVID $-19$ ", others were saying, "Well, we were only
2		finding $1\%$ are dying", and it's puzzling that a measure
3		that isn't objective, which is terminal, like death,
4		should have accrued such a very wide range of reported
5		observations.
6		There are a number of explanations, and one is that
7		there are different definitions of COVID cases in
8		different countries, so different case definitions were
9		used, and some of the people who died may not have died
10		of COVID; they may have died with COVID. So that could
11		explain some of the variation. And some countries may
12		have had better intensive care capacity than others.
13	Q.	And even within countries, the intensive care capacity
14		can vary.
15	Α.	Indeed, and some thinking nowadays is that possibly some
16		of the early treatment protocols were actually harmful.
17		They were well-intentioned, of course, but they might
18		have actually been causing more harm than good, because
19		current treatment protocols are very conservative. The
20		current approach in general to COVID is one of medical
21		supportive measures, which Mr Gale suggested is
22		equivalent to palliative treatment, which is right.
23		That seems to be the best way of managing patients with
24		COVID, with medical supportive measures, and very
25		importantly nursing them so they're lying on their

1		front, so that the secretions drain out of their mouth,
2		not when they're lying on their back.
3	Q.	Now you deal with a section on, again, a subject that we
4		will be looking at in some further detail, and that's
5		COVID $-19$ and pregnancy $$
6	Α.	Yes.
7	Q.	and the general context of women's issues.
8	Α.	Yes.
9	Q.	You've indicated that there was something of
10		a difference: the risk was higher in the earlier stages
11		of the pandemic, and that there was a different level in
12		the Omicron era of the pandemic.
13		Now, I think you indicate in the first paragraph
14		that the risk was higher if $$ and you give a number of
15		factors, which I think are factors that are associated
16		with risk in pregnancy $$
17	Α.	Yes.
18	Q.	outwith the complication of the pandemic.
19	Α.	Yes. Yes.
20	Q.	And then the data that is available for the Omicron era
21		indicates that:
22		" pregnant women were substantially less likely
23		to have a preterm birth or maternal critical care; fewer
0.4		

stillbirths and no maternal deaths were observed in theUK in this period."

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1		Is there any reason you can $$
2	Α.	Yes.
3	Q.	postulate for that?
4	Α.	Yes. The Omicron era began in November 2021, as
5		I mentioned earlier, so it began late on in the
6		pandemic. So the explanation may be that the treatment
7		protocols had been adapted by then and were more on the
8		lines of supportive care, which was giving better
9		outcomes, and perhaps were less interventionist, using
10		aggressive therapies such as intravenous fluid
11		replacement, whereas oral fluids might have been
12		preferred .
13		So this no doubt is being discussed even as we
14		speak, and the answer to that question should become
15		apparent with the passage of time, but I can just
16		surmise as to what the reasons might have been.
17	Q.	And also the vaccine programme?
18	Α.	Yes, indeed. So many of those women would have been
19		vaccinated and, as we will discuss later, the vaccine
20		does seem to confer, or does confer, based on the
21		Cochrane analysis, less severe disease.
22	Q.	Move on now to 2.17, "Who is at low risk" $$
23	Α.	Yes.

- 24 Q. -- "for severe COVID-19 infection?"
  - Within this passage there is, perhaps, a somewhat
    - 42

- 1 concerning sentence, and one that perhaps needs to be 2 considered in a little more detail. I will read it out: 3 "In general, COVID-19 has a milder disease course in 4 children and young adults than it does in older adults. The majority of children recover completely after acute 5  $\mathsf{SARS}{-}\mathsf{CoV}{-}2$  infection and any persistent symptoms will 6 7 improve with time." 8 Now, I think you're presenting that --9 A. Yes. 10  $\mathsf{Q}.~--$  from the point of view of a public health physician. A. Yes. 11 12  $\mathsf{Q}.\;$  And obviously you are looking at, if  $\mathsf{I}$  can put it this 13 way, the larger, bigger picture. 14 A. Yes. 15  $\mathsf{Q}.\;$  And, of course, within that larger, bigger picture, there will be and will have been exceptions to the 16 17 generality that you are stating there. 18 A. Of course, yes. 19 Q. And I think yesterday we talked about it: that it's 20 perhaps of little comfort to those who have lost 21 someone --A. Yes. 2.2 23 Q. -- whether that person be in the area that is perhaps at
  - most risk, such as the elderly, but also those who have lost someone in the apparently less risk category.
    - meene in the apparently less his

#### 43

1 A. Yes.

24

25

-		
2	Q.	You then go on to talk about the case-fatality rate in
3		the third full paragraph on that page, and then you have
4		set out a table.
5		Can you tell me where that table comes from, and
6		perhaps just take us through it, please.
7	Α.	Yes. That table is taken from what's called the
8		Green Book, which is a Department of Health manual that
9		is used by anybody who is in any way involved with the
10		vaccination process, whether epidemiologists or GPs or
11		nurses who administer vaccines. It used to be
12		a green book, but nowadays it's all online, so this
13		table was taken from the online version, published
14		earlier this year. I've got a copy there.
15		The table shows deaths in 2020 in England, but
16		I think the table can be generalised to Scotland as
17		well, and it breaks the deaths that one can attribute to
18		COVID down into males and females, and it stratifies
19		them very helpfully by age groups.
20		So the first line is the deaths that occurred in
21		the under 18s. So looking really at the right-hand
22		column, there were 32 deaths in England in 2020 in
23		the under 18s that are attributed to COVID $-19$ , so
24		there's a very small rate of death in the under 18s in
25		that year. The following year might have been even

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1	smaller because, as I was saying, the treatment	1		I had meant to put in there a further point, but
2	protocols were better.	2		perhaps it was obvious, but one of the standard
3	2020, the height of the pandemic, the rate was,	3		textbooks I've been citing did go on to say that usually
4	100,000 children, 0.26. So that's equivalent to two per	4		they get better. Usually they get better. We have to
5	million; two out of a million children would have died	5	~	take that on trust.
6	of COVID that year.	6	Q.	I am reminded, can you just perhaps indicate what we
7	As we move up the age categories, that number gets	7		probably know the word "Kawasaki" from a different
8	higher and higher, until we get into those who are 85	8		context, but could you tell us what Kawasaki disease is?
9	and older, and you can see there were 26,954 deaths in	9		I don't know what that is.
10	total attributed to COVID, so a massive number, in the	10		You don't know?
11	85s and over, and the rate there for every 100,000	11	Α.	It's clearly a very rare disease that paediatricians are
12	people who are 85 and over, it's actually 19,160.	12		familiar with and they were surprised to see this in
13	LORD BRAILSFORD: 1,900, I think.	13	~	children .
14	A. Well, that's sorry, for every million.	14	Q.	Okay. Right.
15	LORD BRAILSFORD: Every million.	15		You then go on to the pathological processes that
16	A. So let's take 100,000. Thank you, my Lord. So rate per	16		occur in COVID-19.
17	100,000 is 1,916.51.	17		Mm.
18	I did a little calculation on that, and if you take	18	Q.	I think probably we can simply read that section at 2.18
19	the over 65s, that comes to 59,628 deaths, those	19		for ourselves and perhaps move on to 2.19, which are the
20	over 65, and that is 89% of all the deaths.	20		clinical features of COVID-19.
21	LORD BRAILSFORD: 89?	21		You refer first of all to early features. Perhaps
22	A. 89% of all the deaths were in those over 65, and in fact	22		you could just go through those, please.
23	one in four of them was in those over 85.	23	Α.	Yes:
24	LORD BRAILSFORD: Yes.	24		"In patients with symptomatic COVID-19 infection,
25	A. So very much a disease related to age and extremes of	25		the initial symptoms are non-specific and appear after
	45			47
1	are based on the England figures but I would	1		an incubation period of approximately 2 to 7 days:
1	age, based on the England figures, but I would	1		an incubation period of approximately 2 to 7 days;
2	confidently suggest that Scottish figures would be	2		typically [these initial ] symptoms will include:
2 3	confidently suggest that Scottish figures would be comparable.	2 3		typically [these initial] symptoms will include: "- fever;
2 3 4	confidently suggest that Scottish figures would be comparable. MR GALE: Yes. You don't see any reason why they would be	2 3 4		typically [these initial] symptoms will include: "— fever; "— headache;
2 3 4 5	confidently suggest that Scottish figures would be comparable. MR GALE: Yes. You don't see any reason why they would be different?	2 3 4 5		typically [these initial] symptoms will include: "— fever; "— headache; "— myalgia (i.e. muscle pain) and
2 3 4 5 6	<ul><li>confidently suggest that Scottish figures would be comparable.</li><li>MR GALE: Yes. You don't see any reason why they would be different ?</li><li>A. I don't see any reason.</li></ul>	2 3 4 5 6		typically [these initial ] symptoms will include: "- fever; "- headache; "- myalgia (i.e. muscle pain) and "- malaise (i.e. general unwellness).
2 3 4 5 6 7	<ul><li>confidently suggest that Scottish figures would be comparable.</li><li>MR GALE: Yes. You don't see any reason why they would be different ?</li><li>A. I don't see any reason.</li><li>Q. If you go over the page to page 30, you make a reference</li></ul>	2 3 4 5 6 7		<pre>typically [these initial ] symptoms will include: " - fever; " - headache; " - myalgia (i.e. muscle pain) and " - malaise (i.e. general unwellness). "At the same time [or around the same time], the</pre>
2 3 4 5 6 7 8	<ul> <li>confidently suggest that Scottish figures would be comparable.</li> <li>MR GALE: Yes. You don't see any reason why they would be different ?</li> <li>A. I don't see any reason.</li> <li>Q. If you go over the page to page 30, you make a reference there to:</li> </ul>	2 3 4 5 6 7 8		<pre>typically [these initial ] symptoms will include: " - fever; " - headache; " - myalgia (i.e. muscle pain) and " - malaise (i.e. general unwellness). "At the same time [or around the same time], the patiently may experience anosmia (i.e. loss of smell),</pre>
2 3 5 7 8 9	<ul> <li>confidently suggest that Scottish figures would be comparable.</li> <li>MR GALE: Yes. You don't see any reason why they would be different ?</li> <li>A. I don't see any reason.</li> <li>Q. If you go over the page to page 30, you make a reference there to:</li></ul>	2 3 4 5 6 7 8 9	0	<pre>typically [these initial ] symptoms will include: " - fever; " - headache; " - myalgia (i.e. muscle pain) and " - malaise (i.e. general unwellness). "At the same time [or around the same time], the patiently may experience anosmia (i.e. loss of smell), and dysgeunia (i.e. distortion of taste)."</pre>
2 3 4 5 6 7 8 9 10	<ul> <li>confidently suggest that Scottish figures would be comparable.</li> <li>MR GALE: Yes. You don't see any reason why they would be different ?</li> <li>A. I don't see any reason.</li> <li>Q. If you go over the page to page 30, you make a reference there to:         <ul> <li>"A very small majority of children infected with SARS-CoV-2 (approximately 1 in 3,000) developed</li> </ul> </li> </ul>	2 3 4 5 7 8 9 10	Q.	<pre>typically [these initial ] symptoms will include: " - fever; " - headache; " - myalgia (i.e. muscle pain) and " - malaise (i.e. general unwellness). "At the same time [or around the same time], the patiently may experience anosmia (i.e. loss of smell), and dysgeunia (i.e. distortion of taste)." And I think we probably are all familiar with those</pre>
2 3 4 5 6 7 8 9 10 11	<ul> <li>confidently suggest that Scottish figures would be comparable.</li> <li>MR GALE: Yes. You don't see any reason why they would be different ?</li> <li>A. I don't see any reason.</li> <li>Q. If you go over the page to page 30, you make a reference there to: <ul> <li>"A very small majority of children infected with SARS-CoV-2 (approximately 1 in 3,000) developed a multi-system inflammatory syndrome with Kawasaki</li> </ul> </li> </ul>	2 3 4 5 7 8 9 10 11	Q.	<pre>typically [these initial ] symptoms will include: " - fever; " - headache; " - myalgia (i.e. muscle pain) and " - malaise (i.e. general unwellness). "At the same time [or around the same time], the patiently may experience anosmia (i.e. loss of smell), and dysgeunia (i.e. distortion of taste)." And I think we probably are all familiar with those being publicised at the time of the pandemic, and</pre>
2 3 4 5 6 7 8 9 10 11 12	<ul> <li>confidently suggest that Scottish figures would be comparable.</li> <li>MR GALE: Yes. You don't see any reason why they would be different ?</li> <li>A. I don't see any reason.</li> <li>Q. If you go over the page to page 30, you make a reference there to: <ul> <li>"A very small majority of children infected with SARS-CoV-2 (approximately 1 in 3,000) developed a multi-system inflammatory syndrome with Kawasaki disease-like features; this is known as mucocutaneous</li> </ul> </li> </ul>	2 3 4 5 6 7 8 9 10 11 12	Q.	<pre>typically [these initial ] symptoms will include: " - fever; " - headache; " - myalgia (i.e. muscle pain) and " - myalgia (i.e. general unwellness). "At the same time [or around the same time], the patiently may experience anosmia (i.e. loss of smell), and dysgeunia (i.e. distortion of taste)." And I think we probably are all familiar with those being publicised at the time of the pandemic, and I think any of us who have had COVID will probably</pre>
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1		congestion, shortness of breath, and low oxygen
2		saturation, or it could be some kind of cardiac
3		syndrome, or coagulopathy, meaning a clotting disorder
4		syndrome, or some other immune system that results in
5		treatment difficulties .
6	Q.	Would you just continue on reading?
7		Yes. So:
8		"Other symptoms [beside these syndromes], such as
9		profound fatigue and skin rashes may also be present.
10		"50% of patients with confirmed COVID-19 will report
11		gastrointestinal symptoms [mainly] diarrhoea (in
12		38% of those who are sick) and vomiting (in 13%)."
13		And sometimes the patient will have gastrointestinal
14		symptoms and nothing else.
15		"Some patients with severe COVID-19 may deteriorate
16		rapidly and develop life – threatening complications,
17		including:
18		"– thromboembolic events [clotting events];
19		"– cardiac disease;
20		"– acute kidney injury;
21		''– sepsis ;
22		"– septic shock; and
23		"– multi—organ failure."
24		Which is the herald of death.
25	Q.	Yes. Just continue on, please.
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A. So:

1	Α.	So:
2		"Natural immunity"
3		When you've acquired SARS $-$ CoV $-2$ naturally $$
4		naturally means it lasts up to one year before beginning
5		to wane, and that sort of fits in with the natural
6		immunity we normally experience with influenza:
7		" although the new strains and variants, such as
8		Omicron, appear to exhibit greater immune escape [so
9		they manage to evade the immune system] making
10		reinfection more common."
11	Q.	You now deal, doctor, with, "How does COVID $-19$ present
12		in the elderly?", and I think we look at this bearing in
13		mind the material that we've looked at $$
14	Α.	Yes.
15	Q.	in relation to death rates.
16	Α.	Yes.
17	Q.	So perhaps you could $$ again, it's perhaps a section
18		that is useful for you to read through, albeit that
19		I appreciate you have a table there. If you could just
20		read the text and just take us through the table.
21	Α.	Yes. So, in the elderly, the presentation is different
22		and atypical. The elderly may experience delirium and
23		reduced mobility $$ also immunocompromised individuals
24		as well $$ and often they don't have a fever.
25		So there's a table summarising how COVID-19 presents

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1	in the olderly. Control on the second s
1	in the elderly. So the non-specific signs and symptoms
2	are different. So often they don't have a fever. They
3	may not be breathless. They may, however, become
4	delirious, and even severely delirious. They often
5	don't have lung problems, particularly, but they can
6	have clotting problems, thromboses, or gastrointestinal
7	upset, diarrhoea and vomiting, like we've just talked
8	about. So it can be difficult to pick up COVID $-19$ in
9	the elderly if you're caring for them, or a doctor or
10	nurse.
11	The outcomes are different. Often they carry
12	COVID-19 virus asymptomatically for extended periods.
13	The elderly have high morbidity, that means they are
14	more likely to have severe disease, and mortality,
15	they're more likely to have a fatal outcome.
16	The elderly who survive COVID-19 will often
17	experience functional decline, meaning their natural
18	ability to function in their environment will get worse,
19	and they may need rehabilitation, which is likely to be
20	extensive and expensive.
21	Here is the word "frailty" again. Those old people
22	who are frail, over and above being old, have
23	particularly poor outcomes, but even people who are very
24	frail , it seems, can acquire COVID $-19$ and survive.

frail, it seems, can acquire COVID-19 and survive. And then it says here a frailty assessment is a good

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1		tool. I'm not quite sure how it's done, but there are
2		numerical measures you can use to categorise somebody as
3		being frail or not, and they can help people, for
4		example, who manage care homes to decide as to how to
5		manage a particular individual and what risk they may or
6		may not be at. But they shouldn't be the only
7		consideration; other factors should be involved as well.
8	Q.	Obviously all of those signs and symptoms in an elderly
9		person would be distressing $$
10	Α.	Yes. Oh, yes.
11	Q.	for that person and for those who are their
12		relatives, carers, loved ones.
13	Α.	Yes.
14	Q.	But particularly, I suppose, delirium.
15	Α.	Particularly delirium, when the person in front of you
16		is just not the person that you knew two weeks ago, but
17		someone quite different, yes.
18	Q.	You go on now to a subject that I think we are hearing
19		more and more about, and that is long COVID.
20	Α.	Yes.
21	Q.	The audience will be aware that the Inquiry has
22		published an opinion on long COVID, to the extent that
23		it intends to investigate long COVID.
24		So, with that in mind, could you just take us

25 through that relatively short passage that you have at

1		2.22 et man 22 to 24 en lenn COVID
		2.22, at page 33 to 34, on long COVID.
2	Α.	Yes. It's relatively short because there isn't much
3		about it in the textbooks as yet. It is a recent
4		phenomenon. But here we are:
5		"As is the case also with other viral infections,
6		such as infectious mononucleosis (i.e 'glandular
7		fever ' ) "
8		Glandular fever can often result in very long-term
9		debilitating symptoms:
10		" COVID-19 may give rise to prolonged symptoms
11		that persist for more than 4 weeks; this is known as
12		long COVID. In the UK, 4.5% of COVID $-19$ cases report
13		long-term symptoms 12-16 weeks after initial infection."
14		So about 1 in 20 of cases:
15		"Other terms for long COVID include post-COVID
16		syndrome, and post-acute sequelae of COVID-19 (PASC).
17		"Reported symptoms of long COVID are varied,
18		involving most organ symptoms and affecting both
19		physical and mental health. Commonly-reported long
20		COVID symptoms are:
21		"- shortness of breath;
22		"- fatigue;
23		"- headache; and
24		"- difficulty thinking or concentrating.
25		"In addition to [those four common symptoms], there

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1		is growing evidence of long-term cardiovascular sequelae
2		of COVID-19, including cerebrovascular disorders
3		[and I guess that means minor strokes, transient
4		ischaemic attacks], cardiac dysrhythmias [where the
5		heart rhythm isn't normal], heart failure [where the
6		heart pump is no longer efficient ], ischaemic and
7		non—ischaemic heart disease [same thing, really],
8		myocarditis [inflammation of the myocardium, the muscle
9		of the heart], pericarditis [inflammation of the fibrous
10		sac surrounding the heart] and thromboembolic disease
11		[which means long—term clotting disease]."
12		So all of those would fit under the category of long
13		COVID.
14	Q.	Yes.
15		In this Inquiry we have a group representing $$ it's
16		called Long Covid Kids.
17	Α.	Yes.
18	Q.	So obviously children suffering long COVID.
19	Α.	Yes.
20	Q.	Is that something of which you are aware of any research
21		having been done?
22	Α.	I would hope there's extensive research being done into
23		long COVID, but I'm not familiar with the details of
24		what research is being done in various centres.

25  ${\sf I}$  believe it was first recognised as an entity in

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1		the UK, and initially other countries weren't aware of
2		this phenomenon. But they now have become more aware,
3		so it may be research is being done in other countries
4		as well.
5	Q.	Yes, thank you.
6	Α.	The belief $$
7	Q.	l'm sorry.
8	Α.	I'm so sorry. I understand that the belief is that for
9		most people with long COVID, they do gradually get
10		better; for most, obviously not for all . By analogy
11		with glandular fever-type symptoms, where people can be
12		very exhausted for months and months, but gradually they
13		get better. But in the short term they will be often
14		very disabled indeed.
15	Q.	You move on to a section on diagnostic tests.
16	Α.	Yes.
17	Q.	I'm, with respect, going to take that as read. $I$ think
18		a lot of the tests are quite well known to us from our
19		own experiences, as are the $$ and ${\rm I'm}$ not going to take
20		you through the laboratory findings or the radiological
21		abnormalities.
22		But what I would like to take you on to is 2.26 at
23		page 36, please, which is, "How is COVID $-19$ treated?"
24		and "Medical supportive care". I think this is
25		something, again, we touched on yesterday $$
		55
1	Δ	Yes.
2		—— under reference to, I think, one of the Cochrane
-	۹.	and a restricted to, i timit, one of the coefficience

2	Q.	under reference to, I think, one of the Cochrane
3		reviews.
4		Perhaps you could just read through what you have
5		said there in section 2.26.
6	Α.	Yes:
7		"In the early stages of the pandemic, ${ m COVID}{-19}$
8		patients with severe respiratory distress were often
9		treated aggressively with intravenous fluids and
10		mechanical ventilation; it became apparent however that
11		intravenous fluids could exacerbate fluid in the lungs
12		and further reduce oxygenation.
13		"Another early clinical observation was that lying
14		in a prone position (i.e. on the stomach, [is better
15		than lying in the] supine position on the back
16		[which is how you lie in intensive care, you're on your
17		back]) led to improved oxygenation in patients who were
18		receiving supplemental oxygen therapy through a face
19		mask or nasal tubes. This [simple nursing measure]
20		resulted in fewer intubations [where a patient is first
21		of all paralysed through drugs and then a breathing tube
22		inserted into them] which themselves were $a[n$
23		additional] cause of morbidity and mortality."
24		All of that is taken from standard textbooks, not my
25		opinion.

1		Then:
2		"The current mainstay of COVID—19 management is
3		medical supportive care.
4		"COVID-19 patients who are coughing should initially
5		be managed using simple non-drug measures (e.g. honey)."
6		This is the British National Formulary advice to
7		doctors, give them non-drug measures initially.
8		If a patient has a distressing cough, you could use
9		a cough suppressant, a simple cough linctus, in the
10		short term, for example codeine phosphate.
11		If a COVID $-19$ patient has a fever, the
12		pharmaceutical advice is tell them:
13		" to drink fluids regularly to avoid dehydration,
14		and to take [simple] antipyretics [drugs to take down
15		the fever] (e.g. paracetamol or ibuprofen)"
16	Q.	The second aspect of COVID-19 treatment is
17		pharmacological therapy.
18	Α.	Yes.
19	Q.	You say that most drugs tested have shown marginal or
20		disappointing efficacy against SARS, and you give the
21		reference at footnote 186, which I think is to Louten,
22		Essential Human Virology ——
23	Α.	Yes.
24	Q.	—— and it's either a paper or a book from 2023, so it's
25		post the height of the pandemic.
		57
1	Α.	Yes.
2	Q.	I suppose to most of us, who immediately think that
3		there's a pharmacological remedy for anything that we're
4		suffering
5	Α.	Yes.
6	Q.	that may sound quite a surprising finding.
7	Α.	Yes.
8	Q.	Did you find it surprising?
9	Α.	Well, first of all I might qualify that by saying that
10		the steroids don't come into the category. Steroids
11		seem to be effective, dexamethasone. But I think what
12		she's talking about there are antiviral drugs, so
13		viral – specific drugs. Steroids come into the category
14		of sort of standard, non-complicated measures.
15		But a large number of antiviral drugs at various
16		times were put forward as the wonderful remedy, and
17		I think one came into the timeline with the words saying
18		"Great news, this antiviral drug has now been approved
19		for COVID", and it was a little bit surprising to see it
20		stated that antiviral drugs don't seem to have much
21		efficacy .

- I got a bit worried about this, because in the UK 22
- 23 Inquiry they were told the opposite; they were told that
- 24 drug therapy had had a remarkable effect in improving
- 25 COVID outcomes. Again, I think what was really meant

1	there was probably dexamethasone. So I was a bit
2	concerned.
3	Last week I thought: well, I'll see if there's
4	a Cochrane review about $$ I just chose one drug at
5	random $$ remdesvir, to see what the Cochrane people say
6	about it. I found a Cochrane review which was published
7	earlier this year, so it's publicly available. I'll
8	just read one line from it.
9	Cochrane review, published in January 2023, and is
10	called , "Remdesvir for the treatment of COVID $-19$ ". They
11	found a number of studies. They used the standard
12	Cochrane methodology. They found nine randomised
13	controlled trials of remdesvir to treat COVID $-19$ , 11,218
14	participants, and they were randomised to receive
15	remdesvir or not receive remdesvir.
16	I won't go through the details of the studies,
17	they're available, but the authors' conclusions:
18	"Based on the available evidence up to 31 May 2022
19	[which is their $cut-off$ point for the trial ], remdesivir
20	probably has little or no effect on all $-cause$ mortality
21	or in-hospital mortality of individuals with moderate to
22	severe COVID-19."
23	So that was certainly the position as of last year.
24	So
25	LORD BRAILSFORD: You say you found that; was that produced
	59
1	in the bundle of documents?
2	A. It wasn't. We could have had Cochrane reviews for every

- 3 test, every --4 LORD BRAILSFORD: True, but could we get a copy of that, 5 Mr Gale, please? 6 MR GALE: Sure. LORD BRAILSFORD: Thank you. 7 A. Yes. Indeed, there will be  $--\ {\rm a}$  number of other 8 9 antiviral drugs are mentioned there, my Lord, and there 10 will certainly be Cochrane reviews, either published or 11 in progress, for all of those. 12 Of course, bearing in mind that Cochrane reviews are 13 dynamic, and as they say, in a year's time they might 14 change their view, but it's unlikely they would change 15 it. 16 MR GALE: There is only one other sentence I would like to 17 take you to. It's page 39. 18 A. Yes. 19 Q. It is in relation to -- it's after the various drugs 20 that are mentioned, including remdesvir. 21 A. Yes. 22 Q. There's a paragraph which says: "The safety of COVID-19 antiviral treatment during
- 23 24 pregnancy has not been established."
- 25  ${\sf I}$  think the reference you give to that is from the

1	British National Formulary.	1
2	A. Yes. It's to $$ yes. Yes, thank you, yes. Yes.	2
3	Yes, the British National Formulary have become	3
4	rather conservative, and they don't want doctors to	4
5	start giving antiviral treatments, perhaps because the	5
6	patient is demanding it, because they feel that the	6
7	safety margin is still under exploration.	7
8	MR GALE: Right.	8
9	My Lord, that's perhaps a useful point at which to	9
10	break.	10
11	LORD BRAILSFORD: Of course, yes. Thank you.	11
12	We'll take 15 or so minutes now. Thank you very	12
13	much indeed.	13
14	Thank you, doctor.	14
15	(11.28 am)	15
16	(A short break)	16
17	(11.53 am)	17
18	LORD BRAILSFORD: Thank you. We're just about to start	18
19	again.	19
20	However, there's something I would like to say. It	20
21	has been brought to my attention, I should say, by	21
22	Mr Gale's junior counsel, who must have been talking to	22
23	people during the coffee break, that some of the	23
24	solicitors that are present here are busy and	24
25	assiduously taking notes.	25
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1	Can I save them some work, to be perfectly honest $$
2	and I apologise, perhaps I should have thought about
3	this yesterday $$ but this is all being recorded. The
4	availability of a transcript will be there, and you will
5	be able to get a transcript of this . I cannot say $$
6	I'll try and say, perhaps, at the beginning of the
7	afternoon session $$ when you can expect it, but my
8	understanding is it should be available in very short
9	order, probably next week sometime.
10	So if that assists you and eases your hand muscles,
11	I hope I'm doing some good.
12	Right, Mr Gale, when you're ready.
13	MR GALE: Thank you, my Lord.
14	Just another piece of housekeeping. Dr Croft
15	referred to the Cochrane review of remdesvir, of which
16	he handed a copy, I think, to you. There is now a copy
17	available for your Lordship.
18	LORD BRAILSFORD: Thank you.
19	MR GALE: And we have copies if anybody wants a copy. It
20	will be available, perhaps at lunchtime, to be picked
21	up. Fortunately, it's not quite of the length of the
22	other Cochrane reviews that we have; it's only two
23	pages, so it 's manageable.
24	Right, Dr Croft, can we go back to your statement at
25	2.28, please, because you begin here with

3		COVID $-19$ prevented?", and there are various aspects of
4		that.
5		We will look at this in some more detail in
6		section 3 of your report, which we will be going to
7		next, and in particular the physical measures taken
8		against COVID, but perhaps you can just take us through,
9		first of all, the general public health measures that
10		you identify.
11	Α.	Yes. Shall I read on $$
12	Q.	Yes, please read on.
13	Α.	So general public health measures to prevent COVID $-19$ :
14		"COVID $-19$ may be prevented through standard
15		infection control measures, along with the public health
16		management of infected cases.
17		"The most basic public health measure against
18		$\ensuremath{COVID}\xspace{-19}$ , which was implemented in all countries during
19		the pandemic, was promoting frequent handwashing.
20		Large-scale frequent surface decontamination efforts
21		were deployed in public spaces, but the effect of these
22		cleanings on reducing transmission was and remains

a consideration of probably what is a general but

discrete area, and is in the context of, "How is

## 

Q. I think that's something that we will be touching on in

uncertain."

due course.

1	Α.	We will, yes.
2	Q.	We move on now to PPE.
3	Α.	So the second category of prevention is PPE:
4		"All countries advised the use of personal
5		protective equipment (PPE) by frontline healthcare staff
6		during the COVID-19 pandemic. Challenges included the
7		rapid depletion of PPE, the lag between the spread of
8		infection and the acquisition of evidence required to
9		inform precautions to control its spread, and frequent
10		changes in PPE guidance in response to its
11		availability ."
12	Q.	I think, just pausing there, one of the other challenges
13		may also have been the varying quality of some PPE.
14	Α.	Yes, indeed. And most countries recommended, and in
15		some cases enforced, the use of face coverings by all
16		adults, not simply healthcare staff, in places where
17		close contact was likely.
18	Q.	Yes.
19		We move from, as it were, PPE and general health
20		measures to lockdowns now.
21		I think you commented yesterday, under reference to
22		the approach taken by the government of China in
23		relation to lockdowns $$
24	Α.	Yes.
25	Q.	and I think the terminology came from that time.

1		Would you just read on, please, at 2.30.
2	Α.	Yes. Of course, there's a definition of lockdown in
3		the
4	Q.	There is, yes.
5	Α.	We will take that as read.
6		"A major strategy for attempting to limit the spread
7		of SARS-CoV-2 was the introduction by some governments,
8		starting with China, of extreme physical distancing
9		measures; these have been termed lockdowns.
10		"The components and restrictiveness of lockdowns
11		varied, and not all countries employed lockdowns. Where
12		lockdowns against COVID-19 were introduced, they
13		typically included:
14		"- the closure of schools, workplaces, non-essential
15		shops, sporting and entertainment venues;
16		"- a move to 'remote' (i.e. computer-based) working
17		where possible;
18		"- banning mass gatherings;
19		"– curfews;
20		"- stay-at-home orders; and
21		"- other local, national and international travel
22		restrictions .
23		"In some countries where extreme physical distancing
24		measures were employed early in the COVID-19 pandemic

(e.g. New Zealand), they resulted in complete, although

#### 65

- 1 temporary, eradication of virus in the community."
- 2 Q. You say there that in relation to New Zealand --
- 3 A. Yes.

25

- 4 Q. -- it was complete, although temporary, eradication of
  5 the virus. What happened after that temporary
  6 eradication, do you know?
- A. I'm assuming what it means there is that the lockdown
   temporarily eradicated -- temporarily, there were no
- 9 COVID cases, because they had a policy of zero COVID,
- 10 but then new cases emerged. But that's something that 11 does need investigation. I believe there may be some
- 12
   evidence taken from New Zealand later on.
- 13 The same was seen in China, of course, where even
- 14 this year, even earlier this year, they were still
- 15 having intermittent lockdowns focused on particular
- cities . They only abandoned it because of severe public
   unrest.
- 18 Q. Yes.
- 19Right, the next area of prevention is social20distancing. Again, would you read that, please.
- 21 A. Yes. Social distancing:
- 22 "In countries where extreme physical distancing
- 23 measures (i.e. lockdowns) were not considered necessary,
- 24 or else were temporarily relaxed, social distancing
- 25 strategies were employed instead; these involved keeping

66

- 1 people physically separate (a target of [greater than or 2 equal to] 2 metres was used in the UK). 3 "Vulnerable adults, including older and 4 immunocompromised people, were advised to curtail all 5 social interactions; this strategy was termed shielding, in the UK." 6 7 Q. Finally in this section: test, trace and isolate 8 measures. 9 A. So test, trace and isolate measures: 10 "Other measures used to limit, or attempt to limit, 11 the spread of SARS-CoV-2 were high levels of case identification , with widespread testing in order to 12 13 identify cases and ensure public health follow-up of 14 potential cases, and enforcing quarantine measures for 15 cases, contacts and travellers from high-incidence countries. The combination of such strategies has been 16 17 termed test, trace and isolate (TTI). 18 "More novel approaches to limit, or attempt to 19 limit , the spread of SARS-CoV-2 included the use of 20 mobile phone apps, and (depending on jurisdiction and 21 legal constraints) use of CCTV footage and tracking of 22 a contact's digital signature. 23 "In the UK (including Scotland), and in other 24 countries also, the processes of death certification
- 25 were streamlined in early 2020, to deal with anticipated

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1		surges in deaths."
2	Q.	What is the significance of that?
3	Α.	The significance is that, under certain conditions,
4		a pathologist is required to perform a postmortem, but
5		those conditions were relaxed significantly , and for
6		a time ${\sf I}$ believe postmortems weren't even being done on
7		$COVID{-19}$ cases. So, to some extent, the certainty that
8		could be attributed to whether or not a person died of
9		COVID-19 or with $COVID-19$ has to be considered
10		a compounding factor in assessing the mortality. It
11		wasn't done to, if you like, obfuscate the situation; it
12		was a practical measure to deal with the anticipated
13		very large number of deaths.
14	Q.	Right.
15		Now, at 2.33, page 42, we go on to the sixth aspect
16		of prevention, and this is, in terms of what you say,
17		the most detailed, and that's vaccination.
18		Now, again, vaccination is something we're going to
19		come to in section 4 of your report, so $I'm$ going to
20		take this, with respect, relatively short.
21	Α.	Yes.
22	Q.	I think we can see, at the very beginning, the COVID
23		vaccine was developed at record speed $$
24	Α.	Yes.
	~	

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25~ Q. -- and you identify four factors for that: prior

1		research, the state of vaccine technology, abundant
2		funding and a large group of willing volunteers.
3		I think probably everybody who, again, remembers the
4		circumstances of the pandemic and the development of the
5		vaccine, and without the level of information that you
6		would have had, probably thought, expressing a personal
7		view here, as indeed did I, that a vaccine, I expected,
8		would have taken a great deal longer than it did.
9		You have identified these factors. Was there any
10		worry about the fact that it was developed so quickly?
11	Α.	Well, yes, people have expressed concern, and people
12		were expressing concern at the time, and ideally
13		a vaccine should be developed over a period of time to
14		allow close understanding of how the vaccine may benefit
15		the population and, equally, how harms may arise that
16		might not be foreseen at first. So the speed of
17		development was of concern.
18		Then some vaccines are developed guickly, and
19		vaccines for seasonal influenza are often developed
20		quite quickly, because they will be based on the
21		previous season's circulating virus, and typically they
22		can be developed in seven or eight months. The
23		influenza season ends and the companies that make
24		vaccines start to develop the one that they anticipate
25		will be effective in the next season. So there are some
		69
1		precedents for fast vaccine development.
2		But, in general, it's not ideal to develop a drug or
3		a vaccine at high speed because it means that
4		potentially key stages in the analyses of either the
5		efficacy or the harms might be missed or skipped over.
6	Q.	One of the things you mention $$ and I think you've
7		already mentioned $$ at page 43 in the first paragraph,
8		you mention that vaccine development, the phases were
9		often run concurrently, so that had the effect of
10		speeding up the process.
11	Α.	Yes.

- 11 A. Yes.
- 12 Q. And I think also it's fairly obvious that this was
  13 a situation at which, if one can say it, money was
  14 little object.
- 15 A. Indeed, yes.
- 15 A. Indeed, yes.
- 16
   Q. Now, you give a date of 27 July 2020 in relation to the

   17
   Pfizer-BioNTech vaccine, and of the Moderna vaccine, and
- 18  $\hfill I$  think then you say that globally vaccines against
- 19 COVID-19 fall into one of three categories.
- 20 A. Yes.
- 21- Q. It's perhaps useful if you just explain this. I think
- 22 we probably touched on it a little yesterday in relation
- 23 to viral vector vaccines.
- 24 A. Yes.
- 25~ Q. Perhaps you could just explain the difference  $\,--$  well,
  - 70

1		what each category of vaccine is and what are the
2		differences .
3	Α.	Yes. So a vaccine works by presenting antigens from the
4		pathogen to the body's immune system, and the pathogen
5		is surrounded by a number of molecules that the body's
6		immune system will recognise as foreign, and the trick
7		is to work out which of these molecules are particularly
8		antigenic, which are the ones that especially trigger an
9		immune response, and then put those into your vaccine
10		and, in that way, trigger an immune response before the
11		body is exposed to the pathogen.
12		So component vaccines, in very crude terms, are
13		conventional vaccines. You could regard them as being
14		mashed up viruses; mash them all up and inject them into
15		the person. It's not quite as simple as that because,
16		in general, there's an attempt to try and extract some
17		components from the whole architecture of the virus and
18		put them into the body, if you like, preferentially .
19		But that's a very rough way of looking at conventional
20		vaccines.
21	Q.	Can you give an example of a conventional vaccine?
22	Α.	Yes. For example, a conventional vaccine would be, for
23		instance, the smallpox vaccine, which was efficient in
24		eradicating smallpox in 1978, and that was effective
25		because smallpox is a DNA virus, and DNA viruses are
		71

1 more stable. Therefore, if you achieve immunity against 2 smallpox, you will never get smallpox. So you can 3 vaccinate against smallpox and it will be very effective 4 for your whole life. So that was a conventional 5 vaccine. 6 Q. And coronaviruses are RNA viruses? A. Well, this is the next sort of vaccine. It's possible 7 8 to have a conventional vaccine against coronaviruses, 9 because you just mash up the virus and inject it into 10 patients, and, in very crude terms, that was what was 11 done with the conventional technology that produced 12 conventional vaccines. 13 Q. Right. A. But there was a new approach, which was a genetic 14 15 approach, to COVID-19. It had been tried out over about 16 the previous decade, really since SARS, and the idea of 17 the genetic approach really was to instruct the body of 18 the host, the human host, to produce antibodies that 19 would stop the virus from entering the cells . 20 So we mentioned the spike protein earlier on that is 21 the Yale key that attaches to the receptor on the cells. 22 fuses with the receptor and opens the cell membranes so 23 that the virus can get into the cells . So the spike 2.4 protein, based on earlier research with SARS, the 25 original SARS virus, was judged correctly to be, if you

- 1 like, the key to achieve entry into the cells and so, 2 therefore, was the target for the genetic approach to
- 3 designing vaccines.
- 4 Q. Now, you refer also to viral vector vaccines against 5 these --
- 6 A. Yes.
- 7 Q. -- and that is, you say, using novel technology.
- 8 A. Yes.
- 9 Q. Can you explain, please.
- 10 A. Yes. So there are two ways of instructing the cell to 11 produce antibodies against -- actually, I jumped ahead 12 a bit. You're instructing the cell -- vou're 13 instructing the body to produce spike protein, and then 14 the immune system of the body then recognises that spike 15 protein and produces antibodies. I should have made 16 that clear. That's the way vaccines based on genetic 17 approaches work: they instruct the body to produce spike 18 protein, so you produce spike protein, and then your 19 immune system recognises a spike protein and responds to 2.0 that by producing antibodies.
- 20 that by producing antibodies.
- 21 So viral vector vaccine, they work by modifying 22 harmless viruses that are not going to produce disease
- harmless viruses that are not going to produce disease when they're injected into an individual, and the
- 23 when they re injected into an individual, and the 24 viruses are modified so they're carrying the DNA -- DNA
- 24 viruses are modified so they re carrying the DNA -- DNA
   25 being genetic code -- that instructs the body to

- 1 produce -- manufacture spike protein. 2 The RNA viruses work slightly differently. They're 3 carrying messenger RNA, which goes into the cells, into 4 the nucleus of the cells , and the nucleus -- and then 5 the -- and then -- can I just check this one, my Lord. 6 Essentially, the end result is that the cells 7 likewise produce spike protein, but through two slightly 8 different approaches. 9 Q. Right. 10 You have set out or taken a table which you can find 11 at page 44 --12 A. Yes Q. -- of your report, and I think at the bottom of page 43, 13 you say that the distinction between conventional and 14 15 novel technology vaccines are shown the table overleaf. 16 A. Yes 17 Q. And the first three categories in the table are shown, 18 and these are: live attenuated vaccines --19 A. Yes. 2.0 Q. -- inactivated, killed-off whole-cell vaccines, and 21 component vaccines. So the component vaccine was the 2.2 one that you were referring to in your text. 23 A. Yes. Yes. Yes 24 Q. But thereafter we are looking at novel technology.
- 25 Does that have any meaning other than the fact it is

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- 1 new? So "novel technology". Or does it imply something 2 beyond it being a newly developed technique? 3 A. It's a way of categorising vaccines that is helpful. 4 The first two categories are really the traditional 5 ways. The component vaccines are kind of relatively modern ways by which they try and identify particular 6 7 components of the pathogen that are likely to be especially immunogenic, and the components are 8 9 concentrated in the vaccine, so they are an advance on 10 the earlier two categories. Then the two bottom 11 categories are the genetic approaches to producing 12 vaccines. 13 Q. So those two categories are the viral vector vaccines --14 A. That's right, yes. 15 Q. -- and the nucleic acid vaccines. A. Exactly, yes. Yes. 16 17 Q. And I think we can see that COVID-19 falls within both 18 the viral vector vaccines and the nucleic acid vaccines. 19 A. Yes 20 Q. But also within the component vaccines, which I think 21 you've explained as the -- you put it as the mashed-up 2.2 vaccine. 23 A. Yes. That's right. So just to re -- the viral vector 24 vaccines carry DNA that codes for spike protein. They 25 go into the nucleus and the nucleus produces 75 1 messenger RNA, which goes into the ribosomes, which produce the spike protein. The bottom category have RNA 2 3 which sort of bypasses the first process: the RNA goes 4 straight to the ribosomes and produces spike protein. 5 We can perhaps elaborate on that a little bit later. 6 It comes a bit later in my report. 7 Q. Yes 8 At page 45, at the top, you say that in the States, 9 two mRNA vaccines were approved -- well, received 10 emergency use authorisation in December 2020 by the FDA. 11 A. Mm 12 Q. These were the Moderna vaccine for use in individuals 13 18 and over, and the Pfizer BioNTech vaccine, again for use in a similar -- not quite similar, 16 or over age 14 15 group.
  - 16
     So you pass on, then, to look at the initial COVID

     17
     vaccines procured in the UK, and I think -- again,
  - 18  $\hfill taking this short <math display="inline">--$  you've listed four vaccines there:
  - 19 the AstraZeneca, the Janssen, the Moderna and the
  - 20 Pfizer-BioNTech.
  - 21 A. Yes.
  - 22  $\,$  Q. I think at the bottom of page 45, you notice that the
  - 23 UK Government did announce in April 2021 that 20 million
  - 24 doses of the Janssen vaccine had been ordered from the
  - 25 manufacturer, but you go on to say that this vaccine has

2 Α. 3

4

5 Q.

6 7 A.

8 Q.

9

10

11 Α.

12 Q.

13

14

15 Α.

16 Q

17

18 19 20

21

22

23 24

never been used in the UK.	1		virus, so yo
Yes. That's my understanding. Later on, I think we may	2	Q.	Yes.
have time to consider the MHRA report, and they have	3	<b>_</b> .	l think
nothing to say about the Janssen vaccine because it	4		note that the
hasn't actually been used on the public.	5		was that CO
Am I right in thinking that it was used in Ireland?	6		a two-dose
I believe it was used in Ireland, yes. Yes, it was.	7		each dose.
But we don't at present $$ and you are not able to	8	A.	Yes. Some
assist us in knowing what happened post the ordering of	9		interval, bu
20 million doses?	10		then an inte
Where the order went to, we don't know. We don't know.	11	Q.	And again –
The following page, at 46, you deal with later $COVID-19$	12		That was the
vaccines procured in the UK. Again, you've provided	13		I think
these, and I think this takes us into booster use.	14		is obviously
Yes.	15		ability of th
I think you've set that out in the second paragraph.	16	A.	Yes. Yes.
Then, at 2.36 of your report, you talk about the	17	Q.	So there cou
current vaccination programme against COVID-19 in the	18		Yes.
UK, and you summarise that. I think you say, to begin	19	Q.	Yes.
with, that the three fairly obvious aims were:	20		One poir
"- to provide protection for individuals who are	21		the middle o
considered at highest risk of severe illness or death	22		COVID-19
from COVID	23		course.
"- to reduce hospitalisations; and	24	Α.	Yes.
"- to protect frontline health and social care staff	25	Q.	Has that alw
77			
from exposure."	1	A.	lt's a stand
Yes.	2		strategy tha
And I think that you then go on to indicate that all UK	3		or three dos
adults and children aged five and a half or over are	4		for each of t
currently eligible for a primary vaccination course.	5		slightly dif
Just explain what a primary vaccination course is.	6		immunity by
It probably is obvious, but just tell us.	7		use.
I think I might have the wrong citation, I do beg your	8	Q.	Right. Now
pardon. That citation should be to the British National	9		at the way in
Formulary.	10	A.	Yes.
Oh, right. Well, with that correction, can you just	11	Q.	You look firs
tell us what a primary vaccination course is.	12		vaccines
Primary vaccination means the initial exposure of the	13	Α.	Yes.

25

- 1
- 2 Α.
- 3 Q. 4
- 5
- 6 7
- 8
- Α. 9 10
- 11 Q. 12
- 13 A. Primary vaccination means the initial exposure of the
- 14 recipient to the vaccine. So some vaccines are just
- 15 a one-off exposure, just one vaccine will give you
- 16 protection for life . Some require two or three
- 17 sequential vaccines separated by a defined time interval
- 18 in order to achieve immunity to the pathogen being
- 19 immunised against.
- 20 Q. Yes.
- 21 A. So, for example, the hepatitis B vaccination, which
- 2.2 I have had, which all doctors have to have, it's
- 23 normally three courses of hepatitis B vaccine that you
- 24 have over a period of six months, and that generally
- 25 gives lifelong immunity to hepatitis B, which is a DNA

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- so you would expect that. think at page 47, the first full paragraph, you hat the manufacturers' initial advice during 2021 nat COVID-19 vaccines should be administered as -dose schedule with three to four weeks between lose. Some manufacturers had a slightly different al, but the idea was there should be a first dose, in interval of some weeks and then a second dose. gain --was the idea. think with other things that we will look at, that viously dependent on the willingness and the of the person to attend for the second dose. Yes ere could be some failures in that programme. ne point you raise -- it's a single paragraph in iddle of page 47 -- is that where possible the same D-19 vaccine should be used for the entire primary at always been possible, do you know? 79 standard principle of immunisation technique -gy that when you have a vaccine that requires two ee doses, you will try and use the same vaccine ch of those doses, because vaccines tend to work
  - ly differently , and you may not achieve proper nity by chopping and changing as to what vaccine you

  - Now, in the next two sections, doctor, you look
  - way in which novel COVID-19 vaccines work.
- ook first at vector vaccines and then mRNA
- 13 Α. Yes
- Q. -- going over on to page 48. Again, I will, with 14
- 15 respect, take that as read from you without going into 16
  - the detail of it. But I would like to look, please, at 2.39 at page 49, which are booster doses.
- 17 18 A. Yes.

25

- 19  $\mathsf{Q}.\;$  And I think you note at the beginning that in
- 2.0 September 2021, Israel became the first country to
- 21 demonstrate waning protection from Pfizer vaccine,
- 22 showing a decline in protection even against severe
- 23 disease at around six months. This was perhaps the --
- 2.4 at least the booster, for boosters, I suppose, if I can
  - put it that way.

- 1 A. Yes.
- 2 Q. This was something that set us on the trail of booster 3 doses
- 4 A. Indeed, I think it had been hoped that boosters wouldn't 5 be necessary. Clearly the hope was that two doses would
- give extensive protection for a long period of time, but 6
- 7 it became apparent this wasn't the case and the idea of 8 boosters then came in.
- 9 Q. I think you say -- perhaps it would be useful to note --
- 10 in the penultimate paragraph on page 49 that:
- 11 "Protection against hospitalisation after an mRNA 12 'booster' reaches over 90% in the 2 weeks after
- 13 vaccination and then declines towards a stable plateau
- 14 of around 60% by 6 months."
- 15 Again, is that something that was expected?
- A. With hindsight, and given the -- as you described it, 16
- 17 Mr Gale -- fact that we were dealing with a moving
- 18 target, it should have been expected, but I don't think
- 19 that was conveyed to the general public as a likely
- 2.0 outcome. Certainly in England the expectation was we
- 21 went into lockdown, but the vaccines were coming and
- 22 they would release us from lockdown and everything would
- 23 return to normal pretty much straight away.
- 24 Q. Yes. So you set out at the bottom of page 49 the 25
  - current UK practice in relation to the offering of

- 1 a first booster. Perhaps you would just take us through 2 that, please 3 A. Shall I read it out? 4 Q. Yes, please. 5 A. So: 6 "Current UK practice ..." 7 And this is drawn from the latest text in the 8 Green Book which I've got here, which is April 2023, 9 I believe: 10 "... is to offer a first 'booster' ... at least 11 3 months after completion of primary immunisation to the 12 following groups ... " And there are three groups: firstly , all individuals 13 14 aged 16 and over; secondly, children aged 12 to 15 years 15 in clinical at-risk groups or who are household contacts 16 of immunosuppressed individuals; and thirdly, children 17 aged 5 to 11 years with severe immunosuppression. 18 Q. Perhaps just carry on --19 A. Yes. 20  $Q_{-}$  - to the bottom of that section, doctor. 21 A. And then as well as boosters of the primary courses. 2.2 also seasonal boosters that are programmed for spring 23 and autumn every year. And the current UK practice is
- 24 a seasonal booster, in addition to any booster you might
- 25 already have had for your primary course, to be offered,

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- 1 provided there has been an interval of at least 2 three months from the previous dose, to the following 3 groups, and there are six groups here. 4 Firstly, residents of and staff working in care 5 homes for older adults. Secondly, frontline health and social care workers. Thirdly, all individuals aged 6 7 50 years and over. Fourthly, individuals aged 5 years and above in a clinical at-risk group. Fifthly, 8 9 individuals aged 5 years and over who are household 10 contacts of immunosuppressed individuals. And finally, 11 individuals aged 16 years and over who are carers. 12 Q Yes. You go on now to discuss specific patient groups. 13 The first group you look at are pregnant females, and 14 I think we've already touched on this matter. 15 A. Yes. 16 Q. But you say that current UK advice is that pregnant 17 females should be offered immunisation against COVID-19 18 as pregnancy is a risk factor for severe COVID 19 infection . 20 A. Yes 21 Q. So it's looking at it from that perspective, from the 22 risk of infection? 23 A. Yes 24 Q. I think also we have individuals with severe 25 immunosuppression. Again, we've touched on this. 83 1 Perhaps it would be useful at this stage if you gave
  - an indication of what is understood in the public health field as severe immunosuppression. A. Yes. So immunosuppressed people are those whose immune system doesn't work -- either doesn't work at all or
  - 6 doesn't work efficiently to protect them against
  - 7 pathogens.
  - 8 Q. Yes.

2

3

4

5

- 9 A. And that could be because they have disease, either
- 10 a chronic general disease such as diabetes or
- 11 cardiovascular disease or kidney disease, or because
- 12 they've got a disease specific to their immune systems
- 13 like leukaemia, so they have no white cells or very few
- 14 white cells; or alternatively they may -- or HIV
- 15 disease, which is a disease of a subset of the white
- 16 cells ; or alternatively they may be taking
- 17 immunosuppressant drugs such as steroids or some of the
- 18 current anticancer drugs, for example, methotrexate or
- 19 monoclonal antibodies, and they work by deliberately
- 20 suppressing the immune system so as to dampen down the
- 21 inflammatory reaction of the body.
- 2.2 Q. I think what you say at the bottom of page 50 is 23 effectively a summary of what is contained in the
- 24 previous two paragraphs, particularly about children.
- 25 A. Yes

Day 2

_	- ·	···· 8- ··· ·-, F-8- · ··· ··F ·····	
2		"Current UK advice is that people with HIV	
3		infection, regardless of their CD4 count, should	
4		likewise be offered a third dose of [COVID] as part of	
5		the primary course, along with subsequent 'booster'	
6		doses."	
7	Α.	Yes.	
8	Q.	You now look briefly at an area that you entitle "How	
9		safe are COVID $-19$ vaccines?", and you begin with	
10		thromboembolic clotting events. Perhaps you would just	1
11		read through that, please.	1
12	Α.	Yes:	1
13		"Thromboembolic (clotting) events.	1
14		"In early 2021 there were multiple reports of	1
15		vaccine-induced immune thrombocytopaenia [that means low	1
16		platelets ] and thrombosis [that means clotting] (VITT)	1
17		with the adenovirus vector vaccines Vaxzevria [which is	1
18		the AstraZeneca vaccine, the Oxford vaccine] and	1
19		Nuvaxovid [which is a Janssen vaccine]. VITT is	1
20		a severe but rare blood clotting condition; it develops	2
21		within 5 to 30 days of receiving vaccination."	2
22	Q.	When you say that there were multiple reports, do we	2
23		have a figure for those reports?	2
24	Α.	We have one later on. We do, yes. The citation I was	2
25		using here, which was the British National Formulary,	2
		85	
1		doesn't particularly mention the figure, but there is	
2		a figure, yes.	
3	Q.	Yes, okay. We will come to that in due course.	
4	Α.	Yes.	
5	Q.	And as you say, as from early 2023, AstraZeneca was not	
6		routinely supplied in the UK, and Janssen, as we've	
7		already heard, was initially procured but has never been	
8		supplied .	
9	Α.	Yes.	
10	Q.	The second area of safety you look at is myocarditis.	1
11		Again, if you would just read through that, please.	1
12	Α.	Yes:	1
13		"Myocarditis	1
14		"The mRNA that is delivered to cells [messenger RNA	1
15		that is delivered to cells ] following challenge with	1
16		COVID-19 nucleic acid vaccines (i.e. mRNA vaccines) is	1
17		said to be normally degraded within a few days.	1
18		"There have been reports of vaccine-associated	1
19		myocarditis [that means inflammation of the heart	1
20		muscle] with all COVID-19 mRNA vaccines."	2
21		Again, the quote there is from the British National	2
22		Fermeulen u	~

1~ Q. You also go on to say at page 51 at the top that:

21	Again,	the	quote	th
22	Formulary:			

- 23 "Although the mRNA monovalent Spikevax (Moderna) is
- 24 licensed in the UK for use in children aged [greater
- 25 than or equal to] 6 Years, current guidance is that the

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1		preferred COVID $-19$ vaccine for use in children is the
2		mRNA monovalent [Pfizer vaccine], due to a lower
3		reported rate of myocarditis [with the Pfizer vaccine]."
4	Q.	Right. You then go on to what are described as other
5		adverse effects .
6	Α.	Yes.
7	Q.	And we will come in due course to look at the Yellow
8		Card system and the report on that.
9	Α.	Yes.
10	Q.	What we have here is, I think, a reference to it which
11		is :
12		"A two—year analysis of Yellow Card reports (i.e.
13		spontaneously—reported vaccine adverse effects),
14		published in 2022 by the [MHRA], documented 2,362
15		spontaneous reports suggesting a fatal outcome following
16		COVID-19 vaccination; while of concern, the association
17		does not prove causality."
18		So you are noting there that, through the use of the
19		Yellow Card report, there have been documented over
20		2,000 spontaneous reports of a fatal outcome. Of course
21		that, as you say, is of concern. It does not prove
22		causality . Is that $$
23	Α.	lt doesn't, no.
24	Q.	Yes.
25	A.	Still , that would be a high number that one would not
		07
		87

1		expect to see with certainly most vaccines.
2	Q.	Yes. The other adverse events commonly reported are
3		include, and you have listed them there: Bell's palsy;
4		Guillain—Barré syndrome, which is ascending paralysis;
5		transverse myelitis, spinal cord inflammation; and
6		menstrual disorders and vaginal bleeding.
7	Α.	Yes.
8	Q.	Could you go on then and I think I'll ask you just to
9		read through the final section in this part of your
10		report, the future course of COVID $-19$ .
11	Α.	The future course of COVID-19:
12		"On 5 May the World Health Organization declared
13		that COVID-19 [was no longer] a public health emergency
14		of international concern.
15		"Epidemiological surveillance suggests that
16		SARS-CoV-2 [which is the cause of COVID-19] is now
17		becoming endemic (i.e. the virus is circulating at about
18		the same incidence over a long period of time);
19		endemicity is a feature of the four coronaviruses that
20		have been known for many years to cause mild to moderate
21		respiratory tract illness , including the common cold.
22		Potentially, SARS-CoV-2 can still cause severe illness
23		in those not previously exposed to the virus, either
24		through natural infection or through vaccination.
25		"It is possible to model the possible future

1	behaviour of SARS-CoV-2 infection; no model however will
2	be better than the assumptions on which it was built,
3	and disease models are typically phrased in mathematical
4	terms which can make them difficult to understand for
5	the non-mathematician, and also lend them an air of
6	exactitude that they seldom merit."
7	That's a quote from a great Swedish epidemiologist,
8	Johan Giesecke, who has written a really very good book
9	about infectious disease epidemiology.
10	Q. I think that's the final footnote, footnote 264.
11	A. Yes, it is.
12	MR GALE: Right.
13	My Lord, I wonder if I could take five minutes
14	simply to rearrange papers and $$
15	LORD BRAILSFORD: Of course, absolutely.
16	MR GALE: Before we go into the next set. It will only be
17	a few minutes.
18	LORD BRAILSFORD: Surely.
19	Five minutes then, ladies and gentlemen.
20	(12.37 pm)
21	(A short break)
22	(12.39 pm)
23	MR GALE: Dr Croft, going on to part 3 of your report.
24	A. Yes.
25	Q. You deal here with physical measures taken against
	89
	07
1	COVID-19. To a certain extent, this has already been
2	prefaced in what we've been looking at.
3	A. Yes.
4	Q. You begin with a section in block here, and it's headed
5	"Specific knowledge – pre–pandemic". This, I think,
6	derives from the Jefferson 2011 paper Cochrane review.
7	A. Yes, that summarised this state of knowledge, yes.
8	Q. I wonder if you would just, first of all, take us
9	through the key messages $$
10	A. Yes.
11	$Q. \$ and then we will look to a certain extent at the
12	supporting statistics . But if you take us to the key
10	

13 messages, they are set out in the block section at 14 page 54 of your report. 15 A. Yes. Yes. Yes. Thank you, my Lord. 16 These key messages I cut and pasted from the review 17 itself , in the plain language summary of the review, 18 which is on page 355. 19 Q. Yes. 20 A. I think it's right at the very bottom paragraph, page 355, six lines up: 21 22 "Respiratory virus spread can be reduced by hygienic 23 measures (such as handwashing) ...' 24 That's where all of that comes from. So these 25 aren't my words; these are word-for-word transcriptions 90

1		of the plain language summary key messages for
2		laypeople, essentially .
3	Q.	Well, perhaps before we do that, we can have a look at
4		the Cochrane review.
5	Α.	Yes.
6	Q.	So this is document number 8 within the bundle, and it's
7		at page 354. I think we can see there that the lead
8		author is Tom Jefferson, who was at that time at the
9		Centre for Evidence Based Medicine at Oxford.
10		Do you know Tom Jefferson?
11	Α.	Yes, I do know him. I haven't seen him for 20 years or
12		so, but I know him. He trained at Glasgow in medicine.
13	Q.	I think, just looking at some of the detail of this, the
14		publication status and date, it says that, albeit it's
15		2011: "Edited ([but] no change to conclusions),
16		published in issue 4, 2020". So there has been some,
17		presumably, iterative updating of the document, but as
18		it says, no change in conclusions.
19	Α.	Yes.
20	Q.	Then if we go on to the abstract, we can see that the
21		background is, it says:
22		"Viral epidemics or pandemics of acute respiratory
23		infections like influenza or severe acute respiratory
24		syndrome pose a global threat. Antiviral drugs and
25		vaccinations may be insufficient to prevent their
		91
1		spread."
2		That's the context in which the authors of the
3		Cochrane review were proceeding.
4	Α.	Yes.
5	Q.	Then set out are the objectives, and it seems a single
6		objective :
7		"To review the effectiveness of physical
8		interventions to interrupt or reduce the spread of
9		respiratory viruses."
10	Α.	<b>N</b> <i>A</i> <b>A</b>
11		Mm-hm.
	Q.	Mm—hm. We then have a passage on search methods, and I think we
12	Q.	
	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria,
12	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that.
12 13	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria,
12 13 14	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says:
12 13 14 15	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says: "In this update, two review authors independently
12 13 14 15 16	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says: "In this update, two review authors independently applied the inclusion criteria to all identified and
12 13 14 15 16 17	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says: "In this update, two review authors independently applied the inclusion criteria to all identified and retrieved articles and extracted data. We scanned 3775
12 13 14 15 16 17 18	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says: "In this update, two review authors independently applied the inclusion criteria to all identified and retrieved articles and extracted data. We scanned 3775 titles , excluded 3560 and retrieved full papers of 215
12 13 14 15 16 17 18 19 20 21	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says: "In this update, two review authors independently applied the inclusion criteria to all identified and retrieved articles and extracted data. We scanned 3775 titles , excluded 3560 and retrieved full papers of 215 studies, to include 66 papers of 67 studies. We
12 13 14 15 16 17 18 19 20 21 22	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says: "In this update, two review authors independently applied the inclusion criteria to all identified and retrieved articles and extracted data. We scanned 3775 titles , excluded 3560 and retrieved full papers of 215 studies, to include 66 papers of 67 studies. We included physical interventions (screening at entry ports, isolation , quarantine, social distancing, barriers , personal protection , hand hygiene) to prevent
12 13 14 15 16 17 18 19 20 21 22 23	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says: "In this update, two review authors independently applied the inclusion criteria to all identified and retrieved articles and extracted data. We scanned 3775 titles , excluded 3560 and retrieved full papers of 215 studies, to include 66 papers of 67 studies. We included physical interventions (screening at entry ports, isolation , quarantine, social distancing, barriers , personal protection , hand hygiene) to prevent respiratory virus transmission. We included randomised
12 13 14 15 16 17 18 19 20 21 22	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says: "In this update, two review authors independently applied the inclusion criteria to all identified and retrieved articles and extracted data. We scanned 3775 titles , excluded 3560 and retrieved full papers of 215 studies, to include 66 papers of 67 studies. We included physical interventions (screening at entry ports, isolation, quarantine, social distancing, barriers , personal protection, hand hygiene) to prevent respiratory virus transmission. We included randomised controlled trials cohorts, case—controls,
12 13 14 15 16 17 18 19 20 21 22 23	Q.	We then have a passage on search methods, and I think we can, with respect, pass over that. Then some information about selection criteria, which may be quite interesting just to read. It says: "In this update, two review authors independently applied the inclusion criteria to all identified and retrieved articles and extracted data. We scanned 3775 titles , excluded 3560 and retrieved full papers of 215 studies, to include 66 papers of 67 studies. We included physical interventions (screening at entry ports, isolation , quarantine, social distancing, barriers , personal protection , hand hygiene) to prevent respiratory virus transmission. We included randomised

1		And then we go on to see, on the following page at
2		355, the main results.
3		Now, these are obviously preparatory to what is
4		contained within the plain language study. I think it
5		might be useful, doctor, if you would just read out what
6		were the main results, so far as the authors were
7		concerned at that time.
8	Α.	Yes. So "Main results". This is on page 355, my Lord:
9		"We included 67 studies including randomised
10		controlled trials and observational studies with a mixed
11		risk of bias. A total number of participants is not
12		included as the total would be made up of a heterogenous
13		set of observations (participant people, observations on
14		participants and countries (object of some studies)).
15		The risk of bias for five [randomised controlled trials]
16		and most cluster-[randomised controlled trials] was
17		high. Observational studies were of mixed quality.
18		Only case-control data were sufficiently homogeneous to
19		allow meta-analysis. The highest quality
20		cluster – [randomised controlled trials] suggest
21		respiratory virus spread can be prevented by hygienic
22		measures, such as handwashing, especially around younger
23		children. Benefit from reduced transmission from
24		children to household members is broadly supported also
25		in other study designs where the potential for

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1		confounding is greater. Nine case-control studies
2		suggested implementing transmission barriers, isolation
3		and hygienic measures are effective at containing
4		respiratory virus epidemics. Surgical masks or N95
5		respirators were the most consistent and comprehensive
6		supportive measures. N95 respirators were non-inferior
7		[meaning they were the same] to simple surgical masks
8		but more expensive, uncomfortable and irritating to
9		skin. Adding virucidals or antiseptics to normal
10		handwashing to decrease respiratory disease transmission
11		remains uncertain. Global measures, such as screening
12		at entry ports, led to a non-significant [meaning
13		statistically non-significant] marginal delay in spread.
14		There was limited evidence that social distancing was
15		effective , especially if related to the risk of
16		exposure."
17	Q.	Right.
18		Just as a matter of detail $$ and I think we will
19		come to look at this in some detail later on $$ N95
20		respirators , what are they?
21	Α.	I would hope they would define them, but they're clearly
22		some kind of advanced respirators which isn't just
23		a cloth mask. They must incorporate some kind of
24		screen.
25	~	

- 25~ Q. So it's not sort of an advanced form of surgical mask;
  - 94

1	it is something $$
2	A. No.
3	Q. And clearly they have the potential, as is observed
4	there, to be uncomfortable and irritating.
5	A. Yes.
6	LORD BRAILSFORD: What does respirator mean?
7	A. A respirator is a gas mask, basically. So it's not just
8	relying on cloth; it's relying on some kind of screen or
9	mesh. Certainly military gas masks, which I'm familiar
10	with, there's a charcoal filter as well. So the air
11	goes through a filter . But it's one step up from
12	surgical masks.
13	But in any event, they are no more effective than
14	surgical masks.
15	MR GALE: Right.
16	Doctor, we go on, then, to the authors' conclusions,
17	which are just in two lines. Would you read those out,
18	please.
19	A. "Authors' conclusions
20	"Simple and low-cost interventions would be useful
21	for reducing transmission of epidemic respiratory

- 2.2 viruses . Routine long-term implementation of some
- 23 measures assessed might be difficult without the threat
- 24 of an epidemic."
- 25 Q. Then we have the plain language summary which forms the

#### 95

- basis for what is on page 54 of your report.
- 2 A. Yes.

1

5

6

- 3 Q. So from whichever source you want, can you read out what
- 4 the plain language summary and the key messages are.
  - A. Yes. Shall I just go to the second paragraph, Mr Gale?
  - Q. Yes.
- 7 A. The first paragraph is the background. So second 8 paragraph:
- 9 "We included 67 studies ..."
- 10 Mixed risk of bias for the observational studies,
- 11 and that's a reference to the hierarchy of evidence.
- 12 They are saying there are observational studies, but
- 13 they are likely to be biased; some of them very biased, 14 some of them slightly biased.
- 15 Then they go on to say, third line down -- this is 16 where I take up my direct quotation:
- 17 "Respiratory virus spread can be reduced by hygienic 18 measures (such as handwashing), especially around
- 19 younger children. Frequent handwashing can also reduce
- 20 transmission from children to other household members." 21 My third bullet point was the next one:
- 22 "Implementing barriers to transmission, such as
- 23 isolation, and hygienic measures (wearing masks, gloves 24 and gowns) can be effective in containing respiratory
- 25 virus epidemics or in hospital wards."

1	I think there are some words missing. I think there	1		language summary which you replicate. It's page 54 of
2	were probably some words there, "in clinics or in	2		your report.
3	hospital wards", because they're quite emphatic that the	3		I wonder if we could just look a little more at that
4	evidence for these barriers to transmission is strong	4		Jefferson paper.
5	for healthcare environments, but it isn't strong in the	5		Could you go, please, to page 367 within the paper.
6	community generally.	6	A.	Yes.
7	Q. So we shouldn't just restrict it to hospital wards?	7	Q.	I think we can see there that there's a summary of the
8	A. Well, we should restrict it, but hospital wards and	8		evidence. Again, it's perhaps a slightly arduous task,
9	clinics .	9		but I wonder if you would just read through that, so we
10	Q. Yes.	10		have that into the notes, please.
11	A. I think that's what they are saying, yes, but they are	11	А.	Yes. So the evidence seems to be mainly based on
12	saving there's not much evidence that these type of	12		cluster randomised trials, and we know what they are
13	barriers are useful in the community, although of course	13		now. So:
14	they're relatively cheap.	14		"The highest quality cluster – randomised trials
15	"We found no evidence that the more expensive,	15		indicate most effect on preventing respiratory virus
16	irritating and uncomfortable N95 respirators were	16		spread from hygienic measures in younger children.
17	superior to simple surgical masks. It is unclear if	17		Perhaps this is because younger children are least
18	adding virucidals [chemicals that kill viruses] or	18		capable of hygienic behaviour themselves and have
19	antiseptics to normal handwashing with soap is more	19		longer-lived infections and greater social contact,
20	effective ."	20		thereby acting as portals of infection into the
21	So they're saying probably handwashing with soap is	20		household Additional benefit from reduced
22	probably as effective as the more complex agents:	21		transmission from them to other members of the household
23	"There is insufficient evidence to support screening	23		is broadly supported by the results of other study
24	at entry ports and social distancing (spatial separation	23		designs where the potential for confounding is greater."
24	of at least one metre between those infected and those	24		Shall I carry on?
20	of at least one metre between those infected and those	2.5		
	97			99
1	non—infected) as a method to reduce spread during	1	Q.	Yes. Just carry on reading for the extent of the
2	epidemics."	2		evidence summarised.
3	And the reason there is insufficient evidence is	3	Α.	Sure.
4	probably because high-quality randomised controlled	4		"The pooled case—control studies [and those are
5	trials haven't been done.	5		level Ib evidence], which focused on the SARS
6	Most of the data is, they admit, taken from	6		coronavirus suggest that implementing barriers to
7	case-controlled studies, level IIb evidence, and studies	7		transmission, isolation and hygienic measures are
8	that are even less powerful evidence than	8		effective with the use of relatively cheap interventions
9	case-controlled studies; this is in contrast with the	9		to contain respiratory virus epidemics. We found
10	later review, which they focus very much on randomised	10		limited evidence of the superior effectiveness of
11	controlled trials .	11		devices such as the N95 respirator over simple surgical
12	MR GALE: Perhaps we can look at the later review after	12		masks. This evidence is supported by a high quality
13	lunch.	13		hospital-based trial $\dots$ which reports non-inferiority
14	My Lord, it might be an appropriate point to pause.	14		between face barriers [meaning face masks are the same
15	LORD BRAILSFORD: Very good.	15		as N95 respirators]. Overall masks were the best
16	Again, we stop a little early, so we will come back	16		performing intervention across populations, settings and
17	a little earlier . About 1.40, please.	17		threats. More expensive and uncomfortable (especially
18	(12.53 pm)	18		if worn for long periods) than simple surgical masks,
19	(The short adjournment)	19		N95 respirators may be useful in very high-risk
20	(1.40 pm)	20		situations but additional studies are required to define
21	LORD BRAILSFORD: Right, good afternoon, everyone.	21		these situations.
22	Mr Gale, when you're ready.	22		"It is uncertain whether the incremental effect of
23	MR GALE: Thank you, my Lord.	23		adding virucidals or antiseptics to normal handwashing
	5 . 5			6
24	Dr Croft, we were looking at the Cochrane review,	24		actually decreased the respiratory disease burden

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1		upon which we reported. The extra benefit may have
2		
2 3		been, at least in part, accrued by confounding
		additional routines.
4		"Studies preventing transmission of [respiratory
5		syncytial virus] and similar viruses appeared to be
6		closer to real life and suggest good effectiveness.
7		However, methodological quality concerns of the
8		controlled before and after studies, mentioned
9		previously, suggest benefits may have been due to
10		population differences, especially virus infection
11		rates. These were poorly reported in most studies.
12		"Routine long—term implementation of some of the
13		measures assessed in this review would be problematic,
14		particularly maintaining strict hygiene and barrier
15		routines for long periods of time. This would probably
16		only be feasible in highly motivated environments, such
17		as hospitals, without a real threat of a looming
18		epidemic. Most of the trial authors commented on the
19		major logistic burden that barrier routines imposed at
20		the community level. However, the threat of a looming
21		epidemic may provide stimulus for their inception.
22		"A disappointing finding was the lack of proper
23		evaluation of global and highly resource-intensive
24		measures such as screening at entry ports and social
25		
20		distancing. The handful of studies (mostly conducted
25		<b>.</b>
20		101
		101
1 2		<b>.</b>
1 2		101 during the SARS epidemic) do not allow us to reach any firm conclusions."
1 2 3		101 during the SARS epidemic) do not allow us to reach any firm conclusions." They end by saying:
1 2 3 4		101 during the SARS epidemic) do not allow us to reach any firm conclusions." They end by saying: "It is remarkable that despite a long lead time to
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21 A. Yes.

 $\begin{array}{rrrr} 22 & \mbox{Q. I think they then go on to say that, in a way, attention} \\ 23 & \mbox{might be focused were there to be a more urgent and} \end{array}$ 

- pressing pandemic problem.
- 25 A. Yes.

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1	Q.	Obviously, that perhaps leads us conveniently on to
2		where we are now.
3	Α.	Yes, indeed.
4	Q.	Would you look, please, at the authors' conclusions at
5		367 on the right—hand column.
6	Α.	Yes.
7	Q.	I think what the authors say there $$ they divide it
8		into two sections. One is "Implications for
9		practice" ——
10	Α.	Yes.
11	Q.	and then they go on to "Implications for research".
12		For present purposes, can we just look at the
13		implications for practice.
14	Α.	Yes.
15	Q.	I think what they highlight there:
16		"The following effective interventions should be
17		implemented, preferably in a combined fashion, to reduce
18		transmission of viral respiratory disease "
19		They then listed:
20		"1. frequent handwashing with or without adjunct
21		antiseptics ;
22		"2. barrier measures such as gloves, gowns and masks
23		with filtration apparatus; and
24		"3. suspicion diagnosis with isolation of likely
25		cases.

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1		"Special efforts should be focused on implementing
2		the three above interventions in order to reduce
3		transmission from young children, who are generally the
4		most fecund sources of respiratory viruses."
5		I think anybody who has had a child will know that
6		getting a child to wash their hands is probably one of
7		the larger difficulties of parenthood.
8	Α.	Yes.
9	Q.	For completion, doctor, can we go to pages 464 to 466
10		within that, so the last few pages in the first volume,
11		my Lord.
12	Α.	Yes.
13	Q.	I think there we see the summary. Table 2 is the
14		summary of main events.
15	Α.	Yes.
16	Q.	${\sf I}$ think we can see the events that were considered by
17		the authors utilising the randomised trials went from
18		handwashing, handwashing with an antiseptic, surface
19		disinfection , gargling with iodine ,nose wash, etc. $\ensuremath{ I'm}$
20		not going to go through them all. But that's a summary
21		in tabular form of the results which they obtained.
22	Α.	Yes.
23	Q.	Right.
24	Α.	Just commenting on that, obviously the left-hand column
25		is the most reliable evidence, and then there's slightly

1		less $$ the left two columns are the randomised
2		controlled trials, and then as you go to the right, you
3		get less and less reliable evidence.
4	0	Could we go to the other Cochrane review, which is
5	Q.	document 9. Could we go to page 477. It's the first
		5 1 5
6		document in the second volume, my Lord.
7		Now, this is the Jefferson Cochrane review of 2023.
8	Α.	Mm-hm.
9	Q.	And, again, we can see, at page 477, that its
10		publication status and date is that it has been edited,
11		no change to conclusions, and it was published in 2023.
12		No precise date is given.
13		Again, looking at the abstract, we can see there
14		that there's something that we've already read, but
15		I think it goes further, where it says:
16		"Viral epidemics or pandemics of acute respiratory
17		infections pose a global threat. Examples are
18		influenza (H1N1) caused by the H1N1 $\dots$ virus in 2009,
19		severe acute respiratory syndrome (SARS) in 2003, and
20		coronavirus disease 2019 (COVID-19)"
21		So just getting the context, we have material in
22		here which has regard to the circumstances of the COVID
23		pandemic.
24	Α.	Yes, we have now. Yes, indeed.
25	Q.	It goes on to say:

1		"Antiviral drugs and vaccines may be insufficient to
2		prevent their spread."
3		I think that's something that was also observed in
4		the Cochrane 2011 abstract.
5		It says:
6		"This is an update of a Cochrane Review last
7		published in 2020 [which I think we've seen]. We
8		include results from studies from the current COVID $-19$
9		pandemic."
10	Α.	Yes.
11	Q.	So we have information informed by the experience of
12		that pandemic.
13	Α.	Mm-hm.
14	Q.	Again, the objectives:
15		"To assess the effectiveness of physical
16		interventions to interrupt or reduce the spread of acute
17		respiratory viruses."
18	Α.	Yes.
19	Q.	I'm not going to read through them, but there's then
20		selection criteria and data collection and analysis.
21		If one goes over to the next page $$
22	Α.	Yes.
23	Q.	478, we see a passage that begins "Main results".
24		Again, I don't intend to go through that in any detail
25		at this stage, but I think the potential measures are

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1		then grouped: "Medical/surgical mask compared to no
2		masks", "N95/P2 respirators compared to medical/surgical
3		masks", and then "Hand hygiene compared to control".
4		Then we find the authors' conclusions there, and
5		perhaps you would read through that, Dr Croft, so again
6		we have it in the evidence.
7	Α.	Yes. Authors' conclusions from the January 2023
8		Jefferson updated review:
9		"The high risk of bias in the trials , variation in
10		outcome measurement, and relatively low adherence with
11		the interventions during the studies hampers drawing
12		firm conclusions. There were additional RCTs
13		[randomised controlled trials] during the pandemic
14		related to physical interventions but a relative paucity
15		given the importance of the question of masking and its
16		relative effectiveness and the concomitant measures of
17		mask adherence which would be highly relevant to the
18		measurement of effectiveness, especially in the elderly
19		and in young children.
20		"There is uncertainty about the effects of face
21		masks. The low to moderate certainty of evidence means
22		our confidence in the effect estimate is limited, and
23		that the true effect may be different from the observed
24		estimate "
25		I think they mean the calculated estimate of the
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1		effect :
2		"The pooled results of RCTs did not show a clear
3		reduction in respiratory viral infection with the use of
4		medical/surgical masks. There were no clear differences
5		between the use of medical/surgical masks compared with
6		N95/P2 respirators in healthcare workers when used in
7		routine care to reduce respiratory viral infection.
8		Hand hygiene is likely to modestly reduce the burden of
9		respiratory illness , and although this effect was also
10		present when [influenza-like illness ] and
11		laboratory-confirmed influenza were analysed separately,
12		it was not found to be a significant difference for the
13		latter two outcomes. Harms associated with physical
14		interventions were under—investigated."
15		Finally ——
16	Q.	Just pausing on that, the reference to, "Harms
17		associated with physical interventions were
18		$under-investigated", it's\ not\ expanded\ upon\ there.$ What
19		do you understand by that comment?
20	Α.	Well, "harms" is a broad term encompassing everything
21		from inconvenience to death, and probably also including
22		economic costs and societal costs. That, I think, is
23		what they're getting at; that some of the interventions
24		carry a very modest or almost no risk of harm, and they
25		would probably include $$ and almost none $$ they would

1 include, probably, handwashing. They say you don't want 2 to wash your hands too often at one point. So they 3 would carry almost no risk of harms. But other 4 interventions -- and here I think they would include social distancing and -- would have a greater risk of 5 6 harm. 7 They talk about the harms of closing international 8 boundaries, and there I think they are just talking 9 about the economic and the harms to people wanting to 10 travel. That's a basic -- a fundamental restriction on 11 our civil liberties . So those are harms that are in 12 a different category. 13 The specialised respirators, it comes up again and 14 again in the trials that people don't like wearing these 15 close-fitting N95 and P2 respirators. So the harms of 16 that have to be taken into account, even though they 17 might seem to be very effective. Nevertheless, are 18 people really going to wear them when they are not in 19 a highly disciplined environment like a hospital? 2.0 So it's a broad term, and this is a feature of 21 randomised controlled trials. The authors want to 22 stress the benefits of the new drug, the new vaccine, 23 the new product that they've investigated, and they tend 24 to downplay the potential harms because that's kind of 25 human nature. 109 1  $\mathsf{Q}.\;$  And as I think you've indicated, the harms can range 2 from matters of probably relatively insignificant harm, 3 such as inconvenience --4 A. Yes. 5  $\mathsf{Q}.~--$  irritation, perhaps, looking at the N95 6 respirators --7 A. Yes. 8 Q. -- but across to more serious socio-economic harms. 9 A. Yes. 10 Q. Again, I think we discussed yesterday that you would see 11 that as being part of your remit --12 A. Yes. 13  $\mathsf{Q}. \ -- \text{ as a public health consultant.}$ A. Yes. Yes. Indeed. 14 15 Q. I think we go on to see, again, a plain language 16 summary, and the key messages that are derived from the 17 research by Jefferson and others are those that are 18 reproduced at page 55 in the block section of your 19 report; is that right?

- A. Yes, they are. Yes. They only have two key messages 20 21 there, so I have just transcribed them directly into the 22 report at page 55. 23 Q. Yes
- 24 I think, again, utilising the plain language 25 summary, there's a list of physical measures set out

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1 there which I think, again, are reflected elsewhere. 2 A. Mm 3 Q. And we also have a passage, "What did we want to find 4 out?", and the authors say: 5 "We wanted to find out whether physical measures stop or slow the spread of respiratory viruses from 6 7 well-controlled studies in which one intervention is 8 compared to another, known as randomised controlled 9 trials .' 10 Can I take you, then, to page 510, which is a more expansive view or summary of the authors' conclusions in 11 12 the left -- hand column. 13 I think we can possibly -- well, again, can I burden 14 you, doctor, with reading through what is said there. 15 I don't think it's necessary to intersperse the various 16 studies, but if you could just read through the text 17 under "Implications for practice". 18 A. Yes: 19 "Implications for practice 20 "The evidence summarised in this review on the use 21 of masks is largely based on studies conducted during 22 traditional peak respiratory virus infection seasons up 23 until 2016. Two relevant randomised trials conducted 24 during the COVID-19 pandemic have been published, but 25 their addition had minimal impact on the overall pooled

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1	estimate of effect. The observed lack of effect of mask
2	wearing in interrupting the spread of influenza $-$ like
3	illness $\dots$ or influenza/COVID-19 in our review has many
4	potential reasons, including: poor study design;
5	insufficiently powered studies arising from low viral
6	circulation in some studies; lower adherence with mask
7	wearing, especially amongst children; quality of the
8	masks used; self-contamination of the mask by hands;
9	lack of protection from eye exposure from respiratory
10	droplets (allowing a route of entry of respiratory
11	viruses into the nose via the lacrimal duct); saturation
12	of masks with saliva from extended use (promoting virus
13	survival in proteinaceous material); and possible risk
14	compensation behaviour leading to an exaggerated sense
15	of security
16	"Our findings show that hand hygiene has a modest
17	effect as a physical intervention to interrupt the
18	spread of respiratory viruses, but several questions
19	remain. First, the high heterogeneity between studies
20	[meaning different study characteristics ] may suggest
21	that there are differences in the effect of different
22	interventions. The poor reporting limited our ability
23	to extract the information needed to assess any 'dose
24	response' relationship , and there are few $head-to-head$
25	trials comparing hand hygiene materials (such as

2sustainability of hand hygiene is unclear where3participants in some studies achieved 5 to 104handwashings per day, but adherence may have diminished5with time as motivation decreased, or due to adverse6effects from frequent hand—washing. Third, there is7little evidence about the effectiveness of combinations8of hand hygiene with other interventions, and how those9are best introduced and sustained. Finally, some10interventions were intensively implemented within small11organisations, and involved education or training as a12component, and the ability to scale these up to broader13interventions is unclear.14"Our findings with respect to hand hygiene should be15considered generally relevant to all viral respiratory16infections, given the diverse populations where17transmission of viral respiratory infections occurs.18The participants were adults, children and families, and19multiple congregation settings including schools,20childcare centres, homes, and offices. Most respiratory21viruses, including the pandemic SARS-CoV-2, are22considered to be predominantly spread via respiratory
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21 viruses, including the pandemic SARS-CoV-2, are
22 considered to be predominantly spread via respiratory
23 particles of varying size or contact routes, or both
$24 \qquad {\sf Data from studies of SARS-CoV-2 \ contamination \ of \ the}$
25 environment based on the presence of viral ribonucleic

- 1 acid and infectious virus suggest significant fomite 2 contamination ... Hand hygiene would be expected to be 3 beneficial in reducing the spread of SARS-CoV-2 similar 4 to other beta coronaviruses (SARS-CoV-1, Middle East 5 respiratory syndrome ... and human coronaviruses), which 6 are very susceptible to the concentrations of alcohol 7 commonly found in most hand-sanitiser preparations  $\ldots$ 8 Support for this effect is the finding that poor hand 9 hygiene, despite the use of full personal protective 10 equipment ... was independently associated with an 11 increased risk of SARS-CoV-2 transmission to healthcare 12 workers in a retrospective cohort study in Wuhan, China in both a high-risk and low-risk clinical unit for 13 patients infected with COVID-19 ... The practice of hand 14 15 hygiene appears to have a consistent effect in all 16 settings, and should be an essential component of other 17 interventions ." 18 Q. I think I can stop you there, doctor. 19 The summary of the main results -- and I can simply 20 give the reference to this -- is to be found at 21 pages 770 to 772. 22 A. Yes, in the tables.
- 23 Q. In the tables.
- 24 A. Yes.
- 25~ Q. It's an overall summary. Each area of study also has

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1		a summary as well. So the detail is there and then it
2		is aggregated into a final table.
3	Α.	Interestingly , these tables , compared to the previous
4		ones, are focusing on randomised controlled trials.
5		They don't include the others. Not in the tables.
6	Q.	There's one matter that I would like to ask you about,
7		and it takes us back to page 509 in the Jefferson
8		review, which is quite close to where we were previously
9		reading. I think in the right-hand column, towards the
10		top of 509, there's a paragraph which begins:
11		"The two RCTs of medical/surgical masks during the
12		SARS-CoV-2 pandemic found uncertain evidence of a small
13		or no effect The study by Abaluck 2022 found a
14		statistically significant benefit of masks versus no
15		masks for COVID-like-illness, however, this study was
16		rated at high risk of bias for five of the six domains
17		due to issues including baseline imbalance, subjective
18		outcome assessment and incomplete follow-up across the
19		groups. Despite this study contributing $45\%$ of the
20		weight towards the meta-analysis of
21		influenza/COVID-like-illness for masks versus no masks,
22		the updated conclusions from the analysis strengthened
23		around little or no effect of mask use."
24	Α.	Yes.

25~ Q. Those two studies, I think you've helpfully reproduced

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1		at I think it's appendix 5.
2		My Lord, if my Lord wishes $$ and anyone else
3		wishes $$ the references, the study by Abaluck is in the
4		bundle at pages 952 to 964, and the study by Bundgaard
5		is at pages 965 to 974.
6		Perhaps we can shortcut that by looking to
7		appendix 5, please.
8	Α.	Yes.
9	Q.	Perhaps you could just help us by taking us through what
10		was the Bundgaard $$ the Bundgaard study was, I think,
11		in Denmark.
12	Α.	It was carried out in Copenhagen, I believe. Yes.
13	Q.	And the Abaluck study was carried out in Bangladesh.
14	Α.	Yes.
15	Q.	Could you just take us through what you say, first of
16		all in relation to the Bundgaard study.
17	Α.	Yes. Shall I just read it through?
18	Q.	Yes, please.
19	Α.	"The Bundgaard study
20		"The study was a randomised controlled trial
21		carried out in Denmark in April–May 2020 (i.e. at the
22		start of the COVID $-19$ pandemic). At that time, mask
23		wearing was not amongst the recommended public health
24		measures in Denmark.

"There were 6024 participants in the study. They

25

1		were community-dwelling adults, previously uninfected			
2		with SARS-CoV2, who did not wear masks in their daily			
3		work. They were randomised into either (i) wearing a			
4		surgical mask outside the home for [more than] 3 hours,			
5		or (ii) not wearing a mask, i.e. control group. Testing			
6		for SARS-CoV-2 was carried out at 1 month."			
7		So a very simple study, and a nice flow diagram that			
8		is in there:			
9		"At 1 month, 42 (1.8%) of the mask—wearing			
10		participants tested positive for COVID $-19$ , whereas 53			
11		(2.1%) of the non-mask wearers tested positive. The			
12		odds ratio was 0.82 (i.e. suggesting a benefit from mask			
13		wearing) "			
14		But once this was statistically analysed, the result			
15		was not significant . The confidence interval ranged			
16		from 0.54 to 1.23. So because the odds ratio crossed			
17		the line of no effect, this had to be considered			
18		an inclusive study $$ an inclusive finding, but			
19		an interesting study.			
20	Q.	I think we can see that at page 109 of your report in			
21		the appendix, "Analysis 1.1: Comparison 1: Randomised			
22		trials : medical/surgical masks versus no masks", and			
23		I think we can see the Abaluck study is added into the			
24		list of studies $$			
25	Α.	Yes.			
		116			
		117			
1	0	and is the first in that list . So we can see the			
2	۹.	material that they were working from at that stage.			
3	А	That's right. The Bundgaard one that we were just			
4	7.0	looking about, it's in the second lot there, isn't it?			
5		The $$			
6	0	l'm sorry?			
7	•	So Bundgaard, the second block, the third small red			
8		square, and you can see how the upper limit of the			
9		confidence interval does cross the line of no effect.			
10	Q	Yes.			
± •	٩.				

Go on to the Abaluck study, please.

11

	5.1
12	A. Yes. The Abaluck study, this was a large group of
13	investigators . Most of the investigators came from the
14	United States. There were a few Bangladeshi
15	investigators as well.
16	They carried out a cluster randomised controlled
17	trial carried out in rural Bangladesh in November 2020
18	to April 2021. Here, the unit of randomisation wasn't
19	individuals; it was villages. So they enrolled 600
20	villages in the study, and the villages were randomised

21 into either wearing a mask and being shown a video and

- 22  $\hfill a brochure on how to use masks, or else no intervention, <math display="inline">\hfill$
- 23  $% \left( {{\rm{ie}}}\right)$  ie doing nothing. That was the control group. Then
- 24 SARS-CoV-2 infection was determined in two ways: partly

25 by self-reported symptoms that were consistent with

118

1 COVID-19, and partly by laboratory testing. 2 "The study authors concluded that the intervention 3 [ie the wearing of a mask and also being shown a video 4 and given a brochure] reduced symptomatic seroprevalence 5 (i.e. a composite measure of positive symptoms and 6 positive antibody tests). The all-age odds ratio was 7 0.91 ... " 8 Meaning that it showed a reduction in COVID-19 with 9 an odds ratio of 0.9, so a modest reduction. The 10 confidence interval there just touches 1, so they're 11 only just significant , because an odds ratio of 1 means 12 no effect. 13 Then I've got here the assessment, what the Cochrane 14 reviewers had to say about these two studies. Shall 15 I carry on? Q. Yes. 16 17 A. So the Cochrane reviewers looked at these two studies, 18 which were obviously of great interest because they were 19 carried out in the pandemic. They interpreted the 20 studies in the context of pre-existing evidence, rather 21 than the standalone studies, which is the correct way of doing it, and they applied the standards of scientific 2.2 23 rigour that are routinely used in Cochrane reviews. 24 They used the Cochrane risk of bias tool and, using 25 this, the Bundgaard study was found to be at low to 119 1

moderate risk of bias, and the Abaluck study at high risk of bias.

1	included in	this	section	ot	my report part of
that					

5 Q. Yes.

2

3 4

6	Α.	So the Abaluck is at the top, and you can see, my Lord,
7		the five red signs that indicate high risk of bias, and
8		then coming down towards the bottom, Bundgaard is pretty
9		good; it's got three greens, two reds and one uncertain.
10		Carrying on:
11		"When the findings of the Bundgaard and Abaluck
12		studies were combined through meta-analysis with the
13		findings of other [previous, pre-existing]
14		medical/surgical mask [randomised controlled trials],
15		they contributed modestly to the overall finding that
16		mask wearing may be effective in preventing the
17		acquisition of SARS-CoV-2 infection – but statistically
18		[using statistical rigour], and because the confidence
19		intervals for the various pooled effect measures, shown
20		below as black diamonds $\dots$ in all cases include 1, the
21		results are not significant ."
22		And then I show the forest plot which compares
23		medical/surgical masks versus no masks using only
24		randomised controlled trials , so very high-quality
25		evidence, and the outcome here is viral $$ illness $$ $$

1		various sorts of viral illness , but including SARS-CoV-2
2		illness .
3		So Abaluck is the very top line . It shows they
4		had $$ they seem to $$ they disaggregated the villages
5		into a number of participants. So they had 111,000
6		villagers who were wearing the masks and 155,000 who
7		weren't wearing the masks, and you could see there
8		seemed to be a modest effect. It's a large red square
9		indicating a large number of participants. But even
10		then the final $$ if you go down eight rows, the black
11		diamond is the pooled estimate of effect, and that
12		plainly does cross the line of no effect.
13		So pooling all the evidence from all the studies
14		shows with a degree of reliability that there's really
15		no effect, statistically, from wearing a mask versus no
16		mask in the community. That's what we're talking about.
17		We're talking about community studies. For hospital
18		studies and clinic studies, there's no dispute about it;
19		they're good. But in the community, the benefit hasn't
20		been shown.
21	Q.	Now, the reference to Abaluck and Bundgaard are
22		significant , obviously, for inclusion within the 2023
23		Jefferson Cochrane review
24	Α.	Yes, that's right.
25	Q.	in that they are randomised trials taken during the
		101
		121
1		
1		COVID pandemic.
2		COVID pandemic. Correct.
2 3		COVID pandemic. Correct. You said on a number of occasions that the Cochrane
2 3 4	Q.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process.
2 3 4 5	Q. A.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes.
2 3 4 5 6	Q. A.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes. Would one expect there to be further such trials
2 3 4 5 6 7	Q. A.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes. Would one expect there to be further such trials emerging, either at present or have already emerged, and
2 3 4 5 6 7 8	Q. A. Q.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes. Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future?
2 3 5 6 7 8 9	Q. A. Q.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes. Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future? Yes. I am pretty sure other studies are emerging. They
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2 3 4 5 6 7 8 9 10 11	Q. A. Q.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes. Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future? Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. A. Q. A. Q.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes. Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future? Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't got the findings yet, but we will report about them later on". So, effectively , what one has, based on Abaluck and Bundgaard, and indeed the other, is a conclusion drawn by the Cochrane reviewers which is static as at 2023. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. A. Q. Q. A. Q.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes. Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future? Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't got the findings yet, but we will report about them later on". So, effectively , what one has, based on Abaluck and Bundgaard, and indeed the other, is a conclusion drawn by the Cochrane reviewers which is static as at 2023. Yes. As at this year.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. A. Q. Q. A. Q.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes. Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future? Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't got the findings yet, but we will report about them later on". So, effectively , what one has, based on Abaluck and Bundgaard, and indeed the other, is a conclusion drawn by the Cochrane reviewers which is static as at 2023. Yes. As at this year. That's right. Yes, indeed. Indeed.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. A. Q. Q. A. Q.	<ul> <li>COVID pandemic.</li> <li>Correct.</li> <li>You said on a number of occasions that the Cochrane review process is a dynamic process.</li> <li>Yes.</li> <li>Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future?</li> <li>Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't got the findings yet, but we will report about them later on".</li> <li>So, effectively , what one has, based on Abaluck and Bundgaard, and indeed the other, is a conclusion drawn by the Cochrane reviewers which is static as at 2023.</li> <li>Yes.</li> <li>As at this year.</li> <li>That's right. Yes, indeed. Indeed.</li> <li>In fact, it's not as at this year, really, Mr Gale.</li> </ul>
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. A. Q. A. Q. A. Q.	<ul> <li>COVID pandemic.</li> <li>Correct.</li> <li>You said on a number of occasions that the Cochrane review process is a dynamic process.</li> <li>Yes.</li> <li>Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future?</li> <li>Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't got the findings yet, but we will report about them later on".</li> <li>So, effectively , what one has, based on Abaluck and Bundgaard, and indeed the other, is a conclusion drawn by the Cochrane reviewers which is static as at 2023.</li> <li>Yes.</li> <li>As at this year.</li> <li>That's right. Yes, indeed. Indeed.</li> <li>In fact, it's not as at this year, really, Mr Gale.</li> <li>It's probably whenever the last day they did a search.</li> </ul>
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. A. Q. A. Q. A. Q.	<ul> <li>COVID pandemic.</li> <li>Correct.</li> <li>You said on a number of occasions that the Cochrane review process is a dynamic process.</li> <li>Yes.</li> <li>Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future?</li> <li>Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't got the findings yet, but we will report about them later on".</li> <li>So, effectively , what one has, based on Abaluck and Bundgaard, and indeed the other, is a conclusion drawn by the Cochrane reviewers which is static as at 2023.</li> <li>Yes.</li> <li>As at this year.</li> <li>That's right. Yes, indeed. Indeed.</li> <li>In fact, it's not as at this year, really, Mr Gale.</li> <li>It's probably whenever the last day they did a search.</li> <li>Yes. Yes.</li> </ul>
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. A. Q. A. Q. A. Q.	<ul> <li>COVID pandemic.</li> <li>Correct.</li> <li>You said on a number of occasions that the Cochrane review process is a dynamic process.</li> <li>Yes.</li> <li>Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future?</li> <li>Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't got the findings yet, but we will report about them later on".</li> <li>So, effectively , what one has, based on Abaluck and Bundgaard, and indeed the other, is a conclusion drawn by the Cochrane reviewers which is static as at 2023.</li> <li>Yes.</li> <li>As at this year.</li> <li>That's right. Yes, indeed. Indeed.</li> <li>In fact, it's not as at this year, really, Mr Gale.</li> <li>It's probably whenever the last day they did a search.</li> <li>Yes. Yes.</li> <li>It's July 2022. But at that point — that's the point</li> </ul>
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q. A. Q. A. Q. A. Q.	COVID pandemic. Correct. You said on a number of occasions that the Cochrane review process is a dynamic process. Yes. Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future? Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't got the findings yet, but we will report about them later on". So, effectively , what one has, based on Abaluck and Bundgaard, and indeed the other, is a conclusion drawn by the Cochrane reviewers which is static as at 2023. Yes. As at this year. That's right. Yes, indeed. Indeed. In fact, it's not as at this year, really , Mr Gale. It's probably whenever the last day they did a search. Yes. Yes. It's July 2022. But at that point —— that's the point at which they stopped searching and then they present
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. A. Q. A. Q. A. Q.	<ul> <li>COVID pandemic.</li> <li>Correct.</li> <li>You said on a number of occasions that the Cochrane review process is a dynamic process.</li> <li>Yes.</li> <li>Would one expect there to be further such trials emerging, either at present or have already emerged, and in the near future?</li> <li>Yes. I am pretty sure other studies are emerging. They may even refer to some. Sometimes Cochrane reviews say, "We are aware of other studies going on but we haven't got the findings yet, but we will report about them later on".</li> <li>So, effectively , what one has, based on Abaluck and Bundgaard, and indeed the other, is a conclusion drawn by the Cochrane reviewers which is static as at 2023.</li> <li>Yes.</li> <li>As at this year.</li> <li>That's right. Yes, indeed. Indeed.</li> <li>In fact, it's not as at this year, really, Mr Gale.</li> <li>It's probably whenever the last day they did a search.</li> <li>Yes. Yes.</li> <li>It's July 2022. But at that point — that's the point</li> </ul>

1	Q.	Yes, point taken. Thank you.
2		Could we go back to your report, please, doctor, and
3		go back to 3.1. You've listed there $$ this is at
4		page 56.
5	Α.	Thank you.
6	Q.	You head it as, "Physical measures taken in Scotland
7		against COVID-19".
8	Α.	Yes.
9	Q.	You have utilised the list that I think we've already
10		looked at from Jefferson.
11	Α.	Yes.
12	Q.	Perhaps you would read on from the bottom of page 56,
13		beginning, "When the COVID $-19$ pandemic was declared".
14	Α.	"When the COVID-19 pandemic was declared, in March 2020,
15		the response of most governments around the world was to
16		safeguard their citizens by simultaneously advocating
17		multiple protective physical measures (sometimes

- referred to as a 'layered' approach to population protection) that had been deployed in earlier epidemics
- of acute respiratory illness . This section [of my
- report] describes how in Scotland, as in most
- 2.2 count[r] ies, a wide range of physical measures against
- COVID-19 was either recommended or else mandated, from
- early 2020 onwards. Some of the measures were
  - undoubtedly effective. Others were harmful."

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- In fact, they probably all were harmful to some degree, because even having to buy a mask, you know, harms you. I think they cost a pound. But the harms were obviously more intense with some of the interventions. Q. Yes. A. So I give a little comment there. Q. So your comment, please. A. My comment is: "As the pandemic struck, in early 2020, SARS-CoV-2 was treated as an acute respiratory virus. At that time, the best evidence for the effectiveness or otherwise of physical measures to prevent the spread of respiratory viruses was from a decade-old Cochrane review, Jefferson 2011 [we called it Jefferson 1]. This review was updated as the pandemic progressed, and was reissued in revised form towards the end of the pandemic, Jefferson 2023."  $\mathsf{Q}.\;$  Now, what you then go on to do, doctor, in 3.1.1 is list the physical measures advised or mandated in the period from March to July 2020. A. Yes.

- $\mathsf{Q}.~\mathsf{I}$  think, for the sake of brevity, we will take those all
- as read. I think everybody of our generation will
- remember the event of 23 March 2020, which is on

- 1.

2

3

4

- 1 page 55, when the then Prime Minister said, "You must
- 2 stay at home. I give you this simple message", I think
- 3 is how he prefaced it.
- 4 You make a comment about that towards the bottom of 5 page 58.
- 6 A. Yes.
- 7 Q. Perhaps you would just read that and perhaps expand on 8 it, please.
- 9 A. Yes. This, of course, is my own comment as 10 a professional public health physician: "See the first 'Scientific knowledge' box, above. 11 12 During March to July 2020 there was limited scientific 13 evidence and in some cases no scientific evidence (e.g.
- 14 as regards lockdowns) to support the physical measures
- 15 that were mandated in Scotland against COVID-19. Such
- evidence as there was (e.g. for mask wearing) mostly 16
- 17 came from hospital settings, rather than community
- 18 settings - and arguably was not applicable to the
- 19 general, non-hospital population."
- 20  $\mathsf{Q}.\;$  You say "arguably"; can you explain the basis of that 21 surmise?
- 2.2 A. Of course, yes. Well, perhaps some policymakers might 23 have extracted one randomised controlled trial that
- 24 showed quite a strong effect in a hospital and thought: 25
  - well, our people are disciplined or can be trained to be

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1 disciplined and can be trained or educated to use masks properly, so we will apply that to the general 2 3 population. 4 The Cochrane review authors were quite insistent 5 that hospital environments are not the same as domestic 6 environments, and hospital staff could be educated and, 7 to some extent, monitored in the correct use and the 8 consistent use of these inconvenient and uncomfortable 9 measures. 10 Q. I suppose also it could be considered that there would 11 be an ongoing education process in relation to the 12 general population. 13 A Yes 14 Q. Particularly with the seriousness of the situation in 15 which we were in. 16 A. Yes. Yes, that's true. They talk about the need to 17 emphasise the importance of it and the gravity of the 18 threat that was being faced. Yes. 19 Q. Thank you. 20 You then go on, in 3.1.2, to list the physical 21 measures advised or mandated in the period between 2.2 August and December 2020. 23 A. Mm-hm 24 Q. Again, I think we can just take that as read. 25 Effectively, your comment at the bottom of page 59 is

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- really the same. A. It's the same, yes. Q. Then you talk about, in 3.1.3, the temporary easing of physical measures in the run-up to Christmas, and
- 5 I think we all remember that there was a great deal of
- pressure on the policymakers and the politicians --6
- 7 A. Yes
- 8 Q. -- to allow us to have some form of Christmas --
- 9 A. Yes.
- 10 Q = -in 2020
- 11 A. Yes
- 12 Q. I think you've indicated those measures that were put in 13 place by the Scottish Government.
- 14 Then at page 60 you comment again, which again is
- 15 a comment in relatively similar terms to what you've
- 16 already said.
- 17 A. Yes
- 18 Q. Perhaps you would just read it out.
- 19 A. Again, my professional comment:
- 20 "The easing of the centrally-mandated COVID-19
- 21 restrictions over the 2020 Christmas period differed, in
- 22 different parts of the UK [the different nations]. It
- 23 is not clear to what extent, if at all, the easing of
- 24 the restrictions was based on a better understanding of 25 the pathogenicity and transmission characteristics of

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#### 1 SARS-CoV-2."

2	Q.	Moving on, the next period that you're looking at is the
3		period in early 2021, and you list those up to page 61,
4		and obviously this is bearing in mind the terms of the
5		Inquiry's remit, taking it into the date on 22 June when
6		the then First Minister, Nicola Sturgeon, announced:
7		" a new indicative date for the whole of Scotland
8		to move to level 0 on 19 July 2021, provided all
9		necessary vaccination and harm reduction measures [were]
10		met."
11		Again, can we just have your comment on that.
12	Α.	So my comment:
13		"Physical measures intended to restrict the spread
14		of $SARS{-}CoV{-}2$ remained in place in Scotland throughout
15		2021, and some were still in place in 2022."
16		There are more milestones, more bullet points, and
17		they are at the appendix to this report. All of those
18		milestones I took from the official timeline that's on
19		the Inquiry website, which is extremely helpful.
20	Q.	Right.
21		We move on now to part 4 of your report dealing with
22		vaccines, and I think we need to have in mind on this
23		the material that you've already provided us with in
24		section 2 of your report on vaccines.
25	Α.	Yes.

1	Q.	Give me a moment.
2		(Pause)
3		My Lord, bear with me for a moment.
4		(Pause)
5		Thank you, my Lord, apologies.
6		Right, Dr Croft, we are at page 62 of your report.
7	Α.	Yes.
8	Q.	Again, there is a block section in which you note the
9		position post-pandemic, and it's headed, "What are the
10		benefits and risks of vaccine for preventing COVID $-19?$ ",
11		and there are certain key messages.
12		Yes.
13	Q.	I would be grateful if you would just read through that,
14		please.
15	Α.	Yes. These are taken from the Cochrane review by Graña
16		and colleagues, 2022:
17		"Key messages
18		" • Most vaccines reduce, or probably reduce, the
19		number of people who get $COVID-19$ disease and severe
20		COVID-19 disease.
21		"• There is insufficient evidence to determine
22		whether there was a difference between the vaccine and
23		placebo in terms of death because the numbers of deaths
24		were low in the trials .
25		<ul> <li>Many vaccines likely increase number of people</li> </ul>
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1 2		129
		129 experiencing events such as fever or headache compared
2		129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no
2 3		129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being
2 3 4		129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are
2 3 4 5		129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they
2 3 4 5 6		129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short-term.
2 3 4 5 6 7		129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short-term. "• Many vaccines have little or no difference in the
2 3 4 5 6 7 8		129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short-term. "• Many vaccines have little or no difference in the incidence of serious adverse events compared to placebo.
2 3 4 5 6 7 8 9		129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short-term. "• Many vaccines have little or no difference in the incidence of serious adverse events compared to placebo. "• Most trials assessed vaccine efficacy over a
2 3 4 5 6 7 8 9	Q.	129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short-term. "• Many vaccines have little or no difference in the incidence of serious adverse events compared to placebo. "• Most trials assessed vaccine efficacy over a short time, and did not evaluate efficacy to the COVID
2 3 4 5 6 7 8 9 10 11	Q.	<ul> <li>129</li> <li>experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short-term.</li> <li>" • Many vaccines have little or no difference in the incidence of serious adverse events compared to placebo.</li> <li>" • Most trials assessed vaccine efficacy over a short time, and did not evaluate efficacy to the COVID variants of concern."</li> </ul>
2 3 4 5 6 7 8 9 10 11 12	Q.	<pre>129 experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short-term.     " • Many vaccines have little or no difference in the incidence of serious adverse events compared to placebo.     " • Most trials assessed vaccine efficacy over a short time, and did not evaluate efficacy to the COVID variants of concern." I think we can find that material at the Graña Cochrane</pre>
2 3 4 5 6 7 8 9 10 11 12 13	Q.	<ul> <li>129</li> <li>experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short-term.</li> <li>" • Many vaccines have little or no difference in the incidence of serious adverse events compared to placebo.</li> <li>" • Most trials assessed vaccine efficacy over a short time, and did not evaluate efficacy to the COVID variants of concern."</li> <li>I think we can find that material at the Graña Cochrane paper, which is paper number 7 and is at pages 50 and</li> </ul>
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q.	<ul> <li>129</li> <li>experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short—term.</li> <li>" • Many vaccines have little or no difference in the incidence of serious adverse events compared to placebo.</li> <li>" • Most trials assessed vaccine efficacy over a short time, and did not evaluate efficacy to the COVID variants of concern."</li> <li>I think we can find that material at the Graña Cochrane paper, which is paper number 7 and is at pages 50 and following.</li> <li>I think if we go to page 53 within the bundle, can we just look at some of the accompanying text. Going to page 53, I think we can see the objective of the research at the bottom —— well, let's start logically with the background:</li> </ul>
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q.	<ul> <li>129</li> <li>experiencing events such as fever or headache compared to placebo ([defined as] sham vaccine that contains no medicine but looks identical to the vaccine being tested). This is expected because these events are mainly due to the body's response to the vaccine; they are usually mild and short—term.</li> <li>" • Many vaccines have little or no difference in the incidence of serious adverse events compared to placebo.</li> <li>" • Most trials assessed vaccine efficacy over a short time, and did not evaluate efficacy to the COVID variants of concern."</li> <li>I think we can find that material at the Graña Cochrane paper, which is paper number 7 and is at pages 50 and following.</li> <li>I think if we go to page 53 within the bundle, can we just look at some of the accompanying text. Going to page 53, I think we can see the objective of the research at the bottom —— well, let's start logically with the background:</li> <li>"Background</li> <li>"Different forms of vaccines have been developed to</li> </ul>

- 24
- And then the objective was: 25
- "To assess the efficacy and safety of  $\ensuremath{\mathsf{COVID}}{-19}$

1		vaccines (as a full primary vaccination series or
2		a booster dose) against SARS-CoV-2."
3		So that's the objective
4		We then have the research materials and, I suppose,
5		methodology.
6		If one then goes on to the main results on page 54,
7		I think we can see that the authors:
8		" included and analyzed 41 RCTs"
9	Α.	Yes.
10	Q.	" assessing 12 different vaccines, including
11		homologous and heterologous vaccine schedules and the
12		effect of booster doses. Thirty-two RCTs were
13		multicentre and five were multinational. The sample
14		sizes were 60 to 44,325 participants. Participants
15		were aged: 18 years or older in 36 RCTs; 12 years or
16		older in one RCT; 12 to 17 years in two RCTs; and three
17		to 17 years in two RCTs. Twenty-nine RCTs provided
18		results for individuals aged over 60 years, and three
19		RCTs included immunocompromized patients. No trials
20		included pregnant women. Sixteen RCTs had two-month
21		follow—up or less, 20 RCTs had two to six months, and
22		five RCTs had greater than six to 12 months or less.
23		Eighteen reports were based on preplanned interim
24		analyses."
25		There is then an indication the overall risk of bias
		101
		131
1		was low in eight RCTs, while 33 had concerns for at
2		least one outcome.
3		We then see that, in the main results, the authors
4		divide this up into confirmed symptomatic COVID-19,
5		severe to critical COVID $-19$ , and serious adverse
6		effects. We can obviously read the data if we wish in
7		respect of each of those trials .
8		But then we have the authors' conclusions at the top
9		of page 55, and I wonder if you would just read that,
10		please.
11	A.	Yes:
12		"Authors' conclusions
13 14		"Compared to placebo, most vaccines reduce, or
13 14		"Compared to placebo, most vaccines reduce, or likely reduce, the proportion of participants with
13 14 15		"Compared to placebo, most vaccines reduce, or
13 14 15 16		"Compared to placebo, most vaccines reduce, or likely reduce, the proportion of participants with confirmed symptomatic COVID-19, and for some, there is high-certainty evidence that they reduce severe or
13 14 15		"Compared to placebo, most vaccines reduce, or likely reduce, the proportion of participants with confirmed symptomatic COVID-19, and for some, there is
13 14 15 16 17		"Compared to placebo, most vaccines reduce, or likely reduce, the proportion of participants with confirmed symptomatic COVID-19, and for some, there is high-certainty evidence that they reduce severe or critical disease. There is probably little or no difference between most vaccines and placebo for serious
13 14 15 16 17 18		"Compared to placebo, most vaccines reduce, or likely reduce, the proportion of participants with confirmed symptomatic COVID $-19$ , and for some, there is high-certainty evidence that they reduce severe or critical disease. There is probably little or no

- COVID-19 vaccines, and this review is updated regularly 21
- 22 on the COVID-NMA platform ..."
- 23  $\mathsf{Q}.$  Then I think, significantly , the "Implications for
- 24 practice". Would you read that? 25
  - A. Yes:

- 1 "Implications for practice
- 2 "Due to the trial exclusions, these results cannot
- $3 \qquad \qquad$  be generalized to pregnant women, individuals with
- 4 a history of SARS-CoV-2 infection, or immunocompromized
- 5 people. Most trials had a short follow-up and were
- 6 conducted before the emergence of variants of concern."
- Q. To a certain extent, implications for practice there isexcluding certain matters. What would you take from the
- 9 authors' conclusions and your review of what is
- 10 contained in the Graña Cochrane review? What would you
- 11 take as the message for the implication for the
- 12 practitioner?
- 13  $\,$  A. What I take is the key messages that I extracted and put  $\,$
- 14 my report which follow in the plain language summary.
- 15 Q. Yes.
- 16~ A. So I could go straight to them or read them from here.
- 17 Q. Yes.
- 18 A. So the first message:
- 19 "- Most vaccines reduce, or probably reduce, the
- 20 number of people who get COVID-19 disease and severe 21 COVID-19 disease.
- 22 "– Many vaccines likely increase number of people
- experiencing events such as fever or headache compared
- 24 to placebo (sham vaccine ...). This is expected because
- 25 these events are mainly due to the body's response to

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- 1 the vaccine; they are usually mild and short-term." 2 Q. Yes 3 A. "- Many vaccines have little or no difference in the 4 incidence of serious adverse events compared to 5 placebo." 6 However, I think there ought really to be 7 a qualifying phrase for that little bullet point, as 8 there is to the next one, so if I read the next one. 9 Q. Yes. 10 A. It says: 11 "- There is insufficient evidence to determine 12 whether there was a difference between the vaccine and 13 placebo in terms of death because the numbers of deaths 14 were low in the trials ." 15 So in the same way, I think really they should have 16 qualified the previous phrase by saying the numbers of 17 severe adverse events were low, and so therefore we 18 can't make a firm conclusion about that. 19 Q. Other than to note that the numbers were low. A. The numbers were low, yes. So the numbers were low, so 2.0 21 therefore the confidence intervals were wide. 2.2 Yes, and then finally : 23 "- Most trials assessed vaccine efficacy over 24 a short time, and did not evaluate efficacy to the COVID 25 variants of concern."
  - 134

- 1 That's really because many of the trials started 2 before the variants of concern had even emerged so, 3 therefore, they're not to be blamed for that. It was 4 just the way that history worked out. LORD BRAILSFORD: Can I take you back to page 54, under the 5 heading "Main results". 6 7 A. Yes LORD BRAILSFORD: You told us, when you were talking about 8 9 protective measures, that Cochrane reviews did report on 10 the trials underway about which there was no result 11 available at the time of authorship. 12 A. Yes. LORD BRAILSFORD: I see in this particular Cochrane report 13 there is an entry under "Main results": 14 15 "We identified 343 registered RCTs with results not 16 vet available " 17 Is that what it's talking about? 18 A. It is, but if you look at the number of trials that they looked at, they initially identified 600, of which they 19 20 narrowed it down to 41. So that's not to say that we're 21 suddenly going to be confronted with 343 eligible trials 22 in a year's time. Those numbers will be whittled down 23 because many of them will actually be looking at 24 something else. But they have potentially randomised
  - 25 controlled trials that will provide results in the

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future. So there will be --1 LORD BRAILSFORD: You guessed where I was going. 2 3 A. Yes. There will be an increase in the evidence. The 4 evidence base will be enlarged. LORD BRAILSFORD: But not by 343 --5 A. No, maybe by four or five or ten. And, of course, not 6 7 all those randomised controlled trials are really 8 relevant to the people of Scotland because they are 9 looking at vaccines that were used elsewhere. They look 10 at the whole range of vaccines. LORD BRAILSFORD: Notwithstanding those caveats, is it 11 12 likely -- you may not know the answer to this -- because 13 of the likely emergence of a number of randomised 14 controlled trials, that there will be an update to this 15 particular Cochrane review at some stage? 16 A. Yes, I'm sure there will be a hard copy update, and they 17 are the important ones, because they are the ones that 18 are peer reviewed before they are launched. So there 19 will be, I would guess in maybe two years' time. 2.0 LORD BRAILSFORD: Two years' time. Thank you. 21 Sorry. Mr Gale. 2.2 MR GALE: No, not at all, my Lord, thank you. 23 Let's perhaps indulge in a little speculation, 24 Dr Croft. 25 The key messages, the first of which is that:

1		"Most vaccines reduce, or probably reduce, the
2		number of people who get $COVID-19$ disease and severe
3		COVID-19 disease."
4		Further research $$ and my Lord has just indicated
5		the extent of that that is noted as ongoing,
6		and I appreciate you saying that that will be filtered
7		for those that actually input into a subsequent Cochrane
8		review, as edited.
9	Δ	Yes.
10	Q.	Would one anticipate that it may be possible that that
11		terminology might be altered so that it could be
12		increased in its strength, perhaps by removing the word
13		"probably"?
14	Α.	Yes, that could be the case, yes. Yes, if enough trials
15		come along which are measuring that particular outcome
16		and are judged to be suitable to include in the
17		meta-analysis. That's part of the catch-22. Not all of
18		them are suitable. What we might be looking at might be
19		the mashed-up vaccines, for example $$ not wishing to
20		denigrate them $$ so they might not be suitable to
21		compare to genetic instruction vaccines.
22		But, in general, when looking at an estimate of
23		effect , it doesn't tend to vary $$ it doesn't jump
24		around. It tends to sort of move down the same
25		trajectory, but with the confidence intervals getting
		137
1		narrower and narrower and narrower as more evidence
2		comes in. That's generally what Cochrane reviews find.
3	Q.	Right.
4		Could you go back to page 62 in your report $$
5	Α.	Yes.
6	Q.	—— and, "Vaccines procured against COVID—19".
7		I think, again, this is somewhat repetitive of what
8		you've already said and what we have looked at.
9	Α.	Yes.
10	Q.	There are a number of individual $$ I think they are
11		called pivotal studies in relation to vaccines, and
12		I think we can see those referred to at page 63.
13	Α.	Yes.
14	Q.	My Lord, for my Lord and for the benefit of others, the
15	•	Folegatti report is paper number $4$
16	Δ	Yes.
17		and is at pages 27 to 34 of the bundle; Sadoff is
18	۹.	paper number 17 and is at pages 917 to 930 of the
19		bundle; Polack is number 13 and is at pages 864 to 876;
20		
		Baden is number 2 and is at pages 5 to 18; and I'll also
21		give the reference to Ramasamy, which was a follow-up
22		report on the AstraZeneca vaccine, which is number 15,
23		and that's at pages 887 to 901.
24		Now, again, it may be useful, doctor, without
25		actually going through what you actually say in your

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1 text, to go to page 64 and your comment, because you do 2 make a comment on the AstraZeneca study. 3 A. Yes 4 Q. Perhaps you would just read that. A. This is a comment on -- it's really on Folegatti, the 5 pivotal study, and my comment is: 6 7 "Strength of the AstraZeneca study [Folegatti] are 8 that it is a randomised controlled trial. It appears 9 not to be sponsored by industry." 10 It seems to be an academic study emerging from 11 Oxford University. 12 "Limitations include (i) the relatively small number 13 of participants ([1,077 in total] 543 people in the 14 vaccine arm); ( ii ) the use of a different vaccine as the 15 control, rather than saline (this would tend to result 16 in an unrealistically favourable assessment of the study 17 vaccine's true tolerability ); ( iii ) the short period of 18 follow-up ([28 days or] 4 weeks); and (iv) the lack of a 19 study flow chart in the published report (even though 20 this is mandatory [nowadays when you report an RCT])." 21 Q. Yes. I think that's a reference to a document we looked 2.2 at yesterday, Altman. 23 It is, yes, and that makes it very difficult to Α. 24 understand what they were doing. 25 Q. The Janssen vaccine which you refer to at 4.1.2, I think 139 1 probably again, with respect, we can ignore, because 2 I think as you've already indicated, it was not 3 a vaccine that was made available in the UK or in 4 Scotland. 5 A. No, that's right. 6  $\mathsf{Q}.\;$  One goes on, if I may, then, to the Moderna vaccine at 7 4.1.3. Again, we can read what is said there. The 8 pivotal study was the Baden paper which I have given 9 reference to. I think we can see there were 30.000-plus

- 10 participants, and you make a comment on that at the top
  - of page 66.
- 11 of page 12 A. Yes.
- 13 Q. Again, if you would read that, please.
- 14 A. Yes. So:

15	"Strengths of the Moderna study are that it is
16	a randomised controlled trial [that's the gold standard
17	of evidence]. It uses a true placebo [the placebo was
18	saline ]. The trial incorporates a [nice] study flow
19	chart [so very easy to see what was done]. Limitations
20	include (i) it is an industry—sponsored study"
21	It's sponsored by Janssen, which is a Dutch study.
22	So inevitably, with industry studies, there will
23	probably be some reporting bias:
24	" (ii) the differing follow-up periods for
25	different participants groups is confusing."

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A. Yes.

studies, so ...

Q. -- pages 19 to 21?

Q. Yes, I think it's at --

1		It's confusing to me, anyway.
2	Q.	I think you said that it was sponsored by Janssen.
3	Α.	Yes.
4	Q.	I think this is the Moderna $$
5	Α.	I'm terribly sorry. It's sponsored by Moderna.
6	Q.	Top of 66.
7	Α.	I beg your pardon, yes. Moderna, which is an American
8		company. I beg your pardon, yes. Janssen was the Dutch
9		company. Moderna is an American company which, as we
10		were saying yesterday, got a lot of money from the
11		US Federal Government for this development of this
12		vaccine.
13	Q.	Yes.
14		You then go on at 4.1.4 to look at the Pfizer
15		vaccine. The pivotal study is the Polack study, which
16		we've given reference to.
17	Α.	Yes.
18	Q.	There's a follow–up study to that, which is Thomas,
19		which I' II give the reference to: it's paper number 19,
20		at pages 937 to 949.
21		Could you just, again, go to the comment that you
22		make in relation to the Pfizer vaccine.
23	Α.	Yes. So:
24		"Strengths of the Pfizer study are that it is
25		a randomised controlled trial . It uses a true placebo
		141
1		[which is described as saline, which is good]. It
2		incorporates a study flow chart."
3		Nice study flow chart on the fourth page of the
4		study, page 867.
5	Q.	That makes it Altman–compliant, if I can put it that
6		way.
7	Α.	It makes it Altman–complaint, yes, of course. You can
8		see exactly what they are doing. But interestingly, in
9		the next study, it's pretty much exactly the same flow
10		chart, which isn't what I would have expected, but there
11		we are.
12		"Limitations include (i) it is an industry—sponsored
13		study "
14		Sponsored by Pfizer, a very wealthy company that
15		invented Viagra. That's why they're so wealthy, and
16		that's why they were able to fund this study entirely

- 17 without outside interference: 18  $"\ldots$  (and hence its reporting is liable to
- 19 commercial bias); (ii) short period of follow-up for the
- 20 majority of participants." 21 Oh, shall I carry on with the further comment?
- 22 Q. Yes, you make a further comment.
- 23 A. Further comment. In September 2021, there was
- 24 a follow-up study by Thomas, and this was meant to sort
- 25 of carry the story forward, because as far as we can

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1		tell, all of these four products were given authority to
2		supply, approval to supply $$ it's not the same as
3		licensing in the UK $$ on the basis that the
4		participants would be studied after two years. So they
5		are meant to be two-year studies. But what happened was
6		that the study participants started to drop out in
7		massive numbers. So what I put here:
8		"There were multiple drop—outs from the original
9		'pivotal' Pfizer study; the study in effect had shrunk
10		in size . The follow-up study found that vaccine
11		efficacy declined at 'an average of 6% every
12		2 months' [which hadn't been anticipated in the original
13		study]. The lack of transparency in the data presented
14		by Pfizer in their follow-up study was strongly
15		criticised in an online editorial in the British Medical
16		Journal "
17		Which I cite as Doshi ——
18	Q.	Yes, you've given us that reference and, again, for
19		my Lord and those following, that's document number 3 at
20		pages 19 to 21
21	Α.	Yes.
22	Q.	of the bundle.
23		Perhaps, just to understand what the criticism was,
24		can you just tell us what Mr Doshi was saying?
25	Α.	I'll refer to his papers.
		143
1	Q.	Yes.
2	Α.	It's quite hard to follow some of his arguments, but he
3		seemed to be making a number of, I thought, rather valid
4		points, which is why I included them, my Lord, in the

A. So what he seems to be commenting on, my Lord, is

the study flow diagram to continue for another

same as the previous one, which is a bit odd.

six months, but in fact his study flow diagram is the

doing is -- all the pre-print is doing, according to Doshi, is measuring -- in fact, again, telling us what

vaccine efficacy was at two months. Although it

of the way they have presented the data, it doesn't

actually add any more information.

with influenza vaccines.

So really what he's saying is that really all it's

purports to be a study taking the story forward, because

Dr Doshi is saying waning immunity is a big problem

"If vaccine efficacy wanes over time, the crucial

vaccine provide when a person is actually exposed to the

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question becomes what level of effectiveness will the

a pre-print of Thomas 2021, when we would have expected

Opus 2 Official Court Reporters

1	virus?	Unlike covid	vaccines,	influenza	vaccine

- 2 performance has always been judged over a full season, 3 not a couple months.'
- 4 Then Mr Doshi talks about the Israeli experience
- 5 of ---

- Q. Yes, I was just going to draw your attention to that. 6
- 7 A. Okav.
  - Q. Midway down page 19, just below halfway down page 19,
- 9 Dr Doshi makes reference to the Israel experience, which
- 10 I think we did touch on earlier this morning. 11
- A. Yes, and then Dr Doshi says -- we have to take his word 12 for it -- the FDA, the Food and Drug Administration --
- 13 I believe he's based in the United States.
- 14 Q. Right
- 15 A. He says they expect an approvable vaccine to have at
- 16 have found that the Pfizer vaccine efficacy had fallen 17
- 18 to 39% when the new variant came along, the Delta
- 19 variant, and so he considered this to be pretty poor
- 20 performance. 21
- Then he says: well, okay, what's happened? We've 22
- now got this booster. He puts "booster" in inverted 23
- commas. I agree with him. I think "booster" is
- 24 a misnomer. It's actually an odd-on to try and get the 25 vaccine up into the stratosphere. The booster is what

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1		you use when you've already achieved immunity, just to
2		keep the immunity going.
3		Then he talks about US plans for all fully
4		vaccinated adults to have a booster. Then he says more
5		about —— he says:
6		"Waning efficacy has the potential to be far more
7		than a minor inconvenience the bottom line is that
8		vaccines need to be effective [especially when new
9		variants are circulating ].
10		" it is unclear whether the 2-dose series"
11		Yes, so he goes back to the two-dose series, the
12		original primary course, which was presented as the
13		solution to COVID-19, and he says: would this even meet
14		the FDA's approval standard of six or nine months for
15		a vaccine?
16		So I think what he's saying is, in a way, we were
17		sold a pup, in a way. They were sold a product that
18		wouldn't have met the ordinary FDA regulations under
19		normal circumstances.
20	Q.	So I think essentially what Dr Doshi is doing is it 's
21		an online editorial ——
22	Α.	Yes.
23	Q.	and, like many online editorials, the writer tends to
24		like to pose questions $$
25	•	No.

- 25 A. Yes.
- 146

- 1 Q. -- without necessarily providing you with the answer.
- A. Yes. We looked yesterday at Fiona Godlee's editorial 2
- 3 after the swine flu vaccine. She was pretty angry as
- 4 well, and he's obviously quite angry.
- 5 Q. Yes, okay.
- Can we go to 4.1.5 at page 67 --6
- 7 A. Yes
- 8 Q. -- which is the COVID-19 vaccination timeline.
- 9 Just on the question of timeline,  $\, {\rm I} \,$  think you
- 10 previously indicated that you'd had regard to the
- 11 Inquiry timeline. I think the timeline you've been
- 12 given is what's called the SPICe timeline.
- 13 Α. Yes, it is, yes.
- 14 Q. That's a timeline that was provided by the Scottish
- 15 Parliament.
- A. Right. Thank you, Mr Gale. 16
- 17 Q. So you begin at 4.1.5 by saying that:
- 18 "On 8 December 2020 the first vaccinations against
- 19 COVID-19 were given in Scotland to those who would be
- carrying out the subsequent population-wide vaccination 20
- programme; this included both medical and non-medical 21
- personnel.' 22
- 23 Then the milestone of care home residents and staff
- 24 were vaccinated from 14 December 2020 onwards, and 25
  - high-risk clinical groups were offered vaccinations in

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- 1 early 2021. 2 A. Yes 3 Q. Then you list the various milestones from then right 4 through to the end of 2021. 5 A. Yes 6 Q. I think we can see, as at December 2021, you make 7 reference to it being the one-year anniversary of the first COVID vaccination in Scotland. 8 9 Α. Yes 10 Q. Since then, 4.3 million first doses have been 11 administered, 3.9 million second doses and 1.9 million 12 boosters and third doses have been administered from 13 around 1 200 locations A. Mm-hm. 14 15 Q. So you then go on to make a comment, and I wonder if you 16 would just read that out, please. 17 Α. Yes. So: 18 "Comment. The COVID-19 vaccination programme in 19 Scotland continued throughout 2022 and is still in place in 2023. In autumn 2022, MHRA approved bivalent 2.0 21 vaccines from Moderna and Pfizer. 2.2 So those are vaccines that are designed to provide 23 protection against the original strain of the virus and 2.4 also the variant strain, one variant strain:
  - "The vaccination milestones are summarised in

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July 27, 2023

1	Appendix 9 to [my] report."	1	"The December 2022 MHRA publication"
2	Q. I think it's actually appendix 10 $$	2	I've got this here. This is what it looked like,
3	A. Oh, is it?	3	my Lord. So it:
4	Q. $$ but it makes little difference. We can easily	4	" lists 2,362 Yellow Card reports with a fatal
5	find it.	5	outcome"
6	Right. You then go on at 4.1.6 to refer to vaccine	6	In other words, where the person had received a
7	adverse events reported in the UK.	7	vaccine and they had died, and somebody, maybe a doctor
8	A. Yes.	8	or a relative, reported it as linked to the vaccine.
9	Q. I think we can probably work it out, but what do you	9	Of these, 1,044, or 47%, were in females, and 1,189,
10	regard, or what do you and other public health	10	in other words 53%, were in males. Of these reported
11	practitioners regard, as a vaccine adverse event?	11	fatalities , 809, 34%, occurred in people who were aged
12	A. Yes. There's a fine distinction between an adverse	12	less than 69 years. So relatively young people.
13	event and an adverse effect. An adverse effect is	13	And then:
14	considered to be indisputably linked to the drug or	14	"During the 2-year period of assessment [by the
15	vaccine being considered.	15	MHRA], vaccine—associated adverse events (other than
16	An adverse event will be something that's reported,	16	fatal events [so non-fatal events]) were reported as
17	usually in the early days, but often later on, in the	17	follows "
18	history of a drug or a vaccine. An adverse event is	18	With AstraZeneca COVID $-19$ vaccine, a huge number of
19	simply practitioners $$ healthcare practitioners,	19	reports: 246,866; with Moderna, there was fewer: 47,045;
20	doctors or nurses $$ and nowadays members of the public	20	and with Pfizer, there was somewhere in between:
21	can report any untoward physical or psychological or	21	177,900. So a very large number of reports.
22	mental problem that they consider is linked to the prior	22	What I couldn't get from the report was how many
23	taking of the drug or use of the vaccine.	23	doses had been given, what's the proportion of the
24	Q. And that's, in part, the Yellow Card referral.	24	number of doses given. But just taking those as ball
25	A. It's done through the Yellow Card system, yes. For	25	numbers, very high numbers, and far more than you would
	149		151

1		doctors there was always, at the back of the British
		5.
2		National Formulary, a Yellow Card pre-printed, and if
3		a patient to whom you prescribed a drug $$ and it would
4		usually be a kind of novel drug $$ had a funny reaction
5		to it, and you thought, "This is odd, I need to report
6		that to the precursor of the MHRA", you would fill out
7		the card and send it off. There was always a lot of
8		under-reporting, but responsible doctors would try and
9		report adverse events, even though they may not even
10		become aware of them. Some patients would die $$ you
11		might give them a drug, they might die, and you might
12		just never really link it to your having given them
13		a particularly powerful drug. That's part of the
14		difficulty of spontaneous reporting systems.
15	Q.	Go to the bottom of page 69 of your report and what is
16		said at 4.1.6. Perhaps you would just read from the
17		beginning of that. Some of it, I think, is material you
18		have now already covered or alluded to, but perhaps you
19		could just read what you say.
20	Α.	So "On 1 December" onwards:
21		"On 1 December 2022 the UK Medicines and Healthcare
22		Products Regulatory Agency (MHRA) published a summary of
23		the spontaneously-reported adverse events (Yellow Card
24		reporting) that had been received by the agency between
25		9 December 2020 to 23 November 2022

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#### 1 expect to see with vaccines. 2 So my comment here: 3 "A reported adverse event from a drug or vaccine 4 (e.g. sudden death) does not prove causality - although 5 adverse events that are reported frequently and 6 consistently often do point to a true causal 7 association. The risk of vaccination need to be weighed against the risks of severe COVID-19. Historically, the 8 9 UK's Yellow Card system for reporting adverse events has 10 resulted in under- rather than over-reporting; the 11 MHRA's December 2022 report on the potential harms of 12 COVID-19 vaccines may therefore have underestimated the 13 scale of the vaccine-associated harms, rather than 14 overestimating it." 15 Shall I carry on. 16 Q. Please carry on, yes. 17 A. "Aside from fatal events, analysis by the MHRA of two 18 consecutive years $\dots$ " So basically they were looking at 2021 and 2022 $\ensuremath{\mathsf{up}}$ 19 20 until November, and then basically they stopped 21 analysing: 22 "... suggests [strongly suggests, I'd say] that 23 COVID-19 vaccination may cause an increased risk of the 24 following serious adverse events."

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And then I list --

1	Q.	You list them.
2	Α.	And these are ones that they themselves have highlighted
3		as coming up a lot. So:
4		"• Anaphylaxis (i.e. immediate—onset,
5		life — threatening allergic reaction) "
6		They received 990 reports, mostly with the
7		AstraZeneca product.
8		"• Bells' palsy (i.e. unilateral facial nerve
9		paralysis )"
10		So half of your face becomes paralysed. They seem
11		to imply that they get a lot of reports of that, but the
12		numbers weren't in the report; at least I couldn't find
13		them. They say it's continuously reviewed. That is
14		what they are saying. Although at the end of the report
15		they tell us they're stopping routine reviewing, which
16		is a bit odd.
17		"• Guillain – Barré syndrome (i.e paralysis of
18		the lower limbs) "
19		It's occasionally seen with other vaccines, but with
20		these particular vaccines seems to have been seen quite
21		often. Again, the actual numbers were not disclosed in
22		this report; at least I couldn't find them.
23		Immune thrombocytopenia. That sounds pretty grave,
24		because that means you've got very few platelets, so
25		you're going to have severe problems with clotting. You
		153
1		won't be able to clot your blood if you cut yourself.
2		Then major thromboembolic events. That means very
3		serious life -threatening blood clots. There were 486
4		reports to the MHRA of these, mostly with AstraZeneca,
5		although, again, we don't know what proportion of the
6		vaccines administered were AstraZeneca. But assuming

- they were one-third, they clearly have been strongly
  associated with AstraZeneca.
  Menstrual disorders. A huge number of reports to
- 10MHRA, 51,000, and the MHRA says they were "mostly11transient [and we] will continue to review [this12problem]".
- 13Myocarditis. That's the inflammation of the heart14muscle. Again, very large number of reports to MHRA, in15my view: 1,241 in total, and 15 of these were reported16as having a fatal outcome. The MHRA comment is the17"reports ... are being monitored closely".
- Pericarditis , which is inflammation of the fibrous
  sac surrounding heart. Again, a very large number of
  reports to MHRA which were associated with the vaccine,
  at least in the people reporting them. 954 of these.
  Finally, transverse myelitis, which is rather
- rare -- in fact, very rare -- inflammation of the spinal
   cord, going right across the spinal cord, would cause
- 25  $$\ensuremath{\text{paralysis}}$  of the limbs, and there were 179 reports in
  - 154

- 1 total; again, most of these originating from vaccination 2 with the AstraZeneca product. The comment from MHRA 3 was ---4 Q. Perhaps can we just -- I'm sorry, I think you're going 5 on to the comment on transverse myelitis. 6 A. Yes 7 Q. That, "the product information has been updated". 8 A. Yes. Yes, indeed. 9 MR GALE: Can we just stop there, doctor, because we have to 10 be mindful of the burden on the stenographers, and 11 I think we've passed our normal time. So perhaps we can 12 just stop there and we will return to finish in a few 13 minutes LORD BRAILSFORD: Very good. Thank you. 14 15 (3.11 pm) 16 (A short break) 17 (3.30 pm)18 MR GALE: Dr Croft, just another few hours. 19 Can we go to page 71 of your report, please. 20 A. 71. 21 Q. You've got a comments section. I think that's as far as 2.2 we had got --23 A. Yes. 24 Q. -- in your read-through. Would you read the comment 25 section in its entirety, please. 155 1 A. Yes. Comment: "See the ' Scientific knowledge' box, on Page 62 of 2
- 3 this report." 4 And that was summarising the key messages from 5 Graña ... 6 (Interruption to the live stream) "  $\ldots\,$  of COVID-19 vaccines states that it is unclear 7 8 as to whether or not vaccination has made any difference 9 to the numbers of deaths from COVID-19 [and there is a 10 quote from the Cochrane review:] ('there is insufficient 11 evidence to determine whether there was a difference 12 between the vaccine and placebo in terms of death 13 because the numbers of deaths were low in the trials'): 14 future updates of the review may resolve this important 15 point. Minor adverse events (e.g. fever, headache) 16 occur commonly with many of the currently-available 17 COVID-19 vaccines. For many of the currently-available 18 COVID-19 vaccines, serious adverse events (e.g. cardiac 19 and neurological events, and sudden death) appear to be 2.0 few, based on the reported RCTs. However this 21 apparently low number may be due to (i) the very short 2.2 follow-up period in many of the reported vaccine RCTs, 23 ( ii ) the fact that the candidate vaccine was not 2.4 compared against a true placebo, (iii) the number of 25 participants in the reported RCTs was small, (iv) the

1		RCT participants were optimally healthy at time of
2		vaccination, or were otherwise unrepresentative of the
3		majority of the UK population, or $(v)$ a combination of
4		any or all of the foregoing. In early 2023 MHRA
5		announced that it would no longer be issuing special
6		publications on the spontaneously-reported adverse
7		events associated with COVID-19 vaccines."
8		Although they do say $$ so this is the last of its
9		kind $$ that they will report on the autumn booster for
10		2023.
11		"The reasons for this announcement are unclear.
12		Around the same time, and for reasons that are also
13		unclear, the December 2022 report [that's the two-year
14		report, this one] was removed from the agency's
15		website."
16		At least I couldn't find it when I tried to find it
17		on there. By good fortune, I downloaded it, I think,
18		around about Christmas, when it came out, so I had
19		а сору.
20	Q.	Finally, in relation to this, can we go to the MHRA
21		document, please.
22	Α.	Yes.
23	Q.	This is a summary of Yellow Card reporting published on
24		1 December 2022, as you have just said.
25		Can we go to page 819 within the second bundle of

## Can we go to page 819 within the second bundle of

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1		documents, please.
2		815 shows us the cover sheet:
3		"Coronavirus Vaccines.
4		"Summary of Yellow Card reporting.
5		"Published 1 December"
6		And the data included data from 9 December 2020 to
7		23 November 2022.
8	Α.	Yes.
9	Q.	Can we go to page 819 within that document.
10	Α.	Yes.
11	Q.	I think we can see there this is the summary section.
12	Α.	Mm-hm.
13	Q.	Reading the first four paragraphs I think is perhaps of
14		particular interest , and I' II just read those to you:
15		"Over the first 27 months of the pandemic over
16		178,397 people across the UK have died within 28 days of
17		a positive test for coronavirus Vaccination is the
18		single most effective way to reduce deaths and severe
19		illness from COVID $-19$ . A national immunisation campaign
20		has been underway since early December 2020."
21		Now, again, as a public health consultant and
22		epidemiologist, is that a general statement with which
23		you would agree?

24 A. Thank you, Mr Gale. If I could refer you back to Altman 25 and his statement. So that is quite a powerful

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1		statement. Doug Altman says $$ that's in the bundle of
2		documents, my Lord $$ only randomised trials allow valid
3		inferences of cause of effect. Therefore, I would
4		expect that statement there $$ "Vaccination is the
5		single most effective way to reduce deaths and severe
6		illness " $$ to be supported by the evidence from
7		randomised controlled trials . But that isn't what the
8		randomised controlled trials show at the moment. It may
9		do at some point in the future.
10	Q.	It may do at some stage in the future.
11	Α.	Yes, they may do.
12	Q.	Right.
13		Then the document goes on:
14		"Three COVID-19 vaccines – the Pfizer/BioNTech
15		AstraZeneca and Moderna $-$ were used in the
16		primary and booster vaccination campaigns up to the end
17		of August 2022. All have been authorised for supply by
18		the (MHRA) following a thorough review of safety,
19		quality and efficacy information from clinical trials .
20		In clinical trials , these vaccines showed very high
21		levels of protection against symptomatic infections with
22		COVID-19. Data are available on the impact of the
23		vaccination campaign in reducing infections, illness and
24		mortality in the UK."

25 Then it goes on:

# 159

1		"The MHRA confirmed on 9 September 2021 that the
2		COVID-19 vaccines made by Pfizer and AstraZeneca can be
3		used as safe and effective booster doses. Following
4		a review of the data for the COVID $-19$ Vaccine Moderna
5		vaccine, the MHRA and Commission on Human Medicine
6		experts also concluded that this vaccine can be used as
7		a safe and effective booster dose. All vaccines and
8		medicines have some side effects. These side effects
9		need to be continuously balanced against the expected
10		benefits in preventing illness."
11	Α.	Yes.
12	Q.	If one turns over the page to 820, there's separate
13		comments on each of the vaccines, the Pfizer-BioNTech,
14		AstraZeneca and Moderna.
15	Α.	Yes.
16	Q.	And then towards the bottom of that page, if one can see
17		penultimate paragraph:
18		"The MHRA continually monitors safety during
19		widespread use of a vaccine. We have in place a
20		proactive strategy to do this. We also work closely
21		with our public health partners in reviewing the
22		effectiveness and impact of the vaccines to ensure the
23		benefits continue to outweigh any possible side
24		effects ."
25	Α.	I would like to know who these public health partners

2

1		are because it's not really explained, but it's
2		interesting
3	Q.	To a certain extent you take that on trust.
4	Α.	We have to take that that on trust, yes, because the
5		MHRA isn't really resourced to conduct epidemiological
6		analysis of the reports coming to it, not really . They
7		count the reports. They are not like NICE, National
8		Institute of $$ who do. They can assess the benefits
9		and harms of new drugs. MHRA isn't really like that.
10		They will depend on other people to do that for them.
11	Q.	If one goes to page 821, in the first full paragraph
12		I think we can see that as at the data date,
13		23 November 2022, 17,965 Yellow Cards have been reported
14		for the Pfizer, 246,866 have been reported for
15		AstraZeneca and 47,045 for Moderna.
16		If one then goes to the bottom of that page, three
17		paragraphs from the bottom:
18		"For all COVID-19 vaccines, the overwhelming
19		majority of reports relate to injection-site reactions
20		(sore arm for example) and generalised symptoms such as
21		'flu—like' illness , headache, chills , fatigue
22		(tiredness), nausea (feeling sick), fever, dizziness,
23		weakness, aching muscles, and rapid heartbeat.
24		Generally, these happen shortly after the vaccination
25		and are not associated with more serious or lasting
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1	illness ."
2	Again, to the bottom of that page, the last
3	sentence:
4	"Overall, our advice remains that the benefits of
5	the vaccines outweigh the risks in the majority of
6	people. Further comments on use in specific populations
7	and details on the specific safety topics can be found
8	within Section titled Analysis of data."
9	Then we have a conclusion section there. Again, we
10	have a very generalised statement, which is:
11	"Vaccines are the best way to protect people from
12	$COVID{-19}$ and have already saved tens of thousands of
13	lives . Everyone should continue to get their vaccination
14	when invited to do so unless specifically advised
15	otherwise.
16	"As with all vaccines and medicines, the safety of
17	COVID-19 vaccines is being continuously monitored.
18	"The benefits of the vaccines in preventing COVID $-19$
19	and serious complications associated with $COVID-19$ far
20	outweigh any currently known side effects in the
21	majority of patients."
22	And then there's a reference to further information.
23	So, again, can I just ask you on the first part of
24	that concluding section, is that something with which,
25	in general terms, you agree?

3		which is that only randomised trials allow valid
4		inferences of cause and effect, and the randomised
5		trials don't show that the vaccines have that effect in
6		saving lives, in preventing deaths.
7	Q.	Would it be right in saying, doctor, that it doesn't
8		satisfy your test and standard, but it might satisfy
9		others?
10	Α.	Well, it isn't my personal test. It's the professional
11		test that all epidemiologists would use before making
12		those kind of categorical statements, yes.
13	Q.	But other epidemiologists might have a more liberal
14		approach, if I can put it that way, to adherence to the
15		Altman rule, so you might find others who disagree with
16		you.
17	Α.	Possibly, yes. I'll just say again what the Cochrane
18		review says, and that's:
19		"There is insufficient evidence to determine whether
20		there was a difference between the vaccine and placebo
21		in terms of death."
22		That has to be the $$ a valid inference of cause and
23		effect .
24		(Pause)
25	Q.	I think we do have some data at pages 825 and 826.
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A. Well, no, because again the first part -- it may be

correct, but it's not demonstrated by the Altman rule,

## 163

1		Perhaps if we just look at that.
2		Table 1 discloses those who have received a first
3		dose of the vaccine for $COVID-19$ up until
4		11 September 2022.
5	Α.	Yes.
6	Q.	For Scotland, the figure is 4.5 million , second dose is
7		4.285 million, and those who have received a third or
8		booster, again in Scotland, is 3.5 million . I think
9		these are figures you've given already $$
10	Α.	Yes.
11	Q.	in the terms of your report.
12	Α.	Yes.
13		Yes, just to clarify what I've just said, my Lord.
14		So it's correct that deaths started to decline, if you
15		like , as the pandemic progressed, but there may be other
16		reasons for that, including what we talked about
17		earlier , which was the better treatment protocols that
18		weren't contributing to the patient's morbidity. That's
19		just the obvious reason. So just to say, "Well, the
20		deaths were declining at the same time as the vaccines
21		were being given to people" is not scientifically sound,
22		in my professional opinion.
23	Q.	Could I, just in conclusion, ask you to look at page 855
24	•	within that document.
25	Α.	Yes.
20		

- 1 Q. I think these are tables 11 and 12 which show, first of
- 2 all , the number of UK reports with a fatal outcome --
- 3 A. Yes.
- Q.  $\,--$  received for COVID-19 vaccines by a patient up to and 4 5 including 23 November 2022.
- A. Yes 6
- 7 Q. So for all vaccines the total is 2,362.
- 8 A. Yes
- 9 Q. But, again, causality is not being established here.
- 10 A. Of course. Indeed. And the true number may be higher.
- 11 It's likely to be higher based on historical
- 12 under-reporting. Or it may be lower because there may 13 have been over-reporting.
- 14 Q. Yes
- 15 A. But it's what has been reported. That's the data as we 16 know it
- Q. It is possible that it's just simply a coincidence --17
- 18 A. Yes.
- 19 Q. -- between particularly, perhaps, an elderly person who 20 has been vaccinated and subsequent death.
- 21 A. Potentially, although if you see very many of the --
- 2.2 very large numbers are in the middle-aged and young
- 23 groups there, which wouldn't tend to give that kind of
- 24 pattern of reporting.
- 25 Q. I see.

- 1 I think also in table 12 you have that stratified 2 into male and female. 3 A. There doesn't seem to be much of a difference between 4 male and females. Actually, slightly more males, actually: 53% are males, 47% are females. So there is 5 6 a difference there, yes. 7 Q. I think we can inform ourselves on that if we look at 8 the accompanying text at 854. 9 A. Yes. 10 Q. If one goes to the penultimate paragraph, you see: 11 "A report with a fatal outcome on the Yellow Card 12 scheme does not necessarily mean that it was caused by 13 the vaccine ... ' A. Yes. 14 Q. "... only that the reporter has a suspicion it may have 15 16 been. Underlying or previously undiagnosed illness 17 unrelated to vaccination can also be factors in such 18 reports. The relative number and nature of UK reports 19 with a fatal outcome are subject to many factors that 20 influence ADR reporting. They should therefore not be 21 used to directly compare the safety of the different 2.2 vaccines." 23 A. Yes, I would agree with the last sentences. 24 Q. Could we just go finally to the conclusions on page 858.
- 25 These are essentially the same conclusions that we've

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- 1 seen in the summary and, again, I draw your attention 2 again to what is said at the penultimate paragraph: 3 "The benefits of the vaccines in preventing COVID-19 4 and serious complications associated with COVID-19 far 5 outweigh any currently known side effects. As with all vaccines and medicines, the safety of COVID-19 vaccines 6 7 is continuously monitored, and benefits and possible 8 risks remain under review." 9 Again, I understand the clarification that you've 10 made in relation to that, a statement of that 11 generality. 12 Α. Mm-hm. 13 Q. And I presume you would make it again in relation to 14 this? 15 A. Yes. Yes. 16 Q. Right. Doctor, you will be pleased to know we're nearly 17 there 18 A. Thank you. Q. Can we go to section 5 of your report, please. This is 19 20 at page 73 and following. This is a summary, "what do 21 we know now?" 22 So do I take it really here you are giving, from 23 your perspective of a consultant public health physician 24 and as an epidemiologist in particular, what is your 25 professional, informed opinion? 167 1 A. Indeed, yes. 2 Q. And these statements are statements which, in your view,
  - 3 are borne out by the material that you have
  - 4 considered --
  - 5 A. Yes
  - 6 Q. -- and looked at?
  - 7 A. Yes. Mr Gale.
  - 8  $\mathsf{Q}.\;$  So on that basis, doctor, would you just read through
- 9 that section, please.

10	A. So:
11	"Summary — what do we now know?
12	"The COVID $-19$ pandemic of 2020 $-2023$ , caused by
13	a novel coronavirus, was a national emergency which
14	threatened the lives of certain groups in society: the
15	very old, and the very sick [but especially the very
16	old ].
17	"Other groups (children [by which I mean healthy
18	children], healthy young adults) were not ever at risk
19	of severe disease.
20	"By early 2023 the pandemic had abated but there
21	were reports of many people with long COVID and of othe
22	people with long—term cardiovascular sequelae of
23	COVID-19 infection."
24	So some bullet points about physical measures
25	against COVID-19. These, I hope, all arise organically
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1		1		
1 2	from what has been said earlier in the report. So the	1 2		typographical error but it might be seen as being
3	first bullet point: "• From March 2020 onwards, and in common with many	3		significant . In the first bullet point I think the date
4	other governments, the Scottish government recommended	4	٨	should be January 2021. Yes. Yes, thank you. Thank you, Mr Gale. Yes. Thank
5	or mandated a range of physical measures intended to	5	Л.	you so much.
6	limit of spread of SARS–CoV–2, the novel coronavirus	6		So fourth bullet point:
7	which was the cause of $COVID-19$ .	7		"• Vaccination against COVID-19 became
8	"• The physical measures recommended or mandate by	8		a prerequisite of travel to many countries, and some UK
9	the Scottish government ranged from simple public health	9		employers made it obligatory for their workforce.
10	practices (the encouragement of frequent handwashing,	10		"• It remains unclear as to whether or not COVID-19
11	cleaning of environmental surfaces, the use of PPE in	10		vaccination has resulted in fewer deaths from COVID-19.
12	hospitals and care homes) to coercive and/or intrusive	12		"• COVID—19 vaccines have been shown in randomised
13	measures (face mask mandates outside of healthcare	13		controlled trials to be effective, or probably
14	settings; lockdowns [and there's a definition for that];	14		effective, in reducing the number of people acquiring
15	enforced social distancing; test, trace and isolate	15		COVID-19 or severe COVID-19; however vaccine-induced
16	measures).	16		protection against COVID-19 is short-lived."
17	"• In 2020 there was scientific evidence to support	17		So there's waning immunity which is not mentioned at
18	the use of some of the physical measures (e.g. frequent	18		all in the MHRA report, I should add.
19	handwashing, the use of PPE in hospital settings)	19		The last point:
20	adopted against COVID-19.	20		"• Because of the antigenic variability of all
21	"• For other measures (e.g. face mask mandates	20		coronaviruses [this concept of them being a moving
22	outside of healthcare settings, lockdowns, social	22		target], including SARS $-CoV-2$ , it was foreseeable that
23	distancing, test, trace and isolate measures) there was	23		COVID—19 vaccines would only provide short—term
24	either insufficient evidence in 2020 to support their	24		protection against COVID-19 (as is the case also with
25	use $-$ or alternatively, no evidence; the evidence base	25		current vaccines against seasonal influenza).
20	• •	20		
	169			171
1	has not changed materially in the intervening	1		"• Because the novel gene technology vaccines
2	three years [even though there have been two additional	2		procured by the UK government had been tested on
3	reports about face masks].	3		relatively small study populations, and had been
4	"• It has been argued that the restrictive measures	4		assessed for safety over short follow-up periods only,
5	introduced during the COVID-19 pandemic resulted in	5		rare and sometimes serious adverse effects (including
6	individual, societal and economic harm that was	6		reported fatal events) emerged, once the vaccines had
7	avoidable and that should not have occurred."	7		been used on a mass scale in the UK and in other
8	And in fact that's now one of the textbook standard	8		countries."
9	points that seems to be indisputable.	9	Q.	Doctor, there's one point in your summary that I would
10	So "Vaccines against COVID $-19$ ". We have eight	10		like to touch on with you, and that goes back to that
11	bullet points. Firstly :	11		first section at page 73.
12	"• Vaccines against COVID-19 became available to the	12	A.	Yes.
13	UK general public in [January] 2020; initially only the	13	Q.	It's the second paragraph, the short paragraph.
14	high—risk groups (the very old, the very sick) [also	14	Α.	Yes.
15	healthcare workers] were targeted.	15	Q.	"Other groups (children, healthy young adults) were not
16	" • All the COVID-19 vaccines procured by the	16		ever at risk of severe disease."
17	UK government during 2020 and 2021 were nucleic acid	17	Α.	Yes.
18	vaccines using novel gene technology."	18	Q.	Now, I think I understand the context in which you're
19	But more recently they had procured a couple of	19		saying that $$
20	conventional vaccines.	20	Α.	Yes.
21	Thirdly:	21	Q.	but I think you are saying that in the $$
22	"• As additional vaccine supplies became available,	22	Α.	In a population —— in a population ——
23	vaccination was extended to young, middle-aged and	23	Q.	context of a public health practitioner looking at
24	elderly adults, and to children."	24		large ——
25	Q. Can I just stop you, doctor. There is one small	25	Α.	That's right, yes.

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1	Q. And of course we know $$	1	INDEX
2	A. Yes.	2	DR ASHLEY CROFT (continued)
3	Q. $$ and we will hear and we know of instances where	3	Questions from COUNSEL TO THE INQUIRY9
4	children and healthy young adults were at risk of severe		(continued)
5	disease?	4	
6	A. Right, yes, of course.	5	
7	MR GALE: Doctor, you will be pleased to know that is all	6	
8	I have to ask you. If his Lordship wishes any	7	
9	clarification , but at the moment, thank you very much	8	
10	for the report that you have provided and the work that	9	
11	you have done, and on behalf of the Inquiry, I thank	10	
12	you.	11	
13	THE WITNESS: Thank you.	12	
14	LORD BRAILSFORD: I'm happy to say I've got nothing I wish	13	
15	to ask you. Thank you very much. I simply repeat what	14	
16	Mr Gale has said.	15	
17	THE WITNESS: Yes.	16	
18	LORD BRAILSFORD: This is, of course, simply the first stage	17	
19	in the presentation of scientific evidence. There will	18	
20	be a considerable volume, at the moment we can't be sure	19	
21	exactly how much further evidence of science or	20	
22	epidemiology in relation to COVID $-19$ , and what we've	21	
23	heard today will no doubt figure in the evidence we hear	22	
24	in the future because, of course, all subsequent experts	23	
25	who give evidence in whatever capacity will have the	24	
	150	25	
	173		175
1	opportunity to see what you've written. But in the		175
1 2			
∠ 3	meantime, thank you very much indeed. I'm very grateful.		176
4	So far as the audience is concerned, our thanks to		
	you for attending for two long days. I'm very grateful.		
5 6	You for attending for two long days. I mivery graterul. And, as I suppose they say in show business, I look		
7			
8	forward to look seeing you on 28 August at Murrayfield. Thank you all.		
° 9	(4.00 pm)		
9 10	(4.00 pm) (The hearing adjourned until Monday, 28 August 2023)		
11	(The hearing aujourned until Monday, 20 August 2023)		
12			
13 14			
14 15			
15 16			
10 17			
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10 19			
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20			

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