Thursday, 30 January 2025

(10.00 am)

LADY HALLETT: Mr Keith.

MR KEITH: My Lady, the first witness today is Professor Sir Nicholas White. Could he be sworn, please.

PROFESSOR SIR NICHOLAS WHITE (sworn)

Questions from LEAD COUNSEL TO THE INQUIRY FOR MODULE 4

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

A. Nicholas John White.

Q. Thank you very much. And thank you for attending today, of course, and thank you also for your provision of your expert report, dated 15 December 2024.

Just in terms of the formalities relating to that report, it is obviously your own work. Were you provided, for the purposes of writing that report, a number of documents, quite a lot of material consisting, in the main, of witness statements submitted to this Inquiry by witnesses as well as some, but not I think all, of the expert reports that the Inquiry had commissioned?

A. I was.

Q. Commencing, please, with your qualifications. You are Professor of Tropical Medicine at Oxford University and at Mahidol University in Bangkok. You have been for

many years a consultant physician at the John Radcliffe Hospital in Oxford, you've chaired for some time the Wellcome South East Asian Research Units. They're in Thailand and Vietnam; is that right?

A. Yes.

Q. And for many years, your specialty, the area of research, has been on infectious diseases, and in particular, the assessment of therapeutic responses?

A. Yes, that's correct.

Q. In the course of the Covid-19 pandemic, were you in fact directly concerned in one of the major trials that was undertaken at that time?

A. Yes.

Q. Was that the COPCOV trial?

A. Yes.

Q. We'll come to that later. And therefore, you were directly concerned with an important piece of pharmacometric assessment?

A. Yes.

Q. You also chair, is this right, the Scientific Advisory Committee of the Drugs for Neglected Diseases Initiative. What is that?

A. It's a non-governmental group based in Geneva, founded with the money from the MSF Nobel Prize, which develops drugs for diseases that predominantly affect

low-resource settings.

Q. Thank you.

Happily for you, Professor, much of your report has been traversed through the evidence that my Lady has already heard in the course of this module, and therefore, by the happy coincidence that you're almost the last witness in this module, much of your report won't need to be re-examined. But I'd like you, please, to start by explaining, in the context of trying to respond to a pathogenic outbreak, a disease, why it's so important to have drugs or therapeutics available, whether -- or whether or not there is a vaccine available?

A. So we need -- in the context of an outbreak or a pandemic, we clearly want to stop people dying and suffering, and the way we do that in the longer term is by developing a vaccine, but that takes time. So in -- before a vaccine is generally available, and for the many people who can't, or some who won't, take that vaccine, we need to have medicines that will both, if possible, prevent and also to treat, with the objective, as I said, of reducing suffering and death.

Q. From your report, it's obvious that there are a number of different types of medicines or therapeutics, from small molecule drugs to what are known as neutralising

monoclonal antibodies.

Is it of benefit, in very general terms, to have as wide a variety of types of drug or medicine as possible?

A. Initially, yes, because we don't know what we are facing. Ultimately, you would like to be able to develop a highly potent, highly cost-effective, safe, well tolerated medicine. But at the beginning you don't, so yes, you need to have a large armamentarium from which to choose your best weapons.

Q. Does the time that is required to identify, develop and make available a drug vary between different types of drug?

A. Yes. It does. It depends on many factors, but yes, it varies.

Q. In the course of responding to the Covid-19 pandemic, it's self-evident that some drugs which were already in production and available, and for which authorisation had been given, were repurposed to face the exigencies of the Covid-19 pandemic. Other drugs had to be made from scratch. Presumably, those repurposed drugs are able to be brought to the marketplace and to be made available much more speedily than new drugs; that's self-evident, isn't it?

A. Yes, that's correct.

Q. And therefore, for the purposes of that latter category,

new drugs, you've got to have up and running, have you not, an efficient, rapid and well-managed process by which those drugs can be identified, trialled, and ultimately authorised?

A. Yes, because the repurposed drugs, in general, will not be as good as the bespoke drugs that you develop specifically for the infection.

Q. Why is that? Is that because if they had been suitable for the particular pathogenic outbreak, they would have been already authorised for that particular purpose?

A. Yes.

Q. And in the course of this pandemic, of course, one of the greater successes was dexamethasone. Was that a repurposed drug?

A. Yes, dexamethasone is a drug -- it's a corticosteroid, a drug that's widely used in medicine, and it was not really expected to be very effective in Covid.

Q. Given that one of the most successful therapeutics was, in fact, a repurposed drug, why is it necessary to still keep on pushing for the identification and production and manufacture of new therapeutics?

A. So the -- so dexamethasone was an anti-inflammatory drug. It's not a drug specifically for infections; it's a drug to stop the harsh effects of infection on the body. But you need specific drugs to treat infections.

We call them antibiotics, antibacterials, antivirals, anti whatever the nasty pathogen is. And those ones you need to develop. If you haven't got one already, we need to develop it specifically. And we did not have any drugs available specifically for coronaviruses.

Q. You say, I won't take you to it, but you say at page 84 of your report:

"The more severe the illness is, the broader the potential use of antiviral medicines."

What did you mean by that?

A. In a potentially lethal pandemic, your objective, primary objective, initially, is to save lives. So anything that works is to be welcomed, but if it doesn't work very well, clearly you're going to have to try to develop something which is more effective. So, initially, we had no idea what would work or what didn't work. The first studies showed that a lot of the things we thought might work, the repurposed drugs, didn't, and then we were very gratified, in fact the most important outcome, I think, of all clinical research in Covid, was the discovery that steroids worked. That was a surprise, but it saved lots and lots of lives.

But then we still had to address the problem of the infection itself. So we had to get drugs that worked to stop that infection that we could use in the community,

we could use to prevent the infection, and we could save lives in hospital.

Q. And was dexamethasone in fact a corticosteroid?

A. Dexamethasone is a potent corticosteroid.

Q. So just on this issue of, in very broad terms, of the benefit of therapeutics, it's important to make sure that you can identify, develop and make available drugs that reduce not just hospitalisation and death at the topper end of the terrible consequences of a pathogenic outbreak, but that you can also develop drugs, and make them available, that reduce the symptoms of the disease and the general levels of illness that they bring about?

A. Yes, in general, yes. So if I may amplify that a little?

Q. Please.

A. We try to develop vaccines to stop people getting ill at all and we try to persuade people -- we provide the evidence that these work. If people do get ill for whatever reason, either they didn't get the vaccine or it didn't work, we still need to treat those people. Ideally, from a public health perspective, we want people to not go to hospital and die. So if we can treat people early in the community, that's better than later on in the hospital, when they may become sick and die. But, of course, you have a trade-off there,

because the -- so that's why we have to identify who needs it most, can we afford to give it to those people? Is it safe and well tolerated, and so on.

So in the end you have to make some choices.

For drugs that are very safe and very well tolerated and very inexpensive and affordable, we deploy them more widely and for drugs which are not so available, more toxic and so on, we are more restricted in who we advise should get them. And we have this debate commonly about antibiotics.

Q. Still on the subject of the potential benefit of therapeutics, the great benefit and the great purpose of the use of dexamethasone was recognised I think in the summer of 2020. Vaccines were not, of course, made available until the winter, until December of 2020, and then January 2021.

But had new therapeutics been identified, trialled and made available, in the summer of 2020, particularly antivirals, would that have had a dramatic impact upon the course of the pandemic and the response, in terms of societal illness and the consequences?

A. I think so.

Q. And is that what the aim has to be in any future --

A. Yes.

Q. -- pandemic: is to make sure that you've got that option

of therapeutics being available, pending the development or, perhaps, in the complete absence of a vaccine?

A. Yes, Covid killed seven million people around the world. That's far too many. We don't want that to happen again.

Q. Turning to the issue of the trial process, we've heard a great deal of evidence about the way in which in particular the phase II clinical trial process operated in the United Kingdom. It is clear from your report that there was a great deal of funding available for clinical trials. We've seen some evidence to suggest that the Clinical Research Network of the National Institute of Health, now the Health and Care Research, NIHR, received, I think, over 1600 applications for trials. 101 of them were badged with urgent public health approval, and there were, I think, over a million participants, is that right, some 1.3 million participants?

So it's obvious that a great deal of attention was paid to the trial process and it was a massive undertaking.

At the same time, Professor, the Inquiry has received some evidence that's quite critical of, in particular, the phase II therapeutic process, from Sir Jeremy Farrar, from Eddie Gray, and

Professor Sir John Bell in particular.

At the heart of any clinical trial process at the phase II stage, are there quite considerable difficulties associated with identifying the standard that must be reached, what that phase II trial is trying to achieve?

A. Yes. So let me say that in the -- overall, if we look at medical research in Covid, the UK was very strong in clinical research. And perhaps the weakest part of that impressive portfolio was phase II. So phase II is that transition, when you've got a drug, a new drug or even an old drug at a different dose, your first attempt to try to see does it work in people or not? And for that, you need a way of measuring that. And unfortunately, we didn't have a good way of measuring it and what people did was a large number of small, and unfortunately inconsequential trials, which could never have answered: did the drug work or not? We needed a better method and that was not developed.

Q. And just pausing there, it's self-evident that the more people you have in a trial, the wider the range of results, of course, and the firmer the conclusions are that can be drawn from it?

A. Yes, this is a very important point. When you have a very large benefit, you do not need many people to be

studied to show that very large benefit. But when you have a relatively small benefit, for example a reduction in the death by 20%, you need very many people to show that with confidence. So yes, large trials. In general, trials are too small. Very seldom are they too big.

Q. We'll come back to the question of why and what can be done about ensuring there aren't so many underpowered, that is to say small, trials next time, in a moment.

I enter into the next topic with some degree of trepidation, Professor, but in the course of phase II trials, there are two particular assessments which are required to be carried out, are there not? One is that of pharmacokinetics, that is to say assessing the concentration in the body over time, of the amount of drug which is left in it, in the body; and secondly, the issue of pharmacometrics, which is trying to assess how quickly the infection in the body resolved by the receipt of the drugs; is that broadly right?

A. Yes, very briefly, pharmacokinetics is what your body does to the drugs, how -- the levels that you get in different parts in the body. Pharmacodynamics is what happens to the infection, in this case, how quickly it goes away, how quickly it is killed, and melding those together is called pharmacometrics. It's rather

complicated terminology but it's the science of trying to understand how much drug do I need to give -- first of all, does it work, how much do I need to give?

Q. And a phase II trial in general terms will only be effective or useful if it can answer those questions?

A. Yes.

Q. Are there standards, technical standards in place, as far as you understand, to ease the path of the scientists and the clinicians and the researchers, in answering those questions?

A. I think this is one of the weakest parts of the drug development. It requires innovation, and, in general, the regulatory authorities who ultimately make the decision whether a drug should be registered or not, are fairly conservative. Both on this side of the Atlantic and on the other side.

Q. So is one of the recommendations that you invite the -- invite my Lady to consider the production or the call for clearer, technical standards, in order that everybody may better assess the worth or the efficacy, the effectiveness, of phase II trials?

A. Yes, standards and methodologies.

Q. That's on the technical side. Then, in terms of the administration of this process, there are obviously, we've heard from the evidence, a number of moving parts,

from the setting up of the trials, the funding of the trials, the regulation and the administration surrounding the trials, and of course recruitment.

Is it your assessment that there needs to be a higher degree of co-ordination on the administrative side? That is to say, a better management of the funding, the setting up, and the oversight of the phase II trial process?

A. In simple terms, yes. We have to have some sympathy at the beginning of this dreadful pandemic for the organisation -- or disorganisation that -- but ultimately, I think, it should have coalesced into something simpler. We had probably too many committees. But yes, overall my short answer is yes.

Q. You're aware that in her July 9 witness statement Professor Charlotte Deane, of UKRI, UK Research and -- innovate, is it?

A. Probably.

Q. The acronyms have finally, on the last day, defeated me. Anyway, UKRI, the very significant funding body.

LADY HALLETT: Research and Innovation?

MR KEITH: Research and Innovation. There we are. Thank you very much.

She has suggested in her witness statement that there should be a UK-wide structure to select potential

interventions to direct resources, and to coordinate with regulators the rapid setting up of trials. Would you agree?

A. In general, yes.

Q. As it happened, there were, though, nevertheless, some extremely impressive and effective phase II trials; is that right?

A. There were some.

Q. There were some?

A. There were some, and there were a lot of ones which were not. And I'm afraid the ones which were not were -- the majority wasted resources and effort.

Q. And so that we can be clear not to damn the very effective phase II trials with that observation, Professor, AGILE is a trial of which we've heard much, at the University of Liverpool --

A. Yes.

Q. -- which is one of the very effective phase II trials?

A. Yes.

Q. ACCORD is another trial which produced very useful and effective results.

If there were a better UK-wide structure for the administration, funding and oversight of, particularly, phase II trials, do you think there would be a need for the amazing proliferation of panels and review groups

that appear to have been in place during the course of the pandemic, such as the UK Covid-19 Therapeutics Advisory Panel, the therapeutic subcommittee of NERVTAG, RAPID-C19, the Neutralising Monoclonal Antibodies Independent Advisory Group and the prophylactic oversight group?

A. Well, the short answer is I think that could have been rationalised, but I understand how it evolved.

Q. Turning to the important issue of diversity, diversity may be measured, of course, in a number of different ways, but perhaps two of the most important ways are ethnicity and age.

How important is it that all clinical trials have a sufficient depth and breadth of diversity?

A. This is a very important point. I think it depends at which stage of the development we are. So it's not necessary at the beginning, in, for example, the pharmacometric studies we've just discussed, to have a range of diversity, because these are small trials. Then, based on prior knowledge and understanding of the drugs, when you go to the larger, the definitive, phase III trials, which are the ones which precede the regulatory approval, at that stage you do need to proactively try to engineer diversity.

But I think there is an important point, if I may

add, and that is that in the context of a rapidly evolving pandemic which is killing lots of people, speed is paramount, and that speed benefits the diverse population. So getting to an answer more quickly is more important than having an engineered diversity which might slow down the recruitment to the trials.

Q. That's very clear. In general terms, but particularly by comparison to vaccines, do therapeutics have the same effect on all aspects or all parts of the population? So are there sectoral or subpopulation groups who may be more aversely affected by the receipt of a therapeutic, or who may not benefit to such a degree as other --

A. Yes.

Q. -- other parts of the population?

A. Yes, there are well described genetic and, therefore, ethnic differences in the way our bodies process drugs. And that we know a fair amount about, but we need to be aware of that with new drugs, and to proactively try to investigate whether there are issues that might result, ultimately, in a different way of dosing, or some people not getting the drug, or not being -- not you recommending against giving the drug to a particular population. So yes. Short answer: yes.

Q. So diversity is vital not just for the purposes of promoting public confidence and reducing hesitancy in

the receipt of therapeutics, but it's directly relevant to both safety and effectiveness?
A. Yes, in general, most -- it's in general not a problem but it can be an important problem and therefore in developing new treatments one has to be aware of it.
Q. I apologise, I forgot to ask you one final question in relation to phase II trials that I want to go back to.

You had mentioned the -- you'd observed that there was, in your opinion, a large number of small or underpowered trials. Do you think that if there is a clearer technical standard, a better understanding of what threshold, in terms of effectiveness and outcome, phase II trials should be required to meet, and better administration of the overarching process, that there would be a reduction in the number of, ultimately, not very helpful underpowered trials?
A. Short answer, yes. But I would like to emphasise that the method of doing the trial is critical. You can be very efficient in figuring out whether something works or doesn't, using a relative -- in a relatively small trial. But that was not the design that was employed in most trials. So it's the way you do the studies as well as the size of the studies.
Q. And if the health authority, the DHSC, or the regulator, the MHRA or its advisers, the CHM, set out more clearly

how the trial should work and what is the ultimate outcome, do you think that problem would dissipate to some extent?
A. I think so. If I may give one specific example.
Q. Please.
A. So with the monoclonal antibodies, there was, as I think you've all heard, some concerns about whether some should have been approved, some shouldn't have been approved and so on. The overall problem was that the decisions on whether to deploy the monoclonal antibodies were based on tests in the lab. Those tests were never calibrated. So a particular value in the lab, it wasn't known what that meant. If the monoclonal was completely useless in the lab, it probably was completely useless in a person. But let's say the measure of how good it was had gone down tenfold, we had no idea what that meant in a person. You need to calibrate these things.
Q. Was there another, additional difficulty, which was that for many of the trials, the in vitro work was going on at a time, well, further towards the beginning of the pandemic, but by the time that certain drugs were authorised and then being utilised in the community, the context had changed violently, both by way of the success of the vaccine programme, but also because there were variants circulating against which the drug might

actually prove to be less effective?
A. Yes. So as we all know, the pandemic changed dramatically over a few years. So, at the beginning, there were no drugs, nothing worked, and we had no vaccine, and there were a lot of deaths. But very quickly the vaccine substantially exceeded our expectations. I mean, WHO would have taken a 30% protective vaccine. We got much better vaccines than that. And that took the pressure off developing the drugs.
Q. It's well established that there are two particular cohorts, children and pregnant women, who are, by and large -- well, they're often excluded from clinical trials because investigators assess that it's simply not worth the risk, you don't know what the consequences might be of trialling unknown therapeutics on children and pregnant women. There is always the possibility, perhaps the probability, that the next pandemic, particularly if it's a flu pandemic, may hit children more, or worse. How do we resolve that conundrum, which is that children, having been by and large excluded from trials may nevertheless be the people to whom those trials will most benefit? Or are required to benefit, I should say.
A. Yes, this is a very, very important point and it is

a dilemma. But in general, and I'll be very general, I think everyone, including the regulatory authorities, now accepts that we should much earlier, in the course of developing new therapies, evaluate them in children and have a plan for evaluating them in pregnant women, if that is the appropriate thing to do.

So whilst I can't resolve the dilemma, I can just say that everyone accepts that it is a dilemma and we need to move more quickly into these two very large and very critical subgroups of people who may disproportionately benefit.
Q. Standing back, as you were asked to do in your report, and looking in an overall sense at the regulatory process that applied to the development and authorisation of therapeutics in the United Kingdom, is it your view that in terms of output, and you refer particularly to the PRINCIPLE, RECOVERY, and PANORAMIC trials, the regulatory system worked well? It produced -- it allowed the production of properly regulated and safe therapeutics?
A. Yes.
Q. Do you have a view as to whether or not in that difficult balance between imposing regulatory requirements, perhaps a certain degree of administrative bureaucracy, and speed of output, that the system worked

well enough?
A. Reasonably well.
Q. Professor, I detect a certain reticence on your part in answering that question. Do you -- and the solution has presented itself, it may be thought, but do you say in your report, that there was at least the impression that there was quite a significant degree of bureaucracy in the process, and the process was generally becoming quite a burdensome one in terms of the regulation of trials, but that, as it happened, since the pandemic, the legislative process for regulating clinical trials has been significantly amended by the introduction of new legislation, in fact in December of last year?
A. Yes, and I hope that that does facilitate the development of new medicines and vaccines.
Q. Can we now turn, please, to the issue of Evusheld, which was, as we all now know, a monoclonal antibody, which was authorised but which was never bought by way of advance purchase and ultimately was not made generally available for use, it simply wasn't -- a decision was taken that it wouldn't be made available.

I'm not going to ask you any questions about the first stage of the process, that's to say the decision making around the lack of an advanced purchase in 2020, but I wanted to ask you, please, about the process that

was applied towards the end of 2021, and into 2022, when there was a reassessment of whether or not it should be made available.

In very general terms, a recommendation was made by, in particular, the Office of the Chief Medical Officer in the form of the Deputy Chief Medical Officer, Professor Jonathan Van-Tam, that the Evusheld therapeutic was required to be put through its paces in terms of an assessment by what was called the RAPID-C19 Committee. There was a debate as to whether or not it should be assessed by another process called the PROTECT-V process, and ultimately, it was assessed by a body -- a process operated by NICE, the National Institute for Clinical Excellence.

It appears that all that took quite a long time, and by comparison to the assessment of the effectiveness of vaccines and other therapeutic drugs, it appears to have become somewhat bogged down.

Why do you think that was?
A. I agree, it was rather slow in comparison to other decision-making processes. I think the problem was, and I think some of the -- this has been highlighted in some of the reports -- was that there wasn't a way of extrapolating from the lab tests to the clinical use, as I just described. So it's a monoclonal -- so, actually,

two monoclonal antibodies, and it was clear that as the virus was evolving, the lab tests were showing that the monoclonal antibodies were not as good as they had been before. But what did that mean in people? Nobody knew. And that uncertainty pervaded the decision-making process.
Q. So, coming back to the point you made earlier, was there a heightened requirement, something that wasn't in fact done, for there to be greater pharmacometric testing on the effectiveness of that combined monoclonal antibody?
A. Yes, and that was recognised by the panel. But none was commissioned or recommended.
Q. Why do you think a decision was taken not to make it available --
A. I think --
Q. -- without those clinical tests, the pharmacometric tests, having been done?
A. I assume that the panel or panels made a decision that these laboratory tests created sufficient uncertainty as to the value of the monoclonal antibodies that it wasn't worth deploying it, I guess.
Q. Might an alternative or perhaps better outcome, have been to say: well, we won't make a decision about whether it should be made available until those pharmacometric tests have been done, so that we can have

a better understanding of the effectiveness of Evusheld?
A. Yes.
Q. All right. And are you, insofar as one is ever critical in this scientific field, are you critical of that process in your report?
A. Yes.
Q. By the time that decisions had to be taken as to whether or not Evusheld should be put through the RAPID-C19 process and ultimately the NICE process and a decision taken on benefit, had, as you were saying earlier, the context changed radically? So we're talking now about the beginning of 2022. What had changed in terms of the use of a moderately effective therapeutic?
A. Well, everything was getting better. The vaccines were much better than we thought, people were acquiring natural immunity, and we saw the arrival, now, of bespoke, specific small molecule drugs, notably molnupiravir and then Paxlovid, so the need for other interventions was diminishing.

However, had they been very, very good, I think -- as always, it's a balance between costs and risks and benefits and deployability.
Q. Do we take it that if there had been those technical standards in play, of which you spoke earlier, if there had been a greater focus on pharmacometric testing, and

if, as you say, speed and rapidity of outcome has to sometimes outweigh competing considerations, do you think, if all that had been done, as you suggested should generally be done, Evusheld -- the outcome of Evusheld might have been different?

A. It might have been different.

Q. And, of course, Evusheld is a therapeutic which could have been of great assistance to, in particular, the immunosuppressed?

A. Yes, but we also have to acknowledge that that information, that calibration, still hasn't been done, but it is beginning diminished -- well, pretty confident it wouldn't work now. But was there a window of opportunity for Evusheld? Possibly.

LADY HALLETT: Mr Keith phrased his question in a particular way. Isn't it speculation to say it might -- I mean, I appreciate it's conditional, "might have", but because it's not been done it's speculation, isn't it?

A. Yes.

MR KEITH: I think, to be fair, I've put it on the basis that we're concerned here with the processes and the systems. It's important to recognise that you've got to have a better system in place and -- regardless of what the outcome might have been in an individual case.

That, then, brings us on to the last specific

discrete issue, which is hydroxychloroquine.

Hydroxychloroquine was, I believe, a therapeutic which was licensed, already licensed, for some conditions; is that right?

A. Yes, its older brother, chloroquine, was developed in 1945 and actually became the drug to which human beings have most been exposed, 300 metric tonnes were used every year to treat malaria, and then in the 1950s, but more in the 1960s, it became clear that chloroquine or hydroxychloroquine could be used in rheumatological conditions like rheumatoid arthritis.

Q. The issue of whether hydroxychloroquine should be authorised by way of repurposed use for Covid and whether it was beneficial at all, became highly polarised, did not --

A. Yes.

Q. -- in the public domain? Why did that particular therapeutic, Professor, become so viciously polarised?

A. There was a subsequently retracted claim from a very prominent French, previously very eminent researcher claiming that it works in a very small trial. This was endorsed by heads of state on both sides of the Atlantic. This then made it politically polarised, and the scientific community became, I think, affected by this.

Q. The study, which raised the issue of whether or not hydroxychloroquine in fact would harm recipients or patients, was published in an article. Was that article subsequently retracted when concerns came to light concerning the accuracy of the study?

A. Yes. If I may, just a little bit -- so these drugs are very safe if you use them at the right doses, but they are dangerous if you use them at the wrong doses. So -- and we knew that because this extensive experience both in malaria and in rheumatological conditions.

But then suddenly, in May of 2020, this report appearing in The Lancet claiming that, actually, hydroxychloroquine killed people, and made the heart go too fast, and that people died. But it very -- well, over 48 hours we investigated this and realised that this study could not have taken place as it had been described, and ultimately it turns out that the data have never been provided. They couldn't have been provided. And the editor of the Lancet himself declared that they'd been fabricated. But the damage was substantial.

Q. As a result of the publication, the MHRA, the UK regulator, got in touch with the investigators of I think the eight trials that were then going on concerning hydroxychloroquine, and posed questions of

them as to what the meaning of the study was, of course, and no doubt asked for data. Did there come a time when, as a result of the article, recruitment in the majority, the vast majority, of those trials was suspended and of course the process came to a juddering halt?

A. Yes. So regulatory authorities across the world acted in a similar way. In the UK, the RECOVERY trial was nearing the end of its enrollment with hydroxychloroquine and got a special dispensation from the MHRA. All other trials were stopped immediately. And then it took some time for them to restart and by that time the wave of cases had declined so recruitment became difficult, and also the adverse publicity lingered. So many of the trials never restarted.

Q. One of the trials, and you referred to it earlier, did restart, the COPCOV trial. That was the trial with which you were directly associated, were you not?

A. Yes.

Q. But ultimately, on 5 June, the Commission on Human Medicines was in fact in session. It was informed through a press release from the RECOVERY trial that the RECOVERY trial itself had been stopped by its own investigators. Was that because -- it had nothing to do with any suggestion of harm, it just appeared that the

data was beginning to indicate that the clinical benefit was less than perhaps had been hoped, and therefore was insufficient to justify the continuation of the trials?

A. Yes, it's an important point that RECOVERY was a trial in severe disease, COPCOV was a prevention trial. So you have prevention, you have treatment of mild disease, and treatment of severe disease, and it's not -- you shouldn't extrapolate necessarily from one to the other. But the reason the RECOVERY trial stopped was it was quite clear that hydroxychloroquine was not beneficial in the treatment of hospitalised patients.

Q. But it might have been or could have been beneficial in the context of addressing symptoms and allowing people, perhaps, to return home or to recover more quickly in the community.

A. That would be speculation.

Q. But we'll never know?

A. We'll never know. But just to say that it's much easier to prevent a disease than it is to treat it. So drugs which are quite weak in treatment can still be useful in prevention.

Q. And is it for all those reasons, the story of the suspension of the trials in hydroxychloroquine and the retraction of, or at least the difficulty in pursuing the trials at the time that the article was published,

lead you to one of your recommendations, which is that in quite a general sense, it's vital, in the context of therapeutic clinical trials, to protect the system, to protect that process from political or press speculation, and to allow the professionals, the scientists, the clinicians, the investigators, to go about their work uninterrupted or un -- (inaudible).

A. Yes.

LADY HALLETT: I'm not quite clear how one could do that without impinging on the freedom of expression. How could one protect the system from media believing it's a legitimate interest upon which, a public interest upon which they want to comment? And politicians the same. How would one protect the system?

A. I think the -- with a clinical trial, it's -- there are various ways in which a clinical trial can be obstructed or facilitated. So clearly a clinical trial involves recruitment of people, and it's really important that people have a fair chance to understand why -- to give fully informed consent, as we say. So of course we can't protect people from learning all sorts of things, but what we should do is try to discourage politicians, journalists, from making claims which are not true, and which might influence people adversely. I mean, it's of great contemporary interest across society at the

moment.

So I think that's the protection: the protection to maintain honesty and to try to facilitate the understanding of the science by the public.

And then the other thing which -- the other organisations which bent under political pressure were the regulatory authorities themselves. And that shouldn't happen. I mean, the regulatory authorities should be absolutely independent, and they should not be pressurised, as they were, for example, across the Atlantic. The US FDA was definitely pressurised by government and that should not be allowed to happen. I think that is something you can enforce.

But I agree with you, you know, people -- you can't protect people from -- well, in a free society, you can't protect people from access to information. But what you can try to do is ensure that lies are not told.

MR KEITH: That brings us quite neatly back to the phase II trial process to which you were speaking earlier, and the final remaining problem that arose in the course of the pandemic, which was, in a general sense, recruitment. And you've referred to the problems of recruitment.

Although, overall, there were a very large number of people who were recruited, and you've told us there were

over a million people, a problem arose particularly towards the end of 2020 with reaching the right levels of recruitment for particular trials. There were trials going on and they were coming to a halt because they just couldn't recruit enough people.

In the context of vaccines, there was a vaccine registration system which allowed members of the public to sign up to trials for vaccines. Do you think more needs to be done in terms of encouraging recruitment in the context of clinical therapeutic trials and/or for setting up of a more formal system for recruitment through registration?

A. Yes, I think that can be done. It was done, to a certain extent. The particularly favoured trials, particularly, for example, PANORAMIC and PRINCIPLE trials, had extensive support via the National Health Service to encourage recruitment, and I think that could be -- that process can certainly be strengthened.

Q. And so turning, then, to your conclusions and your recommendations, we've covered many of them in the course of your evidence, but, to summarise, you would endorse the strong rationale for having a -- as effective and as rapid a process of development for non-vaccines prophylactics and therapeutics, you would endorse the need for a better co-ordination, both by way

of technical standards and administratively, of, in particular, phase II clinical trials?

Thirdly, you make a broad appeal for better pharmacometric analysis to be carried out in the course of, particularly, phase II trials, so as to avoid the sorts of problems that arose in relation to Evusheld?

A. If I may interrupt?

Q. Yes, please.

A. Specifically to calibrate laboratory tests which are used to inform decision making.

Q. Thank you.

And finally this: the Inquiry is well aware that under the 2011 government pandemic strategy, we stockpiled large numbers of therapeutics -- a large number of a therapeutic, I think Tamiflu, to cater for the possibility that the next pandemic would be a flu one. Of course it was a gamble that failed to come off.

There is obviously a very high level of risk in terms of stockpiling for Disease X or the pandemic. You just don't know which one it's going to be. But is there nevertheless a huge importance in stockpiling something to cover a range of pathogenic outbreaks, just to be able to try to reduce, at the outer edges, the worst impacts of it?

A. Yes, and I think we are reasonably confident what the

next pandemic will be. It will be influenza. It was for every decade except the last one. And I think we're all rightly concerned today about the potential for a devastating or at least a bad flu pandemic, and were avian influenza to become readily transmissible we'd be in very, very serious trouble. So whereas I don't think we need to stockpile drugs for Ebola or Marburg or Lassa fever or exotic viruses, the one that is most likely to come is influenza, and we do know that coronaviruseses may come as well, so those are two virus groups where I think it would be wise, I think, to have a stockpile. Indeed, the country does have a stockpile, I understand, for influenza. And that's a wise decision.

What we don't have is information about what to stockpile, for the reasons we've just discussed at length.

Q. But some therapeutics will have some effect or likely to have some effect, by way of a repurposed use, and therefore it's essential to have something there to at least help ease the passage of the response to the next pathogenic outbreak?

A. Yes, for those two specific viruses, influenza viruses and coronavirus, yes, we have drugs which should work.

MR KEITH: Thank you very much.

LADY HALLETT: Thank you very much, Mr Keith.

Mr Wagner. Mr Wagner is over there.

Questions from MR WAGNER

MR WAGNER: Good morning, Professor White. My name is Adam Wagner and I act on behalf of Clinically Vulnerable Families, who represent the clinically vulnerable, the clinically extremely vulnerable, and the immunosuppressed.

I've just got one area to ask you about, and it relates to the different kind of drugs that were trialled during the pandemic and the resources that were allocated respectively to the different trials.

So, at paragraphs 5.26 to 5.29 in your reports, you discuss the large-scale trials, for example, PRINCIPLE, that were established to evaluate the efficacy of repurposed drugs in the treatment of Covid-19, and you say that PRINCIPLE eventually published results for six candidate drugs but five of these showed no benefits in terms of reducing the risk of hospitalisation and death.

Then you say, at 5.39 -- you refer to the efficacy of specific antivirals, so specifically designed antivirals, molnupiravir and Paxlovid, that were ultimately procured for the treatment of early Covid-19 disease.

So my two questions are these: first of all, in light of those results, do you think that an appropriate

balance was struck in terms of resources and time that were being allocated to the evaluation of repurposed drugs in comparison to the resources and time allocated to the development of direct acting antivirals for the treatment of Covid-19?

A. In brief, overall, yes. Because we -- you have to think at the beginning we had nothing, and then we had something. So initially, when we have nothing, we look for the most promising of potential repurposed drugs with a low expectation that they will be successful. But then, as the specific, if you like, bespoke antivirals develop, these have a high prospect of being successful. And so resources then shift towards the evaluation of those.

But overall my answer to your question is yes, I think the balance was approximately -- was, in my opinion, reasonable.

Q. And having had that experience of the Covid-19 pandemic and the success and failure of various developed drugs, do you think there are any lessons to be learned for the future in terms of that respective attention and resources? In other words, do you think that is precisely the model that will always be seen, at the beginning you forecast on one thing and then you move on to another, or are there other lessons we can learn

about different models of resource allocation to try to get better, more, and faster drugs available?

A. Well, I think we've already discussed that to some extent. The idea that you have a reasonable predictive -- a reasonable prediction about what's coming, what might come, and therefore the probabilities of these things happening, and then you have things in-house that you think should work against those particular organisms.

Now, you might need to modify those. So, initially, you would repurpose or use the things that you already have, but then you would try to improve them. This is what the pharmaceutical industry does all the time. It takes a drug that works reasonably well and tries to make it better. So that process, I think, does work reasonably well.

MR WAGNER: Thank you.

LADY HALLETT: Thank you, Mr Wagner.

And Mr Thomas who is just there, you'll see him when he stands up.

Questions from PROFESSOR THOMAS KC

PROFESSOR THOMAS: Good morning, Professor White, my name is Leslie Thomas and I'm representing FEMHO, the Federation of Ethnic Minority Healthcare Organisations.

Professor White, in your report at paragraph 8.3,

you state that as part of your recommendations:

"An open forum for exchange of information in the relevant scientific community should be created with clear and capable leadership."

Question. From the perspective of securing proportional representation, would you see benefit in this sort of open forum, including medical experts or healthcare leads from ethnic minority communities who can speak directly to ethnic minority interests?

A. Yes and no. So it depends entirely on the experience, capability, qualifications of those individuals. I really think it's important to have ethnic minority representation in some form, but it might be better to have that in terms of community representation. For example, often the problem isn't so much of biology but it's of access or behaviour, and these people understand that better. So whether it's critical to have medical experts represented, I'm not so sure, but I do think representation is important in the way that is most effective, which perhaps you would guide.

Q. Thank you. Can I move on to my second question. You talk positively in your report about the success of the RECOVERY trial. For example, at paragraph 5.69 of your report you talk about the proportional representation by ethnicity that that trial was able to recruit.

Specifically, you, say:

"With regard to the UK's Covid-19 therapeutics trials, although not perfectly matched to the population, the representation was generally better than many other trials. Whilst the RECOVERY trial did not report a detailed breakdown of ethnicities, the proportion of its participants who were non-white was similar to the UK population in the 2021 census, reflecting broad recruitment across many different hospitals."

My question is this, how might lessons from the RECOVERY trial be applied globally to standardise proportional representation in rapid clinical trials?

A. It's a very good question, and I think the UK is better placed, perhaps, than most to respond to that appropriately. So by simply spreading the net very wide, one got the -- or the RECOVERY trial got a reasonable representation of the community at large. I think in other countries it is more difficult.

It is an important point, but I'd just like to reiterate a point I made earlier: what really matters is speed, because everyone will benefit if we get an answer more quickly. And if there are underrepresented groups in the trial, then after getting the result, then you can then address that, whereas slowing a trial down in

order to engineer representativeness may be to everyone's disadvantage.

So I think it's a very important point, and I think the NHS was particularly well suited to engineering this, and -- but I do think that speed is of paramount importance in an epidemic or a pandemic.

PROFESSOR THOMAS: Thank you, Professor White.

Thank you, my Lady.

LADY HALLETT: Thank you, Mr Thomas.

That completes the questions we have for you, Professor, thank you so much.

Have you flown in from Thailand especially for us?

THE WITNESS: Yes.

LADY HALLETT: Thank you very much for going to that amount of effort. As you appreciate, there's an awful lot in your report that we haven't been through today but I will make sure that I am completely on top, with the assistance of my team, of all the matters there, and your report has helped inform our investigation and our questioning of others witnesses.

So thank you very much indeed for your help.

THE WITNESS: Thank you, my Lady.

MR KEITH: My Lady, may I just make plain, before I get a phone call from His Majesty's Treasury, that Professor White flew into Europe in part to attend this

Inquiry, but also for other professional purposes.

(The witness withdrew)

LADY HALLETT: Thank you very much. I shall return at 11.20.

(11.01 am)

(A short break)

(11.20 am)

LADY HALLETT: Ms Williams.

MS WILLLIAMS: My Lady, the next witness is Helen Knight. Please could she be sworn.

MS HELEN KNIGHT (sworn)

Questions from COUNSEL TO THE INQUIRY

MS WILLLIAMS: Thank you for coming today and assisting the Inquiry. You have provided a witness statement dated 18 November 2024 on behalf of the National Institute for Health and Care Excellence, also known as NICE. And the INQ for that is 000474611. Are the contents of that statement true to the best of your knowledge and belief?

A. Yes, they are.

Q. Thank you. Just, first, touching briefly on your professional background, you are currently the Director of Medicines Evaluation at the Centre for Health Technology Evaluation at NICE?

A. Yes, correct.

Q. And during the pandemic you were also -- you were

Programme Director for Health Technologies at the start?

A. Yes.

Q. And then Deputy Director, and then Acting Director?

A. Correct.

Q. In terms of the centre, is it its role to undertake health technology evaluations?

A. It is, yes.

Q. Could you please explain, just in brief terms, what a health technology evaluation or appraisal actually is.

A. So at NICE we conduct independent and evidence-based guidance to the NHS on treatment of new medicines and health technologies, and we make that assessment on a review of the clinical effectiveness and the cost effectiveness to provide guidance to the NHS.

Q. Thank you. I think it's right to say there are different forms of these evaluations, but during the relevant period for this module, the majority of the evaluations for non-Covid treatments followed the single technology appraisal process; is that right?

A. Yes, that's right. So for medicines, yes, the majority of the work was single technology appraisals.

Q. Does a standard one of these appraisals usually take about 44 weeks?

A. So that's an average. It varies, sometimes between 39 and 60 weeks, but yeah, on average, 45-50 weeks.

Q. So, early on in the pandemic, was it recognised that there was a need to adapt NICE's usual ways of working to provide access to treatments for Covid patients as quickly as possible?

A. Yes, that's right. Yeah.

Q. And ultimately that's what led to the establishment of RAPID-C19?

A. Yes.

Q. I should say that stands for research to access pathway for investigational drugs for COVID-19.

Ms Knight, the focus of your evidence today is going to be on RAPID-C19's consideration of the prophylactic drug Evusheld, but before that, I'd like to ask you just a few questions about the work of RAPID-C19 more broadly.

So RAPID-C19 was established in April 2020.

A. Yes.

Q. And was it stood down at the end of March 2023?

A. Yes, that's right.

Q. It was a multi-agency initiative involving, in particular, NHSE, MHRA, NIHR and NICE. And is it right to say its focus was on access to therapeutics within England because it's a devolved activity?

A. Yes, that's right.

Q. But representatives from the devolved nations

participated in the initiative and attended meetings?

A. Yeah.

Q. RAPID-C19's role was to identify and monitor the development of potential therapeutics, and then assess their clinical effectiveness in order to facilitate rapid access; is that correct?

A. That's correct, yeah.

Q. Was this primarily through clinical trial evidence?

A. Yes, that's right.

Q. And did RAPID-C19 initiate, approve, conduct any trials itself?

A. No, we weren't responsible for, kind of, research initiatives or commissioning any research studies.

Q. And is it right to say that unlike the usual technology appraisal process, the RAPID-C19 process didn't consider cost effectiveness?

A. Correct. No consideration of cost effectiveness.

Q. Could you just explain why that approach was taken?

A. Yeah, I mean, the initiative was set up as part of the temporary emergency circumstances of the time, and the focus was very much around identifying medicines for Covid that had, you know, a signal that they would be clinically effective and therefore important to roll out rapidly in the NHS once we were confident that they would work.

Q. Thank you. You've set out in your statement how RAPID-C19 went about its work. I'm not going to go through this in detail but if I could just summarise in very broad terms. First, potential therapeutics were identified through horizon scanning of clinical trials, and then ranked against various criteria to, kind of, prioritise them for consideration?
A. Yeah, that's right.
Q. And then topic briefings were produced and kept up to date with emerging evidence?
A. Yes.
Q. And was there an oversight group that then met to review these topic briefings and consider the therapeutics?
A. Yes, we did, yeah.
Q. Were the senior members of that group the same -- representatives from the same organisations we've touched upon, so NHSE, NICE, MHRA, NIHR?
A. Yes, that's correct.
Q. A long list. And were you one of the representatives for NICE?
A. I was, yeah.
Q. So is it right to say that the Oversight Group would meet and then decide (a) whether to recommend access, (b) whether to continue monitoring the drug, or (c) whether to deprioritise?

A. Yeah, so in particular on the recommendation, it was where we felt that we had seen or we could be confident that the medicine looked to work, and therefore, we would provide that signal to the Chief Medical Officer for England, and the Department of Health, to be considered for rollout into the NHS.
Q. And you'd do that by producing a report, a written report with an opinion for the Chief Medical Officer, and DHSC.
A. That's right.
Q. But ultimately, it was for DHSC to decide whether to actually go ahead and provide access to the drug?
A. Correct.
Q. Just turning now to the therapeutics that were recommended for rapid access, I think -- is it right to say that at the end of October 2022, the initiative had resulted in over 200,000 patients receiving treatments?
A. Yes.
Q. Did RAPID-C19 contribute to access to both repurposed and also new drugs?
A. Yes, it did.
Q. I think there are ten set out in your statement. I'm not going to list them all but did they include remdesivir, dexamethasone, sotrovimab, molnupiravir, and Paxlovid?

A. Yes.
Q. And in your statement you helpfully set out some tables which show the timescales for access to these drugs. We don't need to bring them up now, but is it right to say for repurposed drugs the majority of them were made available within a few days of the trial results -- RAPID-C19 becoming aware of the trial results?
A. Yeah, that's right.
Q. And, in fact, for dexamethasone it was on the same day as the trial results?
A. It was on the day that the trial results were published so we were able to -- patients in the NHS were able to access it on the same day.
Q. And in terms of new drugs which, of course, need a marketing authorisation, is it right to say that generally access was made to those within two to six weeks from authorisation?
A. Yes, that's right.
Q. So I think it's fair to say that both repurposed and new drugs were made available through the initiative much quicker than would have been the case through NICE's usual processes?
A. Yes.
Q. Ms Knight, in your view, what were the principal factors that contributed to RAPID-C19 being able to achieve

this?
A. I think it was key to have the right representation within the groups. There is, as you identified, four key organisations that all are experienced in reviewing clinical effectiveness data, clinical trial data, but brought slightly different perspectives from the organisation. We were, when we met regularly, every week, we were able to have an open discussion, transparent discussions, to make sure that we could make, you know, the best quality review of the data and support rapid access where it was, you know, where a medicine was shown to be effective.
Q. And I think one of the other things you say in your statement is that the horizon scanning of the trials worked particularly well; is that right?
A. Yeah, so it was a comprehensive undertaking from the team to actually monitor all of the ongoing trials for Covid medicines. And that wasn't just UK trials; it was worldwide. So that was a significant level of activity that was done on a daily basis.
Q. Thank you.
I'd like to turn now to Evusheld, because that was one of the drugs that was not made available through the initiative.
A. Yeah.

Q. So the Inquiry has heard a considerable amount of evidence about this prophylactic drug, and in particular the Vaccine Taskforce's early work and the ministerial decision not to proceed with it at that stage. Was RAPID-C19 involved at that moment?
A. We weren't involved in those early stage discussions, so we first became aware of Evusheld from February 2021.
Q. And that's when you first started to consider it?
A. Yeah, that's right.
Q. And how did that come about, in February 2021?
A. So my recollection was that this came via the ATTF at the Department of Health, so we were -- it was signalled that there was a conversation with the company AstraZeneca, and that's when -- we had already identified it, but we brought that discussion -- within RAPID-C19 we brought that forward and had the first discussion in February.
Q. And its focus on Evusheld was as a pre-exposure prophylactic?
A. So it was being trialled for several different uses, but the key focus at RAPID-C19 or the majority of the discussion was around the pre-exposure prophylaxis.
Q. And of course, as the Inquiry has heard, the significance of this is that that could benefit those who might not be protected by a vaccine?

A. Yeah.
Q. So just looking at the period between February 2021 and November 2021, RAPID-C19 essentially at this stage were just noting the ongoing trials and monitoring them for any key results?
A. Yeah, that's right.
Q. And then it was in December 2021 that there was trial evidence which first suggested it might be effective?
A. Yeah.
Q. So if we could just turn to the report in December 2021, then.

And that's INQ000479901. Thank you. We're on the right page already, page 12.

We can see there that's the report to the CMO dated 23 December 2021. We've got the various names for Evusheld. We can see the senior RAPID-C19 members, and it includes -- there's expert advice from the Prophylaxis Oversight Group. We'll come back to that group in a moment. We can see then it's -- RAPID-C19 is reviewing the trial results from PROVENT.

And if we could go straight to the recommendation at page 16, please.

So we can see there on the second bullet point it says:

"[Evusheld] is the first medicine to show robust

benefit in pre-exposure prophylaxis."

And then moving down, please, there's "some unanswered questions" about the results, and we can see, in the middle of that, it says:

"The ... Prophylaxis Oversight Group noted that there is a risk associated with introducing a partially or minimally effective therapy and do not currently recommend routine use of this treatment until more data on efficacy against Omicron are available."

And then at the bottom:

"Overall ..."

There's a reference there to:

"... strong signal of efficacy that warrants action to prepare for ... access subject to:

"[First] marketing authorisation being granted, and

"[Second] confirmation of continued activity against Omicron ..."

A. Mm.
Q. That can come down for now, thank you.

So, at this stage, the main concern was whether Evusheld was effective against the Omicron variant?
A. Yes, that's right.
Q. And was this is an issue that not only affected Evusheld but actually other types of neutralising antibodies?
A. Yeah, that's right.

Q. I think in fact you say in your statement that changes in effectiveness due to the variants was one of the key challenges for your work?
A. Yeah, it was.
Q. Could you just explain what the implication was for this in respect of clinical trial evidence?
A. Yes, so the key challenge really was, although the trial data would show there are clinical -- there's clinical effectiveness in terms of protection, what we couldn't be sure of is if that same level of protection would be seen in clinical practice when different variants were circulating, in clinical practice, versus the variants that were circulating during the trial period.
Q. So essentially you couldn't be sure it was effective at the time you were actually looking at considering access based on what might have been outdated trial results?
A. Yes, that's right.
Q. Was there a difficulty with getting update clinical trial evidence?
A. Yeah, I think we recognised that, kind of, repeating those clinical trials would be a challenge, particularly with the way that the virus was changing, that we would be presented with that problem moving forward.
Q. I think one of the other things you say is that there was little appetite from commercial sponsors to

undertake further trials?
A. Yes, that's right.
Q. So then were in vitro -- and when I say in vitro, I mean lab-based studies -- were they the quickest way of trying to assess any ongoing activity against the variants?
A. Yes, so obviously -- and you've referred to it -- we invite the Prophylaxis Oversight Group experts to come because we recognised within RAPID-C19, which was set up to assess clinical effectiveness data, we didn't have the necessary expertise, and with the neutralising monoclonal antibodies it became clear that, actually, in vitro data was going to be an important consideration for these products.
Q. Just in relation to the lab-based studies, you obviously said that RAPID-C19 didn't have the necessary expertise. Is it right that another issue with these studies is that they were quite difficult to interpret and to extrapolate from the lab tests to clinical effectiveness?
A. Yeah, what we heard at the time is that there were no real standard methods for assessing the quality of the in vitro studies and the results of those in vitro studies, and we didn't have any scientific consensus on how in vitro results could actually be interpreted into

clinical effectiveness outcomes.
Q. Thank you. Just moving on, then, to May 2022. I think there was an Oversight Group meeting on 18 May, and that resulted in another report to the CMO --
A. Yes.
Q. -- on 30 May 2022.

Could we have back up that same document, please, and this time turning to page 8. Thank you.

So is it right to say that at this point Conditional Marketing Authorisation has been granted, and you now have the in vitro data from UKHSA, and also from Oxford University, but I think the focus was on the UKHSA data.
A. Yeah, that's right.
Q. Turning then to page 10, which is where the recommendation is set out. Thank you.

At the second bullet point, it says:

"RAPID-C19 does not consider that the available non-clinical data supports ... clinical effectiveness ..."

It refers to difficulties interpreting the data, and I think that's the point we were just discussing.
A. Yeah.
Q. And then if we go down to the last bullet point, for now, on this page, essentially because of the difficulties, is it right to say that there was no

certainty that Evusheld would work, and there was a particular concern about the population that might get Evusheld in terms of their vulnerabilities?
A. Yeah, that's --
Q. You can just see at the bottom it says:

"... the risks of proceeding to ... access are considered to outweigh the risks of not providing the treatment ..."
A. Yeah.
Q. Could you just explain that a little more?
A. Yeah, of course. I mean, we were very aware that we were discussing a prophylactic medicine for patients who had a high unmet need, but were also very clinically vulnerable and shielding at the time. And so we felt, you know, these were people that weren't infected with the virus and therefore, you know, we wanted to make sure that we had a high confidence that the treatment would protect this clinically vulnerable group because, you know, we wanted to be confident that that protection would continue and we didn't see the evidence to say that it would.
Q. Thank you. And just staying on this page, moving up slightly, it's recognised it is:

"Not feasible to obtain clinical effectiveness data ... There is a need to understand how non-clinical trial

data [so that's the lab tests] could be used to support decision making on clinical effectiveness," in the face of the variants essentially.

And then it also says it's going to be an ongoing issue for these types of drugs.

Then if we could turn over to the next page, at the top we've got the ultimate recommendation which is not to proceed. But under the "proposed actions" in the final bullet point:

"RAPID-C19 will contribute as needed to system-wide work to consider what evidence is required to be confident ... The Antivirals and Therapeutics Taskforce will be taking this work forward."

Thank you. That can come down now, thank you.

What type of work is being referred to there?
A. So what we were trying to understand was, you know, exactly we what we'd said about creating, you know, standardised methods for actually understanding the quality of in vitro studies and therefore the results that you can take from them, and more importantly, how can you then translate in vitro results to the clinical effectiveness of a medicine? So they were the particular areas that we were wanting to be explored.
Q. I think you will have seen in his report, and probably heard this morning, as well, Professor White raises the

issue of pharmacometrics, and I think he explained this morning, that's the combination -- forgive the technical detail -- of both pharmacokinetics and pharmacodynamics. His view is that this type of data may have answered any unresolved questions about Evusheld's efficacy.

Did RAPID-C19 consider getting this type of data?

A. So during the discussions at RAPID-C19, and again, you know, acknowledging we, around the table, weren't experts in that field, we had the Prophylaxis Oversight Group come to help us, the term "pharmacometrics" was never raised or discussed. We talked about the neutralising effect that you can get from in vitro studies, and we referenced more PK/PD analysis but pharmacometrics studies was not something that was ever raised or discussed.

I don't know that that would actually answer the key question that we were looking at, which was how can you translate in vitro data into clinical outcomes? I'm not sure that pharmacometrics studies would actually answer that question.

Q. Thank you. In terms of the work that was discussed, are you aware whether the Antivirals and Therapeutics Taskforce took this forward?

A. So NICE was invite to a roundtable in September of 2022 to start some discussions. There was a brief follow-up

meeting but I'm not aware of anything further that happened.

Q. Just pausing there for a moment because I think we're going to come on to the final report in the chapter, which is in August 2022, but between May and August, were you asked to contribute to any further work on this?

A. So we were aware of the potential considerations of the, kind of, real world evidence studies that were being conducted in other countries, and we were also considering and having, you know, discussions about whether or not there may be a potential for Evusheld to be enrolled in one of the platform studies, in particular PROTECT-V, but other than that, I'm not aware of anything else that happened.

Q. Just in terms of RAPID-C19's role, I think one of the other things that Professor White says in his report is that the various committees were generally passive in that they did not direct or initiate research. Insofar as that might relate to RAPID-C19, do you think that's a fair assessment?

A. I mean, I wouldn't necessarily say RAPID-C19 was passive. I mean, it was a significant undertaking working proactively to identify medicines for Covid-19. I think what we tried to do was signal when there was

clinical effectiveness evidence to roll a medicine out. And where there were gaps in the evidence, we certainly signalled that for consideration within the -- and I think you can see that in the CMO reports.

Q. Well, on the CMO reports, we're going to come to the last one now, in August 2022, and at this point is it right that the ATTF had asked you to look at real-world evidence from countries which had deployed Evusheld?

A. Yes.

Q. The same document again, please. Page 1, thank you.

At this point, we can see the Prophylaxis Oversight Group is still providing experts' advice.

Again, just turning to page 6, please, for the recommendation.

At the bottom there -- thank you -- essentially the evidence is still insufficient at this stage to progress.

A. Yes.

Q. Then, looking at the proposed actions, please, on the next page. So here RAPID-C19 is recommending further research, and is recommending pharmacokinetic analysis. Do you know whether this work at this point was taken forward?

A. So this -- because this report was in the August, I think that was what led to the roundtable that was

taken forward in the September by the ATTF.

Q. Could you just help the Inquiry -- obviously, we can see here that you are recommending further research and also, specifically, pharmacokinetic analysis, but didn't recommend that back in May. Can you explain why.

A. I think -- you know, from the notes, I wasn't actually at that May meeting myself but, you know, I think -- you know, had it been a key area for consideration, we would have flagged that for the ATTF to consider.

I mean, I think with pharmacokinetic and pharmacodynamic data, it requires, you know, the drug to be able to understand that, and of course the RAPID-C19 members were not in control of accessing the treatment, nor were the other research organisations.

Q. Is it right by this point that NICE then received a referral from DHSC to conduct a full technology appraisal of Evusheld, and ultimately it is not recommended through that process either?

A. Yes, that's right. In -- but if I can just also add, during that kind of summer period, you know, I mentioned that we were potentially exploring whether Evusheld could be used within the platform study PROTECT-V, and really, that -- you know, we felt that would have provided an opportunity to somehow link in vitro data to actual clinical outcomes. But as I said, unfortunately

that was never taken forward.
Q. Are you aware why it wasn't taken forward?
A. No. I mean, again, it would require the company making the treatment available for us to roll out that in a clinical trial.
Q. Just looking overall at the picture between February 2021 and August 2022, to the extent you've not already answered this, do you think RAPID-C19 could have done more to consider the effectiveness of Evusheld?
A. I think we responded as quickly as possible to all the new available data. We -- you know, you can see from all of the reports, you know, we considered it extensively. And as I said, because of the particular patient population whom we were talking to, you know, we detailed that we required a high level of confidence to be able to signal that, you know, this would be considered for use in the NHS, and ultimately we didn't have that confidence from the data.
Q. I think this is probably self-evident from your last answer, but did you have in mind, when making these decisions, just how important a possible prophylactic treatment for these types of groups might be?
A. Absolutely.
Q. Just in terms of the overall system more broadly, not just RAPID-C19, if we could just get up paragraph 136.

I think it's at page 55 of your statement. Thank you.
We can see there that you discussed the European Medicines Agency's Emergency Task Force statements on antibodies and Evusheld, and the FDA's suspension of Evusheld in the US. You then go on to say:
"NICE considers that, with the benefit of hindsight, the UK public health and regulatory system could have looked more intensively at whether or not Evusheld was effective against SARS-CoV-2 variants."
Could you just help us understand which parts of the system you're talking about, and how you think they could have looked at this issue more intensively?
A. Yeah, I think here this is -- you know, it became clear that these neutralising monoclonal antibodies were very much impacted by the changing virus, and, you know, I wonder whether more could have been done to help try to create that link between in vitro data and clinical outcomes.
You know, as I said previously, when RAPID-C19 were considering this information, there were no standardised methods to assess the quality of that -- you know, those in vitro studies. So, you know, potentially that was something that, you know, would have helped us understand the confidence of that data. But equally, the virus was changing so quickly, you know, it would be

difficult to keep up with that, and I also don't know what resources the UKHSA and the MHRA would have to be able to track and monitor that.
Q. But, for the future, do you think that's something that those organisations should be looking at?
A. Yeah, I think it should be explored.
Q. Thank you. And just on lessons for next time, I think one of the things you refer to in your statement is an in vitro expert advisory group that's been commissioned by NICE. Could you tell the Inquiry a little bit more about that, please.
A. So at NICE, we stood up an in vitro advisory group to help inform the technology appraisals that we were to conduct as part of the routine consideration of these Covid treatments. And, in the absence of data, we pulled together a representative group of experts, and that discussion and framework helped us understand the neutralising effect of the monoclonal antibodies and how that could be considered within the appraisal and translated into clinical effectiveness.
Q. So has it actually made a practical difference to NICE's work since the pandemic?
A. Yeah, I mean, like I said, in the absence of anything, because we knew we were going to have to undertake the appraisals, we felt we needed to, you know, to provide

that information to our independent committees. Was it perfect? I don't know. Is there more that could be done? Potentially. But, you know, it was very clear when we looked at the medicines at that time that the neutralising effects in some was either reduced or absent, and that really help to guide the committee's decision making.
Q. So do you think that could be helpful in the face of a future pandemic?
A. Yes.
Q. Are there any other improvements that you think could be made around research on this issue?
A. I think -- we've obviously touched on the key aspects already. I think it would be helpful to consider how we might be able to have more diverse people included in clinical trials. You know, we didn't really see very much data particularly on those clinically vulnerable groups. There may be a challenge, there may be ethical issues with that, but, you know, more understanding on how differently or not a medicine might work in those groups would be helpful. And in particular, exploring medicines in groups of people who we think won't respond to the vaccine or can't have a vaccine.
Q. In your statement -- we don't need to get it up -- but you say, just in terms of development of therapeutics,

that the system could do more. Is that essentially what you've just touched upon in terms of the types of trials and the types of participants in those trials?

A. Yeah, and also -- I mean, we obviously, you know, particularly for the monoclonal antibodies, we know that the effectiveness can be impacted with different variants. So maybe in the research and development actually trying to identify, you know, the particular spike proteins that they will work on to try and get a broader -- you know, to maintain a broader effectiveness even when the virus changes. It's not my area of expertise, but I wonder whether it is something that could be taken forward.

MS WILLLIAMS: Thank you.

My Lady, those are my questions.

LADY HALLETT: Thank you very much.

Ms Douglas has some questions for you. She's over there.

Questions from MS DOUGLAS

MS DOUGLAS: Thank you, my Lady.

Could morning. I act on behalf of Clinically Vulnerable Families who represent the clinically vulnerable, the clinically extremely vulnerable, and the immunosuppressed. You have explained in your statement, and also touched upon earlier this morning, that the

RAPID-C19 process did not include consideration of cost effectiveness, and that that was appropriate in responding to an unprecedented public health emergency, for the focus to be on the clinical effectiveness and not the cost effectiveness.

You've also explained that that approach was a deviation from the standard routes of access to therapeutics available on the NHS.

But we've seen it, of course, that the ultimate decisions in government regarding Evusheld did cite cost effectiveness. As an example, Sir Sajid Javid has said that the advice he was given in June 2022 was that Evusheld was too expensive for the advantages that it would give.

So my question is this: if NICE's primary purpose ordinarily in routine times is to conduct a cost effectiveness analysis to ensure value for the taxpayer and the financial sustainability of the NHS, how did you ensure that those cost considerations did not end up influencing your discussions, advice, and recommendations about Covid-19 therapeutics, and particularly Evusheld?

A. Yeah, I mean, obviously I attended those meetings, and we never considered the cost, particularly with Evusheld, we were very much focused on understanding the

clinical trial data, which obviously was positive, but how that would translate into clinical effectiveness in the NHS. We didn't consider cost for Evusheld in the same way that we didn't for all of the other medicines that we were considering, some obviously which did show effectiveness and then were rolled out in the NHS, and others that didn't show effectiveness and therefore weren't.

So at no point were we thinking about cost or cost effectiveness in our discussion on the evidence and our advice up to the CMO.

Q. Thank you. And so you would have no concerns that those types of considerations influenced any of the ultimate advice?

A. I mean, in RAPID-C19 there was no consideration at all. I can't, obviously, comment on conversations that may have happened elsewhere but I can confidently say that it was not a discussion point within the RAPID-C19.

MS DOUGLAS: Thank you.

Thank you, my Lady.

LADY HALLETT: Thank you, Ms Douglas.

That concludes the questions we have for you, Ms Knight. Thank you very much indeed for your help to the Inquiry and for coming along today and thank you also for the work you and your team did -- I think the

horrid modern word is pivot, isn't it? -- but for getting the process done more smoothly and more efficiently because we were in a national emergency. So thank you very much indeed.

THE WITNESS: Thank you.

(The witness withdrew)

LADY HALLETT: Mr Mansell?

MR MANSELL: My Lady the next witness is Dr Clive Dix. If he could be sworn, please.

DR CLIVE DIX (affirmed)

Questions from COUNSEL TO THE INQUIRY

LADY HALLETT: Sorry if we kept you waiting, Dr Dix, but you are, I think, our last witness.

MR MANSELL: That's right, my Lady, the last witness of this module.

Dr Dix, could you give it your full name to the Inquiry, please?

A. Clive Dix.

Q. Thank you very much for coming today to assist the Inquiry. You have provided a witness statement for Module 4, that's INQ000474423. It's signed by you, and is it true?

A. Yes.

Q. Thank you.

You served as deputy chair of the Vaccine Taskforce,

or VTF, under Dame Kate Bingham, from June to December 2020?
A. Yes.
Q. We've heard from Dame Kate -- I don't wish to embarrass you, Dr Dix, but she described you in one word: phenomenal. There we go. Perhaps I have embarrassed you.
A. Yes, you have.
Q. Then you served as chair of the VTF from December 2020 to April 2021?
A. That's correct.
Q. Briefly just going back through your education and career, you graduated from Leeds with a first class degree in pharmacology?
A. That's right.
Q. Following which you obtained a doctorate?
A. True.
Q. And after several post-doctoral fellowships at the Royal Free Hospital in London, you moved into the pharmaceutical industry?
A. That's correct.
Q. Since 2001, you have held several chief executive officer, chairman and non-executive director posts, at a range of pharmaceutical companies, specialising in vaccine research and development, some of which you

co-founded?
A. Yes, that's correct.
Q. And you explain in your statement that you have significant experience and knowledge of the pharmaceutical industry and the finance community supporting the sector?
A. That's right.
Q. And it was no doubt that experience that you drew on in your work with the VTF. And the first topic I'd like to ask you about, please, is your role as Deputy Chair of the VTF, particularly in building the UK's vaccine portfolio. Is this right: that on joining the VTF your role was to build and head a team which would identify the most promising vaccines currently in development?
A. That's right.
Q. How prepared, in your assessment, was the UK to undertake such a task?
A. It didn't have any infrastructure or thinking at the time, at all.
Q. What about the links between the government and industry? What state were they in when you took that role on?
A. They were sort of transactional, to do with buying things and very, I would say, adversarial. They weren't fabulous relationships. Partly because of things like

drug pricing, which tended to be adversarial events anyway.
Q. The aim was to have a diverse portfolio of vaccines, including vaccines based on different technologies?
A. Yeah.
Q. You were working on a list of around 200 vaccine candidates initially?
A. That's right.
Q. How did you go about the task of narrowing down that list?
A. It was a very rigorous process that -- the sort of process you use when you're looking at science generally in pharmaceutical companies deciding what to do. So we had access to a thing called Airfinity, which was a database, it was a brilliant database that was continually being updated with what was going on in the world of vaccines. And then we set a set of criteria of which we tested each, looked at each of the vaccines in turn and decided whether they met those criteria and then moved on. So it was a set of filters, if you like. And that honed it down quite quickly.

One of the key filters was could this vaccine ever be in a human being, to be tested within that year, so by the end of December 2020? And that took a lot of them out, basically. So it wasn't a difficult process

to get to a smaller number, but then what we had to do was meet with the businesses, the companies that were making these vaccines. So we set up NDAs with all of them and we contacted them, built relationships with them, and asked them to show us all of their data so we could analyse it together as a team and look at it from all the different aspects and decide whether it was a going concern, really.
Q. You explain that the list of 200 was reduced through applying this criterion to around 15, before you approached the various companies.
A. Yes.
Q. And at that stage you were carrying out what you described as deep due diligence. So what did that involve?
A. Well, that involved asking the company to let us into all of their documents, and see every piece of information that they'd already gained on these molecules, and also what their plans were. So we judged whether their plan was going to work and whether they -- also we did a lot of detailed analysis of their manufacturing capabilities, and we saw where the weaknesses were and the strengths. And, in fact, in all of them, there was a chance, then, to say, "Well, we can help you with some of this because you haven't quite got

it right", and then, you know, we brought in experts that would help with the clinical trials sometimes, sometimes help with manufacturing, and linking them to the MHRA so they could get advice on what was required for the full clinical studies.

So it was just detailed analysis of the science behind these vaccines.

Q. Would that result in a report that your team put together on whether a particular company or vaccine candidate was a promising one, which you would then present to the Vaccine Taskforce steering group for a decision ultimately --

A. Yeah.

Q. -- to be made on whether it would be backed?

A. Yeah, every single vaccine had a diligence report with a recommendation in it that went into the steering committee and eventually, if it became the one we took forward, it went as far as the ministerial panel.

Q. You would then look at what could be done to incentivise development of a particular vaccine, you've touched upon this, but clinical trial support, providing and investing in manufacturing facilities and fill and finish capabilities for that particular candidate?

A. Absolutely. Right from the outset, Kate and I sat down and talked about how can we be the first? What's it

going to take to make the vaccine industry come here rather than go to America, for instance? And so we basically were salesmen on "This is the best place to do it, so we can show you what we can help you with", and we did, and we put things in place, and clearly that worked.

Q. Being the best client?

A. Yeah.

Q. And that 200 list of promising -- or vaccine candidates, initially, went down to 15, and then the 7 in the Vaccine -- the VTF's portfolio.

There came a point in December 2020 when you took over as chair of the VTF?

A. That's right.

Q. And I don't want to go into the details, but suffice it to say you were not happy with how the role of chair was framed post Dame Kate's position. And in particular, you were concerned about the lack of having a single point of accountability to a minister, which Dame Kate had had and wasn't going to be the case for you?

A. Absolutely. I got a letter of appointment which didn't have that, and I then rewrote my letter of appointment -- with a bit of help from Kate, as it happened -- and asked for this to be considered. And it was considered and rejected.

So it became very difficult, because we knew that the success of the VTF at that point was basically down to that single point of accountability, and the ability to ensure that the steering group really did scrutinise all the recommendations and have all the right expert input before it went to ministers.

Q. Why was that so important, that single point of accountability to a minister?

A. Because you wanted to ensure that all of the input that came from the Vaccine Taskforce from all the experts, as well as the government officials, was sound, and it was brought together as one, and that there wasn't any room for, you know, manoeuvre into the wrong areas. So it was important to ensure it was crisp and clean and moved fast.

Q. You stepped down in April 2021 as chair and soon after that Sir Richard Sykes became the chair of the VTF.

A. That's correct.

Q. The Inquiry has heard a great deal of very positive evidence about the work of the VTF and what it achieved.

I'd be interested in your views, please, in whether the key features are captured in a document authored by Lord Vallance.

Can we have on screen, please, INQ000101626.

This is a document which was authored by

Lord Vallance, titled "Key features of the Vaccine Task Force", dated 10 February 2021. And we can see here that he has set out the seven factors which he has highlighted as being the key features which led to the success of the VTF:

"Content experts were brought in rapidly ..."

Number 2:

"An at-risk investment mindset was taken ..."

Number 3:

"Procurement was part of the process ..."

A. Yeah.

Q. Number 4:

"There was a very clear and measurable outcome objective."

Number 5:

"... a single point of accountability for the whole activity and that person was empowered and answerable to the PM."

So the point, perhaps, you were making a moment ago.

A. Yes.

Q. Number 6:

"Private sector engagement was key ..."

Number 7:

"Long term legacy was built into the thinking from the beginning."

Do you agree with the analysis set out in this document? Does this capture what made the VTF so successful?

A. Absolutely, and the long-term legacy was at the forefront of the minds of everybody as we were doing the deals with the companies, so that -- can we attract them to be here as part of the future, and therefore part of preparedness for the future?

Q. Thank you. That document can come down.

And it really is that long-term legacy that I'd like to turn to now, Dr Dix, because in your statement you are highly critical of the UK's current preparedness for the next pandemic. You say the UK is in a weaker position now than it was prior to the Covid-19 pandemic, you say we have less resilience now, and have failed to learn the lessons from the pandemic.

And I just want to focus on some of the specific criticisms you make, with a focus on the lessons that can be learned, please.

A. Okay.

Q. The first topic is Valneva. And the Inquiry has heard that the contract with Valneva was terminated in September 2021. And this matter has been raised with a number of the Module 4 witnesses, including Professor Dame Jenny Harries, Sir Sajid Javid, and

Nadhim Zahawi, and I'm just going to briefly encapsulate what's said about that, and then we'll get your view, please.

But in essence it's said that the advice, which was from the VTF -- although given after you had left -- was that the contract should be cancelled because trial data suggested the Valneva vaccine would be ineffective as a booster dose. It was appropriate for the UK Government to try to achieve value for money for the taxpayer by cancelling the contract in light of that trial data. And that the relationship with the company was considered as part of the decision and the cancellation has not damaged relations with industry. What do you say?

A. Not that. In terms of relationships with industry, it was devastating, I would say. Devastating for the company but also the ripple effect from that to other companies, that this was the way they were treated. That was the first thing.

The second thing was that the data they used to make that decision was poor. It actually wasn't a full study. It was a study that was done in a rush to see if we could get booster data because we wanted to boost by the end of the year.

Q. Just pausing there, this was the COM-COV boost study?

A. COM-COV boost study. And they only left two months, two and a half months between primary vaccination and boost. And anybody that knows about vaccines and vaccine development would know you would not see significant boosting at that time. So it was putting a vaccine through a test that was going to be negative. And given that the government had funded the study, the phase III study, which was about to report out 6,000 people, that the MHRA had put together the criteria that needed to be passed for it to be approved, and that study was going to read out one month after that decision was made.

That study showed the vaccine was better than the AZ vaccine.

Q. So the final, the final --

A. -- (overspeaking) --

Q. -- data from the study, did it contradict the COM-COV booster?

A. Well, doesn't contradict, it was just a very poor study. So you know when you do vaccine development that you do some small studies and sometimes there's a bit of a red flag or sometimes they look really good. But you don't suddenly stop because of that, you wait and see the real, proper, well-controlled, large studies, and get the full readout. And when that readout came, it showed that the vaccine was as good as and probably was going

to be one of the better vaccines, if it was still around, even today.

And what still perplexes me is the phase I and phase II studies, which had been done and were available, were not looked at for that decision. The small, what I would say was a flawed booster study, was the only study that was used to make that decision and that was -- I don't believe any experts were part of that analysis. I just can't believe there's an expert that would ever make a decision based on that data.

LADY HALLETT: So who conducted the flawed analysis?

A. It wasn't the company. It was a Professor Saul Faust in Southampton, and it was done under a UK research group's funding. They did it across all the vaccines, because they were looking for ones that would definitely be best for boosting. And unfortunately, some of the science says that once you've vaccinated people with an mRNA vaccine, the level of antibodies are so high, until they've fallen down, you shouldn't even try boosting because it's probably going to be very difficult to boost.

So it was just a flawed study.

MR MANSELL: This advice had come from the VTF, you weren't the chair at the time, but it --

A. But I don't think --

Q. It had come from the VTF, so in terms of who was looking at it, the VTF had looked at it --
A. Clearly.
Q. -- and had something changed in the approach the VTF was taking? Or --
A. Well, I heard some of the evidence that the experts round the table agreed. Well, unfortunately, I know all the experts, because I worked with them. None of them were consulted.
Q. These are members of the VTF --
A. Well, they were the diligence team, basically, the people that knew the vaccines inside out and were part of the people that you would consult when you made big decisions, and none of them were ever consulted on this decision. So I actually don't know who the experts were and I didn't see any experts in the VTF once, once I left.
Q. Moving on. Next topic, another issue about which you were critical is the Vaccines Manufacturing and Innovation Centre, or VMIC, and the Inquiry has heard that VMIC was sold in April 2022, and that's subsequently been mothballed.

You characterise that as having a serious negative impact on the UK's ability to develop and manufacture vaccines at speed in the face of a future pandemic.

The Inquiry has heard evidence about the new strategic partnership with Moderna, Moderna's Innovation and Technology Centre, and the AstraZeneca investment in Speke, Liverpool. Do those projects allay your concerns.
A. No. It is very good that we have got the manufacturer of an mRNA vaccine, because they will be part of the future, without a doubt. On their own, they are not the answer, though.

The AstraZeneca investment actually hasn't happened and it seems to be faltering.

But what needs to be made clear -- I heard a lot of evidence about manufacturing, and I think some people talked about having "sovereign" manufacturing. The UK Government does not have to invest in manufacturing, and shouldn't invest in manufacturing, particularly for a pandemic. It's impossible for the government to be running state-owned or even state-invested manufacturing. It's not the future.

VMIC was an example of something that went wrong. VMIC was a vaccine innovation centre. The idea was that when small companies that make vaccines or are developing vaccines want to move through to clinical trials and then move on to manufacturing, they don't normally have the wherewithal to know how to formulate

those vaccines properly and the Vaccines Manufacturing and Innovation Centre was there to encourage that to happen and therefore bring people to the UK because it was going to be a centre of excellence.

There was a decision which I didn't particularly agree with, I wasn't part of, but to actually turn it into a manufacturing centre, which is a very -- manufacturing is very cut and dry. It's -- you know, it's hard, grungy work, it's not innovative, and they tried to mould the two into one in that centre and it sort of went astray, and then the whole thing got sold, the innovation piece got lost, and that's the piece that the country should still have. That innovation centre was a fantastic idea, it came out of the Office for Life Sciences' strategic reviews, and we've lost it.

But coming back to manufacturing, what we need is the ability to have really good relationships with the pharmaceutical industry, show them -- like we did at the beginning of the VTF, show them what the UK can offer, and encourage them to come here and do their research, development, clinical trials, and then manufacturing, and have manufacturing as part of their remit in the UK, and then you've got manufacturing, and it's run by them, it's paid for by them, and the government can just be there incentivising and understanding it, not trying to

run it. And I think that's really important.

It's a bit different to saying we need to invest in manufacturing. I don't think we do.
Q. So the state doesn't --
A. No.
Q. -- invest in manufacturing --
A. No.
Q. -- instead, you make the UK an attractive place for companies --
A. Absolutely.
Q. -- to invest in and build manufacturing facilities here --
A. Yeah.
Q. -- that they run, and presumably you'd then have step-in rights in the event that --
A. Well, step-in, probably not necessary, because if you've got good relationships, you can say that -- you know, make sure you've got a line that's available. And you can go all the way to step-in rights if you want, but I don't think that's necessary.
Q. So how do we do it? How do we make the UK attractive for that type of investment?
A. Well, we do the sort of things that we did with Valneva to start with: we helped them with clinical trials, we helped extend their factory, because they hadn't got

enough cash at the time. And if that was still in place now, we would be selling vaccine to the rest of the world, which would have fitted our second objective, and we'd have had something as part of a legacy for the third objective.

So it's having the vision and understanding of how you can do that and do it over and over again. And we have all the right elements. The vaccine registry needs extending, the MHRA probably need to think about having a more dedicated vaccine unit within there that understands regulation and knows how to deal with the vaccines all the time. And I think we need this vaccine agency.

Q. And we will come to it, Dr Dix, I promise, the recommendation you made in December 2020 for a national vaccines agency.

Just before we move away from this issue of VMIC and investment in manufacturing, I've made reference to the Moderna Innovation and Technology Centre. Do you share a concern that others have about an overreliance on mRNA technology when it comes to vaccines?

A. Absolutely.

So there's rose-tinted glasses for mRNA because it was so good in the pandemic. It was a brilliant vaccine for an emergency. It's far from a perfect vaccine. At

the moment, the cold chain is terrible and storage is difficult. The duration of action of these vaccines isn't great, six months it seems to wane.

The cellular immunity, which is a classic important part of an immune response for vaccines to give you long-term immunity, is weak.

So they will get there but they still need developing to become the perfect vaccine but they're not there yet.

And then when it comes to pandemic, resilience for pandemic will not come from just having RNA. I can paint a picture of a virus coming our way that mRNA will not work for, and that's not what we want. We don't know what virus is coming but if it's a virus that we haven't done a lot of background research on, like we had with SARS and MERS -- and we knew the best protein, the spike protein, was the antigenic protein; if we don't know that, an mRNA vaccine won't work. What you've got to do is take every single protein on that virus and develop every one to see which one works. That's a huge amount of work, and it takes a long time.

I have always said that the reason we had Valneva, it's a live, attenuated -- a live, inactivated virus. For me, it was like crown green bowls, you always have your back stop, so if everything goes wrong, you've

still put that one there behind and you may still win. Valneva was that. If a virus comes along that we don't know a lot about, all we've got to do is condition it to grow in cells, and we can start manufacturing it as a whole virus and then just inactivate it.

It may not be a future-sexy technology, but it works. And we've eradicated polio, we use a very similar technology for flu at the moment. It works and it's trusted and it's safe and it's less reactogenic than all the other vaccines.

So there's nothing wrong with it, it's just old-fashioned and people don't like old-fashioned, but it works.

Q. Next topic, please, is the monoclonal antibody cocktail Evusheld. We've heard a lot of evidence about Evusheld. We've heard some of it today from Helen Knight. The story is really in two chapters, the first is about the VTF's position and the OCMO advice, the CMO, DCMO advice in late 2020, early 2021, and the second chapter is on RAPID-C19, that's what Helen Knight was giving evidence about.

But focusing on the first chapter, the Inquiry has heard from Professor Sir Chris Whitty and Professor Sir Jonathan Van-Tam about Evusheld, and I just want to sketch out their rationale for the decision making that

they made, that they fed into the advice they gave, so you can give your response.

They say in essence this: that the clinical picture on Evusheld was unclear, there was no clinical trial data, no information on side effects. Indeed, it was not authorised by the MHRA until 17 March 2022.

It was not clear to whom it would be given, because even those with a degree of a compromised immune system can benefit from a vaccine.

It would be wrong to compare it to purchasing vaccines at risk, because they're very different products. Unlike vaccines, you have to keep giving Evusheld over and over again and it's less likely to be effective as the virus mutates.

And finally, it was a lot more expensive on a per-dose basis than a vaccine, and had a short shelf life, which could lead to wastage. That is the rationale underpinning the advice that was given. What is your view?

A. I actually feel most of those are excuses, and the actual reason that it wasn't purchased was cost.

I'll take you through the thinking. So, shelf life is -- it's an error. The shelf life of the -- we did all the diligence on these vaccines, by the way, on these antibodies. The shelf life was, at the time when

we put the recommendation in, already six months, but with a statement that all of the antibodies in this category in the past had had shelf lives of over 18 months to 2 years and that they were likely to have the same.

Shelf life isn't even an issue, because you don't get a medicine of any type into your hands until it's approved. And once it's approved, you agree a delivery schedule to have it at the rate that you can use it. So that just isn't an argument, it's fatuous.

In terms of giving it over and over again, this antibody protected people for six months, and we were talking about buying enough to give people two doses, to get them through this early stage of the pandemic and free them from a lockdown. So I don't understand, over and over again. Two doses, six months.

And then there were some discussions about it being difficult to deliver to the patient and they needed specialist clinics. It was intramuscular. It was an injection in the bum. There was -- so these arguments sound great but I honestly don't believe they're valid at all.

Q. You were in post when this advice was being received --

A. I think I was leaving at the time, so it was right towards the end, yeah.

Q. Do we have a sense of a wider view, in terms of prophylactics, from this document, please, INQ000066712. This is an email from Charlotte Taylor regarding Astronaut data on prophylaxis. Charlotte Taylor, of course, was the acting director of the Antivirals Taskforce and Therapeutics Taskforce, and she is relaying here a conversation she's had with Lord Vallance about trial data on Evusheld as a prophylactic. And she says this:

"I've had a brief conversation with GCSA, including the Astronaut data on prophylaxis. I said that there is limited enthusiasm for prophylactic use across the system. His reply:

"'I think that is misguided. There is a clear place for them and it just needs to be defined.'"

That can come down, please.

A. Yeah, I agree.

Q. Does that accord with your experience?

A. Yes, absolutely.

Q. A lack of enthusiasm for prophylaxis?

A. The Vaccine Taskforce had a very entrepreneurial way about going about things, and very much getting things done, and the prophylactic antibodies moved into the therapeutics space rather than stay within the Vaccine Taskforce, and therefore it started to be looked at in

a very different way. And so yes, there was less enthusiasm.

Interestingly though, Professor Jonathan Van-Tam was part of the VTF and was very enthusiastic about us getting the antibodies to start with, and was a sponsor, if you like. So I don't know what changed, but in the end, the only thing I can see that's consistent is cost.

Q. Antivirals. The VTF looked at whether to include antivirals within its remit. You had experience of antiviral drug discovery and development, but it's your view that including antivirals in the remit of the VTF would distract from the task in hand, and you note that antivirals need a very long development time and extensive long-term safety data to be approved.

Now, in a context where everything is being thrown at vaccines, in order to expedite normally long development timelines, why couldn't the same approach have been taken to antivirals?

A. I think it could, but it would have overwhelmed the VTF and I don't think we'd have been successful. One of the things you learn when you run particularly small businesses, unless you focus, you die. You've got to focus and you've got to keep that focus really honest, and antivirals is a completely different set of skills, we'd have to have had a completely different set of

people looking at them and it would have made the VTF's role rather complex, I would say.

Q. That's a case for not including them within the remit of the VTF?

A. Yes, yes.

Q. Should antivirals have been looked at in a more intensive way by a VTF-like body tasked with that, or were they?

A. I think so. I think it could have been -- they are still very difficult things to find, and it does take a long time to develop them -- so unless there's something in development already that happens to flip over into Covid use, then it would take a long time. So it didn't look like it was in the same timeframe as the vaccines.

Q. Final topic, Dr Dix, is recommendations. And we are there, we are at the National Vaccines Agency, which I know you're keen to talk about.

Can we have on screen, please, INQ000330659.

This is a recommendations document from December 2020 that was co-authored by you and Dame Kate Bingham. Is that right?

A. Yes, and a lot of input from the Vaccine Taskforce.

Q. We can see at the bottom of that page, that you recommend the creation of a National Vaccines Agency,

and it states that it's clear that having the ability to draw together networks is crucial to pandemic preparedness.

Just pausing there, that is perhaps a key lesson, is it, of the VTF?

A. Absolutely.

Q. Bringing together industry, academia and government; yes?

A. Yes, absolutely.

Q. You state:

"The VTF recommends the creation of a new executive agency within BEIS [it's no longer BEIS] as its successor as the central body responsible for co-ordination of industrial and public sector assets ..."

And then you talk there about maintaining the relationship with the UK vaccines industrial base and HMG.

Over the page, page 2, please. Just a couple more aspects of this, we can see it says:

"It would also monitor and relay current threat assessment of novel diseases to industrial partners, working in partnership with cross-government functions on horizon-scanning and intelligence."

And "Governance", please, a bit further down. You

say:

"An independent, industrially experienced chairman and board should be established to bring together the work of the various strands ..."

So that is what you're setting out in that recommendation document.

Thank you, that can come down.

Before you expand on some of these points, perhaps, Dr Dix, can I just put the counterargument to you: is it really necessary to add another permanent level of bureaucracy to the vaccine development landscape?

Why can't we rely on existing systems that are in place now and then, if necessary, just set up a VTF-like body when the next pandemic hits?

A. You can, and then you're relying on what the UK has at the time, which wasn't very much when we started the VTF, and probably wouldn't be -- it might be even less next time. But I think the real point here is this is part of peacetime now. The -- if you think about vaccines, vaccines are the best preventative medicine. We're talking about health prevention rather than waiting to deal with health problems. So there's a need to understand vaccines in a much broader context all the time, and to be sure that we, as a country, are vaccinating our population with the best vaccines, for

the diseases that are there already, and maybe ones that are coming down the line that aren't going to be pandemic or endemic. So there is a proper long-term role for a group that really understand this, and at the same time, become world renowned for being able to do it and understand it.

And then linked to all these bodies like the WHO, like CEPI, and be a world leader on the world's -- name the person in the government that's a world leader in vaccines? You need it. And I think an agency might be the wrong word. I mean, I think it comes up with all sorts of connotations. It just needs that -- the UK needs a central body that understand vaccines, and actually understand new vaccine developments that are happening and whether they're the right things to do, and encourage them to be done in the UK, and so we're really on top of it, and we are the world leader in the whole area of vaccines. Then you're, sort of, safe for the pandemic. Because you've got so much access to everything, and the knowledge.

Q. If Matt Hancock was here now, he may say that such an agency as you've sketched out was unnecessary because that is what UKHSA are doing. That's essentially what he said when he was giving evidence to the Inquiry a little earlier in this process. And we heard from

Professor Dame Jenny Harries about the Vaccine Development and Evaluation Centre, or VDEC. Why aren't the systems that are in place now, put in place by the UKHSA, why aren't they sufficient, in your view?

A. First, I'd like to say that the UKHSA has a much broader remit and has to do an awful lot of things and it does an awful lot of things very well for the country. That's important. But it hasn't got any leadership in vaccines.

And the Vaccine Development Evaluation Centre, as it's called, was a small little lab when we started the VTF with some very good people that could test vaccines if they were brought to them in live assays, and some very specialist stuff. That's what it is. It's a testing centre. It has no vision, it has no leadership, and no understanding of how you develop vaccines. So the name is false, it's actually just a laboratory testing centre, but a very specialised one.

And I think that's misguided or it misinforms, I would say.

Q. The final thing I want to ask you about is this: that the Inquiry has heard a suggestion from Lord Sharma that short of creating a National Vaccines Agency, what should be established is a vaccine expert advisory panel, a body which comprises industry experts,

ministers, civil servants, perhaps people from academia drawing together those strands, which is something you've stressed. They would meet regularly, horizon scan, audit the UK's capabilities, and make recommendations for investment. Rather than an agency, an expert panel, and then use that as the platform for establishing the VTF if and when a next pandemic hits.

What are your thoughts on that?

A. I just don't think it'll work. I think the agency has to be a place that -- or the activity has to be a place that fosters the relationships with industry, and an advisory panel getting together every so often is no way of doing that. And it has no power, so it's not going to make things happen. And we know what happens to advice. It gets put on the shelf. It doesn't get -- it's got to be part of the business. It's got to be part of running the country. And so I just don't agree with advisory panels.

MR MANSELL: My Lady, those are all my questions.

LADY HALLETT: Can I just pursue that point about an agency. As you'll probably know, it's not that easy to persuade any government, whatever political hue, to create a new body that will cost money. How would you, if I were to be persuaded to make the recommendation, how would you frame it to persuade government that it was worth the

amount of money it would cost to set up the agency in the long term?

A. I think I would use the analogy of the MoD. And we spend a lot of money there, and we have real expert people. We have military soldiers that know what they're doing, running it, and being part of it. And unless we have that in the UK for vaccines, then when the next pandemic comes, we'll be back where we started. We really need to invest in -- and I think investing in vaccines for health is the way to think about it, not for a long-term future thing. That's very hard to justify, but knowing that having it for health and being the best place in the world for vaccines, means that you are covered. And I don't think it needs to be hugely expensive, either. It's not a -- they won't be doing, they will actually be corralling and bringing on board the industry and making it all work and helping putting it together. So I don't think it needs to be this huge cost centre.

LADY HALLETT: Is there any argument that if such an agency was set up and the expertise were gathered together and they corralled and developed the relationships you're talking about, that that might attract investment into the UK?

A. Absolutely, absolutely.

LADY HALLETT: Because that's the kind of argument that might appeal to government.

A. Well, I think that's what I was saying earlier, about the VTF actually leveraged the activities in the UK to attract investment. So we were very close with two other companies of having them come to the UK and set up their manufacturing there as I left, and I understand that those discussions just became so entrenched in government thinking that they just walked away in the end, because they weren't being given the vision of why it would be great to be here. And there is plenty of very good things the UK has that you can actually attract companies to come to the UK.

LADY HALLETT: Thank you.

Just a couple more questions from Mr Thomas, who is over there.

Questions from PROFESSOR THOMAS KC

PROFESSOR THOMAS: Good afternoon, Dr Dix. I've just got a couple of questions for you. My name is Leslie Thomas, I'm representing FEMHO, the Federation of Ethnic Minority Healthcare Organisations.

At paragraph 7.4 of your statement, you make mention of the communication plan that was fronted by Dame Kate Bingham. You state that:

"[Our] members of the [Vaccine Taskforce] were asked

to participate in podcasts and zoom meetings with various ethnic groups to help disseminate understanding of vaccines. As I recall, this was frowned upon by HMG comms [that's the government communication centre] and eventually stopped. In particular, the [Vaccine Taskforce] podcast had been paused indefinitely by 17 November 2020, with one episode remaining unpublished. In my opinion this was wholly short sighted."

Dr Dix, could you elaborate on the reasons why the Vaccine Taskforce sought to participate in the podcast and Zoom meetings with ethnic groups? Why was that important?

A. We felt that, as a group, we had a level of credibility and trust, and that these groups desperately needed information and they needed to be given solid information that was well thought through and presented in a way that was digestible by different groups.

Q. Just on that, what sort of reach were you expecting to have?

A. Well, you never know with podcasts, sometimes they go nowhere and sometimes they become the podcast of the year. So, you know, we were working with communicators to actually make those podcasts, you know, live and real. So we didn't really know what was the reach; we

just thought it was an important thing to do.
Q. And further, at paragraph 7.5 of your statement, you say this, you say:
"HMG comms did not want the [Vaccine Taskforce] to participate in comms. In fact they were paranoid about the Vaccine Taskforce saying anything publicly."
Question: why did you think this type of communication was frowned upon by HMG comms?
A. I don't really know, apart from that the government was fixated in controlling all information. And there was probably a lack of trust, I think. But we were just told to stop doing it and -- or Kate was told to stop doing it. And she had a proper programme of communication and was told that it was the government's job to do that and not the taskforce.
Q. In any event, no rational explanation provided?
A. No, no, there wasn't a rational reason. It was paranoia, I think.
PROFESSOR THOMAS: Thank you, my Lady.
LADY HALLETT: Thank you, Mr Thomas.
Dr Dix, I'm going to embarrass you again: to be described as "phenomenal" by someone like Kate Bingham is praise indeed.
A. I had to pay her a lot of money.
LADY HALLETT: I'm sure you did, but we are very fortunate

that people of your skills and ability and experience were prepared to step up in a national emergency, so, on behalf of us all, I express my gratitude for what you did during the pandemic and for your help to the Inquiry.
THE WITNESS: Thank you, and I'd do it again.
LADY HALLETT: Good.
THE WITNESS: Thank you.
(The witness withdrew)
LADY HALLETT: Right, I think that completes the evidence, Mr Keith.
MR KEITH: It does, my Lady.
LADY HALLETT: Very well. I shall return at 1.45 to begin the closing submissions.
(12.43 pm)
(The Short Adjournment)
(1.45 pm)
LADY HALLETT: Ms Murnaghan. There you are. You were over there earlier, weren't you?
MS MURNAGHAN: No.
Closing statement on behalf of the Department of Health (Northern Ireland) by MS MURNAGHAN KC
MS MURNAGHAN: Good afternoon, my Lady.
My Lady, I make this closing statement on behalf of the Department of Health for Northern Ireland, which

I'll refer to in the course of my submissions as "the Department", and by this closing statement the Department wishes to confirm that it has carefully listened to and reflected on all of the evidence adduced and the issues that have emerged in the course of these hearing sessions.
By these submissions, the Department would also like to address some issues that pertain to its role in the implementation of the vaccine rollout programme in Northern Ireland.
We would also like to make some points about the lessons that the Department has learned and its preparedness for the next pandemic.
My Lady, it is considered on a fair analysis that the vaccination programme in Northern Ireland was a success. Some successful factors included the level and extent of preparedness which was in place at the time when the vaccines began to become available, the manner in which the Department was able to overcome logistical and technical problems in order to develop and administer a programme which resulted in the vaccine being made available to everyone who was eligible, in line with JCVI advice, the development of the Vaccine Management System, which has been referred to as the VMS, that accurately recorded all Covid-19 vaccinations

which were administered; the fact that the Department ensured that the Northern Ireland programme closely coordinated with the other UK vaccination programmes which were considered to be important, both in terms of vaccine equity, and also in terms of public confidence.
Finally, my Lady, we considered that the maximisation of access to the vaccination programme which was delivered from GPs through HSE trusts and through over 400 community pharmacies throughout Northern Ireland resulted in a high percentage of the population being vaccinated in an orderly and an efficient manner.
Another key aspect of the programme and one which the Department believed represented a strong outcome was the fact that the Department ensured that residents in care homes were prioritised and vaccinated in the first tranche of vaccinations, thereby providing protection to some of the most vulnerable in our society.
This success, of course, must be viewed in the context wherein the Covid-19 vaccination programme was the largest and most challenging in the history of the Northern Ireland self-service.
Another important aspect, my Lady, of the successful rollout of the vaccination programme was the close co-ordination across the four nations. As my Lady no

doubt remarked was clear from the evidence that was given by all four of the Senior Responsible Officers, that close co-ordination between the SROs meant that Northern Ireland was able to benefit from the experience of others when issues were encountered and, in turn, provide insight into how it resolved issues when they arose in Northern Ireland.

Of course, my Lady, there were naturally challenges in the implementation of such a significant vaccination programme, both in terms of the unprecedented scale, and the speed within which it had to be established.

The Inquiry has heard evidence about the challenges faced throughout the UK, and there were challenges in the vaccination programme that were particular to Northern Ireland. For example, the Department had to consider and address issues arising from the additional regulatory requirements that were imposed by dint of the Northern Ireland Protocol. These additional requirements were relevant both to the authorisation and the access to the vaccines.

The Department worked closely with the MHRA to ensure that appropriate measures such as the use of the temporary authorisations under Regulation 174 of the Human Medicines Regulations 2012 were progressed in order to ensure that Northern Ireland could access the

vaccines at the same time as others in the UK.

The Department was also obliged to work closely with the Vaccine Management Taskforce to ensure that the vaccines that were supplied to Northern Ireland met all regulatory requirements, again, arising from the Northern Ireland Protocol.

I'd like to say something now, my Lady, about the hard-to-reach groups. The Department confirms that it took specific action to address those difficult-to-reach groups in order to promote vaccine equity. These actions included proactive outreach to ethnic minority groups, to socially deprived areas, to isolated occupational groups, to migrant workers, to the disabled, the housebound and those living in our rural communities.

In order to improve vaccine uptake the Department deployed a range of award-winning communications which included the use of specifically-targeted social influencers and trusted voices in its engagement with community groups.

My Lady, these actions were driven by data that was gleaned from the Vaccine Management System, and also from local intelligence that came through our Public Health Agency's links with community groups. The ability to communicate and connect with those groups at

the appropriate grassroots level was as a result of the PHA having a longstanding and trusted relationship with many of those groups.

In terms, of course, then, my Lady, of misinformation and its impact on vaccine hesitancy, we would say that the Department confronted the challenges of misinformation and vaccine hesitancy largely by seeking to understand the challenges of the anti-vax messages and the specific concerns that were particular to Northern Ireland. In addition to engagement with the low uptake groups, we were conscious of the importance of public messaging and the Department accordingly published myth buster or fact file information that was delivered through public health campaigns, through its community pharmacies in its Living Well service.

My Lady, it should also be noted that Northern Ireland residents were able to and in fact did participate in a large number of the Covid trials, some of which included RECOVERY, REMAP-CAP, PANORAMIC and others. Additionally, Northern Ireland recruited well for the Novavax vaccine study.

I'd like to say something more about the Vaccine Management System which was a considerable undertaking. The Department had realised from the spring of 2020 that if there was going to be a mass vaccination programme,

it would need a sophisticated system in order to be able to record accurately all of the vaccinations.

Accordingly, from that early stage, steps were taken to investigate how such a system could be developed. As more information regarding the vaccines became available, those steps were put in train.

Although the capability of the Vaccine Management System developed over time it should be noted that it was operational from the first day of the vaccine programme on 8 December 2020.

There was clearly a challenge to make sure that the operators were able to confidently use the system, and that it effectively interacted with our GPs' IT systems, but all of the elements of this vaccination programme, including trusts, GPs and community pharmacies, had access to the Vaccine Management System and the benefits of the receipt of the information in such a prompt time were, we considered, significant.

The fully operational Vaccine Management System allowed for accurate and timely access to vaccine uptake data, which, in turn, allowed areas of low uptake to be identified and targeted actions to be taken.

In particular, the introduction of the Vaccine Management System was a key enabler of our ability to deploy into community pharmacies. It facilitated

communication and the prompt updating of medical records following the vaccination.

Of course my Lady, Northern Ireland already had existing data recording systems, and it built on and developed from those systems to develop its dashboards and the Vaccine Management System, both of which were expanded and improved throughout the course of the vaccination programme.

It is hoped that these improvements will allow for a more nimble and data-driven approach in any future pandemic. Moreover, being able to communicate in a contemporaneous and transparent way with the Northern Irish public, we felt inspired hope, which, in turn, led to confidence in the system.

My Lady, the Department's work on vaccine rollout has left a legacy, a legacy of UK-wide cooperation and a better understanding of the importance of societal efforts at a time of emergency.

The Department now has a greater insight into potential barriers to the uptake of vaccines and the importance of vaccine equity.

There is also a legacy of technological advances, such as the VMS, which is currently used in our other vaccination programmes. Regrettably, my Lady, in current programmes, there are continuing challenges with

vaccine hesitancy, but important lessons have been learned and work is ongoing to fully understand and address the multiple reasons behind this hesitancy.

I'd like also, my Lady, to say something about the integrated care system and the impact on the vaccination programme.

A key advantage of our integrated care system in Northern Ireland was that it allowed the Department to use social care and community resources more effectively, thereby vaccinating those who were housebound or in care homes.

A clear advantage was the increased level of co-ordination with social and health care sectors, which contributed to the development of a more efficient and better coordinated approach to the vaccination programme.

In the integrated care system, there were demonstrable advantages in the fact that policy colleagues were experienced in working closely together, which meant, in turn, less red tape and fewer organisational boundaries for the smooth processing of work.

A practical example of the benefit of the integrated care system was the speed at which the Department was able to roll out its vaccinations into care homes by

dint of redirecting trust assets so that by 8 January 2021, 90% of care homes had been visited by vaccination teams.

My Lady, in terms of lessons learnt, the Department considers that it has improved its understanding of how to develop -- deliver successful vaccination programmes as a result of the work that it undertook on this Covid vaccination programme.

It considers that it continues to learn from its experience of delivering vaccination programmes more widely, and in evidence, the Deputy Chief Medical Officer referenced the importance of providing the public with a fuller understanding of the steps taken to secure us safe vaccinations and the means by which any consequential effects of the vaccine should be put on record and collated.

In addition, the Department continues to develop its understanding of the behavioural and social science factors which lead to vaccine uptake.

It is acknowledged that the success of our vaccination programme was the best form of defence against Covid-19, and was crucially important in ensuring that Northern Ireland could return to a level of normality.

The practical lessons learnt from how to implement,

swiftly and effectively, vaccination programmes, will be, undoubtedly, invaluable in any future pandemic.

To conclude therefore, this module of the Inquiry has been focused on vaccine rollout and it should be emphasised that the successful rollout in Northern Ireland would not have been possible without the contribution and commitment of the staff involved, and the response of the citizens of Northern Ireland.

The Department believes that this is an appropriate point at which to again express its sincere thanks to everyone involved for their unerring and unselfish commitment.

Thank you very much, my Lady.

LADY HALLETT: Thank you very much, Ms Murnaghan.

Mr Thomas.

Closing statement on behalf of the Federation of Ethnic Minority Healthcare Organisations by PROFESSOR THOMAS KC

PROFESSOR THOMAS: My Lady.

"The reality is we [cannot] change history but we can change the present. And I think that that's something very important to remember ... every day is an opportunity to rebuild trust, and ... I think Covid was a huge opportunity to try to rebuild that trust, and now is a big opportunity."

Dr Heidi Larson on 16 January at this Inquiry.

My Lady, the evidence presented during this module has revealed undeniable failings that disproportionately impacted ethnic minority communities, including inadequate engagement, systemic inequality and bureaucratic delays.

FEMHO submits that these issues are emblematic of the deeper structural inequities that pervade our healthcare system and public healthcare strategies. Addressing these failings is not merely a question of fairness, but a matter of necessity.

One of the most glaring takeaways from this module is a lack of a coherent, national effort to engage minority ethnic communities during the vaccine rollout.

My Lady, government witnesses have acknowledged that health disparities and concerns about the uptake were foreseeable. Yet, despite this knowledge, there was no nationally funded coordinated campaign to address these challenges in realtime. Instead, what we had was fragmented, piecemeal efforts characterised by the government's approach which, as Dame Kate Bingham testified, "significantly hindered" progress and caused harm to the efforts that were being made across the country by individual groups and organisations.

My Lady, no one is denying that the task was huge. There was not only historic mistrust, but also mis- and

disinformation during the pandemic that were pressing concerns. Organisations like FEMHO stepped up because they wanted to help.

My Lady, you'll remember Dr Salman Waqar's mention of the Brandolini principle, or commonly known as the BS principle, which emphasises the great effort it takes to debunk misinformation, in comparison to the relative ease to creating that misinformation.

Healthcare workers like Dr Waqar found themselves having to do more work with less resources in order to tackle that mis- or disinformation, and build trust.

This fragmented approach was further compounded by the fact that private companies often stepped in where government failed. As Dr Waqar pointed out, platforms such as Facebook provided funding and support for community engagement work when that should have been a government responsibility.

The British Islamic Medical Association launched the BIMBA(?) myth buster series, a campaign led by trusted Muslim healthcare professionals to dispel misinformation, and low confidence within the Muslim and ethnic minority communities.

This initiative reached vast audiences through social media and grassroots networks and was widely praised for its cultural sensitivity and

community-driven approach.

You see, my Lady, it's about trust. Trust is the cornerstone of public health. Hard to build, easy to break, and essential to repair.

Dr Waqar, Dr Larson, and Dame Kate Bingham all underscored the importance of trust in driving vaccine confidence and uptake. You see, building trust requires more than government messaging. It demands meaningful engagement led by trusted community leaders who can bridge the gap between institutions and the people they serve.

Practical measures such as ensuring that tools like the Yellow Card Scheme are accessible and available in multiple languages, are also critical. Simplifying the reporting systems and tailoring communications to resonate with diverse communities. Not just recommendations. They are imperative for building trust.

Do you remember the full circle argument? What was clear in Module 4 is the full circle argument, broken down by Dr Larson, which FEMHO hopes will resonate with this Inquiry. It all starts with the fact that pre-existing health inequalities and historic mistrust are unaddressed, despite them being foreseeable, which, in turn, means that there is poor engagement with

minority ethnic communities in respect of the national vaccine rollout scheme, which then causes poor diversity in clinical trials, low trust in vaccines, and low uptake by the same communities, which means sentiments hardened, and there's a general growth in vaccine hesitancy, or lack of confidence, which means government then needs to consider policies like the vaccinations as a condition of deployment to drive uptake, which might increase uptake in the short term but then has a knock-on effect of building and reinforcing distrust, which means coming back full circle, that there's an impact in years to come regarding vaccines, trust in government, and perpetuating and worsening health inequalities in our society.

This vicious cycle must be broken. Without systemic reform and continuous sustained meaningful engagement, my Lady, these issues will reoccur with future public health crises.

The issue of diversity in clinical trials. You may have seen me twitching in my seat when this was being raised by various witnesses. Let me explain why one was twitchy. It's important to clarify that outsourcing diversity to countries such as South Africa or Brazil, while providing data on certain ethnic groups, fails to address the unique challenges of mistrust, vaccine

hesitancy and systemic inequities faced by minority ethnic communities in the UK. The government and vaccine companies fundamentally misunderstood the nature of low confidence, treating it as if it was a biological issue. They assumed that providing safety in black populations abroad would automatically translate into trust amongst ethnic minority communities in the UK.

However, my Lady, vaccine mistrust is not just about biology. It's deeply rooted in historical injustices, systemic racism and lived experience of unequal treatment in healthcare.

The assumption that: well, we tested it on black people in another country, therefore UK ethnic minorities should trust us, is gravely misconceived and tone deaf, because it ignores historical mistrust and structural racism in the UK healthcare, the very reason why many ethnic minorities had low confidence in the first place.

Secondly, it assumes that trust in one healthcare system automatically translates into historical trust in another system. That's not how it works. It conflates racial identity with shared experience when racial ethnic minorities in the UK have different social, cultural and historical contexts than in South Africa or Brazil.

My Lady, can I just come on to -- and I've nearly finished, a couple of additional considerations.

We've got to avoid the over-simplification of racial and ethnic identities. We've got to realise that while communities of colour globally may have shared experience of racism, the causes and manifestation of mistrust are deeply shaped by their local histories and social systems.

All of this did not happen in a vacuum, nor was it a quirk of history. It's real. It's persistent. It must end. Squeamishness around race and racism in our healthcare system has been consistently demonstrated by several witnesses and cannot continue. Whether it's a matter of vaccinations as a condition of deployment, clinical trials or data, racism is undeniably a key determinant in outcomes of the experience of black, Asian and minority ethnic communities.

So, my Lady, let me conclude by saying this: you will remember Health Secretary Mr Hancock acknowledging the longstanding structural racism within the healthcare system, noting that part of the work was trying to understand what to do with structural inequalities, yet in practice, this recognition did not translate into meaningful action.

So, to conclude, FEMHO wants an acknowledgement that

ethnic minority groups, healthcare workers and community leaders have made immeasurable sacrifices to help the government during the rollout. They have an enormous pride in the fact that, despite racism, they took the approach of being "We're all in this together". Yet, despite that, the government failed to take the invitation seriously, asserting that "We did all we could" when ultimately they did not.

We know this because the uptake was affected, diversity in clinical trials was poor, resentment for the government increased. And as a result, Covid-19 impacted ethnic minority communities at a far greater rate than their counterparts.

The paucity of data also meant that negative trends were not being properly monitored by central government.

Finally, this. My Lady, the failures we have examined here are not simply historical. They are present, they are urgent, they must be addressed. Dr Waqar rightly said it all goes back to trust. Every day is, indeed, an opportunity to rebuild trust.

My Lady, let this Inquiry be a catalyst for transformative change, ensuring that trust is not just restored, but earned through meaningful systemic reform.

My Lady, the time to acknowledge is now. The time for reform is now. The time to act is now.

Thank you.

LADY HALLETT: Thank you very much, Mr Thomas. Very grateful.

Mr Rawat.

Closing statement on behalf of the United Kingdom Health Security Agency by MR RAWAT

MR RAWAT: Thank you, my Lady. I make this closing statement on behalf of the United Kingdom Health Security Agency, or UKHSA, as I'm going to refer to it, today.

Your Ladyship is by now familiar with the role of UKHSA and the circumstances in which it was established.

The considerable work that UKHSA is already doing to implement the lessons that are being learned from the pandemic is set out in the statements that we have provided to the Inquiry. You have also heard in this module from Professor Harries and from Dr Ramsay.

I do not want to summarise that work today, but, rather, what I wish to take my time for is to touch on four themes with relevance to the future.

The first, which has already been alluded to today, is the importance of data preparedness and transparency in responding to future health threats and pandemics. This is a theme that we have addressed you on in previous modules.

But improving the safe collation and sharing of data across the healthcare system to a point where there is a unified approach offers significant opportunity to improve health outcomes, but it must be seen in the context of similar moves in other parts of the public sector.

As we have pointed out before, the use of data raises important legal and ethical questions.

Further, and with this module in mind, where, as you've just heard, trust is central to combatting low vaccine hesitancy and promoting vaccine uptake, the data systems developed in peacetime must be sufficiently robust to maintain public trust.

Consideration must also be given to the potential that relaxing restrictions on data sharing during an emergency could undermine public trust, so actually having a counter effect of increasing vaccine hesitancy and/or reducing vaccine uptake.

The benefits of sharing data are inevitably contingent on the quality of the underlying data. Recommendations for enhanced data collection are complicated by individuals' reluctance to give personal information. And, as has been articulated during this module, a lack of robust national data in relation to certain groups, for example undocumented migrants,

Gypsy, Roma, and Traveller communities.

It is, therefore, important that information sourced from local networks is not overlooked, because that risks worsening the exclusion of individuals and communities that already struggle to access healthcare services or, simply put, are not registered with a GP.

The second thing that we would address you on today concerns the complex question of how to improve vaccine uptake among communities who are already underserved by the healthcare system. Ensuring that vaccine uptake coverage is not only high overall, but high within such communities is essential to an effective elimination strategy.

This is not an issue to be left for a pandemic. It is, as Dr Ramsay put it, an issue for all time, and one which requires a concerted long-term commitment of time and resources, from multiple organisations, to lay the foundations for an effective response in a pandemic.

UKHSA has an important but defined role to play in addressing barriers to vaccine uptake. In delivering routine immunisation programmes, UKHSA, as PHE, that's Public Health England, did before the pandemic, seeks to publish resources that are culturally competent, targeted, available in different languages and media.

UKHSA works with the NHS England, MHRA and academic

partners to deliver the surveillance and evaluation of immunisation programmes, which is critical to vaccine safety and confidence. The public health teams that Public Health England had embedded in the NHS have now been transferred to the NHS, but UKHSA maintains links with that expert network and with the wider public health systems in the NHS and local authorities.

However, as Dr Ramsay pointed out, it must be remembered that vaccination is a medical intervention delivered at specific points in time.

Trust is a key factor in addressing barriers to vaccine uptake within underserved communities. And so working closely with trusted organisations over the long-term is fundamental to ensuring the success of outreach activities.

To avoid a one-size-fits-all approach to addressing barriers to vaccine uptake, there should be a local to national public health response, building on work led by directors of public health, and emphasising the importance of those working at the local level who are likely to be more attuned to the specific needs of the communities in their area, and can build trust over the long term in partnership with those communities.

Finally, we should not forget that low vaccination uptake in underserved communities reflects a broader

picture of inequalities across the health system and should not be seen in isolation. There needs to be a whole-system approach. If those who are underserved are better able to access high-quality primary care and other services in peacetime, then the likely benefit would be an increase in vaccination uptake.

Were this Inquiry to highlight the importance of a holistic approach to tackling health inequalities at a local level, with community services being able to offer sustained engagement through trusted workers, then that would be of real value to embedding continuity of care in the longer term.

My Lady, the third theme that we would address is whether more can be done to ensure that the public is as informed as possible about vaccines.

You have received written and oral evidence about the strategies that PHE, and now UKHSA, have deployed and do deploy to provide accurate information on the benefits and the risks of any vaccination. This includes publishing information on the gov.uk website and through the NHS, which clearly enjoys a great deal of public trust.

All this work ensures informed consent and promotes vaccine confidence. But it is a feature of the pandemic that a great majority of the population, some perhaps

for the first time, sought out information about vaccines. They did so in an age where inaccurate information about a vaccine's effectiveness and safety can be so easily spread. And so establishing a single authoritative resource for immunisation, such as a dedicated website accessible to both the public and to healthcare professionals, would play an important role in countering misinformation.

Such a resource could, in a very practical way, enhance public awareness of safety signals, facilitate informed consent, and sustain vaccine confidence.

Recognising that consent is a process, not a one-off event, this resource would complement rather than replace the use of written materials and face-to-face conversations with healthcare practitioners, which should remain an integral resource, particularly for those facing digital exclusion.

Finally, my Lady, the last theme that we wish to address you on today concerns the potential recommendation which the Inquiry has explored of a national vaccines agency which, as Dame Kate Bingham explained, would sit slightly outside government, have very strong external input, and the independence and authority to be able to report directly to the Prime Minister.

It would be envisaged that this agency would have an end-to-end role.

In that sense, any such agency would be similar to the Vaccine Taskforce. However, whilst superficially attractive, the proposal prompts obvious questions which are not easy to answer including, for example, what budget would this new agency need? That's a question that your Ladyship put to Dr Dix a short while ago. It reflects, of course, the premise that the vehicle may be less important than the resource.

The VTF's initial funding was over 5 billion. UKHSA currently operates to provide all of its services, including non-infectious disease science and response and global surveillance within 3% of its original pandemic budget, a figure that, as we've pointed out before, is akin to that allocated to a moderate district hospital.

Second, how do you manage conflicts of interest if your external input is short-term secondment from industry, bearing in mind that relationships with industry, if poorly managed, can contribute to vaccine hesitancy?

Third, how do you maintain the independence of the JCVI and the MHRA?

Fourth, you'll recall Dr Dix explaining that the

ability to focus just on vaccines was a strength of the VTF. Would you therefore need a separate national therapeutics agency, given that a vaccine is not always a certainty?

And finally, given that there are no discrete boundaries in clinical and scientific research, would a vaccines agency ultimately lead to the creation of multiple bodies, all essentially doing the same thing?

My Lady, the VTF was a remarkable success. It was stood up at a time when virtually everything stopped for Covid. The country's good fortune was that the political will to take risks in an emergency meant investment in a wide vaccine platform in response to a single pathogen.

Peacetime asks a different question, namely, are the systems in place capable of addressing multiple different threats, capable of being scaled up, and of being made even more timely in their response?

This is the type of system that UKHSA is already working towards and is seeking to maintain for the future. Embedding that system could save lives and protect the economy.

In our opening statement, we pointed to four capabilities which need to be nurtured for the future. They were: sustained research and development;

strengthening partnerships between government, industry and academia; the benefit of routine vaccination work; and the importance of surveillance and monitoring.

These are perhaps more prosaic than the call for a new agency, but they need to be supported because they reflect the long-term work pre-pandemic which underpinned the VTF.

And this is why, for example, UKHSA has improving health outcomes through vaccines as a strategic priority. It is why it undertakes funded research, often in collaboration with academia and industry partners. And an example is the funding provided by the Coalition for Epidemic Preparedness Innovations, which is an international partnership between public, private, and civil organisations, for UKHSA to develop a laboratory assay for Mpox, the first step to developing a vaccine.

It is why UKHSA continues to develop ongoing relationships with industry. While the Moderna Strategic Partnership may be the example that's best known to the Inquiry, in this module you've heard evidence as to how, post-pandemic, UKHSA is working with other companies, Valneva and Seqirus being examples.

It's why UKHSA has established the vaccine development and evaluation centre, or VDEC as it's been

referred to, with a remit to support the identification of the most promising vaccine candidates and to provide pre-clinical and clinical trial testing of vaccines.

We note Dr Dix's view of VDEC, but its relevance as an initiative is because it goes towards strengthening relationships with industry and academia.

And finally, the final example I would give is that UKHSA has built a new global surveillance system and is developing a UK priority pathogen tool aligned to, and working with, the World Health Organisation.

My Lady, since the pandemic, UKHSA and others have sought to build systems ready to respond to a future threat. In considering the recommendation to establish a national vaccine agency, the Inquiry will want to assess the impact that such a step would have on the work that has been done and which is planned. Would such a reset undermine the progress made, and so set pandemic preparedness back?

There is, of course, more to be done. What can be achieved will inevitably be a function of spending priorities. It is better, however, to focus on those steps which might not make a headline, but which will improve, in the long term, the country's resilience.

And such steps include increasing the number of those with the science background in policy-making roles

in government, attracting and retaining scientists and clinicians to undertake research within government, and giving licence to the Civil Service to look for innovation and to find ways of avoiding ending up working in silos.

My Lady, that is the statement for UKHSA.

Thank you very much.

LADY HALLETT: Thank you very much for your help, Mr Rawat.

Ms Drysdale. I think you got moved, did you?

MS DRYSDALE: Good afternoon, my Lady. Can you hear me?

LADY HALLETT: I can, thank you.

Closing statement on behalf of the Scottish Government by MS DRYSDALE KC

MS DRYSDALE: My Lady, I appear for the Scottish Government with my juniors Ian Halliday and Kenneth Young.

The Scottish Government wishes to reaffirm its commitment to assisting the Inquiry with examining what happened during the pandemic and reflecting on areas for improvement. It pays tribute to the many clinical, scientific and health and social care workers who responded to the major public health challenge.

Frontline health and social care workers had a much greater risk of exposure to Covid by infection due to their work but bravely continued to roll out the vaccine with support from a range of partners. The Scottish

Government worked effectively, allowing decisions to be taken in extremely challenging and uncertain circumstances.

The fast-moving public health emergency had to be matched by rapid decision-making, reflecting the development of scientific understanding, and the spread of new variants.

The overarching objective of the Scottish Government was to protect the population from the harms of Covid-19 and to minimise the loss of life. The vaccine rollout in the UK was the fastest in the world, and one of which we should be enormously proud.

Across Europe, the greatest number of lives were saved in countries such as Scotland that implemented early vaccination programmes that reached high vaccination coverage. Vaccination through increased immunity allowed governments to reopen society as Covid-19 became less of a risk for the population, bringing hope that life could potentially return to normal.

The Scottish Government recognises that there were many thousands of deaths and people left disabled directly or indirectly due to Covid-19, and in very rare cases, from the vaccine itself. Each one is a tragedy. And it appreciates that the clinically vulnerable

continue to feel the effects of the virus.

In recognising the enduring loss suffered by so many, as highlighted in the Every Story Matters report, it is important to understand everyone's unique experience of what happened.

The Scottish Government is committed to honouring those who lost their lives by ensuring that all available lessons and recommendations are learned in order to reduce the harm caused by a future pandemic.

Due to time constraints, my Lady, I am unable to address all of the topics which will be covered in full in the Scottish Government's written closing statements. Instead, in this oral closing statement, I wish to address your Ladyship on four key themes: equalities, delivery, messaging, and data.

Turning first to equalities. We are a multi-cultural society, and it is important that vaccine rollout reflects society. But it should also reflect a fairer society. Many underserved communities in Scotland experience poor public health in general. This makes it even more important that they access vaccination. Barriers to vaccination must be addressed if the UK is to be prepared for any future pandemic.

Maximising the number of people who could receive a vaccine or who could be protected from serious illness

by therapeutics was an important part of the strategy in Scotland to reduce transmission and save lives.

The Every Story Matters report states that some contributors from minority ethnic backgrounds described how previous experiences of discrimination and racism had led them to distrust the government and the health system more broadly.

During the pandemic, the Scottish Government was aware that certain communities had relatively higher levels of mistrust in government, and that working in partnership with them was necessary.

Inequalities were routinely considered as part of decision making. The Scottish Government worked with community organisations and charities to understand concerns, and remove barriers. And since the pandemic, the Scottish Government has worked with Public Health Scotland, and partners, to ensure inclusion and equalities considerations continue to inform strategy and decision making across all of Scotland's vaccination programmes.

They provided for inclusion as a priority in Scotland's new 5-year vaccination and immunisation framework, a dedicated vaccines inclusion working group, permanent funding for inclusion-focused mobile vaccination units, and the ongoing collection and use of

ethnicity data to inform decisions.

Public Health Scotland engaged with stakeholders and undertook a health inequality impact assessment which provided recommendations to health boards. Clear direction and guidance were issued to health boards from the Scottish Government asking them to prioritise inclusive efforts. Each health board also carried out their own health inequalities impact assessment or inclusion plan, informed by their local community knowledge and engagement.

The Scottish Government and Public Health Scotland worked together to capture data relating to uptake inequalities. The Scottish Government has focused on ethnicity data collection through the programme, which allowed the use of realtime disaggregated data to identify trends and concerns, and target efforts towards those communities who were not accessing the vaccine.

Some key issues that had been raised during this module were recognised and managed in Scotland throughout the vaccine rollout. For example, the Scottish Government worked with trusted partners to alleviate concerns from refugee and asylum seeker communities with tailored messaging. In addition, in Scotland, health boards were asked to put in place outreach for Gypsy, Roma, and Traveller, GRT

communities, recognising a high level of historic distrust of authority within these communities.

Partnerships were forged with local trusted figures to support engagement, and data was collected on uptake rates for GRT communities when the ethnicity data question was introduced to the Vaccine Management Tool, or VMT.

The Inquiry has heard evidence that a perceived lack of diversity in vaccine trials caused some members of minority ethnic communities to lack confidence in the vaccine. That underscores the need to improve the way in which public bodies across the UK work with traditionally underserved communities to build trust and confidence.

Part of that will, no doubt, involve a step change in the way that data is held and used, as helpfully noted by counsel for The Traveller Movement in this module.

Recognising the need to have in place a single national system to record details related to Covid vaccine delivery, the Scottish Government developed the Vaccine Management Tool. Ethnicity data was collected in the programme from November 2021 with the addition of a mandatory question in the VMT. From March 2021, Public Health Scotland began to publish this detailed

vaccine uptake by ethnicity and -- in areas of deprivation. This allowed both the public and decision makers to understand differences in vaccine uptake by population demographics, and it enabled the programme to respond and flex in response to realtime evidence of low uptake in underserved communities.

Other vaccines have since been added to the Vaccine Management Tool and the Scottish Government are committed to data improvement across all its vaccine programmes to ensure a continued focus on equalities.

High confidence in routine immunisation must be built. This is particularly important in underserved communities with historically low uptake of routine vaccinations.

Turning now to the delivery and the Barnett formula. During the pandemic, Scotland received a share of vaccines calculated on the basis of the Barnett formula. The Welsh government made a call in their opening statement for a needs-based formula for vaccine supply to the devolved nations instead.

At the time of the pandemic, the Scottish Government was content with the Barnett share, noting that more comprehensive modelling to inform supply was not possible in the timeframe available, and would have delayed vaccination.

In general, the UK Government and UKHSA were willing to engage early and often with the devolved nations regarding supply, and were clear on decisions.

In terms of advance planning, it's difficult to hypothesise on the nature of a future public health emergency, and how vaccines should be distributed in that context.

In general, Scotland adhered to the advice of the JCVI, but as the Inquiry has heard, there were instances where this advice did not reflect the Scottish delivery approach landscape. Where this occurred, officials worked hard to develop a suitable approach, or definition, and communicate this appropriately.

In Scotland, health boards are responsible for the local delivery of vaccination programmes. This decision was taken as part of contract negotiations between the Scottish Government and the British Medical Association on behalf of GPs in 2018.

It was reasonable for the Scottish Government to divert the resource-intensive duty of mass vaccination away from GPs. This policy helped to ensure resilience in the primary care sector in Scotland.

The Scottish Government recognises the challenge of geography, particularly in the Highlands and Islands, and that in rural areas, people may have had to travel

longer distances to access vaccination.

Mobile units were made available to reach these communities, and health boards used their local knowledge and realtime uptake data to pivot their approach to ensure suitable clinic availability. In addition, health boards worked with local partnerships and charities to mobilise volunteers and free accessible transport options to get people to their appointments.

The Scottish Government recognised that attending a mass vaccination centre would not be suitable for everyone. A range of measures were put in place by health boards to ensure that the vaccine reached everyone. Work is ongoing with partners to ensure that all current and future vaccination programmes are fully accessible, no matter where in the country some one lives.

Decisions taken regarding delivery, such as the vaccination of care home staff, at the same time as care home residents, led to higher uptake among care home workers in Scotland, but it is difficult to compare uptake, as there were only marginal differences in the vaccination programmes across the UK. The uptake figures for the four nations are broadly in alignment.

Turning now to messaging. Public health messaging in Scotland was broadly effective, demonstrated by the

overall levels of vaccine uptake. Communications evolved in response to changing advice and evidence, as well as emerging insights, feedback, and research.

Increasing levels of fatigue, misinformation and disinformation, impacted vaccine confidence, and influenced the approach to messaging as the pandemic went on.

Disinformation was a continual issue over the course of the pandemic and was particularly difficult to deal with on social media. The Scottish Government took an effective approach of repeating factual statements that countered this without being drawn into direct confrontation with the publishers. Trusted medical professionals were often used to deliver these messages, recognising high levels of public trust in the NHS.

In addition, there was a dedicated team leader in the vaccine policy team responsible for managing disinformation, liaising with partners in Scotland, but also making connections with other UK nations. The former First Minister took a central, visible role in public messaging.

Vaccination was promoted from an early stage, as a positive intervention that would support easing of restrictions.

The Scottish Government has already begun its work

with partners to identify areas for improvement and embed learning into its vaccination programmes.

In January 2024, responsibility for national oversight of all vaccination programmes in Scotland was transferred to Public Health Scotland.

Finally, my Lady, turning to data. Throughout this module, the Inquiry heard evidence to the effect that the lack of accessible data hampered vaccine delivery across all four nations. At the start of the programme, there were challenges regarding accessible and publicly available supply data, which impacted the Scottish Government's ability to communicate appropriately with the public and build and maintain trust in the programme. This later improved as supply became steadier.

The Scottish Government worked with partners to improve its programme data throughout the course of the rollout to ensure that it was able to plan its resources and approach appropriately. Its future pandemic preparedness programme of work has identified data as a priority area for improvement.

My Lady, in conclusion, the Scottish Government wishes to thank all those who have given evidence during Module 4, and to pay tribute to all those in the NHS and across society who served others during the pandemic by

developing, delivering and administering vaccines and therapeutics.

The Scottish Government is wholeheartedly committed to assisting the Inquiry in fulfilling its terms of reference and identifying findings and recommendations. It is determined to emerge from the public health crisis with the a stronger and fairer society, building on the common purpose within the vaccination and therapeutic pandemic response in Scotland.

Now that we have emerged from this tough challenge, there is an opportunity to renew our country, building a fairer society with more equitable access to healthcare. The Scottish Government has laid strategic foundations to prepare its vaccination, and therapeutic systems for the next pandemic, to improve routine immunisation programmes, and to put it in a strong position to respond to new threats.

LADY HALLETT: Thank you, Ms Drysdale.

Mr Stanton.

Closing statement on behalf of the British Medical Association by MR STANTON

MR STANTON: Thank you, my Lady.

My Lady, the closing oral statements of the British Medical Association is as follows. The BMA's position remains as stated at the outset of these hearings: that

the Covid-19 vaccination programme was one of the biggest successes of the pandemic, as clearly demonstrated by the estimate of the UKHSA that, as at September 2021, vaccination in the UK had prevented more than 24.3 million infections and over 123,000 deaths.

The BMA also recognises and commends the speedy development and authorisation of the vaccine, which took place without compromising safety.

However, the BMA's interests in this module primarily relate to vaccination rollout and deployment, and in particular, the following: the role of general practice in delivering the vaccination programme, barriers to vaccine uptake, workforce planning and capacity, data sharing, and vaccination as a condition of deployment.

In respect of the role played by general practice, the BMA considers that GPs and their practice teams made a major contribution to the success of the vaccination programme.

The BMA proactively made the case in England that the vaccination programme should be delivered by general practice, and the Inquiry heard from Dame Emily Lawson that, in England, GPs were the right model, particularly for the most at-risk priority groups, including care home residents and the elderly.

This use of existing infrastructure and delivery of vaccines at a local level was highly effective, and by the end of October 2021, 71% of vaccines in England had been administered by GPs and their teams and community pharmacies.

The Inquiry was told that many people felt more comfortable and had greater levels of trust in receiving their vaccination from their local GP rather than at a vaccine centre. GPs have substantial experience of delivering vaccinations, and have existing knowledge of and relationships with their patients, particularly elderly patients.

This, coupled with the proximity of GPs to their local populations, helped to overcome barriers to access.

In addition, GPs have the experience to address questions or concerns about the vaccine and to encourage uptake in the local communities.

And as confirmed by the UKHSA, being able to receive a vaccine in a familiar environment can support public confidence.

My Lady, turning to barriers to uptake. The Inquiry has heard a substantial volume of evidence on disparities in vaccination uptake amongst different population groups, including ethnic minority

communities, migrants, Gypsy, Roma, and Traveller communities, disabled people, and those living in deprivation.

These disparities highlighted longstanding problems of inclusion within UK healthcare systems, and it was well known before the pandemic that there was a historic mistrust of the healthcare system and vaccines within certain communities.

A 2016 report of Public Health England on flu vaccination showed lower uptake by people from ethnic minority backgrounds than for people with white British or white Irish backgrounds. And this trend was also seen in the lower rates of Covid-19 vaccine uptake amongst ethnic minorities. Again, with vaccine uptake highest amongst those from a white ethnic background.

The Inquiry also heard that deprivation was a factor in lower uptake in all groups, with vaccine uptake higher in areas of greater affluence, something the BMA highlighted in its fifth Covid-19 review report.

People from ethnic minority and deprived communities had worse health outcomes before the pandemic, and had a higher likelihood of becoming infected with, and experiencing severe symptoms from, Covid, not least because of wider health inequalities.

Disabled people were also at significantly greater

risk from Covid, and from dying as a result of infection.

With this in mind, the BMA submits that there should have been greater consideration of these groups when planning the vaccine rollout.

Professor Van-Tam's witness statement reflects this position, and sets out that:

"It is well known that vaccine uptake tends to be lower in marginalised, deprived, and ethnic minority communities. It was therefore foreseeable that a similar pattern would be observed when it came to delivery of the COVID-19 vaccines, as indeed it was. It is ... therefore arguable that more should have been done in the planning phase to consider this."

The mechanisms of the programme also, on occasion, caused barriers to vaccination. For example, although disabled people were a focus of prioritisation, the less than full identification of people living with a learning disability and the lack of clarity on the level at which a learning disability provided priority eligibility created a barrier in accessing vaccination for this vulnerable group.

This must be addressed in advance of any future pandemic to ensure that the main means of offering vaccination in a mass vaccination programme does not

rely on self-identification.

The Inquiry also heard of physical barriers preventing vaccine uptake, such as the distance to a vaccination site, the cost of transport, and difficulties or concerns for the clinically vulnerable, disabled, elderly, or housebound from attending a vaccine centre.

The lack of an NHS number also presented issues for people in the homeless population, the Gypsy, Roma, and Traveller communities, and vulnerable migrants.

The BMA recognises that efforts were made to address vaccine hesitancy and to overcome barriers to assessing vaccines, but more still needs to be to instill confidence.

Evidence before the Inquiry supports ongoing engagement with marginalised and underserved communities which has been lacking.

The disparities in access and uptake to the vaccine laid bare the disparities in access to healthcare more broadly, and highlight an important area for governments across the UK to prioritise for urgent improvement.

As the Inquiry's experts in vaccine delivery and disparities warned:

[As read] "We cannot be complacent. We have to be continuously promoting uptake of vaccinations. And it

needs to be resourced."

Misinformation and disinformation also contributed to vaccine hesitancy, and the Inquiry has heard about these issues from a number of witnesses in these hearings, including the Director General with overall responsibility for the Counter Disinformation Unit, who told the Inquiry that: disinformation is defined as the deliberate creation and dissemination of false information, which is intended to deceive and mislead. And misinformation is the same, but without the deliberate intent.

During the pandemic, the BMA ran its own social media campaign to address vaccine hesitancy, and called on the UK Government to take more action to tackle misinformation online.

It goes without saying, then, that the BMA entirely rejects the assertion made by the former Minister for Equalities, Kemi Badenoch, in her oral evidence, that the BMA was itself responsible for misinformation.

The background circumstances to this issue are that the BMA raised legitimate concerns in June 2020 within a number of letters to Ms Badenoch and the Secretary of State for Health and Social Care, following publication of the Public Health England review into inequalities and disparities.

And my Lady, you heard evidence on this issue in Module 2.

The BMA had anticipated that the review would address why there was such disproportionate deaths and serious illness in healthcare workers from ethnic minority backgrounds. However, when the review was published, it failed to address the staggeringly higher proportion of deaths amongst healthcare workers from ethnic minority backgrounds.

In response to Ms Badenoch's criticisms, Professor Banfield, the BMA's chair of UK Council, issued an immediate public response on Monday of this week which concluded:

"To suggest the BMA was spreading misinformation at this time is highly disingenuous. All we were doing was asking the government to be transparent about how and when it was planning to take action to save lives and address racial inequalities."

In respect of workforce planning and capacity, the BMA's view is that general practice was the right delivery vehicle for Covid vaccination. However, the BMA remains concerned that insufficient consideration was given to workforce planning in connection with the vaccination programme, and that delivery of the programme further reduced the already limited workforce

capacity in general practice, with GPs and other healthcare workers required to work additional hours to administer vaccinations whilst still continuing to deliver Covid and non-Covid care.

During the pandemic, the BMA engaged with NHS England and the Department of Health and Social Care, to address the increasing demands on general practice, the rising workloads and workforce shortages, and make clear that general practice was at breaking point, and there were simply too few GPs.

Against this background, the comments made in the published witness statement of the former Secretary of State for Health, Sir Sajid Javid, that the BMA sought to take commercial advantage of the vaccination scheme are shameful and offensive, and expose complete ignorance of the reality for GPs on the ground, including the overwhelming demand, the lack of capacity, and the abuse faced by GPs and their staff whilst they did their best to manage unmanageable workloads.

The vaccination programme was substantial additional work that general practice delivered in the national interest, requiring the existing or additional staff to take on increased hours, often at weekends. It did not result in GPs being paid twice, as alleged, and the efficiency with which GPs delivered vaccines was more

cost effective than costs per dose at mass vaccination centres.

My Lady, on the question of data sharing, access to GP data is subject to a number of checks and balances. These are put in place to preserve the integrity of the doctor-patient trust relationship, and to ensure that GPs uphold their obligations as data controllers under GDPR.

However, the BMA was broadly supportive of measures put in place to support the UK's pandemic response which lowered the threshold on access to GP data. The Inquiry heard evidence that such measures should be brought back to enable better sharing of health data. The BMA agrees that improved data sharing is essential to providing safe, high-quality healthcare, and to enable healthcare services to respond to emergencies, such as a future pandemic.

However, great care must be taken to safeguard patient confidentiality.

Finally, my Lady, on the issue of vaccination as a condition of deployment (VCOD), the Inquiry has heard differing views on the merits of this policy. The BMA's position is that it strongly urges doctors and frontline healthcare workers to be vaccinated, and uptake amongst doctors of the Covid-19 vaccine was high, but the BMA

considers that mandating vaccination is not the right approach, and would worsen the existing recruitment and retention crisis within health and social care, as seen when the policy was implemented for a short period of time within social care in England, which caused significant reductions to the workforce.

Covid-19 vaccines have been very successful at controlling serious disease and death, but they do not prevent transmission. And Professor Sir Chris Whitty, while acknowledging that VCOD was a political decision, expressed his scepticism that it was a good idea, and told the Inquiry that mandation has not got a very happy history.

He also highlighted that doctors have a clear professional responsibility to protect patients by having vaccinations, but said that there is a big difference between responsibility and mandating it so that you lose your job.

A similar view was held by Dame Jenny Harries, who advised in February 2021 that there was no evidence that the policy would have more benefit than harm.

In conclusion, my Lady, while there is no doubt that the Covid vaccination programme was a success, there are lessons to be learned from this experience, and from vaccination programmes before it, that can lead to

increased uptake and reduced disparities, which will in turn further reduce the risk of infection and save more lives.

My Lady, thank you to you and your team for facilitating the core participation of the BMA at the Inquiry.

LADY HALLETT: Thank you very much, Mr Stanton.

Ms Domingo, I won't cut you off before the break as I did last time.

Closing statement on behalf of the National Pharmacy Association by MS DOMINGO

MS DOMINGO: Thank you, my Lady.

This is the closing statement on behalf of the National Pharmacy Association.

Over the past three weeks the Inquiry has heard evidence from many sources of the vital role played by community pharmacy in the delivery of the Covid-19 vaccination programme, and of the efforts made by the National Pharmacy Association on behalf of its members to advocate for an increased role for community pharmacy in supporting vaccine delivery.

The NPA welcomes the Inquiry's scrutiny of the rollout of the vaccination programme, and particularly those areas where there are lessons to be learnt for the future.

This statement for the NPA seeks to address two broad points arising from the evidence heard in this module. First, the key role that community pharmacy played in the success of the vaccination programme and the need for early involvement of community pharmacy in planning and delivery for future vaccination programmes. And, secondly, the role of community pharmacy in addressing health inequalities, overcoming barriers to vaccination, encouraging vaccine uptake and countering vaccine hesitancy.

Primary care, including community pharmacy teams, were crucial to the successful delivery of the Covid-19 vaccination programme, and all four UK nations relied on community pharmacy to differing extents in ensuring that vaccines were readily available throughout the country. Community pharmacy teams have helped to protect and save the lives of tens of millions of people in the UK.

Given its years of experience and expertise in delivering annual flu vaccinations, and given the reach and resources of the approximately 13,000 community pharmacies embedded in communities across the UK, community pharmacy is ideally equipped to deliver a vaccination programme.

The Inquiry has heard that the Covid-19 vaccination programme benefited from the infrastructure already in

place for the delivery of routine immunisation programmes, and that programmes delivered at local level have proved highly effective.

However, as the Inquiry has also heard, community pharmacy was not involved in the initial phases of the rollout, in large part due to the programme requirements in England that vaccination sites administer at least 1,000 doses per week and remain open 12 hours a day, seven days a week.

The NPA voiced concerns that community pharmacy was under-utilised in the early days of the rollout, and evidence before the Inquiry shows that in January 2021, the Prime Minister also questioned whether enough was being done through community pharmacies.

Amongst reasons put forward for not including community pharmacy from the outsets were the difficulties transporting and storing the Pfizer vaccination, and while the NPA well understood these challenges, by early January 2021 the Oxford-AstraZeneca vaccine was available and was very suitable for community pharmacy to deliver. The requirement of 1,000 vaccines per week was, in the NPA's view, no longer required, and risked creating new health inequalities.

It has also been suggested that it was supply constraints which demanded that vaccine sites deliver

1,000 doses a week, and this approach was devised to protect as many people as quickly as possible in the fairest way possible.

However, the very first Covid-19 vaccine delivery plan, issued by DHSC on 11 January 2021, emphasised that local vaccination services, including community pharmacy sites, provided the largest number of sites, supported the country's highest-risk individuals, and delivered vaccination to people unable to attend vaccination centres, including reaching vulnerable groups such as the homeless.

This document recognised that community pharmacies are integral parts of local communities and will be accessible and approachable places from which to deliver vaccination.

The NPA submits that the balance reached in the early part of the vaccination programme, prioritising large vaccination centres in favour of a higher number of local sites, was wrong. A more balanced approach that relied on existing health infrastructure, including the extensive network of community pharmacies across the country would that have ensured broader, more equitable access to the vaccine at an earlier stage, and could have been achieved, had community pharmacy been consulted and involved earlier in the planning process.

As a final point on the role of pharmacists in vaccine delivery, and as mentioned in the NPA's opening statement, the NPA asks the Inquiry to take account of the impact of delivering the vaccination programme in a system that was already stretched to breaking point by the pandemic.

Healthcare workers and community pharmacy and general practice provided crucial vaccination services on top of existing commitments, and any future vaccination programmes must ensure that experienced health professionals have sufficient capacity to deliver the programme in a safe and sustainable way.

The second broad area relates to vaccine uptake, barriers and hesitancy. The Inquiry has heard of the benefits of working at local level through general practice and community pharmacy, including high levels of patient registration, the ability to rapidly identify clinical at-risk groups, and value in being able to receive a vaccine in a familiar environment which supports public confidence.

The Inquiry's expert in vaccine hesitancy, Professor Larson, told the Inquiry that access was a big issue, and to quote:

"The more we can try to engage locally, and again, that doesn't have to wait and shouldn't wait for another

crisis, whether it's through a local GP or a pharmacy, the more we can bring vaccines closer to people is only an asset."

Many witnesses have described the trust relationship that exist at a community level, and GPs and community pharmacists have been described as by far the most trusted health professionals in their communities. Approximately 50% of the NPA's membership are from ethnic minority backgrounds, and their role as trusted healthcare professionals at the heart of their communities allowed them to respond to the needs and concerns of their patients, addressing health inequalities and vaccine hesitancy within their communities. Their ability to debunk myths and misconceptions improved vaccine uptake, particularly in patients who expressed scepticism about the vaccination.

Community pharmacies are disproportionately located in poorer areas, and they play a particularly important role in deprived and rural communities, which often have less access to other healthcare services, and where there are increased barriers to accessing a vaccine centre.

Community pharmacies are accessible without an appointment, and 99.8% of the population in areas of highest deprivation have access to a community pharmacy

within a 20-minute walk.

Community pharmacies have tried and tested mechanisms of reaching out to patients to reduce vaccine inequity in local populations, as well as being innovative in delivering patient care.

The NPA's witness statement in this module included the following account from a member pharmacy that had set up a process with their local director of public health to vaccinate individuals from marginalised communities.

The pharmacy team recognised the importance of vaccinating people from inclusion health groups, given they are already experiencing significant health inequalities, and are at higher risk of poor outcomes should they contract Covid-19.

Inclusion health groups comprised people who might struggle to access mainstream healthcare, and include vulnerable migrants, asylum seekers, refugees, people experiencing homelessness, sex workers, Gypsy, Roma, Traveller communities, and people struggling with addiction.

The walk-in model was particularly useful for helping including health populations who are typically not registered with a GP, and have no NHS number or access to the Covid-19 vaccine as they are unable to use

the national booking system appointment system.

The NPA believes that the significance of vaccine hesitancy and other barriers to vaccine uptake were not fully appreciated early enough. Barriers to vaccination need to be understood and addressed at a community level, and again, the early involvement of community pharmacy and planning could have better identified these issues, and allowed greater scope for the positive role that community pharmacy can play.

To conclude, my Lady, the Inquiry has heard that throughout the relevant period, community pharmacy delivered just under 21% of all Covid vaccinations in England, and in the recent winter campaign for flu and Covid, community pharmacy delivered over 40% of vaccinations.

As highlighted by Dame Lawson, the role that pharmacy plays in vaccination, particularly in areas which are underserved by both primary and secondary care, is absolutely vital.

The NPA believes there is substantial scope for community pharmacy to play a greater role in vaccination planning and delivery, which will benefit future pandemic preparedness.

Thank you.

LADY HALLETT: Thank you very much, Ms Domingo. We will

take our break now. I shall return at 3.25.

(3.07 pm)

(A short break)

(3.24 pm)

MR JACOBS: My Lady, can you hear me?

LADY HALLETT: Not quite.

MR JACOBS: Let's try again.

LADY HALLETT: Got you. Yes.

Closing statement on behalf of the Traveller Movement by MR JACOBS

MR JACOBS: My Lady, the Traveller Movement is grateful to you for the opportunity to participate in this module of the Inquiry. Public inquiries are important because they are capable of catapulting significant but perhaps neglected issues into public consciousness, and into the minds of institutions which hitherto failed to act appropriately when needed. And as a result of its participation in your inquiry, the Traveller Movement believes that the sands have shifted insofar as there is now an institutional awareness and public understanding that Roma, Gypsies and Travellers were largely abandoned in the vaccination programmes and, importantly, that they were, in many ways, statistically invisible, and not properly captured, certainly in England, in census records and other national data.

It was uncontentious during the rollout in December 2020 that the Traveller communities were a health inclusion group. And that means that by virtue of social exclusion, poor health outcomes, and a high risk of missing out on vaccination, they were particularly vulnerable.

Yet it's clear from the limited data that we have and the compelling evidence given before you by Ms MacNamara on 16 January that not enough was done to address the significantly low uptake of vaccines that ensued.

My Lady, the evidence over the last three weeks has confirmed that the level of institutional failure towards the three GRT communities was indeed significant.

You will recall that the director of the health -- of the public health programmes at the UK Health Security Agency, Dr Ramsay, stated in evidence on 21 January, in answer to questions from ourselves, that, apart from a single workshop, she was not aware of any concerted effort at national level to ensure the inclusion of GRT and targeting of GRT into the vaccination programme.

Furthermore, my Lady, on 27 January, Kemi Badenoch, the Minister for Equalities at the time of the vaccine

rollout, was asked again by ourselves about the lack of targeted initiatives such as pop-up clinics or bespoke community engagement in respect of Travellers.

And she said that it was her understanding that there were GRT-based activities, but that of all the groups that the government was trying to reach, this was the most difficult group.

Ms Badenoch went on to say that the lack of engagement with Travellers might have been down more to the fact that GRT were difficult to reach, rather than simply because nothing was done.

Significantly, she clarified that she might be able to explain this, but not as a minister, but from her experience as a constituency MP, where she had noted that there was a hostility to state bodies within the communities.

My client is keen to impress upon the Inquiry that the underlying reason why some members of the Traveller community appear to be hostile or reluctant to interact with the state lies in the fact that discrimination and marginalisation necessarily breeds distrust and non-cooperation., and this particularly applicable in a number of pockets of chronic exclusion around the UK, such as unregistered sites, where, as we've already stated, approximately 10,000 Travellers are forced to

live as a result of local authorities failing to meet spatial planning requirements.

I gave examples in my opening submissions of discrimination during the pandemic: deaths occurring because ambulances were required to wait for police escorts before entering sites, and heavy police presence at funerals.

You will recall that Ms MacNamara told you, in her evidence on 16 January, about cases where police were sent to sites to stop residents going out to buy fuel for generators, those very generators which were used to power the refrigerators on sites that stored medication.

My Lady, I echo what Mr Thomas KC told you earlier, it's about trust. Trust is vital. The fundamental problem with the authority's approaches to the GRT communities is that prior to the pandemic, only very limited steps were taken to proactively engage to address mistrust and lack of cooperation, so by the time of the vaccine rollout in December 2020, as Ms MacNamara put it so well, the flood had already started and it was too late to build the ark.

And that chimes, my Lady, with the evidence of Dr Chantler on 27 January, and she said there needs to be an ability to build trust and relationships, so that you don't have to suddenly gather people together.

My Lady, the way to generate trust is through effective community engagement, and the two are very much connected, and equally important. Ms MacNamara confirmed that mobile health services for the GRT community are no longer in existence, and that this important outreach should be reinstated because it had been crucial to building the relationships with communities that are so needed at times of health crisis, for example.

Ms MacNamara went on to say that the mobile health services, when in existence, had allowed people to have someone they could go to with health concerns or issues, who they could build up a relationship of trust and confidence with. She stated that these services might have proved very useful when the vaccinations were rolled out, because questions about vaccinations would have been dealt with by health professionals, who the Travellers knew and trusted, and in circumstances where the Travellers would be more familiar with the healthcare system.

Dr Richardson said, on 28 January, that it is important that the message is transmitted by the right messenger, and my client couldn't agree more.

My Lady, you will recall that misinformation was a significant issue for the GRT community. Ms MacNamara

told the Inquiry that rates of child mortality and miscarriage are high in these communities, and that rumours spread to the effect that vaccines could lead to infertility in children, and -- sorry, to infertility, and autism in children.

These rumours spread quickly through what is traditionally an oral community and went unchecked, and it's important to note that a community which suffers from digital exclusion and literacy issues is not only less able to receive vaccine invitations by letter or look at government alerts on the Internet, but will also be unable to access government messaging so as to counter misinformation.

My Lady, I spoke earlier in relation to the evidence about the lack of any meaningful initiatives at national level to ensure the inclusion of GRT, and targeting GRT into the vaccination programmes, the evidence that was given by the Director of Public Health Programmes.

Regrettably, it was the case that local interventions were also sparse, particularly in England. Aside from local programmes at the Appleby Horse Fair and an initiative in Shropshire involving a well-known TV figure, there doesn't appear to be any evidence that much was done at a local level in England.

Witnesses have pointed to the Community Champions

Scheme, but the Traveller Movement maintains that this initiative did not address the problem of low vaccine uptake notwithstanding that local authorities had an awareness, of course, of where the Traveller sites, or some of them at least, were located.

The situation was handled much better in Scotland, as Ms Drysdale KC on behalf of the Scottish ministers has set out in her submissions today. We note that Mr Grieve told the Inquiry, on 28 January, that the Scottish Government's approach was to respond to feedback that they received from particular communities.

And there is evidence in a February 2022 Scottish Government document entitled "Inclusive vaccinations", phase I of the Covid-19 vaccination programme, INQ000376293, that the National Health Service in Scotland worked with local authorities and ambulance services and visited Traveller sites in the Forth Valley and the Boswell Fair to deliver vaccination.

My Lady, I turn, perhaps as I must, to the issue of data. The Traveller Movement's position is that problems of lack of trust and lack of engagement were compounded by the fact that GRT, which as we've said, constitute possibly up to 1% of the UK population, are statistically invisible, and particularly in England.

Now, as I pointed out in my opening submissions, the

contrast between data capture in Scotland and in England is shown at pages 58 and 59 of the expert report of Dr Kasstan-Dabush and Dr Chantler. My Lady, of course I don't have time to put all this on the screen, but you'll note at page 59, when you come to analyse the report, that there's a table containing the Public Health Scotland data where GRT are recorded as the highest unvaccinated group, as I've said, at 55% unvaccinated and the least likely group to receive at least one dose.

Yet on the preceding page, if you go back in the report, you'll see the data from England that fails to refer to the GRT groups at all. These communities are nowhere in sight as far as the English data is concerned.

And Dr Chantler helpfully confirmed in his evidence on Tuesday that in England, healthcare records do not routinely record membership of certain health inclusion groups.

And we have heard this in other evidence. The government's final report on progress to address the Covid-19 health inequalities, or the quarterly review, you might recall, dated December 2021, so a year before the rollout, that confirms -- and it's INQ000089747, at page 124 -- the vaccination estimates for Gypsy, Roma

and Irish Traveller populations are not available as NHS systems do not have these categories available to choose.

So it was out in the open.

The same report recommends, at pages 134 and 136 that it was a high priority next step to improve ethnicity coding and health datasets amongst other things to allow information for the GRT groups to be presented. Yet it appears, of course, that this recommendation has not been implemented.

Dame Emily Lawson accepted in her evidence, answering Mr Keith King's Counsel on 28 January, that we would not find any figures relating specifically to GRT in the NHSE documentation, and she confirmed that GRT are not in the NHS Data Dictionary.

Dame Emily also said in her evidence that ethnicity data was in the process of being updated, but you will recall that Ms MacNamara also said on the 16th that her organisation, the Traveller Movement, for whom I act, has been calling for such inclusion since 2012.

My Lady, it is just unacceptable that this situation is permitted to continue, and we say that if the Inquiry makes any recommendation in relation to GRT, and we hope there will be more than that, but if it makes any one recommendation, it must emphatically recommend that the

NHS changes its data recording procedures to include the GRT communities.

It is self-evident, of course, that data capture has a strong bearing on vaccine uptake. You will recall that Ms MacNamara told the Inquiry that without proper data capture, GRT community members would not have received NHS text messages that were sent out to vulnerable communities during the pandemic. And Dr Kasstan-Dabush referred to GRT in his evidence on 28 January, and he said that you need an NHS number to be called up in the first place.

One would have thought it quite obvious, really.

TM's uncontroversial position is that without inclusion in NHS data, people are going to be overlooked in local and national health strategies and delivery. And that's what happened in the Covid pandemic and it will happen again, if not addressed.

There's another issue to which Ms MacNamara referred in her evidence which I want to address briefly, which is that GRT are no longer provided with handheld medical records. Now, this was a measure that addressed the longstanding problem of inclusion in healthcare that GRT face, where, for example, GRT members relocate frequently between sites or between houses. And we ask you to recommend that the system of providing handheld

records for members of the GRT communities is restored. These records would make it easier to register with a GP. They might break the pattern of Travellers being turned away from surgeries.

GP registration is, of course, important. As Ms Stephenson of counsel put to Ms MacNamara on 16 January, the invitations to vaccinate were linked to GP registration. If you're excluded from the system, you're just not going to get the information. It's noteworthy that many GRT members did not have an NHS number during the pandemic, and that in itself amounted to an impediment to obtaining a vaccination dose.

In conclusion, my Lady, I would repeat what I said in my opening submissions: there are three actions which would have been effective to improve immunisation uptake amongst the GRT communities. These are, firstly, maintaining trust within the Traveller groups locally; secondly, specialist health attendances on GRT; and thirdly, high-quality data.

And these are effectively the recommendations that we seek. Having heard the detailed evidence over the last three weeks, it is even clearer that these measures are needed.

It should now be uncontentious that unless the authorities take appropriate steps to establish trust

with the GRT communities, restore specialist health visitor outreach services, and capture high-quality data describing family ethnic groups, the mistakes that were made -- and they undoubtedly were made -- around vaccination in the Covid-19 pandemic, will be carried through to any future pandemic.

My Lady, the Traveller Movement ask that you recommend that these measures are implemented by policy makers now. Dr Kasstan-Dabush told the Inquiry, on 28 January, that there is a need to create an agenda for change in partnership with underserved groups, and my client emphatically agrees.

Furthermore, these problems don't just arise when there is a pandemic on the horizon.

As Mr Stanton on behalf of the BMA stated before the afternoon break: Dr Chantler told the Inquiry in her evidence that we cannot be complacent. She said we have to be continually promoting uptake of vaccinations and this needs to be resourced.

Now finally, my Lady, your Inquiry represents a once-in-a generation opportunity to address vaccine inequality within these three highly-marginalised and vulnerable communities.

And we submit, or the Traveller Movement submits, that the Inquiry must make robust recommendations to

ensure GRT engagement, and inclusion in the future.

I repeat Ms MacNamara's very apt analogy: you can't build the ark after the flood has happened, and we say that building process must start now.

Unless I can assist further, those are my submissions.

LADY HALLETT: Thank you very much indeed for your help, Mr Jacobs.

Ms Parsons, are you over there?

Closing statement on behalf of the Covid-19 Bereaved Families for Justice Cymru by MS PARSONS

MS PARSONS: My Lady, I make this closing statement on behalf of the Covid-19 Bereaved Families for Justice Cymru.

By way of introduction, as the Inquiry is aware, a priority of the Covid-19 Bereaved Families for Justice Cymru group is to scrutinise where the Welsh Government discharged its duty to protect the lives of people in Wales.

This closing statement flags key concerns of the group in relation to that issue. It will focus in particular on the delivery of vaccinations in the first few months of the programme to the most vulnerable groups in Wales.

It is important, when considering these issues, to

remember what a devastating period this was, with care homes in Wales experiencing 465 Covid-19-related deaths in January 2021 alone, and, at times, as many as 20 deaths a day.

Vaccinations in Wales commenced on 8 December 2020. However, by 16 February 2021, over two months later, only 82% of care home residents in Wales had been vaccinated.

Whilst at first blush that might seem a high proportion, in fact, it was significantly below some of the other phase I priority groups. This was despite the JCVI having identified care home residents as the most vulnerable group, and the first priority group on the list.

The source of this information is the Welsh Government's vaccination update.

That's at INQ000410143.

This update also demonstrates that during February 2021, up to the 16th of that month, almost no vaccines were delivered to care home residents.

Time was of the essence for many vulnerable people in Wales, as powerfully described by the group's co-lead, Sam Smith-Higgins, from whom, my Lady, you heard earlier this month.

She told the Inquiry about her fears for her

73-year old father, who was admitted to hospital in January 2021 for cancer-related treatment and was immune suppressed and vulnerable.

Ms Smith-Higgins made efforts to secure a vaccine for her father prior to his admission but was told this was not possible. Tragically, just three weeks after being admitted to hospital, he died from a Covid-19-related infection acquired in hospital.

So, against that backdrop, my Lady, the key concerns.

Key concern number 1: the Welsh Government's decision to deliberately slow the rate of vaccine delivery and its failure to vaccinate in accordance with JCVI priority cohorts.

The group's members are extremely concerned at the decision of the Welsh Government to intentionally slow the delivery of vaccines in January 2021 to vulnerable people, and the group requests, my Lady, that the Inquiry gives this matter careful consideration.

The former First Minister, Mark Drakeford, made a public statement on 18 January 2021 explaining that vaccinations in Wales would be staggered because, I quote:

"... it would be logistically very damaging to try to use all of that in the first week and then have all

of our vaccinators standing around with nothing to do ..."

This bizarre statement was roundly criticised, and it might be thought to be an off-script comment made in error. However, it was, in fact, the policy of the Welsh Government, as seen from the ministerial advice to the First Minister, Mr Drakeford, on 24 November 2020.

That is at INQ000361639.

That ministerial advice stated as follows:

[As read] "Given the constraints around transportation of the Pfizer vaccine to care homes, it is recommended that the vaccine is not used in care homes for the first four weeks of delivery."

This policy, my Lady, was also contrary to the JCVI priority cohorts and to the approaches taken in other UK countries, as can be seen from the Cabinet Office meeting minutes of 12 January 2021, and those minutes are at INQ000088889.

The minutes read as follows:

[As read] "300,000 doses had been delivered to Wales but short of 90,000 had been used so far. The press have picked up that this was down to the Welsh Government. It would be useful to have regular publication of how many vaccines had been delivered. The Welsh Government's approach was slightly different

to other nations, as it had prioritised NHS staff for the Pfizer vaccine."

And, my Lady, you heard the anger and confusion that this decision, the decision to delay the vaccination to vulnerable, had caused people in Wales.

Ms Smith-Higgins told you in her evidence:

"... the vaccinations had started coming out on 8 December ... and I was a carer for an 85-year old, my mother ... and so I expected her to be ... vaccinated relatively soon, but as December went through, I was tweeting like mad everybody, MPs, MSs, head of NHS, saying: What is going on? Why hasn't my mother been vaccinated? And it soon became apparent that actually, in Wales, they were focusing on the healthcare workers and not ... aged or the most vulnerable.

"By 11 January, Cardiff and Vale Health Board tweeted that up to date, up to 11 January, they had vaccinated 12,300 people, of which [just] 69 were in care homes and only 75 were over 80."

The group wishes to make clear that they take absolutely no issue whatsoever with the prioritisation of frontline healthcare workers as advised by the JCVI, but that wasn't what happened in Wales, with significant numbers of administrative staff vaccinated before the vulnerable.

Ms Smith-Higgins refers in her witness statement to one such example, a relative in her fifties with no underlying health conditions who worked in an administrative department of one of the Welsh health boards and who received her vaccination as early as December 2020.

The concern and anger about this issue was amplified by the history of neglect of care homes in Wales during the pandemic. This was epitomised, my Lady, by the evidence of the former First Minister, Mark Drakeford, in Module 2B, when he told the Inquiry, and I quote:

"There is no single register of where every care home in Wales is located."

This of course begs the question: how was vaccination progress being managed and monitored among this most vulnerable priority group when the government didn't even know of their existence?

The group, many of whom witnessed the death of their loved ones from Covid-19, want to know how many deaths could have been prevented if the Welsh Government hadn't delayed the vaccination in December 2020 and January 2021? They want to know how many deaths could have been prevented if the Welsh Government hadn't prioritised non-frontline healthcare workers over older people and the vulnerable.

Key concern number 2, my Lady: overreliance on a small number of mass vaccination centres, despite the geographical and demographic challenges of Wales.

The group is concerned at the decision of the Welsh Government to heavily rely on delivery through larger vaccination centres. This decision is particularly difficult to understand, given the geography of Wales, with many rural and remote communities, and also the demographic of Wales, which, as explained by Dr Richardson in her oral evidence, is an older population, with greater healthcare needs than other parts of the UK.

My Lady may recall the evidence of Sam Smith-Higgins when she told the Inquiry that the mass vaccination centres in Wales covered huge geographical areas requiring lengthy journeys by car, bus or several buses.

She told the Inquiry:

"... for people who have been ... shielding for months and months and months, to suddenly have to take an hour-and-a-half journey within the same health board to then stand outside for an hour-and-a-half queueing to get into a sports centre, it [just] wasn't the best thought out ..."

The group wants to know why the Welsh Government used this model, a person-to-vaccine model, rather than

a vaccine-to-person model, when it would have been so obviously a disadvantage to those who were vulnerable and/or who could not travel.

The group believes that trusted healthcare professionals such as GPs and community pharmacists who are embedded within communities and easily accessible were insufficiently utilised by the Welsh Government in the delivery of vaccines compared with other UK countries.

The group believes that this was a missed opportunity by the Welsh Government.

The group also believes that the difficulties of storing and transporting the Pfizer vaccine, while real, are too often relied upon to explain away poor performance or justified poor decisions. The Oxford-AstraZeneca vaccine became available at the beginning of January 2021 and was widely used in Wales from this time, as can be seen from a Wales Covid-19 vaccination programme daily situation report.

That's at INQ000505456.

That is a daily situation report of 29 January 2021, and it records that some 138,000 AstraZeneca vaccines had been delivered by end of January 2021.

The ministerial statement of the former Minister for Health and Social Services, Vaughan Gething, in his

statement made on 4 January 2021, described the AstraZeneca vaccine as a game changer.

He said as follows in his statement:

[As read] "Members will be aware of the widely reported benefits of this latest vaccine. It is cheaper and supply will be more plentiful. However, crucially, it presents significantly fewer logistical challenges than the Pfizer vaccine, with storage at normal fridge temperatures. As NHS capacity continues to build over the coming weeks, we will be able to get the vaccine to where it is needed in every part of Wales. Much more flexible and mobile deployment models will be activated. Every care home will be within reach, and this priority group will be a key focus for the NHS over coming weeks."

In these circumstances, my Lady, the group submits that it is clear that the issues experienced in storing and transporting the Pfizer vaccine cannot be used to justify poor decisions and performance such as the overreliance on mass vaccination centres and the delays in vaccinating the most vulnerable.

Key concern number 3, communications.

The group's experience of Welsh Government is that it is strong on rhetoric and weak on delivery. And they submit that this was also a feature of the delivery of

the vaccination programme.

The first milestone of the Welsh Government strategy was not based on the number of vaccines delivered, but on the number of invitations issued to JCVI priority groups 1 to 4 for their first dose vaccinations.

Vaughan Gething announced, on 12 February 2021, that this first milestone had been met. There are many things wrong with using a meaningless metric, such as the number of invitations issued, as a milestone, including, as already indicated, the fact that at the date the achievement announced, only 82% of care home residents had received their first dose of the vaccine. However, its lack of substance is best illustrated by the experience of Ms Smith-Higgins, as she explained in her witness statement: an invitation was sent out to her father one week after his death; no doubt an invitation which helped the Welsh Government meet its milestone.

Further, measuring achievement in such a superficial way takes no account of the difficulties experienced by the many who did not receive their invitation, or who received an invitation but experienced difficulties booking and travelling to an appointment, or, as in the case of many care home residents, those who were still waiting for their vaccination to be administered at the point the Welsh Government announced it had met its

milestone.

And there were also communication problems in relation to the vaccine themselves. The Audit Wales report, reported on the rollout of the vaccination programme in Wales, and identified a number of problems. That's at INQ000066528.

By way of example only, there were problems with identical letters inviting people for their first and second doses, and there were problems with the clarity of the invitations themselves, which used English and Welsh interchangeably over several pages of information, making it very difficult to understand.

Those are the communication difficulties.

Turning, my Lady, to the fourth point --

LADY HALLETT: I'm afraid you're going to have to take it very quickly, because you're substantially over time and I've got to be fair to everyone. I'm sorry, Ms Parsons.

MS PARSONS: My Lady, I will in that case wrap up by referencing one more concern about the policy before concluding, and that was that the policy adopted, was to proceed to vaccinate the next priority cohort, once only 50% of the vaccination had been achieved in a higher priority group, which may explain, perhaps, why, by mid-February 2021, there remained so many care home residents still to be vaccinated.

And I turn to my concluding remarks, my Lady. I have already identified the concerns that the Bereaved Families for Justice Cymru invite you to consider, but may I say this by way of conclusion: the group is conscious of the need for the Inquiry to deliver its work within a reasonable timeframe. However, it has been disappointed at the limited time spent in this module on issues specific to Wales. As we know you are aware, my Lady, the Inquiry's proceedings take a very significant toll on the families who are engaged, and this is particularly so for families in Wales who have to contend with a government that has exhibited in earlier hearings a remarkable ignorance about the issues for which they were responsible, whose actions do not match their words, and prominent members of which have destroyed potentially relevant information.

The group remains wholly committed to your Inquiry, and looks forward to working with your Inquiry team in future modules to hold decision makers in Wales to account.

My Lady, thank you.

LADY HALLETT: Thank you, Ms Parsons.

Mr Weatherby.

Closing statement on behalf of Covid-19 Bereaved Families for Justice UK by MR WEATHERBY KC

MR WEATHERBY: Thank you.

Through our opening submissions, the Covid Bereaved Families for Justice UK families have been clear to highlight the fact that this Inquiry should learn lessons from what went right, as well as from failures, but the Module 4 evidence has shown that even where there were successes, there were shortcomings, and even where things went right this time, there are stark lessons going forward, very stark lessons.

And behind many of the perceived successes, there is underlying evidence of a lamentable lack of planning and preparedness and resilience, and whilst it is right to note -- still right to note great efforts to save lives from a standing start, history will repeat itself if we do not set those efforts against the reality that the United Kingdom and its four nations was so remarkably unready. And next time, a standing start may produce very different results. As we well know, the development of vaccines and therapeutics for the next Disease X may well be very different.

Nadhim Zahawi likened the UK approach to building a plane whilst flying it; if ever there was an analogy which cautioned "Don't do it again", that was it.

And similarly, we submit, the perspective of Yvonne MacNamara from the Traveller Movement about which you've

been reminded only a few minutes ago by Mr Jacobs, that you can't build an ark after the flood has started. The plane and the ark need to be built now, outside of an emergency.

I anticipate all of us will recognise the importance of the evidence of Dame Kate Bingham underlined by that of the "phenomenal" Dr Dix, who played a central role in the initial period of the VTF.

A bottom line has been to caution that as the pandemic eased, the UK, in many respects, relaxed back to where it was in January 2020, and this conclusion rests not only on Kate Bingham and Dr Dix, but on several other witnesses.

Only on Wednesday, Lord Bethell, minister during the pandemic, gave the following alarming assessment. His words, and I quote:

"Frustratingly ... I think we are in a worse shape today than we were five years ago. The NHS is clearly under a huge amount of pressure in terms of capacity, the workforce are under pressure, and there's been a drop-off on recruitment. International surveillance of viruses is not where it could or should be. In terms of the institutions of resilience, UKHSA, for instance, should be a national agency with heft and resources, and I'm disappointed that it has been denuded in the way it

has been.

"Local Resilience Forums remain a shadow organisation ... I could go on ..."

Kate Bingham reminded us that Covid was the seventh pandemic of this century, yet there was no UK Government plan for development, manufacture, supply and rollout and little consideration of vaccines at the DHSC beyond flu.

A key initiative that could have made a significant difference, as we heard earlier, was the Vaccines Manufacturing and Innovation Centre, conceived in 2017, to onshore vaccine manufacture, and expressly to supply manufacturing capacity during a pandemic.

It had not progressed by the onset of the pandemic despite the allocation of hundreds of millions of pounds of public money. By the time the project was abandoned, it had not contributed a single vaccine dose, with its publicly-funded centre sold off to a private US healthcare company and then mothballed.

From the evidence, it's unclear how much of the public funding has been recovered, but it's a salutary example of abject governmental failure. We are told the Moderna Innovation and Technology Centre will become operational later this year, more than five years from the onset of the pandemic, and we heard about the

limitations of that this morning.

Kate Bingham told us that there should be no need for taskforces. Competent government, she said, should maintain readiness and capabilities for vaccines and therapeutics. She identified not only the complete absence of planning in this area but the suspicion of industry from within the Civil Service, a lack of science and technology skills possessed by those recruited via its fast-track graduate entry scheme and a risk-averse culture as key problems. Better not to try than to fail, lest you be criticised, seemed to be the accepted working practice.

And these were views largely echoed by Eddie Gray from the Antivirals Taskforce.

Kate Bingham brought a wealth of relevant and crucial experience to the VTF, a team of seasoned experts to hit the ground running. However, as she laments, and we heard this morning, that once she'd left, her successor soon followed her out of the door because of the lack of support from civil servants, and the industry experts were dispensed with too, which "reflected incredibly badly on the UK". Her words, not mine.

She commented that thereafter there has been a concentration on one platform, which is bad for the UK

going forward. Contracts with smaller vaccine producers, including Valneva, Novavax, were cancelled, causing losses of jobs in Scotland and Darlington, a move which Kate Bingham described as not only inexplicable, but "improper" -- again, her word not mine -- and driven by cost cutting to the detriment of industry relations for the future, a view underlined by Dr Dix today.

The failure to take up the Evusheld cocktail left the UK to be the only western country not to prophylactically protect its immunosuppressed.

This was forthright evidence from two key figures in the vaccine response. Not all of it is accepted by those involved, of course, both regarding Evusheld and the cancelled contract. But her views and those of Dr Dix are compelling.

She proposes that there should be a vaccine tsar -- this time my word not hers -- working alongside the responsible minister, with similar status and access to the National Security Adviser, and she and Dr Dix call for the vaccine agency. We endorse the thrust of those proposals.

But moreover, we call for a clear, published UK Government vaccine and therapeutic plan to cover development, resourcing, manufacture, supply and

rollout, and we also propose that there should be similar overarching plans in each of the devolved administrations to ensure that there is both full cooperation and proper protection of devolved powers.

We fully recognise the importance of planning remaining flexible, because the characteristics of the next pandemic and its effects may be very different to this one, but there are also constants and themes which will arise: a need to identify the vulnerable, the imperative to combat consequences of discrimination, the infrastructure of both supply and delivery of vaccines and drugs, prioritisation, protection of key workers, and so forth.

The Inquiry has heard a deal of evidence regarding inequalities and different vaccine percentages across different groups. We endorse and follow the submissions made by Mr Thomas King's Counsel earlier, amongst others. The problems should not be seen as hesitancy or one of so-called "hard to reach" communities. The problem is systemic, and must be addressed and solved or mitigated systemically.

There are two key points to vaccine coverage. The first is safety and efficacy, and the second, access. There has been somewhat complex evidence regarding diversity of clinical trials. Dr Waqar gave evidence

that there has been a historical problem with the lack of diversity in trials. Big pharma insists that the Covid trials were fully diverse, and point to trials elsewhere which ensured that there were sufficient non-white participants and people with different ethnic groups involved.

The expert Professor Prieto-Alhambra gave figures which show that participants in the UK AstraZeneca trials were disproportionately white, with the same caveat: that diversity was improved by other non-UK trials.

Meanwhile, Kate Bingham comments that the Cabinet Office were not prepared to front a publicity campaign to ensure sufficiently diverse volunteers in the UK, whilst the MHRA opined that the trials were satisfactory in terms of diversity but there remained work to be done.

There are notorious cases of drugs deployed having been tested against other demographics which have gone catastrophically wrong. Diversity of testing is universally recognised as a necessary precursor to authorisation. It's not only about confidence. For example, a quick Google of open source material reveals a case within the last 30 years regarding the use of a novel drug to treat children in Nigeria by a major

pharmaceutical company, despite the fact that it had only been trialled on adults, and which resulted in dire consequences.

Given the evidence, and particularly from the MHRA, we do not suggest that the Covid trials were unsafe, but we do say this Inquiry should focus on the evidence of work to be done, and that should be taken seriously.

In our view, there should be a requirement before authorisation that clear evidence of trial diversity must be produced and published. Trial diversity must mean that, to the greatest extent possible, the trialists should be representative of the population within which the trial takes place.

Where there are barriers to that, and we know there are real barriers, for example involving pregnant women or those where there are issues of consent, the applicants for authorisation must set out the limitations of their trials.

If there was a clear public requirement for a higher standard of diversity before authorisation will be granted, then those designing and operating and resourcing the trials will solve or mitigate issues such as ethical diversity, which are not intractable.

We submit this Inquiry should recommend such a public diversity requirement.

Requiring diversity for safety and efficacy purposes overlaps with and leads on to the second point of confidence. If UK clinical trials do not reflect the whole community, if individuals cannot see "people like us", there will be an inevitable adverse perception by those that are thereby marginalised, irrespective of whether that lack of diversity is mitigated by trials taking place elsewhere.

The evidence of experts Professor Evans and Professors Chantler and Kasstan-Dabush was that, ultimately, trust in marginalised communities is a structural and historical issue. But as well as tackling those fundamental whole-system problems, confidence can and must be addressed to reduce the coverage gap.

This is not done by projecting the problem back on marginalised individuals, by describing them as "hesitant" or "hard to reach"; it's done by proper planning, both in terms of a more general strategy to combat health inequalities, but by specific pandemic planning itself.

It's well known, as I've touched upon, that there are real adverse prior examples from around the world occurring disproportionately away from the wealthiest nations, and historical memory was acknowledged amongst

others, by Dr Gillian Richardson, the SRO from Wales.

Disparities of coverage can be mitigated by systemic planning to identify the issues ahead of the emergency, working with people and organisations from within those communities, before the emergency arrives, ensuring not only that vaccines and drugs are safe and efficacious for all, but ensuring that they're seen to be so with clear public messaging, and planning ahead of time to message and supply those new treatments in ways in which and places appropriate to those communities, ensuring also that intersectional issues are recognised and addressed, including language and literacy barriers.

And finally, I turn to evidence from the bereaved themselves. As in other modules, you've heard that evidence before you it is undeniably powerful. Jean Rossiter was the first Module 4 witness. She and her family lost their son Peter, an otherwise healthy 39-year-old teacher and key worker.

She raises two particular issues. Firstly, prioritisation and secondly dosage intervals.

As a matter of logic, had Peter been vaccinated earlier or had his second dose earlier, as manufacturer recommended, his chances of contracting and succumbing to Covid would have been exponentially reduced.

Although we've heard justifications for

prioritisation and dosage intervals which amounted to a policy to do the greatest good with limited supplies, there are two points. Firstly, those limitations of supply might have been much reduced had there been proper planning and resilience in onshore manufacturing.

And secondly, there was recognition that some key workers should be prioritised whilst others were not. And there were differences of approach with respect to certain sectors, for example care home staff in England, and in Scotland.

It's not hard to understand Jean's distress and frustration at the effect of those decisions, not only her loss. In Jean's statement, not only in the oral evidence she gave, there are accounts of others within the Covid Bereaved Families for Justice group.

I'll mention simply two. Winifred Partington, aged 82, died in hospital unvaccinated in March 2021. She'd been in hospital for some months, and despite receiving vaccination letters to her home, and despite the hospital being a vaccination centre, inpatient vaccination did not start until five days before she tested positive. The family are understandably distressed and frustrated that she would have been vaccinated if she'd been at home, yet not in hospital with the additional risks that that brought.

Sara Meredith's son Daniel, seven years old, had complex needs. Sara campaigned and spoke with MPs and peers to have vulnerable children prioritised for vaccination. Sadly, Daniel contracted Covid shortly after receiving his first vaccine dose too late, and died.

Each of those cases, and more, illustrate the real-life consequences of a failure to plan for a pandemic and the real-life consequences of decisions which left particularly vulnerable people unprotected until too late. The families look forward to your recommendations to ensure that next time others do not find themselves in the same position. Thank you very much.

LADY HALLETT: Thank you, Mr Weatherby.

Mr Wilcock.

Closing statement on behalf of Northern Ireland Covid Bereaved Families for Justice by MR WILCOCK KC

MR WILCOCK: My Lady, as you know, I represent Northern Ireland Covid Bereaved Families for Justice, along with Mary-Claire McDermott and instructed by PA Duffy Solicitors.

In opening this module, your counsel, Mr Keith King's Counsel, stated that the evidence you will hear in this module overwhelmingly suggests that the

UK Covid-19 vaccines successfully protected the people of the UK against a virus that was killing and liable to kill hundreds of thousands of people. He was right.

He was also right to observe that this remarkable achievement was built on the UK's formidable science and clinical research infrastructure, including those who volunteered for vaccine clinical trials.

Northern Ireland Bereaved Families for Justice echo the calls of the many witnesses you have heard urging you to recognise the importance of maintaining and strengthening this infrastructure in peacetime, so to speak, so that the UK scientific and biomedical research centre receives the funding necessary to ensure that it is sufficiently resourced and robust to continue experimental research of vaccines and therapeutics, so that we might be as well prepared as we can be when we are inevitably next at risk to the as-yet-unknown pathogen X.

My Lady, as Mr Weatherby presaged, those who do not learn from history are doomed to repeat it. And in that context, it was incredibly disappointing to those I represent to hear both Lord Bethell and Dr Dix tell you in different ways that the UK now is in worse shape today, in many ways, in terms of vaccine resilience, than it was five years ago.

My Lady, with those general remarks, and making clear that we adopt the general submissions you have heard from Mr Weatherby King's Counsel, can I return to some of the evidence you have heard in relation to Northern Ireland, which, given its inevitable reliance on the UK's greater scale, research capacity and purchasing power, related more to rollout than it did to the development and national supply of the Covid vaccines.

Although the only evidence the Inquiry was able to hear directly during this module about Northern Ireland came from Dr Naresh Chada, Northern Ireland's Deputy Chief Medical Officer, we know and make clear to those listening to these remarks that you will also bear in mind the plethora of other written evidence you have received during the course of this module relating to the provision of vaccines and therapeutic medications in the north of Ireland.

And they include the extensive witness statement of the ever-present Chief Medical Officer, Professor Sir Michael McBride, and the former head of the Northern Ireland Covid-19 vaccination programme, Dr Patricia Donnelly.

And we accept that there were no easy or straightforward answers to a number of challenges that

the rollout of the vaccination programme in Northern Ireland faced. And we also accept that many of these challenges were successfully faced and overcome. Vaccination centres were established, and processes were put in place that allowed vaccines to be distributed to these centres as well as GPs and community pharmacies.

You will have noted Dr Chantler's specific approval during the course of her expert evidence of Northern Ireland's "very novel approach of a twin-track approach ... whereby different priority groups could either go to the trust or to the GP surgery at the same time".

That said, the approach we urge upon the Inquiry, and other Core Participants from the north of Ireland is not simply to comment or congratulate themselves on the considerable efforts that were undeniably made by those involved in the Northern Irish vaccination programme, but to examine whether the rollout of that programme could have been improved as far as Northern Ireland was concerned, in order to hopefully learn the lessons to stop history repeating itself, and put those involved on the front foot, rather than the back foot, when, sadly, those efforts will again be required in the future.

My Lady, this isn't just a topic for academic study. In describing the difficulties caused by the fact that GP practices were initially unable to handle the Pfizer

vaccine, Dr Chada stated that he did not think that the Northern Irish programme was particularly constrained by that. It was only just a matter of a week or two.

Now, of course, we know what he was trying to say and what he meant. But you have heard from our witness, Fiona Clarke, that even that short timescale continues to haunt those who lost loved ones who could only have been fully vaccinated outside that short period he described.

In his written statement to the Inquiry, Dr Chada explained that his initial input into the vaccination programme was in the context of Northern Ireland not then having a permanent Senior Medical Officer lead for vaccinations within the Department of Health. You will recall Dr Dix's evidence to you this morning about the need for someone in government to fully understand vaccines. We suggest that this reasoning might equally be thought to apply to the Northern Ireland Department of Health.

In July 2020 the Northern Ireland Covid-19 Vaccination Programme Oversight Board was established to set the direction and oversee the progress of planning and ultimately the implementation for a future Covid-19 vaccination programme.

As a director general of the Department for

Business, Energy and Industrial Strategy, Ms Alexandra Jones, told you, this didn't ensure more than limited Irish involvement in the early phase of the UK Vaccine Taskforce at around the same time.

My Lady, will recall that Ms Jones told you that although there were "conversations" that were happening within the devolved administrations, we didn't join them up because of the inevitable growing pains of establishing a Vaccine Taskforce.

And Ms Jones offered this to you as something she would specifically want to learn from in the future.

But back to the Oversight Board. Whilst both Dr Chada and Dr Donnelly were participants in the Oversight Board, it was not until October 2020 that Dr Donnelly was appointed as the head of the vaccination programme to oversee and drive the planning and operation and delivery of the programme. And furthermore, in his evidence to you, Dr Chada stated that even then, he and Dr Donnelly had to work with what he described as "a relatively small core team of people in the department to try to get the vaccination programme up and running."

And Dr Chada told you, and we have seen nothing to indicate to the contrary, that notwithstanding the small infrastructure, he and Dr Donnelly really worked quite

well together. But the question we ask the Inquiry to consider is whether the system might have worked better had it been on the front foot from the outset, and not on the back foot because of the lack of vaccination lead, and the, perhaps, surprisingly late appointment of Dr Donnelly as head of the vaccination programme many months after, it must have been clear, that a vaccination programme was inevitably going to be necessary.

And perhaps as an example of the Northern Irish Public Health Authority being on the back foot in terms of their vaccination plans in 2020, the Inquiry will recall Dr Chada's uncertainty as to whether Northern Ireland ever had its own public vaccine plan, and his acceptance that, given the significance of communication in vaccine delivery, such a written document, which is there and available for people to see, is -- perhaps an understatement -- really important.

Dr Chada also explained that prior to the pandemic, Northern Ireland had no single IT system that captured vaccination data. This necessitated the development of the Vaccine Management System, which although operational by early December 2020, required what Dr Chada described as "quite a lot of refinement and development and improvement of its capabilities to

ensure timely access to timely and reliable uptake data."

Now, Dr Donnelly, in her written statement, I seek to remind you, described the lack of such a system at the beginning of the vaccine programme as "a major drawback", and your Ladyship will recall that immediately after Dr Chada gave evidence, Dr Chantler described to you how having these systems in place was extremely crucial. We ask your Ladyship to bear those points in mind when considering some of the submissions your Ladyship heard earlier on this afternoon from the Department of Health about this system.

In relation to data, you heard Dr Chantler repeat to you what other witnesses have sadly told you in relation to other modules: we don't have as much access to evaluations under the Northern Ireland devolved administration as we do in relation to the other three. It's a recurring theme.

In spite of these data, and we submit therefore, transparency limitations, Dr Chada gave a relatively positive review of the work that the Northern Ireland low uptake group were able to do in dealing with low uptake among identified occupational groups, ethnic minorities, and areas of social deprivation in Northern Ireland.

You know from your travels that Northern Ireland has some of the most socially deprived areas in the United Kingdom. Plainly, as Professor Sir Chris Whitty told you, bringing data together in this area is vital, but so is transparency, particularly given Dr Kasstan-Dabush's observations to you for the need for alignment of how data is collected and stored if we are going to be able to identify trends and/or evaluate success in this area on a UK-wide basis.

My Lady, before I finish, can I deal with one discrete topic which affects the whole of the UK. My Lady has heard evidence in relation to Parliament's Vaccine Damage Payment Scheme. It is unfortunate that, as we understand the evidence, Parliament has not revisited the threshold and the amount of the award of this scheme since 2007. It certainly seems to those I represent, that Ms Scott from the Vaccine Injured Bereaved UK had a point when she described the scheme as it presently stands as not fit for purpose.

And accordingly, we urge you to consider carefully how your Ladyship can best, most effectively reflect this similar evidence for the need for reform in this area that you heard from Lord Sharma and other witnesses, notwithstanding the obvious point that, plainly, the Parliamentary origin of the scheme and the

fact that it may be thought questions on the extent and detail of it are inevitably political questions involving both Parliament and the payment of public monies.

But in conclusion, we say that the three issues of Northern Ireland's relationship and input into UK-wide bodies, the effect of the historical, systemic and structural failings within Northern Ireland's political and health systems you are all too aware, and the weaknesses of its data collection systems, have all featured in previous modules you have dealt with and, I dare say, may feature in modules to come.

At this stage, in relation to this module, I'm conscious that we will be lodging written submissions at a later stage, which will include suggested recommendations for the future. That is all I now propose to say on behalf of the Northern Ireland Covid Bereaved Families for Justice. We are very grateful for the opportunity of addressing you.

LADY HALLETT: Thank you very much indeed, Mr Wilcock.

Ms Mitchell, if you'd like to go tonight, I'm very happy to sit until quarter to.

DR MITCHELL: My Lady might be not be surprised to know THAT it's not going to take me to quarter to.

Closing statement on behalf of the Scottish Covid Bereaved
by DR MITCHELL

DR MITCHELL: I present these submissions as instructed by Aamer Anwar & Company on behalf of the Scottish Covid Bereaved. The Scottish Covid Bereaved understand how lucky we are to have this module on vaccines. Our collective experience would look very different had a Covid vaccine not be found.

Given we don't know what the next pandemic will be, we can only hope that we will find a vaccine for Disease X, but hope isn't necessary, however, to ensure that, when the time comes, there are processes and procedures in place to ensure that the vaccines are developed and deployed at a pace to those who require it most first, and the rest of society as soon as possible thereafter.

In order for that to be done, there are various recommendations that the Scottish Covid Bereaved will make in writing to the chair. Before then, we wish to make the following four points.

One, at the outset of the Inquiry there was discussion about the use of the term "vaccine hesitancy" and it was suggested that "vaccine scepticism" might be a better term. Having listened to the experts, we suggest that the best term is that of "vaccine

confidence", which people may have to a greater or lesser extent. Some members of the Scottish Covid Bereaved, for example, were not confident that they had enough information to make informed decisions about the vaccine. In particular, those with pre-existing health conditions or pregnant women. Concern was also expressed about vaccinating younger people.

We don't know what Disease X will be, but we can be sure that the best inoculation we have against it at present is education. With education and engagement, vaccine confidence may be fostered. In doing so, misinformation and disinformation that abounds in relation to Covid vaccines may be challenged.

It is imperative that prior to the next pandemic as much as possible is done in relation to public health messaging to ensure that the public has confidence in vaccines and the system of dispersal of vaccines in a fair way, which protects the most vulnerable first and the least vulnerable last, to protect us all in the process.

Two, a further important issue, a recurring one, is the need to provide data systems. It stands to reason that, in order to provide vaccines and therapeutics such as antivirals, pending vaccines to the most vulnerable, we must be able to quickly identify whatever might make

them vulnerable to Disease X, be it age, gender, race, physical or learning disability or any other definable data source that we can identify.

Data must be harnessed as a valuable vaccine and therapeutic tool.

Three, the Chair has remarked on occasion that so many interactions and decisions come down to individual relationships with people rather than governmental structures. We saw that perhaps no more clearly than when Dame Kate Bingham explained how she had navigated the governmental process.

Whilst, alas, we cannot ensure that everyone who governs is competent, we can listen to experts like Dame Kate Bingham and Dr Clive Dix, who are, about how best to prepare for the next pandemic.

It may come as no surprise that the Scottish Covid Bereaved support the idea of a national vaccine agency and having someone in government who understands vaccines.

We hear the concerns about cost and independence of government, but we also know that from all the innovations, and speedy changes that occurred forced by the necessity of a pandemic, that where there is a public will, there is a political way.

Four, in relation to barriers to uptake, in addition

to fostering confidence we will make recommendations about vaccines and therapeutics might be best delivered in Scotland, bearing in mind its rural and island communities. Perhaps providing a good practical example of public will leading to a political way that I forementioned, the Chair may be pleased to hear that since the evidence given by Melanie Newdick on behalf of the Scottish Covid Bereaved, routine vaccine delivery is to be restored to Highland GPs, trusted and local healthcare providers, following an intervention by the Health Secretary.

In conclusion, science can and hopefully will provide an effective vaccine come the next pandemic, but vials of vaccines and antivirals will be useless unless they are used, and in order to do so, we must ensure that we have confidence in them, and trust in those who provide and administer them. The recommendations of the Scottish Covid Bereaved will focus on how to ensure that we are best placed to foster these sentiments in all communities to inoculate us from the next pandemic.

These are the submissions on behalf of the Scottish Covid Bereaved.

LADY HALLETT: Thank you very much indeed, Ms Mitchell, and thank you for telling me about the intervention of the Health Secretary. That's one good thing that's come out

of this Inquiry so far. So thank you very much indeed.

DR MITCHELL: Indeed, my Lady, and I think the Scottish Covid Bereaved were delighted that such a practical effect has happened immediately, and people may be protected as a result of that in the future.

LADY HALLETT: Thank you.

Very well, I shall rise now and return at 10.00 tomorrow morning, please.

(4.34 pm)

(The hearing adjourned until 10.00 am the following day)

I N D E X