

OPUS2

Scottish Covid-19 Inquiry

Day 1

July 26, 2023

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1 Wednesday, 26 July 2023
 2 (10.00 am)
 3 LORD BRAILSFORD: Good morning, everyone, and, first of all,
 4 thank you for attending this presentation, which is the
 5 first public gathering of the Scottish COVID-19 Inquiry.
 6 The purpose of today's presentation is to hear
 7 a report prepared by Dr Ashley Croft on the epidemiology
 8 of COVID-19.
 9 It is a presentation — I use that word
 10 deliberately — and it is not a hearing where there will
 11 be opportunity for anyone else apart from Dr Croft to
 12 participate.
 13 Be well aware, however, that you will all or
 14 certainly core participants will get the opportunity to
 15 participate at later hearings, I imagine on more than
 16 one occasion, in relation to epidemiology and any other
 17 matters, because the Inquiry will be hearing evidence
 18 from a number of other sources in relation to the
 19 epidemiology of COVID-19 on a number of occasions
 20 throughout the coming months.
 21 I should also indicate at this stage that the first
 22 public hearing at which core participants will be
 23 offered the opportunity to participate will be
 24 a preliminary hearing to be held at Meadowbank[sic]
 25 Stadium in Edinburgh for two days — we've deliberately

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1 allowed two days, because we appreciate people may have
 2 a lot they wish to contribute — on 28 and 29 August.
 3 For core participants, I can inform you that you will
 4 receive a letter very shortly, at the beginning of next
 5 week, which will outline the format of that hearing and
 6 will also give you more details in relation to the
 7 conduct of it.
 8 So, with that very brief introduction, I should
 9 indicate that the other participants today will
 10 obviously be Dr Croft, the author of the report, and
 11 lead counsel on this part of the Inquiry,
 12 Stuart Gale KC.
 13 The hearing or the presentation has been set down
 14 to — or we have available two days, and I understand
 15 from Mr Gale that it's probable that we will need
 16 two days, although we may finish a little bit earlier
 17 tomorrow.
 18 During the course of today and tomorrow, we will
 19 have a number of breaks. We will have a break both this
 20 morning and this afternoon, both for the benefit of
 21 Dr Croft and Mr Gale, but also obviously for the
 22 convenience of the audience.
 23 So, with that explanation, I would invite Mr Gale to
 24 begin his examination of Dr Croft.
 25 Mr Gale.

2

1 DR ASHLEY CROFT (called)
 2 Questions from COUNSEL TO THE INQUIRY
 3 MR GALE: Thank you, my Lord.
 4 Good morning, Dr Croft.
 5 A. Good morning, Mr Gale.
 6 Q. Just some introductory matters to begin with, please, so
 7 that we know what we're dealing with.
 8 You've provided the Inquiry with a report which
 9 extends to some around about 70 pages, and attached to
 10 that report are a number of appendices which take us up
 11 into the hundreds of pages. You've also provided us
 12 with a total of 22 scientific papers, which have also
 13 been made available on our website and to core
 14 participants.
 15 My intention today and tomorrow is to use your
 16 report as a guide to take us through your presentation,
 17 so everything will largely be under reference to what is
 18 in your report. Occasionally, we will divert into some
 19 of the documents, but at those points I will make it
 20 clear that we are doing that so that you're able to
 21 follow that.
 22 So, doctor, can I begin with some formalities.
 23 Your full name is Ashley Marshall John Croft?
 24 A. Ashley Marcel.
 25 Q. Marcel, I do beg your pardon, first mistake.

3

1 For present purposes, you've provided your CV, which
 2 is contained at appendix 2 of your report, and extends
 3 from pages 80 to 100 for those who want to follow it.
 4 For present purposes, you've given an address at
 5 consulting rooms at 10 Harley Street in London.
 6 A. Yes.
 7 Q. You've also provided, I think, your GMC number.
 8 A. Yes.
 9 Q. How old are you?
 10 A. I'm 70 years old.
 11 Q. Now, at the beginning of your CV, you tell us that you
 12 are a fellow of the Faculty of Public Health Medicine of
 13 the Royal College; is that correct?
 14 A. Yes, that's quite correct. Which page is that?
 15 Q. It's at page 82.
 16 A. Oh, that's right, yes.
 17 Yes, on page 82, my Lord, five blocks down,
 18 "Professional body: Faculty of Public Health Medicine of
 19 the Royal College of Physicians of London", and it is
 20 quite correct, I'm a fellow of that by election.
 21 I became a member by examination in 1995, and a few
 22 years later was elected a fellow.
 23 Q. Now, that organisation — it may be self-explanatory,
 24 but could you tell us what qualifies you for membership
 25 and then fellowship of that organisation?

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1 A. Yes, the Royal College of Physicians of London is
 2 a long-established Royal College which has a membership
 3 consisting of qualified physicians, and they have to
 4 pass examinations and prove their competence.
 5 There are various subsections of that Royal College.
 6 One of them is a Faculty of Occupational Medicine, and
 7 quite a recent subsection is a Faculty of Public Health
 8 Medicine, which came into being about 40 years ago. It
 9 originally was called the Faculty of Community Medicine,
 10 but the name was changed because — I don't know.
 11 I think Community Medicine was a better name. So the
 12 two terms are sometimes used interchangeably.
 13 To become a member of the Faculty of Public Health
 14 Medicine — nowadays they tend to call themselves the
 15 Faculty of Public Health — you have to pass
 16 examinations, part 1 examinations, in the various
 17 specialist disciplines of public health, and in my day
 18 the core disciplines particular to public health were
 19 medical statistics, epidemiology, communicable disease
 20 control, health promotion, health economics and
 21 sociology. So it was common to go on a Master's course
 22 to prepare yourself for those part 1 exams, which were
 23 very hard. Later on, I was a part 1 examiner.
 24 But I passed those exams in 1992, I think — I've
 25 got it down here — and then became a member — I'm so

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1 sorry, I didn't become a member. I passed the part 1.
 2 There's then a part 2 for the membership of the faculty,
 3 and in my day that required you to do two big projects
 4 and two big reports, similar to this report, on some
 5 aspect of the work you were doing. You were meant to be
 6 training in-house and doing public health tasks under
 7 supervision, and you could choose any two things that
 8 were of interest. The idea was they had to be
 9 different. One of them was expected to be communicable
 10 disease control, because that's important — very
 11 important — in our area.
 12 So I did — I prepared two projects. Would you like
 13 to know what they were?
 14 Q. Please tell us.
 15 A. The first one was I looked at — I was working for the
 16 army at the time, and there was a concern about pregnant
 17 service women, that's to say women who were in the army,
 18 navy or air force, because up until about 1990, if they
 19 became pregnant, they had to leave. There was no
 20 facility for pregnant service women in the forces. Then
 21 this was challenged in the European Court, I believe,
 22 around about then, and it was considered illegal to ask
 23 women to leave — quite rightly — if they were
 24 pregnant. So the problem arose as to: how could they be
 25 employed safely where they were pregnant and

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1 breastfeeding?
 2 This was a big problem, and because I was the newest
 3 arrival, they said to me: right, you can sort it out.
 4 So for about a year, I did literature searches and
 5 consulted various authorities and produced a report for
 6 my department, my army department — yes, it was the
 7 army then — and this became army policy. I then wrote
 8 it up as a scientific paper, which we were encouraged to
 9 do, and as one of my first — yes, I think it was my
 10 second research paper that's in my CV:
 11 "Croft AM. The employability of pregnant and
 12 breastfeeding servicewomen. [Journal of the Royal] Army
 13 Med[ical] Corps 1995 ..."
 14 I think a lot of that is still in military policy.
 15 So that was basic epidemiology, really, just looking
 16 at all kinds of environmental infectious disease,
 17 ergonomic, occupational factors that might damage the
 18 health of servicewomen, and trying to find some way in
 19 which they could be accommodated with pregnancy, or not
 20 as the case may be.
 21 Then for my second report, I was rather keen on
 22 Legionnaires' disease. We had that outbreak in the army
 23 computing centre in Worthy Down in Hampshire, and it had
 24 closed down the army computing centre for two days,
 25 which meant for two days the army couldn't actually

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1 function. So I was keen to do that. But I was told,
 2 "No, don't do that; we want you to go and look at a new
 3 anti-malaria drug that's just come in called Lariam, and
 4 just go and evaluate it, it's a really good drug". So
 5 I thought: okay. I wasn't interested in malaria then,
 6 but I thought: well, you do what you're told in the
 7 army.
 8 So I set up — because I had been trained in
 9 epidemiology, I knew the right way to do an evaluation
 10 of a drug or a service or a vaccine is to do
 11 a randomised controlled trial. So in 1993, I did
 12 a little pilot trial in soldiers going to Kenya who were
 13 taking this new drug, and that went well.
 14 Then in 1994 I set up a full-scale randomised
 15 controlled trial of this new drug, and the study
 16 population were the First Battalion of the Grenadier
 17 Guards, who were going to Kenya for six weeks, and
 18 there's malaria in Kenya. So there were about 640 in
 19 the population, and so I — I should have said, I got
 20 research ethics approval, obviously. So they were
 21 randomised into two groups. The first group were
 22 randomly allocated to receive the new drug, which they
 23 would have got anyway, actually, and then the other
 24 group from randomly allocated to receive the old
 25 combination of drugs that they would have got the year

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1 before.
 2 So I did this trial -- and this is relevant,
 3 I think, to what we're going to talk about later on --
 4 but it was a bit unsatisfactory, because the soldiers
 5 going out to Kenya were given a questionnaire on week 2,
 6 at the point where they were flying to Kenya, and then
 7 again at week 8, when they were flying back, and
 8 I entrusted the questionnaire to the Royal Air Force,
 9 who were flying them from Brize Norton, and I didn't get
 10 a very good response; I got about a 56% response for the
 11 first questionnaire and a 48% response rate for the
 12 second questionnaire. That's not really very good in
 13 a randomised controlled trial; you want to aim for 100%.
 14 Another thing that was odd about it was that a lot of
 15 the soldiers -- one of the questions was: have you been
 16 taking the drugs correctly? And about 17% of them, even
 17 though they responded, admitted they hadn't. So this
 18 raised concerns.
 19 But anyway, I wrote the study up, and it was
 20 published in the Transactions of the Royal Society of
 21 Tropical Medicine and Hygiene. I had offered it to the
 22 British Medical Journal, and they said, "Well, Dr Croft,
 23 Major Croft, this is interesting, but normally we expect
 24 a response rate of about 60%. When it falls below that,
 25 when the dropout is so high, you can't really

1 necessarily ascribe validity to your results to the
 2 degree we want it."
 3 So anyway, I then did, the following year -- in the
 4 meantime, I passed my part 2 exam, putting in my
 5 pregnant servicewomen paper and my malaria paper, but
 6 I thought: I will do another randomised controlled trial
 7 just to sort of get to the bottom of this problem: why
 8 are soldiers throwing away their drugs?
 9 The second trial took place between October 1995 and
 10 January 1996, and the trial participants were the
 11 Princess of Wales' Royal Regiment, based in Dover. On
 12 this occasion, I went down to Dover and I spoke to the
 13 second in command. I said, "This is a very important
 14 trial, we need to know how good these drugs are, how
 15 well tolerated they are". So he put it on part 1
 16 orders, which are what soldiers read every day, "You
 17 really must take your pills when we are in Kenya, and if
 18 you don't like them for any reason, just tell the medics
 19 and we will sort it out."
 20 Then I personally went to Brize Norton at 4.00 in
 21 the morning on a number of occasions, because they went
 22 out to Kenya in waves. I personally gave the
 23 questionnaires to the troops, and the idea was they had
 24 to fill out a questionnaire or they didn't get on the
 25 plane. So I got a 100% take-up rate, and it was the

1 same coming back; they wanted to come back. So that was
 2 very good. But unfortunately the -- sorry, there was
 3 a point in the middle where somebody went out and they
 4 did a questionnaire in the middle.
 5 Towards the end of the trial, the whole thing
 6 collapsed because I was taken off the trial and sent to
 7 Bosnia, and also there had been an unexpected event
 8 where a soldier had become psychotic taking Lariam, and
 9 later on another soldier committed suicide from taking
 10 Lariam. So it was very unsatisfactory.
 11 Anyway, I was no longer in charge of the trial and
 12 went to Bosnia, came back, and then the following year
 13 I wrote a Cochrane systematic review of this particular
 14 drug to try and establish what were its proper
 15 properties based on randomised controlled trials,
 16 including mine, and that's how I got involved in
 17 Cochrane reviews.
 18 Q. Right.
 19 You've mentioned there, Dr Croft, a number of
 20 expressions that we're going to become familiar with in
 21 the course of your evidence.
 22 A. Yes.
 23 Q. Can I just pick up just a few of those --
 24 A. Of course.
 25 Q. -- at this stage.

1 Epidemiology --
 2 A. Yes.
 3 Q. -- as I understand what you've said, was an aspect of
 4 public health medicine, a specific aspect of that; is
 5 that right?
 6 A. Yes. It's really an aspect of all medicine, and all
 7 doctors have an intuitive understanding, or sometimes
 8 an academic training, in epidemiology. I'll just
 9 refer --
 10 Q. Well, you've given a definition of epidemiology --
 11 A. Yes.
 12 Q. -- in appendix 3.
 13 A. Page 101, I think it is.
 14 Q. It is indeed page 101. Perhaps you could just read that
 15 out, so we have that in the note.
 16 A. So page 101, this is appendix 3 of my report, my Lord,
 17 and in appendix 3 I define key epidemiological concepts,
 18 and one of the concepts is the word or the term
 19 "epidemiology". The definition I have used here is
 20 a fairly standard one, and it's:
 21 "The monitoring and study of factors related to
 22 health conditions, and the implementation of control
 23 measures to prevent disease occurrence."
 24 So epidemiology might encompass -- often will
 25 encompass -- infectious diseases, but it also extends to

1 noninfectious diseases. So you might study the
2 epidemiology of road traffic accidents, for example, and
3 work out why they're occurring, where they are occurring
4 and how you might try and mitigate them or prevent them.

5 The word "epidemiology", the Greek actually means,
6 "that which falls down upon us from above". So it's
7 quite a good idea. It's really anything that's
8 unexpected or really unfavourable, we try and work out
9 what it is about it that we can know and then how we can
10 mitigate or even prevent it.

11 Q. I think, from what you've said, there are probably many
12 aspects of epidemiology that one has to take into
13 account, but I think possibly two that are of
14 significance would be an understanding and an ability to
15 apply statistics and statistical analysis.

16 A. Yes, indeed.

17 Q. Also, as you say, looking at control measures —

18 A. Yes.

19 Q. — to prevent disease occurrence.

20 A. Yes.

21 Q. Now, would control measures also include prevention of
22 further infection through disease?

23 A. Yes. So if we were looking at a noninfectious disease,
24 motor vehicle crashes, we'd look at helmets and seat
25 belts. For infectious diseases, the control measures

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1 might be, if it was food-borne transmission, a disease
2 caused by food-borne pathogens, you would try and
3 implement food hygiene measures; if it was a respiratory
4 pathogen, you would look at maybe air filtration or
5 ventilation, as well as maybe more extreme measures; if
6 it was a blood-borne pathogen, you would make sure that
7 proper sterile techniques were being used and any blood
8 transfusions were free of pathogens, and so on.

9 So it would be specific to the type of disease and
10 especially the route by which that disease was
11 transmitted. That's really key to mitigating measures
12 for infectious diseases.

13 Q. Okay.

14 Two other phrases that you've used so far, and
15 I think we can helpfully find these referred to in
16 appendix 3.

17 One was randomised controlled trials.

18 A. Yes.

19 Q. Now, I think probably most people who are familiar with
20 medical papers and data will know what a randomised
21 controlled trial is, and probably most people in the
22 general public know what a randomised controlled trial
23 is, but you've given it a specific definition. It's at
24 page 102 in appendix 3, and I think if you could just
25 read that out.

14

1 A. Yes, "randomised controlled trial (RCT)". A randomised
2 controlled trial is defined as:

3 "The 'gold standard' research study in
4 evidence-based medicine (EBM); [in a randomised
5 controlled trial] study participants are assigned to the
6 intervention group or to the control group in a random
7 fashion."

8 Q. So if one is taking, for example, a vaccine —

9 A. Yes.

10 Q. — you would have a group who had been vaccinated, and
11 there would be a control group who either were not
12 vaccinated or had been given a placebo, as it's
13 frequently termed.

14 A. Yes. The experimental group, as it's called, the
15 intervention group, receives the vaccine, and the
16 control group might receive a different vaccine,
17 sometimes, but it's not ideal to have a different
18 vaccine, or they might receive saline, some inert
19 solution that looks as though they're getting
20 an injection but isn't a vaccine.

21 Q. I think if you go back to page 100 in appendix 3 —

22 A. Yes.

23 Q. — you will also find a specific type of randomised
24 controlled trial, which is a cluster randomised
25 controlled trial.

15

1 A. Yes.

2 Q. Perhaps you could just read that out and, if
3 appropriate, just expand on that a little.

4 A. Yes. So, my Lord, in a randomised controlled trial,
5 usually they involve individuals, like in the two
6 examples I just gave of the soldiers, and the unit of
7 randomisation for a trial with individuals is the
8 individual. So you would say you've got a — so my
9 Grenadier Guards, for example, 330 of them are randomly
10 assigned to the intervention, the drug, and the other
11 330 were assigned to the other drug. The numbers are
12 never going to be exactly the same because the
13 randomisation process means that the two arms never have
14 exactly the same numbers, but they usually differ by
15 only a few. So that's randomisation as it normally
16 occurs.

17 But in complex interventions, you might want to use
18 a different unit of randomisation. For example, you can
19 do randomised controlled trials in schools, where your
20 unit of randomisation would be the school itself. So,
21 for example, if you were worried about some aspect of
22 school dinners, for example, you could take all the
23 schools in Scotland, and half of them randomise them to
24 this aspect of school dinners you were worried about,
25 and the other half you randomise them to standard school

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1 dinners, and then you have a randomised controlled trial
 2 which is a cluster randomised controlled trial, and that
 3 is as valid as an individually –based randomised
 4 controlled trial. They are more difficult to set up,
 5 but they can be set up, and indeed some occurred during
 6 COVID and the lead–up to COVID, which we may touch upon
 7 later on.

8 Q. One other expression that you've used so far -- and we
 9 will come back to these, obviously, in some detail
 10 because there are three papers in those that you have
 11 prepared for us --

12 A. Yes.

13 Q. -- that have this title -- and that is "Cochrane
 14 review".

15 A. Yes.

16 Q. Again, there is a useful brief expression of what
 17 a Cochrane review is at page 101 of appendix 3. Perhaps
 18 you could just read that and then, bearing in mind that
 19 we are going to look at these in some detail in due
 20 course, just give an indication of what is a Cochrane
 21 review.

22 A. Yes. Evidence from randomised controlled trials is very
 23 powerful. We may talk a bit more about that in general
 24 terms later.

25 Q. Yes.

17

1 A. It's ideal to -- or often it's very helpful to combine
 2 evidence from a number of randomised controlled trials
 3 using a mathematical method that's called meta–analysis.
 4 Cochrane reviews are an approach to doing that, to first
 5 of all gathering all the evidence that's available on
 6 a particular topic of concern or of interest, and
 7 ideally the evidence should be that from randomised
 8 controlled trials, and then the individual trials are
 9 assessed for their quality and then they're combined
 10 using this method called meta–analysis to produce, in
 11 effect, a larger randomised controlled trial, where
 12 there's a greater degree of confidence in the findings.
 13 That's what a Cochrane review is.

14 They're named after a Scottish public health man
 15 called Archie Cochrane, who was born about 1920 and went
 16 to Cambridge and then worked in England and in Wales.
 17 He ended up in Cardiff as an academic. He was the first
 18 really to highlight that there is an enormous wealth of
 19 biomedical knowledge, the amount of scientific data is
 20 massive, and no clinician, no policymaker, can hope
 21 really to keep up with all that's necessary. So he
 22 conceived the idea of having a sort of central point by
 23 which all of that data was being systematically assessed
 24 and analysed and then summarised, so that individuals --
 25 the individual GP, the individual hospital doctor --

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1 didn't have to go through the process of doing it.

2 Archie Cochrane died in about 1986, and his work was
 3 very influential, and a number of doctors, mainly in
 4 England and also Canada, Scotland as well, came together
 5 to form the Cochrane Collaboration in the early 1990s,
 6 and this is what they set out to do: they ambitiously
 7 set out to consider every important clinical question --
 8 and there are tens of thousands of these -- and to
 9 gradually and progressively examine them all through
 10 systematic review of the evidence for those
 11 interventions, focusing on the potential benefits of the
 12 interventions, and also, importantly, the potential
 13 harms of the interventions.

14 So the Cochrane Collaboration, of which I have been
 15 a member since about 1995 -- I haven't done any reviews
 16 for a few years -- they've now produced, I think, about
 17 10,000 reviews. They cover a tremendous number, a range
 18 of topics. During COVID, towards the end of the
 19 pandemic, an important review came out to do with the
 20 physical measures to try and prevent the spread of the
 21 virus that causes COVID–19 -- we might be looking at
 22 that later, my Lord -- and also last year a review came
 23 out, it was a preliminary Cochrane review, looking at
 24 the efficacy and safety of vaccines to prevent COVID–19.
 25 So very important, extremely important, sources of

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1 evidence for us.

2 Q. Can I just take two points from what you've said.
 3 First of all, you've mentioned the expression
 4 "meta–analysis".

5 A. Yes.

6 Q. I think everybody can probably make a guess at what that
 7 is, but can you tell us from your point of view what it
 8 is?

9 A. Yes. If you were conducting a study where you end up
 10 with some numbers at the end -- I think it might be
 11 helpful if we went into the typical kind of numbers that
 12 you might obtain from a study -- you report those
 13 numbers and they will mean something to people who
 14 understand the numbers.

15 If you then want to combine the results of that
 16 study with a kind of comparable study to get a better,
 17 more precise estimate as to what it is that the
 18 investigators are trying to find, you use this method
 19 which is called meta–analysis. It's to do with
 20 mathematics. It's complicated. I have to take a lot of
 21 it on trust myself. But it's an accepted method of
 22 producing more precise numerical estimates of effect,
 23 and "effect" means whatever it is that the study was
 24 trying to show.

25 Q. Well, on mathematics, I'm afraid you're not going to get

20

1 any help from me.
 2 But the other point that you've perhaps alluded to
 3 is -- I take it that Cochrane reviews are regularly
 4 updated?
 5 A. They are. It depends, really, on what the review topic
 6 is, because some areas don't generate many new
 7 randomised controlled trials, but some areas of medical
 8 science are generating randomised controlled trials all
 9 the time, and so therefore new evidence comes along that
 10 may alter the findings of an existing Cochrane review.
 11 So a Cochrane review, where there's new evidence coming
 12 along, would normally be updated every three to
 13 five years, perhaps.
 14 But what's very helpful about Cochrane reviews is
 15 there often will come a point where the reviewers say:
 16 the evidence for this intervention is so compelling,
 17 there's no need to do any more randomised controlled
 18 trials, please stop doing more research, because the
 19 evidence is there and research funds are limited, and
 20 it's better if you research something else. Equally,
 21 they might say: the evidence against this intervention
 22 is so compelling that you shouldn't really do any more
 23 research. They can say that with authority because they
 24 have -- the endpoint of these reviews is one of quite
 25 significant precision.

21

1 Q. I think, again, this is something that we will come
 2 to --
 3 A. Yes.
 4 Q. -- in some more detail, but in the documents you've
 5 provided us with, one of them you've already referred
 6 to, which is the 2023 Jefferson, principal, main author,
 7 Cochrane review. It's number 9 in the bundle of
 8 documents, and that is a Cochrane review, the title
 9 being the "Physical interventions to interrupt or reduce
 10 the spread of respiratory viruses".
 11 A. Yes.
 12 Q. Now, I think we can see from the date that that is post
 13 certainly the worst of the pandemic, if I can put it in
 14 those simple terms. But before that, document number 8
 15 in the bundle is Jefferson 2011, with a similar title,
 16 "Physical interventions to interrupt or reduce the
 17 spread of respiratory viruses".
 18 A. Yes.
 19 Q. So just looking at those two, as I understand it, there
 20 was not, between 2011 and 2023, an update of a Cochrane
 21 review on the prevention of respiratory viruses.
 22 A. No, that's true. There wasn't. This particular review,
 23 the 2011 review, had been updated several times.
 24 Q. Yes, I think we can see that --
 25 A. And --

22

1 Q. -- it had been updated several times, but I think what
 2 is important, at least for our purposes in this Inquiry,
 3 is that the 2023 Jefferson Cochrane review did take into
 4 account preventative measures and the lessons learned
 5 from those preventative measures as a consequence of the
 6 COVID pandemic.
 7 A. Oh, the updated one, yes. That covered the entire gap
 8 from 2011 to 2022, and then they published their
 9 essentially further update of their previous update in
 10 early 2023.
 11 Q. Right.
 12 It may seem a little while ago, doctor, but can we
 13 go back to your CV. I think it'll probably be useful to
 14 set a number of concepts and references that you will
 15 make in context.
 16 Your academic qualifications, sir, are at page 83.
 17 A. Yes.
 18 Q. I think we can see, after a year at university in
 19 Madrid, you went to Oxford between 1971 and 1974, and
 20 you graduated from Oxford in 1974; is that right?
 21 A. Yes, that was my BA, which was my first degree, which
 22 was in English.
 23 Q. Yes. So you diverted off after that?
 24 A. I did. I was working in children's publishing for
 25 a while after that, and I thought it would be nice to be

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1 a doctor, and so in the evenings I was studying
 2 A Levels, which I think you call Highers, in science,
 3 and then in 1977 I applied to various medical schools
 4 and was accepted at Guy's Hospital medical school.
 5 In fact, there was a course where you could apply
 6 directly as an arts graduate, or with arts A Levels, and
 7 that was quite common in medical schools at the time.
 8 It used to be the standard way of entry to medical
 9 school. You did classics at school and you did
 10 medicine.
 11 Q. Yes. I was always told that in order to do law, it's
 12 good to have the Latin.
 13 A. Oh, yes, sure.
 14 Q. You also say, sir, just to get this clear, at page 84 of
 15 your CV, you also obtained a Master of Arts degree from
 16 Oxford --
 17 A. Yes.
 18 Q. -- in March 1984?
 19 A. Yes. Yes. At Oxford and Cambridge, you get a Master of
 20 Arts automatically 21 terms after matriculation.
 21 I didn't get round to picking it up until 1984, when
 22 I went in person and got it.
 23 Q. Okay, thank you. Right.
 24 As you said, you attended Guy's medical school
 25 between 1974 and 1984 --

24

1 A. Yes.
 2 Q. -- and obtained your degree in 1984?
 3 A. Between 1978 and 1984.
 4 Q. 1978 and 1984, yes.
 5 A. Yes, correct.
 6 Q. You also subsequently obtained a Master's in community
 7 medicine from the University of London in 1990; is that
 8 right?
 9 A. Yes, that's right. That's when I started my specialist
 10 training in public health medicine.
 11 I should have mentioned that the Faculty of Public
 12 Health Medicine encourage doctors to work as general
 13 doctors, either as GPs or in some clinical specialty,
 14 for a few years before doing public health medicine.
 15 Q. I see.
 16 A. Because, essentially, we're not dealing with patients as
 17 individuals, we are dealing with groups of patients, so
 18 it's good to have pretty good experience of dealing with
 19 patients as individuals.
 20 So I didn't start public health training, which
 21 I started with that MSc, until 1990.
 22 Q. I think we can also see that, also from the
 23 University of London, you obtained two diplomas: one in
 24 the medical care of catastrophes --
 25 A. Yes.

25

1 Q. -- and also in tropical medicine and hygiene; is that
 2 right?
 3 A. Correct.
 4 Q. Just to complete your academic background, you obtained
 5 a doctorate from Portsmouth University in January 2022,
 6 quite recently.
 7 A. Yes.
 8 Q. You've had a long association with the University of
 9 Portsmouth. Can you explain that a little?
 10 A. Oh, yes. I worked in the army as a public health
 11 physician for 27 years and, towards the end of my time,
 12 I started a doctorate course at Portsmouth University
 13 part-time, and this continued and it went on for quite
 14 a long time, nine years. During lockdown, I was able to
 15 complete my thesis. That was part of the, for me,
 16 helpful aspect of lockdown, which was otherwise very
 17 damaging, for me and for everyone.
 18 So I put in my thesis, and the title of my PhD
 19 thesis was, "Evaluating the adverse effects of
 20 anti-malaria drugs", which I had been working on for
 21 nearly 25 years, but the PhD came in only towards the
 22 end of that time. So part of that thesis -- with a PhD
 23 thesis, you're supposed to include as part of it three
 24 or four scientific papers that you've published, and
 25 they will be discussed in the exam. I had 12 papers

26

1 that I included, and they covered a range of
 2 epidemiology, not just malaria.
 3 So I put in my written paper in 2020, and there was
 4 a hiatus because the universities were not functioning.
 5 But in 2021 I was told I could now have an oral
 6 examination on the paper. So this took place in 2021
 7 remotely, and for PhDs you have three examiners who quiz
 8 you on your thesis. Normally, there's one from the
 9 university and two external examiners, so I had three
 10 examiners. It was done remotely.
 11 At the end of it, they can either reject your thesis
 12 or accept it or suggest major changes or minor changes.
 13 But in the end, they said, "You can be a PhD
 14 immediately", which was very nice, "but do make a few
 15 minor changes like typos", and they said, "It would be
 16 helpful if you enlarged a bit on" -- there was a section
 17 where I talked about the need for further research.
 18 They said, "Just write a couple of extra pages for that,
 19 but for practical purposes, you can call yourself a PhD
 20 from" -- that was December 2021. I actually wrote up
 21 the bits they asked me to do in January, after
 22 Christmas, and sent it in, and then I got the letter
 23 back saying, "That's fine", and picked up my PhD in
 24 person in July 2022. By then, everything was open, so
 25 it was very nice.

27

1 Q. You've mentioned now on a couple of occasions
 2 an interest in malaria, and we will come to look at some
 3 of your papers, but I think we can see in your published
 4 papers that you have had, over a very considerable
 5 number of years, an interest in malaria and its
 6 treatment; is that right?
 7 A. Correct.
 8 Q. Thank you.
 9 Just for completion, I think you're also a linguist?
 10 A. Yes.
 11 Q. And you're a member of the Institute of Linguists, and
 12 you're an accredited interpreter in French and Spanish?
 13 A. Yes.
 14 Q. Can we move on, then, from your academic experience,
 15 doctor, to your professional experience.
 16 I think in your CV we can see that, after a year as
 17 a house surgeon/physician in Guy's, you then make
 18 reference to an engagement -- this is at page 85 of your
 19 CV -- in the Falklands.
 20 A. Yes.
 21 Q. I'm inferring from that that that is in connection with
 22 your army career?
 23 A. Yes. I trained in the NHS and paid my own way for most
 24 of it. I did get a grant towards the very end, happily,
 25 but because I had a first degree already, I had to do

28

1 the three years self—funding.
2 So after qualifying as a doctor, you become what was
3 called a house physician, a house surgeon, and during
4 that time you're — it's called preregistration
5 appointment, so you're working under supervision, but
6 when you've completed that year, you then become fully
7 registered with the General Medical Council, and you can
8 then do whatever you like, emigrate to America or
9 whatever.

10 I joined the army then, because I had been in London
11 for seven years. I wanted a change. So I joined the
12 army on what was called a short service commission,
13 which was three years, and I rather liked the army,
14 actually. I got married during that time, and my wife
15 liked the army, so I stayed on.

16 But anyway, so I joined the army in February 1986,
17 after finishing my house surgeon job at Guy's Hospital
18 and Lewisham, and then we had a period of four — I was
19 with about 20 other doctors, one of them from the
20 University of Dundee, and we had four or five months of
21 specific military medicine training to prepare us for
22 a new role as army doctors. At the end of that, I got
23 what was called a posting order to go to Germany. This
24 was in the Cold War, so I was sent to the front line up
25 against the Russians. But they diverted me to the

29

1 Falklands, because they had been told to provide
2 someone. So I didn't go to Germany until the following
3 year. I went to the Falklands for four months, June
4 until October 1986, and worked there. Then I joined the
5 regiment to which I had been assigned, which was the
6 First Regiment Royal Horse Artillery, in Hohne in
7 West Germany.

8 Q. Right.

9 Really just taking it short, doctor, you had various
10 appointments, I think in various capacities, in Germany,
11 London, Bosnia, Afghanistan, and the majority of these
12 were as a public health specialist or consultant —

13 A. Correct, yes.

14 Q. — or grew into that role as —

15 A. Yes, correct, and once I became a public health
16 specialist, from time to time I'd be sent out to the NHS
17 for short secondments, or in one case for a two—month
18 secondment to Heart of Birmingham Primary Healthcare
19 Trust, and that was just really to keep the public
20 health skills up and to help out the NHS, perhaps, and
21 just get the benefit of what they were doing.

22 But my employer during all of that time was the
23 army.

24 Q. Yes.

25 I think you ended your career in the army with two

30

1 stints as a consultant public health physician in the
2 Surgeon General's department in both London and
3 Litchfield?

4 A. Yes, I became a consultant in July 1995 —

5 Q. Yes.

6 A. — after completing, as I was saying, my part 1 faculty
7 exams and my part 2 exams and doing a further exam, and
8 so then I was a consultant for 18 years. So, yes, that
9 takes us through to 2013, when I reached the normal
10 retiring age for army doctors of 60. It's less for
11 non—doctors. So I left the army at that point.

12 Q. What rank were you when you left the army?

13 A. Lieutenant colonel.

14 Q. Thank you.

15 Now, I think — and we will look at some of your
16 scientific papers as we go on — a lot of your
17 scientific papers are either directly or indirectly
18 related to interests that you might have had as a public
19 health consultant in the army.

20 A. They are quite army—specific, but of course that was my
21 employer and they were the kind of tasks I was being set
22 to do.

23 Q. Could I look at some of the other appointments that
24 you've had.

25 At page 86, I think we can see that you were

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1 a visiting fellow at the Effective Healthcare Research
2 Programme Consortium at the University of Liverpool.
3 Just tell me what that was about.

4 A. Yes. The University of Liverpool tropical medicine
5 department had a very close link with the Cochrane
6 Collaboration's infectious diseases branch, so they
7 hosted that and they provided secretarial support and
8 other support, for example in locating trials and doing
9 library searches and so on.

10 So for a period of just over a year, I was at that
11 point updating my systematic review that I'd written in
12 1996, which is one of the first Cochrane reviews to come
13 out and was published in the British Medical Journal at
14 the same time, and the updating process was quite
15 complex because we'd broadened the scope of the review,
16 and so I was appointed just to this title because it
17 then gave me use of the library and use of the
18 facilities at Liverpool while I was doing this task,
19 which took about a year.

20 So I was still in the army, but I had this kind of
21 extra — it was an honorary appointment as visiting
22 fellow.

23 Q. I think also, for a number of years, you were
24 an honorary lecturer in travel medicine —

25 A. Yes.

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1 Q. -- at De Montfort University in Leicester.
 2 A. Correct.
 3 Q. Finally, for about, I think, ten years, you were also
 4 the editor-in-chief of Human Parasitic Diseases. Can
 5 you tell us what that is, please?
 6 A. Yes. The editor-in-chief sounds very grand, but really
 7 I was there to really oversee the correct conduct of the
 8 publication process and the peer-reviewing process that
 9 was going on for this journal, Human Parasitic Diseases.
 10 It wasn't a paid appointment; it was, again,
 11 an honorific appointment.
 12 My role usually was to act as a kind of final
 13 arbiter, where a paper had been submitted to the journal
 14 for publication and two of the peer reviewers had said,
 15 "This is wonderful" and two had said, "This is terrible
 16 and should never be published". So, if you like, the
 17 managing director of the company would come to me and
 18 say, "Here is the paper, here is what the reviewers say,
 19 what do you think?" So I would arbitrate like that.
 20 They would also from time to time say to me, "We
 21 want to put out a special issue with a call for papers;
 22 what are the kind of topics of interest in the field of
 23 parasitological diseases?" So I would list topics of
 24 interest, and I would also perhaps from time to time
 25 suggest possible peer reviewers for papers.

33

1 So it wasn't a very onerous task, but it was
 2 interesting, and it meant I'd often have to read papers
 3 that were -- I'd know about them, but they were to
 4 a depth that I hadn't been familiar with, and I would
 5 have to kind of really try and nut out what it was that
 6 was being said and come to a decision as to whether this
 7 was something we would want to publish in that form or
 8 not.
 9 In the end, the publishing house that owned Human
 10 Parasitic Diseases, which was based in New Zealand, they
 11 sold out their titles to Elsevier, which is like a big
 12 publishing giant, and so this journal was merged with
 13 an existing Elsevier parasitological diseases publication,
 14 so it doesn't exist anymore, and I wasn't required
 15 because they already had an editor-in-chief for their
 16 new journal.
 17 Q. Again, it's probably a useful interjection because
 18 you've mentioned, in relation to your position as
 19 editor-in-chief of Human Parasitic Diseases, peer
 20 reviewing papers.
 21 A. Yes.
 22 Q. Now, again, for many of us, this is a probably a concept
 23 we're all relatively well familiar with, but it perhaps
 24 does need a little explanation.
 25 So can you just tell us, what is peer reviewing for

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1 the purposes of publication? How does it proceed? Who
 2 is it done by? Really as much information as you can
 3 give us about it.
 4 A. Yes. Yes, "peer reviewing" is a term which means that
 5 when a scientific paper is put forward to an editor of
 6 a journal, generally before the editor makes a decision,
 7 he or she will send it out to a number of acknowledged
 8 experts in that particular field, and they may be people
 9 that the editor knows about or they may be experts that
 10 they find by seeing who else has published in this
 11 field, and the peer reviewers -- they do it for nothing.
 12 I've done a lot of peer reviewing in my time. They do
 13 it for nothing. It's just meant to be part and parcel
 14 of what you do if you're a responsible scientist. They
 15 will read the paper, they will often be told to try and
 16 do it within a week or so, and they will often have
 17 a checklist that's provided by the editor to say: well,
 18 are the methods set up correctly? Are the results
 19 reported properly? And so on. Are the statistics
 20 sound, as far as you can tell? There will often be
 21 a separate statistics peer reviewer, because statistics
 22 is quite a specialised area. And then at the very end
 23 you will be given, usually -- this is what we had in my
 24 journal -- a list of options: publish as it is, or
 25 publish with major revisions, or publish with minor

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1 revisions, and you could specify what those are, or
 2 don't even think about publishing it. But you would
 3 normally have to give your reasons. So you send that
 4 in, and other peer reviewers will be doing the same, and
 5 then the editor makes a final decision as to whether or
 6 not to publish.
 7 They have to do that, firstly to guard against
 8 research fraud and possible -- or unintentional errors
 9 that might have been made by the investigators that
 10 perhaps they weren't aware of, and so to some extent
 11 it's protecting the editor's own back. But it acts as
 12 a sifting-out process. Really, the idea is that the
 13 best ideas get published quicker in the best journals.
 14 That's the idea of it.
 15 But the top journals will reject 90% of the papers
 16 submitted to them, usually after peer review, because
 17 there's just too much science that's being produced all
 18 at once to get into the most prestigious journals.
 19 Q. So can I just ask you, do I take it from what you're
 20 saying that you've been on both sides of the peer
 21 reviewing exercise, both as a peer reviewer and
 22 submitting papers that are subject to peer review?
 23 A. Of course, yes. I have been -- exactly, I have had
 24 papers peer reviewed. Unfortunately -- I think it's
 25 unfortunate -- peer reviewers tend to be anonymous, so

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1 you don't know who has actually reviewed your paper, and
2 it could be your worst enemy who has reviewed it, and
3 this does happen. So your worst enemy, a rival in your
4 field, could peer review your paper because he's the
5 only other person who knows about this unique topic, and
6 they could just review -- they could say to the editor,
7 "Don't publish this", and so there's no real redress
8 against rejection.

9 So I have been in the position of having papers peer
10 reviewed and accepted by the editor, or sometimes not
11 accepted, and I have been a peer reviewer for about
12 a dozen journals, and then I have been at the stage
13 beyond that, where I have been the arbitrator, where
14 peer reviewers have reached an impasse where they
15 couldn't decide amongst themselves whether to publish or
16 not. So I think I'm familiar with the process.

17 Q. Thank you.

18 Just moving on to one other appointment, you
19 mentioned that you have been an appraiser of General
20 Medical Council registered consultants and general
21 practitioners from April 2021 to date. This is again at
22 page 86 of your CV.

23 Now, I don't wish you to breach any confidences,
24 either personal or professional, but can you just tell
25 us what that role involves?

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1 A. Yes. About ten years ago, the General Medical Council
2 and also, I believe, the General Nursing Council,
3 introduced the idea of annual appraisals -- I'm sorry,
4 nurses don't do annual appraisals; they do three-yearly
5 revalidation. But doctors were required to do annual
6 appraisals to a certain format, and the format is
7 dictated by a document called "Good medical practice",
8 which is produced by the General Medical Council. So
9 you have to show during your annual appraisal that
10 you've conformed to the principles of good medical
11 practice, and it's set out in various domains, and they
12 cover areas such as courtesy to patients, good
13 record-keeping, clear handwriting, keeping up with your
14 topic, keeping up with your area, and patient
15 confidentiality and so on.

16 So that's the background to doctors' annual
17 appraisal. Everyone has to do it, and you have to do it
18 with an appraiser who is also a GMC doctor.

19 Then after five years, your responsible body --
20 which is the body that you belong to that, in a way,
21 guarantees your professionalism, your competence -- will
22 make a recommendation to the GMC: this doctor, Dr Smith,
23 has undergone the five year appraisals.

24 Also, yes, during that period you have to do what's
25 called a 360-degree reflection, which means your peers

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1 are meant to comment on your performance, patients are
2 meant to comment on your performance, or nurses, and
3 that's part of the revalidation process. You're also
4 meant to conduct a quality assessment exercise of your
5 own practice to try and improve your practice.

6 So, provided all those criteria are met, the
7 responsible body will make a recommendation as to
8 whether or not you should carry on for another
9 five years as a GMC registered doctor.

10 So it's quite bureaucratic, but I think it's good.
11 I think it actually does improve medical practice.

12 Q. Just, again, diverting away briefly from the GMC, if we
13 go back to page 82 of your CV, I think your responsible
14 body for appraisal and revalidation is the Independent
15 Doctors' Federation in London.

16 A. Yes, it is.

17 Q. So you undergo this process?

18 A. Oh, yes, certainly, I undergo it every year, and my
19 appraisal is coming up in October. So there's quite
20 a lot of bureaucracy I've got to go through then, and
21 you have to show your appraiser that you've kept up to
22 date with your -- well, your faculty normally will have
23 a requirement to do a certain amount of CPD every year.
24 In my case, we're expected to do about 50 hours of
25 continuous professional development of various kinds,

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1 but the aim is to do 100 hours. So you show that you
2 have done that and that your faculty has confirmed that,
3 and then they will ask you, killer question: are there
4 any investigations against you? Are there any
5 complaints against you? And if there are complaints
6 against you with the GMC, you have to declare them. You
7 can't conceal them because they already know, because if
8 there's a GMC investigation against a doctor, the GMC
9 will notify the doctor's responsible body, and so the
10 appraiser will already know. So if there is
11 an investigation, it's not necessarily the end of the
12 world, because often the investigations don't come to
13 anything, but you have to discuss it with your appraiser
14 and you reflect on what you might have learned or the
15 background, and then that's recorded. You also tell
16 them about your general health.

17 I'm happily in the position there has never been any
18 complaint against me to the General Medical Council, and
19 I think I'm right in saying that all General Medical
20 Council investigations are logged and registered in
21 perpetuity, so it's not something that one can really
22 get away from if it should ever occur.

23 Q. Okay.

24 Can we go back to the GMC, please.

25 A. Yes.

40

1 Q. Can I ask: what qualifies you for a role with the GMC as
2 an appraiser?
3 A. Actually, I believe any doctor can appraise another
4 doctor, as long as it's done in the correct way, with
5 the recognition of a responsible body, but I myself went
6 on a three-day training course with the Independent
7 Doctors' Federation because they needed some appraisers,
8 and then I did some appraisals after that, based on that
9 training, which very closely followed what I was just
10 mentioning, the good medical practice guidelines.
11 So the appraiser doesn't actually -- it's not the
12 appraiser who says at the end, "You're fit to go, carry
13 on for another year", they just go through the process.
14 It's the responsible body that, on the basis of the five
15 successful appraisals, will say to the GMC, "Right, we
16 recommend the doctor for revalidation for a further
17 five years".
18 Q. Can I ask -- again, without involving you in any
19 compromise of confidentiality -- can you indicate the
20 areas in which you may have been an appraiser?
21 A. As an appraiser, you can appraise any doctor in any
22 discipline, either a GP or a consultant, because the
23 principles of good medical practice apply to all
24 doctors. So let's say you are a psychiatrist. You
25 don't have to be appraised by a psychiatrist. You can

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1 be appraised by a GP. I myself have been appraised in
2 the past by a psychiatrist -- really good, excellent,
3 best appraisal I have had -- and by GPs and by
4 rheumatologists, and my current appraiser is
5 an occupational physician. So the specialty doesn't
6 matter, as long as they follow the format that's
7 approved.
8 Q. So would I take it from that that, in order to be
9 an appraiser, you would have to have a certain standing
10 within the profession?
11 A. You would have to be registered with the General Medical
12 Council. Yes, that's what you have to do to be an
13 appraiser. Because you're doing this on behalf of the
14 General Medical Council, you have to have a GMC number.
15 Q. Also, would I be right in thinking that you would have
16 to have the quality of independence?
17 A. Of course. And -- thank you very much -- so really the
18 appraiser shouldn't be known to you. It should be
19 somebody you don't know. And every three years, you
20 ought to change your appraiser. I think that is
21 a requirement. So you can't have the same appraiser for
22 20 years. That wouldn't be appropriate.
23 The system isn't perfect, and clearly sometimes it
24 breaks down, and doctors are charged with the most
25 heinous crimes, correctly, and that's terribly

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1 unfortunate. But it's rare, I believe.
2 Q. Briefly, can I look with you at your postgraduate awards
3 and decorations, which are at pages 87 to 89.
4 A. Yes.
5 Q. Really, again, just taking these relatively briefly,
6 you've had two decorations specifically in relation to
7 your military career. I think you received the NATO
8 Medal for service in Bosnia in 1996, and also the
9 Campaign Medal for active service in Afghanistan in
10 2008.
11 A. Yes.
12 Q. I'm particularly interested in the last reference on
13 page 89 to the Cochrane Club award. Obviously there's
14 a similarity in the name. Could you explain what that
15 was for?
16 A. Yes. The year before -- so I was given this award in
17 Auckland in New Zealand at the Cochrane annual
18 colloquium. That's the big meeting they have every
19 year, which moves around to different Cochrane centres
20 around the world. So that year it was in Auckland, and
21 I'm just going to look to see what Cochrane review I was
22 given it for. It was for doing a podcast in relation
23 to ... Yes, I produced a Cochrane review about the use
24 of helminth -- so here we are. So page 93, that's
25 right, the fourth one down. I produced, with two

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1 co-authors, a Cochrane review which was titled,
2 "Helminth therapy (worms) for allergic rhinitis". We
3 looked at various trials where people suffering from
4 allergic rhinitis were assigned to be given helminth
5 therapy or placebo to try and improve their allergic
6 rhinitis. We found there was a modest effect in
7 improvement of the hay fever, and I produced a podcast.
8 I think I was given an award because it was such
9 a novel area, said to be interesting and out of the
10 usual run of Cochrane reviews, so it was very nice.
11 Q. You've also appended to your CV an extensive list of
12 publications --
13 A. Yes.
14 Q. -- which are divided into what you describe as main
15 scientific publications; then there's a section of
16 research letters, which I understand they are what they
17 say they are: they're letters which are submitted to
18 medical publications relating to areas of research --
19 A. Yes.
20 Q. -- and there is then a list of books that you've made
21 contributions to, and then a list of national and
22 international presentations.
23 I'll come in a little to look at the list of
24 occasions on which you've been invited to be an expert
25 adviser to official inquiries, but obviously everybody

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1 can read the list of your publications and those with
2 which you are associated.

3 As I have said earlier, you appear to have an
4 extensive interest and have written extensively on
5 malaria. Again, can you confirm that?

6 A. Yes.

7 Q. Again, also a lot of your papers are associated with
8 your time in the military —

9 A. Yes.

10 Q. — and relate to circumstances experienced in the
11 military.

12 A. Yes.

13 Q. I think you've also made reference to one paper in
14 relation to pregnancy and breastfeeding women, who at
15 that time, their careers came to an end in the military.
16 That's paper number 2 at page 90.

17 There's another paper, I think, that relates to —
18 I'll just find the reference.

19 Yes, there's a reference at page 91. It's the third
20 paper from the bottom, in which you were a co-author.
21 It's entitled:

22 "Does military service damage females? An analysis
23 of medical discharge rates in the British armed forces."

24 A. Yes.

25 Q. Can you just tell me what journal that was published in?

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1 I assume it's Occupational Medicine.

2 A. That's right, yes.

3 Q. Can you just indicate what was the subject matter beyond
4 the title of that paper?

5 A. That's one of the few papers I didn't write entirely
6 myself. I contributed to it, but the lead author there
7 was Squadron Leader Katie Geary, who was my public
8 health trainee. She had an interest in this. She was
9 doing this as one of her big project, Katie. And then
10 David Irvine, the second named author, he was a civilian
11 epidemiologist who was working with us in the Surgeon
12 General's department of the Ministry of Defence.

13 So Katie Geary just set out the information she had
14 about medical discharges from the armed forces. This is
15 when somebody joins the armed forces and carries on for
16 a little while but then has to be sent back to civilian
17 life because they're not medically fit. It was
18 a concern at the time because the rates of medical
19 discharges were going up, and so she, I think, had been
20 told to look into this particularly and try and draw
21 some conclusions. I can't actually remember in detail
22 what her conclusions were, but it led on to some other
23 research which you might be coming on to, Mr Gale, which
24 was to do with training injuries.

25 Q. Okay.

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1 Just finally, in relation to your papers, you also
2 presented a paper — this is at page 95, the third from
3 the bottom — entitled, "Trends in post-deployment
4 mental disorders".

5 A. Yes.

6 Q. Can you explain what your contribution to that as
7 a public health consultant would be?

8 A. Yes.

9 Again, I was reporting on data that was being
10 routinely collected at the time by the medical
11 statistics department in relation to the incidence of
12 mental disorders in troops. They were rising then and
13 they continued to rise over the next decade, and there
14 are a number of reasons for that; amongst them the fact
15 that there were still many troops who had served in the
16 Falklands, where they'd been exposed to traumatic
17 events, and many who had been in Northern Ireland, where
18 they'd been exposed to traumatic events, or, again,
19 Iraq. So they were the main contributors to the rising
20 trends, and I was simply describing what was being
21 observed without actually — it wasn't based on my own
22 primary research into that area, other than just really
23 summarising what other people were finding and trying to
24 fit that into some kind of pattern and sharing that
25 information with other NATO colleagues.

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1 Q. I think we can divert from your CV now briefly,
2 Dr Croft, and could we go back to the very beginning of
3 your statement —

4 A. Yes.

5 Q. — and the circumstances of your instruction for this
6 Inquiry.

7 I think at preface page i, under the heading "Scope
8 of this report", you say that:

9 "This report was commissioned in May 2023 by the
10 Scottish COVID-19 Inquiry. The Inquiry's Letter of
11 Instruction is reproduced at Appendix 1."

12 If you could bring up, please, appendix 1 so that
13 you can look at it, we just see the terms of that
14 instruction.

15 This was a letter to you from Ms Clements, who is
16 the interim Deputy Solicitor to the Inquiry, and it
17 reads:

18 "Dear Dr Croft

19 "As the interim Deputy Solicitor to the Scottish
20 COVID-19 Inquiry ... I would be grateful if you would
21 accept this letter as your instruction to utilise your
22 expertise as an independent Consultant in Public Health
23 Medicine and provide the Inquiry with a written report
24 which will subsequently form the basis of ... evidence
25 to be given at the Inquiry which is likely to take place

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1 in late July 2023.”
 2 And that’s where we are.
 3 Then there’s a passage on the scope of your report,
 4 and there’s a reference to discussions that you had with
 5 Ms Soper, the co–secretary of the Inquiry, and indeed
 6 with myself as the co–lead Counsel to the Inquiry.
 7 After the sentence that ends with my name and
 8 co–lead counsel, it continues on:
 9 “The report that the Inquiry wishes you ...”
 10 Could you just read the remainder of that paragraph
 11 out to us, please?
 12 A. Yes:
 13 “The report that the Inquiry wishes you to provide
 14 is one which will provide the Inquiry with a factual
 15 narrative detailing the state of accepted scientific
 16 knowledge concerning Coronavirus and COVID–19 as that
 17 knowledge was understood by public health practitioners
 18 in the period between late 2019 and the end of 2022.”
 19 Q. Would you just go on, please?
 20 A. “In particular, your report will include the evolving
 21 state of scientific knowledge around (a) the nature of
 22 Coronavirus and COVID–19 and its pathogenicity; (b) the
 23 ability or otherwise of masks and other forms of PPE or
 24 other measures as recommended to medical, nursing and
 25 care practitioners and the public at various stages

1 during the period from late 2019 to the end of 2022 to
 2 prevent or restrict transmission of the virus; and (c)
 3 the utility or otherwise of handwashing, social
 4 distancing rules or guidance, social isolation measures
 5 or guidance for those at risk and/or those infected,
 6 COVID–19 specific treatments and vaccines at various
 7 stages during the period from late 2019 and the end of
 8 2022 to prevent or restrict transmission of the virus.”
 9 Q. Right. I think we can leave it there.
 10 As is inevitable, there is a word used in that
 11 section which perhaps it is useful to get your
 12 definition of at this stage, or your understanding of,
 13 and that is “pathogenicity”.
 14 A. Oh, yes.
 15 Q. Now, just before we do that, there is a definition
 16 within your appendix 3 at page 102 of “pathogen”.
 17 A. Yes.
 18 Q. Now, it may be my simplistic approach to matters, but
 19 the extent to which “pathogen” and “pathogenicity” are
 20 related may exist in my mind, but perhaps not in yours.
 21 So perhaps you could just explain, first of all, what
 22 a pathogen is —
 23 A. Yes.
 24 Q. — and then what you understand by pathogenicity.
 25 A. Yes.

1 A pathogen, as I have explained, my Lord, is
 2 a microorganism, so it’s a small organism that — I was
 3 trying to avoid the word “living”, because of course
 4 viruses aren’t living — a very small organism that
 5 causes infection. Pathogens are generally divided into
 6 fungi, like candida, for example, aspergillus; bacteria,
 7 we know about those; and viruses; and also protozoa,
 8 such as the malaria parasite, which is to say more
 9 parasites.
 10 So “pathogenicity” is the term that describes how
 11 grave a threat are they to the potential host, the
 12 humans or the animal host, and that is an umbrella term
 13 that will include their transmissibility and also their
 14 lethality or otherwise. So it’s a rather broad term
 15 that, in a real–life context, you would break down into
 16 what exactly it is that you’re — what aspect of their
 17 disease–causing ability is the one that you’re
 18 interested in.
 19 Q. Thank you.
 20 Now, going back to your instruction, obviously by
 21 accepting that instruction you accepted that you
 22 required to have a sufficient degree of expertise from
 23 the standpoint of a consultant in public health
 24 medicine, as you say, in the pathogenicity of COVID–19
 25 and coronaviruses in general.

1 I would like to just investigate with you briefly,
 2 doctor, where that knowledge and expertise has come
 3 from.
 4 You’ve said in your disclaimer at preface page i of
 5 your report, at the bottom of the first full paragraph,
 6 that you have acted as an adviser in a medicolegal
 7 capacity for both sides in a number of legal actions
 8 relating to COVID–19.
 9 A. Yes.
 10 Q. Now, again, conscious of confidentiality here, but could
 11 you give us some indication of what that has involved?
 12 A. Yes. If you’re instructed in a medicolegal action by
 13 either party, or jointly instructed, you, as an expert,
 14 will write a report addressed to the court, and it’s
 15 important that you are independent as an expert. So
 16 perhaps the wording there might have been phrased
 17 slightly differently. So the focus of whatever advice
 18 you are giving is in fact the judge or the court as
 19 a body, and I was approached a number of times during
 20 2021 onwards to give advice of this kind for civil
 21 actions and took on those instructions. And there were
 22 other advisory roles that I had taken on as well, which
 23 we may come to, where I acted as an independent adviser
 24 to, shall we say, established bodies.
 25 Q. And do I take it, by accepting instructions in those

1 situations --

2 A. Yes.

3 Q. -- you require to inform yourself of in general, as
4 we're talking about COVID-19 and coronaviruses in
5 general, of the pathogenicity of those?

6 A. Of course, yes. In fact, the first approaches I had
7 were in 2020, I had some very early approaches, and
8 those I declined because I said: well, the knowledge is
9 still evolving, and I wouldn't be in a position really
10 to assist you helpfully, and I might have to revise my
11 position as time went on. So I didn't accept
12 instructions, though I did have some approaches, really
13 until the middle of 2021. By then, I'd also -- we might
14 come on to this -- been advising the General Medical
15 Council on some general matters to do with COVID.

16 I'd also advised a big insurance company. Insurance
17 companies were caught out by COVID-19 and they had a lot
18 of business interruption claims, which I believe is
19 possibly going to be part of this Inquiry, and one of
20 the big insurance companies came to me -- I don't know
21 how they got my name -- and they said, "Could you do
22 a horizon-scanning exercise for us of all the infectious
23 diseases that there are, and which of them might become
24 a pandemic in the future?" So that was quite
25 a challenge, and they wanted it in two weeks, of course,

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1 but it took me about a month.

2 So that was helpful in terms of crystallising my
3 thoughts and my knowledge as to every infectious
4 disease, and I came up with a list of about 12 -- top of
5 the list was influenza. I thought influenza is always
6 mutating and potentially could cause a serious epidemic
7 any time. That was amber to red. I had about 10 for 12
8 amber infections that potentially could cause serious
9 epidemics. One of them was monkey pox, which was
10 interesting, before it came a problem. And then the
11 rest of the infections, I said these are not ever going
12 to cause a pandemic because they are not pathogenic
13 enough. Their pathogenicity is not sufficient that they
14 will ever be a major problem. They will cause minor
15 problems, but there won't be business interruptions on
16 a large scale.

17 LORD BRAILSFORD: It's approaching 11.30.

18 MR GALE: Can I just take one more matter, my Lord?

19 LORD BRAILSFORD: By all means, yes.

20 MR GALE: It will be fairly brief.

21 Dr Croft, just to conclude this section and conclude
22 this session, you have provided us with obviously
23 an extensive list of your medical publications.

24 Could we go to page 93, please.

25 A. Yes.

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1 Q. Can we look at the last two articles of which you are

2 a co-author with Dr Mawson and Dr Gonzalez-Fernandez.

3 A. Yes.

4 Q. There are two there. The first is, "Clues to
5 understanding the pathogenesis of coronavirus
6 infection", and then you give it the COVID-19 and
7 SARS-CoV abbreviation, and then the second is -- again,
8 with the same two co-authors -- "Liver damage and
9 exposure to toxic concentrations of endogenous retinoids
10 in the pathogenesis of COVID-19".

11 Can you briefly tell us what those were about,
12 beyond the terms that we can read there?

13 A. Yes. These two papers, which are publicly available,
14 they were -- the first one was published in the BMJ
15 online quite early on in the COVID pandemic, I think it
16 was March 2020, and the second paper was published in
17 a peer-reviewed journal, Viral Immunology, in 2021. But
18 they dealt with a common theme, and that was the
19 proposal that I and my co-authors were putting forward
20 that one aspect of COVID-19 that was puzzling then, and
21 still is puzzling to some extent, could be explained if
22 we consider the disease as being in part an assault on
23 the liver, a virological assault on the liver, such that
24 the liver, which stores retinoids, which are vitamin A
25 precursors, normally in a safe form, the liver becomes

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1 inflamed, and the retinoids, which potentially are
2 toxic, spill into the general circulation and then cause
3 distant systematic effects throughout the body. We
4 simply reviewed the biochemical and clinical literature
5 to explain how we arose at this hypothesis, and we set
6 out various strategies by which the hypothesis could be
7 potentially tested.

8 Q. The first of your papers, I think, was published in the
9 BMJ; is that right?

10 A. It was the BMJ online, yes. Because of the peer-review
11 process that we were talking about earlier, which is
12 quite long-winded and laborious, many journals now have
13 an online section where they will publish papers more
14 quickly. They're still subjected to peer review, but
15 that was where that was published.

16 Q. The second paper is in, I presume, a publication called
17 Viral Immunology.

18 A. Yes.

19 Q. Where is that published?

20 A. I think it's published in America. It's a hard copy
21 paper, but there was also, as is often the case now,
22 a pre-print electronically a few weeks before it became
23 hard copy. But, again, a peer-reviewed journal.

24 Q. So, against that background, Dr Croft, and going back to
25 the terms of your instruction, are you satisfied that

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1 you have the requisite degree of expertise to inform
 2 this Inquiry in the context of what you've been asked to
 3 advise on?
 4 A. Yes, I have. I set out my qualifications frankly at the
 5 time I was approached and there was a period of
 6 consideration, and then the Inquiry team came back to me
 7 and appointed me, and I do feel I have those qualities.
 8 The main quality I feel I have which is important is
 9 independence from any lobbies or factions, and I wasn't
 10 giving advice formally during the pandemic to any
 11 government bodies or commercial organisations. So
 12 really, like other people, I was really an observer of
 13 what was going on, but I hope an educated observer, and
 14 a self-educated observer. So I now come to the Inquiry
 15 from that standpoint, as a, if you like, qualified
 16 public health physician who experienced and studied what
 17 was happening, and coming to explain what the general
 18 scientific background was to the COVID-19 pandemic.
 19 MR GALE: Thank you very much, Dr Croft.
 20 My Lord, perhaps that's a useful point to stop.
 21 LORD BRAILSFORD: It is indeed. Thank you very much indeed.
 22 Very good, ladies and gentlemen. We will have
 23 a break now for 20 minutes, please. We are actually
 24 a minute slow. I apologise. If you could be back at
 25 11.51. Thank you.

1 (11.32 am)
 2 (A short break)
 3 (11.52 am)
 4 LORD BRAILSFORD: Before we start, I'm terribly sorry, but
 5 I have an apology to make. I have been informed that
 6 I made a mistake in my brief opening remarks. I said
 7 that the preliminary hearing on 28th and 29th was in
 8 Meadowbank Stadium. I cannot imagine how I made that
 9 mistake. I genuinely can't imagine. I have never been
 10 in Meadowbank Stadium in my life. It really is in
 11 Murrayfield, where I have been on several occasions --
 12 not in a team, I should say, simply to observe.
 13 So the preliminary hearing is in Murrayfield
 14 Stadium, my apologies.
 15 Yes, Mr Gale.
 16 MR GALE: Thank you, my Lord.
 17 Dr Croft, having looked at these matters in your
 18 background and your qualifications before the break,
 19 there is one matter that I would like to raise with you
 20 before we go into the substance of your report.
 21 You have been made aware that your engagement as
 22 a scene-setter in this Inquiry has been the subject of
 23 some recent comment in the press.
 24 Can I first of all refer you to an article which
 25 appeared some two weeks ago, and I think you've seen

1 a copy of this. You don't need to have it in front of
 2 you, but if I can just read some passages from it for
 3 your comment.
 4 The article is in these terms or contains these
 5 terms:
 6 "A doctor commissioned as an expert witness for
 7 Scotland's Covid-19 Inquiry claimed just four years ago
 8 that routine childhood vaccinations 'could be
 9 contributing to increasing rates of autism'.
 10 Then it is said that -- and again, I'm quoting from
 11 the press report:
 12 "Medics have expressed concern that Dr Croft was
 13 still referencing the vaccine-link claim, which has been
 14 widely debunked and led to its originator being struck
 15 off."
 16 I think that's a reference to Dr Andrew Wakefield,
 17 who has been struck off.
 18 A. I presume so, yes.
 19 Q. The article goes on to say.
 20 "A recent paper, by Dr Croft, published in 2019 --
 21 'Rubella Virus Infection, the Congenital Rubella
 22 Syndrome and the Link to Autism' -- includes claims that
 23 rapid increases in autism coincided with the expansion
 24 of the vaccination schedule."
 25 And it goes on:

1 "Two more papers published by Dr Croft and
 2 a co-author, Anthony Mawson from Jackson State
 3 University in the USA, also include claims about an
 4 increased risk of autism in vaccinated children.
 5 "Claims of a link between the MMR vaccine and autism
 6 were initially promoted by Andrew Wakefield, a doctor
 7 who was subsequently found guilty of fraud and serious
 8 professional misconduct.
 9 "Wakefield was struck off the medical register by
 10 the General Medical Council in 2010."
 11 So that's really the context that I would like to
 12 ask you some questions.
 13 Could we go to your list of papers, and I think we
 14 can see on page 93 of your CV that the paper that is in
 15 fact referred to in the press article is the fifth
 16 article from the bottom of that particular section and
 17 is, as is said:
 18 "Rubella virus, the congenital rubella syndrome, and
 19 the link to autism."
 20 A. Yes.
 21 Q. That appears to have been published in something called
 22 the IJERPH. What is that publication?
 23 A. Yes, I have a copy of the paper here.
 24 Q. Yes.
 25 A. And that stands for the International Journal of

1 Environmental Research and Public Health, 2019.
 2 Q. Is that an American Journal?
 3 A. I don't know whether it's American or not. It's not
 4 clear from the —
 5 Q. Do you know —
 6 A. Beg your pardon: "Licensee: MDPI Basel, Switzerland", so
 7 it seems to be a Swiss journal.
 8 Q. Does that have, so far as you're aware, any particular
 9 status in the field of public medicine?
 10 A. I believe it has, yes. It's a peer-reviewed journal.
 11 The publications of the journal are available online,
 12 which is always a good thing, because it means that
 13 they're being transparent in what they publish. My own
 14 journal, Human Parasitology, was one of the first online
 15 journals in this field. So it's one with credibility
 16 and authority.
 17 Q. Right.
 18 Now, can you just tell us, in as brief terms as is
 19 possible, what that article was about?
 20 A. It was on the same lines — it was developing the same
 21 theme, exploring the same theme, that I've brought up
 22 earlier in regard to my two coronavirus articles.
 23 It might be best if I read the abstract, or part of
 24 the abstract. Would that be all right?
 25 Q. That would be very helpful, yes, if you would.

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1 A. That way I couldn't be said to be misremembering it or
 2 getting key —
 3 Q. That would be very helpful.
 4 A. Yes. So I happen to have it here. I don't carry it
 5 around with me all the time, but I've got it here
 6 because I thought I might be asked about it.
 7 So the article is called "Rubella Virus Infection,
 8 the Congenital Rubella Syndrome, and the Link to
 9 Autism", and the authors are Anthony R Mawson and
 10 Ashley M Croft.
 11 The abstract is quite short, about half a page, but
 12 I'll read it all. If there's anything that you want
 13 clarifying, I would be happy to do so.
 14 The paper, by the way, is very long. It's 28 pages
 15 and there are 198 citations. So it's not an easy read,
 16 even for me. But the abstract is short.
 17 Q. Before you do, doctor, was that paper peer reviewed?
 18 A. Of course, yes. Yes, certainly, yes. Yes. Yes.
 19 Q. Please continue.
 20 A. Okay. So abstract:
 21 "Rubella is a systemic infection that is usually
 22 mild. It can, however, cause severe birth defects known
 23 as the congenital rubella syndrome ... when infection
 24 occurs early in pregnancy."
 25 I should say at this point, I have perhaps

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1 a conflict here, in that my own brother, my youngest
 2 brother, had congenital rubella syndrome. He was born
 3 in 1963, and he must have acquired rubella in utero from
 4 my mother in 1962, when she was carrying him. So he was
 5 born with this syndrome which I'll go on to discuss, and
 6 he had some of the disabilities that we talk about in
 7 this paper.
 8 Q. I mean, I don't wish to pry into your personal
 9 background and familiar background. Could you just tell
 10 us what the symptoms that your brother had?
 11 A. Indeed, yes. Okay. Right. Oh, he had deafness, and he
 12 had locomotive problems, so he was in and out of
 13 orthopaedic hospitals as a child.
 14 With hindsight, because he's now dead, he had many
 15 endearing qualities, but he probably had a degree of
 16 autism, I think, because he didn't go to university —
 17 he went to school and got some O Levels — he didn't
 18 ever marry, and he didn't hold down a job for any length
 19 of time. Towards the end of his life, he was
 20 effectively the carer to my parents, who both
 21 predeceased him. So that was his case.
 22 Q. Sorry, I have interrupted you. Carry on.
 23 A. Not at all.
 24 So this is the next bit:
 25 "As many as ~8%13% of children with [congenital

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1 rubella syndrome] developed autism during the rubella
 2 epidemic of the 1960s compared to the background rate of
 3 about 1 new case of autism per 5000 children. Rubella
 4 infection and [congenital rubella syndrome] are now rare
 5 [and that's because of vaccination, which is good] in
 6 the U.S. and in Europe due to widespread vaccination.
 7 However, autism rates have risen dramatically in recent
 8 decades to about 3% of children today, with many cases
 9 appearing after a period of normal development
 10 ('regressive autism'). Evidence is reviewed here [in
 11 this paper] suggesting that the signs and symptoms of
 12 rubella may be due to alterations in the hepatic
 13 metabolism of vitamin A (retinoids) ..."
 14 That's what I and my co-authors were talking about
 15 also with regard to coronavirus:
 16 "... precipitated by the acute phase of the
 17 infection. The infection [rubella] causes mild liver
 18 dysfunction and the spillage of stored vitamin A
 19 compounds into the circulation, resulting in an
 20 endogenous form of hypervitaminosis A. Given that
 21 vitamin A is a known teratogen [that means it can cause
 22 foetal malformations under certain conditions], it is
 23 suggested that rubella infection occurring in the early
 24 weeks of pregnancy causes CRS through maternal liver
 25 dysfunction and exposure of the developing fetus to

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1 excessive vitamin A."
 2 That's the basis of our hypothesis:
 3 "On this view, the multiple manifestations of
 4 [congenital rubella syndrome] and associated autism
 5 represent endogenous forms of hypervitaminosis A. It is
 6 further proposed that regressive autism results
 7 primarily from post-natal influences of a liver-damaging
 8 nature and exposure to excess vitamin A, inducing
 9 CRS-like features as a function of vitamin A toxicity,
 10 but without the associated dysmorphogenesis [the
 11 physical abnormalities that occur]. A number of
 12 environmental factors are discussed that may plausibly
 13 be candidates for this role, and suggestions are offered
 14 for testing the model. The model also suggests a number
 15 of measures that may be effective both in reducing the
 16 risk of fetal [congenital rubella syndrome] in women who
 17 acquire rubella in their first trimester and in
 18 reversing or minimizing regressive autism among children
 19 in whom the diagnosis is suspected or confirmed."
 20 That's the end of the extract.
 21 Q. Thank you.
 22 Now, you mentioned, in connection with that article,
 23 the word "hypothesis".
 24 A. Yes.
 25 Q. I think you have discussed in discussions that we've had

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1 the concept of a hypothesis paper.
 2 A. Yes.
 3 Q. Will you just explain what that is, again for those of
 4 us who aren't as familiar with these papers as you are?
 5 A. Yes. "Hypothesis", again, is a Greek word. It means
 6 an idea, an abstract idea, that potentially can be
 7 tested experimentally or through other laboratory
 8 methods and may or may not turn out to be correct, or
 9 part of it may turn out to be correct, and it's a very
 10 common sort of paper in medical science. There are
 11 entire journals that are called a journal of medical
 12 hypothesis, and in those journals scientists will put
 13 forward ideas, often of a revolutionary nature, and
 14 often wrong in fact. But, nevertheless, they explore
 15 various ways by which observable medical or
 16 physiological events plausibly could be explained
 17 biochemically or through what's known about the normal
 18 bodily functions.
 19 So it's a kind of blue-sky thinking sort of paper,
 20 which is rather long, but we had to -- or, as will be
 21 usual with a hypothesis paper, explain every link in the
 22 reasoning through reference to existing research that
 23 would support the hypothesis, and it's customary -- it's
 24 normal with a hypothesis paper to end by saying: this is
 25 the hypothesis, and this is how it could be tested, and

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1 if it was tested and found to be true, this would be the
 2 implications for clinical practice.
 3 Q. Now, looking back to what I quoted to you from the
 4 newspaper article, on one reading --
 5 A. Yes.
 6 Q. -- there may appear to be within that article
 7 a suggestion that you are a fellow traveller of
 8 Dr Wakefield in relation to, as it said, his widely
 9 debunked theory which led to his being struck off; are
 10 you?
 11 A. Not at all. No, I have never met Andrew Wakefield, who
 12 was a gastroenterologist, and his theory, I accept, has
 13 been debunked and has no credence.
 14 Q. Can I just pause again. Can I go back to page 90 of
 15 your CV.
 16 A. Yes.
 17 Q. Because I think you've written on rubella before.
 18 A. Yes.
 19 Q. And I think if we look just about halfway down --
 20 A. Yes.
 21 Q. -- you are the co-author, with Adams, Winfield and
 22 Richards, again, obviously a paper written with your
 23 military experience --
 24 A. Yes.
 25 Q. -- called, "An outbreak of rubella in British troops in

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1 Bosnia", and I assume that's Epidemiological Infection.
 2 Again, is that another academic journal?
 3 A. Epidemiology and Infection.
 4 Q. Can you just give us a little background to that?
 5 A. Yes. Again, I've got the paper here. But in 1996, the
 6 year before, I was in Bosnia, having been sent there at
 7 very short notice, and I was there for about
 8 seven months. In April of that year, a soldier who was
 9 in the army air corps developed rubella. This was
 10 before -- no, I'm sorry, there was MMR vaccination at
 11 that time. So he developed rubella. He obviously
 12 hadn't been immunised against rubella at any time
 13 because he was 24, I think. And this was of grave
 14 concern, because the period of deployment for the army
 15 was usually six months, and in the middle of it you
 16 would go back to wherever you came from, Germany or
 17 Britain, to be with your spouse or girlfriend, and
 18 potentially, if soldiers were acquiring rubella in
 19 Bosnia through living in close confined quarters, as
 20 they were, then there was a potential for them to go
 21 back and infect their spouse or partner, who might have
 22 been in the early stages of pregnancy, and then she
 23 would then potentially be at risk of congenital rubella
 24 syndrome.
 25 Q. Yes.

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1 A. Had she not been vaccinated against rubella, that was
2 the key thing. And there had in fact been a case like
3 this in the German army, where a German soldier had gone
4 back and exactly that had happened. I think the spouse
5 there had been vaccinated, but she hadn't mounted
6 an immune response, so they had a second child who had
7 congenital rubella syndrome. So this was a matter of
8 concern.

9 So the paper just describes what mitigation measures
10 we took as epidemiologists, and I had to go round the
11 various sort of camps where the army air corps were. We
12 anticipated there would be more cases coming up, and we
13 tried to do a proactive case finding of the cases and
14 then isolate them in Bosnia until their rubella had
15 cleared up before allowing them to go back home.

16 We made recommendations for the future as to how to
17 prevent this possible scenario of soldiers acquiring
18 rubella on deployment or on exercise and then going back
19 and infecting their spouses, one of the recommendations
20 including MMR for all troops, MMR for all recruits,
21 regardless of previous vaccination status. That, in
22 fact, the very last phrase of that sentence, we say --
23 and in fact, the Canadian forces were doing that at this
24 time. All their recruits, men and women, were all given
25 MMR, even though -- really to protect against congenital

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1 rubella system. MMR stands for measles, mumps and
2 rubella. And even though for adults it's a mild
3 condition, the danger is if the mother develops the
4 condition in the first trimester of pregnancy.

5 So our last sentence in this paper, Adams and Croft
6 et al:

7 "Alternatively, military planners could choose to
8 act now by adopting the Canadian strategy of
9 administering MMR vaccine to all recruits regardless of
10 any history of previous vaccination."

11 Q. That approach that you've referred to in your 1997
12 paper, is that an approach that you repeated in your
13 most recent paper that has been referenced in the press
14 article?

15 A. The general idea is the liver being damaged by external
16 factors and then spilling over the retinoids into the
17 circulation was at the heart of the papers. But the
18 recent papers didn't mention vaccination, as far as
19 I can recall.

20 Q. Did you in fact say, looking at what you actually said
21 in that article, in that paper, that the proven primary
22 prevention strategy for congenital rubella syndrome is
23 and will continue to be the vaccination of young women?

24 A. We did say that, and that's obviously correct.

25 Q. Right.

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1 Can we move on, doctor, and can we go to finally,
2 you will be pleased to know, the substance of your
3 report.

4 A. Oh, good.

5 Q. If we go to page 2 at part 1 of your report, this is
6 headed "Evidence-based medicine". We will look at this
7 in a little more detail but, as a principle, is this
8 a principle which you, as a public health physician and
9 an epidemiologist, regard as particularly significant?

10 A. Yes, evidence-based medicine is the underlying
11 philosophy, operating principle, of medical practice
12 throughout the world.

13 Q. I think within your report you begin with a discussion
14 of evidence-based medicine, and then you go on to
15 certain aspects of evidence-based medicine.

16 A. Yes.

17 Q. So can I just ask you to read through, just to begin
18 with, section 1.1, please.

19 A. Yes. Would you like me to read the whole section?

20 Q. Yes, if you would.

21 A. So section 1.1 -- and, of course, here I'm citing from
22 standard textbooks, so none of this is my own opinion;
23 I'm simply setting the scene for the Inquiry, and I'm
24 conveying the accepted, undisputed principles of
25 evidence-based medicine as understood everywhere.

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1 So:

2 "Evidence-based medicine (EBM) derives from the
3 understanding that there exists a hierarchy of
4 scientific evidence. All clinical and medical policy
5 decisions should be based on the best available research
6 evidence."

7 And there's a reference to a very short paper by
8 Torpy of one page:

9 "Contrary to popular belief, not all scientific
10 evidence is of equal merit. Many scientific studies are
11 prone to bias (e.g. commercial bias ...)"

12 Bias means sort of incorrect influences coming to
13 bear on the results which might transform those results
14 in a negative way. That's what bias is in a nutshell:

15 "Some scientific evidence is more reliable than
16 other evidence. Many studies, and perhaps the majority,
17 incorporate 'findings' that are false."

18 And there's another reference there:

19 "EBM [evidence-based medicine] denotes the
20 principle, now accepted by all modern medical
21 practitioners, that clinical practice and health policy
22 decisions should be informed by high-quality research
23 into the benefits and harms of healthcare interventions,
24 rather than be informed by low-quality studies,
25 theoretical speculation, expert committee reports or

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1 anecdote.
2 "While the concept of EBM is simple, an obstacle to
3 its implementation in clinical practice is the
4 uncontrolled explosion that has occurred in scientific
5 data. Over 30,000 biomedical journals are currently in
6 circulation, and over 17,000 biomedical books are
7 published annually. As long ago as 1992 it was
8 calculated that a physician would have to read
9 approximately 11 scientific articles per day to maintain
10 their scientific currency; the challenge now is
11 exponentially greater."

12 Just as an aside, I understand during the COVID
13 pandemic 2 million scientific articles were written
14 about COVID. No one could read 2 million scientific
15 articles, so we have to focus on the ones that are the
16 most credible, give the best results, the most
17 reliable --

18 Q. Can you just pause there and look at two of the papers
19 that you refer to.

20 Could we look at Torpy --

21 A. Yes.

22 Q. -- which is paper number 20 in the bundle, and it's at
23 page 950.

24 A. Yes.

25 Q. I think this is a single page --

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1 A. Yes.
2 Q. -- from a publication called -- assuming one takes the
3 letters together -- JAMA, a patient page; is that
4 correct?
5 A. Yes, JAMA is the Journal of the American Medical
6 Association, and it's the number 2 most prestigious
7 journal in the United States.
8 MR GALE: Thank you.
9 LORD BRAILSFORD: New England Journal of Medicine being the
10 most --
11 A. Yes, quite right. The New England Journal of Medicine
12 resisted evidence-based medicine for a few years,
13 funnily enough, but they are now on board.

14 MR GALE: Right.

15 Again, if we can just look at what's said there,
16 I think we can see the author is Dr Janet Torpy.

17 A. Yes.

18 Q. And interestingly, perhaps, in the block on the
19 right-hand side of that page, there is a statement, "For
20 more information", and the second of those is the
21 Cochrane Collaboration.

22 A. Yes.

23 Q. Also, I think we can tell, perhaps, from the wording of
24 what is on that page, this is directed towards
25 practitioners --

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1 A. Yes.

2 Q. -- largely.

3 A. Well, JAMA, at that time -- recently they've stopped,
4 unfortunately -- towards the end of every -- the journal
5 comes out every week, and the last few pages there would
6 be a page that would be for your patients, and it would
7 talk about prostate cancer or pneumonia or whatever it
8 was, and the idea was that you would keep these in
9 a file on your desk, and if a patient came in who had
10 prostate cancer, you would give them this information
11 page and there are websites there they could follow.

12 So it was primarily directed to patients, but the
13 initial reader would be doctors.

14 Q. And hence the red stamp at the bottom of the page --

15 A. Yes.

16 Q. -- "JAMA copy for your patients".

17 A. Yes.

18 Q. Would you just read through the first paragraph and then
19 the second paragraph of "Looking for evidence", so we
20 just have that in the notes.

21 A. "Looking for evidence"?

22 Q. No, sorry, start at the beginning.

23 A. Oh.

24 Q. Under the block heading "Evidence-Based Medicine", "In
25 the 1990s". If you just read that paragraph and then

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1 the next paragraph of "Looking for evidence".

2 A. Of course:

3 "In the 1990s, evidence-based medicine [which is in
4 bold print] emerged as way to improve and evaluate
5 patient care. It involves combining the best research
6 evidence with the patient's values [very important] to
7 make decisions about medical care. Looking at all
8 available medical studies and literature that pertain to
9 an individual patient or a group of patients helps
10 doctors to properly diagnose illnesses, to choose the
11 best testing plan, and to select the best treatments and
12 methods of disease prevention. Using evidence-based
13 medicine techniques for large groups of patients with
14 the same illness, doctors can develop practice
15 guidelines for evaluation and treatment of particular
16 conditions. In addition to improving treatment, such
17 guidelines can help individual physicians and
18 institutions measure their performance and identify
19 areas for further study and improvement."

20 Then it says this article is:

21 "... about the importance of using evidence-based
22 medicine to develop practice guidelines."

23 And there seems to be a condensation of a larger
24 article published a few years earlier in JAMA, in 2006.
25 This is distilled into one page.

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1 Q. Yes. Then the next paragraph.
 2 A. Yes. So it's "Looking for evidence in medical
 3 literature". It talks about -- so it says:
 4 "Systematic reviews of the medical literature, large
 5 randomized controlled trials (the best way to assess the
 6 efficacy of a treatment), and large prospective studies
 7 (followed up over time) are types of research published
 8 in the medical literature that can be helpful in
 9 providing evidence about tests and treatments. Reports
 10 of the experiences of individual patients or small
 11 groups usually provide less reliable evidence, although
 12 they may provide important clues about possible adverse
 13 effects of treatments.
 14 "Using evidence-based medicine.
 15 "Practice guidelines developed using evidence-based
 16 medicine have helped to reduce mortality (chance of
 17 dying) from heart attacks. Evidence-based medicine
 18 guidelines have also improved care for persons with
 19 diabetes and other common medical problems.
 20 Evidence-based medicine does not replace physicians'
 21 judgment based on clinical experience. Any
 22 recommendations taken from evidence-based medicine must
 23 be applied by a physician to the unique situation of an
 24 individual patient. Sometimes there is no reliable
 25 research evidence to guide decision making, and some

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1 conditions are rare enough that there is no way to do
 2 large studies."
 3 Q. I think I can stop you there, doctor.
 4 Just one phrase that I think we can see there and
 5 which we haven't, I don't think, looked at a definition
 6 of is "systematic review". I think you will find
 7 a definition of that in your appendix 3 at page 103.
 8 A. Yes.
 9 Q. And I think, to save you looking at it, it's:
 10 "A type of scientific study which summarises the
 11 existing research in a particular area in
 12 a comprehensive and impartial way; known as 'evidence
 13 synthesis' or 'meta-analysis'.
 14 A. Yes.
 15 Q. Right.
 16 Passing on from the reference to Torpy, could we go
 17 to the reference to the paper by Ioannidis, which is
 18 number 10 in the bundle. It's at pages 806 and 807. It
 19 begins, I'm sorry, at page 802.
 20 It's under the headline, if I can put it that way,
 21 "Why Most Published Research Findings Are False" --
 22 A. Yes.
 23 Q. -- which might send most people into a spiral of
 24 concern.
 25 Can you just explain what -- I think it's now

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1 Professor Ioannidis, who I think is now attached to
 2 Stanford University in the States.
 3 A. Yes.
 4 Q. I think at the time of writing he was attached to Tufts
 5 New England Medical Center. You find that in the
 6 footnote on the first page.
 7 Could you just read out the summary, please?
 8 A. Yes. This is a summary of Professor John Ioannidis'
 9 paper and he says:
 10 "There is increasing concern that most current
 11 published research findings are false. The probability
 12 that a research claim is true may depend on study power
 13 [that essentially means the size of the study] and bias
 14 [we mentioned bias], the number of other studies on the
 15 same question, and, importantly, the ratio of true to no
 16 relationships among the relationships probed in each
 17 scientific field. In this framework, a research finding
 18 is less likely to be true when the studies conducted in
 19 a field are smaller; when effect sizes are smaller; when
 20 there is a greater number and lesser preselection of
 21 tested relationships; where there is greater flexibility
 22 in designs, definitions, outcomes, and analytical modes;
 23 when there is greater financial and other interest and
 24 prejudice; and when more teams are involved in a
 25 scientific field in chase of statistical significance.

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1 Simulations show that for most study designs and
 2 settings, it is more likely for a research claim to be
 3 false than true. Moreover, for many current scientific
 4 fields, claimed research findings may often be simply
 5 accurate measures of the prevailing bias. In this
 6 essay, I discuss the implications of these problems for
 7 the conduct and interpretation of research."
 8 MR GALE: So what do you take from that?
 9 LORD BRAILSFORD: Do you happen to know what
 10 Professor Ioannidis' academic background is? Is he
 11 a statistician, a mathematician?
 12 A. Oh, he's an epidemiologist.
 13 LORD BRAILSFORD: He's an epidemiologist, is he?
 14 A. Well, I presume he is because he writes from the
 15 Department of Hygiene and Epidemiology at the University
 16 of Ioannina, Greece, and then later on he's moved to the
 17 United States.
 18 LORD BRAILSFORD: Sorry to interrupt you.
 19 MR GALE: Dr Croft, what do you take from that?
 20 A. Well, of course, this needs to be interpreted carefully
 21 because he's not saying research mustn't be done. He's
 22 focusing really on pure biomedical research, which is
 23 exploring entirely new areas, new concepts, and he makes
 24 that clear further on. Further on in the paper he does
 25 talk about randomised controlled trials as being the

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1 type of research that is most likely to yield accurate
 2 results .
 3 But it's really pure and investigative research that
 4 is the real focus of what he's exploring there, and this
 5 was written when sort of molecular medicine was in its
 6 infancy, and the idea of that is you explore thousands
 7 or millions of hypotheses connecting a particular gene
 8 to a particular disease or a particular aspect of
 9 disease, and essentially what he's saying is that if you
 10 were exploring on a massive scale, on an industrial
 11 scale, you will find apparent associations that are
 12 actually not true but have just arisen by chance. That
 13 is his key message, as I understand it.
 14 Q. I think if you go to pages 806 and 807 of that document,
 15 I think we can see on the right—hand column of 806
 16 a section headed "How Can We Improve the Situation?"
 17 A. Yes.
 18 Q. And perhaps you would just read the — well, perhaps
 19 read until I ask you to stop, is probably the best
 20 thing.
 21 A. Okay:
 22 "How Can We Improve the Situation?
 23 "Is it unavoidable that most research findings are
 24 false, or can we improve the situation? A major problem
 25 is that it is impossible to know with 100% certainty

1 what the truth is in any research question. In this
 2 regard, the pure 'gold' standard is unattainable.
 3 However, there are several approaches to improve the
 4 post—study probability."
 5 That is the mathematical concept he discusses
 6 earlier :
 7 "Better powered evidence, e.g., large studies or
 8 low—bias meta—analyses, may help, as it comes closer to
 9 the unknown 'gold' standard. However, large studies may
 10 still have biases and these should be acknowledged and
 11 avoided. Moreover, large—scale evidence is impossible
 12 to obtain for all of the millions and trillions of
 13 research questions posed in current research.
 14 Large—scale evidence should be targeted for research
 15 questions where the pre—study probability is already
 16 considerably high, so that a significant research
 17 finding will lead to a post—test probability that would
 18 be considered quite definitive . Large—scale evidence is
 19 also particularly indicated when it can test major
 20 concepts rather than narrow, specific questions."
 21 Q. Can I just stop you there, doctor, and then can I ask
 22 you to read on at the bottom of that column, the
 23 paragraph that begins "Second"?
 24 A. So:
 25 "Second, most research questions are addressed by

1 many teams, and it is misleading to emphasize the
 2 statistically significant findings of any single team.
 3 What matters is the totality of the evidence.
 4 Diminishing bias through enhanced research standards and
 5 curtailing of prejudices may also help."
 6 Q. Can I stop you there. I think that's probably all
 7 I need to ask you about there, unless there's anything
 8 further that you would wish to draw to our attention?
 9 A. Just at the very bottom of that section, he says:
 10 "... in other fields, the principles of developing
 11 and adhering to a protocol could be more widely borrowed
 12 from randomized controlled trials."
 13 Randomised controlled trials, you normally define
 14 what you're going to do before you do it and you don't
 15 start changing what it is you're measuring because of
 16 what's emerging. That's part of the rigour of
 17 randomised controlled trials.
 18 Q. So the idea is to have a defined protocol before you
 19 start?
 20 A. Yes, and not move the goalposts as you proceed.
 21 Q. Exactly. Right, thank you for that.
 22 Can we go back now to your report. Can we go to the
 23 top of page 3 and paragraph 1.2, and would you read on
 24 there.
 25 There is in that page a table taken from a standard

1 textbook for medical students which is referenced at the
 2 bottom, I think it's the — yes, it's the bottom, "Good
 3 medical practice" textbook, and we will look at that
 4 table perhaps in some detail in a moment, but if you
 5 just read through what you say in 1.2.
 6 A. I'll just wait for the screen to change.
 7 (Pause)
 8 Shall I start reading, my Lord? 1.2:
 9 "What are systematic reviews?"
 10 Thank you:
 11 "A pragmatic solution is the systematic review (also
 12 known as an evidence synthesis or meta—analysis).
 13 Systematic reviews are a relative new form of research.
 14 Their aim is to present a balanced and impartial summary
 15 of the existing research, enabling decisions on
 16 effectiveness to be based on all relevant studies of
 17 adequate quality.
 18 "The systematic review has established itself at the
 19 highest level of evidence in the [evidence—based
 20 medicine] hierarchy because it summarises the available
 21 evidence on a particular topic, in a comprehensive and
 22 up—to—date manner. Properly—conducted systematic
 23 reviews constitute Level Ia evidence. The bottom rung
 24 in the EBM hierarchy is Level IV evidence, obtained from
 25 expert committees, authoritative opinions and the like .

1 This is demonstrated in the table below, [which is]
 2 taken from a standard textbook for medical students.”
 3 Q. Could we just look at that table. As you say in your
 4 text, the gold standard is Ia, and we see that as:
 5 “Evidence obtained from meta-analysis of randomised
 6 clinical trials.”
 7 A. Yes.
 8 Q. And there are then various intermediate standards, if
 9 I can put it that way —
 10 A. Yes.
 11 Q. — down to Level IV, which is, as you’ve said:
 12 “Evidence obtained from expert committee reports or
 13 opinions and/or clinical experiences of respected
 14 authorities.”
 15 Now, that might seem slightly counter-intuitive.
 16 Those qualifications, expert committee reports, clinical
 17 experiences of respected authorities, might suggest that
 18 they are worthy of a higher ranking than the lowest
 19 ranking that is given in that category. Can you explain
 20 why that is?
 21 A. Well, it’s a paradox because often the randomised
 22 controlled trial might be being done by some junior
 23 registrar and it’s producing a surprising result that
 24 the respected authorities, the senior consultants, may
 25 choose to disagree with.

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1 But the point of the hierarchy is that the
 2 traditional way of developing medical decisions was
 3 often for, in a hospital setting, for example, the
 4 senior consultants to sit around and agree between
 5 themselves as to what was the best surgical approach to
 6 appendicitis or the best antibiotic to give
 7 osteomyelitis, shall we say. And that kind of
 8 approach — by the way, it’s sometimes called in the
 9 medical literature the GOBSAT approach. GOBSAT,
 10 G—O—B—S—A—T, means “good old boys sitting around
 11 a table”. It’s a bit —
 12 Q. Probably a relief it wasn’t something else.
 13 A. But it’s a recognised term, and obviously it sounds —
 14 you know, they must know what they’re talking about
 15 because they’re professors and they’re senior
 16 consultants. But in reality biases can creep in, not
 17 only of a financial nature, but just of a chance nature.
 18 You know, the senior professor might just happen to have
 19 used a particular antibiotic on five not very sick
 20 patients because he didn’t get the very sick patients,
 21 he gave them to the juniors, and so this antibiotic just
 22 worked well for him but that was chance.
 23 So this is what the concept of evidence-based
 24 medicine is trying to disentangle: the authoritative
 25 opinions that come from experience, but are liable —

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1 often very strongly liable — to be influenced by
 2 factors of bias coming from various directions.
 3 Q. By according that the lowest level in that table, is
 4 that suggestive that one ignores it?
 5 A. No, and when there is no good quality Level Ia or
 6 Level Ib evidence, or Level II or III, that would be
 7 a reasonable starting point. But at the same time it
 8 would be necessary to qualify very carefully any
 9 interpretations that one could put on the weight of
 10 evidence that’s coming from that kind of source. It
 11 would need to be managed in a very prudent way with
 12 a lot of caveats.
 13 Q. And those levels are then translated into grades of
 14 recommendation at the bottom of the table —
 15 A. Yes.
 16 Q. — which simply follow the levels of evidence
 17 themselves.
 18 A. That’s right. And nowadays, with clinical guidelines,
 19 of which there’s a vast number, the best guidelines will
 20 say: if a patient presents with these series of
 21 symptoms, consider doing this test, and then they will
 22 put in brackets “Grade A” or “Grade B”, and that will
 23 indicate the kind of strength of the recommendation
 24 based on this hierarchy, and so therefore being explicit
 25 about the nature of the advice that’s being given to

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1 those who will be reading the guidelines. That’s often
 2 called the grade approach to evidence. The two terms
 3 are interchangeable.
 4 Q. Right.
 5 Can we pass on to page 4 and paragraph 1.3, which is
 6 in relation to randomised controlled trials.
 7 Now, to a certain extent we’ve looked at this
 8 a little in what you’ve already been telling us, but
 9 just so that we again have it in the note, can you read
 10 through 1.3, please.
 11 A. “1.3 What are randomised controlled trials?
 12 “Systematic reviews seek evidence of benefit from
 13 randomised controlled trials (RCTs).
 14 “In an RCT, participants are allocated randomly
 15 either to the treatment (or intervention) of interest,
 16 or to the existing standard treatment, or to a placebo.
 17 The purpose of randomisation in [randomised controlled
 18 trials] is to minimise bias and confounding. In order
 19 to minimise patient bias, the participants are unaware
 20 of their treatment allocation; this is termed
 21 a single-blind RCT.”
 22 Some of the vaccine trials look at single-blind RCTs
 23 because if the doctors knew — so:
 24 “In order to minimise doctor bias, treatment
 25 allocations are also withheld from investigators; this

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1 then is termed a double-blind RCT. To recruit
 2 sufficient numbers of patients, and to examine the
 3 effects of treatments in different settings, it may be
 4 necessary to conduct the trial at several locations;
 5 this is termed a multicentre RCT."
 6 Or sometimes it's called an international RCT:
 7 "To determine the reliability of a particular
 8 [randomised controlled trial], a number of features in
 9 the study design need to be assessed. To ensure that
 10 there is no selection bias, the process of randomisation
 11 must be seen to be robust."
 12 So it's easy for authors to say, "We randomised
 13 patients to receive the drug or the placebo", but they
 14 have got to be more specific. They have got to say how
 15 did they do it, because often investigators, they don't
 16 really know how to do randomisation. But there are
 17 correct approved and non-approved ways of doing it. It
 18 must be done in a proper way, because randomisation is
 19 really the key to why randomised controlled
 20 trials (inaudible).
 21 And then blindness of allocations means that the
 22 person doesn't know whether they are on drug A or
 23 drug B, and that should be imposed rigorously at the
 24 start of the randomised controlled trial, and it ideally
 25 should be maintained throughout this study, especially

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1 if a subjective outcome is being measured, such as
 2 relief of pain or alleviation of depression:
 3 "All the patients enrolled into a trial should be
 4 properly accounted for, at its conclusion. Finally, the
 5 trial must be reported adequately — and as a minimum, it
 6 should include a flow chart ..."
 7 Also called a trial profile, there should be a flow
 8 chart which has various arrows coming out of it:
 9 "... depicting the progress of participants through
 10 the trial.
 11 And I finish here by saying:
 12 "The need to report [randomised controlled trials]
 13 accurately was recognised in the mid-nineties and has
 14 been reiterated many times since then."
 15 Q. I think the paper that you refer to as Altman, that is
 16 the first paper in the bundle, and it's at pages 1 to 2.
 17 Sorry, it's not — it's at pages 3 to 4.
 18 A. Yes.
 19 Q. And I think it's an entitled "Better reporting of
 20 randomised controlled trials: the CONSORT statement".
 21 What does one attach to the CONSORT statement?
 22 A. The CONSORT statement was a statement put out by
 23 clinicians and epidemiologists and statisticians around
 24 about this time, and it was published in various
 25 journals, including the British Medical Journal, the

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1 Lancet, JAMA. It wasn't published at that time in the
 2 New England Journal, because they were resisting
 3 evidence-based medicine, but eventually they came
 4 around.

5 Douglas Altman, who is a statistician, who used to
 6 write beautiful little articles in the British Medical
 7 Journal of half a page on medical statistics every few
 8 issues, he was a great proponent of evidence-based
 9 medicine. One of the founders of the
 10 Cochrane Collaboration. I don't know him personally,
 11 but I went to some of his workshops.

12 So what he's saying is that not only must the
 13 randomised controlled trials — this is what we want, we
 14 want RCTs because they are the best form of evidence,
 15 but not only must they be designed correctly, they must
 16 also be reported fully and accurately. That's
 17 essentially what he's saying there.

18 And really —
 19 Q. I think if one is interested, one really — I don't need
 20 you to read through it, but one finds that in the first
 21 paragraph and the beginning of the second paragraph in
 22 his paper.

23 A. Yes. Could I just read out one sentence?

24 Q. Yes, please.

25 A. Key sentence. This is his starting point, and it's

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1 indisputable. This is 1996. It's even more
 2 indisputable now than it was then:

3 "Only randomised trials allow valid inferences of
 4 cause and effect. Only randomised trials have the
 5 potential directly to affect patient care ..."

6 So only from randomised trials can we have valid
 7 inferences of cause and effect.

8 Q. So that's the second sentence in the first paragraph of
 9 that paper.

10 A. Of course. But he goes on to say there still could be
 11 bias in them.

12 Q. Yes.

13 Right, can we then move on to section 1.4, "Pooling
 14 scientific evidence". There's again a reference to
 15 Altman there, but could you read through what you say
 16 there, please.

17 A. So section 1.4, "Pooling scientific evidence". So
 18 pooling means merging scientific evidence, really means
 19 merging numbers to get a slightly better number. So:

20 "In recent years, systematic reviews have sought to
 21 pool evidence from RCTs. This is done through
 22 meta-analysis, which is a statistical method that
 23 quantitatively summarises the systematic review findings
 24 ... Unpublished trials should ideally be identified and
 25 included in the meta-analysis to avoid publication bias

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1 (i.e. non-inclusion of 'negative' trials that are less
2 likely to have been published ...)"

3 So when you do a systematic review, you not only try
4 and find all the papers that have been in print, but
5 also the ones that never saw the light of day because
6 the journals rejected them or the authors got
7 discouraged because they weren't showing what they
8 expected, and that's all relevant evidence if it is
9 a randomised controlled trial.

10 "Meta-analysis results in a pooled estimate of
11 effectiveness which is more precise than the effect
12 estimates from the individual [randomised controlled
13 trials]. This is because the pooled estimate is based
14 on a larger number of participants, and hence is less
15 liable to random error.

16 "... [some] systematic reviews also assess
17 non-[randomised controlled trial] evidence; these
18 additional sources of evidence include qualitative
19 research, animal studies and modelling."

20 But the core of the symptomatic review will be
21 randomised controlled trials, and the review:
22 "... should systematically identify and evaluate
23 (i.e. through an explicit and prespecified and
24 well-validated methodology) all appropriately-designed
25 studies that address the clinical question being

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1 considered. Where appropriate, the results of these
2 included studies should be combined.

3 "To be fully valid, a systematic review must satisfy
4 a minimum of three criteria:

5 "i. It must try to identify all relevant studies
6 [the published ones and the unpublished ones].
7 "ii. It must assess the quality of the included
8 studies [because some randomised controlled trials are
9 better than others].
10 "iii. It must try to combine the study results
11 [through meta-analysis], as long as it is reasonable to
12 do so."

13 Q. Right. Against that background, you go on to the
14 Cochrane reviews.

15 A. Yes.

16 Q. Can we just start a little about the Cochrane reviews.
17 I think we will need to pause because there are various
18 matters that I need to look at in some detail with
19 you --

20 A. Yes.

21 Q. -- in relation to Cochrane reviews, but perhaps you can
22 just read on to page 6 of your report, please.

23 A. So:

24 "A Cochrane review is a systematic review that uses
25 methodology that has been tested and refined over three

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1 decades by the Cochrane Collaboration. [These] reviews
2 are prepared and maintained, usually on a pro bono basis
3 [pro bono meaning the reviewers just volunteer, they're
4 not paid], by members of the collaboration working in
5 small teams; in 1993 the active members of the Cochrane
6 Collaboration numbered less than 100, but by early 2016
7 this number had grown to over 30,000 reviewers in more
8 than 100 countries."

9 Q. Just pausing there, am I right in thinking that you are
10 a Cochrane reviewer?

11 A. Yes, I am, yes. I have written five or six Cochrane
12 reviews. Yes, I'm a reviewer in various fields,
13 infectious diseases but also airways and guts, the gut
14 field. So I have been involved in different branches of
15 the organisation, yes.

16 Q. Did I pick you up right by you saying that you've been
17 a reviewer in relation to airways?

18 A. Yes, I wrote a Cochrane review that was to do with --
19 exploring the same idea we had earlier about helminths
20 treatment for allergic rhinitis.

21 Q. Oh.

22 A. Actually, that was done under the auspices of airways.
23 We prepared another review that was looking at helminths
24 treatment for asthma.

25 Q. All right.

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1 If you just carry on, doctor.

2 A. Yes. So:

3 "Historically, the focus ... has been on
4 quantitative data, with study results combined using [a
5 software program called] Revman ... Since 2003, the
6 quality of included studies [randomised controlled
7 trials] ... has been assessed through the Cochrane risk
8 of bias tool; this automatically grades each included
9 study into a High risk of bias, Low risk of bias or
10 Unclear risk of bias category, and [that then] allows
11 [the reviewers to do] a reliable appraisal of the
12 overall robustness or otherwise of the accumulated
13 evidence."

14 So if the accumulated summary evidence is based on
15 not very reliable randomised controlled trials, they
16 will place less confidence in that particular outcome,
17 whereas if it's based on very low bias studies, they
18 will have more confidence in the outcome.

19 Then:

20 "An important feature of Cochrane reviews is that
21 they are published electronically in the Cochrane
22 Library, and ... clinicians, policymakers and
23 researchers [can access them]. In most countries
24 [including Britain] ... [they] can be downloaded free of
25 charge."

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1 That's because the costs of the Cochrane
 2 Collaboration's overheads are met in part by the
 3 Department of Health, or the Department of Education.
 4 But there's a lot of government funding to support
 5 Cochrane reviewing in this country, and most countries.
 6 Not all countries, but most countries:
 7 "For better accessibility, every Cochrane review
 8 since 2001 has included [what they call] a Plain
 9 Language Summary ..."
 10 So it's like an executive summary, a simple one— or
 11 two—page —
 12 Q. A summary to which I automatically go when I'm trying to
 13 understand it.
 14 A. Of course, yes. Of course. Because that's actually —
 15 trying to get away from the jargon, that is inevitable
 16 in scientific work, and it's trying to say: what does
 17 this actually mean in practice to the ordinary consumer
 18 of health, which is clearly the end user of these
 19 medical interventions? So they're always well worth
 20 reading.
 21 In addition, they have the standard abstract, which
 22 is introduction, methods, results and conclusions.
 23 "The collaboration has its own press office, which
 24 promotes new reviews ..."
 25 And then Cochrane reviewers are — they are expected

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1 to:
 2 "... update their review as and when there is a
 3 substantive new body of evidence ..."
 4 Which means, for many reviews, about every three to
 5 five years.
 6 Q. Yes.
 7 A. And that means actually, my Lord, that the reviews that
 8 we might be looking at later on, by the time this
 9 Inquiry finishes, will probably have been updated. But
 10 it's unlikely there will be significant differences,
 11 I think, because the time to do randomised controlled
 12 trials in a COVID arena was in 2021 and 2022. We are
 13 moving to a different phase. So there will be some
 14 modifications to opinions, but I wouldn't have thought
 15 they would be that significant.
 16 Q. I think, just to conclude, doctor, you refer to three
 17 Cochrane reviews: the two Jefferson reviews that we've
 18 looked at briefly —
 19 A. Yes.
 20 Q. — in 2011 and 2023 —
 21 A. Yes.
 22 Q. — and Graña, which is 2022, which relates to vaccines.
 23 A. Vaccines for COVID-19.
 24 MR GALE: I'm sorry, yes, COVID-19.
 25 We will look at those, my Lord, I would suggest

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1 after lunch.
 2 LORD BRAILSFORD: Yes, by all means.
 3 We are a little early. So I had indicated that we
 4 should try and come back, or would have indicated we
 5 should come back, at 1.45, but could we make it 1.40,
 6 given we've got five minutes at this end.
 7 So 1.40, please. Thank you very much.
 8 (12.54 pm)
 9 (The short adjournment)
 10 (1.40 pm)
 11 LORD BRAILSFORD: When you're ready, Mr Gale.
 12 MR GALE: Thank you, my Lord.
 13 Dr Croft, we finished before lunch by looking at
 14 Cochrane reviews, the three that you have produced for
 15 our consideration: the two by Jefferson and the Graña
 16 review.
 17 I would like to ask you a little bit about the
 18 approach that one takes to those reviews, and can we do
 19 this under reference to appendix 4 to your report, which
 20 is at page 105 and 106.
 21 A. Yes.
 22 Q. I think here you get into what are for most of us
 23 probably the dreaded statistics and analysis of that
 24 nature.
 25 A. Yes.

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1 Q. Can we just look at what you set out there. You look
 2 at, I think, three concepts: odds ratios, risk ratios
 3 and confidence intervals.
 4 To begin with, can you explain and read what is
 5 meant by odds and odds ratios?
 6 A. Yes. So all of these terms are used regularly in
 7 statistical analysis which is, as I was explaining, the
 8 process by which you analyse the numbers that have
 9 derived from your studies, and they're common terms used
 10 by all investigators everywhere.
 11 So, first of all:
 12 "What is meant by odds and odds ratio?
 13 "Odds and odds ratio are effect measures which are
 14 commonly used in the statistical analysis of
 15 research ...
 16 "[For a particular group] The odds for a particular
 17 group is defined as the number of patients in the group
 18 who achieve the stated end point, divided by the number
 19 of patients who do not."
 20 So there's an example here:
 21 "... the odds of acne resolution during treatment
 22 with an antibiotic in a group of 10 patients may be 6 to
 23 4 (6 with resolution of acne divided by 4 without =
 24 1.5); in a control group the odds may be 3 to 7 (0.43).
 25 "The odds ratio ... is the ratio of two odds."

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1 And those are the figures, if you're going to try
 2 and summarise statistics from different studies, you
 3 will use, and the odds ratio is just a ratio of the odds
 4 of the treatment group to the odds of the control group.
 5 So in this case the odds ratio would be 3.5, so that's
 6 1.5 divided by 0.43. It's actually 3.488, but 3.5 for
 7 practical purposes.
 8 So if you have a study where you end up with an odds
 9 ratio of 1, that means there's no effect. What's
 10 happened in the treatment group, the intervention group,
 11 is really the same as the comparator group.
 12 People who are gamblers understand these terms
 13 instinctively, I'm told. But most of us struggle. But
 14 there is a logic to it.
 15 Q. I am glad you say that.
 16 A. Yes. Okay.
 17 So relative risk is — risk and relative risk and
 18 risk ratio. Risk ratio is equivalent to relative risk.
 19 It's approaching the same goal by slightly different
 20 means. They are also used by researchers. Risk is
 21 slightly different to odds. So it's the number of
 22 patients who achieve the stated endpoint, divided by the
 23 total number of patients.
 24 So in the first example, the risk — those who
 25 achieve the stated endpoint, who got better with the

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1 antibiotic, would be 6 out of 10, so the risk is 0.6.
 2 You could think of risk, in a way, as: what is the
 3 likelihood of achieving it? What is the absolute
 4 likelihood? So the likelihood of achieving it is 0.6,
 5 which is you've got a 60% likelihood that you will get
 6 better with the antibiotic, whereas those in the control
 7 group, 3 out of 10 of them got better anyway, so their
 8 risk of getting better was 0.3 or 30%. So even if you
 9 don't take the antibiotic, there's a 30% chance your
 10 acne will get better anyway, so therefore that gives you
 11 a risk ratio of 6 divided by 3, which is 2, a relative
 12 risk of 2, or risk ratio of 2.
 13 So, again, if you're using this approach to analyse
 14 your statistics, if you end up with a relative risk of
 15 1, it means there's no difference between your two
 16 groups, and often at that point people are so
 17 discouraged by the negative results of their trial that
 18 they just don't bother to get it published, which is
 19 a shame, because it nevertheless contains important
 20 information about the merits or otherwise of that
 21 particular intervention.
 22 Q. Can we move on to confidence intervals, please.
 23 A. Yes.
 24 So confidence interval is the next logical step, and
 25 the last step that we need to go into here, and that

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1 really means: how much confidence can you put in your
 2 findings? By convention, by statistical convention,
 3 what you — well, I'll read it:
 4 "... all studies with a control group, such as
 5 randomised controlled trials ... are based [only] on a
 6 sample of the population, [not based on the whole]
 7 population ... [so] there will always be some
 8 uncertainty around the reliability of the effect
 9 measures ... [based on the fact that it is just a]
 10 sample. The true effect measure may be larger than the
 11 estimated effect measure — or ... it may be smaller."
 12 So as well as measuring the odds ratio or the
 13 relative risk, nowadays investigators are expected to
 14 calculate the parameters within which the true effect
 15 measure must lie with a 95% degree of confidence. These
 16 parameters are known as the 95% confidence interval.
 17 I notice Pfizer call them the 95% credibility interval,
 18 which is fine, but it's a new term to me.
 19 So:
 20 "The true effect measure may be higher than [that
 21 you've] estimated ... or it may be lower — but there is
 22 a 95% chance that [the true measure] will lie somewhere
 23 between the upper boundary and the lower boundary of the
 24 95% [confidence intervals]."
 25 Q. Can I stop you there.

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1 A. Sure.
 2 Q. Who came up with the 95% figure?
 3 A. I don't know whether anybody particular came up with it,
 4 but there was a time when 99% confidence intervals were
 5 much spoken about. But 95% just seems to be a pragmatic
 6 measure that is useful in clinical terms.
 7 But you're quite right, Mr Gale, it's arbitrary.
 8 It's arbitrary, but it's universal.
 9 Q. It's universal, but arbitrary, and —
 10 A. Exactly.
 11 Q. — accepted.
 12 A. Oh, absolutely. Absolutely. Every scientific paper
 13 will have a 95 — well, the good ones will have 95%
 14 confidence intervals attached to the data. If they can
 15 be calculated. It's not always possible to calculate
 16 them, but nearly always it is.
 17 Q. Right.
 18 Please continue, just the last paragraph.
 19 A. Yes. So in general, the larger the study — the larger
 20 the randomised controlled trial, the greater the
 21 likelihood that your estimated effect measure will be
 22 close to the true measure, because you're doing multiple
 23 observations in a rigorous and scientific way, whereas
 24 if you've only got a very small study, the effect
 25 measure you've calculated may actually be inaccurate

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1 because it's based on small numbers.
 2 So for small studies, you have wide confidence
 3 intervals, and for larger studies, you have smaller
 4 confidence intervals. So you have more and more and
 5 more confidence in your finding, in your calculated
 6 finding, if either you have done a large randomised
 7 controlled trial, or you've done a systematic review
 8 combining trials of a similar kind through meta-analysis
 9 that gives you a more precise estimate with smaller
 10 confidence intervals.
 11 I'll just go through this again, because it's quite
 12 complicated.
 13 So let's say you're covered with acne, Mr Gale, and
 14 you went to the GP and the GP said, "I've got a really
 15 good antibiotic for you, Mr Gale, here it is, it is
 16 going to make you better", you could say to him, "Right,
 17 what are the odds I will get better?", and the GP would
 18 look at the trial on the screen and say, "Right, the
 19 odds are 6 to 10 you will get better". So he would say,
 20 "Right, okay, the odds — and so therefore your odds
 21 would be 1.5, and that's quite good". But you could
 22 say, "What are the odds of my getting better, even if
 23 I don't take the antibiotic?" And the GP would have to
 24 admit that it was going to be about 0.45, because some
 25 people don't take the antibiotic and they get better

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1 anyway.
 2 So you would ask about the — you would say, "What's
 3 the odds ratio, doctor?" So the doctor would say,
 4 "Right, okay, 3.5". So you think that was pretty good.
 5 And then you might say, "What about the risk? What's
 6 the risk? What's the risk I would get better?" You
 7 would get a funny look from the GP, but they would say:
 8 "Right, okay, the risk" — so what you mean is what is
 9 the likelihood you're going to get better, the absolute
 10 likelihood, and they'd say, "The risk is 60%". So your
 11 likelihood you're going to get better is 60%. And then
 12 you would say, "Right, okay, in the control group, what
 13 was the risk that they got better?", and the GP would
 14 say, "The risk was 30% of them got better anyway". So
 15 then you would say, "Right, okay, so the relative risk
 16 is only 2", things aren't looking that good, but still
 17 in the same order of magnitude.
 18 So you could then say, "Right, okay, what's the
 19 confidence intervals?" And at that point the GP would
 20 think, "Who is this crazy lunatic who is asking me
 21 this?", but it's a reasonable question to ask, because
 22 the confidence you could have in those small numbers
 23 wouldn't be that great, so the GP would have to concede
 24 there wasn't much confidence. Therefore, they would
 25 have backtracked from their original position, which

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1 was, "Here is a really good antibiotic", to saying,
 2 "Well, there's some evidence that it will help you, but
 3 I don't have much confidence in the results".
 4 So that's why you really need large trials and
 5 systematic reviews, and that's what evidence-based
 6 medicine is about. We probably ought to use them more
 7 in our encounters with clinicians than we do, but we
 8 rely on their — we rely really on them having sifted
 9 the evidence for us and arrived at those kind of
 10 conclusions.
 11 Q. And perhaps rely on the fact that a patient may not have
 12 the level of understanding to ask those questions.
 13 A. Sure, yes. Yes, indeed. And one could say, well,
 14 individual patient encounters aren't that important,
 15 because of course they are. But by the same token,
 16 population-level decisions are very important, and they
 17 should really be based on this kind of very careful
 18 weighing up of the pros and the cons and the confidence
 19 we can have in the scientific evidence behind the
 20 apparent measures of effect.
 21 Q. Right.
 22 Can we perhaps look at this in operation.
 23 A. Mm.
 24 Q. As I say, we have three Cochrane reviews, and can we
 25 look at just an example from the third of the Cochrane

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1 reviews, at least chronologically, and that is the
 2 Jefferson 2023 review, paper 9 in the bundle.
 3 I wonder if we could look at an example that is
 4 summarised at page 659.
 5 A. Yes.
 6 Q. It is in the second volume, if anyone is looking at the
 7 references in the volumes.
 8 A. Yes.
 9 Q. It's headed "Analysis 6.2".
 10 A. Mm—hm.
 11 Q. The title is, "Comparison 6: Randomised trials: gargling
 12 compared to control, Outcome 2: SARS-CoV-2".
 13 A. Yes.
 14 Q. Now, first of all, we can see that there are two trials
 15 that are referred to there. One is Almanza-Reyes
 16 2021 —
 17 A. Yes.
 18 Q. — and the other one is Gutiérrez—García 2022.
 19 A. Mm—hm.
 20 Q. Just so we understand what these are, we can find the
 21 Almanza trial at pages 539 to 540.
 22 A. Mm—hm.
 23 Q. Perhaps we could just look at that, so we know what the
 24 context is.
 25 Almanza—Reyes 2021 is at the bottom of page 539.

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1 A. Yes.
 2 Q. And we see there the methods:
 3 "[Randomised controlled trial] randomised using
 4 a computer-generated block scheme and stratified
 5 according to duty position, work shifts and the
 6 area/department of the service."
 7 We have to read that in context of what followed on,
 8 although I think the follow-up duration is said to be
 9 nine weeks; is that right?
 10 A. Yes.
 11 Q. And at the bottom we have a note of participants.
 12 A. Mm-hm.
 13 Q. And it says:
 14 "Workers (doctors, nurses, administrators) in
 15 a hospital for the exclusive recruitment of patients
 16 diagnosed with COVID-19 'General Tijuana Hospital'.
 17 Moving over, I think we can see that the
 18 interventions are then described, including:
 19 "Experimental group: mouthwash and nose rinse."
 20 And then silver mouth wash, details are then given
 21 of that, and then mouth spray, and then:
 22 "Control group: instructed to do mouth wash and nose
 23 rinse with a conventional mouthwash the way they
 24 normally did before the study."
 25 So, essentially -- perhaps you can probably describe

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1 it much better than I can -- what is being compared
 2 there?
 3 A. What they call the experimental group are asked to use
 4 the sodium -- sorry, silver nanoparticle solution, to
 5 mix it up with 20 ml of water and to gargle it for 15 to
 6 30 seconds three times a day. That's, if you like, the
 7 treatment that's being tested here. Or, alternatively,
 8 they could wash the inner part of their nose with it
 9 with a cotton swab twice a day.
 10 So there are two -- basically, the idea seems to be
 11 to sterilise their nasal passages and, as we will learn
 12 later, the virus that causes COVID-19 is predominantly
 13 in the nasopharynx in the early stages. So it's kind of
 14 a reasonable thing to do, one would have thought.
 15 The control -- what did the control group do? The
 16 control group just do the mouthwash or the nose rinse or
 17 both, using a conventional mouthwash the way they
 18 normally do it. So they could use Listerine or water or
 19 anything that they might normally use as a mouthwash.
 20 Q. And the other trial is the Gutiérrez-García trial, which
 21 I think we will find at page 567.
 22 A. Yes.
 23 Q. At the top of 567.
 24 A. Yes.
 25 Q. And it's a:

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1 "Single-blind (analyst) randomised controlled trial
 2 carried out in a single centre in Mexico City during
 3 September to November 2020. Randomisation was through
 4 tokens in opaque envelopes but the trial was open to all
 5 except the data analysts. There were some imbalances in
 6 age groups post-randomisation at baseline in age and
 7 comorbidities."
 8 Can you translate that for us, please?
 9 A. Single-blind means that those who were analysing the
 10 data, the statisticians, didn't know what particular arm
 11 of the trial the participants belonged to, but the
 12 participants weren't blinded themselves because, as
 13 might become apparent, it might have been difficult to
 14 try and conceal what arm of the trial they were in. But
 15 that shouldn't matter as long as the randomisation has
 16 been done correctly, and that's what we come on to next,
 17 I believe.
 18 Q. Right. I think probably that's sufficient, just looking
 19 at those.
 20 Can we go back, please, to page 659.
 21 A. Yes. Yes. So the --
 22 Q. And just before we do, I think the reason that this has
 23 been selected is that it's a two study or group
 24 comparator, and frankly it's relatively straightforward.
 25 A. Yes.

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1 Q. At least --
 2 A. Exactly. It shows striking results.
 3 Q. Yes. So perhaps you can just take us through what is
 4 shown on that page.
 5 A. Yes. So this is one of the analyses that the reviewers
 6 of this systematic review undertook, and when you do
 7 a systematic review, you do sometimes several dozen or
 8 even 100 analyses, and you're encouraged to present the
 9 most compelling ones in a chart like this, which is
 10 called a forest plot. You don't want to have 100 forest
 11 plots; you just want the most important ones. So
 12 they've chosen this one because they obviously found it
 13 of interest.
 14 What they're comparing is gargling compared to
 15 control, which in this case was gargling with ordinary
 16 water or ordinary solution, and --
 17 Q. Can I just pause you there. What was the -- I'm putting
 18 it this way -- the end product or the aimed-for end
 19 product in this? What were they trying to seek to do?
 20 A. They were trying to seek if SARS -- ah, interesting.
 21 Well, let's look again. The outcome is whether the
 22 people who were gargling were less likely to develop
 23 COVID-19, the people who are gargling with the approved
 24 solutions, than the control group.
 25 Q. Right.

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1 A. So the outcome was COVID—19 assessed through different
2 methods.
3 Q. Yes.
4 A. Some of the trials, the COVID—19 is assessed
5 subjectively by whether people felt they had a new onset
6 cough and loss of smell and taste, but in other trials
7 it was assessed through laboratory measures. We haven't
8 looked exactly to see how, but I think for these two it
9 was assessed by laboratory measures. So it was assessed
10 quite robustly, I believe.
11 Q. Yes. And what was the outcome?
12 A. Well, looking at the — going back to the forest plot,
13 which is on page 659, both of these trials, randomised
14 controlled trials, were carried out in Mexico, it seems,
15 which is interesting, and the numbers are quite large,
16 and the square boxes give an indication of the size, the
17 numbers of participants in the individual trials. The
18 diamond at the bottom indicates the combined effect of
19 the trials.
20 So the first line — if I read across it, my Lord.
21 So Almanza—Reyes, that was the one Tijuana City, which
22 is Mexico, I believe. Right. So they were looking
23 at — what they wanted to find out was: was gargling
24 with this silver nanoparticles solution likely to have
25 fewer people getting COVID—19 as compared to those who

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1 were gargling in the ordinary kind of way? And they had
2 two events with the mouth rinse. I hope you can see
3 that, two events?
4 Q. Yes.
5 A. There are 114 people in total, so 2 out of the 114
6 acquired COVID who were gargling with the silver
7 nanoparticles.
8 Would you agree with that, Mr Gale?
9 Q. I'm taking your word for it, Dr Croft. I can see what
10 it says, yes.
11 A. Well, what about the control group? Remarkably, the
12 control group had 33 cases of COVID—19 out of a total of
13 117. So the total number of participants was 231, and
14 they'd been randomised into the gargling group and the
15 control group, and the gargling group had very few
16 cases, just 2, compared to 33, a much higher number of
17 cases in the control group there.
18 So they did the calculations we were just describing
19 now, and they came out with a risk ratio of 0.06. That
20 means — I think this is right — you're 94% more likely
21 to get COVID if you're not gargling with a special
22 solution than if you are.
23 So Gutiérrez—García, who did something similar, but
24 they used a different solution, they were using — they
25 weren't using silver nanoparticles; they were using

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1 neutral electrolysed water to prevent COVID, and what
2 did the — the control people must have used something
3 else. It's not clear what the control group — anyway,
4 the control people weren't using neutral electrolysed
5 water. They were followed up for only two weeks.
6 They had similar results. Yes, similar results.
7 Slightly smaller numbers, so — oh, sorry, I should have
8 said — beg your pardon — with the first one,
9 Almanza—Reyes, the horizontal line there, my Lord,
10 represents the 95% confidence interval for their
11 calculated risk ratios. So the calculated risk ratio
12 was 0.06, but the 95% confidence that they had in that
13 ratio indicated that the true effect may lie anywhere
14 between 0.02 to 0.25. But the key thing is that the
15 confidence interval doesn't cross the line of no effect.
16 The line of no effect is that central vertical line,
17 which is 1. If it crossed 1, then you would have to say
18 the results suggest there might be an effect from
19 gargling, but it's not statistically significant. But
20 in this case it is statistically significant.
21 So Gutiérrez—García, the gargling group comprised 84
22 people, and these were healthcare workers, I believe.
23 Yes, they were frontline healthcare workers, so very
24 highly exposed to COVID. I understand this was carried
25 out in the first half of 2020. So those who were

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1 gargling had only one event where the individual
2 received — 1 out of 84 acquired COVID, and those who
3 weren't gargling or who weren't using the neutral
4 electrolysed water had 10 events. So they had 10 out of
5 79.
6 So the risk ratio there was 0.09, so not quite as
7 good as the other people, the silver seems to be better,
8 and that's plausible because silver seems to have
9 virucidal and antibacterial properties. Nurses use it
10 for silver dressings for burns. They're expensive
11 dressings, but where you don't want any bacteria or
12 viruses, you might use dressings. So their risk ratio
13 wasn't quite as compelling, but nevertheless, there it
14 is: it's 0.09. So the study authors could say that this
15 shows statistically that gargling using this neutral
16 electrolysed water will protect you from COVID within
17 95% bounds of credibility or probability.
18 Then the Jefferson — the review authors have
19 summarised this, have pooled these results, and that's
20 shown by the diamond there, which really gives a more
21 precise measure of effect because the confidence
22 intervals have been narrowed. The two horizontal
23 corners of the diamond indicate the extent of
24 confidence, and so therefore there's even more
25 confidence now in this pooled result than there was in

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1 the individual results, and here we are. The risk ratio
 2 is 0.07, so they consider there's a 93% chance you won't
 3 get COVID under these circumstances, and it might be as
 4 much as 98% chance you won't get COVID, but it might be
 5 as little as 77% chance. But the best estimate of
 6 effect is that 0.07 risk ratio that's been calculated in
 7 that way.

8 Q. Given that there were two trials that were in
 9 comparison --

10 A. Yes.

11 Q. -- there, and relatively small numbers --

12 A. Yes.

13 Q. -- in the intervention group of 114 and 84 and the
 14 control group of 117 and 79 --

15 A. Yes.

16 Q. -- what degree of confidence would you take from
 17 a result such as that and a comparison such as that?

18 A. Yes. Well, I take a lot. And there are some numbers
 19 underneath that, my Lord -- tau, I-squared -- and those
 20 numbers are indicating -- they are different
 21 mathematical measures to indicate whether or not the two
 22 trials being assessed are similar in terms of what's
 23 going on, the statistics, and those numbers actually
 24 show that -- particularly the I-squared, the I-squared
 25 is a measure of variability between the trials, and when

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1 there's an I-squared of 0, it means that the trials are
 2 very comparable and you would expect that you could
 3 combine them without having to make qualifications.

4 So it's entirely appropriate to combine those two
 5 trials, and reading about the background of the trials,
 6 one could see why they've turned out to be so
 7 comparable, because they are a similar population and
 8 it's a similar kind of intervention. So you wouldn't
 9 want to make any qualifications based on the fact that
 10 the results are a bit different. They were the same.

11 With very compelling results, you will get strong
 12 effect measures even with small numbers. You could get
 13 strong results even with small numbers. The first trial
 14 ever done was the James Lind trial, which had only 12
 15 participants in, but proved pretty persuasively that the
 16 cure for scurvy was oranges and lemons. That was done
 17 in 1747. So that changed the whole understanding of
 18 scurvy and became a model for future trials. That was
 19 more by good luck than by design, but it goes to show
 20 how you can have even just a handful of people in your
 21 trial and, provided you're on the right lines in
 22 investigating what is genuine, you could get reliable
 23 results just from compiling really rather small numbers.

24 Q. So identifying comparators, is that an art or is it
 25 a science?

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1 A. Perhaps a bit of both, but the key thing is that, at the
 2 outset of doing a systematic review, you identify what
 3 trials you're going to include and what nature of trials
 4 you're going to include and combine, and what ones
 5 you're not going to combine.

6 So if you're going to do a trial, going back to the
 7 acne example, you wouldn't combine, in this way, a trial
 8 of acne treatments where some of the trials were using
 9 oral antibiotics and some were using topically applied
 10 antibiotic cream because they're just too different.
 11 But you could well do a randomised controlled trial
 12 looking at different antibiotics, just to answer the
 13 question: does antibiotic treatment cure acne?

14 Q. Right.

15 Could we look at another example of these measures
 16 in operation.

17 A. Yes.

18 Q. This time can we look in the Graña report, and it's
 19 number 7, and at page 101 to 102, please.

20 A. Yes.

21 (Pause)

22 Q. Now, this is of course in relation to vaccines, and
 23 I think, looking at 101, we have figure 13, and
 24 analysis 2.1.4:

25 "... non-replicating viral vector vaccine. Outcome:

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1 all-cause mortality."

2 And then there's a reference to Kulkarni 2021 and
 3 also to Voysey, also 2021, and data pooled from four
 4 trials.

5 So, first of all, can we have a little better
 6 understanding of the terminology.

7 A. Yes.

8 Q. Non-replicating viral vector vaccine, what is that?

9 A. Right. Well, we haven't really gone into the detail
 10 of --

11 Q. We haven't.

12 A. -- the different sorts of vaccines that are available,
 13 but, essentially, one category of vaccine against
 14 COVID-19 has been to use a virus, a non-pathogenic
 15 virus, a virus that's harmless to humans, that will
 16 enter the body and go into cells but, while going into
 17 cells, will carry genetic instruction, but won't
 18 replicate, won't cause disease. It will just carry the
 19 genetic instruction. Various of these non-pathogenic,
 20 non-replicating viruses have been used. The word
 21 "vector" means carrier. So they're just used as
 22 a carrier.

23 So possibly they are actually comparing slightly
 24 different trials, but nevertheless the same sort of
 25 trial, because they're all using the same methodology.

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1 Q. I think it's important to note, because we are taking
2 this as an example at this stage, that the outcome that
3 is looked at is all-cause mortality. So there isn't
4 a suggestion of mortality being caused by the vaccine.
5 A. No.
6 Q. It is a fact of mortality —
7 A. Yes, precisely.
8 Q. — post-vaccination?
9 A. That's right. Any mortality occurring during
10 vaccination is what they are looking at, and mortality
11 is not a subjective event; it is a terminal event, you
12 don't dispute it. So it's quite a good outcome to look
13 at.
14 Q. Now, can you just — again, as you did with the gargling
15 exercise — take us through what is shown in figure 13.
16 A. Okay. I'll have to put my glasses on for that. I've
17 got some reading glasses here fortunately. You might
18 have to lend my Lord your magnifying glass.
19 LORD BRAILSFORD: Ah, I see.
20 MR GALE: Sorry.
21 LORD BRAILSFORD: It's all right.
22 A. It's disappointing that the writing is very small. If
23 that could be corrected in the future.
24 Oh, no, I'm all right. You might need them.
25 So, yes, what has happened here is they have found

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1 five randomised controlled trials that are all done in
2 2021 that are looking at this important outcome. So
3 these are vaccines of various kinds, where the way the
4 vaccine works, or is assumed to work, is based on
5 a virus, a harmless virus, that is carrying a genetic
6 code — we can talk about that later on — into the
7 cells of the recipient. The whole purpose of the
8 vaccination was — well, part of the purpose potentially
9 was to prevent serious COVID-19, especially serious
10 COVID-19 and death. So they are looking at death.
11 So let's take the first line. Asano 2021. So —
12 have you got that, my Lord?
13 LORD BRAILSFORD: Mm—hm.
14 A. So they followed up the participants for 1.9 months.
15 They gave them the vaccine, they followed them up for
16 1.9 months to see — and they were looking at other
17 parameters as well, but they were recording how many
18 died in that period of time, and that's the name of the
19 vaccine, ChAdOx1. It's the AstraZeneca vaccine,
20 basically.
21 The group intervention 1 are the participants who
22 received the vaccine, and intervention 2 received
23 placebo. Placebo means probably an injection of normal
24 saline, so there was no active constituent. I suspect
25 that was a single-blind study, I'm not sure, but we

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1 could look up the details if we're particularly
2 interested.
3 So what happened? How many deaths were there in the
4 vaccination arm? They were 0 out of 192. How many
5 deaths were there in the placebo arm? Again, there were
6 0 out of 64.
7 It's interesting the two arms are different in
8 numbers, and probably that's because the vaccination arm
9 probably — there were probably three arms, in fact: one
10 with high-dose vaccine, one with low-dose vaccine and
11 then a third arm which was placebo. So it's
12 a three-armed trial, which is good.
13 Just looking across to the extreme right-hand
14 column, you can see that there was, according to the
15 Cochrane review authors, a well-designed trial. It was
16 all green for the risk of bias. So there are various
17 domains for bias, but they gave it a five-star rating in
18 terms of study design.
19 So the next one down is Falsey 2021. This was a big
20 study, and if you just go straight to the numbers,
21 again, they had 21,587 people who were given the
22 vaccine, probably a high-dose and a low-dose group, and
23 10,792 who just received placebo, they had no vaccine.
24 The period of follow-up was two months, and just
25 because there were so many people, you would expect some

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1 mortality in any event, but you might have expected
2 there would be less mortality at this time of high COVID
3 from the vaccine group. So let's see if that was the
4 case.
5 The vaccine group, that was twice the size of the
6 control group, had seven deaths, and the control group
7 who just received saline had seven deaths.
8 Would you agree with that, my Lord?
9 LORD BRAILSFORD: Mm—hm.
10 A. So, therefore, they have calculated an effect measure,
11 which is that little tiny square — the square is tiny
12 because it's just tiny transcription — but there's
13 a very wide confidence interval there because the
14 numbers we are interested in, which is the deaths, are
15 quite small. So those sort of numbers could have arisen
16 by chance, is what we are saying here.
17 So because the upper end of the confidence intervals
18 goes over the vertical line of no effect, the authors of
19 that trial, if we actually looked at the trial, would
20 have to say that it's suggested there were fewer deaths,
21 but we couldn't say that with statistical certainty.
22 Statistically, it was not significant.
23 But anyway, as we come to add more and more
24 evidence, we might reach better significance.
25 So the next one, next study, is Kulkarni 2021. They

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1 studied their participants for six months, which is
2 good. I mean, really, you should study vaccine
3 participants for a year or two, but you've got to
4 provide interim results. They had 900 and 300, so 900
5 in the vaccine arm — again, that suggests that there
6 were two groups: a high-dose vaccine and a low or
7 medium-dose vaccine group — and then there were 300 in
8 the placebo arm. They had no deaths. I'm not quite
9 clear why that was.

10 Then Madhi, next one down — two more to go — Madhi
11 in 2021, they followed up their trial participants for
12 two months. Again — oh, yes, Kulkarni were using
13 a different vector — a different vaccine. I don't know
14 what that is. But there we are. That could be why they
15 had no deaths.

16 So Madhi had very small numbers, tiny numbers. Only
17 52 in — they had two arms, only 52, and there were no
18 deaths in the vaccine arm, one death in the placebo arm.
19 So you can see the result. The little black dot is on
20 the side which says "Vaccine better", but the confidence
21 intervals are so huge, they're off the scale, because
22 we're only talking about one finding there. But,
23 nevertheless, that contributes to the overall finding
24 which we are coming on to very soon.

25 I think we are now on Voysey. Voysey, same sort of

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1 vaccine. 4.1-month follow-up, and ChAdOx. They had two
2 types of control measures. One was MenACWY, that's
3 a vaccine against meningitis. So they used a dummy
4 vaccine, in effect, as a comparator, which isn't ideal,
5 really. You should use a placebo in vaccine trials.
6 You should really use saline. But anyway, they had
7 those two different sorts of controls. They had 12,282
8 participants who received the vaccine, the COVID-19
9 vaccine, and 11,962 received the dummy vaccine or the
10 placebo. They had two deaths out of the
11 COVID-vaccinated ones and four out of the control group.

12 So, again, their results do favour — do err on the
13 side or they land on the side of vaccine probably —
14 well, you would have thought it would be better, but
15 again, because the confidence intervals were so wide,
16 they were very wide because of very tiny numbers, you
17 couldn't say categorically that this was a statistically
18 significant result.

19 So here we are. So now we come to, if you like, the
20 crunch, which is: what does that mean when you add all
21 these figures together? That's in the top blue diamond,
22 the elongated blue diamond. Again, even though it's
23 added the results from three trials, because two trials
24 didn't contribute any of the data, the confidence
25 interval still crosses the line of no effect. So even

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1 combining those data, you cannot say — which we would
2 like to say — that using this vaccine prevents deaths.
3 You couldn't say it.

4 Now, it may be that no doubt there will be other
5 trials in progress that will add to the data in due
6 course, and then, as they add to that data, the pooled
7 estimate of effect will get narrower as more data go
8 into the analysis. It will get narrower, and the
9 confidence interval will get smaller. Then, as long as
10 it's not touching the line of no effect, you can impute
11 a degree of confidence to that estimate of effect.

12 Q. Again, from your perspective, what do you take from
13 that?

14 A. Well, I read the data as it's presented. I would
15 immediately go back to the plain language summary which
16 we can all understand, and if I do that, I think from
17 memory the plain language summary just says we cannot
18 with confidence say the vaccines prevent deaths. So
19 let's do that.

20 Q. I think probably, before we do that, actually,
21 Dr Croft — we'll come to that, and if anyone wants to
22 read it, the plain language summary is at page 55.

23 A. Oh, right, okay.

24 Q. But we'll come to that when we look at your section on
25 vaccines.

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1 A. Yes.

2 Q. I'm just using this at this stage as an example.

3 A. Yes. It's interesting that even though there are
4 thousands of participants here, comparing to the
5 gargling trials, where there weren't that many
6 participants, but there was a very confident finding
7 there, this really just indicates a very high level of
8 uncertainty for this particular outcome.

9 Q. Yes.

10 I think, just for reference, if anyone is interested
11 in it, there is a further analysis on the following page
12 at 102, which is figure 14, analysis 2.1.5. Again, same
13 non-replicating viral vector vaccine. The outcome that
14 is looked at here is serious adverse events, SAEs. So
15 one is not looking there at all — cause mortality, one is
16 looking at serious adverse events.

17 We will look at this again in the context of your
18 passage in section 4 of your report on vaccines, but it
19 is just to give the reference to that at this stage.

20 A. Yes.

21 Q. Right.

22 Dr Croft, I think I can now, having done that
23 exercise with you, move back to your report.

24 Can we go to part 2 of your report, beginning at
25 page 8.

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1 A. Yes.
 2 Q. Now, before we do this, because you're setting out
 3 here — and this is the longest passage within your
 4 report. It goes from page 8 to page 50—something,
 5 I can't remember the number.
 6 A. Yes.
 7 Q. It's the longest passage in your report. A lot of it
 8 is — and this is not a criticism in any way — in
 9 certain respects a series of dates and it is a narrative
 10 of what you see as significant events.
 11 But before we do that, could we just look a little
 12 bit of background, and in particular could we look at
 13 appendix 4.
 14 A. Yes.
 15 Q. I'm sorry, I've got the wrong number. It's appendix 7.
 16 A. Yes.
 17 Q. It's at page 111 of your report. I'll be asking you to
 18 look also at appendix 8 and appendix 9.
 19 In these appendices you give some background to
 20 previous pandemics and epidemics.
 21 A. Yes.
 22 Q. The first that you refer to is the immediate First World
 23 War influenza pandemic. I think it's also known as
 24 Spanish flu. I think, as we can see, perhaps it was
 25 rather something of a misnomer for it. But perhaps you

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1 would just read through there and read through your
 2 comment on that.
 3 A. Shall I read the part in italics as well?
 4 Q. Everything, if you would, please, yes.
 5 A. So appendix 7:
 6 "The 1918–1919 influenza pandemic.
 7 "The 1918–1919 influenza pandemic, known also as the
 8 'Spanish flu', has been described as being among the
 9 most deadly events in recent human history. The
 10 pandemic killed between 50–100 million people. In
 11 countries such as the UK and the USA, and for reasons
 12 that have never been adequately explained, there was
 13 a high case–fatality rate at all ages, including amongst
 14 20–40 year–old individuals."
 15 That's an age group who are normally at low risk for
 16 severe influenza. However:
 17 "... in some countries (e.g. in Spain itself) the
 18 influenza took the form of 'normal' seasonal flu, with
 19 average or close–to–average mortality."
 20 So here I give my comment. I try not to interpose
 21 my comments in the main body of the report, but my
 22 report would be bland and not have much meaning unless
 23 there was some comment at some point.
 24 Q. No, I appreciate that.
 25 A. So I give my take on this. I made it clear this is my

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1 comment. So I have proposed here:
 2 "The unusually high mortality in young adults with
 3 'Spanish flu' that occurred in some countries (e.g. UK
 4 and USA) is now thought to have been in large part due
 5 to harmful treatment protocols used in those countries
 6 [like the UK and USA]. In the early weeks ..."
 7 Oh, here we are:
 8 "In the early weeks of the COVID–19 pandemic the
 9 case–fatality rate was reported to be as high as 15%,
 10 causing widespread alarm. This high reported rate may
 11 likewise have been due, at least in part, to harmful
 12 treatment protocols ..."
 13 And I give an example of some that might have been
 14 harmful instead of beneficial, for example
 15 over–enthusiastic use of intravenous fluids, nursing
 16 patients in the supine, meaning on their backs rather
 17 than on their stomachs, and the sort of treatments that
 18 are no longer routinely used for COVID management.
 19 That's just a suggestion. I have put here:
 20 "The crude case–fatality rate for COVID–19, averaged
 21 across all age groups, is now considered to be around
 22 0.5–1%."
 23 I get that from — that's in the earlier section of
 24 my report. And in Scotland I put it was only 0.29%.
 25 That was my own calculation:

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1 "The overwhelming majority of COVID–19 deaths occur
 2 in those who are very old ..."
 3 And that's overwhelmingly the highest risk factor.
 4 Those who are over 80 are the ones who most likely to
 5 get severe COVID and to die. Also the very sick, but
 6 that's less of a risk factor, having the pre–existing
 7 medical conditions:
 8 "In 2020 and 2021 some commentators drew parallels
 9 between COVID–19 and the high mortality rates in young
 10 people that were reported in some countries during the
 11 [Spanish flu epidemic of 1918 to 1919]. Arguably, the
 12 drawing of these historical parallels was misleading,
 13 and [added] to the atmosphere of panic that prevailed in
 14 2020 and 2021 — and that hence facilitated [made easy]
 15 the introduction, in some countries, of repressive and
 16 authoritarian response measures against COVID–19 that
 17 were often harmful at a societal level, but that were
 18 declared as necessary to 'contain' SARS–CoV–2."
 19 Within that opinion or comment I have got a
 20 scientific reference which talks about Spanish flu.
 21 Essentially, what was happening there in the UK and USA
 22 was there were massive stocks of penicillin around,
 23 because the First World War had just finished,
 24 penicillin that had been made by Bayer, a German
 25 company, had gone off patent, so it was really, really

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1 cheap, so doctors in large cities used this new wonder
2 drug on patients and were using it at such high doses
3 that they were often damaging them and actually caused
4 their death. That wasn't understood properly at the
5 time, but it was intuitively recognised as the pandemic
6 progressed, and in later flu epidemics aspirin doses
7 were much lower. It's hard to prove, but it seems to be
8 the case.

9 That also would explain why in Spain -- Spain hadn't
10 been in the war and so didn't have massive stocks of
11 aspirin -- it was just like ordinary seasonal influenza,
12 a bit worse, but it wasn't killing young people in their
13 tens of thousands.

14 Q. I think you said earlier massive stocks of penicillin ;
15 you are actually meaning --

16 A. I'm so sorry, I mean aspirin. I beg your pardon.

17 In the United States they had this very frightening
18 phenomenon of military barracks -- they had very large
19 military barracks of 10,000 troops or so, and there
20 might be hundreds of deaths per day that were going on,
21 because the doctors were pumping the young soldiers with
22 penicillin -- sorry, with aspirin. I'm probably
23 confused -- my own grandfather died in the Spanish flu.
24 He was in the merchant navy and he died in 1918. He was
25 in Portsmouth, and I suspect he probably got the full

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1 whack of aspirin that possibly killed him. It's
2 a reasonable interpretation of mismanagement. Not to
3 say -- it was probably a virulent form of influenza, but
4 that particular influenza epidemic and no other
5 especially affected healthy young people, and no one
6 really knows why. But only in some countries. If it
7 was really due to the very pathogenic nature of the
8 pathogen, it would have been across the board, but it
9 wasn't.

10 MR GALE: I think the --

11 LORD BRAILSFORD: But that falls into the category of
12 informed conjecture by you.

13 A. Well, it's not by me, it's by other people.

14 LORD BRAILSFORD: By other people, yes, I beg your pardon.

15 A. Yes, it is. Yes. It is informed conjecture. It's
16 based upon a reasonable scientific model.

17 LORD BRAILSFORD: Yes.

18 MR GALE: I think the paper you refer to is the paper by
19 Dr Karen Starko.

20 A. Yes.

21 Q. And for those who want to look at it, it's document 18.
22 The synopsis is at page 931. I don't think it's
23 necessary to -- unless there's anything there you want
24 to particularly take from it.

25 A. No, I was simply going to say this isn't central to

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1 COVID-19, but it's an important pandemic, the worst
2 pandemic ever that has occurred, and there may be
3 lessons we can draw from that. I think that's one that
4 the numbers might be overstated for various reasons that
5 are not actually truly related to the pathogen, that is
6 truly related to the way people responded to the
7 pathogen, with the best of intentions, but potentially
8 making, in the first stages, the patient worse rather
9 than better.

10 Q. I think you make the point in your comments section at
11 page 111 that:
12 "Arguably, the drawing of these historic parallels
13 was misleading ..."
14 When one is looking at it --

15 A. Yes, I think so, yes.

16 Q. -- in the context of --

17 A. Yes, I think -- yes, yes.

18 Q. -- of COVID-19.

19 A. And I think I'm right in saying many commentators were
20 saying, "Oh, we're facing the worst pandemic since the
21 Spanish flu of 1918/1919", but that was always
22 misleading, because 1918/1919, there were a lot of young
23 people who were affected, and this is very unusual with
24 flu, but there's a potential explanation for that.
25 Starko says that the case-fatality rate in young people

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1 was as high as 3%. That seems a tremendously high rate
2 of death. So there's another explanation which could
3 explain why that was.

4 Q. Yes.

5 A. Whereas in COVID it was never the case that young people
6 were ever going to be at very high risk, because it was
7 known from the very outset it was the very old, and that
8 could be inferred also from the fact that the previous
9 coronavirus epidemic, with a very similar virus, SARS --
10 which we might talk about shortly -- it was known from
11 that that, although it had a high mortality rate, it was
12 in the very old, very old, yes.

13 So all I'm saying is that of course one can look
14 back in history and cite examples of very serious public
15 health events, but the particular imputation that was
16 being in many cases given that we were facing widespread
17 deaths of young people in the tens of thousands, was
18 not, in my view, appropriate on the occasions when it
19 was used. I don't know if scientists were using it.
20 I would hope not. But certainly media commentators were
21 using it, and obviously it frightened people because
22 many people still have a folk memory of the 1918/1919
23 Spanish flu.

24 Q. And I think it's right to say, doctor, that for those
25 who suffered losses of family members and loved ones who

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1 were in the young group, that's probably of little
2 comfort to them.

3 A. Oh, I agree. Yes, certainly. Certainly, yes. Yes,
4 indeed. I would certainly accept that, yes.

5 Q. Can we go on to appendix 8, please, at page 112.
6 A. Yes.

7 Q. This is your reference to the 2009/2010 swine flu
8 epidemic. Again, this is more modern history, and
9 probably something that we all remember to a certain
10 extent, the H1N1, as sort of letters and numbers
11 embossed in our memory.

12 But perhaps you could just read out the block
13 section at the top and then your comment on it.

14 A. Yes. So the block section I have taken from a standard
15 textbook of microbiology, the Oxford Handbook of
16 Infectious Diseases and Microbiology, and summarises the
17 swine flu pandemic in a few sentences:

18 "The H1N1 'swine flu' pandemic of 2009/2010 spread
19 rapidly throughout the world. Rates of infection were
20 highest in those [less than] 25 years old and, unlike
21 seasonal flu, low in those over 65 ..."

22 The explanation for that might have been that the
23 over 65s already had some pre-existing immunity to that
24 particular virus because they'd encountered it in the
25 1950s, whereas the young people didn't. So the young

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1 people were getting infected, but they weren't dying
2 particularly, on the whole:

3 "Secondary attack rates were probably similar to
4 those of seasonal flu, but rates of hospitalization and
5 mortality were higher, especially amongst the pregnant
6 and immunosuppressed."

7 Interestingly, they weren't higher amongst the very
8 old, probably for the reason we've just suggested: that
9 the very old had probably encountered something like
10 this virus in their youth. But it was the pregnant and
11 immunosuppressed who were hospitalised and who were
12 likely to die.

13 So:

14 "Unlike the seasonal [influenza virus] H1N1
15 circulating at the time [this is important] [less than]
16 99% of pandemic [swine flu] strains were susceptible to
17 [Tamiflu] ..."

18 Which is the drug that the government brought in
19 very large quantities. It's called oseltamivir. Its
20 trade name is Tamiflu. So the government, in response
21 to this pandemic — the World Health Organization
22 declared it a pandemic — they bought in very large
23 stocks of an antiviral drug on the assumption that it
24 would reduce symptoms and reduce pressures on
25 healthcare, but basically the strain was resistant to

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1 it, so it really had no effect, or very little effect.
2 Then by the following season, this new pandemic
3 strain of the virus had become just the standard
4 circulating influenza strain. It had merged into the
5 background strain of influenza viruses that cause
6 seasonal flu, and it's now considered a seasonal virus.

7 So it was rather alarming when it first appeared.
8 Some people died. Some people got ill. Not that many.
9 But that particular pandemic fizzled out. It started in
10 about — it was declared in the middle of the year 2009,
11 it built up a head of steam during the autumn, and at
12 Christmastime it just fizzled out completely.

13 I remember working in the Surgeon General's department
14 then. We had to implement the policies of getting
15 vaccines out to outlying military stations, and we came
16 back from Christmas in January and no one was talking
17 about it anymore. It was all a bit embarrassing. It
18 was no longer regarded as being a serious threat at all.

19 There was then an official inquiry, the Deirdre Hine
20 report, which came out very quickly. She reported in
21 July 2010. It is a very, very good report, actually,
22 which I read just recently, and she made some very
23 perceptive observations.

24 So here is my comment — again, this is just my
25 personal view, which I accept is my personal view, and

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1 I have qualified at the beginning of the report that my
2 own personal view is not necessarily or not to be taken
3 as in any way indicative of the Inquiry's view, but
4 I have said here:

5 "The above short summary of the 2009–2010 swine flu
6 pandemic is taken from a standard textbook for medical
7 students. The response to the pandemic by the UK
8 government at the time (i.e. the Labour government of
9 Gordon Brown) was unduly influenced by 'worst-case'
10 modelling ..."

11 And that was something Deirdre Hine mentions in her
12 executive summary. She said: people keep using this
13 term, "this is a reasonable worst-case scenario". It is
14 a reasonable worst-case scenario that millions of people
15 are going to die in this country. She said a worst-case
16 scenario cannot be reasonable, is I think what she's
17 saying, and I think lawyers would understand that.

18 So it was:

19 "... influenced by 'worst-case' modelling and by
20 alarmist predictions in the media that originated from
21 WHO officials and UK academics who had undeclared
22 conflicts of interest ..."

23 That's now well established. There was a remarkable
24 paper by Kate Mandeville and some colleagues at the
25 London School of Hygiene, who looked at what scientists

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1 were telling the media, what stories they were feeding
 2 to the media. That's one of my attached papers.
 3 Q. Just to give the reference to that, that is at pages 808
 4 to — it's a short paper.
 5 A. Yes. It didn't come out until 2014, so four years after
 6 it was all over.
 7 Q. To 814.
 8 A. Yes, thank you. Four years after it was all over, these
 9 investigators, this is what they said. Essentially,
 10 they said:
 11 "There is evidence of [conflict of interest] among
 12 academics providing media commentary during the early
 13 [swine flu] pandemic. [And this led to] Heightened risk
 14 assessments ..."
 15 I'm reading from the abstract of that paper,
 16 "Conclusions":
 17 "Heightened risk assessments, combined with advocacy
 18 for pharmaceutical products to counter this risk, may
 19 lead to increased public anxiety and demand."
 20 And then they finish with the line:
 21 "Academics should declare, and journalists report,
 22 relevant [conflicts of interest] for media interviews."
 23 Q. I think, just again for the note, you are reading there
 24 at page 808 —
 25 A. I'm reading at 808.

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1 Q. — from the abstract and the conclusions section.
 2 A. Correct, yes.
 3 Q. Thank you.
 4 Right, if we go back to your comment.
 5 A. Yes. So I have put here:
 6 "... in fact the swine flu pandemic quickly reached
 7 a state of natural equilibrium by early 2010."
 8 In fact, it was already declining by November of
 9 2009. It already reached its peak and was waning. But
 10 anyway, by early 2010 it was all over.
 11 So here we are:
 12 "Important additional mistakes made in —20092010 by
 13 the UK government [it's great to be wise with hindsight]
 14 included (i) the stockpiling at great expense to the UK
 15 taxpayer of ineffective antiviral drugs (notably
 16 oseltamivir, or Tamiflu) ..."
 17 And here I cite the editor of the British Medical
 18 Journal, Fiona Godlee, who said exactly that in 2010.
 19 She said we've spent billions on completely ineffective
 20 antiviral drugs. Other countries were not panicking to
 21 this position, but Britain was, France was. Poland
 22 wasn't, and she said this is not acceptable.
 23 Then I put (ii), here is an additional mistake:
 24 "... emergency—use authorisation given to
 25 inadequately—tested vaccines (notably the

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1 GlaxoSmithKline vaccine Pandemrix, which in a
 2 significant but undisclosed number of children caused
 3 narcolepsy, a devastating and lifelong neurological
 4 disease)."
 5 So there wasn't any vaccine around to counter this
 6 new strain of influenza, which was serious in pregnant
 7 women and those who were immunosuppressed, so the
 8 process of authorisation for vaccine—use was speeded up,
 9 and some vaccines were re—purposed from seasonal flu to
 10 be used against this new variant of flu. One of these
 11 was Pandemrix, and it had a terrible side effect in
 12 a small number of children, but it was nevertheless
 13 a significant number, some hundreds of children, who had
 14 developed this very severe neurological disease as
 15 a result of this vaccine.
 16 Obviously, it was contested. The manufacturers
 17 contested. They said association doesn't mean proved.
 18 But it is now in the textbooks that that particular
 19 vaccine was the very unfortunate cause of this incurable
 20 condition, and the following year or maybe the year
 21 after, it was withdrawn. It was being slowly developed
 22 for use in seasonal influenza, but the manufacturer,
 23 GlaxoSmithKlein, withdrew it.
 24 Unfortunately, the government had committed to
 25 buying large quantities of this vaccine, along with

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1 another vaccine, which actually seems to have been quite
 2 effective, but didn't cause neurological problems, but
 3 GlaxoSmithKlein wouldn't allow a break clause, which is
 4 one of the criticisms Deirdre Hine makes in her report.
 5 So, in other words, they wouldn't say, "All right, we
 6 will take the vaccine back, now you don't want it"; they
 7 said, "No, you've got to pay for it". So that was
 8 a lesson that was identified then.
 9 Q. Just to give the reference to the Godlee piece, that is
 10 document number 6 in the bundle, and it is at pages 48
 11 to 49 of the bundle.
 12 I think, as you said, Fiona Godlee was the then
 13 editor—in—chief of the BMJ; is that right?
 14 A. She still is, yes.
 15 Q. And still is. And this was effectively, as I understand
 16 it, as headed, an editorial article by her.
 17 A. Yes. She's also very critical of secret emergency
 18 committees, and — a very hard—hitting editorial and
 19 short, nice, well worth reading.
 20 She also talks about independent experts and how
 21 hard they are to find. That's quite interesting.
 22 Experts who are involved with industry could be
 23 consulted — she is really talking about government
 24 departments. You could consult experts on vaccines and
 25 pharmaceutical products like antivirals who are involved

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1 with industry, but she says they should be consulted but
 2 excluded from decision-making. So there we are.
 3 She says:
 4 "As for the [World Health Organization], its
 5 credibility has been badly damaged."
 6 And then she goes on to enlarge on that point.
 7 Q. Thank you, doctor.
 8 A. Thank you.
 9 MR GALE: My Lord, I'm going on to appendix 9, which will
 10 maybe take a little while, perhaps more than
 11 five minutes, so perhaps it may be an opportune moment
 12 to stop.
 13 LORD BRAILSFORD: Yes. Just choose your moment, Mr Gale.
 14 MR GALE: I have chosen.
 15 LORD BRAILSFORD: You have chosen, okay. I thought you said
 16 in a few minutes.
 17 Very well, we will take 15 minutes, which makes it
 18 broadly 3.10. Good.
 19 (2.53 pm)
 20 (A short break)
 21 (3.15 pm)
 22 MR GALE: Dr Croft, can we go to appendix 9, please,
 23 pages 113 to 114 of your report, where you look at
 24 previous coronavirus epidemics.
 25 I know you're going to be referring to SARS and MERS

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1 as we progress through section 2 of your report, but
 2 it's perhaps useful to take what we have here, and
 3 perhaps again, if you do what we've done in the past
 4 with the other appendices, could you read through the
 5 block sections and then your comment.
 6 A. Yes.
 7 This appendix 9 is about previous coronavirus
 8 epidemics. Until about 2000, there were four known
 9 coronaviruses, just by way of background, but it wasn't
 10 thought that they were particularly dangerous; they just
 11 caused upper respiratory tract infections and colds.
 12 But then these two novel coronaviruses came along which
 13 caused quite serious epidemics, particularly the first
 14 one, SARS, and then the second one, MERS. Of course, as
 15 we know, COVID-19 is caused by yet another novel
 16 coronavirus.
 17 So, first of all, "Severe Acute Respiratory Syndrome
 18 (SARS) coronavirus". These are two sections, again,
 19 from a standard textbook, 2017. So this was knowledge.
 20 This is accepted knowledge. It was known at the time of
 21 the COVID-19 outbreak.
 22 So:
 23 "SARS was recognized in China in November 2002 and
 24 had spread to affect 29 countries across the world by
 25 February 2003."

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1 I think there were three cases in the
 2 United Kingdom. No deaths.
 3 "The epidemic had died out by July 2003; [in total]
 4 8096 cases were reported, with a [case-]fatality rate of
 5 11% (43% in those over 60 ...)"
 6 I think that was skewed very much towards the
 7 over 70, over 80. There we are.
 8 "Between July 2003 and May 2004, there were four
 9 small and rapidly contained outbreaks of SARS, three of
 10 which were associated with laboratory releases and the
 11 fourth thought to be due to an animal source. The cause
 12 was a novel coronavirus. Animals are thought to be the
 13 main reservoir. Transmission is by droplets and contact
 14 with contaminated surfaces – nosocomial transmission
 15 [nosocomial means hospital-associated/hospital-acquired
 16 transmission] was common in the early stages of the
 17 outbreak. The virus is present in stool and may cause
 18 diarrhoea."
 19 Three bullet points: clinical features, diagnosis
 20 and treatment.
 21 "■ Clinical features – incubation is to 2–10 days.
 22 A 3– to 7–day febrile prodrome ..."
 23 That means a pre-illness phase, when you're not
 24 feeling quite right, but you're not entirely unwell, you
 25 just don't feel right. So there's this early period of

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1 feeling unwell.
 2 "... notable for the absence of upper respiratory
 3 symptoms. The respiratory phase typically starts
 4 [abruptly] with a dry cough, progressing to
 5 breathlessness and progressive pulmonary infiltrates on
 6 [chest X ray].
 7 "■ Diagnosis – during the outbreak, [reverse
 8 transcriptase polymerase chain reaction] was performed
 9 but sensitivity appeared to be limited."
 10 Sensitivity is more or less the ability of the test
 11 to pick up cases, and the testing was:
 12 "... ([less than] 70% positive on NPAs [I think that
 13 means nasopharyngeal aspirates] in week 2 of illness).
 14 No systematic study was performed to validate tests.
 15 Serological testing by ELISA ..."
 16 That means testing for antibodies, that's what
 17 serology is, ELISA is enzyme-linked immuno assays. It's
 18 a technique for estimating antibody levels:
 19 "... at 3 weeks appeared most sensitive."
 20 This is important, I think:
 21 "■ Treatment – no specific therapy. Care is
 22 supportive. Patient isolation and infection control
 23 precautions were key to the control of the ... outbreak.
 24 This was ... facilitated by the long prodrome [so cases
 25 could] be identified early and isolated before they

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1 became infectious.”
 2 So that’s all very relevant, I think, my Lord,
 3 because when SARS-CoV-2 came along, the virus was very
 4 similar to the SARS virus. Quite a lot of work had been
 5 done on it. 79.5% similarity to — and very many of the
 6 features of SARS-CoV-2 had already been seen in SARS,
 7 which, as you have just read, died out.

8 So Middle East Respiratory Syndrome. That was
 9 rather different, although still a coronavirus. It’s
 10 a virus that is closely related to several bat
 11 coronaviruses. This was identified in 2012 from a man
 12 admitted to hospital in Saudi Arabia who had pneumonia
 13 and renal failure. About the same time, an identical
 14 virus was identified in Qatar, in a patient with similar
 15 features who had been to Saudi Arabia. Then there were
 16 cases all round the Middle East and five other countries
 17 from patients who had returned from the Middle East, and
 18 UK, France, Italy and Tunisia reported limited
 19 human-to-human transmission to close contacts of the
 20 index cases. This had a very high case-fatality rate of
 21 60%. I don’t know why — I don’t think anybody knows
 22 why that was. But luckily didn’t spread.

23 “▪ Clinical features — incubation period of around
 24 5 days (but [less than] 10 days). Symptoms ranged from
 25 none (positive [reverse transcriptase polymerase chain

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1 reaction] tests were found is several asymptomatic close
 2 contacts) ...”

3 So, in other words, they had the infection but they
 4 had no symptoms.

5 “... mild respiratory illness, to severe pneumonia
 6 requiring ventilation or extracorporeal membrane
 7 oxygenation [at the most extreme end]. Other symptoms:
 8 pericarditis [inflammation of the pericardium of the
 9 heart], renal failure, DIC [disseminated intravascular
 10 coagulopathy, which is a clotting disorder], and
 11 diarrhoea. Those with underlying medical problems seem
 12 at greater risk of severe disease.

13 “▪ Diagnosis — [reverse transcriptase polymerase
 14 chain reaction] testing of lower respiratory tract
 15 specimens is most sensitive.”

16 We all know PCR testing is probably best.

17 “Testing multiple specimens at different times from
 18 different sites increases the likelihood of detecting
 19 virus. Guidance should be sought from national public
 20 health authorities regarding who to test, based on
 21 contemporary epidemiology.

22 “▪ [Again] Treatment is supportive, and infection
 23 control paramount.”

24 Q. Before you go on to your comment section, doctor,
 25 a couple of points.

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1 In relation to SARS, I think you say that animals
 2 are thought to be the main reservoir.

3 A. Yes.

4 Q. Can you explain that, please?

5 A. That will be explained later on if we go to that
 6 particular point of my part 2.

7 Q. Right.

8 A. But the coronavirus is 79.9 — sorry, the virus here
 9 was — actually, I’m not quite sure what animals it was
 10 thought to have come from. I can’t be certain. But it
 11 could well have been bats as well. Please accept my
 12 apologies on that.

13 Q. No, no, we will come back to that if needs be.

14 A. Sure.

15 Q. There are two references in both SARS and MERS to “Care
 16 is supportive”.

17 A. Yes.

18 Q. What is that meant to signify?

19 A. What that is meant to signify is that during these
 20 emergencies — and the first one was an emergency
 21 especially in China, the second one was an emergency in
 22 the Middle East — there would have been attempts to use
 23 antiviral drugs and extreme or, should we say, what
 24 could be called aggressive medical interventions to save
 25 the patients who were getting unwell, but they weren’t

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1 successful.

2 So, essentially, the accepted wisdom as regards
 3 these two viruses — which are still around, but they
 4 are not causing problems — is if you get a patient with
 5 them, just nurse them with ordinary nursing care. Don’t
 6 try anything fancy, it is going to make them worse, just
 7 to put it into very simplistic terms. But that’s what
 8 supportive care means: it means give them oral fluids,
 9 give them painkillers, simple painkillers, but don’t
 10 sort of get out your antiviral drugs from the cupboard,
 11 just because they are there to see if it’s going to
 12 help, because it probably won’t, and may make them
 13 worse.

14 Q. Is that viewed as being almost what one might term
 15 palliative care?

16 A. Yes. Yes. Yes. Although palliative care has
 17 connotations that the person is going to die, supportive
 18 care has connotations the person is going to recover.

19 They’re more likely to recover. So therefore —

20 Q. Yes, I wanted to make that distinction, yes.

21 A. Indeed, yes.

22 Q. Right.

23 If you go on to your comment section, doctor,
 24 please.

25 A. Thank you, yes. Again, my Lord, these are my

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1 interpretations because the data is very bland.
 2 So I have put:
 3 "The above short summaries of ... SARS and MERS ...
 4 epidemics ..."
 5 Interestingly, WHO never designated them as
 6 pandemics. They could have been, but they weren't.
 7 They are taken from standard textbooks for medical
 8 students. This knowledge was available when COVID-19
 9 started in March 2020, and like the swine flu pandemic
 10 of 2009 to 2010 the MERS pandemic of 2012 proved to be
 11 self-limiting, although there still are sporadic cases.
 12 So MERS seems to be over — seems to be over as a kind
 13 of major public health threat, but SARS is somewhat
 14 different:
 15 "The 2002–2003 SARS epidemic ... first recognised in
 16 China ... then spread to 28 other countries [so it was
 17 widespread] was also self-limiting, since most [of
 18 those] countries did not adopt emergency measures
 19 against SARS [particularly] and yet the epidemic died
 20 out."
 21 I'm sorry, there's a typographical error there. The
 22 epidemic died out by July 2003. So whereas in all other
 23 countries — so we had SARS in this country, and we
 24 didn't go into emergency state. There were prudent
 25 measures taken, but in China, by contrast, they went

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1 into full lockdown mode. This is when lockdown was
 2 invented, and I call them a series of repressive and
 3 authoritarian measures, including lockdowns, meaning
 4 closures of schools, workplaces, entertainment venues
 5 and stay at home orders.
 6 And then social distancing was imposed in China,
 7 enforced spatial separation of at least 1 metre between
 8 those infected and those not infected, and they had
 9 border closures and compulsory face mask wearing. They
 10 are all mandated by the Communist Party of China. So
 11 I've written:
 12 "These extreme government-mandated measures were
 13 afterwards judged by the Chinese government — but
 14 without any scientific evidence [any rigorous scientific
 15 evidence] to support this judgment — to have resulted in
 16 the 'containment' of the SARS epidemic."
 17 And they used exactly the same package of measures
 18 when COVID-19 came along because in their view they'd
 19 worked. But in fact they had the worst experience of
 20 SARS of any country. So a contrary view would be that
 21 their extreme package of measures made what should
 22 have — an epidemic that should have reached natural
 23 equilibrium quickly, it actually prolonged it.
 24 Q. Would that be possibly through containment of
 25 individuals in close proximity to each other?

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1 A. Well, yes, indeed. So if people were being contained in
 2 their flats during the winter in conditions where
 3 a virus that wasn't that transmissible would easily
 4 infect the other person in the same apartment, then that
 5 would provide a micro-focus of infection that would
 6 perpetuate the infection, whereas if they'd been allowed
 7 to go about their ordinary business, it may not have
 8 occurred to the same degree.
 9 Q. Yes.
 10 A. So:
 11 "In respect to SARS, China was the worst-affected
 12 country ... by a wide margin."
 13 And especially, as I repeat, in the very old, the
 14 over 80s, they were the group that were really very much
 15 at risk of death:
 16 "Since secondary attack rates of coronavirus within
 17 households are high, the 'containment' measures against
 18 SARS ..."
 19 I put "containment" in inverted commas because this
 20 is one of Deirdre Hine's points, that you cannot contain
 21 these respiratory transmitted viruses. You can slow
 22 their spread, but the idea that you can contain them
 23 isn't possible with that sort of transmission.
 24 Q. Just remind us who Deirdre Hine is.
 25 A. I beg your pardon. Deirdre Hine was appointed to — she

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1 was chair, like Lord Brailsford, of the official inquiry
 2 after the swine flu epidemic and she wrote her inquiry
 3 report in July 2010. And she doesn't like the phrase
 4 "reasonable worst-case scenarios". She says it's
 5 a contradiction in terms and engenders unreasonable
 6 panic. And she doesn't like the phrase "containment".
 7 She doesn't like the concept of containment, even though
 8 they were talking all the time then about containing
 9 swine flu.
 10 So:
 11 "The 'containment' measures against SARS that were
 12 adopted by the Communist Party of China may have made
 13 the SARS experience worse, not better — for example, by
 14 creating hundreds of new foci for the ready acquisition
 15 of SARS in people's homes. Notwithstanding these
 16 uncertainties, [exactly] the same 2002/2003 package of
 17 repressive and authoritarian 'containment' measures,
 18 (and with the additional new measure of population-wide
 19 electronic surveillance of citizens' movements) was
 20 adopted by the Communist Party of China in 2019–2020, at
 21 the [very] start of the COVID-19 pandemic."
 22 They adopted the same measures in January 2020:
 23 "In early 2020, with high COVID-19 case numbers
 24 occurring in most countries — including China itself —
 25 the Chinese model of coronavirus 'containment' was

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1 adopted by many other governments, including the UK and
2 the Scottish governments. In Scotland, two
3 population-wide electronic surveillance schemes on the
4 Chinese model were procured; these were (i) Test and
5 Protect, procured by the Scottish Government in
6 May 2020, and (ii) Protect Scotland, procured ... in
7 September 2020."

8 I don't know much about them, but I got that data
9 from the timeline that's on the website.

10 In England the measure that was adopted there was
11 procured in 2020 by the then Secretary of State for
12 Health, Matt Hancock, called Track and Trace. I do know
13 that that was hugely expensive and that it was not at
14 all effective .

15 So I end up by saying that there's no evidence of
16 these -- of any effectiveness of these population-wide
17 electronic surveillance schemes, as far as I know, in
18 [sic] helping to spread SARS-CoV-2 infection.

19 Q. Right. We will come back to some of that as we progress
20 on, particularly in section 3, but if we now go back to
21 your statement, please, at section 2.

22 A. Yes.

23 Q. I think it's page 8. Yes, page 8, "The COVID-19
24 pandemic".

25 Now, again, Dr Croft, if you would read through

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1 that, and I think fortunately I probably don't have to
2 interrupt you very often on this because I think it is
3 largely factual.

4 A. Yes.

5 Q. So if you would start reading at 2.1 and continue.

6 A. Yes, thank you. So 2.1:

7 "What is COVID-19?"

8 COVID-19 is a syndrome, and that's the jargon term
9 meaning a multisystem illness, caused by a virus which
10 we now know as SARS-CoV-2, and in the UK it's
11 a statutorily notifiable disease, meaning that if
12 doctors diagnose or suspect it, they have to report to
13 the local authority:

14 "COVID-19 has a varying presentation ranging from
15 asymptomatic or insignificant to respiratory distress
16 and death. The death is milder in children, with the
17 greatest risk of severe illness and death in those aged
18 85 years and older.

19 "SARS-CoV-2 was responsible for a global pandemic in
20 2020-2023."

21 The pandemic has now been declared over:

22 "The pandemic has been associated with severe
23 negative impact in most countries, with decreases in
24 gross domestic product and an increase in inequalities
25 among lower socio-economic groups."

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1 Quite a strong statement. I have taken it from
2 a standard textbook. Everything here is from standard
3 medical textbooks. I consider it would be not
4 contested, my Lord.

5 Then the last paragraph here, which is interesting :
6 "A subset of individuals ... "

7 Oh, I beg your pardon. That's the wrong way round:

8 "A subset of individuals [with SARS-CoV-2 infection]
9 have progressed to a recurring pattern of physical and
10 cognitive symptoms known as long COVID. The public
11 health measures used to manage the pandemic have also
12 led to social isolation with adverse mental health
13 consequences."

14 Q. Right. Having said I wasn't going to interrupt you,
15 I now contradict myself and do so.

16 Two things I would like just to clarify .

17 A. Yes.

18 Q. The first sentence on 2.1, you refer to a multisystem
19 illness ?

20 A. Oh, yes, yes.

21 Q. Again, that may be probably self-evident, but can you
22 just explain what that is?

23 A. By multisystem is meant many body systems. So it's an
24 illness that could affect the brain, the lungs, the
25 heart, the kidneys, the liver , the lymph nodes. Just

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1 pretty much any system in the body could potentially be
2 caused by SARS. Although we have tended to regard it as
3 a respiratory illness , there are people who are quite
4 ill but their lungs are fine. So there are many
5 dimensions to this illness .

6 Q. Right. And in the third paragraph on that page you make
7 reference to severe and negative impacts in most
8 countries --

9 A. Yes.

10 Q. -- with decreases in GDP and an increase in inequalities
11 among lower socio-economic groups. And then you also go
12 on in the next paragraph to say:

13 "The public health measures used to manage the
14 pandemic have also led to social isolation with severe
15 mental health consequences."

16 A. Yes.

17 Q. Now, can I just understand -- put yourself, Dr Croft, in
18 the situation of someone with your public health and
19 epidemiological background who is asked to advise either
20 a public body such as a government or a public body such
21 as an authority --

22 A. Yes.

23 Q. -- or a commercial organisation, or a local authority --

24 A. Yes.

25 Q. -- about restrictive measures that may be thought of

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1 being considered so as to combat COVID-19?
 2 A. Yes.
 3 Q. Within your area of expertise, would you feel it
 4 appropriate for you to highlight what you might envisage
 5 to be the negative aspects of restrictions such as
 6 you've identified here?
 7 A. I would expect to — well, I would look at economists,
 8 to give detail on the economic damage that says — that
 9 was caused, and mental health experts to talk about the
 10 adverse mental health consequences.
 11 What I'm really doing here is in a way providing
 12 what appears to be incontestable knowledge that such
 13 consequences did occur.
 14 Q. Well, we've got that, I suppose, with the benefit of
 15 hindsight.
 16 A. We have, yes.
 17 Q. But at the time of formulating restrictions, would you
 18 issue, as it were, a warning in relation to these
 19 issues?
 20 A. Yes. I have worked in policy making to an extent and
 21 when I was doing it we would normally make
 22 a recommendation and there what we call an impact
 23 statement. There might be some other jargon. The
 24 impact of this policy would be blah blah blah, and so
 25 therefore there would be a recognition that every policy

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1 decision would have some kind of knock-on effect that
 2 would often be undesirable.
 3 So in making any policy decisions which might or not
 4 be taken up, I would expect there to have been something
 5 like an impact statement that this will have the
 6 following potential consequences in these areas of
 7 society, because these were measures that were affecting
 8 the public at large. They weren't individual measures.
 9 Q. So, again from the perspective — from your perspective
 10 as a public health practitioner and consultant or
 11 specialist, if you were considering with policy makers
 12 matters such as isolation of elderly people in care
 13 homes, would you again, as that policy was being
 14 considered, think it appropriate to issue some form of
 15 caution, if I can put it that way, about the potentially
 16 adverse consequences of that?
 17 A. I would expect it to form part of the decision-making
 18 process. But whether or not the government went so far
 19 as to put out a health warning, so to speak, that
 20 incidentally we're now going to see many more cases of
 21 mental illness and social isolation, would just depend
 22 on the context. I — that would just really be a matter
 23 of how expedient it was thought to be.
 24 It's similar to — going back to — going to the
 25 general practitioner, the general practitioner would

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1 say: try these pills and I have to tell that you there
 2 are some side effects associated with them. So it
 3 would — or they can necessarily assume that because
 4 there's a package insert telling about the side effects,
 5 that would be part and parcel of the contract between
 6 yourself and the general practitioner.
 7 But all public — all decisions that affect the
 8 public health have consequences beyond the immediate
 9 ones and they need to be taken into account.
 10 Q. And within your discipline of being a public health
 11 practitioner, would you feel both competent and
 12 confident in at least alerting a decision-maker, or
 13 potential decision-maker, to these potentially
 14 deleterious effects?
 15 A. Yes, although it may not be the case that the exact
 16 detail of the deleterious effects might fall outside my
 17 immediate competence. So if they were economic or
 18 educational, for example. But I would have to at least
 19 alert the decision-maker that there would be
 20 consequences of that nature. Sometimes they would be
 21 self-evident, but they might need to be spelt out, that
 22 more factors need to be taken into account than just the
 23 medical benefit to be derived.
 24 Q. So, for example, do you find it in any way surprising
 25 that social isolation had adverse mental health

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1 consequences?
 2 A. I think that would be a foreseeable and regrettable
 3 consequence of the social isolation, the mental health
 4 sequelae.
 5 Q. Yes.
 6 A. We are social animals and we have to associate with
 7 other people, and when we can't we suffer consequences.
 8 Q. Yes. Can we go on to section 2.2 at page 9, please.
 9 Again, if you just read on.
 10 A. Yes. So here we talk about viruses:
 11 "What are viruses?"
 12 "Viruses are small (20–150 nm) protein packages.
 13 They are much smaller than other infectious agents.
 14 "Viruses have a central nucleic acid core (genome)
 15 surrounded by a protective coat (capsid) that is
 16 antigenically unique for a particular virus. The virus
 17 genome consists of either DNA (i.e. deoxyribonucleic
 18 acid) or RNA (i.e. ribonucleic acid), but not both."
 19 So it's one or the other.
 20 Q. Right. Can I just stop you there, doctor. It might be
 21 helpful, although it's coming subsequently in your
 22 report, if you refer to the figure —
 23 A. Yes.
 24 Q. — on page 14 under the heading 2.5.
 25 A. Yes.

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1 Q. "What characterises SARS-CoV-2?" It's perhaps useful if
 2 you can describe what is a virus under reference to that
 3 figure.
 4 A. Yes. Shall I explain some of those terms?
 5 Q. It would be helpful, I think, yes.
 6 A. Thanks. I'll come back to that as and when.
 7 So just -- there's a lot of jargon, but I think we
 8 need to understand it because when we come to the
 9 papers, the investigators use these terms.
 10 So the genome means the entirety of the genetic
 11 instruction of an organism. It's what it is that makes
 12 the organism what it is, and we each have a genome. The
 13 capsid a protective coat. So we go on to say the virus
 14 genome consists of DNA -- that's explained there -- RNA,
 15 ribonucleic acid, but not both.
 16 So DNA and RNA are nucleic acids. They are classed
 17 as nucleic acids, and nucleic acids consist of many
 18 nucleotides that are joined together, bonded together,
 19 and a nucleotide is a sugar and a phosphate base -- this
 20 biochemistry -- and then a sugar and phosphate element
 21 with a nitrogenous base attached to it. And the
 22 nitrogenous base may be -- in the case of DNA it's
 23 guanine, adenine, cytosine or thiamine. In the case of
 24 RNA the nitrogenous base might be guanine, adenine,
 25 cytosine or uracil. So they use four of those bases and

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1 that gives it its particular characteristic. The bases
 2 can change round, and that's part of the process of
 3 mutation that RNA and DNA can undergo.
 4 Q. Yes.
 5 A. So I don't think we can really -- so looking at the
 6 figure, so there's -- on page 14 of my report, there's
 7 the virus that causes COVID-19. It's called SARS-CoV-2
 8 and the RNA is in the middle of the virus there, and
 9 that's the genetic constituent of the virus. The viral
 10 genome is that totality of viral RNA that's in the
 11 middle of the virus there.
 12 In humans the genome is contained within the nucleus
 13 of the cell. We are probably coming on to that later,
 14 but viruses don't have a nucleus as such. So the RNA --
 15 the genome is sort of scattered around within the middle
 16 portion of the virus.
 17 Have we said -- oh, yes, the next paragraph down.
 18 So you can see the envelope round the RNA virus will go
 19 to -- that comes in the next paragraph on page 2.2.
 20 The envelope -- so some viruses, for example,
 21 coronaviruses, have an outer envelope which consists of
 22 lipid, that's fat, and protein. And this is important
 23 because envelope viruses can't survive as well in the
 24 environment. So they can -- they have to get quickly
 25 from one infected person to the next, and so they're

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1 spread by respiratory, sexual or blood-borne routes.
 2 Non-enveloped viruses survive better in the
 3 environment and they are predominantly transmitted by
 4 faecal-oral route or respiratory routes.
 5 So coronaviruses then are enveloped and they can't
 6 survive as well in the environment.
 7 Q. Yes.
 8 A. That has implications for ventilation of rooms and being
 9 out of doors. The viruses just don't survive very long
 10 outdoors, and they survive for better periods indoors,
 11 and in contained -- contained environments:
 12 "Some viruses contain enzymes."
 13 We're back to section 2.2. So HIV, human
 14 immunodeficiency virus, contains an enzyme called
 15 reverse transcriptase. Then we talk about viruses being
 16 grouped into orders, families, subfamilies and genera.
 17 There's a lot of, shall we say, uncertainty about how to
 18 group viruses. At the moment only about half of viruses
 19 have actually been properly classified and the
 20 classification may change.
 21 Viruses have colonised most life forms, including
 22 bacteria, plants, insects and animals, but viruses are
 23 not alive. They are metabolically inert. So they're
 24 metabolically not metabolising. So they have to live
 25 intracellularly within the cells of their hosts. And

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1 they can't replicate independently. So if there's virus
 2 on the surface, it can't produce more viruses. It has
 3 to get into a host, a living host, in order to
 4 replicate.
 5 So what they do is they subvert host cellular
 6 processes in order to synthesise their nucleic acids.
 7 Q. Right. I think you are going to have to explain that.
 8 A. I'm so sorry. It's an exact quote from -- so what this
 9 means is that they get into the cell. Cells do know how
 10 to produce new cells. Viruses can't really do it. So
 11 they have to take over the cells' replicating functions
 12 in order to synthesise their nucleic acid so as to
 13 create more RNA copies of themselves or DNA copies of
 14 themselves, and then they multiply within the cells and
 15 then they burst out of the cells into the extracellular
 16 environment and penetrate new cells, and then the same
 17 process repeats itself.
 18 So there's a sort of -- there's a time element
 19 involved in viral infection. They can do this pretty
 20 quickly, but a virus won't infect you one day and --
 21 won't infect you and then kill you an hour later because
 22 it needs time to get into the cells, replicate, get into
 23 more cells, replicate, get into more cells.
 24 Q. Yes.
 25 A. But because they're in the cells -- this is, I'm sorry,

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1 ex tempore, but because they're in the cells, you can't
2 treat viruses with antibiotics in the way that you can
3 treat bacteria that are generally extracellular. You
4 could possibly use antiviral drugs that interfere with
5 some of those replicating strategies, but generally
6 viruses don't respond to antibiotics, and this has
7 important treatment implications.

8 So we are saying now that whereas bacteria may have
9 several thousand genes, and a gene is the basic unit of
10 heredity, a gene is defined as a small section of -- in
11 humans a gene is a small section of DNA. We've said DNA
12 is deoxyribonucleic acid, and a gene is a little section
13 of DNA that codes for a particular protein. The
14 proteins are the substances in our body that actually do
15 things rather than just being inert like fats and
16 sugars. Proteins do things. And there are 20,000
17 proteins in our body. Many of them we don't really know
18 what they do, but some of them have clearly defined
19 functions like haemoglobin, which carries oxygen from
20 the lungs to the tissues as a protein. So what a gene
21 does, it will instruct the body to produce a particular
22 protein.

23 So viruses -- viruses have the ability to produce
24 more than one protein from the same gene by means of
25 what's known as RNA splicing or frameshifting.

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1 The protein -- yes.

2 (Pause)

3 Yes -- okay. I'm just seeing if any of that needs
4 explanation.

5 (Pause)

6 Yes. I have put a little note about proteins.
7 Proteins are also known as polypeptides. Some of the
8 papers we refer to call them polypeptides. They are
9 complex molecules made up of chains of amino acids.

10 Amino acids are the basic building blocks of
11 proteins. There are 22 of them that we require to build
12 protein. Some of them we derive from food. We break
13 down food, animal proteins and vegetable proteins, and
14 re-use those amino acids to make our own proteins, and
15 some of them we can synthesise ourselves.

16 So, just to continue:

17 "Viruses evolve rapidly due to the high number of
18 genome duplications undergone in short spaces of time."

19 So because they have subverted the cellular
20 replicative processes they are rapidly multiplying.
21 That's the whole purpose of their existence. And in
22 doing so, because those bases that I was talking about
23 the cytosine, adenine and -- sorry, guanine, adenine,
24 cytosine, uracil that are in RNA viruses, because the
25 way the bases may get rearranged, there may be

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1 mutations, changes in the virus structure as it's
2 replicating.

3 So therefore genetic sequencing of isolated viruses
4 is important to identify new mutations and variants, and
5 experience has shown that most viruses, if they produce
6 copies of themselves that aren't exactly like
7 themselves, those copies probably won't be as efficient
8 as the parents, but occasionally the new -- the new
9 variant, the new strain may be especially pathogenic or
10 it may be less pathogenic than the parent strain.

11 Q. I think this is probably the first time that you've
12 mentioned variants, and I think --

13 A. Yes.

14 Q. -- this is one of the things that we will come on to,
15 because I think we are all familiar with the various
16 variants that there were, the Delta, the Omicron, etc.

17 A. Yes.

18 Q. Can you just indicate how significant would the variant
19 have to be in order to constitute, as it were, a new
20 variant?

21 A. This -- yes, that's true. This is -- there's
22 a committee that actually decides whether this new form
23 of virus is a new variant or a subtype. So that's
24 defined by virological experts. They use certain
25 criteria as to whether what has been seen is like --

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1 entirely new or just relatively new. That's my best
2 understanding of the situation.

3 So it isn't something that's intuitive. It has to
4 be discussed and thought about and then pronounced upon.

5 Q. And this -- the identification of a new mutation or
6 variant is dependent on the genetic sequencing?

7 A. Yes, exactly, exactly. So viruses can -- can't be seen
8 with light microscopes. They can be identified through
9 electron microscopes, and their genetic sequence can be
10 established. The order in which the molecules are
11 arranged is all important to what it is that the virus
12 can do, and in special research laboratories the viruses
13 can be, if you like, numerated in great detail, and
14 those who are expert in this field will think, oh,
15 that's interesting, that sequence of bases is different
16 to the sequence that we would normally expect from this
17 virus. And this could be -- we could be looking at an
18 entirely new variant or strain of the virus.

19 Q. If you go on at the bottom of page 10, doctor.

20 A. Thank you.

21 Q. I think to a certain extent this is something you've
22 already said, that effectively they're parasites.

23 A. Yes, they're parasites. They need the internal
24 environment of a host cell in order to create new virus
25 particles. The infectious virus particles are called

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1 virions . Periodically , maybe every few hours or every
 2 few days, new virions are discharged to the exterior of
 3 the infected cell , and so therefore the cycle of viral
 4 infection is perpetuated.

5 MR GALE: Right.

6 That’s probably a point to stop, my Lord. The next
 7 section is slightly lengthy.

8 LORD BRAILSFORD: No, no, not at all. Very good.

9 Well, thank you, Dr Croft.

10 A. Thank you.

11 LORD BRAILSFORD: Thank you, everyone else. We will adjourn
 12 now until 10 o’clock tomorrow morning.

13 Thank you very much indeed.

14 (3.58 pm)

15 (The hearing adjourned until Thursday, 27 July 2023 at
 16 10.00 am)

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