Thursday, 23 January 2025

(10.00 am)

LADY HALLETT: Would you like Sir Sajid to be sworn?

MR KEITH: Yes, please.

SIR SAJID JAVID (affirmed)

Questions from LEAD COUNSEL TO THE INQUIRY for MODULE 4

LADY HALLETT: Welcome back, Sir Sajid, thank you very much for coming back to help us.

THE WITNESS: Thank you. It's good to see you in person.

MR KEITH: Could you commence your evidence, please, by giving us your full name.

A. Yes, it's Sajid Javid.

Q. Thank you very much for attending today and for your provision of a witness statement, a further witness statement for this module, dated 2 October 2024, running to some 80 pages as to which you have appended the usual declarations to the truth of its contents.

Sir Sajid, you were Economic Secretary to the Treasury from September 2012; Financial Secretary to the Treasury from October 2013; Secretary of State for Culture, Media and Sport, and also Minister for Equalities, subsequently; and then Secretary of State for Business, Innovation and Skills; latterly, Secretary of State for Communities and Local Government and, for our purposes, most fundamentally, you were Secretary of

State for Health and Social Care, from 26 June 2021. You were also Chancellor of the Exchequer and Home Secretary prior to that but, most importantly, you were Mr Hancock's successor as Secretary of State?

A. Yes.

Q. The role of Secretary of State, indeed the role of the DHSC was a very wide one in the context of vaccination and therapeutics, was it not?

A. Yes, it was.

Q. You have set out in your statement something of the nature of the role; you were concerned with funding for new research, the oversight, although the MHRA reported to the Secretary of State on the question of authority but the oversight of the approval of vaccines, and also therapeutics, the liaison with and the taking advice from the MHRA, the JCVI, and other expert bodies; you had to make decisions about the vaccination programme. Also about deployment, the effectiveness of the deployment, and the huge subject of delivery.

And may we take it, it's obvious, that throughout your time as Health Secretary, there were meetings on all these subjects, all these matters, every day? There were goal meetings, there was hourly meetings, there were emails, texts, i-messages, probably every -- well, day and night.

A. Yes, you may. And if I may, just on the -- you just on -- more generally, if I may, my Lady, just say that I think the vaccine programme overall and related therapeutics was a huge success for the country. It saved many lives, saved many people from being ill. Obviously I recognised that wasn't the case for every single person; there were some people that were sadly injured, and may we get on to that as well. But I just want to place on record my thanks to all those people who were involved, all -- from the civil servants, the officials, the scientists, all the clinicians, NHS -- the clinicians and others, all the volunteers in the vaccine deployment centres but also the many, almost a million, people that came forward for trials. Without what they did, we wouldn't have had that success. And I think that's very important to recognise.

Q. The first issue in this context that I want to ask you about is the -- concerns the vaccination of young people.

A. Yes.

Q. And as I told you, we're simply going to deal with a handful of discrete issues which are of particular importance in the context of this module, but which arose in the course of the vaccine and therapeutic programmes.

A. Yes.

Q. The position with the vaccination of young people was that technically, formally, the Pfizer and the Moderna vaccines were authorised for use by the MHRA, in the case of Pfizer for 12 to 15-year-olds in June 2021, and, for Moderna, 12 to 17-year-olds in August of 2021.

And what -- was the way in which it worked was that you or somebody else would invite the JCVI to give advice on whether or not formal authority having been given for use in supply to the population, it should actually be offered to the population and in what way? So you had to await for advice from the JCVI?

A. That's right. So we would -- before any decision could be made to offer any vaccine to any group of people, and of course you're asking me about children in this case, the same sort of general safeguards and rules applied. The vaccine first had to be approved by the MHRA, as safe and effective, and then the JCVI, the sort of -- the group of independent experts that would look at it in much more detail and then look at both our trials and evidence from abroad and take into account a number of factors, they would consider it and then provide advice to me as the Secretary of State.

Q. And your predecessor, Mr Hancock, had formally asked for advice from the JCVI?

A. Yeah.
Q. You took up that post on 26 June.
A. Yes.
Q. Very shortly after your arrival in the department the JCVI provided interim advice, as it happens, dated 5 July. But on 6 July there was a meeting conducted by you.
We'll have INQ000480653, please.
A. Yes.
Q. We can see from the top third of the page the date, and the attendees, including yourself, permanent secretary Clara Swinson, from whom we've heard, and a number of officials, including from the Office of the Chief Medical Officer, the CMO --
A. Yes.
Q. -- JVT -- Jonathan Van-Tam that is -- and also officials from -- or members of the Vaccine Taskforce, and your own department of officials.
There is a reference halfway down the page to ... yes, thank you very much -- to the CMO, Professor Sir Chris Whitty, saying:
"... JCVI are 'sitting on the fence'. They have failed to land on a conclusive view one way or the other."
But they:

"... will have to advise conclusively on whether they deem the benefits of the vaccine to outweigh the harmful impacts of children catching COVID ..."
And Professor Whitty said that:
"... on clinical grounds, he would write to the JCVI ... to ask that the Committee answer that question."
Did you think that there had been any degree of untoward delay in the JCVI responding to your predecessor's request formerly for advice as to whether or not 12 to 17-year olds vaccination should be offered?
A. No, I didn't feel that there had been any kind of unnecessary delay. I think that clearly the work of the JCVI, for all groups, including of course children, is vital, and that it's given the time to consider. And I also, I think I would have thought at the time, the -- in terms of priority, in terms of the population, clearly adults and older groups were, you know, starting with the eldest, were -- for lots of reasons, were the most important, that's where the JCVI started, and it eventually, once it's given its views on older groups, eventually it has got to be thinking about children. I believe, at this time, even though there were other countries using vaccines for children, they'd authorised it for earlier use than the UK had, so I think the JCVI wanted to also look at that evidence.

So I think it took its, sort of, time, but, I would say, in a good way.
Q. The JCVI had, of course, in December 2020 produced the prioritisation list?
A. Yes.
Q. And phase I had had its nine cohorts. By this time, is this right, the targets for the offering of vaccines to everybody in that priority -- phase I priority list, had been met? So we were dealing here or you were dealing here, weren't you, with the decisions about whether to offer vaccines to people against the background that the prioritised people had already been offered, all of them, a vaccine, because that original priority list was for 18-year-olds and above --
A. That --
Q. -- unless they had particular health issues?
A. Yeah, that's right. But they -- but in considering whether the vaccines should be offered to children, there were other factors that you might not have considered for adults that had to be taken into account.
Q. So it was in fact it was a more difficult -- there was a more difficult debate to be had --
A. I wouldn't say it was necessarily more difficult; it's just there are different elements to the debate, and you wanted to -- I would want to be reassured that the JCVI

and my own clinical advisers such as the CMO, DCMO, had considered that before I'd make a decision as the Secretary of State.
Q. On the individual level there was the perennial debate about whether or not the benefits outweighed the risks --
A. Yeah.
Q. -- significantly, such as to merit authority --
A. Yes.
Q. -- authorisation, and then offer?
A. Yes.
Q. And then with children, were there the additional considerations as to whether or not the vaccination of children would promote good educational practice, would lessen the disruption to their education, and also have a wider beneficial impact in terms of getting children back to school and have their life prospects bettered? So it was a less straightforward issue than, perhaps, the issues concerning those persons who'd been in the original priority list?
A. I think that's the case, but especially, I think, when it came to the 12 to 15 cohort, when the decision was made in September, so it was starting with older groups so 12 to -- so I think 15 to 17 first, I believe, that was in August --

Q. That's right.
A. -- in terms of the universal offer. Of course there were offers to children that either -- (overspeaking) -- living with vulnerable people, or in vulnerable -- households with vulnerable people, or they had other, you know, exceptional reasons to take the vaccine earlier, but in terms of a general offer for the real -- the, sort of, I remember a lot of discussion around wider issues about potential benefits of offering vaccines to children particularly in September, and that was around the 12-15 cohort.

The other thing I would add, my Lady, if I may, I also remember around that time, sort of, through that summer, really, sort of, July/August, and then leading on to when the decision on 12 to 15-year-olds was made in September, the Prime Minister was incredibly keen to start offering vaccines as soon as possible to children. So there was an immense amount of pressure from the Prime Minister directly, and from, therefore, from his team at Number 10 to try to speed up the process, to make a decision quicker, the Prime Minister would often say to me, "Why are other countries" -- he would often mention Portugal, Spain, other countries in Europe -- Israel, he mentioned a lot, saying they're doing a much better job than us, the way he would phrase it, in terms

of vaccinating children a lot more quickly, why are we taking so long? And my answer, generally to him, was always that we've got a process to follow for a reason to make sure it meets our standards and just because other countries are doing it, doesn't mean to say we should be doing it. We might get there eventually, but we have a process, MHRA, JCVI, our own advisers, and we must follow that process.
Q. I think it's fair to say that there are number of people in government in the Office of the Chief Medical Officer, within the Cabinet Office, as well as the Prime Minister himself, who expressed concern about an apparent delay in the summer of 2021 in getting the JCVI decision advice out of the door.
A. Mm.
Q. There had been plenty of reference to concern about apparent delay in the paperwork. Do you agree?
A. There was, and as I say, for the Prime Minister himself and the team around him, there'd be that constant pressure and sometimes I'd be told -- not directly by the Prime Minister, but some of the people around him, "Oh, the Prime Minister is not very happy with you, he doesn't think you're doing a good enough job, you're not taking this seriously enough, why aren't you getting those children vaccinated a lot more quickly? Why

aren't you getting them jabbed?", and all that kind of pressure. And my view was simply, really, pretty much, just to ignore that pressure because it wasn't my job to have the Prime Minister decide that children should get vaccinated, I had to listen to the evidence and the scientific advice and that's exactly what I did.

Had someone been in my job that was perhaps less experienced in government, I mean, you mentioned -- sorry, you mentioned at the start that I'd had various different roles in government before I ended up in that position. I think, by then, I'd just sort of learnt that -- how to do a Cabinet-level job, I guess, more effectively, and to ignore certain pressures and just do -- what you want to focus on as the right thing to do and not be led by necessarily always what the Prime Minister of the day wants you to do.
Q. All right.

If we look at INQ000089048, this is in fact the minutes of a cabinet meeting on 20 July 2021, so in the middle of the first debate about 16 and 17-year-olds.

And page 12, thank you very much.

You can see there that somebody was saying, probably the Prime Minister, that:

"The UK had been a world leader in its vaccination programme but was being overtaken by countries like

France, Italy, Canada and the US who had all taken the decision to vaccinate those over twelve ... It was unclear why the ... (JCVI) were taking so long to come to a decision ..."

So that's a clear reference, I think, to that which you've described exactly, which is that the Prime Minister was vexed at the speed at which the process was taking.
A. Yes.
Q. As it happened, that was 20 July. On 3 August you receive advice from the JCVI on vaccinating children aged between 12 and 15 who had underlying health conditions, so it wasn't a universal offer at that stage.
A. Yeah.
Q. You were focusing on those with health conditions. And you agreed almost straight away.

On 4 August, the issue then arose as to whether or not 16 and 17-year-olds should be offered a universal vaccine, whether they should be offered universally a vaccine, in addition to those who were aged 16 and 17 who were at risk, who were in risk groups, and there was a meeting on 2 September by the JCVI in which they considered 12 to 15-year-olds who were not in a clinical risk group.

The JCVI decided that whilst the direct benefits of vaccinating children and young people marginally outweighed the risks, there were wider educational and societal issues which required examination, and they wrote -- or they wrote to you and your department wrote to all the UK CMOs asking for their view.

The UK CMOs published their advice on 13 September. But the result of bringing the CMOs into that process and seeking their formal advice and then waiting for the advice, delayed the process. It took more time.

Were you concerned, as the Secretary of State, that the process to address universal vaccination of 12 to 15-year-olds had become further slowed down? Was that something of concern to you?

A. I don't recollect that I was particularly that concerned. Just on the basis that, again, there'd -- in my mind there's a clear process to be followed: of getting expert advice and then basing my decisions on that. And once I'd received the JCVI advice, which was, as you said, that it was -- that said marginal, but it said there may be wider factors to consider which really wasn't in their purview, that's why I asked the CMOs for their views. And clearly for them to come to a view they had to have the full JCVI advice, and I think I remember at the time thinking, certainly with the

England CMO, Professor Chris Whitty, I think he said he also wanted to talk to Royal colleges and other consultants and paediatricians and just get wider input, and also speak to people in education, I believe, as well, and I think that was the right thing to do.

And despite, I think, the CMOs having to speak to a group, I think my recollection is they did it fairly quickly and in a speedy manner. They treated it urgently. And so there wasn't -- it wasn't a process that really sort of -- that lasted days. And eventually when they gave their advice, and which they published in a letter to all MPs and public consumption, I thought it was quite detailed, actually, and very clear. And they set out the case very clearly, which I accepted, and that's why I decided to make an offer of the vaccine. But I think we sort of called it a non-urgent offer, it was a general offer, but -- and based on the reasoning that we had set out in the CMO letter and the JCVI advice.

Q. And the submission went to you after the UK CMOs had advised?

A. Yes.

Q. It's dated 13 September.

INQ000401383, if we can just have page 2 up first. Thank you very much.

We can see there the date, 13 September 2021, "Private Office Submissions". It's to the Secretary of State, yourself. And it sets out the issue, which is that:

"The JCVI concluded in ... 19th July that children aged 12-15 who are 'at risk' ... should be offered vaccination."

But:

"... they did not consider [that] the benefits outweighed the risks for healthy 12-15-year-olds."

And so, having considered that there was a marginal benefit for healthy 12 to 15-year-olds of benefit against risk of vaccination, they'd wanted the CMOs consulted.

Did you have any difficulty with agreeing to that position? Ultimately, of course, it was a matter entirely for the Secretary of State, was it not?

A. It was. And I didn't have difficulty, because of both -- I took both pieces of advice together, and considered them in that way. The JCVI advice, but also what was very important to me was the advice of the CMOs. And by CMOs, I mean all four CMOs of all parts of the UK, and they were, all four were -- they were all agreed on the position and the way forward. And then I felt that as Secretary of State, that the groups of

people, the JCVI, the CMOs had considered this very carefully, I felt that their reasoning and their arguments they set out were well balanced, well thought through, and I accepted the advice on that basis.

Q. Arguably, it then got harder, or even harder, because the JCVI were written to by your department in November 2021 asking for their formal advice as to whether or not there should be a universal offer to 5 to 11-year-olds, so the younger cohort. The formal authorisations for the use, in fact, of smaller doses of vaccines for 5 to 11-year-olds and then subsequently six months to four-year-olds had been granted in December 2021 and then, respectively, December 2022. So after the -- around about the time of the first authority, that's to say for use for 5 to 11-year-olds, you'd started the process rolling by which the JCVI would give advice on whether or not they should be offered vaccines.

You asked the DHSC to draw up a business case dealing with issues such as the impact on reduced paediatric intensive care admission, educational disruption, and the potential benefit of reducing anxiety in children and loved ones by having them vaccinated, or by contrast, what level of anxiety might be engendered by offering them a vaccination.

Why did you take that additional step of seeking extra advice on those wider ancillary issues?
A. Because I felt that -- so first, as we've just gone through, the decision, I felt that when it came to children the key cohort, in my mind, were the 12 to 15-year-olds or 12 to, say, 17 in total. And to go below the age of 12, so 5 to 11, in this case, would require an even stronger argument because, for example, with educational disruptions, and I remember some discussion at the time with the CMO and others, that there was an argument that educational disruption was sort of -- it was more disruptive to a, sort of, 12- to 15-year-old cohort than it would be to younger cohorts. So I thought maybe that argument in itself wasn't strong enough.
And so I can't remember the exact discussions that took place but we had a number of discussions as group with the CMO, and all the others in the room, about what would be the case if we were going to go lower than 12 years, and at the same time, by the way, there was still a huge amount of pressure coming from the Prime Minister at Number 10. The Prime Minister just wanted to go as low as he could go, and kept pressuring that we make these decisions much more quickly. Again, I didn't want to succumb to that pressure, and I didn't,

and I wanted a proper, thoughtful consideration. I think that's how -- together with my team, how we came up with the factors that must be looked at.
Q. A submission went to you dated 10 February 2022 -- this is, again, in relation to 5 to 11-year-olds?
A. Yes.
Q. INQ000112227. We can see SO -- Secretary of State, at the top left, private secretary. And it comes from an unredacted name but in fact it was a submission from your department --
A. Yeah.
Q. -- based upon the advice which had then -- by then been received from the JCVI. And it was, as we can see, to do with vaccination, the offer of vaccination to 5 to 11-year-olds. And we should make plain, shouldn't we, Sir Javid, that authority, authorisation for the formal use of vaccines for 5 to 11-year-olds had been granted by the MHRA, so the Prime Minister was entitled to say, "Authorisation has been granted, let's get on with it."
And we can see the recommendation to accept the JCVI advice, agree the statutory products, agree the proposed timing of publication.
And at pages 4 to 5, starting with paragraph 14, we can see there under the heading of "Benefits and cost effectiveness":

"Vaccinating this cohort is unlikely to provide any significant benefits against the current Omicron wave."
And then over the page at paragraphs 15 to 17, the point is made:
"For this policy to be cost effective, a future wave of infections would need to come about while vaccine effectiveness in children is still high ..."
Then at 16:
"An alternative policy ... would be to postpone a decision to deploy these vaccines until a heightened threat is identified ..."
So it was altogether a more difficult decision, but the balance was more finely weighed, or was required to be more finely weighed, by comparison to the earlier decision for over-12-year-olds; is that fair?
A. That's fair, yes.
Q. In your statement you say that in relation to the vaccination of 5 to 11-year-olds, you personally were somewhat reluctant, and "reluctant" is the word you use in your statement, because you believed it was a measure that, perhaps arguably, had not yet proven to be necessary, and you were concerned about it.
Given your personal view, and you were concerned, as I say, or you had a degree of reluctance about this, why did you agree to accept the advice from the JCVI in

relation to the offer of vaccination to this cohort?
A. It was -- so it was the one piece of advice from JCVI where they made a recommendation that I was very reluctant. And I was reluctant because, as you've seen in some of the evidence that has just been shared, and from what I remember at the time, that I thought the decision of the JCVI was very finely balanced, because as -- it references we were at the Omicron wave or -- I think almost all infections by that time were Omicron. Omicron, we knew, in a general sense, was a lot more severe, a lot more people had been infected because of its rate of infection, so many children would probably already have been infected. And -- but then the argument of JCVI and others that supported the offer was that: well, this is where we are with Omicron, but you don't know what's going to be around the corner, the advice could change again, it could mutate and by then it might be too late to vaccinate this group. So I felt it was very finely balanced.
I was also, again, getting a huge amount of pressure from the Prime Minister on this cohort as well. He -- his view was, again, it couldn't happen quickly enough. He was aware of this advice, so it would go to his -- his office would be told that I'd received advice and the broad conclusion of that advice. And then I felt,

when I put that together, it would have been very hard for me to take a decision to ignore the advice of the JCVI and say, "Look, I" -- and say, "Look, I know what they're saying, but I'm not going to make that decision", because my -- I felt my job clearly is not to do what I personally think is right or wrong for me or my family, it's to do what is right for the country and the population, and I had to base that decision on the expert advice that I had been given.

Q. And the JCVI is, of course, the independent --

A. Yeah --

Q. -- expert, in fact statutory body --

A. Yeah.

Q. -- tasked with the obligation of giving advice to ministers as to the correct way forward?

A. That's right. And also, I did some -- when I looked at the way the JCVI had phrased their -- even their recommendation, I think they called it a non-urgent offer, and so it wasn't -- to make the vaccine available to children, obviously for their parents to decide, but as a non-urgent offer it wasn't something that either myself, as the Secretary of State, or the department more generally, were going to, sort of, push, I guess, or advertise in the same way as the more important vaccinations early on in the pandemic for adults.

Q. And it's right to say that when the statement was made on 16 February that an offer would be made to 5 to 11-year-olds, it was very much couched in terms of this being a non-urgent offer?

A. Yes.

Q. And that was how the JCVI put it.

A. Yeah.

Q. Was the DHSC directly concerned with the rollout of the offer and the operational side of offering vaccines to 5 to 11-year olds, that there was, as it happens, a policy by which there was, I think, a 12-week wait following Covid infection before -- well, which had to be allowed to elapse before 5 to 11-year-olds could be offered the vaccine or take the vaccine.

Was that a policy that found its genesis in the DHSC, do you know, or was that an NHSE/Public Health England issue?

A. I think in general the recommendations and sort of clinical decisions around the 12-week period and/or other issues around the gaps between, sort of, one vaccine and your next vaccine, those were your rightly clinical decisions, but I believe in general they would either have come from the JCVI itself, or from the UKHSA, the UK Health Security Agency, and what was, before, Public Health England.

Q. All right. VCOD. Vaccine as a condition of deployment.

A. Yes.

Q. I'm aware you gave evidence in Module 3, and I repeat my apology that you've had to come back and give evidence again.

When you gave evidence in Module 3, the focus of much of the questioning was about the impact on the care and health sector of the introduction of the initial policy, which was to mandate vaccination as a condition of deployment for care workers in registered care homes --

A. Yeah.

Q. -- and what was the impact on the sector.

A. Yeah.

Q. But there was a later policy, at least a consultation for a policy, as to whether or not this mandated vaccination policy should be rolled out to the wider care and healthcare sector, health sector.

And particularly with an eye on the impact of -- on vaccine confidence or, alternatively, hesitancy, I want to ask you some questions about the rationale for that second policy.

A. Yeah.

Q. Which ultimately wasn't, in fact, introduced. It was pulled on 1 March 2022.

So if you could look at a briefing paper, please. INQ000497213.

This is the document, in fact, which provides the most recent public health evidence from the UK Health Security Agency on vaccine effectiveness, because it provided the foundation or rather government needed the up-to-date position in terms of public health evidence in order to be able to make a final decision as to whether or not that wider policy should be implemented.

If we look at page 2 -- and this was a document that went -- a briefing paper that went to you -- at paragraphs 9 and 10, we can see that this -- that the preliminary data showed that there was some protection being given against infection through vaccination. Compared to unvaccinated healthcare workers who'd not also had a prior infection, those with two doses were 32% less likely to be infected with coronavirus, but the estimate was uncertain because the range of possible effectiveness was large, and includes evidence of no effect.

And then, at 10:

"Preliminary evidence from UKHSA [also showed] that the effectiveness of all vaccines against symptomatic infection is lower in all periods against Omicron compared to the Delta variant ..."

So was this the position, by January, February 2022, as you've rightly said, Omicron was rife and the emergence and the application -- or the presence of the Omicron variant had a significant effect on the data as to the effectiveness of the vaccines, and therefore a further subsequent effect or ancillary effect on the efficacy, the effectiveness, of a VCOD policy. Was it worth it, bluntly. Was that the position that was reached at the beginning of 2022?

A. Yes. And the way I would perhaps explain it is that when the original decision was made on, you know, V-C-O-D, VCOD as we referred to it in the department, in 2021, the end of 2021, that was at a time when there was no such thing as Omicron, the Omicron variant did not exist, so it was based on the virus at the time, the dominant variant, I believe was Delta, and there was some Alpha, and those were the facts taken into account. By January 2021, and certainly by February 2022, in February 2022, the -- almost all infections, I think, by that time, were Omicron. In fact, I believe something like, by the end of January, almost a third of all infections that had ever taken place during the pandemic were Omicron, and that meant that the policy had to be reassessed in light of that evidence, and the facts changed. And if the facts changed, we changed the

policy.

Q. Page 5, paragraph 33, please, on this document.

In addition, is this correct, there was obviously also significant concern about the impact on the workforce, and this is something that you addressed in Module 3, but we can see there the figures about, firstly, the number of persons in the NHS who weren't already vaccinated, and also further down, and if you can scroll back out, you can see 34, 35, 36, what the possible impact might be of mandatory vaccination in terms of staff leaving the sector.

So it wasn't just a question about effectiveness of the vaccines in the face of Omicron; the government obviously had to be aware also of, firstly, whether or not vaccination was required to be imposed mandatorily, given the current uptake, and secondly, what the possible impact would be on the sector if the policy were to be pursued.

Is that right?

A. So can you ask me the question again? What's the question?

Q. Was the government also concerned, not just with putting Omicron into the general picture in seeing whether or not vaccination was required, or at least whether or not mandatory vaccination would lift the uptake of

vaccination uptake and protect the workforce, but also, whether or not members of the sector, the workforce, would leave their posts rather than agree to be vaccinated?

A. That wasn't a decisive factor, no.

Q. If we then look at paragraphs 20 and 21, I think on page 3, the submission says:

"The evidence set out above means that the cost/benefit case for the current VCOD policy is more finely balanced than before. It is very likely that the effect of VCOD as a means of protecting patients and people with care needs is less than it was ... While protection against severe disease and hospitalisation is much higher and takes longer to wane, this is not the purpose of VCOD."

So it was a much more finely balanced policy decision than the earlier emanation had been and, ultimately, the government didn't pursue it; is that right?

A. That's correct.

Q. Were you concerned also about the impact on members of ethnic minority communities and as well as, of course, the care and health sector workforce itself in terms of a longer-term impact on vaccine confidence? By imposing a mandatory programme on healthcare workers, was there

a risk that there would be a wider disbenefit in terms of decreasing confidence in vaccination generally?

A. There was clearly --

Q. A backlash.

A. Yeah, it was clearly one of the risks that we had to consider, and we did, and as has been referred to and I think is evident from the evidence paper, it was a balanced decision. It was a balanced decision to implement the policy in the first place and it was also a balanced decision to change it when the facts had changed.

But in terms of -- you referred to ethnic minority workers, and relative to the population, there's a disproportionate number of people actually that work in the NHS that are from ethnic minority backgrounds and we're incredibly proud of them, I think we're proud of everyone that works in the NHS, whatever their background, but my view was very firmly that everyone, regardless of their ethnicity, they should be treated equally, and the whole purpose of this policy was to reduce the rate or the risk of infection for vulnerable people, patients of the NHS, those in hospital, and that's the purpose, and the virus didn't discriminate about whether it was infecting a black, brown or white person, and that was why we clearly had to follow the

same policy for everyone, regardless of their ethnicity and that was the correct way to do it.

Q. Widening out the debate, to what extent was the DHSC focused on reducing barriers to uptake and increasing confidence in the vaccines generally? Was that part of your core functions?

A. Just to check, do you mean with respect to VCOD or do you mean --

Q. No, no, generally, more -- widening it out -- (overspeaking) -- debate?

A. Oh yes, I felt it was a very important part of my core responsibilities, but also more widely in the department, including with my junior ministers, and particularly the vaccine minister.

Q. It's obvious that there were a number of parts in the government machine concerned with the issue of reducing barriers to uptake --

A. Yes.

Q. -- and increasing vaccine confidence?

A. Yes.

Q. From the more operational end of things, NHS England, the voluntary, charitable and -- the voluntary and charitable sector, and the military and the volunteers at the operational end, as well as at the heart of government, Cabinet Office, DHSC, OCMO was obviously

plainly very concerned about this issue.

A. Yes.

Q. Which government department do you assess was in the driving seat when it comes to trying to drive through measures to try to reduce barriers to uptake and to increase confidence? Who was driving forward the government machinery on this, in your view?

A. I think -- well, first, I think there was a general shared responsibility, but in terms of the department, the big two that I think that were really essential to this: one was my own, and we were, rightly, I think, it was the health department responsible for the delivery of the vaccine, the uptake of the vaccine, and I think as the -- both as the Secretary of State but also all the expert advice, the CMO, the DCMO and others that worked with the department played a crucial role in building vaccine confidence. But the other department would be the Cabinet Office, because there was a -- I think that's the one department that can coordinate properly across government, and that you could -- one could see a role virtually in every department how other ministers, cabinet ministers and others could play a role.

So, for example, you could see there would be a role in the Education Department, in the Department for Work

and Pensions, in the Home Office, you know, for example, with migrants and others, and so I think the Cabinet Office was the right department to, once a sort of battle plan, a strategy was agreed, to make sure that all other departments were doing their bit, and that was being checked and improved, if it could be improved.

Q. And could you give us, please, some idea of the amount of time that was devoted to this issue or the priority that was given to it in your department? I mean, were you on a daily basis or a weekly basis trying to focus on what practically could be done at the operational end on reducing barriers to uptake, by way of getting the message about vaccination out there --

A. Yeah.

Q. -- making the vaccine practically available, operationally available, trying to deal with some of the conspiracies and the myths and the tropes surrounding vaccination? Who was responsible for making sure that that general drive was actually being put into practice and -- (overspeaking) --

A. Well, I felt ultimately it was my responsibility as the Secretary of State, and it's something that I worked on, I'd say, almost every day. Because every day in my department -- certainly every weekday in the department, we would have, at some time in the morning, a meeting of

what was -- the vaccine, sort of, delivery team. And that included our colleagues from the NHS, which we were -- who were primarily responsible for delivery of the vaccines, and also VTF and CMO and others. And I would chair that meeting, and there would be an agenda, and I would say almost every time we had that meeting, one of the agenda items would be vaccine uptake, especially in combating hesitancy, building vaccine confidence, and also discussions, especially if there had been some incident or something around conspiracy theories and issues of that nature.

And we would agree in those calls, the -- in every, sort of, video calls, with everyone joining in, we would agree that what would be the -- following that meeting, would be the action points. And then the next day, because we'd talk about it again, I would want to make sure that what we had agreed previously had been done, what were the results, what we were doing.

Also I'd hold number of meetings with groups, especially with, for example, the ethnic minority groups, with the media, and -- from -- that might represent certain communities, as I've tried to sort of, myself, do something when I was trying to reach out.

And then, lastly, I also felt that, not specifically with vaccines, but I felt throughout my time in that

role, was that health generally, there were a lot of inequalities including regarding ethnicity but also more broadly based on gender, disabilities and more broadly, and deprivation. And that was an area I did a lot of work in. And I felt that if it was clear that this was something I was and the government was taking perhaps more seriously than before, that would help to build up general confidence in the health system.

So, for example, the inquiry -- the independent review I asked for from Dame Margaret Whitehead into the inequalities of medical devices and instruments, although that wasn't related, of course, to vaccines, I just felt it would show that there were some real issues around ethnicity, for example, and healthcare, and the government was taking them seriously, and I felt that would help build up confidence.

Q. The material before the Inquiry suggests provisionally that, whilst there were a great many people and bodies concerned with issues as to whether or not barriers to access could be reduced, could be further reduced, and confidence increased, that there was a general failure, perhaps, to utilise or to focus upon greater use of local-level means, practical solutions, to make sure that the barriers to access in the way of ethnic minority communities, disabled people, migrant groups

and other marginalised parts of society, were -- well, whether there was enough use of local methods to try to reduce barriers.

And it was obvious that there were a great deal of government departments and people concerned in this issue, and, in the best of faith, doing their best. Is there an argument for having a more focused, specific government body, department, entity, that can focus all its intention on ensuring that these important issues are addressed: that vaccine confidence is maintained, and barriers, practical barriers to access, are reduced? It appears to be a very fragmented, disparate picture in terms of the outcome of the work that the government did.

A. In general, yes, there is. I think, for me, one of the lessons learnt should be that even in peacetime, like now, we should be preparing for the next pandemic, of course, and one of those areas of preparation should be a vaccine or, even more broadly, therapeutics delivery, because the next pandemic it might not be vaccines; it might be antivirals, for instance. But whatever that pharmaceutical, sort of, intervention is, I think there is a strong argument to have a unit, a group of officials, experts, that are very focused on that in peacetime. For example, what they could be doing today

is actually building that sort of confidence with communities, you know, Traveller communities, different ethnic minority communities and others, today, because I think to try and sort of -- it's very hard to build that confidence quickly. It needs to be built slowly over time, and around healthcare more generally, in peacetime. And that is why I felt the work I was doing in inequalities was so important. Which, sadly, the successor, sort of, secretaries of state and the current government haven't continued. And that's why I did all the work I did on a draft White Paper which was to look at all these inequalities and issues --

Q. Was that the draft White Paper on health inequalities?

A. That's correct, yeah. Was to try to sort of build more confidence with communities that I felt, in some ways, had been left behind in healthcare and in consideration of their health needs.

Q. A witness said very pertinently, I think, a couple of days ago that if you can't see and assess the scope of the problem, you can't fix it. Did you assess that you -- or do you assess that you had sufficient data, sufficient information, as the Secretary of State, about the extent of the practical barriers to access, and the particular unique needs of all of these various communities, from Gypsy, Roma and Traveller communities,

through migrants, through ethnic minority communities and so on, so as to be able to formulate proper policies for their resolution and to put operational plans in place? Did you know enough about what it was like on the ground?

A. I felt that -- well, I was told that the data that I was getting was a significant improvement on what my predecessor had had at the start of the pandemic, and I can understand why, and -- you know, a lot had been done to improve things, even by then.

Your question was: was there enough data points? And -- and I think that could be improved, and that's just a -- I think just a sort of -- in -- it's easier to say in retrospect, but I think there are areas, for example, in sort of behavioural science, behavioural data, that could be used. And there were instances of that, where I asked for such an analysis and got it, but it wasn't -- I think it could -- something like that could be more, sort of, a fixed part of the process.

So, for example, there was an idea -- and it's good to look at lots of different ideas, especially what other countries were doing, and I remember someone had said in one of those meetings -- I referred to daily meetings -- said: look -- I can't remember what country it was in Europe, but they were offering young people --

younger people -- teenagers, like -- in their early twenties, theatre tickets or cinema tickets to get vaccinated, like an inducement to get vaccinated. And I was sceptical about that. I just felt that if you get a vaccine, it should be for a positive reason: to want to protect your health or protect your loved ones from infection, rather than some kind of inducement. But I thought it would be -- wouldn't be right of me just to ignore it and then pretend I know better, because I wasn't an expert on it.

So I did ask for a -- behavioural science work to be done on that and similar ideas. And what we got back was that basically my scepticism was, I think, proven, that it could backfire.

So that was useful data, useful analysis, but I think having more of that kind of analysis would be helpful.

Q. So let's be clear on this. In relation to the passive receipt of data as to the reality on the ground, you think more could be done, there are always improvements that can be put into place?

A. Yes.

Q. But also, there is a case for taking more positive steps in terms of accumulating knowledge and seeing whether or not there may be incentives or nudges based on

behavioural science that might improve the general lot of in terms of availability of vaccination?

A. Yes.

Q. All right. Prophylactics. When you were Health Secretary between June 2021 and July 2022, a significant part of your time appears to have been taken up by considering the issue of post-authorisation making available of prophylactics in particular, but therapeutics generally.

Shortly after you arrived at the DHSC on 12 July 2021, there was a meeting on the topic of prophylactics. INQ000497986. And the email is from the private secretary to Lord Bethell, who was one of the ministers in the department. I don't think that you had been an attendee at the meeting, but Lord Bethell's private secretary had, as well as the Deputy Chief Medical Officer, Professor Sir Jonathan Van-Tam, and a number of other officials.

We can see remarks from Sir Jonathan to the effect that:

"... Covid will remain prevalent in the population, and that therefore those who are immunocompromised and [clinically extremely vulnerable] are concerned."

And he notes the fact that:

"... JCVI will likely prioritise the

immunocompromised for booster vaccinations."

And over the page at page 2, JVT says in the second indent, he:

"... believes that there is a requirement for a clinical lead on the immunocompromised. This person needs to be able to pick up work on shielding, therapeutics, antibodies, and the vaccine agenda. There currently isn't anyone who is able to step into this space, and this is something that needs to be fixed. There needs to be further discussion with Ministers, but there is currently a gap."

Was this something that was brought to your attention -- (overspeaking) -- agenda?

A. I don't believe I was at this meeting --

Q. No, you weren't.

A. -- but yes, generally, I would say yes, this issue was about doing as much as we can to make sure, when we're thinking about pharmaceutical defences, it's not just vaccines, but it's -- obviously, vaccines is important for certain members of the immunocompromised community but it doesn't work for everyone, and so we were looking broadly at therapeutics and antibodies and antivirals.

Q. It's obvious that whilst vaccines had been purchased at risk, that is to say hugely expensive and fundamentally

important decisions had been made about whether to procure vaccines had been taken without knowing whether, clinically, they would be effective or significantly effective. In relation to therapeutics, by contrast, whenever a decision had to be made about whether or not to pursue a particular therapeutic, there had to be an assessment of its cost effectiveness as well as the risk-reward balance, and HMT ultimately had to take a view as to whether or not it would be funded?

A. Yeah.

Q. Why was the DHSC in that position? Why could you not simply pursue a range of therapeutics, in particular prophylactic treatments, on the basis that you could purchase them at risk and then see whether or not they would be clinically effective?

A. Well, I think -- firstly, I think a lot of the decision making on that issue about how much funding there was or how that funding would be accessed for, sort of, pharmaceutical, you know, intervention in general, whether that's vaccines, therapeutics, antivirals, et cetera, they were made before I was in the department. A lot of that had been, sort of, set in train, as it were, before I joined as Secretary of State in June of 2021. But my -- from what I saw, was that -- well, what I can say, because it was self-evident, was

that by the time I came to the department in June 2021, obviously the vaccine -- finding a vaccine that worked had been successful, those vaccines had started to be delivered, there were still a lot more people to vaccinate, but I think the, sort of, broadly, the focus was more shifted on vaccines and getting them delivered, because they were broadly working, albeit of course not for everyone, they weren't appropriate, and I felt that there was less focus or -- and including from the Treasury -- on having something other than vaccines. And that particularly, you know, became an issue for me in, it was around, I think -- quite early on, when I became Secretary of State, I think August of 2021, where there was an Antivirals Taskforce led by Eddie Gray, and he had spoken to my officials and then he had spoken to me and written to me, sort of, recommending the purchase of antivirals, two antivirals in particular manufactured in the US, and I agreed fully with his arguments and what he'd set out and the clinical and the medical reasons for that, and not just because I thought they could be perhaps more useful with certain groups of people where vaccines were less useful, but I just thought it would be another line of defence, because especially at that time, in August of 2021, of course, we didn't know about Omicron at that time but it was

a widespread view that the pandemic wasn't over and Covid was likely to mutate many more times and we don't know what was going to come down the line or whether the same vaccines were going to work.

So I also felt almost something like an insurance policy that we should have something else, but his recommendation that he gave me was for over, I think, between the two antivirals, procuring over two million units in -- and I had to have a big battle with the Treasury and with Number 10, and eventually I did secure some, but it was a lot less than I had wanted.

Q. You secured agreement for the purchase on 19 December 2021 of 1.75 million courses of molnupiravir and I think a further two and a half million doses of Paxlovid. So that's absolutely right in terms of the outcome. But coming back to the question of risk. In your statement you say:

"I saw firsthand the approach to funding the vaccine and the willingness to take risks did not even last the length of the pandemic."

So from that statement, from that observation, you appear to be saying not enough was done, as it was and had been done very successfully with vaccines, to take a punt, to take a risk on the purchase of therapeutics.

A. Yeah, I felt the -- again, obviously, I wasn't there at

the start of the pandemic, but it felt to me the attitude had changed towards funding of pharmaceutical defences by, sort of, middle of -- the second half of 2021. And just to say something, the reference that you just made to the antivirals that were eventually purchased, I -- in my arguments to get more antivirals, there were actually two distinct phases: there was the pre-Omicron phase and there was the post-Omicron phase. And in pre-Omicron I had a huge amount of resistance from Treasury, from even the Number 10 team, parts of the Number 10 team, and in that case I did manage to secure, but it was a lot less than I wanted. And I think it was collectively about 800 -- 700,000 units.

When Omicron was a reality, then I'd received -- I'd asked for fresh advice about antivirals and about what role they could play right on the onset of Omicron, right at the start of November, and I had fresh advice from Eddie Gray that I asked the CMO and even the CSI -- the CSA, the Chief Scientific Adviser to comment on, and they all said that we should get more antivirals. There was a very strong, I thought, advice from all three of them, and they were my -- very -- they were very important advisers to me, and that is when I asked for funding for a lot more antivirals in light of Omicron, because especially at that time when I got the advice,

we weren't even sure if the vaccines were going to work with a booster effectively against the Omicron and I felt that we had to go and secure whatever we could because there was a global competition for these antivirals. There were only two manufacturers in the world: they were US, meaning the US would get the first supplies, whatever it wanted, and then all other countries had to fight for what was left. And I felt we had to get orders in, and quickly. And if it turned out that we couldn't get what we wanted after we ordered it, that's not something in our control, but I felt we had to do whatever was possible and was in our control.

Q. In September of 2021, and as you say, there was what was described, in fact, by you as quite frustrating debate about whether or not the recommendations to buy antivirals would be accepted by the Treasury, and it's clear from your evidence and other evidence that the Treasury, in particular in the form of the Chief Secretary to the Treasury, Steve Barclay, was concerned about how efficacious antivirals were, and told his officials that they had to be extremely clear about whether or not the funding was justified, and to be rigorous in their approach.

We can see some emails between Sir Patrick Vallance, Eddie Gray, who was the Head of Antivirals Taskforce,

and Sir John Bell of Oxford, INQ000399326, concerning antivirals. And on the first page of 399326, we can see Eddie Gray, the Head of the Antivirals Taskforce, writing to Sir John Bell and Sir Patrick Vallance, and saying this:

"We have at least stopped the DHSC trying to negotiate itself down under pressure from the Treasury. SOS has been impressive [that's you, of course], is running with our proposal and telling officials that if any compromises are to be made, he'll make them with the [Prime Minister] and Chancellor, not officials."

Now in hindsight, do you think that there is a better way of trying to get approval for therapeutics in the teeth of a pandemic, than having to negotiate in each case through the iron fist of the Treasury?

A. I'm not sure there is, because the Treasury is the only department that has money in government, and you're not going to be able to buy anything without the money. And so ultimately the Treasury has to agree in one way or another. I think where things can improve is that, you know, the -- I felt the Treasury officials -- because it was more about the officials rather than the Chancellor himself at the time -- they were trying to sort of argue with my officials, who were clinicians and scientists and, you know, experts and -- on vaccines and

therapeutics, they were trying to argue with them on the science of the antivirals and whether they were effective or not. And I don't feel that was their place.

I mean, they -- by all means they can say: look, it might be effective but we're not going to fund them because of some other reason. That's their prerogative. But I felt the arguments were -- and there were arguments between officials, and that's why in this note I think it refers to -- I didn't want my officials agreeing that any kind of sort of backing down on the requests with Treasury officials. I felt that if -- whatever agreement we -- ultimately was going to be reached, it has to be done by me and the Prime Minister and the Chancellor, so that both of my colleagues, the Prime Minister and Chancellor, could see just how important this was, and how important I thought it was to pandemic defences.

Q. And if we scroll back out, I think we'll see a reference to the difficulty of getting decisions across the Prime Minister and the Chancellor.

Perhaps it's on the second page. Yes, at the top, in the top email.

An email from Eddie Gray to Sir John Bell:

"As of now that response [that's the response from

the government] is most frustrating. We have ordered a small amount of PF, but late and at a level that we'll get no priority."

So that's the point you make about --

A. Yeah.

Q. -- being in the priority lane from the standpoint of manufacturers.

"Mck [that's a manufacturer] have given us a deadline of Friday and we are in danger of falling in same trap. Very annoying. [The Secretary of State] has supported our recommendations which is good, but getting decision across him, [the Prime Minister] and [the] Chancellor, ridiculously hard."

In relation to vaccines, Sir Sajid, there was a ministerial panel which brought together, forced to sit at the same table, Treasury, BEIS, DHSC and -- I'll be reminded, there was one other minister there, I can't now remember -- Cabinet Office -- thank you -- in which -- in the course of which meetings decisions to fund over the level of £150 million were taken then and there, rather than having to make a case, a business case -- although business cases were made for each vaccine and each expenditure -- one after the other to get final ultimate approval from the Treasury.

Why was consideration not given to have a similar

ministerial panel in relation to therapeutics, which might have reduced the level of difficulty which appears to have been encountered in getting decisions made and authorised?

A. I think, actually, if there was it wouldn't have made much difference, because the key decision is not to have a sort of ministerial panel. I mean, it does -- helpful in the process of making a final decision to buy something or not buy something. The key decision is to allocate a budget.

And so the ministerial panel that has just been referred to, on vaccines, that was established, you know, once the Treasury had already decided there's a budget. In the case of vaccines, again, that decision was made before I was there, but it was almost, you know, unlimited budget, that "Go after vaccine candidates and it's going to cost what it's going to cost", and as a panel, you just sort of make the final decision. But there's a budget, an overall budget you've already got control of. And so there's a budget delegated to that panel.

But if there was a panel on antivirals, but it hasn't -- it doesn't -- there's no budget above it, then it makes no difference.

Q. So the problem with therapeutics, including antivirals,

was that there was no overarching budget?
A. There was no budget.
Q. In the same way that there'd been a £5 billion budget for vaccines, there was no overarching budget to which appeal could be had and recourse could be had?
A. There was no budget, and you might recall in a previous session we talked about the spending review for the NHS, I believe in Module 1, I can't be sure, but where -- you know, around -- prior to this moment that we're -- you're considering now, in sort of September, November 2021, in the summer of 2021, I had to agree the overall spending envelope for my department for the next three years. And that included a -- vis à vis the budget, it included, sort of, budget cover for -- as it's referred to, "budget cover", by the Treasury -- for vaccines and other, sort of, responses by the NHS to the pandemic, in terms of more staff and more diagnostics and so forth.

At that time, I was specifically asking for a budget for antivirals, and that was unsuccessful, and the decision that was made eventually was that we're not -- that you're not going to get a budget for antivirals. Should you -- should the nature of the pandemic change, should there be a new variant and you need antivirals, then you'll have to come back and revisit it.

And I knew at the time that that will delay things, at best. At worst, it will mean, you know, there would be a real lack of funding when it was needed.
Q. So when it came to seeking Treasury approval for expenditure in relation to specific therapeutics, was there then an additional block in the flow of money, which is that you were told on occasion, or perhaps regularly: if you want funding for this particular therapeutic, you're going to have to make a cut elsewhere in your health budget.
A. That's correct, yes.
Q. All right. And in relation particularly to Evusheld, about which we've heard a great deal, you received a submission on 20 June 2022 -- this is later, so post-Omicron -- INQ000497090 -- in which ministers were asked to agree that the department shouldn't deploy Evusheld in a prophylactic programme at that time, and that Evusheld should be considered through the technology appraisal process run by NICE, the National Institute for Clinical Excellence.

And briefly, in relation to Evusheld, was all the advice that you received from OCMO, from your department, from officials, pointing in one direction: which is that, given the background of Omicron, given the background of the success of the vaccination

programme, and given the state of clinical evidence as to the effectiveness of Evusheld, it wasn't something that could be pursued at that time, it had to go through a further technology appraisal process?
A. Yes. Essentially, yes. That by -- so Evusheld, I believe was -- the sort of the research and development of Evusheld had begun towards the start of the pandemic.
Q. Yes.
A. But it didn't receive MHRA -- it took a lot longer than vaccines, and it didn't get MHRA approval until March of 2022. By March of 2022, almost every infection was Omicron. So the nature of the virus had changed dramatically. And my understanding was that all sort of testing or trials that had been done of Evusheld to date had been with the Delta and Alpha virus, and a variant, and not with Omicron. And I received the very clear advice, I think -- firstly it was in May of that year, 2022, that there's not enough evidence at that point that Evusheld is going to work. I think the trials were held by a group called RAPID C-19, and the advice was that it's -- there was not enough evidence that it was effective against Omicron and more trials are required, and that's what was -- more testing was done.

Then in June of 2022, I had very clear advice from

the CMO and others that they believe that Evusheld is not effective enough against Omicron, and therefore it would not be value for money to purchase it.
Q. Following that decision being made, there was a meeting with AstraZeneca on 4 July 2022, AstraZeneca was the manufacturer --
A. Yeah.
Q. -- for Evusheld and no doubt quite a difficult meeting ... you were at the meeting and you explain why the decision had been taken not to procure Evusheld.
A. Yes.
Q. AstraZeneca expressed obvious and understandable concern as to why they thought they were being forced through a different process.
A. Yes.
Q. Their product, Evusheld, was being put through a further clinical technological appraisal trial rather than being authorised -- sorry, being agreed to be used and procured.
A. Yes.
Q. Following that meeting, I think you resigned or fairly shortly thereafter you resigned. And then you sent a message to your successor, Steve Barclay who had been Chief Secretary to the Treasury but who became Secretary of State?

A. Yeah.
Q. And in a WhatsApp message with him dated 13 August, you said that:
[As read] "Just a quick on Evusheld. I wanted to make sure you know that the week before I left, I agreed a deal with AstraZeneca that would have allowed us to generally roll out the drug to vulnerable people but we would only pay if it turned to work against current subvariants as defined by us."
Ie, no success, no, fee.
We want to know, please, whether or not you had actually agreed a formal or commercial deal with AstraZeneca, because the meeting with AstraZeneca on 4 July very clearly indicates that, of course, they were very unhappy that there was no deal, and Evusheld was not going to be pursued.
A. Yes, so in that meeting -- as you say, I wanted to be very open with AstraZeneca, because I felt that -- well, I think it was just the right professional approach in that they, AstraZeneca, I think, first of all, in the -- throughout the Covid pandemic as a company had put a lot of time and effort in developing vaccines and other therapeutics around the pandemic. They had invested a lot in Evusheld, so I felt that they deserved a full explanation of the government's decision, and

I explained that the advice was that it was not effective against Omicron.
AstraZeneca's view was that the advice was wrong, and that it is effective against Omicron, broadly put. And they said that they could prove that if only it was used more widely, you know, you, the government, would see. And that is when I raised this idea with them and said, "Okay, if you're so convinced then why don't we test it, and have this, kind of, generally put, no success no/fee arrangement", and the two gentlemen from AstraZeneca were very positive about having such an arrangement.
They did say, you know, it wasn't something that you could, sort of, just shake a hand on there and then and do it. It was -- they had to go away and think about it, and see how it could be done, speak to their superiors, but it was left in a sort of positive position where there might be a deal to be done on that basis.
But then, as you referred to, I think within a week or a few days after that, I left that role. And then Steve Barclay, as you mention, took over, and I -- and maybe I shouldn't have, because it was no longer my role, but I was just keen that he knew of the nature of the discussion I had, because I thought it was very

important, and that he should know because there might be a deal to be done.
Q. I think -- I'm not sure about superiors not being there, because the meeting was attended by Mr Pangalos, who was the head of AstraZeneca, but is this the sum of it: you agreed a way forward with AstraZeneca or an understanding as to how you might proceed but there was certainly no commercial deal or formal contract?
A. That's correct, yeah.
Q. All right. Two final questions, please. Whilst you were Secretary of State you received a number of submissions concerning the operation of the Vaccine Damage Payment Scheme, and you were given a number of options as to whether or not the scheme could be reformed, and if so, whether or not the flat rate of £120,000 could be increased and backdated for those persons to whom payments had already been made.
You received a submission on the 22 March 2022, and again on 27 May 2022, and actually, I think, it was the third briefing in June 2022. Do you happen to know whether or not there were any changes made to the scheme? You had indicated your strong preference for one of the options, which was an increase in payment, a flat rate, and backdating. But your officials told you it would cost between £1.2 million and £8.9 million.

Do you know whether or not your recommendation was taken up or whether there were any changes made generally?
A. My understanding is that no changes have since that time been made even now. And I felt that the VDPS is something that my department had inherited from, I think the Department of Work and Pensions, and I was happy to take it on because I felt it wasn't fit for purpose and it needed a lot of focus on it. And in the paper I think you just referred to, there were a number of recommendations that were made, and one of the key ones was the, as you said, the amount of compensation which hadn't been changed for years, but also I felt it was too slow, it was bureaucratic, the people working there weren't, sort of, expert enough. And also, what was called the disability threshold was too high.
And if I may say, even -- and when I left the department soon after, I was -- which -- and then I had a meeting with my successor as well about it, because I was contacted by one of my constituents, as I was with my, sort of, MP hat on, which was that the wife of a constituent, my constituent's name was John Cross, and I think his experience is really important here just to understand how dysfunctional this scheme is, in that he was a retired pharmacist, he got vaccinated in January 2021 --

Q. With respect, I'm afraid I don't want to go into the details of any individual case and I'm not sure that he would necessarily want us or you to describe his case in public.

Is it fair to say, and I suspect this is where you're heading, you did form the view that this scheme required fundamental reform? You may even have been of the view that it wasn't fit for purpose?

A. Yes, that was my view, and with regards to the case, I won't go through the case but if it's possible, I think the Inquiry should look at this particular case and I'd be happy to furnish the details of that --

Q. I'm sorry, we can't look at individual cases, it is outside our scope.

LADY HALLETT: It is also one of the issues that was raised by a contributor to the impact film, so I'm very conscious of it, and I can see in the public gallery there are those who are acutely distressed ...

A. All right. Thank you, my Lady.

MR KEITH: And I should make absolutely plain that we are asking a number of other witnesses about the nature, the scheme, and the susceptibility for reform in relation to the Vaccine Damage Payment Scheme.

A. Yeah.

Q. Finally, Valneva, the contract for manufacture of

vaccines in Scotland.

The paperwork appears to indicate that advice was given on the cancellation of the Valneva contract on 9 September 2021. You were the Secretary of State for Health at that time, but the advice from, it transpired, the Vaccine Taskforce, was -- well, it concerned whether or not the merits of that contract should be pursued and whether or not the deal should continue.

Was the decision to cancel the contract taken by the DHSC or was it taken by the Treasury in the form of the Chief Secretary?

A. It was taken -- ultimately it was taken by the DHSC.

Q. And did the DHSC take advice from the Treasury as to whether or not the contract should proceed?

A. No, I think it would have been -- I think it was a very clear decision, and so therefore I think that we would have notified -- we would have told the Treasury of the decision, and the Treasury was very happy with the decision, and it's very important the decision was based on one absolute key factor in that I received a very clear advice in September of 2021 that the vaccine, the Valneva vaccine, was ineffective as a third dose, and that's what we were looking for at that time, which was -- the real need was for a third so-called booster dose, that it was ineffective, and that it was no better

than the study placebo, and on that basis it would not have been good value for money for the Treasury or the government to purchase something that it was never going to use.

Q. And if we have INQ00514013 up, finally, please.

9 September, did you receive advice from the director of strategy, VTF? So the Vaccine Taskforce, recommending you:

"Issue [something] ..."

Something contractual.

"... to Violet ..."

Violet was the codename for this contract?

A. Yes.

Q. "... against our expectation of their failure to meet the current delivery schedule, and based on legal advice ...

"Inform the company of our decision and issue the notices after Friday ..."

And:

"... write to the Ministerial Panel ..."

And if we scroll back out, we can see over the page a great deal of data or a great deal of information about the commercial nature of the contract, but also the clinical effectiveness of the vaccines that they were seeking to produce.

A. Sorry, what's the question?

Q. The question is: was it the VTF who made the submission to the department concerning the termination of the contract?

A. The main submission came from the VTF, that's correct.

MR KEITH: Thank you very much.

LADY HALLETT: Thank you, Mr Keith.

A few more questions but we'll definitely complete by 11.35.

Mr Wagner.

Questions from MR WAGNER

MR WAGNER: Thank you.

Good morning, Sir Sajid. I'm over here.

A. Good morning.

Q. I act on behalf of Clinically Vulnerable Families, who look after the interests of the clinically vulnerable and the clinically extremely vulnerable and the immunosuppressed. I've got one area to ask you about. It's vaccination about 12- to 15-year-old children. You were asked quite a lot of questions about it by Mr Keith at the beginning.

So the JCVI has said that vaccination should, on balance, benefit the person, in this case the child, receiving vaccination. That is, it would not be acceptable to advise that a child be vaccinated where

the benefit was primarily to another individual, including an adult, who can be directly protected themselves, for example, by receiving the vaccination.

I think you agreed this morning already that once -- is it fair to say that once the agreement -- sorry, once the decision reaches government, the other factors can be taken into account: for example, the importance of education?

A. That's right.

Q. Yeah. Would you also agree that another relevant factor would be the benefit, if there was one, in reducing transmission of Covid-19?

A. In certain cases, yes.

Q. And following from that, what about the potential benefit to clinically vulnerable or clinically extremely vulnerable people who are close contacts of children, whether that's other children or adults living in the same household? Would that be something that could in theory be taken into account?

A. Yes. And I believe the JCVI did do that.

Q. Did you do that?

A. Yes -- because my job was to respond to the JCVI advice. And so, for example, in August of 2021, I believe that -- it was around the same -- maybe it was the same piece of advice they gave me around 16 to 17-year-olds

in the first dose, they also addressed the issue of those over the age of 12 that had household contacts that were clinically extremely vulnerable.

Q. Yes. So it's an important factor --

A. Yes.

Q. -- in those decisions?

A. Yes.

Q. Yes. And then finally, the JCVI's statement of 4 August 2021 records reports of Long Covid in children, by that time. So that's a year and a half, I guess, into the pandemic. And those reports were coming through?

A. Yes.

Q. What consideration, if any, was given to that risk in the decision making around the vaccination of children's?

A. Well, it would have been for the JCVI and the other clinical advisers that the government had, such as the CMO and others. But just as with the adult population, the risk of Long Covid or other sort of concerns would have been taken into account, and it would have been a balanced decision.

Q. Do you recall yourself taking it into account as part of your decision making?

A. Yes.

Q. Okay, thank you.

LADY HALLETT: Thank you, Mr Wagner.

Ms Morris.

Ms Morris is over there, and if you could make sure your voice carries on into the microphone.

THE WITNESS: Yes.

Questions from MS MORRIS KC

MS MORRIS: Thank you, my Lady.

Mr Javid, I ask questions on behalf of the Covid Adverse Reaction and Bereaved groups. These groups represent those who have suffered injury or bereavement following their voluntary acceptance of the Covid-19 vaccines.

My Lady, to assist you, Mr Javid mentioned Mr Cross, and you noticed -- some concern --

LADY HALLETT: I did realise it was his daughter who was --

MS MORRIS: Yes. And you'll recall, my Lady, that Mr Cross's story was featured in the impact film at the opening of Module 4, and his daughter Liz sits in the public gallery --

LADY HALLETT: The reason I didn't acknowledge it publicly was I wasn't sure whether his daughter and the rest of his family were happy for me to name him.

MS MORRIS: I'm grateful, and I've clarified that, thank you.

Mr Javid, my questions are about the Yellow Card Scheme, a matter of some importance to those I represent, as you'll understand.

A. Yes.

Q. You said in your statement when you were Secretary of State for Health that the Yellow Card Scheme was something that didn't come to your attention and therefore you couldn't answer the inquiry's questions about whether it was effective, and you couldn't make any observations about the scheme and how it could be improved.

My question is, then, how, then, was the government effectively monitoring adverse reactions if the Health Secretary, yourself, the individual responsible for overseeing the nation's health, was unaware of the primary tool designed for this purpose?

A. Yeah, thank you. It's a very reasonable question, of course, and what I would say -- so I wasn't aware of the Yellow Card, sort of, scheme, which I, you know, I understand is -- the scheme has been there for many years, in terms of if there is -- if someone suspects an adverse effect, they can report it especially to the MHRA and make sure obviously it is taken account of, but I think, just because a Secretary of State is not aware of a particular sort of system or process within the

wider department, whether it's in the NHS or to do with the MHRA or the various other multiple bodies that fall under the department, doesn't mean to say it's not taken seriously or it's not happening.

The -- you'll know, obviously, the department itself is the biggest department in government by its spending, you know, if you take the NHS, there's well over 1.4 million employees and things. So there's so many different processes and procedures, especially clinical procedures, but especially independent procedures. And I think on those, they would only tend to come to the attention of the Secretary of State if there was a problem or an issue or something had to change, or be addressed. And this particular case as I understand it, the Yellow Card, I believe, that's for the MHRA. And I think that because the very important independence of the MHRA, I think that's another reason why generally the Secretary of State wouldn't interfere unless there was a good reason to.

Q. Understood, but you said in answer to questions to Mr Keith that you were having meetings about vaccine delivery every day. You were the central role responsible for the -- driving the vaccine project forward. Would you agree that not knowing about the Yellow Card system, one of the centrepiece systems for

adverse effect reporting, highlights a significant gap in the systems designed to ensure that key decision makers like yourself were informed about critical mechanisms for monitoring vaccine safety during the rollout?

A. I think that -- with respect, what I'd say is that I'm not sure me not knowing what the Yellow Card system is or was would have made any difference, in that -- because I'm not aware -- and it certainly hasn't been brought to my attention at this point -- that there was a problem with the system, there was an issue with the system, and so -- and I would suspect the reason it wasn't brought to my attention in those meetings that you just referred to was because no one within my department or the wider department thought it was an issue that was important enough to bring to the Secretary of State.

Now, that -- is it possible that it could have been -- that's a mistake for someone, they should have brought it to my attention because there was a problem? I'm not saying that isn't the case, I just don't know enough of the detail. But the fact it wasn't brought to my attention or an issue is not brought to my attention is in and of itself not a problem because not everything can land at the Secretary of State's desk because the

department is just too vast, especially if it's dealing with a pandemic as well as normal healthcare at the same time and social care, to just -- to have everything landing at the Secretary of State's desk.

MS MORRIS: Thank you.

Thank you, my Lady.

LADY HALLETT: Thank you, Ms Morris.

Thank you very much indeed, Sir Sajid. I appreciate you didn't realise Mr Cross's daughter was in the room and I know you didn't intend to cause her any distress, but that is one of the reasons why we don't go into individual circumstances, but anyway --

THE WITNESS: That's right. And just to say, my Lady, I did ask Christine Cross in advance if I could raise the case --

LADY HALLETT: Oh, you did, right.

THE WITNESS: -- and she was very happy for me to do so.

LADY HALLETT: I understand. Well, well done you for taking that precaution.

Thank you very much indeed for your help. I'm sorry I wasn't here last time in person, but I'm really grateful to you for all that you've done to help the Inquiry, and for your evidence today.

THE WITNESS: Thank you very much, thank you.

LADY HALLETT: Thank you, I shall return at 11.50.

(The witness withdrew)

(11.34 am)

(A short break)

(11.50 am)

MR KEITH: My Lady, the next witness is Professor Wei Shen Lim, please.

PROFESSOR WEI SHEN LIM (sworn)

Questions from LEAD COUNSEL TO THE INQUIRY for MODULE 4

LADY HALLETT: I hope you were warned that there might be a delay before we got to you, Professor.

THE WITNESS: That's fine, thank you.

MR KEITH: Could you commence your evidence, please, by giving us your full name.

A. Lim Wei Shen.

Q. I hope I don't embarrass you, Professor, by observing that we've had plenty of knights in the course of giving evidence in this Inquiry, I think the collective noun for knights is a rout of knights, but anyway there's been a rout, it's right to point out that you were appointed an Honorary Knight Commander of the Order of the British Empire, and therefore you're an Honorary Knight, entitled to use the post-nominal letters KBE, but not to call yourself Sir Wei Shen Lim?

A. That's correct.

Q. I think it's important giving the recognition to the

JCVI and yourself, as well as many of your colleagues.

You have provided, and we're very grateful to you, two witness statements, INQ000471988 and INQ000474527, dated March and October 2024. They both contain the usual declarations that they are true to the best of your knowledge and belief.

Professor, you are, I think, one of the founder members of NERVTAG; is that right?

A. Yes, that's right.

Q. And you sat on the main committee until 2023, and you were also, and you may still be a member of -- you were a member of the National Institute for Health and Care Research.

A. So I do research that is funded by NIHR, as you say. In particular, I guess, for this, in relevance, it's the RECOVERY trial and dexamethasone. That was researched -- it was funded by NIHR, in fact before the Covid pandemic. It was funded for an influenza pandemic. And I was chief investigator for that.

Q. You were the chief investigator.

Would you just keep your voice up, Professor. It's very important that we can hear what you have to say, and your evidence is being recorded remotely through a stenographer.

For our purposes, the most important feature of your

distinguished professional career is that you have been a longstanding member on the Joint Committee on Vaccination and Immunisation. And in April 2020, is this right, the chair of the JCVI, Professor Andrew Pollard, who is at the Department of Paediatrics at Oxford, recused himself because he'd been involved in the development of the Oxford adenoviral vaccine, and because he recused himself, you became the de facto chair from 6 May 2020; is that right?

A. That is correct.

Q. And that is why, of course, you are the witness on behalf of the JCVI today.

A. **(Witness nodded)**

Q. The JCVI was originally an advisory board for polio immunisation. I think it took on its current emanation as a statutory body under the NHS Act 1977; is that right?

A. That's correct.

Q. And under that statutory framework, it is an independent Departmental Expert Committee as well as being a statutory body?

A. That is correct, yes.

Q. The significance of its statutory genesis is that, insofar as England is concerned, in certain circumstances, where, for example, you have opined on

the cost effectiveness of a vaccine, the government must accept your recommendation, but in other circumstances, where you've not opined on cost effectiveness, the Secretary of State for Health and Social Care is expected to follow your advice, or place considerable reliance on it, and would need a compelling reason not to accept it; is that fair?

A. That is fair. And that's reflected in the language that is used. So in JCVI terms, if we offer a recommendation to the Secretary of State, then that reflects a cost-effectiveness evaluation, whereas if we offer advice, then it is the latter, as you describe.

Q. In relation to Wales is there a similar position in place, which is that the JCVI is regarded as a departmental expert committee which gives advice to Welsh ministers, and then, as with the Secretary of State for Health, the Welsh minister or ministers are then accountable to their own Parliamentary assembly?

A. That's correct.

Q. Scotland, there's no statutory basis for the provision of advice by the JCVI; it's up to Scottish ministers whether they accept or reject your recommendation?

A. That's right.

Q. And is the position the same in Northern Ireland?

A. The same for Northern Ireland and Scotland, yes.

Q. All right.

A. And I would like to stress that JCVI is independent. Completely independent to all of the organisations it's offering its advice to.

Q. Indeed. My next question was going to be: is it functionally and operationally independent?

A. Yes, correct.

Q. It seems there were three committees set up within JCVI to deal with Covid. There is the -- there was the Covid-19 Committee, there was a Covid-19 subcommittee, and a Vaccine Monitoring Working Group Committee; is that right?

A. That's right.

Q. To what extent are the terms of reference of the JCVI agreed to by all the health departments in each of the four nations of the United Kingdom, and to what extent does the remit of the JCVI extend over the whole of the United Kingdom?

A. As far as I'm aware, the terms of reference apply across all four nations, but with the caveats that you describe about standing committees as regards England and Wales versus Scotland and Northern Ireland.

Q. Were UK health departments, that's to say health departments in each of the four nations, all made aware of the JCVI advice, and were they closely concerned with

and connected to the operations -- the dealings of the JCVI?
A. Yes, they are. And there are co-opted members from each of the devolved administrations who are at JCVI meetings as well as added observers from devolved administrations.
Q. And does that go for the JCVI in total, as well as the committee, the subcommittees of which you've spoken?
A. It applies to the JCVI Covid committee and the JCVI Covid subcommittee. The monitoring committee was actually for information, rather than for any decision making, so perhaps less observers attended those.
Q. And did all the nations of the United Kingdom, therefore, through their health departments, receive committee papers, all the documents, and, as you say, attend relevant meetings?
A. Indeed, yes.
Q. Could we, please, have the Code of Practice. Is there a Code of Practice applicable -- is there a Code of Practice which applies to the JCVI?
A. Yes, there is.
Q. It is, please, INQ000145984. And if we could just have, please, page 12.
"All members of the Committee and its Subcommittees must demonstrate high standards of conduct."

We can see in paragraph 35 a reference to the Nolan Principles. Did they apply to the JCVI?
A. Yes, indeed.
Q. And over the page we can see references to the need for the Chair, yourself, to provide effective leadership?
A. That's correct.
Q. And then at 38, "Conflicts of interest". Is there a complex and rigorous structure by which conflicts of interest or perceived conflicts of interest are managed within the JCVI?
A. Yes, these are detailed in the Code of Practice, and at the start of every meeting all members are required to declare any potential conflicts of interest.
I should also add that with every of our published statements we also published conflicts of interest at the end of each of the statements.
Q. So when we see some of the JCVI papers in a moment, do we see that, at the beginning of every meeting, there's a very long list of perceived issues, or nominal conflicts, but in truth they're not, because if they were, they would disentitle the person from attending -- listed at the beginning of every meeting? And at the end of very paper there are, again, equally long lists or references of possible nominal connections?
A. Correct.

Q. All right.
And in your statement, if we could have INQ000471988 at page 6, please. Paragraph 22:
"... industry representatives are not invited to meetings and may not present to the main committee."
Is that right?
A. That is correct. And perhaps I can add there -- oh, it says here -- that the reason for constituting a subcommittee is to allow industry to present to the subcommittee.
Q. So members of or representatives from industry may attend, and may be expected or indeed ordered to attend a subcommittee, to give an account of themselves and to present data and information, but they are self-evidently not there as a member of the committee?
A. Correct.
Q. All right. And on paragraph 26, at paragraph 26 on the following page, do we see that there is also a register of relevant interests reviewed and maintained, which contains everything that could possibly be relevant.
And at paragraph 27, is this right, that the members and subcommittee members must declare personal pecuniary interests, personal family interests, and then over the page, non-personal pecuniary interests and then finally, personal non-pecuniary interests?

A. That is right.
Q. All right. So it's a very extensive obligation, is it not?
A. Yes.
Q. The JCVI first met on 7 May 2020 to discuss its provisional advice on prioritisation. And we're not going to go into the details of it but there were numerous papers prepared on prioritisation. The subcommittee met in September on the 24th. And then, I think, there were a number of meetings, a very considerable number of meetings, between May 2020 and, of course, the end of the pandemic, June 2022.
Give us some idea, please, Professor, of the number of times the main committee met in that two-year period?
A. The main committee and the subcommittee for Covid-19 I think we met 98 times during the period in question.
Q. And the subcommittee?
A. Sorry, those were the two combined.
Q. That was the combined figure for the main committee and the subcommittees?
A. Yes.
Q. All right. And did you provide substantive advice or recommendations, depending how you phrase it, to the Secretary of State on 28 occasions?
A. Yes, that's right. And these were all published

clinical statements that are available publicly.
Q. And did the Secretary of State, firstly in the form of Matt Hancock, and then secondly in the form of Sir Sajid Javid, agree?
A. They agreed to -- yes, they agreed to the advice. I should say it's obviously for JCVI to provide advice to the Secretary of State and not to make the decision. it is for ministers to make the decision.
Q. Ministers ultimately have the call. It's their call. They decide. But, as you've already described, they are expected to follow -- or at least to follow -- if they don't follow, to give good reason -- your recommendations, which is why it's couched in terms of recommendation or advice. But they agreed on every single occasion?
A. Yes.
Q. At the start of this process, why was the JCVI asked to consider and to give provisional advice on prioritisation, in truth some months before the vaccines were even authorised, let alone rolled out?
A. As you can imagine, we were going to embark on what would be the largest mass vaccination programme in the UK, and that would take a lot of effort to organise, to help the public understand, and a lot of information for advisory groups like JCVI to get through. So it was

important, we felt, that we provided interim advice as far as ahead of time as possible to allow all these processes to take place.
Q. And there was a lot to consider, was there not, from the likely scientific rationale for any particular prioritisation programme, issues about deliverability, public acceptability, fairness, the equity of having a prioritisation programme, all of which had to be considered even before you knew whether or not they would work?
A. Indeed. So all of that information had to be learnt, as it were, by the committee, because we were dealing with a new pathogen, a new disease, and we didn't know what was necessarily in store for us.
Q. But the substance of what you were doing did not differ, did it, from what you had always done historically, which is provide advice on how to make offers of vaccination and how they should be taken up, as you might have done or did do with polio or something like that?
A. That's correct.
Q. All right. The JCVI is not involved, though, is it, with procurement, delivery --
A. **Witness nodded**).
Q. -- the operational rollout **--**

A. **(Witness nodded)**.
Q. -- NHSE, Public Health England, Public Health Scotland, Wales and Northern Ireland work, let alone damage payment schemes **--**
A. **(Witness nodded)**.
Q. -- or vaccine donations to other countries; it's not within your reach?
A. It's not within our remit. Correct.
Q. All right. The evidence before the Inquiry shows very clearly that you alighted upon, no doubt after a great deal of consideration, a relatively simple, straightforward -- at least on paper straightforward, but in practice, of course, very much more difficult, but a relatively simple, straightforward, prioritisation programme that focused on the clinical vulnerability of recipients -- so obviously the elderly, the very elderly, then the elderly, then the less elderly, because they were the most vulnerable followed by the less vulnerable -- and a system which simultaneously focused on maintaining the health and care structures around the most vulnerable.
Why, in brief, did you come across, or why did you determine that that was the right way to proceed, by contrast, perhaps, to targeting economically active people and saying, well, we're going to vaccinate by

occupation or societal role?
A. So give me a few moments to explain this. There are two main concepts when using a vaccine in a pandemic situation, where there is constrained vaccine supply. And the two main concepts are either to target those people directly with a protective vaccine and protect those people, or to use the indirect benefits of a vaccine by targeting people who might be responsible for transmission of disease, and therefore indirectly protecting those most at risk themselves. Obviously, I say these things as though they are two completely separate, there is overlap. But those are the two main principles.
If we want to adopt an indirect protection model, ie, vaccinating, say, younger adults who are the main people responsible for transmission of infection, then there are two prerequisites for such a model to work well. The first is you need a vaccine that will effectively block transmission, hopefully, and secondly, one needs a high degree of vaccine uptake within that population in order to achieve the indirect benefit, whereas, on the counter side, if you were to use the direct effect of the vaccine, then you would choose the most at-risk population and directly protect those.
Q. And in the summer of 2020, as you were deciding upon

which, strategically, was the right way forward, did you have a clear understanding as to whether or not the vaccines would reduce transmission, or the degree to which they would reduce transmission?

A. We didn't.

Q. But you knew, because you'd seen the impact of Covid, that Covid killed in far greater numbers the most elderly?

A. Correct, yes.

Q. So they were the ones who, on an individual basis, required the greatest attention, along with the people who look after them?

A. Yes.

Q. And is that the nub of why you developed the prioritisation scheme that you did?

A. That is one aspect. I do want to stress the importance of a limited or constrained vaccine supply.

Q. What is the relevance of that?

A. So if you have only a limited number of vaccines, then using direct protection means every vaccine that is given, every dose that is given, will offer protection to a vulnerable person, whereas if we try to use the vaccine for its indirect benefits then, as an example, you would be vaccinating a 30-year old who would have less individual benefit, and until you vaccinated enough

30-year olds to block transmission, you would not be directly protecting -- you would not be protecting the most vulnerable.

Q. So there were two problems there: one is you didn't have a -- you couldn't have had and you wouldn't have for some time a clear understanding, assuming there was an effective vaccine at all, of the nature of the supply, how limited it would be, how difficult it would be to get it into the population, and you also wouldn't have a clear understanding as to how quickly the vaccination of less vulnerable people would reduce transmission in society as a whole?

A. Yes. And there's a third element to that, if I may. Usually the uptake of vaccination is influenced by how vulnerable somebody feels, and if one were to offer vaccination to a 30-year old who felt that they were personally not so vulnerable, the uptake may be lower in that population. So that was also an uncertainty.

Q. When you began to design the prioritisation list, the phase I list of cohorts, did you have regard to a great deal of data concerning efficacy, transmission, and the possible impacts of any future vaccine that might be authorised?

A. Not until the clinical trials reported results, we --

Q. When did they start reporting the results?

A. Towards the latter part of 2020. So very close to when the first vaccines were approved by MHRA.

Q. So presumably a great deal of work had to be done in December 2020. When you realised that there were vaccines coming, you had the data, the safety data and the effectiveness data, in determining whether or not the course you had begun to develop in May was the right one?

A. Indeed.

Q. To what extent did you consider, as you drew up the scheme, equity? That is to say inbuilt pre-existing health inequalities, the barriers to access which are embedded in society which prevent particular groups from receiving healthcare, and in particular vaccines, and the need to ensure that their needs were promoted as far as could be, in terms of vaccination?

A. Yes, these were considered in something September and November of 2020 as part of the overall strategy.

And I should say at this point that equity is promoted if there is a simple-to-deliver message, because that enables understanding across a wide range of society. And that understanding then promotes confidence, and therefore vaccine uptake.

Advice alone does not save any lives. The advice has to be disseminated, listened to, and somebody has to

agree to go and be vaccinated before any lives are saved.

Q. May it be put another way, Professor: if you put into place a system for prioritisation and for delivery of vaccines, and you reduce transmission, death, and disease across the whole population, you will protect, inevitably, even those persons in front of whom barriers to access have been placed or, for a variety of reasons, have not been able to take up a vaccine?

A. That's correct.

Q. That's the nub of it. All right.

Could we then look, please, at the final emanation of your hard work, which was the priority list -- INQ000354469 -- dated 30 December 2020. There it is.

I'd want very briefly just to pick a some of the most significant features of it, please, Professor.

Page 3, there's a reference there to what the committee had regard to, and you made plain you've reviewed published and unpublished safety data from the manufacturers, both in relation to Pfizer-BioNTech and AstraZeneca.

It was Pfizer which had been authorised on 2 December and AstraZeneca at the end of December, and those are the two, therefore, that you focus on; is that right?

A. That's right.
Q. At the bottom of the page, there is a reference to the two-dose schedule, and over the page:
"... the JCVI places a high priority on promoting rapid high levels of vaccine uptake among vulnerable persons.
"... given [the] data indicating high efficacy ... the committee advises that delivery of the first dose to as many eligible individuals as possible should be initially prioritised over delivery of a second vaccine dose."
Is this the first dose prioritisation issue?
A. That's right.
Q. And in relation to that, had there been, within JCVI, debate over the previous two to three weeks, or two weeks, over whether or not, notwithstanding that the formal MHRA authorisation for Pfizer-BioNTech, provided for a minimum of three weeks by way of a gap between the first and second dose, of the issue of whether or not in practice the interval could be extended so as to get as many first doses into people's arms as possible?
A. We discussed the possibility of using a one-dose schedule, even before we issued the advice on 3 December. It is part of JCVI's role and responsibility to decide how best to use the limited

supplies of vaccine we had, and one of those roles is to examine whether the dose schedule that is prescribed by the manufacturer may indeed be the optimal dose schedule in the first place.
And so from the very start, we were not only looking at the dose schedule that the manufacturers were testing in their clinical trials, but we were also looking to see if we could do even better. Could one dose be as effective? Could a separation in a dose be as effective?
So these are other strategies that, as a scientific body with huge amounts of expertise, we were able to examine and wanted to examine, even before December.
Q. But the formal authority from the MHRA allowed at least three weeks, and said no more. Because you were concerned with efficacy, with priority, with practical delivery, you said in relation to Pfizer: the vaccine may be given between 3 to 12 weeks after the first dose, and in relation to AstraZeneca, 4 to 12?
A. Correct.
Q. Page 5. There's a reference to the direct protection against transmission reduction issue. What was that?
A. These are the two strategies I described just two minutes ago about direct protection versus indirect protection, ie, transmission.

Q. So you were considering that -- you were just simply summarising there the debate?
A. Yes.
Q. Then we can see if we scroll rapidly over the next three or four pages, particular cohorts, "Age" -- if we go -- not too quickly, I'm so sorry, if we go back to page 5, "Age", and then over to page 6, "Older adults resident in care homes", "Health and social care workers", "Clinically extremely vulnerable", "Women who are pregnant", "Women who are breastfeeding", "Children less than 16 years", "Persons with underlying health conditions", and then "Mitigating inequalities".
So in this report in your -- in the published advice, were you there setting out your general approach to each of those potential cohorts?
A. That's right.
Q. And on mitigating inequalities, page 11, were you at pains to say that you had considered the particular needs of those persons who suffer under inequalities, health inclusion groups, ethnic minority communities, and, as we'll see, homeless, those in detention, and migrants -- migrant groups.
And in this advice, do you therefore seek to set out why you've gone for the age/clinical vulnerability approach?

A. Yes, I think the -- perhaps one way to understand it is the advice is given here about mitigating inequalities, firstly, because we had examined that issue in close detail. And, secondly, as an instruction, almost, to deployment teams that it was very important to take note of these inequalities and to do our best to mitigate against these inequalities by having tailored measures to deliver the vaccination programme.
Q. So this wasn't just an explanation of your position; it was a call to deployment groups to say: "You've absolutely got to be on top of this"?
A. Correct.
Q. All right. Then the list is on page 13. It'll be very familiar. Phase I -- there were two phase, weren't there, but this is phase I: Residents in a care home; 80; 75; 70 and extremely clinically vulnerable people; 65; anybody 16-64 with underlying health conditions; then 60; then 55; then 50. And that's where the line was drawn.
I now want to ask you some questions about some particular groups of people, starting with children and young persons.
In relation to children and young persons, there is a much more difficult balance to be drawn on an individual level, is there not, as to whether or not the

benefit of vaccination, which must take into account whether they're likely to get Covid or to suffer seriously from it if they do, against the risks of vaccination which may, in some circumstances, be increased vis younger people in relation to mRNA vaccines?

A. Yes, and if I can elaborate on that, the list that you just showed, phase I, there is a line at the bottom of that that says that we expect phase I to include people who are responsible for 99% of the mortality from Covid-19.

Children and young people -- we're talking, I think, here, about healthy children and young people, not children and young people with underlying health conditions -- have a much, much lower risk of serious illness from Covid-19.

And just to put some figures to that, the number needed to vaccinate to prevent one person from dying in cohort 1 was calculated by the institute of actuaries as 20. In other words, if we vaccinated 20 people who are residents in an old age care home, we would protect one life.

The same number needed to vaccinate to prevent one person from dying in a 65-year old cohort was 1,000, and of the number needed to vaccinate -- to prevent one

life -- save one life in the 50-plus cohort is 8,000.

So by the time we get to children and young people who have no underlying health conditions, then the number needed to vaccinate to prevent one adverse outcome -- clinical outcome, not safety outcome -- is in the many tens of thousands.

Q. Because of the prospect or the risk of serious disease requiring hospitalisation, or, god forbid, death, in a child or young person, is very much less than in an elderly person?

A. Correct.

Q. Right.

A. And it is that benefit that needs to be weighed against the potential harm that might arise from vaccination itself.

Q. And then at the same time, on the reverse side of the coin, there is the issue of risk from vaccination. And was there a concern, which we'll look at in a moment, about the potential, in very rare cases indeed, of myocarditis and pericarditis in children and young persons?

A. Correct.

Q. Right. How many -- or, roughly, how many people in the population of the United Kingdom does that 99% of the most vulnerable people amount to?

A. That's a good question. I don't know offhand.

Q. Roughly. It's to be measured in the tens of millions?

A. Yes, yes.

Q. So your prioritisation scheme was deliberately designed to sweep up and protect 99% of those persons who were most at risk of morbidity or mortality, serious illness or death, in the whole population?

A. That's right.

Q. And that was millions of -- tens of millions of people?

A. Yes.

Q. Does it follow that as a result of that prioritisation approach, sweeping up and protecting the most vulnerable, the rollout of the vaccines did directly avert hundreds of thousands of deaths?

A. That's right. Yes. And I should add, because this may be helpful, timing is also important. By the time we had vaccines that were approved by MHRA for use in 12 to 15-year-olds, we're talking June 2021, by that time, phase I of the vaccination programme had already run. So the most vulnerable people in the population had already been offered not just one dose of vaccine, but two doses of vaccines by this time. So they were already highly protected from serious illness.

Q. Children and young persons. On 4 June 2021, authority was given by the MHRA -- authorisation was given by the

MHRA to Pfizer to allow the use of its vaccine in 12 to 15-year-olds. So the decision then had to be made by the JCVI, what advice to be given as to whether or not people are actually offered a vaccine if they're 12 to 15.

You were asked by the DHSC to give advice on the possible extension of the vaccination programme for 12- to 15-year olds and you issued a statement on 15 July 2021, INQ000387481, "Statement on Covid-19 vaccination of children and young persons aged 12 - 17".

And what you decided, I think, is that 16 and 17-year-olds who had risk conditions, who were vulnerable, should be offered vaccination, but you deferred the issue of whether there should be a universal call to all 16 and 17-year-olds, and you deferred the issue of whether or not 12 to 15-year-olds should be offered vaccination, either universally or to those with a risk condition. I think that's right.

A. I want to add something to that.

Q. Please.

A. So at the start of the vaccine programme in December 2020, our advice was that 12-year-olds and above who had certain severe neuro disabilities in a residential setting should be offered vaccination, even in phase I, even though they were children and the vaccine was not

necessarily approved for them at that time, we, as JCVI said there should be off-label use for this highly vulnerable group, because we noted from the evidence that there were a concentrated number of serious illnesses happening in this group.

And I just want to raise that. We were very aware of the risk to children and wanting to protect them, such that we were willing to offer off-label advice even in December 2020.

Q. So let's be absolutely clear about that. Although the MHRA had given authorisation formally only for use, I think, for 18-year-olds and above for AstraZeneca and 17-year-olds and above for Pfizer, it is permissible for the JCVI to state in terms: on clinical advice, and after speaking to your doctor, particular cohorts who are vulnerable may receive a vaccine off-label, that is outwith the terms of the authorisation?

A. Correct.

Q. That's the position?

A. That's the position.

Q. And that's what you did?

A. And that is what we did, and that is something that JCVI has done in the past with other vaccines as well. So this is something that the expert committee is -- we are used to doing if we have to do it and we think it's in

the best interests of the public.

Q. There is very clear evidence that there was a great deal of political pressure being applied to speed up the process of giving advice about children, and young persons, both now and later, as we'll see, when it came to what to do about 5 to 11-year-olds.

Do you consider that you gave this advice on 15 July as reasonably, as quick as possible -- or as reasonably as soon as possible?

A. We were pre-warned as to the likely time when MHRA would give approval for vaccinations -- or for the vaccines for 12 to 15-year olds, and we were asked by the Department of Health to give advice by the end of June 2020 (sic). We missed that by a couple of days because we actually gave the advice up to the Secretary of State on 2 July. That was when our meeting was held, and our advice was formulated. The advice was published on 19 July, I believe, because of the internal discussions after we had submitted our advice to the Secretary of State.

Q. And indeed the paperwork shows there was a meeting on 6 July, attended by the Secretary of State, at which your advice was considered, so that publication date, which is the document that we have, actually post-dates JCVI's actual decision on 16 and 17-year-olds?

A. Correct.

LADY HALLETT: I think you said "by the end of June 2020". I think you meant 2021.

THE WITNESS: Sorry, thank you.

MR KEITH: On 4 August 2021, JCVI announced that 16 and 17-year-olds should be offered a first dose of Pfizer universally, so not just those in high-risk groups, particularly high-risk groups, who had been able to have a vaccine off-label, and nor was it concerned with 16 and 17-year-olds in high-risk or risk groups who had already received the nod from the JCVI.

There was an extraordinary meeting of the JCVI on 2 September 2021.

Let's have, please, INQ000354535 and it was concerned on the issue, page 2, of what to do about 12 to 15-year-olds who were not therefore in a clinical risk group; is that right?

A. Correct.

Q. We can see there the heading at paragraph 2, "12 to 15-year-olds in a clinical risk group."

If we then go forward to -- sorry, if we look further down the page, we can see a reference, can't we, to the issue of myocarditis in paragraph 9 -- at paragraphs 8 and 9 -- in fact 7, 8 and 9 -- 6 to 9.

A. Yes.

Q. Because by this stage in September, data and reports had already started to emerge, particularly from abroad, about the very rare but nevertheless significant occurrence of myocarditis following vaccination, without expressing a view as to whether or not it was coincidental, caused by Covid, possibly caused by a vaccine, or certainly caused by a vaccine. You were aware of the issue.

And so was this issue of myocarditis highly relevant to your determination on the balance -- risk-benefit balance to be drawn for 12 to 15-year-olds?

A. Indeed, it was very relevant. You may recall, the public may recall, that the US, Canada and Israel started their childhood or their 12 to 15-year-old programme just before the UK, because the vaccine was regulated and approved in those countries earlier, and when they started delivering the vaccines in large numbers to younger people, they noticed this signal of myocarditis, particularly from Israel. And we had many discussions and meetings with our colleagues overseas to understand from them what was happening with myocarditis at that time.

Some of the -- this is obviously new for them as well, and they were sharing with us hot information, as it were. And some of their cardiologists were saying

that while myocarditis appeared to be short-lived, they didn't know the full extent of the potential medium or long-term effects of myocarditis. And so some cardiologists were advising children who had developed myocarditis and had recovered after a few days, not to, for example, do any strenuous physical exercise for up to six months, because of the risk that it might trigger something that is cardiac related.

So these were important, very important, safety concerns, where the picture was only just emerging. And you will understand, because the benefit to children from the vaccine, direct benefit, is small, as we've discussed, any safety concern in that situation would need to be taken highly, highly seriously.

Q. And the position concerning myocarditis was uncertain. You had data, but you didn't know to what extent it would develop as a condition following vaccination, and you didn't, of course, have an idea -- an accurate idea as to how likely -- well, it is a very rare condition nevertheless, but what the percentages were?

A. Yes.

Q. And so in that risk-benefit analysis, as you said earlier, between the marginal benefits of vaccination against the very rare but not to be ignored risk of myocarditis, was it a more difficult balance to draw?

A. It was a very difficult balance, a hugely fine balance, quite unlike the balance of an older person who might have an adverse effect from vaccination.

Q. Do you also consider in the balance, health inequalities, Long Covid, the impact on mental health of children and young persons of being vaccinated or not being vaccinated, as well as the ethics?

A. Correct. We consider all those things.

Q. And if we look at page 4, paragraph 25, we can see a nod in the discussion to all the main issues which you looked at.

Thank you very much.

There may be wider societal or educational benefits in vaccinating children. It will allow them to go back to school; for those who live in deprived conditions, that's of additional importance. It may have a wider societal benefit, because it will allow the day-to-day running of life and society in the United Kingdom to continue as normal. But were those wider potential benefits and disbenefits at a population level matters for you, or did you only consider, and did you only allow yourself to consider, the risk-benefit on an individual level?

A. In usual practice, JCVI considers the health benefits, and would not consider wider societal benefits or

economic benefits. That is in usual practice.

During the pandemic that remained the case, and I had communications with DHSC to explain that the educational benefits that might arise from a vaccination programme were an area that was not in our usual remit and would be difficult to integrate with the way that we balanced risk and benefits.

That is not to say that we did not take into account qualitatively what the impact would be. We had meetings with the Department for Education to try to understand what the impact would be of missing school.

One other aspect that I want to stress is that a lot of the absenteeism from school was not due to the infection itself, but due to the social distancing regulations or rules or advice put around being infected. As an example, we already know that many, most children, potentially, who were infected with Covid-19 developed no symptoms or hardly any symptoms. And in the usual run of things those children would go to school because they physically are able to.

Children who might be symptomatically infected are, again, mildly symptomatically infected and may miss a few days of school, but not an extended number of days at school.

And if we then ask what can the vaccine provide in

terms of preventing absenteeism from those episodes of the symptomatic illness, then it's a much more limited number of absenteeism from school than it is as imposed because of infection control or social distancing measures.

Q. Why, then, did you refer the matter to the United Kingdom chief medical officers for advice on the wider education and public health benefits if, quantitatively, it was something you could have regard to?

A. I think -- well, quantitatively, I -- quantitatively, we couldn't have regard to. We asked the Department for Education specifically if they could tell us what does it mean for a child or a pupil to miss five days of school? And they couldn't tell us, because it would depend which year/grade they were in, it would depend what time of year, whether they were coming up to exams, a whole host of reasons whereby five days missed of school would mean different things educationally to different people at different times.

That makes it very difficult to put quantitative measurements to put into any model to decide what does this mean.

Q. So a good idea was to go to the UK CMOs and ask them to give a paper on the wider educational and societal

benefits, which you could then feed into the mix?
A. Correct. And I just want to maybe clarify what we did.
We offer advice directly to Secretary of State, and in that advice we suggested to the Secretary of State that the Secretary of State, before he or she makes a decision on policy, may want to also take advice from the CMOs. And there are two key reasons for asking the CMOs: the first is they have a wider responsibility for health, including educational health, as well as the fact that the CMOs are much more closely in touch and have greater responsibility for the infection control measures and social distancing measures in schools, which were the main reason, we think, why children did not attend so many days at school.
So they were more relevant for that aspect. And just as an analogy, perhaps, for most of the vaccine programme we were asking Secretary of State to take note of JCVI's advice and, on the pillar of JCVI's advice, make a decision.
On this one occasion we suggested to the Secretary of State that he might want to take advice using two pillars of advice: one from JCVI and from the CMOs, because of the educational importance to children. So we were not passing the decision on to the CMOs, and I think that's an important point to make, neither were

we trying to exclude or deny the importance of educational impacts. We were trying to say to the Secretary of State: these are both important, but we have to act within our remit, which is health, and that is one pillar, but one pillar only, to this decision.
Q. Well, we've heard, of course, from Professor Sir Chris Whitty, and he describes how, exactly as you've put it, they give their advice on the wider educational basis, on the premise that, at an individual level, the benefit marginally outweighs the risk, as the JCVI had determined, and they give their views.
Do you think that that seeking of the views of the UK CMOs and digging further into the issue of wider educational and societal benefit or public health benefit impermissibly delayed or unacceptably delayed the process by which the JCVI came to an ultimate view? There is before the Inquiry numerous references to political and administrative pressure to speed up the process. There are a number of interlocutors who refer to concerns about delay on the part of JCVI around this time.
A. I think it would incorrect to characterise the advice we gave and the timing of our advice as delay. We gave advice in July and we gave further advice in August, and this is all within the context of trying to understand

in greater detail what was the risk to children from myocarditis. And you will imagine that in a vaccination programme that's progressing at high speed in other countries, they would be gathering information on myocarditis every week, if not -- and every month.
Q. And you've got to have access to all that?
A. Correct. And that is time. There is nothing that you can do except wait until the information comes.
Q. And at the same time, were children and young persons most at risk from Covid?
A. No.
Q. Indeed. Right.
Pregnant and breastfeeding women.
At the beginning of December 2020 when you were drawing up the final iteration of the prioritisation list, the position before the JCVI was that there was no data as to the safety of the vaccines in pregnancy because pregnant women and breastfeeding women had deliberately not been included in the trials; is that right?
A. That's right.
Q. And you nevertheless sought information, and as much data as you could possibly gather, in part by asking for expert bodies, including the Royal College of Obstetricians and Gynecologists to come and present to

you, the JCVI; is that right?
A. That's right.
Q. And you looked for data from abroad --
A. Yes.
Q. -- to see whether that could provide information upon which you could reach a view. But the advice which you gave on 30 December could not positively extol the virtues of vaccination for pregnant women and breastfeeding women because you didn't have an underlying data-driven foundation sufficient to make a positive recommendation. Is that a fair summary?
A. That is fair. I should also add the context that vaccine confidence among this particular group, women who were pregnant, as reflected in vaccine uptake rates, the usual vaccination programme is lower than in other groups. And so we were particularly concerned to pay attention to their needs and their wishes, which is to understand the safety of these vaccines.
Q. Obviously adult pregnant women remained at risk from Covid. And so when you gave what might be thought to be equivocal advice, which is that pregnant women should discuss the risks and benefits of vaccination with clinicians, do you think -- and I emphasise in hindsight -- that that left pregnant women and their clinicians in rather a difficult position? Because they

didn't have a positive recommendation to rely upon, there was no data which would have helped them resolve on an individual case whether they should be vaccinated, and that gave rise to a considerable degree of doubt, concern, and difficulty?

A. I agree. If we knew -- well, if we knew then what we know now, that the vaccines are indeed very safe for women who are pregnant, then we could have been more positive in our advice. But we were reflecting what the evidence was at the time.

Q. In March, on the 16th, there was another extraordinary meeting, one of the many hundreds or one of the many that you had, and the issue of vaccination for pregnant women was re-debated, was it not?

A. Yes.

Q. And the committee agreed that there should be a universal offer to all pregnant women of vaccines, of vaccination. By that stage, by 16 March, had more data been made available?

A. Yes.

Q. And in essence, what did it consist of?

A. These were post-approval, post-rollout data. You've heard yesterday about phase IV studies, so these were phase IV studies, data from, particularly, the US, where they had already vaccinated at least 90,000 women who

were pregnant, and found no safety concerns.

So this was positive information on safety.

Q. As a matter of interest, that extraordinary meeting was on 16 March. I don't believe that the statement -- the position of the JCVI was made public until 16 April. Do you happen to know why there was that elapse of time of a month?

A. I don't know offhand. I can go and find out.

Q. All right. If you don't know off the top of your head, don't worry.

Therefore, the position remained at the end of April, or the position was at the end of April, that pregnant women were offered the vaccine but they were still encouraged to discuss the risk and benefits of vaccination with their individual clinicians. Why was it deemed necessary to add that caveat? It is not a caveat, of course, that is applied in relation to other cohorts who receive prioritised access under the schemes.

A. I think this is an acknowledgement of the confidence and the safety concerns that pregnant women express regarding vaccination. And we are relying also on evidence that is not from clinical trials, but relying on evidence that are phase IV studies about the safety of these vaccines. So --

Q. So they weren't randomised control trials; they were observational studies?

A. Correct, yes.

Q. And do you, as a result of this issue, which was obviously extremely difficult for the JCVI, do you, in one of your recommendations, reflect that pregnancy must be a key issue for consideration in any future pandemic? It is vital to ensure that relevant and significant data is developed as early as possible to avoid precisely what of course occurred in relation to Covid?

A. Exactly.

Q. Disabled people were obviously the focus of prioritisation, were they not?

A. Yes.

Q. In two regards: individuals with Down's syndrome fell within priority group 4; and there was an issue about the extent to which those with learning disabilities should fall within priority group 6.

Did the JCVI appreciate, particularly in relation to those with learning disabilities in group 6, whether or not an individual disabled person would know that they were entitled to receive the vaccine would depend to a huge extent as to whether or not the state regarded them as being within the terminological description in cohort 6?

A. I think you're referring here to how somebody might know that they should go to be vaccinated. And you're right: there was -- and that may still be the case -- less than full identification of who is living with a learning disability. Which makes -- both analysing the data and understanding who really is at risk or not at risk, and who is taking up the vaccine or not taking a vaccine, that makes it difficult. It also makes it difficult to call up the correct people for a vaccination programme.

I should point out that in a mass vaccination programme, the main means of asking people to attend for vaccination should not be self-identification. It should be a patient being asked, by some system, to go and be vaccinated. Because the question of self-knowledge of medical categories of illness does not apply simply to people living with learning disabilities.

Q. But that all rests on the premise that there is a coherent and effective system for recording learning disabilities, for example, or that the NHS or GPs have medical codes in their records which accurately reflect related conditions such as cerebral palsy, which is a medical code, it gets a medical code in the system.

You were aware that the systems for recording, objectively, the medical condition or the disability

sadly encountered by people in this cohort, did not work there people well, which is why you actually wrote to the DHSC yourself making -- or attempting to make recommendations as to how the system would navigate its way around this data-driven issue?

A. Correct, yes.

Q. And did you feel, did you assess that enough was done to try to bring together, for example, learning disability registers across the United Kingdom, medical codes in four different NHS boards, for cerebral palsy, for example, together so that everybody would know reasonably whether or not they were entitled to vaccines?

A. Yes, I should point out that delivery of the programme, as we said, is not within the remit or responsibility of JCVI. But we wanted to understand how well deployment teams were doing.

In regard to the specifics of how people were being identified, there were two means at least that were being used centrally. One is to use the GP codes for diagnostic conditions that would map on to somebody who might be living with a learning disability. And those codes are published, they are publicly available. I think there are over 443 codes that are being used to identify people, as well as using the GP Learning

Disability Register, as well, I should add, asking local teams to also identify people as best as possible.

And I guess what I'm trying to emphasise, although it's not JCVI's responsibility, is that deployment teams were trying to do their best to identify as many people as possible that will come under JCVI's advice for prioritisation with as many means as possible. And where we know that there are gaps in the data, then the help of non-centralised bodies such as charity groups, self-help groups, word of mouth, all of these are important as well, because what we want is as many people who can benefit to benefit.

Q. In relation to unpaid carers, at the beginning of December 2020 when you drew up the draft prioritisation list, there wasn't, I think, a reference to sole or primary carers in the draft list. There was a footnote or a reference to the clinicians' Green Book. By the end of December, there was an express footnote in the list which referred to main carer or sole or primary carer. I can't recall which. Which was it, Professor?

A. I think in end of December --

Q. It's a memory test --

A. -- it was main carer.

Q. Main carer?

A. Yes.

Q. Right. There was a considerable difficulty, was there not, in defining what was meant by sole or primary carer or main carer? Was that something that the JCVI was able to get on top of, or was that a matter which had to be left to the operational experts who were delivering the vaccines?

A. That was -- the precise definition is mainly left to the UKHSA and deployment teams, because the precise actionable definitions need to be something that the deployment teams can use to call people up.

Q. There was in the list, for the reasons that you've described, no reference to any particular occupation, other than care home workers in the top priority, and to wider care and health workers in a lower priority.

But there was also no reference to particularly socially excluded groups such as homeless people, sex workers, vulnerable migrants, the Gypsy, Roma and Traveller communities, detained people, or people who have come through the wrong end of the justice system.

It was obvious to the JCVI that those groups were likely to have poorer health outcomes, to be more subject to the intersectionality of deprivation, poor housing, stigma, discrimination, and so on.

And the committee was asked to give its views on homeless groups, and it didn't put them into the group,

but it did say: operationally, you might want to think about them as being in cohort 6, and, on the ground, make a universal offer.

Why didn't the JCVI take that sort of similar approach, or that sort of approach, to those other marginalised or inequitably treated groups?

A. In the paper from Public Health England, as it was at that time, inclusion groups -- inclusion health groups include a wide range, as you've just described. The most information was available for people living with homelessness. That's thanks to excellent work done in London by some colleagues from UCL. So we had understanding of people living with homelessness, and importantly, there were already efforts in influenza vaccination to reach out to people living with homelessness and to understand their underlying health problems and their willingness to be vaccinated.

In that same paper that describes inclusion health groups, I think it might be in the last paragraph, the advice from PHE and the equity group was very clear that outreach to different communities may sometimes be counterproductive if it's not done in -- in a correct way, and without engagement of trusted organisations. And the reason why there was less information for some of the other inclusion health groups is precisely

because there had been less engagement previously. And so we had less data.

The paper, actually, very much put forwards that outreach teams, when they go out to offer vaccination to people who live -- living with homelessness, whether they could have a formal piece of advice from JCVI to exercise the operational flexibility that we had already described in December 2020. So this was not an addition or any change; we were not making a decision to suddenly move people living with homelessness as a priority group. We were simply saying: yes, please exercise the operational flexibility that we had already described for this group of people, because, if you are reaching out to them -- and we know that in flu vaccination campaigns they would respond positively -- then please do so. This was a formal piece of advice from JCVI on that front.

For the other groups, we mentioned in the advice that there should be concerted efforts to keep on trying to engage with them in order to bring them into the system and be vaccinated.

Q. All right. Thank you very much.

My Lady, I have five more minutes to go and there's ten minutes of Rule 10s.

LADY HALLETT: Professor, would it help you if we carried on

and finished your evidence before lunch?

THE WITNESS: That would be most helpful, thank you.

LADY HALLETT: Right. Carry on, please.

I may be able to relieve Ms Beattie of asking her question by asking it shortly in a minute.

MR KEITH: TTS.

LADY HALLETT: We'll see, see whether you think I have.

MR KEITH: We'd heard evidence from Dame June Raine and from Mr Hancock concerning the TTS issue, which arose, of course, between late February/early March of 2021 and the beginning of April, when there was a press conference given on 7 April attended by yourself, Sir Jonathan Van-Tam, Dame June Raine. And in the course of those few weeks it's obvious that there were a significant number of JCVI meetings, meetings of the MHRA, the CHM, OCMO and DHSC.

And in essence, what was being tackled was whether or not the emerging data of TTS required either authority to be withdrawn or altered at the hands of the MHRA, or the JCVI to give advice as to whether or not AstraZeneca should be offered to a particular age group, or perhaps to specify by age precisely who should receive or more pertinently who should not receive AstraZeneca vaccine.

What we're concerned about is the passage of time

again. The first report of potential -- and it's extremely rare, I emphasise, but potential adverse effect of TTS first emerged at the end of February. Abroad, in fact.

Data was received immediately from AstraZeneca and from observational studies and epidemiological studies as to the risks. But, notwithstanding the number of meetings, it wasn't until just before the Bank Holiday weekend, on 1 April, that a decision appeared to have been taken as to what should be done. The MHRA took a view and told clinicians and public -- primary care network directors of the position, but it wasn't until after the Bank Holiday weekend there was a press conference and a public statement and so on.

Why did it take so long, from the vantage point of persons who were younger and might therefore be at greater risk of TTS, for a decision to be reached?

A. It's a complex decision, as you have already discussed with many other witnesses. At that time, we in the UK were using AstraZeneca vaccine alongside the Pfizer-BioNTech vaccine in our vaccination programme, by age. And at the end of February in England, I believe we were just calling up people who are aged 64 years and above. So still very much at high risk.

The amount of AstraZeneca vaccine being used at that

time was about 50% of the programme. There's -- some people have alluded to other countries where the AstraZeneca product was stopped or withdrawn from their vaccine programme very early on, without clear data.

We were left in a difficult position because the AstraZeneca vaccine was such a large part of our vaccine programme and at that time we were offering vaccination to some of the most vulnerable people in our population.

And so, on the one hand, we have to balance the risk of withdrawing one vaccine product, possibly our main product, from the programme without sufficient data or support from MHRA that this indeed was a vaccine-related problem --

Q. Can I interrupt you there to say that is all justification for the ultimate position on authorisation reached by the MHRA on advice for vaccination given by the JCVI. Why did that -- and you've said it's a complex process -- why did that decision-making process on your part, the JCVI, have to take from 25 February to 7 April?

A. We were asking MHRA for their viewpoint regarding safety and who was at risk and who was not at risk. We'd had earlier reports that the clusters of people where myocarditis -- TTS was occurring was younger people. And at that point, as I say, our vaccine programme was

delivering the vaccine to older people, not younger people. So the people at risk were not yet being offered the vaccine.

I should also add that at that point we were delivering vaccine doses at about 1 million or more per week. If we had delayed rollout of the vaccine by, just, say, two weeks, that would be 2 million doses not given to people who were aged 64 and above --

Q. Professor, forgive me, again, that all goes to the merit, for which there is a very strong case, for the ultimate decision you reached, but, bluntly, why didn't the JCVI reach a decision mid-March and give its public statement at a press conference then?

A. We didn't have the information that was required to make that decision.

MR KEITH: Thank you.

Professor, those are all my questions. Thank you very much.

Questions from THE CHAIR

LADY HALLETT: Given the time, I'm going to try to reduce the amount of time left for the questions.

I gave permission to the Disabled People's Organisations to ask a question about the definition of "carer", and we can explain why you and Mr Keith got in some confusion about what was the definition, because

it's explained in the question. 30 December 2020, JCVI included main carers in cohort 6, but then the definition was narrowed on 12 February 2021 to those who are the sole or primary carer. And the question from the organisations is this: Given many disabled people rely on more than one carer to have an effective and independent life, did the JCVI give any thought to the confusion that this narrow definition of "carer" might cause?

A. Just to clarify the situation, carers were included in the Green Book advice at the start of December. It was only also included as a footnote at the end of December because there was feedback that it was difficult to find the advice, and so we wanted to make it clear that the advice was already there, but people needed to look in the Green Book for the definition.

And the Green Book is indeed the place where one reaches all the definitions for the very many conditions. We don't list definitions within the clinical statements for obvious purposes.

The definition that was in the Green Book and -- at the start of December and the end of December, was the same definition that was used to identify carers for the influenza programme.

In February -- I'm speaking here on behalf of UKHSA,

who are the editors of the Green Book, it is not the JCVI, but Mary Ramsay, who gave witness a few days ago, I think she said this as well: that the clarification in February was not actually a clarification around the definition of carers; that was not the intended clarification. The clarification was to enable NHSE to identify who was being cared for. That was where the clarification was intended. So I think any misunderstanding regarding main, sole or primary carer is just that. It's -- there is no intended narrowing of the definition of "carer" by those change in words.

LADY HALLETT: Thank you.

Just so that Ms Beattie doesn't think I'm picking on her, I'm going to ask Mr Wagner's question too.

I gave permission for this question to be asked by the Clinically Vulnerable Families: do you agree that the mRNA Covid-19 vaccine protection has been shown to wane after five to six months?

A. That is information we now know, yes.

LADY HALLETT: Do you also agree that Covid-19 has not transitioned into a seasonal virus like influenza?

A. That's correct.

LADY HALLETT: In which case, Mr Wagner wanted to know why did the JCVI not recommend more frequent vaccinations for all clinically vulnerable groups?

A. We -- clinically vulnerable groups. I'm just trying to think where we are.

So clinically vulnerable groups were offered vaccination as a primary course, and then every autumn, 2021 and 2022, 2023 and 2024. The phrase "clinically extremely vulnerable" obviously was disbanded after a while, and so it's difficult to separate out that from the later programmes. They would come in under people who were clinically at risk.

In spring 2022 JCVI I think was the first country (sic) in the world to suggest that we should have a spring booster campaign. And this was a precautionary position for those people in whom we thought their immunity might wane before the autumn programme. No other country had done this. And at that point we were not sure just how quickly immunity would wane.

So we know some things now but we didn't know all of them then, and so the spring booster campaign in 2022 was specifically directed at those who were most vulnerable and most likely to lose their immunity because of immune senescence, which is loss of immune protection because of age or a less good immune system. Hence it was narrowed to those people aged 75 and above and people who have poor immune systems.

LADY HALLETT: Thank you very much indeed, Professor. That completes all the questions we have for you. I know that we're all extremely grateful for all the work that you did during the pandemic and obviously your colleagues too. I know you'd want to share the credit with your colleagues. And we are indebted to you. And thank you very much for showing similar care in giving your evidence before the Inquiry. Thank you so much for your help.

I shall return at 2.10.

(The witness withdrew)

(1.15 pm)

(The Short Adjournment)

(2.10 pm)

LADY HALLETT: Mr Mansell.

MR MANSELL: My Lady, the next witness is Ben Osborn, please. If he could be sworn.

MR BEN OSBORN (sworn)

Questions from COUNSEL TO THE INQUIRY

Q. Could you give the Inquiry your full name, please.

A. My name is Benjamin John Osborn.

Q. Mr Osborn, thank you very much for coming along today the Inquiry. You have also provided a witness statement for this module of the Inquiry, it is INQ485977, and this is your witness statement provided on behalf of

Pfizer Limited; is that right?

A. That is correct.

Q. That statement is signed by you. Are the contents of it true to the best of your knowledge and belief?

A. They are indeed.

Q. Thank you.

You explain in the statement that Pfizer is a US-headquartered multinational pharmaceutical and biotechnology company which develops and produces medicines and vaccines in a wide range of therapeutic areas.

A. Indeed.

Q. Its UK affiliate, Pfizer Limited, was incorporated in 1953 and has sites across England?

A. That's correct.

Q. Since December 2023, you have held the position of President, International Commercial Office, at Pfizer?

A. That's correct.

Q. You were previously Managing Director and UK Country Manager of Pfizer Limited from December 2018 to January 2022?

A. Yes.

Q. From January 2022 to September 2022, you held the position of Regional President, Hospital Business Unit, International Developed Markets?

A. I did.

Q. And during your time as UK Country Manager, the role which is the most relevant, I think, for your evidence today --

A. Yes.

Q. -- your responsibilities included leading Pfizer's UK biopharmaceuticals organisation, overseeing key business and operational matters relating to Pfizer's medicines and vaccines in the UK?

A. That's right.

Q. The first topic I'd like to deal with with you, please, is the development of the Pfizer-BioNTech vaccine, brand name Comirnaty.

So the vaccine was created, is this right, in partnership with the German company BioNTech?

A. That is correct.

Q. And Pfizer had been working with BioNTech since 2018, seeking to develop an influenza vaccine based on messenger ribonucleic acid (mRNA) technology?

A. That's right.

Q. We have heard a bit about of mRNA technology during the course of this module of the Inquiry. It's sometimes called a novel vaccines. It was the first time it was authorised as a vaccine technology, is that right, in relation to the Covid-19 Pfizer-BioNTech vaccine?

A. It was indeed, although the research and the science into mRNA vaccines had actually been ongoing for some two decades, widely across the world but in particular through our BioNTech partner.

Q. In your statement you set out vaccine development timelines. And include a useful diagram which, I believe, was originally utilised by Professor Sir Jonathan Van-Tam in November 2020.

We can see that, please, in your statement at page 16, if we could zoom in on that. Thank you very much.

And you set out here the traditional vaccine development timeline and the accelerated timeline below it. Just looking at the traditional vaccine development timeline, we can see that phases I, II and III occur consecutively.

A. That's right.

Q. The regulatory review aspect of the process occurs at the end of the clinical trial process; is that right?

A. That's correct.

Q. And then, once authorised, there is then the move to large-scale production and distribution?

A. Indeed.

Q. But overall this is a process that, as the arrow shows us at the bottom of that first diagram, takes several

years?
A. Absolutely.
Q. The accelerated timeline, this is the timeline that was used in relation to the Covid-19 vaccines --
A. Yes.
Q. -- including the Pfizer-BioNTech vaccine, we see there the clinical trial phases, phase I, phase II and III overlapping; is that right?
A. That's right.
Q. There's rolling regulatory review throughout this process, yes?
A. Yes, not through -- so the way to think about it, in the traditional R&D model, one would run a phase I, or multiple phase I studies. Potentially there's a period of time where there's then a break, phase II, break, assessment, and then into phase III. Potentially then a break as manufacturing decisions are made, certain investments, et cetera. I think what you see in the document here and in this diagram is actually how there was much more parallel processing here.

So from a trial perspective actually we rolled straight from phase I into phase II and into the pivotal phase III study, which provided the evidence that we submitted to the regulator.

And once we had that data, that's what the MHRA and

other regulators around the world assessed our vaccine on.
Q. Is it right that there are perhaps two aspects to the rolling review. You've got the aspect you were just speaking about --
A. Yes.
Q. -- which deals with authorisation --
A. Indeed.
Q. -- and the information that needs to be submitted to the regulator in terms of authorisation, but also, during the trial process --
A. Yes.
Q. -- and getting authorisation for trials, that is also something that can happen on a rolling basis and did happen on a rolling basis during the pandemic?
A. So, indeed, the regulator is involved right from the very start. In fact, before any patient is vaccinated, before phase I, there is discussions with regulators, with the MHRA and others around the world, and they are then assessing our data, our protocols, our manufacturing steps at all stages of the development of this vaccine.

In terms of the rolling review to the MHRA, that began in October. And as you're aware, the actual pivotal phase III study, the actual results of that came

out, I think it was, early November.

So they had already started to assess some elements of the vaccine before the major phase III study read out.
Q. We can also see a difference here in the stage at which the manufacturing process begins because at-risk manufacturing is taking place during the phase III trial process?
A. That is right. Typically we would wait until we had the confirmation of, essentially, a medicine that we believed would then be approved by regulators around the world. We knew in this situation that if we waited to those timelines, we wouldn't necessarily be able to serve the global needs and the volume of vaccine that would be required. So we invested over $1 billion in 2020, at risk, our own financial risk, because we didn't take any investment from any government around the world, to essentially start that manufacturing scale-up.
Q. The process has gone from the traditional timeline, taking several years, to ten months plus. With that accelerated development timeline, did that come at the expense of safety assessments?
A. No. Safety is absolutely at the forefront of all of our decision making as Pfizer.
Q. That can come down from the screen, thank you.

You explain that two clinical trials form the basis for the initial authorisation of the vaccine: study 1 and study 2. Study 2 included those pivotal phase III clinical trials.

We've heard evidence about this already but there were almost 44,000 enrolled study subjects?
A. That's right.
Q. The trial was conducted by Pfizer in the United States, Germany, South Africa, Turkey, Argentina, and Brazil?
A. Correct.
Q. Were the same clinical trial processes followed in relation to that trial, as would be followed in respect of a trial taking place in a non-pandemic setting?
A. Yes, absolutely. The standards, the requirements under Good Clinical Practice, GCP, were exactly the same as for any other pivotal phase III study that would be conducted.
Q. You mentioned GCP, are those the international, ethical and scientific quality standards that are applied?
A. They are the standards essentially applied to our industry and academics running such studies, yes.
Q. Is it right that no suspected unexpected serious adverse reactions, or SUSARs, were reported during those trials?
A. That is correct.
Q. Now, an issue the Inquiry has been looking at is the

ethnic diversity of the clinical trials.
A. Yes.
Q. You may have seen the evidence of Professor Prieto-Alhambra yesterday and, indeed, in his report he explains that the Pfizer phase III trials had -- 83% of the participants were white, 9% black, 4% Asian, and 2% multi-racial. Were those trials sufficiently diverse?
A. Yes, they were.
Q. And can you expand on that, please?
A. Yes, as we began the development of this vaccine, diversity was absolutely critical to us and, indeed, we knew, to the population that were ultimately going to be using this vaccine. They needed to have confidence in the vaccine. We sought to ensure that our study was run across multiple sites, across a diverse population, so that the data that ultimately we submitted to the regulator for independent assessment was reflective of the population that would ultimately be vaccinated around the world.
Q. We've seen other figures that explain that the trial had 42% of global participants and 30% of US participants with a racially and ethnically diverse background. How can we make sense of the two figures side by side?
A. Yes, sure. So the 42% is essentially reflective of

a black, Asian, Latino population. So that's how we essentially square that one.
Q. So taking into account the sites in Argentina and Brazil, and the --
A. Indeed. The Latino population were also, in terms of the overall summary, included in the 82.9% that were classified as white. So it's essentially a sub racial group within the 82.9%.
Q. From an industry perspective, do you have any recommendations as to what can be done in the UK to ensure greater ethnic diversity in clinical trials?
A. I think it goes beyond, actually, racial diversity here. I think it's really encouraging and helping society at large to understand the importance of clinical trials, and the role that every member of our society, no matter which group one would essentially fall into, to really understand the value of being part of a clinical trial, and what is involved as part of that.

So I think it goes back to education, and really our government and others and the NHS really investing time, effort and energy in education around the value of clinical trials. And then making sure that essentially, when the clinical trials are being run, that we are reaching all aspects, all members of society with the opportunity to partake in a clinical trial.

Q. Is this right, that pregnant women and immunocompromised individuals were excluded from the clinical trials?
A. That is correct, and certainly when it comes to clinical trials, certainly the pre-authorisation phase, it is standard procedure in the vast majority of trial cases that pregnant women are not involved at that stage.
Q. But Pfizer conducted post-authorisation studies, including among pregnant women, but there were challenges with that, you explain in your statement, because by that point, vaccination had been recommended among pregnant women, so there was not the cohort there to draw upon for the phase IV clinical trials. Is that a fair summary?
A. Indeed. So as part of our agreed pharmacovigilance follow-ups, so one of the PASS studies, post-authorisation safety studies, was in pregnant women, and we essentially found that across the world, many pregnant women had already started to be vaccinated, given local and national immunisation guidelines. And so recruitment became a real challenge in this situation, and ultimately the trial was stopped because we weren't able to sufficiently recruit enough women into this study.
Q. That raises the obvious question, is there a case for including such groups like pregnant women in

pre-authorisation studies so that you can get the randomised control trial data that otherwise you may not be able to obtain?
A. I think that's a matter for the regulator to decide whether a population such as pregnant women and children should be included in such studies.
Q. What about the immunocompromised? Did that post-authorisation trial complete successfully?
A. Immunocompromised patients weren't involved because the very nature of their immunocompromised state means that they typically would not respond to a vaccine. So they required other treatments, as we've heard over the last few days through the Inquiry.
Q. Let's turn now to authorisation and pharmacovigilance, please. You explain that following assessment by the MHRA, the vaccine was authorised under Regulation 174 of the Human Medicines Regulations on 2 December 2020.
A. That's right.
Q. The Inquiry is, by now, very familiar with Regulation 174 authorisation. It is not the same as a market authorisation?
A. No, it's not.
Q. And you observe that the legislative provisions setting out requirements for post-authorisation of monitoring medicines and vaccines are normally directed at the

marketing authorisation holder, which would be the company?
A. Yes.
Q. Pfizer and BioNTech in this example.
Because this was authorisation under Regulation 174, was there less stringent conditions imposed upon Pfizer as a result of that, in terms of pharmacovigilance?
A. No, they were not less stringent. I would say they were incredibly rigorous. I think everyone recognised the scrutiny that would be given to these vaccines. They were very robust, and they went beyond what we would typically see, I would say, in many cases, in terms of the frequency of review. So not the standards, but the frequency of data review, given the volume of patients that were being vaccinated in the UK and across the world.
Q. We can perhaps look at some of those pharmacovigilance monitoring obligations now, please, just to run through them. Is it right that Pfizer was required to submit, and update when appropriate, a risk management plan?
A. That's right.
Q. Is it right that Pfizer was required to maintain a global safety database containing adverse events for its vaccine?
A. That's correct.

Q. And also provide periodic safety update reports to the MHRA?
A. Yes.
Q. Could you just explain what those are, please, and what the reporting requirements were.
A. So essentially these are -- as you've described, we collect data on a global basis, and at specific time points we were required, mandated under this temporary authorisation, to provide the safety update reviews directly to the MHRA and other regulators across the world, so that then, in the case of the MHRA, they could then take this dataset that we had collated and then assess that alongside those potential adverse events that had been reported through the Yellow Card Scheme.
Q. Those periodic safety update reports are normally provided every six months?
A. I believe so, yes.
Q. But the timescales applied were more exacting in relation to the Covid-19 vaccine, I think?
A. They were indeed. They were much more frequent, yes.
Q. They were provided monthly for 11 months --
A. That's right, and then --
Q. -- the reports?
A. And then I think we went to every other month after that. So it was a sustained period of increased

frequency of submission.
Q. You've mentioned post-authorisation safety studies. There was a commitment on the part of Pfizer to conduct ten post-authorisation safety studies; is that right?
A. Yes.
Q. Now, you may have seen Professor Prieto-Alhambra's report. He recommends that there should be greater obligations on pharmaceutical companies to conduct early post-authorisation safety studies with a particular focus on the risk-benefit of vaccines among groups underrepresented in, or excluded from, phase III trials. So perhaps groups like pregnant women, we've already spoken about, but he also places an emphasis on ethnic minorities -- not excluded from trials but perhaps underrepresented -- elderly people with frailty or multiple comorbidities, and people with disabilities.
A. Yes.
Q. A greater obligation on pharmaceutical companies in that regard. What is your view of how workable such a recommendation is?
A. I mean, it's an obligation we take very, very seriously. I think in the first instance we seek to make our clinical trial programme and certainly our phase III programme reflective of the population in which we ultimately intend to serve. Our intention then is to

very quickly, but in a regulated way, in line with decisions directly from the MHRA and other regulators, to move through the appropriate subsequent studies in a phase IV setting.
So the PASS studies to which you're referring to are agreed directly with the regulators. It is not Pfizer here saying we wish to study an X, Y and Z population; it is a direct agreement with the regulator.
Q. There is a commitment made to conduct --
A. In the --
Q. -- a certain PASS as part of authorisation being granted -- (overspeaking) --
A. Exactly, yes.
Q. And will that be decided on a case-by-case basis, a vaccine-by-vaccine or drug-by-drug basis, how many PASS need to be conducted?
A. Yes, it will.
Q. And which groups it needs to be focused on?
A. Yes, it well.
Q. What about reporting timescales? Are there requirements in relation to that when a PASS has to report to the public?
A. I'm not aware of the details specifically on the reporting timescales. My belief is that it would be in line with when essentially sufficient data has accrued

that a decision can be -- or data can be then submitted to the regulator.
Q. I think it's right to say that two of the studies, two of the ten PASS studies that Pfizer committed to have been published to date; is that right?
A. That's right, yes.
Q. And the others are pending, in various stages?
A. Ongoing assessment, indeed.
Q. Pharmacovigilance monitoring. We've spoken about the obligations on the company, on Pfizer, in this particular case, in relation to pharmacovigilance monitoring. As safety signals are assessed, as they come to light, is this right: that it can lead to an update of the product information?
A. It can indeed.
Q. That product information is approved by the MHRA?
A. That's right.
Q. And it is, is this right, a central way in which the public and healthcare professionals are updated about the safety profile of a drug, in this case a vaccine?
A. That is correct. And I think the example of anaphylaxis, actually, in the very first few days of vaccination in the UK, is a really good demonstration of this process actually doing exactly what it should have done.

So on 8 December there were a number of rare cases of anaphylaxis associated with the Pfizer-BioNTech vaccine. They were discussed with the MHRA and assessed by the MHRA and their independent experts on 9 December. And on 10 December, the SPC and the patient information leaflet and subsequent guidance to the NHS vaccination centres was changed.
Q. Yes --
A. Rapidly, that potential safety signal was translated back into a clinical practice.
Q. People would be familiar with the 15-minute observation period that was introduced as a result.
A. Exactly.
Q. You've spoken about anaphylaxis. Let's look at myo- and pericarditis, please.
A. Yes.
Q. And I'm going to ask you about updates to the product information regarding those conditions. But firstly, is it right that myocarditis and pericarditis are conditions which, as well as having an association with mRNA vaccines, can also be caused by Covid-19 itself?
A. Indeed. And I think the data, as we stand today, demonstrate that the frequency is actually higher in an unvaccinated population who have had Covid-19, and indeed the myocarditis and pericarditis is typically

more severe than that seen in relation to that induced by a vaccine.
Q. The first reports of myocarditis and pericarditis emerged from safety surveillance in Israel?
A. That's correct.
Q. And at that stage, no signal had been validated based on the data available to Pfizer-BioNTech, and no other regulator had raised similar concerns?
A. That's right.
Q. Pfizer worked to determine the relevant background rates for myocarditis and pericarditis, and performed an observed versus expected analysis. Could you just explain to us what that is, please?
A. Yes. So if we just look at the chronology here. So a number of rare cases were identified on 28 December, as you say, in Israel. Actually, it was in April that Pfizer-BioNTech met with the MHRA to begin the conversations on myocarditis, or specifically, sorry -- to have conversations on myocarditis. We continued, then, to assess our data, as the MHRA did. What we then saw in May was the Center for Disease Control in the US, their data demonstrated a similar potential signal to that seen in Israel.
At this time we were asked strictly by the MHRA for further data, which included an assessment of what was

the baseline prevalence of myocarditis in the general population and specific population, so younger men? Because what they were looking to do was to identify, was this a vaccine-driven event, or not? And so, by understanding what the baseline incidence was, one could compare the incidence rates in real life.
Q. So in terms of from the point that the safety signal emerged, was there close contact and communication with the MHRA about the work you had been doing and the signals you were receiving in relation to this condition?
A. So there was constant dialogue, as there is for all of our safety assessments with the MHRA and other regulators, and when the -- essentially we presented the data back to the MHRA on 22 June, a decision was then made on the 25th and rapidly that translated into an updated SPC and patient information leaflet.
Q. You've mentioned 25 June 2021. That is the date on which the -- at that point I think referred to as the Regulation 174 product information was updated?
A. Indeed.
Q. We can see that, please, the Reg 174 information for healthcare professionals.
It's INQ000507930. There it is. And page 5, please.

We have section 4.4 at the bottom of that page. And that's "Special" -- we have "Special warnings and precautions for use". And when we can move on to the next page, please, page 6.

There's the anaphylaxis you mentioned earlier, but, at the top of this page:

"Myocarditis and pericarditis

"There have been very rare reports of myocarditis and pericarditis occurring after vaccination with [that's the Pfizer-BioNTech vaccine] often in younger men and shortly after the second dose ... typically mild ... and individuals tend to recover within a short time following standard treatment and rest."

And then what healthcare professionals should be alive to --

A. That's right.

Q. -- in relation to that.

That can come down, please.

Because, of course, that is the product information, the Regulation 174 information for healthcare professionals but we can see the information for recipients at INQ000507943.

Page 3, please.

"Possible side effects", section 4. And we can see:

"Side effects may occur with [the] following

frequencies ..."

And under "Not known", towards the bottom of the page:

"... (cannot be estimated from the available data)."

And including "inflammation of the heart, (myocarditis or pericarditis)".

So that's what patients are being told as of 25 June 2021 in the information provided.

A. That's correct.

Q. And then things further develop -- that can come down, thank you -- and we move to 14 March 2022 when further analysis has been done, you've been liaising with the regulator on -- on an ongoing basis?

A. Yes.

Q. And at this stage, because I think by this point the vaccine had market authorisation, it's what we know as the patient information leaflet (PIL). We can see that, please, INQ000507969, page 3. So this is from 14 March 2022.

"Possible side effects"

And:

"Very rare side effects: may affect up to 1 in 10,000 people

"- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart

(pericarditis) ..."

And the symptoms there.

And that can come down. Thank you.

So as more information had come to light and been analysed, there was greater clarity about the frequency of this association.

A. That is exactly right. And that's the nature of how the pharmacovigilance process works: that at the time, and as essentially these events are accrued and understood, then the -- I guess the confidence of the event rate is then able to translate into the data and the numbers that we see then in the SPC and PIL.

Q. The Inquiry's expert, Professor Evans, suggested that a new approach is needed to patient information leaflets. We were just looking at one there. His view is that they need to be updated, perhaps changed, made available much more online, and split into categories to make them perhaps easier to digest for recipients: what you need to know about the risks before you're given a medicine, what you need to know about risks while you're taking the medicine, and what you need to know in the event that an adverse reaction has occurred that might be as a result of taking the medicine.

Now, from the perspective of the manufacturer, what is your view of whether those are sensible suggestions

for reform?

A. I think in terms of the characterisation of pre, during post is very sensible. I think from my perspective and that of the industry's, I think the most important thing is that these are tested with patients. These patient information leaflets are regulatory documents. They are decided by the MHRA under a particular template and format. This is not the discretion of Pfizer or another company.

And I think this is perhaps a situation where, actually, there's a great opportunity to involve patients here. What worked for patients? There's a huge range of, obviously, knowledge across patients in terms of their scientific understanding of the medicines which they're taking, and it needs to work for everybody.

So I think this is an opportunity to test with patients. I don't think it's for me to say what this should look like.

Q. Next topic is the Yellow Card.

We've heard a lot about that during the course of the Module 4 evidence. We're familiar with what it is. In your statement you note that:

"During the pandemic, quick access to safety reports was more important than ever, however the time lag

between the data being shared via the [Yellow Card] Platform and being passed on to Pfizer meant that Pfizer did not have immediate awareness of that portion of UK Adverse Events which were available to MHRA ..."

So just to sketch in some of the background here: Pfizer receives information about an adverse event. You have to tell the regulator.

A. That's right.

Q. The regulator, the MHRA, receives information about an adverse event through the Yellow Card platform.

A. Yes.

Q. It shares that information you at Pfizer.

A. Yes.

Q. So that it can inform your picture of the safety profile of the vaccine; is that a fair summary?

A. That is a very fair summary, yes.

Q. Yet you talk about time lags here. What sort of period are we looking at, and what were the consequences, if any, of that delay?

A. So I'm not aware of any consequences as a result of that delay. I mean, in effect, unless a patient or a HCP were to report in tandem to both the MHRA and to Pfizer, there will, in effect, be a delay, because the event has been submitted, it needs to be processed, assessed, through the MHRA, before it's reported to Pfizer.

I don't know the specific details on how long that delay would be, but it wasn't consequential to any patient or safety assessment, because all of those reports were being continuously monitored by the MHRA.

If any signals were identified, they were immediately raised with Pfizer.

Q. Nevertheless, you suggest that the system could be made more efficient --

A. Indeed.

Q. -- with an investment in technology and a strong encouragement for electronic rather than paper submission --

A. Yes.

Q. -- of Yellow Card, Yellow Card reports.

I just want to deal with a couple of other recommendations with you, if I may. The first is in relation to clinical trials, because in your statement you make the point that the UK is falling behind other comparable countries when it comes to clinical trials, commercial clinical trials being conducted in the UK. You point out that we're tenth in the world for industry phase III trials, falling from fourth in 2017, and far behind countries --

A. Yes.

Q. -- such as Spain, is the example that you give. What

can be done to make the UK a more attractive place to conduct those commercial phase III trials?

A. I think the Lord O'Shaughnessy report actually captures very, very clearly the approach, the strategy that the UK should take. I can't do that justice this afternoon, but I think there are several things. I think there's a recognition of the association between the investment that companies will make in R&D in a particular country, and the utilisation of that. So what I mean by that is making sure that we have a whole system-wide approach to the pharmaceutical and biotech industry and making sure there is a seamless transition between research and actually those medicines, those vaccines, then benefiting the population in which they've been trialled.

So I think I note in my evidence there is often too long a delay between the research in the UK and actually then the routine use in clinical practice for patients. Reducing that gap down so that it is a seamless flow would significantly improve things.

Q. The final point I want to raise with you, Mr Osborn, is one of the recommendations made in a document called Breakthrough Nation II.

This is INQ000507914, please.

And this is a suggested agenda that Pfizer has put

together for prevention, innovation and investment in life sciences in the UK.

And we can see -- thank you -- that number 1, in terms of the recommendations in that document is about the "mission-led approach" of the Vaccine Taskforce, which Pfizer's view, in Pfizer's view, should be applied to address other major healthcare challenges.

That can come down. Thank you very much.

How was the VTF's approach different in terms of industry, from where you sat in industry? You describe it as a single front door for industry.

A. That's right. It was a very significant shift for us in terms of our relationship and working with government. It provided single points of accountability, it provided a very rapid and agile decision-making approach. It ensured that when there were issues, when there were challenges that needed to be navigated, there was a rapid access to the right expertise to essentially resolve those, in a very collaborative partnership way.

So yeah, I think when you then look at some of the big societal health challenges that we face, cancer, Alzheimer's, and other such diseases, that there are some significant learnings that we can take from the approach of both the Vaccine Taskforce and Antivirals Taskforce as well.

Q. And in terms of facing the next pandemic, it's an approach you would like to see replicated?
A. Very much so, and I think in particular, and we have heard this from other witnesses: the importance of that expertise that was around and involved in the Vaccine Taskforce was absolutely central to the approach.
MR MANSELL: Thank you, Mr Osborn.
My Lady, those are all my questions. I believe Mr Weatherby KC has a question.
LADY HALLETT: Indeed. Thank you very much indeed, Mr Mansell.
Mr Weatherby.

Questions from MR WEATHERBY KC

MR WEATHERBY: Thank you very much.
Mr Osborn, I ask questions on behalf of the Covid Bereaved Families for Justice UK group. Just one point from me, and it rather picks up from the last point that you were speaking about, I think.
In your witness statement, and for the record, it's paragraph 38, under the heading of "Pfizer's understanding of the preparedness of the [UK] for the rapid development of a 'Disease X' vaccine in early 2020", you state, and I quote:
"... the focus on an influenza pandemic, together with an assumption that a pandemic specific influenza

vaccine based on existing influenza vaccines, could be made available within 4 - 6 months after the start of a pandemic, meant that there had been limited co-ordinated investment in development of vaccines against new viruses."
Does it follow from that, that your view is that the UK Government had not done enough to facilitate research and development of vaccines to address Disease X, prior to 2020?
A. I think, as we've seen from across -- both here in the UK and across the world, we weren't ready for Covid-19 overall. From a very specific Pfizer perspective, it didn't impact the development of our vaccine or delay at all. We didn't take any government money from the UK or indeed across the board.
Q. With respect, that rather avoids my question. The statement that you put in your witness statement is that the focus on influenza vaccines meant that there'd been limited coordinated investment in this area.
Do you agree that that was in fact the case, and that the UK Government should have been in a better position?
A. I think there had been less focus, both in the UK and further afield --
Q. Yes.

A. -- in this space, and I think it's one of the key learnings now as we move forward that we need to make sure we're not just putting our eggs in one basket. We need to look broadly across the range of technologies, the range of expertise, companies, academics, that will ultimately contribute to solutions for future pandemics.
MR WEATHERBY: Thank you very much.
LADY HALLETT: Thank you, Mr Weatherby.
Thank you very much indeed, Mr Osborn. Those are all the questions that we have for you. Thank you for your help in providing the statement and answering our questions and thank you for your help coming along today.
THE WITNESS: Thank you.
LADY HALLETT: I'm very grateful to you.

(The witness withdrew)

LADY HALLETT: Mr Keith.
MR KEITH: My Lady, the next witness is Dr Justin Green, please.

DR JUSTIN GREEN (sworn)

Questions from LEAD COUNSEL TO THE INQUIRY for MODULE 4

LADY HALLETT: Sorry if we've kept you waiting, Dr Green.
MR KEITH: Can you please commence your evidence by giving us your full name.
A. Justin Anton Green.

Q. Dr Green, thank you very much for attending today and for providing the witness statement which you have, dated 7 November 2024.
You are, is this right, a UK-qualified infectious diseases and general internal medicine physician, you obtained an MA from Cambridge, a BM BCh in medicine and surgery from Oxford, you're a Fellow of the Royal College of Physicians, you have a diploma from the London School of Tropical Medicine and Hygiene and from the College of Physicians of London, a PhD from Imperial, and notably -- and most importantly, for our purposes -- in November 2020 you were one of the three global clinical product leads for the Oxford-AstraZeneca vaccine.
A. Correct.
Q. I want to ask you, please, about some events that occurred in Singapore in 2002-3. Were you at that time working in the hospital as a registrar?
A. Yes, I was a clinical registrar on the wards in a thousand-bed hospital, which is a big hospital, in Singapore.
Q. And what did you have to deal with during your time there?
A. So general infectious diseases, but for well over three months, I was the -- one of the clinical

registrars looking after hundreds of patients with SARS-CoV-1 in the first coronavirus outbreak in 2002 to 2003, where I looked after hundreds of patients with this condition, including some of my colleagues who got infected in the hospital, two of whom died.

Q. So you've seen firsthand the impact -- well, you saw then the impact of a pandemic?

A. It was an epidemic, but yes, but certainly this disease, you know, this -- this disease.

Q. The evidence before this Inquiry demonstrates that the Oxford-AstraZeneca vaccine which was rolled out in great numbers from January 2021, and in particular during those first three months of 2021, saved thousands of lives in the United Kingdom. You're aware, I'm sure, of a mathematical modelling study which estimates that vaccinations generally have prevented over 14 million deaths from Covid in 185 countries?

And also of estimates to the effect that in the United Kingdom, by September 2021, the Covid vaccines had prevented more than 23 million infections and 123,000 deaths?

In your statement you identify a number of very general reasons or explanations why the Oxford-AstraZeneca vaccine was able to be produced, manufactured and subsequently rolled out. And I just

want to ask you about those reasons.

Had there been, in the years leading up to the pandemic, considerable research done on the technology, the vaccine platform, chimpanzee adenoviral Oxford platform from which the Oxford-AstraZeneca vaccine was derived?

A. Yes. Dame Sarah Gilbert's team and other teams in Oxford had worked on this platform in a number of conditions, and pertinent to this was another coronavirus called MERS, which is Middle East Respiratory Syndrome, which is very similar, and therefore that gave them confidence that (a) they had phase I data that looked at safety of this in a small number of healthy volunteers, but also that they might have a product that could give a suitable immune response against that condition, and therefore increased our confidence that that might be the case in SARS-CoV-2.

Q. And had the technology also been worked on for the purposes of trying to develop vaccines for influenza and other pathogenic diseases --

A. Yes, and other ones.

Q. -- such as Zika?

A. Zika, malaria, HIV, others. They'd done a number of phase I studies, so actually we had quite a lot of

phase I data, albeit in different diseases, with the same vector that gave us confidence that there should be a high chance of success in phase I, at least.

Q. How important, secondly, to the development of the vaccine was the degree of funding for research and development, in particular from the UK Government and the bodies such as NIHR and UKRI and others, and the recruitment or the ability to recruit into clinical trials?

A. So obviously this is Professor Pollard's team, so I speak with that in mind in terms of it was a collaboration between us, us and Oxford, but I think he's made it clear that the availability of funds, particularly for what they call the CoV-1, which is the phase I study that they did, with 1,000 patients, and then rapidly moving into the CoV-2 study, was incredibly important that that was made available, and made available early, with reassurance from the other phase Is that it was a worthwhile investment to make, albeit at a higher risk than you might make at other times in -- not in a pandemic setting.

Q. And to what extent did your team find that there was a heightened degree of a greater level of recruitment in the course of planning and conducting the trials for the Oxford-AstraZeneca vaccine, and to what extent did that

level of recruitment make a difference?

A. So those recruited very fast. I mean, I think it's fair to say vaccine studies often, even outside of the pandemic setting, but -- that these studies do recruit fast, because you've got ambulatory healthy individuals volunteering for studies. But certainly in the context of the operational team at Oxford, they were, you know, really pleased and obviously were able to recruit those very rapidly, those trials.

Q. Thirdly, you refer in your statement to what has been very clearly established by the evidence in the course of this Inquiry so far, to the effect that the MHRA permitted data in relation to trials to be submitted on a rolling basis, rather than waiting to the end of the clinical trial process to receive all the data together, and, similarly in relation to the application for authorisation, was prepared to consider the data, the paperwork, on a rolling review basis.

Did that help with taking an overall review on the efficacy and the speed of the process with getting to the point of authorisation?

A. I mean, undoubtedly it did. We did a data lock in early November. We provided the final clinical documents, I think the headline results were on 23 November, and then obviously the approval was in late December and,

you know, that really is very accelerated and that was clearly related to our ability to submit on a rolling basis, not just clinical information, information from pre-clinical studies which had already been completed and therefore were ready to be submitted, and manufacturing.

Q. Was safety in any way compromised or reduced by virtue of that ability afforded to you by the MHRA to provide data on a rolling basis?

A. No.

Q. Finally on this topic, you pay tribute in your statement to the prioritisation by all the stakeholders, to use your phrase, involved in this process. So everybody in Oxford, at AstraZeneca, and on the part of the state, and in particular the regulatory authority, the MHRA, worked extremely hard and very fast to make sure that the process was completed within as short a time as could reasonably be permitted. I mean, bluntly, did this mean that by contrast to what had gone before, phone calls were made every time of day and night, emails were sent immediately, meetings were scheduled and held repeatedly and with great frequency? The system was made to run very, very hot.

A. I mean, I think it was very clear that the reason we were able to go so rapidly was because almost the entire

machinery of AstraZeneca was turned over in order to support these trials for this and our monoclonal antibody Evusheld as well. And also, the same was happening in Oxford and at the MHRA and other agencies. And there were, you know, everybody was ready to respond rapidly, but with the same level of quality in that very busy time.

Q. The effectiveness of the Oxford-AstraZeneca vaccine has been trawled over and reported upon and countless reports published on its effectiveness, but in addition to that issue, was the Oxford-AstraZeneca vaccine a vaccine which was produced and manufactured and made available without profit?

A. Yes.

Q. And was that something which Oxford-AstraZeneca was prepared to agree not just with the United Kingdom Government but with other government's around the world?

A. Absolutely.

Q. And another hugely important aspect of that vaccine was, by contrast to one particular other vaccine, was it a vaccine which was more readily transported, stored and physically delivered?

A. Certainly earlier -- early in the pandemic we knew that we had a vaccine which could be stored at 2 to 8 degrees, and therefore from a global perspective, was

going -- from a logistical perspective, was going to be incredibly advantageous for people that had a similar supply chain set-up in non-pandemic settings in order to ensure that large volumes of this product could be supplied globally as well as obviously within the UK, in the sense of going to harder-to-reach regions.

Q. Turning now to the subject of clinical trials, please, Dr Green. Are clinical trials an ordinary part of all medicines' development and manufacture?

A. Yes. Not just vaccines, obviously -- of small molecules, monoclonals, other therapies.

Q. Could you say something, please, in general terms about the degree of scrutiny directed towards the Oxford-AstraZeneca vaccine by comparison to historic vaccines, perhaps by comparison to the Covid vaccines, was it a vaccine which has been subject to unprecedented degrees of scrutiny?

A. By whom? I think everybody was scrutinising it. So I think we had a high level of scrutiny, obviously in the public domain, in the press, but also obviously from not just the regulatory agency in the UK, the MHRA, but in parallel we had submissions in Europe, so we were dealing with getting a European approval, which we got in late January. We had interactions with WHO. We had -- certainly in early 2021, we were dealing with the

Brazilian government and other independent regulators that were asking their questions of our data. Not all of those questions were the same, and therefore we were answering all of those during that early part of 2021.

I think, just to put that into some kind of context, we answered 1,500 clinical questions, and I think at AstraZeneca, of all of the products that we've got, that's three times more than any other product we've ever had.

Q. In general terms, were the clinical trials led by Oxford as opposed to AstraZeneca, or was it a shared endeavour?

A. So the University of Oxford sponsored the trials. Professor Pollard's team did a heroic effort of managing those trials and then we partnered with them in terms of then using the data that they had collected in order to support the file that we made and the authorisation that we got, but we then became what's called the market authorisation holder, and therefore responsible, after authorisation, for that product.

Q. So you made the authorisation applications, you helped with the analysis of the data and it's interpretation, and no doubt you provided software and a great deal of the number crunching as well, in support of your applications for authorisation?

A. We did, although the original analysis was actually done

by Oxford and repeated by us, and that was very important for Oxford, as well as ourselves, and that's not usual, that actually we came to the same conclusion on the same datasets.

Q. So expand on that, the data having been made available from the output from the clinical trials, it was looked at by both AstraZeneca and Oxford?

A. Yes.

Q. Independently of each another in order to reach a view as to the significance of the data --

A. Well, to come to exactly the same numbers so that we were completely confident that the way it had been analysed was actually giving exactly the same numbers in terms of efficacy but also, obviously, safety and immunogenicity.

Q. All right. There were a number of Oxford-AstraZeneca trials or Oxford trials, perhaps, COV001, 2, 3 and 5. They are the ones I'm most concerned about. Some of the trials took place abroad, and in particular, COV002 trial and COV001 trial took place in the United Kingdom; is that right?

A. That's correct.

Q. And just, please, help us with a general overview of the scope and the scale of these trials, the COV001 trial in the United Kingdom, roughly how many trial centres did

that involve?

A. I think it was five.

Q. And roughly how many participants?

A. The final analysis was 1,077 patients.

Q. COV002 was in the United Kingdom. It was a phase II, phase III trial. Was that over 10,000 participants?

A. About 12,000, yeah.

Q. 12,000. COV003 was in Brazil -- over 10,000?

A. -- (overspeaking) -- in about seven sites.

Q. And COV005 in South Africa, and how many participants?

A. About 2,000 and then some of those were HIV positive as well, which was important.

Q. Were all of the trials randomised and controlled?

A. They were all randomised and controlled, yes.

Q. Most were single-blinded, and we now know --

A. Yes.

Q. -- what single-blinded means and one, I think was -- (overspeaking) --

A. COV005 was double-blind.

Q. And were the trials carried out even though some of them had taken place abroad, in accordance with the MHRA's good clinical practice for clinical trials?

A. Yes, I mean, the way that they were conducted was certainly done to international standards, of which the MHRA's is a very good example of that, but yes.

Q. And is that because the MHRA standards or assurances are agreed at international level, and at least consistent with what other international regulators demand?

A. Yes, the International Conference on Harmonisation, or ICH, would say within that the MHRA standards fulfil what we consider that GCP, good clinical practice, is.

Q. Staying with the issue of diversity of trials, could you please look at the article in The Lancet, INQ000153551. This is an article dated 8 December 2020. And Dr Green, did Oxford-AstraZeneca put its data from four of its ongoing blinded randomised controlled trials, and the analysis into the public domain, through Lancet?

A. That's right. That was published, I think on the -- online and is open access as well, so you don't have to pay to or be part of a library to access that. And that, we felt, was very important, that any publications were done swiftly, that they were done in high impact journals with, you know, high standards of peer review, and therefore, we were pleased that Lancet agreed to publish that paper.

Q. And is it self-evident that the degree of detail is at a very high level? The numbers, the data, the percentages, it's all there?

A. Well, there's a high level of detail here and we were pleased that Lancet gave us a little bit more space to

get more information in than their usual articles, but actually, what lies behind this is hundreds and hundreds of pages of documents that I helped edit and write with my colleagues that formed the basis of the readout of the clinical trial that was then submitted to the MHRA. This is a summary, and this is a précis of that summary.

Q. All right. But we can see from the findings that information is given there not just about overall vaccine efficacy, but also about the fact that in relation to -- was it one of the trials or all the trials? -- there were ten cases hospitalised for Covid, all in the control arm, and two were classified as severe Covid-19, including one death. So in the control arm. Was that across all of the trials or one of the trials?

A. No, this is a pooled analysis and so that was across all of the trials, although the -- you know, and so that gave us a really good indication that we had an excellent product here that was going to be really effective.

Q. And so we're absolutely clear, during the course of the trials, amongst the cohort of participants who did not receive the vaccine, because they were in the control arm, some were hospitalised, two got severe Covid, and one died?

A. And unfortunately one died, yes.
Q. Had you not known with absolute certainty that that poor individual who'd died had not received a vaccine, and they had died without that knowledge, you wouldn't have known whether or not they'd died from the vaccine or from Covid?
A. Well, you'd know that information after you'd unblinded the trial. So --
Q. Quite so, but --
A. You may, during the course of a trial, occasionally understand who, particularly in the context of serious safety issues, you might unblind an individual, but you would only know that at the end of the trial. So you would know that you'd had ten severe cases and you'd had one death but until you unblinded the trial in late November 2020, you wouldn't know whether that person had had vaccine or not.
Q. But the general point is that of course people could and did die from Covid itself?
A. Yes.
Q. There's a reference there to person months of safety follow-up, 74,341 person months. What is that?
A. I mean, it's large --
Q. Well, what does it mean?
A. -- and extensive, and what it means is that, you know,

if you totalled together the number of participants and how much each individual contributed to the safety database, because this was an interim data readout, you know, one individual could have contributed 1 month and one finished could have contributed 11 months, but overall, there was a cumulative amount of safety in 74,000 person months.

The median time that individuals had been followed up at the time of the submission of our original file was about two months, so we knew we had that very early, and importantly in a vaccine study, we had information where we considered the most likely time that these adverse events will present that are likely to be related to vaccine.

Q. And then turning to severe adverse events, there are a number of severe adverse events amongst -- out of the total number of participants, 168 people?
A. Yes, you'd expect that in 23,000 individuals. But what's more important is the attributable ones, so the ones that either the investigators prior to unblinding, or even after unblinding, you felt were related to the vaccine, and the number of those were very, very low.
Q. Eighty-four events amongst the group of people who had received the Oxford-AstraZeneca vaccine, but there were 91 severe adverse events amongst the control group who

had had no vaccine at all?
A. Yes, and the imbalance is driven mainly by the fact that unfortunately they got very severe Covid and that's likely to lead to a serious adverse event, because they would have been hospitalised.
Q. And that's because many of these severe adverse events appear in the community coincidentally -- (overspeaking) --
A. Yes, I mean, if you break your leg and end up in a hospital it may not because of the vaccine but you'd still have had a serious adverse event.
Q. Of those severe adverse events occurring in the vaccine participant group -- sorry, of the total number of severe events, three events were classified as possibly related to a vaccine, one in the vaccine group, one in the control group, and one in a participant who remains masked to group allocation. So did Oxford-AstraZeneca carry out enquiries in each case of severe adverse events and try to determine what link, if any, there was to the vaccines as opposed to the severe adverse event occurring coincidentally?
A. Yes, usually prior to unblinding you have that information and then subsequent to unblinding you look at those individual that have had vaccine, and actually the one in the vaccine group, because actually of those

three, only one of them ended up being in the vaccine, was somebody that had a very high fever, and sought medical advice for that fever, and therefore reached the qualification to be a serious adverse event. But that was self-limiting, and actually, we now know that individuals having fever with this vaccine in the first seven days of delivery is not uncommon.
Q. Can we just look at some other aspects of this report please. Page 3, there's a reference to the COV002 trial, so that's one of the two trials that was in the United Kingdom, we can see in the bottom left-hand corner. It says:

"Enrolment particularly targeted individuals working in professions with high possible exposure to SARS-CoV-2, such as health and social care settings."

So as part of that trial, you were focusing on particularly people in the health and social care sector?
A. That's correct.
Q. Page 4, there's a reference to the COV003 trial in Brazil and the COV005 trial in South Africa. May we presume that because they were trials in Brazil and South Africa, there was a higher or there was a more diverse racial and ethnic make-up amongst the participants?

A. Yes, that's right. I mean, the ethnicity of individuals in Brazil is often very mixed because of the historical migration patterns, and then obviously in South Africa, we had a high proportion of black individuals.

Q. But because the UK trials tended to be, I think, larger, or at least one of the UK trials was quite large, in terms of overall ethnicity of the trials, you've got to pool all the participants in all the trials, and see what the overall figures are, and so that's why, elsewhere in this report, the overall figure is about 76% participants were white, 10% black, 4% mixed ethnicity, 3% Asian and 7% other. Is that right?

A. That's correct.

Q. Right. We've learnt a great deal about pharmacovigilance, and I needn't ask you about the general system. It is clear that Oxford-AstraZeneca appointed, for the purposes of the clinical trial process and seeking authorisation, a data safety monitoring board.

Amongst the papers before the Inquiry it's clear that the trial was paused in September 2020 to investigate a suspected unexpected serious adverse reaction, a SUSAR, a case of transverse myelitis, in fact, and the issue arose as to whether it was associated with the receipt of the vaccine.

Was the pausing of the trial something that would have been ordered by the data safety monitoring board embedded within AstraZeneca -- or Oxford-AstraZeneca?

A. No, that would be done by the study team. So usually, you would consider there's a number of people that might pause a trial. So the pause might come from the investigator, so you would say: we're going to stop and we're going to find out about this case and then we're going to discuss that with the D -- what's called the DSMB, which is the Data Safety Monitoring Board. It could be done by the Data Safety Monitoring Board and sometimes it's done by the regulator.

Q. All right. So there are different degrees and levels of, I suppose, safety supervision?

A. Yes.

Q. And do you recall how it was the position was reached that the trials could be recommenced?

A. Yes, there was discussion obviously between the sponsor, which was Oxford, and the clinical team, which was Professor Pollard's team, with our input, to the DSMB, and the DSMB agreed that they felt that there was insufficient evidence of causality from the vaccine, and therefore, that was then -- what you do is you then agree with the regulator that your position is that vaccination should restart. And obviously, in the

context of new safety findings, you would be very much looking for those conditions, and obviously all the other conditions you are expecting to find, and therefore it would have been agreed with the MHRA.

And in actual fact, because we had other international clinical trials ongoing at the time, it was also agreed with other international regulatory agencies that we would start -- restart our trial, and that they agreed with that.

Q. The safety monitoring, safety supervisory system obliges a manufacturer, pre-authorisation, to provide pre-clinical studies, clinical trial data, it would seem almost any data or information related to safety and the issue of whether or not a prospective authorisation might be impacted by that event.

But did AstraZeneca and Oxford also receive and make available reports from members of the public who'd taken part in the trials?

A. So I don't think I fully understand your question.

Q. We know from the pharmacovigilance system that there's a process by which members of the public and clinicians can report through the Yellow Card system.

A. So are you talking about --

Q. We're post -- post-authorisation.

A. That's post, okay.

Q. But was there a system in place whereby, either pre- or post-authorisation, anybody who had taken place in an Oxford-AstraZeneca trial could get in touch with Oxford-AstraZeneca directly and report suspected side effects --

A. Yes.

Q. -- to you directly?

A. Yes, so the usual conduct, and the conduct in this case with the clinical operations team at Oxford who ran the trials, would -- was that the -- that Professor Pollard had a number of staff working for him, some of which were physicians, and that all of those participants would have been informed at the beginning of the trial how they could contact the trial site, on a 24-hour basis, seven days a week, if they had any symptoms that they were concerned about. And that's encouraged. You know, that is part and parcel of the covenant of working with people who volunteer to be in your trials, is that you really give them easy access to trial staff so that they can report those, even if they're late.

So sometimes, you know, we might even find out something after someone has finished a trial. And if they report that, that would then be subsequently included in the database.

Q. And are these reports from those participants analysed

by the company, put through your data systems, followed up in certain circumstances as well as being reported to the regulator, the MA, or the MHRA, whoever it is?

A. They are, and in fact we put in a number of reports in terms of the clinical study report that was submitted. So we put the rolling submission in in late 2020, but in the second quarter of 2021 we submitted formal clinical study reports of the early part of the trials, and then later, we submitted final study reports which reported on the totality of the safety and efficacy data of all of those individuals in those four trials, followed up to completion of the -- completion of those studies.

Q. Did trials continue after the date of authorisation?

A. Yes. So for many months afterwards. So we were looking at, in those four trials, we were looking at everybody being followed up for a year, and a large number of those individuals were actually rolled into another study to look at the second year of safety in a study called Cov-9, which has subsequently finished.

Q. And was there a large trial, I think with sites in the US, Peru and Chile, which carried on throughout 2021, following authorisation, an RCT (a randomised control trial) double-blind --

A. Yes, we --

Q. -- reported subsequently?

A. Yes, we also started a trial in the late summer of 2020 which was using sites in the three countries that you've quoted, and that reported in late March 2021, and, very reassuringly, in a second complete dataset, so a second phase III study, we demonstrated very similar efficacy, almost identical efficacy, against severe disease.

And what was most reassuring for us at the time was very similar safety profile. Although I might add we did not see any cases of transverse myelitis in that dataset.

Q. Another important part of the monitoring, the safety monitoring process, is the provision of a risk management plan.

Can we just have a look at this, at INQ000506071.

We will see a risk management plan which was submitted on behalf of the Oxford-AstraZeneca adenoviral vaccine, AZD1222, to the EMA, and this is -- is this a document which is, in its first instance, drawn up by the company?

A. Yes, you draw it up prior to authorisation or approval, and often in the late stages of -- as you get towards an authorisation, you would negotiate to update this, and obviously then mutually agree what the contents of this are, because it's critically important for post-approval -- post-authorisation planning and

delivery of particularly safety information, but also effectiveness.

Q. So you set out what you propose to do if authorisation is given, and how, precisely, you're going to continue to monitor safety and report on it.

And we can see the data lock point for this document is 4 November 2020, so pre-authorisation.

A. That's right. And you identify which safety issues you either already know about and which ones you continue to have concerns about, despite the fact that you may not have seen them in a clinical trial, because there are some generic understandings of doing vaccine trials whereby you always are concerned about particular adverse events that have been associated with many other vaccines, not necessarily within the Covid space.

Q. Because, for example, in relation to some vaccines, perhaps the Covid-19 vaccines, there is always the possibility of a thromboembolic event, and that's one of the -- it's AESIs that are identified in --

A. That's right, and -- but let's be clear that that thromboembolic event would be something we would expect to see in a clinical practice, like a deep vain thrombosis or a pulmonary embolus and not something associated with low platelets. Different pathophysiology.

Q. If we can quickly just go through pages 3, we can see here the index and the sorts of issues which are covered by the risk management plan: prevention of Covid, the non-clinical start of the safety specification, information about the trial process, who were not studied in the clinical trials, post-authorisation experience, identified and potential risks.

And, over the page, the pharmacovigilance plan setting out all the things that will be done, going forward, for the purposes of maintaining this high level of safety.

A. That's right, and you can see there, lower down page 47 and below, that also requires you to complete, report out and report back to the regulators the trials that you've done. So that kind of is -- it's not just about new activities; it's about ensuring that you've completed the activities that you are undertaking at the time of authorisation.

Q. And just to pick up some of the pieces of evidence which the Inquiry has explored during the course of the hearing, if we look at page 33 we will see, by way of example, what is known as the missing information. So the absence of pregnant and breastfeeding women in the course of the AstraZeneca trials, as well as those with a severe immunodeficiency. So you're reporting on all

aspects of safety for the purposes to of the trials.

Page 36. Details of the obligations to examine the data sources for signal detection, safety signal detection.

Page 39, detailed information concerning the ICSRs, the case safety studies, signal evaluation, and I could go on.

A. The -- under authorisation, the 174, I think what was made abundantly clear to us, and it's clear in this document, is that actually the commitment for pharmacovigilance was no different to what you would get in a routine conditional marketing approval. So the pharmacovigilance part of the RMP was definitely as expected for any other product in or outside of a pandemic.

Q. We've not enjoyed acronyms, generally, by RMP you mean --

A. Risk management plan.

Q. All right.

And then if we look at the MHRA, risk management plan, INQ000506077, I think I have engaged in an acronym there, the medicinal health -- Medicines and Healthcare products Regulatory Agency, we can see there the country-specific addendum to that risk management plan precisely for the purpose of the agency and the

United Kingdom?

A. That's right.

Q. Post-authorisation, there were a number of obligations imposed on you, were there not, to provide summary safety reports, periodic safety update reports, provide scientific and medical reports which have been published in the literature, data from your database, anything to do with adverse events, as well as specific post-authorisation safety studies. Is that a fair summary?

A. That's right, but in the context of this, this -- actually it was heightened. I mean, there were twice-weekly phone calls, which is unusual. There were monthly reports, which again is unusual, and was increased for what would be expected for a normal product.

But that was a reflection of fact that we knew that this was an important product that was going to be used in many millions of people very quickly.

Q. How many post-authorisations safety studies do you recall were done?

A. I think there are nine listed.

Q. And were they all given to the EMA, the European Medicines Agency, and the Medicines and Healthcare products Regulatory Agency?

A. They have all been completed. Only one is not reported, which is unsurprising, because it's a pregnancy study. But all of the others have been completed. The clinical study reports have been completed. They are available. In the public domain. Many in almost unredacted forms. And a number of those have also been published in peer-reviewed journals.

Q. All right. Fees. Does a manufacturer wishing to seek authorisation for the use in a particular country, or in the United Kingdom, of a medicinal product, including a vaccine, have to pay a fee?

A. Yes.

Q. Do you also pay fees, I think a subscription fee, for particular portals overseen or run by the regulator?

A. Yes.

Q. Is there any financial link between AstraZeneca and the MHRA?

A. None whatsoever.

Q. The authorisation was granted on 29 or 30 December 2020, and were there a number of conditions attached to the authorisation by the regulatory agency?

A. Yes.

Q. Did those conditions concern not just use of the vaccine, but also, the continuing obligations of pharmacovigilance?

A. Yes, they did.

Q. If we can look, please, at INQ000413711, at pages 3 to 4, we'll see at the bottom of the page, paragraph 23:

"[AstraZeneca] must operate a comprehensive pharmacovigilance system for this product ...

"[It] ... must submit to MHRA inspections to assess compliance ..."

There must be:

"... full product lifecycle compliance with the risk management plan ...

"... promptly and regularly liaise with the HMRA to ensure the safety specification ...

"... submit protocols ..."

And so on.

So it's a condition of the authorisation that this stringent process continues?

A. That's correct.

Q. All right.

Another important part of it is the system by which the company produces product information about the vaccine; is that right?

A. Yes.

Q. And must all the product information which you provide about your product be approved by the regulatory agency?

A. Yes.

Q. Because this was a process under Regulation 174 of the medicines regulations, did you produce for healthcare professionals, and then for UK recipients, something known as Regulation 174 information?
A. Yes, that's right.
Q. We'll look at the healthcare professional one first, INQ000413715.
If we go to page 2, you can see there the name of the product, the qualitative and quantitive composition, pharmaceutical form, clinical particulars. And does it set out a great deal of detail about the nature of the product, the risks, the benefits, the contraindications, and so on?
A. It does.
Q. And then the information for the patient, UK recipient, INQ000413716, page 2., what the vaccine is, what you need to know, how it's given, possible side effects, how to store, and contents of the pack and other information?
A. It is. But this document particularly we were at pains to try our very best to make sure that it was written in a language and a style that was understandable to everybody that might receive the product.
Q. The information you provided subsequently found its way into what we know to be the patient information leaflet

and also the summary of product characteristics.
Is that information updated as you go along.
A. Yes. You update it as and when you have information that you feel is important for people to understand the product that they might receive.
Q. And by and large, are those changes agreed with the regulator?
A. Always.
Q. Does the regulator have an ability to say, "You may not want that information" or "You've got a good argument by that information doesn't need to be put in or it's not relevant, but we, the regulator, want it in anyway"?
A. I think what you're describing is actually quite common in pharmaceutical medicine, which is an imposition, which is --
Q. That's a technical -- or it's a term of art?
A. That's the technical description of what you're saying, which is that we would have an opinion about a particular adverse event or a particular set of wording within the -- either the patient information leaflet or the summary of product characteristics, but ultimately, the regulator would insist on that language and we would come to usually a mutual conclusion about the best language for that, and that would then go into that label and would be disseminated.

Q. In your statement you, very helpfully, included a table listing all the changes that were made in the product information, by reference to all adverse drug reactions, whether demonstrated to be linked to a vaccine, the vaccine, or merely associated with the vaccine, or just suspected to be associated or maybe not connected at all, but an adverse event about which public concern has been expressed in relation to whether it is connected to the vaccine.
And just by way of example, if you can have page 34 of your statement, INQ000474537, have you provided a summary of how the product information was changed in relation to thrombosis with thrombocytopenia syndrome, TTS, called by some, VITT. It's very rare; is that what the data showed?
A. Yes.
Q. The summary of product characteristics, SmPC, was changed on 7 April 2021?
A. Yes.
Q. Following that Bank Holiday weekend, in fact. And a description was added to section 4.8 referring to "very rare events of major venous and arterial thrombosis with concurrent thrombocytopenia", noting that "a causal relationship has not been established."
That note was then removed on 15 April and I think

that was the final change made, was it, to the Summary of -- (overspeaking) --
A. Regarding that particular adverse reaction.
Q. TTS, all right. So that gives us a good idea. And that the same approach was applied in relation to any other adverse events suspected, confirmed or just argued to be connected to vaccines, in this list?
A. That's right. So when we read out our US trial, for example, we had a bit more information about the early reactogenicity reactions, and we made adjustments with that information. So you're data driven, and once you have that information, you update it so you've got the best summary in that document and obviously the patient-facing version of that document, so that people fully understand what it is that is associated with this product.
Q. Finally, you've helpfully provided in your statement a number of -- you've identified a number of lessons learnt and made a number of recommendations and I just want to very briefly run through those.
In relation to clinical trials, you refer to the possibility of encouraging the government to ensure that there be trial hubs which can be pandemic-ready to support institutions with recruitment and efficient operation of trials. What did you mean by "trial hubs"?

A. Well, I think what we found in the UK I in Covid was that Professor Pollard, you know, has a lot of colleagues who very rapidly were able to mobilise clinical trial sites that either already existed or they created subsequently new clinical trial sites, trained up investigators that would be appropriate to look after participants of the vaccine. And it's really understanding that you need a sustainable system of clinical trial sites that can pivot towards a pandemic setting, but also more likely in that context, expand so that you would have the capacity, because you're not only doing clinical trials of one vaccine, you know, there were several vaccines that might want to be trialled at any one time, so you've got the best opportunity of getting one that's safe and efficacious, but also, monoclonal antibodies because monoclonal antibodies like Evusheld are critical in the context of having an armoury of products that could be used, because not everyone will respond to a vaccine, and also therapeutics for individuals that are ill with the disease and might actually have less severe disease once ill, with small molecules.

And all of that will require thought, will require planning, and it needs to be sustainable so that you're not suddenly doing it today having not had that capacity

yesterday.

Q. You've spoken about the rolling review of clinical trial data, and of the data supporting the application for authorisation. Was that process, adopted by the regulatory agency to deal with the exigencies of this particular crisis, something you would recommend for future use?

A. That was incredibly important.

Q. And finally, is there anything that you would ask the Inquiry to consider to be done in relation to access to medical health records, electronic data records, and essentially information from the NHS concerning the possibility of adverse events?

A. So post-authorisation, post-approval, the availability of real world evidence is incredibly important. It was incredibly powerful for us, because data coming in February from Scotland, from Public Health Scotland, was incredibly important in confirming how well our vaccine was working, but what we found was that we had to set up our own real-world evidence studies as well as the ones that were being done and, more importantly, is the triangulation of information that already exists. So the triangulation of primary care data, where people may well first present with disease, may have a diagnosis made, with laboratory data, which is often in

a different electronic system, with hospital data.

And it's that if you're going to do really effective post-approval real-world evidence studies, having those three systems that can actually triangulate and be drawn into one source of information that can then be analysed would be incredibly powerful and incredibly helpful.

Q. You've referred to a study. Is this the position: that on 19 February the first set of real-world effectiveness data, the vaccine, was published by Public Health Scotland and a number of Scottish universities, but it was the only one published at that time. What you're calling for is that there be a better regulated and managed system for the provision of that sort of real-world post-authorisation data?

A. But wouldn't it have been amazing if that also had really deep and rich safety data? And we could have had that at the same time.

MR KEITH: Thank you very much, Dr Green. Those are all the questions I ask.

LADY HALLETT: Thank you very much indeed, Dr Green.

Thank you to you and your colleagues for all you did to develop the vaccine. Obviously, there are millions of people around the world who are very grateful to you and your team. And thank you very much for all that you and your colleagues have done to help the Inquiry,

producing the statement and coming on today to help us.

THE WITNESS: Thank you.

LADY HALLETT: Thank you. I hope we haven't denuded AstraZeneca, you seem to have a number of colleagues with you. Thank you very much indeed.

10.30 on Monday, the 27th. Thank you.

(The witness withdrew)

(3.47 pm)

(The hearing adjourned until 10.30 am on Monday 27 January 2025)

I N D E X